



The Treatment Of cardiovascular Risk in Primary care using Electronic Decision supOrt (TORPEDO) study- protocol for a cluster randomised, controlled trial of an electronic decision support and quality improvement intervention in Australian primary health care

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2012-002177
Article Type:	Protocol
Date Submitted by the Author:	03-Oct-2012
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Primary Subject Heading:	General practice / Family practice
Secondary Subject Heading:	Health informatics
Keywords:	PRIMARY CARE, CARDIOLOGY, Information technology < BIOTECHNOLOGY & BIOINFORMATICS

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TITLE

The Treatment Of cardiovascular Risk in Primary care using Electronic Decision supOrt (TORPEDO) study- protocol for a cluster randomised, controlled trial of an electronic decision support and quality improvement intervention in Australian primary health care.

ABSTRACT

Background

Large gaps exist in the implementation of guideline recommendations for cardiovascular disease (CVD) risk management. Electronic decision support (EDS) systems are promising interventions to close these gaps but few have undergone clinical trial evaluation in Australia. We have developed HealthTracker, a multi-faceted electronic decision support and quality improvement intervention to improve the management of CVD risk.

Methods/ design

It is hypothesised that use of HealthTracker over a 12 month period will result in: (1) An increased proportion of patients receiving guidelines-indicated measurements of CVD risk factors; and (2) an increased proportion of patients at high risk will receive guidelines-indicated prescriptions for lowering their CVD risk.

Sixty health services (40 general practices and 20 Aboriginal Community Controlled Health Services (ACCHSs) will be randomised in a 1:1 allocation to receive either the intervention package or continue with usual care, stratified by service type, size and participation in existing quality improvement initiatives. The intervention consists of point of care decision support; a risk communication interface; a clinical audit tool to assess performance on CVD-related indicators; a quality improvement component comprising peer-ranked data feedback and support to develop strategies to improve performance. The control arm will continue with usual care without access to these intervention components. Quantitative data will be derived from cross-sectional samples at baseline and end of study via automated data extraction. Detailed process and economic evaluations will also be conducted.

Ethics and dissemination

The general practice component of the study is approved by the University of Sydney Human Research Ethics Committee (HREC) and the ACCHS component is approved by the Aboriginal Health and Medical Research Council HREC. Formal agreements with each of the participating sites have been signed. In additions to the usual scientific forums, results will be disseminated via newsletters, study website, face to face feedback forums and workshops.

ARTICLE SUMMARY

- **Article focus**

This articles outlines:

- The development of a multi-faceted decision support tool and quality improvement intervention
- The methods to test the effectiveness of this intervention in improving guideline recommended screening for cardiovascular risk and management for individuals identified at high risk.

- **Key messages**

- This study tests a novel intervention that incorporates point of care decision support, risk communication and resources for patients, health service audit tools and use of data for supporting quality improvement initiatives.
- In addition to assessing practitioner performance on indicators correlated with improved health outcomes, the study also includes detailed process and economic evaluations.

- **Strengths and limitations of this study**

The strengths of the study are that it assesses an innovative complex intervention that is implemented in routine primary health care settings. It will provide rigorous evidence on process, clinical and economic outcomes and addresses an important issue facing health systems worldwide—namely scalable interventions that are able to achieve improvements in performance.

The main limitation is that it is conducted in one country, Australia, and thus its generalisability may be influenced by the prevailing health system context.

BACKGROUND

• CVD burden in Australia

Despite recent gains, cardiovascular disease (CVD) remains Australia's biggest killer accounting for 18% of the total disease burden and 11% of health system expenditure in Australia.¹

Aboriginal and Torres Strait Islander peoples experience around five times greater CVD burden than other Australians.² Current estimates project that by 2030 annual CVD expenditure will rise by around 100% to \$16 billion.³ Primary care based strategies that improve the uptake of best practice recommendations could substantially reduce both the Indigenous and non- Indigenous CVD burden and help improve health system efficiencies.

• Evidence-practice gaps in CVD prevention

In addition to lifestyle modification, a number of drug therapies have been shown to be highly effective in preventing cardiovascular events, primarily through modification of blood pressure, lipids and platelet function.⁴⁻⁸ However, there is compelling evidence of the failure of current clinical practice to adequately implement such treatments, and to translate current knowledge into maximally improved health outcomes. Three recently completed cross-sectional studies of CVD risk management in Australian general practice and Aboriginal Community Controlled Health Service (ACCHS) settings⁹⁻¹¹ demonstrated that 50% of routinely attending adults lacked sufficient recorded information to comprehensively evaluate vascular risk. For those identified at high vascular risk, only around 40% were prescribed guideline-indicated medicines. Similar findings have been noted in other Australian studies.¹²⁻¹⁵ These surveys have demonstrated failure to adequately implement the "absolute risk" paradigm for CVD prevention. Numerous tools are now available to estimate an individual's 5- or 10- year absolute risk of coronary heart disease and/or cardiovascular disease.¹⁶⁻²¹ Despite their availability, only a minority of Australian general practitioners (GPs) use these risk assessment tools, and then primarily for patient education, rather than to guide management decisions.^{9,22,23} Australia's first absolute risk assessment guideline was released in 2009 by the National Vascular Disease Prevention Alliance (NVDPA)¹⁷ and in 2012 this was augmented by a single management guideline.²⁴ Despite these guidelines now becoming available, there remain substantial challenges in effectively implementing their recommendations. We have found that CVD risk assessment and treatment works best when negotiated as part of a shared decision making approach, taking an average of fifteen minutes even where only one guideline needs to be consulted.²⁵

• The role of Electronic Decision Support (EDS) in closing evidence practice gaps

Electronic decision support (EDS) systems are among the most promising interventions to improve uptake of guideline-based recommendations in clinical practice. In five systematic reviews on the effectiveness of EDS, around two-thirds of studies demonstrated improvement in practitioner performance.²⁶⁻³⁰ One systematic review identified four decision support system features associated with improved performance: incorporation in routine work flow, provision at the time and location of patient consultation, use of computer-based tools and provision of treatment recommendations rather than just assessments.²⁸ Of 32 systems that incorporated all of these elements, significant improvements in performance were noted in 30. There are relatively few controlled evaluations of EDS systems that are integrated with electronic health records (EHRs) in the area of CVD.³¹⁻³⁵ Effect sizes vary greatly depending on the variables studied and the type of EDS system. In one systematic review of on-screen point-of-care reminder systems the absolute improvements ranged from 1% to 24% for test ordering and from 3% to 28% for medication prescribing.²⁷ In New Zealand, an EDS system that is fully integrated with the

country's most popular primary care software has been successfully implemented.³⁶ To date, we are unaware of an EDS system aimed at assisting comprehensive cardiovascular risk management based on Australian guidelines. Furthermore, we are not aware of any randomised evaluations of such systems in Australian primary care settings. Globally, few examples exist and the evidence base remains poor.

INTERVENTION DEVELOPMENT

HealthTracker is a novel electronic decision support system to facilitate guidelines-based assessment and management of CVD risk. Outlined below are the key steps taken in development of the intervention.

- **Algorithm development and validation**

A single screening and management algorithm was developed based on a synthesis of recommendations from several primary care screening and management guidelines (Table 1). The algorithm calculates a person's five year absolute CVD risk based on the Framingham risk equation and NVDPA recommendations^{17 20} and provides management recommendations based on the guidelines listed in Table 1. In 2008-9 a beta version of HealthTracker was developed in a stand-alone software system and independently validated for accuracy and compliance with the prevailing guidelines.²² In 2011 the algorithm was extensively revised to incorporate recommendations from newly published guidelines. A similar validation process was then conducted consisting of three levels:

Level 1 was an iterative process where each of the calculations programmed in the algorithm were tested to ensure they were consistent with recommendations from the guidelines. This was conducted using de-identified data from 337 patients involved in the pilot. Programming modifications were made where necessary and all variables were re-tested to ensure they were programmed correctly.

Level 2 involved giving a plain language summary of the algorithm to a research fellow who had not been involved in the development of the algorithm. She independently programmed the algorithm into a statistical software package. Using data from 9,077 patients from three representative cross sectional general practice surveys,⁹⁻¹¹ we then assessed whether the outputs from HealthTracker correlated with those generated from the independently programmed version. For 60 of the 63 output variables HealthTracker achieved perfect correlation with the independently programmed version. For the remaining three variables minor programming errors were identified and corrected.

Level 3 involved user acceptance testing and scrutiny of the algorithm by the study investigators, twenty health professionals working in both General Practice and ACCHSs, and three national professional organisations- the NVDPA, the Royal Australian College of General Practitioners and the National Prescribing Service. Following this feedback, a number of minor algorithm and user interface changes were incorporated into the final version of the tool. The Level 2 testing process was repeated following these changes and perfect correlation between HealthTracker and the independently programmed version was achieved for all variables.

- **Integration of HealthTracker with the primary care electronic health record and quality improvement tools**

HealthTracker interfaces with the two Australian clinical practice software systems most commonly used in General Practice and ACCHS settings (Medical DirectorTM and Best PracticeTM). There are four components to the system:

- **Point of care decision support:** HealthTracker is built in the Pen Computer Systems PrimaryCareSidebarTM, third party software that interacts with the primary EHR system. Figure 1 shows the HealthTracker user interface and its integration with the PrimaryCareSidebarTM and the EHR. A prompt function is used to encourage health professionals to conduct a cardiovascular assessment if guideline recommended. Where possible, the tool populates with information from the patient's record. If essential information required for the calculation of absolute risk is missing or out-of-date, a traffic light prompt alerts the health professional and updated information can be entered. If the patient is receiving sub-optimal treatment then a traffic light recommendation is made to consider initiation of treatment or additional agents. Information about eligibility for the Australia Government Pharmaceutical Benefits Scheme subsidy is provided if lipid lowering medicines are recommended. All outputs are qualified by statements emphasising that the final decision to commence or change therapy should be made by the health professional based on all available information.
- **A patient oriented risk communication interface.** A key finding from the pilot evaluation was the role of the output in risk communication. GPs wanted to interactively alter current risk factors and perform 'what if' scenarios to demonstrate to patients the effects of current and altered risk over time. This functionality has been built into HealthTracker and uses the concept of "Heart Age" to demonstrate to patients the discrepancy between current risk and an ideal risk based on well controlled risk factor levels. Figure 2 shows an example of how a patient's heart age changes with the effect of smoking cessation.
- **A data extraction tool.** This will provide health professionals with immediate feedback on their performance on screening and management of CVD risk for their entire patient population. Figure 3 shows an example of screening performance for a range of CVD risk factors. Practitioners can use this tool to identify specific patients in whom there may be a particular risk factor measurement missing or a potential prescribing gap. Customised point of care prompts can then be created. When a patient record is opened an alert is provided to notify the practitioner of the particular management issue and this can then be actioned.
- **A quality improvement (QI) component** has been developed which is aligned with the methods of the Improvement Foundation of Australia (IFA) Australian Primary Care Collaboratives (APCC) program. De-identified data extracts of clinical performance are securely exported to a web-based central repository managed by the IFA. This repository provides access to site-specific feedback reports on performance compared with other anonymised sites. Figure 4 shows an example of how this information is presented.

STUDY OBJECTIVES

The TORPEDO study will test HealthTracker's performance in assisting health professionals and patients in making evidence based management decisions to help prevent heart attack, stroke and related conditions.

Hypotheses:

Using a cluster randomised, controlled trial design, two specific hypotheses will be tested. Compared with control practices, those practices randomised to receive HealthTracker will have:

- (1) An increased proportion of patients receiving appropriate (guidelines-indicated) measurements of their CVD risk factors.
- (2) An increased proportion of patients at high risk receiving appropriate (guidelines-indicated) prescriptions for management of their CVD risk.

These aims will be augmented by formal economic and process evaluations to provide crucial information on large-scale implementation and sustainability.

STUDY DESIGN

HealthTracker will be evaluated using a cluster randomised, controlled trial design. At end of study, HealthTracker will be made available to both the intervention and control arms for a further 12 months free of any license fees. The study schema including site and patient eligibility criteria are highlighted in Figure 5.

• **Eligibility criteria**

Health Service

1. Use of Medical Director™ or Best Practice™ for EHR management.
2. Exclusive use of these systems to record risk factor information, pathology test results and prescribe medications. Services using 'hybrid' paper and electronic system for these features will not be eligible.
3. Agreement by all GPs and other designated staff to use HealthTracker.

Patients

1. Aboriginal and Torres Strait Islander people 35+ years and all others 45+ years (age criteria are based on NVDPA guideline screening recommendations³⁷), and
2. Attendance at the general practice or ACCHS at least 3 times in the previous 24 month period AND at least once in the previous 6 month period.

Site recruitment

Participating general practices have been recruited from the Sydney region in collaboration with primary health care organisations known in Australia as Medicare Locals. Participating ACCHSs have been recruited in partnership with two state representative bodies for ACCHSs, the Aboriginal Health & Medical Research Council (AH&MRC) of NSW and the Queensland and Aboriginal Islander Health Council (QAIHC). A \$500AUD reimbursement to participating sites will be made to partially compensate for health service staff time commitment to study-related

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2 activities. Sites randomised to the intervention will receive training support in use of the system
3 predominantly via face to face visits and webinars. All license costs and technical support
4 associated with the intervention will be provided free to the intervention sites in the first 12
5 months and to all sites for the following 12 months after completion of the trial. A newsletter and
6 networking web site will be provided to participating sites. Royal Australian College of General
7 Practitioners Quality Assurance and Continuing Professional Development points will be offered
8 to participating GPs in both arms of the trial.
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10 11 • **Randomisation**

12 Sixty services (40 general practices and 20 ACCHSs) will be randomised in a 1:1 allocation to
13 use HealthTracker or 'usual care' for twelve months. Clusters will be stratified at three levels-

- 14 1. ACCHS vs. general practices
- 15 2. Service size (<500 patients meeting eligibility criteria vs. >=500)
- 16 3. Participation in existing quality improvement programs (current involvement in one of
17 five national and state programs involving regular audit and feedback vs. past or never
18 involved in these programs)

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20 A site assessment survey will be administered to all sites to assess for service eligibility and
21 these stratifying variables. Permuted block randomisation will be centrally performed using a
22 web-based form. As this is a pragmatic trial, allocation will be single blinded with outcome
23 analyses conducted blinded to treatment allocation.
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25 26 ***Intervention group***

27 The intervention arm will receive the four components of the system described above (point of
28 care decision support software, risk communication tools, data extraction tools, and access to the
29 quality improvement portal). Clinical staff will be given training in use of the tools and a support
30 service will be available for any technical queries. One initial face to face training visit and
31 subsequent site visits and webinars targeting strategies to improve quality of care will be
32 provided.
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34 35 ***Control group***

36 Sites allocated to this arm will continue usual practice with their current systems without
37 implementation of HealthTracker. As the George Institute holds exclusive rights to the
38 distribution of the system, there is no possibility of control sites having access to HealthTracker.
39 If these sites already routinely use data extraction tools for assessing their quality of care then
40 this will continue as normal. As with the intervention arm, services participating in any quality
41 improvement initiatives will continue participation as usual. For those sites not routinely using
42 data extraction tools, the automated data extraction tool will be temporarily installed for data
43 collection purposes only and then uninstalled that same day. A feedback report on performance
44 will be provided at study completion only.
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46 47 ***Quantitative data collection (Figure 5)***

48 Cross-sectional data will be collected in an automated manner for all patients who satisfy the
49 eligibility criteria at each service. These data will then be sent securely to the George Institute
50 via an export function for analysis of primary and secondary outcomes.
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Pre-randomisation: 1 month prior to randomisation, de-identified data will be collected from all sites. These data will be fed back to all sites as a formal report highlighting areas where data quality issues may be occurring.

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Randomisation: Baseline data will be collected and sites will be randomised to intervention or control.

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End of intervention period: At the end of 12 months, data will be collected in both study arms.

11 • Primary Outcomes

- 14 • Change in the proportion of eligible patients receiving appropriate measurements of their CVD risk in the previous 12 months (measured at randomisation and at 12 months).
- 17 • Change in the proportion of eligible patients assessed at high CVD risk receiving appropriate prescriptions for their CVD risk factors in the previous 12 months (measured at randomisation and 12 months).

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Appropriate measurement of CVD risk factors is defined as having recorded or updated *all* the essential risk factors for measurement of CVD risk (smoking status, blood pressure (BP) in the previous 12 months, total cholesterol and High Density Lipoprotein (HDL) cholesterol in the previous 24 months) among those in whom risk assessment is guideline-indicated. Unless explicitly recorded, diagnoses of diabetes or left ventricular hypertrophy will be assumed to be absent.

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High CVD risk is defined as a calculated 5-year CVD risk of >15%, a history of CVD or the presence of any clinically high risk conditions (as per NVDPA recommendations). Based on audit data this is expected to comprise ~30% of the patient population.^{10 11}

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Appropriate prescriptions is defined as a prescription for one or more BP lowering drug *and* a statin for people at high risk without CVD; or a prescription for one or more BP lowering drug *and* a statin *and* an antiplatelet agent (unless contraindicated by oral anticoagulant use) for people with established CVD.

41 • Secondary Outcomes

- 44 • Change in measurement of individual risk factors separately (smoking status, BP, cholesterol, other non-Framingham risk factors- BMI, Chronic Kidney Disease (CKD) screening with urinary Albumin to Creatinine ratio, estimated Glomerular Filtration Rate);
- 47 • Intensification of existing medication regimes among patients at high CVD risk (. additional BP and lipid lowering agents)
- 50 • Changes in mean systolic BP, total cholesterol, LDL cholesterol, HDL cholesterol
- 53 • New CVD and CKD diagnoses

54 • Statistical Considerations

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Randomisation of 60 services (30 per arm) will provide 90% power to detect a $\geq 10\%$ absolute higher occurrence in each primary study outcome among practices receiving HealthTracker. The

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2 following assumptions are based on our three audits in ACCHSs and mainstream general
3 practices⁹⁻¹¹ and include an assumed improvement of 10% in the two primary outcomes in
4 control practices as a result of study participation.
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- 7 1. Cluster size of eligible population will range from 200 in a small service through to 2000 in a
8 large service. An average cluster size of 750 is assumed.
- 9 2. Recording rates of essential risk factors needed for risk assessment in the target group (first
10 primary outcome) average 50%.^{10 11}
- 11 3. 30% of the cluster will be either be at high CVD risk or have established CVD (n=250) and
12 prescription of appropriate medicines to high-risk patients (second primary outcome) is 50%.
13 This is based on our published data on drug prescriptions for individuals with and without
14 established CVD.⁹⁻¹¹
- 15 4. An intra-class correlation coefficient of 0.05 for both primary outcomes. based on our audit
16 data⁹⁻¹¹
- 17 5. Two-sided alpha = 0.05
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21 Data analysis will be performed on an intention-to-treat basis using generalised estimating
22 equations.³⁸ Subgroup analyses will be carried out using the three pre-specified strata: (1)
23 ACCHS vs. general practices, (2) service size (small vs. large) and (3) current participation in
24 quality improvement programs vs. past or no involvement in these programs.
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27 • **Economic evaluation**

28 The economic evaluation will have a trial-based component and a modeled evaluation of long
29 term costs and outcomes. The incremental cost will be based on software, training and other
30 costs incurred with transitioning practices to using HealthTracker. This will help determine the
31 cost barriers experienced by different practices in adopting the system. Data on medications,
32 laboratory tests, consultations and newly recorded diagnoses of CVD events incurred by eligible
33 patients during the trial will be obtained from the data extraction tools. Costs will be calculated
34 from prevailing Medicare rates and standard Australian National Diagnosis Related Groups cost
35 weights for CVD hospitalisations. The incremental cost consequences of the HealthTracker
36 system in achieving each of the primary outcomes will then be estimated e.g. cost per eligible
37 patients assessed at high CVD risk receiving appropriate prescriptions. Trial-based data,
38 however, cannot capture costs and outcomes beyond the trial. To address this, *a modeled*
39 *economic evaluation* will enable quality of life and survival to be examined and allow
40 incremental cost-effectiveness ratios to be calculated in terms of cost per Quality Adjusted Life
41 Years gained. Using a Markov model, the eligible patient population in both study arms will be
42 hypothetically tracked over an extended period. Transition between various defined health states,
43 costs and quality of life attached to various health states and the projected long term intervention
44 effects from that observed in the trial will be based on published evidence. With appropriate
45 discounting, estimates of long-term costs and outcomes will fold out of the model. Sensitivity
46 analyses will be conducted on discount rate, uncertainty in outcome estimates and assumptions
47 made in costing (e.g. varying efficiencies with different patient practice ratios to those of the trial
48 setting). This will better inform policy makers as to the resource consequences of rolling out this
49 program to scale.
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55 • **Process evaluation**

56 The qualitative evaluation of the beta-version of HealthTracker suggested that a critical factor
57 affecting the uptake of EDS interventions is whether and how they become embedded in routine
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2 health care²². In the TORPEDO trial we will build on this observation through a detailed process
3 evaluation to better appreciate the factors that might influence sustainability beyond the trial
4 setting. Two qualitative methods will be utilised to explore these factors.
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7 **Semi-structured interviews with health professionals and staff.** A maximum variation
8 sample will be taken to ensure diverse opinions are gained from patients, clinical and managerial
9 health staff and sites with low and high uptake of the intervention.³⁹ Key issues to be explored
10 will include (1) how practitioners use HealthTracker; (2) what effects it has on organisational
11 practices and personnel; and (3) what are patients' experiences of being presented with
12 HealthTracker outputs and what impact does this have on the healthcare encounter. Individual
13 informed consent will be sought and data will be collected toward the end of the intervention
14 period so as not to unduly influence trial outcomes.
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17 **Audio/ video ethnography.** A key component of understanding barriers/enablers to use of
18 HealthTracker is a better appreciation of how practitioners and patients use it at the point of care.
19 Data collection using audio/video recording will capture how technological innovations are
20 actually used in practice.⁴⁰ Ethnographic analysis will greatly augment the interview accounts
21 and will particularly shed important light on (1) how the intervention impacts on the flow of the
22 clinical encounter; (2) how risk information is communicated between health professional and
23 patient; and (3) how the patient receives and interprets the information and the role it may play in
24 shared decision making processes. Although audio/video recorded clinical encounters are
25 commonly used for primary care teaching purposes, such a technique can be potentially sensitive
26 and therefore will be restricted to a small number of sites. Recordings will be conducted toward
27 the end of the intervention period when both health staff and patients are thoroughly familiar
28 with the system. This will occur over a one week period at each site. Participants who are
29 approached for an interview will be invited to participate in this component. They will be given
30 the option of having their healthcare encounter audio or video recorded. A follow-up interview
31 will be arranged with these participants (both staff and patients) where the recording is played
32 back for participant interpretation of the data.
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37 These data will be supplemented by project officer field notes to identify any key processes,
38 events, staffing and other resource issues occurring during the intervention period that may be
39 relevant in gaining a better understanding of barriers and facilitators to implementation.
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42 A multidisciplinary research team will guide the analysis process. As is common with qualitative
43 inquiry, data analysis will commence early and be conducted contemporaneously with data
44 collection. This method allows for interview content to be refined for subsequent data collection
45 and to actively pursue emergent themes of interest. Although interviewing will continue until
46 thematic saturation is achieved and therefore the exact number of interviews is unknown, we
47 anticipate from prior experience that around 80 interviews (40 patients and 40 staff) will provide
48 sufficiently rich data to meet our objectives.
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51 Interview data will be digitally recorded, and professionally transcribed. NVivo 9 (QSR
52 International Melbourne, Vic) will be used to assist with data organization and coding for key
53 themes. Video data will be directly analysed and coded for key themes within NVivo. Feedback
54 of findings to participants will be provided by a variety of methods, including workshops,
55 summary reports, newsletters and via the study website.
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ETHICAL CONSIDERATIONS

The General Practice component of the study is approved by the University of Sydney Human Research Ethics Committee (HREC) and the ACCHS component is approved by the Aboriginal Health and Medical Research Council HREC. Formal agreements with each of the participating sites have also been signed. Quantitative data will be obtained from de-identified clinical audits. Ethical approval to grant waiver of the usual requirement to obtain individual patient consent has been obtained. In participating ACCHS sites, eligible patients can request to 'opt out' from having data in the clinical audit data extracts exported. Data exports will be compliant with privacy legislation, centrally managed by the George Institute and held in strict confidence. Some individual health professionals (GPs, practice nurses, etc) and patient participants will have their informed consent taken at the site to allow data collection through semi-structured in-depth interviews and/or the use of audio/videotaped healthcare encounters. Participation in this component will be optional. Patient Information Statements and Consent Forms have been approved by each ethics committee and formatted in accordance with their own guidelines and requirements.

The study will be conducted in accordance with the principles set out in the National Health and Medical Research Council and the NSW Aboriginal Health and Medical Research Council guidelines. Specific effort will be taken to respect the autonomy and governance of participating ACCHSs. The intellectual property rights of ACCHSs will be recognised and preserved. It is also recognized that ACCHSs have rights and responsibilities regarding the use of health-related information for their attending clients. Collaborators on the TORPEDO study will be encouraged to disseminate information from the project in a manner that supports health improvement for Aboriginal and Torres Strait Islander peoples and local benefit to participating ACCHSs.

DISCUSSION

The TORPEDO study will seek to provide reliable evidence about the effectiveness of quality improvement interventions incorporating electronic decision support in Australian primary care settings. The implications of use of such systems for CVD risk management extend well beyond being a point-of-care clinical resource. Improving health system performance is central to the aims of this initiative and this is especially pertinent to addressing Aboriginal health inequities where the CVD burden is five-fold greater. There is potential for substantially better health outcomes from CVD in Australia with improved implementation of existing evidence in primary health care, where most of the opportunity to manage cardiovascular risk occurs. The strategy proposed is the first of its kind in Australia and is strongly aligned with national strategy recommendations for health system reform. If effective, HealthTracker could have widespread applicability for prevention and management of other chronic diseases.

TRIAL REGISTRATION

The trial is registered with the Australian Clinical Trials Registry ACTRN 12611000478910.

Funding

This study is funded by an Australian National Health and Medical Research Council (NHMRC) Project grant (ID 1010547) and NSW Department of Health. DP is supported by a NHMRC Translating Research into Practice Fellowship. AP is supported by an NHMRC Senior Research Fellowship. JR is funded by a Postdoctoral Fellowship co-funded by the NHMRC and National Heart Foundation.

ACKNOWLEDGEMENTS

We gratefully acknowledge the support of the general practices and Aboriginal Community Controlled Health Services involved in this study

- **HealthTracker Steering Committee**

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- **Pen Computer Systems**

- **Improvement Foundation of Australia**

COMPETING INTERESTS

We declare that we have no competing interests

Contributorship

DP, AP and TU developed the original concept of this study. All authors contributed to the study design. DP, KP, BP, MH, TU, JH are involved in the implementation of the project. DP wrote the first draft of the protocol and the final manuscript was reviewed by all the authors.

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FIGURES AND TABLES

• **Table 1: Guidelines used in the HealthTracker algorithm**

Professional Organisation	Guideline
National Vascular Disease Prevention Alliance	Guidelines for the Assessment of Absolute Cardiovascular Disease Risk 2009
National Heart Foundation	Reducing Risk in Heart Disease 2008 Guide to Management of Hypertension 2008- Updated Aug 2009 Aspirin for cardiovascular disease prevention 2003
National Heart Foundation/ Cardiac Society of Australia and New Zealand	The Lipid Position Statement 2005
National Stroke Foundation	Clinical Guidelines for Stroke Management 2010
Royal Australian College of General Practitioners	Guidelines for preventive activities in general practice 2009
Diabetes Australia	Diabetes Management in General Practice 2010/2011 NHMRC Evidence Based Guidelines for Type 2 Diabetes 2009- Case Detection and Diagnosis NHMRC Evidence Based Guidelines for Type 2 Diabetes 2009- Diagnosis, Prevention and Management of Chronic Kidney Disease
Kidney Health Australia	Chronic Kidney Disease Management (CKD) in General Practice 2007
Department of Health and Aging	Schedule of Pharmaceutical Benefits Scheme 2011 General Statement for Lipid Lowering Drugs

Figure 1- HealthTracker user interface

The screenshot displays the HealthTracker application within a medical software environment. The main window shows a patient assessment for Heather Andrews, a 47-year-old female. Key data points include:

- Essential Items:** Smoker (checked), Average Systolic BP: 133 mmHg, Average Diastolic BP: 83 mmHg, Total cholesterol: 6.6 mmol/L, Triglycerides: 2.0 mmol/L, HDL Cholesterol: 0.9 mmol/L, LDL Cholesterol: 3.8 mmol/L.
- Past Medical History:** Left Ventricular Hypertrophy, Cardiovascular Disease, Diabetes, Chronic Kidney Disease.
- Estimated 5 Year Risk:** 9% Low risk, with a color-coded bar from green to red.
- Screening Recommendations:**

Item	Frequency	Next Due
BP	6 monthly	22 Apr 2011
Lipids	2 yearly	16 Jul 2012
Chronic Kidney Disease	12 monthly	22 Oct 2011
Creatinine	12 monthly	01 Jul 2011
Proteinuria	2 yearly	04 Nov 2012
Risk Assessment	2 yearly	04 Nov 2012
Diabetes	-	-
- Treatment Advice:**
 - BP Lowering:** Lifestyle Advice, Medication.
 - Lipid Lowering:** Statin, Fibrate.
 - Blood Thinning:** Anti-platelet, Warfarin.
- Screening Recommendations Table:**

Item	Frequency	Next Due
BP	6 monthly	22 Apr 2011
Lipids	2 yearly	16 Jul 2012
Chronic Kidney Disease	12 monthly	22 Oct 2011
Creatinine	12 monthly	01 Jul 2011
Proteinuria	2 yearly	04 Nov 2012
Risk Assessment	2 yearly	04 Nov 2012
Diabetes	-	-

Callouts provide additional context:

- PrimaryCareSidebar:** Pen Computers Sidebar application automatically extracts data from the primary care health record.
- Health Tracker- CVD:** Health Tracker- CVD screening and management panel.
- Risk of heart attack or stroke:** Risk of heart attack or stroke in the next 5 years.
- Recommended screening tests:** Recommended screening tests based on national guidelines.
- Treatment Advice:** Traffic light treatment recommendations based on national guidelines.
- GP Health Record:** The patients GP health record.
- Risk Factor Information:** Risk factor information extracted from the patient's health record.
- Resource Link:** A resource link providing access to clinical guidelines.

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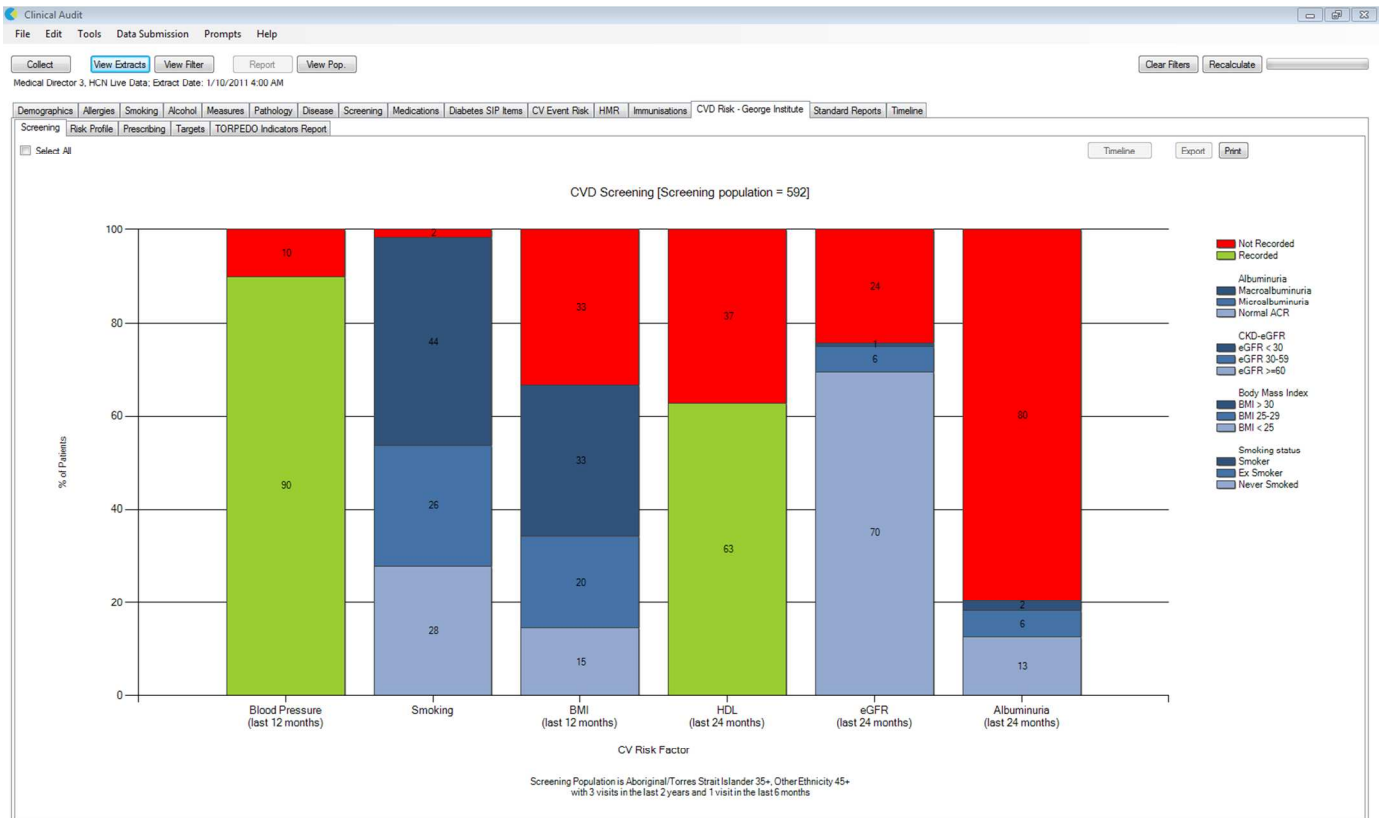
BMJ Open: first published as 10.1136/bmjopen-2012-002177 on 19 November 2012. Downloaded from <http://bmjopen.bmj.com/> on April 19, 2024 by guest. Protected by copyright.

• Figure 2: HealthTracker- CVD risk communication interface



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• Figure 3: Sample output of performance in CVD risk factor screening

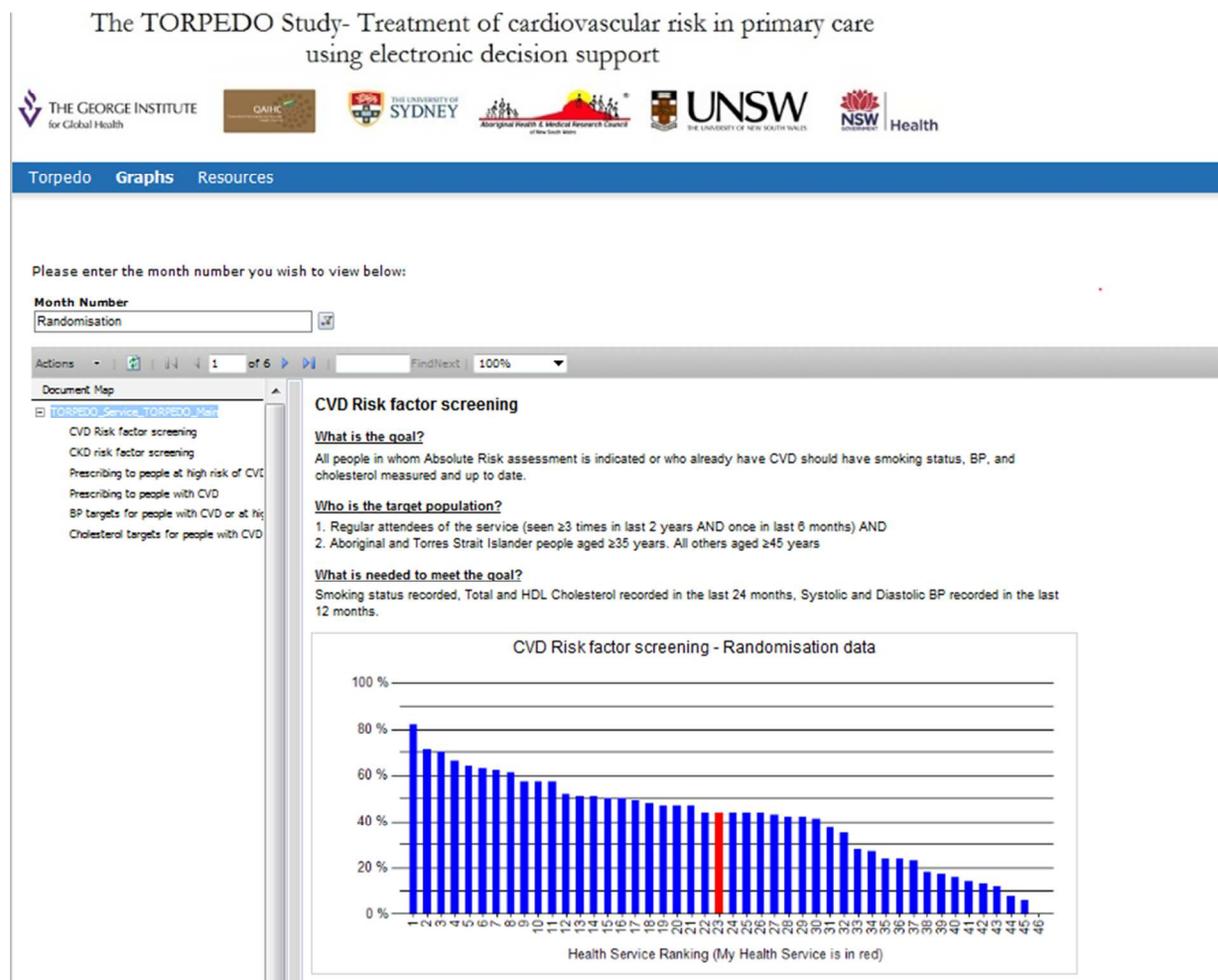


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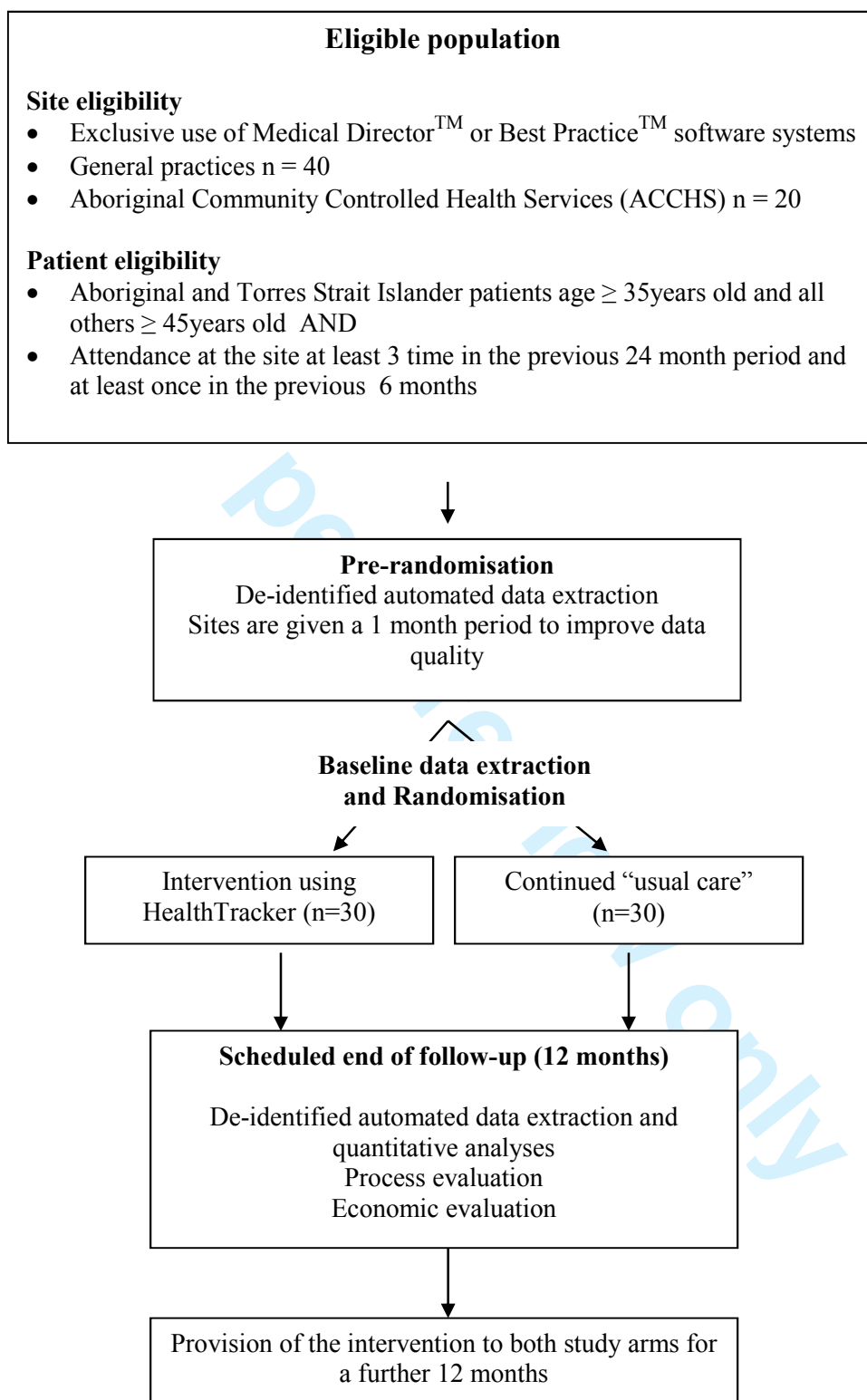
• **Figure 4: Sample display from the Quality Improvement portal**



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• **Figure 5: TORPEDO study schema**



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For peer review only



The Treatment Of cardiovascular Risk in Primary care using Electronic Decision supOrt (TORPEDO) study- protocol for a cluster randomised, controlled trial of an electronic decision support and quality improvement intervention in Australian primary health care

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2012-002177.R1
Article Type:	Protocol
Date Submitted by the Author:	18-Oct-2012
Complete List of Authors:	Peiris, David; The George Institute for Global Health, Usherwood, Tim; University of Sydney, Panaretto, Katie; Queensland Aboriginal and Islander Health Council, Harris, Mark; University of New South Wales, School of Public Health and Community Medicine Hunt, Jenny; Aboriginal Health and Medical Research Council, Patel, Bindu; The George Institute for Global Health, Zwar, Nicholas; University of New South Wales, School of Public Health and Community Medicine Redfern, Julie; George Institute, Cardiovascular Division MacMahon, Stephen; The George Institute for Global Health, Colagiuri, Stephen; University of Sydney, Hayman, Noel; Queensland Health, Inala Indigenous Health Service Patel, Anushka; The George Institute for Global Health,
Primary Subject Heading:	General practice / Family practice
Secondary Subject Heading:	Health informatics
Keywords:	PRIMARY CARE, CARDIOLOGY, Information technology < BIOTECHNOLOGY & BIOINFORMATICS

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TITLE

The Treatment Of cardiovascular Risk in Primary care using Electronic Decision supOrt (TORPEDO) study- intervention development and protocol for a cluster randomised, controlled trial of an electronic decision support and quality improvement intervention in Australian primary health care.

ABSTRACT

Background

Large gaps exist in the implementation of guideline recommendations for cardiovascular disease (CVD) risk management. Electronic decision support (EDS) systems are promising interventions to close these gaps but few have undergone clinical trial evaluation in Australia. We have developed HealthTracker, a multi-faceted electronic decision support and quality improvement intervention to improve the management of CVD risk.

Methods/ design

It is hypothesised that use of HealthTracker over a 12 month period will result in: (1) An increased proportion of patients receiving guidelines-indicated measurements of CVD risk factors; and (2) an increased proportion of patients at high risk will receive guidelines-indicated prescriptions for lowering their CVD risk.

Sixty health services (40 general practices and 20 Aboriginal Community Controlled Health Services (ACCHSs) will be randomised in a 1:1 allocation to receive either the intervention package or continue with usual care, stratified by service type, size and participation in existing quality improvement initiatives. The intervention consists of point of care decision support; a risk communication interface; a clinical audit tool to assess performance on CVD-related indicators; a quality improvement component comprising peer-ranked data feedback and support to develop strategies to improve performance. The control arm will continue with usual care without access to these intervention components. Quantitative data will be derived from cross-sectional samples at baseline and end of study via automated data extraction. Detailed process and economic evaluations will also be conducted.

Ethics and dissemination

The general practice component of the study is approved by the University of Sydney Human Research Ethics Committee (HREC) and the ACCHS component is approved by the Aboriginal Health and Medical Research Council HREC. Formal agreements with each of the participating sites have been signed. In additions to the usual scientific forums, results will be disseminated via newsletters, study website, face to face feedback forums and workshops.

The trial is registered with the Australian Clinical Trials Registry ACTRN 12611000478910.

ARTICLE SUMMARY

• Article focus

This articles outlines:

- The development of a multi-faceted decision support tool and quality improvement intervention
- The methods to test the effectiveness of this intervention in improving guideline recommended screening for cardiovascular risk and management for individuals identified at high risk.

• Key messages

- This study tests a novel intervention that incorporates point of care decision support, risk communication and resources for patients, health service audit tools and use of data for supporting quality improvement initiatives.
- In addition to assessing practitioner performance on indicators correlated with improved health outcomes, the study also includes detailed process and economic evaluations.

• Strengths and limitations of this study

The strengths of the study are that it assesses an innovative complex intervention that is implemented in routine primary health care settings. It will provide rigorous evidence on process, clinical and economic outcomes and addresses an important issue facing health systems worldwide—namely scalable interventions that are able to achieve improvements in performance.

The main limitation is that it is conducted in one country, Australia, and thus its generalisability may be influenced by the prevailing health system context.

BACKGROUND

• CVD burden in Australia

Despite recent gains, cardiovascular disease (CVD) remains Australia's biggest killer accounting for 18% of the total disease burden and 11% of health system expenditure in Australia.¹

Aboriginal and Torres Strait Islander peoples experience around five times greater CVD burden than other Australians.² Current estimates project that by 2030 annual CVD expenditure will rise by around 100% to \$16 billion.³ Primary care based strategies that improve the uptake of best practice recommendations could substantially reduce both the Indigenous and non- Indigenous CVD burden and help improve health system efficiencies.

• Evidence-practice gaps in CVD prevention

In addition to lifestyle modification, a number of drug therapies have been shown to be highly effective in preventing cardiovascular events, primarily through modification of blood pressure, lipids and platelet function.⁴⁻⁸ However, there is compelling evidence of the failure of current clinical practice to adequately implement such treatments, and to translate current knowledge into maximally improved health outcomes. Three recently completed cross-sectional studies of CVD risk management in Australian general practice and Aboriginal Community Controlled Health Service (ACCHS) settings⁹⁻¹¹ demonstrated that 50% of routinely attending adults lacked sufficient recorded information to comprehensively evaluate vascular risk. For those identified at high vascular risk, only around 40% were prescribed guideline-indicated medicines. Similar findings have been noted in other Australian studies.¹²⁻¹⁵ These surveys have demonstrated failure to adequately implement the "absolute risk" paradigm for CVD prevention. Numerous tools are now available to estimate an individual's 5- or 10- year absolute risk of coronary heart disease and/or cardiovascular disease.¹⁶⁻²¹ Despite their availability, only a minority of Australian general practitioners (GPs) use these risk assessment tools, and then primarily for patient education, rather than to guide management decisions.^{9,22,23} Australia's first absolute risk assessment guideline was released in 2009 by the National Vascular Disease Prevention Alliance (NVDPA)¹⁷ and in 2012 this was augmented by a single management guideline.²⁴ Despite these guidelines now becoming available, there remain substantial challenges in effectively implementing their recommendations. We have found that CVD risk assessment and treatment works best when negotiated as part of a shared decision making approach, taking an average of fifteen minutes even where only one guideline needs to be consulted.²⁵

• The role of Electronic Decision Support (EDS) in closing evidence practice gaps

Electronic decision support (EDS) systems are among the most promising interventions to improve uptake of guideline-based recommendations in clinical practice. In five systematic reviews on the effectiveness of EDS, around two-thirds of studies demonstrated improvement in practitioner performance.²⁶⁻³⁰ One systematic review identified four decision support system features associated with improved performance: incorporation in routine work flow, provision at the time and location of patient consultation, use of computer-based tools and provision of treatment recommendations rather than just assessments.²⁸ Of 32 systems that incorporated all of these elements, significant improvements in performance were noted in 30. There are relatively few controlled evaluations of EDS systems that are integrated with electronic health records (EHRs) in the area of CVD.³¹⁻³⁵ Effect sizes vary greatly depending on the variables studied and the type of EDS system. In one systematic review of on-screen point-of-care reminder systems the absolute improvements ranged from 1% to 24% for test ordering and from 3% to 28% for medication prescribing.²⁷ In New Zealand, an EDS system that is fully integrated with the

country's most popular primary care software has been successfully implemented.³⁶ To date, we are unaware of an EDS system aimed at assisting comprehensive cardiovascular risk management based on Australian guidelines. Furthermore, we are not aware of any randomised evaluations of such systems in Australian primary care settings. Globally, few examples exist and the evidence base remains poor.

INTERVENTION DEVELOPMENT

HealthTracker is a novel electronic decision support system to facilitate guidelines-based assessment and management of CVD risk. Outlined below are the key steps taken in development of the intervention.

- **Algorithm development and validation**

A single screening and management algorithm was developed based on a synthesis of recommendations from several primary care screening and management guidelines (Table 1). The algorithm calculates a person's five year absolute CVD risk based on the Framingham risk equation and NVDPA recommendations^{17 20} and provides management recommendations based on the guidelines listed in Table 1. In 2008-9 a beta version of HealthTracker was developed in a stand-alone software system and independently validated for accuracy and compliance with the prevailing guidelines.²² In 2011 the algorithm was extensively revised to incorporate recommendations from newly published guidelines. A similar validation process was then conducted consisting of three levels:

Level 1 was an iterative process where each of the calculations programmed in the algorithm were tested to ensure they were consistent with recommendations from the guidelines. This was conducted using de-identified data from 337 patients involved in the pilot. Programming modifications were made where necessary and all variables were re-tested to ensure they were programmed correctly.

Level 2 involved giving a plain language summary of the algorithm to a research fellow who had not been involved in the development of the algorithm. She independently programmed the algorithm into a statistical software package. Using data from 9,077 patients from three representative cross sectional general practice surveys,⁹⁻¹¹ we then assessed whether the outputs from HealthTracker correlated with those generated from the independently programmed version. For 60 of the 63 output variables HealthTracker achieved perfect correlation with the independently programmed version. For the remaining three variables minor programming errors were identified and corrected.

Level 3 involved user acceptance testing and scrutiny of the algorithm by the study investigators, twenty health professionals working in both General Practice and ACCHSs, and three national professional organisations- the NVDPA, the Royal Australian College of General Practitioners and the National Prescribing Service. Following this feedback, a number of minor algorithm and user interface changes were incorporated into the final version of the tool. The Level 2 testing process was repeated following these changes and perfect correlation between HealthTracker and the independently programmed version was achieved for all variables.

- **Integration of HealthTracker with the primary care electronic health record and quality improvement tools**

HealthTracker interfaces with the two Australian clinical practice software systems most commonly used in General Practice and ACCHS settings (Medical Director™ and Best Practice™). There are four components to the system:

- **Point of care decision support:** HealthTracker is built in the Pen Computer Systems PrimaryCareSidebar™, third party software that interacts with the primary EHR system. Figure 1 shows the HealthTracker user interface and its integration with the PrimaryCareSidebar™ and the EHR. A prompt function is used to encourage health professionals to conduct a cardiovascular assessment if guideline recommended. Where possible, the tool populates with information from the patient's record. If essential information required for the calculation of absolute risk is missing or out-of-date, a traffic light prompt alerts the health professional and updated information can be entered. If the patient is receiving sub-optimal treatment then a traffic light recommendation is made to consider initiation of treatment or additional agents. Information about eligibility for the Australia Government Pharmaceutical Benefits Scheme subsidy is provided if lipid lowering medicines are recommended. All outputs are qualified by statements emphasising that the final decision to commence or change therapy should be made by the health professional based on all available information.
- **A patient oriented risk communication interface.** A key finding from the pilot evaluation was the role of the output in risk communication. GPs wanted to interactively alter current risk factors and perform 'what if' scenarios to demonstrate to patients the effects of current and altered risk over time. This functionality has been built into HealthTracker and uses the concept of "Heart Age" to demonstrate to patients the discrepancy between current risk and an ideal risk based on well controlled risk factor levels. Figure 2 shows an example of how a patient's heart age changes with the effect of smoking cessation.
- **A data extraction tool.** This will provide health professionals with immediate feedback on their performance on screening and management of CVD risk for their entire patient population. Figure 3 shows an example of screening performance for a range of CVD risk factors. Practitioners can use this tool to identify specific patients in whom there may be a particular risk factor measurement missing or a potential prescribing gap. Customised point of care prompts can then be created. When a patient record is opened an alert is provided to notify the practitioner of the particular management issue and this can then be actioned.
- **A quality improvement (QI) component** has been developed which is aligned with the methods of the Improvement Foundation of Australia (IFA) Australian Primary Care Collaboratives (APCC) program. De-identified data extracts of clinical performance are securely exported to a web-based central repository managed by the IFA. This repository provides access to site-specific feedback reports on performance compared with other anonymised sites. Figure 4 shows an example of how this information is presented.

STUDY OBJECTIVES

The TORPEDO study will test HealthTracker's performance in assisting health professionals and patients in making evidence based management decisions to help prevent heart attack, stroke and related conditions.

Hypotheses:

Using a cluster randomised, controlled trial design, two specific hypotheses will be tested. Compared with control practices, those practices randomised to receive HealthTracker will have:

- (1) An increased proportion of patients receiving appropriate (guidelines-indicated) measurements of their CVD risk factors.
- (2) An increased proportion of patients at high risk receiving appropriate (guidelines-indicated) prescriptions for management of their CVD risk.

These aims will be augmented by formal economic and process evaluations to provide crucial information on large-scale implementation and sustainability.

STUDY DESIGN

HealthTracker will be evaluated using a cluster randomised, controlled trial design. At end of study, HealthTracker will be made available to both the intervention and control arms for a further 12 months free of any license fees. The study schema including site and patient eligibility criteria are highlighted in Figure 5.

• **Eligibility criteria**

Health Service

1. Use of Medical Director™ or Best Practice™ for EHR management.
2. Exclusive use of these systems to record risk factor information, pathology test results and prescribe medications.
3. Agreement by all GPs and other designated staff to use HealthTracker.

Services that do not have a compliant software system will be excluded from participation. Services using 'hybrid' paper and electronic systems for recording risk factor information, pathology results and medication prescription will also not be eligible to participate.

Patients

1. Aboriginal and Torres Strait Islander people 35+ years and all others 45+ years (age criteria are based on NVDPA guideline screening recommendations³⁷), and
2. Attendance at the general practice or ACCHS at least 3 times in the previous 24 month period AND at least once in the previous 6 month period.

Site recruitment

Participating general practices have been recruited from the Sydney region in collaboration with primary health care organisations known in Australia as Medicare Locals. Participating ACCHSs

1
2 have been recruited in partnership with two state representative bodies for ACCHSs, the
3 Aboriginal Health & Medical Research Council (AH&MRC) of NSW and the Queensland and
4 Aboriginal Islander Health Council (QAIHC). A \$500AUD reimbursement to participating sites
5 will be made to partially compensate for health service staff time commitment to study-related
6 activities. Sites randomised to the intervention will receive training support in use of the system
7 predominantly via face to face visits and webinars. All license costs and technical support
8 associated with the intervention will be provided free to the intervention sites in the first 12
9 months and to all sites for the following 12 months after completion of the trial. A newsletter and
10 networking web site will be provided to participating sites. Royal Australian College of General
11 Practitioners Quality Assurance and Continuing Professional Development points will be offered
12 to participating GPs in both arms of the trial.
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15 16 17 • **Randomisation**

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19 Sixty services (40 general practices and 20 ACCHSs) will be randomised in a 1:1 allocation to
20 use HealthTracker or 'usual care' for twelve months. Clusters will be stratified at three levels-

- 21 1. ACCHS vs. general practices
- 22 2. Service size (<500 patients meeting eligibility criteria vs. >=500)
- 23 3. Participation in existing quality improvement programs (current involvement in one of
24 five national and state programs involving regular audit and feedback vs. past or never
25 involved in these programs)
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28 A site assessment survey will be administered to all sites to assess for service eligibility and
29 these stratifying variables. Permuted block randomisation will be centrally performed using a
30 web-based form. As this is a pragmatic trial, allocation will be single blinded with outcome
31 analyses conducted blinded to treatment allocation.
32
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34 ***Intervention group***

35 The intervention arm will receive the four components of the system described above (point of
36 care decision support software, risk communication tools, data extraction tools, and access to the
37 quality improvement portal). Clinical staff will be given training in use of the tools and a support
38 service will be available for any technical queries. One initial face to face training visit and
39 subsequent site visits and webinars targeting strategies to improve quality of care will be
40 provided. Unless requested by health services the intervention will not be modified or
41 discontinued. Reasons for discontinuation will be outlined and all analyses will be conducted on
42 an intention to treat basis (see below).
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46 ***Control group***

47 Sites allocated to this arm will continue usual practice with their current systems without
48 implementation of HealthTracker. As the George Institute holds exclusive rights to the
49 distribution of the system, there is no possibility of control sites having access to HealthTracker.
50 If these sites already routinely use data extraction tools for assessing their quality of care then
51 this will continue as normal. As with the intervention arm, services participating in any quality
52 improvement initiatives will continue participation as usual. For those sites not routinely using
53 data extraction tools, the automated data extraction tool will be temporarily installed for data
54 collection purposes only and then uninstalled that same day. A feedback report on performance
55 will be provided at study completion only.
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Quantitative data collection (Figure 5)

Cross-sectional data will be collected in an automated manner for all patients who satisfy the eligibility criteria at each service. These data will then be sent securely to the George Institute via an export function for analysis of primary and secondary outcomes.

Pre-randomisation: 1 month prior to randomisation, de-identified data will be collected from all sites. These data will be fed back to all sites as a formal report highlighting areas where data quality issues may be occurring.

Randomisation: Baseline data will be collected and sites will be randomised to intervention or control.

End of intervention period: At the end of 12 months, data will be collected in both study arms.

• Primary Outcomes

- Change in the proportion of eligible patients receiving appropriate measurements of their CVD risk in the previous 12 months (measured at randomisation and at 12 months).
- Change in the proportion of eligible patients assessed at high CVD risk receiving appropriate prescriptions for their CVD risk factors in the previous 12 months (measured at randomisation and 12 months).

Appropriate measurement of CVD risk factors is defined as having recorded or updated *all* the essential risk factors for measurement of CVD risk (smoking status, blood pressure (BP) in the previous 12 months, total cholesterol and High Density Lipoprotein (HDL) cholesterol in the previous 24 months) among those in whom risk assessment is guideline-indicated. Unless explicitly recorded, diagnoses of diabetes or left ventricular hypertrophy will be assumed to be absent.

High CVD risk is defined as a calculated 5-year CVD risk of >15%, a history of CVD or the presence of any clinically high risk conditions (as per NVDPA recommendations). Based on audit data this is expected to comprise ~30% of the patient population.^{10 11}

Appropriate prescriptions is defined as a prescription for one or more BP lowering drug *and* a statin for people at high risk without CVD; or a prescription for one or more BP lowering drug *and* a statin *and* an antiplatelet agent (unless contraindicated by oral anticoagulant use) for people with established CVD.

• Secondary Outcomes

- Change in measurement of individual risk factors separately (smoking status, BP, cholesterol, other non-Framingham risk factors- BMI, Chronic Kidney Disease (CKD) screening with urinary Albumin to Creatinine ratio, estimated Glomerular Filtration Rate);
- Intensification of existing medication regimes among patients at high CVD risk (. additional BP and lipid lowering agents)
- Changes in mean systolic BP, total cholesterol, LDL cholesterol, HDL cholesterol
- New CVD and CKD diagnoses

• Statistical Considerations

Randomisation of 60 services (30 per arm) will provide 90% power to detect a $\geq 10\%$ absolute higher occurrence in each primary study outcome among practices receiving HealthTracker. The following assumptions are based on our three audits in ACCHSs and mainstream general practices⁹⁻¹¹ and include an assumed improvement of 10% in the two primary outcomes in control practices as a result of study participation.

1. Cluster size of eligible population will range from 200 in a small service through to 2000 in a large service. An average cluster size of 750 is assumed.
2. Recording rates of essential risk factors needed for risk assessment in the target group (first primary outcome) average 50%.^{10 11}
3. 30% of the cluster will be either be at high CVD risk or have established CVD (n=250) and prescription of appropriate medicines to high-risk patients (second primary outcome) is 50%. This is based on our published data on drug prescriptions for individuals with and without established CVD.⁹⁻¹¹
4. An intra-class correlation coefficient of 0.05 for both primary outcomes. based on our audit data⁹⁻¹¹
5. Two-sided alpha = 0.05

Data analysis will be performed on an intention-to-treat basis using generalised estimating equations.³⁸ Subgroup analyses will be carried out using the three pre-specified strata: (1) ACCHS vs. general practices, (2) service size (small vs. large) and (3) current participation in quality improvement programs vs. past or no involvement in these programs.

• Economic evaluation

The economic evaluation will have a trial-based component and a modeled evaluation of long term costs and outcomes. The incremental cost will be based on software, training and other costs incurred with transitioning practices to using HealthTracker. This will help determine the cost barriers experienced by different practices in adopting the system. Data on medications, laboratory tests, consultations and newly recorded diagnoses of CVD events incurred by eligible patients during the trial will be obtained from the data extraction tools. Costs will be calculated from prevailing Medicare rates and standard Australian National Diagnosis Related Groups cost weights for CVD hospitalisations. The incremental cost consequences of the HealthTracker system in achieving each of the primary outcomes will then be estimated e.g. cost per eligible patients assessed at high CVD risk receiving appropriate prescriptions. Trial-based data, however, cannot capture costs and outcomes beyond the trial. To address this, *a modeled economic evaluation* will enable quality of life and survival to be examined and allow incremental cost-effectiveness ratios to be calculated in terms of cost per Quality Adjusted Life Years gained. Using a Markov model, the eligible patient population in both study arms will be hypothetically tracked over an extended period. Transition between various defined health states, costs and quality of life attached to various health states and the projected long term intervention effects from that observed in the trial will be based on published evidence. With appropriate discounting, estimates of long-term costs and outcomes will fold out of the model. Sensitivity analyses will be conducted on discount rate, uncertainty in outcome estimates and assumptions made in costing (e.g. varying efficiencies with different patient practice ratios to those of the trial

1
2 setting). This will better inform policy makers as to the resource consequences of rolling out this
3 program to scale.
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6 • **Process evaluation**

7 The qualitative evaluation of the beta-version of HealthTracker suggested that a critical factor
8 affecting the uptake of EDS interventions is whether and how they become embedded in routine
9 health care²². In the TORPEDO trial we will build on this observation through a detailed process
10 evaluation to better appreciate the factors that might influence sustainability beyond the trial
11 setting. Two qualitative methods will be utilised to explore these factors.
12

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14 **Semi-structured interviews with health professionals and staff.** A maximum variation
15 sample will be taken to ensure diverse opinions are gained from patients, clinical and managerial
16 health staff and sites with low and high uptake of the intervention.³⁹ Key issues to be explored
17 will include (1) how practitioners use HealthTracker; (2) what effects it has on organisational
18 practices and personnel; and (3) what are patients' experiences of being presented with
19 HealthTracker outputs and what impact does this have on the healthcare encounter. Individual
20 informed consent will be sought and data will be collected toward the end of the intervention
21 period so as not to unduly influence trial outcomes.
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25 **Audio/ video ethnography.** A key component of understanding barriers/enablers to use of
26 HealthTracker is a better appreciation of how practitioners and patients use it at the point of care.
27 Data collection using audio/video recording will capture how technological innovations are
28 actually used in practice.⁴⁰ Ethnographic analysis will greatly augment the interview accounts
29 and will particularly shed important light on (1) how the intervention impacts on the flow of the
30 clinical encounter; (2) how risk information is communicated between health professional and
31 patient; and (3) how the patient receives and interprets the information and the role it may play in
32 shared decision making processes. Although audio/video recorded clinical encounters are
33 commonly used for primary care teaching purposes, such a technique can be potentially sensitive
34 and therefore will be restricted to a small number of sites. Recordings will be conducted toward
35 the end of the intervention period when both health staff and patients are thoroughly familiar
36 with the system. This will occur over a one week period at each site. Participants who are
37 approached for an interview will be invited to participate in this component. They will be given
38 the option of having their healthcare encounter audio or video recorded. A follow-up interview
39 will be arranged with these participants (both staff and patients) where the recording is played
40 back for participant interpretation of the data.
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45 These data will be supplemented by project officer field notes to identify any key processes,
46 events, staffing and other resource issues occurring during the intervention period that may be
47 relevant in gaining a better understanding of barriers and facilitators to implementation.
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49 A multidisciplinary research team will guide the analysis process. As is common with qualitative
50 inquiry, data analysis will commence early and be conducted contemporaneously with data
51 collection. This method allows for interview content to be refined for subsequent data collection
52 and to actively pursue emergent themes of interest. Although interviewing will continue until
53 thematic saturation is achieved and therefore the exact number of interviews is unknown, we
54 anticipate from prior experience that around 80 interviews (40 patients and 40 staff) will provide
55 sufficiently rich data to meet our objectives.
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2 Interview data will be digitally recorded, and professionally transcribed. NVivo 9 (QSR
3 International Melbourne, Vic) will be used to assist with data organization and coding for key
4 themes. Video data will be directly analysed and coded for key themes within NVivo. Feedback
5 of findings to participants will be provided by a variety of methods, including workshops,
6 summary reports, newsletters and via the study website.
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9 **ETHICAL CONSIDERATIONS**

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11 The General Practice component of the study is approved by the University of Sydney Human
12 Research Ethics Committee (HREC) and the ACCHS component is approved by the Aboriginal
13 Health and Medical Research Council HREC. Formal agreements with each of the participating
14 sites have also been signed. Quantitative data will be obtained from de-identified clinical audits.
15 Ethical approval to grant waiver of the usual requirement to obtain individual patient consent has
16 been obtained. In participating ACCHS sites, eligible patients can request to 'opt out' from
17 having data in the clinical audit data extracts exported. Data exports will be compliant with
18 privacy legislation, centrally managed by the George Institute and held in strict confidence.
19 Some individual health professionals (GPs, practice nurses, etc) and patient participants will
20 have their informed consent taken at the site to allow data collection through semi-structured in-
21 depth interviews and/or the use of audio/videotaped healthcare encounters. Participation in this
22 component will be optional. Patient Information Statements and Consent Forms have been
23 approved by each ethics committee and formatted in accordance with their own guidelines and
24 requirements.
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29 The study will be conducted in accordance with the principles set out in the National Health and
30 Medical Research Council and the NSW Aboriginal Health and Medical Research Council
31 guidelines. Specific effort will be taken to respect the autonomy and governance of participating
32 ACCHSs. The intellectual property rights of ACCHSs will be recognised and preserved. It is
33 also recognized that ACCHSs have rights and responsibilities regarding the use of health-related
34 information for their attending clients. Collaborators on the TORPEDO study will be encouraged
35 to disseminate information from the project in a manner that supports health improvement for
36 Aboriginal and Torres Strait Islander peoples and local benefit to participating ACCHSs.
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40 **DISCUSSION**

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42 The TORPEDO study will seek to provide reliable evidence about the effectiveness of quality
43 improvement interventions incorporating electronic decision support in Australian primary care
44 settings. The implications of use of such systems for CVD risk management extend well beyond
45 being a point-of-care clinical resource. Improving health system performance is central to the
46 aims of this initiative and this is especially pertinent to addressing Aboriginal health inequities
47 where the CVD burden is five-fold greater. There is potential for substantially better health
48 outcomes from CVD in Australia with improved implementation of existing evidence in primary
49 health care, where most of the opportunity to manage cardiovascular risk occurs. The strategy
50 proposed is the first of its kind in Australia and is strongly aligned with national strategy
51 recommendations for health system reform. If effective, HealthTracker could have widespread
52 applicability for prevention and management of other chronic diseases.
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56 **TRIAL REGISTRATION**

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58 The trial is registered with the Australian Clinical Trials Registry ACTRN 12611000478910.
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For peer review only

FUNDING

This study is funded by an Australian National Health and Medical Research Council (NHMRC) Project grant (ID 1010547) and NSW Department of Health. DP is supported by a NHMRC Translating Research into Practice Fellowship. AP is supported by an NHMRC Senior Research Fellowship. JR is funded by a Postdoctoral Fellowship co-funded by the NHMRC and National Heart Foundation.

ACKNOWLEDGEMENTS

We gratefully acknowledge the support of the general practices and Aboriginal Community Controlled Health Services involved in this study. We also acknowledge the support of the Queensland Aboriginal and Islander Health Council, Aboriginal Health and Medical Research Council, Western Sydney Medicare Local, Inner West Sydney Medicare Local, and Nepean-Blue Mountains Medicare Local.

- **HealthTracker Steering Committee:** David Peiris (Co-Chair), Anushka Patel (Co-Chair), Mark Harris, Tim Usherwood, Nicholas Zwar, Katie Panaretto, Jenny Hunt, Stephen Colagiuri, Stephen McMahon, Rod Jackson, Bruce Neal, David Sullivan, Fiona Turnbull, Alan Cass, Noel Hayman, Alex Brown, Jessica Stewart, Bindu Patel
- **TORPEDO Study Project Staff:** Marilyn Lyford, Maria Agaliotis, Sharon Parker, Lyn Anderson, Melvina Mitchell, Chris Henaway, Catriona McDonnell, Olly Shestowsky
- Pen Computer Systems for their support in developing the HealthTracker software and the data extraction tool
- Improvement Foundation of Australia for their support in developing and hosting the quality improvement portal

COMPETING INTERESTS

We declare that we have no competing interests

EXCLUSIVE LICENSE

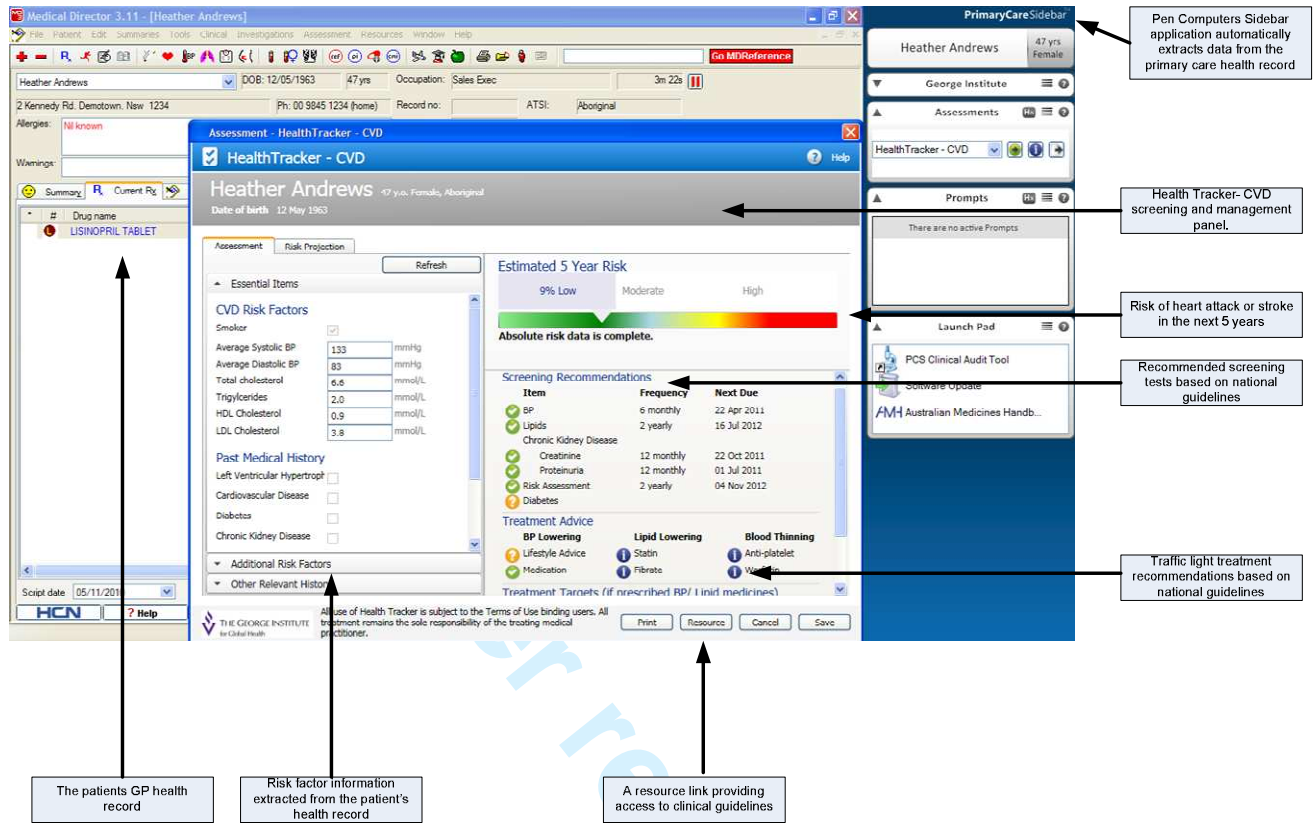
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FIGURES AND TABLES

- **Table 1: Guidelines used in the HealthTracker algorithm**

Professional Organisation	Guideline
National Vascular Disease Prevention Alliance	Guidelines for the Assessment of Absolute Cardiovascular Disease Risk 2009
National Heart Foundation	Reducing Risk in Heart Disease 2008 Guide to Management of Hypertension 2008- Updated Aug 2009 Aspirin for cardiovascular disease prevention 2003
National Heart Foundation/ Cardiac Society of Australia and New Zealand	The Lipid Position Statement 2005
National Stroke Foundation	Clinical Guidelines for Stroke Management 2010
Royal Australian College of General Practitioners	Guidelines for preventive activities in general practice 2009
Diabetes Australia	Diabetes Management in General Practice 2010/2011 NHMRC Evidence Based Guidelines for Type 2 Diabetes 2009- Case Detection and Diagnosis NHMRC Evidence Based Guidelines for Type 2 Diabetes 2009- Diagnosis, Prevention and Management of Chronic Kidney Disease
Kidney Health Australia	Chronic Kidney Disease Management (CKD) in General Practice 2007
Department of Health and Aging	Schedule of Pharmaceutical Benefits Scheme 2011 General Statement for Lipid Lowering Drugs

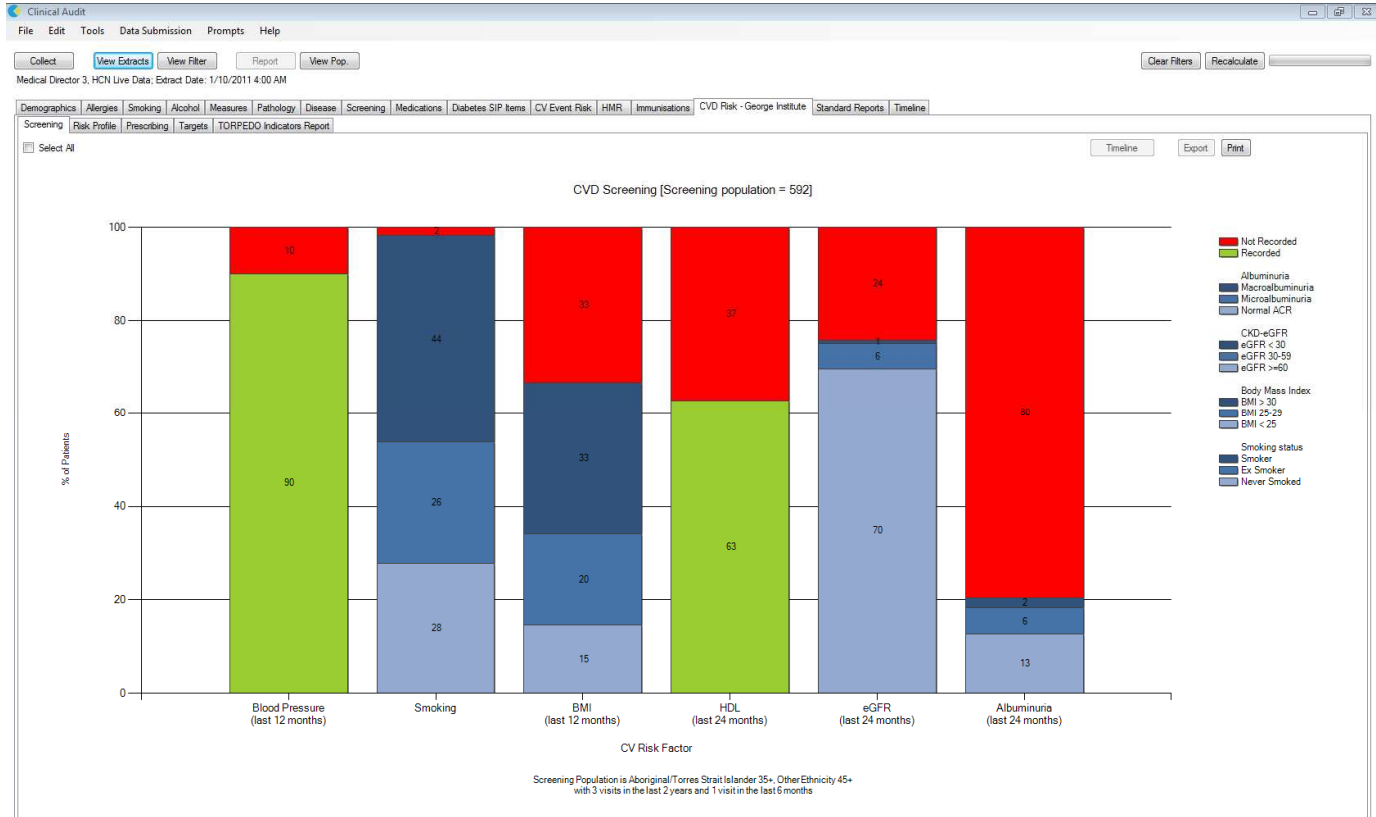
Figure 1- HealthTracker user interface



• **Figure 2: HealthTracker- CVD risk communication interface**

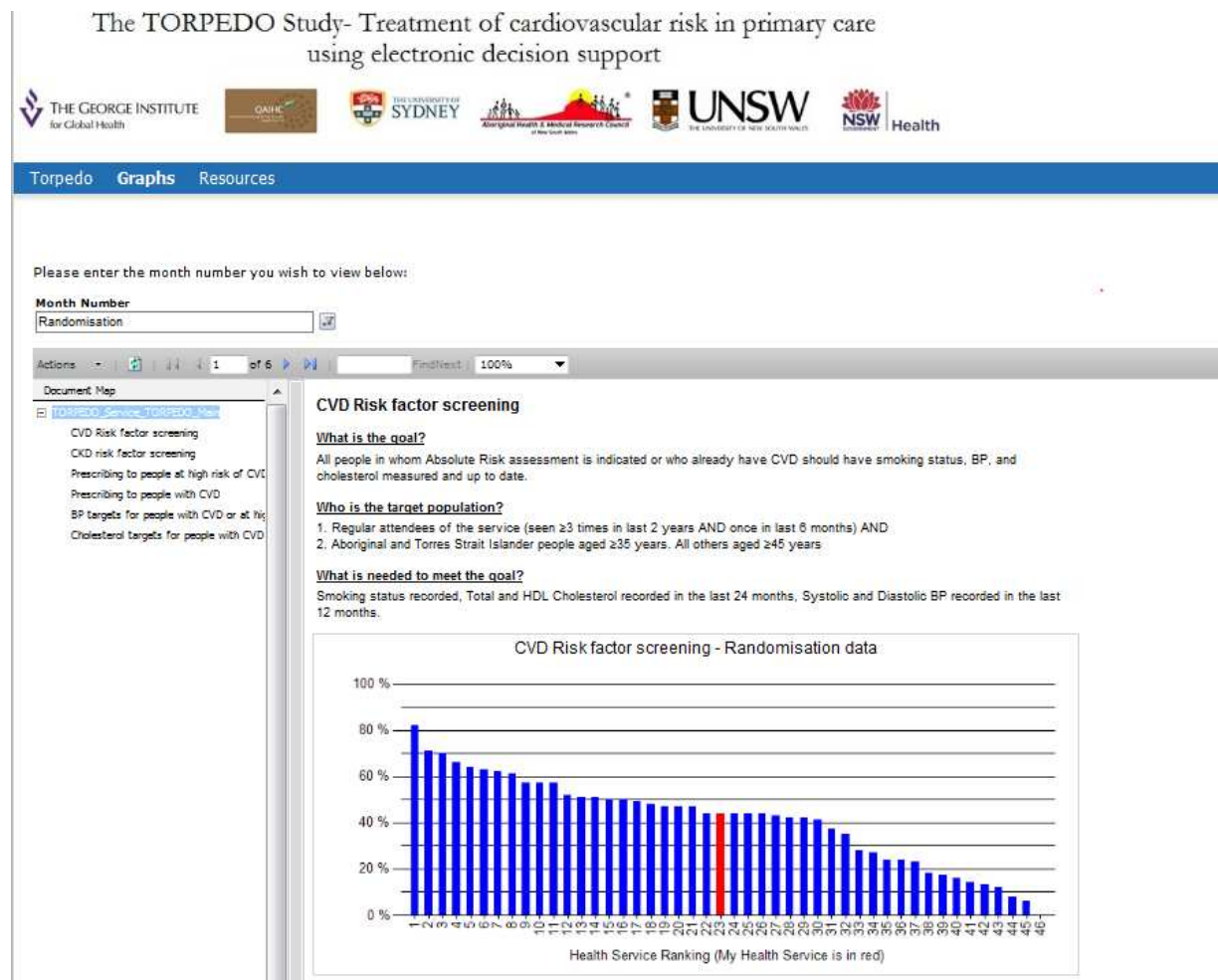


• **Figure 3: Sample output of performance in CVD risk factor screening**



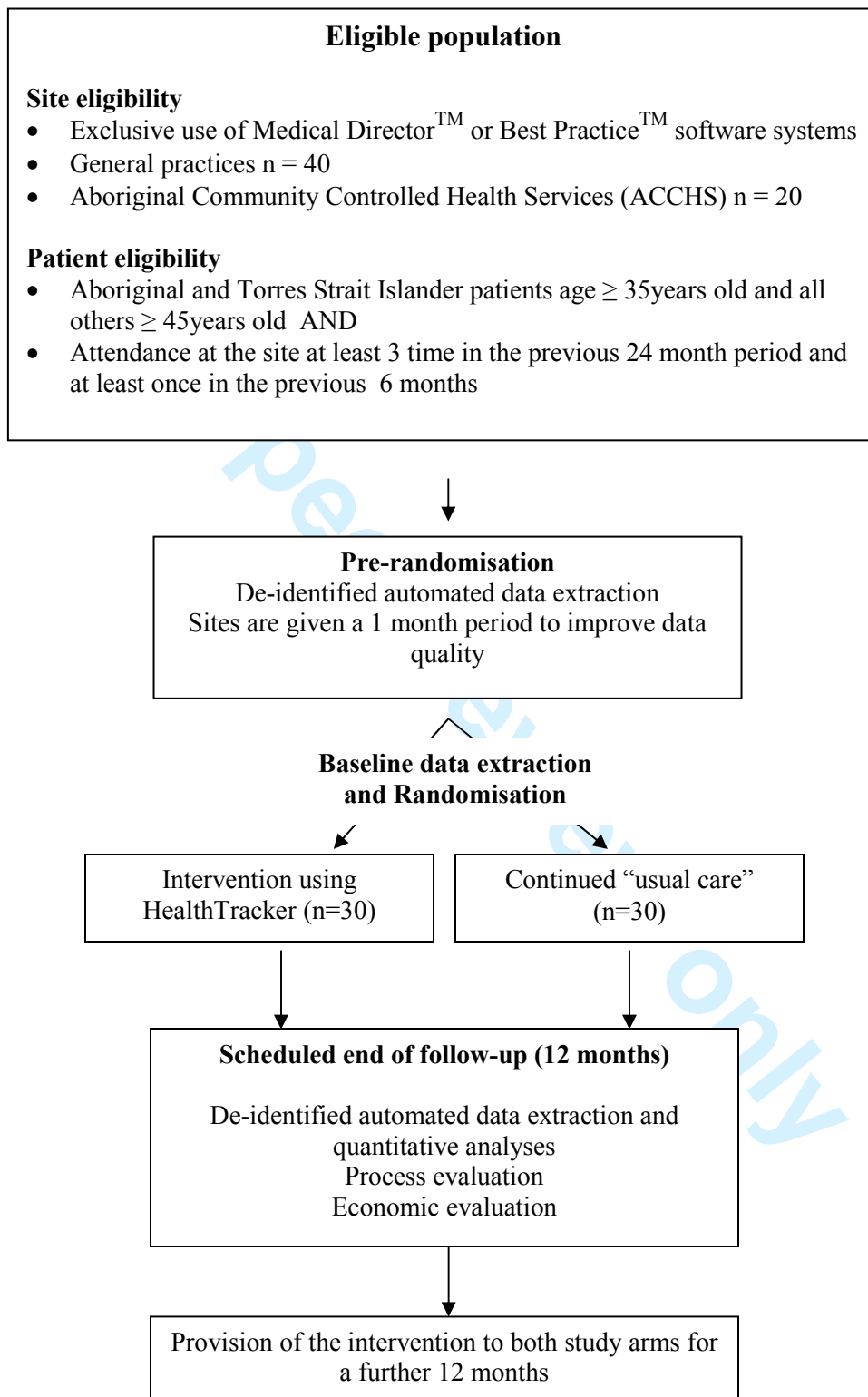
view only

• **Figure 4: Sample display from the Quality Improvement portal**



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• **Figure 5: TORPEDO study schema**



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TITLE

The Treatment Of cardiovascular Risk in Primary care using Electronic Decision supOrt (TORPEDO) study- [intervention development and](#) protocol for a cluster randomised, controlled trial of an electronic decision support and quality improvement intervention in Australian primary health care.

ABSTRACT

Background

Large gaps exist in the implementation of guideline recommendations for cardiovascular disease (CVD) risk management. Electronic decision support (EDS) systems are promising interventions to close these gaps but few have undergone clinical trial evaluation in Australia. We have developed HealthTracker, a multi-faceted electronic decision support and quality improvement intervention to improve the management of CVD risk.

Methods/ design

It is hypothesised that use of HealthTracker over a 12 month period will result in: (1) An increased proportion of patients receiving guidelines-indicated measurements of CVD risk factors; and (2) an increased proportion of patients at high risk will receive guidelines-indicated prescriptions for lowering their CVD risk.

Sixty health services (40 general practices and 20 Aboriginal Community Controlled Health Services (ACCHSs)) will be randomised in a 1:1 allocation to receive either the intervention package or continue with usual care, stratified by service type, size and participation in existing quality improvement initiatives. The intervention consists of point of care decision support; a risk communication interface; a clinical audit tool to assess performance on CVD-related indicators; a quality improvement component comprising peer-ranked data feedback and support to develop strategies to improve performance. The control arm will continue with usual care without access to these intervention components. Quantitative data will be derived from cross-sectional samples at baseline and end of study via automated data extraction. Detailed process and economic evaluations will also be conducted.

Ethics and dissemination

The general practice component of the study is approved by the University of Sydney Human Research Ethics Committee (HREC) and the ACCHS component is approved by the Aboriginal Health and Medical Research Council HREC. Formal agreements with each of the participating sites have been signed. In additions to the usual scientific forums, results will be disseminated via newsletters, study website, face to face feedback forums and workshops.

[The trial is registered with the Australian Clinical Trials Registry ACTRN 12611000478910.](#)

ARTICLE SUMMARY

• Article focus

This articles outlines:

- The development of a multi-faceted decision support tool and quality improvement intervention
- The methods to test the effectiveness of this intervention in improving guideline recommended screening for cardiovascular risk and management for individuals identified at high risk.

• Key messages

- This study tests a novel intervention that incorporates point of care decision support, risk communication and resources for patients, health service audit tools and use of data for supporting quality improvement initiatives.
- In addition to assessing practitioner performance on indicators correlated with improved health outcomes, the study also includes detailed process and economic evaluations.

• Strengths and limitations of this study

The strengths of the study are that it assesses an innovative complex intervention that is implemented in routine primary health care settings. It will provide rigorous evidence on process, clinical and economic outcomes and addresses an important issue facing health systems worldwide—namely scalable interventions that are able to achieve improvements in performance.

The main limitation is that it is conducted in one country, Australia, and thus its generalisability may be influenced by the prevailing health system context.

BACKGROUND

• CVD burden in Australia

Despite recent gains, cardiovascular disease (CVD) remains Australia's biggest killer accounting for 18% of the total disease burden and 11% of health system expenditure in Australia.¹ Aboriginal and Torres Strait Islander peoples experience around five times greater CVD burden than other Australians.² Current estimates project that by 2030 annual CVD expenditure will rise by around 100% to \$16 billion.³ Primary care based strategies that improve the uptake of best practice recommendations could substantially reduce both the Indigenous and non- Indigenous CVD burden and help improve health system efficiencies.

• Evidence-practice gaps in CVD prevention

In addition to lifestyle modification, a number of drug therapies have been shown to be highly effective in preventing cardiovascular events, primarily through modification of blood pressure, lipids and platelet function.⁴⁻⁸ However, there is compelling evidence of the failure of current clinical practice to adequately implement such treatments, and to translate current knowledge into maximally improved health outcomes. Three recently completed cross-sectional studies of CVD risk management in Australian general practice and Aboriginal Community Controlled Health Service (ACCHS) settings⁹⁻¹¹ demonstrated that 50% of routinely attending adults lacked sufficient recorded information to comprehensively evaluate vascular risk. For those identified at high vascular risk, only around 40% were prescribed guideline-indicated medicines. Similar findings have been noted in other Australian studies.¹²⁻¹⁵ These surveys have demonstrated failure to adequately implement the "absolute risk" paradigm for CVD prevention. Numerous tools are now available to estimate an individual's 5- or 10- year absolute risk of coronary heart disease and/or cardiovascular disease.¹⁶⁻²¹ Despite their availability, only a minority of Australian general practitioners (GPs) use these risk assessment tools, and then primarily for patient education, rather than to guide management decisions.^{9,22,23} Australia's first absolute risk assessment guideline was released in 2009 by the National Vascular Disease Prevention Alliance (NVDPA)¹⁷ and in 2012 this was augmented by a single management guideline.²⁴ Despite these guidelines now becoming available, there remain substantial challenges in effectively implementing their recommendations. We have found that CVD risk assessment and treatment works best when negotiated as part of a shared decision making approach, taking an average of fifteen minutes even where only one guideline needs to be consulted.²⁵

• The role of Electronic Decision Support (EDS) in closing evidence practice gaps

Electronic decision support (EDS) systems are among the most promising interventions to improve uptake of guideline-based recommendations in clinical practice. In five systematic reviews on the effectiveness of EDS, around two-thirds of studies demonstrated improvement in practitioner performance.²⁶⁻³⁰ One systematic review identified four decision support system features associated with improved performance: incorporation in routine work flow, provision at the time and location of patient consultation, use of computer-based tools and provision of treatment recommendations rather than just assessments.²⁸ Of 32 systems that incorporated all of these elements, significant improvements in performance were noted in 30. There are relatively few controlled evaluations of EDS systems that are integrated with electronic health records (EHRs) in the area of CVD.³¹⁻³⁵ Effect sizes vary greatly depending on the variables studied and the type of EDS system. In one systematic review of on-screen point-of-care reminder systems the absolute improvements ranged from 1% to 24% for test ordering and from 3% to 28% for medication prescribing.²⁷ In New Zealand, an EDS system that is fully integrated with the

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8 country's most popular primary care software has been successfully implemented.³⁶ To date, we
9 are unaware of an EDS system aimed at assisting comprehensive cardiovascular risk
10 management based on Australian guidelines. Furthermore, we are not aware of any randomised
11 evaluations of such systems in Australian primary care settings. Globally, few examples exist
12 and the evidence base remains poor.

13 INTERVENTION DEVELOPMENT

14 HealthTracker is a novel electronic decision support system to facilitate guidelines-based
15 assessment and management of CVD risk. Outlined below are the key steps taken in
16 development of the intervention.

17 • Algorithm development and validation

18 A single screening and management algorithm was developed based on a synthesis of
19 recommendations from several primary care screening and management guidelines (Table 1).
20 The algorithm calculates a person's five year absolute CVD risk based on the Framingham risk
21 equation and NVDPA recommendations^{17 20} and provides management recommendations based
22 on the guidelines listed in Table 1. In 2008-9 a beta version of HealthTracker was developed in a
23 stand-alone software system and independently validated for accuracy and compliance with the
24 prevailing guidelines.²² In 2011 the algorithm was extensively revised to incorporate
25 recommendations from newly published guidelines. A similar validation process was then
26 conducted consisting of three levels:

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29 **Level 1** was an iterative process where each of the calculations programmed in the algorithm
30 were tested to ensure they were consistent with recommendations from the guidelines. This was
31 conducted using de-identified data from 337 patients involved in the pilot. Programming
32 modifications were made where necessary and all variables were re-tested to ensure they were
33 programmed correctly.

34
35 **Level 2** involved giving a plain language summary of the algorithm to a research fellow who had
36 not been involved in the development of the algorithm. She independently programmed the
37 algorithm into a statistical software package. Using data from 9,077 patients from three
38 representative cross sectional general practice surveys,⁹⁻¹¹ we then assessed whether the outputs
39 from HealthTracker correlated with those generated from the independently programmed
40 version. For 60 of the 63 output variables HealthTracker achieved perfect correlation with the
41 independently programmed version. For the remaining three variables minor programming errors
42 were identified and corrected.

43
44 **Level 3** involved user acceptance testing and scrutiny of the algorithm by the study investigators,
45 twenty health professionals working in both General Practice and ACCHSs, and three national
46 professional organisations- the NVDPA, the Royal Australian College of General Practitioners
47 and the National Prescribing Service. Following this feedback, a number of minor algorithm and
48 user interface changes were incorporated into the final version of the tool. The Level 2 testing
49 process was repeated following these changes and perfect correlation between HealthTracker and
50 the independently programmed version was achieved for all variables.

- **Integration of HealthTracker with the primary care electronic health record and quality improvement tools**

HealthTracker interfaces with the two Australian clinical practice software systems most commonly used in General Practice and ACCHS settings (Medical Director™ and Best Practice™). There are four components to the system:

- **Point of care decision support:** HealthTracker is built in the Pen Computer Systems PrimaryCareSidebar™, third party software that interacts with the primary EHR system. Figure 1 shows the HealthTracker user interface and its integration with the PrimaryCareSidebar™ and the EHR. A prompt function is used to encourage health professionals to conduct a cardiovascular assessment if guideline recommended. Where possible, the tool populates with information from the patient's record. If essential information required for the calculation of absolute risk is missing or out-of-date, a traffic light prompt alerts the health professional and updated information can be entered. If the patient is receiving sub-optimal treatment then a traffic light recommendation is made to consider initiation of treatment or additional agents. Information about eligibility for the Australia Government Pharmaceutical Benefits Scheme subsidy is provided if lipid lowering medicines are recommended. All outputs are qualified by statements emphasising that the final decision to commence or change therapy should be made by the health professional based on all available information.
- **A patient oriented risk communication interface.** A key finding from the pilot evaluation was the role of the output in risk communication. GPs wanted to interactively alter current risk factors and perform 'what if' scenarios to demonstrate to patients the effects of current and altered risk over time. This functionality has been built into HealthTracker and uses the concept of "Heart Age" to demonstrate to patients the discrepancy between current risk and an ideal risk based on well controlled risk factor levels. Figure 2 shows an example of how a patient's heart age changes with the effect of smoking cessation.
- **A data extraction tool.** This will provide health professionals with immediate feedback on their performance on screening and management of CVD risk for their entire patient population. Figure 3 shows an example of screening performance for a range of CVD risk factors. Practitioners can use this tool to identify specific patients in whom there may be a particular risk factor measurement missing or a potential prescribing gap. Customised point of care prompts can then be created. When a patient record is opened an alert is provided to notify the practitioner of the particular management issue and this can then be actioned.
- **A quality improvement (QI) component** has been developed which is aligned with the methods of the Improvement Foundation of Australia (IFA) Australian Primary Care Collaboratives (APCC) program. De-identified data extracts of clinical performance are securely exported to a web-based central repository managed by the IFA. This repository provides access to site-specific feedback reports on performance compared with other anonymised sites. Figure 4 shows an example of how this information is presented.

STUDY OBJECTIVES

The TORPEDO study will test HealthTracker's performance in assisting health professionals and patients in making evidence based management decisions to help prevent heart attack, stroke and related conditions.

Hypotheses:

Using a cluster randomised, controlled trial design, two specific hypotheses will be tested.

Compared with control practices, those practices randomised to receive HealthTracker will have:

- (1) An increased proportion of patients receiving appropriate (guidelines-indicated) measurements of their CVD risk factors.
- (2) An increased proportion of patients at high risk receiving appropriate (guidelines-indicated) prescriptions for management of their CVD risk.

These aims will be augmented by formal economic and process evaluations to provide crucial information on large-scale implementation and sustainability.

STUDY DESIGN

HealthTracker will be evaluated using a cluster randomised, controlled trial design. At end of study, HealthTracker will be made available to both the intervention and control arms for a further 12 months free of any license fees. The study schema including site and patient eligibility criteria are highlighted in Figure 5.

• Eligibility criteria

Health Service

1. Use of Medical Director™ or Best Practice™ for EHR management.
2. Exclusive use of these systems to record risk factor information, pathology test results and prescribe medications. ~~Services using 'hybrid' paper and electronic system for these features will not be eligible.~~
3. Agreement by all GPs and other designated staff to use HealthTracker.

Services that do not have a compliant software system will be excluded from participation. Services using 'hybrid' paper and electronic systems for these features recording risk factor information, pathology results and medication prescription will also not be eligible to participate.

Patients

1. Aboriginal and Torres Strait Islander people 35+ years and all others 45+ years (age criteria are based on NVDPA guideline screening recommendations³⁷), and
2. Attendance at the general practice or ACCHS at least 3 times in the previous 24 month period AND at least once in the previous 6 month period.

Site recruitment

Participating general practices have been recruited from the Sydney region in collaboration with primary health care organisations known in Australia as Medicare Locals. Participating ACCHSs have been recruited in partnership with two state representative bodies for ACCHSs, the Aboriginal Health & Medical Research Council (AH&MRC) of NSW and the Queensland and Aboriginal Islander Health Council (QAIHC). A \$500AUD reimbursement to participating sites will be made to partially compensate for health service staff time commitment to study-related activities. Sites randomised to the intervention will receive training support in use of the system predominantly via face to face visits and webinars. All license costs and technical support associated with the intervention will be provided free to the intervention sites in the first 12 months and to all sites for the following 12 months after completion of the trial. A newsletter and networking web site will be provided to participating sites. Royal Australian College of General Practitioners Quality Assurance and Continuing Professional Development points will be offered to participating GPs in both arms of the trial.

• Randomisation

Sixty services (40 general practices and 20 ACCHSs) will be randomised in a 1:1 allocation to use HealthTracker or 'usual care' for twelve months. Clusters will be stratified at three levels-

1. ACCHS vs. general practices
2. Service size (<500 patients meeting eligibility criteria vs. >=500)
3. Participation in existing quality improvement programs (current involvement in one of five national and state programs involving regular audit and feedback vs. past or never involved in these programs)

A site assessment survey will be administered to all sites to assess for service eligibility and these stratifying variables. Permuted block randomisation will be centrally performed using a web-based form. As this is a pragmatic trial, allocation will be single blinded with outcome analyses conducted blinded to treatment allocation.

Intervention group

The intervention arm will receive the four components of the system described above (point of care decision support software, risk communication tools, data extraction tools, and access to the quality improvement portal). Clinical staff will be given training in use of the tools and a support service will be available for any technical queries. One initial face to face training visit and subsequent site visits and webinars targeting strategies to improve quality of care will be provided. Unless requested by health services the intervention will not be modified or discontinued. Reasons for discontinuation will be outlined and all analyses will be conducted on an intention to treat basis (see below).

Control group

Sites allocated to this arm will continue usual practice with their current systems without implementation of HealthTracker. As the George Institute holds exclusive rights to the distribution of the system, there is no possibility of control sites having access to HealthTracker. If these sites already routinely use data extraction tools for assessing their quality of care then this will continue as normal. As with the intervention arm, services participating in any quality improvement initiatives will continue participation as usual. For those sites not routinely using data extraction tools, the automated data extraction tool will be temporarily installed for data

collection purposes only and then uninstalled that same day. A feedback report on performance will be provided at study completion only.

Quantitative data collection (Figure 5)

Cross-sectional data will be collected in an automated manner for all patients who satisfy the eligibility criteria at each service. These data will then be sent securely to the George Institute via an export function for analysis of primary and secondary outcomes.

Pre-randomisation: 1 month prior to randomisation, de-identified data will be collected from all sites. These data will be fed back to all sites as a formal report highlighting areas where data quality issues may be occurring.

Randomisation: Baseline data will be collected and sites will be randomised to intervention or control.

End of intervention period: At the end of 12 months, data will be collected in both study arms.

• Primary Outcomes

- Change in the proportion of eligible patients receiving appropriate measurements of their CVD risk in the previous 12 months (measured at randomisation and at 12 months).
- Change in the proportion of eligible patients assessed at high CVD risk receiving appropriate prescriptions for their CVD risk factors in the previous 12 months (measured at randomisation and 12 months).

Appropriate measurement of CVD risk factors is defined as having recorded or updated *all* the essential risk factors for measurement of CVD risk (smoking status, blood pressure (BP) in the previous 12 months, total cholesterol and High Density Lipoprotein (HDL) cholesterol in the previous 24 months) among those in whom risk assessment is guideline-indicated. Unless explicitly recorded, diagnoses of diabetes or left ventricular hypertrophy will be assumed to be absent.

High CVD risk is defined as a calculated 5-year CVD risk of >15%, a history of CVD or the presence of any clinically high risk conditions (as per NVDPA recommendations). Based on audit data this is expected to comprise ~30% of the patient population.^{10 11}

Appropriate prescriptions is defined as a prescription for one or more BP lowering drug *and* a statin for people at high risk without CVD; or a prescription for one or more BP lowering drug *and* a statin *and* an antiplatelet agent (unless contraindicated by oral anticoagulant use) for people with established CVD.

• Secondary Outcomes

- Change in measurement of individual risk factors separately (smoking status, BP, cholesterol, other non-Framingham risk factors- BMI, Chronic Kidney Disease (CKD) screening with urinary Albumin to Creatinine ratio, estimated Glomerular Filtration Rate);

- Intensification of existing medication regimes among patients at high CVD risk (. additional BP and lipid lowering agents)
- Changes in mean systolic BP, total cholesterol, LDL cholesterol, HDL cholesterol
- New CVD and CKD diagnoses

- **Statistical Considerations**

Randomisation of 60 services (30 per arm) will provide 90% power to detect a $\geq 10\%$ absolute higher occurrence in each primary study outcome among practices receiving HealthTracker. The following assumptions are based on our three audits in ACCHSs and mainstream general practices⁹⁻¹¹ and include an assumed improvement of 10% in the two primary outcomes in control practices as a result of study participation.

1. Cluster size of eligible population will range from 200 in a small service through to 2000 in a large service. An average cluster size of 750 is assumed.
2. Recording rates of essential risk factors needed for risk assessment in the target group (first primary outcome) average 50%.^{10 11}
3. 30% of the cluster will be either be at high CVD risk or have established CVD (n=250) and prescription of appropriate medicines to high-risk patients (second primary outcome) is 50%. This is based on our published data on drug prescriptions for individuals with and without established CVD.⁹⁻¹¹
4. An intra-class correlation coefficient of 0.05 for both primary outcomes. based on our audit data⁹⁻¹¹
5. Two-sided alpha = 0.05

Data analysis will be performed on an intention-to-treat basis using generalised estimating equations.³⁸ Subgroup analyses will be carried out using the three pre-specified strata: (1) ACCHS vs. general practices, (2) service size (small vs. large) and (3) current participation in quality improvement programs vs. past or no involvement in these programs.

- **Economic evaluation**

The economic evaluation will have a trial-based component and a modeled evaluation of long term costs and outcomes. The incremental cost will be based on software, training and other costs incurred with transitioning practices to using HealthTracker. This will help determine the cost barriers experienced by different practices in adopting the system. Data on medications, laboratory tests, consultations and newly recorded diagnoses of CVD events incurred by eligible patients during the trial will be obtained from the data extraction tools. Costs will be calculated from prevailing Medicare rates and standard Australian National Diagnosis Related Groups cost weights for CVD hospitalisations. The incremental cost consequences of the HealthTracker system in achieving each of the primary outcomes will then be estimated e.g. cost per eligible patients assessed at high CVD risk receiving appropriate prescriptions. Trial-based data, however, cannot capture costs and outcomes beyond the trial. To address this, a *modeled economic evaluation* will enable quality of life and survival to be examined and allow incremental cost-effectiveness ratios to be calculated in terms of cost per Quality Adjusted Life Years gained. Using a Markov model, the eligible patient population in both study arms will be hypothetically tracked over an extended period. Transition between various defined health states, costs and quality of life attached to various health states and the projected long term intervention effects from that observed in the trial will be based on published evidence. With appropriate

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8 discounting, estimates of long-term costs and outcomes will fold out of the model. Sensitivity
9 analyses will be conducted on discount rate, uncertainty in outcome estimates and assumptions
10 made in costing (e.g. varying efficiencies with different patient practice ratios to those of the trial
11 setting). This will better inform policy makers as to the resource consequences of rolling out this
12 program to scale.

13
14 • **Process evaluation**

15 The qualitative evaluation of the beta-version of HealthTracker suggested that a critical factor
16 affecting the uptake of EDS interventions is whether and how they become embedded in routine
17 health care²². In the TORPEDO trial we will build on this observation through a detailed process
18 evaluation to better appreciate the factors that might influence sustainability beyond the trial
19 setting. Two qualitative methods will be utilised to explore these factors.

20
21 **Semi-structured interviews with health professionals and staff.** A maximum variation
22 sample will be taken to ensure diverse opinions are gained from patients, clinical and managerial
23 health staff and sites with low and high uptake of the intervention.³⁹ Key issues to be explored
24 will include (1) how practitioners use HealthTracker; (2) what effects it has on organisational
25 practices and personnel; and (3) what are patients' experiences of being presented with
26 HealthTracker outputs and what impact does this have on the healthcare encounter. Individual
27 informed consent will be sought and data will be collected toward the end of the intervention
28 period so as not to unduly influence trial outcomes.

29
30 **Audio/ video ethnography.** A key component of understanding barriers/enablers to use of
31 HealthTracker is a better appreciation of how practitioners and patients use it at the point of care.
32 Data collection using audio/video recording will capture how technological innovations are
33 actually used in practice.⁴⁰ Ethnographic analysis will greatly augment the interview accounts
34 and will particularly shed important light on (1) how the intervention impacts on the flow of the
35 clinical encounter; (2) how risk information is communicated between health professional and
36 patient; and (3) how the patient receives and interprets the information and the role it may play in
37 shared decision making processes. Although audio/video recorded clinical encounters are
38 commonly used for primary care teaching purposes, such a technique can be potentially sensitive
39 and therefore will be restricted to a small number of sites. Recordings will be conducted toward
40 the end of the intervention period when both health staff and patients are thoroughly familiar
41 with the system. This will occur over a one week period at each site. Participants who are
42 approached for an interview will be invited to participate in this component. They will be given
43 the option of having their healthcare encounter audio or video recorded. A follow-up interview
44 will be arranged with these participants (both staff and patients) where the recording is played
45 back for participant interpretation of the data.

46 These data will be supplemented by project officer field notes to identify any key processes,
47 events, staffing and other resource issues occurring during the intervention period that may be
48 relevant in gaining a better understanding of barriers and facilitators to implementation.

49 A multidisciplinary research team will guide the analysis process. As is common with qualitative
50 inquiry, data analysis will commence early and be conducted contemporaneously with data
51 collection. This method allows for interview content to be refined for subsequent data collection
52 and to actively pursue emergent themes of interest. Although interviewing will continue until
53 thematic saturation is achieved and therefore the exact number of interviews is unknown, we
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anticipate from prior experience that around 80 interviews (40 patients and 40 staff) will provide sufficiently rich data to meet our objectives.

Interview data will be digitally recorded, and professionally transcribed. NVivo 9 (QSR International Melbourne, Vic) will be used to assist with data organization and coding for key themes. Video data will be directly analysed and coded for key themes within NVivo. Feedback of findings to participants will be provided by a variety of methods, including workshops, summary reports, newsletters and via the study website.

For peer review only

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ETHICAL CONSIDERATIONS

The General Practice component of the study is approved by the University of Sydney Human Research Ethics Committee (HREC) and the ACCHS component is approved by the Aboriginal Health and Medical Research Council HREC. Formal agreements with each of the participating sites have also been signed. Quantitative data will be obtained from de-identified clinical audits. Ethical approval to grant waiver of the usual requirement to obtain individual patient consent has been obtained. In participating ACCHS sites, eligible patients can request to 'opt out' from having data in the clinical audit data extracts exported. Data exports will be compliant with privacy legislation, centrally managed by the George Institute and held in strict confidence. Some individual health professionals (GPs, practice nurses, etc) and patient participants will have their informed consent taken at the site to allow data collection through semi-structured in-depth interviews and/or the use of audio/videotaped healthcare encounters. Participation in this component will be optional. Patient Information Statements and Consent Forms have been approved by each ethics committee and formatted in accordance with their own guidelines and requirements.

The study will be conducted in accordance with the principles set out in the National Health and Medical Research Council and the NSW Aboriginal Health and Medical Research Council guidelines. Specific effort will be taken to respect the autonomy and governance of participating ACCHSs. The intellectual property rights of ACCHSs will be recognised and preserved. It is also recognized that ACCHSs have rights and responsibilities regarding the use of health-related information for their attending clients. Collaborators on the TORPEDO study will be encouraged to disseminate information from the project in a manner that supports health improvement for Aboriginal and Torres Strait Islander peoples and local benefit to participating ACCHSs.

DISCUSSION

The TORPEDO study will seek to provide reliable evidence about the effectiveness of quality improvement interventions incorporating electronic decision support in Australian primary care settings. The implications of use of such systems for CVD risk management extend well beyond being a point-of-care clinical resource. Improving health system performance is central to the aims of this initiative and this is especially pertinent to addressing Aboriginal health inequities where the CVD burden is five-fold greater. There is potential for substantially better health outcomes from CVD in Australia with improved implementation of existing evidence in primary health care, where most of the opportunity to manage cardiovascular risk occurs. The strategy proposed is the first of its kind in Australia and is strongly aligned with national strategy recommendations for health system reform. If effective, HealthTracker could have widespread applicability for prevention and management of other chronic diseases.

TRIAL REGISTRATION

The trial is registered with the Australian Clinical Trials Registry ACTRN 12611000478910.

FUNDING

This study is funded by an Australian National Health and Medical Research Council (NHMRC) Project grant (ID 1010547) and NSW Department of Health. DP is supported by a NHMRC Translating Research into Practice Fellowship. AP is supported by an NHMRC Senior Research Fellowship. JR is funded by a Postdoctoral Fellowship co-funded by the NHMRC and National Heart Foundation.

ACKNOWLEDGEMENTS

We gratefully acknowledge the support of the general practices and Aboriginal Community Controlled Health Services involved in this study. [We also acknowledge the support of the Queensland Aboriginal and Islander Health Council, Aboriginal Health and Medical Research Council, Western Sydney Medicare Local, Inner West Sydney Medicare Local, and Nepean-Blue Mountains Medicare Local.](#)

HealthTracker Steering Committee:

- David Peiris (Co-Chair), Anushka Patel (Co-Chair), Mark Harris, Tim Usherwood, Nicholas Zwar, Katie Panaretto, Jenny Hunt, Stephen Colagiuri, Stephen McMahon, Rod Jackson, Bruce Neal, David Sullivan, Fiona Turnbull, Alan Cass, Noel Hayman, Alex Brown, Jessica Stewart, Bindu Patel

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TORPEDO Study Project Staff:

- Marilyn Lyford, Maria Agaliotis, Sharon Parker, Lyn Anderson, Melvina Mitchell, Chris Henaway, Catriona McDonnell, Olly Shestowsky

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- Pen Computer Systems [for their support in developing the HealthTracker software and the data extraction tool](#)

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- Improvement Foundation of Australia [for their support in developing and hosting the quality improvement portal](#)

COMPETING INTERESTS

We declare that we have no competing interests

EXCLUSIVE LICENSE

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8 **FIGURES AND TABLES**
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10 • **Table 1: Guidelines used in the HealthTracker algorithm**
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Professional Organisation	Guideline
National Vascular Disease Prevention Alliance	Guidelines for the Assessment of Absolute Cardiovascular Disease Risk 2009
National Heart Foundation	Reducing Risk in Heart Disease 2008 Guide to Management of Hypertension 2008- Updated Aug 2009 Aspirin for cardiovascular disease prevention 2003
National Heart Foundation/ Cardiac Society of Australia and New Zealand	The Lipid Position Statement 2005
National Stroke Foundation	Clinical Guidelines for Stroke Management 2010
Royal Australian College of General Practitioners	Guidelines for preventive activities in general practice 2009
Diabetes Australia	Diabetes Management in General Practice 2010/2011 NHMRC Evidence Based Guidelines for Type 2 Diabetes 2009- Case Detection and Diagnosis NHMRC Evidence Based Guidelines for Type 2 Diabetes 2009- Diagnosis, Prevention and Management of Chronic Kidney Disease
Kidney Health Australia	Chronic Kidney Disease Management (CKD) in General Practice 2007
Department of Health and Aging	Schedule of Pharmaceutical Benefits Scheme 2011 General Statement for Lipid Lowering Drugs

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Figure 1- HealthTracker user interface

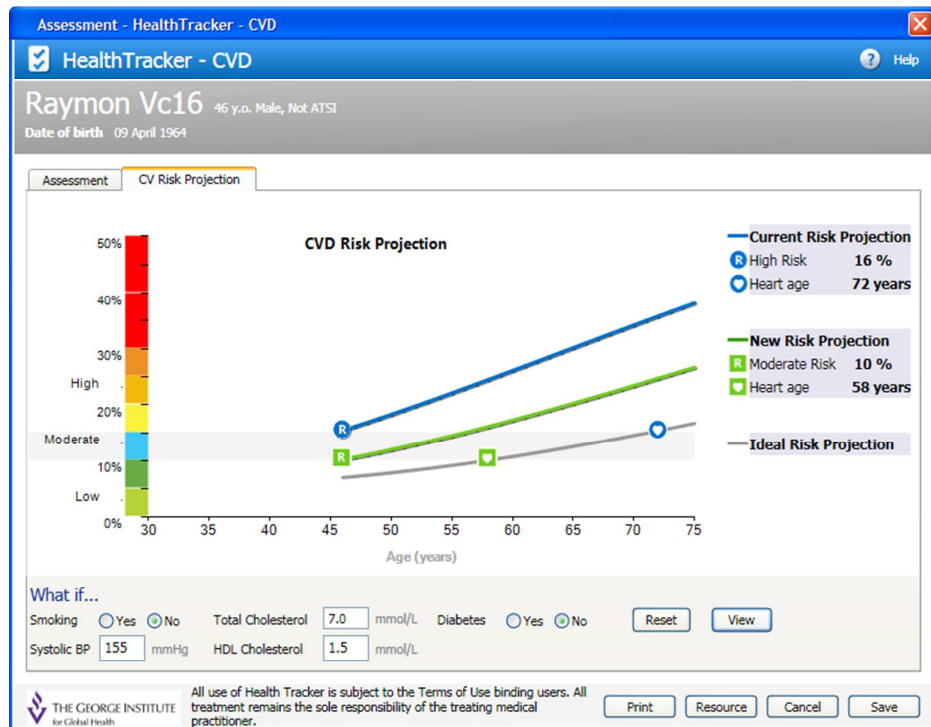
The screenshot displays the HealthTracker interface for a patient named Heather Andrews. The main window is titled 'HealthTracker - CVD' and shows an 'Estimated 5 Year Risk' of 9% (Low). The interface includes several sections:

- Essential Items:** CVD Risk Factors (Smoker, Average Systolic BP: 133 mmHg, Average Diastolic BP: 83 mmHg, Total cholesterol: 5.8 mmol/L, Triglycerides: 2.0 mmol/L, HDL Cholesterol: 0.9 mmol/L, LDL Cholesterol: 3.8 mmol/L).
- Past Medical History:** Left Ventricular Hypertrophy, Cardiovascular Disease, Diabetes, Chronic Kidney Disease.
- Additional Risk Factors:** Other Relevant History.
- Screening Recommendations:** A table listing items like BP, Lipids, Creatinine, Proteinuria, Risk Assessment, and Diabetes with their respective frequencies and next due dates.
- Treatment Advice:** BP Lowering (Lifestyle Advice, Medication), Lipid Lowering (Statins, Fibrates), and Blood Thinning (Anti-platelet, Vitamin K).
- Primary Care Sidebar:** Located on the right, it shows patient details and a 'Launch Pad' with links to 'PCS Clinical Audit Tool' and 'Sovereign ePrescribe'.

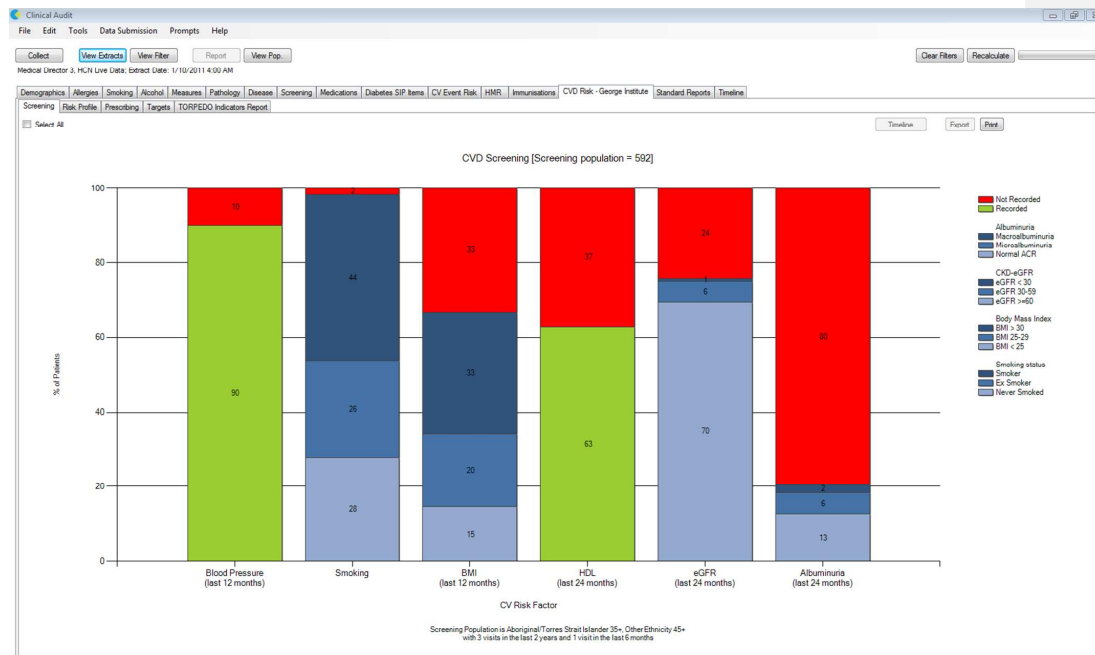
Annotations with arrows point to various parts of the interface:

- 'The patients GP health record' points to the patient information at the top.
- 'Risk factor information extracted from the patient's health record' points to the 'Essential Items' section.
- 'A resource link providing access to clinical guidelines' points to the 'Launch Pad' section.
- 'Pen Computers Sidebar application automatically extracts data from the primary care health record' points to the Primary Care Sidebar.
- 'Health Tracker - CVD screening and management panel.' points to the main assessment area.
- 'Risk of heart attack or stroke in the next 5 years' points to the 'Estimated 5 Year Risk' bar chart.
- 'Recommended screening tests based on national guidelines' points to the 'Screening Recommendations' table.
- 'Traffic light treatment recommendations based on national guidelines' points to the 'Treatment Advice' section.

• Figure 2: HealthTracker- CVD risk communication interface

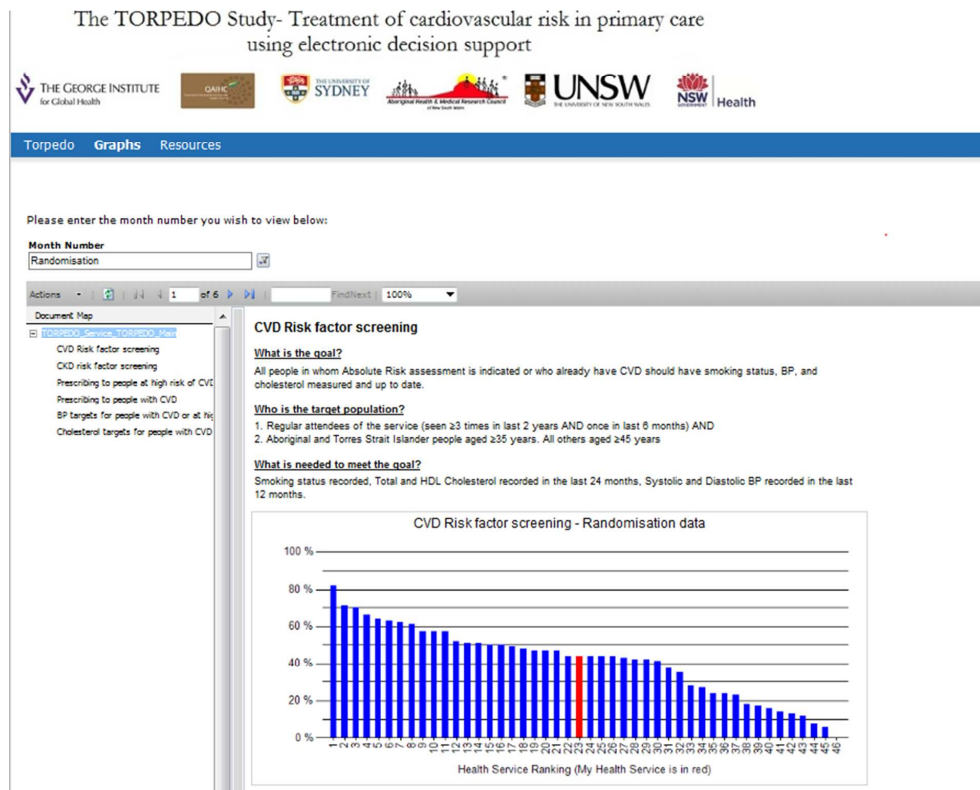


• Figure 3: Sample output of performance in CVD risk factor screening



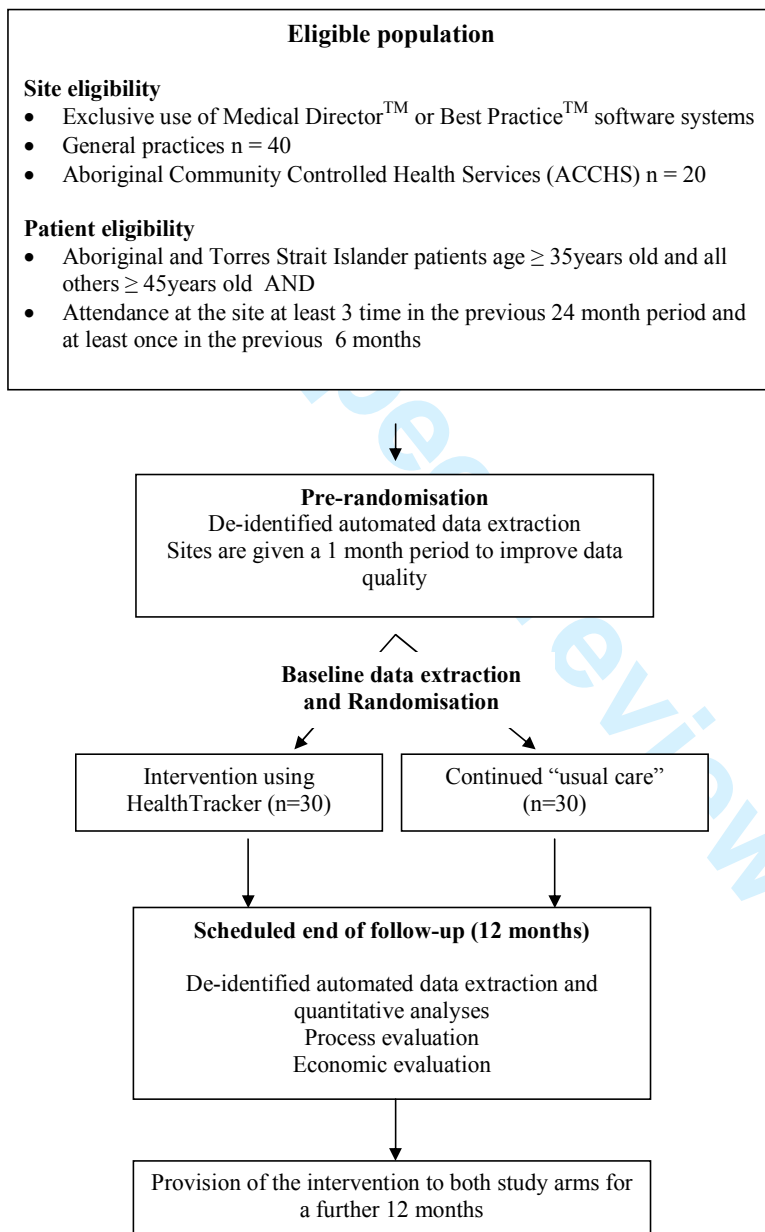
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• Figure 4: Sample display from the Quality Improvement portal



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• **Figure 5: TORPEDO study schema**



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