Getting evidence to and from general practice consultations for cardiovascular risk management using computerised decision support

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Abstract

Background

Cardiovascular disease (CVD) has an enormous impact on the lives and health of New Zealanders. There is substantial epidemiological evidence that supports identifying people at high risk of CVD and treating them with lifestyle and drug-based interventions. If fully implemented, this targeted high risk approach could reduce future CVD events by over 50%. Recent studies have shown that a formal CVD risk assessment to the systematically identify high risk patients is rarely done in routine New Zealand general practice and audits of CVD risk management have shown large evidence-practice gaps. The CVD risk prediction score recommended by New Zealand guidelines for identifying high CVD risk patients was derived from the US Framingham Heart Study using data collected between the 1960s and 1980s. This score has only modest prediction accuracy and there are particular concerns about it's validity for New Zealand sub-populations such as high risk ethnic groups or people with diabetes.

Aims

The overall aims of this thesis were to investigate the potential of a computerised decision support system (CDSS) to improve the assessment and management of CVD risk in New Zealand general practice while simultaneously developing a sustainable cohort study that could be used for validating and improving CVD risk prediction scores and related research.

Methods

An environmental scan of the New Zealand health care setting's readiness to support a CDSS was conducted .The epidemiological evidence was reviewed to assess the effect of decision support systems on the quality of health care and the types and functionality of systems most likely to be successful. This was followed by a focused systematic

review of randomised trials evaluating the impact of CDSS on CVD risk assessment and management practices and patient CVD outcomes in primary care.

A web-based CDSS (PREDICT) was collaboratively developed. This rules-based provider-initiated system with audit and feedback and referral functionalities was fully integrated with general practice electronic medical records in a number of primary health organisations (PHOs). The evidence-based content was derived from national CVD and diabetes guidelines. When clinicians used PREDICT at the time of a consultation, treatment recommendations tailored to the patient's CVD and diabetes risk profile were delivered to support decision-making within seconds. Simultaneously, the patient's CVD risk profiles were securely stored on a central server. With PHO permission, anonymised patient data were linked via encrypted patient National Health Index numbers to national death and hospitalisation data. Three analytical studies using these data are described in this thesis. The first evaluated changes in GP risk assessment practice following implementation of PREDICT; the second investigated patterns of use of the CDSS by GPs and practice nurses; and the third describes the emerging PREDICT cohort and a preliminary validation of risk prediction scores.

Results

Given the rapid development of organised primary care since the 1990's, the high degree of general practice computerisation and the New Zealand policy (health, informatics, privacy) environment, the introduction of a CDSS into the primary care setting was deemed feasible. The evidence for the impact of CDSS in general has been moderately favourable in terms of improving desired practice. Of the randomised trials of CDSS for assessing or managing CVD risk, about two-thirds reported improvements in provider processes and two-fifths reported some improvements in intermediate patient outcomes. No adverse effects were reported.

Since 2002, the PREDICT CDSS has been implemented progressively in PHOs within Northland and the three Auckland regional District Health Board catchments, covering a population of 1.5 million. A before-after audit conducted in three large PHOs showed that

CVD risk documentation increased four fold after the implementation of PREDICT. To date, the PREDICT dataset includes around 63,000 risk assessments conducted on a cohort of over 48,000 people by over 1000 general practitioners and practice nurses. This cohort has been followed from baseline for a median of 2.12 years. During that time 2655 people died or were hospitalised with a CVD event. Analyses showed that the original Framingham risk score was reasonably well calibrated overall but underestimated risk in high risk ethnic groups. Discrimination was only modest (AUC 0.701). An adjusted Framingham score, recommended by the New Zealand Guideline Group (NZGG) overestimated 5-year event rates by around 4-7%, in effect lowering the threshold for drug therapy to about 10% 5-year predicted CVD risk. The NZGG adjusted score (AUC 0.676) was less discriminating than the Framingham score and over-adjusted for high risk ethnic groups. For the cohort aged 30-74 years, the NZGG-recommended CVD risk management strategy identified almost half of the population as eligible for lifestyle management +/- drug therapy and this group generated 82% of all CVD events. In contrast the original Framingham score classified less than one-third of the cohort as eligible for individualised management and this group generated 71% of the events that occurred during follow-up.

Implications

This research project has demonstrated that a CDSS tool can be successfully implemented on a large scale in New Zealand general practice. It has assisted practitioners to improve the assessment and management of CVD at the time of patient consultation. Simultaneously, PREDICT has cost-effectively generated one of the largest cohorts of Māori and non-Māori ever assembled in New Zealand. As the cohort grows, new CVD risk prediction scores will be able to be developed for many New Zealand sub-populations. It will also provide clinicians and policy makers with the information needed to determine the trade-offs between the resources required to manage increasing proportions of the populations and the likely impact of management on preventing CVD events.

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Dedication

Every hour of every day in New Zealand, someone dies from or is admitted to hospital with cardiovascular disease. This thesis is dedicated to these people and their families.

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List of Abbreviations

ACC	Accident Compensation Corporation
AUC	Area under the curve
BP	Blood pressure
CDSS	Computerised decision support system
CHD	Coronary heart disease
CHE	Crown Health Enterprise
CHF	Congestive heart failure
CI	Confidence interval
CMDHB	Counties Manukau District Health Board
CPOE	Computerised physician order entry
CSC	Community Services Card
CVD	Cardiovascular disease
DHB	District Health Board
DBP	Diastolic blood pressure
EHR	Electronic Health Record
EMR	Electronic Medical Record
FTE	Full time equivalent
GMS	General Medical Benefits System
GP	General Practitioner
HDL	High-density lipoprotein
HPI	Health Practitioner Index
HUHC	High Use Health Card
ICD	International Statistical Classification of Disease
ICVD	Ischaemic cardiovascular disease

IPA	Independent Practitioner Association
IT	Information Technology
LDL	Low density lipoprotein
LOINC	Logical Observations, Identifiers, Names and Codes
NHI	National Health Index
NMDS	National Minimum Data Set
NZDep	New Zealand Deprivation Index
NZGG	New Zealand Guidelines Group
NZHIS	New Zealand Information Health Service
NZNO	New Zealand Nursing Organisation
PHO	Primary Health Care Organisation
PMS	Patient Management System
RNZCGP	Royal New Zealand College of General Practitioners
ROC	Receiver-Operating Characteristics
SAS	Statistical Analysis System
SBP	Systolic blood pressure
SD	Standard deviation
SE	Standard error
SNOMED-CT	Systematized Nomenclature of Medicine — Clinical Terms
TC/HDL	Total cholesterol to high density lipoprotein ratio
XML	Extensible Markup Language

1. Introduction

1.1 The burden of cardiovascular disease

Cardiovascular diseases (CVD) are the leading cause of death and disability worldwide. Of the approximately 58 million deaths in 2005, one in three was due to CVD.[1] Looking ahead, it is estimated that more than one in 10 of all disability-adjusted life years lost in 2020 will be attributable to CVD.[2] Cardiovascular diseases include coronary heart disease (CHD) and stroke along with other diseases of the heart and blood vessels. In the most part, these diseases are the expression of a long term inflammatory process of damage, hardening, and loss of elasticity of arteries (atherosclerosis) throughout the body.

In New Zealand in 2000, 40% of all deaths were attributable to CVD (22% CHD, 10% stroke and 8% other diseases of the heart and circulation).[3] However, the key issue is not the cause of death per se but whether lives are lost prematurely and if the disease burden falls inequitably. In New Zealand, there are major CVD disparities by gender, ethnicity and socio-economic deprivation. The age-standardised CHD mortality rate for men is twice the rate for women (114/100,000 compared with 56/100,000)[3] and are highest for Māori followed by Pacific people. Among Māori aged under 65 years, the CHD mortality rate is three to four times higher than that for non-Māori non-Pacific people.[3] While national statistics do not separately categorise different Asian ethnicities, the CHD mortality rates for people of Indian ethnicity is also higher than European and other non-Māori non-Pacific ethnicities.[4] The same patterns of ethnic disparity are also seen for stroke.[5]

Important social class gradients for both CHD and stroke mortality have been reported over the last thirty years[6] and still remain,[7] [8] with mortality higher in groups with greater levels of socio-economic deprivation.

While the majority of deaths occur in old age, one in five CHD deaths occur in New Zealanders less than 75 years[3] and it has been estimated that CHD accounts for 33% of

life years lost between 45 and 64 years of age.[9] Furthermore, CVD case fatality is lower in younger age groups,[10] so while CVD deaths are relatively uncommon, nonfatal events in younger people contribute significantly to the burden of illness and disability within the community. Approximately 77% of all nonfatal CVD events resulting in hospitalisation occur in people less than 75 years.[10] Using a summary measure of both quality and quantity of life lost, cardiovascular disease is estimated to account for 24% of the total disability-adjusted life years (DALYs) lost by the New Zealand population.[9]

CVD has a substantial impact on our health care services and our economy. In the early 1990s the cost of CHD alone to New Zealand society including direct medical costs, indirect and intangible costs was estimated.[11] Using the Reserve Bank of New Zealand consumer price index calculator,[12] this 1993 estimated cost has the equivalent purchasing power in 2008 of $NZ 434–$NZ 662 million per year.

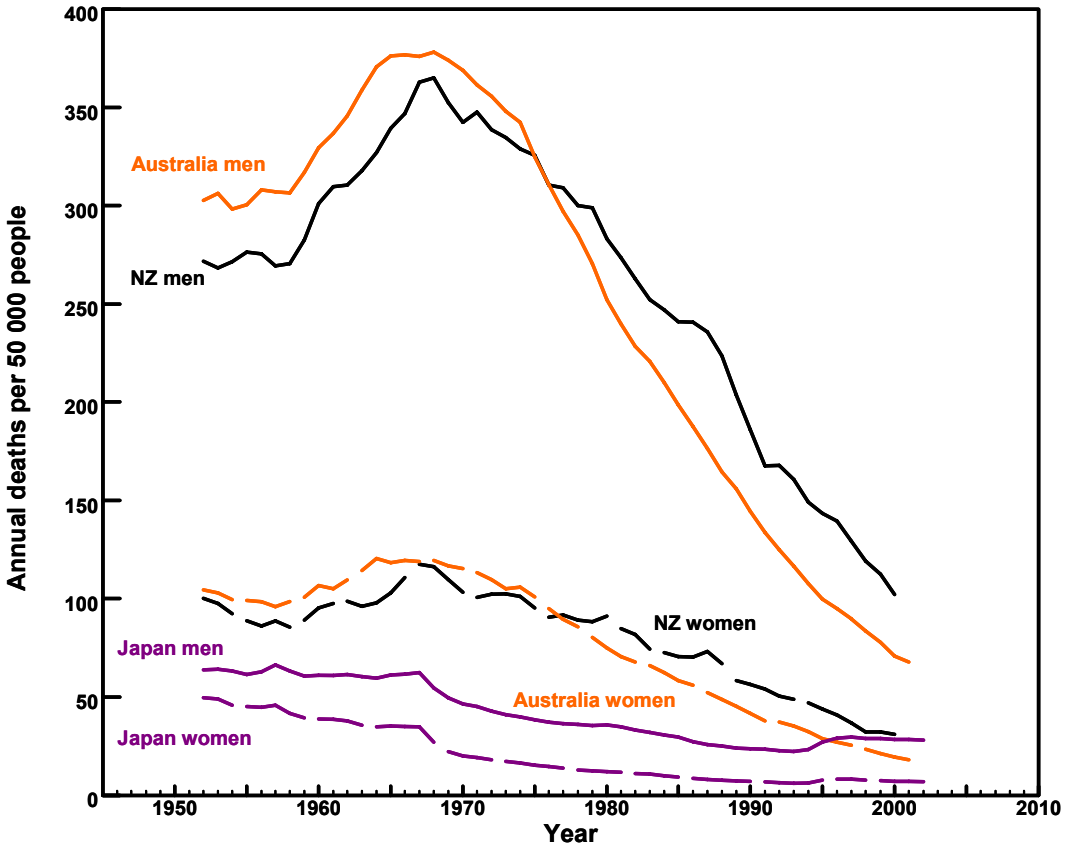
1.2 The scope for CVD prevention

Despite the burden of disease attributable to CVD in New Zealand, recent trends provide some good news. CHD mortality has been declining steadily over the last four decades and stroke mortality for at least a decade longer. Between the years 1966 to 1970 and 1996 to 2000, the age-standardised CHD death rates fell by 61% in men and 56% in women, a decline of 3.7% per year.[3,13] Over the same period age-standardised stroke mortality declined by 62% in men and 64% in women. Similar trends have been noted internationally in many high income countries.[1] However, although death rates have fallen, further large reductions in mortality and morbidity are possible. In 2004, New Zealand ranked 24th out of 27 OECD countries[14] for age-standardised CHD mortality rates and 20th for stroke mortality rates while Japan had the lowest mortality from CHD and Switzerland had the lowest stroke mortality.

The magnitude of decline in CHD mortality in New Zealand has not been as great as in many other countries including our closest neighbour, Australia (Figure 1.1). An investigation of the decline in CHD deaths in the United States from 1980 to 1990 suggested that over two-thirds of the decline was due to improvements in the

management of patients with established CHD (only 6% of the population aged 35–84 years) through risk factor reduction and improvements in medical/surgical treatment while only about a quarter of the decline was due to risk factor reductions in blood pressure, lipids and smoking in the majority of the population with no prior CVD.[15] Given the potential to prevent most CVD,[16] there is no reason why New Zealanders should not enjoy the same CHD rates as the Japanese and stroke rates of the Swiss (or even lower).

Figure 1.1. Annual deaths from CHD per 50,000 middle-aged (50–64 yrs) men and women: selected Asia Pacific countries



[1]Standardised to the age and sex distribution of the 2002 UK population, 3-year weighted averages.
Graph produced by Dr Gary Whitlock in 2005 (Clinical Trial Service Unit, University of Oxford) and reproduced with permission.

1.3 The evidence — CVD risk factors, risk prediction & risk management strategies

One of the key advances in 20th century medicine has been the discovery that most CVD is preceded by measurable and modifiable risk factors. It has been estimated that up to 75-80% of the burden of CVD is attributable to cigarette smoking and raised levels of blood pressure, blood cholesterol and blood glucose.[17,16] For each risk factor, the higher the level, the higher the likelihood of developing CVD. However, high levels of single risk factors have been shown to be poorer predictors of CVD risk than moderate levels of these risk factors when combined together. Each factor has a cumulative and synergistic effect on the risk of developing CVD, the combined effect being greater than the sum of the effects of individual risk factors.[18]

There is a large body of high quality empirical evidence that reduction of these risk factors through drug, dietary and other interventions can prevent or delay CVD events. Almost all adults could achieve between 50-80% relative reduction in CVD risk if they took a combination of a lipid-lowering drug, a blood pressure lowering drug and aspirin.[19] However, interventions are associated with both benefits and harms, including opportunity costs. No health service is likely to have the resources to treat everyone. While the harms from treatment remain relatively constant, it has been demonstrated that the higher the pre-treatment CVD risk, the greater the absolute benefit (and therefore the greater the cost-effectiveness of treatment).[18]

Increasingly, multifactor risk prediction scores are being used to inform treatment decisions and the intensity of management instead of using individual risk factor thresholds (such as treat above a blood pressure of 140/90 mmHg). Most national and international guidelines on the management of CVD risk now include a CVD risk prediction tool[20-24] to help practitioners target treatment to high risk patients. Until recently most have used a score derived from the Framingham Heart Study[25], a long-term cohort study undertaken in the 1960s–1980s in approximately 5,000 mainly European-Americans. From the mid 1990s, New Zealand national guidelines developed by the New Zealand Guidelines Group (NZGG) have recommended conducting a formal

CVD risk assessment using a Framingham 5-year CVD score. The intensity of management of single risk factors is then determined by the calculated risk score – the higher the score, the more immediate and more intensive the recommended management. During the 1990s, guidelines were published for the management of blood pressure[26 27] and the management of dyslipidaemia.[28] However, in 2003 a new CVD risk guideline incorporated both blood pressure and lipid-lowering guidelines and further shifted the emphasis from managing individual risk factors to managing total CVD risk primarily based on the estimated 5-year CVD risk score.[23] Treatment recommendations were determined by the risk score irrespective, for the most part, of the individual risk factor level- a radical departure from the usual recommendations only a decade before. A recently published modelling study from Canada suggests that the New Zealand guideline approach is both effective and efficient when compared to a range of international guidelines for statin treatment for preventing deaths from CHD.[29]

Population-wide interventions to lower salt consumption, obesity prevalence and blood cholesterol levels in the entire population and high risk approaches that treat individuals according to their baseline CVD risk can prevent a substantial proportion of CVD deaths.[30] While both strategies will be necessary to significantly reduce the burden of CVD in our community, recent studies have suggested that a targeted CVD risk reduction strategy that treats high risk patients with aspirin, statins and blood pressure lowering drugs is likely to be more effective than population-wide interventions in developed countries.[29 30]

1.4 The research gap and the evidence-practice gap

Both research gaps and evidence-practice gaps can have a major impact on the quality of health care. The research gap is the gap between what we know and what we need to know to maximise benefits and minimise harms of medical care.[31] Often the evidence for best practice is limited or lacking. The other common gap is between what is known and what is actually done – the evidence–practice gap.[32 33] Historically the medical profession has placed more value on developing the basic science of medicine, new drugs and technologies and has largely ignored the process by which that science is

translated into practice.[34] [35] This gap between what research evidence shows and what patients receive can be large and can influence the quality of health care in three different ways: through misuse (i.e. medical error) and overuse or underuse of proven therapies. The landmark Institute of Medicine Report "To Err is Human" focused on medical error, estimating that as many as 98,000 Americans die annually as a result of medical error and advocated for changing health care systems to improve safety.[36] However, a much greater number of people are likely to die from underuse and possibly overuse of evidence-based therapies.[37,32] Treatments known to be effective are often not reliably delivered to those in need[35] and ineffective treatment has often been normalised such as the use of antibiotics for a sore throat particularly in populations with low prevalence of rheumatic fever.[38] It has been reported that American people on average receive only 55% of recommended effective health care interventions.[39] Delivery of proven preventive health services is even lower.[40-41]

These two gaps, the research and evidence–practice gap are considered here in relation to CVD risk management in New Zealand.

1.4.1 CVD risk prediction research gap

One of the major research gaps in CVD risk management in New Zealand relates to the accuracy of the Framingham Heart Study risk prediction score currently recommended by the NZGG CVD guidelines. CVD risk prediction scores, including the Framingham scores, have been found to be far more accurate than physicians intuitive estimates of the probability of a future event for their patients.[42] In addition, these scores are significantly better estimates of risk than the individual risk factor thresholds that have been traditionally used as proxy measures of risk to inform treatment decisions.[42] However, studies internationally[43-46]and in New Zealand[47] suggest that the risk prediction scores derived from Framingham have only modest accuracy. There are also increasing concerns about the validity of using Framingham-based scores among high risk ethnic groups, those who are socio-economically deprived, people over 75 years, people with diabetes or those patients who are already on treatment at the time of risk assessment.

Large cohort studies with locally derived data are needed to validate current prediction tools or develop new ones.

Many countries and regions are now developing their own prediction tools. Current European guidelines use a risk prediction tool derived from the Systematic Coronary Risk Evaluation (SCORE) project that is based on a large European dataset combining results from 12 cohorts, with 205,000 patients, 2.7 million person-years of observation and 7,900 fatal cardiovascular events.[48] Because of the limited number of similarly measured risk factor and outcome variables available from each of these 12 cohorts, SCORE predicts only fatal CHD events and includes relatively few risk variables, which limits its potential accuracy and discriminatory power at the individual level. Furthermore, it does not include any data on high-risk non-European ethnic groups. Nevertheless, it provides better estimates of actual risk than Framingham in many European populations because it has been calibrated to each country's national mortality statistics.[48]

The world's largest CVD risk prediction cohort has recently been created in the United Kingdom by electronically extracting data from the clinical records of about 1.3 million general practice patients. From these data the investigators have developed the QRISK score.[49] Unfortunately, one of the costs of generating such a large retrospective cohort has been compromised data quality. For example, only 40% of the people included had their blood lipids recorded. Furthermore, the score currently excludes people with diabetes, with previous CVD and those taking statins, and is based on CVD events coded by general practitioners, that may be incomplete. However, the QRISK project demonstrated that an area-based social deprivation score and family history of premature CVD are significant risk predictors in the UK population and despite the amount of missing data, it performed better than Framingham risk scores.

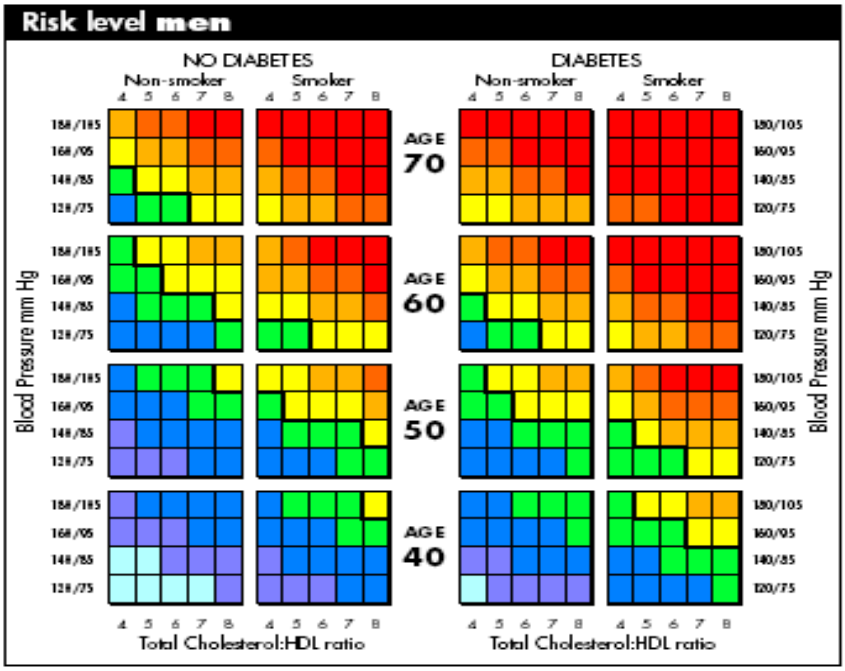
Neither SCORE nor QRISK risk prediction scores have been validated in New Zealand but their development has demonstrated that it should be possible to improve on the Framingham risk prediction equations.

1.4.2 CVD risk assessment and management evidence–practice gaps in New Zealand

Risk assessment gap

To support CVD risk assessment and targeting treatment according to multi-factorial CVD risk, the Framingham risk score was converted into the New Zealand paper-based coloured risk charts in the early 1990s (Figure 1.2).

Figure 1.2. The New Zealand CVD risk chart – example for men



They were incorporated into guidelines and into stand-alone calculators for computers (with and without coloured graphical display). The paper-based New Zealand CVD risk prediction chart was widely distributed to general practitioners and was also available in a drug compendium that was used daily by most New Zealand general practitioners (GPs). However, a national survey in 1999 showed that while most GPs had used the risk charts, 70% reported using them only once a month or less.[50] As CVD and risk factor management is one of the most common reasons for GP visits in New Zealand,[51] these findings suggested that the charts were significantly underutilised.

Risk management gap

New Zealand audits of care indicate that both over- and under-use of cardiovascular interventions is common.[52] [53] A recent audit of consecutive patients with established CVD found that while most were receiving aspirin, 30% were not on a statin and a further 30% were not prescribed blood pressure lowering drugs.[52] An audit of cardiac rehabilitation services in 2003 found that only 36% of those eligible were referred; of those referred, 56% did not attend cardiac rehabilitation; and of those who attended, only 19% completed the programme.[54]

An audit of over 25,000 patients visiting their general practitioners in 2000 showed that fewer than two-thirds of people with established cardiovascular disease were receiving recommended management. In those patients without a history of CVD, there was little evidence that CVD risk management was being targeted to those at highest risk. Furthermore, the number of low risk patients being treated far exceeded the number of high risk patients treated.[53]

1.4.3 A proposal to close the gaps

The goal of this thesis was to address both the research–evidence gap and the evidence–practice gap taking into account the strengths and constraints present in the New Zealand health care setting.

Closing the evidence gap on the accuracy of CVD risk assessment

To address the research gap (inaccurate risk assessment score) a large cohort study drawn from the New Zealand population is needed to develop New Zealand-specific CVD risk prediction tools. This cohort requires adequate numbers of Māori and other high risk populations to generate prediction equations with acceptable predictive power. Recent New Zealand experience has indicated that it is increasingly difficult to recruit representative population samples using electoral rolls or household surveys because of falling response rates. For example, in 1993–1994, the Auckland Heart and Health Study had a 72% response rate from central Auckland general electoral rolls.[55] When the more

recent Diabetes Heart and Health Study sampled the Auckland electoral rolls using the same approach, they were able to achieve only a 60% response rate.[56] In contrast, workplace-based studies and other studies that recruit people as part of routine practice have been more successful.[55 57] Therefore, a CVD risk prediction cohort study based within a routine primary care practice setting would be more likely to generate representative population samples than through electoral roll sampling. Furthermore the proposed data collected would be more relevant given the primary care setting is where risk prediction tools are mainly used.

The necessary 'ingredients' for generating a large representative population-based cohort are available in the New Zealand primary care setting: most New Zealanders visit their GPs at least annually,[58] most GPs have electronic patient medical records potentially enabling large-scale data extraction; and almost all New Zealanders have a unique national health index (NHI) number that would enable risk factor data collected in primary care to be linked to outcomes such as hospitalisations or deaths (note: all national health-related data collections include individual patient NHI numbers). However, while primary care clinicians are creating important new clinical data in electronic records on a daily basis, these data are often documented in unstructured and idiosyncratic ways, making retrieval and analyses a challenge.[59]

Closing the evidence–practice gap

Over the last 20 years, much work has been done to develop high quality pre-appraised evidence resources such as systematic reviews, evidence–based summaries and guidelines from the primary literature[60] to support best practice at the time of consultation. The pinnacle of these resources are computerised decision support systems (CDSS) that can rapidly and automatically convert the recommendations from evidence-based syntheses into guidance for clinicians, tailored for an individual patient's profile.[60] It is acknowledged that there is a variety of tools and approaches for implementing guidelines[61] and that multifaceted strategies are more likely to be successful than single approaches. While CDSS are likely to be implemented in association with many other strategies; the focus of this thesis is to explore CDSS as a potential strategy for guideline implementation. Two other key elements were present at

the time initiating this thesis to facilitate the development of a CDSS tool: the availability of high quality national and international CVD guidelines and local health information technology specialists with the ability to develop a reliable CDSS software platform.

1.5 This thesis

My research question was as follows:

Using a computerised decision support system, is it possible to enhance the uptake of evidence-based recommendations in routine clinical practice to improve the quality of care for CVD risk assessment and management while simultaneously getting evidence out of practice to conduct CVD risk prediction and related epidemiological research?

Aims

The two overall aims of this thesis were to investigate the potential of a computerised decision support system (CDSS) to improve the assessment and management of CVD risk in the New Zealand general practice setting while simultaneously developing a sustainable cohort study that could be used for validating and improving CVD risk prediction scores and related research.

Objectives

The specific objectives of the research outlined in this thesis were:

1) to understand the unique context of the New Zealand health care setting within which a computerised decision support system (CDSS) would function and determine the setting's readiness to support, and feasibility of, implementing a CDSS tool

2) to review the literature assessing decision support systems as agents to firstly improve the quality of health care in general, secondly for CVD risk assessment and management specifically and types and functionality of systems most likely to be successful.

3) to collaboratively design and develop a CDSS that would integrate routine practice, epidemiological research, and evidence-based knowledge

4) to investigate the impact of this CDSS on CVD risk assessment and management within a general practice setting

5) to generate a CVD cohort derived from routine clinical care and

6) to investigate the ability of this cohort to inform CVD risk prediction and other CVD epidemiological research.

Hypotheses

The major hypotheses being tested were:

1) that evidence-based recommendations for individual patients on CVD risk assessment and risk management could be delivered at the point of decision making in primary care in a sustainable way

2) that the provision of a CDSS tool for CVD risk assessment and management is associated with improvements in clinical practice

3) that the development of a large cohort using CDSS in routine practice would be feasible and would enable high quality CVD data to be collected for developing improved CVD risk predictions tools and for multiple other research purposes.

The structure of the thesis

As this research requires long-term sustainability, a major part of this thesis is devoted to describing the setting and the tool –- the readiness of the health care environment and general practice in particular for such a structural change, the evidence for benefit from implementing this change and the type of system and IT standards that would best perform the tasks.

There are three broad sections in this thesis: i. the setting; ii. Clinical Decision Support Systems (CDSS) and the development of the PREDICT CDSS; and iii. the evaluation of the performance of the PREDICT CDSS in changing practice and generating a research cohort.

The setting

The first section (Chapter 2) describes the setting within which the CDSS tool would be implemented. The section briefly describes the socio-political and health care organisational environment (past and present) in New Zealand with particular focus on primary care, general practice and informatics and defines key terms that will be used in subsequent chapters.

Clinical Decision Support Systems

The second section briefly describes CDSS, the types of systems available and presents evidence from previous systematic reviews on their effectiveness in delivering health care outcomes in general (Chapter 3). This is followed by a new systematic review (Chapter 4) of the effectiveness of CDSS (overall and by sub-type) specifically for CVD risk assessment and management in the primary care setting. Lastly a description of the design and development of the PREDICT CDSS is given (Chapter 5).

Evaluation: performance of PREDICT in closing the evidence-practice gap

Chapter 6 describes the implementation of PREDICT in a primary care organisation. Two formal evaluations were undertaken to investigate changes in provider behaviour with regard to CVD risk and risk factor documentation (Chapter 6) and the patterns of adoption and use of this CDSS tool (Chapter 7).

Evaluation: performance of PREDICT to close the CVD research gap

Chapter 8 details the methodology of the CVD PREDICT Cohort study and preliminary results are provided in Chapter 9. These include descriptive analyses of the emerging cohort and validation of the Framingham risk prediction equation for this population.

Chapter 10 provides a critique of the strengths and weaknesses of the PREDICT Cohort study. Chapter 11 concludes the thesis with the next steps required.

Theoretical frameworks and viewpoint

The underlying theoretical frameworks for this thesis are those of knowledge translation and quality improvement. Both have varying definitions but the two that best fit this thesis and research processes are as follows.

Knowledge translation is the " synthesis, dissemination, exchange and ethically sound application of knowledge to improve the health of people, provide more effective health services and products and strengthen the health care system".[62]

AND

Batalden and Davidoff (2007) propose that *quality improvement* is the:

" combined and unceasing efforts of everyone – health care professionals, patients and their families, researchers, payers, planners and educators- to make changes that will lead to better patient outcomes (health), better system performance (care) and better professional development (learning)".[63]

Within these frameworks, the 'knowledge' translated and the 'indicators' used to assess quality improvement are derived primarily from epidemiological research. The two theoretical frameworks and the epidemiological perspective reflect my triple specialist training in public health, general practice and epidemiology as well as my goal to integrate personal and population health perspectives. I practised as a general practitioner for a decade in a moderate sized (5-doctor, 4-nurse) central Auckland practice affiliated to a large primary care organisation and subsequently trained as a public health medicine specialist. This thesis was done while in my current position as a senior lecturer in clinical epidemiology and quality improvement.

Study investigators and collaborating organisations

Professor Rod Jackson had the vision for PREDICT in the late 1990s – a web-based general practice CVD risk assessment tool that could routinely collect patient CVD profiles and be linked anonymously to national CVD morbidity and mortality datasets to develop new risk prediction equations. National CVD risk charts, guidelines for evidence-based assessment and management of CVD risk, widespread acceptance of developing an anonymised CVD cohort and focusing the New Zealand cardiovascular research agenda are to a great extent due to his efforts and advocacy.

The work described in this thesis has been achieved collaboratively by many parties between 2002 and 2008. Integrating epidemiological research, routine clinical care and evidence-based practice using health information technology has required a large number of people and organisations to be actively and continuously involved including primary and secondary care clinicians, primary heath organisations (PHOs), district health boards, the National Heart Foundation, Diabetes New Zealand, the New Zealand Guidelines Group and the Ministry of Health.

The thesis describes two CDSS development projects (PREDICT-CVD and PREDICT CVD-Diabetes) and three separate but connected research projects, the HRC PREDICT Cohort Study, the PREDICT-CVD Evaluation study and the PREDICT Health Provider Study.

Counties Manukau District Health Board (CMDHB), the Procare Network Ltd (a primary care organisation) and the Ministry of Health funded my role as the clinical co-ordinator for the first CDSS (PREDICT-CVD) development project. PREDICT-CVD was implemented in the three ProCare PHOs in 2002 and subsequently as the CVD module within the CMDHB Chronic Care Management Programme. In 2003 our research team founded on a Māori/non-Māori partnership received research funding from the Health Research Council of New Zealand to conduct a large cohort study to develop more accurate cardiovascular risk prediction scores. Prof Rod Jackson was the team's supervisory investigator. After the release of new national cardiovascular risk and diabetes guidelines at the end of 2003,[23 64] the Ministry of Health funded my role to lead

the update of the first PREDICT CDSS to produce PREDICT CVD-Diabetes in 2004. This was a much bigger and more complex project than the first CDSS project and had both a development group and a national governance group. The latter group was charged with overseeing all the processes and ensuring that the product accurately reflected the intentions and recommendations in New Zealand Guidelines Group *Guidelines for the Assessment and Management of Cardiovascular Risk*[23] and the *Guidelines for the Management of Type 2 Diabetes.*[64]

The role of the candidate

My role was to convert the vision for PREDICT into reality and combine clinical utility, evidence-based practice and epidemiology. I lead the design, development, clinical–IT interface and safety testing of both PREDICT systems which in combination took at least 2 years. The work included the development of the CVD risk assessment and management dataset (i.e. equivalent to questionnaire development in a standard epidemiological study), ensure alignment with clinical work process and develop the evidence-based clinical content so that it could be used as decision support. These elements were translated onto a CDSS platform developed by Enigma Publishing Ltd (IT knowledge management specialists) and integrated into general practice patient management systems. I was responsible for meeting the requirements of the national governance group that the processes from dataset, content development, focus group and vignette testing to sentinel site testing, satisfied multiple (clinical, cultural, evidence-based, health care organisational) constituencies. I have been involved in all aspects of beta-testing as well as implementation and evaluation in primary care and continue to lead the safety monitoring and clinical updates.

As discussed above the PREDICT research is founded on a Māori/non-Māori partnership with Dr Tania Riddell being the Māori co-principal investigator. My work has been at a more general/national level towards improving all New Zealander's CVD and diabetes health outcomes (but with a strong desire to also address Maori health inequalities concurrently. The primary focus of Dr Riddell's research (as the most appropriate person to be undertaking this work) is to reduce CVD and diabetes health

inequalities for Maori as the Treaty of Waitangi partners, and indigenous people, of New Zealand.

This PhD does not focus on the technical process of CDSS development but on the early outcomes of its use. My involvement has been as the co-principal investigator of the HRC PREDICT Cohort Study (Chapter 8 and 9), the principal investigator of the PREDICT-CVD Evaluation study (Chapter 6) and co-investigator of the PREDICT Health Provider Study (Chapter 7). My individual contribution to each of these studies is documented in the methods sections of these chapters.

Research funding

This research has been funded by the following organisations:

2003 HRC PREDICT Cohort Study – the Health Research Council of New Zealand

2004 PREDICT-CVD Evaluation Study – Waitemata District Health Board and Future Forum

2004–2006 – National Heart Foundation Research Fellowship

2007 PREDICT Health Provider Study – the Health Research Council of New Zealand

2. The Setting – features of the New Zealand health care environment relevant to clinical decision support systems

"….health information technologies are tools that support the delivery of care - they do not, in and of themselves, alter states of disease or health. As such, how these tools are used and the context in which they are implemented are critical."

Chaudry B. et al. (2006)[65]

2.1 Introduction

For over a decade New Zealand CVD guidelines have recommended that risk management be based primarily on a patient's absolute risk of having a CVD event over a five year time period. These clinical guidelines were world leading and guidelines in the United Kingdom and western European have subsequently adopted a similar risk-based approach. However, uptake of CVD risk assessment and management recommendations in routine practice is variable and substantial evidence-practice gaps have been described.[52] [53] Simultaneously, computerised decision support systems (CDSS) as vehicles for delivering clinical guidelines have been rapidly evolving over the last ten years, with technological advances increasing access to computer systems in clinical practice. These systems have been widely acknowledged as having the potential to improve the quality of care provided.[33] However, new technology is expensive and all innovations are associated with opportunity costs. The degree of success of CDSS depends in part on the setting or context within which these systems are based.

The initial target users of a CDSS for CVD risk assessment and management are general practitioners and practice nurses. This chapter provides an environmental 'scan' of New Zealand general practice, national systems and policies to determine the feasibility of developing and readiness of implementing a CDSS. The chapter starts by describing the New Zealand health care system, the current policy environment, the evolution of primary care organisations and the primary care workforce. To achieve

measurable population health improvements while simultaneously conducting epidemiological research using a CDSS, general practice would need to be highly computerised, the electronic patient management systems would need to be adaptable to fit life course disease management and a secure health network for data exchange would need to be present.

2.2 Historical context of present day New Zealand health care system

Basic structures for our health care system were put into place by the 1872 Public Health Act and the 1885 Hospital and Charitable Institutions Act.[66] The 1885 Act created local hospital districts that remained essentially unchanged until the health reforms in the 1990s. These Acts also set the tenor of the early New Zealand health care system- separate health systems for the rich and the poor, for public health (and preventive services) and clinical services, and for primary and secondary care.

In 1938, a Labour government brought in the Social Security Act with the plan to *"establish a fully state-funded, integrated national health service -- from free and universally available primary care and general practice services through to fully funded and accessible mental health and hospital-based services".*[66] The Act was strongly opposed by the medical profession[67] who resisted losing professional independence and autonomy with the proposed introduction of capitation funding. A compromise was reached in 1941. The aim of a free general practice service was changed to one that was government subsidised via a General Medical Benefits System (GMS). GPs were able to claim the subsidy of seven shillings and sixpence for each patient consultation as well as retaining the right to charge a fee-for-service. Initially, the GMS allowed a reasonable income for GPs and anecdotally many patients received free services through the 1950s and 1960s.[68] However, over time and successive governments, the GMS was never adjusted for inflation and the patient co-payment as a proportion of the overall service fee became greater and greater. By the 1990s, the GMS benefit subsidy was $1.35 per patient. In my own general practice this meant that an adult patient was paying over 80% of the overall fee. The GMS was eventually changed in 1992 with a

government subsidy targeted at low income families and those with high health needs. For everyone else, no subsidy was available. However those most in need were often unaware of these subsidies and there was inconsistent uptake in the most deprived communities.[69]

2.2.1 Health reforms

In response to accelerating health care costs, from the early 1990s the New Zealand health system underwent ten years of reforms. In 1993, the role of health purchaser was separated from health providers assuming that a commercial approach to managing funds and competitive tendering for contracts to provide health services would result in increased efficiencies in delivery of health services and increased responsiveness to consumers.[70 71] The country was divided into four regional health purchasing authorities (with responsibility for defined geographic areas) and hospitals were reconfigured as for-profit provider businesses named Crown Health Enterprises (CHEs) and subject to ordinary company law.[67] There was considerable discussion in government circles about the need reform and organise primary care but no policy changes were made at this stage. The expected efficiency gains from the reforms in terms of increased productivity and other anticipated benefits did not occur.[66 72-75] They were expensive (estimated between 2-10% of the total annual health vote)[75] and the market oriented system generated large contract transactional costs as well as invisible costs to collegial networks and collaborative relationships.

However, there were some unexpected successes from the reforms, particularly in primary care with the development of Māori health providers, community health trusts and collective groups of GPs coming together under the umbrella of independent practice associations (IPAs).[71] By contracting with the regional health authorities to hold budgets for laboratory and pharmaceutical spending (heavily subsidised by the government), IPAs could make substantial savings that could be reinvested into other primary care services or into the establishment of new services.[76] These savings were important for IPAs as, with success, other GPs were encouraged to develop or join these collectives. It allowed infrastructure to be built: staff employed, information systems to be

developed, quality improvement initiatives, development of shared local guidelines, peer groups and GP continuing medical education groups. Perhaps more importantly, IPAs supported GPs to look at a bigger dimension - that of population health, and the potential of collective strategic planning. Furthermore, IPAs facilitated a focus on preventive care as well as the provision of acute reactive treatment services. Information systems within individual practices were being supported as well. As a member of the Central Auckland IPA (later to become part of the ProCare Network), my general practice received one-off funding from the Northern Regional Health Authority to support the acquisition of computers. Although our practice had already made the capital outlay to computerise the front desk and practice administration, this allowed us to expand the role of our systems to go from paper-based to electronic recall systems for immunisation, cervical and breast screening and start to develop chronic disease registers. Furthermore, electronic receipt of laboratory results instead of the traditional paper-based reporting delivered once daily by courier was emerging as a rapid, consistent and reliable way to receive this information.

From Crown Health Enterprises (CHEs) to District Health Boards (DHBs)

In 1996, the four regional purchasing authorities were amalgamated into one central purchasing authority, the Health Funding Authority. The Crown Health Enterprises (CHEs) were renamed as 'Hospitals and Health Services'. The emphasis on competitive contracting shifted to collaboration and cooperation to foster teamwork and co-ordination of health care delivery that had suffered as a result of the business-oriented health model.[72] Although the health service was suffering from "reorganisation fatigue",[72] further structural changes were introduced in 1999. Hospital and Health Services became 21 District Health Boards (DHB) and a population-based funding formula was introduced.

Of great significance was that for the first time in the New Zealand health care system, most of the vote health funding was devolved to the DHBs, each of which became responsible for *both* primary and secondary services *as well as* public health services for defined geographic areas.[70]

2.3 National Health Care Strategies

Coupled with these changes, a series of national health care strategies were formulated to set the direction and priorities for health service delivery; the New Zealand Health Strategy (2000),[77] the New Zealand Disability Strategy (2001),[78] the Primary Health Care Strategy (2001)[79] and the Māori Health Strategy (2002).[80] The overarching aims of the New Zealand Health Strategy were to improve the health of New Zealanders by focusing on areas that would ensure the greatest benefits and reduce health inequalities. Thirteen population health objectives were identified, six of which have direct relevance to cardiovascular disease.[77]

The 13 population health objectives are to:

1. reduce smoking
2. improve nutrition
3. reduce obesity
4. increase the level of physical activity
5. reduce the rate of suicides and suicide attempts
6. minimise harm caused by alcohol and illicit and other drug use to both individuals and the community
7. reduce the incidence and impact of cancer
8. reduce the incidence and impact of cardiovascular disease
9. reduce the incidence and impact of diabetes
10. improve oral health

11. reduce violence in interpersonal relationships, families, schools and communities

12. improve the health status of people with severe mental illness

13. ensure access to appropriate child health care services including well child and family health care and immunisation.

The Primary Health Care Strategy was seen as the key step in achieving these goals[81] and represented a radical restructuring of primary care delivery in New Zealand. This strategy took a population health approach to the funding, planning and delivery of health services consistent with the Alma–Ata Declaration[82] and the original 1930 welfare state intentions. Primary health care would include:

- health improvement and preventive services as well as first line treatment services
- community participation, shared governance and decision making reflecting the needs and priorities of the community;

and move:

- from individual practitioners to a network of primary care providers who provided co-ordinated service
- from individual health care to the health of enrolled populations and local communities.

Key to this strategy was the establishment of Primary Health Organisations (PHOs), not-for-profit organisations funded by the District Health Boards on a capitation basis initially under two needs-based funding formulae - Access and Interim. The Access Formula funded those PHOs that served populations with high health needs i.e. Māori, Pacific and those living in socio-economically deprived areas. Access-funded PHOs were able to provide free or very low charge GP visits. Patients who belonged to Interim funded

PHOs paid much the same as they previously had. The Interim Formula was so-named as the government intended to extend the higher capitation rate to all New Zealanders over subsequent years.[83] In 2003, increased subsidies were provided to Interim-funded PHOs for children and adolescents (aged 6-17 years) and in 2004 for older people (aged 65 years and over). The transition to complete low cost access for 18-64 yrs occurred in 2006 (aged 45-64 years) and mid 2007 (24-44 years)[83-84] Significantly unlike the GMS, capitation payments are annually adjusted for inflation.

Reducing health inequalities between different population groups has been identified as a major concern and priority in all the national health strategies. Higher capitation payments[84] continue to be paid for health promotion and Services for Increased Access (SIA) for Māori and Pacific populations and people living in deprived areas. As a result of this and other capitation funding, PHO-wide programmes were initiated for preventive care in general practice and the community (such as CVD risk assessment and management). Such programmes aimed to reduce health inequalities particularly for Maori as the Treaty of Waitangi partners, and indigenous people, of New Zealand.

From IPAs to PHOs

While membership of a PHO was voluntary[81] the concept was generally acceptable to general practice, given that in many ways they were similar to IPAs and there were significant financial incentives to make the transition. Some original IPAs have been merged into PHOs while others remain partially or largely independent entities from PHOs.[71] Some large IPAs have become the management services organisations for a number of PHOs. By 2005, 77 PHOs had been established with 3.83 million New Zealanders enrolled (93% population)[85] and by 2007, 82 PHOs had enrolled 95% of the New Zealand population.[86]

2.4 New Zealand primary health care workforce

In New Zealand, there is an extensive range of primary health care providers including community health workers, social workers, midwives and early childhood service

providers (e.g. Plunket, dental nurses, vision-hearing testers), community and outreach nurses, doctors and practice nurses working in general practices or Accident and Medical Clinics, medical officers of health and other public health officers, dentists, dietitians, psychologists, pharmacists, technologists (e.g. laboratory and radiation), optometrists, physiotherapists, occupational therapists, podiatrists, chiropractors, osteopaths and other therapists.

The general practitioner remains the key gate-keeper to secondary and tertiary hospital or specialist medical services. In general, apart from independent midwives, a few specialist outreach services and small amount of patient self-referral (e.g. to dermatology and gynaecology), most referrals to specialist medical care occur through general practice.

The New Zealand General Practitioner workforce

In 2006, 33% of the 9547 active medical workforce were general practitioners with an additional 3% classified as working in primary care other than a general practice. On average there were 73 full time equivalent (FTE) GPs per 100,000 patients (a ratio of 1 full-time GP to 1,379 people). When classified according to District Health Board, the highest and the lowest GP densities (ratio:population) were in the Auckland region with 54 FTEs per 100,000 population (1:1,850) in Counties Manukau District Health Board and 92 FTEs per 100,000 (1:1090) in the Auckland District Health Board catchment.[87] The number of active GPs in 2006 was similar to 2000/01 levels[87] and FTE per 100,000 were also similar to recent GP density surveys in Australia (between 72 to 96 FTE per 100,000).[88] However, GP density only provides a crude measure of patient access to GP care and the capacity of the workforce to meet the needs of a population. It does not take into account factors such as geographic distance to the nearest GP, age and socio-economic deprivation of populations, the burden of disease within differing communities or the availability and competencies of other health workers (such as the number of practice nurses and their scope of practice).[88] Furthermore, in a 2004 analysis of the New Zealand General Practitioners Workforce[89] and a subsequent editorial in the New Zealand Medical Journal,[90] sustainable capacity of the general practice workforce was and remains a key concern. Factors include; an ageing GP population (60% of all GPs

over 46 years, 37% being over age 50 years); a decline in new graduates choosing general practice as a specialty choice; increased numbers of women in the medical workforce (less FTE) and increasing reliance on overseas trained doctors especially in rural areas.

The New Zealand primary care nursing workforce

In 2004, of the 34,660 active registered nurses, midwives and enrolled nurses, 10.6% (3672) were classified as working in primary health care including practice nursing. This did not include nurses working in public health, district, palliative care or in continuing care of the elderly.[91] There are currently 47 independent nurse practitioners with ability to prescribe medications within their nominated areas of expertise. Five of these nurse practitioners specialise in diabetes or CVD chronic disease management.[92]

Use of GP services

Every year, 80% of New Zealanders will see their GP at least once irrespective of ethnicity.[58] Age groups with higher health care needs are more likely to visit their GP. Over 90% of older people (over 65 years) and children aged 0-4 years were reported as visiting their GP at least once in a year. In terms of frequency of consultation, overall 62% made 1-5 visits/year and 12% had 6 or more visits per year. At consultation, 70% received a prescription.[58] Although referrals to laboratory and other diagnostic (e.g. radiology) and treatment (e.g. physiotherapy) services are common, most of the time, a consultation with a GP does not result in referral to other specialist medical or hospital services.

2.4.1 Implementation of the Primary Health Care Strategy

Although GPs were generally supportive of the philosophy embodied in the Primary Health Care Strategy, there was no clear implementation strategy. The process of implementation was deemed to be evolutionary and *"DHBs will work with these organisations (sic IPAs, Māori Provider Organisations, rural trusts) and their communities in order to find the best way locally"*.[81]

McAvoy (2005)[71] highlighted key implementation concerns including inadequate management funding or support for PHO establishment and infrastructural costs, information systems, reporting systems, co-ordination of services, management of resources and developing governance capacity. Additional concerns included the lack of publicity of PHOs, their role and potential benefits for the community and lack of advice around enrolment for the general public which has led to duplicate enrolments and large shifts in funding when mobile populations shift between PHOs. Financial viability has been an issue where GPs belonging to Interim funded PHOs are in the same neighbourhood as GPs belonging to Access funded PHOs with patients leaving to go where it is cheaper. GP workforce and workload issues were also concerns especially with increasing expectations of preventive care and chronic disease management and the need to provide PHOs with practice data and other additional administrative tasks which are usually not remunerated. Workforce issues and increased expectations have affected not just the doctors but other members of the general practice team, especially nurses who have an expanded role under the strategy especially in chronic disease management.

2.4.2 National chronic disease management initiatives

Of relevance to this thesis are two national Chronic Disease Management programmes (Get Checked Diabetes Aotearoa and Care Plus) that facilitate team-based care, chronic disease proficiency and information sharing by providing a unified dataset to be gathered (either paper-based or electronically) in general practice and contribute to monitoring service delivery.

Get Checked Diabetes Aotearoa

The Get Checked programme was first introduced in 2000 and is funded by the Ministry of Health. It is targeted to patients with diabetes and facilitates a free annual check up with their GP or practice nurse.[93] The objectives of the programme are to:

- systematically screen for the risk factors and complications of diabetes to promote early detection and intervention
- agree on an updated treatment plan for each person with diabetes
- update the information in the diabetes register used as a basis for clinical audit and planning improvements to diabetes services in the area
- prescribe treatment and refer for specialist or other care if appropriate.[93]

Care Plus

Care Plus was introduced in July 2004 as a new funding initiative as part of the Primary Health Care Strategy. It was targeted to patients who are high-health users (holding a High Use Health Card) or have chronic conditions, acute medical or mental health needs or terminal illness requiring intensive medical management. A person is eligible for a High Use Health Card if they have six GP visits in 6 months or 12 visits within a year. A Care Plus patient could expect to receive a funded extended initial appointment with a nurse or doctor and together develop an individualised care plan. After this consultation, it is expected that the patient will be followed up and have at least three further free visits over the next 12 months.[94] The concept was well supported, with 80% of PHOs delivering Care Plus in some or all their practices by April 2006.[94]

These two new funding streams facilitated chronic disease management in general practice and in particular gave practice nurses an opportunity to expand their role and develop new skills. Many practices where the GP was initially the sole provider of chronic disease care adopted a team-based approach or devolved care to their nurses. An evaluation of Care Plus found that doctor-only care was delivered in 5% of practices, nurse-only care in 5% of practices and for 90% of practices there was a 50:50 split of team-based care (GP-led but shared with nurse or nurse-led but shared with doctor).[94]

However, these initiatives also highlighted a large nursing-skill gap and the need for the provision of postgraduate practice nurse training in chronic disease management, further qualifications and the need to review prescribing rights.

The most recent evaluation of the Primary Health Strategy[84] has reported that fees have generally fallen for patient groups where new funding has been provided (especially in Access-funded PHOs and for the over 65s in Interim-funded practices). There have been marked increases in consultation visits for almost all age groups, community service card holders and groups with high health needs. Furthermore, there appears to be increased involvement of nurses in primary health care delivery (as measured by the proportion of nursing visits over time) but this may be due to changes in reporting.[84]

2.5 Measuring quality improvement in primary health care

Over the last 15 years, there has been substantial growth in clinical governance and quality improvement-related activities in the New Zealand primary care sector.[95] Significant drivers included the establishment of IPAs and more active professional and collegial bodies (Royal New Zealand College of General Practitioners [RNZCGP], New Zealand Nursing Organisation [NZNO]). In addition the New Zealand Medical Council has introduced vocational registration status requiring completion of an approved postgraduate vocational medical training programme and continuing accreditation requirements towards maintenance of professional standards for all medical specialties including general practice. The Primary Health Care Strategy[79] has provided further momentum with requirements to measure the performance of health care delivery to achieve national, regional and local community goals. Several PHOs (e.g. HealthCare Aotearoa, the ProCare Network, Pinnacle) and the RNZCGP have already developed their own quality improvement indicators. However, in 2003/2004, national performance indicators for PHO contracting were proposed[96] and in 2005, a staged approach to the PHO Performance Management Programme began.[96] The programme was led by the combined District Health Boards (DHBNZ) and included primary care and Ministry of Health representatives. It started with an establishment phase (see table 2.1 below) providing prerequisites that PHOs needed to meet to be eligible for incentive payments and a set of eight phase 1 “clinical indicators” in combination with “process/capacity” and “financial” indicators.[96] While only one of these indicators has relevance to CVD and diabetes, it was proposed that the second and third phases would emphasise prevention

and treatment of chronic disease particularly diabetes, cardiovascular disease and cancer. The second phase indicators are still being developed in 2008[97] and are close to release.

Table 2.1 PHO Performance Management Programme[96]

Establishment phase prerequisites 2005

- Recording of ethnicity for at least 85% of patient register
- Compliance with fees agreement in the PHO contract
- A signed contract with the current national PHO service agreement with the DHB
- Complete reporting of practitioner information to enable baseline measurement of phase 1 indicators
- Compliance with reporting requirements in the PHO contract
- Recording of ethnicity for at least 85% of patient register

Phase 1 indicators (commenced January 2006)

- Age-appropriate vaccinations for 2 year olds
- Influenza vaccinations for those ≥65 years
- Cervical cancer screening coverage
- Breast cancer screening coverage
- Inhaled corticosteroid prescribing
- Metformin:sulphonylurea ratio of dispensing
- Investigation of thyroid function
- Measurement of acute phase response (Erythrocyte Sedimentation Rate vs C-reactive protein tests)

Phase 2 (proposed indicators -2008/9)[97]

- Disease coding for ischaemic heart disease
- CVD risk recorded in target population within the last 5 years
- Disease coding for diabetes
- Annual review for those people coded as having diabetes

It is not the purpose of this thesis to provide a critique of the appropriateness of performance indicators, the compliance costs associated with data collection, how the results will be used, from what or whose perspective, possible perverse incentives and privacy issues invoked. They are mentioned here along with the other organisational, workforce and policy discussion to serve as contextual features of the health care environment that may serve as enabling (or rate-limiting) factors towards improvements

in preventive practice and treatment for CVD and diabetes and the potential success of a tool designed to assist these conditions.

Overview of the current New Zealand health care environment

In summary, after 150 years of separate funding and organisation of primary care, secondary care and public health (health promotion and disease prevention), in the last few years these services and their funding have been brought much closer. National health strategies and general practice funded programmes are facilitating a unified population health direction as well as targeting inequities and those with chronic disease. Development of Māori health providers, community health trusts, collectives of general practitioners (IPAs) and latterly PHOs (bringing together community and all primary health care providers) have brought a new focus on the needs of populations as well as the awareness of the need for infrastructure to support the quality of health care provided and to measure improvements. However, considerable barriers to population-based services still remain. Currently, general practice is still coming to terms with capitation, population health and how to implement the Primary Health Care Strategy while still being primarily fee-for-service small businesses. To conduct systematic, equitable disease prevention and management programmes such as the CVD risk and diabetes management programme that is the focus of this thesis, there will need to be a more sustainable primary care clinical work force and increased capacity and skills to meet the demand. Furthermore, there are increasing requirements in PHOs for administration, contracting, reporting and population health expertise. This additional load (and its associated compliance costs) is duplicated in 21 District Health Boards and 82 PHOs within a national population smaller than many international cities. A computerised decision support tool therefore would need to support these requirements.

2.6 Primary care information systems

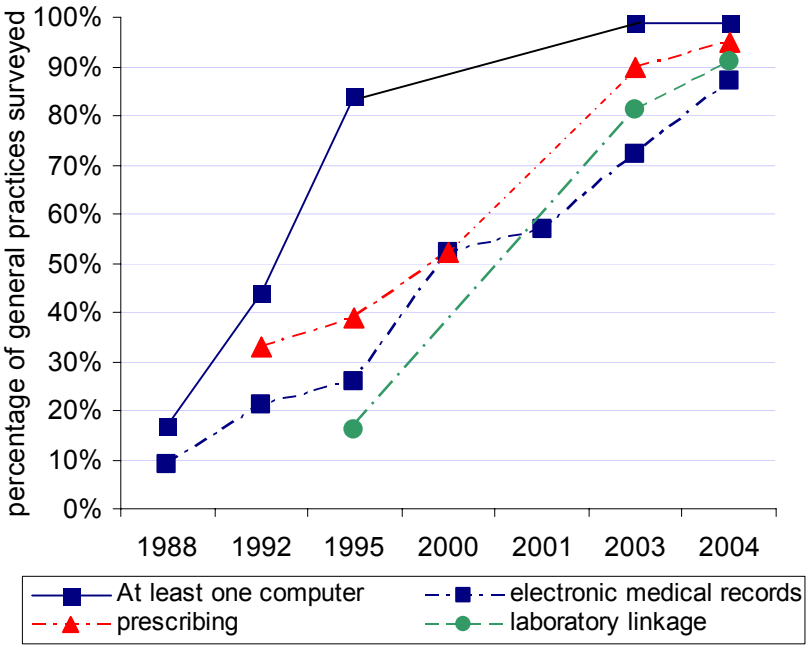
To achieve measurable population health improvements, primary care information systems needed to develop in step with the policy environment. The next sections describe current features of health information technology (IT) in New Zealand of

relevance to the feasibility of development and implementation of a computerised decision support system within a primary care setting and the ability to securely exchange, store and link patient health data.

2.6.1 Development of GP information systems in New Zealand

Since the 1980s, electronic systems in general practice have moved from the front desk administration to include the consultation room to electronically linking data within and across primary and secondary care sectors. From a series of general practice surveys [98-104] conducted in New Zealand, trends in computerisation from 1988 to 2004 have been plotted in Figure 2.1.

Figure 2.1.Trends in general practice computerisation from 1988 to 2004



In 1988, 17% of general practices reported having at least one computer although they were mainly used for accounting and administrative needs.[98] By 1995 this had reached 84%,[101] increasing to 99% in 2003-2004.[103] The use of electronic medical records (EMRs) increased at a similar rate but 5-10 years later. GPs tended to initially use the

prescribing functions of electronic records followed by electronic notes and electronic linkage to laboratory test results.

The term EMR is not used consistently around the world.[105] The definition of electronic medical record used here is that used by Protti (2007): *"EMR generally refers to computer-based clinical data of an individual that are location specific and kept by a single physician office or practice, community health centre or possibly ambulatory clinic"*.[105] The use of EMRs in New Zealand primary care was 9% in 1988[98] steadily rising to 87% in 2004.[104] Community pharmacists in New Zealand are also highly computerised with about 98% now using computers as part of their business.[106]

For GPs in New Zealand, around 15 different patient management system (PMS) software applications for managing patient EMRs have been available, with one PMS, MedTech, holding 60% of the market share in 2003.[103]

Internationally, other countries with a similar degree of general practice computerisation (over 90%) include Australia, Austria, Denmark, England, Germany, The Netherlands, Norway, Scotland and Sweden.[105] In contrast, only 17% of American primary care physicians used a computerised PMS for their clinical notes in 2002,[107] with a similar figure reported for US physicians in 2007.[108] The key international driving forces for a high degree of primary care computing identified by Protti (2007) were government policy and/or funding support, government mandated electronic billing, college or professional association leadership, peer influence, accreditation of vendor systems, the degree of support received and use of coding systems.[105]

Reasons for uptake in New Zealand

Key drivers in the 1990s were the development of IPA funding and quality initiatives that required practice data (such as laboratory and prescription medicine budget holding), the delivery of electronic laboratory results (widely available from around mid-1990s) and other secure health information messaging available via HealthLink (a private company). Electronic receipt of laboratory records enabled the direct input of data into a patient's electronic clinical record and facilitated the transition to fully computerised clinical notes.

This resulted in large time efficiencies. In my own practice and for most of my peers, paper–based laboratory results were individually pasted, taped or stapled into paper-based records. However, it is likely that the mandating of electronic claiming of the GMS (General Medical Subsidy) in 1998 tipped the balance. Full computerisation of practices was seen as inevitable with increasing obligations to maintain professional standards/vocational registration within the College of GPs (e.g. having disease registers, undertaking audits of care) and to provide information to the Ministry of Health, DHBs and PHOs.[103] In addition there was increasing availability of electronic linkage to secondary care (e.g. booking systems, electronic discharge summaries) and to other health care organisations (e.g. electronic billing of accident and injuries to Accident Compensation Corporation [ACC]).

Unlike the United Kingdom,[105] GP computerisation occurred in the absence of national strategies, legislation or other health policy. While computerisation was high, data systems developed in unsystematic ways. Primary care providers received scant or no training on the use, features and functionality of their PMS software. An expert currently training GPs estimates that the base GP knowledge/competency of their PMS system is on average around 65% of the software functionality, with variability in knowledge largely individual rather than determined by the practice as a whole.[109] Patient EMRs were (and to a great extent remain) mostly based on the traditional paper-based record with the focus on recording each patient consultation as is the clinical practice imperative. Data were gathered and stored commonly in unstructured, idiosyncratic formats and retrievability even in terms of simple practice audits was (and remains) a major issue.

The first national health information discussion document, *From Strategy to Reality, The WAVE Project*[110] was published in October 2001 followed by the Health Information Strategy for New Zealand in 2005.[106]

2.7 Towards an electronic health record: linking with health care delivery services and national datasets

"Information's unusual quality is that it grows more valuable when it's given away."
The WAVE Project 2001[110]

People are referred by GPs to hospital or other services (and discharged back), they receive prescriptions, blood tests and other investigations. Co-ordination and retrieval of such data per person, per practice or per population and translation into useable knowledge to optimise care is much more challenging. Hence the need for unified standards and common methodologies from the collection of personal data, coding of conditions, procedures and investigations, messaging and data exchange, security and network infrastructure while at the same time ensuring that patient privacy and autonomy is respected. Definitions for two other terms, the electronic patient record and the electronic health record (EHR), are needed for clarity. These terms are used inconsistently and sometimes interchangeably in the literature and are defined by Protti, 2007 as below.[105]

Electronic Medical Record (EMR) – computer-based clinical data of an individual that are location specific and kept by a single physician office or practice, community health centre or possibly ambulatory clinic.[105]

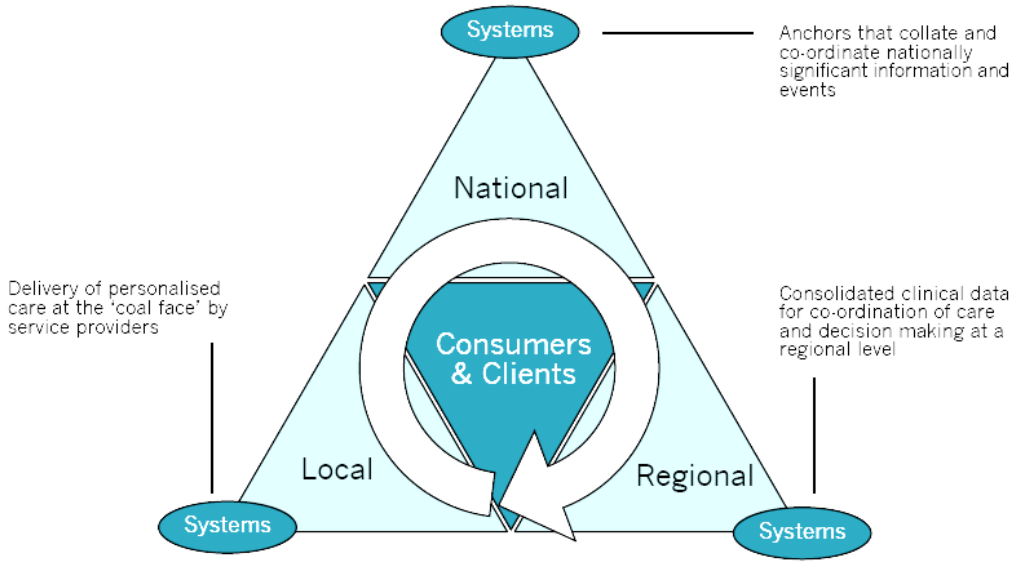
Electronic Patient Record – computer-based clinical data of an individual that are location specific and kept by a single health care organisation such as a hospital, acute care facility or regional health authority .[105]

Electronic Health Record (EHR) – computer-based clinical data of an individual that are available across multiple locations. It is sometimes referred to as a longitudinal health record, which includes data about the individual from a number of different interoperable EMRs and electronic patient records. An electronic health record is shared across jurisdictions such as primary and secondary care.[105]

In this thesis, only two terms are used; EMR (for electronic GP patient records) and EHR (patient health records integrated with and accessible across multiple sites). This section focuses on the EHR, a longitudinal health record that would allow co-ordinated primary health care as per the Primary Health Care Strategy and monitor health improvement and reduction in health inequalities as per the New Zealand Health Strategy (2000),[77] and other national policies.

The 2005 Health Information Strategy Steering Committee recognised that a single electronic health record (EHR) that brings all information together within one physical repository was *"neither a panacea nor practicable, affordable or achievable"*.[106] The adoption of what is termed 'distributed' EHRs where information is spread across many physical repositories but can be linked and referenced electronically was considered to be the best way forward. An example of a successful distributed EHR model was established at the Regenstrief Institute in Indianapolis, Indiana, USA.[111] The proposed model of the distributed EHR in New Zealand within the Health Information Strategy is given below in Figure 2.2.

Figure 2.2. New Zealand distributed Electronic Health Records Model as described in the New Zealand Health Information Strategy 2005[106]



Local systems such as EMRs held by GPs, dentists, and residential aged care facilities carry in-depth data about an individual's previous and current health, consultations and

care planning. Regional systems gather specific clinical data at a DHB level or PHO level to inform service delivery and co-ordination of care. These data include hospital discharge summaries or disease management applications that support the sharing of data. National systems provide 'anchors' that co-ordinate nationally significant information and events and allow sharing of information. The key anchors referred to in Figure 2.2 are the National Health Index (NHI) number and the Health Provider Index (HPI) currently being implemented.[106]

2.7.1 The National Health Index (NHI) number

Each New Zealander has a national health index number assigned to them that is used to document health service interaction. The NHI is recorded on each patient EMR within GP patient management systems as well as all national health data collections managed by the New Zealand Health Information Service (NZHIS). These include the National Minimum Dataset (NMDS) for in-patient and day-stay hospital discharges, the national mortality collection, the national pharmaceutical collection (prescription data) and the national laboratory claims collection (laboratory test usage data) as well as several other databases (e.g. Cancer Registry, National Immunisation Register).

The NHI number is linked to data on a patient's date of birth, gender, ethnicity, domicile (census area unit) and, more recently, the New Zealand Deprivation Index score.[112] The latter score is an indicator of socio-economic deprivation by location of residence within a census area unit. A study undertaken in 2004,[113] indicated that linkage of demographic data collected from general practice to hospitalisation data via an encrypted NHI number was associated with 99.6% matching for date of birth, 99.1% for sex, and 84% for ethnicity. They concluded that NHI-linked datasets would provide a sound basis for research into publicly funded health care.[113]

2.7.2 The Health Provider Index (HPI) number

Health providers have had to use multiple identifiers for 'logging in' to access patient information or for making transactions with other health organisations. For example, a

GP might have an ACC claim number, a New Zealand Medical Council number, an IPA number, a maternity agreement number as well as laboratory and screening programme identifiers. Furthermore, the WAVE Strategy also indicated that a number like "12345" could belong to a nurse, doctor or dentist all at the same time.[110] In order to provide a consistent way of finding and securely identifying practitioners and allowing appropriate access and transfer of health-related information, the health provider index number (HPI) was considered an important additional anchor.[106] It is a unique identifier divided into three indexes; providers (who they are), provider organisations (who they work for) and physical facilities (where they work).[114] The HPI will initially hold only information on providers sourced from responsible authorities (e.g. Medical, Nursing and Dental Councils) and include practitioner name, qualifications, practicing status, scope of practice, conditions on practice, and, in some cases, contact details.[114] Implementation of the HPI began in 2006 with initial phases to develop the practitioner registry with completion and linkage to ACC and national data collections in 2009/10.[115]

2.7.3 National data collections

The National Minimum Dataset (NMDS) is a national collection of public and private hospital discharge information, including clinical information coded according to ICD-10-AM (International Statistical Classification of Diseases 10th Revision, Australian Modification) for inpatients and day patients.[116] All records must have a valid NHI number and this is audited regularly for duplicates. Data have been submitted electronically in an agreed format by public hospitals since 1993 and by private hospitals for publicly funded events (e.g. births and geriatric care) since 1997.[116] There is no legislative requirement for private hospitals to provide data on privately funded events such as private cardiac surgery. Submission is voluntary and also often very limited with one only code e.g. hernia repair without any other diagnoses.

The NZHIS Mortality Collection classifies the underlying cause of death for all deaths registered in New Zealand using the ICD-10-AM 2nd Edition and the WHO Rules and Guidelines for Mortality Coding. The dataset has NHI-linked deaths registered from 1988 onwards.[116]

The Pharmaceutical Collection contains claim and payment information from pharmacists for subsidised dispensings and was started in July 1992. The Laboratory collection was established in 2000 and contains data from July 1997. It contains claims and payment information for primary care laboratory tests.

2.7.4 Information sharing

The 2005 Health Information Strategy Steering Committee identified other emerging features with regard to international health information systems. Of note was the recognition of the need for connectivity to a secure and reliable network to increase the level of information sharing and the co-ordination of care.[106] This includes access to scheduling systems, pharmacy systems, messaging to and from other providers, the use of web-based CDSS systems, tele-health for monitoring home-based services and image sharing particularly for providers in isolated rural areas. These applications require high bandwidth (broadband) network technology. There are gaps in the current national broadband infrastructure in some areas of New Zealand and the Ministry of Education and the Ministry of Economic Development are currently leading a provincial broadband project (PROBE) to address these gaps.[106]

To be able to share this information and maintain public trust, there needs to be agreement on standards for the quality of the information (e.g. datasets and coding), and standards for data messaging and security. This next section details these issues as they are critically important to the development (and future design updates) of CDSS, data collection within input templates, data exchange of patient information and decision support output and data linkage with national datasets.

2.7.5 Semantic interoperability

Clinical data can be crudely divided into structured and unstructured data[117] Unstructured data in the form of narrative text is very rich in meaning and can *"capture human-interpretable nuances that numbers and codes cannot"* (Ontrup 2005).[117] However, they are difficult to retrieve reliably (natural language differs within and

between doctors over time) and systematically (difficulty of capturing all the variations ascribed to a certain condition or procedure). To be able to share data across providers and other sectors they need to be structured so that, with consistent representation of data, clinical information can be unambiguously exchanged.

The central principle in unambiguous communication between remote computer systems is semantic interoperability. This is a state whereby the meaning of a message's content (in contrast to merely its structure) is unambiguously understood by both the sending and the receiving computer system.[118]

The basic requirements for semantic interoperability are:[118]

1) *Equivalent and robustly specified data types:*

The basic types of data that can be expressed as data elements (similar to an alphabet, numbers and punctuation). These need to be consistently specified. Examples are 'date', 'integer', 'text', 'ordered list'.

2) *Common semantics*

This refers to vocabulary (which words can be used, and their meaning) and conceptualisation (what is meaningful to say).

For example; when Dr A says "smoker" he means "yes, a smoker", whereas when Dr B says "smoker" she means "smoker, ex-smoker, non-smoker" - seemingly equal entries in a patient management system from two different vocabularies that actually have different meanings. An example for conceptualisation is as follows. "The dog eats red meat" vs "The dog sings blue trees" - both conform to the same vocabulary, grammar and syntax, but the latter makes no sense.

3) *Agreed format:*

This refers to grammar (rules for combining vocabulary and data into statements) and syntax (how a statement is structured). For example; "The patient was given pain

medication" vs "The patient was given medication for pain" – both conform to the same vocabulary, grammar and conceptualisation, but have different syntax.

4) A formal standard for exchange

This refers to how to exchange data between systems without loss of meaning. For example; "I can't understand it" compared with "je ne le comprends pas" – using two separate "standards" (languages) to exchange an idea.

2.7.6 Clinical coding standards

Existing coding systems or controlled clinical terminologies such as READ codes, SNOMED CT ®, LOINC laboratory codes and ICD codes, provide a taxonomy of terms or reference datasets to facilitate semantic interoperability. The READ coding system is the most widely available classification system in New Zealand general practice to classify patient reasons for consultation.[119] This system was first developed by James Read in the 1980s in the United Kingdom (UK). In 1990, the copyright was purchased by the UK National Health Service and further development of codes continued.[120] In 1999, the READ codes were amalgamated with the American SNOMED ® system developed by the College of American Pathologists to form SNOMED-CT ® (Systematized Nomenclature of Medicine - Clinical Terms). This is currently being touted as the most comprehensive multilingual clinical health care terminology in the world.[121] New Zealand, along with nine other nations, is a founding member of the International Health Terminology Standards Development Organisation (IHTSDO, also known as SNOMED SDO). In 2007, the Ministry of Health secured the rights for New Zealand to use SNOMED-CT and are putting in place the arrangements required for licensing, distribution and adoption across the health sector.

A separate coding system, LOINC (Logical Observations, Identifiers, Names and Codes), was developed by the Regenstrief Institute in Indianapolis, USA in 1994.[122] A subset of these codes, laboratory codes, has been localised for use in New Zealand. In 2005, LOINC codes were introduced for Haematology, Clinical Pathology and

Immunology tests in New Zealand.[122] The plan is to include Microbiology, Histology and other commonly performed hospital laboratory tests in the next few years.

New Zealand hospitals have used the International Statistical Classification of Diseases (ICD) for the past 30 years. Currently, public hospitals throughout New Zealand code their data using ICD-10-AM and ICD-O (Internal Classification of Diseases for Oncology). These two standards are the basis of disease classification in seven national data collections described previously (e.g. Mortality national collection). They were formally endorsed as standards in 2006 by the Health Information Strategy Advisory Committee (HISAC).[123]

2.7.7 Messaging standards

GPs and PHOs often need to interact with a variety of external services, for example on-line submission of electronic referral letters to secondary services, ACC forms and Special Authority forms for restricted medicines or obtain an NHI number for a newly enrolled patient via the NHI lookup service. Many of these interactive services use different architecture and standards to implement data exchange. These create complexity, confusion and often duplication of effort to translate from one system to another. Furthermore, because of the different approaches, health care providers have needed to install, learn and operate a range of interfaces and techniques, which can provide further barriers to clinical data collection and information exchange.[124]

The 2001 *WAVE* project recommended the adoption of Health Level Seven (HL7) standards for data models and XML messages (defined below)[110] which have been further endorsed in the Health Information Strategy for New Zealand.[106] Basically, they provide consistent, robust approaches for one computer server to link with another.

Definitions

HL7 – internationally monitored standards, protocols and methodologies for flexible, cost-effective inter-operability between health care information systems.[110]

Data Model – a logical (abstract) description of the structure (syntax) of data and relationships as represented in an information system. It tells us how the individual words and phrases of a statement are stored, by providing the attributes of each data item as well as the relationships between them.[118]

XML (short for eXtensible Markup Language) – a language designed for exchanging data across the web, in a simple human-readable form.[110]

2.7.8 Health information privacy and security

Identifiable health information needs to be exchanged between providers to ensure co-ordination of care – that the right thing happens to the right person at the right time. The challenge is to protect information while at the same time making it available for appropriate purposes.[110] The 1993 Privacy Act and the 1994 Health Information Privacy Code provide a national framework for collecting, holding, using and disclosing personal information. The Code is about ensuring information is used consistently with the purpose for which it was obtained and that it is understood by the person from whom it was obtained. It is not that personal health information cannot be shared, but that the person needs to be advised before collection and sharing, and the reasons explained. Individuals have the right to access and request that their data be corrected.[110] The code sets out 12 rules which are provided in Appendix 2.1.

The WAVE strategy contended that health information in the context of the Privacy Act was about identifiable individuals, *not anonymous or anonymised data.*[110] The Health Information Strategy noted that a *"balanced approach is required to ensure that the system is secure and that the public has enough trust to allow sensitive information to be shared between providers during the delivery of care"*.[106] Aggregated information is necessary to monitor service delivery, health planning and assess trends in health outcomes over time and *"is both necessary and expected by patients and taxpayers alike"*.[110] Therefore, health information for statistics must initially be about identifiable individuals to enable information to be linked. Once in the collections, the identifiers could be encrypted ensuring individual anonymity. This policy, and the social

discussions that preceded it, made it possible to consider epidemiological research based on suitably anonymised (encrypted) linked patient data.

2.8 Conclusion

This chapter was an environmental 'scan' of New Zealand general practice and national systems and policies to determine the feasibility of developing and readiness of implementing a CDSS to improve the prevention and treatment of cardiovascular disease in the New Zealand primary care setting and to develop a sustainable CVD risk prediction cohort.

Knowledge of the setting and systems is a prerequisite to tailoring a clinically-based intervention. The introduction of a web-based computerised decision support (CDSS) for evidence-based guidelines for diabetes and CVD risk assessment and management would seem feasible given the role of general practice in New Zealand, the advent of organised general practice, the health policy environment, focus on chronic diseases (CVD and diabetes) and preventive care and the evolving sophistication of electronic systems.

New Zealand general practice is highly computerised and is world leading. In recent years, unified standards for collecting, coding, messaging and network infrastructure to support patient and population health have been developed along with sound health information privacy statutes to safeguard patient interests. Any new CDSS system must not only be best practice in terms of evidence content but also comply with best practice in terms of informatics. The NHI number is a key anchor for connecting patients, health care delivery and health outcomes. Via the NHI number, population health research for linking patient profiles to major health outcomes becomes possible.

3 Computerised Clinical Decision Support Systems: definition, types, and impact on health care outcomes

3.1 Introduction

In recent years, there has been increasing interest in the use of CDSS to support the processes and quality of medical care. However, prior to the introduction of any new health technology, it is important to assess the evidence for benefit and harms and the system types that are most likely to succeed. This chapter defines CDSS, briefly describes types of CDSS systems and critiques the published systematic review evidence for their effectiveness in delivering health care outcomes. There are many systematic reviews on CDSS covering a wide range of health-related dimensions. The critique presented here is of epidemiological systematic reviews of particular relevance to this thesis and the proposed development of a CDSS tool. These reviews describe;

- the effect of health information technology on quality, efficiency and costs of medical care
- the impact of CDSS on provider performance and patient outcomes
- reviews on system sub-types, features and functionality of CDSS systems that determine success
- the use of computerised systems for the management of chronic diseases in the primary care setting.

3.2 Definition of CDSS

A CDSS has been defined by Wyatt and Spiegelhalter (1991) as "*a system that uses two or more items of patient data to generate case-specific or encounter-specific advice.*" [125] More

complex systems model the likelihood of future events and the effectiveness of proposed interventions based on individual patient data and knowledge of risks and the effectiveness of interventions.[126]

The main purpose of a CDSS is to aid clinical decision making. It may function by providing:

- an electronic reminder about opportunistic provision of care for a patient at the time of a consultation
- an alert to clinicians for drug interactions when prescribing
- a computerised patient interview with data input template to assist in diagnosis or assessment
- an interpretation of complex investigations (e.g. an electrocardiogram)
- a calculation (e.g. drug doses or prediction of the risk of an event)
- management recommendations based on individual patient data and evidence-based guidelines.

All CDSS have the following generic features: input data, search process, knowledge base and output data. The input data are usually patient data often directly extracted from an electronic medical record. The inference engine or as Wyatt (2000) calls it, the 'reasoner' programme, uses those patient data to search a knowledge base with predefined algorithms.[127] The knowledge base is made up of a set or sets of machine-readable facts. The output to the clinician is the patient-specific advice derived from the knowledge base.

CDSS systems may differ in their integration with patient electronic medical records, whether the output is automatically provided or requires user initiation, the knowledge base and inference engine and their ability to allow users to incorporate the output into further workflow processes (such as making a referral to other services).

3.3 Types of CDSS

Three broad types of CDSS have been developed; rules-based, probabilistic and cognitive systems.[128] In simplistic terms, a rules-based system is made up of logical rules that generate advice on the basis of the information represented. In a probabilistic system, inferences for individuals are made from calculations based on numerical population-based data. Cognitive models may be simulation models that simulate a patient's life into a series of events with movement across states determined by estimated probabilities[128] or machine learning systems – computers that can learn from experience.[129] As most of the clinical systems used and evaluated to date relate to rules-based and probabilistic systems, further description of them is given below.

3.3.1 Rules-based systems

A rules-based system is based on logic that can include, propositional calculus such as if 'a' is true then 'b' is also true. Complex propositions can be built up with the operators *and, or, implies,* and *not*.[120] Other forms of logic include predicate calculus and fuzzy logic. Predicate calculus is a "way of expressing that some thing or class of things has a particular property"[120] or it can be a way of denoting a relationship or association between two or more things.[120] For example, a symptom 'chest pain' may have a particular feature 'referred to the jaw and down left arm' that is associated with 'sweating' and the output advice maybe 'urgent referral to hospital'. Fuzzy logic is useful when rather than being 'true' or 'false' or 'yes or no' there are multiple states such as that found with continuous data. An example is in applications where an output value such as intravenous fluid delivery rate is determined on the basis of a series of other continuous inputs such as urinary output and arterial blood pressure.[120] When each is categorised into high, low or normal, there are nine possible combinations determining the intravenous fluid rate which might be set according to a mean aggregated function for each combination.[120]

Rules based systems (like all CDSS) are dependent on the availability of valid patient input data (errors can occur on data entry), a rigorously developed knowledge base (errors can occur due to inexplicit or inconsistent guideline recommendations) and the

complexity and functionality of the inference system (errors can occur if using only a small subset of potential patient parameters).[128] For example, a reminder to clinicians to perform a preventive care process is usually based on simple logic and triggered by the presence of a defined set of variables. A reminder to check patient lipid levels might be triggered by a READ code for diabetes and a time lapse (e.g. no documentation of a lipid test result within a specified time period). Advantages of reminder systems are that the scope of output can be broad, covering multiple preventive and therapeutic activities for multiple conditions as well as interactions between conditions and therapies.

Some key disadvantages of rules-based systems are that:

- they are dependent on clinical status, tests and services being documented

- where documented, availability is dependent on the ability to use clinical data in all parts of the EMR. Input information for reminders have commonly been limited to specific parts of an EMR where clinical details are coded or systematically classified such as laboratory data or pharmaceutical prescriptions rather than free text entries. Only recently have advances been made in acquiring useable information from free narrative text.[117]

- because of their simplicity, logic requirements may be fulfilled but the reminder is inappropriate for an individual patient (e.g. suggest a cervical smear when the patient has had a hysterectomy).

Further disadvantages to rules-based systems are that knowledge and opinion changes leaving the recommendations within a CDSS frozen in time and requiring update of clinical algorithms and subsequent testing. This takes time and is costly. Furthermore, the rules are often context specific.[128] Rules that are both acceptable and credible based on New Zealand health policy and guidelines may not be in keeping with clinical practice in America. Similarly rules developed for secondary care may not be practical or reasonable for primary care.

3.3.2 Probabilistic systems

"The trick in diagnosis is to work out, given the symptoms, what the disease is. Or at least what the disease probability is." Taylor P. (2006) [120]

Probabilistic systems model patient input data against population-based data to infer the probability of future events either for prognosis (e.g. CVD risk assessment) or diagnosis (e.g. appendicitis). Several systems based on probability theory have been built. A well-known example of this type of system developed in the 1970s was the Leeds Acute Abdominal Pain system. It was devoted to the diagnostic probabilities of differing conditions presenting to hospital with acute abdominal pain.[130]

A key advantage of probabilistic systems is that they separate knowledge (statistical probability data) from reasoning and therefore the knowledge base can be easily updated.[128] Furthermore, machines can perform mathematical calculations consistently and within seconds, unlike humans who find it difficult and whose estimates of risk are often very imprecise.[42] [131] However, the clear disadvantage for such systems is the availability and validity of statistical data. More often than not, pre-test probabilities are simply unavailable for diagnosis. Furthermore, the accuracy of a prognostic or diagnostic score for an individual may be, at best, only modest. Other data are still needed to guide everyday practice such as history taking, examination, further diagnostic tests as well as clinical judgement.

As discussed previously, CDSS often differ by whether the output is automatically provided or requires user initiation. The advantage of not requiring any active input from clinicians is that it ensures an alert for unmet service provision is made systematically each time a patient consults a clinician. However, this can have the negative effect of 'prompt fatigue' where attention to alerts fades over time and alerts may be ignored.[132] [133] Reminders may also be inappropriate for a specific patient or may reflect other system issues e.g. a reminder is given to refer for retinal screening when this has already been done but not identified by the system.[134]

An alternative strategy for computer applications is for the user to initiate the system when clinically required. While some systems simply involve 'clicking into' an icon to receive an alert, others require clinicians to input some or all of the necessary clinical data in order to receive assistance with diagnosis and/or management at the time of patient consultation. While the latter is likely to provide more accurate, patient-appropriate support and facilitate comprehensive chronic disease management, these applications have the potential to be more time consuming, are often condition-specific and narrow in focus.

3.4 Evidence that the use of CDSS tools improves quality of health care

A literature search was conducted to identify the systematic review evidence for the use of CDSS tools to improve quality of health care and the specific features that are associated with successful use. The databases searched were Medline, MEDLINE in-Process, Embase, the Cochrane Library (Cochrane Database of systematic reviews, ACP Journal Club, Database of Abstracts of Reviews of Effectiveness, Cochrane Central Register of Controlled Trials), CINAHL, SCOPUS, Current Contents and TRIP. No time period was specified. The concepts used (and related synonyms) were broad including 'decision support systems (clinical and management)', 'information systems' and 'medical informatics'. Where possible within the databases, a systematic review search filter was applied. Multiple systematic reviews were identified and those of relevance to this thesis were selected and appraised. There has been no systematic review specifically investigating the clinical impact of CDSS for CVD risk assessment and evidence-based management in any setting. The reviews are summarised below, from broad overviews to specific reviews on subtypes of CDSS, components of CDSS systems that determine success, the use of computers in the primary care setting in general and specifically for the management of chronic diseases.

Systematic review on the general impact of health information technology on quality, efficiency and costs of medical care.

Chaudhry et al. (2006)[65] investigated the general impact of health information technology on quality, efficiency and costs of medical care and included 257 descriptive, comparative studies and systematic reviews of health care technology. Information systems included electronic health records, computerised provider order entry, decision support, electronic results reporting, electronic prescribing, mobile computing, telemedicine, electronic health communication, data exchange networks, administration and knowledge retrieval systems. Three major benefits were found for quality of care (particularly in association with preventive care). These were increased adherence to guideline-based care, enhanced surveillance and monitoring and decreased medication errors.[65] The major efficiency benefit was decreased demand for health services such as laboratory or radiology referrals after provision of pre-test probability for diagnostic tests or displaying previous test results. Cost data were limited and no conclusion regarding cost-effectiveness was reached. Of note, 24% of these studies came from four benchmark institutions in the United States that had implemented internally developed systems over decades; only nine studies evaluated multifunctional, commercially developed systems.[65] The authors note in their conclusion a concern as to whether widespread achievement of similar health information technology benefits could be achieved in other institutions given that effectiveness is determined by both how a tool is used and the context within which it is implemented.

Systematic reviews investigating CDSS on a broad range of provider behaviours and patient outcomes

Garg et al. (2005), Hunt et al. (1998) and Johnston et al. (1994) investigated the impact of a range of CDSS on provider (mainly doctors) performance and patient outcomes.[135-137] The review by Garg et al. (2005)[135] is an update of the two previous systematic reviews.[136 137] These were conducted with many of the same authors and therefore only the Garg review is summarised here. Garg et al. (2005) included randomised and non-randomised studies with a concurrent control group that compared routine care with a CDSS (range of types and varying sophistication) to routine care without a CDSS. This review had clear

inclusion and exclusion criteria and the authors had decided a priori what defined a successful outcome and under what groups studies would be categorised. The main summary outcome studied was an improvement in practitioner performance or patient outcomes defined as a statistically significant positive effect on at least 50% of the specific outcomes measured. Their search was broad, including all major biomedical databases, conference proceedings, reference lists and they contacted primary authors. However, only English language studies were included. They identified 100 randomised and non-randomised trials with 3826 practitioners or practices caring for more than 92,895 patients, in ambulatory (67%) or in-patient (33%) settings. CDSS were divided into four main types: systems for diagnosis (10 trials), reminder systems for prevention (21 trials), systems for disease management (40 trials) and systems for drug dosing and drug prescribing (29 trials). The authors did not separately examine the results for randomised controlled trials from non-randomised studies and reported the following.

CDSS improved practitioner performance in 62/97 (64%) studies including: 4/10 (40%) of diagnostic systems, 16/21 (76%) of reminder systems, 23/37 (62%) disease management systems and 19/29 (66%) drug dosing or prescribing systems.

Fifty-two trials assessed one or more patient outcomes of which seven (13%) reported improvements. The authors concluded that many CDSS improve practitioner performance but the effects on patient outcomes were understudied and inconsistent.[135]

A further review by Randell et al. (2007), investigated the impact of CDSS on nursing performance specifically and or patient outcomes.[138] They identified randomised controlled trials, controlled clinical trials, controlled before-after studies and interrupted time series studies. Eight studies were identified but not meta-analysed. The studies varied by clinical area, CDSS system and outcome measures. The effect of CDSS for nursing performance was reported as inconsistent.[138]

In a further systematic review of all CDSS by Sintchenko et al. (2007), it was suggested that effectiveness of CDSS was associated with severity of patient presentation, type of clinical decisions and type of decision support.[139] CDSS appeared to be more successful in acute care (100% of identified in-patient studies had positive clinical outcomes) than in

primary care (31% of studies identified had positive outcomes). The authors hypothesised that this finding might be due to a greater impact of clinical decisions on patient outcomes in the acute setting (and within a shorter time frame) compared with chronic disease decisions or that many of the in-patient studies were prescribing interventions that might be easier to optimise.[139]

Systematic reviews investigating subtypes of CDSS

Five systematic reviews are summarised in this section including:

- computerised alerts or reminders for preventive care services [140 141]
- audit and feedback [142]
- reminders and feedback on medication management [143]
- computerised physician medication order entry systems [133 144]

Alerts or reminders

Shea et al. (1996) identified 16 randomised controlled trials of clinical reminder systems for preventive care in ambulatory settings prior to 1995.[140] The studies were grouped into 6 categories; vaccinations, breast cancer screening, cervical cancer screening, CVD risk reduction, and other preventive services (e.g. screening for glaucoma, dental services). The studies were heterogeneous with respect to interventions (computer reminders, manual reminders, both and control) and randomisation unit (physicians or individual patients). Overall, computer reminders increased preventive practices compared with a control group by 77% (OR 1.77; 1.38-2.27). For CVD risk factor reduction, including reminders to check a patient's blood pressure, follow-up of those with a diagnosis of hypertension, smoking assessment, smoking counselling, dietary assessment, dietary counselling and cholesterol screening, the effect estimates and 95% confidence intervals for computer-based reminders vs control was OR 2.01; 1.55-2.61, manual reminders (OR 1.86; 1.41-2.47) and computer plus manual reminder (OR 2.57;1.89-3.51).[140] The authors potentially missed relevant sources of literature by using only a subset of

available electronic databases. Furthermore, no details were provided on how studies were selected, number of reviewers, independence of review, or methodology of appraisal.

Balas et al. (2000) conducted a similar review including trials up to 1996.[141] They identified 33 randomised controlled trials of heterogeneous preventive services involving 1547 clinicians (internal medicine, general practice, obstetrics) and 54,693 patients (all but one study were of adult populations). The average study length was 83 weeks (range 5-161 weeks). The outcome of interest was the ratio of the number of preventive care actions to the number of eligible physician-patient consultations where virtually every visit is an opportunity to provide preventive care. All prompts were delivered before a consultation (e.g. yearly during a patient's month of birth, following randomisation, 1 month, or 1 night before a scheduled visit or the morning of the visit at the reception desk). The majority of the reminders were presented to clinicians in a written form (computer generated then paper-based display in front of paper-based chart or inside the medical record).

Overall prompts increased preventive care by 13.1% (95% CI 10.5%-15.6%). Of the six studies relating to CVD risk factors (four studies of diabetes management, one on smoking cessation and one on high blood pressure diagnosis and follow-up), all reported showing a positive effect on preventive care practices but were not separately meta-analysed. Analyses were conducted to take into account publication bias using a referenced method of calculated tolerance which was defined as the number of additional unpublished negative studies that could reverse the conclusions of this study. They estimated that over 130 additional negative studies would be required.[141]

Audit and feedback

In a Cochrane systematic review, Jamtvedt et al. (2006) assessed the impact of audit and feedback on professional practice and health care outcomes.[142] Audit and feedback was defined as any summary of clinical performance over a specified time. While some of the audits were manually derived and feedback delivered in written or verbal format, the systematic review is of relevance to this thesis as many studies use electronic

extraction of data and/or electronic feedback. The mode of audit and delivery of feedback was not independently assessed in this review. The authors found that audit and feedback can be effective in improving practice but results varied. The adjusted risk difference of compliance with desired practice ranged from a 16% absolute decrease in compliance to a 70% increase in compliance. The median was an absolute improvement in compliance with desired practice of 5% (3% to 11%). Therefore, the effects were generally small to moderate. The authors found the size of the effect greater when baseline adherence to recommended practice was low and feedback was delivered more intensively. [142]

Reminders or audit and feedback

Bennett and Glasziou (2003) conducted a systematic review of 26 randomised controlled trials that assessed the use of computers to assist in identifying patients and generating reminders or feedback of medication management in both inpatient and outpatient settings.[143] Meta-analysis was not possible because of heterogeneity of studies. In outpatient settings, six of twelve comparisons of reminders demonstrated positive effects (relative rates of intervention rates/control rates varied from 1.0 to 42). Five of seven comparisons of provider feedback showed improvements but this was less than that found with reminders (relative rates of intervention rates/control rates 1.0 to 2.5). The authors concluded that reminders were more effective than feedback in modifying physician behaviour.[143]

Computerised physician order entry (CPOE) systems

Computerised physician order entry (CPOE) systems are systems that automate medication ordering (or blood tests or referrals) and ensure standardised and complete orders. Decision support is built into almost all CPOE systems to varying degrees.[144] There are two systematic reviews on the effect of computerised physician order entry (CPOE) systems for medication; one focusing on medication safety in the hospital setting (Kaushal et al. (2003)[144], the other on safety, costs, adherence to guidelines, prescribing time and frequency of ignored alerts in the outpatient setting (Eslami et al. (2007)).[133] The use of CPOE (+CDSS) and CDSS alone was found to deliver substantial

improvements in serious inpatient medication error rates[144] but the reviews were not sufficiently powered to detect differences in adverse drug events in either inpatient or outpatient settings.[144] [133]

In the outpatient setting, there was some evidence for increased adherence to guidelines but the effect on medication costs was equivocal, with only 3/8 studies showing significant reductions.[133] On the negative side, three studies showed that the total time for direct and indirect patient care increased with the introduction of CPOE and four studies of user response reported a high frequency of ignored alerts. These studies showed that between 55% and 91% of alerts were ignored by the physicians with 'clinical irrelevance' cited as the main reason for overriding them.[133]

Systematic reviews investigating features and functionality that determines CDSS success

Two systematic reviews, Shiffman et al. (1999) and Kawamoto et al. (2005), have investigated CDSS features or functionality that determined CDSS success.[145] [146]

Shiffman et al (1999) included 25 publications from 20 studies where computers were used as part of an implementation strategy for clinical practice guidelines and included an evaluation component studying some aspect of the effectiveness of the system in a practice setting.[146] Thirteen out of twenty studies addressed patient management issues and therapy, the other seven provided guidance with screening and disease prevention activities. The 20 studies included nine randomised controlled trials, one non-randomised trial and 10 time series studies (none of which had an external control). Pairs of reviewers examined papers for the presence or absence of components decided a priori by the authors as being information management services that promoted workflow integration: These components were:

- recommendations (from guidelines)
- documentation (collecting, recording and storing information)
- explanation (rationale for recommendation)

- presentation (user interface/output)
- registration (recording and storage of demographic, administrative data identifying patient, provider, date and type of encounter)
- communication (between clinician and other information providers)
- calculation (manipulation of numeric/temporal data to derive information)
- aggregation (population-based information from individual patient data).

The basis for this categorisation did not appear to have been derived from reviewing the literature or the studies themselves. All systems reviewed provided patient-specific recommendations and all recommendations were delivered at the same time as patient care. However, the authors' bottom-line was that as many studies failed to describe their systems in any detail, they were unable to create meaningful summary ratings of individual systems that might correlate with the outcomes described.

A further attempt to identify features of CDSS that were critical to successfully improving clinical practice was conducted by Kawamoto et al. (2005).[145] They investigated clinical (as opposed to computerised) decision support systems that could be *electronic or non-electronic*. They identified 70 studies of English-language randomised trials evaluating: decision support systems' ability to improve a desired clinical practice in a real clinical setting, the use of a system by clinicians directly involved in patient care and the assessment of improvements in practice via patient outcomes or process measures.

They excluded studies where there was mandatory compliance to the clinical decision support system, lack of description of system content or clinician interaction with the system or where the study was of poor quality according to their rating system.

The most common types of decision support were computer-based systems that provided patient-specific advice in printed form (34%), non-electronic systems providing patient-specific advice to medical charts (26%) and decision support systems within computerised physician order entry systems (16%).

For each exposure and comparison group, two reviewers independently assessed whether the system resulted in a clinically and statistically significant improvement. The reviewers then determined the presence or absence of specific features of decision support systems that could potentially explain why a system succeeded or failed, using a set of 22 potential explanatory features (technical and non-technical) identified by at least three literature sources (relevant reviews and primary studies). These were categorised into general system features, clinician-system interaction features, communication content features and auxiliary features. Of these, 15/22 could be included in the analyses because their presence or absence could be reliably extracted from most studies. For each feature they individually determined whether possession was associated with clinical success or improvement in the outcome investigated. The authors then conducted multivariate analyses adjusted for study setting (academic vs non-academic, outpatient vs inpatient) and whether decision support content was for acute or non-acute care.

Decision support systems significantly improved clinical practice in 68% of the randomised trials. Multivariate analyses identified four features as being independent predictors of improved clinical practice:

- automatic provision of decision support as part of clinician workflow (not requiring user initiation)
- provision of recommendations rather than just assessments (e.g. suggest prescribing anti-depressants rather than just identifying patient as depressed)
- provision of decision support at the time and location of decision making
- computer-based decision support (computer automatically queries database instead of requiring manual chart audit).[145]

Of the 32 systems possessing all four features, 94% significantly improved clinical practice. Extra features that improved care included periodic performance feedback, sharing recommendations with patients and requesting documentation of reasons for not following recommendations.

Systematic reviews on the use of computers within primary care and for chronic diseases

Four systematic reviews were identified investigating the use of computers within primary care,[147 148] for the management of hypertension in ambulatory care[149] and for the use of computers for chronic diseases.[150]

The use of computers in primary care

Mitchell et al. (2005)[147] is an update of the earlier Sullivan review[148] conducted by the same authors. These reviews included English-language randomised and non randomised trials or other prospective studies that included doctors or nurses in a primary care setting and described any computing system designed for use by a doctor, either in routine clinical practice or for a specific project. The comparison was inferred as routine care without computerisation. They investigated effects on the consultation process, on a doctor's performance, and on patient outcomes. Additional outcomes were potential barriers to effective implementation and use of computers. Sixty-one studies examined effects of computers on practitioner performance, 17 evaluated their impact on patient outcomes and 20 studies determined attitudes to computers in primary care. Nine studies examined more than one of these grouped outcomes. The studies were grouped according to clinical application and combined in a descriptive summary. The results of the randomised controlled trials and the non-randomised trials were not examined separately.

Immunisation, blood pressure (BP) and cervical screening rates generally improved. However, in several studies it was reported that rates fell when reminders were no longer provided. Four studies evaluating standards of diabetes care found improvements of 5–69%, with the greatest improvement when physicians used an electronic protocol. Two studies of hypertension management found improvements of 18–53%, where again the greatest improvement occurred if an electronic protocol was used. A CDSS for lipid management demonstrated no real differences and system use was less than expected. CDSS led to increased prescribing of generic drugs, reduction in number of tests ordered and cost savings as a result. However, consultation length increased by 48–130

seconds in 5/6 studies, although this declined after variable time periods. Some studies showed 11–100% increased time spent on computerised records (compared to not having a CDSS) mainly because of increased administrative tasks and preventive issues prompted by computer use.[147]

Seventeen of the reviewed studies investigated patient outcomes. Use of computers in management of hypertension showed significant improvements in lowering diastolic BP and one study on CDSS for lipid management reported 55% reduction in the number of expected referrals. Four studies on patient satisfaction detected no significant changes when computers were introduced. Practitioners and patients were found to be generally positive about computers, particularly in terms of access to records, accuracy and improvement in patient care. Five themes emerged as potential barriers to primary care computerisation; loss of privacy and confidentiality, possible changes to the doctor–patient relationship with the doctor interacting more with the computer than the patient, costs of computerisation, time commitment to learning to use the computers and lack of training on how to use the computers. The authors noted that while many CDSS improve practitioner performance, few studies evaluate patient outcomes and that research has centred around GPs, with little published on the impact of computers on nurses or other members of the primary care team.[147]

The use of computers for the management of hypertension in ambulatory care

Montgomery and Fahey (1998) conducted a systematic review of the use of computers and CDSS in the detection and management of high BP in general practice or hospital-based ambulatory settings.[149] The review included seven randomised trials with studies critically assessed and data extracted independently. The studies were of diverse populations (new or established hypertensive patients), interventions (CDSS type and functionality) and outcomes (administration, physician performance, BP control), precluding meta-analysis. In these studies:

- 4/5 trials reported improvement in patient administration (BP documentation, follow-up visits, surveillance of hypertensive patients)

- 2/3 trials reported improvements in physician performance (knowledge of BP management and recording of key information necessary for BP management)

- 2/6 trials reported improvements in blood pressure control

The authors commented that while computers had a favourable effect on uptake and follow up of patients in hypertensive management, the effect on physician knowledge, recording of information and blood pressure control is less conclusive.[149]

The use of computers for chronic illness

In 2007, Dorr et al. reported a review of the understanding of information system components that are important for supporting team-based collaborative care for chronic disease.[150] They searched broadly using the concepts of information systems, patient care management, collaborative care and chronic illness. The review identified 109 studies, 50 (46%) were 'experiments' having a control or comparison group, the rest were descriptive studies with and without evaluation or case studies. The chronic diseases studied were diabetes (43%), heart disease (37%), depression (16%) and schizophrenia (7%). A third of the studies involved multiple illnesses. The majority were implemented in outpatient settings (58%). Many studies targeted multiple user groups with physicians being the most common intended users (46%) followed by nurses (36%) and patients or caregivers (26%). Like many of the other reviews, formal meta-analysis was not possible. The authors cited a lack of randomised controlled trials, varying definitions of positive outcomes, inconsistent outcomes and a lack of CDSS description. Around two-thirds (67%) of the controlled trials had positive results. The system components associated with success were connection to an electronic medical record, computerised prompts, population management (including feedback and reports), specialised decision support, electronic scheduling and personal health records.[150] Barriers identified were resource costs, data privacy and security issues, the impact on the consultation, increased time to use systems and failure to consider workflow.[150]

3.5 Conclusion

This chapter has provided an overview of the types of CDSS, the evidence for benefit and harms and gaps in knowledge that will inform the development, implementation and evaluation of a CDSS tool in New Zealand. Approximately two-thirds of CDSS evaluations (randomised and non-randomised trials) have taken place in ambulatory care settings and most have targeted doctors as the clinical users. Results are variable, with CDSS representing a heterogeneous group of interventions that are often multifaceted, including both computerised and non-computerised interventions. Most of the systematic reviews have been unable to conduct a formal meta-analysis because of heterogeneity of both interventions and outcomes. As a whole, over 60% of the studies were found to produce small to moderate improvements in documentation, preventive care, chronic disease management, drug dosage and prescribing and possibly diagnostic performance. By type, reminders have been shown to dependably improve preventive care in the short term. Audit and feedback interventions can improve practitioner performance but appear to be less effective than reminders. The use of CPOE produced substantial improvements in serious inpatient medication error rates and outpatient adherence to guidelines. There has been no systematic review specifically investigating the clinical impact of CDSS for CVD risk assessment and evidence-based CVD risk management in any setting. Adverse effects of CDSS include increased time for direct and indirect patient care and the production of clinically irrelevant reminders. Negative aspects of computerisation raised were: loss of privacy and confidentiality, possible changes to doctor–patient relationship, lack of training and the time commitment involved with implementation and learning to use computers or systems. The cost of computerisation and implementation of CDSS was also a commonly cited problem but there are few data on costs and cost-effectiveness.

The effects on patient outcomes were understudied and inconsistent. Many studies and reviews have lacked the power to detect measurable changes in patient outcomes, while others have not measured patient outcomes because of limited time and resources.[151] Of the 24 randomised controlled trials of CDSS assessing patient outcomes identified by Sintchenko et al. (2007), the duration of follow-up was between 3 and 12 months, a time

frame too short to detect potential effects especially for chronic disease management in the outpatient setting. Furthermore, where patient outcomes were studied, they were generally intermediate or surrogate outcomes (such as BP control or process measures such as eye examinations), rather than outcomes that are important to patients (such as blindness, adverse drug events, hospitalisation or death).[139,152]

Perhaps the most useful general review identified in the context of this thesis is by Kawamoto et al. (2005) who identified four key components of clinical decision support systems associated with improvements in care - being computerised, providing decision support automatically, producing recommendations (not just assessments) and providing decision support at the time and place of decision making.[145]

Process outcomes are considered valid where there is good evidence that links processes of care to desirable outcomes. In general, process measures are easier to measure, easy to interpret, sensitive to deficiencies in care and less vulnerable to confounding.[153] [154] Health care systems have been described as containing *structures* (e.g. hospital buildings, staff, clinical tools or machines), involving the *processes* of health care delivery and producing patient health *outcomes*.[155] A change in structure is therefore relevant when there is evidence that good structure enables good process that in turn improves likelihood of good outcomes. Information technology (IT) and specifically CDSS systems represent structural change in health care services. However, unlike buildings and other 'plant', IT is a rapidly evolving science, a moving target of innovations. By the time a large-scale trial is completed, which is usually both costly and resource-intensive, technology has often moved on.[151] Therefore, it is not surprising that most studies have short time frames and that a sizeable percentage have been conducted in a few institutions or 'potentially idiosyncratic' academic environments.[153] This limits their generalisability. Furthermore, trial reports often do not describe features that may help with transportability of a system into other settings or characteristics of the users such as baseline IT literacy, uptake of the system, implementation strategies (e.g. opinion leaders, training), professional and organisational culture or the baseline risk of the populations studied.[139]

4 Systematic review of computerised decision support systems for CVD risk assessment and management in primary care

4.1 Introduction

Clinical decision support systems over a range of health conditions, functions and settings have been reported to produce modestly favourable improvements in desired outcomes. However an important gap in knowledge is how these systems work for CVD risk assessment and management. This chapter describes a systematic review of the published evidence on the effectiveness of CDSS for CVD risk assessment and evidence-based management in primary care. The outcomes of interest were the achievement of changes in clinical behaviour with respect to specific processes of care and improvements in patient health outcomes.

4.2 Criteria for considering studies for this review

This review is limited to randomised controlled trials, published in any language, that allocate either practices, individual primary care clinicians or their patients to either CDSS or to a comparison (routine care or to another intervention). The randomised trial design was chosen over other study designs because this design limits the potential for confounding.

Definition of CDSS

A computerised decision support system (CDSS) was defined according to Hunt et al. (1998) as any computerised system that is designed to *"aid directly in clinical decision making, in which characteristics of individual patients are used to generate patient-specific assessments or recommendations that are then presented to clinicians for*

consideration."[136] The taxonomy of CDSS described in the previous chapter includes reminders, audit and feedback and other interactive software.

To be included in this review, the CDSS needed to be responsive to and provide information on individual patient characteristics. Audits and feedback of aggregated clinical data (i.e. not providing individual patient-specific data) were therefore excluded. Electronic versions of paper guidelines, textbooks or other electronic media were also excluded.

CDSS systems may be:

- available on PDA, wireless laptop or desktop computers
- web-based systems or intranet or individual installation
- integrated with the patient electronic medical record or stand alone.

Following input of relevant patient characteristics, the provision of the decision support output may occur prior to, during or after a patient consultation.

4.2.1 Types of participants

Inclusion was limited to adult patients attending primary care, ambulatory care or hospital outpatient services and receiving health care from clinicians involved in these services.

Hospitalised adults and individuals aged under 18 years were excluded.

Target user of CDSS

The target user of the intervention was defined as the primary care or outpatient care provider (doctor, nurse, pharmacist or other allied health worker). Electronic interventions designed for and used only by patients or consumers were excluded.

4.2.2 CDSS knowledge content and target medical conditions

A CDSS must be responsive to specific characteristics of an individual patient's CVD or CVD risk profile. This includes previous coronary heart disease (including angina, acute coronary syndrome, coronary artery procedures), ischaemic stroke and transient ischaemic attack, peripheral vascular disease, congestive heart failure or risk factors related to atherosclerotic CVD (diabetes, blood pressure, lipids, waist circumference, BMI). Cardiovascular diseases such as cardiac arrhythmias, valvular dysfunction, cardiomyopathies and other disorders were excluded. Computerised tools specifically for anticoagulation monitoring and therapy were also excluded.

Interventions therefore could include:

1. automated electronic prompts/reminders to clinician for CVD risk assessment or to check BP, lipid, diabetes or smoking status compared to usual care

2. CDSS integrated with patient medical record assessing CVD risk or CVD risk factors compared with computerised decision support systems standing alone from patient electronic medical record (non-integrated)

3. CDSS, integrated or non-integrated with patient electronic medical record, providing an estimate of CVD risk compared with usual care or paper based risk assessment tools (e.g. risk charts)

4. CDSS, integrated or non-integrated, assessing CVD risk, CVD risk factors or concurrent management providing recommendations based on evidence-based guidelines compared with CVD risk assessment only, or usual care

5. electronic registries or audit of electronic medical records providing patient-specific feedback compared with aggregated feedback or usual care.

The aim of this review was to determine the independent effect of CDSS. Therefore, studies were excluded where electronic tools were assessed within a multifaceted intervention compared to usual care or studies where an electronic tool plus a further

intervention (such as a patient questionnaire) were compared with the electronic tool alone (without a usual care control group).

4.2.3 Types of outcome measures

A framework of structure, process and outcome as described by Donabedian (1988)[155] was considered when classifying outcome measures. The introduction of CDSS represents a structural change in delivery of health care services and effects were assessed according to changes in provider consultative process and patient health outcomes. The assumption is that each effect estimate is associated with downstream health improvement. Examples of possible outcomes include:

Changes in provider process

- increase in documentation of cardiovascular disease, CVD risk or CVD risk factors
- increase in documentation of advice given (e.g. dietary advice, smoke quit advice)
- increase in testing, referral or follow-up of risk factors or disease
- increase in new medications prescribed in accordance with guidelines
- increase in recommended medication (e.g. change from one therapy to recommended therapy, or optimising dosage in accordance with guidelines)

Changes in patient risk factors and other health-related outcomes

- mean improvements in continuous risk factors (e.g. LDL, HbA1c, BP or HDL)
- increasing quitting rates among smokers
- improvement in health-related quality of life
- improved patient satisfaction with quality of health care and other patient-centred measures

- reduction in CVD hospital admissions
- reduction in mortality

Functionality, usability or frequency of use of CDSS were excluded as outcomes of interest, as they did not address effects on desired preventive practice or patient outcomes.

4.3 Search strategy and identification of studies

Databases

The following databases were searched for articles in any language and covering all time periods referenced until the end of January 2008: Medline (1950–2008), MEDLINE in-Process, PubMed, Embase (1988–2008), Cochrane Library (last quarter 2007) including Cochrane Database of systematic reviews, ACP Journal Club, Database of Abstracts of Reviews of Effectiveness and Cochrane Central Register of Controlled Trials, CINAHL (1982–2008), ERIC (1965–2008), PsychInfo (1806–2008), SCOPUS, Current Contents and TRIP.

Supplementary methods of finding studies included review of article reference lists, PubMed related articles feature, informatics conference proceedings, information provided by primary study authors and other recent reviews.

Search strategy

Box A. Cochrane Randomised Controlled trial search string phase 1 and 2

1. Controlled study/ or randomised controlled trial/
2. Double blind procedure/
3. Single blind procedure/
4. Crossover procedure/
5. Drug comparison/
6. Placebo/
7. Random$.tw
8. Latin square.tw
9. Crossover.tw
10. Cross-over.tw
11. Placebo$.tw
12. ((doubl$ or singl$ or tripl$ or trebl$) adj5 (blind$ or mask$)).tw
13. Comparativ$ adj5 trial$).tw
14. Clinical adj5 trial$.tw
15. Animal/ not (human/and animal/)
16. Or/1–14
17. 16 not 15

The forward slash (/) denotes Medline Subject Heading (MeSH) term, the suffix .tw denotes a text word (or words) found in the title or abstract, adj5 denotes that the words are associated together in the text with a separation of no more than five other words

Box B. Decision Support Systems or reminder systems search

1. Decision support system/
2. Computer assisted diagnosis/
3. Computer assisted therapy/
4. Reminder system/
5. Computer$ adj3 remind$.mp
6. Computer$ adj3 alert$.mp
7. Computer$ adj3 decision.mp
8. Computer$ adj3 clinic$ adj3 decision$.mp
9. Computer$ adj3 diagnosis.mp
10. Computer$ adj3 therap$.mp
11. Computer$ adj3 treat$.mp
12. Web$ adj3 decision.mp
13. Or/1–13

*the suffix .mp denotes words found in the title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name

Box C. Cardiovascular diseases and risk assessment or risk factors

1. Cardiovascular disease/
2. Cardiovascular risk/
3. Cardiovascular adj3 risk.tw
4. Cardiovascular adj3 risk adj3 factor.tw
5. Blood pressure/
6. Diabetes mellitus/
7. Lipid/
8. Cholesterol/
9. Smoking/
10. Smoking related phenomena/
11. Or/1–10

Box D. General practice and ambulatory care

1. Primary medical care
2. Primary Health Care/
3. General practice/
4. Family Practice/
5. Ambulatory care/
6. Outpatient care
7. Outpatient clinics
8. Physicians, Family/
9. General adj practitioner$.tw
10. Or/1–9

The search query then combined each Box compilation: A.17 *AND* B.13 *AND* C.11 *AND* D.10

4.4 Methods of review

4.4.1 Selection of studies and data extraction

All citations were screened and the abstracts of each article reviewed if there was any indication of a computer or electronic tool or reminder and EITHER any CVD risk factor or CVD OR primary care or preventive service. These abstracts were excluded if they clearly met exclusion criteria (e.g. only hospitalised patients included, decision tool was a booklet). Full-text articles of the remaining abstracts were retrieved. These publications were reviewed to determine if they met eligibility for inclusion. Excluded studies were listed separately with reasons for exclusion. Those studies that met inclusion criteria were critically appraised. Where data from one trial were published in more than one article, the principal publication (usually the first) was identified and the study counted only once. Critical appraisal was conducted in two steps – first using the GATE method[156] and second using the seven standard quality criteria used for randomised controlled trials from the data collection checklist developed by the Cochrane Effective Practice and Organisation of Care Review Group (EPOC).[157]

The GATE method

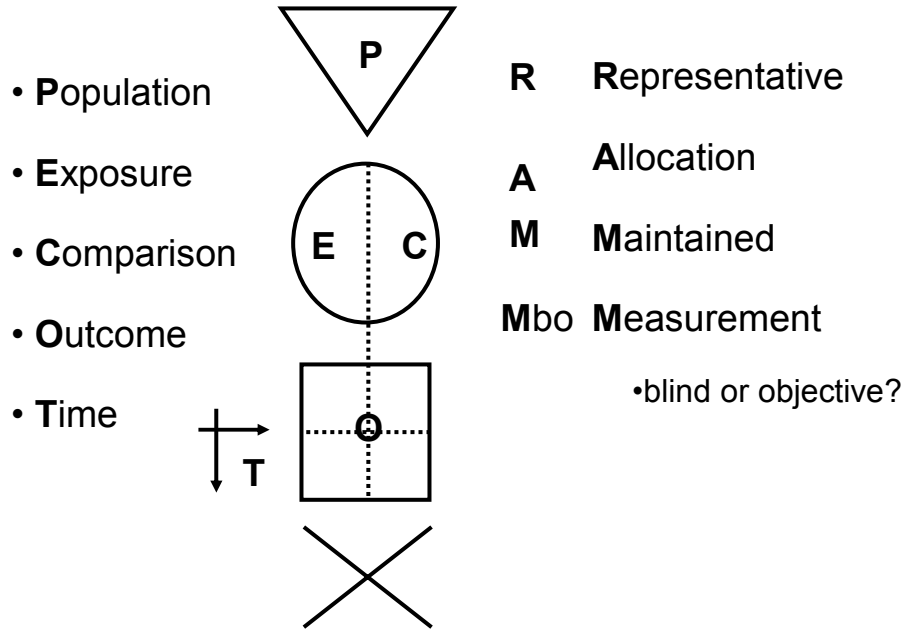
Each study was described using the GATE frame (Figure 4.1) which defines five generic design components (denoted by the acronym PECOT), namely:

- the participants in the study (P)
- the exposure of interest (in this case the type of CDSS) (E)
- the comparison (alternative intervention/s or routine care) (C)

- the outcome/s assessed (O) and
- the time period of the study. (T)

Further description and methodology of the GATE framework is found in Jackson et al. (2006)

Figure 4.1. GATE framework for study design and validity criteria



The quality of each study was then appraised using the four (plus two) GATE validity criteria tailored specifically for appraising the quality of randomised controlled trials. These validity criteria make the mnemonic 'RAMMbo' (Figure 4.1) and criteria are outlined below.

R= Representative

Are participants representative of the eligible population? Is the eligible population a definable, meaningful population?

A= Allocation

How were participants allocated to exposure and comparison groups? How was randomisation conducted? Was concealment of allocation assignment adequate? In other words, were those involved in the trial shielded from knowing upcoming assignment to exposure or comparison groups?[158] Was randomisation successful in terms of reported baseline characteristics of allocated groups?

M= Maintained

Was the integrity of random allocation maintained? (i.e. were participants 'maintained' in their allocated groups). This is based on an assessment of blinding to allocation assignment (e.g. to CDSS or the other comparison group/s), compliance with the intervention, contamination (did anyone in the comparison group receive the intervention), co-intervention (did anyone in the either group receive other therapies) and losses to follow-up.

Mbo= Measurement– blind or objective

Was assessment of outcomes conducted blind to the knowledge of the allocated group and were measurements of the outcome/s conducted objectively (e.g. laboratory tests)?

Three additional validity criteria for statistical analyses were also used. Firstly, were analyses conducted according to the intention-to-treat principle? This is a strategy where all patients who were originally randomly assigned to intervention groups are analysed by these groups regardless of whether they satisfied entry criteria, received the intervention, withdrew or deviated from protocol.[159] Secondly, did the authors account for clustering by practice, team of clinicians or by GP? Observations on individuals within the same cluster tend to be correlated (non-independent) and so the effective sample size is less than the total number of individual participants.[160] Thirdly, was there adjustment for known confounding factors? Confounding is defined as the mixing of effects[161] where the effect of the study exposure (on the study outcome) is mixed up with the effect of another variable. This can lead to either an under or overestimate of the true effect of the study exposure.

The included studies appraised according to PECOT and RAMMbo were summarised in Evidence Tables and are located in Appendix 4.1.

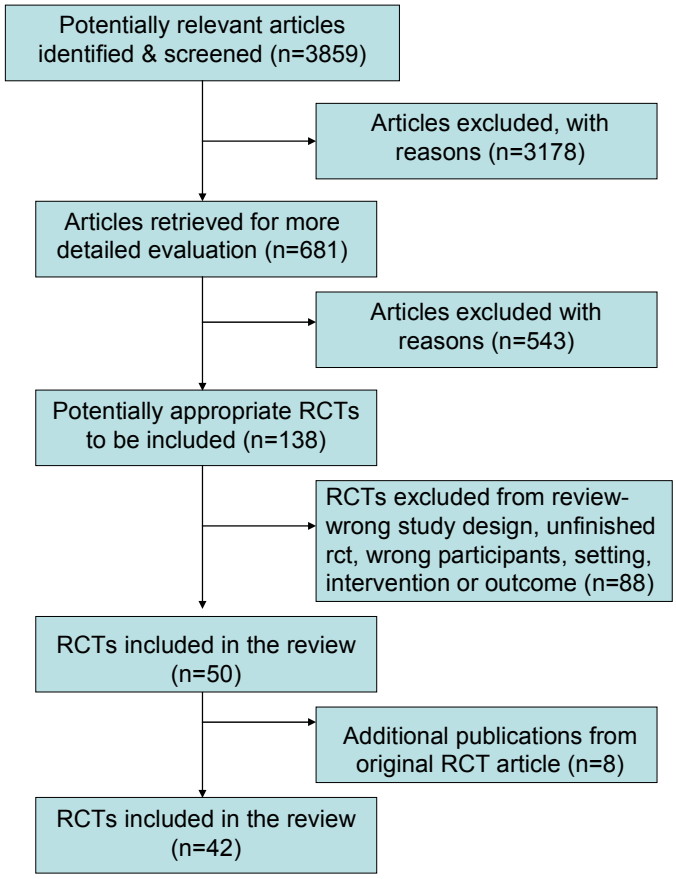
The seven standard quality criteria for randomised controlled trials from the data collection checklist[157] developed by the Cochrane Effective Practice and Organisation of Care Review Group (EPOC) were used as a supplementary scoring system. This involves scoring as "Done", "Not clear" or "Not done" for allocation concealment, follow-up of professionals, follow-up of patients, blinded assessment of primary outcome(s), baseline measurement, reliable primary outcome measure(s) and protection against contamination. Each study was scored by allocating two points for "Done", one point for "Not clear" and zero points for "Not done". The scoring of each study is included with the Evidence Tables (Appendix 4.1).

A data-extraction tool from the Cochrane Acute Respiratory Infections Group was also used to provide further validity and as a template for data extraction should meta-analysis be possible.

4.5 Results of search

Figure 4.2 (an adaptation of the Quorum statement[162] flow diagram for meta-analyses of randomised controlled trials (RCTs)) presents the results of the search, study retrieval and inclusion of studies in this review. Only those studies that clearly did not meet inclusion criteria as discussed previously were excluded from the initial screening. For many articles it was difficult to ascertain the study design, who the participants were and what the intervention was until retrieval and more detailed evaluation. When in doubt, the article was retrieved. Of these, 543/681 were excluded (mostly informatics articles without an evaluation component).

Figure 4.2. CDSS systematic review flow diagram with results of search, publication retrieval and included studies



4.5.1 Characteristics of excluded studies (n= 88)

Of the 138 potentially appropriate studies, 88 were excluded at the time of critical appraisal. The complete references to these studies are listed in Appendix 4.2. There were 4 major reasons for exclusion: wrong study design or unfinished trial (protocol only or preliminary discussion and analyses), wrong participants, setting, intervention or outcome.

Wrong study design or unfinished trial (n=44)

- non-randomised cohort studies of an intervention including before–after studies with or without a control group (Bassa 2006, Brownbridge 1986, Cleveringa 2007,

Frijling 2003, Garr 1993, Goldberg 2000, 2002, Grant 2003 , Hirsch 2002, Jackson 2005, Keefe 2005, Mazze 1994a,b, Mazze 1995, Mazzuca 1990, Montori 2002, Murphy 2000, O'Connor 2005, Ornstein 1993, Sciamanna 2004, Tannen 2006, Toth-Pal 2004, van den Hoogen 1990, Vaughan 1996)

- cross-sectional validation study of an electronic tool compared with a paper-based tool (Hingorani 1999), or CDSS output to patient characteristics validated by a clinical review panel (van der Lei 1991)

- cross-sectional survey (Schmittdiel 2004)

- randomised trial protocol only (Bosworth 2004,Eccles 2000, 2002, Freitheim 2003, Holt 2006, McClean 2004, Phillips 2002)

- early analyses or preliminary results of a randomised controlled trial and/or discussion (Keller 1991, McClean 2006, Thomas 1983, Whitty 2004)

- design, development +/-feasibility study of CDSS (Carson 1990, Ginsberg 1998, Grant 2006, Levin 2002, Sciamanna 2004b)

- commentary on a randomised controlled trial (McMullin 2006).

Wrong participants/setting (n=3)

- hospitalised patients only (Echeverry 2005, Overhage 1996, Weir 2003)

Wrong intervention (n=39)

- electronic intervention designed specifically for patient's use (Aveyard 2003, Feder 1995, Frame 1994, Glasgow 2005, Hurwitz 1993, King 2006, Lafata 2002, McMahon 2005, Munoz 2007)

- non-electronic reminder intervention – paper-based or manual stamp or sticker on medical chart identifying a smoker (Boltri 2007, Cummings 1989, Feder 1995b, Green 1997, McDermott 2001, Shanley 1999, Shannon 2001, van Steenkiste 2006)

- aggregated rather than individual patient data given as feedback (Frijling 2002, 2003b, Mehler 2005)

- no CVD related intervention (related to other preventive primary care services such as cervical screening, mammography) (Litzelman 1993, McDonald 1980, McPhee 1989, Tape 1993, Thomas 2006, Turner 1989, van Wijk 2001)

- oral anticoagulation management in primary care (Fitzmaurice 2000)

- multifaceted intervention (unable to determine the effect of CDSS) (Ansari 2003, DICE 1991, Eccles 2007, Freitheim 2006 a,b, Glasgow 2005b, McAlister 1986, Thomas 2007, Vinicor 1987, Williams 2007)

- where the same CDSS is present for both exposure and control groups and the study explores the additional impact of another non-electronic intervention/s (Stroebel 2002, Subramanian 2004)

Wrong outcome (n=1)

- frequency of use of a computerised template (Tai 1999).

4.5.2 Description of Included studies

Articles included (n= 50 representing 42 studies)

Fifty publications representing 42 randomised controlled trials of CDSS in primary care or ambulatory settings were included in this review, involving over 4000 health professionals (mainly doctors but some nurses and pharmacists) and over 250,000 patients from 10 countries. The countries included USA, Canada, UK, The Netherlands, Germany, Spain, Italy, Norway, Australia and New Zealand.

The key features determining success for clinical (electronic or non-electronic) decision support systems identified by Kawamoto et al. (2005)[145] and outlined in Chapter 3 were used to inform the grouping the 42 computerised decision support studies. As all CDSS

were computerised, the three other features were automatic provision of decision support, timing of provision and location (integrated, non-integrated, on-site, off-site) and provision of recommendations (not just assessments). There were six groups of interventions identified (Table 4.1 below) that could be broadly classified by whether the clinician automatically receives advice or voluntarily engages with and initiates an electronic tool or template in order to receive specific information. These could be further refined according to whether the patient-specific advice was available at the time of consultation or at some later time, post-consultation. All automatic delivery CDSS were derived by extraction (usually automated) of patient data from a clinical database. In the case of provider-initiated informatics tools, to have the CDSS accessible through the patient's electronic medical record (EMR) and able to share patient data with the CDSS and vice versa (i.e. integrated with the EMR) was regarded as being distinctly different in terms of work flow and processes from those CDSS located within separate software or systems (either on-site or off-site). Automatic delivery CDSS could be divided into reminders and alerts occurring at the time of consultation, audit and feedback studies occurring post-consultation and other variant automated systems. Most audit and feedback studies provided assessments only not recommendations. CDSS requiring provider initiation at the time of consultation were grouped according to being integrated with the patient electronic medical record or only available as separate software. A third type of provider-initiated CDSS was typified by filling out input templates or data entry forms and receiving guideline advice back some time after the consultation had occurred.

Table 4.1. Classification of computerised decision support systems

Computerised decision support systems					
Automatic delivery			**Provider-initiated delivery**		
Advice available			*Advice available*		
At time of consultation	Post-consultation	Post-consultation	At time of consultation – integrated	At time of consultation – not integrated	Post-consultation – not integrated
Intervention	*Intervention*	*Intervention*	*Intervention*	*Intervention*	*Intervention*
Reminder or alert	Audit and feedback	Continuous monitoring system, or e-mail system	CDSS advice integrated with patient medical record	CDSS advice via separate on-site computer system or separate software	CDSS advice received after sending patient details to off-site computer

Table 4.2 categorises the 42 randomised controlled trials of CDSS for CVD risk assessment and management according to the classification outlined in Table 4.1

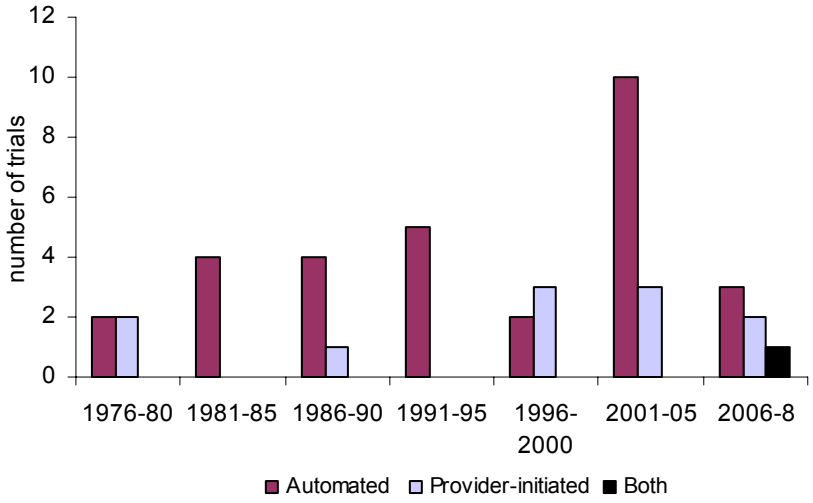
Table 4.2. Included trials categorised according to the classification in Table 4.1

Type of study	No of studies	References
Automatic delivery vs usual care	*26*	
Advice available at time of consultation		
Computer-generated reminders vs usual care	21	Barnett 1983, Becker 1989, Demakis 2000, Filippi 2003, Frances 2001, Goldstein 2005, Kenealy 2005, Lobach 1997(Lobach 1994), McDonald 1976, McDonald 1984, McDowell 1989, McPhee 1991, Martens 2007,Murray 2004, Nilasena 1995, Ornstein 1991, Rogers 1979, (Rogers1982 & Rogers1984), Rosser 1991, Rossi 1997, Sequist 2005, Tierney 2003,
Advice available post-consultation		
Audit and feedback vs usual care	4	Bonevski 1999, Dickinson 1981, Mitchell 2005 (Mitchell 2004), Winickoff 1985
Computer-generated advice post-consultation vs usual care	1	Lester 2004 (Lester 2006)
Automatic delivery vs other type of automatic delivery	*4*	
Reminder/alert vs other reminder at time of consultation	1	Bloomfield 2005,
Reminder/alert vs other reminder (post-consultation)	1	Augstein 2007,
Reminder/alert vs audit and feedback	2	Phillips 2005 (Ziemer 2006), Tierney 1986
Provider-initiated delivery vs usual care	*11*	
Decision support integrated with electronic medical record – advice available at time of consultation	7	Bulpitt 1976, Cobos 2006, Coe 1976, Eccles 2002, Hetlevik 1998 (Hetlevik 1999 & Hetlevik 2000), Meigs 2003, Montgomery 2002
Decision support not integrated with medical record – advice available at time of consultation	1	Hobbs 1996
Decision support not integrated with medical record – advice available post- consultation	3	Grover 2007, Lowensteyn 1998, McAlister 1986
Automatic delivery vs provider-initiated delivery	*1*	*Van Wyk 2008*

*In brackets are the author and year of additional publications for the same trial.

Seventy-one per cent (30/42) of CDSS trials included automated CDSS, 26% (11/42) of the studies were provider-initiated systems and one trial in 2008 compared these two types of CDSS head-to-head. The CDSS trials were published between 1976 and 2008. Figure 4.3 shows the publications of these trials in 5-year blocks (except for 2006-2008) classified according to having an automated CDSS, provider-initiated CDSS or both.

Figure 4.3. CDSS trials for CVD risk assessment and management in primary care or ambulatory services by publication year



While automated CDSS trials for CVD risk assessment and management in primary care have been spread over this time period, provider-initiated CDSS included two early trials in the late 1970s, a further trial in late 1980s and then no trials for a decade, followed by a series of trials between 1996 and 2008. Possible reasons for the recent increase in provider-initiated CDSS could be the rapid improvements in computer technology and greater availability of computers in clinical practice. While major changes in technology have occurred, the older trials were considered relevant as the actual mode of use in clinical practice was exactly the same as some of the recent trials. The majority of CDSS reminders were generated from automated chart audits of electronic medical records and presented to providers as paper-based reminders along with the patient visit or 'encounter' forms as is the custom in US clinical practice. Patient data from paper notes were then usually entered into an electronic medical record by an administrative assistant. Trials of reminder systems in the last 5 years from the US still involve paper-

based advice although some providers can now directly interact with computerised systems to order tests and other referrals.

Provider-initiated CDSS systems functioned either by using a structured paper-based input sheet that was later entered into a computer mainframe to generate advice or through direct engagement with computer decision support software at the time of consultation. The latter approach required the use of a desktop computer and networked patient management systems.

Tables of study characteristics by intervention type/s have been constructed below summarising studies according to CVD-relevant CDSS exposures, specified CVD outcomes only and relevant effect estimates where available. The full study details are documented in Appendix 4.1.

AUTOMATIC CDSS

Computer generated reminders (exposure group) at time of patient consultation compared with control group ([1]control group is usual care unless otherwise reported) (21 studies)

Study EPOC score	Provider (n) Patient (n)	Exposure Group (EG) (cf Control Group[1] CG)	Primary outcome/s	Effect estimate provider process	Effect estimate patient outcome
Barnett 1983 USA 8/14	nr[2] 115	Reminder	% follow-up attempted or achieved for hypertensive patients, repeat BP recorded	Follow-up RR 2.13 (1.59-2.86) Repeat BP RR 1.35 (0.99-1.83)	No patient outcome reported
Becker 1989 USA 8/14	nr 1050	EG1 preventive reminders to doctors only ; EG2 to doctors and patients	CVD-relevant outcome-BP measurement	Changes in BP measurement from baseline not reported	No patient outcome reported
Demakis 2000 USA 13/14	275 12,989	Reminders for 13 standards of care	Adherence to CVD-related standards: CHD-lipid tests, Diabetes-HbA1c, urinalysis, nutrition counselling, eye & foot examinations Smokers- cessation counselling Post MI-β-blocker	All others –ns except for Diabetes-, urinalysis (OR 1.38;1.13-1.68), eye examination (OR 1.60;1.29-2.00), foot examination (OR 1.26;1.02-1.56), smoke counselling (OR 1.44;1.01-2.05),	No patient outcome reported
Filippi 2003 Italy 10/14	300 15,343	Reminder for anti-platelet treatment for high risk patients with diabetes	% receiving 2 or more prescriptions for antiplatelet drugs	Antiplatelet treatment (OR 1.99;1.79-2.22);	Not reported

Study EPOC score	Provider (n) Patient (n)	Exposure Group (EG) (cf Control Group[1] CG)	Primary outcome/s	Effect estimate provider process	Effect estimate patient outcome
Frances 2001 USA 11/14	66 730	Computer reminder + written reminder at time of patient visit	% patients on aspirin; % MI patients with β-blocker; % receiving lipid-lowering drug; % patients LDL in target range (<100mg/dL) % patients hospitalised for MI and patient mortality	No significant differences (ns)	No significant difference
Goldstein 2005 USA 12/14	42 4,533	Computerised patient specific advice on hypertension prescribing	% hypertensive patients with guideline concordant drug regimen % patients with BP less than 140/90mmHg	Concordant drug treatment (Additional from baseline +10.9% EG vs +3.8% CG)	No significant difference
Kenealy 2005 New Zealand 13/14	112 5,628	EG1 GP computerised reminder EG2 patient self-assessment given to GP at consultation EG3 both	Blood glucose testing	GP reminder vs usual care OR 2.31 (1.4 to 3.82)	No patient outcome reported
Lobach 1994, 1997 USA 11/14	58 359	Computer generated diabetes advice	Overall & individual reminder compliance for foot examination, physical examination, glucose monitoring, urinary protein, cholesterol, eye examination, influenza & pneumococcal vaccination	Overall Compliance 32% vs 16% Foot exam 56% vs 30% complete physical exam 33% vs 7%, glycaemia monitoring 57% vs 53%, urinary protein test 73% vs 4% cholesterol level 44% vs 13%, eye examination,19% vs 3% Vaccinations: flu 29% vs 23% pneumococcal 20% vs 0%	No patient outcome reported

Study EPOC score	Provider (n) Patient (n)	Exposure Group (EG) (cf Control Group[1] CG)	Primary outcome/s	Effect estimate provider process	Effect estimate patient outcome
McDonald 1976 USA 9/14	63 257	Computer generated advice based on diabetes protocol	1) ordering laboratory test or repeat BP 2) change in BP drug treatment	Ordering tests or BP 36% vs 11% Change in drug treatment 28% vs 13%	No patient outcome reported
McDonald 1984 USA 12/14	126 12,467	Computer generated reminders (average 6/patient)	Response to CVD related reminders including dietary counselling for weight reduction, β-blockers after myocardial infarction, long acting nitrates to prevent angina and treatment of CHF	Dietary counselling 44% vs 19% Results for , β-blockers, long acting nitrates and heart failure treatment not reported	No patient outcome reported
McDowell 1989 Canada 11/14	~24 5,744	EG1 GP reminder, EG2 patient letter reminder EG3 patient phone reminder	% BP recorded during study period Cost-effectiveness of each exposure group (cost per BP reading gained)	BP recorded GP alert vs CG 30.7% vs 18.6% GP reminder most cost-effective	No patient outcome reported
McPhee 1991 USA 12/14	40 2,331	Preventive service reminders	Mean %annual rate of CVD relevant screening procedures including smoking assessment, smoking counselling, dietary assessment and dietary (fat and fibre) counselling)	Smoking assess 45.0 (16.6) vs 32.4 (13.9) Smoking counselling 58.8 (23) vs 41.8 (22.2) Diet assess 23 (23.8) vs 7 (11.4) Diet counselling 14 (17.5) vs 0.6 (1.4)	No patient outcome reported

Study EPOC score	Provider (n) Patient (n)	Exposure Group (EG) (cf Control Group[1] CG)	Primary outcome/s	Effect estimate provider process	Effect estimate patient outcome
Martens 2007 The Netherlands 11/14	53 ? 	Computer reminder for statin treatment (cf reminder for antibiotic, asthma and COPD treatment)	% appropriate statin prescription according to recommendations	No differences in prescribing for those recommended EG 88 (71-100%) vs CG 72 (52-81%) or those for whom not recommended (EG 100% vs CG 98% (94-100)	No patient outcome reported
Murray 2004 USA 11/14	150 712	EG1 Physician advice for BP treatment EG2 Pharmacist advice EG3 both physician and pharmacist	Generic health-related quality of life, emergency department visits & hospitalisations, BP measurements, patient satisfaction, compliance with drug therapy recommendations	No statistically significant differences between groups	No significant difference between groups
Nilasena 1995 USA 8/14	35 164	Computer generated reminders for diabetes preventive care	Overall compliance & compliance by clinical category- medical history, physical examination, laboratory tests/referrals and patient education	No statistically significant difference in overall compliance. Results by clinical categories not reported	No patient outcome reported
Ornstein 1991 USA 11/14	49 7,397	EG1 physician reminders EG2 Printed patient reminders; EG3 Both physician and patient reminders	Adherence to 5 preventive services (CVD relevant-cholesterol measurements)	% increase cholesterol tests from baseline physician reminder 12.3% (11.3-13.2%) vs controls 9.1% (8-10.1%)	No patient outcome reported

Study EPOC score	Provider (n) Patient (n)	Exposure Group (EG) (cf Control Group[1] CG)	Primary outcome/s	Effect estimate provider process	Effect estimate patient outcome
Rogers 1979, 1982, 1984 USA 7/14	Nr 484	Computer printout plus handwritten medical record (cf hand-written paper record)	Incidence and duration of hospitalisation per patient per year Tests, procedures and counselling conducted for patients with hypertension, obesity and/or renal disease, mean BP, mean pounds overweight; patient's perceptions of their own health status and quality of communication.	*Hypertensive patients:* Renal function test 60.9%vs 50.3%, Fundal exam 7% vs 4.7%, *Obese patients:* Dietary review 33.8% vs 20.3% *Renal disease patients :* Renal function test 70.3% vs 55.6% Urine culture 25% vs 20% Urinalysis 46.9% vs 31.1%	EG-more positive perceived health status & quality of communication Reduced mean lbs o/weight No diff in SBP, DBP, or hospitalisation
Rosser 1991 Canada 12/14	~30 5,883	EGI physician reminder; EG2 patient letter reminder EG3 patient telephone reminder	Compliance with CVD relevant reminders BP measurement and assessment of smoking status	BP measurement 30.7% physician reminder vs 21.1% CG Smoking status 22.8% physician reminder vs 11.9% CG	No patient outcome reported
Rossi 1997 USA 11/14	71 714	EG reminder to change from CCB to other BP therapy	Prescription changes from CCB to other antihypertensive medications	EG 11.3% were changed to other BP medications compared to less than 1% CG	For those that had changed therapy– no difference in BP, follow-up visits or hospital admission
Sequist 2005 USA 12/14	194 6,243	EG reminders for diabetes and coronary artery disease	Proportion of 5 diabetes and 4 coronary artery disease reminders resulting in recommendation action.	*All Diabetes reminders* EG 19% vs CG 14% (Adj OR 1.30; 1.01-1.67). *Coronary reminders* *EG* 22% vs CG 17% (Adj OR 1.25;1.01-1.55).	No patient outcome reported

Study EPOC score	Provider (n) Patient (n)	Exposure Group (EG) (cf Control Group[1] CG)	Primary outcome/s	Effect estimate provider process	Effect estimate patient outcome
Tierney 2003 USA 13/14	201 706	EG1 Physician advice for patients with heart failure or CHD EG2 Pharmacist advice EG3 both physician and pharmacist	Provider compliance with reminders of guideline recommendations Patient outcomes: Health related QOL (SF-36), exacerbations of heart disease. Patient satisfaction, medication compliance, direct health care costs	All cardiac care suggestions EG1 23% vs CG 22%	No significant difference in patient related outcomes

[1] Control group received usual care unless otherwise stated. [2] If more than one intervention (Exposure Group), then these are listed as EG1, EG2 etc

Automated audit and feedback studies providing advice (post-consultation) vs control group

Study EPOC score	Provider (n) Patient (n)	Exposure Group (EG) (cf Control Group[1] CG)	Primary outcome/s	Effect estimate provider process	Effect estimate patient outcome
Bonevski 1999 Australia 12/14	22 3115	EG computer CME programme with feedback on GP performance of preventive services for individual patients CG CME programme with no feedback	BP and cholesterol screening, smoking classification	BP screening EG 94% vs CG 87% cholesterol screening 81% EG vs CG 60%. Overall accuracy of smoking classification EG 76% vs CG 75%	No patient outcome reported
Dickinson 1981 USA 13/14	41 250	EG1 Monthly computerised feedback by BP control; EG2 Physician self-education EG3 both	Number of follow-up patient visits; Physician knowledge Change in SBP and DBP % patients improved SBP and DBP over study period	EG1 vs CG Patient visits Feedback 3.4 ± 0.4 vs control 2.6± 0.6 ($p<0.05$) No knowledge differences EG1 vs CG	No significant differences in mean SBP, DBP or improvements in BP control
Mitchell 2004 &2005 UK 11/14	52 practices (~208 doctor) 30.345	EG1 audit and aggregated feedback on numbers of hypertensive patients, known hypertensives treated, known treated hypertensives controlled EG2 as above plus patient CVD risk over 10%	Change in BP recording from baseline, Change in BP treatment from baseline (BP untreated if ≥160/90mmHg) Proportion patients with controlled BP	BP recording and control ns Baseline CG 89.6% vs audit 84% vs risk 96.1% increasing to CG 92.3% vs audit 86% vs risk 96.6%	No significant differences in adjusted final SBP or numbers with uncontrolled BP BP control was better in the audit plus risk (adj OR 1.72 (1.09 -2.70)) vs control or audit only.
Winickoff 1985 USA 6/14	32 ?	EG1 quarterly feedback to providers about individual patients & peer comparison feedback	proportion completing initial lab testing for high blood pressure, BP control and follow-up	no sig differences in scores between EG and CG in initial testing (87% vs 87%), or follow-up (79% vs 77%)	No significant difference in BP control (58% vs 59%)

[1]Control group is usual care unless otherwise reported. [2] If more than one intervention (Exposure Group), then these are listed as EG1, EG2 etc

Automated Computer generated reminders/advice to physicians *post* consultation compared with usual care

Study **EPOC score**	**Provider (n)** **Patient (n)**	**Exposure Group (EG) (cf Control Group CG)**	**Primary outcome/s**	**Effect estimate provider process**	**Effect estimate patient outcome**
Lester 2004, 2006 USA 10/14	15 256	EG E-mail advice CG usual care	change in statin prescription change in LDL levels,	statin prescription changes EG 24.6% vs CG17.1% but ns	No significant difference in LDL levels

Automated Computer generated reminders/advice to clinicians *at time of* patient consultation compared with *alternative interventions*

Study **EPOC score**	**Provider (n)** **Patient (n)**	**Exposure Group (EG) (cf Control Group CG)**	**Primary outcome**	Effect estimate provider process	**Effect estimate patient outcome**
Bloomfield 2005 USA 10/14	92 1349	EG1 computer generated reminder at time of patient visit EG2 Computerised lipid management progress note for each patient a few days prior to visit CG letter to patient to discuss lipid-lowering meds at visit and sent 1-2 weeks prior letter about lipid management prior to visit	% target patients prescribed lipid-lowering drugs	Individual baseline prescription rates not reported but increased to 39.4% for reminders, 40.7% for progress notes, 36.9% for patient letters and with no statistically significant difference between type of prompt.	No patient outcome reported

Automated computer generated reminders/advice to physicians *post* patient visit compared with *alternative intervention*

Study EPOC score	**Provider (n)** **Patient (n)**	**Exposure Group (EG) (cf Control Group CG)**	Primary outcome	Effect estimate provider process	Effect estimate patient outcome
Augstein 2007 Germany 12/14	nr[1] 49	EG diabetes management CDSS & continuous glucose monitoring system CG continuous glucose monitoring system only	mean change in HbA1c from baseline, mean sensor glucose hypo- or hyperglycaemic excursions, bread exchange unit (BU), daily insulin dose	No provider outcomes reported	Statistically significant mean change in HBA1c EG -0.34± 0.49% vs CG 0.27± 0.67% from baseline, reduced mean serum glucose Reduced duration hyperglycaemia (1hour/day vs 4.6 hours) without increasing hypoglycaemia

Automated computer generated reminders/advice to clinicians vs audit and feedback (or both or neither)

Study **EPOC score**	**Provider (n)** **Patient (n)**	**Exposure Group (EG) (cf Control Group CG)**	**Primary outcome**	**Effect estimate provider process**	**Effect estimate patient outcome**
Phillips 2005 (Ziemer 2006) USA 13/14	345 4138	EG1 reminders at patient visits EG2 face-to-face feedback on performance EG3 both CG neither	Change in mean HbA1c Change in mean BP & LDL Compliance with recommendations categorised by “did nothing” “did something” or “did enough”	ns diff between EG1 or EG2 vs CG but both reminders and feedback had sustained significant differences in compliance	HbA1c changes not significant with feedback or reminders singly vs CG EG3 (both) vs CG Change 0.6% vs 0.2% p<0.02. Similar but non-significant trends for SBP & LDL
Tierney 1986 USA 11/14	135 6045	EG1 Reminders EG2 Monthly feedback reports EG3 Both CG neither	% patients who received the indicated preventive care (CVD relevant reminders –beta blockers, nitrates, aspirin, digitalis)	Overall yes but no significant difference for CVD reminders between CG and EGs	No patient outcome reported

PROVIDER-INITIATED CDSS

Provider-initiated computerised decision support (integrated with patient medical record) *at time of patient consultation*.

Study EPOC score	Provider (n) Patient (n)	Exposure Group (EG) (cf Control Group[1] CG)	Primary outcome/s	Effect estimate provider process	Effect estimate patient outcome
Bulpitt 1976 UK 6/14	nr 278	EG structured input template then a summary document produced at each follow-up visit CG medical records held on standard hospital notes	Documentation patient history, patient symptoms and risk factors, BP control, drop-out rates, frequency of performing recommended investigations	Structured input form resulted in much fuller documentation ($p<0.01$) of patient history, symptoms and risk factors, No diff in frequency investigations (e.g. U & E, MSU, urinary VMA, CXR, ECG, IVU).	No significant differences in BP control or drop-out rates
Cobos 2006 Spain 8/14	44 practices 2221	EG computerised data collection form giving immediate advice plus table cloths and magnets CG computerised data collection form without advice	Effectiveness defined as: meeting guideline LDL goal if ≥20% 10yr CVD risk ;or remaining <20% CVD risk at study end, total costs of lipid management	No difference in effectiveness EG 54.02% vs CG 50.48% Overall less use of lipid-lowering drugs EG 40.8% vs CG 59.1 particularly in low risk non-CHD patients 24.9% saving in treatment costs and 20.8% total costs	No significant difference in lipid profiles
Coe 1977 USA 6/14	? 116	EG Structured input template then computer based recommendations to physician CG Structured input template without advice	Adequacy of BP control	No provider outcomes reported	No significant difference in BP control RR 0.82 (0.55-1.23)

Study EPOC score	Provider (n) Patient (n)	Exposure Group (EG) (cf Control Group[1] CG)	Primary outcome/s	Effect estimate provider process	Effect estimate patient outcome
Eccles 2002 UK 13/14	62 practices 9811	EG Computerised guidelines for management angina CG computerised guidelines for management of asthma	1)Recording of : BP,smoking status, ECG, exercise ECG, Haemoglobin, Thyroid function, cholesterol, HbA1c or blood glucose recorded. 2) Recorded or advised:- exercise and weight; 3) Recommended CVD drugs prescribed	No significant differences in any of the processes of care.	No patient outcome reported
Hetlevik 1998, 1999 (b) Norway 12/14	56 2239	EG Received guidelines training and installation of CDSS on hypertension, diabetes and hyperlipidaemia CG Usual care	Documentation of BP, cholesterol, smoking, family history, BMI, and having all variables for calculation CVD risk Changes in systolic and diastolic BP, cholesterol, BMI and CHD risk, % smokers	No significant differences in any of the processes of care.	Mean difference In DBP EG -1.0 (-1.9 to -0.2). No other significant differences in patient risk or risk factors
Hetlevik 2000 (c) Norway 12/14	56 1034	EG Received guidelines training and installation of decision support on hypertension, diabetes and hyperlipidaemia CG Usual care	For diabetic patients: Documentation of HbA1c, BP, cholesterol, smoking status, family history of CVD, BMI, risk score. Improvements in patient HbA1c, DBP, SBP, cholesterol	Significant decreases EG vs CG in the absence of documentation of smoking (-11.9% ;-16.3 to -7.5), BMI (-14.8% ;-19.5 to -9.9) and variables to make risk estimation possible (-7.2%; -10.3 to -4.1).	Only significant difference was a decrease in DBP of -2.3 (-3.8 to -0.08)

Study EPOC score	Provider (n) Patient (n)	Exposure Group (EG) (cf Control Group[1] CG)	Primary outcome/s	Effect estimate provider process	Effect estimate patient outcome
Meigs 2003 USA 10/14	66 598	EG web-based decision support tool for Diabetes CG Usual care	HbA1c tests, LDL tests, BP documentation, eye & foot screening Change in most recent value HbA1c, LDL and BP compared with most recent value in previous year	EG vs CG stat sig differences HbA1c tests/yr (+0.3 vs -0.04) LDL tests/yr (+0.2 vs +0.1) At least one foot exam/yr +9.8% vs -0/7%)	HbA1c decreased 0.2% EG vs increased 0.1 CG % patients with LDL<130 mg/dl increased by 20.3% EG vs 10.5% CG
Montgomery 2002 UK 13/14	85 614	Computer based decision support for calculating CVD risk plus paper-based CVD risk chart EG2 CVD risk chart CG Usual care	Reduction of patients with 5-yr CVD risk ≥10% Systolic BP, diastolic BP and prescribing of CV drugs	No significant improvement in prescribing CVD drugs-- CDSS vs usual care	CDSS vs usual care ns difference in SBP and DBP No significant reduction of CVD risk- CDSS vs usual care

Provider-initiated non- integrated computerised decision support vs usual care *at time of patient consultation*.

Study **EPOC score**	**Provider (n)** **Patient (n)**	**Exposure Group (EG) (cf Control Group[1] CG)**	**Primary outcome/s**	**Effect estimate provider process**	**Effect estimate patient outcome**
Hobbs 1996 UK 6/14	25 practices 4533	EG Rule based decision support system for lipid management separate from practice system CG usual care	Changes in hospital lab testing, specialist referral, lipid-lowering drug prescribing, provider knowledge of lipid disorder management	No statistically significant differences	No patient outcome reported

Provider-initiated non-integrated computerised decision support vs usual care *post consultation*.

Study **EPOC Score**	**Provider (n)** **Patient (n)**	**Exposure Group (EG) (cf Control Group[1] CG)**	**Primary outcome/s**	**Effect estimate provider process**	**Effect estimate patient outcome EG vs CG**
Grover 2007 Canada 11/14	230 3053	EG computerised decision support for provision of CHD risk profile (-sent later from computer centre) CG Completed medical evaluation but no risk profile sent back	Mean reduction in LDL, TC/HDL ratio and % patients reaching national lipid targets	n/a	LDL -1.33 (0.76) vs -1.24 (0.77) TC/HDL - 1.5(-1.1) vs -1.3(1.0) Lipid targets overall OR 1.26;1.07-1.48 patients with CVD ns diff but for patients without CVD, (OR 1.26; 1.04-1.53), mainly due to impact on those with diabetes (OR 1.42;1.11-1.81)
Lowensteyn 1998 Canada 10/14	253 958	EG Risk assessment completed. CHD risk profile sent back within 10 days EG Baseline risk assessment completed. Received risk profile only if patient clinically re-evaluated during a 3-month follow-up visit	Likelihood of high risk vs low risk patients being seen at 3-month follow-up. Changes in risk factors and CHD risk in those reassessed	Follow-up- ratio of high risk/low risk significantly higher for EG 1.23 (0.96-1.60), for CG 0.77 (0.58-1.03)	Significantly greater mean reduction in LDL (-0.4 vs 0.0mmol/l). TC/HDL (-0.6 vs-0.2) and 8-year coronary risk (-1.8 vs -0.3%)
McAlister 1986 Canada 6/14	50 2833	EG Computer feedback based on treatment protocol mailed back to GP, plus reminder appointment sent to patients. EG data collection form filled only.	Decision to treat with BP drugs Mean change DBP % of patients who achieve goal of DBP 90mmHg	No statistically significant differences in decision to treat	No statistically significant differences in DBP or achieving DBP goal

Provider-initiated computerised decision support (integrated with patient medical record) vs automated CDSS reminder/ alerting *at time of consultation*

Study **EPOC score**	**Provider (n)** **Patient (n)**	**Exposure Group (EG) (cf Control Group[1] CG)**	**Primary outcome/s**	**Effect estimate provider process**	**Effect estimate patient outcome**
Van Wyck 2008 The Netherlands 14/14	80 92,054	EG1 on-demand CDSS requiring initiation of the overview screen to access recommendations EG2 Alerting CDSS showing recommendations automatically CG usual care	% patients screened for lipid abnormalities % treated patients	Screening: CG 25% On-demand 35% (RR 1.28; 0.98-1.68) Alerting 65% (RR 1.76; 1.41-2.20) % treated CG 36% On-demand 40% (RR 1.19; 0.94-1.50) Alerting 66% (RR 1.40; 1.15-1.70)	No patient outcome reported

4.5.3 Quality assessment of the included studies

Most of the studies 34/42 (81%) were cluster randomised controlled trials where the unit of randomisation was the practice or clinic (10/42, 24%), practice teams within a clinic (5/42, 12%), individual health professionals (17/42, 40%) or the family (2/42, 5%). The unit of analysis was the patient (or usually the patient's electronic medical record). For all trials, the knowledge content of the CDSS was 'a gold standard' of best practice identified either by local expert consensus, national guidelines or a mix of both.

Representativeness

For the majority of the studies, the sampling frame was clearly identifiable e.g. all practices within a geographical area, register of primary care providers or all clinics within a specific Health Maintenance Organisation (HMO). Compared with many other primary care trials, the proportions of eligible providers (and patients) who participated was high; 20/42 (48%) studies had close to 100% participation as the intervention involved all providers within teams or clinics who all used the same electronic medical records. For a further 18/42 studies (42%), the median participation rate of primary care providers was 60% (range 10–78%). Only 4/42 (10%) of the studies did not report the percentage of the eligible population that took part.

Allocation

The method of randomisation was not reported in 64% of the studies. Allocation concealment was also very poorly reported with only 5/42 (12%) able to be described as adequate. All but 7/42 (17%) reported baseline characteristics of the allocated groups.

Maintainance

Because of the nature of CDSS interventions, it was not possible to blind participants but some studies reported participants being blind to the research hypothesis. Compliance in terms of system installation and availability to participants was uniformly 100% – all received the interventions. The potential to avoid contamination was best addressed by

15/42 (36%) of studies that randomised whole practices or teams of providers to one exposure group. The remaining 64% of studies randomised individual professionals within a clinic or practice or patients (or families) of providers, potentially allowing health providers to use knowledge gained from the CDSS intervention for control patients (or their families). Although not specifically reported in any study, co-intervention within control groups probably did not occur very frequently. These were busy clinicians within primary care practices for whom structural changes in the delivery of patient-specific information was secondary to usual patient care. No study reported any external incentives to improve provider performance.

Losses to follow-up were variably reported, with some studies addressing patient losses, others reporting loss of providers, both or neither. Where clinic computerised records were assessed or data was automatically extracted, follow-up of patients was generally very high (around 80–100%). However, reliance on automated extraction or electronic practice records was also associated with large losses to follow-up when entire practices dropped out or IT problems resulted in mass data deletion within practices.

Measurement of outcomes, blind or objective

The majority of studies involved unblinded measurement of outcomes from electronic patient medical records. The method of data extraction was by manual chart review or computerised automated extraction. Only 7/42 (17%) studies reported outcome assessment that was blind to exposure group status and two other studies reported reliability scores for extracted data. However, the outcomes measured were generally objective (e.g. blood tests ordered, drug prescriptions, or documentation of risk factor status).

Statistics

About half (22/42) of the trials conducted intention to treat analysis. The majority 21/34 (62%) of the cluster randomised controlled trials accounted for clustering within the analyses. Power calculations taking into account reduction in effective sample size (depending on average cluster size and degree of correlation between clusters or intercluster correlation)[160] were presented in the majority of these studies but only one

study[163] reported an intercluster correlation co-efficient. Only 15/42 (36%) reported adjustment for potential confounding by patient or practitioner co-variates.

Overall EPOC scores

EPOC scores ranged from 6/14 to14/14 (median 11/14). Of the 11 studies scoring 9/14 or less, 73% were published in the 1970s and 1980s. Of the 17 studies scoring 12/14 or more, 76% were published in the last 10 years, indicating improvements in quality of the reporting of studies over time.

Methods for pooling results

The types of CDSS interventions were grouped separately as per categories described in Table 4.1. The intention was to pool outcomes by CDSS type using Review Manager (Revman 4.2.8) software from the Cochrane Collaboration. However, formal meta-analysis was unable to be performed because of inconsistency of the outcomes measured and varying definitions of success used. Therefore, a simple article counting method was used. The main outcomes for practitioner performance or patient outcomes were categorised by a positive improvement, negative (or harm) or no effect. Practitioner performance was further divided into separate processes that are used during a patient consultation: documentation of patient history, examination, investigation/s, provision of advice and a management plan.

Publication bias

It was noted that seven potentially relevant randomised trials reported as protocols or preliminary results in conference proceedings dating between 1983 and 2006 are yet to be published.[164-172]

4.6 Results of systematic review

4.6.1 Automatic computer-generated reminders at time of consultation

There were 21 studies of computer-generated reminders or alerts compared with usual care that related to patients diagnosed as:

- having existing coronary heart disease[173-177], heart failure[175 177],
- having diabetes[174 176 178-183]
- having hypertension[184-189]
- having raised blood pressure (BP)[190], raised lipids[174], being a smoker[178 191] or obese or overweight[186-188]
- overdue for preventive care e.g., no documentation of risk factors or if documented, being outside of the frequency recommended.[175 178 191-197]

The reminders varied from one simple message per patient (e.g. blood glucose testing as a screening procedure for diabetes) to multiple messages generated per patient. No automatic reminder study alerted clinicians to document an absolute CVD risk or included absolute risk within primary or secondary outcomes. The median study duration for these trials was 12 months (range 2–24 months).

Overall changes in provider behaviour from automatic reminders

Fifteen of 21 (71%) studies of automated reminders compared with usual care reported improvements in provider processes. Where reported, there were large variations in overall compliance to reminders within and between individual clinicians. Compliance was reported as lower for prevention rather than treatment-oriented reminders[178] and clinicians became less likely to respond over time[178] or were “desensitised”.[173] Reasons

given included system errors, inappropriate or poorly tailored reminders[175 182], the system not being helpful for making individual decisions about patients[177], being simply too busy to respond[176], lack of familiarity with the guidelines[176] and poor "buy-in" by clinicians.[173]

Meta-analysis of overall compliance with reminders for CVD-related processes was not possible because:

- some studies of multiple outcomes did not report an overall compliance estimate (only gave individual outcome results)
- patient numbers were not given for intervention group (EG) or control group (CG), just proportion of patients for whom a positive response to reminder was identified in the study period (% response only)
- some reported compliance per instances of reminders given (possible multiple reminders for one recommended outcome per patient)
- some reported absolute change from baseline only while others reported % overall response to reminder without reference to baseline rate of recommended care
- others did not report an effect estimate for a CVD-related reminder, just an overall result for multiple CVD and non-CVD related reminders.

Impact of automatic reminders on categories of provider process

An analysis was conducted with respect to separate provider processes that are part of a patient consultation: documentation of patient history, examination, investigation/s, provision of advice and a management plan. These were also unable to be pooled given the variation in provision of data and definition of outcome.

Documentation of patient history

Three studies investigated the ability of computerised reminders to improve the documentation of patient history with respect to smoking status[191 197], fat and fibre dietary assessment[191] and documentation of unspecified patient history variables for patients

with diabetes.[183] Two studies showed significant improvements in documentation over usual care.[191 197]

Examination

Eight studies investigated aspects of physical examination: BP measurement[190 193 195], diabetes related foot or fundal examination[176 178 180 181 183] and hypertension-related fundal examination.[186-188] In terms of BP measurement, one study did not report a separate effect estimate, only that there was a statistically significant improvement in overall preventive care from multiple reminders.[193] Barnett et al. (1983) and McDowell et al. (1989) reported improvements in BP recording that could be pooled using Revman 4.2, the combined result being an increase by 68% (OR (fixed) 1.68 (1.39,2.05)).[190 195]

Only two[178 181] out of the four studies of eye or foot examinations provided consistently defined outcomes so these results were not pooled. Reported results were mixed, with one study showing a statistically significant improvement in diabetes foot or fundal examinations[178] but two others reporting no statistical difference from usual care.[176 181] Similarly, Rogers et al.(1979)[186] found little difference in fundal examinations for patients with hypertension.

Investigation

Eight studies of computerised reminders compared with usual care[176 178 181-183 188 196] reported outcomes relating to investigations: lipid tests for primary and secondary prevention, monitoring for patients with diabetes (HbA1c, urinary protein), monitoring for patients with hypertension (liver function tests, renal function tests, urinalysis, urine culture, electrolytes, haemoglobin and white cell count) and screening for diabetes (fasting blood glucose). Seven out of eight studies reported improvements in all or some of the investigations prompted by the reminders.

Advice

Five studies were identified that prompted clinicians to give patients dietary or smoking cessation counselling.[175 178 183 188 191] Four out of the five studies reported improvements in provision of all or some of the counselling prompted by the reminders.

Management plan – pharmaceutical management or follow-up

Thirteen studies investigated the impact of reminders on planned care in terms of: prescribed management of individual drugs (e.g. aspirin, statin, β-blocker and ACE inhibitor therapy), guideline concordant management for patients with coronary artery disease, congestive heart failure, hypertension and raised lipids, influenza or pneumoccocal immunisation for patients with diabetes and attempted or achieved follow-up.[173-179 181 182 184 185 189 190] Seven out of thirteen of these reported improvements.

Impact of automated reminders on patient outcomes

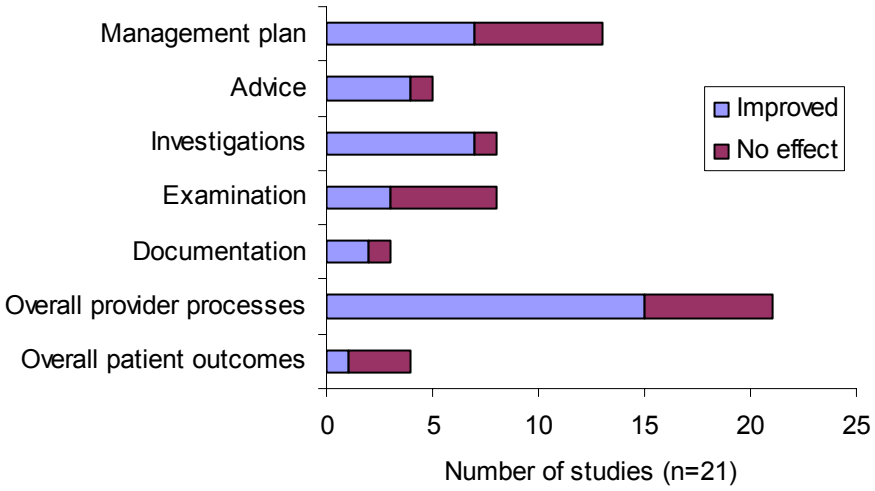
Only 4/21 (19%) of automated reminder studies reported patient-specific outcomes.[173 177 184 187] These included mean pounds overweight,[188] change in mean systolic and diastolic blood pressure,[188] proportion of patients with LDL or BP in target range,[173 184] self-reported health-related quality of life,[177 187] patient satisfaction with care,[177] patient-assessed quality of communication with health professionals[187], compliance with medication[177] or more downstream outcomes of hospitalisation[173 186] and mortality.[173]

Only one out of the four trials reported statistically significant improvements in patient outcomes in terms of reductions in mean pounds overweight, more positive perceived health status and perceived quality of communication with health professionals[187] although follow-up time for most of the studies were probably too short to expect any differences and the studies were not powered to detect a difference in these secondary outcomes.

Summary results automatic reminder/advice compared with usual care

Figure 4.4 gives the summary results for computerised automated reminder trials There were no reported adverse effects to provider process or patient outcomes.

Figure 4.4. Summary results of automatic computerised reminders compared with usual care at the time of patient consultation



4.6.2 Audit and feedback for CVD risk assessment and management

There were four trials of audit and feedback for CVD risk assessment and management compared with usual care, ranging in duration from 3–27 months.[163 198-201] For each trial the audit was conducted on computerised patient medical records with feedback to providers that included lists of individual patient profiles stratified according to concordance with particular guideline targets. These studies were unable to be pooled given the variation in reported data and definition of outcome chosen. Results were mixed, with 2/4 studies reporting statistically significant improvements in provider processes with audit and feedback interventions. While they were all cluster randomised trials, only one study (Mitchell et al. 2005) reported an intracluster correlation coefficient of 0.1.[163]

Impact of automated audit and feedback on categories of provider process

History taking

Only one trial investigated the impact of audit and feedback on the classification of smoking status and found no statistically significant differences.[198]

Examination

Two studies included recording of BP as an outcome.[163 198] For Mitchell et al. (2005), the baseline BP documentation was already moderately high, with unadjusted rates varying between 66–81% depending on exposure group. Levels of documentation increased in all intervention groups by 4.5–7.9% with no statistically significant differences reported.[163] Bonevski et al. (1999) also reported high levels of baseline BP recording (85–86%) with feedback improving documentation of BP by 9% compared with 1% in the control group ($p<0.001$).[198]

Investigations

Cholesterol screening was investigated by Bonevski et al. (1999) Audit and feedback improved cholesterol screening by 17% from baseline compared to 5% in the control group ($p<0.001$).[198]

One of the outcomes for Winickoff et al. (1985) was the overall completion of initially recommended laboratory testing for patients confirmed as being hypertensive according to national guideline and locally accepted practices. This included performing an ECG, chest X-ray, urine analysis, haemoglobin, creatinine, potassium and cholesterol blood tests. No differences between audit and feedback compared with usual care were reported, as both groups had very high completion rates (87%) of initial tests.[201]

Advice

No studies of audit and feedback had advice or counselling as an outcome.

Management Plan

Two studies[199 201] investigated follow-up and number of repeat patient visits as a result of audit and feedback compared with usual care. Winickoff found no differences in follow-up rates but Dickinson found that patients of physicians who received performance feedback made twice as many visits as control patients.[199 201]

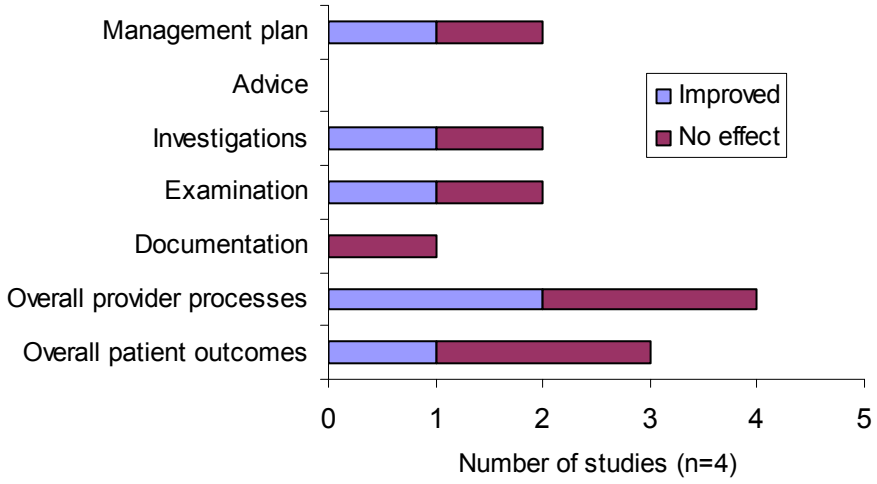
Impact of automated audit and feedback on patient outcomes

Three out of four studies of audit and feedback compared with usual care investigated patient outcomes.[163 199 201] All outcomes related to patient blood pressure; either changes in mean systolic blood pressure[163 199], changes in mean diastolic blood pressure,[199] proportion of patients with improved BP[199] and control of BP according to guideline criteria.[163 199 201] Three of the four reported no significant differences in any of these outcomes while Mitchell et al. (2005) reported significant improvements.[163] In this latter study, when adjusted for practice and patient characteristics, the control of BP was better in the practices who received audit and feedback plus colour-coded, patient-specific list ranked according to estimates of absolute risk of death from stroke in the next 10 years compared with audit and feedback alone or control practices (adj OR 1.72; 1.09 to 2.70).

Summary of results for automated audit and feedback compared to usual care

Figure 4.5 gives the summary results for the four trials of computerised extraction of patient data and feedback to practices. No trial reported adverse effects on provider process or patient outcomes using this type of automated CDSS.

Figure 4.5. Summary results of automated audit and feedback compared to usual care



4.6.3 Other trials of automated CDSS

Variants to trials of reminders or audit and feedback compared with usual care were identified.[202-208] Bloomfield et al. (2005) found that whether a reminder was delivered at the time of patient visit or a few days prior to a patient consultation, there was a similarly increase in prescription rates for lipid-lowering drug prescription by around 40% (from a baseline 8%).[203] However, e-mail advice generated automatically to clinicians' mailboxes based on audit of a patient's lipid status and other factors from the electronic medical record showed no significant impact on statin prescribing or patient LDL levels.[205] Therefore, delivery of advice prior to or at the time of patient consultation may be associated with greater improvements than advice given post-consultation. Two trials compared reminders at the time of patient visit with audit and feedback on performance (i.e. post-consultation), both or neither.[206-208] The IPCAAD study (Improving primary care of African Americans with diabetes)[206 208] showed no differences over control alone for either reminders or face-to-face feedback on performance but combining the two interventions led to sustained clinical compliance with guideline recommendations. Furthermore, there were statistically significant reductions in HbA1c and non-significant trends towards reducing systolic blood pressure and LDL levels. Tierney et al. (1986) considered a suite of 13 preventive care services and impact of monthly feedback

reports on performance versus immediate reminders, both or neither.[207] CVD-relevant advice included β-blocker, nitrate, digitalis and aspirin prescribing and possibly pneumococcal vaccination (patient target population not reported). The impact of the decision support interventions compared with control varied according to service being recommended. However, the overall results suggested that both feedback and reminders can increase physician compliance but reminders at the time of patient visit had a greater effect. Furthermore, unlike the IPCAAD study, there was no evidence of an additive effect (reminders plus feedback).

Augstein et al. (2007) demonstrated that the addition of guideline advice for insulin-dependent diabetes management as well as continuous glucose monitoring advice (compared with continuous monitoring alone) resulted in statistically significant reductions in patient HbA1c levels, mean serum glucose and reduced duration of hyperglycaemia without increasing episodes of hypoglycaemia. Therefore, it seems that decision support that adds value or renders complicated medical issues more meaningful and interpretable might be associated with improved patient outcomes.

4.6.4 Integrated provider-initiated CDSS- advice generated at the time of consultation

There were seven trials of CDSS that were integrated with the patient electronic medical record and generated advice at the time of patient consultation (compared to usual care) with study durations ranging from 12–18 months.[151 209-216] These trials related to patients with:

- hypertension[209 211 213 214 216]
- angina[212]
- diabetes[151 215]
- or without existing coronary heart disease with raised total cholesterol[210].

Three studies provided advice on absolute CVD or CHD risk.[210 213-216]

The trial by Hetlevik et al. was reported in 3 different publications in 1998, 1999, 2000, one reporting provider processes in response to a guideline-based CDSS[214], the second reporting patient outcomes for the CDSS[213] and the third providing a separate report on provider processes and patient outcomes for patients with diabetes.[215]

The CDSS interventions provided a structured individualised summary document for care of patients with hypertension,[209] an electronic calculator for CVD risk estimation,[216] computerised treatment guidelines for the management of angina,[212] type 2 diabetes,[151] hypercholesterolaemia,[210] hypertension[211] and diagnostic and therapeutic decision support incorporating three guidelines for the management of hypertension, diabetes and hypercholesterolaemia.[213-215]

Overall changes in provider behaviour with integrated provider-initiated CDSS

Four out of the seven (57%) studies of integrated provider-initiated CDSS showed some improvements in provider processes. Where reported, there was a large variation in engagement and consistency of use of CDSS by individual clinicians.[151 212 215] For example, Hetlevik et al. (2000) reported that the CDSS was used in the management of 14% of the eligible people with diabetes and varied between clinicians from zero to 50%. Meta-analysis of overall success was not possible as no overall provider process measure could be identified.

Impact of provider-initiated integrated CDSS on clinical processes

Documentation of patient history

Three studies investigated the impact of integrated CDSS on: documentation of smoking, family history of CVD and having all variables necessary for calculation of CVD risk[213-215], documentation of hypertensive patient history, patient symptoms and risk factors[209] and recording of smoking status, exercise or weight.[212]

Two of these studies reported significant differences compared with usual care. Bulpitt et al. (1996) found that the structured input form resulted in much fuller documentation of patient history symptoms and risk factors.[209] Hetlevik et al. (2000) reported significant

increases in smoking status documentation and variables required to be able to assess CHD risk in patients with diabetes.[215] However, Eccles et al. (2002) found no significant differences in documentation of smoking, exercise or weight in patients with angina.[212]

Examination

Three trials reported the effects of integrated CDSS on the measurement of BP[151 212-215], BMI[213-215], and examination of eyes and feet of patients with diabetes.[151] Two of the studies showed significant improvements in some of the desired patient examination outcomes investigated. Neither Hetlevik et al. (1998, 1999, 2000) nor Eccles et al. (2002) found significant differences in blood pressure measurement over the control group but Hetlevik et al. (2000) did find a significant improvement in BMI documentation in patients with diabetes.[212-215] Meigs et al. (2003) reported a very high baseline blood pressure measurement rate in diabetic patients (97–98%) in the exposure and comparison groups, with no statistical differences in the follow-up period.[151] While both eye and foot examinations increased over control group, only the foot examination difference was statistically significant compared with usual care.[151]

Investigations

Four studies investigated the frequency of performing recommended investigations:

- for patients diagnosed with hypertension – renal function tests, urinalysis and culture, urinary VMA, CXR, ECG and IVU,[209] cholesterol[213-215]
- for patients with angina – ECG, exercise ECG, haemoglobin, thyroid function, cholesterol, HbA1c or blood glucose[212]
- for patients with diabetes – HbA1c, cholesterol, LDL[151 213-215]

Only 1/4 studies reported significant improvements in tests performed with integrated provider-initiated CDSS compared with usual care.[151]

Provision of advice

One study investigated whether exercise or weight was recorded or advised and found there was no significant differences from the control group.[212]

Management plan

Four studies included indicators of plan of management, investigating appropriate prescribing of lipid-lowering drugs,[210] drug therapy for patients with angina[212] and patients with hypertension.[216] Cobos et al. (2005) found that there was significantly less prescribing of lipid-lowering drugs in the CDSS group compared with control particularly in the group of patients at low CVD risk where drug management was not recommended.[210] This resulted in substantial cost savings. The other two studies found no significant differences between intervention and control groups. The fourth study, by Bulpitt et al. (1976), assessed drop-out rates from an ambulatory hypertensive clinic and found no differences from patients of providers who used standard medical notes. [209]

Impact of provided-initiated integrated CDSS on patient outcomes

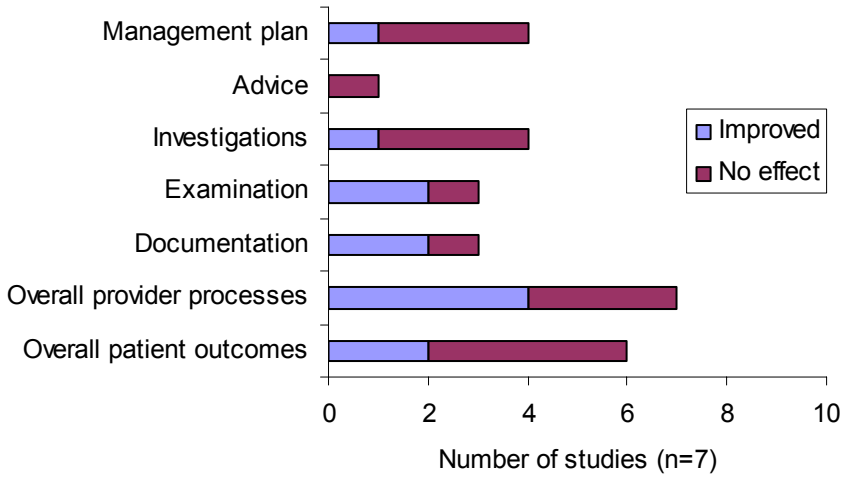
In contrast to studies of reminders, all but one of the trials assessing integrated CDSS investigated patient outcomes in terms of improvements in CVD risk factor levels,[151 213-216] or CVD risk[210 216] or meeting guideline criteria for blood pressure[209 211] or lipid management.[210] No trial assessed more downstream patient outcomes such as hospitalisation or mortality.

Two of the six trials reported modest improvements in some of the CVD risk factors measured. Hetlevik et al. (1998,1999, 2000) reported a small but statistically significant reduction in mean diastolic BP for hypertensive and for diabetic patients[213-215] and Meigs et al. (2003) reported that the proportion of patients with an LDL <130 mg/dl (<3.3 mmol/l) increased significantly by 20.3% in the intervention group (compared with 10.5% in the control group).[151] There were no significant differences compared with the control group for all the other risk factors studied.

Summary of provider-initiated integrated CDSS at the time of patient consultation

Figure 4.6 gives the summary results for the seven trials of provider-initiated CDSS integrated with the EMR compared with usual care. There were no reported adverse effects to provider process or patient outcomes using this type of CDSS.

Figure 4.6. Summary of provider-initiated CDSS integrated with the EMR at time of patient consultation



4.6.5 Non-integrated provider-initiated CDSS

Non-integrated CDSS at the time of patient consultation

One trial investigated the impact of a non-integrated CDSS at time of consultation. This was a rule-based decision support system for lipid management which was provided to GPs on a computer completely separate from the practice system.[217] This required GPs and nurses to go to a separate computer and input all patient data. After data entry, the system generated lipid management advice. Most providers used it fairly infrequently (mean 12 patients range 0–47), with 50% practices using the system on less than 12/130 possible working days. Compared with control practices, CDSS had no effect on requests for lipid tests or lipid prescribing although there was a “shift towards appropriate follow-up requests and greater emphasis on full lipid profiles” and a 55% decrease in

referrals to secondary services (no decrease in the control group) which was not statistically significant because of low study numbers.[217]

Non-integrated CDSS with advice received post consultation

A 1986 trial investigating computerised feedback for the management of patients with raised blood pressure or on BP-lowering drugs randomised GPs to either filling in a data collection form and receiving computerised guideline feedback by mail or just filling in a data collection form.[218] The study found no differences in the decision to treat with BP-lowering drugs, no change in mean diastolic BP and no differences in the proportion of patients meeting guideline BP goals.[218]

Two Canadian trials published 9 years apart,[219] [220] both from the same University, investigated computerised decision support providing an absolute CHD risk for patients. Both these trials required GPs to fill in a medical evaluation form with all data required for a CHD risk assessment which was sent to an independent centre. Those in the intervention group received a CHD risk profile within ten days and patients had a second visit to discuss this with their doctors. Both trials provided a visual CHD risk teaching tool and allowed clinicians to demonstrate the potential for risk reduction by various interventions to lower risk factors. The later trial published in 2007[219] also included another risk communication metric, 'the cardiovascular age', which compared the patient's risk profile with that of the mean age- and gender-specific profile of the Canadian population. At the end of the study period, patients in the intervention group had significant reductions in LDL and TC/HDL ratio[219] [220] with reduction seen in 8-year CHD risk[220] and overall patients were more likely to reach lipid targets (OR 1.26;1.07-1.48).[219] This was mainly because of the impact on those patients with diabetes and no previous CVD event.

4.6.6 Provider-initiated integrated CDSS vs automated reminder

In January 2008, the first trial to investigate what the authors termed as alerting (automatic provision of advice) compared with on-demand CDSS (requiring provider-initiation to receive advice) and usual care was published.[221] This well-designed trial

within 38 Dutch general practices (77 GPs) and 87,886 patients, measured the percentage of patients screened and treated for dyslipidaemia after twelve months of follow-up. In the alerting group, the patient's current risk profile as interpreted from auditing the patient electronic record (coded data, structured data and free text data) was presented along with a recommended action for lipid management. This showed up automatically as an interactive overview screen or dashboard accessible from the opened patient-specific electronic patient record. The on-demand version was exactly the same but the user had to actively initiate the screen to access the recommendations. In the alerting group, 65% of the target patients were screened (RR vs control 1.76; 1.41 to 2.20), while 35% of patients in the on-demand group (RR vs control 1.28; 0.98 to 1.68) and 25% of the control group were screened. Similarly in the alerting group, 66% of patients meeting treatment criteria were treated compared with 40% of patients in the on-demand group and 36% patients in the control group.[221] When compared head-to-head, automatically providing decision support based on guidelines resulted in greater improvements than the same system requiring provider initiation.

4.7 Discussion

This systematic review has synthesised the evidence from studies examining the impact of CDSS tools for CVD risk assessment and evidence-based management in primary care in achieving changes in clinical behaviour with respect to specific processes of care and effects on patient health outcomes. A taxonomy of 'types' was identified following the literature review in Chapter 3 to classify studies in this review. It was not possible to pool results using meta-analysis because of the large variation and inconsistency of reporting of outcomes. Overall, improvements in provider processes were reported for 22/33 (67%) trials of CDSS systems compared with usual care, 15/21 (71%) of automatic reminders, 2/4 (50%) of audit and feedback, 4/7 (57%) of provider-initiated integrated CDSS, and the one head-to-head trial vs usual care. Patient outcomes were less likely to be investigated (15/42 trials) and only 6/15 (40%) of these trials of CDSS compared with usual care reported some improvements for intermediate patient outcomes with relevance to CVD or CVD risk. No improvements were noted for the few studies that investigated hospitalisation and mortality although studies were of short

duration and underpowered for these outcomes. No harms were reported. The time periods for the trials ranged from 2 months to 27 months (median 12 months). Advice available at the time of consultation (or immediately prior to the patient visit) compared with advice post-consultation appears to be more effective in producing changes in clinical behaviour, the effect on patient outcomes was equivocal and inconsistent. Reminders appear to be more effective than audit and feedback and provider-initiated CDSS but their effect was noted in some trials to decay over time. Where reported, there was large variability of use of the CDSS tools by clinicians.

These findings, related specifically to CDSS for CVD risk assessment and management, were highly consistent with the findings of broader systematic reviews described in Chapter 3. The overall success as defined by having some improvements in provider outcomes investigated was 67% for the CVD trials compared with around 60% noted for the other reviews (often with a mix of study designs).

This systematic review covered all time periods, multiple databases and included supplementary methods of finding studies. However, the retrieval, appraisal and data extraction was done by only one person (SW). It is planned to update this systematic review in early 2009 with colleagues and independently conduct the review with any disagreement resolved by consensus.

5 Development of the PREDICT Clinical Decision Support System

5.1 Introduction

In order to collaboratively design and develop a CDSS that would integrate routine practice, epidemiological research, and evidence-based knowledge, it was necessary to be informed by the unique context of the New Zealand health care setting (Chapter 2) within which a computerised decision support system (CDSS) would function. Furthermore, the literature reviews (Chapter 3 and 4) assessing the effect of decision supports on the quality of health care provide both an evidence-base for embarking on this project as well as types and functionality of systems most likely to be successful.

This chapter describes the development process and the design of PREDICT-CVD and the updated version – PREDICT CVD-Diabetes. As the PREDICT Clinical Decision Support System (CDSS) also serves as the data collection tool for the epidemiological research undertaken for this thesis, the rationale for the design of the input templates and a description of the input variables is given here.

5.1.1 Background to PREDICT

PREDICT was conceived, prior to my involvement in the programme, at a meeting in Auckland in 1997 on the potential of electronic systems to help improve CVD risk assessment and management practice in primary care. The meeting was organised by Professor Rod Jackson and led to the establishment of a partnership between Dr Martin Entwistle of Enigma Publishing Ltd and Professor Rod Jackson of the University of Auckland to develop PREDICT. Enigma Publishing Ltd is a New Zealand owned and operated company specialising in electronic health knowledge management systems.

Dr Dwayne Crombie, who headed the Northern Division of the Health Funding Authority attended the meeting and agreed to fund the initial development phase of PREDICT. Also at the meeting was Robin Churchman, the CEO of MedTech, a company that had

developed the leading electronic patient management system (PMS) used in primary care in New Zealand. Much of the future development of PREDICT was done within the MedTech PMS due to Churchman's early support. During 1997, a pilot study was planned in which primary care patients filled in paper-based CVD risk assessment forms that were then manually entered by doctors into a web-based system to derive a CVD risk estimate. The data, anonymised by using an encrypted NHI number, were to be transferred to a secure central server. From the early days of the programme development, it was envisaged that the individual patient CVD risk profiles would be linked to national morbidity and mortality datasets using the encrypted NHI numbers.

Protocols for data collection, transfer and linkage with CVD hospitalisations and death via a web-based system were developed and in 1998 ethics approval was gained for a pilot study. Written patient consent was not required as the data were anonymised and considered to be similar in nature to national morbidity and mortality data collections. Pilot testing of the programme was completed in early 1999 and demonstrated that it was possible to electronically generate CVD risk assessments in routine primary care, to create an encrypted NHI number for each patient, and to securely transfer these data to a central server. However, further funding applications to the National Heart Foundation of New Zealand and the Transitional Health Funding Authority in 1999 to continue this work were unsuccessful.

PREDICT-CVD development

Professor Rod Jackson and colleagues continued to lobby for funding support through 1999–2001 and with the collaboration of three funders (see below), the PREDICT-CVD web-based decision support system project began in January 2002 (Table 5.1). I was employed as the co-ordinator of the project, which was co-funded by the Ministry of Health, Counties Manukau District Health Board (CMDHB) and the ProCare Network. The ProCare Network consists of three PHOs (ProCare North, ProCare Auckland and ProCare Manukau) under one umbrella administrative body. The project was supported by the New Zealand Guidelines Group (NZGG), National Heart Foundation and multiple doctors and nurses in primary and secondary care (mainly from ProCare and Middlemore Hospital – the major hospital serving South Auckland).

The interests of the three funders were as follows.[222] The Ministry of Health saw this joint project as part of a potential generic strategy to implement referral guidelines from the GP electronic desktop for hospital elective services and to improve both quality of care and efficient workflow to and from secondary care.

For CMDHB, a Chronic Care Management Programme had been initiated in the previous year, centred on a suite of long-term disease conditions including diabetes, congestive heart failure and chronic obstructive pulmonary disease. The programme included the exchange of patient information between primary and secondary health care sectors; initially for billing, tracking and reporting purposes, but it also included brief decision support advice based on a small set of simple rules. The systematic management of patients with existing CVD in general practice with support from secondary care services was a natural extension to the chronic care programme and CMDHB had a cardiologist (Andrew Kerr, Head of Cardiology Middlemore Hospital) willing to champion the project.

In 2002, ProCare Manukau GPs were already participating in the CMDHB chronic care programme. The ProCare Network was responsible for organising a continuing medical education programme (CME) for their GPs and a continuing nursing education programme (CNE) for their practice nurses. They faced the challenge of communicating (and ultimately implementing) a burgeoning number of guidelines and other related practice resource material. These resources were mostly paper-based, had a relatively short half-life and needed to be regularly updated with new evidence. ProCare also wished to explore the use of computerised decision support integrated with their PMS systems but delivered from a central server. In this way, any changes could be instantaneously available to all members. Furthermore, ProCare wanted all their GPs members to be connected to the internet and wanted to build information technology (IT) and epidemiological and knowledge management infrastructure so that additional services could be added later. ProCare proposed a programme that focused on opportunistic CVD risk assessment and management using PREDICT within their practices (in addition to involvement with Counties Manukau DHB chronic care programme).[222] Therefore, the PREDICT-CVD software platform was developed to support two different programmes:

- an opportunistic risk assessment and management module for ProCare practices (Auckland-wide)

- a chronic care management CVD module targeted to patients who had already suffered a cardiovascular event to be implemented with the other chronic care modules within general practices in the Counties Manukau DHB catchment area.

5.1.2 PREDICT Clinical Decision Support System development goals

The goals of the web-based PREDICT CDSS development were twofold:

1) To use IT to provide CVD risk assessment and management advice that was fast (within seconds), user friendly, integrated with the patient electronic medical record and would provide:

- a brief action plan for care

- individualised evidence-based recommendations from the guideline for each patient

- the ability to link by patients across primary care services e.g. if patient moved from one practice to another

2) To use IT to simultaneously generate population level epidemiological evidence for evaluating health needs, assessing health outcomes and improving the accuracy of risk prediction scores.

Type of System

Using the taxonomy described in Chapters 3 and 4, PREDICT CVD and the updated PREDICT CVD-Diabetes were provider-initiated rules-based systems with a probabilistic component (i.e. provide probability of a 5-year CVD event based on a set of patient characteristics). Therefore, management advice as well as a CVD assessment is provided. The decision to have a rules-based system was pragmatic as Enigma Publishing Ltd had already developed high quality rules-based software that was

expressly designed to be accessible to clinicians. The other type of CDSS system- a "cognitive" system was not available at the time of decision making.

It was provider-initiated rather than automated for organisational reasons. As PREDICT was designed for two very different programmes of care (chronic disease management and opportunistic screening) the view of the stakeholders was not to provide an automatic alerting function. ProCare were planning to develop an automated reminder/alert CDSS in parallel with PREDICT that covered multiple areas of preventive care as well as CVD. CMDHB had a capped budget and restrictive entry criteria for enrolment into the CVD module of the chronic care management programme and automation would have needed to be very sophisticated to manage this. Furthermore, the additional doctor or nurse time that the CCM programme resourced needed to be at provider discretion.

In terms of location and timing of decision support provision, PREDICT is integrated with the patient EMR and decision support is provided at the time of consultation. A comprehensive audit and feedback reporting functionality was built into the design of PREDICT CVD-Diabetes following clinical request for an instantly available audit of individual patient care (providing a tabulated and graphical display of risk and risk factors for each patient over time) and an aggregated reporting function by practice population or PHO population. This functionality will be able, within seconds, to provide PHO management with a report on the CVD health of their populations required with the proposed DHB performance indicators for 2008/9. In addition, PREDICT CVD-Diabetes design incorporated a CPOE (computerised physician order entry) feature with the ability to refer to other health services e.g. to smoking cessation clinics, Green Prescription, retinal screening and cardiac rehabilitation services.

Table 5.1. Time line of development and implementation

Date	Development
January 2002	PREDICT-CVD development began
June 2002	Sentinel site testing with volunteer ProCare GPs
August 2002	PREDICT-CVD implemented in ProCare PHOs
October 2003	Health Research Council grant successful
December 2003	NZGG CVD risk and diabetes guidelines published
March 2004	PREDICT-CVD-Diabetes development began
Beginning 2005	PREDICT CVD-Diabetes risk assessment tool implemented in HealthWest
July 2005	Sentinel site testing on complete PREDICT CVD-Diabetes began
December 2005	PREDICT CVD-Diabetes released
2006	PREDICT CVD-Diabetes replaces PREDICT-CVD in ProCare PHOs
2006	Full PREDICT CVD-Diabetes implemented in HealthWest PHO
2006	Implementation Northland PHOs
2007	Implementation into other Greater Auckland PHOs
2008–	Updates

5.1.3 The evidence-based content of PREDICT

As there were no up-to-date New Zealand CVD risk assessment and management guidelines available in 2002, the first fully integrated version of PREDICT, known as PREDICT-CVD was based on a number of national and international guidelines for CVD risk assessment and risk factor management; including the 1996 National Heart Foundation Lipid Guidelines,[28] the NZGG 2002 Interim Consensus statement on CVD risk assessment,[223] the 2002 ATP III National Cholesterol Education Panel guidelines,[22] the 2001 ACC/AHA Guidelines for percutaneous coronary interventions,[224] the 1998 NZGG guidelines for moderately raised blood pressure,[27] the 2000 SIGN secondary prevention of CHD following myocardial infarction,[225] the 1997 SIGN Diabetes

Guidelines,[226] the1996 SIGN Obesity Guidelines[227] and the 2002 NZ Smoking Cessation Guidelines.[228]

Subsequently (in December 2003), two new national guidelines were published; the New Zealand Guidelines Group (NZGG) Guideline for the *Assessment and Management of Cardiovascular risk*[23] and the Guideline for the *Management of Type 2 diabetes*.[64] These publications required the development of an updated version of PREDICT, known as PREDICT CVD-Diabetes. These guidelines will be referred to as the NZGG CVD risk and the NZGG Diabetes guidelines respectively from this point forward. The 2003 NZGG CVD risk guideline included all aspects of primary and secondary prevention including management of individual risk factors. The NZGG Diabetes guidelines covered CVD risk assessment and management as well as long-term management of glycaemia, renal disease, and the health of diabetic eyes and feet. Given the overlap between diabetes and CVD risk assessment and management, some sections of the guidelines were developed collaboratively by the two guideline writing teams. The integration of CVD risk assessment and management with diabetes chronic disease management, into one CDSS hugely increased both the functionality required and the complexity of decision support. Therefore, a completely new software platform had to be built. Furthermore, the updated PREDICT CVD-Diabetes programme was developed with much wider health sector input.

The role of the candidate has been described in Chapter 1. I co-ordinated the development of both PREDICT-CVD and the subsequent PREDICT CVD-Diabetes in conjunction with over 250 primary health care providers and secondary care specialist opinion leaders and with multiple primary health care organisations, non-governmental organisations (NZGG, National Heart Foundation, Diabetes New Zealand, Diabetes Auckland), several District Health Boards and the Ministry of Health. None of the published guidelines or consensus statements provided the level of detail required for electronic clinical decision support and therefore I spent many months corresponding with guideline writers to ‘fill in the gaps’. Sometimes, this required a discussion with one or two of the experts involved, while at other times whole guideline teams had to be canvassed.

One important issue was that PREDICT (and future updates) would be aligned with Get Checked Diabetes (and its future updates). Get Checked is the nationally funded annual diabetes discussed in Chapter 2 that was available as an electronic and paper-based template for primary care clinicians to use. 'Core' data items for diabetes were compared between PREDICT and Get Checked datasets and negotiated changes occurred so that the terms, definitions, READ codes and messaging codes were the same (i.e. to achieve semantic interoperability). What this meant for GPs and practice nurses was that completing a PREDICT CVD-Diabetes template could also automatically populate the Get Checked template and vice versa. At the time of developing PREDICT, electronic clinical templates were proliferating with new PMS functionality. They were clinical tools as opposed to population health tools. For the most part they were developed in isolation from each other, tailored only to one location or setting and without the capacity for data to be aggregated even if they were for the same clinical topic.

5.1.4 The PREDICT Software Platforms and the University–Enigma partnership.

The software platforms (PREDICT-CVD and PREDICT CVD-Diabetes), but not the content, were developed and are owned by Enigma Publishing Ltd, a software company specialising in knowledge management. The PREDICT programme has developed into a close public–private partnership between our University of Auckland CVD research team, who are responsible for the PREDICT evidence content and Enigma Publishing Ltd, who are responsible for the software platform. The University team has no commercial role and receives no commercial gain from PREDICT software sales. All data generated by PREDICT 'belong' to their submitting clinicians on behalf of their patients and their PHOs. All research output by the University team is for public good and all funding received by the University team comes from 'public good' sources. The Enigma IT team is funded primarily through the licensing of PREDICT software to health care organisations, plus they receive some funding from the University PREDICT team for work specifically required for the research components of the programme. While the financial relationship between the public and private teams is minimal (and only involves funding going from the University to Enigma), the relationship between the two

organisations is very close with the partnership enabling robust clinical content within a robust inference engine, with rigour around data collection and a high level of security for all platform interaction and storage.

5.1.5 CDSS as a data collection system for epidemiological research

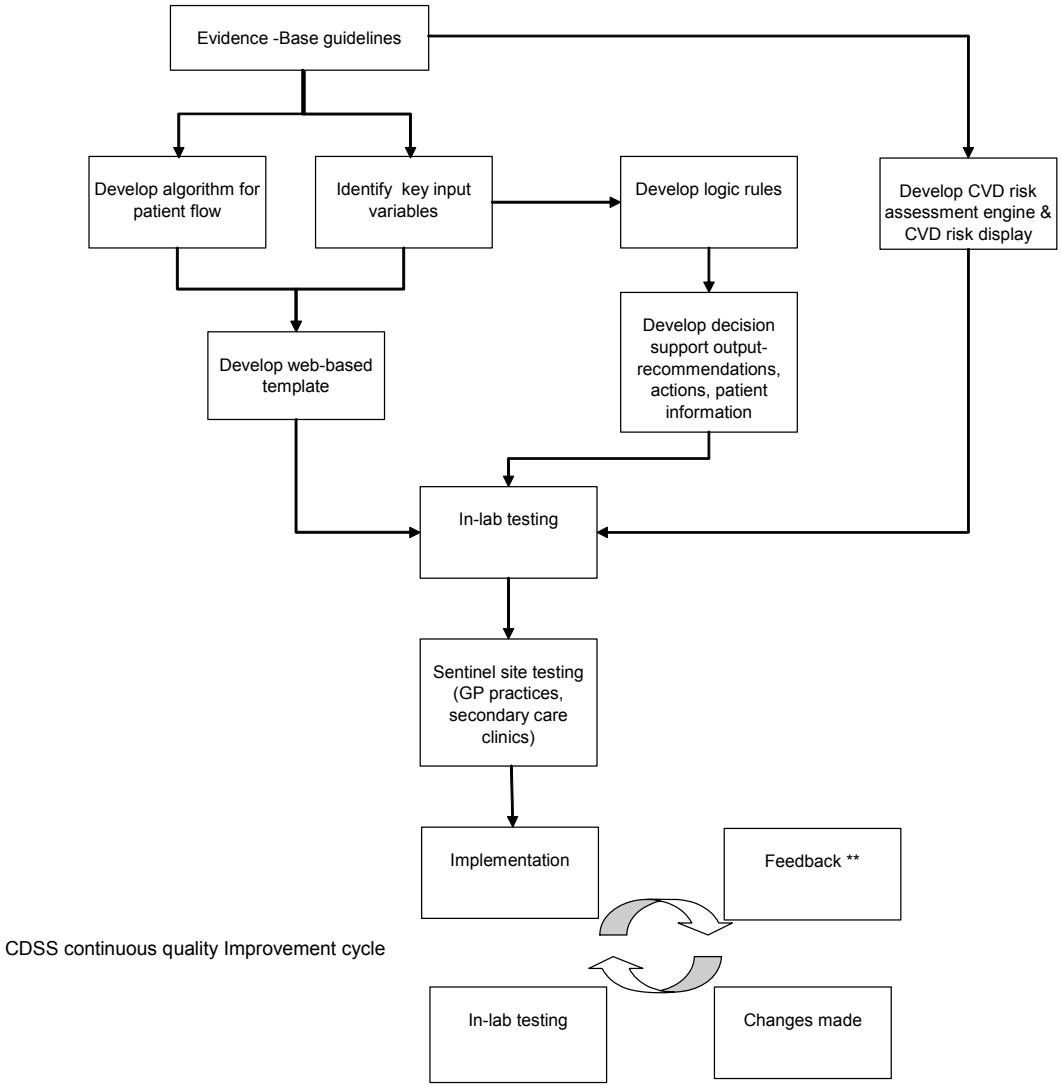
From the early days of PREDICT development, all stakeholders were supportive of conducting a cohort study as part of routine primary care practice in which data collection was done by the clinicians in the process of routine practice rather than by the more traditional approach using research staff and overt study protocols. The data collection tool (CDSS input template) was the proxy research protocol, and had to be compatible with usual practice and facilitate sustainable processes without needing to provide additional funding or substantial research-related support to PHOs or to individual clinicians. The cohort study required the collection of consistent, accurate and complete data for each individual at each assessment. Therefore, the data-collection tool needed to be highly usable, be relevant to the clinical interaction and provide clinical value to doctors, nurses and patients. The CDSS required complete data *before* risk assessment and risk management advice was provided. As this response occurs within seconds, there was an immediate clinical reward for entering valid and complete data. That is, valid data needed to be entered to get a valid risk assessment calculation and then further valid data needed to be entered to get management advice appropriate to a patient's individual risk and management profile.

5.1.6 Key developmental steps to building PREDICT CDSS

PREDICT needed firstly to fit with the clinical process; secondly to follow "best practice" as recommended by national guidelines; and thirdly to support epidemiological research. This prioritisation of requirements influenced every stage of PREDICT development. However, any design decision made to improve the clinical use of the tool or functionality for clinicians could not compromise the intent and integrity of guideline recommendations or the quality of the data collected for epidemiological research.

An overview of the developmental process of the PREDICT CDSS tool, (both PREDICT-CVD and updated CVD-Diabetes) is described in Figure 5.1. In brief, the key steps are design and development, testing (in-lab and sentinel site) and then following implementation, a continuous improvement cycle to enhance usability, improve data quality and maintain evidence currency. As well as co-ordinating health sector input, I also worked with Enigma IT engineers on a near daily basis for many months and have continued to work with them on a weekly basis throughout the project.

Figure 5.1.Overview of the key developmental and continuous quality improvement steps of the PREDICT CDSS tool



**Feedback relates to need for CDSS changes coming from multiple sources — from clinicians (related to ease of use, 'fit' with PMS, other information needs), from HRC PREDICT research team (related to the quality of data generated), from NZGG (new evidence requiring guideline update and therefore CDSS update) and from IT specialists (need to change platform function).

5.2 Translating guidelines for a Clinical Decision Support System

5.2.1 Eligible Population for clinical decision support

In 2002, there were no up-to-date formally agreed national recommendations on the eligible population for CVD risk assessment and management. An interim consensus statement was released by the New Zealand Guideline Group[223] in 2002 and the recommended criteria for risk assessment were used in PREDICT until publication of the NZGG CVD risk guidelines in December 2003.[23]

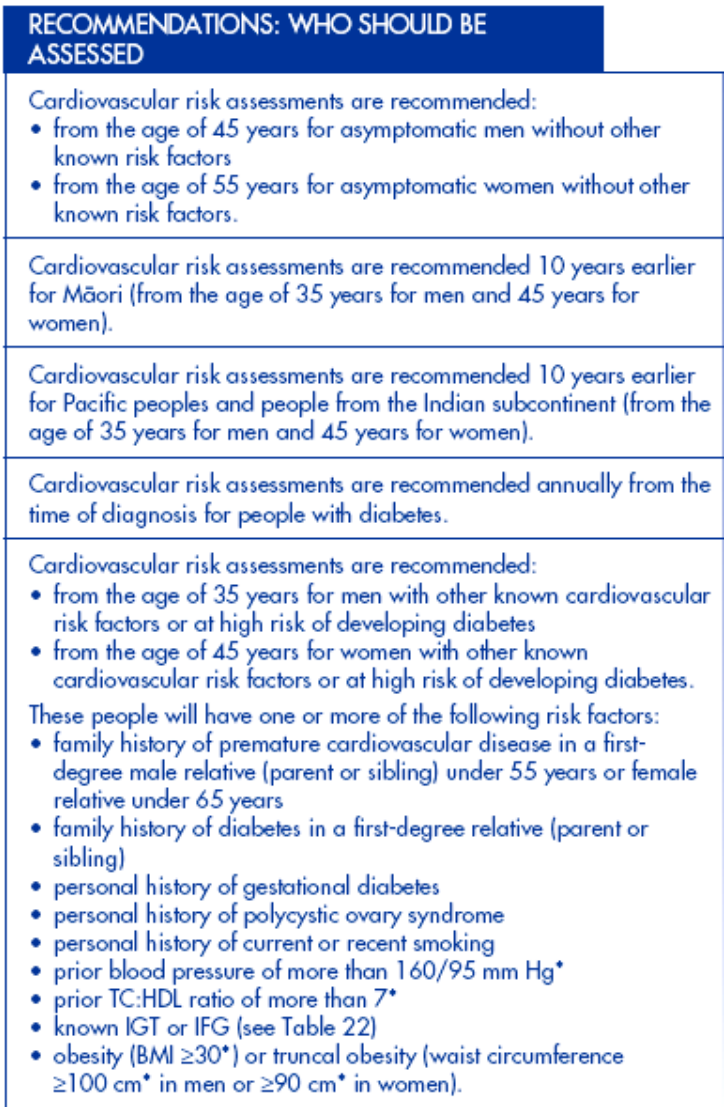
2002–2003 Eligibility criteria for CVD risk assessment and management

- all adults with existing cardiovascular disease
- all adults over 50 years of age with earlier risk assessment for CVD
- all Māori and Pacific people over 40 years of age
- adults over 40 years of age with known CVD risk factors (diabetes, hypertension, smoker, abnormal lipid or if CVD risk assessment was considered appropriate by GP)
- adult over 20 years of age with family history of premature CHD or premature ischaemic stroke in a first degree relative (women <65 years, men <55 years)

2004–2008 Eligibility criteria for CVD risk assessment and management

The subsequent eligibility criteria for CVD risk assessment recommended by the 2003 CVD risk guidelines are shown in Figure 5.2 below.[23] Following release of these guidelines, these new criteria (and new recommendations) were introduced at ProCare cell group meetings throughout 2004 by Rob Cook (the co-ordinator of the NZGG CVD risk guidelines), Rod Jackson, Andrew Kerr, myself and ProCare cell group co-ordinators.

Figure 5.2. Eligibility criteria for CVD risk assessment according to CVD risk guidelines



RECOMMENDATIONS: WHO SHOULD BE ASSESSED

Cardiovascular risk assessments are recommended:
- from the age of 45 years for asymptomatic men without other known risk factors
- from the age of 55 years for asymptomatic women without other known risk factors.

Cardiovascular risk assessments are recommended 10 years earlier for Māori (from the age of 35 years for men and 45 years for women).

Cardiovascular risk assessments are recommended 10 years earlier for Pacific peoples and people from the Indian subcontinent (from the age of 35 years for men and 45 years for women).

Cardiovascular risk assessments are recommended annually from the time of diagnosis for people with diabetes.

Cardiovascular risk assessments are recommended:
- from the age of 35 years for men with other known cardiovascular risk factors or at high risk of developing diabetes
- from the age of 45 years for women with other known cardiovascular risk factors or at high risk of developing diabetes.

These people will have one or more of the following risk factors:
- family history of premature cardiovascular disease in a first-degree male relative (parent or sibling) under 55 years or female relative under 65 years
- family history of diabetes in a first-degree relative (parent or sibling)
- personal history of gestational diabetes
- personal history of polycystic ovary syndrome
- personal history of current or recent smoking
- prior blood pressure of more than 160/95 mm Hg*
- prior TC:HDL ratio of more than 7*
- known IGT or IFG (see Table 22)
- obesity (BMI ≥30*) or truncal obesity (waist circumference ≥100 cm* in men or ≥90 cm* in women).

The 2003 CVD risk guideline had not explicitly recommended or advised against assessment for those under 35 years, nor were there any exclusion criteria. I initiated a consultation process with the CVD guideline committee to provide these specifications. It was decided that it was acceptable for a doctor or nurse to conduct a CVD risk assessment on adult patients under 35 years (but preferably over the age of 18). The management of CVD risk during pregnancy, gestational diabetes and known type 1 or type 2 diabetes during pregnancy was not considered by the guidelines. Furthermore the NZGG guidelines used in developing PREDICT CVD-Diabetes (and PREDICT-CVD) did not cover the specific management of genetic lipid disorders, heart failure, acute coronary syndromes or sleep apnoea.

5.2.1 Guideline recommendations on CVD risk prediction

Since the mid-1990s, New Zealand guidelines[26-28] have recommended estimating a 5-year CVD risk using a risk prediction model derived from the Framingham Heart Study.[25] The Framingham Study was a long-term cohort study of mainly European–Americans aged 30–74 years with no history of cardiovascular disease or cancer and was established in the early 1950s. The cohort was reassessed every two years and in the 1970s the cohort was supplemented by many of the children of original cohort members (the Framingham Off-Spring Study).

The CVD risk prediction score used in the New Zealand guidelines was derived from a 1991 publication by Anderson and colleagues using Framingham data from 5573 participants from the mid 1960s to the 1980s. The 'combined cardiovascular disease' outcomes of interest in the Framingham CVD score included: death related to coronary disease; non-fatal myocardial infarction; new angina; fatal or non-fatal stroke; transient ischaemic attack; the development of congestive heart failure or peripheral vascular disease. A parametric statistical model (Weibull accelerated failure-time model) was used to provide predicted probabilities for this combined outcome score based on the following risk factors and time until the events of interest. The model includes: gender; age (in years); systolic blood pressure (mmHg); smoking (yes/no); total cholesterol:high density lipoprotein ratio (TC/HDL); diabetes (yes/no); and interaction terms of age by gender and diabetes by gender. Other predictive models have used logistic regression or Cox proportional hazards. Logistic regression models (the predicted probability of an event occurring in an interval) does not use 'times to event' data but, as Odell P et al. (1994) note, over long periods this can prove to be a drawback.[229] Cox proportional hazard models include data about time to event but it assumes the hazards remain constant. That is; proportional hazards allow event rates to change over time but require the relative event rates (hazards) for two sets of co-variates to remain constant.[229] The Weibull accelerated failure time model is fully parametric – the shape of the distribution being completely specified. One advantage over the Cox model is that the predicted probabilities can be expressed in a simpler way.[229 -230] In the standard Weibull model, the underlying hazard function also requires the assumption of proportional hazards. However, Anderson 1991[231] rejected the standard model in favour of a non-proportional

hazards Weibull accelerated failure time model so that the underlying hazard (as determined by the shape parameter) depends on the co-variates. The advantage is that this model appears to be more accurate when comparing predicted probabilities between individuals.[231] The CVD risk equation can be found in Appendix 5.1.

There have been two recent systematic reviews assessing the calibration performance (the predicted event rate compared with the observed event rate) of the Framingham score in different populations.[43 232] Both reported similar results. Brindle et al. identified 27 studies from United States, United Kingdom, Europe, New Zealand and Australia with data from 71,727 participants on predicted and observed risk for either CHD or CVD events. For the combined CVD outcome, the range of over- and under-prediction is less than the CHD outcome[232] where the ratios of predicted to observed ranged from a relative under-prediction of 0.43 (95% CI 0.27–0.67) in a high-risk population such as diabetic men in the UK[45] to a relative over-prediction of 2.87 (95% CI 1.91–4.31) in a lower-risk population such as German men and women.[44]. Several studies have reported that the Framingham CHD and CVD scores are reasonably well-calibrated for the New Zealand population as a whole.[43 233]

Just prior to the period that the 2003 NZGG CVD risk guidelines were being developed, an alternative risk score to Framingham, the western European SCORE[48] tool (Systematic Coronary Risk Evaluation) was published. SCORE was derived by combining multiple European cohorts. While it was based on much larger numbers of people and was more current than the Framingham scores, there were several important weaknesses. It was based on a limited risk factor set, included only fatal outcomes, and lacked data on high-risk non-European populations. Given the local concerns about the validity of risk prediction tools among Māori and Pacific populations in particular, the New Zealand guidelines team did not consider that the SCORE tool provided sufficient advantages over the Framingham scores.

The United Kingdom Prospective Diabetes Study (UKPDS) had also produced CHD and stroke risk prediction equations for newly diagnosed people with type 2 diabetes.[234 235] The NZGG CVD risk guideline committee examined these scores but decided not to use them as they only provided separate CHD and stroke risk prediction and it had already been decided that a combined total CVD score was more appropriate.[236]

As there were concerns that the Framingham scores might underestimate the actual CVD risk in some high-risk population sub-groups, a once only 5% upward addition to the calculated 5-year CVD risk was recommended for specific groups by the 2002 interim guideline consensus statement (first 2 bullet points below)[223] and subsequently endorsed and added to by the 2003 CVD risk guideline committee (all bullet points below).[23]

- family history of premature ischaemic coronary heart disease or ischaemic stroke
- Māori or Pacific ethnicity
- Indian subcontinent (South Asian) ethnicity
- diabetes with microalbuminuria
- type 2 diabetes for ≥10 years or HbA1c consistently ≥8%
- metabolic syndrome according to ATPIII criteria

The rationale for adding 5% risk was based on evidence suggesting an increased risk of cardiovascular disease in these subpopulations compared with the general population.[23] The adjustment was set at 5% for pragmatic reasons because at the time the guidelines were developed, the risk charts that most general practitioners used for CVD risk assessment, displayed estimated risk in 5% increments.[237]

The single most frequent criticism of pre-2003 New Zealand risk prediction charts, by clinicians, was the lack of inclusion of a family history of premature ischaemic CVD as a risk factor.[237] A recent systematic review[238] concluded that (after adjustment for other CVD risk factors) a family history of premature CHD was associated with at least a 70% greater (relative) risk of a CHD event. A family history of ischaemic stroke has been associated with a 89% increased risk of ischaemic stroke in men.[239] However, almost none of the studies included in the review were able to adjust for HDL-cholesterol, which may be one of the main reasons why the Framingham risk scores (that include HDL) were unable to demonstrate an independent effect of family history.

The additional risk adjustment for people of Māori, Pacific, and Indian subcontinent ethnicity recommended by the New Zealand Guidelines Group was based on multiple indirect sources of evidence. National mortality and morbidity data have shown an increased burden of diabetes and cardiovascular disease in these ethnic groups compared with other groups.[3 4 240 241] However, at the time of the 2003 guidelines development, there were no published studies that systematically compared CVD risk profiles by ethnic group. There were cross-sectional studies of estimated absolute CVD risk among Māori and Pacific workers (Workforce Diabetes Survey 1988–1990[242-245], Fletcher-Challenge/University of Auckland survey 1992[246]) compared with European people (Auckland Heart and Health Study[192 247-249]) that suggested that differences in CVD outcomes would not be adequately explained by the standard risk factors.

CVD risk assessment in people with a history of CVD

The Framingham CVD equation was derived from (and designed to be applied to) people aged 30–74 years without a prior history of CVD. Therefore, New Zealand guidelines have always separated people into two groups; those assessed clinically as being at high risk because of their previous history of CVD and those without prior CVD for whom a Framingham risk score would be calculated.

The 2002 Interim Consensus statement on CVD risk assessment recommended that the following groups of patients should be considered to be 'clinically at high risk':

i. people with a history of a prior CVD event

ii. those with a genetic lipid disorder (not specified by sub-types)

iii. people with diabetic nephropathy

iv. all people with diabetes.

These groups with 'clinically high risk' were assumed to have a 5-year CVD risk ≥ 20%, based on a review of event rates in the placebo arms of recent CVD secondary prevention trials.

For everyone else, a risk assessment using the Framingham score was recommended. As discussed above, the Framingham risk score was then adjusted[223] by adding a once-only 5% to the calculated 5-year CVD risk score for some patient groups. In addition, people who had isolated high levels of blood pressure (≥ BP170/100 mmHg) or cholesterol (total cholesterol or TC/HDL ≥ 8) were classified as having a risk ≥15% in 5 years regardless of their Framingham score (i.e. they were all considered to be above the recommended threshold for drug management).

Modifications were subsequently made to the clinically high risk classifications and calculated risk score in the 2003 CVD risk guidelines.[23] Whereas the interim statement classified all diabetics and all those with a genetic lipid disorder as clinically at high risk, the 2003 guidelines considered only diabetics with nephropathy and three familial dyslipidaemia subtypes (discussed below in section 5.5.1) to be so classified. For all other people, an estimated 5-year CVD was recommended, with a once-only 5% upward adjustment to a calculated 5-year CVD risk score, for those with any of the additional risk factors discussed previously. The classification of isolated high levels of blood pressure or cholesterol as being at high risk (over 15% 5-year CVD risk) remained the same as in the interim statement.

The process of translation from paper guidelines to CDSS exposed numerous gaps and vagaries in the guidelines. Given that CVD risk assessment is the pivotal factor determining all subsequent clinical CVD risk management (see Appendix 5.1) a report was prepared by Wells and Wiltshire in August 2005.[250] It documents the New Zealand Guidelines Group CVD guideline committee approved translation to decision support for each step of risk assessment, adjustment and classification as being at 15% risk in the presence of a high BP or cholesterol. Furthermore, for other projects or clinical software developers wishing to produce an electronically derived CVD risk assessment, it included proposed technical standards and approved interpretation. This was published as an appendix to the 2003 CVD risk guidelines[23] on the NZGG website.

5.3 CVD and diabetes dataset and input templates

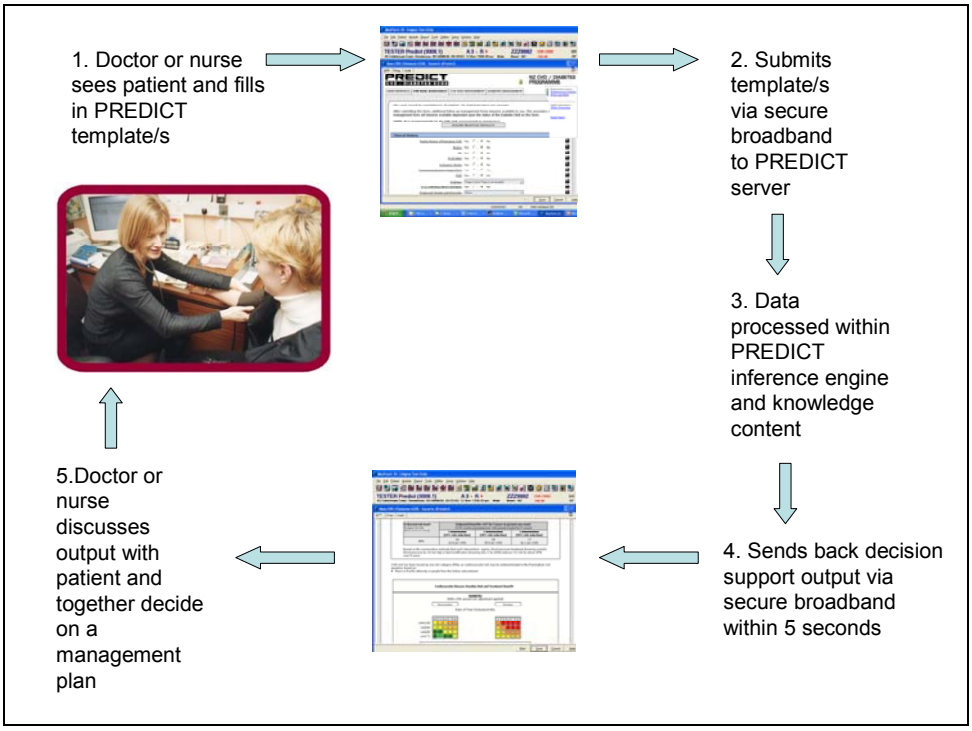
We received frequent feedback that only the minimum dataset necessary for routine CVD risk assessment and management according to the guidelines would be acceptable to most clinicians. Therefore, it was not possible to add additional physiological factors that from the literature might potentially be useful for future risk prediction models, such as uric acid, creatinine and estimated glomerular filtration rate (for all patients), lipoproteinA, clotting factors, B-natriuretic peptide, homocysteine etc.

After multiple iterations and both formal and informal feedback, the variables were defined and the order that each variable was displayed was aligned with typical clinical processes. Variables that were deemed mandatory for completion were made easily identifiable to the clinician as were definitions for each variable. Appendix 5.3 contains the input templates for PREDICT-CVD and PREDICT CVD-Diabetes; graphical display of CVD risk and examples of decision support output.

How PREDICT works in clinical practice

During a consultation, the practitioner simply selects the PREDICT icon on the patient management system toolbar or from a drop-down menu. PREDICT data templates then open using a web browser within a patient's electronic medical record and any relevant data that are available in a structured machine-readable form are automatically downloaded from the electronic medical record to the PREDICT template (Figure 5.3). The practitioner can then check the validity of these data, add any variables not downloaded from the current record directly into the template and then click on the "Get CVD Risk assessment" button. This action submits the data via a secure broadband internet connection to the PREDICT server, which returns the patient's estimated 5-year CVD risk within about five seconds.

Figure 5.3. PREDICT exposure data collection via routine practice



If the clinician wants to use PREDICT to provide management recommendations, two further PREDICT templates – one for people without diabetes and two for people with diabetes – need to be completed (see templates 3 and 4, Appendix 5.3). These templates include additional risk factor and current management information. Again, any data used in these templates that are readable by PREDICT will be automatically downloaded into the templates, including current cardiovascular and diabetes drug treatment documented in the patient electronic record. The clinician can check the validity of the downloaded data on the screen, add any missing data and submit the templates to the PREDICT server. As with risk assessment, patient-specific management advice derived from the CVD risk guidelines[23] is returned within a few seconds. For patients with diabetes, PREDICT also provides management advice derived from the Diabetes guidelines[64] (see Appendix 5.3 for examples of advice for clinicians and patients).

PREDICT input variables

Input variables to the PREDICT forms are presented here in the order they appear in the data entry templates:

1. CVD Risk Assessment template variables: demographic information, clinical history, examination and tests

2. CVD Risk management template variables: anthropomorphic measurement (height, weight, BMI, and waist circumference), current CVD drug management, additional blood tests (fasting lipids and fasting glucose), current lifestyle management

3. Diabetes Management template variables: current drug management, education and dietary assessment; renal function (albumin-creatinine ratio, estimated glomerular filtration rate), assessment of the diabetic foot, assessment of diabetic eyes and retinal screening status.

The details of these input templates variables are described in Appendix 5.4. Where possible, the variables were the same for both PREDICT-CVD and PREDICT CVD-Diabetes. The handling of ethnicity variables (including multiple ethnicities) from the patient EMR and entry within PREDICT is also described in Appendix 5.4. An overview of the Statistics New Zealand Ethnicity Classification relevant to the NZGG CVD risk guidelines is described in Appendix 5.2.

Appendix 5.4 details the differences in definition and data handling where they occurred between PREDICT-CVD and PREDICT CVD-Diabetes as well as functionality of the templates (mandatory fields, automatic data entry, negative defaults, automatic calculation of BMI and eGFR fields, location of definitions for clinicians, field checks, range checks and medication 'look-up' and auto-population)

5.3.1 Data entry ranges for laboratory tests and other measures

Data entry limits for PREDICT-CVD and PREDICT CVD-Diabetes were set after consultation with expert clinicians and setting upper and lower margins in the software. However, a more rigorous approach[251] was established in 2005, using data derived from large numbers of New Zealanders either through aggregated Greater Auckland region community laboratory data or from large New Zealand epidemiological surveys[56 57 246 252 253] for anthropometric and blood pressure measures. A 10% tolerance outside the

observed upper and lower levels was then added to set limits. These ranges are included in Appendix 5.5.

5.3.2 PREDICT data security – submission, access and storage

Given the requirements to link individual data across multiple databases and to enable practitioners to interrogate the PREDICT system for identifiable data on their own patients, a very high level of data security is required. This is described in detail in Appendix 5.6.

6 PREDICT-CVD implementation and evaluation

"This is the first time that a computer is going to give us anything back!"
Dr John Cameron (ProCare GP at the launch of PREDICT 30 July 2002)

6.1 Introduction

The unique opportunities and constraints of the setting as described in Chapter 2 also informed the implementation of the CDSS tool.

PREDICT-CVD software was implemented in the three ProCare PHOs from August 2002. At that time, the ProCare Network (North, Auckland and Manukau PHOs) served about 590,000 patients and had approximately 400 affiliated GPs, located in south, central and north Auckland practices. The implementation programme, including the PREDICT-CVD software and associated support services, was branded as the 'Prompt Programme' by ProCare. This chapter briefly describes the implementation of PREDICT-CVD in ProCare and then describes the design, conduct and results of the 2004 Prompt Evaluation Study. This collaborative evaluation study was designed to investigate whether a CDSS would improve CVD risk assessment behaviour in a routine general practice setting. Four papers on this evaluation study have been published (Appendix 10)

Implementation of the Prompt Programme

The implementation of Prompt, as a PHO-wide programme of opportunistic CVD risk screening and on-going CVD risk management, was managed by ProCare staff. The organisation introduced the programme to its membership (general practitioners [GPs] and practice nurses) via continuing education groups (or cell groups) that met once a month. Guest speakers from the University PREDICT team (Rod Jackson, Andrew Kerr and myself) were scheduled in turn for each cell group to present the rationale for CVD risk assessment, the PREDICT-CVD development process, and to give a 'live' demonstration of how PREDICT-CVD worked. A member of ProCare administration was also present at each cell group meeting to describe the practical support and services

associated with this project. GPs were offered up to $900 ($10 per risk assessment for up to 90 patients) to subsidise the additional costs involved in using PREDICT. As few GPs had broadband internet connections prior to the implementation of the Prompt initiative, this money was presented as a contribution to the cost of secure broadband web access covering installation and three months rental charges. At the time of initial implementation, PREDICT was integrated only with the MedTech patient management system (PMS), which was used by the majority of ProCare GPs. GPs who had the compatible PMS software and who indicated their interest were visited by ProCare practice facilitators who installed PREDICT, ensured connectivity to the internet, and trained the primary care team. The facilitators then provided on-going help as required. For those practices who did not wish to install PREDICT or had incompatible PMS software, CVD risk assessment could be conducted via paper-based risk charts or other electronic calculators.

The Prompt programme was implemented in stages. It was first offered to GPs in south Auckland before being progressively presented and offered at cell group meetings in north and central Auckland. Wide coverage of ProCare GPs was achieved between August 2002 and November 2003. From personal communication with the ProCare IT manager Ken Leech and project manager Kate Moodabe, the key rate limiting steps to PREDICT-CVD implementation were hardware (capability of practice computer systems and internet connections) and software integration issues due to large variations within and between practices in disease coding and how they saved laboratory tests and other risk factors in their electronic records. The first 18 months of implementation was directed towards the GP, who as the business owner, was responsible for the capital outlay required and practice system change. Later, the implementation was directed to both doctor and nurse cell groups.

6.2 Methods

The Prompt Evaluation study (i.e. PREDICT-CVD in ProCare) was a retrospective before-after audit designed to answer three questions:

Will a web-based CVD risk assessment and management CDSS:

- increase the likelihood of CVD risk assessment being documented in the electronic medical records of appropriate patients?

- increase the likelihood of CVD risk factors being documented in the electronic medical records?

- increase the likelihood of risk assessment and risk factor documentation equally among appropriate Māori and non-Māori patients?

6.2.1 Rationale for study design

The ideal study design to assess the impact of PREDICT-CVD in primary care would have been a cluster randomised controlled trial. General practices would have been stratified by enrolled population size and number of GPs and randomised to have access to PREDICT or not. The unit of randomisation would need to be a general practice rather than individual patients or individual GPs, because the installation of PREDICT occurs at the practice level within the practice's electronic management system. Even if PREDICT could have been made selectively available to certain doctors within a practice, contamination would be an issue as clinicians often work in the same consulting room and meet between patients. In addition, observations on patients within the same cluster (the practice) may not be independent of observations on other individual patients in a trial.[254] GPs "attract" their own clientele, they have their own style of providing clinical care, and practices have large differences by full-time equivalents and by practice systems e.g. recalls, disease registers, team based care etc. Patients within any one cluster may be more likely to have similar outcomes, as management is likely to be more consistent within a practice than across practices.[254] This potential clustering of patients associated with a GP or to a practice has a major impact on the sample size requirements for a trial as the effective sample size is less than the total number of individual participants.[254,160] Initial power calculations for a cluster randomised trial to detect a proposed increase in CVD risk assessment rate for eligible patients from 10% to 30% indicated the need for at least 36 general practices to be randomised (18 to intervention and 18 to a control group).

By the time we received funding for an evaluation study, a large proportion of the potentially eligible practices had already implemented PREDICT-CVD and there were too few remaining practices that were potentially eligible (24 practices). We also planned to investigate differences in implementation for Māori and non-Māori patients separately. However, Māori patients were not uniformly spread throughout the practices. Furthermore, the estimated costs of an intervention trial were well above the funds available.

Therefore, it was decided that the most practical and feasible design was a retrospective before-after audit that would measure the level of CVD risk assessment documentation in *all* ProCare practices before and after PREDICT CVD installation for both Māori and non-Māori. The main advantages of this approach was that much larger numbers of practices could be included and it would be possible to investigate CVD risk assessment behaviour by practitioner rather than practice because each practitioner acted as their own control. This approach also made it possible to take clustering by practice into account in the analyses.

Funding

Applications to an international cardiovascular research innovation fund and a District Health Board were successful, with a Future Forum grant received in December 2003 and a grant from the Waitemata District Health Board in June 2004.

Role of the candidate

I was the principal investigator of this evaluation study, led the writing of the grant applications and the research team (Sue Furness, Vanessa Selak, Robyn Whittaker, Natasha Rafter, Alistair Stewart, Dale Bramley, Rod Jackson). I was responsible for liaising with ProCare leaders, Paul Roseman and Kate Moodabe, the GPs and practices, and for contracting a professional clinical audit organisation (The Diabetes Project Trust). Mr Alistair Stewart provided biostatistical support throughout the study. Mrs Sue Furness was the project manager and co-ordinated all the day-to-day running of the study. I was involved in all aspects of the study from design to development of audit forms, ethics application, practice invitation, practice visits, oversight of data collection,

data management, analysis and writing of the four papers that were subsequently published (Appendix 10).

6.2.2 Methods

The sampling frame of eligible GPs was derived from ProCare administrative data.

Eligibility criteria

GPs were eligible to be included in the study if they met all the following criteria:

- were members of ProCare
- had used MedTech as their patient management system for electronic patient records for at least 1 year prior to April 2004
- had PREDICT CVD integrated with their medical record software between August 2002 and May 2004.

Invitation and electronic queries of PMS

All eligible GPs received a combined ProCare–University of Auckland letter describing the study and inviting them to participate. Follow-up telephone calls and faxes were also undertaken in the subsequent weeks. After receiving written consent, the research team conducted electronic queries in each of the participating GP's practices to create lists of eligible patients whose medical records would be audited.

Eligible patients

To be eligible for the evaluation study, patients had to:

- meet the 2003 NZGG CVD risk management guidelines' age, gender and ethnicity criteria for eligibility for cardiovascular risk assessment.[23] (i.e. men to be over 45 years, women over 55 years and ten years earlier if of Māori, Pacific or South Asian ethnicity)

- be registered patients of the participating GP (with registration in general implying that the individual GP takes the responsibility of care for a patient)

- have visited their general practitioner within a four week period, starting one month after the practitioner had first used PREDICT-CVD (i.e. post-PREDICT) or within the same four week period, one year earlier (pre-PREDICT). For example, if PREDICT-CVD was first used on 1 July 2003, the time periods examined were the first 4 weeks of August 2003 (post-PREDICT) and the first four weeks of August 2002 (pre-PREDICT). Audit periods ranged in time from August 2001 to June 2004 with many pre- and post-PREDICT audits occurring in concurrent time periods for different practices due to the staged implementation of the programme.

Information from the patient records identified from these queries (MedTech unique identifier, name, gender, age & ethnicity) were then transferred to electronic spreadsheets. In order to obtain good explanatory power for both Māori and non-Māori, we decided to audit 100% of the electronic medical records of the eligible Māori patients, and a randomly selected 15% sample of non-Māori patients. Lists of all eligible Māori patients who had visited their GP in the pre- and post-PREDICT study periods were printed. For eligible non-Māori patients, a random 15% sample was identified using the Excel random numbers function, and lists were then printed. The printed lists and the electronic files (query outputs and spreadsheets saved on disk) remained in the practice, in a sealed envelope. No identifiable patient information was taken from the practice at any time.

Audit of patient electronic medical records

Trained audit nurses from the Auckland-based Diabetes Projects Trust were contracted to undertake practice audits of the electronic medical records. The Trust has considerable experience in undertaking practice audits of diabetes care and there was considerable overlap in the audit variables routinely collected by the Trust and the variables in this before-after study. Using the lists of eligible patients generated, the nurses conducted audits of the electronic medical records. An anonymised paper audit form (Appendix 6) was completed for each patient using a practice-specific MedTech ‘patient unique identifier’, and using numeric codes to identify the practice and the GP.

Nurses looked back for a maximum of 2 years to find documented risk assessment and risk factor information.

Definitions of key audit variables

Ethnicity

The patient management system (MedTech) has the provision for three separate ethnicity groups for each patient record and New Zealand Health Information Service (NZHIS) Level 2 coding.[255] At the time of the study, many GPs used their own text codes for ethnicity instead. Details of ethnicity coding have been provided in Appendix 5.2. For the purposes of this study, patients were grouped into six ethnicity categories; Māori, Pacific, Asian (includes South Asian and Other Asian), European, Other Ethnicity and a group where ethnicity was not stated.

The following risk and risk factors were collected on the audit form from the patient EMR along with the location within MedTech where it was found (e.g. inbox, screening, daily record, READ coded classifications).

Cardiovascular risk: Specific documentation *of* cardiovascular risk was looked for either as a percentage, risk group (e.g. 5–10%) or CVD risk description (e.g. high risk).

Smoking: Smoking status was defined as smoker, non-smoker, past-smoker (defined as having quit smoking for over 12 months), or not documented.

Diabetes status: The audit nurses noted any documentation of diabetes status such as 'no known diabetes', impaired glucose tolerance, or for patients with diabetes, what type of diabetes was documented. If diabetes was NOT stated, audit nurses looked for any of the following items of information that could indicate diabetes:

- an oral glucose tolerance test result indicating diabetes
- a prescription for glucose testing strips, insulin or an oral hypoglycaemic agent
- HbA1c (glycosylated haemoglobin) test result greater than 6%.

Blood pressure: The most recent blood pressure identified in the audit time period was noted on the audit form, together with the date recorded.

Lipids: The most recent total cholesterol/HDL-cholesterol (TC/HDL) ratio was identified during the audit time period together with the date. If there was no ratio documented, then a total cholesterol value was collected.

History of cardiovascular disease: This was defined as documentation in the patient notes of any of the following:

- Ischaemic Heart Disease (IHD), Myocardial Infarction (MI), Angina, Coronary Artery Bypass Graft Surgery (CABG), Angioplasty or other coronary revascularisation procedure, Ischaemic Stroke (NOT hemorrhagic stroke), Transient Ischaemic Attack (TIA), Claudication or Peripheral Vascular Disease (PVD)

- more than one prescription for oral or transdermal nitrates (e.g. Anginine, Nitroderm TTS, Nitrolingual Pump spray).

Main outcome measures

The primary outcome measures were the proportion of all patients with a CVD risk assessment documented before and after PREDICT-CVD installation and the proportion of Māori patients compared to non-Māori patients with a CVD risk assessment documented before and after PREDICT-CVD installation.

A secondary outcome measure was the completeness of individual CVD risk factor documentation in these groups before and after installation of PREDICT-CVD was also measured.

Data entry

Data from the audit forms were then entered into a Microsoft Access database.

Accuracy of data collection and data entry

In order to estimate the accuracy and reproducibility of data collection by the audit nurses, a sample of approximately 5% of all records was re-audited. A second audit nurse visited a selection of practices and repeated approximately 10 audits per GP.

Analyses

All analyses were conducted using SAS statistical software Version 9.1 (SAS Institute Inc., Cary North Carolina, USA). In the overall analyses for the outcomes of interest, proportions in the total audited population were estimated from Māori and non-Māori sampling populations, weighted according to the sampling fraction. Relative risks and 95% confidence intervals were calculated using a multivariate mixed Poisson regression model with robust variance estimation in which general practitioners were regarded as random effects and all other variables regarded as fixed effects.[256] The model included variables for each practice and patient characteristics that may influence risk assessment behaviour including age, gender, ethnicity, presence of existing CVD, diabetes and holding a High Use Health card (HUHC — provides a government subsidy for those with medical conditions requiring frequent GP visits), or Community Service Card (CSC — provides a government subsidy for lower income families).

For the Māori / non-Māori analysis, the sampling populations were compared and the same multivariate analysis was conducted as described above. An interaction term was used to assess whether documentation of risk or risk factors differed by ethnicity after the implementation of PREDICT.

Sample size estimates

We estimated a priori that on average 30 patients per GP per time period were required from 50 GPs to detect a three-fold increase in the proportion of eligible patients with documented CVD risk. We expected that a full-time GP would see up to 300 eligible patients per month depending on the demographics of the practice population. We aimed for a sample size of 1500 patient records before and after PREDICT implementation. A design effect and between-GP correlation to estimate the sample size

of 80% power to detect an effect at the 5% level of statistical significance was calculated by our biostatistician. Based on a design effect of 4 and a between-GP correlation of 0.5, it would be possible to detect a doubling of the level of risk documentation (from an initial prevalence of 3%) with a power of 80% at the 5% level of significance.

Ethics approval

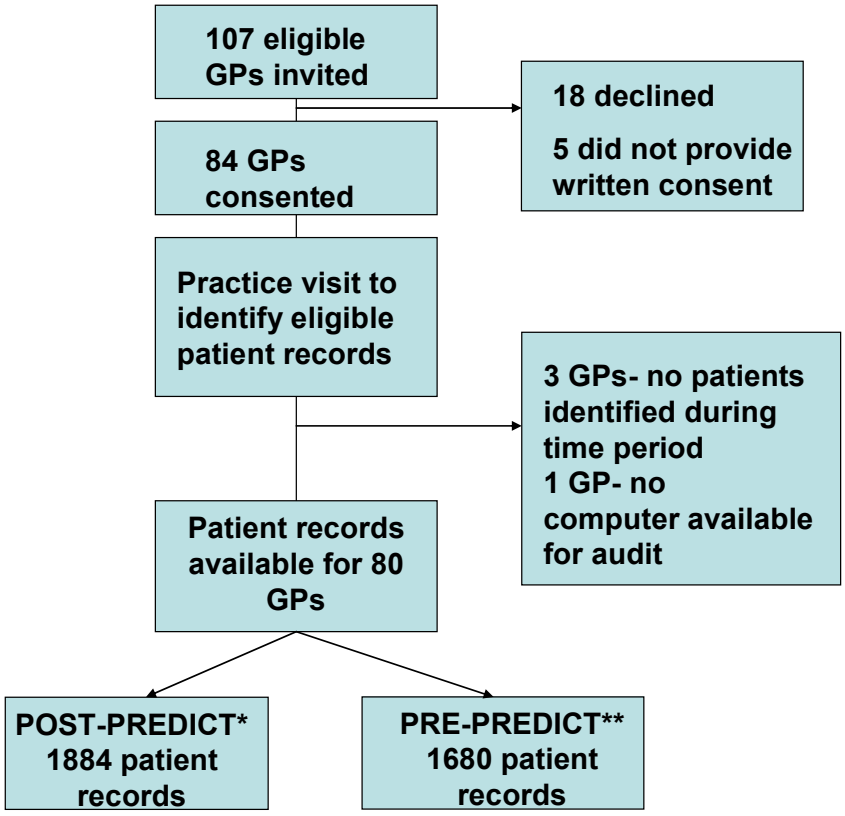
The PREDICT-CVD evaluation study was approved by the Auckland Regional Ethics Committee (AKY/04/07/185).

6.2.3 Results

A flow chart of participation is given below (Figure 6.1). Of the 107 eligible GPs, 84 (78.5%) consented to participate; 18 (17%) declined, four were on leave and one could not be contacted; reason unknown. Patient audit data from 80 GPs (75%) were included in the analyses, with the other 4 excluded because:

- two GPs were on leave during both time periods of interest
- the 15% non-Māori sampling fraction did not generate any patients for one very part-time GP
- one GP did not have a spare computer available to conduct the audit at any time during the study period.

Figure 6.1. Flow chart of PREDICT-CVD audit



* Patients meeting guideline criteria who were seen over a 1 month period, 4 weeks after the installation of PREDICT software

** Patients meeting guideline criteria who were seen over a 1 month period, 12 months before POST-PREDICT time period

Participating and non-participating GPs

Table 6.1 shows characteristics of participating and non-participating GPs. There were no differences by gender or mean number of years since graduation. Most of the GPs in ProCare are members of group practices. While participating GPs were evenly spread over the Prompt installation period, those who declined or were unable to be contacted were more likely to have had Prompt installed between August 2003 and April 2004 (i.e. later installation).

Table 6.1. Characteristics of participating and non-participating GPs

	Participating GPs (n = 84)	**Non-Participating GPs (n = 23)**
	n (%)	n (%)
Mean number of years since graduation	22.43 yrs	21.30 yrs
Female	28 (33.3)	6 (26.1)
Male	56 (66.7)	17(73.9)
Group practice	83 (98.8)	21 (91.3)
Installation Prompt		
Range dates first use Prompt	Aug 02–April 04	Dec 02–April 04
Early Installation (Aug 2002-July 2003)	43 (51.2%)	5 (21.7%)
Later Installation (Aug 2003-April 2004)	41 (48.8%)	18 (78.3%)*

*Early versus later Prompt installation χ^2 = 6.33, p-value = 0.0119

Characteristics of audited populations before and after PREDICT-CVD installation

A total of 3564 audits were conducted, 1680 for the pre-PREDICT period (August 2001 to June 2003) and 1884 for the post-PREDICT period (August 2002 to June 2004).

Pre-PREDICT sampling times ranged between August 2001 and June 2003, and post-PREDICT sampling times from August 2002 to June 2004 (i.e. considerable overlap).Table 6.2 describes the demographic characteristics of the patients seen in the two time periods. There were no clinically important differences between the groups and with the exception of previous CVD (χ^2 = 6.74, p-value = 0.009), there were no

statistically significant differences between the two groups by age, gender, ethnicity, having diagnosed diabetes and holding a HUHC or CSC.

Table 6.2. Characteristics of audited populations before and after PREDICT-CVD installation

	Pre-PREDICT (n=1680)		Post-PREDICT (n=1884)	
	n	%	n	%
Age				
35-44 yrs	107	6.3	118	6.3
45-54 yrs	366	21.8	372	19.8
55-64 yrs	488	29.1	535	28.4
65-74 yrs	377	22.5	420	22.3
75-84 yrs	269	16.0	354	18.8
85-94 yrs	70	4.2	79	4.2
Over 95 yrs	3	0.2	6	0.3
Gender				
Female	827	49.2	970	51.5
Male	853	50.8	914	48.5
Ethnicity				
European	963	57.3	1088	57.7
Māori	474	28.2	484	25.7
Pacific	66	3.9	65	3.5
Asian	54	3.2	74	3.9
Other	15	0.9	25	1.4
Not Stated	108	6.4	148	8.0
High Use Health Card Status				
No HUHC	1519	90.4	1694	89.9
HUHC	161	9.6	190	10.1
Community Services Card Status				
No CSC	919	54.7	1060	56.3
CSC	761	45.3	824	43.7
Diabetes				
No Diabetes	1433	85.3	1587	84.2
Diabetes	247	14.7	297	15.8
Prior CVD event				
No CVD	1353	80.5	1450	77.0
CVD	327	19.5	434	23.0

Characteristics of Māori and non-Māori populations

Māori participants made up 28.2% (n=474) of audited electronic medical records in the pre-PREDICT period, and 25.7% (n=484) in the post-PREDICT period. Table 6.3 compares the characteristics of the two populations.

Table 6.3. Characteristics of Māori and non-Māori audited populations

	Māori (n=958)		Non-Māori (n=2606)		Chi-square* p-value
	n	%	n	%	
Age					
35-44 yrs	187	19.5	38	1.5	
45-54 yrs	360	37.6	378	14.5	$\chi2=760.7$
55-64 yrs	227	23.7	796	30.5	p< 0.0001
65-74 yrs	133	13.9	664	25.5	
75-84 yrs	44	4.6	579	22.2	
85-94 yrs	7	0.7	142	5.5	
Over 95 yrs	0	0	9	0.3	
Gender					
Female	445	46.5	1352	51.9	$\chi2=8.26$
Male	513	53.5	1254	48.1	p=0.004
HUHC Card					
No HUHC	881	92	2332	89.5	$\chi2=4.84$
HUHC	77	8	274	10.5	p=0.028
CSC Card					
No CSC	484	50.5	1495	57.4	$\chi2=13.29$
CSC	474	49.5	1111	42.6	p=0.0003
Diabetes					
No Diabetes	740	77.2	2280	87.5	$\chi2=56.86$
Diabetes	218	22.8	326	12.5	p< 0.0001
Prior CVD					
No CVD	801	83.6	2002	76.8	$\chi2=19.23$
CVD	157	16.4	604	23.2	p< 0.0001

Māori participants were younger (due to the different age eligibility criteria for screening in the NZGG guidelines) and very few were aged over 74 years. They were more likely to be male, have diabetes and have a CSC; and were less likely to have a HUHC or previous CVD, than non-Māori participants. The characteristics of Māori participants did not differ greatly between the two time periods (not shown). The only significant difference among non-Māori participants between time periods was a higher level of previous CVD in the post-PREDICT period (25% of participants compared with 21% in the pre-PREDICT period; χ^2= 5.65, p-value=0.0175).

CVD risk and risk factor documentation before and after PREDICT for the total audited population

Table 6.4 shows CVD risk and risk factor documentation pre- and post-PREDICT installation according to the total audited population (weighted by sampling fraction). Pre-PREDICT, a CVD risk was documented for an estimated 2.8% of the total eligible population, increasing approximately four-fold after installation to 10.7% (multivariate RR 4.0; 95% CI 2.4 to 6.5). It is possible that a CVD risk was calculated for some patients but not recorded in the electronic medical record, therefore another category was defined where either the CVD risk was documented or the medical record documented all the risk factors required for risk assessment. At baseline, 9.2% of patients had either a CVD risk documented or all required risk factors present. This nearly doubled post-PREDICT to 18%. Of all the risk factors documented, blood pressure was most likely to be recorded, followed by lipids, smoking and diabetes status, in descending order. After the installation of PREDICT, documentation of smoking status, blood pressure, lipid measurements and diabetes status increased by 10%, 7%, 8% and 5%, respectively, in absolute proportions. These effects remained statistically significant after adjustment for multiple factors.

Table 6.4. CVD risk & risk factors documented before & after PREDICT-CVD installation

	Pre-PREDICT	Post-PREDICT	Multivariate Model*
	%	%	RR (95% CI)
CVD risk documented	2.8	10.7	4.0 (2.4-6.4)
CVD risk documented or required risk factors present	9.2	18.0	1.9 (1.5-2.3)
Smoking status documented	38.9	48.6	1.2 (1.1-1.3)
Blood pressure documented	85.0	92.3	1.1 (1.0-1.2)
TC/HDL or total cholesterol documented	64.0	72.8	1.1 (1.1-1.2)
Diabetes status documented	14.4	19.7	1.3 (1.1-1.4)

*Multivariate model included GP, practice and patient characteristics of age, gender, ethnicity, CSC, HUHC, diabetes and CVD

Of the 80 general practitioners whose data were included in the analysis, 48 (60%) increased their CVD risk documentation post-PREDICT, 26 (32%) showed no change, three (4%) showed a reduction in risk documentation and three only provided audit data during one of the audit periods.

Māori / non-Māori analyses of risk and risk factor documentation

Table 6.5 shows the level of CVD risk and risk factors documentation before and after PREDICT-CVD installation for Māori and non-Māori patients separately. Prior to PREDICT installation, Māori had slightly higher recording of cardiovascular risk than non-Māori (3.2% vs 2.8%). This difference increased post-installation (14.7% vs 10.5%) although the differences between the two populations were not statistically significant. Similarly, 12.4% of Māori compared with 9.2% of non-Māori patients had either a CVD risk documented or all required risk factors present at the pre-PREDICT audit. Post-PREDICT, this nearly doubled to 24% for Māori and 17.6% for non-Māori. The recording of both smoking and diabetes status was higher for Māori than non-Māori in both periods whereas blood pressure and cholesterol measurements were higher for non-Māori. After the installation of PREDICT, documented smoking status, blood pressure, lipid

measurements and diabetes status all increased in both Māori and non-Māori with no statistically significant ethnic differences in pre- to post- increase after adjustment for multiple factors.

Table 6.5. CVD risk and risk factors documented before and after PREDICT-CVD installation for Māori and non-Māori patients

	Pre-PREDICT period		Post-PREDICT period		Difference in pre- to post- increase between Māori & non-Māori
	Māori n = 474 % (n)	Non-Māori n = 1206 % (n)	Māori n = 484 % (n)	Non-Māori n = 1400 % (n)	p value *
CVD risk	3.2 (15)	2.8 (34)	14.7 (71)	10.5 (147)	0.28
CVD risk or all risk factors	12.5 (59)	9.0 (108)	24.0 (116)	17.6 (246)	0.44
Smoking status	49.5 (235)	38.3 (462)	59.3 (287)	47.9 (670)	0.58
Diabetes status	21.5 (102)	14.0 (169)	23.4 (113)	15.2 (213)	0.53
Blood pressure	71.5 (339)	85.8 (1035)	83.7 (405)	92.8 (1299)	0.62
TC/HDL or total cholesterol	57.6 (273)	64.3 (776)	69.2 (335)	72.9 (1021)	0.23

* Model includes: age, gender, presence of CVD, diabetes, HUHC, CSC

Quality of data collection and data entry

Repeat audits of the original study sample were undertaken by a separate nurse on 147 patient files, from 18 general practitioners in nine practices. Key variables from the paired records that should have been consistently documented (date of birth, gender, primary ethnicity, CSC and HUHC) were compared (Table 6.6). There was a difference between the two audits of 1.4% for gender, 3.4% for card holding status and 7.5% for date of birth. There was only a 2.7% difference for CVD risk, the primary outcome examined. Type of diabetes, diabetes medications, raised HbA1c, history of CVD and total cholesterol/HDL ratio, showed a range of disagreement from 1.4% to 8.8%. Documentation of smoking status was the most unreliable with a 17.7% difference between the paired records.

Table 6.6. Variation in data collection and data entry for 14 key audit variables

Variable	Difference in audit records between original and repeat audit n (%)
Date of birth	11(7.5)
Gender	2(1.4)
Primary ethnicity	8(5.4)
Secondary ethnicity	2(1.4)
CSC	5(3.4)
HUHC	5(3.4)
Diabetes type	12(8.2)
Diabetes medications	2(1.4)
HbA1c >6	3(2.0)
History of CVD	8(5.4)
Prescription of nitrates	0
Total cholesterol/HDL ratio	13(8.8)
Smoking Status	26(17.7)
CVD Risk Documented	4(2.7)

6.2.4 Discussion

Principal findings

The level of documentation of CVD risk assessment in patient records for eligible Māori and non-Māori increased approximately 4-fold following the installation of PREDICT. The documentation of all the major CVD risk factors also increased. Pre-PREDICT, Māori and non-Māori had similar levels of CVD risk and CVD risk factors documentation and demonstrated similar improvements post-PREDICT. The level of documentation was surprisingly low prior to the programme, with less than 3% of eligible patients meeting national guideline recommendations for risk assessment, although almost 10% of records included all the required risk factors and it is possible that risk had been calculated but not recorded. The audit was conducted over only a 4-week period, just one month after the installation of PREDICT-CVD, so the improvement observed resulted from only one cycle of visits for most patients. PREDICT was offered to all ProCare GPs during the PHO-wide Prompt programme designed to increase opportunistic CVD risk factor screening. The programme included an education package

for all GPs and practice nurses, plus the PREDICT software and associated support services for those GPs who requested it. As Prompt was introduced as an opportunistic rather than a systematic screening programme, risk assessments were undertaken only if the practitioner had time during a consultation. Therefore, the post-PREDICT level of documentation of about 11% for CVD risk (and about 20% for the relevant risk factors), while still low, would be expected to improve significantly with time. Nearly two-thirds of GPs increased their levels of risk assessment and documentation following the installation of the CDSS, suggesting that the system was user friendly and could be integrated into the workflow of routine primary care practice.

One of the major benefits of PREDICT compared with non-standardised risk assessment observed during the audit was the quality of data and ease of data retrieval. The complexity of data retrieval from unstructured clinical records was reflected in the differences between the original and repeat audits undertaken by experienced audit nurses. Although some differences were due to data entry errors, most of the variability was due to the limited use of systematic coding and the idiosyncratic free text recording of many variables. All risk factor documentation generated by PREDICT and saved in the electronic medical record was standardised and in a readily retrievable format.

A key objective of the evaluation was to ensure an adequate sample of Māori patients to achieve equivalent explanatory power for Māori. By using data from GP practices from the whole of the ProCare Network, it was possible to achieve this. We would not have had the resources to conduct a large enough randomised trial to achieve the same level of power. The observation of similar improvements in documentation for both Māori and non-Māori suggest that this type of CDSS will not increase ethnic inequalities and, if applied in an appropriate manner, should lead to a reduction in inequalities as Māori have a significantly higher CVD risk than non-Māori.

Study strengths and weaknesses

While a randomised trial would theoretically have been a better design to use for this study, as discussed above, it was neither affordable nor practical in the circumstances. One advantage of the retrospective before-after audit design was that participating general practitioners were unaware they would be audited and therefore their screening

practices are unlikely to have been influenced by knowledge that 'they were being watched'. Furthermore, we chose to start the audit 4 weeks after the installation of PREDICT, rather than immediately after installation, as the novelty of new software would have influenced practice in the first few weeks. As each participating practitioner acted as his/her own control, the potential for confounding was also reduced and we matched the time period before and after (i.e. 12 months apart) to reduce any seasonal differences in patient visiting patterns.

The validity of uncontrolled before-after studies can be weakened by secular trends in practice that would make it difficult to attribute observed changes to the intervention of interest.[257] However, during the period of the study there were no important changes in either health policy or other financial incentives for general practitioners to conduct CVD risk assessments. Furthermore, an independent audit of CVD risk assessment done at about the same time as the post-PREDICT audit in three large general practices (two in south Auckland and one in Hawke's Bay) reported a similar (4.7%) level of documentation as in the pre-PREDICT audit.[258]

General practitioners who installed PREDICT-CVD received NZ$10 per risk assessment up to a maximum of $900, but this payment only partially offset set-up and on-going running costs of broadband web access and did not cover the costs of the additional time taken with patients. Therefore, these findings are likely to primarily reflect the impact of introducing a package involving computerised electronic decision support rather than a financial incentive.

Comparison with other studies

The systematic review conducted as part of this thesis (Chapter 4), found no randomised controlled trials of a provider-initiated integrated CDSS specifically for CVD risk assessment and management. Montgomery et al. (2000) compared a computer-based CVD risk assessment tool (but no graphical display and no management support), with a paper-based risk prediction chart and with usual care[216]. Only use of the paper-based risk chart was associated with a clinically significant reduction in any of the risk factors studied (and only for systolic blood pressure).[216] The computer-based tool was not Windows-based and limited in functionality, only providing a risk score, whereas the

paper chart was simpler to use and provided a visual display of risk. Both these factors were probably responsible for the greater impact of the paper-based tool. Two Canadian randomised trials [219] [220] have investigated a non-integrated off-site computerised decision support programme. GPs and patients were required to complete a paper-based form including all data required for a CHD risk assessment, and then send it to an independent centre. A week or so later they received an absolute CHD risk assessment for each patient in the intervention group. In both trials, they reported a visual summary of the predicted CHD risk with and without treatment that enabled clinicians to demonstrate to patients the potential for risk reduction through various interventions. Grover et al. (2007) also calculated each patient's cardiovascular age based on a comparison of the patient's risk profile with the mean age- and gender-specific profile of the Canadian population. These non-integrated off-site CDSS were more successful than that reported by Montgomery et al. (2000), possibly because of the range of risk communication support provided. Patients in the intervention groups had significant reductions in LDL and TC/HDL ratios[219] [220], a reduction in 8-year CHD risk[220] and were more likely to reach lipid targets[219] than patients in the usual care groups.

The meta-analysis of clinical (electronic and non-electronic) decision support systems by Kawamoto et al. (2005) described in Chapters 3 and 4 identified four key features that were likely to improve practice; automatic provision of decision support as part of clinical work flow; provision of recommendations, not just assessments; provision of decision support at the time and location of decision making and computer-based decision support.[145] At the time of the evaluation study, all these features except for automatic alerts were incorporated into PREDICT-CVD. ProCare have since added an automatic alert prompting GPs to consider undertaking a CVD risk assessment in eligible patients at the time of consultation.

Previous evaluations of integrated CDSSs have shown mixed results and in general the main difficulty has been getting clinicians to use the tools on a regular basis.[212] [214] [259] The relatively frequent use of PREDICT observed during this evaluation, in a busy routine primary care setting, provides an early indication of its acceptability and fit with work processes. This is a reflection of the significant involvement of a team of GPs in the

development of PREDICT which had been through a number of iterations following feedback from users.

Implications and conclusion

The audit reported here is the first step in evaluating the impact of PREDICT on the assessment and management of CVD risk in primary care. The findings are likely to be relevant to most New Zealand primary care practices using electronic patient management systems and with access to basic training and support. Although the level of CVD risk documentation increased substantially after the implementation of this provider-initiated integrated CDSS, the majority of eligible patients are yet to have a documented CVD risk assessment. The next step in the evaluation of PREDICT is to determine whether improvements in the CVD risk assessment process leads to improvements in treatment and ultimately in health outcomes, particularly for individuals and groups known to be at high risk. These further evaluation steps were beyond the scope of this thesis, but are currently being planned by the PREDICT research team.

7 Patterns of adoption and use of PREDICT-CVD

7.1 Introduction

One of the key "acid" tests for a decision support system is the level of adoption and, whether the ease of use and fit with clinical work flow is sufficient to change clinical behaviour.[260] To be sustainable, the benefits must outweigh the time and effort required to use it. Heeks et al. (1999 and 2006) note that although some health care information systems succeed, the majority are likely to fail.[261] [262] The greater the personal and organisational change required by an information technology system, the greater the risk of failure. The system needs to fit with the user's values and any change needs to happen in small enough steps to be achievable by the majority.[261] [262]

Evaluations of computer system usage have been undertaken at all levels of a health service, including the individual, group, organisation, industry and social sector level [263] and have used research methodologies from a range of perspectives such as cognitive psychology and other social science methods, management science, ergonomics, computer science and clinical epidemiology.[135] [263-265] Apart from the epidemiological literature, a detailed discussion of these various methodologies and theories including systems theory (complex interrelationships and interdependencies that form a functioning whole) and diffusion of innovations (particularly with respect to computer systems) is beyond the scope of this thesis, but highly relevant to the topic in general.

However, given the importance of usability to the success of any decision support system, we used mixed qualitative and quantitative methods to conducted the PREDICT Provider Study during 2007. This was a three-part evaluation of the barriers, challenges and attitudes to CVD risk assessment practice and to the use of PREDICT from the perspective of the clinical users – the ProCare doctors and nurses. Tania Riddell and I instigated and provided overall supervision of the study and employed Dr Janine Bycroft (JB), a ProCare GP and Public Health Registrar, as the project manager. Additional members of the study team included Tim Kenealy and Rod Jackson from the University

of Auckland and Paul Roseman and Kate Moodabe from ProCare Network Ltd. The three sub-studies of the PREDICT Provider Study were:

- a qualitative study of experiences, barriers and facilitators with PREDICT using key informant interviews and focus groups with GPs and nurses
- a health provider questionnaire to over 380 GPs and nurses to verify some of the themes and issues identified in the qualitative study
- a descriptive study of the patterns of adoption and use of PREDICT-CVD in ProCare.

The PREDICT Provider Study was approved by the Northern Y Regional Ethics Committee (NTY/07/01/004) in 2007. I was primarily responsible for the third sub-study. This chapter describes the design, conduct and results of this sub-study, describing the patterns of adoption, the characteristics of adopting clinicians and the subsequent frequency of use of PREDICT-CVD in ProCare practices over its lifecycle from 2002 until January 2007.

Investigator roles for the patterns of adoption and use of PREDICT-CVD in ProCare

I (SW) instigated this sub-study and liaised with ProCare management to ensure the acceptability of the processes involved. JB collected ProCare GP practice details under supervision from PR and KM. SW negotiated and received GP data from New Zealand Medical Council (NZMC) Registry. JB accessed Nursing Council Registry (NZNC) data from the Nursing Council website. Mildred Lee (research analyst) managed and merged PREDICT-CVD, NZMC, NZNC and ProCare data supervised by the lead PREDICT data manager Mrs Joanna Broad. SW presented the findings at the Health Informatics New Zealand Conference in 2007 and was invited to submit a paper on the presentation for publication (now published – Appendix 10).

7.2 Methods for Sub-study

7.2.1 Study design

This was a cross-sectional study linking four datasets; the ProCare Clinical Registry, the New Zealand Medical Council Medical Registry, the New Zealand Nursing Council Registry and the PREDICT CVD usage data from August 2002 to December 2006.

ProCare PHO Clinical Registry

JB, a ProCare GP working with members of the ProCare Network management team was given permission to access the PHO registries and other administrative sources to create a dataset of the practices, their location, their PHO (i.e. ProCare Network Manukau, Auckland or North) and the GPs and practice nurses working within each practice.

New Zealand Medical and Nursing Councils' registries

The New Zealand Medical and Nursing Councils' registries included the year of registration, country of training and vocational registration (for doctors) but only the year of registration (for nurses).

After augmenting the ProCare registry with the Medical and Nursing Council data, the new dataset was stripped of personal and practice names. The dataset retained each clinician's New Zealand Medical Council (NZMC) registration number or New Zealand Nursing Council (NZNC) registration number.

PREDICT usage data

When a clinician uses PREDICT, their professional registration number (NZMC or NZNC) plus the time and date of usage is recorded on the PREDICT server, along with anonymised patient risk profile data. These usage data were extracted from the PREDICT server with permission from the ProCare Network and linked to the de-identified clinical registry data

Key data definitions

Years since graduation: This was calculated by subtracting the year of graduation from the year of the study (2007).

Country of medical degree: The country of medical degree was dichotomised into New Zealand and overseas.

Vocationally registered or a FRNZCGP: This identifies a group of doctors who either have specialist training qualifications in General Practice and continue to pass yearly vocational accreditation criteria or have a Fellowship of the Royal New Zealand College of General Practitioners. If a GP is vocationally registered they usually also have a Fellowship but a few older GPs may have an honorary Fellowship without passing specialist examinations.

Main outcome measures

The outcomes measured were:

- differences between adopters and non-adopters of PREDICT
- uptake and usage patterns of PREDICT by clinicians over time
- differences between infrequent compared to frequent users of PREDICT
- patterns of usage by the most frequent users.

Data analysis

Univariate analyses were conducted and differences between categorical outcomes were assessed using the chi-square statistic. These analyses were conducted using SAS statistical software Version 9.1 and usage distributions over time were plotted using Excel functions.

7.3 Results

Description of adopters and non-adopters of PREDICT

Adopters were defined as general practitioners (or nurses) who made at least one PREDICT data submission. To do this they needed to:

- be in a practice with high speed web access
- have PREDICT installed on their patient management system
- have received training in the use of the programme
- have a unique password-protected log-in account.

While the average numbers of GPs and nursing staff working in the ProCare network at any one time over the time period (August 2002 until December 2006) were around 500 and 300, respectively, there were a total of 705 doctors and 435 nurses listed on the Procare clinical registry because of turnover of businesses and staff. A comparison of clinician and practice characteristics for PREDICT adopters and those who were never recorded as having a PREDICT electronic submission (non-adopters) is shown in Table 7.1

Table 7.1. PREDICT adopters and non-adopters by GP or practice nurse

	General Practitioners (GPs)			Practice Nurses		
	Total GPs n=705	GP adopters n=416 (59%)	GP non-adopters n=289 (41%)	Total nurses n=435	Nurse adopters n=117 (27%)	Nurse non-adopters n=318 (73%)
	n	row %	row %	n	row %	row %
Gender						
Male	390	59	41	1	100	0
Female	291	56	44	434	27	73
Unknown	24					
Years since graduation (GP) or registration (nurse)						
<10 yrs	45	69	31	53	15	85
10-19 yrs	185	63	37	70	17	83
20-29 yrs	297	56	44	76	16	84
30-39 yrs	114	54	46	88	18	82
40+ yrs	36	33	67	32	6	94
Unknown	28	96	4	116	58	42
Country of medical degree						
New Zealand	421	60	40			
Overseas	260	53	47			
Unknown	24	100	0			
Vocationally registered or a FRNZCGP						
No	181	47	53			
Yes	500	61	39			
Unknown	24	100	0			

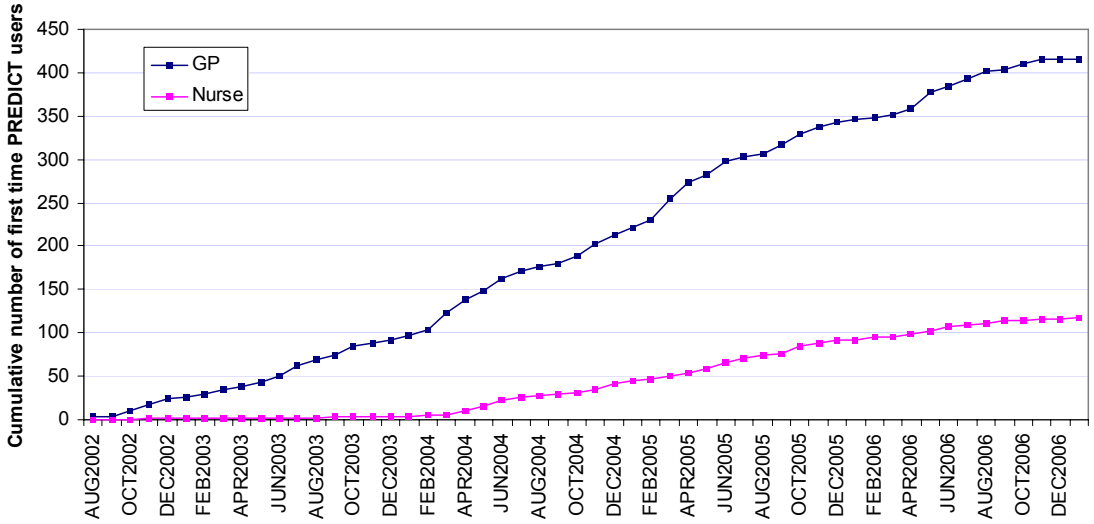
Three-quarters of those who did not adopt the programme during the study period were recorded as having compatible patient management systems in their practice. For 24 GPs (6.5%), the NZMC number was unable to be matched to the Medical Council Register, due to incorrect data entry within the patient management system for PREDICT submission or within the clinical registry. For GPs, there were differences between adopters and non-adopters by known vocational registration status (χ^2 = 10.2, p-value = 0.0014) and year of graduation (χ^2 = 14.1, p-value = 0.0069), with vocationally registered and younger GPs, less than 20 years post graduation, being more likely to adopt PREDICT. No differences were found by gender or country of medical degree. About 20% of GPs, whose data could be matched, had incomplete data, particularly with regard to practice characteristics (funding, size of practice, patient management system) and therefore we could not assess differences between adopters and non-adopters for these variables. Some of the reasons for missing data were: doctors changing practices within ProCare; practices becoming affiliated with another PHO; doctors retiring and

practices being sold; or being a locum and not connected to one practice. Data were incomplete for more than a quarter of the nurses.

Patterns of adoption patterns of PREDICT-CVD by doctors and nurses

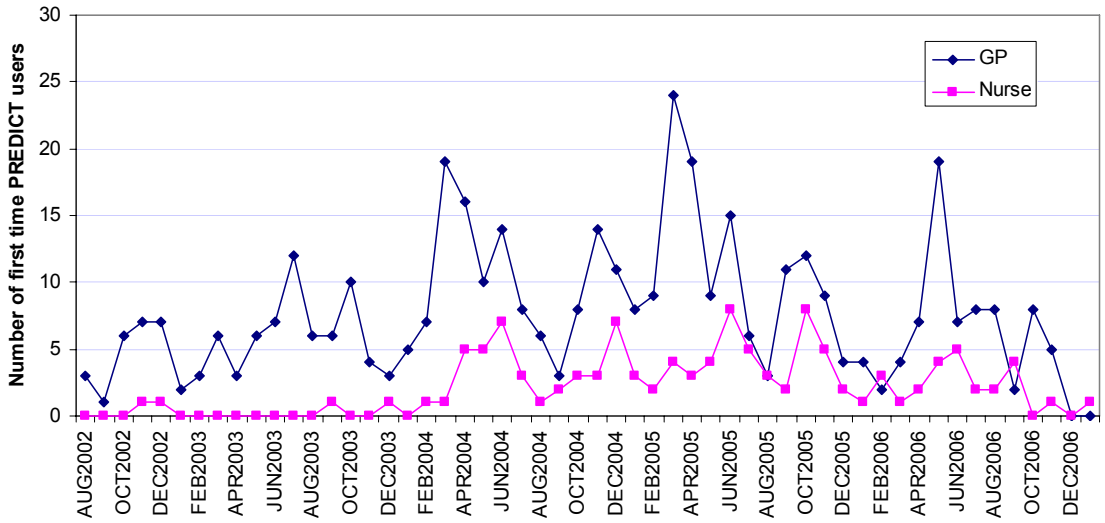
As discussed in Chapter 6, PREDICT-CVD was implemented from August 2002 in planned increments by geographic location. While GPs were the initial target of the implementation plan, it was subsequently promoted among practice nurses. The cumulative rate of PREDICT adoption by doctors and nurses is shown in Figure 7.1. Nurse uptake lagged by 20 months and had a slower trajectory.

Figure 7.1. Adoption by GPs & nurses; cumulative count of first-time users



The same data is displayed as monthly rates of first time users (Figure 7.2), showing annual peaks in adoption which coincide with and lag slightly behind implementation evenings conducted via GP cell groups.

Figure 7.2. Adoption of PREDICT by doctors and nurses; monthly count of first time users

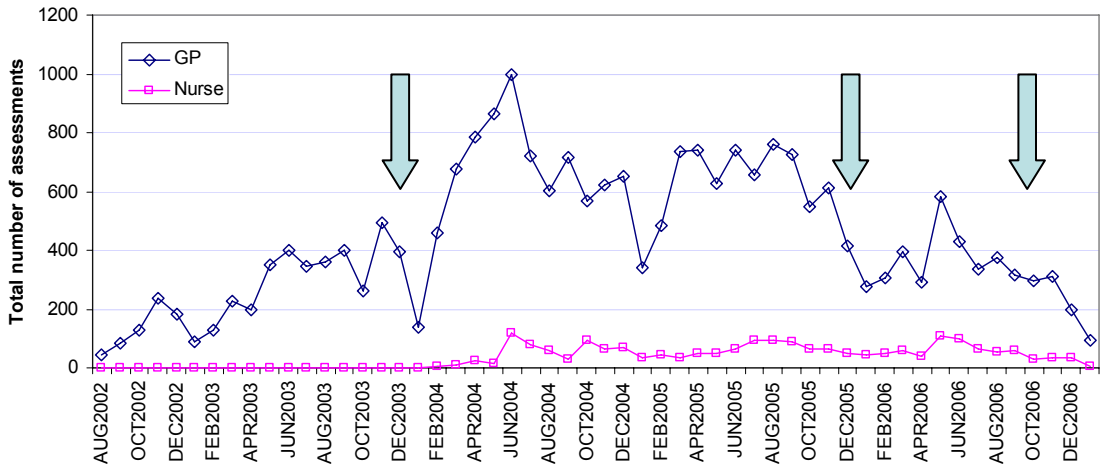


Patterns of use over time, all users

Between August 2002 and January 2007, 45,437 CVD risk assessments were conducted on 25,705 patients by 416 GPs and 117 nurses. The programme was often used multiple times on individual patients within one consultation (e.g. to demonstrate benefits of lifestyle changes such as stopping smoking) and for subsequent follow-up visits until early 2007 (not shown). Figure 7.3 shows assessment patterns over this time period. On average, 485 patients were assessed per month (ranging from 43 in the first month to a peak of 1120 in June 2004). There was a seasonal variation in usage, with CVD risk assessments less likely to be conducted in summer than in any other season (χ^2 = 1273.9, p < 0.0001). Usage declined mid-2004, dropping to 2002 levels by the end of 2006. Key dates of relevance to CVD risk assessment policy during this time are marked by the arrows on Figure 7.3. The national CVD risk guidelines[23] and type 2 diabetes management guidelines[64] were published in December 2003. Following the summer decline, there was a large increase in the use of PREDICT throughout 2004 (possibly with increased awareness of CVD risk assessment recommendations) that appeared to be in a reasonably steady state until the updated PREDICT programme, PREDICT CVD-Diabetes was released for general usage in December 2005 and GPs were aware of the lack of currency of PREDICT-CVD following the summer break. The ProCare Network started a new programme of implementation of this updated

programme in October 2006, although the significant impact of the new programme was not observed until early 2007 (not shown).

Figure 7.3. Total number of patients assessed using PREDICT per month by GP or practice nurse between August 2002 and January 2007



Arrows refer to release of CVD and Diabetes guidelines in December 2003, release of PREDICT CVD-Diabetes in December 2005 and implementation in ProCare in October 2006

There was large variation in the use of PREDICT by ProCare providers. The majority of assessments (92.2%) were conducted by doctors. The mean (sd) number of risk assessments completed by each GP over all the time period was 57(94.2) compared with 17(17.0) by each nurse. The median number of assessments was 15 and 3, respectively. The large difference between the mean and the median indicates that some GPs were very frequent users but the majority were less frequent. The maximum number of patients risk assessed was 621 by a GP and 161 by a nurse. However, 31% (129/416) of GP adopters and 56% (65/117) of nurse adopters completed less than 5 risk assessments.

PREDICT GP adopters were categorised by number of patients assessed using the tool (Table 7.2).

Table 7.2. PREDICT GP users categorised by overall number of patients assessed

	Total GP users n=416	Non-user (<5 patients) n=129	Infrequent use (5–20 patients) n=95	Frequent user (21–89 patients) n=104	Most frequent user (90+ patients) n=88
		row%	row%	row%	row%
Gender					
Male	229	30.3	18.4	22.8	28.5
Female	163	26.8	29.3	30.5	13.4
Unknown	24	66.7	21.0	8.3	4.0
Years since graduation					
< 10 yrs	31	54.8	29.0	9.7	6.5
10-19 yrs	118	28.0	27.1	26.3	18.6
20-29 yrs	168	21.4	22.6	29.2	26.8
30-39 yrs	63	36.5	14.3	28.6	20.6
40+ yrs	12	33.3	16.6	8.3	41.8
Unknown	24	66.7	21.0	8.3	4.0
Country of medical degree					
New Zealand	253	26.5	25.3	23.3	24.9
Overseas	139	33.1	18.7	30.9	17.3
Unknown	24	66.7	21.0	8.2	4.0
Vocationally registered or have FRNZCGP					
No	86	39.5	34.9	19.8	5.8
Yes	306	25.8	19.6	27.8	26.8
Unknown	24	66.7	21.0	8.2	4.0

When the frequent and most frequent users were aggregated and compared to with non-users and infrequent users, there were no statistically significant differences by gender or country of medical degree. Non-users and infrequent users were more likely to be less than 10 years since graduation than the combined frequent user groups (χ^2=17.28, p-value = 0.0017). The older doctors (over 30 years from graduation) were as likely to be in either group. A higher percentage of frequent and most frequent users had vocational registration compared with infrequent or non users (χ^2=22.60, p-value <.0001). We were unable to adjust for full-time equivalent status (FTE), which is likely to influence frequency of use.

Patterns of use over time among the most frequent users

The most frequent users were categorised as having used PREDICT for CVD risk assessment on 90 or more patients (i.e. the criteria for receiving a one-off incentive

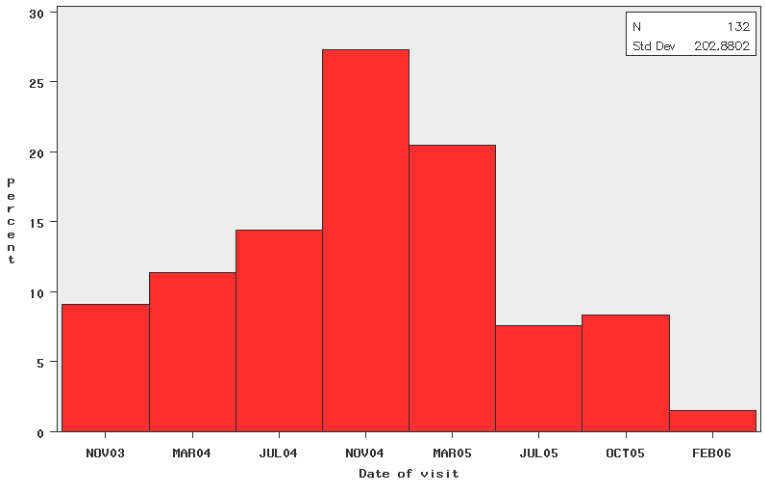
payment of $900 plus GST). There were 88 GPs in this category (21% GP users). Their patterns of use over time were examined individually and four clear types emerged:

- start slowly, build up, then decline (36/88 GPs)
- start with a rush, then slowly decline (29/88 GPs)
- a fairly constant pattern over time with assessment rates at the start similar to assessment rates at the end of the programme (13/88 GPs)
- an “all then nothing” pattern defined as conducting at least 70% usage activity in one 3–6 month time period (10/88 GPs).

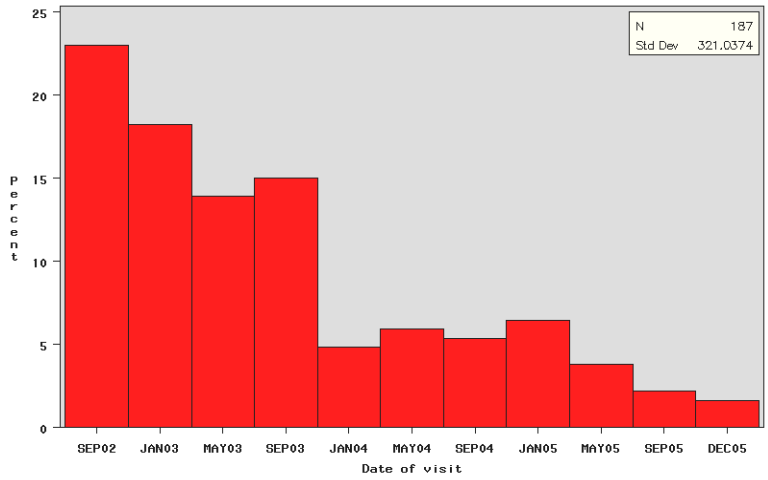
Individual GP examples of these four types are given in Figure 7.4 A–D.

Figure 7.4 A–D. Examples of the four types of usage pattern by GPs who conducted CVD risk assessment on 90 or more patients

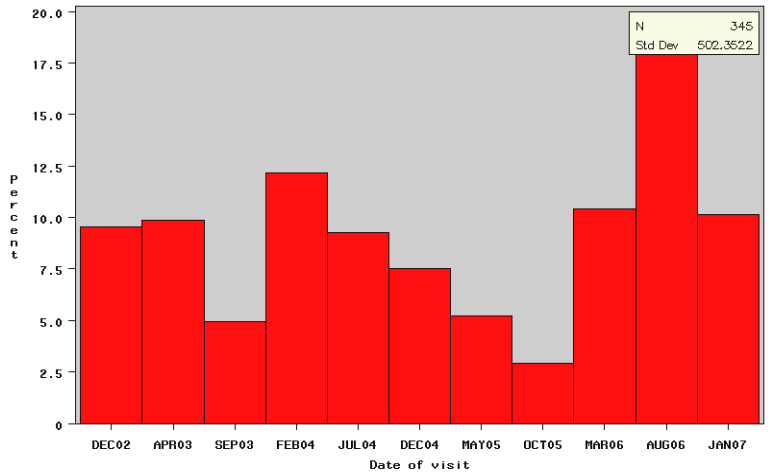
A. Build up then decline (36/88 GPs)



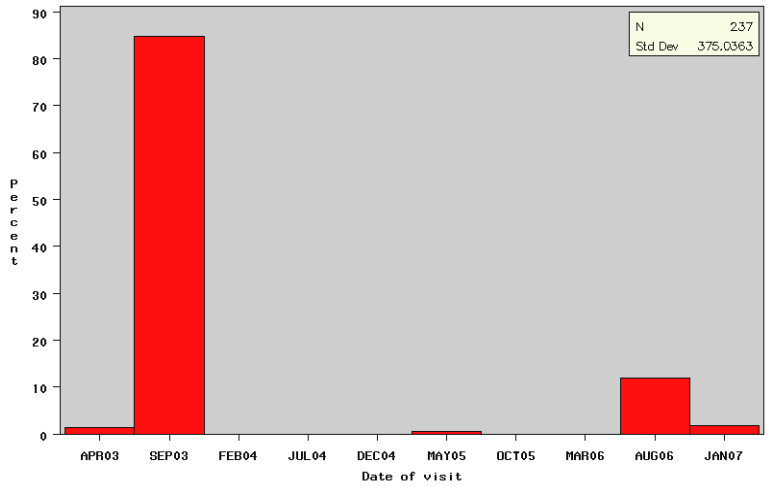
B. Start high then decline (29/88)



C. Fairly constant over time (13/88)



D. All then nothing (10/88)



Of those GPs who met the criteria to receive the one-off $900 incentive payment, 89% demonstrated sustained usage patterns over the 3–4 years following adoption, while only 11% of the most frequent users (2.4% of total GP users) appeared to be directly influenced by the payment target, resulting in a one-off burst of activity then virtual cessation.

7.4 Discussion

This chapter describes the lifecycle of PREDICT-CVD from adoption by 416 GPs and 117 nurses to obsolescence (i.e. when it was replaced by PREDICT CVD-Diabetes). For GPs, there were differences in adoption of PREDICT by year of graduation and by vocational registration status but not by gender or country of medical degree. Adoption patterns had distinct peaks following annual renewed promotion efforts. On average, 400 patients were assessed per month with a marked reduction over summer-time, a time when most GPs have holidays and often take turns covering the practice while partners are away. GPs conducted 92% of the risk assessments and there was a large variation in frequency of use. It is possible that some nurses used a doctor's NZMC number when using practice computers and therefore nurse usage is underestimated.

A higher percentage of frequent and most frequent user GPs had vocational registration compared with infrequent or non-users. However, this finding could be confounded by part-time work. Infrequent and non-users were more likely to have have graduated within the last 10 years. These younger doctors are often practising as locums and therefore spend less time in a practice but we were unable to adjust for this. Of note, just under a third of doctors who had PREDICT-CVD and broadband installed and who had received training and practice support submitted data to the PREDICT server for fewer than five patients.

The incentive payment scheme was unlikely to have been a significant incentive. Firstly, payments were made retrospectively, so that most GPs needed to fund initial broadband installation. Secondly, there were no regular usage reports to give practices feedback on their progress towards the one-off payment. Thirdly, GPs who had reached between 80 and 89 risk assessments were contacted and told that they were very close to their

target, but the remainder were not contacted. Finally, the payment was not intended to offset all costs and at most could be considered as a small acknowledgement of the additional work involved.

In terms of sustainability of usage, while there appeared to be a steady usage state between mid-2004 and late 2005, with just under 800 assessments per month occurring, the rapid decline in usage in 2006 is likely to mirror its loss of clinical currency and practitioners were aware of the development and planned implementation of a new guideline via an updated version of PREDICT. Other possible explanations include practice staff turnover and the need to renew or re-promote programmes to sustain their use. Early indications of usage of the new CVD-Diabetes programme suggest a rapid increase back to the previous high level.

Study limitations

The clinical registry data were derived from multiple primary care administrative datasets linked with data held on medical and nursing council registries. Information was often either lacking or out of date. Identifying nurses on the public register was particularly difficult as many had the same names or used their middle name instead of their first name. Also for nurses, there was no equivalent data to the medical registry on country of training or specialty training. These various problems resulted in a higher rate of unmatched nursing compared with GP data.

In addition, the denominator population of GPs and practice nurses in the Procare Network is by nature constantly changing. Owing to these data quality problems, the interpretation of the findings described in this chapter should be considered as preliminary only. In part informed by this study, ProCare is currently instigating a new web-based practice database that can be updated regularly by practice staff and will be able to provide a more accurate record. We plan to repeat the study when these better data are available.

Comparison with other studies

Studies of physician adoption of information systems (IS) or similar innovations[266-268] often frame their analyses and interpretation based on technology diffusion theory[269] with adoption described in relation to: relative advantage (perceived benefit of an innovation over current practice); compatibility (perceived consistency with values, past experiences and needs); complexity (perceived ease of use); trialability (extent to which innovation can be experimented on); and observability (degree to which results of innovation are visible to others). Alternative models of IS adoption in small businesses have also found the decision maker's characteristics (in this case the GP owner's innovativeness and IS knowledge) and organisational characteristics (business size and level of employee's IS knowledge) to be important.[270]

Specific studies on adoption of expert systems and computerised physician order entry systems have described distinct user adoption groups similar to those presented in this study.[271-273] Determinants of variation of usage are associated with physician attitude towards the effect on time-efficiency, perceived disruption to normal work practices, perceived ease of use and impact on quality of care[268 272 274] but are not associated with gender, years in practice at the study institution[270] or years since graduation.[271 275] Some studies cite prior computer use or experience, level of training, limited IT skills,[276] and rural compared to urban practice, as barriers,[277] while others do not.[271 272 278] Practice size has been shown to be strongly correlated with electronic health record adoption[279 280] but we were unable to assess this association because of missing data.

External incentives such as financial compensation for capital outlay or payment for quality are believed to facilitate evidence-based practice.[267] It is possible that the financial incentive offered for the use of PREDICT may have lowered resistance to adoption. However, we found little evidence that it influenced actual usage. Several studies of primary care guideline implementation via decision support systems[212 214 259] have demonstrated that willingness to adopt electronic tools does not necessarily translate to actual use because of the reality of busy clinical practice and fitting with work processes.

Conclusion

Three key findings are relevant to future improvements in the uptake of PREDICT in primary care. First, adoption of the programme appeared to be responsive to annual promotional activities via GP cell groups. Secondly, while a financial incentive may have helped to facilitate adoption, it had very little impact on the ongoing usage of the tool in routine clinical practice. Thirdly, a substantial number of practitioners who had the programme installed did not subsequently use PREDICT. In retrospect, the lack of regular feedback to clinicians about their usage of PREDICT and the lack of regular review of these data by the support staff who could have identified and addressed some of the barriers to use, were important gaps in the implementation programme.

8 The PREDICT Cohort Study: methods

8.1 Introduction

The main aims of this thesis were to investigate the potential of the PREDICT computerised decision support system (CDSS) to improve primary care assessment and treatment of CVD and simultaneously to generate high quality cohort data, initially to validate and improve the New Zealand CVD risk prediction score. This chapter outlines the methods related to the cohort study component of the PREDICT programme. The two key objectives of the cohort study, as outlined in Chapter 1, were:

- to investigate the potential of the CDSS to generate a CVD cohort derived from routine clinical care

- to investigate the potential of this cohort study to inform CVD risk prediction and other CVD epidemiological research.

8.2 Study design

The study design best able to answer questions relating to prediction/prognosis and to conduct predictive modelling is a prospective cohort study following a group of people that are heterogeneous with respect to exposure history[161] through time until they develop the outcome of interest or until the close of the study. In this way, the natural history of the disease in question can be investigated and risk factors associated with the outcome of interest can be elucidated. We wished to be able to derive patterns of survival expressed as time to an event (death or hospitalisation with an incident CVD event) that could be generalised to the rest of the New Zealand population and to develop CVD risk prediction tools that could be used for decision making both at a population and individual level. Therefore, we needed a study population whose spectrum of disease and risk factor profile was broadly typical of the whole population and the specific sub-populations of interest.

Aims of the PREDICT cohort study

- To describe the prevalence of CVD and CVD risk / risk factors in primary care populations

- To evaluate the accuracy of the original Framingham CVD risk prediction score in a New Zealand primary care population

- To evaluate the accuracy of the current New Zealand Guideline Group adjusted Framingham CVD risk prediction score and subsequently to try to improve the accuracy of this tool for Māori and non-Māori New Zealanders and for identifiable high risk populations.

Co-investigators and my role in the PREDICT cohort study

The co-investigators involved in the design and conduct of the PREDICT Cohort study funded in 2003 by the Health Research Council were Professor Rod Jackson (epidemiologist and supervisory investigator), Dr Tania Riddell (co-Principal investigator and Māori public health physician), Dr Andrew Kerr (cardiologist), Dr Dale Bramley (public health physician), Ms Joanna Broad (epidemiologist/analyst), Dr Sue Crengle (Māori public health physician), Assoc Professor Dr Tim Kenealy (academic and practicing general practitioner), Dr Richard Milne (health economist) and Dr Diana North (GP/public health physician).

My role as co-principal investigator of the HRC PREDICT Cohort Study was to:

- take a lead in the design and redesign of the cohort study and associated sub-studies

- liaise with general practitioners, primary care organisations, secondary care, community and occupational health who use or were considering using PREDICT

- work (as the clinical decision support specialist – now with 6 years 'on the job' training) with IT decision support specialists on all issues relating to the PREDICT software programme and its integration

- support programmes of care for CVD and diabetes in primary, secondary, community and workplace settings using PREDICT, to ensure continued high quality data collection

- conduct provider group training on CVD risk assessment and management to facilitate programme uptake and health sector knowledge base

- work with the New Zealand Guidelines Group expert advisory committees to ensure up-to-date high quality evidence-based clinical content of the PREDICT programme

- ensure all aspects of the cohort study (and sub-studies) were conducted in accordance with approved ethical processes

- ensure the approach and conduct of analyses and interpretation of Māori data were in accordance with processes approved by our Māori governance group

- supervise staff employed on the project

- undertake and supervise statistical analyses and prepare scientific reports and other papers for dissemination.

This role was supported by a National Heart Foundation research fellowship from 2003-2006. While I have been involved with all aspects of data coding, validity checks and interpretation within the clinical context, the cleaning and other data management for all PREDICT Cohort study analyses presented in this thesis were conducted by Joanna Broad (epidemiologist and data manager) and past and present research analysts (Thomas Huang, Pritibha Singh and Mildred Lee). I personally undertook the analyses of the emerging cohort presented in this thesis with help and contributions from Mildred Lee (research analyst), Roger Marshall (biostatistician and co-supervisor), and Rod Jackson (supervisor).

Ethics approval

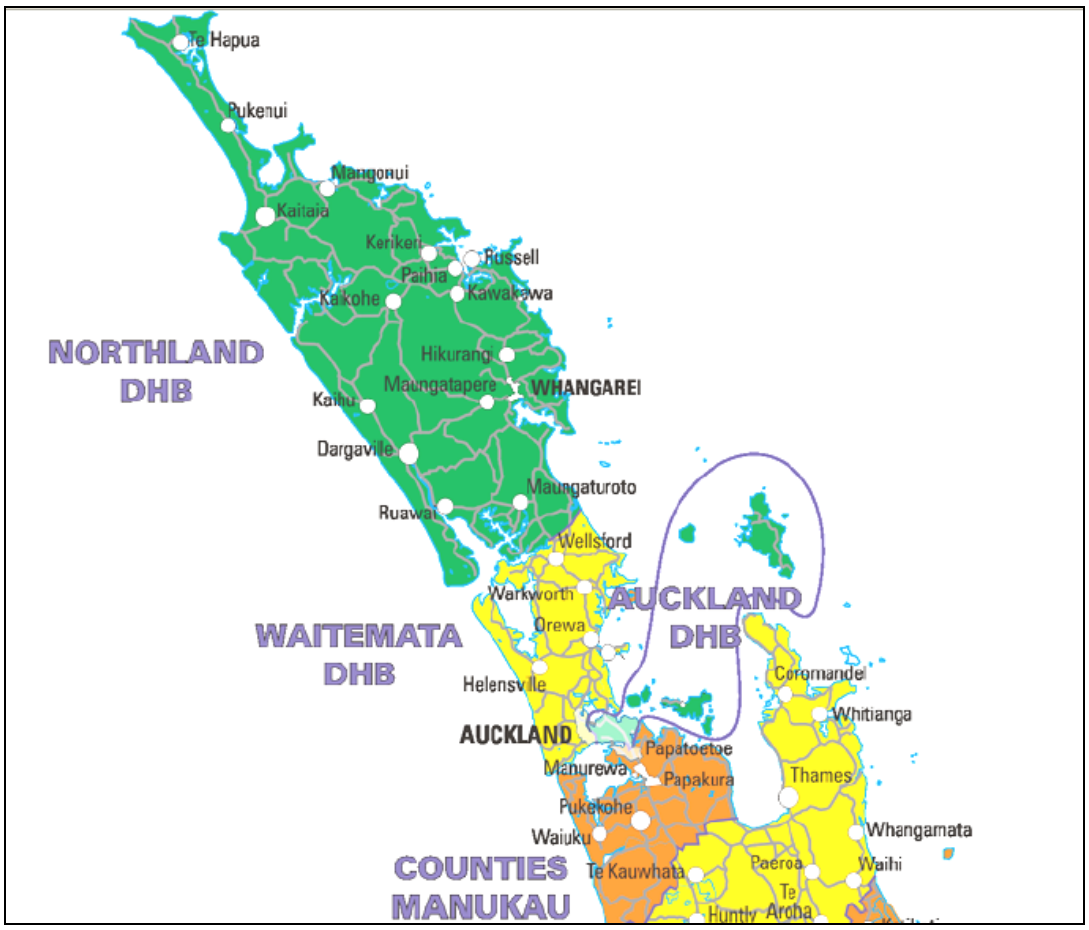
The cohort study and research processes were approved by Northern Region Ethics Committee Y in 2003 (AKY/03/12/314) with subsequent application and approval by the national Multi-Region Ethics Committee in 2007 (MEC/07/19/EXP).

8.3 Study setting

The study setting comprised the Auckland and Northland regions of New Zealand that constitute 37% of the total New Zealand population of 4,228,300 as at 30 June 2007.[281] The Greater Auckland Region has a population of 1,394,000 and is served by three District Health Boards, generally referred to as DHBs (Auckland, Waitemata and Counties Manukau DHBs) and 18 primary health organisations (PHOs). The Northland region has one DHB (Northland DHB) and a population of 153,800 served by six PHOs. The DHBs purchase the majority of health care in New Zealand and provide most of the secondary and tertiary health care services, while the PHOs provide almost all primary health care services.

It is envisaged that the PREDICT database could ultimately include the whole of the relevant New Zealand population. However, an incremental approach was taken. We initiated and developed the programme, including the software, clinical processes and training, in the Auckland region (within the three ProCare PHOs – the ProCare Network North, Auckland and Manukau in 2002 - and another Auckland PHO, HealthWest in 2005). Subsequently, PREDICT was implemented in Northland (within 5 of the 6 PHOs) during 2006-2007, to test the generalisability of the processes to other regions (Figure 8.1). The sixth PHO in Northland, Hauora Hokianga, chose not to use PREDICT as they only had dial-up internet access available rather than broadband web access.

Figure 8.1. Map of the Greater Auckland and Northland Regions by District Health Board and indicating regional townships[282]



There was a small team, Dr Tania Riddell (TR), Prof Rod Jackson (RJ), Dr Andrew Kerr (AK) and myself (SW) involved in PHO recruitment and in providing subsequent support during implementation (and on-going). In 2007, the three Greater Auckland Region DHBs (Auckland, Waitemata and Counties Manukau) purchased the licence for PREDICT on behalf of all their PHOs and PREDICT implementation was offered to these fourteen additional PHOs. These are listed with their enrolled populations in Table 8.1, although not all had started using PREDICT at the time of writing this thesis. The total PHO enrolled populations represents 97% of the expected population in Northland and Greater Auckland Regions. The PHOs vary substantially in size and cover urban and rural areas. Some primarily serve urban Māori (e.g. Waiora Health care Trust) or people of Pacific Island ethnicity (e.g. TaPasefika PHO). Some PHOs have a large number of practices within a relatively small but densely populated geographic area (e.g. ProCare Network Auckland on the Auckland isthmus) or multiple practices spread over a large,

sparsely populated region (e.g. Te Tai Tokerau in the far North of New Zealand extends from Paihia to Te Hapua). Other PHOs have only one group general practice, although these typically provide care for a rural township and surrounding local territorial authority area (e.g. Tihewa Mauriora in Kaikohe, Kaipara Care in Dargaville). The total enrolled population of the PHOs using PREDICT between 2002 and 2006 was 925,676, representing 62% of the total Greater Auckland and Northland enrolled populations.

Table 8.1. PHO-enrolled populations within the four northern district health boards (grey shading indicates PHOs that started using PREDICT from 2002–2006)

District Health Board	Primary Health Organisation (PHO)	Enrolled pop*
Northland	Hauora Hokianga Integrated PHO	6,237
	Kaipara Care Incorporated	11,412
	Manaia Health PHO	79,166
	Te Tai Tokerau PHO Ltd	42,411
	Tihewa Mauriora Charitable Trust	8,457
	Whangaroa Primary Health Organisation	3,225
Waitemata	Coast to Coast PHO (North Rodney)	13,880
	Harbour Health	149,853
	HealthWest	131,764
	Procare Network North Ltd	100,079
	Te Puna PHO	11,349
	Waiora Health care Trust	27,808
Auckland	Auckland PHO Ltd	43,685
	AuckPAC Health Trust Board	37,954
	Langimalie Health Clinic Tongan Health Society	4,927
	Procare Network Auckland Ltd	304,985
	Tamaki Health care Charitable Trust	44,702
Counties Manukau	East Health Services	76,847
	Mangere Community Health Trust	10,106
	Peoples Health care Trust	5,379
	Procare Network Manukau	244,177
	TaPasefika (TaPasefika Health Trust))	22,509
	Te Kupenga O Hoturoa Charitable Trust	34,912
	Otara (Total Health care Otara)	80,124
Total		**1,495,948**

* April 2006 enrolled population sizes from Ministry of Health. [283]

8.4 Eligible population for the PREDICT Cohort study

Each PHO determined the scope of intended CVD programmes of care and funding (if any) for their practices to use the PREDICT tool. Programmes of care have mainly been opportunistic CVD risk assessment and management. As described in Chapter 5, the criteria for risk assessment used in PREDICT pre-2004 were developed from a relatively limited national consensus and from 2004 onwards from the more comprehensive 2003 (December) NZGG CVD risk assessment and management guidelines. The 2003 NZGG criteria for risk assessment were: all men from age 45 years, all women from 55 years and 10 years earlier for Māori, Pacific or South Asian ethnicity or for people who had known CVD risk factors (as defined in Figure 5.2).

The eligible population for the PREDICT cohort study was all patients for whom a PREDICT assessment was completed and submitted to the PREDICT server, who had a valid NHI number and for whom their primary care organisation had given consent for use of anonymised patient data generated during routine care. A person could be assessed using PREDICT at baseline and also at a later date (follow-up assessment). Furthermore, a patient could be assessed by different clinicians within one PHO or across different PHOs or in the community. Several PHOs used the programme for outreach screening in the community (e.g. rugby games, fishing competitions) and workplace assessments. However, each patient has a unique encrypted NHI number which is the same whenever, or wherever the assessment occurred. Similarly each doctor or nurse has their own unique Nursing or Medical Council Number.

8.4.1 Study population

CVD Risk Assessment Greater Auckland and Northland Regions

In 2005, using data from a previous population-based survey,[55] we estimated that at least 72% of people 35 years and over in New Zealand would meet national criteria for a formal CVD risk assessment (Publication provided in Appendix 10).[284] This was based on the NZGG CVD risk guideline age, gender and ethnicity criteria and the proportion of European male smokers aged between 35–45 years and European female smokers

aged 45–55 years. Population prevalence of CVD and CVD risk for the usually resident population 35 years and over for the whole of New Zealand and by District Health Board were also estimated.[284] The total population 35 years and over for the Greater Auckland and Northland Regions projected to 2005 was 731,400, with around 526,600 eligible for CVD risk assessment (Table 8.2).

Table 8.2. Population 35 years and over in the Greater Auckland and Northland DHBs in 2005

District Health Board	Estimated 2005* population (N)
Northland	81,000
Waitemata	248,800
Auckland	202,100
Counties Manukau	199,500
Total	**731,400**
72% eligible for CVD risk assessment	526,608

*From Wells et al. (2006).[284]

Eligible population for CVD Risk assessment in the PHOs using PREDICT between 2002 and 2006

Using our early-adopting PHOs as the denominator study population and PHO enrolment data from the Ministry of Health website,[283] the total estimated enrolled population over 35 years of age was 477,651 (Table 8.3). Approximately 343,900 of these people (72%) would be eligible for CVD risk assessment.

Table 8.3. Estimated population aged over 35 years in the PHOs using PREDICT between 2002-2006

PHO	Estimated population over 35 years (N)
HealthWest	63,877
Kaipara Care Incorporated	6,196
Manaia Health PHO Limited	42,325
Procare Network Auckland Limited	163,763
Procare Network Manukau Limited	117,578
Procare Network North Limited	55,666
Te Tai Tokerau PHO Ltd	22,718
Tihewa Mauriora Charitable Trust	3,786
Whangaroa PHO	1,742
Total	**477,651**
72% eligible for risk assessment	343,908

8.5 Recruitment of participants into the PREDICT cohort

The focus of recruitment was at the PHO level rather than individual clinicians or patients. PHOs determined whether their organisation would support the implementation of PREDICT and the type of clinical programme implemented. If they chose to adopt PREDICT, then members of the University of Auckland research team (SW/RJ/AK/TR) provided continuing medical and nursing education (CME and CNE) and other presentations and support. In addition, patient information and practice posters about PREDICT were distributed, as approved by the research ethics committee (see Appendix 8.1). These materials were designed for the practice waiting rooms to raise

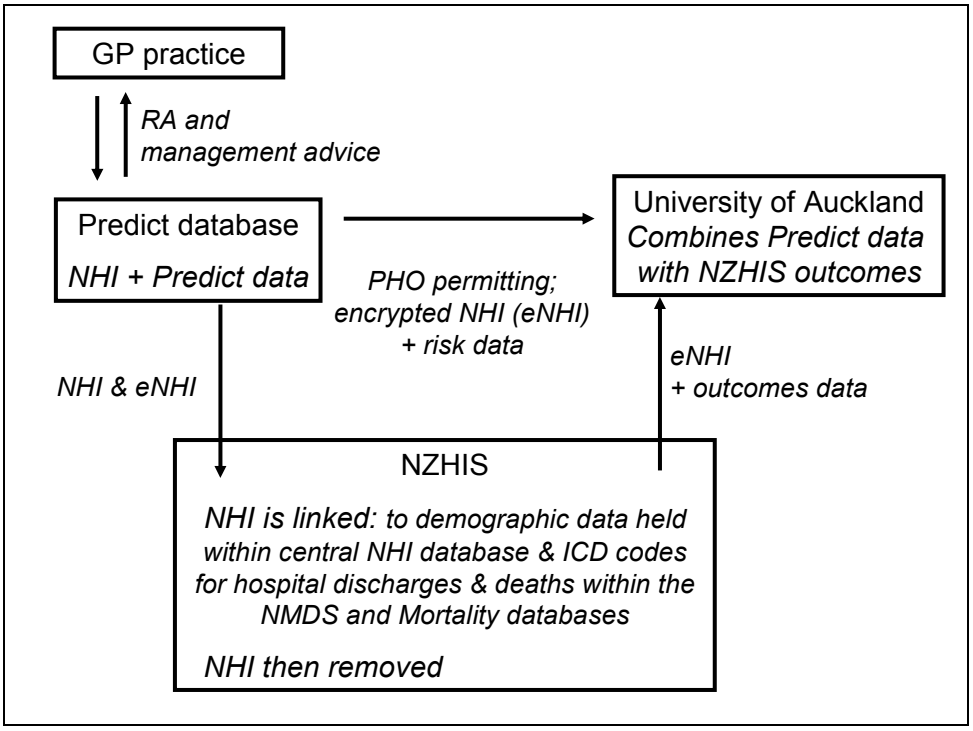
patient awareness of the importance of CVD risk assessment and management and the availability of a web-based software programme to support care. They also advised patients that a copy of their CVD risk data would be transferred to the PREDICT database but that the data would be unidentifiable by anyone other than authorised health professionals involved in their care and that their anonymised information would be used for cardiovascular disease research in New Zealand.

The use of PREDICT as a clinical tool and participation in the research were deliberately separated. Each PHO was approached by the research team (SW/TR) for formal written permission to include anonymised patient data generated by their member clinicians in the PREDICT cohort. Individual PHOs (or even individual GP practices within a PHO) using PREDICT could choose not to participate in PREDICT research but still use the PREDICT software. So far, all PHOs who have been approached have agreed to participate and no GP or individual patient has chosen to opt out of the cohort study.

8.6 Exposure (risk factor) data and linkage to NZHIS

Whenever PREDICT is used, an electronic CVD risk factor profile is stored anonymously for each patient within PREDICT host servers held by Enigma Publishing Ltd in Albany and within CMDHB Health IT Network in South Auckland. Details of data security are in Appendix 5.6. With PHO permission, risk profile data linked to an encrypted NHI (eNHI) are made available to the University of Auckland research team, who receive the data in batches about every 6 months (Figure 8.2). These risk profile data are processed to ensure completeness and accuracy using a variety of standard data management processes. Approximately twice a year since 2003, the New Zealand Health Information Service (NZHIS) has been asked to retrieve a list of the NHIs and the associated eNHIs from the PREDICT server via a password-protected website. The list includes only those NHI/eNHI for whom each PHO has given permission. No clinical data are released. NZHIS then links demographic data (date of birth, gender, area of residence and ethnicity) held within the central NHI database and also links all ICD codes for hospital discharges and deaths among these PREDICT participants from the National Minimum Dataset and mortality data sets. They then strip off the actual NHI and send an electronic file to the University of Auckland that contains these data linked with the eNHI.

Figure 8.2. Data linkage process with encrypted NHI



The PREDICT templates used for collecting exposure data at baseline and follow-up assessments along with data definitions have been described in Chapter 5 and are provided in Appendices 5.3–5.5.

CVD risk assessment

From the data in the PREDICT templates, we identified participants who had had a previous CVD event or diabetes with nephropathy or who had a diagnosed genetic lipid disorder of the sub-types familial hypercholesterolaemia, familial defective ApoB or familial combined dyslipidaemia. Following NZGG guidelines, these people were classified as being clinically at high risk (estimated ≥ 20% 5 year CVD risk) without using the risk score calculator.

For all other participants, we calculated their baseline 5 year CVD risk using the original and the NZGG-modified Framingham scores. The calculations of the Framingham 5-year CVD risk score and the NZGG-adjusted score are shown in Appendix 5.1. As the first version of PREDICT, used in ProCare until early 2006, was developed prior to the publication of the December 2003 NZGG guidelines, data on some NZGG

recommended risk adjustment groups (related to metabolic syndrome and diabetes risk) were not available for all the cohort analyses presented in this thesis.

Following the estimation of the risk scores, all participants were categorised by their 5-year predicted risk of a CVD event: <5%, 5–<10%, 10–<15%, 15–<20%, ≥20% using both the Framingham score and the NZGG-adjusted Framingham score.

8.7 Accrual of person-time of follow-up

The date and time of each PREDICT submission is recorded and stored with each risk profile. The first completed CVD risk assessment template was defined as the baseline measure. For many patients (see Results chapter) a management template was completed simultaneously and these data were included in the baseline information. The date of the baseline assessment was the start date for providing person-time of follow-up in the study. The follow-up time is the time from the date of first assessment until the date of the first CVD event (hospitalisation or death) or until the date when NZHIS searched the National Minimum or Mortality datasets. Participants were assumed to have been event-free over the follow-up period if there was no record of a hospitalisation or death. Reassessments of risk using PREDICT during the follow-up period are recommended for patients initiated on treatment and for most people after five years. These reassessment data were not used in the current analyses as they were not conducted systematically on all participants.

8.8 Cohort study outcome measures

The primary outcomes of this cohort study include hospitalisations (for an event or procedure) and deaths due to cardiovascular disease as recorded in the NZHIS National Minimum Dataset and Mortality datasets using International Classification of Disease (ICD) codes, as shown in Table 8.4 below. CHD outcomes included all fatal and non-fatal acute coronary syndromes, myocardial infarction, sudden cardiac death and coronary artery procedures (percoronary interventions and bypass grafting). Ischaemic cerebrovascular disease outcomes included all fatal and non-fatal ischaemic stroke,

transient ischaemic attack and other cerebrovascular manifestation of atherosclerosis such as cerebral aneurysm or dissection. Peripheral vascular disease (PVD) outcomes included fatal and non-fatal coded PVD and peripheral arterial surgical procedures. Other primary CVD outcomes included congestive heart failure and haemorrhagic stroke that were included for validation analyses of the Framingham prediction equation.[25]

Table 8.4. Outcomes for PREDICT cohort study and corresponding ICD-10-AM codes

Outcomes	ICD-10-AM codes
Ischaemic cardiovascular events	
Coronary heart disease	I20–I25 (except I252) E1053, E1153, E1453
Cardiac arrest or sudden cardiac death	I461, R96, R98
Coronary procedures	3530400–3530501, 3531000–531005 3849700–3850304, 9020100–9020103 3863700, 3845619, 3865308, 3850500
Ischaemic cerebrovascular disease	I63, I64, I66, I678, I693, I694, I698 G45 (except G453), G46, I670, I671
Peripheral arterial disease	I65, I71, I72, I74, I739, I7021, I7022, I7023, I7024
Peripheral procedures	330–331, 3270000–3276318, 3350000–3355400, 3380000–3380612, 3531200–3531501, 3855000–3857101, 3857200, 3870600, 3870601, 3871200, 9023000, 9022900
Other primary outcomes included for Framingham score validation	
Congestive heart failure	I50
Haemorrhagic stroke	160–162, I690, I691, I692

8.9 Projected participant numbers in the PREDICT cohort

PREDICT cohort participants are recruited as a planned but secondary outcome of a clinical consultation in routine primary care practice, so it was not possible to control recruitment numbers. Nevertheless, it was conservatively estimated that about 50 new doctors and nurses would start using PREDICT each year from August 2002, so that by July 2008 there would be 300 clinicians using the programme. It was further estimated that if a doctor or nurse conducted a risk assessment every second day of the working week for 40 weeks a year (i.e. approximately 120 patients/year) then by July 2008, there would be approximately 84,000 patient risk profiles in the cohort study. This assumed a

constant rate of risk assessment for each clinician over the years and that all PHOs agree to their data being used for these purposes. In addition, Māori make up approximately 10% of the New Zealand population over 35 years[285] so if Māori are selected at the same rate as non-Māori as indicated from the PREDICT-CVD evaluation study,[286] we would expect to have approximately 8,400 Māori risk profiles by July 2008.

Looking further ahead, by July 2010, it is expected that approximately 450 clinicians will be using PREDICT routinely and that 200,000 risk assessments will have been completed (including almost 20,000 Māori assessments). Of note, over time, an increasing number of risk assessments will be follow-up assessments, but in the short-term the majority will be first assessments.

8.10 Data management and analysis

The data for these analyses included all assessments from August 2002 until February 2008 from eight out of the nine PHOs who adopted the programme between 2002 and 2006. These were the 3 PHOs within the ProCare Network, plus HealthWest, Te Tai Tokerau, Manaia, Kaipara Care and Tihewa Mauriora. The ninth PHO, Whangaroa PHO has recently given permission for use of their anonymised patient data (in July 2008) but this was too late to include their data in these analyses.

CVD data from the consenting PHOs were received as four unique datasets:

1. PREDICT-CVD dataset from the three ProCare PHOs combined as the ProCare Network (i.e. the first PREDICT CDSS)

2. the updated PREDICT CVD-Diabetes dataset from the ProCare Network

3. PREDICT CVD-Diabetes dataset from HealthWest PHO

4. PREDICT CVD-Diabetes dataset from the five Northland PHOs combined.

Each dataset was checked and cleaned and a baseline record and any follow-up records for each unique participant (by eNHI) were identified. For the three PHOs within the

ProCare Network who had used both PREDICT CVD (2002–2006) and PREDICT CVD-Diabetes (2006 to present), datasets needed to be checked and cleaned and merged, as many participants within the PREDICT CVD-Diabetes database also had earlier (baseline) assessments using PREDICT-CVD.

Following this data cleaning process, the data were merged by encrypted NHI (eNHI), to combine all data into one dataset sorted by the baseline assessment for each participant.

Matching PREDICT data with NZHIS NHI data

The demographic data and eNHI held in the PREDICT primary care record was then matched to the eNHI, date of birth, gender and ethnicity from the central NZHIS repository. It was recognised that neither the primary care data collected within PREDICT nor the NZHIS-NHI datasets were 'gold standards', each undergoing a continuous quality improvement process. In terms of the NZHIS-NHI dataset, the data held is supposed to be checked and able to be updated at each and every hospital admission or when patients formally enrol with a PHO. Should a patient change PHO, the enrolment process would be repeated, with an opportunity to update the NZHIS-NHI database. The national NZHIS-NHI dataset has been present for many years and has been subject to multiple audits and other opportunities to improve data quality. The first national register was the National Master Patient Index, implemented in 1977. This was replaced with the NHI in 1993.[287] In 2003, there was an intensive NHI duplicate resolution programme, identifying and linking duplicates. More than 125,000 duplicate NHI numbers were identified and resolved during this period. This process has continued with the NZHIS conducting daily computerised audits to identify further duplicates.[287]

In contrast to the NZHIS-NHI demographic data, while GPs personally know individual patients over many years, demographic data are normally entered in the patient medical record by the receptionist, practice manager or practice nurse.[288] In recent years, the emphasis has been on full electronic recording of age/gender/ethnicity/NHI fields for capitation purposes.[289] Audits of the accuracy of socio-demographic details in the patient register are rare.[289] A PREDICT validation sub-study was the first study in New Zealand to compare patient ethnicity data in general practice with patient self-identified

ethnicity.[290] The authors found that ethnicity recorded in the primary care record and from a patient questionnaire was identical for 68% of respondents at NZHIS Level 2 coding (defined in Appendix 5.2). However, the clinical impact of this misclassification on subsequent CVD risk assessment and management was minimal because most of the misclassification occurred between Māori, Pacific and South Asian ethnic groups that are all classified as being at high risk.[290] A further PREDICT validation sub-study found that while the agreement between NHI ethnicity and PREDICT recorded ethnicity was reasonably good (kappa score 0.82), the discordances did have a significant effect on ethnic-specific measures of hospital admission rates.[291] A decision was made to accept the nationally held demographic data in preference to the PREDICT primary care demographic data where there were discrepancies with matching.

Rules of Matching

Acceptance of matching was based on paired eNHI (PREDICT and NZHIS), a patient's date of birth (dd/mm/yyyy), gender and ethnicity. If all these parameters were the same in both PREDICT and NZHIS data, they were deemed 'true matches'. If there were discrepancies such as a day-month flip between PREDICT and NHI date of birth but the year was the same, then NZHIS date of birth was taken as the "true" date of birth. This and other rules of matching are provided in Appendix 8.2. Where ethnicity did not match, the ethnicity recorded on the NZHIS-NHI was accepted as the agreed ethnicity. The only exception to taking the NZHIS NHI data in preference to PREDICT data was where the ethnicity was not stated on the central repository but available in PREDICT. If non-matching eNHI did not meet the criteria, they were excluded from analyses.

Multiple admissions to hospital

Only the first CVD-related hospitalisation after a participant's entry into the PREDICT cohort were used for the risk score validation analyses reported in this thesis. Subsequent CVD-related admissions were considered new events when they occurred more than 28-days after the first and each subsequent admission. This definition of new events meant that hospital transfers and rehabilitation admissions occurring within a month of an event did not need to be counted. If a patient died within 28 days of the initial admission then the fatal event took precedence over the hospital admission.

However, if a death occurred after this time frame during the follow-up period, only the first admission would be used in the risk score validation analyses.

Mortality data

Mortality data from 2002–2005 were used in the cohort analyses if the underlying coded cause of death included any of the outcomes listed in Table 8.4 as the primary cause. Data on more recent deaths (2006–2007) were made available by NZHIS. These were not ICD coded but data on the causes of death were provided in a text form. For these death data, relevant CVD fields were identified by a computer algorithm and PREDICT research team members (SW and TR) independently coded each patient. For any discrepancies with outcome coding, an agreement was reached by consensus.

8.11 Statistical analysis

Analyses were conducted using SAS Version 9.1 (SAS Institute, Inc, Cary, NC). Framingham and NZGG adjusted Framingham score calibration and threshold discrimination graphs were developed using Microsoft Excel functions.

Baseline Data

Sociodemographic, CVD history and CVD risk profiles of the study population were summarised as proportions for categorical factors and as means and standard deviations (SDs) for continuous measures. Chi-square tests were used to compare differences between groups for categorical variables. The proportions of the cohort in CVD risk categories by age group and gender were applied to the 2006 New Zealand population over the age of 35 years in order to compare with other population-based prevalence estimates.

Incidence rates (IRs) of first CVD event during follow-up

Crude overall incidence rates and rates by exposure category were calculated by dividing the number of first CVD events by the person-years of follow-up. The person-years in the study is the sum of person-time from date of first risk assessment

(submission of PREDICT template) until date of first CVD event (hospitalisation or death) and otherwise until the date of extract with NZHIS data.

Confidence intervals were calculated assuming a Poisson distribution according to the following formula:

$$\mathrm{IR} \pm 1.96\sqrt{\frac{\mathrm{IR}}{\mathrm{PT}}}$$

where the IR represents the estimated incidence rate and PT represents the sum of person-time.

Direct age-standardised IRs were calculated using the Segi World Population[292] according to the formula below to account for differences in population age structure between strata and to compare groups over time as the PREDICT cohort increased in size. IRs are expressed as the number of events per 1000 person years of time in the study.

Age standardised $\mathrm{IR} = \dfrac{\sum_i w_i \mathrm{IR}_i}{\sum_i w_i}$

Where w_i is the weight for stratum *i* is taken from the Segi World population.

Ninety-five per cent confidence intervals were calculated assuming events have a Poisson distribution and the mean crude incidence rate equals the variance. The formula for the confidence interval was derived from Rothman and Greenland Modern Epidemiology (2nd Edition) page 263.[161]

Age standardised Relative Risks were also calculated by dividing one stratum (the reference category) by each of the other exposure group categories. The formula for the 95% confidence intervals for the age-standardised relative risks were also derived from Rothman and Greenland Modern Epidemiology (2nd Edition) page 263.[161]

Calibration measures of risk prediction scores

Calibration measures how well the average predicted risk of a group of participants in a specified risk category (determined by a risk score) agrees with the observed risk in that group (determined from the actual events that occurred during follow-up). Calibration was examined by plotting the mean 5-year predicted risk according to the Framingham and NZGG-adjusted CVD 5-year risk score categories (<5%, 5–<10%, 10–<15%, 15–<20% and 20+%) against the observed cumulative incidence of a CVD event extrapolated to 5 years using Excel functions. The cumulative incidence was estimated by the cumulative distribution function:

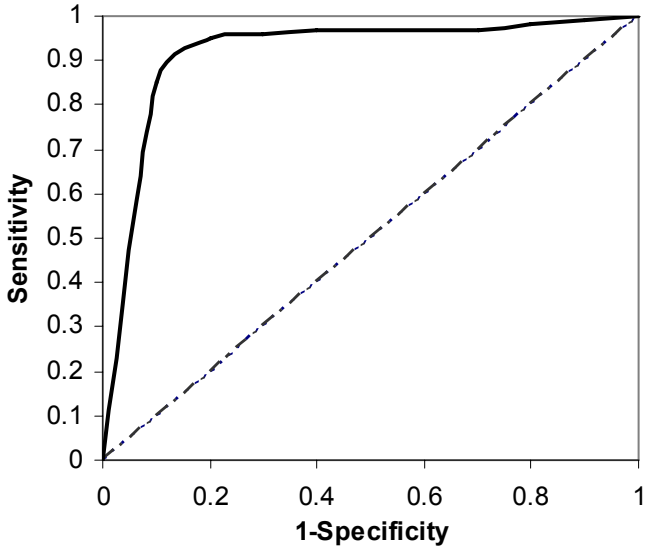
$$\text{Cumulative incidence} = 1 - e^{-IRT}$$

where IR is the incidence rate and T is the assigned period of time (5-years). This method allows the extrapolation, beyond the time set by the limited follow-up. Calibration was described by the degree to which observed event rates were over- or under-predicted in the different predicted risk categories.

Discrimination measures of risk prediction scores

The performance of a risk prediction equation can also be assessed by its ability to discriminate between those people who will have an event (i.e. true positive – equivalent to the sensitivity of a positive diagnostic test result) or will not have an event (true negative – equivalent to the specificity of a negative diagnostic test result) during a defined follow-up period. Discrimination is typically assessed by the area under the curve (AUC) of a receiver operator characteristic (ROC) curve. An example of an ROC curve has been drawn below (Figure 8.3).

Figure 8.3. Example of an ROC curve



The diagonal (straight) broken line from bottom left to top right represents the line of no value, when there is a 50:50 chance of a classification of a patient as having or not having an event during follow-up. Each point on the solid curved line represents the degree of discrimination (sensitivity / 1-specificity) at that point in the distribution of a continuous CVD risk factor or risk score. Perfect discrimination would be achieved if the score of every case was higher than for every non-case.[293] In this ideal scenario the area under the curve (AUC) would be 1, which is the probability that the predicted risk is higher for a case than a non-case.[294] Therefore the AUC measures how well models rank order cases and non-cases[293] (or those that subsequently have a CVD event compared to those who do not).

Receiver operator curves were generated using the SAS proc logistic function where the first event is the dependent variable and the exposure of interest (e.g. Framingham risk) is the independent variable and then the proc gplot function was used to graph the sensitivity curve. AUC values were compared for different risk prediction models (Framingham and NZGG modified Framingham) and for separate risk factors (age, SBP, TC/HDL and NZ Dep Index). The model treated the deciles of the NZ Dep Index as if they were part of a continuous variable.

Threshold discrimination

An analysis was undertaken to assess discrimination at specific risk levels defined by national guidelines as thresholds for determining management recommendations. A weakness of rank-based measures such as the AUC is that they do not account for the distribution of risk in a population (e.g. a small proportion at high risk and majority at low risk).[293] As Cook (2007) writes, "….*differences between 2 individuals who are at very low risk (e.g. 1.0% versus 1.1%) have the same impact on the c statistic (sic AUC score) as 2 individuals who are at moderate versus high risk (e.g. 5% versus 20%) if their differences in rank are the same."* Clinically it is more important to discriminate between people above and below treatment thresholds than between people within a particular risk category, as treatment decisions are based on risk thresholds.[293] For example, the NZGG CVD risk guidelines recommend a specific lifestyle and dietary assessment for those over 10% 5-year CVD risk and drug therapy above 15%. Therefore the most significant clinical- (and policy-) relevant information about the accuracy of a risk prediction score are estimates of the proportions of a target population in risk categories eligible for specified management and the associated proportion of all CVD events in the target population that occur in people in these risk categories.

8.12 Conclusion

This chapter has described the methods of a large cohort study designed as the core of a long-term continuously developing research programme for studying the New Zealand population targeted for CVD risk assessment and management. Participation in the PREDICT cohort is a planned 'by-product' of a clinical decision to risk assess a patient in routine primary care practice. While it is not possible to control the recruitment process, it has been possible to control the quality and completeness of the data entry process by providing user-friendly electronic templates that produce immediate clinically-relevant advice when completed correctly. It is possible to effectively and efficiently identify all subsequent major CVD deaths and hospital events (occurring in public hospitals) for each participant via their NHI number.

9 Results of the PREDICT Cohort Study

9.1 Introduction

This chapter presents the baseline characteristics of the PREDICT cohort, the results of linking the first 48,306 participants in the cohort to national hospitalisation and mortality datasets, plus preliminary analyses validating the New Zealand Guidelines Group (NZGG) CVD risk prediction score and the original Framingham equation from which the NZGG score was derived. The analyses presented here are intended to demonstrate the potential use of PREDICT for cardiovascular epidemiological research rather than to provide definitive findings. PREDICT is an ongoing programme of research with 2–3,000 new participants added monthly and regular new linkages to hospitalisations and deaths. At this stage of the PREDICT programme, follow-up time is relatively short and it will be several years before new CVD prediction scores, for estimating 5 year risk, can be developed.

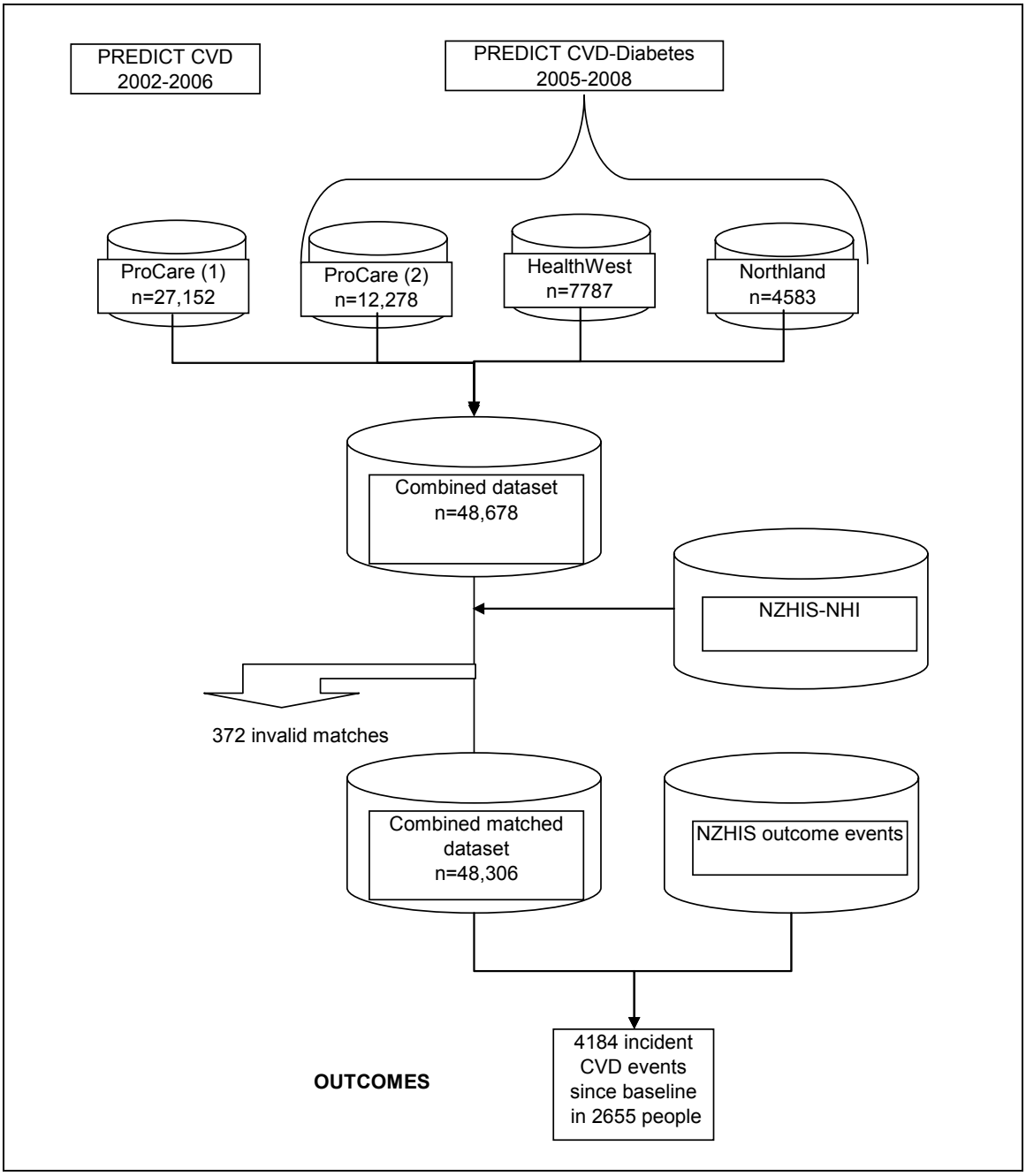
Following a brief overview describing the data sources and study numbers the key results are presented in three main sections:

- baseline characteristics
- follow-up time and CVD events and
- the performance of the Framingham and NZGG-adjusted Framingham scores.

9.1.1 Overview

The PREDICT data flow process including the extraction of the data to form a combined dataset, matching with the encrypted NZHIS-NHI dataset and linkage of the incident CVD outcome events to the PREDICT participants using the encrypted NHI is shown in Figure 9.1. Note: the five contributing PHOs in Northland have been aggregated because of their individual smaller contribution.

Figure 9.1. Overview of participant numbers (by PHO source and PREDICT tool) matching by NZHIS and subsequent CVD outcomes.



ProCare implemented the full PREDICT risk assessment and risk management decision support in 2002 as an opportunistic screening programme in routine primary care practice and has contributed 75% of all cohort participants. The first 27,152 participants from ProCare (ProCare (1) in Table 9.1) were assessed using the first version of the CDSS, PREDICT CVD, while the subsequent 12,278 ProCare participants (ProCare (2))

and all participants from HealthWest and Northland were assessed using the updated PREDICT CVD-Diabetes.

In 2005, HealthWest (16% of the cohort) implemented the CVD risk assessment component of PREDICT CVD-Diabetes as a screening programme both in practices and using a community outreach screening bus. The screening was targeted to Māori and Pacific patients and those located in census unit areas of NZDep decile 5 or higher (i.e. the most deprived). HealthWest subsequently sponsored the full version of PREDICT CVD-Diabetes (risk assessment and management decision support) for opportunistic screening in routine practice in 2007.

The Northland PHOs (9% of the cohort) had the full PREDICT CVD-Diabetes programme for opportunistic screening and management from 2006.

Assessments, participants, practitioners, follow-up

Table 9.1 describes numbers of patients and assessments by data source and in the combined datasets. From August 2002 until February 2008 there were 62,999 assessments conducted on 48,306 individual patients by a total of 775 GPs and 235 nurses. Twenty-seven doctors or nurses submitted assessments from different PHO sources (i.e. moved to practices affiliated to other PHOs). Of all the assessments, 86% were conducted by doctors and 14% conducted by nurses.

There were 3516 patients with 3530 assessments who had an initial PREDICT CVD submission and then had a further assessment with PREDICT CVD-Diabetes. For these participants, only the first assessment was used in the analyses of baseline data. Numbers are given so that the total number of baseline assessments (B) plus the total number of follow-up assessments (F) equals the total number of assessments (A).

Table 9.1. PREDICT cohort: numbers of assessments, health practitioners and participants

Dataset	Total assess-ments (A)	Practitioners completing assessments (GPs / Nurses)	Participants with baseline assessment (B)	Total follow-up assessments (F)	Participants with follow-up assessments
ProCare 1 PREDICT CVD	34,346	768 (601 / 167)	27,152	7,194	5,178
ProCare 2 CVD Diabetes	13,750		12,278	1,022	929
HealthWest CVD Diabetes	10,197	113 (81 / 32)	7,787	2,410	1,794
Combined Northland PHOs CVD Diabetes	5,246	156 (111 / 45)	4,583	663	589
All Combined*	63,473	1010 (775 / 235)	48,678	11,265 (+3530)	8,350 (+3516)
All Combined with NHI match	62,999	1010 (775 / 235)	48,306	11,187 (+3506)	8,295 (+3492)

* the numbers in brackets in the two right hand columns relate to the participants who had their first assessments using PREDICT-CVD and subsequent assessments using PREDICT-CVD Diabetes (discussed in the text)

9.2 Baseline characteristics of cohort

9.2 1 Demographic profile of patients and type of data template submitted

Table 9.2 describes the baseline demographic profile of the patients by PHO data source, age, gender, ethnicity and New Zealand Deprivation Index (NZDep) quintile. The table also indicates whether the basic risk assessment template was completed or if both risk assessment and management templates were submitted to the PREDICT server. 'Risk assessment only' refers to completion of only the risk assessment template (see PREDICT-CVD risk assessment template or Template 1 and 2 of PREDICT CVD-Diabetes Appendix 5.3). 'Risk assessment and management' refers to the additional completion of the management template/s (see PREDICT-CVD risk management template or Template 3 and 4 of PREDICT CVD-Diabetes Appendix 5.3).

Overall 64% of the submissions were for the basic risk assessment only (PREDICT generates only the NZGG-adjusted Framingham score and colour chart position from the basic assessment template) while the remainder were risk assessment and management submissions (PREDICT generates both the NZGG score, colour chart and guideline management advice when both templates are completed). The majority of submissions made by doctors were for 'risk assessment only' (64%). In contrast, the majority of nurse submissions (63%) were for both risk assessment and management.

Table 9.2. Baseline demographic profile of PREDICT cohort participants by data template submitted (risk assessment only or risk assessment and management)

	All Participants		Risk Assessment only		Risk assessment and management	
	N	Col %	N	Row %	N	Row %
All	48306	100	30901	64	17405	36
Data source						
ProCare	36090	75	22436	62	13654	38
HealthWest	7694	16	6371	83	1323	17
Northland PHOs	4522	9	2094	46	2428	54
Age						
<30	401	1	258	64	143	36
30–34	890	2	556	62	334	38
35–44	7086	15	4695	66	2391	34
45–54	14243	29	9157	64	5086	36
55–64	14092	29	8843	63	5249	37
65–74	8078	17	5085	63	2993	37
75+	3516	7	2307	66	1209	34
Gender						
Men	26720	55	16698	62	10022	38
Women	21586	45	14203	66	7383	34
Ethnicity						
European	23327	48	14638	63	8689	37
Māori	6945	14	4496	65	2449	35
Pacific	8215	17	5652	64	2563	36
South Asian	1567	3	932	63	635	37
Other Asian	1575	3	1005	69	570	31
Other	6677	14	4178	59	2499	41
NZDep Quintile						
Missing	119	0	77	65	42	35
NZDep 1–2	7110	15	4585	64	2525	36
NZDep 3–4	8101	17	5183	64	2918	36
NZDep 5–6	8508	18	5093	60	3415	40
NZDep 7–8	10872	23	7365	68	3507	32
NZDep 9–10	13596	28	8598	63	4998	37

Men accounted for 55% of the assessments. The mean age of the cohort was 55 years (standard deviation [sd]:12 years). On average women were 4 years older than men, their mean age (sd) was 58.1(11.9) years compared with 54.2 (11.9) years for men. The ages ranged from 17 to 101 years, the oldest man was 96 years of age with six women aged 95 or over. Of the patients assessed;

- about 3% were aged under 35 years
- about 1% were aged over 85 years

- 90% were aged between 35–74 years
- almost half were European, with 14% Māori and 17% Pacific
- almost 70% were in the more deprived deciles of deprivation (NZDep 5–10).

There were relatively minor differences by age, gender, ethnicity or social deprivation between participants who had a completed risk assessment template compared to those who had both risk assessment and management templates completed. However there were substantial differences by PHO which reflected the type of screening programme implemented in different PHOs.

9.2.2 Baseline profile by participant history and CVD risk characteristics

Table 9.3 shows the baseline profile of the participants by history of CVD, diabetes, diagnosed genetic lipid disorder, family history of premature ischaemic CVD, 5-year Framingham risk and 5-year NZGG-adjusted risk. Overall 12% of the cohort had diagnosed prior CVD, 18% had diabetes and 25% reported a family history of premature CVD at baseline.

As discussed above, 56% of the cohort were assessed using the first version of PREDICT (PREDICT CVD). This version did not record data on overt nephropathy or type of genetic lipid disorder, while PREDICT CVD-Diabetes did record these data. Of the 8542 people in the cohort with diabetes, 4729 (55%) had been assessed using PREDICT CVD-Diabetes. Of these participants, 304 (6.4%) were reported as having overt diabetic nephropathy.

With regard to diagnosed genetic lipid disorders (collected only in PREDICT CVD-Diabetes so reported missing on the 26,774 participants assessed using PREDICT CVD), there are three sub-types: familial hypercholesterolaemia, familial defective ApoB and familial combined dyslipidaemia. Participants with these sub-types are considered by the NZGG CVD risk guidelines to be ‘clinically at high risk’ (i.e. over 20% 5-year CVD risk) and a formal CVD risk calculation using the NZGG-adjusted Framingham score is

not required. Approximately 4% of the cohort on whom this variable was collected were reported to have one of these lipid disorders, with familial hypercholesterolaemia being the most common.

Table 9.3. Baseline CVD risk factors and predicted CVD risk of PREDICT cohort

	All Records (N=48,306)	
	N	Col %
*Prior CVD**		
No	42410	88
Yes	5896	12
Diabetes		
No	39764	82
Yes	8542	18
Diabetes & Renal disease		
Missing*	3813	45
None	3337	39
Microalbuminuria	1088	13
Overt diabetic nephropathy	221	2
Other nephropathy	83	1
Diagnosed genetic lipid disorder		
Missing*	26774	54
None	20351	42
Familial hypercholesterolaemia	769	24
Familial defective ApoB	6	0
Familial combined dyslipidaemia	94	0
Other genetic lipid disorder	312	1
Family history CVD		
No	36210	75
Yes	12096	25
*Framingham 5-yr risk***		
0–< 5%	21343	51
5–<10%	11369	27
10–<15%	5175	12
15–<20%	2259	5
20+%	1399	3
Missing	14	
*NZGG-adjusted Framingham***		
0–< 5%	9183	22
5–<10%	15551	37
10–<15%	7272	18
15–<20%	6872	17
20+%	2667	6
Missing	13	

*the data are missing because these variables were only collected using PREDICT CVD-Diabetes.

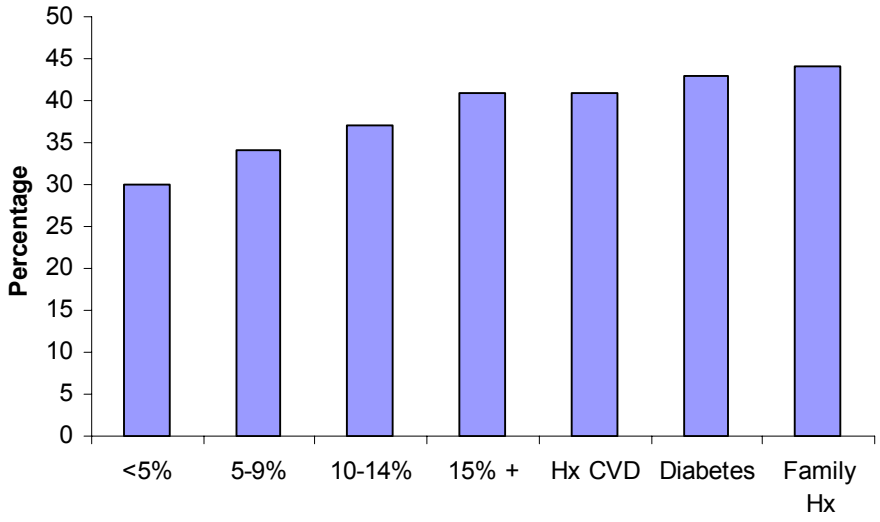
**Framingham risk groups exclude those with prior CVD, diabetes with nephropathy and diagnosed familial genetic lipid disorder

As with people with diagnosed genetic lipid disorders, NZGG CVD risk guidelines also classify patients with prior CVD or diabetes with nephropathy as being “clinically at high risk” or over 20% 5-year CVD risk, so a risk assessment using the NZGG-adjusted Framingham score is not required for these people.

After excluding these clinically high risk participants, the majority of the cohort (78%) were assessed as being at low risk (less than 10% 5-year CVD risk), 12% at moderate risk (10–14% 5-year CVD risk) and 8% at high risk (15+% 5-year CVD risk) according to the original Framingham score. However when using the NZGG-adjusted Framingham score, the distribution of risk shifted upwards with 59% at low risk, 18% at moderate risk and 23% at high risk.

Participants were slightly more likely to have the full risk assessment and management templates completed if they had prior CVD, diabetes, a family history of premature ischaemic CVD and with increasing calculated CVD risk (Figure 9.2).

Figure 9.2. The percentage of the PREDICT cohort with both risk assessment and management templates completed, categorised by % CVD risk, risk factors including diabetes and family history and history (Hx) of prior CVD



Participant characteristics by age and gender

Tables 9.4 and 9.5 describe the demographic characteristics and CVD risk factor prevalences for men and women by age group. Men were more likely to be risk assessed than women under the age of 65 years, but more women were risk assessed than men above age 65 years.

Diabetes prevalence increased gradually with age to 28% in men and 25% in women aged over 75 years. History of a previous CVD event also increased with age in both men and women. Above the age of 75 years, 42% men and 31% women reported a previous cardiovascular event, most commonly coronary heart disease (angina or myocardial infarction).

The reporting of a family history of CVD was highest in the youngest age category. In men, the reported prevalence dropped from 26% in the youngest age category to 13% in the oldest. A similar pattern was observed in women, with prevalence of 29% in the youngest age category and 18% in the oldest.

The overall prevalence of smoking was 16.3% (17.8% in men and 14.6% in women). Among women under 30 years, 24% were current smokers, which decreased with age to 6% in those over 75 years. For men, the highest prevalence of smoking was 23% reported in the 30–34 and 35–44 year age groups, decreasing to 7% in those over 75 years. Among both men and women, mean systolic blood pressure increased with age from 126 mmHg to 136 mmHg in men and from 120 mmHg to 140 mmHg in women.

For men, the mean total cholesterol:HDL ratio (TC/HDL) was 4.3 and decreased with age, while in women the mean TC/HDL was 3.7, also decreasing with increasing age. BMI measurements were available on 36% of participant records as it is only collected when the risk management template is used. The mean BMIs for men and women were 29.2 and 29.7, respectively; BMI also decreased with age.

Table 9.4. Male participant characteristics by age group

		Total Men	<30	30–34	35–44	45–54	55–64	65–74	75+
	N	26720	232	608	5005	8343	7187	3863	1482
Men % of cohort	%	55	58	68	71	59	51	48	42
Ethnicity	N	%	%	%	%	%	%	%	%
European	12369	46	35	42	34	43	50	56	68
Māori	3654	14	15	14	20	14	12	12	6
Pacific	4206	16	17	15	22	16	14	13	11
South Asian	978	4	9	8	6	4	2	2	2
Other Asian	788	3	5	4	3	3	3	2	2
Other	4725	18	19	18	16	20	19	15	11
NZ Dep Quintile (missing =71)									
NZDep 1–2	4259	16	16	14	15	17	17	14	12
NZDep 3–4	4537	17	15	19	17	18	17	16	16
NZDep 5–6	4845	18	15	19	18	18	18	20	17
NZDep 7–8	5786	22	25	25	23	21	21	22	23
NZDep 9–10	7222	27	29	24	27	27	26	27	32
History									
Any prior CVD	3497	13	1	2	3	8	14	28	42
Angina/MI	2551	10	0	1	2	6	10	20	30
PCI/CABG	1080	4	0	0	1	2	5	9	11
Stroke/TIA	831	3	0	1	1	1	3	7	13
PVD*	462	2	0	0	0	1	2	4	7
*Diagnosed GLD***									
None	10985	41	30	29	42	40	40	44	53
Fam hyperchol	392	1	1	2	1	1	2	1	1
Fam def ApoB	2	0	0	0	0	0	0	0	0
Fam combined	58	0	1	0	0	0	0	0	0
Other gld	170	1	0	0	0	1	1	1	1
Other Risk factors									
Family hx CVD	6342	24	26	29	29	27	22	17	13
Diabetes	4473	17	9	9	10	14	19	24	28
Smoking	4752	18	20	23	23	20	17	11	7
Mean(sd) SBP	26720	133 (17.7)	126 (15.6)	128 (15.4)	128 (16.0)	131 (17.0)	135 (18.1)	138 (18.2)	136 (19.1)
Mean(sd) DBP	26718	82 (10.9)	79 (10.8)	82 (11.1)	82 (11.3)	83 (11.0)	82 (10.6)	79 (10.0)	76 (10.0)
Mean(sd) TC/HDL	26714	4.3 (1.3)	4.6 (1.5)	5.1 (1.6)	4.7 (1.4)	4.4 (1.3)	4.1 (1.2)	3.9 (1.1)	3.6 (1.1)
Mean(sd) BMI**	9963	29.2 (5.6)	30.2 (7.1)	30.2 (6.3)	30.4 (6.4)	29.4 (5.8)	29.1 (5.2)	28.3 (4.8)	26.9 (4.4)

* peripheral vascular disease ** diagnosed genetic lipid disorder, familial hypercholesterolaemia, familial defective ApoB, familial combined dyslipidaemia and other genetic lipid disorders

Table 9.5. Female participant characteristics by age

		All Women	**<30**	**30–34**	**35–44**	**45–54**	**55–64**	**65–74**	**75+**
	N	21586	169	282	2081	5900	6905	4215	2034
Women % cohort	%	45	42	32	30	41	49	52	58
Ethnicity	*N*	*%*	*%*	*%*	*%*	*%*	*%*	*%*	*%*
European	10958	51	47	44	42	40	55	55	67
Māori	3291	15	21	16	19	21	13	12	8
Pacific	4009	19	15	20	22	23	17	16	11
South Asian	589	3	7	6	5	4	2	2	1
Other Asian	787	4	6	4	5	5	3	3	2
Other	1952	9	4	10	6	7	9	12	11
NZ Dep Quintile (missing=48)									
NZDep 1–2	2851	13	11	12	13	12	15	14	13
NZDep 3–4	3564	17	15	18	17	17	17	15	16
NZDep 5–6	3663	17	11	21	17	16	17	19	15
NZDep 7–8	5086	24	33	20	21	23	23	24	27
NZDep 9–10	6374	30	30	29	31	32	29	27	28
History									
Any prior CVD	2399	11	3	2	3	5	9	19	31
Angina/MI	1619	8	1	1	2	3	6	13	21
PCI/CABG	369	2	0	0	1	1	1	3	4
Stroke/TIA	674	3	2	0	1	1	2	5	9
PVD	385	2	0	0	1	1	2	3	5
*Diagnosed GLD**									
None	9366	43	33	30	37	45	42	45	51
Fam hyperchol	377	2	4	2	1	2	2	2	2
Fam defective ApoB	4	0	0	0	0	0	0	0	.
Fam combined	36	0	0	0	0	0	0	0	0
Other gld	142	1	0	0	0	1	1	1	1
Other Risk factors									
Family hx CVD	5754	27	29	32	30	29	28	23	18
Diabetes	4069	19	14	15	16	16	18	23	25
Smoking	3140	15	24	22	21	19	14	9	6
Mean(sd) SBP	21585	134 (19.1)	120 (17.2)	121 (15.5)	126 (17.8)	131 (18.2)	135 (18.4)	139 (19.0)	140 (19.7)
Mean(sd) DBP	21583	80 (10.6)	76 (13.4)	77 (11.4)	80 (11.6)	81 (11.0)	81 (10.2)	79 (10.0)	77 (10.1)
Mean(sd) TC/HDL	21578	3.7 (1.2)	4.0 (1.6)	3.9 (1.6)	3.9 (1.3)	3.8 (1.2)	3.7 (1.1)	3.6 (1.1)	3.4 (1.1)
Mean(sd) BMI	7341	29.7 (7.3)	32 (9.6)	31.1 (7.7)	31.7 (8.5)	30.8 (7.9)	29.7 (7.1)	28.7 (6.3)	26.5 (5.5)

9.2.3 NZGG guideline modifications to the Framingham CVD risk score

After excluding 'clinically at high risk' participants who do not require risk scoring to classify their risk, 55% of the remaining participants met NZGG guideline criteria for an upward adjustment of their estimated Framingham score by 5% (Table 9.6). This adjustment was largely driven by the 34% of participants with a high risk ethnicity (i.e. Māori, Pacific or South Asian) and the 24% with a positive family history of a premature ischaemic heart attack or stroke. Many people met more than one adjustment criteria. Therefore, the percentage of participants with at least one adjustment factor was much lower than the sum of percentages for each adjuster (note: each participant can only have their risk adjusted up once by a maximum of 5%). A further 11% of participants had their calculated 5-year CVD risk increased to 15% because the NZGG guidelines recommend this classification for patients with a blood pressure ≥170/100 mmHg or total cholesterol or TC/HDL ≥8.

Table 9.6. Participants eligible for an upward adjustment of their Framingham-predicted CVD score according to NZGG CVD risk guidelines

	All		Men		Women	
	N	%	N	%	N	%
All	41545	100	22795	100	18750	100
High risk ethnicity	14172	34	7414	33	6758	36
Family history CVD	9964	24	5175	23	4789	26
Metabolic syndrome*	2999	7	1636	7	1363	7
Additional diabetes risk**	3149	8	1573	7	1576	8
At least one adjustment factor	22789	55	11968	53	10821	58
BP 170/100 mmHg or higher	4047	10	2333	10	1714	9
TC or TC/HDL 8 or higher	859	2	512	2	347	2
All classification as 15% CVD risk	4640	11	2783	12	2023	11

**Additional diabetes risk criteria were having diabetes and microalbuminuria or having type 2 diabetes for10 years or over or HbA1c consistently 8% or over

*Metabolic syndrome according to ATP III NCEP Diagnostic criteria for metabolic syndrome[22].A person would have 3 or more of 5 risk factors; abdominal obesity (waist circumference ≥ 100cm in men, 90cm in women), triglycerides level ≥ 1.7mmol/L, HDL ≤ 1.0 mmol/L in men and 1.3mmol/L in women, BP ≥130/85 mmHg and elevated fasting glucose (≥ 6.1 mmol/L).

Framingham risk and NZ-adjusted Framingham risk by men and women

Tables 9.7 and 9.8 cross-tabulate the Framingham score with the NZGG-adjusted Framingham risk score for men and women.

Table 9.7. Framingham score compared with NZGG-adjusted Framingham score among men

Framingham score*	NZGG-adjusted Framingham score*					
	<5%	5–9%	10–14%	15–19%	20%+	Total N (%)
<5%	4504	5079	0	724	0	10,307(45.2)
5–9%	0	2747	2832	819	0	6398(28.1)
10–14%	0	0	1500	1884	0	3384(14.8)
15–19%	0	0	0	812	819	1631(7.2)
20%+	0	0	0	0	1075	1075(4.7)
Total N (%)	4504 (19.8)	7826 (34.3)	4332 (19.0)	4239 (18.6)	1894 (8.3)	22,795 (100)

Table 9.8. Framingham score compared with NZGG-adjusted Framingham score among women

Framingham score*	NZGG-adjusted Framingham score*					
	<5%	5–9%	10–14%	15–19%	20%+	Total N (%)
<5%	4658	5776	0	602	0	11,036(58.9)
5–9%	0	1904	2428	639	0	4971 (26.5)
10–14%	0	0	463	1328	0	1791 (9.6)
15–19%	0	0	0	179	449	628 (3.3)
20%+	0	0	0	0	324	324 (1.7)
Total N (%)	4658 (24.8)	7680 (41.0)	2891 (15.4)	2748 (14.7)	773 (4.1)	18750 (100)

***** Framingham risk groups exclude those with prior CVD, diabetes with nephropathy and genetic lipid disorder (diagnosed familial hypercholesterolaemia, familial defective ApoB and familial combined dyslipidaemia)

While the largest proportion of men (45.2%) and women (58.9%) were classified as less than 5% 5-year CVD risk using the Framingham score, these proportions more than halved (19.8% for men and 24.8% for women) with the NZGG adjusted score shifting risk scores up across the risk categories.

Table 9.9 and Table 9.10 show the calculated Framingham risk and NZGG-adjusted Framingham risk by age and gender. The mean 5-year Framingham risk for men was 7.4% (sd 6.2%) and women 5.4% (sd 4.8%) while the NZGG adjusted Framingham risk was 3.1% and 3.4% units higher respectively (in absolute terms). For men and women CVD risk increased progressively with age. The median Framingham risk was 5.7% for

men and 4.0% for women (NZGG-adjusted score median 9.3% and 7.6% respectively) demonstrating a slightly skewed distribution.

Table 9.9. Framingham risk and NZGG-adjusted Framingham risk by age in men

		Total Men	**<30**	**30–34**	**35–44**	**45–54**	**55–64**	**65–74**	**75+**
	N	22795	226	582	4758	7570	6064	2752	843
*Framingham risk**	N	%	%	%	%	%	%	%	%
0–<05	10307	45	99	96	89	56	16	2	1
05–<10	6398	28	1	3	10	32	45	23	11
10–<15	3384	15	0	1	1	8	25	35	32
15–<20	1631	7	0	0	0	2	9	23	30
20+	1075	5	0	0	0	1	5	17	26
*NZGG-adjusted Framingham score**									
0–<05	4504	20	43	37	30	28	10	1	1
05–<10	7826	34	48	46	52	36	29	15	8
10–<15	4332	19	0	0	5	17	29	29	25
15–<20	4239	19	8	16	13	16	22	28	28
20+	1894	8	0	0	0	3	10	27	38
mean (sd) Fram risk*	22795	7.4 (6.2)	1.2 (1.2)	1.6 (1.5)	2.6 (2.2)	5.5 (3.8)	9.8 (5.4)	14.5 (6.3)	16.9 (6.8)
mean (sd) NZGG-adj Framingham score*	22795	10.5 (6.7)	4.7 (4.1)	5.8 (4.8)	6.7 (4.4)	8.8 (5.2)	12.4 (6.2)	16.7 (6.9)	18.7 (7.3)

***** Framingham risk groups exclude those with prior CVD, diabetes with nephropathy and genetic lipid disorder (diagnosed familial hypercholesterolaemia, familial defective ApoB and familial combined dyslipidaemia)

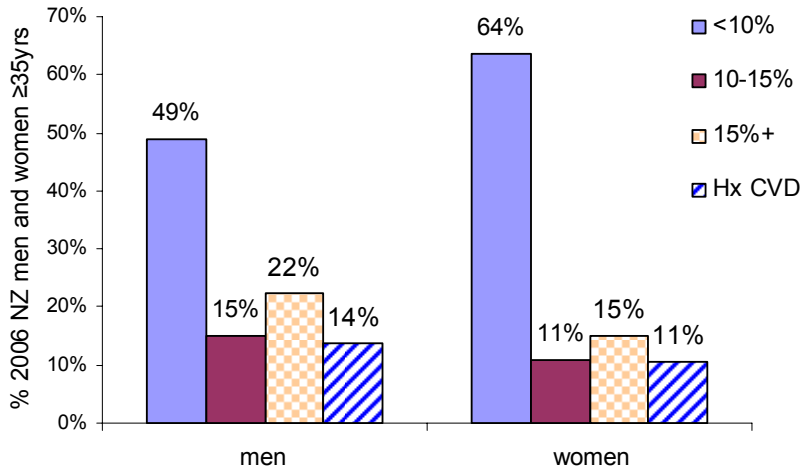
Table 9.10. Framingham risk and NZGG-adjusted Framingham risk by age in women

		All Women	<30	30–34	35–44	45–54	55–64	65–74	75+
		18750	158	270	1975	5496	6146	3333	1372
Framingham risk	N	%	%	%	%	%	%	%	%
0–<05	11036	59	96	98	93	80	56	23	12
05–<10	4971	27	4	2	6	16	30	45	44
10–<15	1791	10	1	0	1	3	9	21	26
15–<20	628	3	0	0	0	1	3	7	10
20+	324	2	0	0	0	0	1	4	7
NZGG-adjusted Framingham score									
0–<05	4658	25	37	35	33	28	29	14	8
05–<10	7680	41	50	56	53	49	36	32	33
10–<15	2891	15	2	1	4	10	17	25	25
15–<20	2748	15	11	8	10	12	14	20	21
20+	773	4	0	0	0	1	4	9	13
Mean(sd) Fram risk*	18750	5.4 (4.8)	1.0 (1.6)	0.9 (1.1)	1.8 (2.1)	3.5 (3.2)	5.7 (4.3)	8.8 (5.2)	10.4 (5.2)
Mean(sd) NZGG-adj Fram score*	18750	8.8 (5.8)	5.0 (4.6)	4.7 (4.0)	5.7 (4.4)	7.4 (4.8)	8.8 (5.5)	11.6 (6.3)	12.6 (6.4)

*Framingham risk groups exclude those with prior CVD, diabetes with nephropathy and genetic lipid disorder (diagnosed familial hypercholesterolaemia, familial defective ApoB and familial combined dyslipidaemia)

Figure 9.3 shows the age-standardised proportions in categories of CVD risk by gender for those over 35 years using the NZGG-adjusted score (including participants with prior CVD who are classified as clinically at high risk). These estimates have been age-standardised to the New Zealand 2006 population over 35 years. The risk categories used represent the three management thresholds recommended by the NZGG CVD risk guidelines: (i) general lifestyle advice only for less than 10% 5-year CVD risk (low risk); (ii) specific lifestyle assessment (dietary, alcohol, smoking and physical activity assessment) for 10–14% 5-year CVD risk (moderate risk); and (iii) drug therapy, specific lifestyle assessment and referral to a dietician for those over 15% 5-year CVD risk (high risk). For those with prior CVD, the same management is recommended as for patients with a calculated risk ≥ 15% (i.e. drug therapy, lifestyle assessment and dietician referral) but more intensively.

Figure 9.3. Percentages of men and women in NZGG-adjusted Framingham risk groups or with prior CVD age-standardised to the 2006 NZ population ≥35 years



*those aged less than 35 years, participants with GLD subtypes or diabetes and nephropathy without a prior history of CVD have been excluded from these histograms

About two-thirds of women and half of all men were in the low 5-year risk category (less than 10%). Just over one-quarter of women and one-third of men in this cohort over 35 years of age met the NZGG eligibility criteria for drug therapy (over 15% 5-yr CVD risk or with prior CVD). Specific individualised management with lifestyle assessment and/or drug therapy would be recommended for half of all of men over 35 years and more than one-third of women over 35 years.

9.2.4 Representativeness of the PREDICT cohort

The cohort described in these analyses represents approximately 14% of all people enrolled in the participating PHOs aged 35 years or more (and a similar percentage when considering only those in the 35–74 age group). Given the mainly opportunistic nature of participant recruitment, there was no expectation that this would produce a representative sample of the source population during the first few years of recruitment. To examine how 'representative' the cohort was, age-standardised (to the 2006 New Zealand population over 35 years) Framingham risk distributions were compared with published risk prevalence estimates based on the 1992–3 Auckland Heart & Health Study (AHAHS) by Wells et al. (2006),[284] and national CVD prevalence estimates based on 2006/07 national datasets by Chan et al (2008).[295]

The Auckland Heart & Health Study[55] (AHAHS) was a population based study of 2507 men and women aged 35–84 years conducted using the Auckland general electoral rolls as the sampling frame (response rate 72%). As Māori and Pacific people were under-represented, only data for non-Māori, non-Pacific people were included. In this study, a history of CVD included self-reported heart attack (with hospital admission) or stroke, plus angina (on nitrates). CVD risk distributions were calculated using the Framingham CVD risk equation[25] without NZGG guideline adjustments and was standardised to the usually resident New Zealand men and women aged over 35 years in 2005 (n = 2,087,200).

The PREDICT definition of a history of CVD is broader than the AHAHS, including all coronary surgical procedures, TIAs and peripheral vascular disease (PVD). In addition, Māori and Pacific people were included in PREDICT. Therefore the CVD risk distribution in the PREDICT population would be expected to be higher, although the PREDICT cohort was recruited at least 10 years later than the AHAHS cohort and population risk is likely to have been declining in line with declining CVD mortality described in Chapter 1.[3]

Chan et al.[295] estimated CVD prevalence for the New Zealand resident population in 2006/07, based on national datasets of public hospital discharges, mortality registrations, and pharmaceutical dispensing over the period 1988–2007. In 2007, a total of 273,970 out of 2,138,308 people over 35 years were estimated to have prevalent CVD (crude prevalence rate 12.8%). However, the CVD codes used by Chan et al. were a broader set than that used for the AHAH estimates or the PREDICT cohort. The codes included angina, MI, all coronary surgical procedures, stroke, TIA, PVD, congestive heart failure (CHF), arrhythmias, hypertensive heart disease and non-specified atherosclerosis. Therefore, the CVD prevalence estimates from this national study were expected to be higher than the more restricted ischaemic CVD definition used in PREDICT.

Table 9.11 compares the prevalence of CVD and Framingham risk groups in the PREDICT cohort (age-standardised to the 2006 New Zealand population) with the two other published estimates.

Table 9.11. Estimated prevalence of CVD and CVD Framingham risk distributions from New Zealand population estimates [284 295] compared with the PREDICT cohort

	Population	Prior CVD	CVD risk >20%	CVD risk 15–20%	CVD risk 10–15%	CVD risk <10%
	N	%	%	%	%	%
AHAHS estimates[1] >35yrs 1992–3 age standardised to NZ 2005 pop	2,087,200	7.3	7.1	6.0	9.9	69.8
PREDICT[2] cohort >35yrs 2002–8 age standardised to NZ 2006 population	2,070,180	12.0	2.6	4.0	9.1	72.0
National CVD[3] prevalence >35 yrs 2007	2,138,308	12.8				

[1]From Wells et al. (2006) Estimated prevalence of cardiovascular disease and distribution of cardiovascular risk in New Zealanders: data for health care planners, funders, and providers[284]
[2]PREDICT cohort numbers exclude those under 35 years, those with no prior history of CVD but with diabetes with nephropathy or high risk types of genetic lipid disorder
[3]From Chan et al (2008). Ethnic and socio-economic disparities in the prevalence of cardiovascular disease in New Zealand[295]

Prior CVD prevalence in the PREDICT cohort was close to the national estimates that were based on triangulating national datasets.[295] As discussed above, while the Chan estimates are likely to best reflect true national prevalence, the definition used was broader than used in PREDICT and included CHF. These results suggest that clinicians using PREDICT may be preferentially selecting those with existing CVD to be assessed and managed.

It also appears that the PREDICT cohort has a more favourable CVD risk distribution than the AHAHS estimates. However the differences were relatively small other than for the very high risk group and unfortunately the comparison of PREDICT CVD and risk distributions with the AHAHS distributions is not very robust. The AHAHS was subject to both random error from the small sample size and possibly systematic error due to the low response rate, but no other equivalent New Zealand data was available for comparison.

9.2.5 Drug management at baseline

Medication data was only available for the 17,434 (36%) of participants who had both a risk assessment and management template completed. As shown in earlier analyses, participants who had a prior history of CVD, diabetes or high calculated CVD risk were slightly more likely to have the management template completed. An analysis was conducted to investigate drug management of participants by risk category at the baseline assessment (Table 9.12). Drugs have been categorised into three classes according to their mode of action affecting blood clotting (anti-platelet or anti-thrombotic therapy), lipid-lowering and blood pressure (BP) lowering. The NZGG CVD risk guidelines[23] recommend triple drug therapy (anti-platelet/anti-thrombotic, lipid-lowering and BP-lowering) for all patients with a CVD risk over 15% or with prior CVD, additionally (or including) a beta-blocker for patients with prior CHD.

Table 9.12. Drug therapy at baseline by prior CVD and CVD risk score

		Framingham 5-yr risk			NZ-adj Fram risk score		
	Prior CVD	15+%	10–<15%	<10%	15+%	10–<15%	<10%
N	2422	1490	2027	11277	3988	2681	8125
	%	%	%	%	%	%	%
Antiplatelet/antithrombotic Rx							
Aspirin	68	28	22	11	21	20	9
Clopidogrel	1	0	0	0	0	0	0
Warfarin	9	2	2	1	2	2	1
Any antiplat/antithromb	73	29	23	11	22	21	9
Lipid-lowering drugs							
Statin	61	26	25	16	22	26	13
Fibrate	4	4	2	2	2	3	1
Other lipid-lowering Rx	2	1	0	0	0	1	0
Any lipid-lowering Rx	63	29	26	17	24	28	14
BP-lowering drugs							
On thiazide	17	18	15	10	16	16	8
On beta blocker	43	18	15	9	15	14	7
On ACE	47	38	31	18	32	29	14
Angiotensin II Receptor	2	1	1	1	1	1	0
On ca antagonist	23	13	12	6	11	10	4
Other hypertension drugs	12	6	5	2	5	5	2
Any BP-lowering drug	74	54	45	27	46	42	22
Antiplat/antithromb & statin	53	15	12	6	11	12	5
Triple therapy	49	13	10	5	10	11	3
aspirin, beta-blocker & statin	29	4	3	2	3	3	1

For those with prior CVD, 73%, 63% and 74% were on anti-platelet/anti-thrombotic, lipid-lowering and BP-lowering drugs respectively with 49% receiving triple therapy. Among the remaining participants there is no evidence of targeting of triple therapy to the higher risk patients among people above the 10% risk threshold (either based on the Framingham or NZGG-adjusted Framingham score). However, it is possible that triple therapy had reduced CVD risk to below 15% for some of those participants now in the 10–15% CVD risk category.

9.3 Follow-up time and CVD events

9.3.1 Follow-up time

Electronic linkage of PREDICT records to NHI-linked databases (demographic, hospitalisation and mortality datasets) was possible for 48,306 PREDICT participants (99% of all participants). Follow-up time was defined as the time from the initial risk assessment to death, or CVD hospitalisation or until the day of linkage with NZHIS datasets, whichever came first. The total person-years (p-yrs) of follow-up included in these analyses was 106,708 p-yrs.

The mean follow-up time for these analyses is 2.21 years, the median 2.12 years. The range in follow-up as of February 2008 was from 2 days to 5.65 years.

Table 9.13. Follow-up time

Follow-up time	Mean (years)	Median (years)	Standard deviation	Minimum	Maximum
All	2.21	2.12	1.41	0.003	5.65
No prior CVD	2.25	2.22	1.41	0.003	5.65
Prior CVD	1.93	1.63	1.41	0.003	5.65

The distribution of follow-up time in six-monthly increments is shown in the two histograms (Figures 9.4 and 9.5); those with no history of CVD and those with CVD. The follow-up time is slightly skewed to the left, particularly between 6–12 months of follow-up. This skewing is more so for those with prior history of CVD than for those with no such history.

Figure 9.4. Follow- up of participants with no prior CVD until event or date of NZHIS linkage

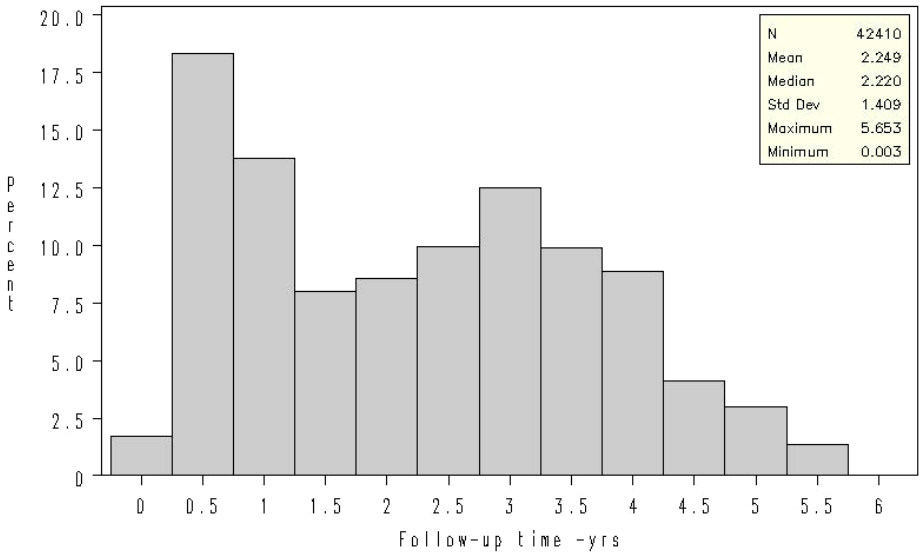
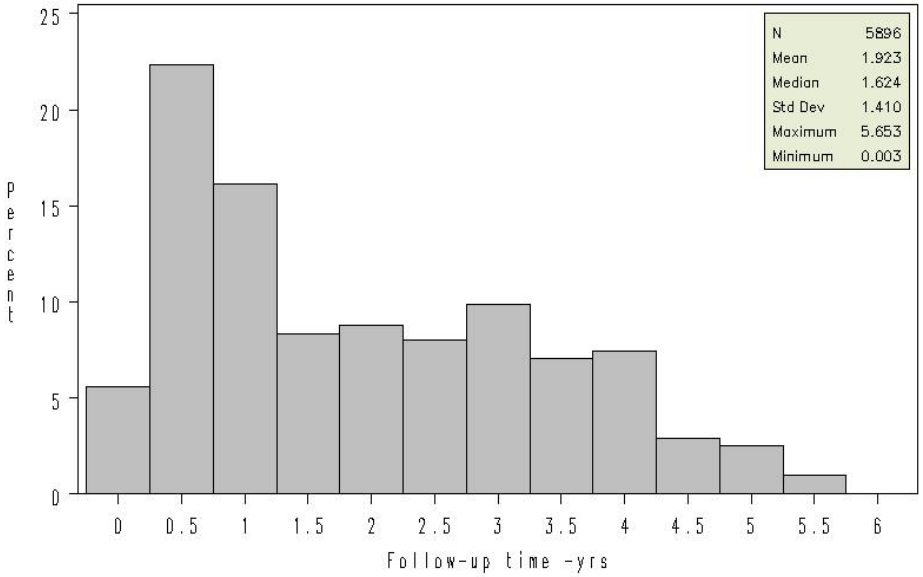


Figure 9.5. Follow-up time for those with prior CVD until next event or date of NZHIS linkage



9.3.2 CVD events during follow-up

Between August 2002 and April 2008, there were 4184 events in 2655 people from the cohort of 48,306 participants. Of those people who experienced a CVD event during follow-up, 497 died and 2158 had one or more hospitalisations coded as CVD (see

Table 8.4 in Chapter 8 for ICD codes used). The date of non-fatal events was timed from the first day of admission. A subsequent admission was not counted as a separate event if it was within 28 days of the previous admission. However, if the patient died within 28 days of admission, then the event was coded as a death rather than a CVD hospitalisation.

An analysis was conducted to determine the distribution of time from recruitment to event. Table 9.14 shows the proportion of all risk assessments categorised by the length of follow-up compared to the proportions of first events during follow-up among participants with and without a prior CVD.

Table 9.14. Proportion of assessments compared to proportion of events occurring by follow-up time

	No prior CVD				Prior CVD			
Follow-up time	Cohort numbers (n)	% of cohort	Events during follow-up (n)	% of events	Cohort numbers (n)	% of cohort	Events during follow-up (n)	% of events
< 6 months	4708	11.1	363	25.6	1019	17.3	446	36.1
6–11 months	7463	17.6	241	17.0	1230	20.9	234	19.0
12–23 months	7762	18.3	380	26.7	1154	19.6	334	27.1
24+ months	22,477	53	437	30.7	2493	42.2	220	17.8
Total	42,410	100	1421	100	5896	100	1234	100

For both participants with and without prior CVD, there were about twice as many events in the first 6 months of follow-up than would be expected based on their proportion of total follow-up. This observation suggests that there is some differential selection of patients for risk assessment (possibly because of patient or clinical intuition) with patients presenting with early but not definitive symptoms of CVD.

9.3.3 CVD events from baseline

Categories of CVD events experienced by participants during follow-up are shown in Figure 9.6 and Table 9.15. Some participants had more than one event (Figure 9.6) and

some (single) events were classified to more than one CVD ICD code (e.g. both ischaemic stroke and CHF). Hence the numbers in each disease category add to more than 100% (Table 9.15). People who had an event are further classified by history of prior CVD at baseline.

Figure 9.6. Percentage of the 2655 people who had a single or multiple CVD events occurring over the follow-up period divided into those with and without prior CVD event at baseline

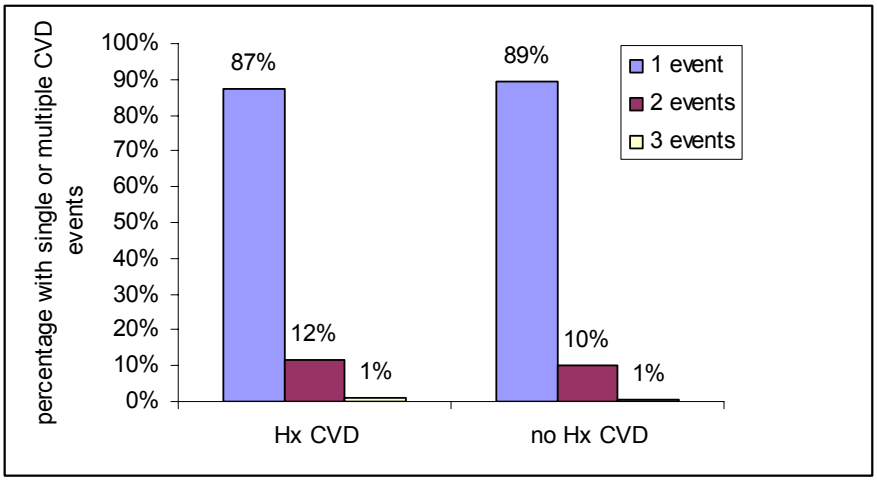


Table 9.15. Categories of CVD events experienced during follow-up

CVD event category	Total number of events in whole cohort n=4184/48,306	People with events in whole cohort n=2655/48306	Events in the total cohort of people with prior CVD (1234/ 5896)	Events in the total cohort of people with no prior CVD (1421/42,410)
	Number of events	Number of people with events	% of all people with CVD events	% of all people with CVD events
CHD	2315	1619	67	56
Ischaemic Stroke	704	576	21	22
PVD	699	411	19	12
All ischaemic CVD	3440	2289	90	83
CHF	1105	725	28	27
haemorrhagic stroke	156	135	4	6
All CVD events	4184	2655		

The majority of events were coded as CHD, accounting for two-thirds of events in those with a history of CVD and over half in those with no history. The proportion of those with ischaemic stroke and with CHF were similar by history of CVD but a greater proportion of those with a history of CVD had an incident PVD event. In this cohort, half of all

ischaemic CVD events (and 46% total CVD events) occurred in those with a prior history of CVD, who made up only 12% of the total population (5896/48,306).

Fatality from CVD events

Table 9.16 shows the proportions of fatal and non-fatal events by event type and by a previous history of CVD. Of the 2655 people who had a CVD event (both prior and no prior CVD event) during the follow-up period, 18% (497) were fatal. People with a prior history of CVD were slightly more likely (20%) to have a fatal ischaemic CVD event (particularly CHD or stroke) or fatal CHF event than participants without a prior history (17%). For the subgroup of peripheral vascular and haemorrhagic stroke events, case fatality rates were of similar magnitude for participants with or without prior CVD.

Table 9.16. Percentage of fatal and non-fatal events by event type and history of prior CVD

	Prior CVD 1234/5896		**No Prior CVD 1421/42,410**	
CVD event category	All events	Fatal	All events	Fatal
	N	%	N	%
CHD	822	21	797	16
Ischaemic Stroke	261	25	304	17
PVD	237	22	174	21
All ischaemic CVD	*1115*	*20*	*1174*	*16*
CHF	348	34	377	23
haemorrhagic stroke	48	42	87	43
All CVD events	*1234*	*20*	*1421*	*17*

Table 9.17 describes the number and percentage of fatal events by history of prior CVD, age group and gender. There were no fatal events in participants less than 35 years.

Table 9.17. Number and percentage of fatal CVD events by history of prior CVD, age group and gender

		% of all CVD events that were fatal in participants with prior CVD		% of all CVD events that were fatal in participants with no prior CVD	
Age (years)	Total	Men	Women	Men	Women
	N	%	%	%	%
35–44	11	8.7	0	14.0	11.1
45–54	41	13.7	14.6	9.7	6.9
55–64	94	15.9	11.5	13.4	13.1
65–74	139	16.5	15.5	19.7	18.8
75+	212	34.1	31.4	30.8	27.4
Total N (%)	497 (100)	146 (20.2)	104 (18.0)	138(16.9)	109 (18.0)

Fatal CVD events (n=497) as a proportion of all first incident CVD events (n=2655) increased with increasing age for both men and women. The proportions of events that were fatal were similar in men and women (age-adjusted risk in men relative to women = 1.10; 95% CI 0.95-1.30).

An analysis of the first event occurring during follow-up by CVD category is shown in Table 9.18.

Table 9.18. **First events by CVD category**

First event category	Frequency	Percentage	Cumulative Frequency	Cumulative Percentage
CHD only	1240	47	1240	47
Ischaemic stroke (IST) only	415	16	1655	62
CHF only	376	14	2031	77
PVD only	233	9	2264	85
Haemorrhagic stroke (HST) only	82	3	2346	88
Two categories				
CHD & CHF	148	5.6	2494	93.9
CHD & PVD	41	1.5	2535	95.5
IST & PVD	22	0.8	2557	96.3
CHD & IST	19	0.7	2576	97.0
PVD & CHF	17	0.6	2593	97.7
IST & CHF	15	0.6	2608	98.2
IST & HST	15	0.6	2623	98.8
CHD & HST	7	0.3	2630	99.1
HST & CHF	2	0.1	2632	99.1
HST & PVD	1	0.0	2633	99.2
Three categories				
CHD & PVD & CHF	13	0.5	2646	99.7
CHD & IST & CHF	3	0.1	2649	99.8
IST & HST & PVD	3	0.1	2652	99.9
CHD & IST & PVD	2	0.1	2654	100.0
IST & HST & CHF	1	0.0	2655	100.0

Of the 2655 first CVD events during follow-up, the majority (88%) were coded to only one CVD category, 11% had 2 categories (e.g. CHD and CHF) and 1% three categories (e.g. CHD and PVD and CHF). When multiple categories were included, 56% of first events were attributable to CHD and 18% attributable to ischaemic stroke (IST).

9.4 Incidence rates of first CVD events during follow-up

Incidence rates (IR) of first CVD event during follow-up were analysed separately by history of CVD at baseline. For each participant group, two tables are presented; firstly by demographic variables and secondly by personal medical history and CVD risk factors. Age-standardised IR per 1000 person-years were calculated using the entire

Segi World population and differences between categories compared using age-standardised relative risks (RR).

9.4.1 Incidence rates of first CVD events for participants with no prior CVD

For those with no prior history of a CVD event (Table 9.19 and Table 9.20), incidence approximately doubled with each decade from 4.4/1000 person-years for the 35–44 year age group to 68.6/1000 person years for the over 75 year age group. The age-standardised incidence rate for men was 42% higher than for women. Māori (9.3/1000 person-years) and Pacific (8.0/1000 person years) ethnicity groups had significantly higher age-standardised rates than European (5.2/1000 person years). Those of South Asian ethnicities had similar rates to European although confidence intervals were wide because of smaller numbers, while incidence rates for Other Asians were 44% lower than that of European (2.9/1000 person-years compared with 5.2/1000 person years). Incidence rates increased with worsening levels of deprivation. People living in the most deprived areas (NZ Dep 7–10) had a 84% higher rate than the least deprived).

Among participants without a history of CVD, those who had diabetes, who smoked, or who had extreme blood pressure levels had 118%, 73% and 43% higher age-standardised RRs respectively than participants without these risk factors. Participants with a high total cholesterol or TC/HDL ratio and those with a reported family history of premature ischaemic CVD in a first-degree relative or the personal history of a familial dyslipidaemia did not appear to be at increased CVD risk compared with those without these risk factors. The highest risk observed among participants without a history of CVD were people with diabetes complicated by nephropathy (37.7/1000 person-years). This rate was only 27% lower than for participants with a prior CVD event (51.8/1000 person years) as shown in Table 9.21.

Table 9.19. Crude and age-standardised incidence rates and relative risks of first CVD event from baseline assessment among participants with no prior CVD – by demographic factors.

	people	CVD event	Follow-up	Person-years of follow-up	Crude incidence rate/1000 p-yr	95% CI for crude incidence rate	Age[1] standardised rate/1000 p-y	95% CI for age-standardised rate	Age-standardised relative risk	95% CI for age-standardised RR
	N	N	Mean	Sum						
All	42410	1421	2.249	95371	14.9	14.1-15.7	5.43	5.1-5.6		
Age										
<35	1265	0	2.463	3116	0.0					
35 - 44	6845	68	2.259	15466	4.4	3.4-5.5				
45 - 54	13323	238	2.245	29913	8.0	7.0-9.0				
55 - 64	12492	430	2.283	28519	15.1	13.7-16.5				
65 - 74	6221	380	2.237	13914	27.3	24.7-30.2				
75+	2264	305	1.962	4443	68.6	61.3-76.7				
Gender										
Women	19187	606	2.225	42685	14.2	13.1-15.4	4.4	4.0-4.8	1	
Men	23223	815	2.269	52686	15.5	14.4-16.5	6.3	5.8-6.7	1.42	1.27-1.59
Ethnicity										
European	20049	814	2.462	49353	16.5	15.4-17.7	5.2	4.9-5.6	1	
Māori	5967	215	1.675	9997	21.5	18.8-24.5	9.3	8.0-10.7	1.77	1.50-2.10
Pacific	7273	272	1.87	13601	20.0	17.7-22.5	8.0	7.0-9.0	1.52	1.32-1.76
Sth Asian	1391	32	2.081	2895	11.1	7.7-15.4	6.2	3.7-8.8	1.19	0.79-1.80
Oth Asian	1445	24	2.221	3208	7.5	4.9-11.0	2.9	1.7-4.2	0.56	0.37-0.86
Other	6285	64	2.596	16318	3.9	3.0-5.0	1.4	1-1.8	0.27	0.20-0.35
NZ Dep Quintile										
NZDep 1–2	6456	181	2.81	18144	10.0	8.6-11.5	3.6	3.0-4.1	1	
NZDep 3–4	7253	219	2.556	18540	11.8	10.3-13.5	4.2	3.6-4.7	1.15	0.94-1.42
NZDep 5–6	7548	245	2.31	17437	14.1	12.4-15.9	5.0	4.4-5.7	1.40	1.14-1.71
NZDep 7–8	9433	375	2.045	19295	19.4	17.5-21.5	6.9	6.2-7.6	1.91	1.58-2.30
NZDep 9–10	11615	398	1.866	21676	18.4	16.6-20.2	6.6	6-7.3	1.84	1.53-2.21
missing	105	3	2.657	279	10.8	2.6-28.7	3.0	-0.9-7.0	0.84	0.23-3.12

[1] Age-standardised to entire Segi World Population

Table 9.20. Crude and age-standardised incidence rates and relative risks of first CVD event from baseline assessment among participants with no prior CVD – by selected personal clinical history and CVD risk factors

	people	CVD event	Follow-up	Person-years of follow-up	Crude incidence rate/1000 p-yrs	95% CI for crude incidence rate	Age[1] standardised rate/1000 p-yrs	95% CI for age-standardised rate	Age-standardised relative risk	95% CI for age-standardised RR
	N	N	Mean	Sum						
All	42410	1421	2.249	95371	14.9	14.1-15.7	5.4	5.1-5.6		
High risk Genetic lipid disorders										
No	41740	1406	2.266	94580	14.9	14.1-15.7	5.3	5.0-5.6	1	
Yes	670	15	1.181	792	18.9	11.0-30.4	6.3	3.0-9.6	1.19	0.70-2.02
Diabetes										
No	35669	994	2.301	82085	12.1	11.4-12.9	4.5	4.2-4.8	1	
Yes	6741	427	1.971	13286	32.1	29.2-35.3	9.8	8.8-10.8	2.18	1.93-2.47
Diabetes with nephropathy										
No	42210	1389	2.254	95150	14.6	13.9-15.4	5.2	5.0-5.5	1	
Yes	200	32	1.098	219	146.1	102-203.8	37.7	23.6-51.8	7.22	4.95-10.5
Family history CVD										
No	32131	1122	2.224	71462	15.7	14.8-16.6	5.3	5.0-5.7	1	
Yes	10279	299	2.326	23910	12.5	11.2-14.0	5.3	4.6-5.9	0.99	0.86-1.14
Smoking										
No	35541	1170	2.294	81538	14.4	13.5-15.2	4.9	4.6-5.2	1	
Yes	6869	251	2.014	13833	18.1	16.0-20.5	8.5	7.2-9.7	1.73	1.48-2.03
BP≥ 170/100 mmHg										
No	38287	1222	2.246	85993	14.2	13.4-15.0	5.1	4.8-5.4	1	
Yes	4123	199	2.274	9378	21.2	18.4-24.3	7.4	6.3-8.5	1.43	1.22-1.68
TC or TC/HDL≥8										
No	40989	1391	2.241	93055	15.0	14.2-15.8	5.3	5.0-5.6	1	
Yes	1421	30	2.6	2316	13.0	8.9-18.2	5.5	3.4-7.5	1.02	0.70-1.49

[1] Age-standardised to entire Segi World Population

9.4.2 Incidence rates of first CVD events during follow-up among participants with a prior history of CVD

For participants with a reported history of an ischaemic CVD event (angina, MI, coronary procedure, stroke, TIA or peripheral vascular disease) at baseline, Tables 9.21 and 9.22 compare the crude and age-standardised incidence rates by demographic and CVD risk factors. The overall age-standardised incidence rate of 51.8 /1000 person-years was almost ten-fold higher than for participants with no prior CVD history (5.4/1000 person-years). The age-specific incidence of an event during follow-up was similar across the three 10-year age groups between 35–64 years. There were too few events in people under 35 to produce a sufficiently precise incidence rate estimate. Among people over 65 years, risk increased with age. The age-standardised incidence in men was about 80% higher than in women.

No significant differences were found between incidence rates by ethnicity although the small number of participants and events in many categories meant that many of these estimates were imprecise. There were, however, statistically significant differences by deprivation score with a trend of larger relative risks with increasing deprivation. Surprisingly, participants with high blood pressure (≥170/100 mmHg) had a 46% lower age-standardised CVD incidence rate than those with lower blood pressure although the precision of the estimates was poor. A reported family history of premature ischaemic CVD in a first-degree relative, a personal history of a familial dyslipidaemia, diabetes, diabetics with nephropathy, smoking or having high cholesterol levels were not associated with statistically significant increases in risk.

Table 9.21. Crude and age-standardised incidence rates and relative risks of first CVD event during follow-up in participants with prior CVD – by demographic factors.

	people	CVD event	Follow-up	Person-years of follow-up	Crude incidence rate/1000 p-years	95% CI for crude incidence rate	Age[1] standardised rate/1000 p-years	95% CI for age-standardised rate	Age-standardised relative risk	95% CI for age-standardised RR
	N	N	Mean	Sum						
All	5896	1234	1.923	11338	108.8	102.9-115.0	51.8	26.2-77.3		
Age										
<35	26	2	2.604	68	29.4	4.4-94.3				
35-44	241	34	1.871	451	75.4	53.0-104.1				
45-54	920	143	1.94	1785	80.1	67.8-94.1				
55-64	1600	260	2.007	3211	81.0	71.6-91.3				
65-74	1857	416	1.956	3633	114.5	103.9-125.9				
75+	1252	379	1.749	2190	173.1	156.3-191.2				
Gender										
Women	2399	510	1.892	4538	112.4	102.9-122.5	36.0	26.1-45.9	1	
Men	3497	724	1.944	5737	125.8	116.9-135.2	63.4	22.2-104.6	1.76	0.87-3.56
Ethnicity										
European	3278	743	2.062	6761	109.9	102.2-118.0	49.1	3.8-94.4	1	
Māori	978	201	1.398	1367	147.0	127.7-168.4	53.4	41.8-64.9	1.09	0.42-2.80
Pacific	942	223	1.771	1668	133.7	117.0-152.1	49.8	39.1-60.5	1.01	0.39-2.61
Sth Asian	176	27	1.885	333	81.1	54.4-116.2	37.7	13.9-61.6	0.77	0.25-3.35
Oth Asian	130	17	1.901	248	68.6	41.1-107.3	11.0	5.6-16.5	0.22	0.07-0.64
Other	392	23	2.456	962	23.9	15.5-35.3	3.9	2.0-5.8	0.08	0.03-0.23
NZ Dep Quintile										
NZDep 1–2	654	113	2.456	1605	70.4	58.3-84.3	12.4	9.4-15.3	1	
NZDep 3–4	848	158	2.261	1917	82.4	70.3-96.0	19.6	14.6-24.6	1.58	1.12-2.25
NZDep 5–6	960	229	2.064	1982	115.5	101.3-131.3	39.9	28.5-51.3	3.22	2.23-4.68
NZDep 7–8	1439	332	1.855	2669	124.4	111.5-138.3	43.1	33.2-52.9	3.49	2.51-4.84
NZDep 9–10	1981	400	1.581	3133	127.7	115.6-140.7	67.2	11.4-122.9	5.43	2.29-12.88
missing	14	2	2.196	31	64.5	9.7-206.8	4.4	-1.7-10.6	0.36	0.09-1.47

[1] Age-standardised to entire Segi World Population

Table 9.22. Crude and age-standardised incidence rates and relative risks of first CVD event from baseline assessment in those with prior CVD –selected personal history and examination variables

	people	CVD event	Follow-up	Person-years of follow-up	Crude incidence rate/1000 p-years	95% CI for crude incidence rate	Age standardised rate/1000 p-years	95% CI for age-standardised rate	Age[1]-standardised relative risk	95% CI for age-standardised RR
	N	N	Mean	Sum						
All	5896	1234	1.923	11338	108.8	102.9-115.0	51.8	26.2-77.3		
High risk Genetic lipid disorders										
No	5697	1199	1.956	11145	107.6	102.6-112.8	52.6	26.2-79.0	1	
Yes	199	35	0.966	193	181.4	128.1-249.2	52.5	22.4-82.6	1.00	0.46-2.14
Diabetes										
No	4095	743	2.044	8373	88.7	82.5-95.3	52.5	18.5-86.5	1	
Yes	1801	491	1.647	2966	165.5	152.2-178.9	54.4	40.8-67.9	1.04	0.52-2.07
Diabetes with nephropathy										
No	5792	1200	1.943	11252	106.7	101.7-111.8	52.1	26.4-77.7	1	
Yes	104	34	0.827	172	197.7	147.6-259.9	87.9	43.5-132.3	1.69	0.84-3.42
Family history CVD										
No	4079	861	1.91	7788	110.6	103.4-118.1	55.3	8.3-102.3	1	
Yes	1817	373	1.953	3548	105.1	96.5-114.4	53.2	22.7-83.8	0.96	0.35-2.68
Smoking										
No	4873	1028	1.973	9616	106.9	101.5-112.5	45.7	18.8-72.6	1	
Yes	1023	206	1.683	1721	119.7	106.6-134.0	71.1	15.2-126.9	1.56	0.58-4.15
BP≥ 170/100mm Hg										
No	5401	1123	1.916	10350	108.5	103.3-113.9	58.3	25.6-91.1	1	
Yes	495	111	1.996	987	112.5	92.9-134.9	31.3	24.0-38.6	0.54	0.29-1.00
TC or TC/HDL≥8										
No	5817	1212	1.92	11169	108.5	102.5-114.8	47.4	21.7-72.3	1	
Yes	79	22	2.14	170	139.4	83.0-192.4	67.0	3.8-130.8	1.41	0.47-4.20

[1] Age-standardised to entire Segi World Population

9.5 Performance of the Framingham equation: calibration

A risk prediction equation is considered to be well calibrated when the mean observed risk is similar to the mean predicted risk, in a group of people categorised by their predicted risk. As the Framingham equation was developed specifically for people aged 30 to 74 years without a prior CVD event, the calibration analyses reported here are only for this subgroup of PREDICT participants. Participants with diabetes plus nephropathy or with familial genetic lipid disorders (n= 851) have also been excluded as these people are considered to be clinically at high risk according to NZGG criteria (i.e. equivalent in risk to people with a history of CVD). In addition, there were 14 other participants excluded because of missing data for whom a Framingham risk could not be calculated. For the remaining 38,946 participants, observed event rates were extrapolated to produce a 5-year cumulative incidence so that meaningful comparisons could be made with the 5-year predicted risk generated by the Framingham and NZGG-adjusted Framingham equation. Table 9.23 shows the number of first CVD events during follow-up, the incidence rate, cumulative 5-year incidence rate and mean predicted risk scores (Framingham and NZGG-adjusted scores) for these participants stratified by age, gender, ethnicity, and socioeconomic deprivation.

In this cohort of 38,946 participants there were 1,080 first CVD events during an average follow-up period of 2.29 years. The overall crude incidence rate was 12.1/1000 person-years considerably lower than the overall cohort (14.9/1000 p-yrs) without prior CVD or CVD equivalent conditions (Table 9.19) due to excluding those over 75 years. The extrapolated mean 5-year 'observed' event rate for this cohort was 5.9% compared with the mean Framingham 5-year predicted risk of 6.2% and the mean New Zealand adjusted 5-year predicted score of 9.5%. The mean Framingham risk performed relatively well by age and gender for the cohort as a whole but underestimated the observed risk for Māori and Pacific ethnic groups and for NZ Dep Index deciles 7–10. In contrast the NZGG-adjusted score overestimated risk for all age groups, gender, ethnicity and NZ Dep Index categories.

Table 9.23. Number of first CVD events, crude incidence rate, cumulative incidence rate and mean predicted risk scores of participants stratified by age, gender, ethnicity and deprivation in participants aged 30-74yrs without prior CVD or CVD risk equivalent or missing data precluding estimation of Framingham risk

	People	Events	Total p-yrs follow-up	Crude Incidence rate /1000p-yrs	Estimated cumulative 5-yr risk	Mean Framingham predicted 5-yr risk	Mean NZGG adjusted 5-yr risk
	N	N	p-yrs		% (95% CI)	%	%
	38946	1080	89020	12.1	5.9 (5.5- 6.2)	6.2	9.5
Age group							
30–44	7585	68	17484	3.9	1.9 (1.5-2.4)	2.2	6.3
45–54	13066	232	29613	7.8	3.8 (3.4-4.3)	4.7	8.2
55–64	12210	417	28162	14.8	7.1 (6.5-7.8)	7.7	10.6
65–74	6085	363	13761	26.4	12.4 (11.2-13.5)	11.4	13.9
Gender							
Women	17220	414	38994	10.6	5.2 (4.7-5.7)	5.1	8.5
Men	21726	666	50026	13.3	6.4 (6.0-6.9)	7.1	10.2
Ethnicity							
European	18157	565	45607	12.4	6.0 (5.5-6.5)	6.2	8.4
Māori	5567	186	9513	19.6	9.3 (8.0-10.6)	6.6	12.0
Pacific	6702	228	12785	17.8	8.5 (7.5-9.6)	6.3	11.7
South Asian	1309	28	2760	10.1	5.0 (3.1-6.7)	5.1	10.5
Other Asian	1341	19	3011	6.3	3.1 (1.7-4.5)	5.0	7.0
Other	5870	54	15343	3.5	1.7 (1.3-2.2)	6.2	8.2
NZ Deprivation Index							
1–2	6040	132	17079	7.7	3.8 (3.2-4.4)	5.6	7.9
3–4	6744	166	17440	9.5	4.7 (4.0-5.3)	5.6	8.3
5–6	7021	187	16464	11.4	5.5 (4.8-6.3)	6.2	9.3
7–8	8509	278	17665	15.7	7.6 (6.7-8.4)	6.6	10.2
9–10	10533	314	20109	15.6	7.5 (6.7-8.3)	6.6	10.6
Missing	99	3	262	11.5	5.6 (-0.7-11.5)	7.0	10.1

Table 9.24 shows the number of first CVD events, the cumulative 5-year incidence rate and mean predicted risk scores (Framingham and New Zealand-adjusted score) of participants stratified by the presence of diabetes and by variables used as adjustment factors in the NZGG CVD risk management guidelines.[23] The mean Framingham risk slightly underestimated the observed 5-year risk among people with diabetes, while slightly overestimating risk for people without diabetes. The mean NZGG-adjusted Framingham score overestimated risk in both people with and without diabetes. The observed event rates were higher than the mean Framingham risk for those meeting the high risk ethnicity criteria (i.e. being Māori, Pacific or South Asian) but lower than the NZGG adjusted score. A similar pattern was observed for the subgroup of diabetics with microalbuminuria, an HbA1c ≥8% or with diabetes diagnosed for ten years or more. Participants with a family history of premature CVD, very high blood pressure (BP ≥

170/100 mmHg) or very high cholesterol (TC or TC/HDL ≥ 8) had similar observed risk to those predicted by the Framingham score. The NZGG-adjusted score overestimated risk in all categories, particularly for family history (by 5%), high blood pressure (by 8%) and high cholesterol values (by 8%).

Table 9.24. Number of first CVD events, cumulative incidence rate and mean predicted risk scores of participants stratified by diabetes and NZGG adjustment factors.

	People	**Events**	**Total p-yrs follow-up**	**Estimated cumulative 5-yr risk**	**Mean Framingham predicted 5-yr risk**	**Mean NZGG adjusted 5-yr risk**
	N	N	N	% (95% CI)	%	%
All	38946	1080	89020	5.9 (5.5- 6.2)	6.2	9.5
Diabetes						
Yes	5789	316	11866	12.5 (11.2-13.7)	10.9	15.1
No	33157	764	77154	4.8 (4.5-5.2)	5.4	8.5
High risk Ethnicity						
Yes	13579	442	25059	8.4 (7.7-9.2)	6.3	11.7
No	25367	638	63961	4.9 (4.5-5.2)	6.1	8.3
Family History						
Yes	9563	248	22670	5.3 (4.7-6.0)	5.7	11.1
No	29383	832	66350	6.1 (5.7-6.5)	6.4	8.9
*Metabolic Syndrome**						
Yes	2832	80	3524	10.7 (8.5 -12.9)	8.5	13.9
No	36114	1000	85496	5.7 (5.3-6.0)	6.0	9.1
*Additional diabetes risk**						
Yes	2853	101	3466	13.6 (11.1-16.0)	10.7	15.8
No	36093	979	85554	5.6 (5.2-5.9)	5.8	9.0
BP ≥170/100 mmHg						
Yes	3799	166	8730	9.1 (7.7-10.4)	10.3	17.4
No	35147	914	80289	5.5 (5.2-5.9)	5.8	8.6
TC or TC/HDL ≥ 8						
Yes	818	28	2156	6.3 (4.0-8.5)	8.4	16.5
No	38128	1052	86864	5.9 (5.5-6.2)	6.1	9.3
Either very high BP or cholesterol						
Yes	4523	188	10640	8.5 (7.3-9.6)	9.9	17.2
No	34423	892	78380	5.5 (5.2-5.9)	5.7	8.5

*Data for presence of these variable only available for PREDICT CVD-Diabetes dataset. Additional diabetes risk includes participants with diabetes plus microabuminuria; type 2 diabetes for at least 10 years or who have an HbA1c consistently over 8%.

The agreement between the Framingham predicted risk and observed risk, is further illustrated in Figures 9.7–9.17 which plot the mean predicted risk for each of five 5-year CVD risk groups (<5%, 5–10%, 10–15%, 15–20% and over 20% 5-year CVD risk) along the x-axis against the observed cumulative 5-year incident CVD events (y-axis).

Figure 9.7 includes the total eligible cohort aged 30-74 years with no prior history of CVD or CVD equivalent conditions, as discussed above. The dotted diagonal line represents the line of perfect agreement between the predicted risk and the observed events. Points below this line indicate an overestimate of predicted risk, and vice versa. The clinical implications of overestimating risk are overtreatment for people with risks inflated above treatment thresholds (e.g. at 15% 5-year CVD risk for drug treatment).

In this cohort aged 30–74 without prior CVD there was a linear increase in observed risk (extrapolated to 5 year CVD event rates) across the predicted 5-year risk groups. The original Framingham performed well with a trivial overestimate of risk at lower risk levels and about 5% overestimation of actual risk for predicted 5-year risk categories above 15%.

Figure 9.7. Calibration of the Framingham score against the cumulative incidence of CVD event in 5 years (with 95% confidence intervals) in participants aged 30-74 years without prior CVD or CVD equivalent condition.

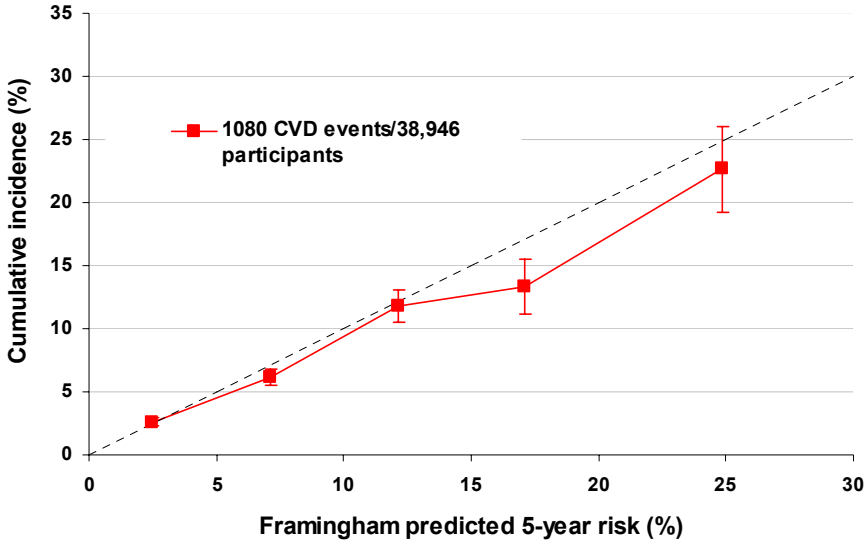


Figure 9.8 shows the same data stratified by gender and demonstrates similar calibration in men and women. The possible difference between men and women in the highest risk category may be due to random error, given the smaller numbers in this category.

Figure 9.8. Calibration of the Framingham score by gender against the cumulative mean incidence of CVD event in 5 years (with 95% confidence intervals) in participants aged 30-74 years without prior CVD or CVD equivalent condition.

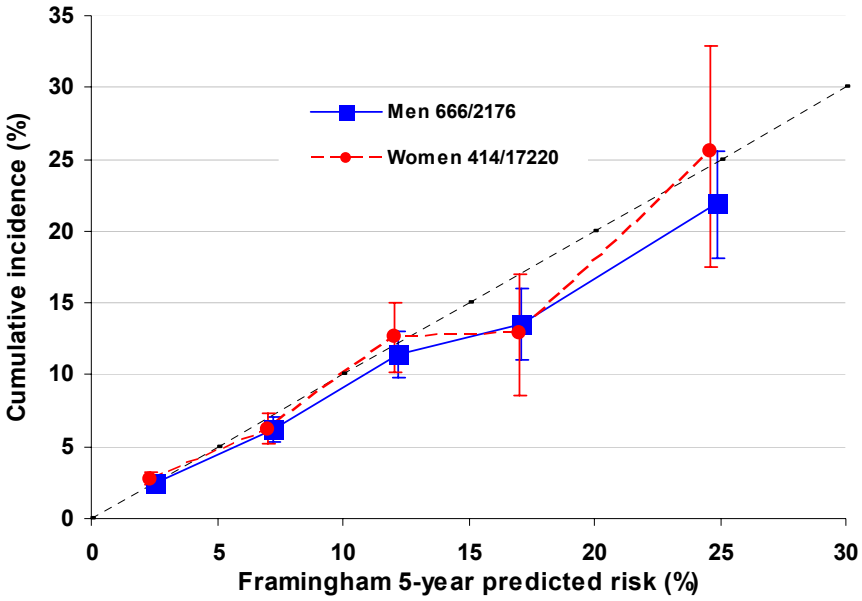
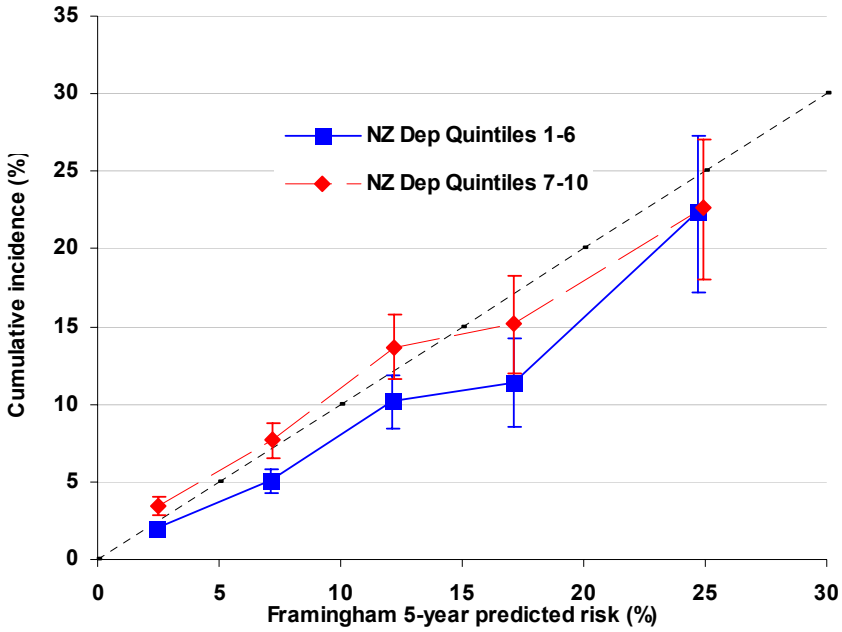


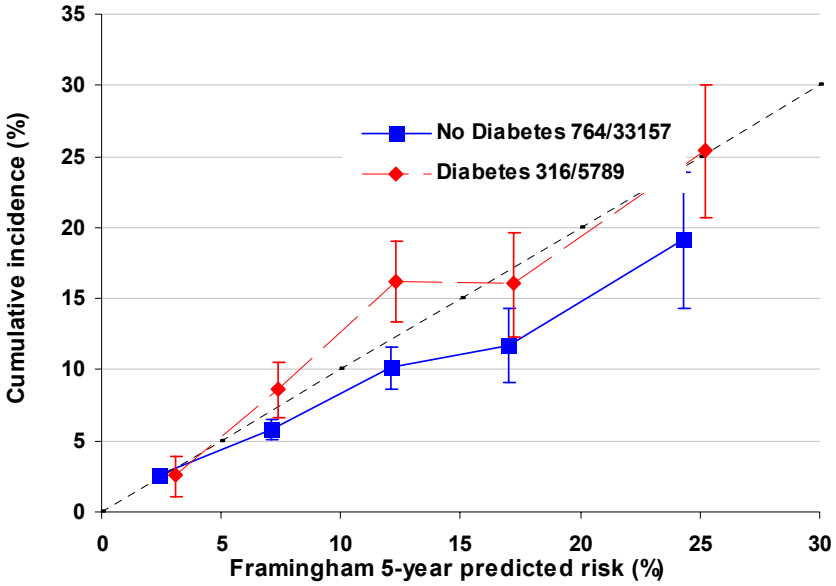
Figure 9.9 illustrates calibration by socio-economic deprivation (dichotomised into deciles to 1–6 [less deprived] and 7–10 [most deprived]). There is a separation between the calibration lines for the two groups except for the highest risk category. For the less deprived deciles, the Framingham score consistently overestimates risk at all levels whereas the Framingham score is better calibrated for the more deprived groups although it tends to slightly underestimate observed risk below 15% 5-year predicted risk and overestimate risk above the 15% 5-year predicted risk.

Figure 9.9. Calibration of the Framingham score by NZ Dep Index Quintiles in participants aged 30-74 years without prior CVD or CVD equivalent condition.



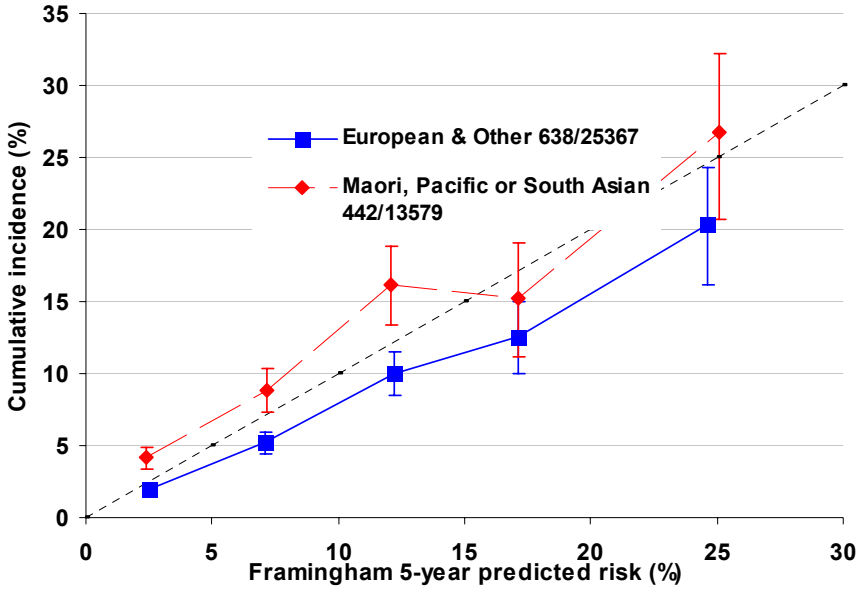
For people with diabetes (Figure 9.10), the Framingham score tends to underestimate observed risk at the lower end of the risk distribution but predicts risk accurately above about 15% 5-year risk. In contrast the Framingham equation overestimates risk for all people without diabetes above a 5-year CVD risk of about 5%.

Figure 9.10. Calibration of the Framingham score by diabetes status in participants aged 30-74 years without prior CVD or CVD equivalent condition.



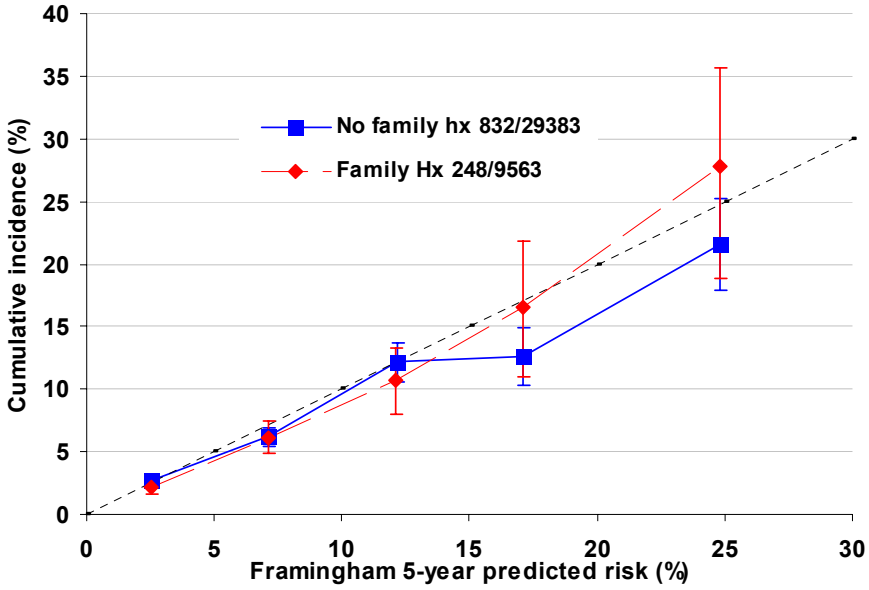
The Framingham score underestimates risk in the combined 'high risk ethnicity groups' (Māori, Pacific and South Asian) in all predicted risk groups under about 15% 5-year risk (Figure 9.11). The potential implication of underestimating risk in these population groups is that they could miss out on appropriate treatment. For all other 'low risk' ethnicities, the Framingham score overestimates the observed 5-year risk.

Figure 9.11. Calibration of the Framingham score by high and low risk ethnicities (according to NZGG criteria) in participants aged 30-74 years without prior CVD or CVD equivalent condition.



A positive family history of premature ischaemic CVD event in a first degree relative (father or brother under 55 years, mother or sister under 65 years) does not appear to increase risk compared with those with no family history up to about 15% year CVD risk (Figure 9.12). Above about a 15% 5-year CVD risk, there appears to be a separation between those with and without a family history. As expected, there is a higher risk in people with a family history but the Framingham score is well calibrated for this group while it overestimates the risk in people without a family history. This suggests that the NZGG upward adjustment of the Framingham score by a blanket 5% for people with a family history is unnecessary.

Figure 9.12. Calibration of Framingham by family history of premature ischaemic CVD in participants aged 30-74 years without prior CVD or CVD equivalent condition.



The NZGG CVD guidelines, recommend that patients with a very high blood pressure or blood cholesterol can be assumed to have a 5 year CVD risk of at least 15%, whatever their estimated Framingham score. A very high blood pressure (BP ≥ 170/100 mmHg) or a very high total cholesterol or TC/HDL ratio (TC or TC/HDL ≥8) does not appear to increase the observed 5-year CVD event rate over and above the risk predicted by the Framingham score (Figures 9.13 & 9.14). However the precision of observed risk estimates was only modest in the higher predicted risk categories, particularly for cholesterol.

Figure 9.13. Calibration of the Framingham score by 'very high blood pressure' (BP170/100 mmHg or over) status in participants aged 30-74 years without prior CVD or CVD equivalent condition.

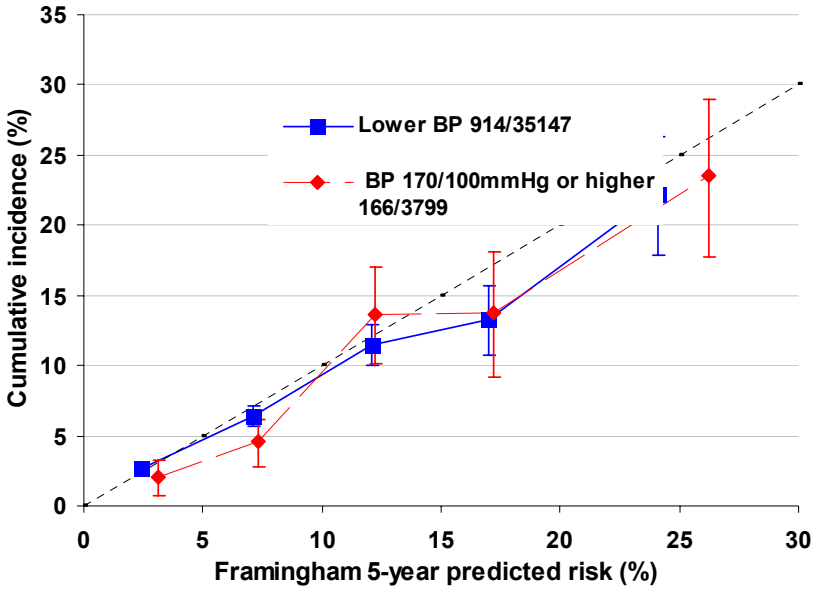
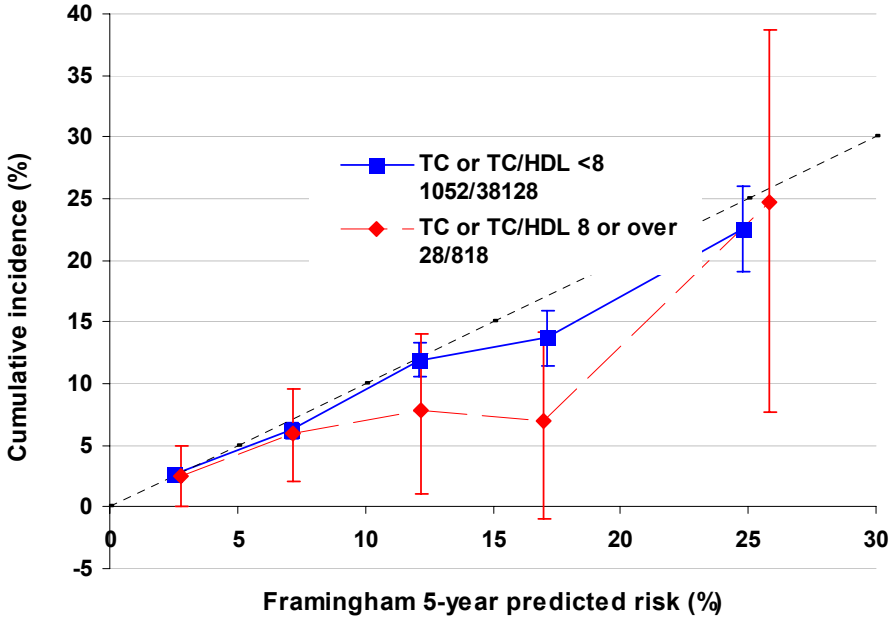
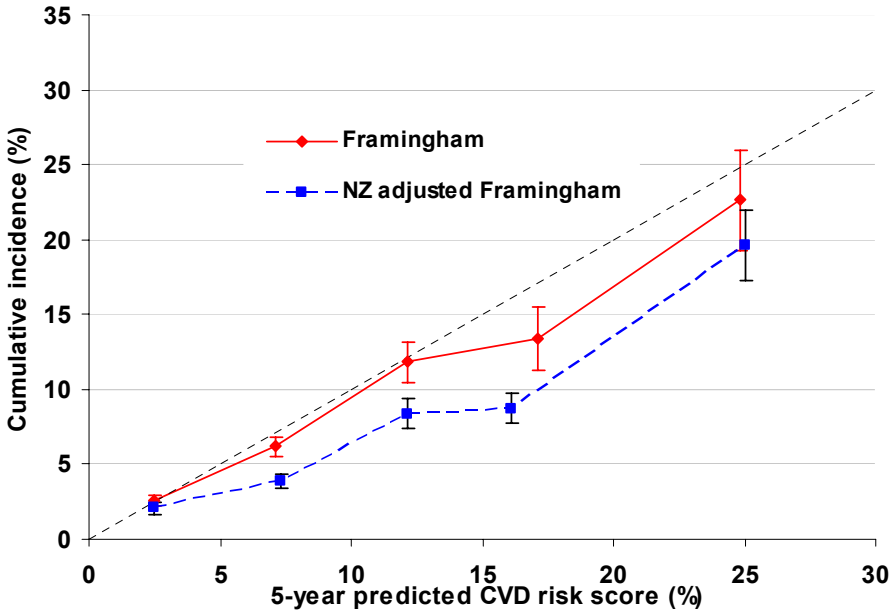


Figure 9.14. Calibration of the Framingham score by 'very high total cholesterol or TC/HDL' (TC or TC/HDL 8 or over) status in participants aged 30-74 years without prior CVD or CVD equivalent condition.



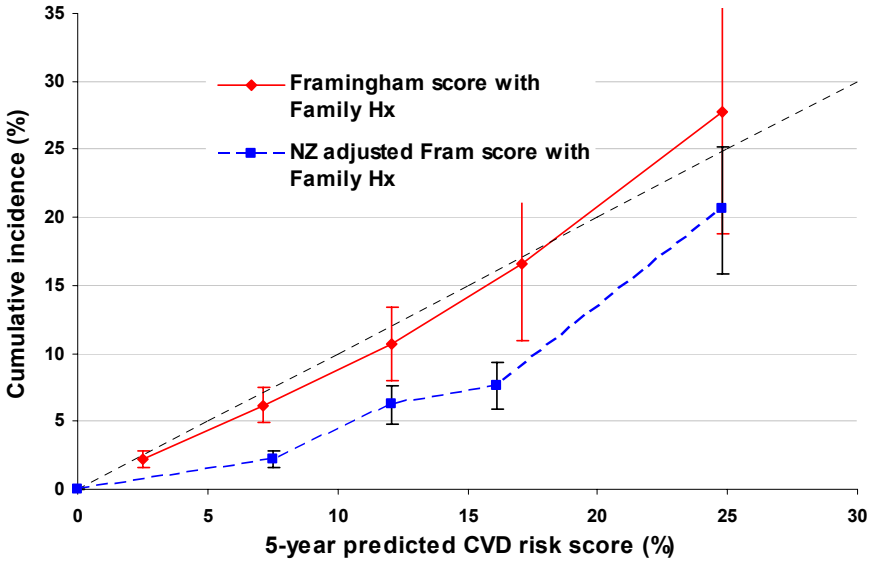
The final calibration graphs (Figures 9.15-9.17) compare the calibration of Framingham scores with NZGG adjusted scores. As there was complete data from the whole cohort for only two of the adjustment factors used in NZGG scores (premature family history and high risk ethnicity, with the other adjustment categories only included in PREDICT CVD-Diabetes), additional figures for participants with these two factors (Figures 9.16 & 9.17) are presented.

Figure 9.15. Calibration of the Framingham score compared with NZGG-adjusted score for participants aged 35–74 years with no prior CVD or CVD equivalent condition.



At all risk levels above a 5% predicted risk, the NZGG-adjusted score overestimated the 5-year event rates by around 4–7%, thus lowering the actual threshold for intensive treatment by this amount. In effect the current NZGG-recommended threshold for drug therapy of 15% score equates to about a 10% 5-year observed CVD risk (i.e. equivalent to the risk threshold used for drug treatment in the UK and Western Europe).

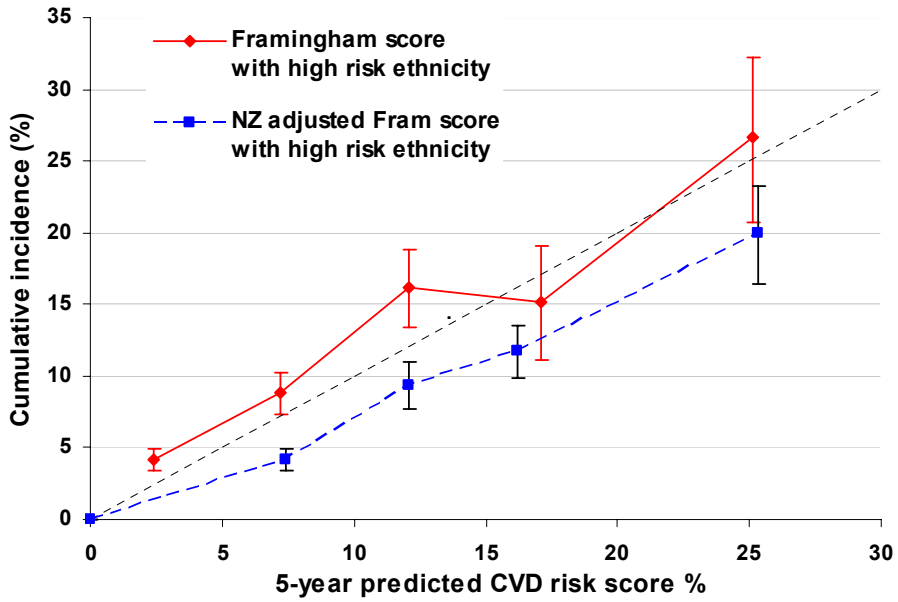
Figure 9.16. Calibration of the Framingham score compared with the NZGG adjusted score in participants with a positive family history of premature CVD (248 events in 22,670 participants)



The overestimated predicted risk using the NZGG score was to a significant extent driven by the systematic overestimation of risk in participants with a positive family history of ischaemic CVD (Figure 9.16) because approximately a quarter of the cohort reported a positive family history (described previously).

While the Framingham equation tended to underestimate the cumulative 5-year CVD event rate for the high risk ethnicity category, the NZGG-adjusted risk score over compensated (Figure 9.17) leading to an overestimated predicted risk across the risk distribution by approximately 2-3%. This over-adjustment is the other significant contributor (along with the family history adjustment) to the observed overestimate of predicted risk using the NZGG-adjusted score, given the substantial proportion of the cohort (34%) who had a high risk ethnicity.

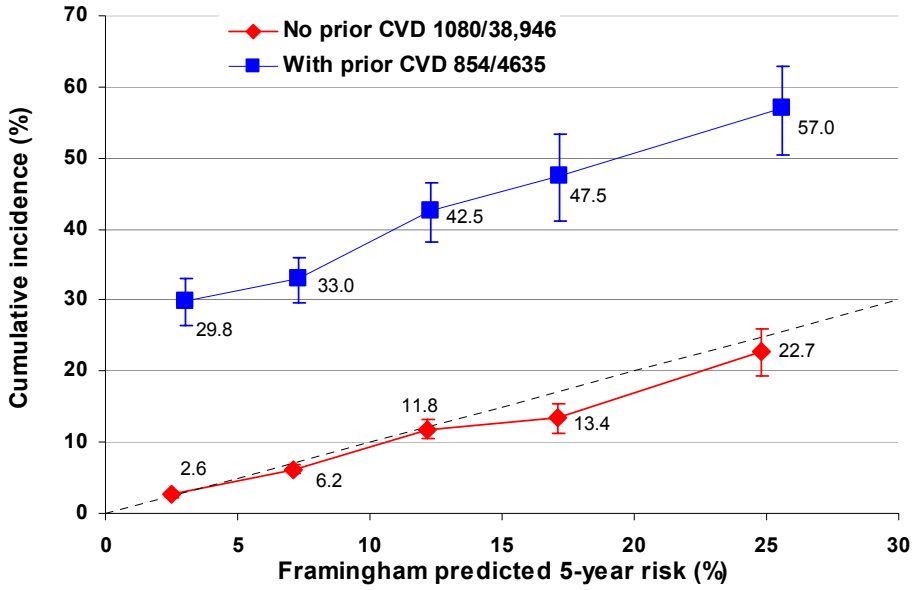
Figure 9.17. Calibration of the Framingham score compared with the NZGG adjusted score in the 'high risk ethnicity' category (i.e. Māori. Pacific and South Asian peoples) who suffered 442 events in 13,579 participants



Comparison of cumulative 5 year incidence by 5-year Framingham CVD risk group for those with and without a prior CVD event

A separate analysis was conducted to assess the appropriateness of NZGG CVD risk guidelines classifying people with prior CVD as having a 5-year risk of a CVD event of at least 20% (i.e. "clinically at high risk"). The risk of an event for those aged 30-74 years with and without prior CVD was compared below (Figure 9.18) after adjusting for CVD risk factors (i.e. using Framingham equation to categorise participants into 5-year CVD risk groups). The cumulative incidence % is given for each category of mean Framingham risk.

Figure 9.18. Comparison of observed cumulative 5 year incidence (%) by 5-year Framingham CVD risk group for those with and without a prior CVD event aged 30-74 years



For those with a prior CVD event, the risk of a subsequent event in five years ranges from about 30% to 57% depending on presence and level of standard CVD risk factors. Participants with prior CVD have 5-yr CVD risks approximately 27-34% higher in absolute terms compared with those without a prior event.

9.6 Performance of the Framingham equation: discrimination

The performance of a risk prediction equation can also be assessed by its ability to discriminate between those people who will have an event (sensitivity or true positive) and those people will not have an event (specificity or true negative) during a defined follow-up period. In this thesis, two aspects of discrimination are examined; a summary measure of discrimination across the whole risk distribution and discrimination at specific risk thresholds.

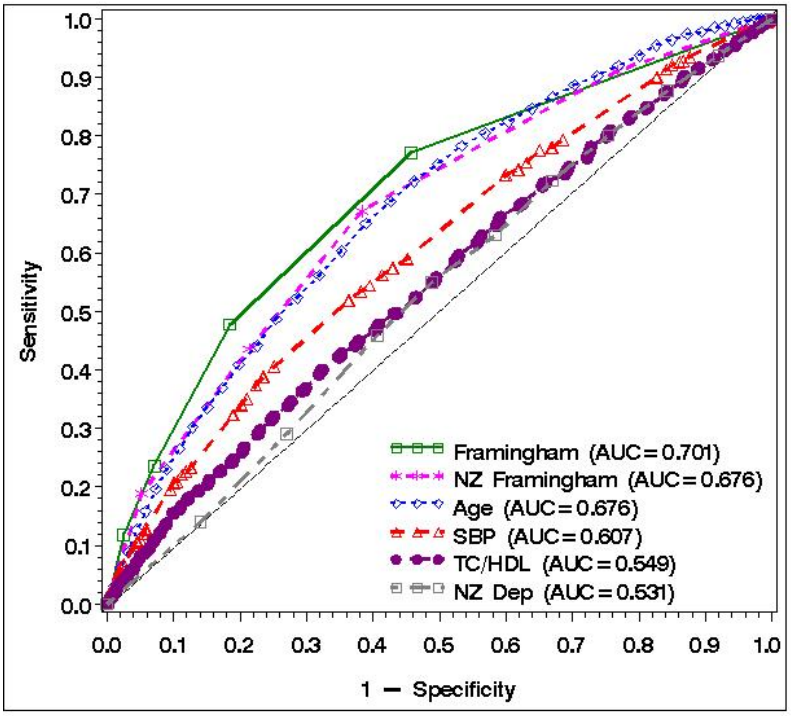
Summary measure of discrimination

A most commonly used summary measure of discrimination is the area under the curve (AUC) of Receiver Operator Characteristic (ROC) graphs. Figure 9.19 shows an ROC curve comparing the discrimination performance of the Framingham score, the NZGG-adjusted score, as well as the performance of age, systolic blood pressure, TC/HDL and the NZ Dep Index (deciles 1–10), each assessed singly. These analyses only include the cohort without prior CVD among whom a predicted risk was calculated (n=38,946). As with the calibration analyses described above, participants with a prior CVD event, diabetes with nephropathy, familial genetic lipid disorders, or aged under 30 years and older than 74 years have been excluded from these analyses (also excluded are the 14 patients with missing data).

The Framingham score (Figure 9.19) had the highest AUC statistic of 0.701; which is a modest result. In other words there is a 70% probability that the predicted risk is higher for those who subsequently had a CVD event compared with those who do not.

Age was the strongest single predictive factor and equally as discriminating as the NZGG-adjusted score (AUC 0.676). Systolic blood pressure (AUC 0.607) performed better than TC/HDL (AUC 0.549), most likely because of the stronger positive association between age and blood pressure than between age and lipid levels. NZ Dep Index (AUC 0.531) had almost no value as a discriminator at higher deciles levels of deprivation and at lower deciles tracked with TC/HDL.

Figure 9.19. ROC curves of the Framingham and NZGG adjusted scores, age, systolic blood pressure, TC/HDL and the NZ Dep Index in participants aged 30-74 years without prior CVD or CVD equivalent condition.



Figures 9.20 and 9.21 present the same analyses as above stratified by gender. The Framingham score performed slightly better for men than women (AUC 0.708 compared with 0.682) as did the NZGG-adjusted score (AUC 0.686 compared with 0.651). For women, age alone was a slightly better discriminator than the NZGG adjusted score (Women Age AUC 0.679 compared with women NZGG-adj score AUC 0.651).

Figure 9.20. ROC curves of risk scores and risk factors for men

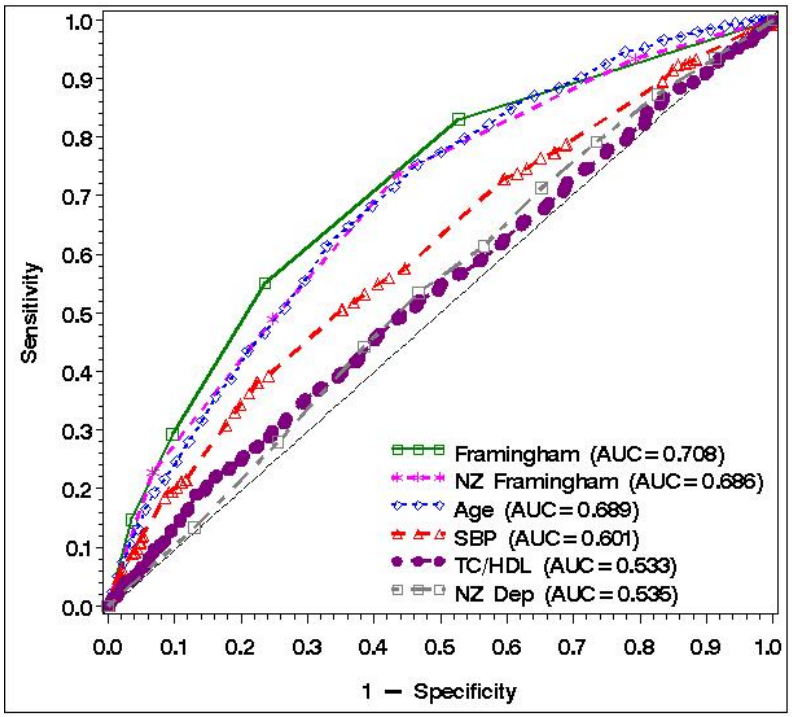
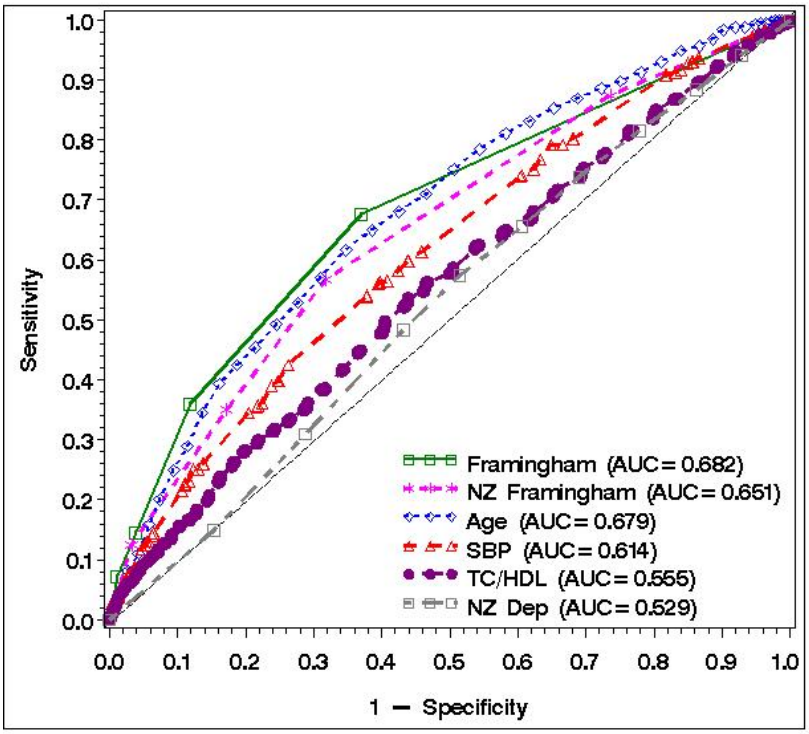


Figure 9.21. ROC curves of risk scores and risk factors for women



9.6.1 Threshold discrimination

An analysis was also undertaken to assess discrimination at the specific treatment thresholds recommended by New Zealand guidelines. As previously discussed, summary measures such as the AUC do not account for the distribution of risk in a population-based cohort. (e.g. a small proportion at high risk and majority at low risk).[293] Clinically, discrimination above and below treatment thresholds is more important than discrimination across the whole range of risk.[293] As discussed previously, the 2003 NZGG CVD risk guidelines stipulated four thresholds for determining subsequent management;

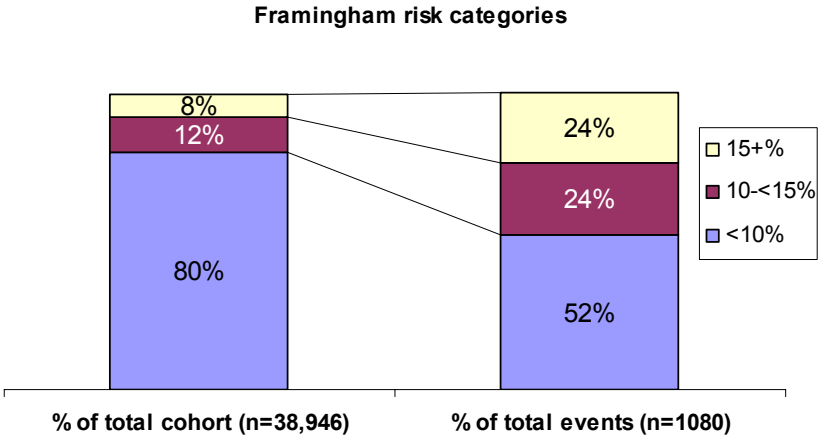
- less than 10% 5-year CVD risk (or mild risk)
- 10-15% 5-year CVD risk (moderate risk)

- over 15% 5-year CVD risk (high risk)
- those with prior CVD (clinically high risk).

Threshold discrimination describes the performance of a risk prediction score at specified clinically relevant thresholds. Here it is shown in the form of two vertical stratified columns, the first column describes the population risk distribution (the denominator) stratified into the CVD risk categories described above, while the second column describes the number of CVD events (the numerator) that occurred in each of the population risk categories during follow-up. These threshold discrimination diagrams have been produced using both the Framingham and the NZGG-adjusted score.

The first two figures (9.22 and 9.23) include the same people as in the calibration and discrimination analyses above (i.e. n=38,946; aged 30–74 yrs; with no prior CVD or CVD risk equivalent condition and no missing data). The second two figures (9.24 and 9.25) also include participants with a prior history of CVD aged 30–74 yrs (n=4637).

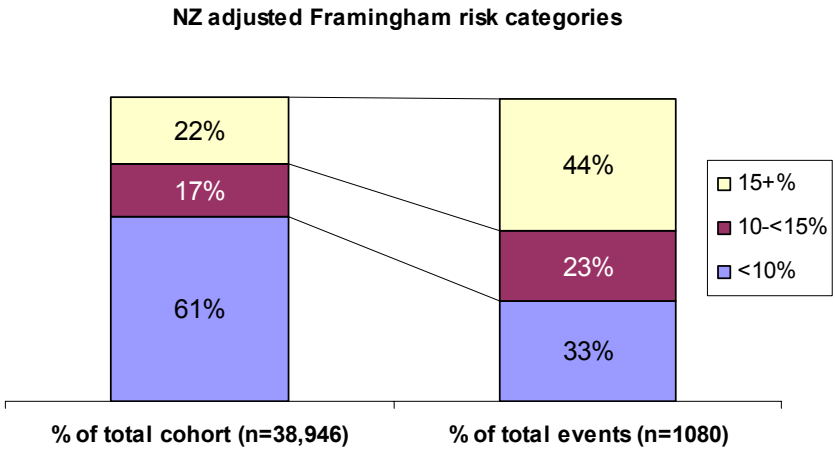
Figure 9.22. The percentages of PREDICT participants in Framingham risk categories and the subset of people by risk category who experienced an event during follow-up (cohort aged 30–74 years without prior CVD event or CVD equivalent risk).



Approximately 80% of the PREDICT cohort aged 30–74 years without prior CVD or equivalent risk, were at low risk according to the original Framingham score (<10% 5-year risk) but generated approximately half of the CVD events in this population. The 8% of the cohort over 15% Framingham risk (eligible for drug treatment) were responsible

for a quarter of the events while another 12% of the cohort between 10–15% risk and eligible for personalised non pharmacological interventions were responsible for a further quarter of all events among participants without a history of CVD.

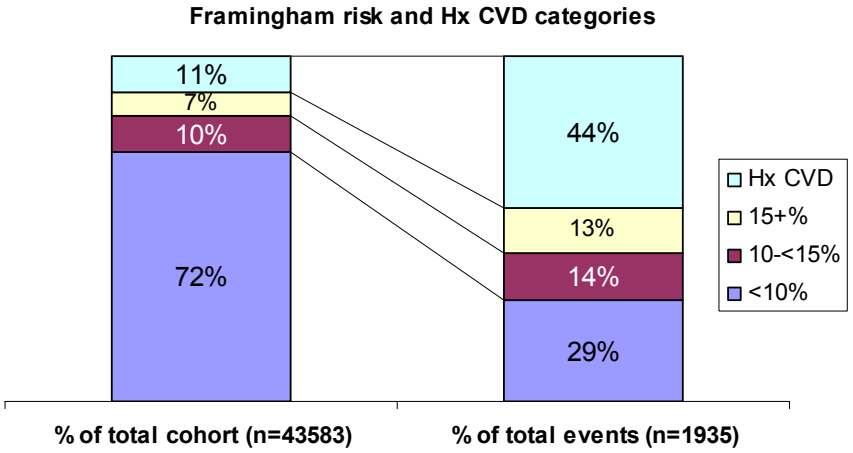
Figure 9.23. The percentages of people by NZGG-adjusted Framingham score categories and the subset of people by risk category who experienced an event during follow-up (cohort aged 30–74 years without prior CVD event or CVD equivalent risk).



Applying the NZGG-adjusted Framingham score rather than the original score, classified three times as many people as eligible for drug treatment (22% vs 8% of the cohort aged 30–74 years) and this group generated just under half the all events among participants with no prior CVD or risk equivalent. A further 17% of the cohort generating about a quarter of events, would be eligible for personalised lifestyle management while the 61% of participants in the low risk category generated one third of CVD events.

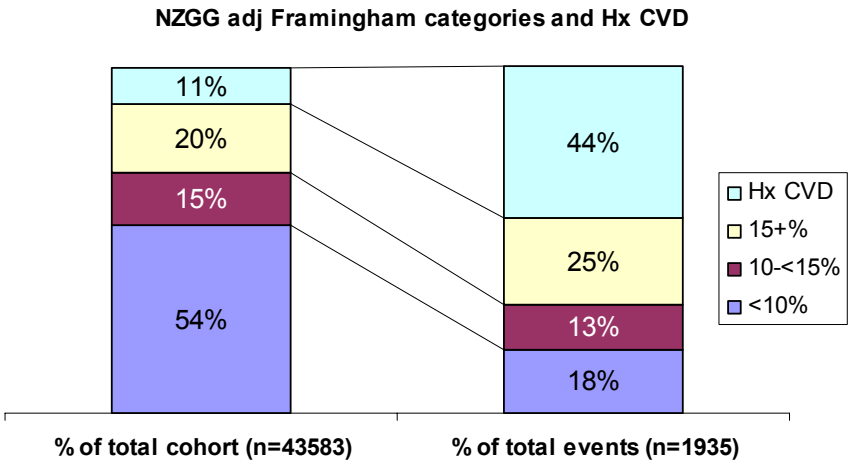
Figure 9.24 combines the primary and secondary prevention groups that need to be managed in a usual primary care practice setting using the Framingham score to classify people without prior CVD. In this cohort aged 30–74 years, 72% were at low or mild risk (less than 10% 5-year CVD risk), 10% at moderate risk (10–15% 5-year CVD risk), 7% were at high risk (15% and over 5-year CVD risk) and 11% had reported a prior history of CVD.

Figure 9.24. The percentages of people in Framingham risk categories and with prior CVD and the subset of people by category who experienced an event (Cohort aged 30–74 years where CVD equivalent groups are excluded).



Almost half of all CVD events occurred in the 11% of the cohort with a prior history of CVD. A further 13% of the events occurred in those assessed as being at high risk (over 15% 5-year CVD risk). Therefore the 18% of the cohort who met the NZGG guideline criteria for intensive management (drug, dietician and lifestyle management) generated 57% of the CVD events occurring during follow-up. If the moderate risk group (10-15% 5-year CVD risk) were also included, then 28% of this cohort would be eligible for 'personalised management' within primary care. This combined group accounted for 71% of the CVD events occurring during follow-up, many of which could be prevented if appropriate treatment had been implemented. However nearly one in three events occurred in the low risk group, for whom only brief general advice is recommended.

Figure 9.25. The percentages of people in NZGG-adjusted Framingham risk categories and with prior CVD and the subset of people by category who experienced an event (cohort aged 30–74 years with and without a prior CVD event; CVD equivalent groups are excluded).



Applying the NZGG-adjusted risk score, 31% of the total cohort aged 30–74 years were at high or very high risk (over 15% or history of CVD) and accounted for 69% of the CVD events during follow-up (compared with 18% accounting for 57% events using the Framingham score - Figure 9.25). If the moderate risk (10–15% 5-year CVD risk) is added, then almost 50% of the population would be eligible for personalised primary care management of their CVD risk. In this scenario, the remaining 54% of the participants at low risk only account for 18% (compared with 29% using the Framingham-based score) of subsequent events.

9.8 Summary of key findings

The current PREDICT cohort with participants from eight PHOs in the Auckland and Northland regions of New Zealand includes 48,306 people and 106,708 person-years of follow-up (median 2.12 years). Most of the cohort (90%) were aged between 35–74 years, 48% were European, 14% Māori, 17% Pacific and 3% South Asian. During follow-up, 2185 people were hospitalised one or more times with a CVD event and 497 people died with CVD coded as the primary cause of death. The majority of events were related to coronary heart disease.

After excluding ‘clinically at high risk’ participants (those with prior CVD, diabetes with nephropathy and high risk genetic lipid disorders), 55% of the remaining participants met NZGG guideline criteria for an upward adjustment of their estimated Framingham score by 5%.

Drug therapy information was only available on the 36% of the cohort with a completed management template. Of these participants, fewer than half of those with prior CVD were on recommended triple therapy (lipid-lowering, BP lowering and either antiplatelet or antithrombotic drug). For those participants over 10% 5-year CVD there was little evidence of appropriate targeting of drug management to higher risk patients as recommended by NZGG CVD risk guidelines.

For participants with no prior CVD, the age-standardised incidence rate of a first CVD event was 42% higher for men than for women. Māori (9.3/1000 person years) and Pacific (8.0/1000 person years) people had significantly higher age-standardised rates than European (5.2/1000 person years) with South Asian peoples having similar rates to Europeans. Age-standardised incidence increased with worsening levels of deprivation, with diabetes, smoking and in participants with very high BP levels (170/100 mmHg or above).

For those with a previous CVD event, the overall age standardised incidence rate of 51.8 /1000 person years was almost ten-fold higher than for participants with no prior CVD history (5.4/1000 person years). Men fared worse than women – the age standardised incidence of a further event about 80% higher than in women.

The performance of the original Framingham score and the NZGG adjusted Framingham score was assessed in three ways; by comparing mean predicted risk (by risk category) with the observed events (calibration), by ROC curves (summary discrimination measure) and by examining the performance of the scores at specified treatment thresholds (threshold discrimination).

The original Framingham score was well-calibrated for the total cohort with the mean risk scores approximating the observed risk at lower risk levels but with about a 5% unit

overestimation for predicted 5-year risk categories above 15%. However, when stratified by other variables the Framingham tool overestimated risk for participants who were less deprived (NZDep 1–6), without diabetes and European or in non-Māori, non-Pacific and non-South Asian ethnic groups. The Framingham risk score was well calibrated for those with a positive family history and adding 5% CVD risk to Framingham score in the NZGG adjusted risk tool does not appear to be justified in this cohort. Of concern, the Framingham score underestimated risk by 2-3 percentage points in the combined high risk Maori, Pacific and South Asian ethnic groups predicted to have a risk of less than 15% in 5 years. However the NZGG adjusted score tended to over-adjust in all clinically relevant risk categories. For all risk levels above a 5% predicted risk, the NZGG adjusted score systematically overestimated the 5-year event rates by around 4–7%. In effect the current NZGG recommended threshold for drug therapy of 15% score equates to about a 10% 5-year observed CVD risk.

Participants with prior CVD have 5-yr CVD risks approximately 27-34% higher in absolute terms compared with those without a prior event. This finding supports the appropriateness of NZGG CVD risk guidelines classifying people with prior CVD as having a 5-year risk of a CVD event of at least 20% (i.e. “clinically at high risk”).

The Framingham score produced the highest summary discrimination score (AUC = 0.701). Age alone was the strongest single risk factor and was as discriminating as the NZGG adjusted score (AUC 0.676).

However, the most clinical- (and policy-) relevant information about the performance of risk prediction scores are the proportions of the target population within recommended treatment categories and the corresponding proportions of events that occur in these categories. These measures provide information on the potential resource implications of setting treatment thresholds and the impact of treatment on event rates if all patients in these categories were appropriately treated. The NZGG adjusted risk score would have classified almost half of the PREDICT cohort above 10% risk (eligible for personalised management) and this group accounted for 82% of the CVD event that occurred during follow-up, whereas the original Framingham score would have classified less than one-third above 10% 5 year risk and accounted for 71% of the events.

With several additional years of follow-up, it should be possible to develop better calibrated and more discriminating risk prediction scores and enable policymakers to determine the trade-off between the costs of individualised management of large numbers of people and the benefits of preventing CVD events.

10 Discussion: the PREDICT cohort study

10.1 Introduction

The main aims of this thesis were to investigate the potential of a CDSS to improve the assessment and management of CVD risk in New Zealand general practice while simultaneously developing a sustainable cohort study that could be used for validating and improving CVD risk prediction scores and related epidemiological research. This chapter presents a discussion of the strengths and weakness of the cohort study generated from PREDICT consultations by applying the same RAMMbo validity criteria used to critique the randomised controlled trials of CDSS in Chapter 4.

10.1.1 Representativeness / Recruitment

The study setting for the PREDICT cohort is the Auckland and Northland regions of New Zealand with a population of around 1.5 million out of the total New Zealand population of approximately 4 million. There are four DHBs and 24 PHOs in the study region and the populations of these regions are ethnically diverse. In Northland just under a third of the population are Māori and almost two-thirds are European, while in the Auckland region, 11.1% are Māori, 14.3% Pacific, 19% Asian and 56% are European or Other ethnicities.[285] This source population for the PREDICT cohort includes large representative groups of all the major population groups of relevance to the study aims.

The eligible population for the cohort is defined according the age, gender, ethnicity and risk factor criteria for CVD risk assessment recommended by the 2003 NZGG CVD risk guidelines.[23] While the majority of eligible people are between ages 35 and 75 years, there are open age ranges of eligibility above and below 35-75 years for specific circumstances according to “clinical judgement”. These broad criteria are appropriate for clinical practice, but the PREDICT cohort is unlikely to be able to recruit a representative sample of those aged under 35 years or over 75 years, unless age-related guideline eligibility criteria change. The participant population recruited to date includes

approximately 14% of those eligible in the 35–74 year age group in the PHOs that introduced PREDICT between 2002 and 2006 in the Auckland and Northland regions (and approximately 9% of the 35–74 year age group in the whole of the Auckland and Northland regions).

A participant selection process could not be proscribed (e.g. consecutive patients) as PREDICT was designed primarily as a clinical tool with the research component being conducted in the background. Some PHOs in the study region may choose not to adopt PREDICT for their member practices and if they do adopt PREDICT, it may be used opportunistically or systematically. As reported in Chapter 7, the way GPs and nurses use PREDICT varies enormously. Therefore it is not possible to describe the selection process. Ultimately this is unlikely to be a problem as 80% of the eligible population visit their GP (or practice nurse) every year and with time, the majority are likely to be included in the cohort. This will be facilitated if the proposed 2008/9 primary care performance indicators as discussed in Chapter 2 are implemented.

It was assumed that in the first few years of PREDICT implementation, the participant population would be at higher risk than the general population through initial targeting of screening to high risk groups. However as shown in Chapter 9 (Table 9.11), the prevalence of CVD and CVD risk distributions in the PREDICT cohort are reasonably similar to other New Zealand population estimates. Anecdotally, selection of patients for risk assessment has been less based on patient characteristics (age, gender, ethnicity, CVD or diabetes) but more on how busy the practice is at the time of consultation, the patient agenda for the consultation and whether the clinician remembers to consider a CVD risk assessment.

Of note, among PREDICT participants without previous CVD, the first year of follow-up accounted for just under one-third of the total person-time follow-up in the study so far, yet 43% of the CVD events identified occurred during this first year. This suggests some higher risk selection effect. The UKPDS CHD and stroke risk equations exclude the first 4 years' events and person-time of follow-up because of a selection bias, although the bias in this study was in the opposite direction.[234] The UKPDS was a randomised trial and the authors report that the strict study selection criteria resulted in lower mortality

rates in the first few years of the study than would be expected in the general population.[234] In the development of risk equations from the Framingham Heart Study, CHD events in the first few months of the study onset tended to have a relatively large influence on prediction modelling and therefore those events occurring during the first four years of follow-up were "*left censored in that interval instead of exact times*".[231 296] No adjustments for early event rates have been required in large scale cohorts such as in the development of the recent UK QRISK score (1.28 million people free of diabetes and CVD)[49] nor in the US Reynolds score (24,558 women aged 45 years or over with no CVD).[297]

Particular attention will need to be paid to these potential selection biases when new risk models are developed from the PREDICT cohort data. The PREDICT cohort has the advantage of being a large open population with new participants continually joining the study. Therefore, the magnitude of any selection bias can be reassessed over time.[161]

Homogeneity at baseline

One of the standard appraisal questions for prognostic studies considers the relative homogeneity of the disease (or risk) staging of the study participants at baseline. Ideally the study population should be recruited at a similar stage of disease progression. For CVD risk prediction modelling, the cohort population does not need to be representative of the source population. What is required is a large population with sufficient heterogeneity of exposure distribution to be able to characterise the range of risk groups in the target population for risk assessment. A risk prediction cohort should in effect comprise multiple sub-cohorts each of which have a different but internally relatively homogeneous CVD risk factor profile.

Exposure data at baseline

One of the limitations of the PREDICT cohort is that there are pragmatic constraints to the number of exposure variables that can be measured. Given the pressure on clinical time, only those variables considered essential and/or recommended by national guidelines have been collected to date. Therefore, it is likely that some relevant

prognostic indicators have not been included. It is hoped that as practitioners become more aware of the potential of PREDICT to address their clinical concerns about risk prediction and other important clinical questions, they will be more receptive to adding a limited number of new variables. Furthermore, if some of the current variables are found to provide minimal predictive power, they could be replaced with other potential candidate variables, without increasing the clinical workload.

The main benefit of a limited set of variables is its limited impact on workload and it is very likely that the uptake of PREDICT is in part a reflection of both a 'pared-down' dataset and the functionality to ease the time burden on the user.

Fortunately there are ways of capturing some important data without adding work to users. Given the way PREDICT has been designed with risk assessment and risk management templates, a large proportion (almost two-thirds) of the cohort do not have baseline data on CVD-relevant drug treatment. However, we have recently received ethical approval to link with national pharmaceutical prescribing data, so in the next phase of the study we will be able to include drug treatment information, on all participants not only at baseline, but also both retrospectively and prospectively.

Many other variables have been shown to be associated with CVD prognosis including factors related to renal function (e.g. serum creatinine, estimated glomerular filtration rate, albumin to creatinine ratio), lipoprotein factors, clotting factors and markers of inflammation.[297] [298] The PREDICT research team are exploring the potential to link to databases from regional community laboratories, particularly in regard to tests often done in the context of routine care (rather than the result of an acute disease process).

10.1.2 Allocation of participants to risk categories: measurement of exposures

"Perhaps the most vital issue in the analysis of any clinical material is the integrity of that data, within which we include the quality, completeness and relevance of the information collected. No amount of analytical sophistication will rescue a project that does not feature these properties…" Bull K and Speigelhalter D (1997). [299]

Chapter 5 described the data entry templates and the exposure variables collected for the cohort study. This study was designed to be conducted within routine primary care practice without research staff and standard study protocols. The completeness of the data was predicated on having mandatory fields in the electronic templates. The validity of the data was facilitated by appropriate template design with built-in range checks and alerts to clinicians at the point of input and with definitions of variables readily available by mouse-over or by one "click" on a helper-text field. As the user received a predicted risk estimate and management advice within seconds of entering the data, these responses from the PREDICT system also provided an indirect validity check on the data as they were based on the data entered. In addition the process of entering data was not viewed by the users as a data collection exercise for someone else's use, but as a clinical tool that required users to enter the "correct" data on patients in order to get the "correct" decision support back. The output from the CDSS was designed to be used for immediate risk communication with the patient, to be saved within a patient's electronic medical record and to be available to support future care. Anecdotally, most GPs and nurses used the CDSS with the patient sitting beside them, with both looking at the input screen. Each variable in turn was entered after checking with the patient. Whether this mode of data collection improved the accuracy of self-reported data (such as smoking history) has yet to be determined. A validation sub-study of data entered in the PREDICT template compared with data held within the patient electronic medical record (EMR) found that data in PREDICT is highly consistent with the data in the EMR (i.e. data stored prior to the PREDICT submission).[300] Another strength identified in this study was that the PREDICT template had a more complete and consistent CVD profile than

the EMR.[300] This systematic approach to data recording in primary care will support future evaluations of chronic disease management programmes, PHO population needs assessment and service planning.[59 301]

Despite the measures put in place to improve the validity of data entry, there are likely to be some misclassification errors in the PREDICT dataset. For example, the history of CVD categorisation depends on the accuracy of clinical reporting of prior CVD. An outcomes validation study conducted by the PREDICT research team in 2008[302] investigated cardiovascular disease history recorded at the most current PREDICT consultation and the cardiovascular hospital events recorded in National Minimum Dataset (NMDS). Of 5,359 PREDICT patients who had CVD hospitalisations within the NMDS, 1597 (30%) were not recorded as such in the PREDICT dataset.

Given the ability to link to hospitalisation and prescribing databases, it will be possible to estimate the size of these problems as well as reclassify people to the appropriate risk groups.

As with the reporting of prior CVD, there will be some misclassification of other exposures. The most important concern with misclassification is whether it is differential or non-differential. Most of these errors are likely to be non-differential as the measurement of each exposure variable is mandatory and therefore independent of the measurement of any other exposure variable. In addition they are unlikely to be related to the outcome data which are generated from a different source at a different time from the exposure data. In general, non-differential misclassification results in bias towards the Null. There are, however, two variables that may be subject to differential misclassification and these need to be interpreted with caution – family history of premature ischaemic CVD and the presence of a genetic lipid disorder (prior to the new diagnosed familial subtype variable). When in doubt there maybe a tendency for clinicians to report these risk factors as positive if the predicted risk would otherwise be low (less than 15% 5-year CVD risk) particularly if the clinician would like to start the patient on treatment. By making these variables positive, the patient's risk may be increased above the drug treatment threshold. The validity of these variables has been flagged for further investigation but is beyond the scope of this thesis.

While fasting tests were recommended for lipid profile and blood glucose measurement by the CVD risk guidelines, non-fasting tests could be entered by the clinician. PREDICT does not allow differentiation between fasting and non-fasting tests so the results reported will be a mix of both. However, the clear message from primary care providers was that any non-fasting patient assessment was far superior to *"wasting a preventive opportunity."* A fasting TC/HDL is not necessary for the purposes of CVD risk assessment, and a raised non-fasting glucose is likely to lead to further investigation. Nevertheless the lipid profile was based on only one measurement and it has been well documented that multiple measurements are required to accurately characterise a person's usual lipid profile due to technical (laboratory collection and measurement) and biological variability.[303] The PREDICT research team are currently investigating the feasibility (with ethics approval and the necessary permissions) of accessing all lipid measures made on participants. If this is possible, the predictive impact of using multiple measures rather than just one, will be able to be examined.

Blood pressure was defined as the average of two sitting measurements at least ten minutes apart. While recording blood pressure to the nearest 2mmHg is recommended, a marked end-digit preference for recording a BP ending in zero was noted (e.g. BP 140/80mmHg). The PREDICT research team have published a paper on the degree of end-digit preference in this dataset; rounding to zero was recorded for 64% of systolic BPs and 62% of diastolic BPs – much more than would be expected by chance alone.[304] This phenomenon has been described previously and disappears with the use of electronic sphygmomanometers as is the trend internationally.[305] [306] When the clinical impact of digit preference is modelled using a variety of guidelines, it was found to be less of a problem when management is based on absolute CVD risk than the traditional BP management guideline based on BP thresholds.[304] But, as with lipid measures, multiple measurements are required to accurately characterise a person's usual blood pressure.[307] [308]

These errors will impact on the predictive performance of risk prediction scores and as shown by the ROC curves in Chapter 9, the contribution of individual risk factors, other than age and gender is modest. This is not surprising given that the probability of a CVD event is related to long-term exposure and one-off measures of risk factors are only

indications of current exposure. The large impact of age on risk suggests that age is probably a better indicator of the accumulated exposure to the known risk factors for CVD than one-off measures of specific risk factors.

An important area for concern is that we are trying to assess what the natural history would be if the participants had no additional treatment. However, a significant proportion of people are already taking one or more CVD drugs at baseline and it could be argued that a CVD risk assessment in itself may interfere with the natural history by inducing additional treatment. This would be manifested by finding lower levels of risk than predicted especially at for higher risk groups as was demonstrated in the calibration graphs in Chapter 9. This confounding-by-treatment needs to be addressed more explicitly. With linkage to national pharmaceutical prescribing data we will be able to identify drug treatment information (retrospectively, at baseline and prospectively) and investigate ways of adjusting for treatment or include drug therapy into risk prediction modelling as in the QRISK score.[49]

More accurate measurement of individual risk factors may improve the predictive power of CVD risk factors in risk scores. Examples include the reclassification of smoking exposure by number of cigarettes rather than the dichotomous smoking/non-smoking variable used in the Framingham score and the reclassification of glycaemia using a continuous measure rather than the dichotomous diabetes/no diabetes variable.

Newer risk assessment tools (QRISK[50] and ASSIGN[24 49]) have included measures of socio-economic deprivation and ethnicity. The calibration graphs in Chapter 9 for ethnicity and socioeconomic deprivation were indicative of the potential to further improve the accuracy of CVD risk prediction. However, major improvements in the accuracy of risk prediction are most likely to come from measures of damage to blood vessels, heart or kidneys. Examples are carotid artery ultrasonography measuring carotid intima-medial thickness,[309-311] the use of echocardiograms to detect left ventricular hypertrophy,[312 313] and measures of microalbuminuria to assess renal vascular disease.[314] These factors, like age, reflect the accumulation of risk over time rather than just current exposure, but they will have to be available, practical and affordable in usual practice to be relevant.

Maintenance of exposure status during follow-up

A potential weakness of the PREDICT cohort is the lack of follow-up measures of exposure. As it is based in routine clinical practice, participants are not systematically followed up with re-measurement of exposures so it is not known whether exposure status has changed (e.g. started smoking). To date only 17% of those with a baseline PREDICT assessments have follow-up PREDICT records. These people are not likely to be a representative sample of the entire cohort and so these data have not been presented in this thesis. However, as discussed, we now have permission to follow up prescribing practices after baseline assessments and we are exploring the potential to link with community laboratory lipid profile data that will enable us to assess changes in blood lipids over time. The other way we will attempt to minimise the impact of changes over time in our analyses is to develop risk prediction scores using very large numbers of people followed for relatively short periods of time rather than small numbers followed for long periods. Given the design of PREDICT, we are fortunate that large numbers of participants will continue to be recruited over many years, enabling us to generate large amounts of person-time follow-up without requiring long-term follow-up.

10.1.3 Length and completeness of follow-up

A major strength of the study is the completeness of follow-up. There appear to be only two ways that participants will be lost to the study – if their eNHI cannot be matched to the NZHIS eNHI or if they emigrate. With respect to matching datasets, fewer than 1% of the PREDICT eNHIs (372/48,678) could not be linked to national datasets over a median follow-up of two years. In regard to emigration, Statistics New Zealand,[315] report the annual permanent and long term departures of New Zealand residents to be around 80,000 persons per year (~2% total population/year). As discussed in Chapter 8, about 72% of the adult population over 35 years meet the eligibility criteria for CVD risk assessment, and assuming those who emigrate are mainly adults, then approximately 1.4% per year are lost to emigration. If our cohort experiences similar emigration rates then we could expect a total loss to follow-up of less than 2% (1.4% + 0.05% non-matching eNHI) per year (~10% over 5 years).

At this stage of the PREDICT programme, follow-up time is relatively short and it will be several years before new CVD prediction scores, for estimating 5 year risk, can be developed.

10.1.4 Measurement of outcomes (blind or objective)

To derive risk prediction equations for all New Zealanders and for high risk population sub-groups, data on relevant fatal and non-fatal CVD outcomes need to be as completely ascertained as possible, be ascribed to the correct person with the correct ethnicity or disease state (e.g. diabetes) and be an accurate record of the actual event.

A strength of PREDICT compared with many other risk prediction cohorts is that the main outcomes (i.e. hospitalisations) were identified and classified blind to knowledge of the exposure data. Most CVD hospitalisations are precipitated by the onset of an acute symptomatic event and the diagnostic classification is based primarily on these symptoms and tests done during the hospital admission. Increasingly CHD-related diagnoses are also based primarily on sensitive and objective laboratory tests, such as cardiac troponins. Many of the deaths will, however, be certified by the same general practitioner who completed the PREDICT assessment so it is possible that knowledge of a patients risk profile may influence the classification of cause of death.

Almost all acute medical conditions requiring hospitalisation in New Zealand receive their initial treatment in public hospitals. However, a weakness of the PREDICT cohort study is that as outcomes are based on admissions to public hospitals and deaths, some incident CVD events will be missed. For example events that are treated in private hospitals (e.g. for stenting or bypass procedures) are not included in the NHI-linked national hospitalisation datasets. Also undiagnosed events in the community and other events that do not result in admission to public hospitals may be missed. Examples include silent myocardial infarction, new stable angina, mild congestive heart failure, TIA or stroke especially in the very old who may be admitted to private geriatric hospitals. In addition, events that occur when a member of the cohort travels overseas will not be recorded in the national dataset.

However, the linkage to pharmaceutical data will ensure that participants with drug-treated angina will be included in the outcomes dataset and the national pharmaceutical dataset will also 'capture' many participants who have their stents or bypass surgery done in private hospitals as poorly controlled angina is one of the major indications for these procedures.

Another potential weakness with regard to outcome classification is the reliance on ICD codes to ascertain the cause of hospitalisation or death. The PREDICT research team undertook a review of the local and international studies on the validity of ICD-based diagnoses to assess the likely extent of this problem in the PREDICT cohort.[302] The last published validation study of New Zealand coronary heart disease ICD codes of hospital discharges was in 1987.[316] At that time ICD 9:410 (acute myocardial infarction) had a sensitivity of 86%. If a broader range of codes was used, ICD 9: 410–414 (all coronary heart disease) then the sensitivity increased to 95%.[316] A 1988 audit of coronary heart disease death certificates and subsequent ICD coding found that ICD 9 410–414 codes had a sensitivity of 91%. Similarly the narrower the range of sub-codes used, the lower the sensitivity.[317]

There are no other published New Zealand ICD coding audits. From international audits of stroke[318-320] it appears that many first events occur outside of hospital (especially if including TIA). We have used ICD codes from both the primary and secondary ICD coding fields. Estimates of coding accuracy show that the sensitivity for using ICD 9:430–436 is high (97% of cases of stroke and TIA) but the positive predictive value is much lower (72% of those coded actually had a stroke event causing admission).[318] The impact of including both primary and secondary codes is that we will overestimate the person-time to first event but ensure that these community events are captured.

Using ICD coding for heart failure events is likely to result in a substantial underestimate with sensitivities reported at 62.8%[321] and 66%[322] and positive predictive values at 87.4%[321] and 77%.[322] As shown in New Zealand validation studies, errors in ICD coding were much more likely to occur in sub-diagnostic categories (acute myocardial infarction or acute coronary syndrome or angina pectoris) and these also change over time due to

changes in diagnostic tests. We were unable to find any validation study of ICD coding for peripheral vascular disease (PVD).[302]

An unpublished report of coding validation based on a random sample of medical notes (*all codes*) from Northern, Waitemata, Auckland and South Auckland hospitals in 1995/96 found that 96% of ICD 9 codes were correct up to 3-digits.[323] From the PREDICT outcome validation review,[302] it appears that the frequency of audits of disease coding by DHB vary from regular (3-monthly) internal service-specific and individual coder audits to very infrequent audits of coding quality. However, for every hospital there is regular feedback from NZHIS if inconsistencies in coding are identified e.g. a male procedure performed for a female patient.[302]

In summary, published estimates of ICD coding sensitivity are relatively high for CHD and stroke, moderate for CHF and absent for PVD. As New Zealand risk prediction scores are designed to predict the risk of major vascular disease, the degree of coding inaccuracies in specific subcategories is less important than for all vascular events. While it appears that the ICD coding practices are reasonably robust in the New Zealand health services, it would be useful to conduct a medical record-based validation study for the combined group of all CVD-relevant death and hospitalisation events to support the development of New Zealand-specific CVD prediction equations.

10.1.5 Study analyses

The main objective of the analyses reported in the previous chapter was to describe the extent and quality of the emerging PREDICT cohort datasets, particularly the linked exposure and outcome data. A secondary objective was to present preliminary analyses validating the Framingham risk prediction score and the adjusted Framingham score used in the NZGG CVD risk assessment and management guidelines. This thesis demonstrates that it is possible to collect reasonably high quality and complete data on the major known CVD risk factors in large numbers of people using the PREDICT system and to link these risk factor profiles to major CVD outcomes.

The next major analytical objective of the PREDICT programme is to develop new risk prediction models and the timing of these analyses will depend on size of the cohort, incidence rates of CVD and the follow-up time. The current risk prediction score used in New Zealand was derived from a US cohort of 5573 people aged 30 to 74 years (Framingham Heart Study and Framingham Offspring Study) enrolled between 1968 and 1975 and followed for up to 12 years (i.e. abut 50,000 person-years of follow-up).[25]

The cohort data presented in this thesis already represent 106,708 person-years of follow-up with a median follow-up of 2.12 years. However, we plan to develop prediction scores for Māori and other high-risk population subgroups and it will be several years before we have similar person-years of follow-up to Framingham for these sub-populations. Also, as discussed above, it will be necessary to investigate whether there is an excess of observed events over expected occurring in the early months after the baseline assessment. Therefore, we plan to aim for a median follow-up time of about 5 years, before developing definitive new prediction scores. During this waiting period we will accrue significant numbers of new participants as well as additional follow-up time for those already recruited. At the same time, the linkage of new data with laboratory and drug prescribing during follow-up will further enrich the cohort dataset.

11 Conclusion

A two-pronged research question was asked at the initiation of this thesis;

Using a computerised decision support system, is it possible to get evidence-based recommendations into routine clinical practice at the time of decision making to improve the quality of care for CVD risk assessment and management while simultaneously getting evidence out of practice to conduct CVD risk prediction and related epidemiological research?

This thesis has demonstrated that the answer to both is yes. Evidence-based recommendations for individual patients on CVD risk assessment and risk management can be delivered at the point of decision making in primary care in a sustainable way and the provision of a CDSS tool for CVD risk assessment and management is associated with improvements in clinical practice. The development of a large cohort using CDSS in routine practice is feasible and has enabled high quality CVD data to be collected for developing improved CVD risk predictions tools and for multiple other research purposes.

This thesis was stimulated by an evidence-practice gap and a research knowledge gap. There were concerns that quantitative CVD risk assessments were rarely done as part of routine primary care practice, despite over ten years of national guidelines recommending risk-based (rather than risk factor-based) management of CVD risk, plus nation-wide education and the dissemination of numerous paper-based risk assessment scores. In addition, concerns had been raised that the currently available risk assessment scores may not be appropriate for New Zealand populations today, given their origin 30–50 years ago in North America.

The potential for CDSS to assist in closing these gaps was raised. However, all interventions are associated with benefits and harms including opportunity costs. Information technology (IT) is expensive and the majority of health care IT projects are likely to fail.[261] Therefore, as this research requires long-term sustainability, a major part of this thesis was devoted to describing the setting and the tool –- the readiness of the

health care environment and general practice in particular for such a structural change, the evidence for benefit from implementing this change and the type of system and IT standards that would best perform the tasks.

The health care setting and policy environment "scan" found that the introduction of a web-based CDSS CVD risk assessment and management was feasible given the advent of organised general practice, the health policy environment and the focus on chronic diseases (CVD and diabetes) and preventive care. New Zealand general practice is highly computerised and is world leading. Unified standards for collecting, coding, messaging and network infrastructure to support patient and population health have been developed alongside sound health information privacy statutes to safeguard patients. The NHI number was the key anchor for connecting patients, health care delivery and health outcomes. Furthermore, via the NHI number, population health research for linking patient profiles to major health outcomes was possible.

Over 60% of the CDSS evaluation studies in a variety of health care settings have reported small to moderate improvements in documentation, preventive care, chronic disease management, drug dosage and prescribing (Chapter 3). The effects on patient outcomes were understudied and inconsistent. Where patient outcomes were studied, they were generally intermediate or surrogate outcomes with study durations too short to expect effects in chronic disease outcomes. Adverse effects of CDSS included increased time for direct and indirect patient care, loss of privacy and confidentiality, possible changes to doctor-patient relationship, lack of training and the time commitment involved with learning to use computers or systems. The cost of computerisation and implementation of CDSS was also a commonly cited problem but there were few data on costs and cost-effectiveness. Kawamoto et al. (2005) identified four key components of clinical decision support systems associated with improvements in care – being computerised, providing decision support automatically, producing recommendations (not just assessments) and decision support provided at the time and place of decision making.[145]

There had been no systematic review specifically investigating the clinical impact of CDSS for CVD risk assessment and evidence-based CVD risk management in any

setting. This was conducted in Chapter 4 using the four Kawamoto components to inform the taxonomy of CDSS for the systematic review. Overall, improvements in provider processes were reported for 22/33 (67%) trials of CDSS systems compared with usual care; 15/21 (71%) of automatic reminders, 2/4 (50%) of audit and feedback, 4/7 (57%) of provider-initiated integrated CDSS, and in the one head-to-head trial of automatic vs provider-initiated CDSS vs usual care. Patient outcomes were less likely to be investigated and only 6/15 (40%) trials of CDSS compared with usual care reported some improvements for intermediate patient outcomes. No improvements were noted for the few studies that investigated hospitalisation and mortality although studies were of short duration (2–27 months) and underpowered for these outcomes. No harms were reported. Advice available at the time of consultation (or immediately prior to the patient visit) compared with advice post-consultation appeared more effective in producing changes in clinical behaviour. Reminders appeared to be more effective than audit and feedback and provider-initiated CDSS. However, reminders were often ignored by clinicians as irrelevant and the effect of the intervention was noted in some trials to decay over time. Where reported, there was large variability of use of CDSS tools by clinicians.

PREDICT CVD and PREDICT CVD-Diabetes were developed, informed by the knowledge of the setting and literature, with the close collaboration from general practice (making it work in right way), information technology specialists (making it work well), guideline experts (making the content right) and a constant feedback loop (continually making it better). The basic tenet was that PREDICT must not only be best practice in terms of evidence content but also comply with best practice in terms of informatics. Using the technical terms described in Chapters 3 and 4, PREDICT CVD and the updated PREDICT CVD-Diabetes were provider-initiated rules-based systems with a probabilistic component (i.e. provide probability of a 5-year CVD event based on a set of patient characteristics). Management advice as well as a risk assessment is provided. In terms of location and timing of decision support provision, PREDICT is integrated with the patient EMR and decision support is provided at the time of consultation. A comprehensive audit and feedback reporting functionality was built into the design of PREDICT CVD-Diabetes. In addition, PREDICT CVD-Diabetes design incorporated a

computerised physician order entry feature with the ability to refer to other health services.

This research has demonstrated that prior to the implementation of an electronic decision support system, CVD risk assessment was recorded in only about 3% of eligible patients seen in primary care in the Auckland region. By taking national guidelines as the agreed standards for care, translating them into patient-relevant actions and making them available at the time of decision making using a web-based system, we found it was possible to increase CVD risk assessment behaviour by approximately four-fold in one cycle of use without increasing inequalities that has been noted with other health innovations.

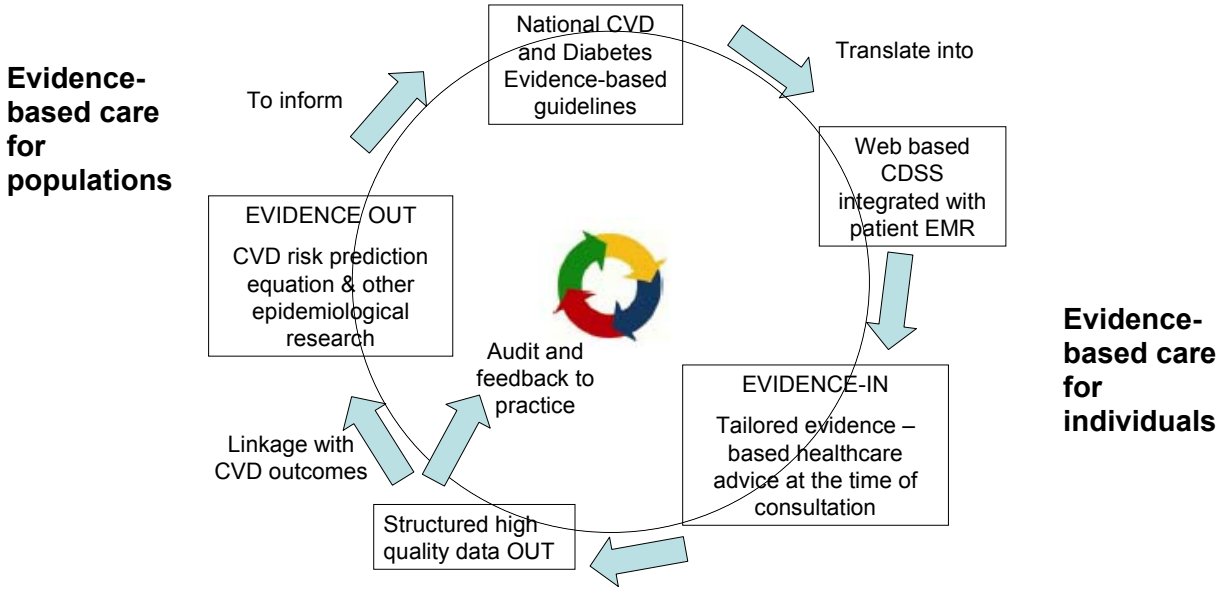
General practitioners who chose to have PREDICT installed were more likely to have vocational registration and to be less than 20 years since graduation. Women were as likely as men to adopt the programme. Adoption appeared to be responsive to annual promotional activities via GP cell groups. While a financial incentive may have helped to facilitate adoption, it had little impact on the ongoing use of the tool in routine clinical practice. There was variability in the use of the programme – 31% of GPs who had the programme installed did not subsequently use it. In retrospect, the lack of regular feedback to clinicians about their usage of PREDICT and the lack of regular review by support staff who could have identified and addressed some of the barriers to use, were important gaps in the implementation programme.

However, this research has also demonstrated that it is possible to develop a large cohort study using a CDSS, and successfully link risk factor data generated in primary care to routinely collected national hospitalisation and mortality datasets. At present the PREDICT database includes 48,306 individuals who have been assessed by over 1000 clinicians and followed for a median of just over 2 years. During that time 2655 people died or were hospitalised with a CVD event. Preliminary analyses by source, patient risk profile, drug management, time to event, incidence rates and validation of risk scores are indicative that high quality meaningful data is being generated that can be used to develop new risk prediction scores specifically for New Zealand populations.

With respect to sustainability, since the last linkage with NZHIS early in 2008, approximately 1000 new risk assessments per month have been accrued from participating PHOs and two further PHOs have agreed to include their patient data into the cohort (having used PREDICT for one and two years respectively). Furthermore, PREDICT submissions to the Enigma servers from other (as yet non-participating) PHOs indicate approximately 2,000–3,000 assessments per month have occurred over the last year. Therefore as of December 2008, approximately 40,000–50,000 additional people may be able to be added to the cohort. A key component of the implementation of PREDICT within all PHOs (participating or initially non-participating) is the distribution of all practice and patient documents so that ethical requirements are met prospectively. Members of the PREDICT Research team are currently approaching each of the non-participating PHOs for permission to pool their accrued CVD profile data.

To address the project's research questions, the thesis draws from the two theoretical frameworks of knowledge translation and quality improvement. In effect, quality improvement cycles of evidence–based care for CVD and diabetes have been created to close both evidence-practice gaps and research gaps by linking population health and individual health care approaches (Figure 11.1). The central pole that these cycles revolve around is the consultation between a patient (and their family) and their primary care provider.

Figure 11.1. Cycles of CVD and diabetes health care quality improvement, the axis revolving around the patient (and their family)



The PREDICT CDSS tool allows practice-relevant data to be readily available to help assess the quality of patient care at the individual practitioner level, at the practice level and at the PHO level. Patient data can also be made available to DHBs and for University research purposes, but only with PHO permission on behalf of their member practice teams and enrolled population. This thesis does not elaborate on the extent of communication and collaboration required to develop the trust required to bring this project together, nor the politics involved with multiple parties at multiple levels. The CDSS tool is the enabler for improvement but it is of limited value without the people who support it, implement it, use it and share it. Sustainability requires trusting relationships to continue and long term research-practice collaboration.

The cycle in the centre of Figure 11.1 represents the clinical audit cycle. This thesis followed one revolution of a clinical audit cycle typified by; setting standards for care, surveying current practice and identifying the size of the gap between current and best practice, developing and implementing an action plan (i.e. the CDSS) and measuring for improvement. The intent of this thesis was not to explore technical and theoretical aspects relating to differing informatics applications, informatics evaluation in terms of

functionality and the human–computer interface, nor to develop a model of CDSS implementation within a primary care environment. Issues related to these themes have been only considered only briefly here.

The next steps for "evidence-in"

A series of next steps for the "evidence-in" component of the PREDICT research programme are already being planned or underway. The four most developed of these new projects are listed below to illustrate the potential of PREDICT for future practice relevant research and development.

Firstly, although the Prompt Evaluation study demonstrated an improvement in CVD risk assessment behaviour, further evaluation needs to be conducted to assess sustainability of the change, and most importantly, to determine whether management practice also improves in line with current guidelines and whether improvements are equitable across populations. A feasibility study to conduct a randomised controlled trial of PREDICT risk assessment alone compared with PREDICT risk assessment and management advice, has been funded by the Health Research Council and is currently underway.

Secondly, the process of translation of guidelines for CDSS and implementing these into primary care has generated, for the first time, a tangible feedback loop from practitioners to guideline developers. A critique of the usability of the recommendations in routine practice, as well as the early analyses discussed in Chapter 9, are currently informing an update of the CVD and Diabetes guidelines. This update will require redesign, content change and safety testing for PREDICT CVD-Diabetes.

A third step will be the adaptation of the tool for specific population groups. Tania Riddell, PREDICT Māori co-principal investigator, is currently leading an HRC feasibility study investigating a whānau ora approach to cardiovascular risk assessment and management. The context of delivery will be different and although the evidence content will not change, the way the content is presented (including the patient information) is likely to be substantially adapted. In addition there has been interest from several Pacific

PHOs to translate the patient information content in PREDICT into multiple Pacific languages.

Fourthly, I am co-leading a project to improve the risk communication component of PREDICT. While primary care practitioners find it challenging enough to routinely assess CVD risk given other competing priorities, supporting patients to change 'risky' lifestyles and behaviour is an additional major challenge. Communicating the meaning of CVD risk is conceptually difficult and it is hard for people to make decisions that require them to change their lifestyles without a clear understanding of what 5-year CVD risk means. The theory and practice of risk communication, patient understanding and decision-making is outside the scope of this thesis. However, after listening to practitioner stories, there appears to be a range of responses from fatalism to denial associated with discussing a patient's risk score; from *"its high, I'm going to die, so there's nothing to be done"* to *"that sounds pretty low, there's nothing to worry about."* Clearly neither response captures the probability of an event, the cumulative damage on the vascular system, or the knowledge that the underlying pathology is highly modifiable or even reversible over very short time frames. Dr Andrew Kerr (cardiologist at Middlemore Hospital and PREDICT co-investigator) and I have been developing a CVD risk trajectory tool (The Heart Forecast) that has been made into an interactive electronic tool. This new project is being undertaken in collaboration with the National Heart Foundation. The tool is designed to be integrated with PREDICT (or any other CVD risk assessment software) and will provide a graphical story at the time of consultation of current risk (where you are now), what that means in terms of arterial health ('your arteries are as old as a healthy x year old'), what happens to your risk as you get older if you make no changes (the risk trajectory), and what would happen to your risk in future if you were able to make changes (e.g. stop smoking). The Heart Forecast integrates both absolute and relative risk concepts and takes a life course approach. This will be piloted in the next few months, amended following patient and provider feedback and then formally evaluated.

The next steps for "evidence-out"

The next main "evidence-out" step is to develop new risk prediction scores for the different at-risk New Zealand populations and to investigate the potential impact of different treatment thresholds on both disease prevention and on resource use. In order to do this, the cohort will benefit from:

- including a greater proportion of the target population to be assessed so we can be confident of the risk distribution in the population for determining the CVD and CVD risk burden in the community and the clinical impact of different thresholds for management

- the addition of CVD drug use data – at baseline to assess pre-treatment risk and to identify disease status misclassification; during follow-up to adjust baseline risk for the likely effect of drugs on event risk; and to identify new onset of non-hospitalised angina as an outcome for risk prediction

- the addition of routinely collected CVD-relevant laboratory data to determine if they will add power to predictive models

- larger numbers in at-risk populations with longer follow-up time, in order to develop more precise new risk prediction equations. Such populations include those with prior CVD, those with diabetes, Māori, Pacific and South Asian ethnicity groups and also older people such as those over 75 years.

- longer follow-up in general to make sure extrapolated 5-year risk is reasonably similar to observed 5-year risk;

- validation studies for CVD-relevant events.

For statistical modelling, both standard approaches for developing new equations as well as novel methods will be used. Standard approaches include using the Weibull fully parametric and Cox semi-parametric proportional hazards models. The Weibull model was used by the Framingham[25] and SCORE[48] investigators while the Cox model was

used in the more recent QRISK model[49] and in the Reynolds model.[297] For the total population modelling, the PREDICT cohort will be randomly divided into derivation and validation cohorts so the models can be derived in the former cohort and validated in the latter, or cross-validation procedures will be employed. Other approaches to developing risk models could include the use of search partition analysis[324] and classification and regression tree modelling.[325] Neural net and associated methodologies will also be investigated.

This thesis has demonstrated the potential of electronic decision support systems to get evidence-based recommendations *into* practice and get meaningful evidence *out of* practice. When robust predictive scores have been developed they will be offered to New Zealand national guideline developers as replacements for the adjusted Framingham score in current use. If accepted, one of the key goals of this research programme will have been achieved.

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Appendices

Appendix 2.1. Health Information Privacy Code 1994: A summary of the main rules

These rules were adapted from HealthPoint: Health Information Privacy Code (http://www.healthpoint.co.nz/default,7866.sm)

Rule 1: Health information can only be collected about you where necessary for a lawful purpose.

Rule 2: The information about you should be collected only from you, unless there is a good reason why not.

Rule 3: At the time information is collected from you, you should be made aware of the following:

- that the information is being collected
- why it is being collected
- who will be able to see that information
- the details of who is collecting and storing the information
- if you have to give the information or can choose not to
- what might happen if you do not provide the information
- your right to see, and if necessary correct, the information.

Rule 4: The information should not be collected in a way which is unfair or unnecessarily intrusive.

Rule 5: Reasonable steps must be taken to protect the information against loss, unauthorised access or other misuse.

Rule 6: You can see the information that is held about you unless there is a very good reason why not.

Rule 7: You are able to request that corrections be made to your health information. If your request is refused (e.g. because there is a difference of opinion about what is correct), you can put your own point of view on the file.

Rule 8: Reasonable steps must be taken to check the information, before it is used, to make sure it is accurate, up-to-date, complete and relevant.

Rule 9: The information should not be kept any longer than is necessary. For health information, however, note that it is often necessary to keep the information for a long time.

Rule 10: The information should generally only be used for the reason it was collected and not used in other ways, unless there is a good reason.

Rule 11: The information will generally not be given to anyone else without your agreement, unless this is one of the reasons for collecting it or unless there is a good reason for doing so.

Rule 12: 'Unique identifiers' (e.g. patient numbers) on health information should only be used for health-related purposes.

Appendix 4.1 Evidence tables for systematic review of CDSS for CVD risk assessment and management

Study author and reference: Barnett GO, Winickoff RN, Morgan MM and Zielstorff RD. A computer-based monitoring system for follow-up of elevated blood pressure. Medical Care 1983; 21:400-09.

Study	Methods and setting	Participants	Intervention	Outcomes & Time	Notes (RAMMBO)
Barnett 1983	RCT randomising patients of primary provider team (adult physicians/ nurse practitioners) Managed care ambulatory care clinic Kenmore Centre, Harvard Community Health Plan Boston, USA. Enrolled pop about 40,000	Patients stratified by age and index diastolic BP (DBP) Incl: 115 adults>16yrs with newly identified DBP>=100mmHg who had not received standard follow-up Excl: patients with labile hypertension followed up within previous 6 months & DBP<100mmHg OR patients receiving standard care (2 follow-up visits within 6 months and if DBP still elevated had tests and placed on treatment). OR DBP>120mmHg	Exposure Group (EG) Computer-generated reminder to physician Comparison Group (CG) usual care	Degree to which follow-up was attempted or achieved Repeat BP measurement recorded Time -2 years	Participants likely to be representative of eligibles. Randomisation method unclear *allocation concealment*- unclear *Baseline characteristics*- not given No blinding, compliance n/a, contamination probable, co-intervention unlikely 10 (8.7%) patients lost to follow-up unblinded outcome measurement from electronic notes but objective ITT analysis, no adjustment in analyses and p-values only given. GATE calculations below.

Bottomline- Computer generated reminders to physicians improved follow-up of patients with high diastolic blood pressure and subsequent documentation BP.

EPOC score 8/14

Concealment of allocation	Not clear
Follow-up of professionals	Not clear
Follow-up of patients	Done
Blinded assessment of 1^0 outcome(s)	Done (Not blind but objective
Baseline measurement	Not done
Reliable 1^0 outcome measure(s)	Done
Protection against contamination	Not Done

Study author and reference: Becker DM, Gomez EB, Kaiser DL et al. Improving preventive care at a medical clinic: How can the patient help? Am J Prev Med 1989;5:353-9.

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
Becker 1989	RCT of patients at University of Virginia Internal Medicine Clinic selected using computerised database based on age 40-60yrs, recorded telephone number, at least one visit within 18 months, house officer or general medicine fellow as primary physician and not in nursing home or psychiatric institution. University of Virginia School of Medicine, Charlottesville, Virginia, USA.	1055 patients met inclusion criteria and randomly assigned to 3 groups of 350 patients each (1050 patients). Excl (487 patients) who died before phone contact, could not be contacted, refused to participate, or no longer received primary care at study site. Using telephone-based questionnaire with patients & chart review, developed individualised patient schedule of preventive care needs and recommended frequency	EG1 (168 patients) patients and physicians received reminders by post or attached to patient chart at first clinic visit after telephone interview EG2 (203 patients) physicians only received reminders CG (192 patients) no reminders to either group Reminders were for services recommended to be obtained within 12 months	Outcomes: 9 preventive care services: BP recording, dental check, ocular pressure measurement, FOB, cervical smear, influenza, pneumocccoal and tetanus vaccinations. Time: 4-8 months post telephone interview	Random sample of excluded patients reported similar to included. Method of randomisation not reported. *Allocation concealment*- not reported. Baseline characteristics No differences by age, gender, ethnicity, financial status, mean number of preventive care needs, residence, mean number of study weeks prior to chart review. Compliance –all received interventions as allocated Contamination likely as patients and providers aware of trial and preventive services under observation. Nil lost to follow-up. Providers & patients not blind. Unblinded outcome assessment- from outpatient medical record but objective measures. ITT- not done, analyses did not take into account clustering by provider.

Bottomline- Overall compliance with preventive services was 18.5% for patient plus physician reminder, 12.9% for physician only and 8.2% for no reminders. The baseline compliance with services prior to the study was not reported. BP measurement as an outcome not recorded.

EPOC score=8/14

Concealment of allocation	Not done	Baseline measurement	Done
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Not done
Follow-up of patients	Done	Protection against contamination	Not done
Blinded assessment of 1^0 outcome(s)	Done		

Study author and reference: Demakis JG, Beauchamp C, Cull WL et al. Improving residents' compliance with standards of ambulatory care. Results from the VA Cooperative Study on computerized reminders. JAMA 2000;284:1411-16.

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
Demakis 2000	Cluster RCT randomising 275 physicians either singly or as a team who work together providing primary care 12 primary care clinics within Veteran Affairs Medical Centres USA	Incl: 12,989 patients for whom at least one standard of care was applicable. 13 standards were used; pneumococcal vaccine, alternative drugs if history of GI bleed from NSAID and 11 other standards relating to CVD or diabetes care (lipid tests, HbA1c, INR, urinary dipstick, counselling on smoking cessation,nutrition, lifestyle, footcare, eye examination, b-blocker post MI),	EG:Computer generated reminder occurring when physician logs into electronic patient record plus reminder placed in paper-based encounter summaries. CG: usual care	Proportion of adherence to standards measured from baseline to last visit Time:17 months	Participants likely to be representative of eligibles. Randomisation method- unclear *allocation concealment*- unclear *Baseline characteristics*- no differences reported in either physician or patient characteristics No blinding, compliance n/a, contamination and co-intervention not likely Full follow-up of patients using EMR data. Lost 24 physicians with no differences in drop-out rates beteen reminder/usual care groups Unblinded outcome measurement from electronic notes but objective ITT analysis by patients, adjusted for clustering of patients within physicians

Bottom-line- Computerised reminders increased physicians compliance with multiple standards of ambulatory care across multiple medical centres. Standards with lowest adherence tended to be prevention rather than treatment oriented. Physicians became less likely to respond to reminders across time course of study.

EPOC score=13/14

Concealment of allocation	Not clear
Follow-up of professionals	Done
Follow-up of patients	Done
Blinded assessment of 1^0 outcome(s)	Done (unblinded but objective
Baseline measurement	Done
Reliable 1^0 outcome measure(s)	Done
Protection against contamination	Done

Overall adherence to standards was 58.8% compared with 53.5% adherence in control OR1.24 (1.08-1.42).
The proportion of all visits in which residents provided proper care according to standards (17.9% vs 12.2%; OR 1.57; 1.-45-1.71). Results for individual CVD-related standards as below:

Outcomes		**Reminder**	**Control**	**OR**
Outcome 1	%adherence all standards	58.8%	53.5%	1.24 (1.08-1.42)
Outcome 2	lipid tests for CHD	79%	78.3%	ns
Outcome 3	Hyypertensive: wgt, physical activity, sodium	55.2%	49.3%	ns
Outcome 4	Diabetes:HbA1c	70.6%	65.9%	ns
Outcome 5	Diabetes:nutrition counselling	61.6%	53.3%	ns
Outcome 6	Diabetes:urinalysis	69.8%	62.6%	1.38 (1.13-1.68)
Outcome 7	Diabetes:eye exam	73.5%	63.4%	1.60 (1.29-2.00)
Outcome 8	Diabetes or PVD:foot exam	48.6%	42.8%	1.26 (1.02-1.56)
Outcome 9	Smoking cessation counselling	63.5%	54.8%	1.44 (1.01-2.05)
Outcome 10	β-blocker post MI	44.7%	41.3%	ns

ns= not statistically significant

Study author and reference: Fillipi A, Mazzaglia G, Sabatini A et al. Effects of an automated electronic reminder in changing the antiplatelet drug-prescribing behaviour among Italian general practitioners in diabetic patients. An intervention trial. Diabetes Care 2003;26:1497-1500.

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
Fillipi 2003	Cluster RCT randomising 300 out of over 550 GPs who participated in the Health Search Database owned by the Italian College of General Practitioners and who met data quality standards Italian College of GPs, Florence and the University of Milan, Italy.	Incl: 15,343 diabetic patients ≥ 30yrs who had at least one CVD risk factor at baseline; TC≥5.2mmol/L DBP>90mmHg, SBP>140mmHg, cigarette smokers or presence of previous CVD Excl: No consultation at baseline and during follow-up.	EG Computer generated reminder activated when opening medical record plus summary of practice guidelines recommending antiplatelet drugs in diabetic patients with at least one risk factor CG: summary of practice guidelines only	Proportion of diabetics with at least one risk factor receiving 2 or more prescriptions of antiplatelet drugs Time: 12months before (baseline) to 7 months after implementation	Participating GPs maybe more interested in coding and have more complete records than those not-participating. Randomisation method unclear *allocation concealment*-unclear *Baseline characteristics*- for all patients appear reasonably similar No blinding, compliance n/a, contamination possible as randomised GPs not practices Co-intervention not likely Full follow-up of patients using EMR data. Unblinded outcome measurement from electronic notes but objective ITT analysis (patients), no adjustment in analyses for clustering of patients within physicians or other co-variates

Bottomline- Short-term study showing effectiveness of electronic reminders over letter containing summary guideline recommendations alone. Results:14% absolute increase in prescriptions from baseline for reminder group compared with 7.8% for letter only group [OR 1.99(1.79-2.22)].The study did not look at inappropriate prescribing of anti-platelet drug for diabetics with no risk factors.

EPOC score=10/14

Concealment of allocation	Not clear
Follow-up of professionals	Done
Follow-up of patients	Done
Blinded assessment of 1^0 outcome(s)	Done (unblinded but objective
Baseline measurement	Not clear
Reliable 1^0 outcome measure(s)	Done
Protection against contamination	Not done

Study author and reference: Frances CD, Alperin P, Adler JS et al. Does a fixed physician reminder system improve the care of patients with coronary artery disease? A randomised controlled trial. Western Journal of Medicine 2001;175:165-6.

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
Frances 2001	Cluster RCT randomising 66 physicians in Veteran Affairs Medical Centres, USA (San Francisco, Palo Alto, Northern California Health Care System)	Incl: 730 patients with ICD-9 code compatible with coronary artery disease or active prescription for nitrates in electronic medical record	EG: Computer generated and written reminders CG:usual care	% patients with prescription aspirin; % MI patients with β-blocker prescription; % receiving lipid lowering drug % patients with LDL in target range (<100mg/dL). Secondary outcomes : % patients hospitalised for MI and patient mortality Time :1 year	Participants likely to be representative of eligibles. Randomisation method -not reported *allocation concealment*- unclear *Baseline characteristics*- for both patients and physicians reported as similar. No blinding, compliance n/a, contamination possible as randomised doctors not practices/teams. Co-intervention not likely 3 doctors left clinics and results reported on patients that were enrolled with remaining 63 GPs Unblinded outcome measurement from electronic notes but objective Not ITT analysis. Logistic regression analysis accounted for patient and physician characteristics. (unclear if any adjustment for clustering)

Bottomline- No statistically significant differences were found for any outcomes. The authors noted that the doctors were not involved in the design of the CDSS and therefore may not have had the “buy in”. Also noted physicians may become densensitised or may have been too busy.

EPOC score=11/14

Concealment of allocation	Not clear
Follow-up of professionals	Done
Follow-up of patients	Done
Blinded assessment of 1^0 outcome(s)	Done (unblinded but objective
Baseline measurement	Done
Reliable 1^0 outcome measure(s)	Done
Protection against contamination	Not done

Study author and reference: Goldstein MK, Lavori P, Coleman R, Advani A & Hoffman BB. Improving adherence to guidelines for hypertension drug prescribing: cluster-randomised controlled trial of general versus patient-specific recommendations. Am J Manag Care 2005;11:677-685.

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
Goldstein 2005	Cluster randomised trial of 42 (all) physician and nurse practitioners in the Department of Veterans Affairs Paolo Alto Health Care System (rural, suburban and urban primary care clinics in San Francisco Bay and Central Valley areas, California, USA 6 dropped out immediately after randomisation Institutions: VA Paolo Alto and Boston Health Care Systems, Stanford University and Harvard Medical School	Incl: 4533 patients with diagnosis of hypertension on their problem list, on at least one BP drug, had at least one primary care clinic visit during study period and not followed by specific hypertension clinic	All clinicians received small group workshops and material on national hypertension guidelines. EG printed form at time of patient visit regarding individual patient concordance with guideline that clinicians needed to sign and return and a list of BP drug treatment for all their own patients at start study and at 3 months. CG general education only	Primary outcome: % hypertensive patients whose drug regimen was guideline concordant Other outcome: % patients whose BP was less than 140/90mmHg Time: 9 months.	Computerised stratified (nurse or physician) randomisation conducted by statistician. A*llocation concealment*- unclear Baseline characteristics patients- no sig differences by mean age, sex,co-morbidity, or mean BP Providers –similar size of practice, clinic site and guideline concordance at baseline. Patients, practices, investigators not blind. Compliance n/a, contamination unlikely but as EG/CG at same clinic co-intervention possible if control group aware of trial and changed behaviour. Blinded computerised data extract. 14% eligible providers dropped out after randomisation.Not reported if differences to those who participated. Follow-up- 0.07% died, 2.7% stopped drug treatment and were not included in main outcome (Not ITT analysis) adjusted for clinican, site and clustering.

Bottomline- Individualised reminders at the time of patient care resulted in major improvement from baseline (+10.9% vs +3.8%) on concordance with recommended BP drug regimen compared with education alone. The differences in patients meeting desired BP level was not significant.

EPOC score 12/14

Concealment of allocation	Unclear	Baseline measurement	Done
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Done
Follow-up of patients	Done	Protection against contamination	Unclear
Blinded assessment of 1^0 outcome(s)	Done		

Study author and reference: KenealyT, Arroll B and Petrie K. Patients and computers as reminders to screen for diabetes in family practice. Randomized-controlled trial. J Gen Intern Med 2005; 20:916-21.

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
Kenealy 2005	Cluster RCT of GPs in Auckland, New Zealand randomising to intervention arms in 2 stages; by potentially eligible GPs (398) and secondly stratified randomisation of practices (taking into account practice size) Inclusion criteria- GPs who used MedTech patient management system, recorded consultations electronically, received laboratory results electronically for at least one year, saw 10 or more patients/month who were ≥50yrs and worked in the Auckland region.	112 GPs in 66 practices were randomised into one of 4 arms. 5,628 eligible patients (50yrs or older, not coded in computer as having diabetes and no diabetes test result in previous 3yrs)	EG1 Computerised GP reminder: flashing icon which when clicked suggested glucose test for patients considered eligible for diabetes screening EG2 Patient reminder: diabetes risk self-assessment sheet (adapted from American Diabetes Association) filled in by patients and given to their GP at consultation EG3 Both patient and computer reminders CG- usual care	Primary outcome: % tested for blood glucose Time: 2 months	*Non-participation* 33% eligible GPs declined. Methods of randomisation stated-independently randomised using Excel table and placed in sealed consecutively numbered envelopes- *allocation concealment*- adequate *Baseline characteristics* –Similar in terms of GP gender, median number of GPs/practice, patient subsidy. Although usual care arm had lower half days per week than others, more patients aged ≥50yrs were seen. No explanation given. Patients & practices not blind, compliance with patient reminders not reported, contamination possible as randomised doctors not practices but co-intervention unlikely and control group screening similar to pretrial screening rate. 100% follow-up. Unblinded outcome assessment but objective measure. ITT analysis with logistic regression allowing for clustering by practice.

Bottomline- A simple icon computer reminder doubled the odds OR 2.31 (1.4 to 3.82) of opportunistic screening for diabetes in a routine GP setting in New Zealand. Compared with usual care, effect of both reminders OR 1.73 (1.16 to 2.59) lower than computer reminders alone and close to patient reminders alone OR 1.90 (1.34 to 2.71).The percentage of eligible patients who were tested with blood glucose: Computer reminder 31.8%, patient 23.9%, both patient & computer reminder 23.7% and usual care 15.5%.

EPOC score 13/14

Concealment of allocation	Done	Baseline measurement	Done
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Not clear
Follow-up of patients	Done	Protection against contamination	Done
Blinded assessment of 1^0 outcome(s)	Done (unblinded but objective)		

Study author and reference: Lobach D F and Hammond W E. Computerised decision support based on a clinical practice guideline improves compliance with care standards. Am J Med 1997;102:89-98.

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
Lobach 1997	Cluster RCT randomising all providers in a medical centre serviced by 58 primary care providers (21 primary care physicians, 2 physician assistants, 2 nurse practitioners and 33 family medicine residents). Duke Family Medical Centre, Department of Community and Family Medicine, Duke University, Durham, North Carolina.	Incl: 58 primary care providers, 884 diabetes visits for 359 patients Inclusion criteria: Provider had to have contact with at least 6 diabetic patients & assessed diabetes care in ≥12 visits during the study period (30 providers) Enrolled patients who had correct diagnosis of diabetes & primarily followed at medical centre	Consensus guidelines were completed by providers 3/12 prior to initiation of the study and incorporated into a computer-assisted management protocol (CAMP) EG Receive computer-assisted management protocol (CAMP) printed on encounter forms when seeing diabetic patients CG Usual care, encounter form with no advice	Compliance with guidelines defined as the proportion of total diabetes recommendations followed Adherence-number of recommendations completed in each encounter Time: 6 months	All potentially eligible included in randomisation then excluded if did not meet number diabetic patient visits. Method of randomisation not stated. *Allocation concealment*-unclear *Baseline characteristics* of patients – similar age, gender, ethnicity. Baseline compliance with recommendations similar between CAMP and usual care providers 6 months previously.Providers unaware of being randomised and probably blind to study hypothesis. Investigators not blind. Contamination is possible with all providers within same medical centre –reported one control provider received one CAMP protocol at a patient encounter. Unblinded data extraction (intra-auditor reliability >90%) Follow-up – 14 (3%) patients did not have charts available for audit. Not ITT-no adjustment for potential confounding or clustering by provider.

Bottomline- Reliability of CAMP=77% (number of correct recommendations/total recommendations). These were mostly false positive recommendations due to system error choosing the first visit not the most recent although some were due to data being in the paper record and not on the electronic record.Compliance defined as; performing the recommendation; scheduling the recommendation to a definite future time or stating why the guideline was not followed (median compliance scores CAMP 32% vs 15.6% usual care).Baseline compliance (6 months prior) similar in both groups. Median adherence (number of recommendations completed in the encounter)= 65% CAMP vs 40% control

EPOC score= 11/14

Concealment of allocation	Not clear	Baseline measurement	Done
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Done
Follow-up of patients	Done	Protection against contamination	Not Done
Blinded assessment of 1^0 outcome(s)	Done (not blind but objective)		

Study author and reference: McDonald CJ. Use of a computer to detect and respond to clinical events: its effects on clinical behaviour. Annals of Internal Medicine 1976;84:162-7.

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
McDonald 1976	Cluster RCT of patients attending an adult diabetes clinic of Wishard Memorial Hospital responsible for around 600 patients. At any given clinical session 3 diabetologists, 2 residents, 2 interns, 4 medical students and 3 nurse clinicians are in attendance. With constant rotation patient has only 30% chance of seeing the provider that cared for him previously. Department of Community Health Sciences & Medicine, University School of Medicine & the Regenstrief Institute for Health Care, Indianapolis, Indiana, USA	Incl: 63 providers seeing 257 patients with diabetes in 794 scheduled visits. Patients randomised to study and control group. Providers used 3 paper reports for each patient encounter- (i)summary report, (ii) encounter form (prescriptions, new medications, findings, ordering tests and referrals) and (iii) surveillance forms which had the protocol driven advice.	EG 301 visits by 119 patients were given surveillance report (protocol driven recommendations) Two types of alerts tested in this study- 1) need for repeat measurement of selected laboratory tests or BP and 2) drug warning or interaction CG- no alerts given for 300 visits by 107 control patients	1) Response by ordering test or repeat BP measurement 2) change in drug treatment Time: 8-months	Likely that all eligibles participated. Patients randomised by computer generated random number. *Allocation concealment*- unclear. *Baseline characteristics*- only mean age reported (EG 61 yrs, CG 58yrs) Compliance –all received computer reports with and without surveillance report. Contamination not reported but likely that clinicians more responsive to control group due to knowledge of alerts for other patients. Providers (& patients) & investigators not blind Follow-up- likely 100% from computer records/encounter forms but not reported. Unblinded but likely objective outcome assessment. Univariate analysis- not adjusted for clustering or confounding.

Bottomline- 36% of alerts for tests (laboratory or BP recording) that had become outdated were responded to compared to 11% of control group. Clinicians appropriately changed therapeutic regimens in 28% of study alerts compared to 13% of control events although some protocols were ignored due to being poorly tailored or not having all the available information recorded. Overall response was 57% (EG) and 23% (CG).

EPOC score=9/14

Concealment of allocation	Not clear	Baseline measurement	Not done
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Not clear
Follow-up of patients	Done	Protection against contamination	Not clear
Blinded assessment of 1^0 outcome(s)	Done (unblinded but objective)		

Study author and reference: McDonald CJ, Hui SL, Smith DM et al. Reminders to physicians from an introspective computer record. A two year randomised trial. Annals of Internal Medicine 1984;100:130-8.

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
McDonald 1984	Cluster randomised controlled trial of 27 practice teams (physician, residents and nurse) within a general medicine clinic. Indiana University School of Medicine, Indianapolis, Indiana, and Purdue University, Lafayette, Indiana,USA.	Incl: 126 physicians (115 residents, 11 faculty members) and 4 nurse clinicians. Excluded- physicians with fewer than 100 reminder messages during study period (those who started service one month before study end and short term physicians)	EG Computer generated reminders (751 different messages) based on physician authored rules (patient state, clinical action indicated) printed out for each patient visit. On average 6 reminders generated per patient CG: Reminders generated but not printed out for clinicians Reminders about preventive care, tests and treatment.	Rate of response to a reminder measured via computer records (referrals, drug changes, orders). Overall response and individual response eg, to CVD related reminders including dietary counseling for weight reduction, β-blockers after myocardial infarction, long acting nitrates to prevent angina and treatment of congestive heart failure Patient outcomes- hospitalizations, ER visits, blood tests, BP etc Time: 2 years	Excluded short term physicians but included all others so likely representative of eligible Method of randomisation not reported. *Allocation concealment*- unclear. *Baseline characteristics-patients* similar gender and ethnicity. Age not reported. Providers (& patients) & investigators not blind Compliance –all recieved interventions, likelihood of contamination lessened by unit of randomisation. Co-intervention possible as all knew they were involved in a trial. Follow-up likely to be complete as based on computer records and extraction from records of changes according to patient state. NB:Only reported residents' response rates. Not ITT, analysis taking into account clustering but not patient/physician factors.

Bottomline- Response to advice for dietary counseling for weight reduction where more than130% of ideal weight (EG 44% vs CG19%). Results for β-blockers, long acting nitrates and heart failure treatment not reported. Prompts included printed reminders from the medical record whenever the computer detected history, physical examination (eg BMI) laboratory or pharmacy data indicating need to for reminder. However, gaps in patient data (particularly historical information) reduced specificity of reminder messages. (NB: Same system as McDonald 1976).

EPOC score 12/14

Concealment of allocation	Not clear	Baseline measurement	Not clear
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Done (as automated extraction)
Follow-up of patients	Done	Protection against contamination	Done
Blinded assessment of 1^0 outcome(s)	Done (unblinded but objective)		

Study author and reference: McDowell I, Newell C and Rosser W. A randomised trial of computerised reminders for blood pressure screening in primary care. Medical Care 1989;27:297-305.

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
McDowell 1989	Family Medical Centre at Ottawa Civic Hospital that has 6 practices each with staff physician, nurse and 3-5 family medicine residents with a total of 8,298 patients aged 18yrs and over & who were not in an institution. Health Research Unit, University of Ottawa, Ottawa, Ontario, Canada.	4/6 practices participated in the trial 4247 families and 5744 individuals randomised Study involved only those (73%) who were overdue for BP check defined as having no BP reading within a year preceding visit or scheduled reminder time. All patients in practices included in denominator	Randomly allocated by family to 4 groups: EG1 computer generated physician alert to conduct BP at patient visit printed on encounter form EG2 letter reminder to patients to have BP check, 2nd letter within 21 days EG3 telephone reminder to patients to have BP check (nurse calls –up to 5 attempts during day to family) Control group usual care	Proportion of patients in each group that had a BP recorded during the study year Secondary outcome- cost – effectiveness of each intervention Time: 12 months from March 1985 to March 1986 and BP checks made befor June 1986 included in outcomes	The 2 practices (1920 families and 2554 individuals) that did not participate had similar proportion to CG of BP recorded at end of study period. Method of randomisation not reported. *Allocation concealment*- unclear. *Baseline characteristics patients*- no significant differences by age, sex, marital status or family size. Compliance – all received interventions,not blind. Contamination not reported but likely that clinicians more responsive to doing BPs-even non-participating practices Follow-up- 100% computer records assessed (Note validation study found 18% BPs not recorded but conducted) Unblinded outcome assessment but fairly objective. Univariate analysis- not adjusted for confounding, separate analysis taking into account clustering by family showed similar results.

Bottomline- Proportion who had BP recorded was 18.6% in CG, 30.7% for the GP alert, 35.7% for letter reminder to patients and 24.1% for the phone reminder to patients. The physician reminder was the most cost-effective followed by the letter reminder ($1.70 vs $14.37 letter vs $22.47 phone cost per BP reading gained).

EPOC score 11/14

Concealment of allocation	Not clear	Baseline measurement	Done
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Not clear
Follow-up of patients	Done	Protection against contamination	Not clear
Blinded assessment of 1^0 outcome(s)	Done (unblinded but fairly objective)		

Study author and reference: McPhee SJ, Bird JA, Fordham D, Rodnick JE and Osborn EH. Promoting cancer prevention activities by primary care physicians. Results of a randomized, controlled trial. JAMA 1991;266:538-44.

Study	Methods & setting	Participants	Intervention	Outcomes &Time	Notes (RAMMBO)
McPhee 1991	307 primary care physicians were invited to participate, 79 (25.7%) indicated interest and were screened against eligibility criteria. University of California, San Francisco, Dapartments of Medicine and Family and Community Medicine, California, USA.	Incl: 40 GPs who worked in full-time, fee for service, solo or small group practices (1-4 physicians) in 5 northern California counties. Only one from each practice was eligible to be enrolled. Random sampling of medical records to identify ~ 60 eligible patients per physician who were ≥40yrs, visited during study period & enrolled for at least 1 year prior to study.	EG (20 GPs) Installation of computer hardware & DOS-based software to generate printed reminders attached to encounter forms listing appropriate screening, assessment and counselling based on patient's age, sex and smoking status. GPs also given patient education pamphlets about cancer screening, smoking cessation and dietary change, information to help patients achieve change, list of local dieticians, local smoking cessation programmes and cookbooks and guides for healthy meals. CG: (20 GPs) usual care	Primary outcomes: performance of screening procedures (FOB, digital rectal exam, sigmoidoscopy, pap smear, pelvic exam, mammography, breast exam) CVD- related performance: % patients assessed during 12 months for smoking status, counseled to quit, % patients dietary advice about fat and fibre. Time: 12 months	Enrolled physicians were reported as having a strong preventive care orientation and therefore may differ from those not participating. Doctors randomised – but no method reported. *Allocation concealment*- unclear. *Baseline characteristics doctors*- no significant differences by mean age, sex, year of graduation, family physician or internists. Compliance – n/a installed or not. Contamination unlikely as installation by practice. Co-intervention possible with other strategies to improve preventive care.No blinding. Follow-up- lost one doctor Unblinded outcome assessment of medical records pre and post installation but fairly objective Multivariate analysis- adjusting for each physician's preintervention score & patient characteristics.

Bottomline- Enormous variation between physicians in performance. Pre-intervention ranged from 1.3% for fat and fibre dietary counseling to 37.3% for smoking counseling and were not significantly different by exposure group allocation. Mean performance scores for CVD related outcomes were significantly higher for EG than CG post intervention with mean %annual rate (sd):Smoking assessment 45.0 (16.6) vs 32.4 (13.9), Smoking counseling 58.8 (23) vs 41.8 (22.2), Diet assessment 23 (23.8) vs 7 (11.4), Diet counseling 14 (17.5) vs 0.6 (1.4).

EPOC score 12/14

Concealment of allocation	Not clear	Baseline measurement	Done
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Not clear
Follow-up of patients	Done	Protection against contamination	Done
Blinded assessment of 1^0 outcome(s)	Done (unblinded but objective)		

Study author and reference: Martens JD, van der Weijden T, Severens JL et al. The effect of computer reminders on GPs' prescribing behaviour: a cluster randomised trial. Int J Med Inform 2007;76S:S403-S416.

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
Martens 2007	Cluster RCT of general practices in the south of The Netherlands in practices that use a specific medical information system. Integrated Care Unit, University Hospital, Maastricht, The Netherlands.	23/33 eligible practices agreed to take part (53/77GPs)	EG computer reminder system integrated with patient medical record providing evidence-based guideline recommendations on prescribing (alternative drug, dose, duration, not to prescribe) of cholesterol lowering drugs. Alert pops up at time of prescribing based on patient details CG As above but for antibiotic, asthma and COPD prescribing therefore blind control	Primary outcome: % appropriate statin prescriptions according to recommendations by individual GP Absolute number of statin prescriptions for specific diagnoses/GP/1000 patients Time: 12 months.	Note: 68% eligible GPs participated- Not reported if any differences. Method of randomisation not reported:- randomised by practice analysed by GP *Allocation concealment*- unclear *Baseline characteristics GPs*- similar age, group vs solo practice and mean number of patients/GP but CG had significantly more male GPs Patients, practices not blind to computer reminders but blind to comparison. Compliance n/a, unlikely contamination or co-intervention Unblinded but objective computerised data extract. 19/53 (44%) dropped out after randomisation.GP characteristics and prescibing behaviour reported to be similar to those who completed. Not ITT analysis.Uncertain whether adjusted for clustering, not adjusted for confounding.

Bottomline- No statistically significant differences in statin prescribing to those for whom it was not recommended (EG 100% vs CG 98% (94-100) or statin prescribing for those for whom it was recommended EG 88 (71-100%) vs CG 72 (52-81%).

EPOC score 11/14

Concealment of allocation	Unclear
Follow-up of professionals	Not Done
Follow-up of patients	Done
Blinded assessment of 1^0 outcome(s)	Done (not blind but objective)
Baseline measurement	Done
Reliable 1^0 outcome measure(s)	Done
Protection against contamination	Done

Study author and reference: Murray MD, Harris LE, Overhage JM, et al. Failure of computerized treatment suggestions to improve health outcomes of outpatients with uncomplicated hypertension: results of a randomized controlled trial. Pharmacotherapy 2004; 24:324-37.

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
Murray 2004	Inner city academic primary care internal medicine practice affiliated with Indiana Medical School and Wishard Memorial Hospital outpatient pharmacy (located one floor apart). Both use same electronic medical records system. Practice has more than150 general internists and residents and provide care to 13,000 adults in four identical adjacent practices each with separate staff. Department of Medicine, Indiana School of Medicine, Indianapolis, Indiana, USA.	Incl:712 patients with uncomplicated hypertension (diagnosis in EMR or at least 2 BPs ≥140/90mmHg and a prescription for at least one BP drug Excl: patients with CHD, stroke, heart failure or renal insufficiency. Also those who could not hear, speak English, follow instructions or had no access to a phone	All providers received printed guidelines for hypertension, presentations and individual academic detailing on the study and guidelines. EG1 *physician only* computerised reminders for care printed onto encounter form and suggested orders on workstations when ordering after patient visit EG2 *Pharmacist only.* Computerised reminders generated by physician system stored in pharmacist system and printed out with drug container labels. When patient came with prescription the pharmacist dispense the drugs; discuss with patient and encourage subsequent discussion with physician; or contact the physician directly by phone or page; or e-mail EG3 *physician and pharmacist* both access to care suggestions CG *Usual care*- neither physician nor pharmacist were shown computerised care suggestions	Health related QOL (SF36 and Bulpitt questionnaire) Other outcomes: Provider compliance with recommendations Symptom profile, side-effects from BP drugs, number of emergency department visits, hospitalisations, BP recording, patient satisfaction with provider, drug compliance and health care changes Time: 12-15months enrollment from Jan1994-May1996. Study period from first patient visit in time period til 30 days after closeout date	85% of eligible participated. Randomised by practice sessions for physicians and pharmacists to avoid contamination. Method of randomisation not reported. *Allocation concealment*- unclear *Baseline characteristics (patients)* – similar age, gender, ethnicity, marital status, education but slightly more people in control group completed study. Compliance all received interventions, Contamination unlikely due to study design. Providers (& patients) not blind but unaware of study hypothesis. Blinding of outcome assessment & interviewers to assignment ITT- for utilization, Not ITT for rule compliance (67% follow-up) and survey results (68% follow-up) Accounted for clustering by physician in analyses but unable to for pharmacists

Bottomline- No differences in generic or disease specific QOL scores. Overall compliance with treatment suggestions was not statistically different across groups: CG 26%, pharmacist 25%, physician 29%, physician and pharmacist 35%. Little effect on other patient outcomes SBP, DBP, emergency department visits, hospital admissions and direct health care charges. However, one year duration of intervention might be too short to detect changes in patient outcomes especially CVD outcomes. Suggestions were passive with requirement for physicians to act on suggestions or explain why did not act.

EPOC score 11/14

Concealment of allocation	Unclear
Follow-up of professionals	Done
Follow-up of patients	Not done
Blinded assessment of 1^0 outcome(s)	Done
Baseline measurement	Done
Reliable 1^0 outcome measure(s)	Done
Protection against contamination	Done

Study author and reference: Nilasena DS and Lincoln MJ. A computer-generated system improves physician compliance with diabetes preventive care guidelines. Proceedings - the Annual Symposium on Computer Applications in Medical Care:640-5,1995.

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
Nilasena 1995	Cluster randomised trial involving 35/36 internal medicine residents in the outpatient clinics at University of Utah and Salt Lake VA Hospitals. Department of Medicine, Veterans Affairs Medical Center and Department of Informatics, University of Utah, Salt Lake City, Utah	Incl:35 residents and 164/480 patients with diabetes at each site who were scheduled for a clinic visit with one of the residents over the study period. At baseline each patient's chart were reviewed to abstract all relevant information from a complete year prior to the start of the study. Excl: 316 patient exclusions were made (reasons not stated)	All residents instructed about content of American Diabetic Association guideline, encounter forms and process of using the reminder system. EG Computer generated report placed in front of patient's chart summarising preventive health status of patient with diabetes and lists of scheduled preventive health activities. CG Received blank report with patient's name, ID number and information about where to return encounter forms plus a generic report without specific recommendations.	Primary outcome: compliance score- the number of items completed in accordance with the guidelines divided by the total number of items recommended for the patient Mean compliance score of all patients seen by a resident was determined for each resident Secondary outcomes- compliance by clinical category- medical history, physical examination, laboratory tests & referrals and patient education. Time: 6 months Oct 1993 & April 1994	97% eligible residents participated but only 34% of the patients with diabetes. Block randomisation by site and year of training. *Allocation concealment*- unclear *Baseline characteristics (patients and providers)* – not reported. Compliance all received interventions Contamination- possible due to residents within centres being randomised to either group. Providers (& patients) not blind. Unblinded outcome assessment of charts at the end of the study but fairly objective outcomes. Appears to be ITT. Accounted for clustering by clinic site and use of encounter forms by the resident but not by patient or provider characteristics.

Bottomline- Compliance with recommended care increased in both EG (baseline 38%, 54.9% at follow-up) and CG (34.6% baseline, 51% at follow-up) with no stat sig differences seen between the two groups. Both Hawthorne effect and contamination likely to be an issue. The authors found that those residents who used the encounter forms showed the greatest improvements suggesting that the computerised system improved compliance more by facilitating the documentation of clinical findings and ordering than by providing the clinician with patient-specific information.

EPOC score 8/14

Concealment of allocation	Unclear	Baseline measurement	Not Done
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Unclear
Follow-up of patients	Done	Protection against contamination	Not Done
Blinded assessment of 1^0 outcome(s)	Done (unblinded but fairly objective)		

Study author and reference: Ornstein SM, Garr DR, Jenkins RG et al. Computer-generated physician and patient reminders. Tools to improve population adherence to selected preventive services. J Fam Pract 1991;32:82-90.

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
Ornstein 1991	Cluster RCT to improve adherence to 5 preventive services (cholesterol measurements, faecal occult blood testing, mammography, Pap smears and tetanus immunization) within 4 separate practice groups at the Family Medical Centre, Department of Family Medicine, University of South Carolina, USA.	Incl: 49 physicians and 7397 active patients 18yrs or older	All:practice teams received health promotion educational sessions including discussion of the preventive services. EG1 computer generated physician reminders attached to medical record at time of patient visit EG2 Printed patient reminders signed by physician (up to 2 letters sent) EG3 Both physician and patient reminders CG-no reminders	Primary outcome Change in adherence to 5 preventive services (cholesterol measurements, faecal occult blood testing, mammography, Pap smears and tetanus immunization) from baseline Time: 12 months Jan 1988- Jan 1989	All eligibles participated. Randomised by practice group. Randomisation method not reported. *Allocation concealment*- unclear *Baseline characteristics (patients)* – statistically significant differences for ethnicity, insurance coverage and visit frequency. White patients over represented in EG3. Percentage uninsured similar in each group. CG had small % of patients who had never made a clinic visit. Compliance n/a. Contamination possible with discussion among doctors and awareness of trial (note significant increase in control group adherence). Providers (& patients) & outcome assessment not blind. ITT analysis but no accounting for clustering or adjustment for baseline patient differences.

Bottomline- All preventive services increased except for Pap smears over 12 months irrespective of intervention status. For cholesterol measurements % change from baseline for controls 9.1% (8.0-10.1%), physician reminder 12.3% (11.3-13.2%), patient reminders 13.6 (13-14.3%) and both physician and patient reminders 18.6% (17.8-19.5%)

EPOC score 11/14

Concealment of allocation	Unclear	Baseline measurement	Done
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Unclear
Follow-up of patients	Done	Protection against contamination	Unclear
Blinded assessment of 1^0 outcome(s)	Done (unblinded but objective)		

Study author and reference: Rogers JL, Haring OM. The impact of a computerized medical record summary system on incidence and length of hospitalization. Medical Care 1979;17:618-630. See also: Rogers JL et al. Medical Care 1982;20:63-74. Rogers Jl et al Quality Review Bulletin 1984;10:65-74.

Study	Methods and setting	Participants	Intervention	Outcomes & Time	Notes (RAMMBO)
Rogers 1979, 1982 1984	Cardiac, Pulmonary and Renal Clinics of Northwestern University, USA developed a computerised medical record system providing information on patient's problems, ommissions in recording of observations, treatment recommendations, ordered procedures not carried out, deficiencies in medical reasoning and able to recommend corrective actions according to selective criteria.	484/1200 eligible patients randomly selected and randomised. Eligible patients were those attending clinics with chronic hypertension, obesity and/or renal disease for more than 6 months. Excl: pregnancy and under psychiatric care	EG Computer printout plus traditional handwritten medical record CG traditional handwritten medical record Physicians randomised to only patients with EG (pure), only patients with CG (pure) or mixed. Patient attitudes assessed using questionnaire answered by 383 patients who came to clinic last quarter of the first and 2nd year	Hypertensive patients: % Renal function tests (blood urea nitrogen, potassium creatinine or creatinine clearance), fundal examination, IVP Obese patients:% diets given or reviewed Renal disease- % renal function tests, urinalysis & culture Incidence & duration of hospitalisation per patient/year , Mean BP, mean weight loss Questionnaire on patient's perceptions of their own health status and quality of communication. Time: 2 years	Likely representative of eligibles. Randomised both patients and providers but method not reported. *Allocation concealment*- unclear *Baseline characteristics (patients)* – similar age, gender, ethnicity, fee schedule, prior weight but more hypertensive males in CG, diabetes and obesity in EG and for all 3 disease areas CG patients had been attending clinics for longer average time than EG. Compliance all received interventions. Contamination possible with discussion amongst doctors as well as some randomised to mix of computer printout or not. Providers (& patients) not blind. Blind retrospective outcome assessment by chart review. Non-validated questionnaire used. 24% died or lost to follow up (similar loss both EG and CG) ITT- not done, analyses adjusted for confounding but not clustering by provider.

Bottomline- More patients had tests/dietary reviews done in EG than CG. In terms of patient outcomes there were no differences in mean SBP or DBP between groups but by 22-24 months patients in EG had lost more weight than controls. No statistically significant differences in incidence of hospitalisation after adjusting for baseline differences. During the second year EG patients spent fewer days in hospital (13.5 vs 20.9 days) and in a subgroup analysis had more completed referrals for consultation (40.9+/-11.3 vs 32.4 +/-11.2), assigned diets, detected new problems and diagnostic tests on record (76.2% vs 61.3% of 20 common diagnostic tests) than patients without the computerised summary. The patients at this clinic are often not seen by the same physician (high staff turnover, large staff) and continuity of care is difficult but the use of a medical

information system via the patient questionnaire was associated with more positive perceived health status and perceived quality of communication. For both groups, patient questionnaire scores became decreased over time.

EPOC score 7/14

Concealment of allocation	Unclear
Follow-up of professionals	Unclear
Follow-up of patients	Not done
Blinded assessment of 1^0 outcome(s)	Done
Baseline measurement	Done
Reliable 1^0 outcome measure(s)	Unclear
Protection against contamination	Not done

Study author and reference: Rosser WW, McDowell I and Newell C. Use of reminders for preventive procedures in family medicine. CMAJ 1991;145:807-86.

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
Rosser 1991	Cluster randomised trial within Ottawa Civic Hospital Family Medicine Centre who have all patients registered on a computer database since 1976. Practice organised into 6 teams (physician, nurse, 3-5 residents) providing care for ~1,200 patients/team Department of Family and Community Medicine, University of Toronto, Department of Epidemiology and Community Medicine, University of Ottawa, Ontario, Canada.	Eligible participants- 8502 patients aged ≥15yrs who had attended the practice in the last 18 months or responded to a letter that still belonged to practice Excl: non-responders or in a hospital or institution. 2 of the 6 teams (2619 patients) did not participate in the study	EG 1471 patients (1122 families) Physician reminder during regular visit of overdue procedure EG2 1468 patients (1104 families) Patient reminder-by telephone EG3 1541patients (1168 families) patient reminder by mail (2nd reminder after 21 days) CG 1403 patients (1056 families) no reminder Non-randomised group acted as further control to assess extent of contamination	Proportion of patients in each study group for whom 5 screening procedures were performed: flu vaccination ≥65yrs, BP measurement ≥18yrs, assessment of smoking status≥15yrs and Pap smear in sexually active women 18-35yrs Time: 12 months from baseline	30% eligibles did not participate but were followed up and provided a separate control group. Randomised via computer programme by family to avoid contamination. *Allocation concealment*- unclear. *Baseline characteristics (patients)*- reported similar age and gender. Compliance- all received interventions Contamination- possible with discussion among teams. Providers (& patients) not blind. Outcome assessment (not blind) by reviewing computerised records. Not ITT- 38 at baseline required no procedure and were excluded. Univariate analyses investigating differences of proportions. No adjustments made.

Bottomline- All three reminder systems significantly improved the delivery of preventive services.Overall procedure completion rates :42% letter reminder, 42% telephone, 33.7% physician reminder vs 14.1% control group. BP measured: 40.5% letter reminder, 37.2% telephone, 30.7% physician reminder vs 21.1% control group. Smoking status assessed: 49.1% letter reminder, 55.8% telephone, 22.8% physician reminder vs 11.9% control group.

EPOC score12/14

Concealment of allocation	Unclear	Baseline measurement	Done
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Done
Follow-up of patients	Done	Protection against contamination	Unclear
Blinded assessment of 1^0 outcome(s)	Done (not blind but objective)		

Study author and reference: Rossi RA and Every NR. A computerized intervention to decrease the use of calcium channel blockers in hypertension. J Gen Intern Med 1997;12:672-8.

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
Rossi 1997	All providers at General Internal Medicine Clinic of Veterans Affairs Puget Sound Health Care System (primary care providers at outpatient clinic). Clinic has comprehensive computerised patient medical information. Health Services Research and Development, Veterans Affairs Puget Sound Health Care System and Department of Medicine, University of Washington School of Medicine, Seattle, WA, USA	71 primary care providers (physicians, nurses, residents, fellows). *Eligible patients* (714)- those seen on a designated study day who had a prescription for calcium channel blockers(CCB) written and filled in past 26 weeks without having a nitrate prescription written or refilled during the same period (ie treatment for hypertension not for angina)	EG Guideline reminder added to patient chart at time of clinic visit attached to medication refill forms. Highlighted the prescription and offered alternative drugs and doses. For continued use of CCB the provider needed to indicate if prescription was for diagnosis other than hypertension, concurrent angina & hypertension, failure of other meds to control BP or adverse effects from other meds. CG no guideline reminder	Primary outcome: Prescription changes from CCB to other antihypertensive medications Time: 6 months between March-August 1996	Likely representative of eligibles. Stratified randomisation according to provider type via random numbers generator. *Allocation concealment*- states investigators blinded to coding identifiers of providers. *Baseline characteristics (providers)* – similar,gender, ethnicity & patients seen per week. *(patients)*- similar age gender, initial BP, weight, mean prescriptions, CCB prescription although more patients in EG were receiving ACE inhibitors and β-blockers. Compliance all received interventions.Contamination possible with discussion among doctors. Providers (& patients) not blind. Outcome assessment (not blind) by reviewing pharmacy database and all charts but objective measure. ITT- done, analyses weighted by number of patients seen per provider but not for other covariates.

Bottomline- 39 patients (11.3%) were changed to other BP medications compared to 1 patient (<1%) controls.Compared to control patients those who were changed from CCBs had no clinically significant change in BP, number of lab tests ordered, follow-up visits or hospital admissions.

EPOC score 11/14

Concealment of allocation	Done	Baseline measurement	Done
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Unclear
Follow-up of patients	Done	Protection against contamination	Not done
Blinded assessment of 1^0 outcome(s)	Done (unblinded but objective)		

Study author and reference: Sequist TD, Gandhi TK, Karson AS, Fiskio JM et al. A randomized trial of electronic clinical reminders to improve quality of care for diabetes and coronary artery disease. J Am Med Inform Assoc 2005;12:431-7.

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
Sequist 2005	Primary care providers at 20 clinics (4 community health centres, 9 hospital-based clinics and 7 off-site practices) in Partners HealthCare System. A patients provider was defined by code on the EMR or having at least 3 visits within past 2 years with same provider. Partners HealthCare System has outpatient clinics, community hospitals & 2 academic teaching hospitals (Brigham & Women's Hospital and Massachusetts General Hospital) & affiliated with Harvard Medical School Boston, MA, USA.	194/255 primary care physicians or residents at 20 clinics. All used to EMR having patient problem list, medication, lab results, patient notes and receiving electronic reminders for overdue preventive services. 6243 patients, (4549 with diabetes and 2199 with CHD) with at least 1 overdue service were identified using coded diagnoses	EG (10 clinics, 2924 patients) electronic reminders or paper based print-out (5 for diabetes care, 4 for CHD care) based on current guidelines. *Diabetes reminders:* annual LDL test, biennial HbA1c, ACE inhibitor initiation in presence of hypertension, statin treatment if LDL≥130mg/dL. *Coronary reminders:* annual LDL test, initiation aspirin, β-blockers, or statin treatment if LDL≥130mg/dL. CG (10 clinics, 3319 patients) no guideline reminder	Primary outcome: Receipt of recommended care Composite diabetes and coronary outcomes-summary proportion of reminders resulting in recommendation action. Time: +6 months between October 2002-April 2003	76% eligible GPs took part. Stratified randomisation according to clinic sites. Method of randomisation not reported. *Allocation concealment*- not reported *Baseline characteristics (providers)* – similar gender,. *(patients)*- CG more likely to be male, slightly older,less likely to be Hispanic and be on Medicaid. Compliance all received interventions. Contamination- possible with discussion amongst doctors Providers (& patients) not blind. Outcome assessment via automated data extraction. Full follow-up ITT- done, analyses taking into account clustering by clinical site and both patient and provider characteristics.

Bottomline- Diabetes reminders resulted in recommended action in 19% of EG patients vs 14% control patients (Adj OR 1.30; 1.01-1.67). Coronary artery disease reminders resulted in recommended action for 22% of EG patients vs 17% CG patients (Adj OR 1.25;1.01-1.55). In a separate physician survey, it is interesting to note that only 1/3 physicians noticed the reminders. Of those that did, 70% reported acting on them.Most common barriers cited to nonadherence to guideline recommendations were lack of time and patient noncompliance or refusal.

However barriers cited by physicians amenable to CDSS include lack of familiarity with specific guideline recommendations, lack of awareness of guideline existence and forgetting to apply the guideline at consultation.

EPOC score 12/14

Concealment of allocation	Unclear
Follow-up of professionals	Done
Follow-up of patients	Done
Blinded assessment of 1^0 outcome(s)	Done (objective outcomes)
Baseline measurement	Done
Reliable 1^0 outcome measure(s)	Done
Protection against contamination	Unclear

Outcomes	**EG**	**CG**	**Hazard ratio (95%CI)**
Diabetes	nr	nr	
Cholesterol test	nr	nr	1.41 (1.15-1.72)
HbA1c	nr	nr	1.14 (0.89-1.46)
Eye exam	nr	nr	1.38 (0.81-2.32)
Hypertension/ACE use	nr	nr	1.42 (0.94-2.14)
Statin if *LDL*≥130mg/dL	nr	nr	1.10 (0.65-1.85)
CHD			
Cholesterol test	nr	nr	0.99 (0.75-1.29)
Aspirin use	nr	nr	2.36(1.37-4.07)
β-blockers,	nr	nr	1.09 (0.72-1.63)
statin treatment if LDL≥130mg/dL.	nr	nr	1.51 (1.05-2.17)

Study author and reference: Tierney WM, Overhage MJ, Murray MD et al. Effects of computerized guidelines for managing heart disease in primary care. J Gen Intern Med 2003;18:967-76.

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
Tierney 2003	Academic primary care group practice affiliated with an inner city public teaching hospital staffed by faculty internists, residents and 1 nurse practitioner (13,000 patients in 4 separate clinics with own staff and computerised medical information system. Division of General Internal Medicine & Geriatrics, Department of Medicine, Indiana University School of Medicine, Indianapolis, Indiana, USA	201 providers caring for 706 patients with heart failure or IHD Diagnosis heart failure: LV dysfunction on echocardiogram or scintigram. Patients with IHD were eligible if had diagnosis of CHD, or definitive diagnostic test eg Echo, scintiscan, ECG, cardiac enzymes test; or 2 or more prescriptions for long-acting nitrates. EMR identified patients meeting these criteria. Patients approached for study when came for appointment Excl:those that could not hear, understand instructions or had no access to telephone	Providers received printed guidelines, presentations and individual academic detailing. EG1 *physician only* computerised reminders on encounter form and also order form EG2 *Pharmacist only.* Computerised reminders from physician system stored in pharmacist system and printed out with drug container labels. When patient came with prescription the pharmacist could discuss with patient encourage discussion with physician; or contact the physician directly EG3 *physician and pharmacist both* had reminders CG Usual care- neither physician nor pharmacist were shown computerised reminders	*Primary outcome:* Provider compliance with guideline recommendation sHealth related QOL (SF-36), exacerbations of heart disease. Secondary outcomes patient satisfaction, medication compliance, direct health care costs Time: 12 months enrollment from Jan1994-May 1996. Study period from first patient visit in time period til 30 days after closeout date	870 (78%) eligible patients agreed to take part, 706 (63%) actually participated. Patients not participating were older (63 vs 58yrs) but no differences in sex, race or number of prior visits. Stratified by physicians and clinic session (to avoid contamination), house staff were randomised using random numbers generator in SAS. Block randomised pharmacists to study group. *Allocation concealment*- not reported. *Baseline characteristics (patients)* –no differences in age, gender, race or number patients completing 12-month interviews. Compliance all received interventions. Contamination unlikely. *Providers (& patients)* not blind. Outcome assessment via automated data extraction and interviewers blind to allocation group using validated questionnnaires. ITT- for utilization, Not ITT for rule compliance (89% follow-up) and survey results (68% follow-up) Accounted for clustering by physician in analyses but unable to for pharmacists

Bottomline- Authors conclusions were that the interventions had no effect on adherence to care suggestions (Physician only, pharmacist only or both 23% vs 22% control). There were also no differences in patient QOL, medication compliance, healthcare utilization, costs or satisfaction with care. Physicians viewed guidelines as providing helpful information but constraining their practice and not helpful in making decisions for individual patients.

EPOC score 13/14

Concealment of allocation	Unclear
Follow-up of professionals	Done
Follow-up of patients	Done
Blinded assessment of 1^0 outcome(s)	Done
Baseline measurement	Done
Reliable 1^0 outcome measure(s)	Done
Protection against contamination	Done

Study author and reference: Bonevski B, Sanson-Fisher RW, Campbell E et al. Randomized controlled trial of a computer strategy to increase general practitioner preventive care. Preventive Medicine 1999;29:478-86.

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
Bonevski 1999	Random sample of 37 GPs within one urban geographic region in New South Wales, Australia who saw ≥100 patients a week and been in a local practice for the previous 12 months invited to take part. Faculty of Medicine, University of Newcastle, Callaghan, New South Wales, Australia.	22/37 GPs agreed to take part Incl patients: 160 patients/GP aged ≥18yrs recruited at baseline (80) and further 80 recruited 3-month later, recruited to study by receptionist and asked to fill in patient health survey. 1666 patients took part at baseline, 1449 participated at 3-month follow-up Excl: Too ill at time of consultation, did not understand English, illiterate or previously involved in the research.	For 6 preventive services, both groups received guidelines for care, consensus standards for care, set individual goals, received patient self-reported survey of smoking, alcohol, benzodiazepine use, cervical screening and completed a checklist of each individual patient's preventive care status EG computerised feedback system on overall performance – patient specific listings and aggregated prevalence CG -no feedback on overall performance	Primary outcome: Accurate classification of smoking, alcohol use, benzodiazepine use, and rates of screening for BP, cholesterol and cervical smears using patient survey as gold standard Time: 3-months follow-up	60% eligibles took part. Method of randomisation not reported. *Allocation concealment*- not reported *Baseline characteristics (patients)*- similar age, gender risk factors and benzodiazepine use Compliance all received interventions Contamination- not likely as all GPs needed to use computerised programme but only EG received feedback. Providers (& patients) not blind. Unblinded outcome assessment but all data computerised Loss to follow-up- 3 GPs, and data on 196 patients. Not ITT, analyses taking into account clustering by doctor.

Bottomline- A very difficult paper to actually understand the intervention and how outcomes were assessed. Doctors in EG were given feedback on their performance for baseline patients and then reassessed with a different group of patients 3-months later to see if initial feedback spurred them into doing this more generally. At follow-up, BP screening conducted in 94% EG vs 87% CG and cholesterol screening in 81% EG vs 60% CG. Overall accuracy of smoking classification EG 76% vs CG 75%.

EPOC score 12/14

Concealment of allocation	Unclear	Baseline measurement	Done
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Unclear
Follow-up of patients	Done	Protection against contamination	Done
Blinded assessment of 1^0 outcome(s)	Done (unblinded but BP/cholesterol tests reasonably objective)		

Study author and reference: Dickinson JC, Warshaw GA, Gehlbach SH et al. Improving hypertension control: Impact of computer feedback and physician education. Medical Care 1989;19:843-54.

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
Dickinson 1989	Duke-Watts Family Medical Centre in Durham with computerised medical information system serving ~12,000 patients, mostly white, female and <40yrs. About 10% have diagnosis of hypertension. *Providers:* 37 residents and 4 faculty physicians divided into 4 separate clinical teams in different locations. Each team randomly assigned to one study group. Department of Community and Family medicine, Duke University Medical School, Durham, North Carolina, USA.	Patient medical records searched for last visit BP and coded diagnosis of hypertension Incl: 250 patients who had made at least one baseline visit to the practice and elevated SBP or DBP at this visit plus had one additional visit during intervention period. Excl <17yrs	EG1 (10 doctors) Monthly computer generated feedback divided into BP control (according to age-specific criteria and presence of diagnosis of high blood pressure. With the exception of those with normal BP/no diagnosis, the other groups had individual patient name, age, date of last visit and last BP plus checklist for action eg, request follow-up visit EG 2 (11 doctors) Physician self-education programme on BP management strategies with emphasis on patient compliance EG3 (10 doctors) Both CG (10 doctors) neither	Number of follow-up patient visits Physician compliance, hypertension management knowledge according to MCQ Change in SBP and DBP Time: 7 months	Participants representative of eligibles. Method of randomisation not stated. *Allocation concealment* not stated *Baseline characteristics – (patients)* no sig differences by mean age, weight, baseline SBP race or new patient status but CG mean DBP lower & EG2 had less male patients. *Providers* – no significant differences by physician age, sex, level of training, baseline knowledge Patients, practices, investigators not blind. CG knew that study about hypertensive patients was being conducted not interventions. Compliance n/a, contamination unlikely but co-intervention possible if control group aware of comparisons and changed behaviour. Completeness of follow-up- reported both Not ITT (appointment compliers)and ITT for all patients. Analysis – adjusted for confounding but not clustering. Unblinded computerised extract & MCQ results by study team.

Bottomline- Feedback system led to all physicians requesting follow-up visits for all listed patients and many more patient appointments that would not have been scheduled otherwise. (Patient visits EG1 3.4+/-0.4 vs CG 2.6+/- 0.6; p<0.05)).The inclusion criteria favoured those patients who complied with appointments. Note combined feedback and education no better than feedback alone in terms of visits and BP control. EG2 vs CG improved knowledge but not EG1 vs CG.

Patient outcomes:
Change in mean SBPmmHg EG1 -12+/-2.8 vs CG -11 +/-4.2 (ns)
Change in mean DBPmmHg EG1 -6+/-1.4 vs CG -4 +/-2.6 (ns)
% improved BP over study period SBP EG1 71% vs CG 55% (ns); DBP 65% vs 58% (ns)

EPOC score 13/14 (*computerised extract considered blinded)

Concealment of allocation	Not clear
Follow-up of professionals	Done
Follow-up of patients	Done
Blinded assessment of 1^0 outcome(s)*	Done*
Baseline measurement	Done
Reliable 1^0 outcome measure(s)	Done
Protection against contamination	Done

Study author and reference: Mitchell E, Sullivan F, Grimshaw JM, Donnan PT and Watt G. Improving management of hypertension in general practice: a randomised controlled trial of feedback derived from electronic patient data. British Journal of General Practice 2005;55:94-101. See also:Mitchell E et al. MEDINFO 2004; 1157-61. (same study)

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
Mitchell 2004, 2005	Scottish general practices (744) using the national computer system GPASS in 1998 stratified by practice size and deprivation payment. Randomly selected from each stratum and recruited in 1999. This study required baseline and follow-up data extraction from practice electronic patient medical records. Tayside Centre for General Practice, University of Dundee, Dundee, Scotland.	Incl: 54/179 (30%) practices contacted agreed to participate providing data on 30,345 patients aged 65-79yrs. 2 withdrew before data collection began 44/54 practices provided electronic patient data 34/54 practices returned more than one set of data	Feedback (3-5months later) to practices from anonymised patient data extract EG1-(16) Audit only-aggregated numbers of hypertensive patients known (BP≥169/90mmHg), known hypertensives treated, known treated hypertensives controlled EG2- (17) As above plus colour coded patient-specific ranked list for patients >10% 10-yr risk of stroke CG (19)–no feedback	*Recording* Change in BP recording from baseline, Treatment change in BP treatment from baseline (BP untreated if ≥160/90mmHg) Control Proportion of patients with controlled hypertension (number with BP of <160/90mmHg compared with total number with hypertension Time: 27 months from Oct1999 to Dec 2001	?representative-Included 30% of eligible practices, only 19% (34/179) eligible returned data that could be analysed. Randomisation method not reported. *Allocation concealment*-unclear. *Baseline characteristics* similar number of GPs, size of practice but control practices were more likely to have most deprived patients, have hypertensive registers, recall systems and be a training practice. Compliance – 34/54 (81%) complied with providing data, all received interventions, no contamination Providers (& patients) & investigators not blind but electronic data extraction tool (+medical records on a random sample of patients were examined to check validity) Not ITT, Accounted for clustering in analyses.

Bottomline- BP recording, proportion treated with BP≥160/90mmHg increased in all groups (no sig differences) and numbers of untreated and controlled patients all reduced. Baseline BP recording CG 89.6% vs audit 84% vs risk 96.1% increasing to CG 92.3% vs audit 86% vs risk 96.6% (ns). Uncontrolled BP at baseline CG 41.5% vs audit 41.3% vs risk 36.1% decreasing to CG 32.3% vs audit 38.3% vs risk 32.6.6% (ns)

There was very little difference between 3 groups with control group doing better than audit only and audit plus feedback. Note that the control group were more likely to be set-up/have systems for quality improvement in place (hypertensive registers, recall systems and be a training practice).When adjusted for practice and patient characteristics, control of BP was better in the audit plus risk (1.72 (1.09 -2.70)) vs control or audit only.

EPOC score 11/14

Concealment of allocation	Not clear
Follow-up of professionals	Done
Follow-up of patients	Not done
Blinded assessment of 1^0 outcome(s)	Done (fairly objective)
Baseline measurement	Done
Reliable 1^0 outcome measure(s)	Done
Protection against contamination	Done

Study author and reference: Winickoff RN, Wilner S, Neisuler R and Barnett GO. Limitations of provider interventions in hypertension quality assurance. Am J Public Health1985; 75:43-6.

Study	Methods & setting	Participants	Intervention	Outcomes & Time	Notes (RAMMBO)
Winickoff 1985	RCT randomising 16 primary provider teams (physicians/ nurse practitioners) Managed care ambulatory care clinic with computerised records Kenmore Centre, Harvard Community Health Plan (HCHP) Boston, USA. Enrolled population 40-50,000	All records of adults>16yrs were searched and classified based on diagnosis and BP recorded over an 18month period ending 3 months before the observation point. Incl: patients who were continuous members of the HCHP during the 18months Excl: DBP>125mmHg, age ≥65yrs, transient or unconfirmed hypertensives or old controlled hypertensive patients	Criteria developed from guidelines EG Concurrent feedback to each physician/nurse pair about individual patients in whom a deficiency was detected and peer comparison feedback – both given quarterly CG usual care	Proportion meeting criteria for inital laboratory test for high blood pressure, BP control and follow-up Time 12 months	Likely to be representative of eligibles Randomisation method unclear *allocation concealment*- unclear *Baseline characteristics*- not given. *Maintained* No blinding, compliance n/a, contamination probable, co-intervention not likely Completeness of follow-up –not reported unblinded outcome measurement from electronic notes but fairly objective ITT analysis? Not reported if all teams randomised into groups remained and how many patients assessed. No adjustment in analyses for clustering by provider

Bottomline- For all hypertensive patients, there were no differences in scores between EG and CG in initial testing of newly diagnosed patients (87% vs 87%), BP control (58% vs 59%) or follow-up (79% vs 77%). The authors hypothesised that the physician/nurse teams were already committed to controlling BP in their hypertensive patients and therefore education and feedback made very little difference in this setting.

EPOC score 6/14

Concealment of allocation	Unclear
Follow-up of professionals	Unclear
Follow-up of patients	Unclear
Blinded assessment of 1^0 outcome(s)	Done (fairly objective outcomes)
Baseline measurement	Not Done
Reliable 1^0 outcome measure(s)	Unclear
Protection against contamination	Not Done

Study author and reference: Lester W, Grant R, Barnett, G and Chueh H. Randomised controlled trial of an informatics –based intervention to increase statin prescription for secondary prevention of coronary disease. J Gen Intern Med 2006;21:22-29. Also: Lester W et al. MEDINFO 2004

Study	Methods and setting	Participants	Intervention	Outcomes & Time	Notes (RAMMBO)
Lester 2006 (2004)	Cluster RCT randomising patients (stratified by physician & baseline LDL (dichotomised at 110mg/dL) to EG or CG GPs were within academically affiliated practices & who had a specific patient management system, used this for the majority (>80%) of clinic visits & had active electronic medication & problem lists Laboratory of Computer Science, Division of Medicine, Massacheutts General Hospital, Boston, USA.	Incl:14 physicians and 235 patients Enrolled patients who were:>age 30 with CHD or CHD risk equivalent (diabetes, PVD, abdominal aortic or carotid arterial disease and seen by GP in past 18/12 & most recent LDL over 100mg/dL obtained 6-24 months prior to study initiation	EG: Interactive e-mail CDSS management tool – patient specific clinical information given to doctors – problem list, medications, allergies, clinical notes, current and previous lipids, LFT as well as NCEP-ATP III guideline support. Faciltated "one click" order writing. CG: Usual care	9/12 after inception, letters requesting fasting lipid profile were generated for doctors to electively sign and mail to all patients without a repeat fasting cholesterol test *Primary outcome:* change in statin prescription *Secondary outcome:* change in LDL levels, Time: 12 months	All eligible consented to enrol Method of randomisation – computer generated number list. -*allocation concealment unclear* *Baseline characteristics (patients)* – similar age, gender, ethnicity, baseline LDL, TC and statin prescription. Patients unaware of trial practices, investigators not blind, but states that doctors blind to control group. Compliance n/a, contamination possible as randomised by patient and doctor could alter management of control patients based on previous advice given. Unblinded data extraction but objective measures. Multivariate (logistic regression) taking into account clustering by provider. States ITT but in the previous paper there were both patients and a doctor missing in the analyses

Bottomline- 99% e-mails were opened, read & completed in 90 seconds (range15 sec-49 minutes). After 1 year, statin prescription changes EG 24.6% vs CG17.1% but not stat sig. No stat sig difference in LDL in overall study cohort. Previous publication GPs (15) and eligible patients (256).

EPOC score 10/14

Concealment of allocation	Unclear
Follow-up of professionals	Done
Follow-up of patients	Done
Blinded assessment of 1^0 outcome(s)	Done (objective measures)
Baseline measurement	Done
Reliable 1^0 outcome measure(s)	Unclear
Protection against contamination	Not Done

Study author and reference: Bloomfield HE, Nelson DB, van Ryn M et al. A trial of education, prompts and opinion leaders to improve prescription of lipid modifying therapy by primary care physicians for patients with ischaemic heart disease. Qual. Saf. Health Care 2005:14;258-263

Study	Methods & setting	Participants	Intervention	Outcomes & Time	Notes (RAMMBO)
Bloomfield 2005	RCT randomising 92 primary provider team adult physicians/ nurse practitioners/ physician assistants from 11 primary care clinics within Veteran Affairs Medical Centres USA. Also had separate non-randomised CG	Incl: 1349 patients diagnosed with CHD during 5yrs before assessment period, with 3 or more visits within past 2 years, LDL <130mg/dl, HDL< 40mg/dl and on no lipid lowering drug during 6 months prior to start of study.	All received educational workshops by opinion leaders EG1computerised reminder to physician in patient EMR at time of visit EG2 Computerised lipid management progress note for a particular patient a few days prior to patient visist CG letter to patient advising discussion of lipid lowering treatment with doctor at visit and sent 1-2 weeks prior	% target patients prescribed lipid lowering drugs over 1 year of intervention Time 12 months	Likely representative of eligibles Randomisation method unclear *allocation concealment*- unclear *Baseline characteristics* not given. No blinding, compliance n/a, contamination unlikely as randomised by site, co-intervention not likely Likely full follow-up using EMR data but not reported Unblinded outcome measurement from electronic notes but objective ITT analysis, adjustment in analyses for provider and site p-values only given.

Bottomline- Prescription rates increased from 8.3% to 39.1% for all the interventions with adjusted OR 3.3 (2.1-4.7). Individual baseline rates not reported but increased to 39.4% for computerised reminders, 40.7% for progress notes, 36.9% for patient letters with no statistically significant difference between type of prompt. The separate control group prescription rate did not change between the two time periods (18.9% baseline to 17.7% post intervention)

EPOC score 10/14

Concealment of allocation	Unclear
Follow-up of professionals	Done
Follow-up of patients	Done
Blinded assessment of 1^0 outcome(s)	Done (objective measures)
Baseline measurement	Not done
Reliable 1^0 outcome measure(s)	Unclear
Protection against contamination	Done

Study author and reference: Augstein P, Freyse E, Vogt L, Heinke P, Kohnert K and Salzseider E. Outpatient assessment of Karlsburg diabetes management system-based decision support. Diabetes Care 2007; 30:1704-8.

Study	Methods & setting	Participants	Intervention	Outcomes & Time	Notes (RAMMBO)
Augstein 2007	RCT randomising patients recruited from 3 general and 2 diabetes specialist outpatient practices who agreed to take part Institute of Diabetes, Karlsberg, Germany.	49 insulin treated patients Incl: type1 or type 2 diabetes, at least 17yrs old, Caucasian, duration diabetes >1yr and able to perform monitoring with capillary glucose measurement system. Excl: did not consent, unwilling to undertake blood glucose testing, concurrent severe diseases, end-stage diabetes-related complications, insulin pump therapy, or participating in another trial at the start of the study	Karlsberg Diabetes Management System (KADIS) system providing advice based on patient's blood glucose, drugs and insulin therapy, carbohydrates in meals and exercise Capillary glucose measurement system (CGMS) provides glucose readings every 5 minutes. Data presented as 24hr glucose profile from 3 days and mean sensor glucose EG: KADIS +CGMS CG CGMS alone	Physicians trained prior to commencing study in both systems; patients trained to use CGMS *Primary outcomes*: mean change in HbA1c from baseline, mean sensor glucose, Secondary outcomes: hypo- or hyperglycaemic excursions/day, bread exchange unit (BU), daily insulin dose Trial lasted 3 months	Not reported % eligible who took part. Simple randomisation from random numbers table with even numbers assigned to CG. A*llocation concealment unclear* *Baseline characteristics* –no significant differences in age, sex, diabetes duration, BMI, insulin application Patients, practices, investigators not blind, Contamination unlikely but co-intervention possible given knowledge of KADIS. Completeness of follow-up- 3/49 dropped out due to incomplete first monitoring.Unblinded outcome assessment but objective measures Logistic regression taking into account baseline HbA1c, GP or diabetes specialist, diabetes type, sex age, BMI. Uncertain if analyses accounted for clustering.

Bottomline- Decision support system demonstrated statistically significant mean change in HBA1c from baseline, was associated with reduced duration of hyperglycaemia (4.6 vs 1.0hr/day) without increasing hypoglycaemia. Mean change HbA1c EG -0.34+/- 0.49% vs CG 0.27+/-0.67% MSG mean diff for KADIS vs CGMS only-0.6;-0.96 to-0.25

EPOC score 12/14

Concealment of allocation	Unclear	Baseline measurement	Done
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Done
Follow-up of patients	Done	Protection against contamination	Unclear
Blinded assessment of 1^0 outcome(s)	Done (objective measures)		

Study author and reference: Phillips LS, Dunbar VG, Ziemer DC, et al. An endocrinologist-supported intervention aimed at providers improves diabetes management in a primary care site. Improving primary care of African Americans with diabetes (IPCAAD) 7. Diabetes Care 2005;28:2352-60. See also :Ziemer DC et al. (IPCAAD) 8. Arch Intern Med 2006;166:507-13.

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
Phillips 2005	Grady Medical clinic- large municipal hospital primary care clinic serving economically disadvantaged population in Atlanta. Study enrolled type 2 diabetic patients of residents supervised by Faculty member of Emory Division of General Medicine. RCT within a training programme- no informed consent (doctors or patients). Division of Endocrinology & Metabolism , Department of Medicine, Emory University School of Medicine, Atlanta, Georgia, USA.	Incl:345 residents caring for 4,138 patients with type 2 diabetes All residents received yearly lectures on management of type 2 diabetes, orientation about trial, pocket cards with treatment goals, letters about completeness of visit notes.	EG1 computerised reminders that provided a print-out of individualised recommendations for management at time of patient visits EG2 face-to-face individualised feedback on performance (5min every 2 weeks) but no consultative advice on individual patient care EG3 both interventions CG Neither interventions	*Primary outcome* Change in mean HbA1c Secondary outcomes Change in mean BP and LDL Provider compliance with reminders. When glucose exceeded 150mg/dL (8.33mmol/L) health care provider classified as"did nothing", "did anything" (any intensification of treatment) or "did enough" (if intensification met guideline recommendations Time: 3-years from July 1999 to Dec2002 Mean follow-up 15 months	Likely representative of eligibles Residents randomised to study group & when completed their time, patients reassigned to a resident receiving same intervention. Stratified by clinic session and by 2 simultaneous clinics. (Only one intervention was conducted in each ½ day clinic at both clinics) Randomisation method not reported. *Allocation concealment*- unclear *Baseline characteristics (patients)* – similar age, gender, ethnicity, BMI, duration of diabetes, HbA1c, LDL, BP but control patients slightly shorter follow-up and fewer clinic visits. Compliance all received interventions. Contamination unlikely but co-intervention possible. Providers (& patients) & outcome assessment unblinded.ITT analyses accounting for clustering within residents and within clinics and adjusted for baseline covariates.

Bottomline (Phillips)- HbA1c improved with all interventions but only feedback + reminders was found to be stat sig from control. SBP and LDL also improved over time but changes not stat significant from control. Note control group HbA1c dropped by 0.16% (8% to 7.84%), SBP -2.42mmHg, LDL -15.45mm/dl so likely contamination or Hawthorne effect.
Multivariate analysis found that endorinologist feedback independently facilitated attainment of ADA goals for HbA1c and SBP.
HbA1c changes ns with feedback or reminders singly vs CG

EG3 (both) vs CG Change HbA1c 0.6% vs 0.2% p<0.02
Similar but ns trends for SBP & LDL

Bottomline (Ziemer)- At baseline residents *did nothing* (no increase in dosage or addition of new diabetic drugs to regimen) in 65% of visits, *did anything* in 35% of visits and *did enough* in 21 % of visits with no significant differences in tendency to intensify therapy according to race sex or postgraduate year. At the end of the 3yr intervention, there was ns diff between reminders alone vs control (initially rose but then returned to baseline but feedback and reminders and feedback sustained sig difference 52% *did anything* and 30% *did enough* over CG.

EPOC score 13/14

Concealment of allocation	Unclear
Follow-up of professionals	Done
Follow-up of patients	Done
Blinded assessment of 1^0 outcome(s)	Done (fairly objective)
Baseline measurement	Done
Reliable 1^0 outcome measure(s)	Done
Protection against contamination	Done

Study author and reference: Tierney WM, Hui SL and McDonald CJ. Delayed feedback of physician performance versus immediate reminders to perform preventive care: Effects on physician compliance. Medical Care 1986;24:659-66.

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
Tierney 1986	General Medicine Clinic of Wishard Memorial Hospital-urban general hospital clinic staffed by Faculty internists, interns and residents who attend clinic ½ day/week during their training and follow an assigned group of patients for 3 yrs. Clinic has 4 geographically separate primary care teams & uses a computerised medical information system. Division of General Internal Medicine, Department of Medicine, Indiana University School of Medicine, Indianapolis, Indiana, USA	135 house staff (6045 patients) 13 protocols for recommended preventive care identified and divided into 2 groups: Group A - FOB, pneumococcal vaccination, PPD, antacids, β-blockers, long acting nitrates, antidepressants Group B -cervical smear, mammography, digitalis, metronidazole, aspirin, calcium supplements Monthly computer search for each patient that had indication for but did not receive preventive action and generated reports that required physician response- i. reschedule patient sooner, ii.do next visit, iii n/a to patient, iv. stop reminder (disagrees with protocol) and v. pull chart for review.	EG1: *Group A* reminders at time of patient visit plus *Group A* feedback report of non-compliance with preventive care guidelines EG2: *Group B* reminders, *Group A* feedback EG3: *Group A* reminders plus *Group B* feedback EG4: *Group B* reminders plus *Group B* feedback	*Primary outcome:* % each physician's eligible patients who received the indicated preventive care. Time: 7 months between April 1983 to January 1984	All eligible providers/patients participated. Randomised house staff by their clinic sessions.Method not reported.*Allocation concealment*-not reported *Baseline characteristics (providers and patients)* – not reported other than no differences in number of patients by EG. Compliance all received interventions Contamination- possible with discussion amongst doctors and other clinic staff. Providers (& patients) not blind. Outcome assessment via automated data extraction. ITT- done, univariate analyses with no account taken for clustering by clinical and possible confounding by patient and provider characteristics.

* n/a= not applicable

EPOC score 11/14

Concealment of allocation	Unclear
Follow-up of professionals	Done
Follow-up of patients	Done
Blinded assessment of 1^0 outcome(s)	Done
Baseline measurement	Not done
Reliable 1^0 outcome measure(s)	Done
Protection against contamination	Done

Bottomline- Results given as the mean rates of compliance with the protocols for all physicians within each study group. Although feedback reports increased compliance with protocols, House staff receiving Group A reminders alone (Group B feedback) showed approximately twice the increased in compliance with protocols than those given feedback reports alone(Group A feedback, Group B reminders). The intervention was not additive – those receiving both feedback and reminders on same Group did not demonstrate increased compliance. As there were 2 groups of reminders and feedback – those who only received Group A (both) or Group B (both) served also as controls.
Across all seven Group A protocols physician compliance increase from 15% controls (Group B only) to 22% feedback only and 30% in those who received reminders.
For the 6 Group B protocols physician compliance increase from 10% controls (Group A only) to 14% feedback only and 15% in those who received reminders.

In terms of % compliance for recommended cardiovascular drugs, it appears that there were no signiciant increases in compliance over control with feedback, reminders or both. The authors noted that physicians more often disagreed with the suggested action for therapeutic interventions (eg, digitalis, nitrates) than for clinical testing (FOB, mammography) suggesting perhaps lack of tailoring of protocol.

Study author and reference: Bulpitt CJ, Beilin LJ, Coles EC et al. Randomised controlled trial of computer-held medical records in hypertensive patients. BMJ 1976;1:677-9.

Study	Methods & setting	Participants	Intervention	Outcome & Time	Notes (RAMMBO)
Bulpitt 1976	Hypertension outpatient clinics at Hammersmith Hospital, Radcliffe Infirmary and King's College Hospital. (number of doctors not reported) Department of Medical Statistics and Epidemiology, London School of Hygeine and Tropical Medicine, London, UK.	278 hypertensive patients in 3 clinics at referral from primary care for management 53% participants from Hammersmith, 33% from Radcliffe and 14% from Kings College clinic. Sructured medical records from computer system and usual medical notes were used at the 3 clinics before and after the trial	EG (136 patients) medical records held in a computer system designed as a structured input template of 15 history items (key symptoms) allowing encoding by computer. At each follow-up visit a summary document was produced with patient history, past BP, symptoms and treatment, blood tests ordered and risk factors (smoking, cholesterol) CG (142 patients) medical records held on standard hospital notes	Primary outcome: Documentation of symptoms and risk factors BP control – mean BP (4x 3/12ly visits) Drop-out rates, Frequency performing investigations Time: 1 year	Not reported % eligibles took part. Method of randomisation not reported. *Allocation concealment*- not reported *Baseline characteristics (patients)*- similar age, gender and mean lying BP & allocation within clinic. Compliance all received interventions Contamination- likely due to patients randomised to EG/CG and full knowledge/use of form by all doctors. No reporting on extent of change in recording using standard notes from baseline. Providers (& patients) not blind.Unblinded outcome assessment via transferring standard case notes to computer input documents for comparison. No reliability score done. ITT- done, analyses not taking into account clustering by clinical site.

Bottomline- Use of structured input form resulted in much fuller documentation ($p<0.01$) of patient history (previous Hx CVD, family Hx, symptomatology and smoking status). For example; intermittent claudication 99% computer records, 38% standard notes. 12/15 symptoms (eg vertigo, depression, PND etc) were recorded more often. Negative diagnoses much more likely to be recorded eg, absence of stroke, non-smoker. After one year there was no significant difference in BP control, drop-out rates and frequency of performing investigations.As all standard procedures for clinic patients, documentation not necessarily related to improved care.

EPOC score 6/14

Concealment of allocation	Not done	Baseline measurement	Done
Follow-up of professionals	Not done	Reliable 1^0 outcome measure(s)	Not done
Follow-up of patients	Done	Protection against contamination	Not done
Blinded assessment of 1^0 outcome(s)	Done (fairly objective		

Study author and reference: Cobos A, Vilaseca J, Asenjo C et al. Cost effectiveness of a clinical decision support system based on the recommendations of the European Society of Cardiology and other societies for the management of hypercholesterolemia. Report of a cluster-randomized trial. Dis Manage Health Outcomes 2006; 13:421-32.

Study	Methods & setting	Participants	Intervention	Outcomes & Time	Notes (RAMMBO)
Cobos 2006	Cluster RCT randomising 42 primary care practices in Spain mainly in Catelonia CardioCare Research Group, Barcelona, Spain.	Incl: 2221 Patients with TC>200mg/dl Excl: Patients with triglyceride >400mg/dl or participating in another study Practices asked to recuit 50 patients per practice-35 previously treated with lipid lowering drugs and 25 not previously treated	EG: Guidelines implemented in a CDSS which gave recommendations on therapy, frequency of follow-up and lab tests. Table cloths and magnets promoting healthy CVD lifestyle also distributed to intervention practices to give to patients CG: Usual care computerised data collection form without decision support advice	Effectiveness defined as success or failure to meet study goals; 1) if >20% 10yr CVD risk LDL goal as per guidelines; 2) if <20% 10yr CVD risk- success defined as still <20% CVD risk at study end Total direct costs of lipid drug management Time: 1 year	Participants selected by GPs-unknown if representative of eligible population. Block randomisation of practices in blocks of four. *allocation concealment*-unclear *Baseline characteristics* –reported similar in age, gender, risk factors, previous CHD. No blinding, compliance all received interventions, contamination not likely, co-intervention possible as aware of trial. Completeness of follow-up) –nearly 25% lost in both groups. Unblinded outcome measurement but objective. ITT analysis taking into account clustering, risk category, previous use of lipid drug treatment and study group

Bottomline- CDSS as effective as usual care in 1 year trial in terms of meeting guideline target LDL according to CVD risk or if lower risk staying at lower risk (EG 54.02% vs CG 50.48%) but substantial cost savings due to less lipid lowering drugs prescribed in low risk patients. EG 40.8% vs CG 59.1 particularly in low risk non-CHD patients EG19% vs 44.2%. This resulted in 24.9% saving in treatment costs and 20.8% total costs.

Success- meeting guideline LDL target or staying <20% risk	OR 1.02 (0.58-1.77)	RD 3.53(-4.97)
Overall treatment with LLD	OR 0.37(0.26-0.52)	RD -0.18 (-0.22 to -0.14) unadj GATE calculation
total cost mean difference	60 Euro (33 to 86)	Saving of 20.8% with CDSS

EPOC score 8/14

Concealment of allocation	Unclear	Baseline measurement	Done
Follow-up of professionals	Not done	Reliable 1^0 outcome measure(s)	Unclear
Follow-up of patients	Not done	Protection against contamination	Done
Blinded assessment of 1^0 outcome(s)	Done (fairly objective)		

Study author and reference: Coe FL, Norton E, Oparil S et al. Treatment of hypertension by computer and physician- a prospective controlled study. J Chron Dis. 1977;30:81-92.

Study	Methods & setting	Participants	Intervention	Outcomes & Time	Notes (RAMMBO)
Coe 1977	RCT randomising patients in 2 ambulatory care hypertension clinics at Michael Reese and Billings Hospitals, Chicago, USA.	Incl: Consecutive patients referred to the clinics in the previous 6 months who met following criteria (n=116): returned for at least 3 visits, BP>140/95mmHg on 3 separate occasions, and reported taking BP medications as prescribed on more than 50% of clinic visits.	EG Computer based treatment recommendations CG usual physician care Preliminary study reported physician acceptance of computer recommendations in 79.9% of cases	Blood pressure control Time:14months	Participating patients more likely to be compliers of drug treatment. Randomisation method not reported. *Allocation concealment- not reported* *Baseline characteristics not reported* Patient unaware of allocation group, physicians/investigators not blind, compliance n/a, contamination possible as doctors had patients in both groups, co-intervention less likely as doctors judged computer as experimental. Completeness of follow-up) not reported but assume complete Unblinded outcome measurement but used machine derived BP measures. ?ITT- not clear. No adjustments reported in analyses

Bottomline- Computerised recommendations met with high acceptance by experienced physicians (7% non-acceptance rate) and resulted in no differences in BP control.

GATE calculations :Adequate BP control CDSS vs physician	**RR** 0.82 (0.55-1.23)	**RD** -0.09 (-0.27 to 0.09)	**NNT** -8 (-3 to ∞ to 11)ns

EPOC score 6/14

Concealment of allocation	Unclear
Follow-up of professionals	Unclear
Follow-up of patients	Unclear
Blinded assessment of 1^0 outcome(s)	Done (fairly objective)
Baseline measurement	Not done
Reliable 1^0 outcome measure(s)	Not clear
Protection against contamination	Not done

Study author and reference: Eccles M, McColl E, Steen N et al. Effect of computerised evidence based guidelines on management of asthma and angina in adults in primary care: cluster randomised controlled trial. BMJ 2002;325:941-50.

Study	Methods & setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
Eccles 2002	Cluster RCT randomising 62 general practices in north east England that had either of two specific computer systems. Excl: solo practices, low levels of computer use, concurrent use of study guidelines or another computer decision support system	Incl: 4851 patients with angina and 4960 asthma registered with participating practices aged 18yrs or over identified from computerised search for relevant disease codes, management or drug treatment	EG Computerised guidelines for management of angina CG computerised guidelines for management of asthma Those that received one CDSS guideline acted as control practice for the other guideline. CDSS was based on PRODIGY software that was currently available to support prescribing for acute conditions and had been integrated into 2 practice computer system software	Adherence to the guidelines, patient reported outcomes and condition specific outcomes. CVD relevant: 1)Recording of : BP,smoking status, ECG, exercise ECG, Haemoglobin, Thyroid function, cholesterol, HbA1c or blood glucose recorded. 2) Recorded or advised:- exercise and weight; 3)Recommended CVD drugs prescribed Time: 12 months after CDSS implemented.	Likely to be representative of eligible population Computer randomisation process stratified by computer system and vocational training status of practice *Allocation concealment*- unclear *Baseline characteristics* of patients not reported. Participating practices were reported to be similar eg, size, vocational training etc. Patients, practices, investigators not blind, compliance all received intervention, contamination and co-intervention not likely. Completeness of follow-up- 2 practices withdrew post randomisation and did not provide data otherwise assume complete. Blind data extraction from practices, mostly objective measures Not ITT analysis using generalised linear modelling for hierarchal data taking into account clustering but no other patient co-variates.

Bottomline- No effect was found on consultation rates, process of care measures (including prescribing) or any patient reported outcome. But there was very low level of usage of the system with the median number active interactions with CDSS being zero for much of the study.

EPOC score 13/14

Concealment of allocation	Unclear	Baseline measurement	Done
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Done
Follow-up of patients	Done	Protection against contamination	Done
Blinded assessment of 1^0 outcome(s)	Done		

Study author and reference: Hetlevik I, Holmen J, Kruger O et al. Implementing clinical guidelines in the treatment of hypertension in general practice. Blood Pressure 1998;7:270-76. See also Hetlevik Iet al. Scan J Prim Health Care 1999;17:35-40.

Study	Methods and setting	Participants	Intervention	Outcomes & Time	Notes (RAMMBO)
Hetlevik 1998	Cluster randomised trial of GPs who used the "leading" computerised system in 2 counties in Norway with a population 380,000. Excl: those who used other systems. 56/213 eligible agreed to participate (26%) National Institute of Public Health, Community Medicine Research Unit, Verdal, Norway	Incl: Patients at each practice with a registered diagnosis of hypertension in the previous 12 months One practice declined after randomisation leaving EG with 17 centres (24 GPs) and 984 patients with hypertension and CG with 12 centres, 29 GPs and 1255 patients with hypertension	EG- Received guidelines training and installation of guideline based decision support on hypertension, diabetes and hyperlipidaemia, aggregated audit feedback on via baseline performance and 4 telephone follow-ups appointments regarding guidelines CG- usual care plus same retrospective aggregated audit but minimum contact with doctors	Adherence to the guidelines based on recommendations for BP recording & review of risk factors eg,smoking, BMI at each check up, annual cholesterol tests, annual review of family Hx CVD, CHD risk in the electronic medical record Time: Data collected 12 months before CDSS implemented then 6, 12 and 18 months after CDSS implemented.	GPs who participated worked in general practice for longer and had used electronic medical records longer. Method of randomisation not stated. - *allocation concealment unclear* *Baseline characteristics* of patients not reported. GPs were reported to be similar age, sex, FTE, years in practice, years with electronic records, specialty in general practice, payment & pre-intervention BP treatment. Patients, practices, investigators not blind, compliance n/a, contamination unlikely but co-intervention possible if control group aware of comparisons and changed behaviour. Follow-up- lost 10% patients similarly from both arms (dead before data collection, moved out of practice or saw specialists). *Unblinded CDSS usage/audit extract by practice team*. Not ITT, univariate before/after analyses with no account for clustering.

Bottomline- No effect was found recording of risk or risk factors. User friendliness of the CDSS was reported as unsatisfactory- with 20/24 doctors judging "the recommended procedures to be too time consuming". The CDSS could populate from the electronic medical record and back.

EPOC score 12/14

Concealment of allocation	Not clear	Baseline measurement	Done
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Unclear
Follow-up of patients	Done	Protection against contamination	Done
Blinded assessment of 1^0 outcome(s)	Done (not blind but objective measures)		

Study author and reference: Hetlevik I, Holmen J, Kruger O . Implementing clinical guidelines in the treatment of hypertension in general practice. Evaluation of patient outcome related to implementation of computer-based clinical decision support system. Scan J Prim Health Care 1999;17:35-40. *(Second paper – same study, patient outcomes studied, data extraction process different)*

Study	Methods and setting	Participants	Intervention	Outcomes and Time	Notes (RAMMBO)
Hetlevik 1999	Cluster randomised trial of GPs who used the "leading" computerised system in 2 counties in Norway with a population 380,000. Excl: those who used other systems. 56/213 eligible agreed to participate (26%) National Institute of Public Health, Community Medicine Research Unit, Verdal, Norway	Incl: Patients at each practice with a registered diagnosis of hypertension in the previous 12 months One practice declined after randomisation leaving EG with 17 centres (24 GPs) and 984 patients with hypertension and CG with 12 centres, 29 GPs and 1255 patients with hypertension	EG- Received guidelines training and installation of guideline based decision support on hypertension, diabetes and hyperlipidaemia, aggregated audit & feedback on baseline performance and 4 telephone follow-ups appointments regarding guidelines. CG- usual care plus same retrospective aggregated audit but with minimum contact with doctors	Patient outcomes level of systolic and diastolic BP, cholesterol, BMI and CHD risk, % smokers Time 18 months	GPs who participated worked in general practice for longer and had used electronic medical records longer. Method of randomisation not stated. - *allocation concealment unclear* *Baseline characteristics* of patients not reported. GPs were reported to be similar age, sex, FTE, years in practice, years with electronic records, specialty in general practice, payment & pre-intervention BP treatment. Patients, practices, investigators not blind, compliance n/a, contamination unlikely but co-intervention possible if control group aware of comparisons and changed behaviour. Follow-up- lost 10% patients similarly from both arms (dead before data collection, moved out of practice or saw specialists). *Unblinded data extraction by first author.* Not ITT, univariate before/after analyses not account for clustering.

Bottomline- Statistically significant mean difference in DBP in favour of EG -1.0 (-1.9 to -0.2). No other significant differences in patient risk or risk factors

EPOC score 12/14

Concealment of allocation	Unclear	Baseline measurement	Done
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Unclear
Follow-up of patients	Done	Protection against contamination	Done
Blinded assessment of 1^0 outcome(s)	Done (not blind but objective measures)		

Study author and reference: Hetlevik I, Holmen J, Kruger O, Kristensen P, Iverson H, Furuseth K .Implementing clinical guidelines in the treatment of diabetes mellitus in general practice. Evaluation of effort, process and patient outcome related to implementation of computer-based decision support system. Intl J of Tehnology Assessment in Health Care 2000;16:210-27. *(Third paper -same study, first author & and practice team data extraction)*

Study	Methods and setting	Participants	Intervention	Outcomes & Time	Notes (RAMMBO)
Hetlevik 2000(c)	Cluster randomised trial of GPs who used the "leading" computerised system in 2 counties in Norway with a population 380,000. Excl: those who used other systems. 56/213 eligible agreed to participate (26%) National Institute of Public Health, Community Medicine Research Unit, Verdal, Norway	Incl:1034 Patients at each practice with a registered diagnosis of diabetes (both Type1 and type 2) in the previous 12 months One practice declined after randomisation leaving EG with 17 centres (24 GPs) and CG with 12 centres, 29 GPs	EG-499 patients Received guidelines training and installation of guideline based decision support on hypertension, diabetes and hyperlipidaemia, aggregated audit feedback on via baseline performance and 4 telephone follow-ups appointments regarding guidelines CG- (535 patients) usual care plus same retrospective aggregated audit but with minimum contact with doctors	Documentation of risk factors eg, HbA1c, SBP, DBP,smoking, BMI at each check up, annual cholesterol tests, annual review of family Hx CVD, CHD risk in the electronic medical record and mean differences in these variables (patient outcomes) Time: Data collected 12 months before CDSS and then 6,12, 18 months after CDSS implemented.	GPs who participated had worked in general practice for longer and used electronic medical records longer. Method of randomisation not stated. - *allocation concealment unclear Baseline characteristics* of patients not reported. GPs were reported to be similar age, sex, FTE, years in practice, years with electronic records, specialty in general practice, payment & pre-intervention BP treatment. Patients, practices, investigators not blind, compliance n/a, contamination unlikely but co-intervention possible if control group aware of comparisons and changed behaviour. Completeness of f/up) lost 23% patients similarly from both arms Unblinded data extraction by first author and unblinded CDSS usage/audit by practice team. Not ITT, univariate before/after analyses with no account for clustering.

Bottomline- Use of tool on 14% of patients with diabetes (variation between 0-50%). There were significant decreases in the absence of documentation of smoking (-11.9% ;-16.3 to -7.5), BMI (-14.8% ;-19.5 to -9.9) and variables needed for CVD risk estimation possible (-7.2%; -10.3 to -4.1). For patients, the only significant difference was a decrease in DBP 2.3 mmHg (-3.8 to -0.08).

EPOC score 12/14

Concealment of allocation	Not clear	Baseline measurement	Done
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Unclear
Follow-up of patients	Done	Protection against contamination	Done
Blinded assessment of 1^0 outcome(s)	Done (not blind but objective measures)		

Study author and reference:Meigs JB, Cheuh H, Cagliero E et al. A controlled trial of web-based diabetes disease management. The MGH diabetes primary care improvement project. Diabetes Care 2003;26:750-7.

Study	Methods and setting	Participants	Intervention	Outcomes & Time	Notes (RAMMBO)
Meigs 2003	Providers in a hospital based primary care practice using both paper-based and an electronic medical record system. There were 39 staff physicians and 109 resident doctors divided into 3 teams who have minimal organised interaction. One team of 13 physicians and 64 residents were not included in the study- reason not given) Harvard Medical School, Boston, Massachusetts,	Incl: 66 providers 26 physicians and 40 residents Incl 598 patients with type 2 diabetes identified via ICD-9 codes 250.00-250.90 in the pre-intervention year Excl- 997 patients with diabetes not seen by study providers (621), patients not seen during intervention year (225), patient clinic chart not found (36), patient otherwise ineligible (115)	EG- 24 providers (307 patients) voluntarily activated web-based decision support (Diabetes DMA) providing a single screen view of patient specific information enabling decision support at the time of patient contact. Lab data displayed both over time and in table form linked to treatment recommendationsactions, links to patient and provider resources CG- 42 providers (291 patients) care, no access to DMA	Change in rate of HbA1c, LDL tests, BP, eye & foot screening Change in most recent value HbA1c, LDL and BP compared with most recent value in previous year Time: 12 months from May 1998 to April 1999	Unclear if 3rd provider team were different from other teams. Coin-toss randomisation *Allocation concealment*-unclear. *Baseline characteristics* for providers and patients reported as similar except CG had less patients managed with diet & exercise only and more patients on insulin and lipid lowering treatment. EG had more patients with hypertension.Compliance –all received DMA but used in 42% scheduled patient visits (1/3 providers used DMA 0-17% of visits) Contamination-no access to DMA by CG. Providers (& patients) & investigators not blind Blinded outcome assessment by 3 nurses. Kappa scores 0.81-0.96 for SBP and DBP but varied between 0.42- 0.76 for eye, foot, microvascular and CVD documentation. Not ITT analysis excluding 30% of patients not seen since baseline or chart not found. Accounted for clustering in analyses.

Bottomline- Very variable use of DMA but some modest improvements in processes of care and risk factor levels. Number of HbA1c and LDL tests and proportion of patients undergoing at least one foot examination per year increased significantly. EG vs CG HbA1c tests/yr (+0.3 vs -0.04), LDL tests/yr (+0.2 vs +0.1), At least one foot exam/yr +9.8% vs -0/7%), HbA1c decreased by 0.2 EG vs increased 0.1 CG and proportions of LDL<130mg/dl increased by 20.3% EG and 10.5% CG.

EPOC score 10/14

Concealment of allocation	Not clear	Baseline measurement	Done
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Unclear (actually mixed)
Follow-up of patients	Not done	Protection against contamination	Done
Blinded assessment of 1^0 outcome(s)	Done		

Study author and reference: Montgomery AA, Fahey T, Peters TJ, MacIntosh C, Sharp DJ. Evaluation of computer based clinical decision support system and risk chart for management of hypertension in primary care: randomised controlled trial. BMJ 2000;320:686-90.

Study	Methods and setting	Participants	Intervention	Outcomes & Time	Notes (RAMMBO)
Montgomery 2000	All 96 practices in Avon area using EMIS and AAH Meditel computing systems were invited. Eligible patients aged 60-80yrs with diagnosis of hypertension and record of prescribed antihypertensive drugs in previous year. From each practice, a random sample of 30 eligible patients was selected. Excl: non-ambulatory, life threatening illness or recent major surgery. Division of Primary Health Care, University of Bristol, UK	Incl: 27/96 practices (74 GPs and 11 practice nurses) and 715 randomly selected patients of which 614 consented to participate	Practices randomised to: EG1 Computer based clinical decision support for calculating CVD risk plus CVD risk chart EG2 paper-based CVD risk chart only CG Usual care	Primary outcome % patients with 5-yr CVD risk ≥10% Other outcomes: Systolic BP, diastolic BP and prescribing of CVD drugs Time: 12 months	?representative- 28% of eligible practices (86% eligible patients) participated. Practices stratified by computing system and randomised using random numbers table by 3rd party. *Allocation concealment*- adequate. *Baseline characteristics* of patients given – similar in terms of age, gender, CVD risk, prior CVD Compliance – all received interventions. Contamination- no other practice had CDSS but usual care could have used risk charts as well. Providers (& patients) & investigators not blind. Blinding of outcome assessment not reported but objective outcome measures. Follow-up -86% at 12 months. ITT- practices not patients Accounted for clustering by practice as well as computing system and patient factors (baseline CVD risk & treatment).

Bottomline- CDSS not integrated with PMS and only estimated risk (given as numerical output only with no additional management recommendations). The chart was required for visual cues to doctors and patient. For people with a 5-yr CVD risk >10%, neither CDSS plus chart or chart alone were any better than usual care. CDSS had poorer CVD risk reduction than chart only. Some evidence that both interventions worked more effectively in higher risk patients compared with usual care although this depended on values assigned to missing cholesterol data. SBP significantly reduced in the chart group only compared to usual care (4.6mmHg). The chart only group were twice as likely to be prescribed 3 or more CVD drugs. The authors conclude that CDSS may have impaired translation of evidence to individual patients.

EPOC score 13/14

Concealment of allocation	Done	Baseline measurement	Done
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Unclear
Follow-up of patients	Done	Protection against contamination	Done for CDSS
Blinded assessment of 1^0 outcome(s)	Done (fairly objective)		

Study author and reference: Hobbs FDR, Delaney BC, Carson A and Kenkre JE. A prospective controlled trial of computerized decision support for lipid management in primary care. Fam Pract 1996;13:133-7.

Study	Methods and setting	Participants	Intervention	Outcomes & Time	Notes (RAMMBO)
Hobbs 1996	All (258) General practices in Birmingham were approached for the study– 22% (56 practices expressed interest) Department of General Practice, University of Birmingham, Birmingham, UK.	25/56 practices expressing interest with computers & who had resources to collect data were selected Excl practices with previous experience with the computerised decision support system of interest	EG (21 practices) CDSS for lipid management separate from practice system CDSS described as a rule-based system running on DOS prompting data capture of sociodemographic, CVD risk factors, history, examination, cholesterol level. User given coronary risk score and advice on management based on protocol developed by lipid specialists. CG (4 practices) usual care	Outcomes: Changes in hospital lab testing, specialist referral, lipid prescribing, provider knowledge of lipid disorder management Time: 6months Had 3-month run-in to collect historical control data (EG) and then data collected further 6 months after installation	About 10% of potentially eligible practices took part. Method of randomisation not reported. *Allocation concealment*- not reported. *No Baseline characteristics reported* Compliance all received interventions. Contamination- unlikely. Providers (& patients) not blind. Method of outcome assessment not reported – likely unblinded audit of electronic medical records from hospital laboratory, prescription pricing authority, MCQ pre and post study. 17 practices provided follow-up data (32% lost to follow-up) ITT- not done, analyses did not taking into account clustering by clinical site.

Bottomline- Authors report that CDSS had no effect on requests for lipid tests or lipid prescribing. There was a shift towards appropriate follow-up requests and greater emphasis on full lipid profiles(ns). There was a 55% decrease in referrals (no decrease in CG) but not stat sig (due to low study numbers). Analysis of CDSS usage based on 14/21 practices. Most used it fairly infrequently (mean 12 patients range 0-47), with 50% practices using the system on less than 12/130 possible working days. 4/14 used the programme extensively, 5 did not use it at all. Knowledge as assessed by MCQ filled in before and after by 31 providers (NB no denominator given) showed significant improvement for practice nurses not for doctors. Users felt that the system was used less than expected due to practical/technical problems; CDSS not loadable onto central server, only one workstation/practice with CDSS software, slow computer, inability to import and export data from practice management system.

EPOC score 6/14

Concealment of allocation	Not done	Baseline measurement	Not done
Follow-up of professionals	Not done	Reliable 1^0 outcome measure(s)	Unclear
Follow-up of patients	Done	Protection against contamination	Done
Blinded assessment of 1^0 outcome(s)	Unclear		

Study author and reference: Grover SA, Lowensteyn I, Joseph L et al. Patient knowledge of coronary risk profile improves the effectiveness of dyslipidaemia therapy. The CHECK-UP Study: a randomized controlled trial. Arch Intern Med 2007;161:2296-2303.

Study	Methods and setting	Participants	Intervention	Outcomes & Time	Notes (RAMMBO)
Grover 2007	Physicians from 10 Canadian provinces identified from multiple sampling frames invited to 1 of 4 meetings. 230/330 (70%) of those attending meetings, participated. 4310 patients of these physicians were screened for eligibility by having CVD or diabetes & being aged 30-70 yrs or men 45-70yrs & women 55-70yrs with a 10-yr CHD risk of at least 10%. Patients had a full medical exam, lipid tests and consented. McGill University, Montreal General Hospital, Montreal Quebec, Canada.	Incl: 3053 patients with CVD or diabetes or CHD risk>30% with LDL≥2.5 or TC/HDL≥4 OR CHD risk 20-30% with LDL≥3 or TC/HDL≥5 OR CHD risk 10-20% with LDL≥4 or TC/HDL≥6 Excl: active liver disease, AST or ALT ≥3 times normal, CK ≥5 times normal, TG>10.6mmol/L, allergic to statins, risk of pregnancy, breastfeeding, hx of pancreatitis and sig renal insufficiency	EG (1510 patients) computerised CHD risk profile sent to doctors to discuss with patients at baseline, 3, 6, 9 &12 months Included risk estimates and life expectancy. For primary prevention patients the profile also had CVD age (age minus life expectancy minus average life expectancy of Canadians of same age and sex)) and age gap (CVD age minus actual age) CG (1543 patients) No risk profile sent to physicians.	Primary outcomes: Change in LDL, TC/HDL ratio and % patients reaching national lipid targets Time: 12 months follow-up from baseline	Interested doctors may be more likely to conduct preventive care practices.Method of randomisation not stated but conducted in central co-ordinating centre. *Allocation concealment probably adequate. Baseline characteristics* patients- no sig differences by mean age, sex, previous Hx, CVD risk factors or drug therapy. Patients, practices, investigators not blind. Compliance n/a, contamination possible but authors state unlikely as risk tables in lipid guidelines only published 1yr previously. Co-intervention unlikely. Follow-up- lost 11%EG, 13% CG. Those who dropped out were slightly older and less likely to be smokers. Unblinded data extract from records but objective tests. ITT adjusted for confounding and clustering by physician.

Bottomline- Significant mean differences of LDL in risk profile group -1.33mmol/l vs CG -1.249 and in TC/HDL ratio - 1.5 vs -1.3. The proportion of patients meeting lipid target was sig improved in the risk profile group (OR 1.26;1.07-1.48) but no differences were found for those with prior CVD. Patients in risk profile group had improvements (OR 1.26; 1.04-1.53), mainly due to impact on diabetics (OR 1.42;1.11-1.81). Patients where CV age > actual age had larger LDL reductions than usual care- the greater the age gap the greater the effect on reaching lipid targets.

EPOC score 11/14

Concealment of allocation	Done	Baseline measurement	Done
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Unclear
Follow-up of patients	Done	Protection against contamination	Not done
Blinded assessment of 1^0 outcome(s)	Done (fairly objective)		

Study author and reference: Lowensteyn I, Joseph L , Levinton C, Abrahamowicz M, Steinert Y and Grover S. Can computerized risk profiles help patients improve their coronary risk? The results of the Coronary Health Assessment Study (CHAS). Preventive Medicine 1998;27:730-37.

Study	Methods and setting	Participants	Intervention	Outcomes & Time	Notes (RAMMBO)
Lowensteyn 1998	24 urban and rural communities in Ontario and Quebec provinces targeting GPs interested in CVD prevention. Cluster randomised trial stratified acc to urban status. Physicians invited to meeting on CVD risk and if interested invited to enroll in study to evaluate feasibility of using computerised CVD risk profiles to identify and treat patients at high CVD risk McGill University, Montreal, Quebec, Canada	Incl: 253 primary care providers, 958 patients Provider invited to select patients in whom a risk profile would be clinically useful. Incl: patients aged 30-74yrs, free of CVD, provided written consent. Baseline risk assessment completed and mailed to study centre	EG (170 GPs) received within 10days, 2 copies of computer generated 8-yr absolute coronary risk profile- one for medical records, one for the patient at a return visit (approx 2wks following initial visit) Classified as high or low risk. High risk defined as being in the upper tertile of risk compared to other Canadians of same age & sex. CG (83 GPs) received profiles only if patient clinically re-evaluated during a 3-month follow-up visit	Hypothesis- those classified as being high risk and received early feedback would be more likely to return for 3-month follow-up & repeat questionnaire Outcomes- 1) likelihood of high risk vs low risk patients being seen at 3-month follow-up. 2) changes in risk factors and CHD risk in those reassessed Time: follow-up 3-6 months after initial visit	253/445 (57%) GPs agreed to participate. Randomisation method-not reported. *Allocation concealment-unclear. Baseline characteristics-* providers –EG more likely to be male, younger, more recently graduated and saw fewer patients/week than CG. Patients- equal proportion of high risk patients per group Only 51% GPs actually enrolled patients, on average EG 7.7+/-0.6 and CG 5.4+/- 0.7 (stat sig after adjustments for age,gender, & number of patients seen/week) Compliance- all received interventions. Contamination unlikely but co-intervention possible as not randomised by practice. Providers (& patients) & investigators not blind although control group not told of control group status. Follow-up- complete.ITT analysis taking into account clustering.

Bottomline- The proportion of high-risk versus low-risk patients who return for follow-up risk assessment reflects patient/provider behaviour rather than patient outcome. The outcome differs for EG and CG with CG returning to get CVD risk & EG to follow-up on known CVD risk. NB: about double the proportion of patients in CG came back compared to EG. High risk/low risk reassessed EG 27.7%/22.6%= 1.23 (0.96-1.60), for CG 45.5%/59.1%= 0.77 (0.58-1.03), an absolute difference of 0.46 (0.08-0.87). After adjusting for clustering and baseline differences, EG had sig greater reductions in TC, LDL, and TC/HDL ratio (mean reduction in LDL (-0.4 vs 0.0mmol/l), TC/HDL (-0.6 vs-0.2) resulting in sig greater reductions in 8-yr CHD risk and 8-year coronary risk (-1.8 vs -0.3%) but likely biased estimates towards the intervention.

EPOC score 10/14

Concealment of allocation	Unclear	Baseline measurement	Done
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Unclear
Follow-up of patients	Done	Protection against contamination	Not Done
Blinded assessment of 1^0 outcome(s)	Done (unblinded but objective)		

Study author and reference: McAlister NH, Covvey H D, Tong C, Lee A, Wigle ED. Randomised controlled trial of computer assisted management of hypertension in primary care. BMJ 1986; 293:670-74.

Study	Methods and setting	Participants	Intervention	Outcomes & Time	Notes (RAMMBO)
McAlister 1986	Cluster randomised controlled trial in primary care Institute of Medical Science, University of Toronto, Toronto Ontario, Canada	Incl: 50 GPs from the Toronto region, seeing 2833 patients with hypertension defined as DBP>90mmHg or if on antihypertensive drug Treatment protocol – diastolic BP>104mmHg to be treated with drugs, those with lower DBP treated only if evidence of target organ damage, stroke or TIA	All GPs given published material about treatment of hypertension advocated by Ontario Council of Health Taskforce on Hypertension Data collection form filled in after each visit by a patient with hypertension. Form sent to research centre EG: 25 GPs (1241 patients) and computer feedback based on treatment protocol mailed back to GP, plus reminder of appointment sent to patients. CG- 25 GPs (990 patients) data collection form filled only.	2727/2833 patient data visits met criteria for hypertension. Outcomes: Decision to treat with BP drugs Mean change DBP % of patients who acheive goal of DBP 90mmHg Analysis of performance of practice via use of a score to denote all observations within one practice (median score for each doctor and combined into mean score per group). Time: 16-months	% recruited from eligibles not reported. Stratified by number of doctors in practice and predominant ethnicity of doctors. Randomised by shuffle of cards to intervention or control. *Allocation concealment*- unclear. *Baseline characteristics*- no significant differences in age, gender, DBP of patients and years since graduation, location of practices, size & ethncity of practices. Compliance –10 doctors (17%) did not attend fill in any forms – Providers (& patients) & investigators not blind Contamination probable given knowledge of trial Follow-up- lost 602 (21%) patients either seen only once or more than one visit but in trial<30days Not ITT analysis. Both univariate and multivariate analysis

Bottomline- For all hypertensive patients there was no statistically significant difference between intervention group and control group in terms of the decision to treat with antihypertensives, mean change in DBP from baseline to last visit and % of patients who acheived goal of DBP <90mmHg.

EPOC score=6/14

Concealment of allocation	Unclear	Baseline measurement	Done
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Not done
Follow-up of patients	Not Done	Protection against contamination	Unclear
Blinded assessment of 1^0 outcome(s)	Not done		

Study author and reference: van Wyk JT, van Wijk MAM, Sturkenboom MCJM, Mosseveld M, Moorman PW and van der Lei J. Electronic alerts versus on-demand decision support to improve dyslipidaemia treatment. A cluster randomized controlled trial. Circulation 2008;117:371-78.

Study	Methods & setting	Participants	Intervention	Outcomes & Time	Notes (RAMMBO)
Van Wyk 2008	Cluster RCT of general practices in the Delft region using the ELIAS electronic health record system and had fully replaced paper based records with electronic records for patient visits for ≥ 1 year. Departments of Medical Informatics and Epidemiology and Biostatistics, Erasmus MC University Medical Center, Rotterdam, The Netherlands	38/56 eligible practices (80 GPs) participated with 92054 eligible patients (men 18-70yrs and women 18-75yrs for whom the 1999 DCGP guidelines for primary and secondary prevention of CVD were applicable). CDSS based on these guidelines and integrated with the EHR. The system uses ICPC coded data, locally defined codes and free text and identifies patients who need lipid screening and those who need lipid therapy.	EG1 14 practices On-demand CDSS requiring initiation of the overview screen to access recommendations EG2 13 practices Alerting CDSS showing recommendations automatically. CG 11 practices usual care CDSS was installed, configured to the practice setting in each practice (disabled in CG) Eligible patients were entered into the study when patient record was opened.	Primary outcome: % patients risk assessed % treated patients according to guidelines Time: at least 12 months or until the practice switched to another EHR or until the patient died.	68% eligible practices agreed to take part. Randomised using random numbers table by researcher not involved with the study and blind to practice identity. *Allocation concealment*- adequate *Baseline characteristics (practices)* differed slightly as baseline screening and treatment performance was slightly lower in the on-demand arm *(patients)* – similar except for %smokers , family Hx of CVD and SBP. Compliance all received interventions. Contamination unlikely Providers (& patients) not blind. Outcome assessment via automated data extraction 2 practices (4168 patients) not included in the analyses. Not ITT analyses accounting for clustering & adjusted for CVD, diabetes and follow-up visits.

Bottomline- 65% of patients in the alerting arm, 35% in the on-demand arm and 25% in the control arm were screened.
Similarly 65.7% of patients in the alerting arm, 39.7% in the on-demand arm and 35.9% in the control arm were treated.
*ICPC =International Classification for Primary Care

EPOC score 14/14

Concealment of allocation	Done	Baseline measurement	Done
Follow-up of professionals	Done	Reliable 1^0 outcome measure(s)	Done
Follow-up of patients	Done	Protection against contamination	Done
Blinded assessment of 1^0 outcome(s)	Done (unblinded but objective)		

Appendix 4.2 Systematic review excluded references

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Appendix 5.1 CVD-Diabetes risk assessment, adjustment and classification

PREDICT™
CVD-DIABETES

ECDS CVD RISK ASSESSMENT:
CALCULATION, ADJUSTMENT AND CLASSIFICATION

VERSION 1.6

Dr Sue Wells, University of Auckland
Chris Wiltshire, Enigma

Aug 05, 2005

THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND HEALTH SCIENCES

ENIGMA

Preface

CVD risk assessment (including adjustment and classification) is the pivotal factor determining clinical CVD risk management. This report was prepared for the Electronic Clinical Decision Support (ECDS) Steering Group in August 2005. It documents the New Zealand Guideline Group CVD guideline committee approved interpretation to decision support for each step of risk assessment, adjustment and classification. The document contains both proposed technical standards, interpretations and, for the purposes of illustration only, screen shots from the Predict application. It includes the risk calculation using Framingham absolute CVD risk prediction equation, events prevented, number needed to treat (NNT), rounding and guideline group agreed recommendations when risk assessment occurs in those under 35yrs or over 75yrs.

The ECDS Steering Group acknowledged receipt of the document on the 12th August 2005 and endorsed the proposed technical standards and interpretations as valuable contributions to public domain knowledge to develop consistency of use of the CVD risk equations across all forms of decision support.
The ECDS Steering Group recommended to NZGG that it consider the proposed technical standards and interpretations as a reference with the source CVD guidelines

Table of Contents

Purpose

To document for clinicians and people working in the clinical-IT interface, the implementation into clinical decision support of the CVD risk assessment component of the Guideline for the Assessment and Management of Cardiovascular risk (NZGG 2003). This document is intended for use in conjunction with the guideline.

Exclusion criteria

The guideline covers the assessment and management of people with known cardiovascular disease, including people with type 1 and type 2 diabetes. The guideline excludes children (defined as less than 18 years of age), specific management of genetic lipid disorders, heart failure, acute coronary syndromes, sleep apnoea. Risk assessment and management is also not appropriate for pregnant women.

CVD-Diabetes decision support module

If a patient is pregnant or has gestational diabetes or aged less than 18yrs, clinicians are advised with the following messages and no risk assessment may proceed.

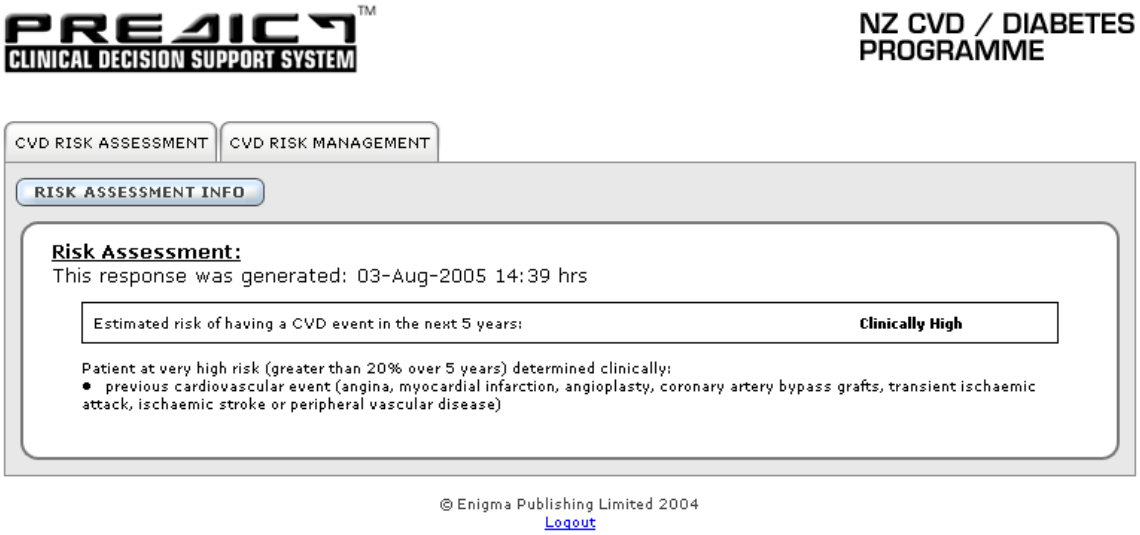
- This module is not applicable to a pregnant patient.
- This module is not applicable to patients under the age of 18

Conditions where people are determined clinically as being at very high risk (>20% over 5 years)

Patients having one or more of the following conditions are defined as clinically being at high risk and the Framingham equation is not applicable:

- Previous cardiovascular event (angina, myocardial infarction, angioplasty, coronary artery bypass grafts, transient ischaemic attack, ischaemic stroke or peripheral vascular disease)
- Diagnosed genetic lipid disorder (familial hypercholesterolaemia, familial defective ApoB and familial combined dyslipidaemia)
- Diabetes and overt nephropathy (albumin:creatinine ratio greater than 30 mg/mmol)
- Diabetes and other renal disease

Example of message to clinician



Framingham risk assessment

If the patient's profile does not meet exclusion criteria or is not clinically determined as being at very high risk, then the Framingham risk calculation is performed using the CVD equation from Anderson et al. CVD risk profiles. Am Heart J 1991;121:293-8.

CVD outcomes predicted

This equation predicts the risk of the following fatal and non-fatal CVD events: myocardial infarction, angina, coronary insufficiency, sudden and non sudden coronary death, stroke, transient ischaemic attack, peripheral vascular disease (claudication), left ventricular failure (symptomatic).

The fields (as below) are A through Z and AA through AE and include the necessary instructions. Once completed eg, using an xcel spreadsheet, the users can feed in any patient's risk factors and determine their probability of a CVD event over 5 years. The equation is applicable to patients aged 35-75 years and may be used for estimating outcome probabilities over a range from 4-12 years.

Fields:

Risk Factors:

A Gender (female =1, male=0)

B Age (years)

C SBP (mmHg) the average of two systolic blood pressures is used

D Smoking (no=0, yes =1): considered as smoker= “0” if non-smoker or quit smoking more than 12 months previously, otherwise smoking=”1”

E/F Total cholesterol /HDL ratio (ideally fasting but not mandatory)

G Diabetes (type 1, 2 or type unknown =1, no=0)

H ECG LVH (yes=1, no=0) note this is not used in New Zealand risk prediction tables

For SBP prediction equation co-efficients

I ß0= 18.8144

J ß1= -1.2146*(A)

K ß2= -1.8443*LN(B)

L ß3= Blank

M ß4= 0.3668*LN(B)*(A)

N ß5= Blank

O ß6= -1.4032*LN(C)

P ß7= - 0.3899*(D)

Q ß8= -0.539*LN((E)/(F))

R ß9= -0.3036*(G)

S ß10= -0.1697*(G)*(A)

T ß11= -0.3362*(H)

U ß12= Blank

V q1= 0.6536

W q2= -0.2402

X m= SUM((I):(T))

Y g= EXP((V)+((W)*(X)))

Z Time (years) (Set at 5 years)

AA U= (LN(Z)-(X))/(Y)

AB Probability of CVD = 1-EXP(-EXP(AA))

AC Relative risk reduction (Set at 25% for one intervention, 45% for 2 interventions and 55% for 3 interventions)

AD Absolute risk reduction = (AB)*(AC)

AE NNT (numbers needed to treat for 5 years to prevent an event) = 1/(AD)

Notes:

* LN is natural log
* EXP = exponential
* Some of the coefficients are blank because other versions of the same basic equation can be used for other endpoints and use additional coefficients

To check that equation is correct:
To check if the equation is written correctly use the following example: woman, aged 70 years, SBP 174 mmHg, smoker, TC = 6 mmol/L, HDL= 1.4 mmol/L, no diabetes, 5 year probability of CVD =22.641% (equation reads 0.22641) ,

Treatment benefits according to the guidelines:
These may be used to estimate the risk reduction that would occur for an individual on no CVD treatments at the time of the risk assessment.

Treatment benefit from one intervention (applying a 25% relative risk reduction)
absolute risk reduction = 5.7% (equation reads 0.056603),
NNT= 18 (equation reads 17.66703)

Treatment benefit from two interventions (applying a 45% relative risk reduction)
absolute risk reduction = 10.2% (equation reads 0.101885),
NNT= 10 (equation reads 9.815017)

Treatment benefit from three interventions (applying a 55% relative risk reduction)
absolute risk reduction = 12.4% (equation reads 0.124526),
NNT= 8 (equation reads 8.030469)

Rounding

There is a statistical confidence interval around each estimated risk. Given this imprecision, it is appropriate only to round up or down to the nearest whole number. For example, if the CVD risk =22.641%, the rounded CVD risk is 23%. The absolute risk reduction and NNT are based on this rounded CVD risk.

PREDICT™ CLINICAL DECISION SUPPORT SYSTEM

NZ CVD / DIABETES PROGRAMME

CVD RISK ASSESSMENT | CVD RISK MANAGEMENT

RISK ASSESSMENT INFO

Risk Assessment:

This response was generated: 03-Aug-2005 14:41 hrs

Estimated risk of having a CVD event in the next 5 years: 23%

Estimated risk level: 5-year CV risk (fatal and non-fatal)	Estimated Benefits: NNT for 5 years to prevent one event (CVD events prevented per 100 people treated for 5 years)		
	1 intervention (25% risk reduction)	2 interventions (45% risk reduction)	3 interventions (55% risk reduction)
23%	17 (5.8 per 100)	10 (10.4 per 100)	8 (12.7 per 100)

Based on the conservative estimate that each intervention: aspirin, blood pressure treatment (lowering systolic blood pressure by 10 mm Hg) or lipid modification (lowering LDL-C by 20%) reduces CV risk by about 25% over 5 years.

This patient's estimated risk value has been calculated using the Framingham CVD risk equation.

Cardiovascular Disease: Baseline Risk and Treatment Benefit

NO DIABETES

Nonsmoker | Smoker

Ratio of Total Cholesterol:HDL

The colour chart and calculated risks vary. Likely cause: patient age or BP fall between two colour chart groups.
Calculated risk value: 23% - Indicated risk range: (15-20%)

Risk Level
5 year CVD risk (non-fatal and fatal)

	>30%	**High**	15-20%		5-10%
Very High	25-30%	**Moderate**	10-15%	**Mild**	2.5-5%
	20-25%				<2.5%

Extremes of CVD absolute 5yr risk: less than 1% and greater than 30%

No person is at 0% risk of a CVD event. Therefore where a patient's risk is less than 1% then the actual risk displayed is rounded up to 1%.
If patient CVD risk is over 30% then actual risk is not displayed but given >30% as per the CVD guideline colour chart.

PREDICT™ CLINICAL DECISION SUPPORT SYSTEM

NZ CVD / DIABETES PROGRAMME

CVD RISK ASSESSMENT | CVD RISK MANAGEMENT

RISK ASSESSMENT INFO

Risk Assessment:
This response was generated: 03-Aug-2005 14:43 hrs

Estimated risk of having a CVD event in the next 5 years: >30%

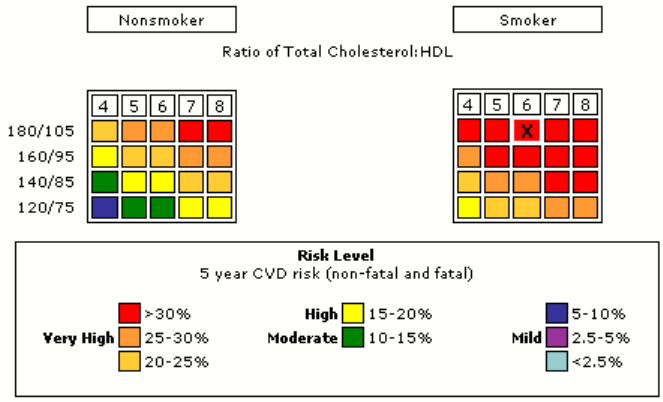
Estimated risk level: 5-year CV risk (fatal and non-fatal)	Estimated Benefits: NNT for 5 years to prevent one event (CVD events prevented per 100 people treated for 5 years)		
	1 intervention (25% risk reduction)	2 interventions (45% risk reduction)	3 interventions (55% risk reduction)
30%	13 (7.5 per 100)	7 (13.5 per 100)	6 (16.5 per 100)

Based on the conservative estimate that each intervention: aspirin, blood pressure treatment (lowering systolic blood pressure by 10 mm Hg) or lipid modification (lowering LDL-C by 20%) reduces CV risk by about 25% over 5 years.

This patient's estimated risk value has been calculated using the Framingham CVD risk equation.

Cardiovascular Disease: Baseline Risk and Treatment Benefit

NO DIABETES



Logout

CVD risk assessment when patient is younger than 35 years or when patient is older than 75 years

The Framingham equation is not directly applicable for those below 35yrs or for those above 75yrs. The CVD risk guideline committee recommended the following wording to be displayed when patients in these age groups were risk assessed;

For those below 35 years

The Framingham equation is not directly applicable for those below 35yrs. and this risk has been calculated as if they were 35yrs as an approximation. The result is given to guide clinical decision making only. Consideration should be given to factors which might require more intensive intervention or specialist referral:

- *suspected genetic lipid disorder*
- *type 1 diabetes*
- *diabetes with microalbuminuria*
- *type 2 diabetes of long duration*
- *HDL either very low or very high (<0.7mmol/l or >2 mmol/L)*

For those above 75 years

The Framingham equation is not directly applicable for those above 75yrs and this risk has been calculated as if they were 75yrs as an approximation. The result is given to guide clinical decision making only.

CVD risk adjustment

If the patient does not meet exclusion criteria or is not clinically determined as being at very high risk, then the Framingham risk calculation is performed. After this calculation, the following groups should be moved up one risk category (5%), as their cardiovascular risk may be underestimated in the Framingham equation:

- People with a family history of premature coronary heart disease or ischaemic stroke in a first degree male relative before the age of 55 years or a first degree female relative before the age of 65yrs
- Maori
- Pacific peoples or people from Indian subcontinent
- People with both diabetes and microalbuminuria
- People who have had type 2 diabetes for more than 10 years or who have an HbA1c consistently greater than 8%
- People with metabolic syndrome

These adjustments should only be made once for people who have more than one criteria (i.e. the maximum adjustment is 5%).

Ethnicity coding and PREDICT CVD-Diabetes

The following code list is the Statistics New Zealand Standard Classification of Ethnicity, Level 2 (except '99', which has been added by NZHIS).

10	European Not Further Defined
11	New Zealand European/Pakeha
12	Other European
21	New Zealand Maori
30	Pacific Island not further defined
31	Samoan
32	Cook Island Maori
33	Tongan
34	Niuean
35	Tokelauan
36	Fijian
37	Other Pacific Islands (not listed)
40	Asian not further defined
41	Southeast Asian
42	Chinese
43	Indian
44	Other Asian
51	Middle Eastern
52	Latin American / Hispanic
53	African
54	Other
99	Not Stated

As indicated by the grey shading, the self-identified ethnicity codes that were used to apply the 5% upward adjustment were.
Ethnicity code 21 (New Zealand Maori)
Ethnicity codes 31 through to 37 (all Pacific islands)
Ethnicity codes 43 (all Indian including Fijian Indian), and the 44 codes (Other Asian).
However we were advised by the CVD-Diabetes guideline project manager that "Indian sub-continent" included ethnicity codes 43 (Indian) and all 44 codes except Japanese and Korean (in grey below).

Level 2, and higher coding levels for Other Asian Ethnicity codes

44	Other Asian
441	Sri Lankan
44100	Sri Lankan nfd
44111	Sinhalese
44112	Sri Lankan Tamil
44199	Sri Lankan nec
444	Other Asian
44411	Afghani
44412	Bangladeshi
44413	Nepalese
44414	Pakistani
44415	Tibetan
44499	Other Asian nec
442	Japanese
44211	Japanese
443	Korean
44311	Korean

Currently PMS systems are only able to pass Level 2 codes (which will include Japanese/Korean).Therefore until PMS systems are able to pass Level 3 ethnicity coding there will be some Japanese and Korean patients whose risk may be overestimated by 5%. New Zealand risk thresholds for treatment are quite conservative compared with other countries. Therefore in consultation with Prof Rod Jackson (Epidemiologist, University of Auckland) it was considered that overestimating CVD risk in a small group of people would be less of an issue than not adjusting and therefore underestimating risk for people of any of 44 codes(other Asian). The Predict CVD Diabetes module contains a mix of Level 2 and relevant Level 3 and 4 codes.

Note: Even if PMS systems change over to Level 3 coding, it is still likely that some GPs will retain their Level 2 'legacy' ethnicity data rather than recode.

Example of PREDICT CVD-DIABETES assessment and risk adjustment

PREDICT™ CLINICAL DECISION SUPPORT SYSTEM

NZ CVD / DIABETES PROGRAMME

CVD RISK ASSESSMENT | CVD RISK MANAGEMENT | DIABETES MANAGEMENT

RISK ASSESSMENT INFO

Risk Assessment:

This response was generated: 03-Aug-2005 14:45 hrs

Estimated risk of having a CVD event in the next 5 years: 16%

Estimated risk level: 5-year CV risk (fatal and non-fatal)	**Estimated Benefits: NNT for 5 years to prevent one event** (CVD events prevented per 100 people treated for 5 years)		
	1 intervention (25% risk reduction)	**2 interventions (45% risk reduction)**	**3 interventions (55% risk reduction)**
16%	25 (4.0 per 100)	14 (7.2 per 100)	11 (8.8 per 100)

Based on the conservative estimate that each intervention: aspirin, blood pressure treatment (lowering systolic blood pressure by 10 mm Hg) or lipid modification (lowering LDL-C by 20%) reduces CV risk by about 25% over 5 years.

CVD risk has been moved up one risk category (5%), as cardiovascular risk may be underestimated in the Framingham risk equation; based on:

- family history of premature coronary heart disease or ischaemic stroke in a first-degree male relative before the age of 55 years or a first-degree female relative before the age of 65 years
- Maori or Pacific ethnicity or people from the Indian subcontinent
- type 2 diabetes for more than 10 years
- both diabetes and microalbuminuria

Cardiovascular Disease: Baseline Risk and Treatment Benefit

DIABETES

(With a 5% upward risk adjustment applied)

Nonsmoker | Smoker

Ratio of Total Cholesterol:HDL

The colour chart and calculated risks vary. Likely cause: patient age or BP fall between two colour chart groups.

Calculated risk value: 16% - Indicated risk range: (20-25%)

Risk Level

5 year CVD risk (non-fatal and fatal)

Very High	>30%	**High**	15-20%		5-10%
	25-30%	**Moderate**	10-15%	**Mild**	2.5-5%
	20-25%				<2.5%

Logout

Classification where risk factor levels are extreme

The NZGG CVD guidelines state;
If blood pressure is consistently greater than 170/100 or total cholesterol greater than 8mmol/L or TC:HDL ratio greater than 8, the person is classified at least at high risk (>15%) and should receive specific lifestyle advice and medication to lower their risk, irrespective of their calculated risk.

The average of two sitting blood pressures are recommended by the guideline when measuring and recording risk factors. Therefore CVD-Diabetes input template includes today's sitting BP and the most recent previous blood pressure (can be 2 sitting blood pressures taken at least 10 minutes apart). An **average** of the two systolic blood pressures is calculated to contribute to the CVD risk prediction equation.

If a person's calculated and adjusted risk was less than 15% but the profile contained extreme values of blood pressure or cholesterol then classification of CVD risk 15% was undertaken when;

- TC/HDL **OR** Total cholesterol greater than or equal to 8 mmol/L
- **{** (systolic BP1 was greater than or equal to 170mmHg **or** diastolic BP1 was greater than or equal to 100mmHg) **AND** (systolic BP2 was greater than or equal to 170mmHg **or** diastolic BP2 was greater than or equal to 100mmHg) **}**

Example of output given below

PREDICT™ CLINICAL DECISION SUPPORT SYSTEM

NZ CVD / DIABETES PROGRAMME

CVD RISK ASSESSMENT | CVD RISK MANAGEMENT

RISK ASSESSMENT INFO

Risk Assessment:
This response was generated: 03-Aug-2005 14:48 hrs

Estimated risk of having a CVD event in the next 5 years: 15%

Estimated risk level: 5-year CV risk (fatal and non-fatal)	**Estimated Benefits: NNT for 5 years to prevent one event** (CVD events prevented per 100 people treated for 5 years)		
	1 intervention (25% risk reduction)	**2 interventions (45% risk reduction)**	**3 interventions (55% risk reduction)**
15%	27 (3.8 per 100)	15 (6.8 per 100)	12 (8.3 per 100)

Based on the conservative estimate that each intervention: aspirin, blood pressure treatment (lowering systolic blood pressure by 10 mm Hg) or lipid modification (lowering LDL-C by 20%) reduces CV risk by about 25% over 5 years.

This patient's estimated risk value has been calculated using the Framingham CVD risk equation.

However, irrespective of calculated risk, the patient is classified as being at least at high risk (15% and over) when their systolic or diastolic BP is consistently greater than or equal to 170/100 or TC/HDL or total cholesterol is greater than or equal to 8.

- Blood pressures were: 170/90 mmHg and 120/100 mmHg

Logout

Risk calculation using the Framingham equation and displayed risk using the colour chart

There are occasions where the calculated risk and the risk indicated in the colour charts may vary. This is due to a combination of factors mostly related to the limitations imposed by the use of categorical variables (colour chart) compared to use of continuous variables (risk prediction equation). The colour charts are the 'best fit' rather than a mathematical equation.

Factors contributing to variation:

- Patient age on the cusp of next colour chart block eg; 45yrs , 55yrs, 65yrs
- Risk equation uses systolic not diastolic blood pressure
- Risk equation uses actual systolic number not within a 20mmHg range as the colour charts
- Risk equation uses actual lipid number not just whole number ie, 6, or 7 as the colour charts

When this variance occurs an explanatory note appears in the CVD-Diabetes module (see below).

THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND HEALTH SCIENCES

ENIGMA

PREDICT™
CLINICAL DECISION SUPPORT SYSTEM

NZ CVD / DIABETES PROGRAMME

CVD RISK ASSESSMENT | CVD RISK MANAGEMENT

RISK ASSESSMENT INFO

Risk Assessment:

This response was generated: 03-Aug-2005 14:56 hrs

Estimated risk of having a CVD event in the next 5 years: 17%

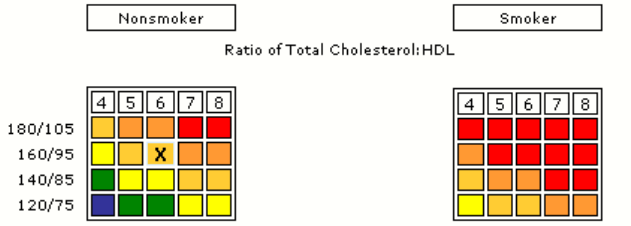
Estimated risk level: 5-year CV risk (fatal and non-fatal)	**Estimated Benefits: NNT for 5 years to prevent one event** (CVD events prevented per 100 people treated for 5 years)		
	1 intervention (25% risk reduction)	**2 interventions (45% risk reduction)**	**3 interventions (55% risk reduction)**
17%	24 (4.3 per 100)	13 (7.7 per 100)	11 (9.4 per 100)

Based on the conservative estimate that each intervention: aspirin, blood pressure treatment (lowering systolic blood pressure by 10 mm Hg) or lipid modification (lowering LDL-C by 20%) reduces CV risk by about 25% over 5 years.

This patient's estimated risk value has been calculated using the Framingham CVD risk equation.

Cardiovascular Disease: Baseline Risk and Treatment Benefit

NO DIABETES



The colour chart and calculated risks vary. Likely cause: patient age or BP fall between two colour chart groups.
Calculated risk value: 17% - Indicated risk range: (20-25%)

Risk Level
5 year CVD risk (non-fatal and fatal)

	>30%	**High**	15-20%		5-10%
Very High	25-30%	**Moderate**	10-15%	**Mild**	2.5-5%
	20-25%				<2.5%

Logout

Appendix 5.2 Statistics New Zealand Ethnicity Classification and PREDICT ethnicity coding

Statistics New Zealand Ethnicity Classification is a hierarchical structure with four levels.[2] The coding system starts with a single digit at Level 1, then further digits are added with each move to a more detailed level, thereby increasing differentiation of ethnic group.[2] There are 5 ethnicity codes at Level one corresponding to European, Maori, Pacific Island, Asian and Other ethnic groups, 9 codes at Level 2, 41 codes at Level 3 and 231 codes at level 4. Each more detailed level can be aggregated to a higher level. For example;

- Level 4 code 44112 is Sri Lankan Tamil
- Level 3 code 441 is Sri Lankan
- Level 2 code 44 is Other Asian
- Level 1 code 4 is Asian

To translate guideline requirements to CDSS, Level 2 and 3 Statistics New Zealand ethnicity codes matching Māori, Pacific and South Asian ethnicities were identified as in the table below.

Statistics New Zealand Standard Classification of Ethnicity, Level 2 (Note: '99' has been added by NZHIS).[2]

10	European Not Further Defined
11	New Zealand European/Pakeha
12	Other European
21	New Zealand Māori
30	Pacific Island not further defined
31	Samoan
32	Cook Island Māori
33	Tongan
34	Niuean
35	Tokelauan
36	Fijian
37	Other Pacific Islands (not listed)
40	Asian not further defined
41	Southeast Asian

42	Chinese
43	Indian
44	Other Asian
51	Middle Eastern
52	Latin American / Hispanic
53	African
54	Other
99	Not Stated

As indicated by the grey shading, the Level 2 ethnicity codes that were used to apply the additional 5% CVD risk were.

- Ethnicity code 21 (New Zealand Māori)
- Ethnicity codes 31 through to 37 (all Pacific islands)
- Ethnicity codes 43 (all Indian including Fijian Indian), and the 44 codes (Other Asian). Unfortunately, the New Zealand Guideline Group 5% upward adjustment for people from South Asia (also documented as Indian subcontinent) did not truly match a Level 2 ethnicity code. The adjustment only applied to selected ethnicities within the '44' code (in grey below). Those who were Japanese or Korean were not considered to be a "high" risk ethnicity.

Level 3 and 4 Ethnicity categories aggregated within NZHIS Level 2: '44' Other Asian Ethnicity code

44	Other Asian
441	Sri Lankan
44100	Sri Lankan nfd
44111	Sinhalese
44112	Sri Lankan Tamil
44199	Sri Lankan nec
444	Other Asian
44411	Afghani
44412	Bangladeshi
44413	Nepalese
44414	Pakistani
44415	Tibetan
44499	Other Asian nec
442	Japanese
44211	Japanese

443	Korean
44311	Korean

Currently PMS systems can only classify ethnicity according to Level 2 codes (which includes Japanese and Korean). Therefore until PMS systems are able to classify according to Level 3 ethnicity coding there will be some Japanese and Korean patients whose risk may be overestimated by 5% within the clinical setting.

Even if PMS systems change over to Level 3 coding, it is still likely that some GPs will retain their Level 2 'legacy' ethnicity data rather than recode. As New Zealand risk thresholds for treatment were quite conservative compared with other countries it was considered that overestimating CVD risk in a small group of people would be less of an issue than not adjusting and therefore underestimating risk for people belonging to ethnicities within the Level 2:44 code[3].

Ethnicity coding in PREDICT cohort analyses

Ethnicity coding was aggregated into six groups: European, Māori, Pacific, South Asian, Other Asian, and all Others. Pacific peoples were defined according to New Zealand Health Information Service ethnicity data protocols[257] as having Level 2 codes 31 to 37 and South Asian defined as Level 2 codes 43 and 44 excluding Japanese and Korean; i.e. being Indian, Fijian Indian, Pakistani, Sri Lankan, Bangladeshi, Nepali, Afghani or Tibetan. For these analyses the Other Asian category included 42 (Chinese), 442 (Japanese), 444 (Korean), 41 (South East Asian) and 40 (Asian not further defined). European ethnicity included Level 2 codes 10, 11 and 12 and the Other Ethnicity group were all other people not coded in any of the other categories. If more than one ethnicity was recorded, they were prioritised as being Māori if there was Māori in any of the three ethnicity fields, Pacific (in the absence of Māori), South Asian (in the absence of Māori or Pacific ethnicities in any field) and then according to their first self-identified ethnicity (in the absence of these three ethnicities).

References

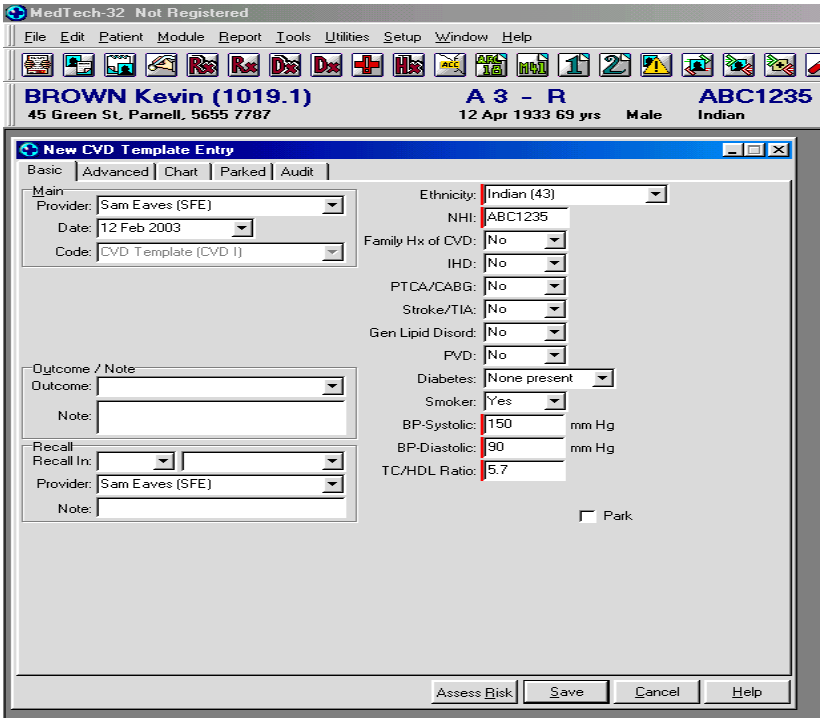
1. Health Information Strategy Steering Committee. *Health Information Strategy for New Zealand*: Ministry of Health, 2005.

2. Ministry of Health. Ethnicity data protocols for the Health and Disability Sector. Wellington: Ministry of Health, 2004.

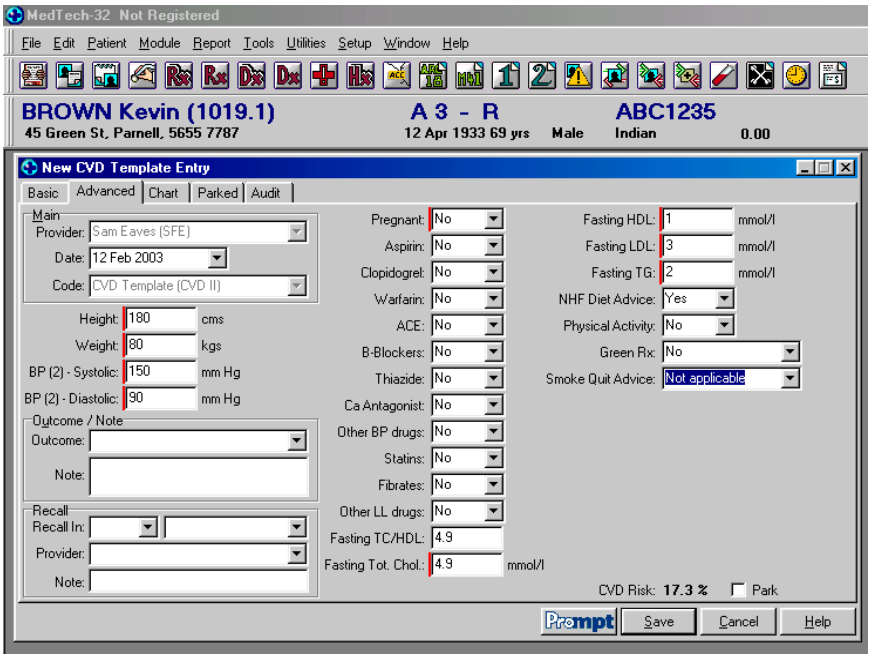
3. Jackson R. Professor of Epidemiology, School of Population Health, University of Auckland, 2005:Personal communication.

Appendix 5.3 Templates of PREDICT-CVD and templates and examples of PREDICT CVD-Diabetes decision support output

PREDICT-CVD risk assessment template (fictitious patient)

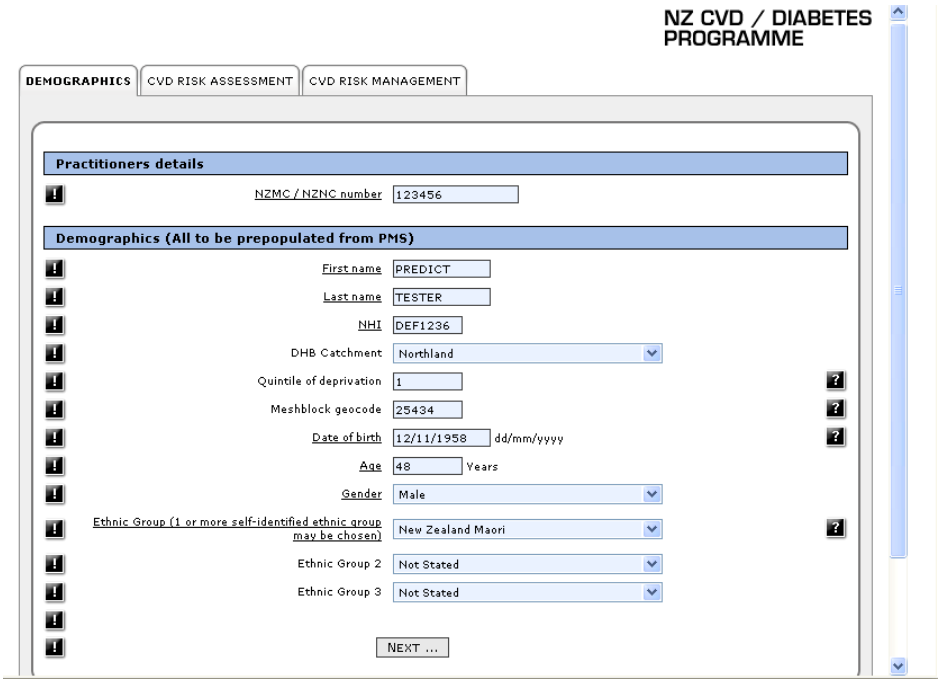


PREDICT-CVD risk management template (fictitious patient)

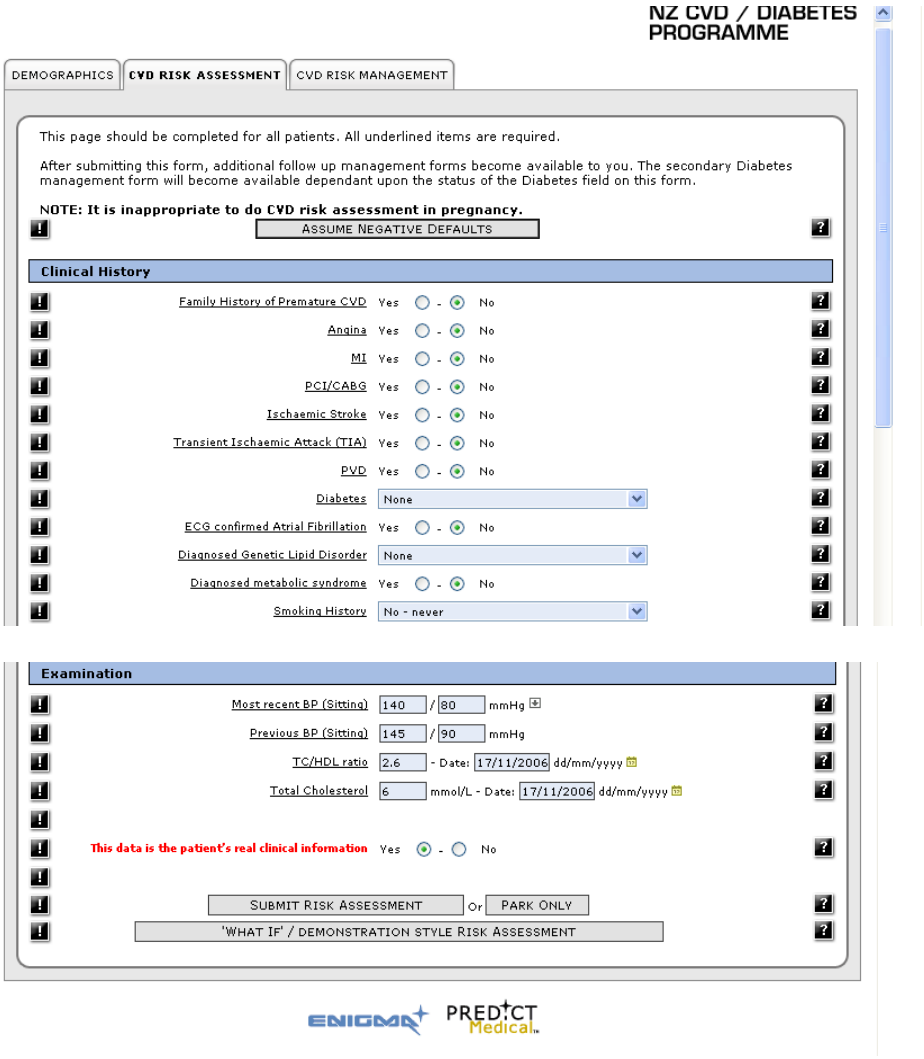


Templates and Examples of PREDICT CVD-Diabetes Decision Support Output

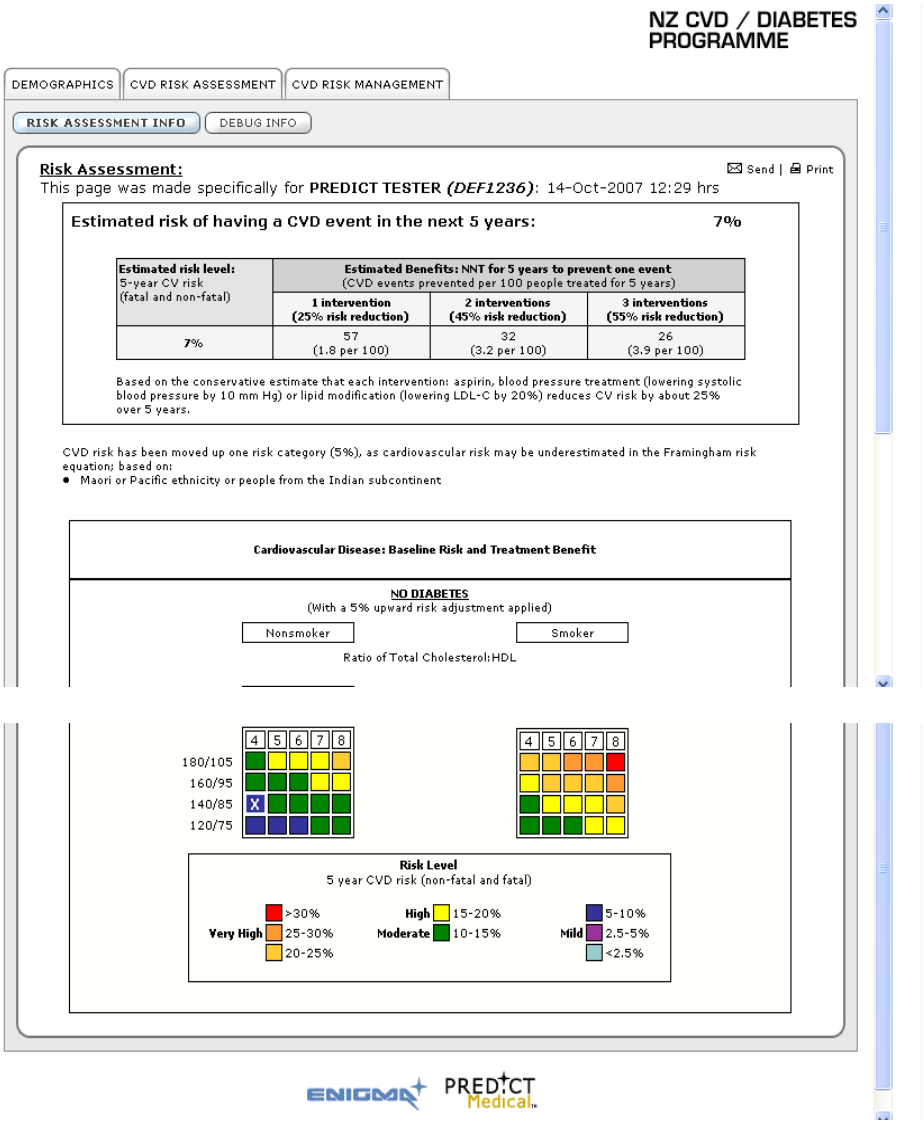
PREDICT CVD-Diabetes template 1 Demographics (example)



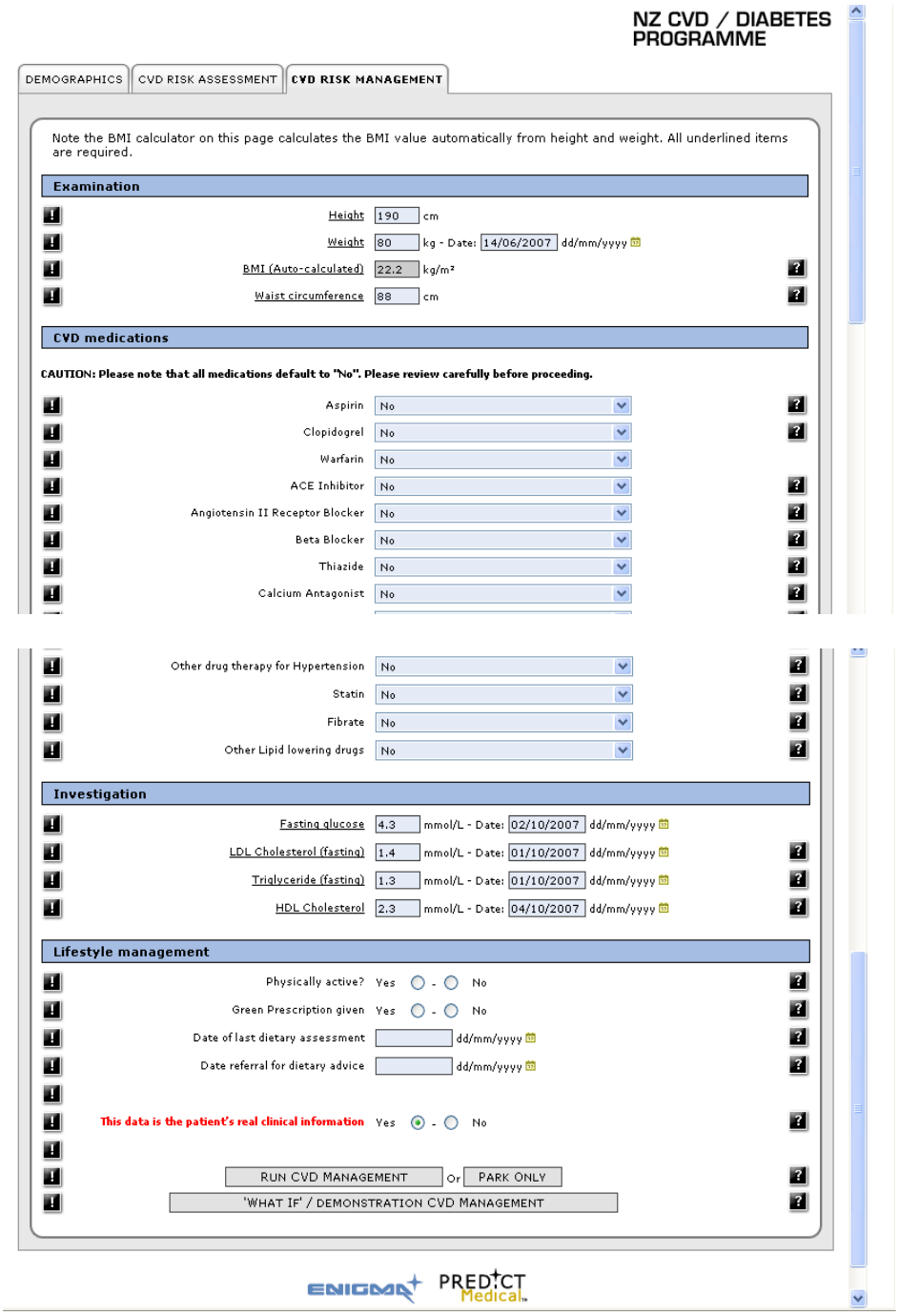
PREDICT CVD-Diabetes template 2 CVD Risk Assessment (example)



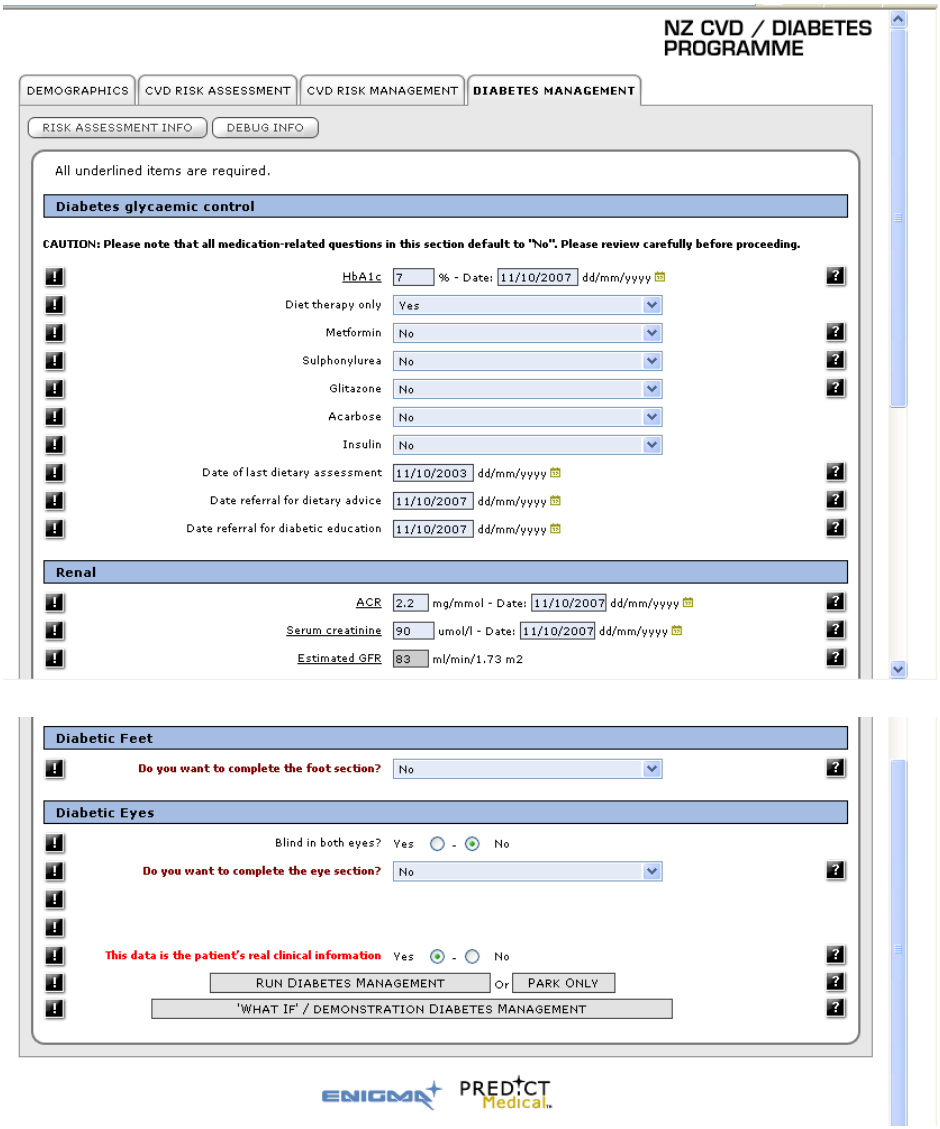
Example: Decision support output :risk assessment estimate



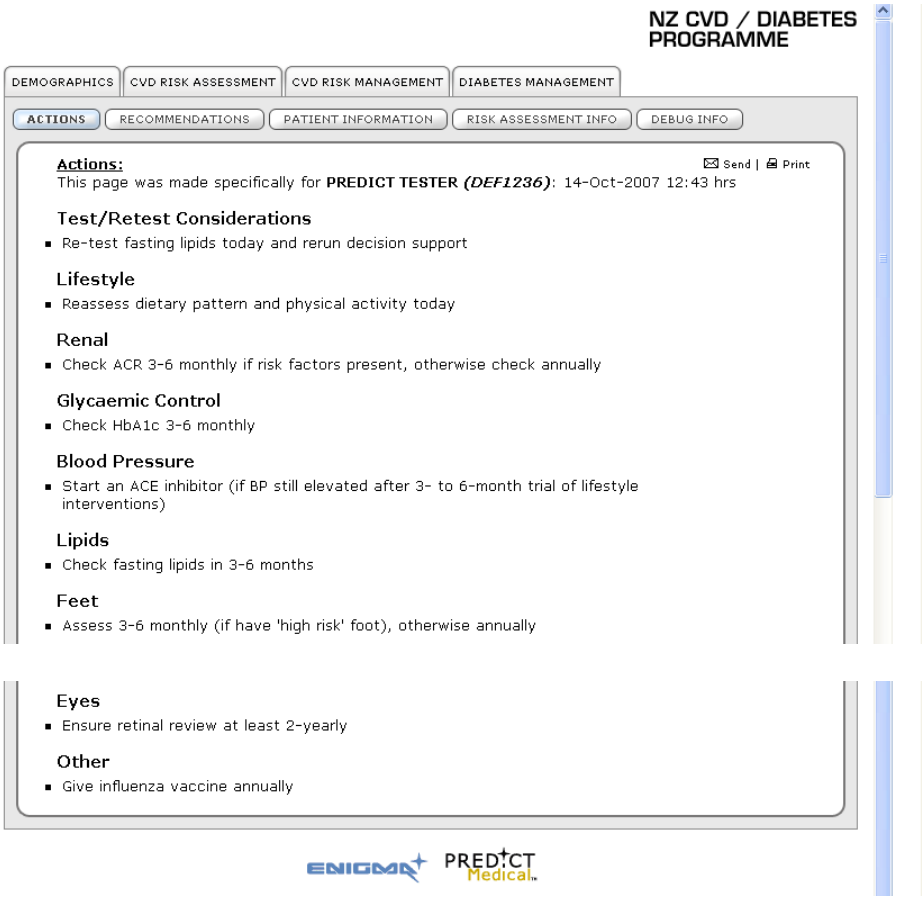
PREDICT CVD-Diabetes template 3 CVD Management (example)



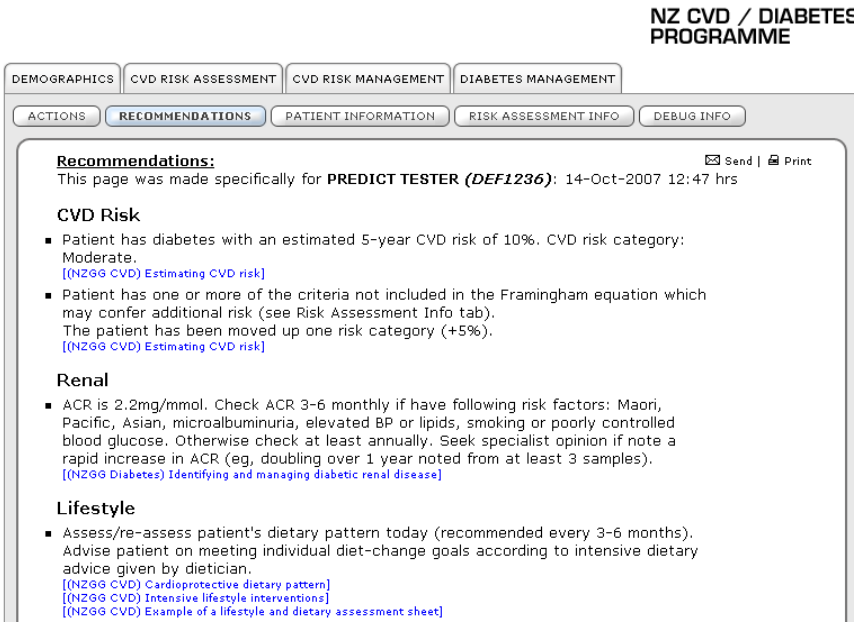
PREDICT CVD-Diabetes template 4 Diabetes Management (example)

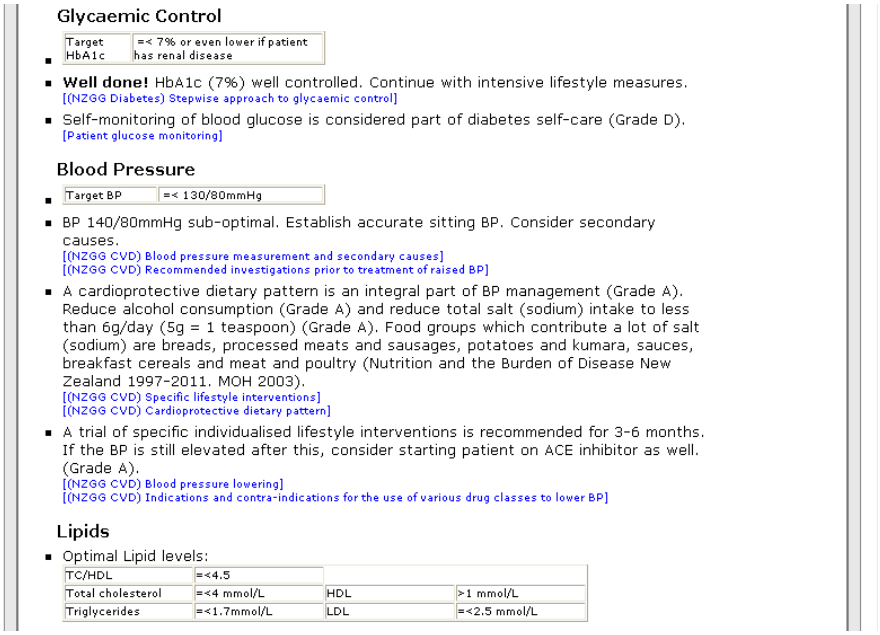


Example : PREDICT CVD-Diabetes decision support output: management advice (Actions)



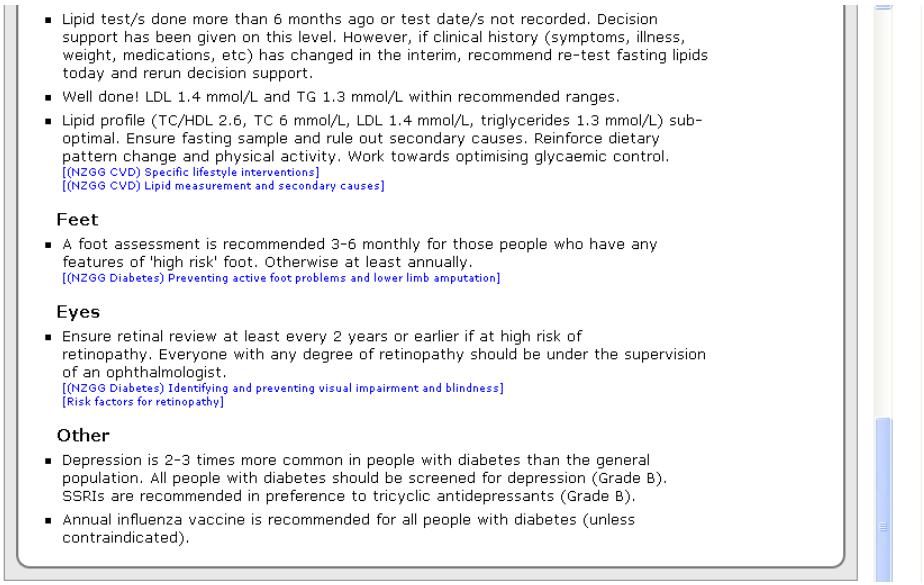
Example: PREDICT CVD-Diabetes decision support output: management advice (Recommendations)





Management Advice continued on next page

Management Advice continued...



- Lipid test/s done more than 6 months ago or test date/s not recorded. Decision support has been given on this level. However, if clinical history (symptoms, illness, weight, medications, etc) has changed in the interim, recommend re-test fasting lipids today and rerun decision support.
- Well done! LDL 1.4 mmol/L and TG 1.3 mmol/L within recommended ranges.
- Lipid profile (TC/HDL 2.6, TC 6 mmol/L, LDL 1.4 mmol/L, triglycerides 1.3 mmol/L) sub-optimal. Ensure fasting sample and rule out secondary causes. Reinforce dietary pattern change and physical activity. Work towards optimising glycaemic control.
  [(NZGG CVD) Specific lifestyle interventions]
  [(NZGG CVD) Lipid measurement and secondary causes]

Feet

- A foot assessment is recommended 3-6 monthly for those people who have any features of 'high risk' foot. Otherwise at least annually.
  [(NZGG Diabetes) Preventing active foot problems and lower limb amputation]

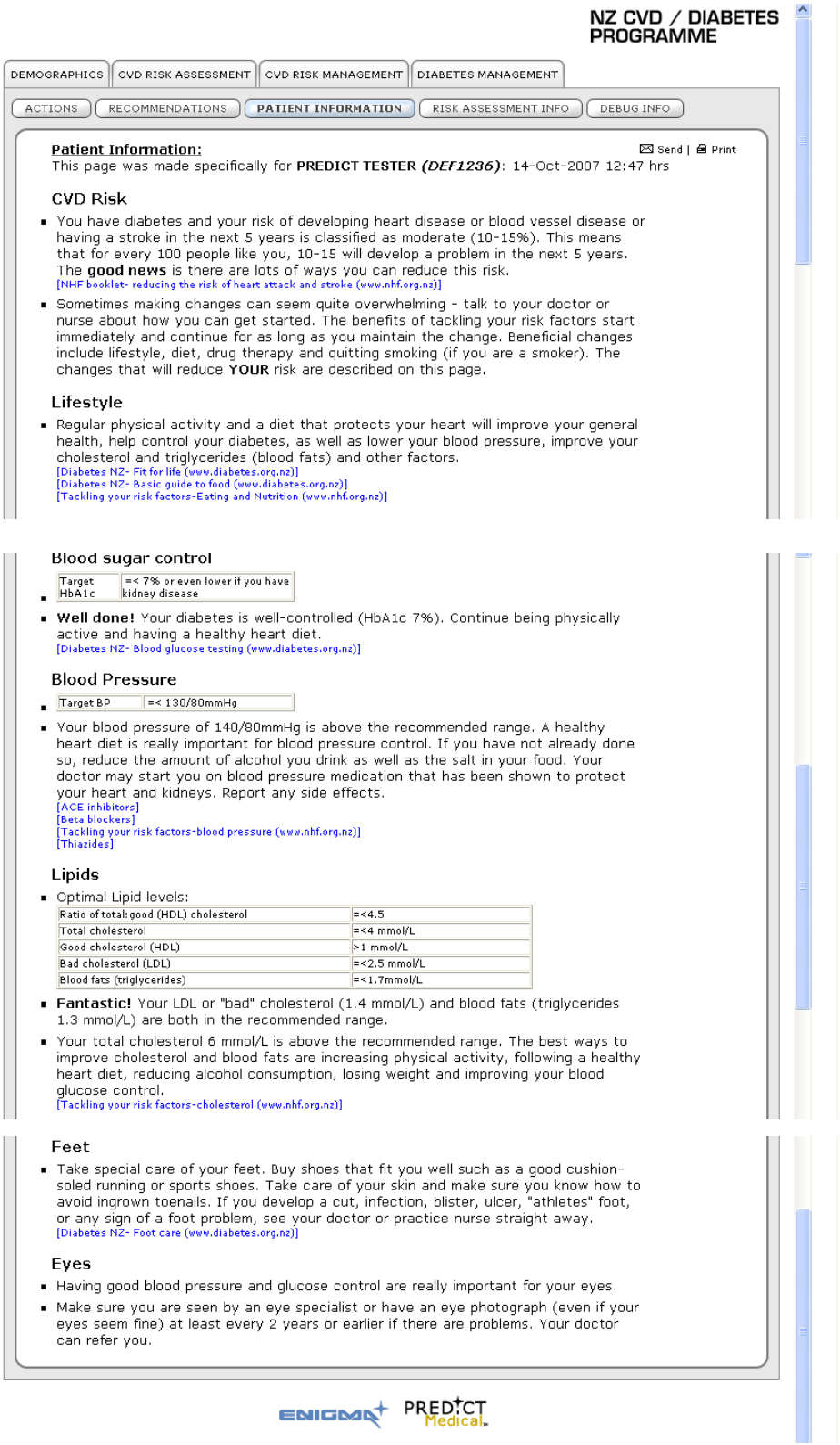
Eyes

- Ensure retinal review at least every 2 years or earlier if at high risk of retinopathy. Everyone with any degree of retinopathy should be under the supervision of an ophthalmologist.
  [(NZGG Diabetes) Identifying and preventing visual impairment and blindness]
  [Risk factors for retinopathy]

Other

- Depression is 2-3 times more common in people with diabetes than the general population. All people with diabetes should be screened for depression (Grade B). SSRIs are recommended in preference to tricyclic antidepressants (Grade B).
- Annual influenza vaccine is recommended for all people with diabetes (unless contraindicated).

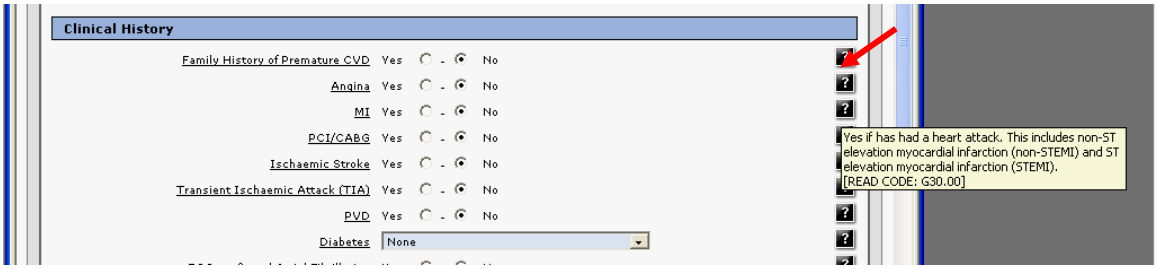
Example: PREDICT CVD-Diabetes decision support output: Patient Information



Appendix 5.4 Description CVD risk Assessment and management variables and functionality of the templates

This appendix describes how the key CVD risk related variables were measured. Where possible, the variables were the same for both PREDICT-CVD and PREDICT CVD-Diabetes. Differences in definition and data handling where they occurred are described below. Mandatory fields were underlined. Definitions for each variable were available to the user on the input template and would automatically appear by hovering the mouse over the variable (PREDICT-CVD) or the question mark (?) in PREDICT CVD-Diabetes as in the screen shot below.

Screen shot of PREDICT CVD-Diabetes showing MI definition appearing after hovering mouse over "?" icon



Data source and template usage

The PREDICT team receive data that identifies the PHO source, the unique provider New Zealand Medical Council (NZMC) or New Zealand Nursing Council (NZNC) number of the clinician completing the template and whether the submitted data come from the CVD risk assessment template, the CVD risk management template or the diabetes management template.

Demographic data

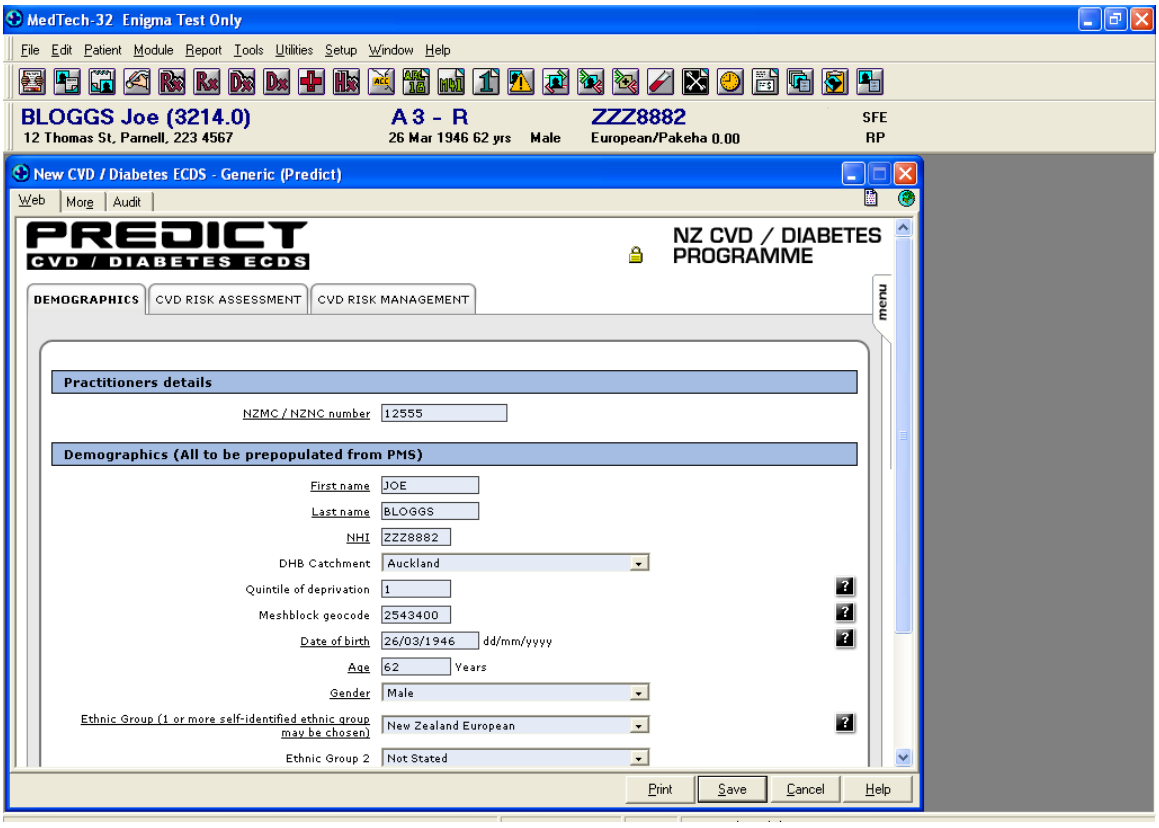
Demographic data collected include age, gender, ethnicity, and an encrypted National Health Index (NHI) number. On linkage to the NZHIS NHI dataset, each participant's domicile code is available that can be linked to the New Zealand Deprivation 2001 (NZ Dep) index. This measure of socioeconomic status is reported as decile of deprivation from 1 (least deprived) to 10 (most deprived). The NZ Dep is a small area index of

deprivation that provides a score for each census meshblock in New Zealand based on nine variables (material and social domains of deprivation) from the 2001 Census.[1]

Template data collection of demographic variables

For PREDICT-CVD, all relevant demographic data in the patient electronic medical record was automatically imported into the submitted data web-stream and did not appear on the input template. A specific demographics input template was introduced for PREDICT CVD-Diabetes that directly populated demographic fields from the patient electronic medical record but was able to be easily checked and overwritten if required by a clinician. The screenshot below shows a fictitious patient electronic medical record (MedTech PMS software) with the PREDICT CVD-Diabetes demographic form open. Joe Bloggs' demographic details can be seen on the PMS header and have been automatically imported into PREDICT on opening the form.

Screen shot showing first part of PREDICT CVD-Diabetes demographic template



The variables included were:

Age

Age in whole years was calculated from the date of birth and date of PREDICT submission by subtracting date of birth from the date of submission and dividing by 365.25.

Gender

This was the gender indicated in the patient electronic medical record (able to be checked and overwritten by a clinician in PREDICT CVD-Diabetes)

Ethnicity data and the New Zealand Guidelines

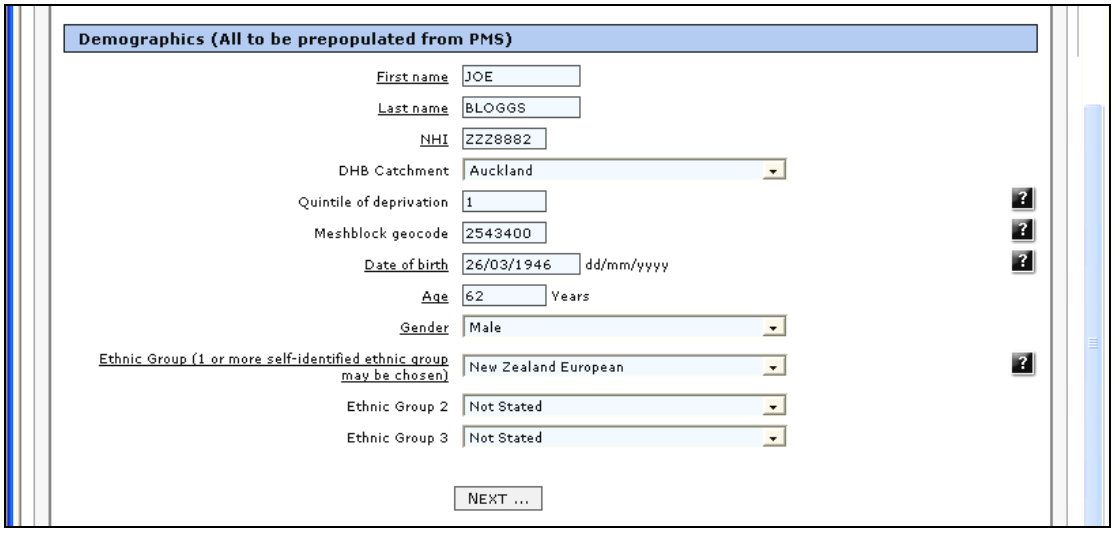
Accurate ethnicity data are required for NZ CVD risk assessment and management as the recommended age of CVD risk assessment is 10 years earlier for Māori, Pacific and people of South Asian ethnicity. Furthermore, people belonging to specific ethnic groups (Māori, Pacific and for 2003 CVD risk guidelines also South Asian) have an additional 5% CVD risk added to their calculated risk. There were no standards in general practice for the collection, coding and recording of ethnicity data prior to the release of the Ethnicity Data Protocols for the Health and Disability Sector in 2004.[2] Ethnicity data have therefore been recorded in multiple and often idiosyncratic ways in the patient electronic medical records.[3]

Ethnicity data in PREDICT

An overview of the Statistics New Zealand Ethnicity Classification relevant to the NZGG guidelines is provided in Appendix 5.2. Ethnicity data automatically imported by PREDICT-CVD are a mixture of Level 2 codes (see Appendix 5.2) and free text codes made up by individual clinicians. PREDICT CVD-Diabetes ethnicity data contains a mix of Level 2 and relevant Levels 3 and 4 codes, the result of having a specific demographics input template (see Figure below). All data imported from the PMS can be over-ridden by the clinician.Most PMS systems also allow up to three separate ethnicity groups to be recorded in each patient record although an audit of general practice records in 2005 found that the recording of a second or third ethnicity for an individual

patient was rare.[3] The Predict CVD-Diabetes input template also had the capacity for three self-identified ethnicities to be entered.

Screen shot of second part of PREDICT CVD-Diabetes demographic template



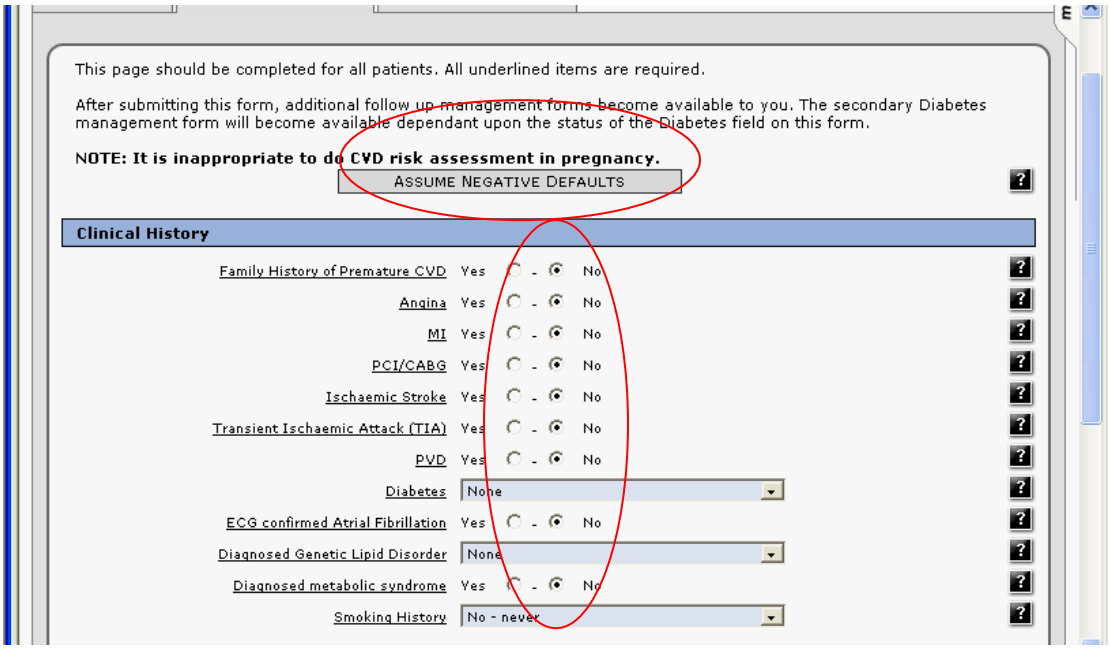
Each of these variables (self-identified ethnicity 1, self-identified ethnicity 2, self-identified ethnicity 3) contain a drop-down menu of all ethnicities meeting the NZGG criteria plus Level 2 codes for all others i.e. a mix of Level 2 and relevant Level 3 and 4 codes. However, by 2005, a PREDICT validation sub-study found that ethnicity data were available in 97% of ProCare patient electronic medical records[3] and with increasing compliance with standardised numerical coding due to PHO capitation funding, it is able to be directly imported. Where more than one ethnicity was recorded, prioritisation was given to a high risk ethnicity (Māori, Pacific or South Asian) for deriving a CVD risk estimate.

Patient history variables

If a history of a prior event was recorded by specified READ codes in the patient electronic management system, this was automatically entered into the PREDICT input template. Otherwise, each data field could be entered manually. In PREDICT CVD-Diabetes, a further option was provided to reduce respondent burden. If none of patient history fields had any data imported from the patient medical record, the user could

check the ASSUME NEGATIVE DEFAULTS button (see Figure below). All of the patient history fields would then be automatically entered as 'no or none'.

PREDICT CVD-Diabetes risk assessment template with ASSUME NEGATIVE DEFAULTS checked



Angina or myocardial infarction

These variables were automatically entered into the PREDICT template if the patient electronic medical record had documented the READ CODES: G33.00; G311.13 or G30.00. Otherwise, the practitioner was expected to enter 'Yes' if the patient has had a history of stable or unstable angina or a previous heart attack, including both non-ST elevation myocardial infarction (non-STEMI) and ST elevation myocardial infarction (STEMI).

Percutaneous coronary intervention or coronary artery bypass graft procedure

This variable was automatically entered if the READ CODE: 792.00 was in the patient record (i.e. a coronary artery bypass graft procedure (CABG) or a percutaneous coronary intervention (PCI) including coronary angioplasty and stenting).

Stroke or transient ischaemic attack (TIA)

This variable was specified to be entered into the PREDICT template for diagnosed or presumed ischaemic strokes with neurological signs and symptoms lasting more than 24 hours [READ CODE: G66.00] but not haemorrhagic stroke (including subarachnoid haemorrhage). A TIA was defined as signs and symptoms typical of a stroke but with full recovery in less than 24 hours [READ CODE: G65.12].

Peripheral vascular disease

This was defined as atherosclerotic peripheral vascular disease of any peripheral arteries (e.g. to legs and feet), including carotid and vertebral arteries [READ CODE: G73.00]. Diagnosis was based on:

- clinical signs and symptoms such as claudication
- diminished foot pulses and carotid bruits
- radiological evidence or prior surgical procedures.

Genetic Lipid Disorder

The definition of this variable differed significantly between PREDICT-CVD and PREDICT CVD-Diabetes as the earlier definition was considered to be too non-specific.

PREDICT-CVD definition for genetic lipid disorder	PREDICT CVD-Diabetes definition for genetic lipid disorder
Patient with a first degree relative who had suffered an ischaemic coronary event before the age of 60 plus having a personal history of TC or TC/HDL greater than or equal to 8.	Patient diagnosed as having; 1=Familial hypercholesterolaemia 2=Familial defective apoB 3=Familial combined dyslipidaemia 4=Other genetic lipid disorder

The initial definition of a genetic lipid disorder in PREDICT-CVD was a pragmatic working definition designed for GPs. It was attributable to government fiscal policy in the 1990s and early 2000, designed to ration the availability of statins.[4] Owing to the high cost of statins during this period, in order to qualify for government subsidised statin

treatment, a patient had to have either a prior history of CVD plus an abnormal lipid level or a genetic lipid disorder (typically associated with a positive family history and markedly elevated cholesterol). Hence, many people without a prior CVD event were classified in GP records as having a 'genetic lipid disorder' to qualify for statins. In 2002, Pharmac (New Zealand's drug purchasing agency) removed these special authority criteria for statin medication[4] and the 2003 CVD risk guidelines defined specific genetic lipid disorders as conditions that should be diagnosed and managed by a medical specialist in conjunction with family tracing for familial hypercholesterolaemia, familial defective ApoB, and familial combined dyslipidaemia. People with these specific disorders were classified as 'clinically at high risk' (i.e. ≥ 20% 5-year CVD risk). People with other genetic lipid disorders (low HDL syndromes, high lipoprotein A, isolated high triglycerides and broad beta disease) were expected to be risk assessed using the adjusted Framingham CVD prediction equation as it was assumed any increased risk would be accounted for in the risk score.

Family history of premature ischaemic CVD

This was defined as a family history of premature ischaemic heart disease or ischaemic stroke in a first degree relative (i.e. father or brother before 55 years of age, mother or sister before 65 years of age).

Diabetes

A patient was defined as having diabetes if they had either Type 1 diabetes [READ CODE: C108.00], Type 2 diabetes [READ CODE: C109.00], or type unknown [READ CODE: C10.00]. Feedback from general practitioners suggested there was some confusion about type of diabetes because of the historic clinical classification of IDDM (insulin dependent diabetes mellitus) and NIDDM (non-insulin dependent diabetes mellitus). Hence, extra wording was supplied for type 2 diabetes in the drop-down menu (as below). Gestational diabetes was defined as current gestational diabetes. As with pregnancy, any woman with current gestational diabetes was excluded from a formal risk assessment.

Type of Diabetes	0 = No diabetes 1 = Type 1 2 = Type 2 (incl type 2 on insulin) 3 = Type unknown 4 = Gestational

Diagnosed metabolic syndrome

This variable was first introduced in the 2003 CVD risk guidelines[5] so it was not present in the PREDICT-CVD dataset. It was defined according to ATP III NCEP diagnostic criteria for metabolic syndrome.[6] The definition required patients to have 3 or more of five risk factors: abdominal obesity (waist circumference ≥ 100cm in men, 90cm in women), triglycerides level ≥ 1.7mmol/L, HDL ≤1.0mmol/L in men and ≤1.3mmol/L in women, BP ≥ 130/85mmHg and elevated fasting glucose (≥ 6.1 mmol/L). PREDICT automatically prompted the practitioner to code this variable if the criteria had been met following entry of the individual parameters.

Smoking

PREDICT-CVD provided three options for smoking history; Yes, No, Past smoker (who had quit for at least 12 months). This was expanded for PREDICT CVD-Diabetes to include a crude measure of smoking dose.

Smoking History	0 = No – never (default) 1 = No – quit over 12 months ago 2 = No – quit within 12 months 3 = Yes – up to 10 / day [READ CODE: C1373.00] 4 = Yes – 11-19 / day [READ CODE: C1374.00] 5 = Yes – more than 20 / day [READ CODE: C1375.00]

Examination and blood test variables

Blood pressure

The average of two sitting blood pressures taken at least ten minutes apart was recommended by both the 2002 interim recommendations and the 2003 guidelines for the CVD risk assessment process. We observed some data entry errors with PREDICT-CVD, e.g. diastolic BP entered into the systolic field or the entire blood pressure entered into the systolic field. Therefore, the PREDICT CVD-Diabetes input template included automatic range checks and generated warnings for entries outside specified ranges.

Lipids

A fasting lipid profile was recommended by the 2003 CVD risk guidelines, including total cholesterol, LDL, HDL, TC/HDL and triglycerides, although only the TC/HDL ratio is used by the Framingham CVD risk equation.

Additional CVD risk assessment variables for a patient with diabetes

For the patient with diabetes, three additional variables were required as part of the 2003 CVD risk guidelines.[5]

Year of diagnosis of diabetes

Patients with type 2 diabetes diagnosed for ≥10 years or with an HbA1c consistently ≥ 8% qualified for an upward adjustment of 5% in 5 years, over and above the Framingham risk score. The year of PREDICT submission was subtracted from the year of diagnosis of diabetes to determine duration of type 2 diabetes.

Renal disease

There were four codable options available for diabetic renal disease. Confirmed microalbuminuria was defined as the presence, after excluding other causes, of an albumin:creatinine ratio (ACR) that is consistently ≥ 2.5 mg/mmol in men and ≥ 3.5 mg/mmol in women. An abnormal initial test required confirmation by at least one further test is required.

Renal disease	0=No nephropathy 1=Microalbuminuria 2=Overt diabetic nephropathy 3=Non-diabetic nephropathy

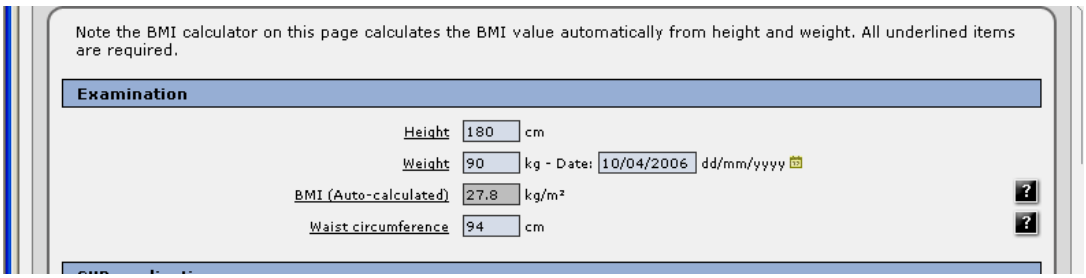
Overt diabetic nephropathy was defined as an ACR ≥ 30 mg/mmol. The 2003 CVD guidelines did not include a definition of non-diabetic nephropathy in a person with diabetes. Our subsequent consultation process resulted in an agreed working definition of an estimated glomerular filtration rate (GFR) less than 60 mls/min in the absence of overt diabetic nephropathy.

CVD risk management template variables

Anthropometric measurements

Anthropometric measurement included height, weight, BMI, and waist circumference. The most recent height in centimetres and weight in kilograms if present in the patient electronic medical record were automatically imported into the PREDICT templates and body mass index (BMI) in kg/m^2 was also automatically calculated. The waist circumference was defined as the circumference midway between the lower rib and the iliac crest to the nearest 1 cm. Guideline instructions for measurement were given as follows:-*To measure waist circumference, ask the person to hold the tape against their iliac crest and to turn around. The person should be relaxed. Measurement is done against the skin. The tape should be snug but not tight and parallel to the floor.*[5]

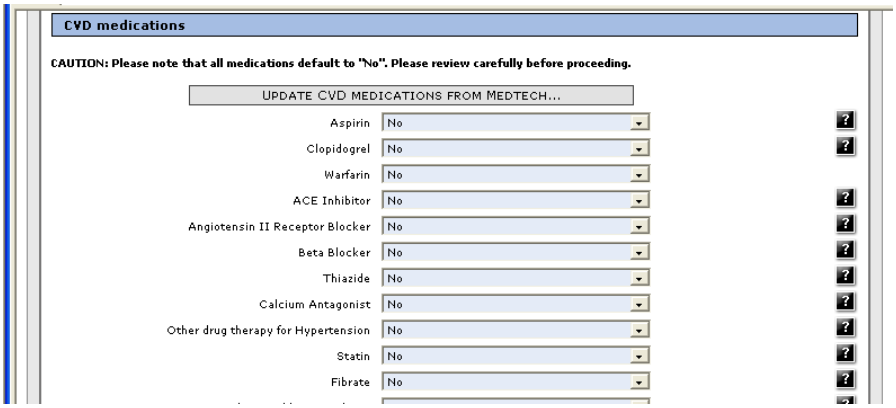
Screen shot of part of PREDICT CVD-Diabetes CVD risk management template showing anthropometric variables



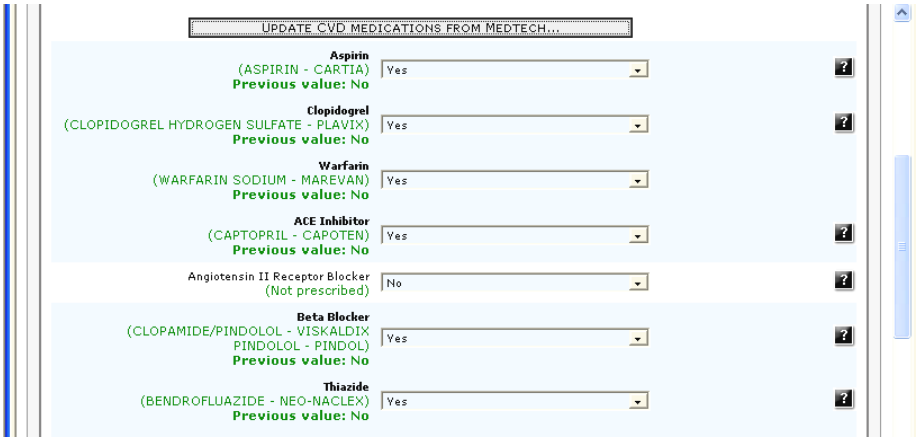
Current CVD drug management

Twelve groups of cardiovascular medications (see Figure below) are specified with options ‘yes, no or contra-indicated/not tolerated’. These also defaulted to ‘no’ to reduce the number of keystrokes required (as requested by GPs). While doctors were used to drug classes (e.g. ACE inhibitor) and individual drug names (generic and branded), nurses found this part of the management template difficult and time consuming. An enhancement to PREDICT CVD-Diabetes was UPDATE CVD MEDICATIONS FROM MEDTECH. When a user clicked this button, the long-term medication list in the patient management system (MedTech) was sent to the PREDICT server and the list compared with all known options of the relevant cardiovascular medications. These data were then sent back to the template, directly populating the appropriate drug field with an additional note stating the actual drug, if any, beside the field (Figure 5.10).

CVD medication fields in PREDICT CVD-Diabetes



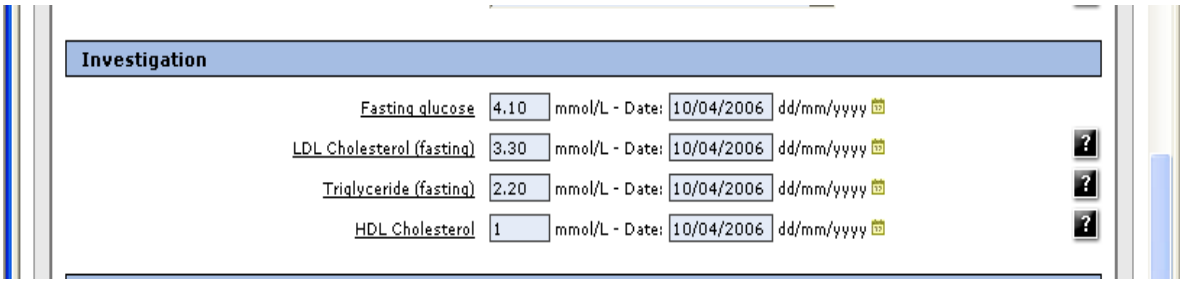
Medication fields updated from long-term medication list



Other blood tests necessary for CVD risk management

A fasting glucose, fasting LDL-cholesterol, fasting triglyceride and separate HDL-cholesterol test were required for informing management recommendations. The PREDICT CVD-Diabetes input template was able to check the recorded variables using the Friedewald equation[7] (where LDL [mmol/L] = total cholesterol – HDL – Triglycerides/2.2) and alert the clinician if the data appeared to be in error. This automatic error check was added to PREDICT after a data quality analysis demonstrated that, in some practices, the automatic download of some data to the PREDICT template had been configured incorrectly in MedTech (with LDL mapping through to HDL and vice versa). This occurred when laboratories changed their codes for tests or through human error when setting up screening terms in the electronic medical record. If the triglyceride level was above 4.5 mmol/L then the Friedewald formula is inaccurate and the laboratory will not report the LDL fraction. In this case, clinicians are asked to input "0". If the triglyceride level was over 13.7 mmol/L, an HDL-cholesterol fraction cannot be derived. In this situation, a TC/HDL ratio is not reported and a CVD risk assessment cannot be performed using the Framingham equation. Additional fasting lipid blood tests are advised, and if still elevated, referral to specialist services is recommended.

Screen shot of PREDICT CVD-Diabetes with laboratory tests automatically imported from PMS



Dates of examination, test or referral

The dates of each blood test, examination or referral were also automatically imported from the patient electronic record in PREDICT CVD-Diabetes but not in the earlier PREDICT-CVD version. In PREDICT-CVD, a risk assessment or management submission could not be made if certain variables were defined as being out of date. This was seen by GPs as a "missed opportunity", so this out-of-date variable restriction

was removed. Furthermore, having a fixed valid time-limit for a variable was inappropriate for many patients. For example, depending on the calculated CVD risk, risk factor profile and current management, the recommendations concerning the frequency of further lipid blood tests may vary from 6–12 weeks to 5-yearly. By including the date of the test on the template, a practitioner could take this into account when advising the patient. The PREDICT decision support recommendations still notified the practitioner that the variable was not current and recommended a follow-up test.

Diabetes Management template

Full details are not provided here for this thesis given the focus on CVD risk assessment and management.

References

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4. Begg E, Sidwell A, Gardiner S, Nicholls G, Scott R. The sorry saga of the statins in New Zealand--pharmacopolitics versus patient care. *New Zealand Medical Journal* 2003;116(1170):U360.

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7. Friedewald WT, Levy RI, Fredrickson DS. Estimation of the concentration of low-density lipoprotein cholesterol in plasma, without use of the preparative ultracentrifuge. *Clinical Chemistry* 1972;18(6):499-502.

Appendix 5.5. Valid data entry ranges

Data entry ranges for PREDICT CVD-Diabetes[1]

Data field		Current CVD-Diabetes limits		DML or other epidemiologic data		Suggested new limits +/- 10%	
	unit	min	max	min	max	min	max
Lipids							
Total cholesterol	mmol/L	0.10	50.0	1.68	32.3	1.51	35.5
HDL	mmol/L	0.10	10.0	0.15	4.69	0.13	5.1
TC/HDL	mmol/L	0.10	50.0	1.20	27.4	1.08	30.1
LDL (1)	mmol/L	0.00	50.0	-2.28	10.49	0.30	11.5
Fasting triglycerides (2)	mmol/L	0.10	20.0	0.18	67.1	0.10	95.0
Non-fasting triglycerides	mmol/L			0.12	92.4		
Renal measures							
serum creatinine	mmol/L	0.01	2.0	0.02	2.017	0.01	2.21
Albumin-creatinine ratio	mg/mmol	0.0	10000	0	1509.9	0.0	1660.0
Glycaemic measures							
random glucose	mmol/L			1.2	49.7		
fasting glucose (2)	mmol/L	no limits set		1.6	34.4	1.1	54.6
HbA1c	%	0.1	30	3.0	18.7	2.7	20.5
Anthropometric measures							
Height	cm	100	300	100	220	90	242
Weight	kg	20	500	30	232	27	255
Waist circumference	cm	30	250	47	161	42	177
Blood Pressure							
Systolic blood pressure	mmHg	25	300	60.0	282.0	54	310
Diastolic blood pressure	mmHg	25	200	29.0	182.0	26	200

Notes

1) LDL calculated according to Friedwald formula. If Triglycerides are greater than 4.5mmol/L, estimates of LDL are unreliable and are not reported by laboratories. If not reported, a "0" value is accepted into this field, otherwise limits are 0.3-12.0.

2) Fasting triglycerides and fasting glucose validation ranges are greater than 10% taking into account non-fasting maximum and minimum

1. Wells S, Broad J. Rationale for CVD-Diabetes validation ranges. Report to the Electronic Clinical Decision Support Steering Group on behalf of HRC grant 03/183 Primary care management of CVD risk: validating risk prediction and assessing risk burden. Auckland: University of Auckland, 2005:Unpublished report.

Appendix 5.6. PREDICT data security- submission, access and storage

The CVD risk factor and management data submitted from the templates is sent to PREDICT servers via a secure broadband (HTTPS/SSL) internet connection, the same level of security used for internet banking. This involves AES128–bit encryption which cannot be intercepted between the desktop and server. HTTPS stands for Hyper Text Transfer Protocol (Secure) and SSL for Secure Sockets Layer which describes the transport layer level of security. AES stands for Advanced Encryption Standard which is also known as Rijndael. AES is a block cipher, available as 128- 192- or 256-bit, and has been adopted as an encryption standard by the United States government. AES 192- and 256-bit encryption is used for U.S. classified top secret information.[1]

The data is securely stored on remote servers, their location depending on the agreement of the PHOs and other organisations in which PREDICT is used. The storage is managed by Enigma Publishing Ltd on behalf of PHOs and has several layers of security; at user login, database level, data level, network level and physical security level as outlined below.[1]

User login security

A requirement requested by the users of the tool was that identifiable patient CVD exposure data submitted to the PREDICT server would always be available by authenticated access at a practice or clinic level to their contributing doctors and nurses. This meant that they could follow an individual patient's history over a series of consultations or audit all their patients who had been risk assessed using PREDICT. Similarly PHOs required a view of risk assessment and management for all patients by clinic within their PHO. To cater for this functionality, Enigma has required user level login security credentials to be given by each user prior to accessing any aspect of PREDICT. This User Account ties the person accessing the system to an organisational unit (e.g. clinic or PHO) that sets access rights to data and user functions accordingly. For the clinic or individual practitioner this can be automated after the first authentic log-

in with the “remember me” function. All user account credentials are stored using AES256bit encryption.

Database server security

Each database / product is separately secured using a distinct and complex password. This helps to prevent any potential compromise spreading to unrelated databases or products. The database server exists on its’ own subnet within the hosting environment and is protected from the outside world and the web hosting segment of the network by a firewall.

Data level security

The identifiable data contained within the databases is encrypted before it is written to the database. Should any compromise occur where an unauthorised party was able to access the data directly, the contents of the database would remain unreadable to them having been transformed by AES256bit encryption.[5]

Network security

The hosting network is protected from network based attacks at a number of layers. There is a firewall that prevents unauthorised parties from attempting to connect to the network and intrusion detection is implemented within the hosting environment. The network has been designed and segmented in a way which helps to protect from any potential attacks. Remote access to the network is firmly restricted.

Physical security

The hosting network is locked in a steel cabinet within a data centre which is alarmed and monitored 24 hours/day.

Reference

Wiltshire C. CIO Enigma Publishing Ltd. Auckland, 2008: Personal Communication

Appendix 6. PREDICT-CVD (Prompt) Evaluation Study audit form

PROMPT Evaluation Study - Data Collection Form MedTech Internal ID #: _____

Date Audit Performed: / / Audit Nurse ID: _____ ProCare Practice #: _____ GP NZMC#: _____

Record information from medical record up to 2 years prior to Audit End Date: / / Pre Audit ☐ Post Audit ☐

DOB: / /	Gender: Male Female	CSC Card: Yes No HUHC Card: Yes No
Ethnicity 1: Maori Pacific Asian Indian NZ/European/Pakeha Other:	Ethnicity 2: Maori Pacific Asian Indian NZ/European/Pakeha Other:	Ethnicity 3: Maori Pacific Asian Indian NZ/European/Pakeha Other:

'CVD Risk Recorded': (may be any method) Yes No

CV Risk as %:_____
OR CV Risk as % Group: <5% 5-10% 10-15% 15-20% >20%
OR CV Risk as Description: Mild Mod High Very High
OR Other (record as written):_____

Where is CV Risk recorded?(circle): INBOX SCREENING DAILY RECORD OTHER: _____

Date Recorded: / / "CVD1 " in SCREENING: Yes No

Smoking Status: Current Smoker Non- Smoker Past Smoker (>12 months smokefree) NR .

Where is Smoking Status recorded(circle)?: CLASSIFICATION HISTORY DAILY RECORD OTHER: _____

Diabetes Status recorded (all types except Gestational): Yes No | No diabetes Type 1 Type 2 IGT Type unknown .

Diabetes Status recorded (circle)?: CLASSIFICATION HISTORY SCREENING DAILY RECORD OTHER: _____

If Diabetes is NOT recorded, does this patient have any of the following:

GTT Result indicating Diabetes or IGT in the past 2 years	Yes	NR
Prescription for oral hypoglycaemic/insulin/test strip	Yes	NR
HbA1C greater than 6%	Yes	NR

Blood Pressure: / Date Recorded: / /

Blood Pressure recorded (circle)?: SCREENING CLASSIFICATION DAILY RECORD OTHER: _____

Lipids: TC/HDL Ratio: or if no ratio then TC: Date Tested: / /

Where are Lipids recorded?: INBOX DAILY RECORD OTHER: _____

Does this patient have a history of ANY of the following? Circle the first item identified:

IHD, MI, Angina CABG/Angioplasty CVA/TIA (excluding haemorrhagic stroke) Claudication/PVD	Where recorded (circle) ? CLASSIFICATION HISTORY SCREENING OTHER: _____

If NO, does this patient have more than one prescription for one of the following? Circle the first item identified:

Anginine Nitrolingual Spray or GTN Spray Nitrates-Oral or transdermal patch	*Data Collection Form* *PROMPT Evaluation Study Ver11DPT - July 2004*	Data Entry - initials

Appendix 8.1. PREDICT Study practice waiting room poster and Patient information sheet

Ask about PREDICT

PREDICT is a computer program that helps your doctor or nurse assess and treat your risk of a heart attack or stroke

A heart risk check is especially recommended for:

- Those who have had a previous heart attack or stroke
- All men over 45 years and women over 55 years, or 10 years earlier if you are Māori, Pacific, or South Asian*
- Those with diabetes, high blood pressure, high cholesterol, or obesity
- Smokers
- Those with someone in their immediate family who has diabetes, heart attack or stroke before age 60

*South Asian includes = Indian, including Fijian Indian, Sri Lankan, Afghani, Bangladeshi, Nepalese, Pakistani, Tibetan peoples

This information will be used to help improve how we predict risk of heart attacks and strokes in the future.

Any information collected and transferred to the **PREDICT** database will be unidentifiable by anyone other than health professionals directly involved in your care.

For more information
ask for a **PREDICT** Patient Information Sheet.

THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND HEALTH SCIENCES

School of Population Health

THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND HEALTH SCIENCES

PREDICT Patient Information Sheet

PREDICT University Research Team
Telephone: +64 9 373 7599 extn 82463

Primary Care Management of Cardiovascular Disease Risk

What is PREDICT?

- Cardiovascular diseases such as heart attacks and strokes are serious but preventable illnesses.
- PREDICT is a computer programme that helps your doctor assess and treat your risk of heart attack and stroke.
- PREDICT is designed to be used for: all adults with existing cardiovascular disease or diabetes; men 45 years or older; women 55 years or older; or 10 years earlier if you are Maori, Pacific, or Indian.

How does PREDICT work?

- Your doctor will ask you some questions about your risk for heart attack or stroke, as well as take some measurements (such as blood pressure) and tests (such as blood cholesterol level).
- She/he will record this information onto the PREDICT programme and receive from it recommendations on how best to advise/treat you and any further tests that you may need to consider.

About the Research

- Participation in this research is entirely voluntary.
- The information collected by your doctor onto the PREDICT programme will be transferred to a database.
- All information collected and transferred to this database will be unidentifiable by researchers or anyone other than health practitioners directly involved in delivering care to you. It will not contain any of your personal details such as name, address or National Health Index number. We value the confidentiality of your health information and undertake to uphold your privacy rights.
- The information collected will be analysed by researchers at the University of Auckland. Their aim is to better understand heart disease and stroke in New Zealand.
- This research has received ethical approval from the Northern Regional Ethics Committee.

- ***Please feel free to contact the University Research Team if you have any questions. Ph 09 3737 599 ext 82463.***

Appendix 8.2 Rules of eNHI matching for PREDICT and NZHIS

Acceptance of matching was based on paired eNHI (PREDICT and NZHIS), a patient's date of birth (dd/mm/yyyy), gender and ethnicity. If all these parameters were the same in both PREDICT and NZHIS data they were deemed 'true matches'.

If not, the following rules were applied:

Rule 1. If there was a day-month flip between PREDICT and NHI date of birth but the year was the same or within 5years, then accepted as a match and NZHIS date of birth taken as the "true" date of birth. Example as below:

PREDICT DOB	NZHIS-DOB	DOB for CVD cohort
06/07/1930	07/06/1930	07/06/1930
01/12/1950	12/01/1951	12/01/1951

RULE 2: If day and month is the same for PREDICT and NZHIS date of birth but the year of birth is different by less than 5 years then accepted as a match and NZHIS date of birth taken as the "true" date of birth. Example:

PREDICT DOB	NZHIS-DOB	DOB for CVD cohort
26/04/1930	26/04/1931	26/04/1931

RULE 3: If month and year is the same for PREDICT and NZHIS date of birth but the day is different then accepted as a match and NZHIS date of birth taken as the "true" date of birth. Example:

PREDICT DOB	NZHIS-DOB	DOB for CVD cohort
30/07/1930	31/07/1930	31/07/1930

RULE 4: If day and year is the same for PREDICT and NHI date of birth but the month is different then accepted as a match and NZHIS date of birth taken as the "true" date of birth.

PREDICT DOB	NZHIS-DOB	DOB for CVD cohort
30/06/1930	30/07/1930	30/07/1930

RULE 5: If the month is the same for PREDICT and NHI date of birth but the day is different and the year out by less than 5 years, then the ethnicity and gender will also be inspected. If this matches then accepted and NZHIS date of birth taken as the “true” date of birth.

PREDICT DOB	NZHIS-DOB	DOB for CVD cohort
15/07/1932 and ethnicity and gender same	30/07/1930 and ethnicity and gender same	30/07/1930

RULE 6: If date of birth is the same for PREDICT and NZHIS, but gender and/or ethnicity don’t match, then the record will be looked at manually and a decision is made whether a match is present or not. For example, A person will be assumed is a true match if the ethnicity code at level 2 is the same, e.g. if NZHIS ethnicity is coded as 31 (Samoan) and PREDICT ethnicity is coded as 30 (Pacific Island not further defined), or if NHI ethnicity is coded as 99 (not stated) and PREDICT ethnicity is coded and vice versa.

All other non-matching eNHI was excluded from analyses.

Following NHI matching the data was then linked to NZHIS hospitalisation and death data.

Appendix 10 Published papers from PREDICT research and awards

The following are published papers from PREDICT research. Only those where the candidate has been first author have been separately appended.

PREDICT-CVD (Prompt) Evaluation Study

Wells S, Furness S, Rafter N, Horn E, Whittaker R, Stewart A, Moodabe K, Roseman R, Selak V, Bramley D, Jackson R. Quality improvement programme to increase CVD risk assessment and management in primary care. Euro J Cardiovasc Prev Rehabil 2008;15:173-78.

Other papers published from PREDICT-CVD (Prompt) evaluation study

Selak V, Wells, S, Whittaker R, Stewart A. Smoking status recording in GP electronic records: the unrealised potential. *Informatics in Primary Care* 2006;14:235-45.

Whittaker R, Bramley D, Wells S, Stewart A, Selak V, Furness S, Rafter N, Roseman R, Selak V, Jackson R. Will a web-based CVD risk assessment programme increase the assessment of CVD risk factors for Māori? NZMJ July 2006; 119:1-8

Rafter N, Wells S, Stewart A, Selak V, Whittaker R, Bramley D, Roseman R, Furness S, Jackson R. Gaps in primary care documentation of cardiovascular risk factors. NZMJ 2008; 121-1269/2930

PREDICT Provider Sub-Study

Wells S, Bycroft J, Lee A-W, Kenealy T, Riddell T, Roseman P, Moodabe K, Jackson R. Patterns of adoption and use of a web-based decision support system in primary care. Health Care and Informatics Review Online 2007 November.
http://hcro.enigma.co.nz/website/index.cfm

Other PREDICT publications

Wells S, Jackson R. On-line management of cardiovascular risk in New Zealand with PREDICT- Getting evidence to the “moment of care”. Health Care and Informatics Review Online 2005 March. http://www.enigma.co.nz/hcro/

Bannink L, Wells S, Broad J, Riddell T, Jackson R. Web-based assessment of cardiovascular disease risk in routine primary care practice in New Zealand: the first 18,000 patients. (PREDICT CVD-1). NZMJ November 2006;119:2313-21.

Riddell T, Bannink L, Wells S, Broad J and Jackson R. Assessing Maori – non Maori differences in CVD risk and risk management in routine primary care practice using web-based clinical decision support:(PREDICT CVD-2). *NZMJ* March 2007; 120;1250.

Marshall R, Zhang Z, Broad, J and Wells, S. Agreement between ethnicity measures in two different New Zealand health databases and the effects of ethnicity discordance on measures of health risk (PREDICT CVD-3). *ANZJ Public Health* 2007; *31(3):211-6.*

Riddell T, Kenealy T, Wells S, Jackson R, Broad J. Audit of health data captured routinely in primary healthcare for the clinical decision support system PREDICT (PREDICT CVD-4). *Health Care and Informatics Review Online* 2008 March. http://hcro.enigma.co.nz/website/index.cfm

Wells S, Kerr A, Broad J, Riddell T, Kenealy T, Jackson R. The impact of New Zealand CVD risk chart adjustments for family history and ethnicity on eligibility for treatment (PREDICT CVD-5). NZMJ September 2007;120/1261/2712

Broad J, Wells S, Marshall R, Jackson R. Zero end-digit preference in recorded blood pressure and its impact on classification of patients for drug treatment (PREDICT-CVD 6). *Br J GP* 2007; 57:897-903.

Kerr AJ, Broad J, Wells S, Riddell T, Jackson RT. Should the first priority in cardiovascular risk management be those with prior cardiovascular disease? *Heart* 2008:hrt.2007.140905.

Riddell T, Lindsay G, Kenealy T, Jackson R, Crengle S, Bramley D, Wells S and Marshall R. The accuracy of ethnicity data in primary care and its impact on cardiovascular risk assessment and management. PREDICT CVD-8. *New Zealand Medical Journal* 2008;121(1281):40-8.

Kerr AJ, Mclachlan A, Furness S, Broad J, Riddell T, Jackson RT and Wells S. The burden of modifiable cardiovascular risk factors in the coronary care unit by age, ethnicity and socioeconomic status. *New Zealand Medical Journal* 2008;121(1285):33-40

Prevalence estimates

Wells S, Broad J, Jackson, R. Estimated prevalence of cardiovascular disease and distribution of cardiovascular risk in New Zealanders: data for health care planners, funders and providers. NZMJ April 2006;119: 1-81.

Chan WC, Wright C, Riddell T, Wells S, Kerr A, Gala G, et al. Ethnic and socio-economic disparities in the prevalence of cardiovascular disease in New Zealand. *New Zealand Medical Journal* 2008;121(1285):3341.

Awards

2006 TUANZ Innovation of the Year Award

Telecommunications Users Association of New Zealand (TUANZ) is a not-for-profit organisation representing the end users of telecommunications. PREDICT CVD-Diabetes was awarded the TUANZ Supreme Winner-Innovation of the Year Award from a selection of 48 finalists recognising the innovative approach of PREDICT to improving the health of all New Zealanders.

2007 Best International Chronic Disease Management Programme

In 2007, ProCare Health's chronic disease management programme was awarded the 'Best International Chronic Disease Management Programme' at the Global Perspectives on Chronic Disease Prevention and Management Conference held in

Calgary, Canada. Paul Roseman, ProCare's Design and Development Manager, attended the conference to present a paper on ProCare's Chronic Disease Management programme. "The scientific judging panel commended ProCare on the programme's completeness, its incorporation of technology (sic PREDICT CVD-Diabetes), the way we have integrated it into our communities and the engagement with health care providers." (From ProCare website)

Wolters Kluwer Health | Lippincott Williams & Wilkins

EUROPEAN SOCIETY OF CARDIOLOGY®

Original Scientific Paper

Integrated electronic decision support increases cardiovascular disease risk assessment four fold in routine primary care practice

Sue Wells[a], Sue Furness[a], Natasha Rafter[a], Elaine Horn[b], Robyn Whittaker[a], Alistair Stewart[a], Kate Moodabe[b], Paul Roseman[b], Vanessa Selak[a], Dale Bramley[a,c] and Rod Jackson[a]

[a]School of Population Health, University of Auckland, [b]ProCare Health Ltd and [c]Waitemata District Health Board, Auckland, New Zealand

Received 2 April 2007 **Accepted** 17 August 2007

Background **A decade of cardiovascular disease (CVD) risk-based guidelines, education programmes and widespread availability of paper-based risk prediction charts have not significantly influenced targeting of CVD risk management in New Zealand primary care practice. A web-based decision support system (PREDICT-CVD), integrated with primary care electronic medical record software was developed as one strategy to address this problem.**

Methods **A before–after audit of 3564 electronic patient records assessed the impact of electronic decision support on documentation of CVD risk and CVD risk factors. Participants were patients meeting national guideline criteria for CVD risk assessment, registered with 84/107 (78.5%) general practitioners (GPs) in one large primary care organization who used electronic patient medical records, and had PREDICT-CVD installed. The GPs received group education sessions, practice IT support and a small risk assessment payment. Four weeks of practice visit records were audited from 1 month after installation of PREDICT-CVD, and during the same 4-week period 12 months earlier.**

Results **Less than 3% of eligible patients had a documented CVD risk before PREDICT-CVD installation. This increased four-fold (RR = 4.0; 95% confidence interval 2.4–6.5) after installation and documentation of all relevant CVD risk factors also increased significantly.**

Conclusion **Documentation of CVD risk in primary care patient records in New Zealand is negligible, despite being recommended as a prerequisite for targeted treatment for over 10 years, suggesting that previous strategies were ineffective. We demonstrate that integrated electronic decision support can quadruple CVD risk assessment in just one cycle of patient visits.** ***Eur J Cardiovasc Prev Rehabil*** **15:173–178 © 2008 The European Society of Cardiology**

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Keywords: cardiovascular disease, clinical, decision support systems, documentation, primary prevention, risk assessment

Introduction

Since the early 1990s, New Zealand CVD management guidelines [1–6] have based treatment recommendations primarily on a patient's absolute risk of a CVD event rather than individual risk factor thresholds. Good evidence exists that the higher a patient's absolute cardiovascular risk, the greater the treatment benefit [7], and a combination of cheap CVD risk lowering drugs can reduce future CVD events by more than half [8]. The New Zealand approach has recently been endorsed by a Canadian study as more efficient than other national and international guidelines [9], and the same authors

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1741-8267

demonstrated that the targeted New Zealand CVD programme could have a major impact on a population's CVD mortality [10].

To support CVD risk assessment in New Zealand, a range of education programmes have been provided and a paper-based CVD risk prediction chart has been widely distributed to GPs since the mid-1990s. A national survey in 1999, however, showed that while most GPs used the risk charts, 70% reported using them only once a month or less [11]. Given that CVD risk management is one of the most common reasons for GP visits in New Zealand [12], and that clinicians are unable to accurately predict cardiovascular risk in their heads [13], the charts should be used considerably more frequently. Moreover, an audit of over 25 000 patients visiting their GPs in 2000 showed little evidence of targeted CVD risk management [14].

Informed by evidence that moment of care electronic decision support can improve practitioner performance [15–18], we developed PREDICT-CVD, a web-based clinical decision support module [19] that is integrated with electronic medical record systems. We report on the first PREDICT evaluation, a retrospective before–after audit of its impact on the documentation of CVD risk and individual CVD risk factors.

Methods

The PREDICT-CVD system

In a joint venture between the PREDICT developers and ProCare Health Limited (a large primary care organization supporting over 350 GPs in Auckland, New Zealand), PREDICT-CVD was offered to all ProCare GPs in 2002. This web-based programme was integrated with primary care patient management software for electronic medical records. PREDICT-CVD automatically extracts CVD risk data from the electronic record, generates a quantitative 5-year CVD risk and provides evidence-based patient-specific decision support according to current New Zealand cardiovascular guidelines. The roll-out of PREDICT-CVD was supported by opinion leader presentations to GPs and a payment of NZ$10 (€5.4) per risk assessment, up to a maximum payment of NZ$900 (€482). As few GPs had broadband internet connections before PREDICT installation (needed for optimal performance of PREDICT), this payment would cover the cost of installation of secure broadband web access and 3 months rental charges. Each practice also received the services of an IT facilitator, who at no cost to the practice, installed the software, ensured safe connectivity to the internet, provided personalized training for the primary care team, and was available for on-going support.

Eligibility criteria

Eligible GPs were those who (i) had compatible practice management software and had used electronic medical records for all their patients for at least 1 year; (ii) had PREDICT-CVD integrated with their medical record software between August 2002 and May 2004 and (iii) had patient registration or billing systems where patients were registered according to a particular GP.

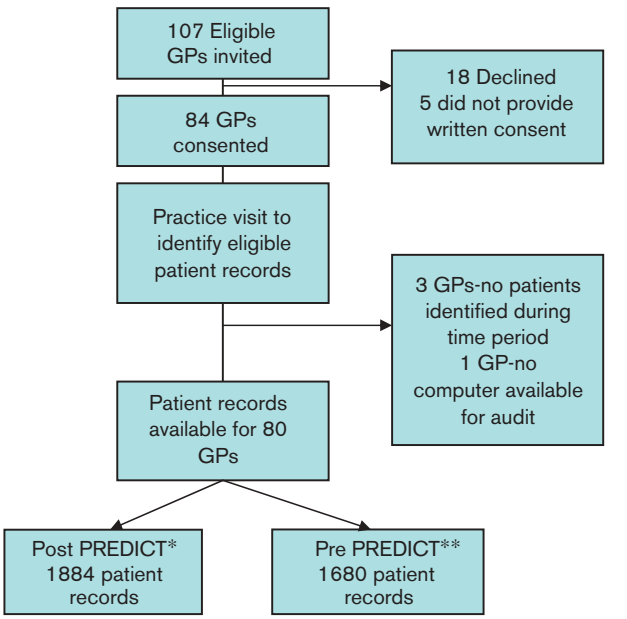
Audit procedures (see Fig. 1)

All eligible GPs received invitation letters and follow-up telephone calls. After receiving written consent, researchers conducted electronic queries of records to create lists of eligible patients. Participants were patients meeting national guideline age, sex and ethnicity criteria for CVD risk assessment [4] who had visited their GP within a 4-week period, starting 1 month after the practitioner had first used PREDICT-CVD (i.e. post-PREDICT) and a similar cohort visiting the same GP within the same 4-week period, 1 year earlier (pre-PREDICT). For example, if PREDICT-CVD was first used on 1 July 2003, the time periods examined were the first 4 weeks of August 2003 (post-PREDICT) and the first 4 weeks of August 2002 (pre-PREDICT). Audit periods ranged in time from August 2001 to June 2004 with many pre-PREDICT and post-PREDICT audits occurring in concurrent time periods for different practices owing to the staged implementation of the programme.

Sample size estimates

We estimated *a priori* that on average 30 patients per GP per time period were required from 50 GP's to detect a

Fig. 1



Flow chart of PREDICT-CVD Audit. *Post-PREDICT records – patients meeting guideline criteria who were seen over a 1-month period, 4 weeks after the installation of PREDICT software. **Pre-PREDICT records – patients meeting guideline criteria who were seen over a 1-month period, 12 months before post-PREDICT time period.

three-fold increase in the proportion of eligible patients with documented CVD risk. On the basis of observed design effect of four and a between GP correlation of 0.5, the observed sample size, however, was able to detect a relative risk of two (from an initial prevalence of 3%) with a power of 80% at the 5% level of significance. To obtain adequate explanatory power for Mâori and non-Mâori (note: New Zealand researchers are encouraged to undertake studies with equal explanatory power for our indigenous population), we planned to audit 100% of the medical records of eligible Mâori patients and a randomly selected 15% sample of non-Mâori patients.

Data collection

Trained independent audit nurses visited the practices and conducted audits of the relevant electronic medical records. An anonymized paper audit form was completed for each patient. The data from audit forms were then entered into a Microsoft Access database.

Key audit variables

The audit nurses noted any description of CVD risk in the electronic record, such as a percentage, a risk range (e.g. 5–10%) or a risk description appearing in context such as 'high (sic CVD) risk'. Similarly, they noted if information on smoking status (smoker, nonsmoker, past smoker), blood pressure and cholesterol (total cholesterol : high-density lipoprotein ratio or total cholesterol) was documented. Diabetes status was considered documented if one of the following criteria was found in the record: (i) diagnosed diabetes; (ii) impaired glucose tolerance; or (iii) a statement that the patient does not have diabetes. Diagnosed diabetes was defined as: a statement that the patient has diabetes; recorded prescriptions for oral hypoglycaemic agents, insulin or test strips; or an HbA1c greater than 6%. A documented previous history of 'ischaemic' cardiovascular disease was defined as any statement of previous ischaemic heart disease (myocardial infarction, angina, any coronary revascularization procedure or more than one prescription for nitrates), stroke (excluding haemorrhagic stroke), transient ischaemic attack or peripheral vascular disease.

Main outcome measures

The proportion of patients with a documented CVD risk was the primary outcome measure. The completeness of CVD risk factor documentation before and after installation of PREDICT-CVD was the secondary outcome measure.

Analyses

For the study outcomes, proportions in the total population were estimated from Mâori and non-Mâori sampling populations, weighted according to the sampling fraction. Relative risks and 95% confidence intervals were calculated using a multivariate mixed Poisson regression model with robust variance estimation, in which GPs were regarded as random effects, and all other variables regarded as fixed effects [20]. The model included variables for each practice and patient characteristics that may influence risk assessment behaviour including age, sex, ethnicity, presence of existing CVD disease, diabetes and holding a high use health card (enabling a government subsidy for those with medical conditions requiring frequent GP visits) or community service card (government subsidy for lower income families). All analyses were conducted using SAS Version 9.1 (SAS Institute Inc., Cary, North Carolina, USA).

Repeat audits

A sample of approximately 5% of all records was reaudited to assess interrater reliability of the data.

Ethical approval

The PREDICT-CVD evaluation study was approved by the Auckland Regional Ethics Committee (AKY/04/07/185).

Results

Of the 107 eligible GPs, 84 (78.5%) consented to participate, four were on leave and were unable to give written consent, one did not respond to invitation letter or telephone messages and 18 declined. Those who declined were more likely to work in small practices where there was either no free computer available and/or space to conduct the audit. Patient audit data from 80 practitioners (75%) were included in the analyses as two were on leave during both time periods of interest, the 15% non-Mâori sampling fraction generated no patients for one very part-time practitioner and one did not have a spare computer available to conduct the audit at any time during the study period. Compared with nonparticipators, practitioners who participated were similar in terms of age, sex, mean number of years since graduation and group practice membership. A total of 3564 audits were conducted; 1680 for the pre-PREDICT period (August 2001 to June 2003) and 1884 for the post-PREDICT period (August 2002 to June 2004).

With the exception of documentation of previous CVD ($\chi^2 = 6.74$: $P = 0.009$), there were no differences between the pre-PREDICT and post-PREDICT groups in terms of age, sex, ethnicity, diagnosed diabetes, holding a high use health card or community service card. Table 1 shows CVD risk and risk factor documentation pre-PREDICT and post-PREDICT installation according to the total audited population (weighted by sampling fraction). Pre-PREDICT, the CVD risk was documented in 2.8% of the total population, increasing approximately four fold after installation to 10.7% (multivariate RR = 4.0; 95% confidence interval 2.4–6.5). At baseline, 9.2% of patients had either a CVD risk documented or their medical record contained documentation on all risk factors required for risk assessment. This nearly doubled

Table 1 CVD risk and risk factors documented before and after PREDICT-CVD installation

	Pre-PREDICT %	Post-PREDICT %	Multivariate model RR (95% CI)
CVD risk documented	2.8	10.7	4.0 (2.4–6.4)
CVD risk documented or all risk factors present	9.2	18.0	1.9 (1.5–2.3)
Smoking status documented	38.9	48.6	1.2 (1.1–1.3)
Blood pressure documented	85.0	92.3	1.1 (1.0–1.2)
TC/HDL or total cholesterol documented	64.0	72.8	1.1 (1.1–1.2)
Diabetes status documented	14.4	19.7	1.3 (1.1–1.4)

Multivariate model included GP, practice and patient characteristics of age, sex, ethnicity, CSC, community service card; HUHC, high use health card, diabetes and CVD. CI, confidence interval; CVD, cardiovascular disease; GP, general practitioner; HDL, high-density lipoprotein.

post-PREDICT to 18%. After the installation of the programme, documented smoking status, blood pressure, lipid measurements and diabetes status increased by 10, 7, 8 and 5%, respectively, in absolute proportions. These effects remained statistically significant after adjustment for multiple factors.

Of the 80 GPs whose data were included in the analysis, 48 (60%) increased their CVD risk documentation post-PREDICT, 26 (32%) showed no change, three (4%) showed a reduction in risk documentation and three only provided audit data from one of the audit periods.

Quality of data collection and data entry

Repeat audits of the original sample were undertaken by a separate nurse on 147 patient files, from 18 GPs in nine practices. Key variables from the paired records that should have been consistently documented (date of birth, sex, primary ethnicity, community services card and high use health card) were compared. A discrepancy between the two audits of 1.4% for sex, 3.4% for card holding status and 7.5% for date of birth was observed. Only a 2.7% discrepancy for CVD risk was observed, the primary outcome examined. Type of diabetes, diabetes medications, raised HbA1c, history of CVD and total cholesterol/high-density lipoprotein ratio, showed a range of discrepancy from 1.4 to 8.8%. Documentation of smoking status was the most unreliable with a 17.7% discrepancy between the paired records.

Discussion

The appropriate documentation of CVD risk increased four fold following the installation of an integrated electronic decision support system for assessing and managing CVD risk. As the audit was conducted over only 4 weeks, just 1 month after the installation of PREDICT-CVD, the change observed is the result of only one cycle of visits for most patients. Further enhancements now being introduced, such as automatically prompting assessments in appropriate patients when their records are opened, should have even larger effects, although long-term sustainability was not assessed. The documentation of all the major CVD risk factors also increased and all PREDICT-generated risk factor documentation was standardized in a readily retrievable format, in contrast to the idiosyncratic, nonstandard way that most risk factors are recorded in clinical records. Well over half the GPs audited increased risk assessment documentation, suggesting that electronic decision support can be effectively integrated into the workflow of routine primary care practice.

We believe the findings are likely to be generalizable to most primary care practices with an electronic patient management system and provision of basic training and support. It was developed with a team of GPs who indicated how and in what way the software would work for them. As it is difficult to achieve changes in physician behaviour, particularly when CVD risk assessment is not routine (3% baseline), our estimates of impact are likely to be conservative.

This retrospective before–after audit ensured that participating GPs were unaware that they would be audited at the time data were documented in patient records. As each participating practitioner acted as his/her own control, the potential for confounding was also reduced and we matched the time period before and after (i.e. 12 months apart) to reduce any seasonal differences in patient visiting patterns. The validity of uncontrolled before–after studies can be weakened by secular trends in practice that would make it difficult to attribute observed changes to the intervention of interest [21]. During the period of the study, however, there were no important changes in either health policy or other financial incentives for GPs to conduct CVD risk assessments, and the audits were all conducted only 1 year apart. Furthermore, an independent audit of CVD risk assessment done at about the same time as the post-PREDICT audit in three large general practices reported a similar (4.7%) level of documentation as in the pre-PREDICT audit [22]. Although GPs who installed PREDICT-CVD received NZ$10 (€5.4) per risk assessment up to a maximum of NZ$900 (€482), this payment only partially offset set-up and on-going running costs of broadband web access. We believe the availability of personalized IT support at no charge was the key determinant of the observed change in practice. Nevertheless, our findings support a package involving electronic decision support and a small payment per assessment.

The complexity of data retrieval from unstructured clinical records is reflected in the discrepancies between original and repeat audits undertaken by experienced audit nurses. Although some discrepancies were due to

data entry errors, most of the variability was due to the limited use of systematic coding and the idiosyncratic free text recording of many variables. PREDICT-CVD encourages a standardized systematic approach to data recording in medical records as the practitioner receives almost immediate (within 5 s) patient-specific decision support if risk factors are keyed in appropriately.

Although computerized decision support programmes are not new, evaluations have demonstrated variable success, with low or suboptimal usage of tools by physicians thought to explain the lack of impact on processes of care or other outcomes [23–25]. What is unique about our study, is the much greater level of usage in routine busy primary care observed, providing an early indication of acceptability and fit with work processes. A recent meta-analysis of clinical decision support systems [26] identified four key features associated with improved practice. PREDICT-CVD incorporates all these features.

Although sustainability has yet to be determined, the programme has since been adopted by over 400 GPs and over 100 practice nurses. Over 30 000 unique standardized electronic CVD risk assessments have already been generated by PREDICT and linked to hospital admission and mortality records using a unique patient identifier, creating the largest cohort study ever conducted in New Zealand. Primary care data generated by PREDICT-CVD can now be used for evaluations of chronic disease management programmes, population needs assessment and service planning, as well as for developing new risk prediction tools for New Zealanders as a whole and for Mâori and other high risk population subgroups. Like other new risk stratification tools being developed [27] we will be able to investigate the additional predictive ability of incorporating other risk variables (e.g. socioeconomic deprivation, BMI, waist circumference, number of cigarettes smoked/day, HBA1c).

As well as demonstrating the effectiveness of electronic clinical decision support in increasing appropriate CVD risk assessment, this study involved the most comprehensive audit of CVD risk documentation in New Zealand primary care records. We were surprised at the extremely low level of CVD risk documentation, despite more than 10 years of nationwide efforts to promote CVD risk assessment and risk-based management. An electronic audit of GP records for patients visiting their doctor in 2000 has also shown that only about a quarter of those with previous CVD were on recommended drug treatment, and only about one in six of other patients who meet current drug treatment criteria (i.e. CVD risk $\geq 15\%$ in 5 years) were appropriately treated [14]. The audit reported here is a pragmatic first step in evaluating the impact of electronic decision support for assessing and managing CVD risk in primary care. We are now planning a randomized controlled trial to investigate the sustainability of the programme, and its impact on patient management and health-related outcomes.

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Patterns of adoption and use of a web-based decision support system in primary care (PREDICT CVD 7)

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    - 2.1.2 PREDICT usage data
  - 2.2 Main outcome measures

Abstract

Objective: To describe the patterns of adoption and use of PREDICT-CVD, a web-based decision support system for CVD risk assessment and management.

Setting: General practices affiliated with ProCare Health Ltd, a network of three Auckland-based Primary Health Organisations.

Population: Approximately 500 general practitioners (GPs) and 450 practice nurses looking after a total enrolled population of around 660,000.

Design: Cross-sectional survey linking ProCare clinical registry data augmented by professional medical and nursing councilsâ€™ data with PREDICT usage data from August 2002 to January 2007.

Results: Over this 53-month period, 45,437 risk assessments were conducted on 25,705 patients by 416 GPs and 117 nurses who had incrementally adopted PREDICT-CVD. GPs who graduated over 30 years ago and those without vocational registration were less likely to adopt the program, but uptake did not differ by gender or country of medical degree. On average, 485 patients were assessed per month with a marked reduction over the December-February holiday period. GPs conducted 92 percent of the risk assessments and there was a large variation in the frequency of use. Four distinct user groups were identified; 31 percent completed a risk assessment on less than 5 patients and were labelled as non-users, 23 percent were infrequent users (5-20 patients), 25 percent were frequent (20-89 patients) and 21 percent were the very frequent users (90 or more patients). Infrequent or non-users were more likely to be less than 10 years since graduation. There was no difference in frequency of use by gender or by country of medical degree. An incentive payment scheme made available for those who assessed at least 90 patients appeared to have had very little impact on usage patterns: 80 percent never reached the target and only 2.4 percent of total GP users completed 90 or more risk assessments in an "all then nothing" pattern.

Conclusions: There were four relatively distinct patterns of use that may inform interventions to improve uptake of electronic decision support systems. Differences were found in uptake and frequency of usage of PREDICT by vocational registration status and year of graduation but may be due to part-time practice. No differences were found by gender or country of medical degree. Adoption of the programme was responsive to promotional activities via GP cell groups but a financial incentive had very little impact on use. Determining why almost one-third of GPs who adopted PREDICT assessed fewer than 5 patients over the study period should be a priority for further evaluation.

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1. Introduction

Since the early 1990s, New Zealand guidelines have advocated CVD risk assessment as a means of identifying those at high risk of cardiovascular disease (CVD) and for targeting subsequent management. However, a national survey of GPs conducted in 1999 showed that while most GPs used CVD risk tools, 70 percent used them about once a month or less.[1] A web-based clinical decision support system, known as PREDICT-CVD was designed and developed collaboratively to facilitate CVD risk assessment and risk based

management whilst also integrating CVD risk prediction research within routine practice.[2] The collaboration included epidemiologists from The University of Auckland, Information Technology specialists from Enigma Publishing Ltd (a private provider of online health knowledge management) and clinicians and support staff from ProCare Health Limited, Counties Manukau District Health Board, New Zealand Guidelines Group, National Heart Foundation and the Ministry of Health.

PREDICT was implemented as an opportunistic CVD risk assessment and management programme under the name of "Prompt" in ProCare in August 2002. This web-based programme was only compatible with MedTech and subsequently Next Generation, primary care electronic medical record (EMR) software programs. These systems were used by the majority of general practices. PREDICT-CVD opens as a window within the EMR, automatically extracts CVD risk data from the EMR, generates a quantitative five-year CVD risk assessment and provides evidence-based patient-specific decision support according to current New Zealand cardiovascular guidelines. The target patient group was those adults (mainly over the age of 40 years) who met guideline criteria for risk assessment. At the same time, aggregated anonymised risk profile data is stored and with permission from providers can be used for epidemiological research purposes. The roll-out of PREDICT-CVD was supported by educational seminars to general practice continuing medical education groups. Adoption of the program was encouraged but entirely voluntary. GPs were also offered $900 including tax per GP as a one-off incentive payment once they had assessed 90 patients. As few GPs at the time had the high speed internet connection required for PREDICT, this money was provided to cover the cost of installation of secure high speed web access and the user charges for three months. GPs who had eligible patient management systems and who chose to adopt PREDICT-CVD were visited by practice facilitators who installed the software, ensured safe connectivity to the Internet and provided limited training to the primary care team. Whilst GPs were the target of the original implementation plan by the primary care organisation, practice nurses were also subsequently encouraged to be users.

The "acid" test for a decision support system is whether it is perceived to be useful enough to be adopted and, once adopted, whether the ease of use and fit with clinical work flow is enough to change clinical behaviour.[3] To achieve sustainable usage, the benefits to individual clinicians must outweigh the time and effort to use it. Heeks et al[4] note that although some heath care information systems succeed, the majority are likely to fail. The greater the personal and organisational change required by an information technology system, the greater the risk of failure. The system needs to fit with the userâ€™s values and change needs to be in small enough steps to be achievable by the majority.[4]

Evaluations of the use of computer systems have focused at multiple levels from the individual, group, organisation, industry or social sector[5] and have used research methodologies from various perspectives such as cognitive psychology and other social sciences, management, ergonomics, computer science and clinical epidemiology.[5-8] We conducted a three-part evaluation using mixed qualitative and quantitative methods of the barriers, challenges and attitudes to CVD risk assessment practice and to the use of PREDICT by a group of New Zealand primary health care doctors and nurses. This sub-study explores the adoption patterns, the characteristics of adopting clinicians and subsequent frequency of use of the PREDICT tool. In particular we wanted to investigate whether:

- Practitioner characteristics such as gender, vocational registration or years since graduation from medicine or nursing made any difference to adoption or subsequent usage; and
- the financial incentive influenced the usage of PREDICT CVD.

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2. Methods

2.1 Data Collection

2.1.1 ProCare PHO Clinical Registry

One co-author (JB), a ProCare GP working with members of ProCare Health management team (PR and KM), was given permission to access the Primary Health Care Organisation (PHO) registries and other administrative sources to create a dataset of practices, location, PHO (ie, ProCare Network Manukau, Auckland or North) and GPs and practice nurses working within each practice. Data were also available on whether practices were Interim, Access or Very Low Access funded. This represents the funding formulae for capitation payments received by a practice. These formulae are based on the proportion of an enrolled primary care population meeting Ministry of Health criteria for being "high needs" (Maori or Pacific ethnicity or living in NZ Deprivation deciles 9/10). These data were then augmented from New Zealand Medical and Nursing Councilsâ€™ registries regarding year of registration, country of training, vocational registration (for doctors) and year of registration (for nurses).

Following collation of the clinical registry, a new dataset stripped of personal and practice names and identifying clinicians only by their New Zealand Medical Council (NZMC) registration number or New Zealand Nursing Council (NZNC) registration number was generated and made available for analysis by the research team.

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2.1.2 PREDICT usage data

When a clinician uses PREDICT for CVD risk assessment and management of patients their professional registration number (NZMC or NZNC), time and date of usage is recorded on the PREDICT server along with anonymised patient risk profile data. This usage data was extracted from the PREDICT server with permission from ProCare Health Ltd and linked to the de-identified clinical registry data via NZMC or NZNC.

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2.2 Main outcome measures

- Differences between adopters and non-adopters of PREDICT.
- Uptake and usage patterns of PREDICT by doctors and nurses over time.
- Differences between infrequent compared to frequent users of PREDICT.
- Patterns of usage by the most frequent users.

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2.3 Data Analysis

Univariate analyses were conducted and differences in dichotomous outcomes assessed using the Chi Square statistic. All analyses were conducted using SAS statistical software Version 9.1 with usage distributions over time plotted using Excel spreadsheet functions.

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2.4 Ethical Approval

This study was approved by the Northern Y Regional Ethics Committee (NTY/07/01/004) in March 2007.

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3. Results

3.1 Description of adopters and non-adopters of PREDICT

An adopter is defined as a general practitioner (or nurse) who chose to acquire high speed web access, have PREDICT installed on his/her patient management system (MedTech or NextGen) and receive training in the use of the program. Three-quarters of those who chose not to adopt the program had compatible patient management systems. Table 1 compares clinician and practice characteristics for PREDICT adopters and those who did not have PREDICT implemented in their practice. For 23 GPs, the NZMC stored on the PREDICT system was unable to be matched to the New Zealand Medical Council Register, possibly due to

incorrect data entry within the patient management system. For GPs, differences were found for adoption of PREDICT by having vocational registration (?2 = 10.19, p-value 0.0014) and year of graduation (?2 = 14.13, p-value 0.0069) with younger GPs less than 20 years from graduation being more likely to adopt. No differences were found by gender or country of medical degree. About 20 percent of GPs that could be matched had incomplete data particularly with regard to practice characteristics (funding, size of practice, patient management system). Some of the reasons were: doctors changing practices within ProCare; practices becoming affiliated with another PHO; doctors retiring and practices being sold; or being a locum and not connected to one practice. Data was incomplete for more than a quarter of the nurses and differences in all nurse characteristics and practice variables (funding, location and size of practice, patient management system) for doctors were not assessed due to missing data.

Table 1. PREDICT adopters and non-adopters by GP or practice nurse

	General Practitioners (GP)		Practice Nurses	
	GP adopters (n=416)	GP non-adopters (n=289)	Nurse adopters (n=117)	Nurse non-adopters (n=318)
	%	%	%	%
Gender				
Male	54.8	55.7	0.9	0
Female	39.2	44.3	99.1	100
Unknown	6.0			
Yr since graduation (GP) or registration (nurse)				
Less than 10years	7.5	4.8*	6.8	14.2
10-19yrs	28.1	23.5	10.3	18.2
20-29yrs	40.1	45.0	10.3	20.1
30-39yrs	14.9	18.0	13.7	22.6
40+ years	2.9	8.3	1.7	9.4
Unknown	6.5	0.3	57.3	15.4
Country of medical degree				
New Zealand	60.8	58.1		
Overseas	33.4	41.9		
Unknown	5.8	0		
Vocationally registered or have FRNZCGP				
No	20.7	32.9*		
Yes	73.6	67.1		
Unknown	5.8	0		

*statistically significant differences

*statistically significant differences

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3.2 Adoption patterns of the decision support system by doctors and nurses

PREDICT-CVD was implemented from August 2002 in planned increments by geographic location (south, central, west and north Auckland). Whilst GPs were the target of the original implementation plan by the primary care organisation, it was subsequently also promoted to practice nurses. Nurse uptake lagged by 20 months and had a slower trajectory. The cumulative rate of PREDICT adoption by doctors and nurses is shown in Figure 1. Figure 2 plots the same data displayed as monthly rates of first time users, showing annual peaks in adoption following implementation evenings conducted via GP cell groups.

Figure1. Adoption of PREDICT by doctors and nurse; cumulative count of first-time users

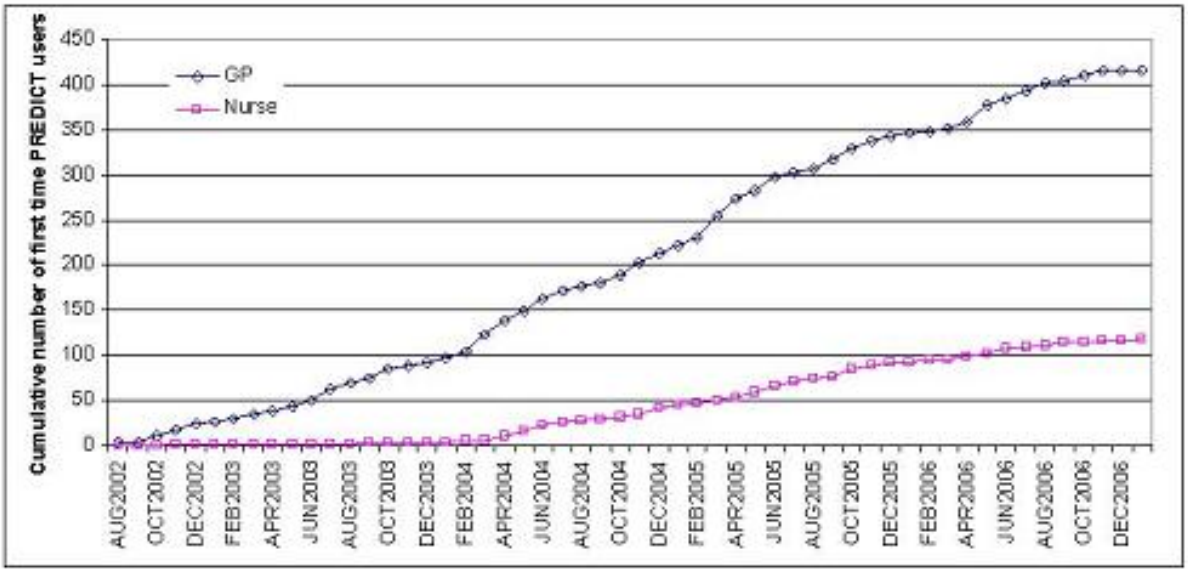
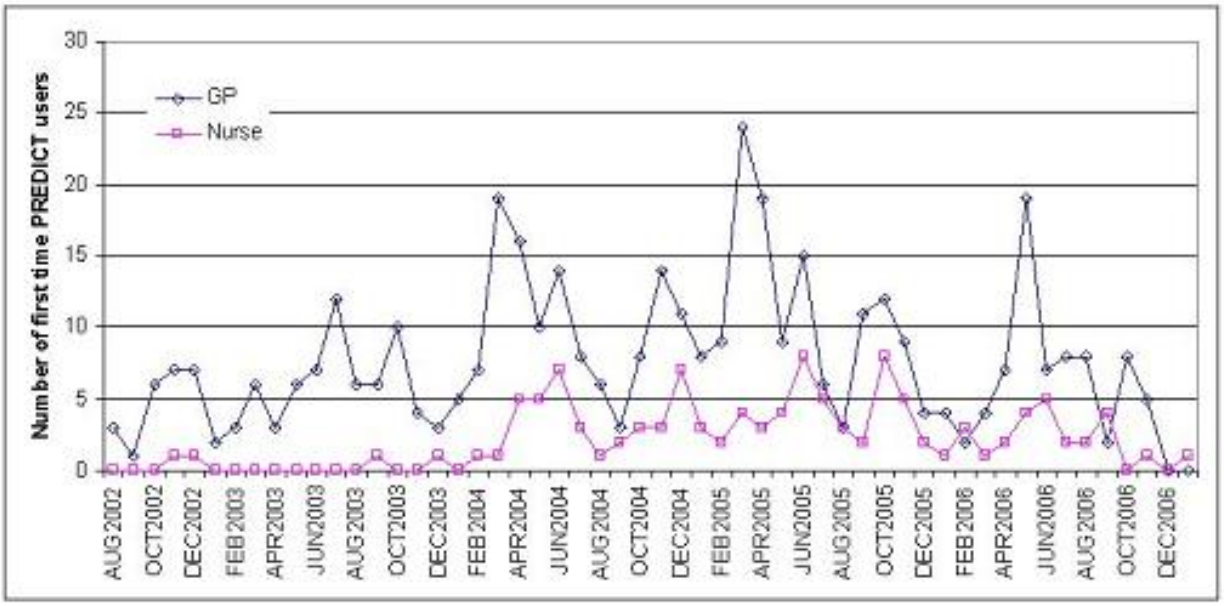


Figure 2. Adoption of PREDICT by doctors and nurses; monthly count of first-time users



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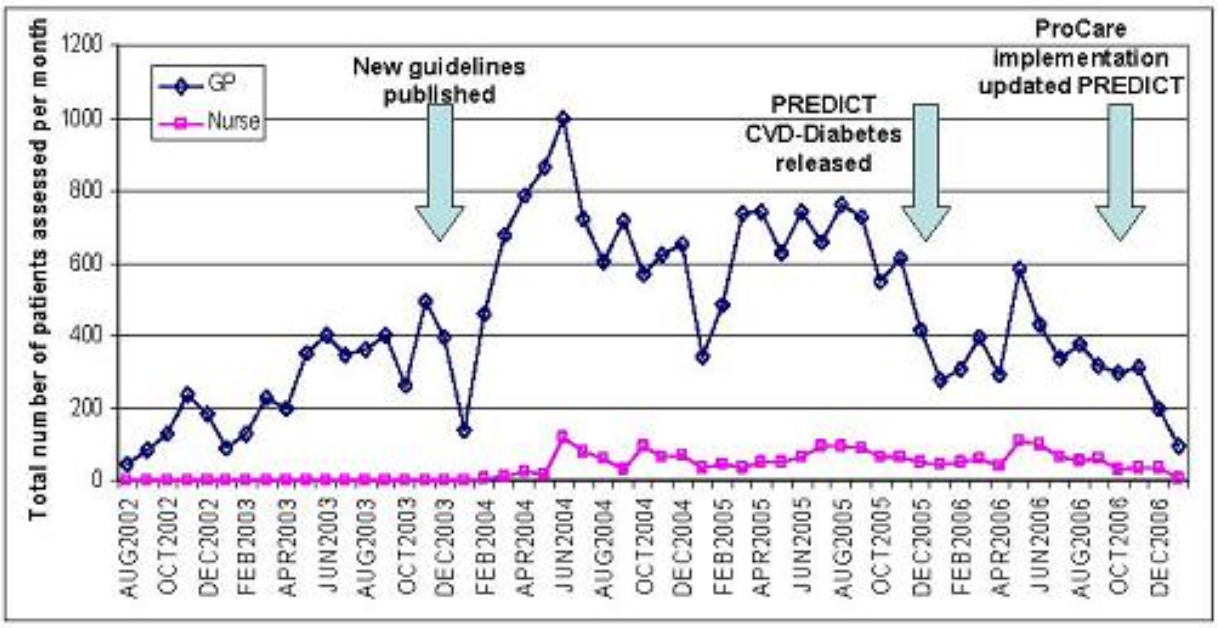
3.3 Patterns of use over time, all users

Between August 2002 and January 2007, 45,437 CVD risk assessments were conducted on 25,705 patients by 416 GPs and 117 nurses. The program was often used multiple times on individual patients within one consultation mainly for the purposes of demonstrating benefits of lifestyle changes (eg, stopping smoking) or drug treatment as well as used for subsequent follow-up of patients. Figure 3 shows assessment patterns over this time period. On average 485 patients were assessed per month (ranging from 43 in the first month to a peak of 1120 in June 2004). Usage declined from this point dropping to 2002 levels by the end of 2006. A key secular change that occurred during this time was the December 2003 publication and subsequent implementation of national guidelines for The Assessment and Management of CVD risk9 and The Management of Type 2 diabetes.[10] Subsequently, a new PREDICT module, PREDICT CVD-Diabetes was developed and released for licence in December 2005. ProCare Health started implementation of this updated program in October 2006. There was a seasonal variation in usage with CVD risk assessments more likely to be conducted in autumn, winter and spring than summer months (?2 = 1273.93, p-value < 0.0001).

Figure 3. Total number of patients assessed per month by GP or practice nurse



There was large variation in the use of PREDICT by providers. The majority of assessments (92.2 percent) were conducted by doctors. The mean (sd) number of risk assessments completed by each GP over all the time period was 57 (94.2) and 17 (17.0) by each nurse. The median number of assessments was 15 and 3 respectively indicating that some GPs were very frequent users. The maximum number of patients risk assessed by provider category was 621 by a GP and 161 by a nurse. However, 31 percent of GP adopters and 56 percent of nurse adopters completed less than 5 risk assessments.

PREDICT GP adopters were then categorised by number of patients assessed using the tool (Table 2); a non-user being classified as completing risk assessments on less than 5 patients; an infrequent user completing risk assessments on 5â€“20 patients, a frequent user, 21â€“89 patients and most frequent user assessing 90 or more patients. We aggregated frequent and most frequent users and compared them to infrequent and non-users. There were no statistically significant differences by gender or country of medical degree. Infrequent and non-users were more likely to be less than 10yrs since graduation (?2=17.28, p-value 0.0017). The older doctors (over 30 years from graduation) were as likely to be in either group. A higher percentage of frequent and most frequent users had vocational registration compared to infrequent or non

users (?2=22.60, p-value<.0001). We were unable to adjust for full-time equivalent status (FTE) which is highly likely to influence frequency of use.

Table 2. PREDICT GP users categorised by overall number of patients assessed

	General Practitioners using PREDICT			
	Non-user (<5 patients) n=129	**Infrequent user (5-20 patients) n=95**	**Frequent user (21-89 patients) n=104**	**Most frequent user (90+ patients) n=88**
	%	%	%	%
Gender				
Male	53.5	44.2	50.0	73.9
Female	34.1	50.5	47.1	25.0
Unknown	12.4	5.3	2.9	1.1
Years since graduation				
Less than 10years	13.2	9.5	2.9	2.3
10-19yrs	25.6	33.7	28.8	25.0
20-29yrs	27.9	40.0	46.2	51.1
30-39yrs	17.1	9.5	17.3	14.8
40+ years	3.1	2.1	1.0	5.7
Unknown	13.2	5.3	3.8	1.1
Country of medical degree				
New Zealand	51.9	67.4	56.7	71.6
Overseas	35.7	27.4	41.3	27.3
Unknown	12.4	5.3	1.9	1.1
Vocationally registered or have FRNZCGP				
No	26.4	31.6	16.3	5.7
Yes	61.2	63.2	81.7	93.2
Unknown	12.4	5.3	1.9	1.1

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3.3.1 Patterns of use over time among the most frequent users

The most frequent users were categorised as having used the PREDICT for CVD risk assessment on 90 or more patients (ie, the criterion for receiving a one-off incentive payment of $900 plus GST). There were 88 GPs in this category (21 percent of GP users). Their patterns of use over time could be classified into four

types. Individual GP examples of these four types are given in Figure 3A-D; A, start slowly, build up then decline; B, start with a rush then slowly decline; C, a fairly constant pattern overtime with assessment rates at the start similar to assessment rates at the end of the programme; and D, an all then nothing pattern defined as conducting at least 70 percent usage activity in one time block (3â€“6months).

Figure 3A. Build up then decline 36/88 (41%)

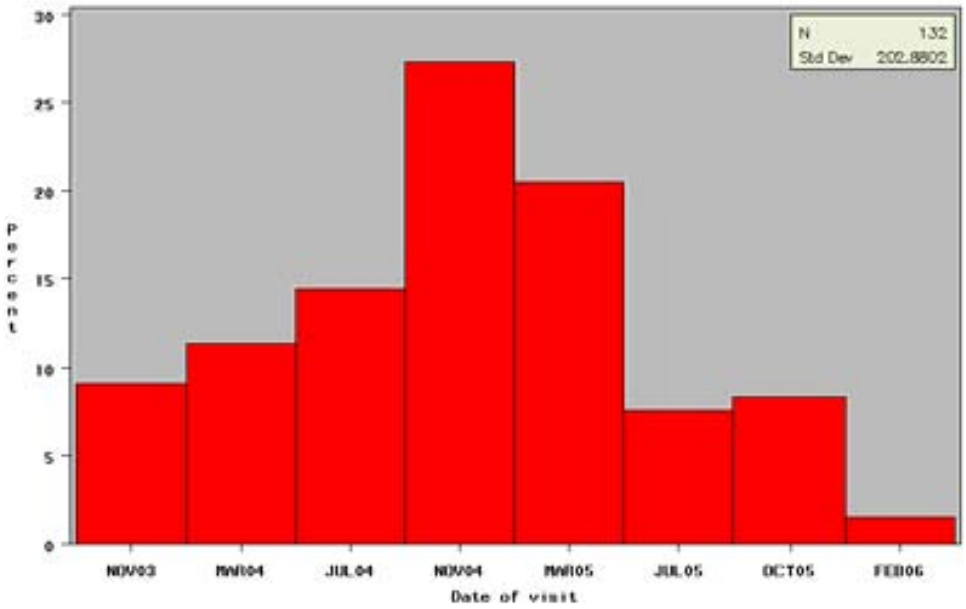


Figure 3B. Start high then decline 29/88 (33%)

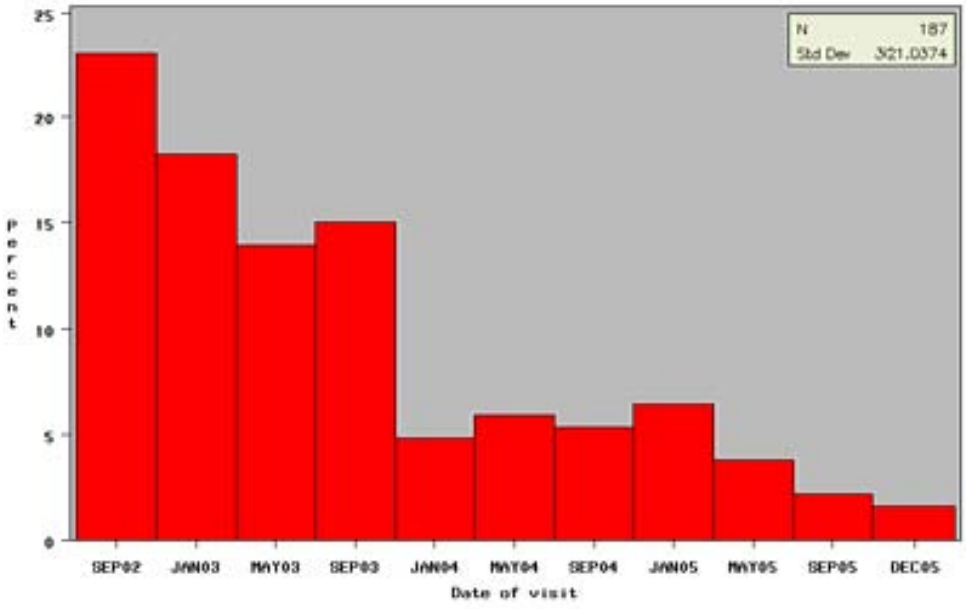


Figure 3C. Fairly constant over time 13/88 (15%)

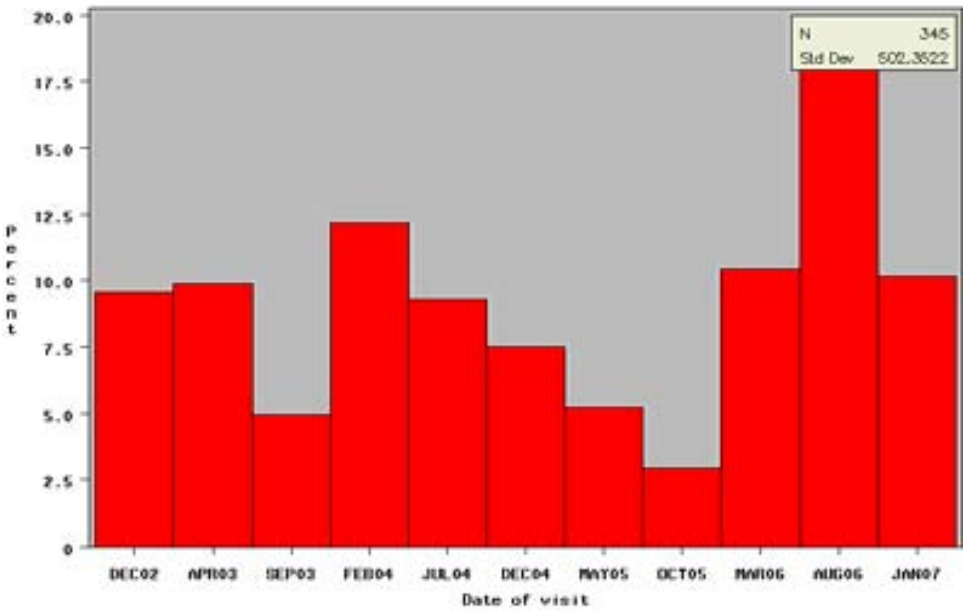
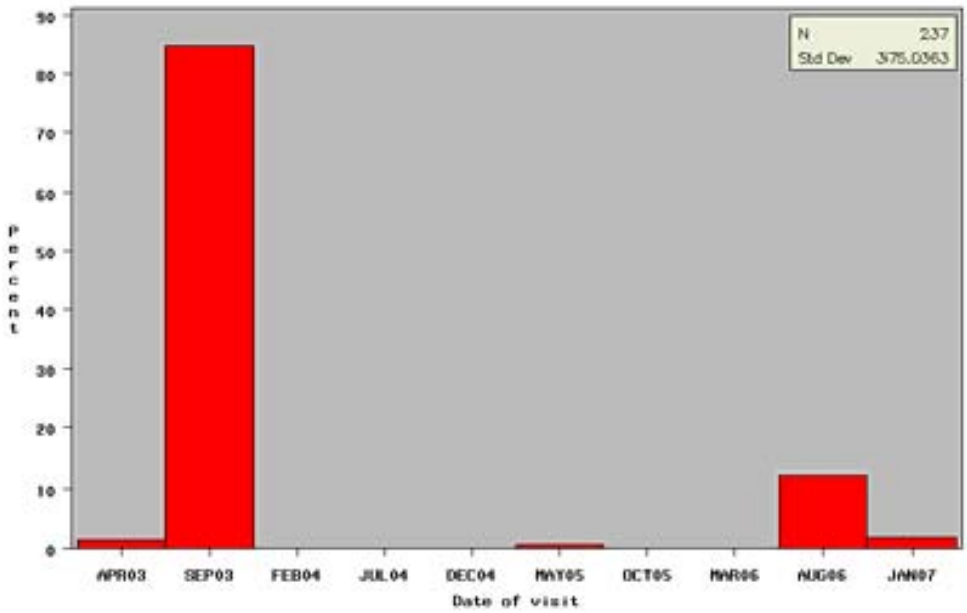


Figure 3D. All then nothing 10/88 (11%)



Of those GPs who met the criterion to receive the one-off incentive payment, 89 percent demonstrated sustained usage patterns over the 3â€“4 years following adoption, whilst only 11 percent of the most frequent users (2.4 percent of total GP users) appeared to be directly influenced by the payment target, resulting in a one-off burst of activity then virtual cessation.

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4. Discussion

This paper describes the lifecycle of version 1 of a CVD risk assessment and management decision support software from adoption by 416 GPs and 117 nurses to obsolescence (ie, when it was replaced by an updated

version that also included diabetes management). For GPs, there were differences in adoption of PREDICT by year of graduation and by vocational registration status but not by gender or country of medical degree. Adoption patterns had distinct peaks following annual renewed promotion efforts. Between August 2002 and January 2007, 45,437 risk assessments were conducted on 25,705 patients. On average, 400 patients were assessed per month with a marked reduction over summer-time, a time when most GPs have holidays and often take turns covering the practice whilst partners are away. GPs conducted 92 percent of the risk assessments and there was a large variation in frequency of use. It is possible that some nurses used a doctorâ€™s NZMC number when using practice computers and we therefore underestimated nurse usage.

When GPs were classified by frequency of use, a higher percentage of frequent and most frequent users had vocational registration compared to infrequent or non-users. However this finding could be confounded by part-time work. Infrequent and non-users were more likely to be less than 10 years since graduation. These younger doctors are often practising as locums and therefore spend less time in a practice but we were unable to adjust for this. There was no difference by gender or by country of medical training.

Of note, just under a third of doctors who had the program and broadband installed and who received training and practice support did not subsequently use the program. A qualitative evaluation examining the barriers, challenges and attitudes to CVD risk assessment practice and decision support is underway and may provide some insight into why this occurred and help identify strategies to increase future usage.

The incentive payment scheme may have been suboptimal. Firstly, payment was in retrospect, so that most GPs needed to fund initial broadband installation. Secondly, there were no usage reports to give practices feedback on their progress towards the one-off payment. GPs who had reached between 80 and 89 risk assessments were contacted and told that they were very close to their target, but other GPs were not contacted. It is possible that a re-designed financial incentive could have been a more powerful driver of uptake and usage.

In terms of sustainability of usage, while there appeared to be a steady usage state between mid-2004 and late 2005 with just under 800 assessments per month occurring, the rapid decline in usage in 2006 is likely to mirror its loss of clinical currency with the development and subsequent implementation of a new guideline via an updated version of PREDICT. Other possible explanations include practice staff turnover and the need to renew or re-promote programs to sustain their use. Early indications of usage of the new CVD-Diabetes program suggest a rapid increase back to the previous high level.

The clinical registry data was derived from multiple primary care administrative datasets linked with data held on medical and nursing council registries. Often information was either lacking or out of date. Identifying nurses on the public register was difficult as there often were nurses with the same names and many nurses used their middle names as their first name. There was also no region or specialty information recorded comparable to the medical registry data. These problems resulted in a higher rate of unmatched nursing data. Moreover, the denominator population of GPs and practice nurses in Procare Health is by nature constantly changing, with GPs and nurses joining or leaving practices, joining or leaving the primary care organisation (eg, moved out of Auckland or changed to another primary care organisation). Therefore interpretation of differences between adopters and non-adopters and categories of users needs to be treated with caution, particularly for nurses.

For both GPs and nurses, no date of birth was available. Years since registration were therefore used as a proxy measurement for this variable. For overseas trained doctors who have only recently immigrated to New Zealand, year of registration may not accurately reflect their age. ProCare Health is currently instigating a new web-based practice database which can be updated regularly by practice staff and will be able to provide a more accurate record.

Despite these weaknesses, valuable information on the users of an electronic decision support system could be generated and linked to usage in a de-identified way.

Comparison with other studies Studies of physician adoption of information systems (IS) or other innovations [11-13] often draw from technology diffusion theory[14] with adoption related to: relative advantage (perceived benefit of an innovation over current practice); compatibility (perceived consistency with values, past experiences and needs); complexity (perceived ease of use); trialability (extent to which innovation can be experimented on); and observability (degree to which results of innovation are visible to others). Other models of IS adoption in small businesses have also found decision maker characteristics (in this case GP ownerâ€™s innovativeness and IS knowledge) and organisational characteristics (business size and level of employeeâ€™s IS knowledge) to be important.[15]

Specific studies on adoption of expert systems and computerised physician order entry systems have noted distinct user adoption groups similar to this study.[16-18] Determinants of variation of usage have been found to be associated with physician attitude towards its effect on time-efficiency, perceived disruption to normal work practices, perceived ease of use and impact on quality of care[3,13,17] but not with sex, or years in practice at the study institution[15] or years since graduation.[16,19] Some studies cite prior computer use or experience, level of training and limited IT skills as barriers,[20] rural compared to urban practices,[21] whilst others have not.[16,17,22] Practice size has also been strongly correlated with electronic health record adoption[23,24] but we were unable to assess this due to missing data.

External incentives such as financial compensation for capital outlay or payment for quality have been cited as facilitators for adopting best evidence into practice.[12] It is possible that the financial incentive offered for the use of PREDICT may have lowered resistance to adoption. However, we found little evidence that it influenced actual usage. Several studies of primary care guideline implementation via decision support systems[25-27] have demonstrated that willingness to adopt various computerised interventions does not necessarily translate to actual use due to the reality of busy clinical practice and fit with work processes.

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5. Conclusions

Differences were found for adoption and frequency of use of PREDICT and were associated with having vocational registration and year of graduation but this may reflect time spent working within a practice. No differences were found by gender or country of medical degree. Three key findings are relevant to future implementation of ECDS in primary care. First, adoption of the program appeared to be responsive to annual promotional activities via GP cell groups. Secondly, while a financial incentive may have helped to facilitate adoption, it had very little impact on the ongoing usage of the tool in routine clinical practice. Thirdly, a substantial number of practitioners who had the program installed did not subsequently use PREDICT and identifying the reasons should be a high priority for future research.

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6. Acknowledgements

We wish to thank ProCare Health Ltd staff and affiliated practices GPs and practice nurses for supporting and participating in this programme. Our thanks to Joanna Broad for her help with analyses.

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6.1 Funding

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The impact of New Zealand CVD risk chart adjustments for family history and ethnicity on eligibility for treatment (PREDICT CVD-5)

Susan Wells, Andrew Kerr, Joanna Broad, Tania Riddell, Tim Kenealy, Rod Jackson

Abstract

Aims Current New Zealand cardiovascular (CVD) risk management guidelines advocate targeting treatment to patients with a high 5-year CVD risk assessed using a calculator derived from the Framingham Heart Study. For some high-risk population subgroups, a 5% upward adjustment to their calculated 5-year CVD risk is recommended. We estimated the impact of these adjustments on eligibility for treatment in a primary care setting.

Methods Between 2002 and 2006, 23,709 patients visting their primary care provider in Auckland, New Zealand had CVD risk assessments as part of an opportunistic screening programme using PREDICT, a web-based clinical decision support system. We calculated their baseline CVD risk with and without the 5% upward adjustment for family history of premature ischaemic CVD or for being of Māori, Pacific or Indian subcontinent ethnicity.

Results A baseline CVD risk could be calculated for 23,693 (99.9%) patients of whom 90% were between ages 35 and 74 years. Unadjusted risk scores classified the majority (70%) below the 10% 5-year risk threshold for specific individualised treatment. A further 11% were between 10 to 15% risk (recommended to receive individualised lifestyle counselling in general practice) and 19% had a greater than 15% risk (recommended for drug treatment and referral to a dietician in addition to individualised lifestyle counselling). Over a quarter of patients were recorded as having a premature family history of CVD; 21% were Māori, Pacific, or Indian subcontinent and thus met the criteria for a single 5% upward adjustment. This increased the number of people eligible for drug treatment, intensive lifestyle management, and dietician referral by approximately 20% and individualised lifestyle assessment and counselling by 50%.

Conclusions The upward adjustments to the calculated CVD risk recommended by the New Zealand CVD risk management guidelines has the potential to substantially increase resource requirements for CVD preventive services in primary care. Moreover the true impact is likely to be underestimated given other adjustment factors related to diabetes risk that were not available in this dataset. Given the impact of these relatively small changes to the CVD risk calculator, locally developed and validated risk equations are urgently needed.

Current New Zealand CVD risk management guidelines (2003) recommend a quantitative CVD risk assessment for all men over the age of 45 years and women over 55 years; 10 years earlier for people of Māori, Pacific or Indian subcontinent

ethnicity or if patients have known CVD risk factors or are at high risk of developing diabetes.[1]

Absolute 5-year CVD risk or the likelihood of a fatal or non-fatal cardiovascular event (including new onset angina, myocardial infarction, stroke, transient ischaemic attack, peripheral vascular disease, and left ventricular failure) in the next 5 years is estimated using a Framingham Heart Study prediction equation.[2] This equation takes into account the synergistic effect of major risk factors and includes age, gender, blood pressure, total and HDL cholesterol, smoking, and diabetes status.[2]

For some population groups, a once only 5% upward addition to their calculated 5-year CVD risk is recommended as the guideline developers considered that their calculated absolute risk was likely to be underestimated by the Framingham equation.[1] These high-risk groups include; people with a premature family history of coronary heart disease or ischaemic stroke; Māori and Pacific people; people from the Indian subcontinent; and patients with diabetes who have microabuminuria; Type 2 diabetes for at least 10 years or who have an HbA1c consistently over 8%; or people with metabolic syndrome.

The rationale for adjusting risk was based on evidence suggesting an increased risk of cardiovascular disease in these subpopulations compared with the general population, over and above their calculated CVD risk.[1]The adjustment was set at 5% for pragmatic reasons because at the time the guidelines were developed, the risk charts that most general practitioners used for CVD risk assessment, displayed estimated risk in 5% increments (Personal Communication, Rod Jackson, 2006).

Management recommendations from the New Zealand CVD guidelines are based primarily on the patient's calculated (and adjusted) absolute 5-year CVD risk and involve general lifestyle advice for those at less than 10% risk, individualised lifestyle assessment and counselling in primary care for those between 10–15% risk and drug treatment together with intensive lifestyle management (referral to a dietician as well as individualised assessment and counselling) for those at high risk (calculated risk ≥15%; or patients with a prior history of a CVD event who are assumed to be at >20% risk).

Whilst intensive treatment has the potential to more than halve future CVD events[4] and will be more cost-effective if targeted to the highest risk patients, direct costs to the health service due to additional drug treatment and other preventive services will accrue earlier and must be planned for. We therefore estimated the potential impact of upward risk adjustment for ethnicity and family history on the number of people eligible for drug treatment and specific lifestyle interventions using data from people risk assessed via an opportunistic CVD screening programme conducted in routine primary care.

Methods

From August 2002, ProCare Health Ltd, a large Auckland primary care organisation, implemented an opportunistic CVD risk assessment and management programme.[5,6] This programme used PREDICT, a web-based real-time decision support programme, that was integrated with the most commonly used practice management system software (MedTech). The programme is delivered as a window within a patient medical record in the same manner as other templates within the patient management system (PMS).

The integration allowed coded CVD risk data to be automatically extracted from a patient's electronic medical record and put into the PREDICT web template. Other data that were not available in the medical record were entered by the general practitioner or practice nurse. These risk profiles were automatically sent via a secure internet connection to a central server. Within seconds the clinician received the patient's calculated 5-year CVD risk as well as evidence-based risk management recommendations derived from New Zealand CVD guidelines. Meanwhile, the central server stored the CVD risk factor profile for each patient and with permission from ProCare were able to be extracted anonymously.

From these patient profiles, we derived a first recorded (baseline) risk estimate for each patient using the New Zealand CVD risk assessment criteria. Those who had had a previous CVD event were classified as being clinically at high risk without using the risk calculator. For all other patients we estimated their risk of a cardiovascular event in the next 5 years according to the Framingham equation.[3] The model includes gender, age, systolic blood pressure, smoking, total cholesterol:HDL ratio, and diabetes.

Valid ranges for the physiological parameters were determined *a priori* according to population based data from New Zealand epidemiological surveys and Diagnostic Medlab, New Zealand's largest community based pathology laboratory (S Wells and J Broad, unpublished report, 2005). Records containing values outside of the valid ranges were removed from the analyses. We then applied the recommended 5% upward adjustment (once only) if the patient's ethnicity was Māori, Pacific, or Indian subcontinent or the patient had a family history of premature ischaemic coronary heart disease or stroke (a first-degree male relative before the age of 55 years or a first-degree female relative before the age of 65 years). Pacific peoples were defined according to New Zealand Health Information Service ethnicity data protocols[7] as having Level 2 codes 31 to 37 and Indian subcontinent defined as Level 2 codes 43 and 44 excluding Japanese and Korean.

As the PREDICT module used in ProCare until 2006 was developed prior to the publication of the 2003 New Zealand Guidelines for the assessment and management of cardiovascular risk,[1] data on the additional risk adjustment groups (related to metabolic syndrome and other diabetes risk) were not available for these analyses.

All analyses were conducted using SAS (version 9.1) software.

The PREDICT research project was approved by the Auckland Ethics Committee (AKY/03/12/314).

Results

Between 2002 and 2006, 41,451 CVD risk assessments were undertaken for 23,709 patients. These assessments were undertaken by 407 GPs and 89 practice nurses. A baseline (unadjusted) CVD risk could be derived for 23,693 (99.9%) patients with 16 patients having data that was outside valid ranges. A profile of those risk assessed by age, gender and ethnicity is shown in Table 1.

Of those risk assessed, 90% were between ages 35 and 74 years. The majority (70%) were below 10% 5-year risk, 11% were between 10 to 15% risk, and 8% had a calculated CVD risk greater than 15%. A further 11% had a prior history of a cardiovascular event (assumed 5-year risk >20%). Three-quarters of those assessed were European & Other (e.g. Middle Eastern, African) ethnicity, 7% were Māori, 11% were Pacific, 3% were Indian subcontinent, and 4% were Asian.

Compared to European & Other, Māori (odds ratio [OR] 1.33; 95% confidence interval [CI] 1.22–1.51) and Pacific (OR 1.33; CI 1.22–1.46) patients were more likely to have a calculated risk of 15% or more or had had a prior cardiovascular event. The risk distribution for Indian was not significantly different to that of European and Other but those of Other Asian ethnicity were less likely to be in high risk groups than European and Other (OR 0.71; CI 0.58–0.87).

Table 2 shows the proportion of patients assessed who met one, both, or either adjustment criteria. Over one-quarter (28%) were recorded as having a family history

of a premature ischaemic CVD event, with the highest reported proportions in those between 45 and 64 years. There was a marked decline in the proportion of reported family history in those aged over 65 years.

Table 1. Estimated (unadjusted) cardiovascular disease (CVD) risk of the assessed population by age, gender, and ethnicity

Variables	n	Unadjusted Framingham CVD risk (%)			Prior history of CVD (%)
		0–10%	>10–15%	≥15%	(≥20%)*
Total Assessed	23693	70.0	10.8	8.0	11.2
Gender					
Women	10288	76.9	8.5	4.3	10.3
Men	13405	64.6	12.7	10.7	12.0
Age groups (years)					
15–34	804	97.9	0.2	0.0	1.9
35–44	3581	95.8	1.0	0.2	3.0
45–54	6926	86.4	5.6	2.0	5.9
55–64	7043	65.6	15.1	8.6	10.6
65–74	3864	36.1	21.3	20.4	22.2
75–84	1326	24.7	17.5	23.6	34.2
85 and over	149	20.8	18.1	17.4	43.6
Ethnicity					
European & Other**	17912	70.7	10.9	7.7	10.7
Māori	1663	65.2	10.4	9.9	14.4
Pacific†	2506	63.4	12.8	9.4	14.4
Indian‡	726	74.5	7.7	5.6	12.1
Other Asian‡‡	886	78.6	7.9	6.5	7.0

*Those with a history of prior CVD are estimated clinically as being greater than or equal to 20% CVD risk; **Not European, Māori, Pacific, or Asian (e.g. Middle Eastern, African); †All Pacific Islands (mostly of Samoan, Tongan, Niuean, or Cook Islands origin); ‡Indian, Fijian Indian, Pakistani, Sri Lankan, Bangladeshi, Nepali, Afghani, Tibetan; ‡‡Asian but not Indian subcontinent (e.g. Chinese, Japanese, Korean).

Table 2. Percentages of the assessed population meeting CVD risk adjustment criteria by age, gender, and ethnicity

Variables	n	Risk adjustment criteria			
		Premature family history CVD*	High-risk ethnic group**	Premature family history CVD AND high-risk ethnic group	Premature family history CVD OR high-risk ethnic group
Total assessed	23693	27.5	20.7	5.3	42.8
Gender					
Women	10288	29.7	21.9	5.5	46.1
Men	13405	25.8	19.7	5.1	40.3
Age groups (years)					
15–34	804	3.9	25.9	9.2	48.3
35–44	3581	17.1	28.0	8.6	50.4
45–54	6926	32.8	23.6	6.6	47.9
55–64	7043	29.2	17.5	4.0	40.6
65–74	3864	13.0	17.7	2.9	36.6
75–84	1326	3.7	10.0	1.7	26.2
85 and over	149	0.3	2.0	0.0	16.8
Ethnicity					
European & Other	17912	28.2	0.0	0.0	28.2
Māori	1663	33.7	100.0	33.7	100.0
Pacific	2506	17.7	100.0	17.7	100.0
Indian	726	34.6	100.0	34.6	100.0
Other Asian	886	23.5	0.0	0.0	23.5

*Includes all those with a family history of premature ischaemic cardiovascular disease; **Includes all those of Māori, Pacific, or Indian subcontinent ethnicity.

Table 3 shows the impact on classification and treatment of the recommended 5% risk adjustment for family history and ethnicity (only applied to patients with unadjusted CVD risk <15% and those without previous CVD events as by definition those ≥15% risk or with a previous history already met drug treatment criteria). The adjustments increased the number of people classified as ≥15% calculated risk by 48% (2790 adjusted compared with 1885 unadjusted—not shown in Table). When combined with those assumed to be >20% risk based on a prior history of CVD, the overall relative increase in the proportion of patients meeting drug and intensive lifestyle treatment criteria was 20%. The increase in the proportion of patients classified as 10–15% risk and therefore requiring individualised lifestyle interventions after adjustment was 48% (3806 adjusted compared with 2569 unadjusted).

Table 3. Classification of CVD risk (5-year CVD risk or personal history of CVD), recommended treatment, and impact on treatment eligibility with additional 5% CVD risk adjustment

Classification of CVD risk	Recommended treatment	Unadjusted CVD risk (N=23693)	Adjusted CVD risk (N=23693)	Relative change in treatment recommendations
<10%	General lifestyle advice	16579	14437	13% decrease
10–15%	Individualised lifestyle assessment & counselling in primary care	2569	3806	48% increase
≥15% or personal history of CVD	Drug treatment and referral to dietician in addition to individualised lifestyle assessment and counselling in primary care	4545	5450	20% increase

Discussion

In this cohort of patients, the 5% upward adjustment of 5-year CVD risk (recommended for patients with a family history of premature CVD and/or being of Māori, Pacific, or Indian ethnicity) increased by approximately 20% the numbers of people eligible for drug treatment (aspirin, blood pressure-lowering medication and statins), intensive lifestyle management, and referral to a dietician.

The adjustment also increased (by almost 50%) the numbers recommended for individualised lifestyle assessment and counselling by the primary care team. These increases were mainly due to over a quarter of patients reported as having a premature family history of CVD.

The basis of the risk adjustment of 5% for people of Māori, Pacific, and Indian subcontinent ethnicity recommended by the New Zealand Guidelines Group appears to have been based on multiple indirect sources of evidence. Indeed, national mortality and morbidity data have shown an increased burden of diabetes and cardiovascular disease in these ethnic groups compared to other groups.[8–11] However, at the time of guideline development, there were no published studies that systematically compared CVD risk profiles by ethnic group.

Epidemiological surveys of CVD absolute risk for Māori and Pacific workers (Workforce Diabetes Survey 1988-1990,[12–15] Fletcher-Challenge/University of Auckland survey 1992[16]) compared to European people (Auckland Heart and Health Study[17–19]) suggested that differences in CVD outcomes would not be adequately explained by the standard risk factors although the healthy worker effect would underestimate true risk profiles. The addition of 5% risk as opposed to 2% or 4% does not appear to be based on robust evidence. However, preliminary analyses from anonymised linkage of the PREDICT cohort to CVD outcomes suggest that the adjustment factor of 5% for ethnicity may be justified.

In terms of family history of premature ischaemic CVD, the single most common criticism by clinicians of the New Zealand risk charts prior to the development of the New Zealand CVD guidelines (2005) was the lack of inclusion of this risk factor and the extent to which this variable increases a patient's risk of a CVD event over and above the standard risk factors (personal communication, Rod Jackson, 2006).

A recent systematic review[20] found that (after adjustment for other known risk factors) a family history of premature CHD was associated with over 70% increased relative risk of a CHD event. Moreover, a family history of ischaemic stroke was associated with a 89% increased personal risk of ischaemic stroke in men.[21]

The cohort of patients described in this study were risk assessed oppportunistically within routine primary care. As these patients represent approximately 10% of the ProCare population aged over 35 years, they cannot be considered a representative sample of a resident population[5]. As this cohort is assembled over time, it is hoped that the data will be progressively more representative. However the pattern of their observed risk levels is very similar to expected New Zealand population estimates in 2005.[22] Not all the adjustment factors in the current New Zealand CVD risk management guidelines were able to be taken into account with this early version of PREDICT and so we have understimated the true impact of adjustment on drug treatment eligibility, lifestyle management, and referral to a dietician.

An updated PREDICT module (CVD-Diabetes), currently being implemented in ProCare practices and other PHOs within the three Auckland regional district health boards (DHB) and in Northland DHB, will be able to address this.

The New Zealand CVD risk guidelines thresholds for intervention were informed by an economic analysis[23] on the cost-effectiveness of screening and lipid-lowering treatment and the resource requirements and sustainability of CVD risk assessment.[1] However the guideline developers did not specifically investigate the potential impact of the recommended 5% upward adjustments in CVD risk on the numbers of New Zealanders who would be eligible for interventions.

The aim of explicit CVD risk assessment linked to graded management according to risk of future CVD events is to achieve a cost-effective and equitable reduction in adverse health outcomes across the New Zealand population.

The recommended upward risk adjustments were instituted to enhance the targeting of interventions to at-risk populations. However the substantial potential impact of these adjustments on resources required for lifestyle assessment and advice and drug therapy is of concern.

We believe comprehensive evaluations should be undertaken to investigate these adjustments as part of a review and update of the current guidelines. Firstly, by linking the PREDICT cohort risk assessments to observed hospital admission and

fatal outcomes, we will be able to directly determine the appropriate adjustments. We are currently waiting for the study to generate sufficient person-years of follow-up for robust estimations. Secondly the evaluation will require an economic analysis to determine if the impact of these adjustments on healthcare costs would be offset by the reduction in future hospital admissions and deaths.

Of note, there was a surprisingly high prevalence of reported premature family history of CVD, and the unexpected variation by age group (higher in younger patients) suggesting a difference in recall. The reliability of this variable needs to be investigated as it potentially compromises the validity of this recommended risk adjustment. We are unaware of any published information on the likelihood of over- or under-reporting of a premature family history of CVD in New Zealand, however.

Internationally, most investigators use dichotomous measures of family history of coronary disease that do not consider family size, number of affected relatives, or relatives' age and risk profile.[24] Reported reliability is around 67–83% senstitivity (true positive) and above 90% specificity (true negative).[25,26]

To enable systematic assessment and management of CVD risk for all eligible New Zealanders, the capacity of primary care to deliver these preventive services needs to be augmented, and the current costs of delivering this preventive service must be planned for. This includes the tools and resources to identify the target population, support patients to access this care, audit to ensure all groups are participating, and train/upskill primary care teams to deliver consistent and systematic care.

Competing interests: None.

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Health Care & Informatics Review Online

1 March 2005 - **Clinical Guideline Decision Support**

Online Management of Cardiovascular Risk in New Zealand with PREDICT™ - Getting Evidence to the "Moment of Care"

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Abstract
Evidence-based clinical guidelines for managing cardiovascular risk recommend treatment decisions based on a patient's absolute risk. Despite the widespread dissemination in New Zealand of both paper-based and stand-alone software tools to rapidly assess cardiovascular risk, studies in general practice have demonstrated that these tools were used infrequently. To address this problem, a web-based clinical decision support programme, PREDICT™-CVD has been developed. The programme was designed so that any member of the clinical team can quickly and simply assess CVD risk and provides real-time, evidence-based "moment of care" advice individualised to the patient's own health profile. The programme integrates seamlessly and securely with existing GP electronic medical records generating important clinical information in a standardised form that can be used for risk profiling populations, developing new risk prediction tools and for clinical audit. Evaluations indicate that PREDICT™-CVD is usable in busy clinical settings and can have a significant impact on practice. Although this programme started in one focused area, it is potentially a forerunner of a major shift towards IT-based evidence-based medicine and the way chronic disease will be managed.

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Background Evidence
Over the past decade there has been a paradigm shift in the management of cardiovascular disease (CVD) risk. Previously, drug treatment was primarily recommended when blood pressure or cholesterol exceeded certain "cut-off" levels. However, clinical guidelines now focus more on absolute or global risk, rather than the levels of individual risk factors.[1-4] Analysis from the Framingham Heart Study,[5] a long-term, follow-up study of cardiovascular risk factors in the US, has demonstrated that the risk of having a cardiovascular event over a defined period of time (ie, the absolute risk) is determined more by the cumulative effect of combinations of risk factors (notably age, gender, smoking, blood pressure, cholesterol, diabetes and a previous history of cardiovascular disease) than by high levels of one or two risk factors. For example, at a given level of systolic blood pressure the risk of a cardiovascular event occurring in the next five years might vary more than ten-fold depending on the level and presence of the other risk factors (figure 1). Moreover, randomised trial evidence has shown that the magnitude of treatment benefits is directly proportional to the pre-treatment absolute CVD risk.[6] Therefore, effective and efficient treatment decisions for managing CVD risk can only be made if the treating clinician is able to accurately determine the patient's absolute CVD risk.

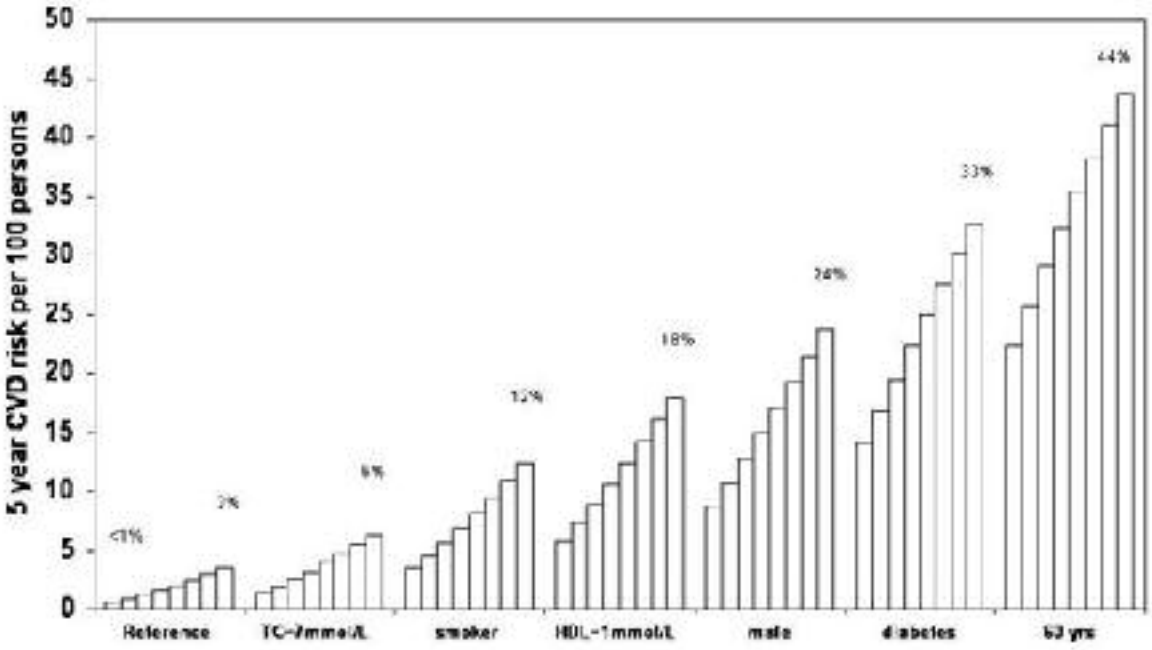

Figure 1: Absolute Risk of Cardiovascular Disease over 5 years in patients by systolic blood pressure (SBP) at specified levels of other risk factors[24]
Reference category is a female aged 50 years with Total Cholesterol (TC) = 4.0 mmol/L, High Density Lipoprotein Cholesterol (HDL) = 1.6 mmol/L, non-smoker, no diabetes. Risks are given for SBP levels of 110, 120, 130, 140, 150, 160, 170 & 180 mmHg. In each of the other categories additional risk factors are added consecutively, for example the diabetes category is a 50 year old, TC = 7 mmol/L, a smoker, HDL = 1 mmol/L, a male and with diabetes. **(Copied from the Lancet)**

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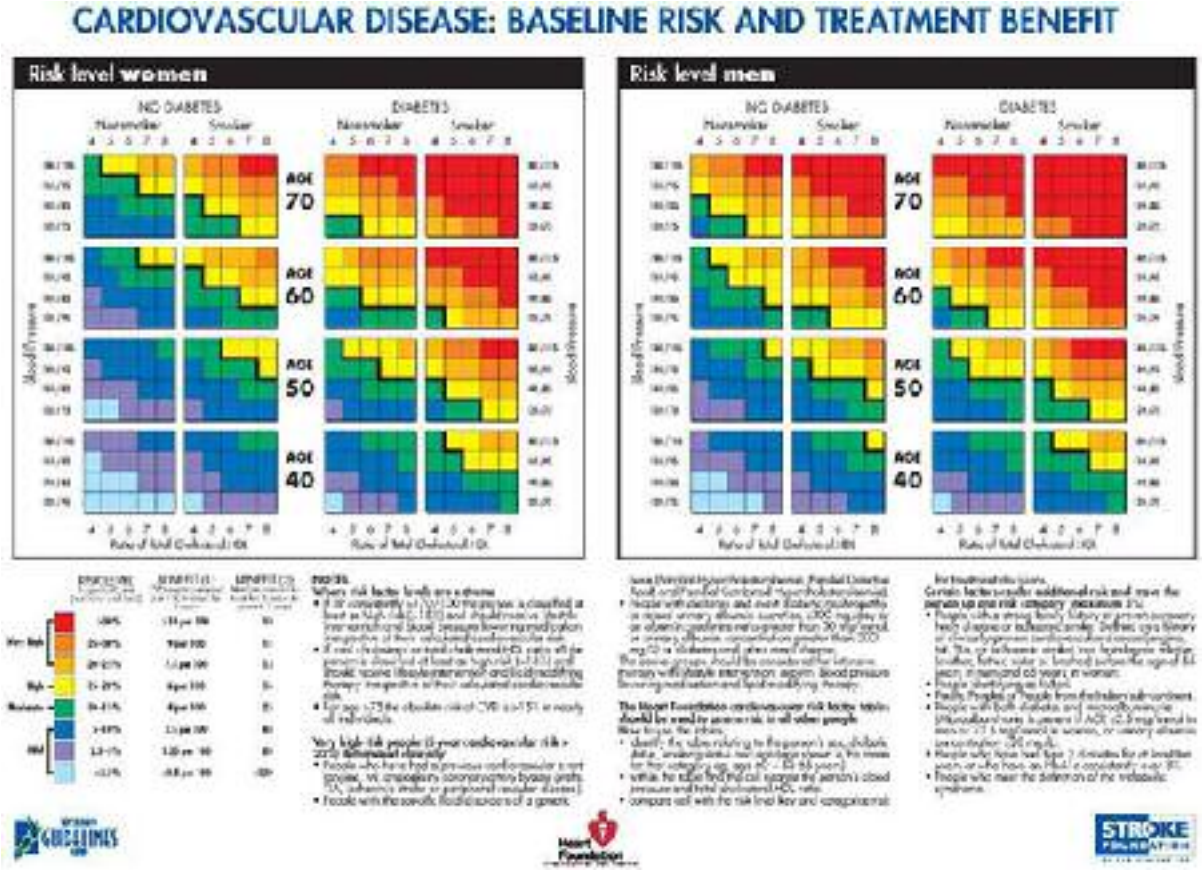
From The Evidence to Clinical Risk Assessment Tools
The findings described above stimulated the development of simple cardiovascular risk charts to provide clinicians in New Zealand with an easy way to estimate absolute cardiovascular risk at the moment of care. Research had demonstrated that clinicians are unable to accurately estimate a patient's cardiovascular risk without help[7] - it has been likened to trying to do your tax return in your head. One of the authors (RJ) had experimented using the style of risk tables developed by the Framingham Study investigators,[8] that required clinicians to add up a series of numeric scores then convert this into an absolute risk score, but found this approach too cumbersome.

First attempts to develop absolute CVD risk charts were incorporated into the 1992 New Zealand guidelines for managing raised blood pressure[9] and the 1993 National Heart Foundation guidelines for managing dyslipidaemia.[10]. These charts used colour coding to denote absolute risk given the presence or level of risk factors. They were improved in response to feedback from clinicians and as a result of international developments[11] and in 1996 new colour charts (figure 2) were included in updated guidelines for managing raised blood pressure[12] and dyslipidaemia.[13]



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These guidelines with their associated risk charts were widely disseminated by repeated mail outs and were printed in the standard drug compendium used by most New Zealand general practitioners (GPs). There was also considerable promotion via medical opinion leaders with initial implementation involving extended road shows throughout the main centres of New Zealand.

In the late 1990s, CVD risk assessment calculators were also developed as an alternative to the paper-based risk charts. These calculators were stand-alone software programs, some of them having the ability to display the colour chart. Some were included in general practice electronic patient management systems although they did not have the functionality to self-populate patient data.

Uptake of Risk Assessment Tools

Despite the ability that risk charts gave practitioners to rapidly assess a patient's absolute CVD risk and much positive anecdotal feedback about their usefulness from GPs, the use of the risk charts to support the management of raised blood pressure and dyslipidaemia in routine clinical practice was found to be disappointingly low. A nationwide survey of 499 randomly selected New Zealand GPs conducted in 1999 found that the majority used CVD risk charts only once per month or less (table 1).[14] Based on typical practice populations we estimated that the risk assessment tools should be used daily.

Table 1: Use of CVD risk charts by GPs in New Zealand in 1999

Never	6%
Less than once per month	39%
About once per month	24%
More than twice per month	31%

(Adapted from Arroll et al 2002)[14]

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The Development of PREDICT^{TM}-CVD – An Integrated Online CVD Risk Assessment and Management Tool

The findings from the Arroll study demonstrated that, in a busy general practice, systematic and comprehensive CVD risk assessment and management would be a challenge. Stimulated by this research, we developed a web-based clinical decision support program, PREDICT^{TM}-CVD Version 1, between 1999 and 2002. We involved a large collaborative group representing clinicians, primary and secondary care organisations, non-governmental organisations (National Heart Foundation and New Zealand Guidelines Group), led in collaboration by clinical epidemiologists at the University of Auckland and Enigma Publishing Ltd (a private provider of online health knowledge systems).

The PREDICT^{TM}-CVD Version 1 program was designed to get the right information to the right people (practitioners and patients) at the right time. There are two main components to PREDICT^{TM}-CVD , a risk assessment component and a risk management component. PREDICT^{TM}-CVD is web-based but integrates into a practitioner's electronic medical record (EMR) system. The front end is a risk assessment screen, much of which will self-populate from the EMR if risk data are available in a standardised format to allow mapping. Using a broadband internet connection PREDICT^{TM}-CVD takes only five seconds to calculate and return a quantified absolute CVD risk assessment based on the data entered at the risk assessment screen. PREDICT^{TM}-CVD also has a risk management screen where additional data on the patient's current management can be entered. PREDICT^{TM}-CVD

then compares the particular patient's current risk assessment and current management with nationally agreed guidelines on managing CVD risk and generates a series of patient-specific management recommendations for the practitioner, again in only five seconds. PREDICT™-CVD also generates a personalised version of these recommendations that can be printed out to help facilitate the patient's care planning and goal setting. Other patient health education materials are also available to be printed out.

PREDICT™-CVD contains a standard core content based on nationally agreed guidelines but the program also allows for local adaptation. This adaptation allows the content of the nationally agreed PREDICT™-CVD module to be modified at district health board or primary care organisation level to reflect care management options locally (for example, contact details of smoking cessation clinics).

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PREDICT™-CVD Implementation

PREDICT™-CVD Version 1, as described above, was implemented in ProCare, a large Auckland primary care organisation (PCO) serving approximately 590,000 patients, during 2003/4 and was also implemented on a smaller scale in a structured chronic care management programme supported by a District Health Board[a] in the Auckland region (Counties Manukau) over the same period. Since then PREDICT™-CVD has been successfully implemented within a Coronary Care Unit of a major Auckland hospital (Middlemore), ensuring that systematic risk management has been completed prior to patient discharge. Currently over 130 GPs are using PREDICT™-CVD and anonymised risk profile data for 12,000 patients has been stored with an encrypted unique identifier.

Version 2 of PREDICT™-CVD is currently in the final stages of testing and now incorporates diabetes risk management guidelines. This version of PREDICT™-CVD/Diabetes is designed for a widespread roll-out throughout New Zealand and it is envisaged that it will be used systematically as the risk assessment and risk management tool by the majority of primary care clinicians in New Zealand within several years.

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PREDICT™-CVD Research and Quality Improvement Opportunities

The academic group involved in developing PREDICT™-CVD plans to work in partnership with the clinical organisations using the program on a range of research and development projects. One of the major research-related benefits of the PREDICT™-CVD approach to CVD risk management is that it encourages the standardisation of clinical data collection and documentation. Practitioners using PREDICT™-CVD are required to enter data in a standardised way to allow the program to generate a risk assessment or patient-specific management recommendations. As the "rewards" for standardised data entry are immediate and clinically relevant, correct data entry is much more likely to be accurate and sustainable.

In the first instance, it will be possible for the first time in New Zealand to electronically extract standardised, uniformly documented, cardiovascular and diabetes risk profile data from primary care clinical records across the country. When PREDICT™-CVD is used systematically in a primary care population – this approach is already being piloted in a second PCO (Health West) – the CVD and diabetes risk factor burden for that population can be determined without the need for expensive one-off surveys.

The second major research and development opportunity will arise when the individual risk factor profiles are linked to national hospitalisation and mortality data using the National Health Index number – a unique health services identifier allocated to each New Zealander – that has been encrypted to ensure confidentiality. With these data linked, it will be possible to develop New Zealand-specific risk prediction tools to replace the risk prediction tool currently used, which is based on data from the American Framingham Heart Study. Moreover, given the large numbers of patients likely to be assessed from implementation of the programme more widely in New Zealand (over 500,000), it should be possible to develop in a timely fashion separate risk prediction tools for different at-risk subpopulations.

The data generated from PREDICT™-CVD can also be used by individual practitioners and their organisations to undertake audits of practice against current guidelines. One of the major problems with current audits is that practitioners do not record data in a standardised way, making electronic audits of practice extremely difficult and time consuming. As all PREDICT™-CVD data will be generated in a consistent, electronic format, audits will be able to be carried out more regularly, accurately and efficiently.

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The Effectiveness of PREDICT™-CVD

An initial evaluation of PREDICT™-CVD was undertaken in 2003, based on self-reported CVD risk assessment practice from 25 GPs who had been early adopters of the program. The results were very promising, with substantial increases in risk assessment being reported (table 2).

Table 2: Self-reported frequency of absolute CVD risk assessment before and after the introduction of PREDICT™-CVD among 25 early adopter GPs

Frequency of CVD risk assessment	Before PREDICT™-CVD	After PREDICT™-CVD
1–2 times per month	25%	0%
1–2 times per week	75%	50%
5–10 times per week	0%	38%
10–20 times per week	0%	12%

(pers comm Kate Moodabe, ProCare and Susan Wells, University of Auckland, 2003)

However, as this evaluation was based on self-reports and because there may be differences between early and later adopters, a large before and after study of all eligible GPs in ProCare, the PCO that had implemented PREDICT™ Version 1, was undertaken. The evaluation was based on a detailed review of multiple clinical records and has only recently been completed. Preliminary analyses indicate that GPs using PREDICT™ increased risk assessment and risk factor documentation more than four-fold (unpublished data).

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Barriers to Implementation

A number of potential barriers to successful implementation were identified In the process of undertaking these PREDICT^{TM}-CVD evaluations. First, although 99% of GPs have computerised practice systems in New Zealand,[15] there are up to 15 different patient management systems (PMS) being used, the most commonly used being MedTech 32 (60%), Intrahealth Profile (12%) and Houston GP (8.9%).[15] PREDICT^{TM}-CVD Version 1 was only integrated into the MedTech PMS system MedTech because it was the most commonly used system at ProCare. Integration into the other systems will be required for a successful national roll-out.

We found huge variability in individual practitioners' computer hardware, software, skills and degree of comfort in using a computerised decision support programme. On-going systems support from the umbrella PCO, long after initial training and installation, was crucial to continuing use. Although PREDICT^{TM}-CVD contained widely trusted and credible content, the format, functionality (including speed of output) and ordering of content was also very important. The ability to respond and adjust the program, especially in the early phases, greatly assisted in tailoring the "fit" to clinical care.

The availability of the new national guidelines in *New Zealand Management of Type 2 Diabetes*[16] and *the Assessment and Management of Cardiovascular Risk*[1] published at the end of 2003, necessitated the development of the updated version of the program: PREDICT^{TM}-CVD/Diabetes Version 2, which will supersede the older version during 2005. Updating the program has been a major undertaking and, to remain credible with practitioners, decision support systems like PREDICT^{TM}-CVD/Diabetes must continue to be kept up-to-date with new clinical evidence.

As the update has led to a broadening of the original programme scope to include the management of two major chronic diseases, it is potentially a forerunner of a shift towards IT-based evidence-based medicine and the way chronic disease will be managed in the future. The feasibility of further increments to the programme such as cardiac rehabilitation, management post-stroke, and the management of atrial fibrillation and congestive heart failure are currently being investigated.

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Conclusions

PREDICT^{TM}-CVD is a flexible, evidence-based, "moment of care", electronic decision support system that also generates important clinical information in a standardised form that can be used for risk profiling populations, developing new risk prediction tools and for clinical audit. As it is web-based, all users always have the same up-to-date version based on current best clinical evidence. While PREDICT^{TM}-CVD contains a standard core content based on nationally agreed guidelines, the program also allows for local adaptation.

As the content has been developed and designed by clinicians for clinicians, it closely mirrors usual clinical care processes. Evaluations indicate that PREDICT^{TM}-CVD is usable in busy clinical settings and can have a significant impact on practice. The PREDICT^{TM} platform has the potential to be used to support prevention and management of multiple conditions across multiple settings. It can be used by a range of practitioners, from community outreach nurses to primary, secondary and tertiary care doctors. Future versions will also be developed for direct patient use.

The next revolution in health care will be electronic, not genomic. Electronic decision support systems like PREDICT^{TM}-CVD will make a major contribution to this revolution.

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Footnote

Under the New Zealand Health & Disability Act 2000, 21 District Health Boards (DHBs) were created throughout the country. Each DHB is responsible for both the funding and provision of services within a defined geographical area. Typically, public hospitals form a substantial portion of the provider operations of a DHB.

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Estimated prevalence of cardiovascular disease and distribution of cardiovascular risk in New Zealanders: data for healthcare planners, funders, and providers

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Abstract

Aims New Zealand cardiovascular risk management guidelines advocate targeted risk assessment based primarily on age, gender, and ethnicity—and recommend drug management for people with a 5-year absolute cardiovascular disease (CVD) risk greater than 15%. To inform service planning and healthcare delivery for district health boards and primary healthcare organisations in New Zealand, we have produced population estimates of CVD prevalence and 5-year absolute CVD risk.

Methods The 1993 Auckland Heart and Health Study provided the data for estimating CVD prevalence and absolute CVD risk distributions using the Framingham CVD risk prediction equation. These estimates were applied to population projections for 2005 based on 2001 New Zealand Census data.

Results Of the projected 2.09 million people aged over 35 years in New Zealand in 2005, approximately 1.5 million (72%) meet national criteria for formal CVD risk assessment. About 151,000 (7%) are estimated to have suffered a non-fatal heart attack or stroke or have angina. A further 262,000 (13%) are estimated to have a 5-year CVD risk greater than 15% based on New Zealand CVD risk charts. This represents around 1 in 5 adults over the age of 35 years in New Zealand for whom pharmacological interventions are recommended according to the New Zealand CVD risk guidelines for the prevention of new or further CVD events.

Conclusions The latest published data available on the burden of CVD risk in New Zealand is now over 10 years old and does not include Maori, Pacific, and other non-European ethnic groups. Current data on the risk profile of adult New Zealanders is required for more accurate service planning. However the information reported here provides a reasonable estimate of the magnitude of the task. Although systematic identification and management of CVD risk in New Zealanders with raised CVD risk will be a major undertaking for healthcare services, it has the potential to produce significant health-gains while reducing health disparities.

Cardiovascular disease (CVD) is the leading cause of death and hospitalisation in New Zealand.[1] There are major disparities in CVD between ethnic groups and significant under-treatment of high-risk patients. Age-specific death rates are two to three times higher for Maori compared with non-Maori in those aged less than 75 years.[2] CVD prevention and management and the reduction of health inequalities have been targeted as priorities in the *New Zealand Health Strategy, He Korowai Oranga (Maori Health Strategy),* and *Primary Health Care Strategy*.

Current New Zealand CVD risk management guidelines recommend targeting CVD risk assessment to all men aged over age 45 years and women aged over 55 years (10

years earlier for people of Maori, Pacific Island, or Indian ethnicity or if they have known CVD risk factors or are at high risk of developing diabetes[3] [Appendix 1]).

Treatment recommendations are based primarily on the patient's estimated absolute risk, with pharmacological treatments recommended for those over 15% 5-year absolute CVD risk.

To inform their health-needs assessments, and to guide healthcare planning and funding decisions, over the previous 2 years we have been asked by district health boards (DHBs) and primary healthcare organisations (PHOs) to provide estimates of the prevalence of CVD and distributions of CVD-risk in the community. As there is limited data on CVD and absolute risk prevalence available in the public domain, we considered that this information would also be useful to other DHBs and PHOs.

Methods

Population estimates were provided by Statistics New Zealand for the projected 2005 adult population aged over 35 years (divided according to 5-year age groups and gender) for the whole of New Zealand, and for each DHB separately. Estimates were based on the 2001 Census usually resident populations, assuming medium fertility, medium mortality, and medium migration term projection methods.

To calculate absolute CVD risk, we used data from the Auckland Heart and Health Study (AHAH)[4] to estimate the proportion eligible for risk assessment and to derive estimates of the prevalence of existing cardiovascular disease and cardiovascular risk factors.

The AHAH study was a population-based cross-sectional survey conducted between 1993 and 1994. The study population included 2507 men and women aged 35–84 years and resident within the Auckland region of New Zealand.

Age-stratified samples were randomly chosen from central Auckland general electoral rolls with a response rate of 72%**.** The investigators aimed to include 250 subjects from each 10-year age/sex category. For our purposes, data were reaggregated into 5-year age/sex categories.

Analyses excluded Maori and Pacific Island ethnic groups as the sampling frame did not include the Maori electoral roll and the general electoral rolls significantly under-represented the true proportions of Pacific and Maori peoples within the general population. A detailed account of AHAH study methodology is presented elsewhere.[4]

The proportion eligible for risk assessment was based as closely as possible to the New Zealand Guideline Criteria (Appendix 1). Data on personal history of gestational diabetes, polycystic ovarian syndrome, known impaired glucose tolerance or impaired fasting glycaemia, and waist circumference were not available. However these omissions are unlikely to add significantly to the number of eligible people.

Previous history of CVD in the AHAH study includes coronary heart disease and previous self-reported stroke—but not transient ischaemic attack, peripheral vascular disease, or previous coronary artery surgery. Coronary heart disease was determined by self-reported myocardial infarction, with hospital admission or angina defined as currently taking nitrate medication. The AHAH study did not collect any data on CVD 'risk equivalents' (genetic lipid disorders or diabetes with nephropathy).

The absolute CVD risk over a 5-year period for each individual was estimated using a risk prediction model based on the Framingham Heart Study.[5] The model includes gender, age, systolic blood pressure, smoking, total cholesterol:high density lipoprotein (TC:HDL) ratio, diabetes, and interaction terms of age by gender, and diabetes by gender. A cardiovascular event is defined in the risk prediction model as a death related to coronary disease, non-fatal myocardial infarction, new angina, fatal or non-fatal stroke, or transient ischaemic attack—or the development of congestive heart failure or peripheral vascular disease.

Summary measures of risk categories (proportion over 20%, 15–20%, 10–15%, and less than 10% absolute CVD risk) were obtained for each 5-year age-gender group.

For the small number of people (1.5%) missing blood pressure or lipid data we calculated their absolute risk using the age/gender specific median value for that risk factor. Rate smoothing via moving

averages was applied to better reflect the naturally occurring patterns within populations and all estimated counts were rounded.

To estimate the numbers of people meeting risk-assessment criteria (as defined in the guideline),[3] we used:

- Statistics New Zealand 2005 population projections for all men aged over 45 years and women aged over 55 years, plus Maori and Pacific men (aged 35–44 years) and women (aged 45–54 years); and
- An estimate of the proportion of other men aged 35–44 years and women aged 45-54 years with one or more risk factors collected in the AHAH study—these factors included those people with a first-degree family history of premature coronary heart disease or stroke, personal history of smoking, blood pressure of more than 160/95 mmHg, TC:HDL ratio more than 7.0, or obesity (body mass index [BMI] over 30).

Results

Of the projected 2.09 million people aged over 35 years in New Zealand in 2005, approximately 1.5 million (72%) would meet national criteria for formal CVD risk assessment. Table 1 shows the proportion of New Zealanders over 35 years with prior CVD and the distribution of absolute CVD risk in those without prior CVD, by gender and 5-year age group for the estimated 2005 population.

Approximately 151,000 people (7%) have suffered a heart attack or stroke or have angina (or a combination of these). About 272,000 people (13%) are at high (CVD risk 15–20%) or very high (CVD risk over 20%) risk of a new CVD event in the next 5 years. Men are about three times as likely to be at high or very high risk than women (19% vs 7%). A further 10% of the total population over the age of 35 years are at moderate risk (CVD risk 10–15% in 5 years).

For each DHB catchment, aggregated estimates of CVD prevalence and CVD risk distributions are shown (Table 2). The proportion of people aged over 35 years meeting criteria for drug treatment (with prior CVD or an absolute CVD risk over 15% in 5 years) varies from 18.3% to 25.5% according to the demographic structure of the DHB.

Discussion

Current New Zealand guidelines for the management of CVD risk are based on evidence demonstrating that the magnitude of benefit from treatment for an individual patient is directly proportional to their pre-treatment absolute CVD risk.[6] Those who have had a prior CVD event and those at high risk of having a first event have the most to gain from identification and coordinated care. In appropriately targeted patients, the New Zealand guidelines suggest that 55% of future CVD events could be prevented.[3] We estimate that 7 out of 10 New Zealanders over 35 years of age should have a baseline risk assessment; and of those risk-assessed people, 1 out of 5 would meet criteria for drug treatment.

Cardiovascular risk prediction based on the Framingham Heart Study[5] is integral to the New Zealand cardiovascular risk assessment and management guidelines. The Framingham Heart Study was a cohort of mainly white Americans living in Massachusetts, USA in the 1970s and 1980s. The resultant cardiovascular risk prediction equation has been found to accurately predict on a population basis the 5-year risk of hospitalisation or death from a first cardiovascular event in New Zealand men aged 35 to 74 years and women aged 35 to 69 years.[7]

Table 1. Prevalence and risk of cardiovascular disease in New Zealand population, by age and sex

	Projected population [1]	Prior CVD [2]		CVD risk >20% [3]		CVD risk 15-20% [3]		CVD risk 10-15% [3]		CVD risk <10% [3]	
	N	Est. N	Est.%	Est. N	Est.%	Est. N	Est.%	Est. N	Est.%	Est. N	Est.%
Men											
35-39	145,600	160	0.1	320	0.2	650	0.4	970	0.7	143,510	98.6
40-44	154,600	1,550	1.0	1,210	0.8	1,480	1.0	2,840	1.8	147,560	95.4
45-49	143,900	3,360	2.3	1,810	1.3	3,130	2.2	8,610	6.0	127,040	88.3
50-54	126,700	6,090	4.8	3,240	2.6	6,410	5.1	14,190	11.2	96,800	76.4
55-59	116,300	8,250	7.1	9,730	8.4	12,350	10.6	21,940	18.9	64,030	55.1
60-64	89,600	10,240	11.4	14,540	16.2	15,280	17.1	20,780	23.2	28,730	32.1
65-69	70,300	10,640	15.1	20,920	29.8	14,730	20.9	15,170	21.6	8,850	12.6
70-74	57,600	13,500	23.4	21,130	36.7	10,900	18.9	9,430	16.4	2,670	4.6
75-79	46,200	13,480	29.2	21,090	45.7	6,500	14.1	4,220	9.1	890	1.9
80-84	29,000	9,990	34.5	13,950	48.1	2,920	10.1	1,920	6.6	200	0.7
85+	17,500	6,100	35.0	8,580	49.2	1,700	9.8	1,060	6.1	0	0.0
All men	**997,300**	**83,370**	**8.4**	**116,530**	**11.7**	**76,040**	**7.6**	**101,150**	**10.1**	**620,280**	**62.2**
Women											
35-39	157,500	150	0.1	310	0.2	620	0.4	930	0.6	155,440	98.7
40-44	164,800	350	0.2	590	0.4	880	0.5	1,300	0.8	161,650	98.1
45-49	149,700	510	0.3	790	0.5	1,320	0.9	2,100	1.4	144,970	96.8
50-54	129,400	2,480	1.9	1,430	1.1	2,180	1.7	4,390	3.4	118,900	91.9
55-59	118,200	3,900	3.3	1,980	1.7	4,300	3.6	10,770	9.1	97,220	82.3
60-64	91,700	5,800	6.3	2,090	2.3	4,830	5.3	14,260	15.5	64,730	70.6
65-69	75,000	8,480	11.3	3,240	4.3	5,790	7.7	16,930	22.6	40,560	54.1
70-74	63,100	10,870	17.2	5,230	8.3	6,430	10.2	15,410	24.4	25,120	39.8
75-79	55,900	13,110	23.5	5,900	10.6	8,070	14.4	15,190	27.2	13,630	24.4
80-84	44,300	11,620	26.2	4,870	11.0	7,650	17.3	12,320	27.8	7,830	17.7
85+	40,300	10,780	26.7	4,280	10.6	7,120	17.6	11,440	28.3	6,730	16.7
All women	**1,089,900**	**68,050**	**6.2**	**30,700**	**2.8**	**49,180**	**4.5**	**105,040**	**9.6**	**836,780**	**76.8**
Total	**2,087,200**	**151,420**	**7.3**	**147,230**	**7.1**	**125,220**	**6.0**	**206,190**	**9.9**	**1,457,060**	**69.8**

Note:

1 Usually resident population aged over 35 years projected to 2005 from 2001 census counts, sourced from Statistics NZ, Feb 2005.

2 Prior CVD estimates based on smoothed rates from Auckland Heart & Health Survey (1992-3 data for non-Maori, non-Pacific people), for age & sex groups, and includes self-reported heart attack (with hospital admission) or stroke, angina (on nitrates), but not PVD, PTCA, CABG or genetic lipid disorder.

3 CVD Absolute risk estimates calculated using by Framingham 5-year CVD risk equation applied to Auckland Heart and Health Survey data.

Table 2. Prevalence and risk of cardiovascular disease (CVD) in New Zealand population, by District Health Board

	Projected population [1]	Prior CVD[2]		CVD risk >20%[3]		CVD risk 15-20%[3]		CVD risk 10-15%[3]		CVD risk <10%[3]	
	N	Est. N	Est. %	Est. N	Est. %	Est. N	Est. %	Est. N	Est. %	Est. N	Est. %
District Health Board											
Northland	81,000	6,420	7.9	6,850	8.5	5,220	6.4	8,350	10.3	54,180	66.9
Waitemata	248,800	17,180	6.9	18,500	7.4	13,920	5.6	22,260	8.9	176,920	71.1
Auckland	202,100	13,280	6.6	14,330	7.1	10,550	5.2	16,870	8.3	147,100	72.8
Counties Manukau	199,500	12,830	6.4	13,740	6.9	10,810	5.4	17,530	8.8	144,590	72.5
Waikato	169,900	12,950	7.6	13,890	8.2	10,330	6.1	16,420	9.7	116,290	68.5
Lakes	51,600	3,770	7.3	4,030	7.8	3,060	5.9	4,910	9.5	35,810	69.4
Bay of Plenty	106,000	9,020	8.5	9,730	9.2	7,030	6.6	10,970	10.3	69,280	65.3
Tairawhiti	21,900	1,640	7.5	1,770	8.1	1,310	6.0	2,070	9.5	15,130	69.0
Taranaki	56,800	4,750	8.4	5,150	9.1	3,650	6.4	5,700	10.0	37,590	66.1
Hawkes Bay	79,600	6,410	8.1	6,950	8.7	5,030	6.3	7,910	9.9	53,270	67.0
MidCentral	83,100	6,820	8.2	7,390	8.9	5,310	6.4	8,320	10.0	55,220	66.5
Whanganui	33,800	2,870	8.5	3,150	9.3	2,210	6.5	3,420	10.1	22,160	65.5
Capital and Coast	133,600	9,060	6.8	9,760	7.3	7,330	5.5	11,710	8.8	95,750	71.7
Hutt	70,000	4,910	7.0	5,320	7.6	3,950	5.6	6,300	9.0	49,500	70.7
Wairarapa	22,500	1,950	8.7	2,110	9.4	1,510	6.7	2,370	10.5	14,570	64.7
Nelson Marlborough	75,400	6,060	8.0	6,490	8.6	4,730	6.3	7,500	10.0	50,580	67.1
West Coast	17,500	1,330	7.6	1,400	8.0	1,070	6.1	1,740	9.9	11,980	68.4
Canterbury	248,300	19,530	7.9	21,260	8.6	15,130	6.1	23,690	9.5	168,660	67.9
South Canterbury	31,700	2,870	9.1	3,140	9.9	2,180	6.9	3,360	10.6	20,100	63.5
Otago	96,200	8,070	8.4	8,780	9.1	6,190	6.4	9,670	10.0	63,490	66.0
Southland	57,700	4,370	7.6	4,710	8.2	3,440	6.0	5,460	9.5	39,690	68.8

Note:

1 Usually resident population aged over 35 years projected to 2005 from 2001 census counts, sourced from Statistics NZ, Feb 2005.

2 Prior CVD estimates based on smoothed rates from Auckland Heart & Health Survey (1992-3 data for non-Maori, non-Pacific people), for age & sex groups, and includes self-reported heart attack (with hospital admission) or stroke, angina (on nitrates), but not PVD, PTCA, CABG or genetic lipid disorder.

3 CVD Absolute risk estimates calculated using by Framingham 5-year CVD risk equation applied to Auckland Heart and Health Survey data.

Extrapolating data collected over 10 years ago from 2507 Aucklanders to the New Zealand population in 2005 requires caution. However they are the only currently available data and are given as 'ball park' estimates only. Our findings may underestimate the true prevalence of CVD in New Zealand as they are based on a study that did not include Maori and Pacific people who have higher risk of CVD. Furthermore, these estimates do not include those who have had a sole diagnosis of other cardiovascular disease including transient ischaemic attack, acute coronary syndrome, percutaneous coronary intervention (PCI), or peripheral vascular disease. However, many people with these diagnoses will have other manifestations of atherosclerotic disease. For example, studies of patients presenting with intermittent claudication indicate that around 50% have evidence of coronary disease on clinical history and ECG,[8,9] (and 90% have coronary disease angiographically[10]).

Nevertheless, the magnitude of the reported CVD risk burden is likely to be reasonable because the effect of excluding Maori and Pacific people, and some CVD diagnoses will be offset by declining secular trends in CVD morbidity and mortality over the previous 10 years.[2]

Despite the limitations of the data, this aggregate information is much needed by PHOs and DHBs to guide service planning and health care delivery particularly with new funding streams (for example the CarePlus programme) and requirements to fulfil key quality indicators for their population's health. The major challenge for primary care is to systematically identify those people most at risk and to ensure they are appropriately managed. If this occurs, the potential to reduce this leading cause of mortality and morbidity in New Zealand, while also reducing disparities between ethnic and socioeconomic groups, will be substantial.

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Appendix 1. Target population criteria for CVD risk assessment

RECOMMENDATIONS: WHO SHOULD BE ASSESSED
Cardiovascular risk assessments are recommended: • from the age of 45 years for asymptomatic men without other known risk factors • from the age of 55 years for asymptomatic women without other known risk factors.
Cardiovascular risk assessments are recommended 10 years earlier for Māori (from the age of 35 years for men and 45 years for women).
Cardiovascular risk assessments are recommended 10 years earlier for Pacific peoples and people from the Indian subcontinent (from the age of 35 years for men and 45 years for women).
Cardiovascular risk assessments are recommended annually from the time of diagnosis for people with diabetes.
Cardiovascular risk assessments are recommended: • from the age of 35 years for men with other known cardiovascular risk factors or at high risk of developing diabetes • from the age of 45 years for women with other known cardiovascular risk factors or at high risk of developing diabetes. These people will have one or more of the following risk factors: • family history of premature cardiovascular disease in a first-degree male relative (parent or sibling) under 55 years or female relative under 65 years • family history of diabetes in a first-degree relative (parent or sibling) • personal history of gestational diabetes • personal history of polycystic ovary syndrome • personal history of current or recent smoking • prior blood pressure of more than 160/95 mm Hg* • prior TC:HDL ratio of more than 7* • known IGT or IFG (see Table 22) • obesity (BMI ≥30*) or truncal obesity (waist circumference ≥100 cm* in men or ≥90 cm* in women).

Source: New Zealand Guidelines Group. The assessment and management of cardiovascular risk; 2003 (reference #3).