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Implementing patient decision aids into general practice clinical decision support systems: Feasibility study in cardiovascular disease prevention

Samuel Cornell [a], Jenny Doust [b], Mark Morgan [c], Kim Greaves [d], Anna L. Hawkes [e], Carl de Wet [f], Denise O'Connor [g,h], Carissa Bonner [a,*]

[a] Faculty of Medicine and Health, School of Public Health, University of Sydney, New South Wales, Australia
[b] Australian Women and Girls' Health Research (AWaGHR) Centre, School of Public Health, Faculty of Medicine, University of Queensland, Queensland, Australia
[c] Faculty of Health Sciences & Medicine, Bond University, Queensland, Australia
[d] Department of Cardiology, Sunshine Coast University Hospital, University of the Sunshine Coast, Queensland, Australia
[e] University of Queensland, Queensland, Australia
[f] Gold Coast Hospital and Health Service, Queensland, Australia
[g] Department of Epidemiology and Preventive Medicine, School of Public Health and Preventive Medicine, Monash University, Victoria, Australia
[h] Monash-Cabrini Department of Musculoskeletal Health and Clinical Epidemiology, Cabrini Health, Victoria, Australia

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ABSTRACT

Objective: Patient decision aids (DA) facilitate shared decision making, but implementation remains a challenge. This study tested the feasibility of integrating a cardiovascular disease (CVD) prevention DA into general practice software.
Methods: We developed a desktop computer application (app) to auto-populate a CVD prevention DA from general practice medical records. 4 practices received monthly practice reports from July-Nov 2021, and 2 practices use the app with limited engagement. CVD risk assessment data and app use were monitored.
Results: The proportion of eligible patients with complete CVD risk assessment data ranged from 59 to 94%. Monthly app use ranged from 0 to 285 sessions by 13 individual practice staff including GPs and nurses, with staff using the app an average of 67 sessions during the study period. High users in the 5-month study period continued to use the app for 10 months. Low use was attributed to reduced staff capacity during COVID-19 and technical issues.
Conclusion: High users sustained interest in the app, but additional strategies are required for low users. The study will inform implementation plans for new guidelines.
Innovation: This study showed it is feasible to integrate patient decision aids with Australian general practice software, despite the challenges of COVID-19 at the time of the study.

1. Introduction

Cardiovascular disease (CVD) is still the leading cause of non-communicable disease in Australia [1] and the world [2]. In Australia, CVD accounts for 13% of the annual total burden of disease, with an estimated loss of 646,000 years of healthy life lost in 2018. Fortunately, CVD progression is largely preventable, and its risk factors are modifiable through lifestyle changes or medication. International guidelines recommend the use of absolute risk assessment to determine who is at highest risk of a heart attack or stroke in the next 5–10 years, with those at higher risk being most likely to benefit from medication [3-5].

The current Australian CVD prevention guidelines have been available for over a decade [6], although their implementation has been poor. Australian general practice data shows that less than half of eligible patients have the required recorded risk factor data to determine whether they are at high risk of a heart attack or stroke [7]. Eligible patients are defined as those that meet the criteria for a Heart Health Check which includes all adults who are aged 45 years and above (30 years and above for Aboriginal and Torres Strait Islander peoples) and are not already known to have CVD. As a result, 56% of patients are not managed according to the guidelines: high risk patients are undertreated with medication that could reduce their risk, and low risk patients are overtreated with medication they are unlikely to benefit from [8]. With 1.4 million Australians at high risk [8], the burden of this implementation failure on the health system has been estimated at $5.4 billion [9].

Abbreviations: API, Application Programming Interface; CDSS1, Clinical Decision Support Software case study 1: Pen CS Topbar; CDSS2, Clinical Decision Support Software case study 1: POLAR system; CVD, Cardiovascular Disease; GP, General Practice or General Practitioner; PHN, Primary Health Network.

* Corresponding author at: Rm 128A, Edward Ford Building, A27, The University of Sydney, NSW 2006, Australia.
E-mail address: carissa.bonner@sydney.edu.au (C. Bonner).

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Research has identified communication difficulties as a barrier to implementing absolute CVD risk assessment guidelines [10,11]. GPs report avoiding CVD risk assessment when communication with the patient is likely to be difficult [10,11], patients often misunderstand absolute CVD risk [12,13], and CVD risk calculators, DAs and consent forms often fail to meet the health literacy needs of the population [14-16]. Many patients have inadequate health literacy to access, understand and act on health information [17], and this is associated with worse CVD outcomes [18]. More support is needed to facilitate communication between GPs and patients about CVD risk.

Patient decision aids are information sources (such as pamphlets, videos, or web-based tools) designed to support active patient decision-making about health treatment and screening options. Such materials outline the benefits and harms of specific options for treatment or screening and enable a patient to ascertain which options are best for them, in consultation with a medical professional [19].

The most recent Cochrane review of decision aids includes 105 randomised controlled trials RCTs, totalling 31,043 participants. It found moderate to high quality evidence that compared to care-as-usual, patients who are provided decision aids are more informed of their options, feel more prepared for the procedure or screening, and are clearer about their personal values and reasons for undertaking a screening or procedure [20]. The review found that patient knowledge improved in 46 out of 52 studies. Furthermore, the review found moderate-quality evidence that decision aids facilitate a more realistic understanding of the benefits or harms of screening or interventions, and no evidence that decision aids lead to adverse effects or worse health outcomes.

Despite this strong evidence that DAs are effective, the implementation of shared decision making has been limited [21,22]. Little research has been conducted to assess the efficacy of implementing DAs within computerised clinical decision support systems (CDSSs), which may provide an avenue to improve uptake of both the CVD prevention guidelines and patient DAs [23].

CDSSs can be integrated into provider electronic health records, accessed via the internet or mobile devices, and provide clinicians with a wide array of functions such as point-of-care clinical prediction rules and guideline-supported management [24-26]. Evidence from systematic reviews of CDSSs has found some improvements in care processes but limited change in clinical outcomes [24,27]. Further research has sought to identify the “active ingredients” that best predict intervention success outcomes [28-30]. Success may be a function of CDSS impact on care processes or clinical or economic outcomes – and each is likely specific to the general practice, its business model and its patient population [30]. Hence, any success outcome is dependent on the actual uptake of the CDSS.

General explanations for poor CDSS uptake in general practice have been proposed across a range of studies. Clinicians commonly report barriers including lack of time, financial constraints, lack of knowledge, confidence, or distrust in CDSS technology, workflow disruption, loss of clinical autonomy, and low usability [31,32].

A systematic review and meta-analysis by Kouri et al. (2022) determined that to ensure modest CDSS uptake, it is necessary for two factors to occur: 1) formal evaluation of the availability and quality of the patient data needed to inform CDSS advice, and 2) identifying and addressing barriers to the behaviour change which the CDSS targets. The review further illustrated that understanding the context of the use of the DA and the CDSS within the workflow was needed to improve their uptake [23].

1.1. Aims

This study aimed to assess the feasibility of integrating a CVD prevention DA with CDSS software in Australian general practice to inform future implementation of revised national guidelines in 2023. It also aimed to assess the feasibility of data extraction and user tracking methods for a larger trial.

2. Methods

2.1. Setting

Australian General Practice. This study is part of the CHAT-GP project, a national partnership that aims to develop and implement decision support tools to improve communication about CVD risk assessment in General Practice. The development of GP and consumer versions of the CVD prevention DA are reported elsewhere [33,34]. The feasibility study ran for five months from July–November 2021, with app use monitored for 10 months to explore maintenance over time after research engagement finished. During this period there were significant disruptions to general practices due to COVID-19 outbreaks, vaccination, and telehealth changes, which reduced most general practices' staff capacity to engage in CVD prevention activities and research.

2.1.1. Case study 1: App access + audit and feedback reports

Recruited practices used the PEN CS (CDSS1) (Pen CS Pty Ltd. https://www.pencs.com.au. (Fig. 1.) Case study 1 was designed as a pilot stepped wedge trial, which involved rolling out the intervention to practices over a five-month period with CDSS1 practices randomised to immediate access, or a 2 month wait list, with monthly data collection commencing in July. (See Figs. 2 and 3.)

2.1.2. Case study 2: App access only

Recruited practices used the POLAR GP software (CDSS2) https://polargp.org.au. (Fig. 1.) CDSS2 practices were not eligible for the approved data extraction method so could access the intervention at any time and only provided app use data. CDSS2 practices were subject to fewer engagements with the study team. CDSS2 practices were provided the Topbar app to test feasibility of providing a decision aid via this platform.

2.2. Intervention

We previously developed a web-based CHAT-GP DA (www.auscvdrisk.com.au) to provide a tool for clinicians to use with patients to calculate CVD risk and to discuss prevention options. We then developed an app that integrates with medical records and clinical audit software to auto populate the fields necessary to calculate CVD risk. In Australian general practices, clinical audit software is generally provided by Primary Health Networks (independent, not-for-profit organisations with regions closely aligned with state and territory Local Hospital Networks or equivalent [36, 37] and funded by the federal government to support primary health care practices). However, general practices are independent businesses and can choose alternative software. Topbar is a CDSS produced by Pen CS and is designed to aid clinicians when deciding on a course of action with their patient. Topbar was chosen because it can integrate with electronic medical record software used in many general practices (Fig. 1).

Practice managers provided consent for app access and data extraction for audit and feedback reports. They were given a brief presentation explaining the intervention and the study, and some practices invited clinical staff to these meetings. As this was a pragmatic feasibility study, staff could choose whether or not to engage with the intervention. They had access to both the website version and the integrated Topbar app, both of which could generate printed summaries of the decision aid for the patient. The website had a 5 min training video explaining how to use the risk calculator and decision aid. Practices that agreed to participate in the study had the Topbar software installed on the practice computer network and agreed to receive monthly audit and feedback reports using the clinical audit software. Each month the study team received a data extraction report which was transferred electronically to the University of Sydney via Cloudstor. The research team summarised the data and disseminated an audit and feedback report to each practice manager (Appendix B.), which detailed areas that the practice could specifically target to increase the quality of their CVD risk assessment data. Practices that participated in the pilot trial were all eligible to receive federal government Practice Incentive

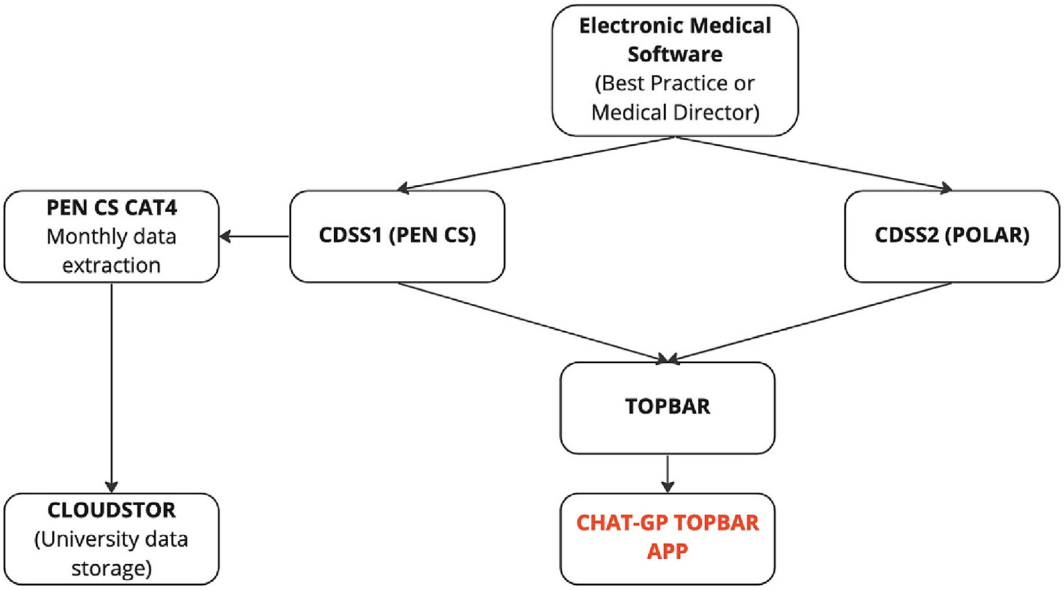

Fig. 1. Clinical decision support system software used in the study. Note: The Topbar app links the web-based CHAT-GP decision aid interface to patient information in the GP medical database software via a Clinical Decision Support System, provided by Pen CS or POLAR. For the purpose of this feasibility study, data was extracted from Pen CS practices using additional software called CAT4, which was used to produce audit and feedback reports. The data was sent by Pen CS to secure Cloudstor storage.

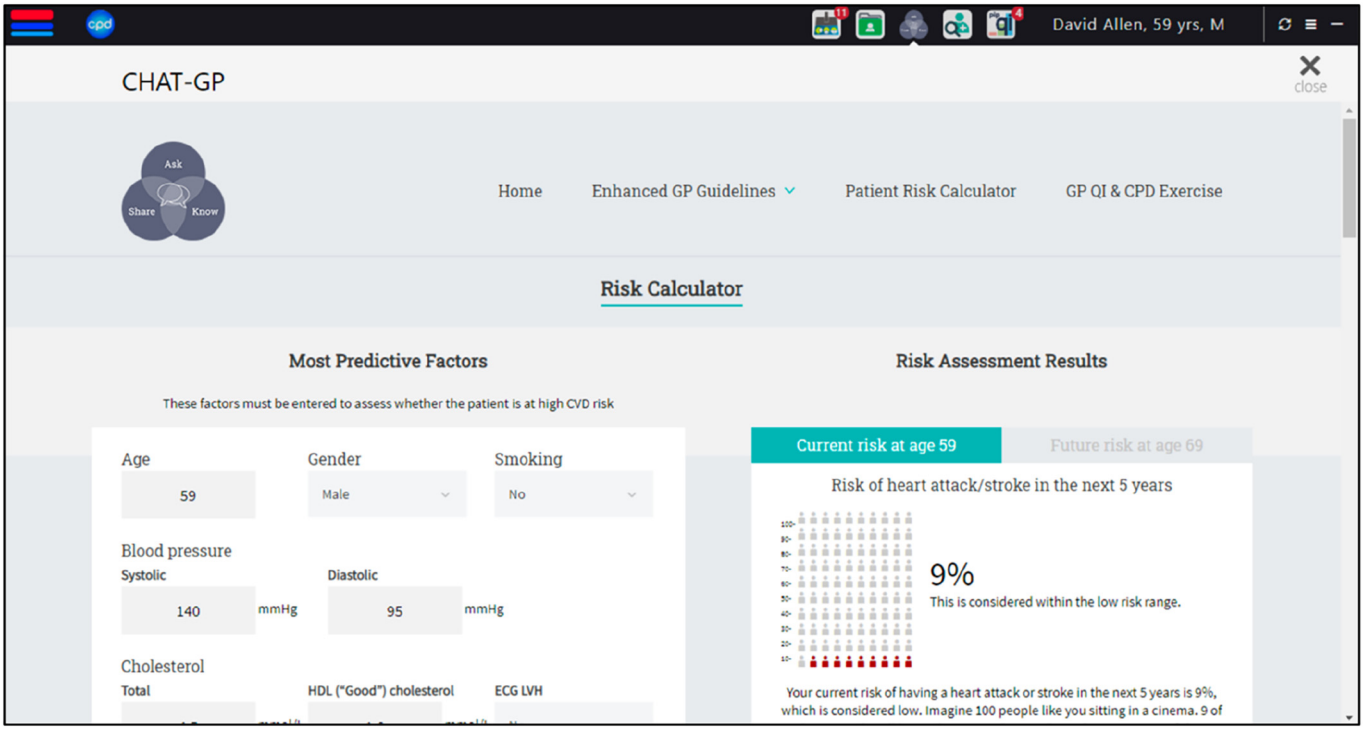

Fig. 2. Displaying the CHAT-GP decision aid and calculator with the Topbar app. Note: the data displayed is not from a real patient. Full details of the interface can be found in the development paper (Bonner et al., Implementation Science).

Program Quality Improvement (PIP QI) payments. However, whether a practice did receive a payment was unrelated to the study and was not recorded.

2.3. Ethical considerations

This study was approved by the University of Sydney Human Research Ethics Committee (project number 2019/1047).

2.4. Recruitment

The research team had existing professional relationships with PHNs around the country stemming from earlier work [38,39]. Through these relationships, PHNs were contacted with an expression of interest form to enrol in the feasibility study. PHNs that consented to take part then identified eligible practices to participate in the feasibility trial. PHNs provided practice details to the study team to make initial contact. SC contacted the practices to arrange a meeting via Zoom where the intervention and

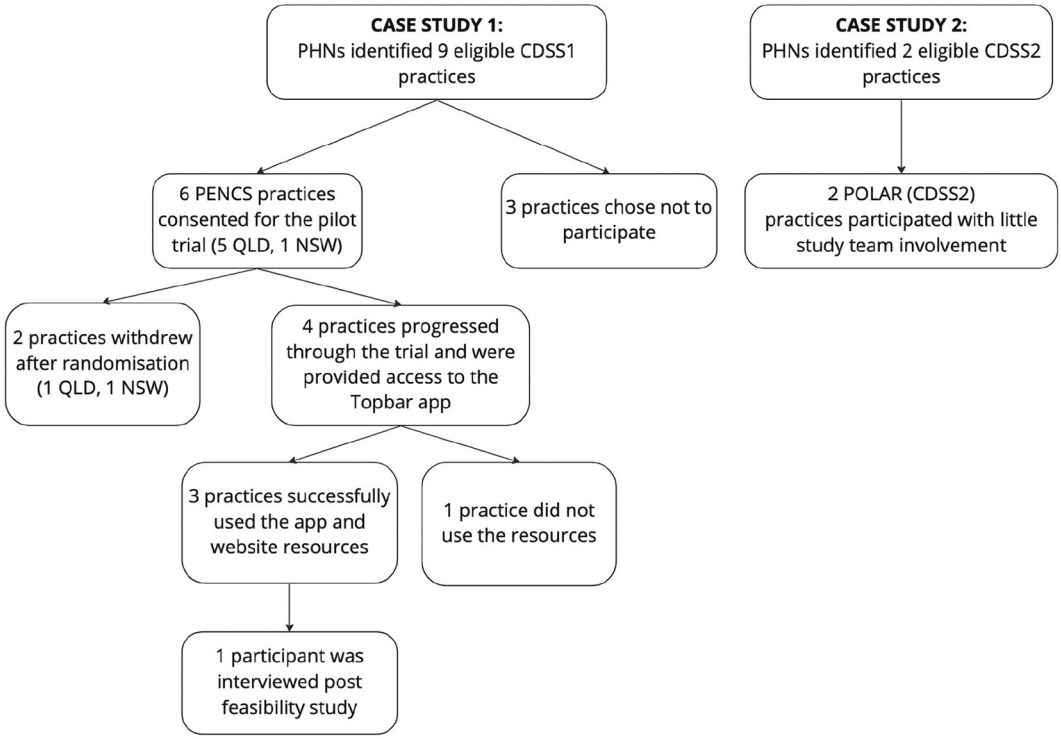

Fig. 3. Flow diagram illustrating the processes of contact and recruitment for the feasibility study amongst Primary Health Networks and General Practices.

study processes were explained. After this meeting, practices were provided with study documentation and a consent form to participate. Practice eligibility criteria included seeing 5 + patients in the target group for absolute CVD risk assessment on a weekly basis and having access to one of the two CDSS.

2.5. Data collection

2.5.1. Quantitative data

We collected clinical audit data from Pen CS, which included complete CVD risk assessment data and management of patients with medication for eligible patients seen in the last month (Appendix A.) and CDSS1 usage data, and Google Analytics which provided data on website usage. Each monthly practice data extraction was analysed and returned to the participating practice as an audit and feedback report, based on PIP QI audit and feedback report templates used in another study [38] (Appendix B). Google Analytics was used to track overall use of the web-based decision aids and referral sources (the latter to be reported separately). Data was analysed with descriptive statistics including means, medians, and percentages.

2.5.2. Observational data

To inform future intervention development and trial process evaluations, we sought feedback from high and low use practices throughout the study, with detailed field notes after each practice interaction. We conducted one formal interview with a particularly highly engaged user to gain further insights into their higher than average uptake, and obtained informal feedback from less engaged participants via email and telephone conversation.

3. Results

3.1. Participating practices

Case study 1: Four CDSS1 practices were enrolled into the pilot trial. Baseline data was extracted from 6 practices in July 2021. Of the three practices randomized to the intervention in August 2021, two withdrew due to staff capacity issues during the COVID-19 vaccination rollout, leaving only one practice in the initial phase (practice 1). The three practices randomized to the control arm (practice 2–4) commenced using the app in October 2021 (Fig. 1). All 4 practices were in metropolitan areas.

Case study 2: An additional two practices using a different CDSS tested the app during the same period, to assess feasibility of implementing the app in 2 different systems.

3.1.1. Quantitative data

Tables 1 and 2 summarise practice characteristics and app use across the practices. CAT4 reports from case study 1 showed the proportion of eligible patients with complete CVD risk assessment data ranged from 59 to 94%, which was relatively stable over time. This was summarised for practices each month in an audit and feedback report. Data provided by Pen CS on CHAT-GP Topbar app use showed that over the period of the pilot trial (July to November), 12 unique users used the app a total of 865 times. App use over a longer 10-months period showed that some high users continued to use the app even after the trial period with no further engagement from the research team. Use of the app varied widely, from high users who used the app a total of 264 sessions during the trial, to low users who used the app only once.

3.1.2. Observational data

Our observational and feedback results are arranged thematically in Table 3 to describe the issues identified in our feasibility study, provide examples and potential solutions for future implementation programs. Common implementation barriers are described in more detail with supporting quotes, below obtained informally through correspondence with participants throughout the trial. Detailed field notes were kept following each interaction with practices to document implementation barriers.

3.1.2.1. Staff capacity issues. Participants narratives suggest the program was suitable and user-friendly, but utilisation was limited by workforce shortages during the COVID-19 pandemic.

Table 1
Practice characteristics for those testing the feasibility of data extraction.

Practice	Eligible patients seen in last month	Clinical staff in practice	App users	Baseline (Jul): % complete CVD risk assessment	After 2 mths access in intervention group (Sep): % Complete CVD risk assessment	After 2 mths access in control group (Nov): % Complete CVD risk assessment
Practice 1 (access in August)	71	6	7	62.0	68.9	59.2
Practice 2 (access in October)	444	5	0	93.5	93.4	92.3
Practice 3 (access in October)	785	8	4	86.3	84.8	83.0
Practice 4 (access in October)	507	7	1	59.4	59.0	58.9

Note: CDSS: clinical decision support system; CVD: cardiovascular disease.
Four CDSS1 practices provided monthly practice data via Pen CS, to test the feasibility of this method for a larger planned trial. The primary outcome is complete CVD risk assessment data, defined as having a record for all risk factors included in a guidelines-based CVD risk assessment: sex, gender, diabetes, smoking, blood pressure, cholesterol.

Table 2
App use over time in all participating practices.

Month Year	Aug 2021	Sep 2021	Oct 2021	Nov 2021	Dec 2021	Jan 2022	Feb 2022	Mar 2022	Apr 2022	May 2022	Total
Case study 1: App access + monthly audit and feedback reports in CDSS1											
Practice 1 (access in August)	10	106	180	197	88	141	125	146	90	116	**1199**
Practice 2 (access in October)	–	–	0	0	0	0	0	0	0	0	**–**
Practice 3 (access in October)	–	–	9	74	14	6	56	76	36	35	**306**
Practice 4 (access in October)	–	–	0	3	0	0	0	0	0	0	**3**
Total	**10**	**117**	**197**	**285**	**105**	**147**	**181**	**222**	**131**	**153**	**1508**
Case study 2: App access only in CDSS2											
Practice 5 (access in August)	–	–	–	–	–	–	–	–	5	2	**7**
Practice 6 (access in August	–	11	8	11	3	–	–	–	–	–	**33**
Total	**0**	**11**	**8**	**11**	**3**	**0**	**0**	**0**	**5**	**2**	**40**

Note: CDSS: clinical decision support system. This table shows the number of sessions app by practice during trial period with monthly reports (Aug-Nov 2021) and a longer maintenance period during which there was limited engagement with practices (Dec 2021 – May 2022). Case study 1 involved more engagement with monthly practice reports in CDSS1. Case study 2 involved a different system with limited engagement.

> *"I think it's fair to say our GPs haven't really used the app but are excited for our nurse to start using it now that vaccination numbers are starting to drop. I went through the heart check with her last week but then we got caught up in vaccinations again."* (Practice Manager, Pen CS practice 4)

At another practice, the manager explained a failure to use the app because of staff shortages.

> *"Unfortunately, due to the COVID-19 outbreak our nurse resigned and at the moment I am very busy, and I couldn't check the CHAT-GP."* (Practice Manager, POLAR practice 1)

Many practices identified that the resources were more suitable to be used by a practice nurse than by a GP.

3.1.2.2. Technological issues. Participants found technological issues (e.g., the app not loading data correctly) which were detrimental to use of the resources.

> *"One thing of note when using the Topbar CHAT-GP app is that when I click print decision aid and then try to download it. It seems to not able to download properly from page 16 is blank. Printing the whole document is fine."* (Practice Nurse, Pen CS practice 1)

A practice manager described being unable to successfully engage in the feasibility study due to ongoing computer issues leading to the removal of all apps from their computer network.

> *"Unfortunately, we had some major and ongoing computer issues for a number of weeks in October, and we had to remove all third-party applications while it was being resolved. Once it was added back in, I did a manual data extraction to send the PHN, but it means no one would have used the tool over this time, given they could barely even open a file. (Practice Manager, Pen CS practice 2)*

3.1.2.3. Contextual issues. One practice manager described how the pandemic derailed all efforts to fully participate in the feasibility study.

> *"I have spoken to our doctors, but unfortunately, they have not really used the app. Covid issues took their focus and priority and there were issues of Topbar not keeping logged in, which meant they forgot to use it."*
> (Practice Manager, Pen CS practice 2)

Another practice nurse described doctors forgetting to use the app because of the burden of COVID-19.

> *"Sadly, as for many other things, COVID has got in the way"*
> (Practice Nurse, Pen CS practice 3)

4. Discussion

Our study aimed to test the feasibility of implementing a CVD decision aid (DA) via CDSS to auto-populate the tool in Australian general practice consultations, and as far as we are aware, is the first instance of this method of DA implementation. In testing the feasibility of such application, we have been able to illuminate the potential barriers and facilitators to the use of such tools for a future larger trial and make recommendations for implementing new CVD guidelines in 2023. We were also able to refine research processes including practice consent, training, and data extraction, to inform a future implementation trial.

This study demonstrated the feasibility of integrating patient DAs with two major CDSS in Australian general practice to enable them to

Table 3
Implementation issues and potential solutions.

	Issue identified in feasibility study	Potential solution for future implementation programs
Clinical decision support software (CDSS)	Practices reported Topbar spontaneously logging out which required GPs to spend time logging in again-often meaning they would not use the interface. There were also reported difficulties connecting to the practice server during use.	Liaison with technical support will always be required for software systems. Choose systems with easier options for practices to troubleshoot, ideally integrated with existing software instead of requiring additional setup and logins. Preferably, stakeholders could work towards patient decision aids being embedded directly in GP electronic clinical records.
Trial data extraction	Data extractions for practice data, related to the main trial outcomes, did not always occur at the same time and on some occasions even failed to extract. This caused delays in providing practices with audit and feedback reports on their practice data.	This issue required Pen CS liaising with the practices to determine the issues of the data extraction process. A practice in the trial failed to send its data twice for a single extraction. This required Pen CS support contacting the practice to rectify the issue.
Intervention website Application Programming Interface (API)	'Refreshing' issues. When the app was clicked on to open the API to the website. The page would often 'refresh' which caused all data currently viewed to temporarily disappear, only to reappear again in ~20 s.	These issues required liaising with the external app developer to fix the issues and also required setting up meetings between Pen CS and the I.T consultant. The study team paid a retainer to the I.T consultant to resolve ongoing issues with the app as they arose.
Intervention website	A practice reported issues downloading decision aids from the website. When downloading to print, some pages appeared blank.	These issues are rectifiable by the research team in coordination with the website developer.
Ongoing app license cost per practice	The cost of each licence per practice is high and requires a significant amount of research funding to implement. The cost may be a major barrier to implementing absolute CVD risk assessment decision aids of this kind in practice by other organisations.	The ongoing cost of implementing eHealth interventions in multiple software systems must be considered by policy makers to make such implementations achievable.
Digital literacy of staff	Our feasibility study highlighted the gaps in general practice staff knowledge of digital health systems. Many practice staff struggled to navigate the I.T specific issues that can arise with new e health tools and we found a reliance on basic and old tools that 'work' such as the built-in BestPractice Absolute CVD algorithm.	Provide specific education on the use of resources. Use software systems that are already acceptable to practice staff and fit with their workflows and business models.
Practice staff withdrawal	Staff turnover was an issue during the feasibility trial, with two practices losing their nurses. This affected implementation due to practices depending on this crucial member of the workforce who often was the champion of the research.	Relying on a practice champion may require appointing a new person to the role when that person moves. Financial incentives at practice and/or staff level may assist this transition to compensate time.
Practice recruitment	Recruitment was time consuming and challenging during the pandemic and was related to workforce shortages. A staff member with an interest in CVD prevention could overcome this.	Practices must consider if the research fits their current priorities and business model. If there is low interest in quality improvement for the topic, then financial incentives may be needed.
Contacting practices	Contacting general practices can be difficult due to competing with patients for reception and practice staff time.	Build rapport with a key contact at the practice to enable smooth and timely correspondence relating to the research matters.
Workforce roles	Even though we developed the app for GPs to use, practice managers and GPs themselves, often felt the app was better suited to use by the practice nurse prior to the patient seeing the GP. This way of working seemed to fit the practice business model better.	Piloting of decision aids needs to determine who in the practice is best suited to utilise the tools that are being implemented and how this fits with practice workflow and business models. Further feedback and input from practice nurses should be sought.
COVID-19 burden	The COVID-19 pandemic arose during the set-up of the reported feasibility study. Contextual challenges including competing priorities, staff shortages and low capacity for research, which led to high dropout and delayed intervention implementation.	A stepped wedge design is time sensitive and was not feasible during the pandemic due to unpredictable and localised disruptions to General Practice. A cluster or patient level trial would be more suitable if recruitment/implementation delays are expected.
Primary Health Networks (PHNs)	In line with our previous research into PHNs [38,39], we found that PHNs who worked with us to recruit GPs were not able to prioritise CVD prevention activities given competing priorities and high staff turnover.	Working with a single PHN would be more feasible than running a trial across many PHNs, if the research is aligned with local needs and programs. An alternative is to recruit practices independently of PHNs.
Time to build relationships	Time to build relationships with many stakeholders (Australia has 31 PHNs and around 37,000 general practitioners working across a variety of practices which vary in size and patient population, with multiple software companies competing) is very time consuming and difficult to sustain for a short-term research project.	A national CDSS with centralised app approval for guidelines would be more efficient than the region-based licenses in the fragmented Australian system. We are exploring options for alternative software integration solutions with the Commonwealth Scientific and Industrial Research Organisation (CSIRO).
Legal requirements	Changes to digital health regulations increased the time required to finalise contracts between stakeholders and internal approvals. Specifically, changes to the definition of a "medical device" after ethics approval increased institutional risk and required additional legal review and administrative processes.	Working closely with eHealth stakeholders ensured we were aware of regulation changes and could take appropriate steps for reapproval. Additional time and costs could be built into future implementation programs to anticipate such changes.
Contamination	Context changes over the course of the study became a contamination issue, including national quality improvement activities and a new program to promote Heart Health Checks.	Working closely with CVD prevention stakeholders ensured we were aware of context changes and could mitigate these to some extent, e.g., by changing the regional focus of recruitment.

Note: API: application programming interface; CDSS: clinical decision support system; CVD: cardiovascular disease; PHN: primary health network. These issues were documented throughout the study using observational methods and field notes after each interaction with a practice.

be auto populated from patient records, which had been identified as a key implementation issue in our previous research [34]. We were able to show uptake of the app in practices with varying engagement in CVD prevention, and this was maintained over 10 months, for some practices.

The study also identified numerous implementation barriers including the challenges of COVID-19 outbreaks and vaccination programs, the rollout of telehealth to general practice, eHealth software market changes, and new regulations defining clinical algorithms as a "medical device". A major issue for Australian general practice is the fragmented health system and software market. We do not have a single system in which to implement new eHealth tools, so developers must review the current market leaders to determine the best options for integration, which requires duplicating development and changing over time. A centralised CDSS and general practice data management system could improve this in future.

We identified recommendations for future implementation trials to overcome the challenges outlined, to reduce time and cost. This includes using a cluster or individual RCT design rather than stepped wedge when time-sensitive challenges are anticipated (i.e., outbreaks during a pandemic), partnering with stakeholders to ensure current knowledge of context changes and mitigate contamination issues, working with a single

region and software system rather than trying to manage multiple organisations over time with changing priorities, and including incentives for practice recruitment and staff champions.

The results of this study can be assessed by the 8 feasibility criteria recommended by Bowen et al., 2009 which include (1) demand, (2) implementation and integration, (3) acceptability, (4) limited efficacy testing, (5) practicality, (6) adaptation, (7) integration, and (8) expansion. Our study is primarily indicated by criteria 1 through 5: demand, implantation and integration, acceptability, limited efficacy testing and practicality.

Demand was indicated by a large number of interested primary health networks prior to COVID-19 (including all regions in the state of Queensland, where the trial was originally planned). Practices enrolled in the study had above average levels of CVD risk assessment data, indicating that additional outreach would be required to reach lower performing practices that were not as engaged with their primary health network. A future trial could target practices directly rather than working through primary health networks to recruit a more diverse sample.

Implementation and integration were assessed by providing the resources (Topbar app license, CHAT-GP app, website) and assessing uptake through analytics data (from Pen CS and Google Analytics). We found that the resources could be successfully implemented into general practice software with minimal support in some but not all practices. The feasibility study highlighted logistical issues associated with implementation of novel CDSS tools when the practice is unfamiliar with underlying software requirements. However we were able to successfully integrate the DA with two different CDSS systems.

Acceptability of the resources was assessed by both usage data and frequent communication with the practices during the feasibility trial, via email, telephone, and video conferencing. Participants were also invited to provide feedback by semi-structured interview but most declined due to COVID-19 capacity issues. Nevertheless our study showed that DAs implemented via CDSS are acceptable to practitioners once they have had an opportunity to use the software and found the electronic resources functional for assessing CVD risk and displaying the communication interface.

This feasibility study provided limited efficacy testing by extracting CVD risk assessment and management data from practices case study 1. We were not able to show a change in CVD risk data for eligible patients seen over the trial period, indicating that more support would be needed to educate and engage clinical staff in use of the intervention. It is also possible that CVD risk assessment was a lower priority than usual during the COVID-19 vaccination rollout period, as indicated by practices with low engagement.

The practicality of the intervention was similarly affected by COVID-19. This study was conducted in July to November 2021 and was affected by staff shortages, the need to divert resources to vaccination rollout, loss of key staff in the practices and staff needing to constantly adapt to changing state and federal requirements regarding isolation, quarantining and testing. Despite these challenges, high users reported the tools to be useful and integrated with workflow.

4.1. Strengths and limitations

Due to COVID-19 disruptions and staff capacity issues, our sample was smaller than we originally intended. We were not able to obtain more detailed qualitative data from the practices that withdrew or had low app use due to COVID-19 burden at the time of the study, so relied on detailed observational notes after each practice intervention. However the sample was diverse in terms of CVD prevention engagement and software systems used. The study produced meaningful insights into how patient decision aids can be integrated with general practice CDSS, and tested study procedures that could be optimised for a large-scale trial in future. Using a mixed methods process evaluation including observation, quantitative data collection, and qualitative feedback from low and high users of the intervention provided a comprehensive overview of barriers and enablers to implementing decision aids for the new CVD prevention guidelines.

4.2. Implications for future research

Shared decision making is an essential part of the CVD risk communication process, and decision aids have been explicitly recommended in the revised Australian guidelines for CVD prevention, due for release in 2023. Internationally, shared decision making is receiving more policy support over time so implementation strategies are an important avenue of research for the field [21,22,41-44]. Identifying optimal ways of implementing decision aids into guidelines and practice via tailoring of resources to identified groups and contexts is a future research priority [41].

This study showed it is feasible to integrate patient decision aids with general practice software to improve integration with workflows, but different software systems will be required in different regions and in future as the market changes. Alternative software solutions and integration with SMS recall systems and health literacy training will be explored in future research.

4.3. Conclusion

This study showed it is feasible and acceptable to integrate patient decision aids with General Practice software to improve implementation. The implementation barriers encountered in this program could be overcome by working with alternative software solutions and partnering with stakeholders to support the uptake of the software with additional education and outreach. This study will inform a future larger trial and implementation plans for the revised 2023 Australian CVD prevention guidelines.

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Declaration of Competing Interest

The authors declare that they have no competing interests.

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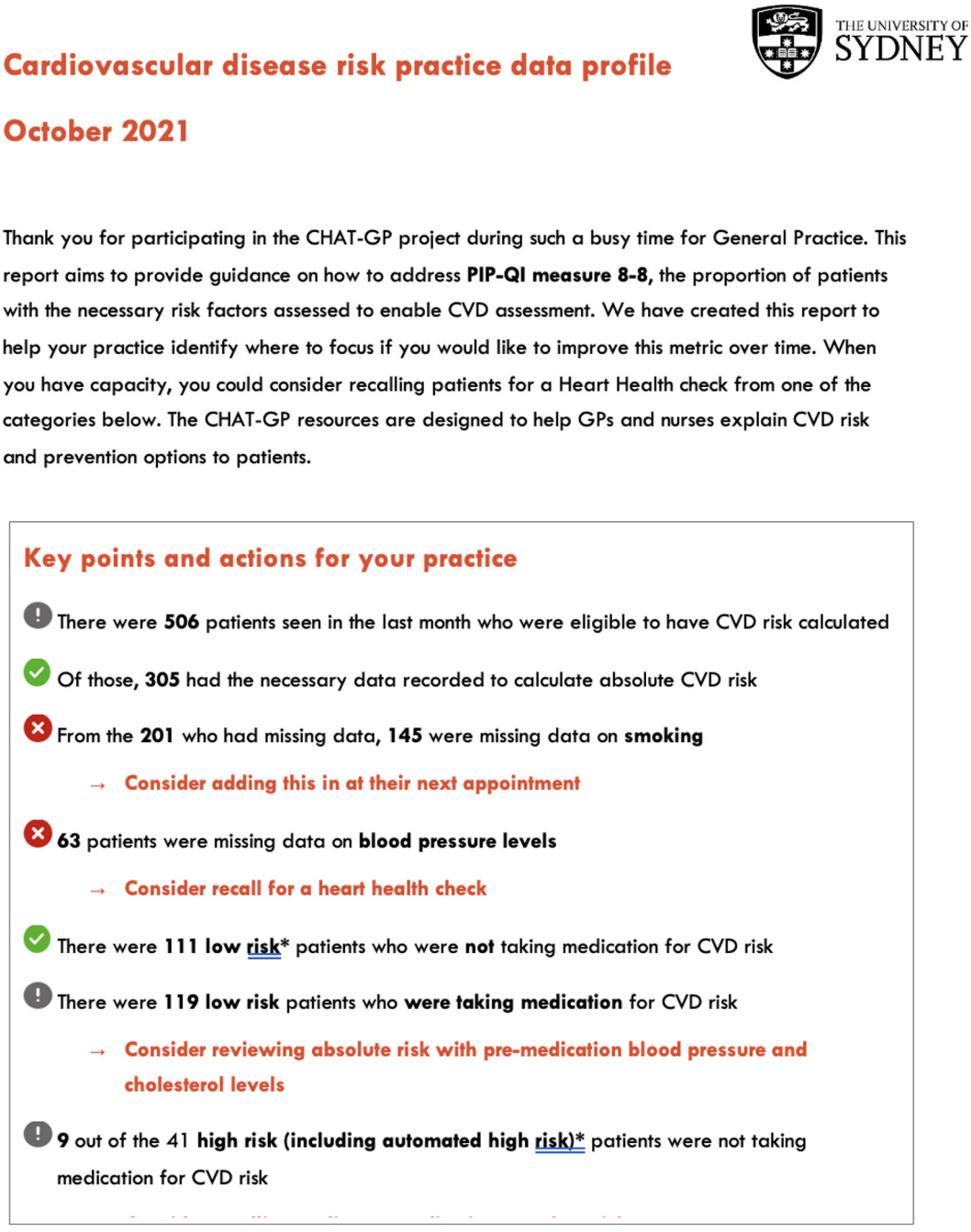
Appendix A. Showing data extracted from Pen CS monthly reports

	Proportion N (%)	%(n) in each CVD Risk Score category			
		Low	Moderate	High	Automatic High Risk
Total eligible patients filtered					
CVD Risk score calculated					
Female					
Male					
Other					
Smoker					
Hypertension					
Diabetes (type 1 or 2)					
Diabetes >60 yrs.					
Diabetes >60 yrs., NOT taking anti-hypertensive OR lipid-lowering medications					
Diabetes + ACR > 2.5 M, 3.5F					
Familial Hypercholesterolemia					
Familial Hypercholesterolemia NOT taking lipid-lowering medications					
Renal Impairment					
Renal impairment NOT taking anti-hypertensive AND lipid-lowering medications					
Measurements					
eGFR <45					
BP systolic ≥ 180					
BP diastolic ≥ 110					
Chol >7.5					
Indigenous Age > 74					
Not taking anti-hypertensive medication					
Not taking lipid lowering drug medication					
Not taking an anti-hypertensive AND a lipid lowering medication					
Taking anti-hypertensive AND taking a lipid lowering medication					
Taking anti-hypertensive medication					
ACE inhibitors/ARB					
Beta blockers					
Calcium antagonists					
Diuretics					
Taking lipid-lowering medication					

Appendix B. Example feedback report provided to practices during the pilot trial on a monthly basis



Cardiovascular disease risk practice data profile

THE UNIVERSITY OF SYDNEY

October 2021

Thank you for participating in the CHAT-GP project during such a busy time for General Practice. This report aims to provide guidance on how to address **PIP-QI measure 8-8,** the proportion of patients with the necessary risk factors assessed to enable CVD assessment. We have created this report to help your practice identify where to focus if you would like to improve this metric over time. When you have capacity, you could consider recalling patients for a Heart Health check from one of the categories below. The CHAT-GP resources are designed to help GPs and nurses explain CVD risk and prevention options to patients.

Key points and actions for your practice

- There were **506** patients seen in the last month who were eligible to have CVD risk calculated
- Of those, **305** had the necessary data recorded to calculate absolute CVD risk
- From the **201** who had missing data, **145** were missing data on **smoking**
  - → **Consider adding this in at their next appointment**
- **63** patients were missing data on **blood pressure levels**
  - → **Consider recall for a heart health check**
- There were **111 low risk*** patients who were **not** taking medication for CVD risk
- There were **119 low risk** patients who **were taking medication** for CVD risk
  - → **Consider reviewing absolute risk with pre-medication blood pressure and cholesterol levels**
- **9** out of the 41 **high risk (including automated high risk)*** patients were not taking medication for CVD risk

References

[1] Heart, stroke and vascular disease—Australian facts, Burden of cardiovascular disease [Internet]. Australian Institute of Health and Welfare. [cited 2022 Mar 15]. Available from: https://www.aihw.gov.au/reports/heart-stroke-vascular-diseases/hsvd-facts/contents/impacts/burden-of-cardiovascular-disease.

[2] Cardiovascular diseases (CVDs) [Internet]. [cited 2022 Mar 15]. Available from: https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds).

[3] National Vascular Disease Prevention Alliance. Guidelines for the management of absolute cardiovascular disease risk; 2012.

[4] New Zealand, Ministry of Health. Cardiovascular disease risk assessment and management for primary care. [Internet]. 2018 [cited 2022 Jul 4]. Available from: https://www.health.govt.nz/system/files/documents/publications/cvd-risk-assessment-and-management-for-primary-care-v2.pdf.

[5] Overview | Cardiovascular disease: risk assessment and reduction, including lipid modification | Guidance | NICE [Internet]. NICE; [cited 2022 Jul 4]. Available from: https://www.nice.org.uk/guidance/cg181.

[6] CVD Check : About NVPD [Internet]. [cited 2022 Mar 15]. Available from: https://www.cvdcheck.org.au/australian-absolute-cardiovascular-disease-risk-calculator.

[7] Practice Incentives Program Quality Improvement Measures: National report on the first year of data 2020-21, Data [Internet]. Australian Institute of Health and Welfare. [cited 2022 Mar 15]. Available from: https://www.aihw.gov.au/reports/primary-health-care/pipqi-measures-national-report-2020-21/data.

[8] Banks E, Crouch SR, Korda RJ, Stavreski B, Page K, Thurber KA, et al. Absolute risk of cardiovascular disease events, and blood pressure- and lipid-lowering therapy in

Australia. Med J Aust [Internet]. 2016 May 2.;204(8) [cited 2022 Mar 15]. Available from: https://www.mja.com.au/journal/2016/204/8/absolute-risk-cardiovascular-disease-events-and-blood-pressure-and-lipid.
[9] Cobiac LJ, Magnus A, Barendregt JJ, Carter R, Vos T. Improving the cost-effectiveness of cardiovascular disease prevention in Australia: a modelling study. BMC Public Health. 2012 Jun;12(1):398.
[10] Bonner C, Jansen J, McKinn S, Irwig L, Doust J, Glasziou P, et al. General practitioners' use of different cardiovascular risk assessment strategies: a qualitative study. Med J Aust. 2013 Oct;199(7):485–9.
[11] Bonner C, Jansen J, McKinn S, Irwig L, Doust J, Glasziou P, et al. Communicating cardiovascular disease risk: an interview study of General Practitioners' use of absolute risk within tailored communication strategies. BMC Fam Pract. 2014 May;15(1):106.
[12] Bonner C, Jansen J, McKinn S, Irwig L, Doust J, Glasziou P, et al. How do general practitioners and patients make decisions about cardiovascular disease risk? Health Psychol Off J Div Health Psychol Am Psychol Assoc. 2015 Mar;34(3):253–61.
[13] Bonner C, Jansen J, Newell BR, Irwig L, Glasziou P, Doust J, et al. I don't believe it, but i'd better do something about it: patient experiences of online heart age risk calculators. J Med Internet Res. 2014 May 5;16(5):e120.
[14] Bonner C, Fajardo MA, Hui S, Stubbs R, Trevena L. Clinical validity, understandability, and actionability of online cardiovascular disease risk calculators: systematic review. J Med Internet Res. 2018 Feb 1;20(2):e29.
[15] Peiris R, Cornell S, Greaves K, Bonner C. Do hospital consent forms for cardiology procedures meet health literacy standards? Evaluation of understandability and readability. Patient Educ Couns. 2022 May;105(5):1254–60.
[16] Bonner C, Patel P, Fajardo MA, Zhuang R, Trevena L. Online decision aids for primary cardiovascular disease prevention: systematic search, evaluation of quality and suitability for low health literacy patients. BMJ Open. 2019 Mar;9(3):e025173.
[17] Statistics c = AU; o = Commonwealth of A ou = Australian B of. Main Features - Main Features [Internet]. c = AU; o = Commonwealth of Australia; ou = Australian Bureau of Statistics. [cited 2022 Mar 15]. Available from: https://www.abs.gov.au/AUSSTATS/abs@.nsf/Lookup/4228.0Main + Features12006%20(Reissue); 2008.
[18] Berkman ND, Sheridan SL, Donahue KE, Halpern DJ, Crotty K. Low health literacy and health outcomes: an updated systematic review. Ann Intern Med. 2011 Jul 19;155(2):97–107.
[19] Barratt A, Trevena L, Davey HM, McCaffery K. Use of decision aids to support informed choices about screening. BMJ. 2004 Aug 28;329(7464):507–10.
[20] Stacey D, Légaré F, Lewis K, Barry MJ, Bennett CL, Eden KB, et al. Decision aids for people facing health treatment or screening decisions. Cochrane Consumers and Communication Group, editor. Cochrane Database Syst Rev [Internet]. 2017 Apr 12. [cited 2020 Mar 12]; Available from: https://doi.org/10.1002/14651858.CD001431.pub5.
[21] Waddell A, Lennox A, Spassova G, Bragge P. Barriers and facilitators to shared decision-making in hospitals from policy to practice: a systematic review. Implement Sci. 2021 Jul 31;16(1):74.
[22] Härter M, van der Weijden T, Elwyn G. Policy and practice developments in the implementation of shared decision making: an international perspective. Z Für Evidenz Fortbild Qual Im Gesundheitswesen. 2011 Jan 1;105(4):229–33.
[23] Kouri A, Yamada J, Lam Shin Cheung J, Van de Velde S, Gupta S. Do providers use computerized clinical decision support systems? A systematic review and meta-regression of clinical decision support uptake. Implement Sci. 2022 Mar 10;17(1):21.
[24] Kwan JL, Lo L, Ferguson J, Goldberg H, Diaz-Martinez JP, Tomlinson G, et al. Computerised clinical decision support systems and absolute improvements in care: meta-analysis of controlled clinical trials. BMJ. 2020 Sep 17(370):m3216.
[25] Delvaux N, Vaes B, Aertgeerts B, Van de Velde S, Vander Stichele R, Nyberg P, et al. Coding systems for clinical decision support: theoretical and real-world comparative analysis. JMIR Form Res. 2020 Oct 21;4(10):e16094.
[26] Sarkar U, Samal L. How effective are clinical decision support systems? BMJ. 2020 Sep 17;(370):m3499.
[27] Shojania KG, Jennings A, Mayhew A, Ramsay C, Eccles M, Grimshaw J. Effect of point-of-care computer reminders on physician behaviour: a systematic review. CMAJ Can Med Assoc J. 2010 Mar 23;182(5):E216.
[28] Van de Velde S, Heselmans A, Delvaux N, Brandt L, Marco-Ruiz L, Spitaels D, et al. A systematic review of trials evaluating success factors of interventions with computerised clinical decision support. Implement Sci IS. 2018 Aug 20(13):114.
[29] Roshanov PS, Fernandes N, Wilczynski JM, Hemens BJ, You JJ, Handler SM, et al. Features of effective computerised clinical decision support systems: meta-regression of 162 randomised trials. BMJ. 2013 Feb 14;(346):f657.
[30] Kawamoto K, Houlihan CA, Balas EA, Lobach DF. Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success. BMJ. 2005 Apr 2;330(7494):765.
[31] Liberati EG, Ruggiero F, Galuppo L, Gorli M, González-Lorenzo M, Maraldi M, et al. What hinders the uptake of computerized decision support systems in hospitals? A qualitative study and framework for implementation. Implement Sci. 2017 Sep 15;12(1):113.
[32] Devaraj S, Sharma SK, Fausto DJ, Viernes S, Kharrazi H. Barriers and facilitators to clinical decision support systems adoption: a systematic review. J Bus Adm Res. 2014 Jul 24;3(2):p36.
[33] Bonner C, Batcup C, Cornell S, Fajardo MA, Hawkes AL, Trevena L, et al. Interventions using heart age for cardiovascular disease risk communication: systematic review of psychological, behavioral, and clinical effects. JMIR Cardio. 2021 Nov 5;5(2):e31056.
[34] Bonner C, Fajardo MA, Doust J, McCaffery K, Trevena L. Implementing cardiovascular disease prevention guidelines to translate evidence-based medicine and shared decision making into general practice: theory-based intervention development, qualitative piloting and quantitative feasibility. Implement Sci. 2019 Aug;14(1):86.
[36] Australia H. Primary health networks (PHNs) [Internet]. [cited 2021 May 11]. Available from: https://www.healthdirect.gov.au/primary-health-networks-phns; 2020.
[37] Smith J, Sibthorpe B. Divisions of general practice in Australia: how do they measure up in the international context? Aust N Z Health Policy. 2007 Jul 13(4):15.
[38] Cornell S, Pickles K, Crosland P, Wet C, Trevena L, Bonner C. The role of Primary Health Networks in cardiovascular disease prevention: A qualitative interview study. Health Promot J Austr. 2021;(Nov 25) hpja.552.
[39] Walker P, Cornell S, Morgan SD, Bonner C, Fiona B, Walker P, et al. Chronic pain and cardiovascular disease prevention in primary care: a review of Australian Primary Health Network needs assessments. Aust Health Rev [Internet]. [cited 2021 Oct 5]; Available from: https://www.publish.csiro.au/AH/justaccepted/AH21058.
[41] Tracy MC, Thompson R, Muscat DM, Bonner C, Hoffmann T, McCaffery K, et al. Implementing shared decision-making in Australia. Z Für Evidenz Fortbild Qual Im Gesundheitswesen. 2022 Jun;171:15–21.
[42] Armenta-Arellano S, Muños-Hernández JA, Pavón-León P, Coronel-Brizio PG, Gutiérrez-Alba G. An overview on the promotion on patient-centered care and shared decision-making in Mexico. Z Für Evidenz Fortbild Qual Im Gesundheitswesen. 2022 Jun 1(171):93–7.
[43] Abbasgholizadeh-Rahimi S, Nguyen N, Alizadeh M, Poenaru D. Moving shared decision-making forward in Iran. Z Für Evidenz Fortbild Qual Im Gesundheitswesen. 2022 Jun 1(171):62–7.
[44] Coulter A, Collins A, Edwards A, Entwistle V, Finnikin S, Joseph-Williams N, et al. Implementing shared decision-making in UK: Progress 2017–2022. Z Für Evidenz Fortbild Qual Im Gesundheitswesen. 2022 Jun 1(171):139–43.