**PROTOCOL: National CHAT-GP stepped wedge trial**

**BACKGROUND**

**The translation problem**

There is good evidence for the prevention of CVD, through addressing lifestyle change at all levels of CVD risk, and prioritising blood pressure and cholesterol lowering medication for those at highest risk who are most likely to benefit.[3](#_ENREF_3) Absolute CVD risk can be assessed using widely available algorithms,[4](#_ENREF_4) but despite NHMRC-endorsed guidelines, there is substantial underuse of these tools in practice.[5-8](#_ENREF_5) The consequences are significant. One study estimated that prescribing based on absolute risk would save the Australian government $5.4 billion over the lifetime of the population aged 35-84 years in 2008 by providing medication to high risk and not low risk patients.[9](#_ENREF_9)Another study found 75% of high risk patients are not receiving recommended medication to prevent death and disability from CVD, while 25% of low risk patients are taking medication they are very unlikely to benefit from.[10](#_ENREF_10)

**Behavioural causes**

To address this, our intervention is based on the ‘behaviour change wheel’ framework, which synthesises 19 health behaviour theories and models to guide the development of rigorous public health interventions and policies.[11](#_ENREF_11) According to this framework, GP barriers to the use of absolute CVD risk guidelines can be attributed to three determinants of behaviour - opportunity, capability, and motivation. Interventions to improve the use of absolute risk assessment in Australia have addressed opportunity barriers in NSW (e.g. consultation time, access to calculators),[12](#_ENREF_12),[13](#_ENREF_13) but these interventions have not been translated into clinical practice nationally. Our previous research amongst GPs and patients identified significant additional barriers in motivation (e.g. habits, beliefs, and attitudes towards guidelines and medication) and capability (e.g. knowledge about how individual risk factors relate to absolute risk models, and communication skills),[14-16](#_ENREF_14) which have not been addressed in previous attempts to implement absolute risk guidelines.

**Evidence-based strategies**

There is strong evidence for the efficacy of two strategies to address these behavioural barriers:

1. Audit and feedback has been shown to motivate clinicians to change current practices, including guidelines-based prescribing, and may be more effective if they include evidence-based behaviour change techniques (e.g. peer comparison and action plans).[17](#_ENREF_17),[18](#_ENREF_18)
2. Decision aids improve capability in terms of doctor-patient communication, accuracy of risk perception and patient involvement in decision making, and shared decision making is more likely to be implemented when both clinicians and patients are targeted.[19](#_ENREF_19),[20](#_ENREF_20)

We have combined these two strategies with national guidelines[3](#_ENREF_3) in a new online intervention funded by partner organisation NHF. Piloting has shown it is acceptable to GPs with high demand and potential efficacy*.*

**The intervention**

Our team developed and piloted the intervention in 2016-18 with NHF and RACGP funding, including:

1. ***Interactive CVD risk calculator*** that automatically combines CVD risk assessment and management algorithms to help GPs identify the correct risk category and guidelines, to address GP capability barriers[14](#_ENREF_14),[16](#_ENREF_16) using best practice risk communication principles;[21](#_ENREF_21)
2. ***Personalised patient decision aid*** that shows the effect of medication/lifestyle interventions on CVD risk to help GPs discuss the benefits and harms of different options, addressing patient capability barriers[15](#_ENREF_15),[22](#_ENREF_22),[23](#_ENREF_23) based on international shared decision making standards;[24](#_ENREF_24)
3. ***Self-directed audit & feedback*** including cases that GPs find challenging for CVD risk assessment and communication,[14](#_ENREF_14),[15](#_ENREF_15) and comparison of management to guidelines, using evidence-based behaviour change techniques to address GP motivation barriers.[17](#_ENREF_17),[18](#_ENREF_18)

GP feedback for the final website at [www.auscvdrisk.com.au](http://www.auscvdrisk.com.au) indicated it was acceptable with high demand and potential efficacy,[25](#_ENREF_25) but identified the need to link with patient data and practice nurses. This proposal will address these barriers, using strategies shown to be feasible in Australian primary care: 1) integrate with medical software;[13](#_ENREF_13) 2) enable pre-consultation access with support from practice nurses;[12](#_ENREF_12) and 3) partner with existing NHF-supported programs to improve CVD prevention in general practice.

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**AIMS**

This project aims to improve GP use of CVD prevention guidelines. This will involve implementing and evaluating a new online format for the guidelines (www.auscvdrisk.com.au), using a national stepped wedge cluster randomised trial. The intervention comprises three evidence-based behaviour change strategies that improve guidelines use and doctor-patient communication: 1) an interactive CVD risk calculator that automatically applies assessment and management algorithms to the patient; 2) self-directed audit and feedback exercise with example cases for GPs; and 3) personalised decision aid for patients. We hypothesise this will increase: 1) complete absolute CVD risk assessment data for patients in the target age range; 2) lifestyle referral for high risk patients; and 3) risk-appropriate prescribing of blood pressure and cholesterol-lowering medication to high risk and not low risk patients.

**METHODS**

**Setting**

The Chief Health Officer Report shows that Queensland (QLD) has a 9% higher death rate for coronary heart disease than the national rate, with regional areas having much higher heart disease death and hospitalisation rates. Australian Heart Maps data indicate that QLD has 10 of the worst 20 national hotspots for heart disease mortality and 12 of the worst 20 regions for heart-related hospital admissions. Australian Health Survey data (2011-12) indicate that 14.5% of men and 4.8% of women aged 45-74 years in QLD have high CVD risk. CVD prevention is therefore a major focus of the QLD Health and Wellbeing Strategic Framework, including “risk assessment and early intervention” as one of six key strategies. To address this, all 7 PHNs in QLD are currently engaged in NHF-supported programs to improve the quality of CVD risk assessment and management, making it an ideal environment in which to implement our intervention. In addition, all QLD PHNs have access to Pen CS software, which can link external websites with practice software. QLD will therefore be the initial focus to evaluate effectiveness and develop new strategies. Due to COVID-19 effects on general practice and Queensland PHN changes to priorities, the decision was made to supplement Queensland practices with practices from other states at each step. A COVID-19 hotspot and lockdown restrictions in Brisbane could quickly reduce patient presentations in 3 PHNs (Brisbane South, Brisbane North, Gold Coast). The trial will therefore be national with a sub-analysis of Queensland practices to assess the state-based outcome of referral to the My Health For Life program.

**Research plan**

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| **Project stage** | **Outcomes** |
| Stage 1: Set up implementation strategies  | * Train staff involved in My Health For Life (MHFL)
* Build Pen CS app to link new resources to GP software
* Link to PHN Health Pathways where possible
* Recruit 3 new GP practices in each PHN
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| Stage 2: Evaluation of implementation | * Pre-intervention stakeholder interviews
* Randomise PHNs to stepped wedge timepoints
* Set up access to new resources at appointed time
* Monthly data extraction via Pen CS reports
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| Stage 3: Process evaluation and stakeholder engagement | * Post-intervention stakeholder interviews
* Recorded GP-patient consultations
* Conduct QLD and national stakeholder workshops
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**STAGE 1: SET UP IMPLEMENTATION STRATEGIES**

The aims of the intervention align with existing quality improvement programs supported by the NHF and PHNs in QLD, with absolute CVD risk assessment being evaluated in practices via Pen CS software through the My Health For Life program. In addition, the national PIP QI program is specifically supporting CVD risk assessment through a new Pen CS Topbar app, expanding the relevance of the intervention to other states. Integrating the website resources with practice software via Pen CS will support existing risk assessment initiatives, reinforced through Health Pathways and local PHN websites.

**Pen CS integration with GP practice software (national)**

* ***Existing resources:*** Most PHNs currently provide licenses for practices to access Pen CS software, to produce audit & feedback reports at the practice and PHN level. The company has developed a third party app toolkit that allows developers to link patient data to external websites via the Topbar tool, without patient data leaving the practice environment. This enables information displayed within GP software to be automatically updated based on external website changes, for example if new evidence or guidelines emerge over the course of the project.
* ***New resources:*** The main implementation issue identified in piloting was the need to integrate the website with practice software. A Pen CS app will be developed to create a notification in Topbar for eligible patients in the target population for CVD risk assessment, which GPs could accept to auto-populate risk factors into the new risk calculator/decision aid. Monthly Pen CS reports on absolute risk assessment and management will support existing programs and compliment the individual audit & feedback exercise on the website.

**My Health For Life (MHFL) program (Queensland only)**

* ***Existing resources:*** This QLD Government-funded initiative targets people at high risk of chronic disease. Its purpose is to curb the prevalence of chronic disease by providing support, knowledge and skills to affect behaviour change. The program takes a goal setting approach utilising motivational interviewing techniques and is being evaluated against the Health Action Process Approach theory of health behaviour change. GPs can refer patients with high risk absolute CVD risk (>15% in 5 years). The NHF is working closely with all 7 PHNs to implement this program, including integration with Pen CS Topbar and Health Pathways, and quarterly audit & feedback reports using Pen CS.
* ***New resources:*** Access to the new risk calculator/decision aid via Pen CS will enable high risk patients to then be linked to referral to MHFL lifestyle change programs. Both the risk calculator/decision aid app and MHFL app will be implemented via Pen CS Topbar.

**STAGE 2: EVALUATION OF IMPLEMENTATION STRATEGIES**

**Design and recruitment**

Each PHN will identify 3 GP practices to be recruited based on: 1) have access to Pen CS and Topbar; 2) can allow researchers access to monthly Pen CS reports from practice data for 6 months; 3) likely to see 5 patients eligible for CVD risk assessment per week. PHNs will be randomised to receive access to the website resources at different time points (2 PHNs / 6 practices per month), where all PHNs start in the control group and end in the intervention group over a period of 5 months. Written consent for the availability of the Topbar app and all forms of practice-level data will be obtained from an authorised representative of each practice. Monthly Pen CS data will be extracted and evaluated for all PHNs by the project team, regardless of whether they are in the control or intervention group at the time. This will be in addition to quarterly reports conducted for existing programs.

Participating practices will receive:

* Access to new risk calculator/decision aid linked to practice software
* Patient resources to help them understand their risk and make a plan to reduce this
* Access to individual audit & feedback with a guided form to apply for 40 QI&CPD points
* Guidance from project team on using Pen CS to produce monthly practice reports

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| --- | --- | --- | --- | --- | --- |
| **Month:** | **1** | **2** | **3** | **4** | **5** |
| PHN1 (Qld) | Control | Intervention | Intervention | Intervention | Intervention |
| PHN2 (Other) | Control | Intervention | Intervention | Intervention | Intervention |
| PHN3 (Qld) | Control | Control | Intervention | Intervention | Intervention |
| PHN4 (Other) | Control | Control | Intervention | Intervention | Intervention |
| PHN5 (Qld) | Control | Control | Control | Intervention | Intervention |
| PHN6 (Other) | Control | Control | Control | Intervention | Intervention |
| PHN7 (Qld) | Control | Control | Control | Control | Intervention |
| PHN8 (Other) | Control | Control | Control | Control | Intervention |

**Sample size and power analysis**

In each PHN we estimate that there will be at least 70 eligible patients seen by the participating practices in each month.1 The stepped wedge design above will then have 80% power to detect a difference between intervention and control groups of 10% in the proportion of eligible patients with the primary outcome (complete CVD risk assessment), with a significance level of 5% and assuming an intra-class correlation coefficient of 0.1.20

**Implementation effectiveness outcomes**

The primary outcome is complete absolute CVD risk assessment data for eligible patients seen in the last month, assessed via monthly Pen CS reports from participating GP practices. Secondary outcomes will include guidelines-based management (medication prescribed for high risk and not low risk patients) as indicated in Pen CS reports, GP referral to the My Health For Life lifestyle program based on standard data collected by partner organisation the National Heart Foundation.

**Statistical analysis of effectiveness outcomes**

We will use generalised linear mixed modelling to compare the proportions of eligible patients with a complete absolute CVD risk assessment while within the intervention and control arms. The model will adjust for clustering by PHN, the secular effect of time and practice and patient level covariates. The same approach will be taken to analyse the secondary binary outcomes of guidelines-based management and referral to lifestyle programs.

**STAGE 3: PROCESS EVALUATION & STAKEHOLDER ENGAGEMENT**

**Process evaluation: stakeholder interviews, recorded consultations, software use**

A process evaluation will be conducted after the 6 month stepped wedge trial to assess processes at the individual level that may influence and explain the trial outcomes at the practice level:

* *Pre-post interviews:* this will explore staff capability (knowledge/self efficacy to assess and communicate CVD risk), opportunity (access to resources), motivation (beliefs, attitudes);4 experiences and feedback regarding the intervention amongst GPs, patients, nurses, program/practice staff, using a Framework Analysis approach;21
* *Recorded consultations:* time taken and shared decision making using ACCEP;22
* *Software usage data:* uptake/use of the Topbar app and supporting patient resources in practices (poster and prescription pad with link to patient risk assessment/lifestyle change tool), and time series analysis of unique/repeat users of the website via Google Analytics.

**Stakeholder engagement: Workshops to present outcomes and brainstorm new strategies**

A workshop will be organised with all stakeholders, including the NHF, PHNs, staff involved in MHFL, GPs, patients/consumers and practice staff. Evaluation results will be presented, and facilitated brainstorming activities will be conducted to identify sustainable maintenance strategies for existing practices, and solutions to resourcing barriers for further dissemination strategies for QLD. A voting process will be used to identify the final strategies to be implemented state-wide.

**STUDY DOCUMENTS**

An overview of the intervention at [www.auscvdrisk.com.au](http://www.auscvdrisk.com.au) is attached:

* CHATGP\_intervention

The PHNs will send a 1 page summary to eligible practices that have existing agreements to use the PHN’s Pen CS license and refer interested practices to the research team:

* CHATGP\_InformationForPHNs\_V3 National Trial
* CHATGP\_Practice\_Invitation\_V3 National Trial

The research team will present an overview to interested practices:

* CHATGP\_Practice\_Presentation\_V2

The research team will obtain written consent from practices that agree to participate:

* CHATGP\_Practice\_PIS\_V3 National Trial
* CHATGP\_Practice\_ConsentForm\_V3 National Trial

Staff within consenting practices and related partner programs will be invited to participate in the process evaluation using the following documents, and can choose to use supporting resources to help patients understand their risk and change their lifestyle:

* CHATGP\_Staff\_Invitation\_V1
* CHATGP\_Staff\_PIS\_V3 National Trial
* CHATGP\_Staff\_ConsentForm\_V3 National Trial
* CHATGP\_Staff\_InterviewQuestions\_V1
* CHATGP\_LifestylePrescriptionPad\_V1
* CHATGP\_WaitingRoomPoster\_V1
* CHATGP\_LifestyleChangeResources\_V1

GPs and practice nurses that choose to participate in recorded consultations will invite eligible patients to use the intervention in a Heart Health Check using the following documents:

* CHATGP\_Patients\_Invitation\_V1
* CHATGP\_Patients\_PIS\_V1
* CHATGP\_Patients\_CF\_V1
* CHATGP\_Patients\_InterviewQuestions