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Chronic disease IMPACT (chronic disease early detection and improved management in primary care project): An Australian stepped wedge cluster randomised trial

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Abstract

Background: Interrelated chronic vascular diseases (chronic kidney disease (CKD), type 2 diabetes (T2D) and cardiovascular disease (CVD)) are common with high morbidity and mortality. This study aimed to assess if an electronic-technology-based quality improvement intervention in primary care could improve detection and management of people with and at risk of these diseases.

Methods: Stepped-wedge trial with practices randomised to commence intervention in one of five 16-week periods. Intervention included (1) electronic-technology tool extracting data from general practice electronic medical records and generating graphs and lists for audit; (2) education regarding chronic disease and the electronic-technology tool; (3) assistance with quality improvement audit plan development, benchmarking, monitoring and support. De-identified data analysis using R 3.5.1 conducted using Bayesian generalised linear mixed model with practice and time-specific random intercepts.

Results: At baseline, eight included practices had 37,946 active patients (attending practice ≥3 times within 2 years) aged ≥18 years. Intervention was associated with increased OR (95% CI) for: kidney health checks (estimated glomerular filtration rate, urine albumin:creatinine ratio (uACR) and blood pressure) in those at risk 1.34 (1.26–1.42); coded diagnosis of CKD 1.18 (1.09–1.27); T2D diagnostic testing (fasting glucose or HbA1c) in those at risk 1.15 (1.08–1.23); uACR in patients with T2D 1.78 (1.56–2.05). Documented eye checks within recommended frequency in patients with T2D decreased 0.85 (0.77–0.96). There were no significant changes in other assessed variables.

Conclusions: This electronic-technology-based intervention in primary care has potential to help translate guidelines into practice but requires further refining to achieve widespread improvements across the interrelated chronic vascular diseases.

Keywords

Electronic medical records, general practice, chronic kidney disease, diabetes mellitus, cardiovascular disease

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Introduction

Interrelated chronic vascular diseases, comprising chronic kidney disease (CKD), diabetes and cardiovascular disease (CVD) are common, affecting around 29% of adult Australians, share common risk factors and have high morbidity and mortality.[1] Together these conditions lead to substantial expense, costing Australia over 10 billion AUD in 2009.[2–4] In Australia, general practice plays a key role in chronic disease diagnosis and management with approximately 85% of the population attending general practice annually[5] and more than 95% of general practitioners using computers for clinical activities.[6]

Despite there being overlapping risk factors and complications of the interrelated chronic vascular diseases, with substantial numbers of patients with more than one of these conditions and in some cases, overlapping management strategies, there is currently little published data assessing electronic-technology-based interventions addressing CKD, diabetes and CVD simultaneously in primary care. Two studies that did include these three conditions and assessed electronic decision support tool-based interventions in primary care, showed an increase in patients with chronic disease with appropriate investigations ordered[7] and increased appropriate cardiovascular screening in those at risk of CVD.[8]

An earlier observational study from our centre demonstrated the potential for an electronic-technology tool-based intervention to assist with quality improvement for CKD in general practice,[9] with benefits seen in risk factor detection, diagnostic testing in those at risk, documentation of CKD, disease monitoring and prescription of recommended pharmacotherapy. There are a small number of published randomised-controlled trials (RCTs) comparing electronic-technology-based interventions in primary care for CKD to usual care and none including practice benchmarking, where practices compare their own guideline adherence to that of other practices. Several showed improved intervention arm management,[10–12] though one only in extended follow-up as treated analysis,[12] others showed no change.[13,14]

Several RCTs, including some with benchmarking,[15–18] compare the use of electronic-technology-based interventions in primary care for type 2 diabetes (T2D) to usual care, in high income countries, with trials from Europe[15,17–19] and North America[16,20–22] showing improvements to management[15–22] while one large Belgian study found no improvement.[23]

Multiple RCTs have assessed the use of electronic-technology-based interventions to address CVD in primary care compared to usual care. A systematic review assessing primary or secondary CVD risk management using electronic decision support tools including multiple studies with primary care physicians found large heterogeneity of interventions and results.[24] There have also been heterogeneous effects seen across RCTs addressing atrial fibrillation (AF),[25–29] heart failure (HF),[30,31] ischaemic heart disease (IHD).[31–33] There are few RCT data addressing risk factor management in people with prior ischaemic stroke (IS), with one UK study finding no improvement[34] and a paucity of RCT data addressing peripheral vascular disease (PVD) or familial hypercholesterolaemia (FH).

The objective of chronic disease IMPACT (chronic disease early detection and improved management in primary care project) was to assess whether an electronic-technology tool-based intervention including education, assistance with quality improvement audit plan development, benchmarking, monitoring and support was able to improve the detection and management of patients in general practice with, and at risk of, the interrelated chronic vascular diseases (CKD, T2D and CVD) in accordance with Australian recommendations (if available, otherwise USA recommendations) and to inform future studies. A summary of guidelines used (and any guideline modifications required in this study due to data limitations) is provided in Supplementary Materials Table S1.

Materials and methods

This study required that the intervention be delivered in clusters, because the intervention was at the level of the practice (one cluster). Available resources permitted intervention delivery to a limited number of clusters and a stepped-wedge cluster RCT provided greater power than other RCT designs.

There were nine clusters, each comprising one general practice. There were four sequences with two to three clusters included in each sequence. There were five periods each of 16-week duration. Rather than one cohort present at baseline that is then followed all the way through, the participants in each period consisted of all eligible patients in the participating practices at that time point (a cross-section).

Eligibility criteria for practices included: general practices located in Victoria, Australia; >2000 patients with electronic medical records (EMRs) within the practice; holding a licence for Pen Computer Systems Clinical Audit Tool (Pen CAT) or the practice being willing to install this; practices not participating in other quality improvement projects targeting similar outcomes; practice using the same EMR system (Medical Director, Best Practice or ZedMed) continuously for ≥2 years. Eligibility criteria for patients within the practices included: age ≥18 years and being an active patient (attendance at the same general practice ≥ three times in the past 24 months – a definition used by the Royal Australian College of General Practitioners [RACGP][35]). De-identified data for study analysis were extracted every 16 weeks from the general practice EMRs using the Pen CAT data extraction tool[36] on site at each of the practices by practice staff. These data were then forwarded to study staff. Serial data

Table 1. Summary of intervention components.

Intervention component	Summary
Electronic-technology tool	Clinical audit software co-designed by physicians and general practitioners together with Pen Computer systems Tool enabled practice staff to visualise graphs showing practice patients at risk of or with the included chronic diseases and proportion of patients documented to have guideline recommended care (see Supplementary Materials Figures S1 and S2) Practice staff could use tool to generate worklists of patients not yet documented to be receiving guideline recommended care, e.g. patients with T2D without up-to-date coded foot or eye examination (see Supplementary Materials Figure S3)
Education provided to practices	All practices received an education session regarding the intervention and guidance on how to use the electronic-technology tool to facilitate a quality improvement clinical audit All practices received an education session from a nephrologist regarding CKD detection and management Practices were offered education sessions regarding the other included chronic diseases and some requested and received a session on FH from a lipid specialist, but no other chronic disease specific education sessions were requested or provided
Monitoring and support provided to practices	Benchmarking report initially provided to practices outlining performance compared to aggregated data from all practices in the study Practices supported to identify areas to be focused on in quality improvement audit project (eligible for continuing professional development points) Study staff visited practices at 16-week intervals and provided reports comparing practices' current performance to their own previous performance Study staff available to answer practice staff queries regarding the electronic-technology tool or clinical questions

sets from each practice were checked by study staff for data reliability prior to analysis.

The intervention consisted of three major components (see Table 1): The electronic-technology tool (co-designed by physicians (specialising in nephrology, endocrinology, cardiology, neurology and lipids) and general practitioners together with Pen Computer Systems); education to practices; monitoring and support to practices. The electronic-technology tool enabled practice staff to identify patients at their practice with, or at risk of, one or more of the interrelated chronic vascular diseases and to see whether they were meeting/not meeting their objectives. Practices could choose which areas they wished to focus on and use the tool to generate a worklist of patients to be targeted for recall and review. Each of the practices received an on-site education session about the intervention and how to use the electronic-technology tool to do a quality improvement project, as well as education about CKD from a nephrologist. Practices were invited to receive other education sessions to be provided by other specialists about the other interrelated chronic vascular diseases. Some practices chose to receive an additional education session about FH from a lipid specialist, but no other CVD- or T2D-specific education was requested by practices.

Prior to intervention commencement, practices maintained usual care. Then, on commencing the intervention, they received a baseline report showing their practice's performance in risk factor and disease detection/monitoring/management compared to an aggregate of all the practices in the study. After reviewing this data, practices were encouraged to consider areas they would be interested to focus on for a quality improvement audit project, for which general practitioners would be eligible for continuing professional development points. Practices were then shown by study staff how to generate worklists of patients meeting the criteria selected by the practice staff using the electronic-technology tool. Worklists did not provide recommended actions for patients, but simply listed the patients meeting specified criteria, for example, all patients with pathology tests indicating a possible diagnosis of CKD but no coded diagnosis of CKD. Study staff visited practices at approximately 16-week intervals to present reports of each practice's latest performance compared to their previous performance. From the time of intervention implementation, study staff were available to answer questions from practices about using the electronic-technology tool and generating worklists as well as any disease specific questions they may have about the interrelated chronic vascular diseases.

During the control phase of the study, prior to being stepped into the intervention, practices provided usual care. They did not have access to the electronic-technology tool provided as part of the intervention (though did have access to standard Pen CAT software) and did not have

any education, monitoring or support provided by study staff. Once practices were in the intervention phase, they maintained access to the electronic-technology tool and monitoring and support from study staff.

There were multiple prespecified outcomes assessing risk factor assessment, risk factor presence, diagnostic testing in those at risk, chronic disease presence and chronic disease management (see Table 2). In order for data to be captured by the data extraction tool, data entered by clinicians must have been entered in specific designated sections of the EMR and would not be detected if entered in free-text. Coded diagnostic data were recorded using Pyefinch for Best Practice, Docle for Medical Director and ICPC2-Plus for Zedmed. Pathology data were only captured if electronically transferred from laboratory to the EMR, but not if only on scanned paper records. Medications were considered to be prescribed if currently listed on a patient's medication list even if the prescription would be out-of-date in recognition that the patient may be receiving their prescription from another specialist.

This study was approved by the Western Health Research and Ethics Committee, HREC/16/WH/124. Each of the practices provided informed written consent to participate prior to study initiation, however there was a waiver of consent for individual patients within the practices (as outlined in the ethics committee application) since this was not practicable, given that only their de-identified data would be analysed and only aggregated data published. The trial was registered with the Australian New Zealand Clinical Trials Registry: ACTRN12617000335392.

Simple randomisation occurred after all practices had been recruited. Once randomisation had taken place, practices were advised of the trial schedule. Practices were enrolled by a project officer who subsequently assigned practices to their sequence as per randomisation schedule. This was an open intervention with no blinding.

At the time of study design, there were few resources available regarding sample size calculation for stepped wedge cluster randomised trials with binary outcomes and CD IMPACT proceeded without sample size calculation. Multiple resources have subsequently been published including an online Shiny CRT calculator.[38]

Statistical analysis

Statistical analysis was performed using R version 3.5.1 and the rstanarm library. A Bayesian generalised linear mixed model with practice and time-specific random intercepts was used to analyse the data. Statistical adjustment for unmeasured characteristics within the practices was done using random effects for practice and time, rather than fixed effects, due to increased efficiency. Odds ratios with two-sided 95% credible intervals are provided, with a threshold for statistical significance at 0.05. A sensitivity analysis excluding a practice with outlying data was conducted.

Results

Practice recruitment and enrolment

A convenience sample of 14 practices was approached with five declining to participate due to having too many other commitments. The first practice enrolled in November 2016, the first clinical data collection from practices was in April 2017 and the last data collection was in July 2018. The intervention commenced in the first practices in April 2017. The trial ran according to schedule and ended at the planned time.

One practice, which was part of sequence two, was excluded from the analysis due to a practice merger prior to study commencement which impacted data quality (see Figure 1).

Practice location ranged from 12 to 165 km from Melbourne's centre with one located in an inner metropolitan area, four from outer metropolitan areas and three in inner regional areas. Six practices had private and two corporate ownerships. Exclusive bulk-billing (government funding of care with no additional cost to patients) took place at two practices, while the other practices required some patients to pay fees in addition to the government funding. All eight practices had index of relative socio-economic disadvantage scores in the lowest four quintiles with five practices below the 50th percentile.[39] Four of the practices were located in areas where over 12% of those whose main language is not English report low English proficiency.[40,41] At baseline in the eight included practices, there were 37,946 active patients aged 18 years or older. The median age was 47.8 years and 39.6% of these patients were male. At final data collection there were 37,385 patients with similar average age and sex distribution to baseline.

Figure 2 shows the practice and patient numbers in each sequence and period.

Aggregated baseline data from April 2017, before any of the practices received the intervention, have been published in detail.[42] A summary table with aggregated raw baseline data and data from July 2018 (after all practices had received the intervention) is provided here (see Table 3).

Risk factor assessment

There was no statistically significant change in the proportion of patients with documentation of risk factor assessment as per recommendations (see Figure 3).

Risk factor presence

There was no statistically significant change in the proportion of patients recorded as having chronic disease risk factors (see Figure 4).

Table 2. Variables assessed.

Risk factor assessment
Smoking status recorded
Lipid profile recorded[a]
Body mass index recorded[b]
Blood pressure recorded[c]
Aboriginal or Torres Strait Islander status recorded
Risk factor presence
Risk factor present for chronic kidney disease (CKD)[d]
Risk factor present for type 2 diabetes (T2D)[e]
Risk factor present for cardiovascular disease (CVD)[f]
Obese (body mass index $\geq$30)
Coded hypertension
Hypertensive reading with no coded hypertension diagnosis[g]
Daily smokers
Aboriginal or Torres Strait Islander
Diagnostic testing in those at risk
CKD diagnostic testing in those at risk[h]
T2D diagnostic testing in those at risk[i]
Chronic disease presence
Tests indicating possible CKD but no coded diagnosis[j]
Tests indicating possible diabetes but no coded diagnosis[k]
Testis indicating possible familial hypercholesterolaemia (FH) but no coded diagnosis[l]
Coded CKD diagnosis
Coded T2D diagnosis
Coded peripheral vascular disease (PVD) diagnosis
Coded ischaemic stroke (IS) diagnosis
Coded ischaemic heart disease (IHD) diagnosis
Coded heart failure (HF) diagnosis
Coded atrial fibrillation (AF) diagnosis
Coded FH diagnosis
Chronic disease management
CKD and prescribed statin

(continued)

Table 2. Continued.

CKD and prescribed angiotensin-converting-enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB)
T2D and estimated glomerular filtration rate (eGFR) within 12 months
T2D and urine albumin creatinine ratio (uACR) within 12 months
T2D and glycated haemoglobin (HbA1c) within 12 months
T2D and foot exam within 12 months
T2D and eye exam within 24 months or 12 months if Aboriginal or Torres Strait Islander
PVD and prescribed statin
PVD and prescribed antiplatelet
IS and prescribed statin
IS and prescribed antiplatelet or anticoagulant
IHD and prescribed statin
IHD and prescribed beta blocker
IHD and prescribed antiplatelet
IHD and prescribed ACEI/ARB
HF and prescribed beta blocker
HF and prescribed ACEI/ARB
AF with CHA2DS2-VASc score[m] >1 in males or >2 in females and prescribed anticoagulant
FH and prescribed statin

[a]Testing as per Royal Australian College of General Practitioners (RACGP) guidelines[37] for people without an existing diagnosis of IHD, PVD or IS from age 45 or from age 35 in Aboriginal or Torres Strait Islander peoples: at least every five years in those with a low absolute CVD risk, every two years in those with a moderate absolute risk and every 12 months in those with a high absolute risk. Denominator used is people without a coded diagnosis of IHD, PVD or IS who are ≥45 or ≥35 years in Aboriginal or Torres Strait Islander peoples.
[b]Measurement required as per RACGP guidelines[37] every 2 years except for people in the following categories: aboriginal or Torres Strait Islander peoples, required every 12 months; people with previous body mass index >25 kg/m^2, required every 6 months.
[c]Testing as per RACGP guidelines[37] for people without an existing diagnosis of IHD, PVD or IS from age 18: at least every two years in those with a low absolute CVD risk, every 12 months in those with a moderate absolute risk and every 3 months in those with a high absolute risk. Denominator used is people with no coded diagnosis of IHD, PVD or IS.
[d]CKD risk factor considered present if no coded diagnosis CKD and recorded to have any of: aboriginal or Torres Strait Islander >30 years; body mass index ≥30 kg/m^2; current smoker; coded diagnosis hypertension; systolic blood pressure (SBP) > 140 mmHg; diastolic blood pressure (DBP) > 90 mmHg; coded diagnosis ischaemic CVD; coded diagnosis type 1 or type 2 diabetes; fasting blood glucose (FBG) ≥ 7 mmol/L; random blood glucose (RBG) ≥ 11.1 mmol/L; HbA1c ≥ 6.5%.
[e]T2D risk factor considered present if no coded diagnosis T2D and recorded to have any of: FBG ≥7 mmol/L; RBG ≥11.1 mmol/L; HbA1c ≥ 6.5%; age >40 years and any of coded diagnosis hypertension, SBP >140 mmHg, DBP >90 mmHg or body mass index ≥30 kg/m^2; coded diagnosis ischaemic CVD; coded diagnosis gestational diabetes; coded diagnosis polycystic ovarian syndrome; prescribed antipsychotic medication.
[f]CVD risk factor present if no coded diagnosis CVD and recorded to have any of: age >60 years and either coded diagnosis type 1 or type 2 diabetes or tests indicating possible diabetes (FBG ≥7 mmol/L, RBG ≥11.1 mmol/L, HbA1c ≥ 6.5%); coded diagnosis CKD or tests indicating possible CKD (eGFR <60 mL/min/1.73 m^2, uACR ≥3.5 mg/mmol in females or ≥2.5 mg/mmol in males); SBP ≥140 mmHg; DBP ≥90 mmHg; coded diagnosis FH; LDL >2; total cholesterol >7.5 mmol/L; current smoker.
[g]Most recent SBP >140 mmHg or DBP >90 mmHg.
[h]Kidney health check comprising all of eGFR, uACR and BP for those at risk of CKD within 2 years, or within 1 year if hypertension or diabetes present.
[i]Diabetes testing comprising any of FBG or HbA1c within 3 years.
[j]Possible CKD based on any of: eGFR <60 mL/min/1.73 m^2, uACR ≥2.5 mg/mmol in men, uACR ≥3.5 mg/mmol in women.
[k]Possible diabetes based on any of: FBG ≥7 mmol/L; RBG ≥11.1 mmol/L; HbA1c ≥ 6.5%.
[l]Possible FH based on either: low-density lipoprotein >6.5 mmol/L; low-density lipoprotein >5 and prescribed a statin.
[m]Risk-based score to determine requirement for anticoagulation in patients with AF: congestive heart failure (1 point); Hypertension (1 point); Age ≥75 years (2 points); Diabetes (1 point); history of Stroke/TIA/systemic thromboembolism (2 points); Vascular disease (1 point); Age 65–74 years (1 point); Sex – female (1 point).

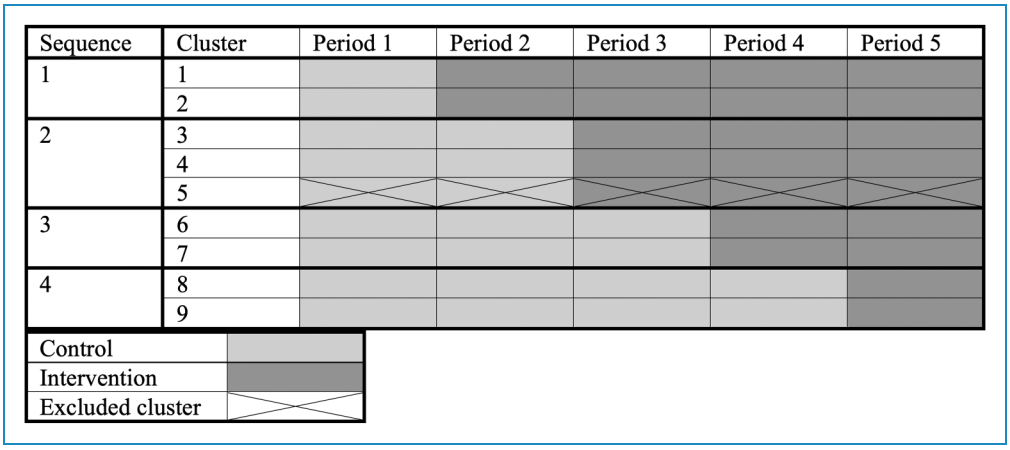

Figure 1. Overview of stepped wedge trial (showing excluded practice).

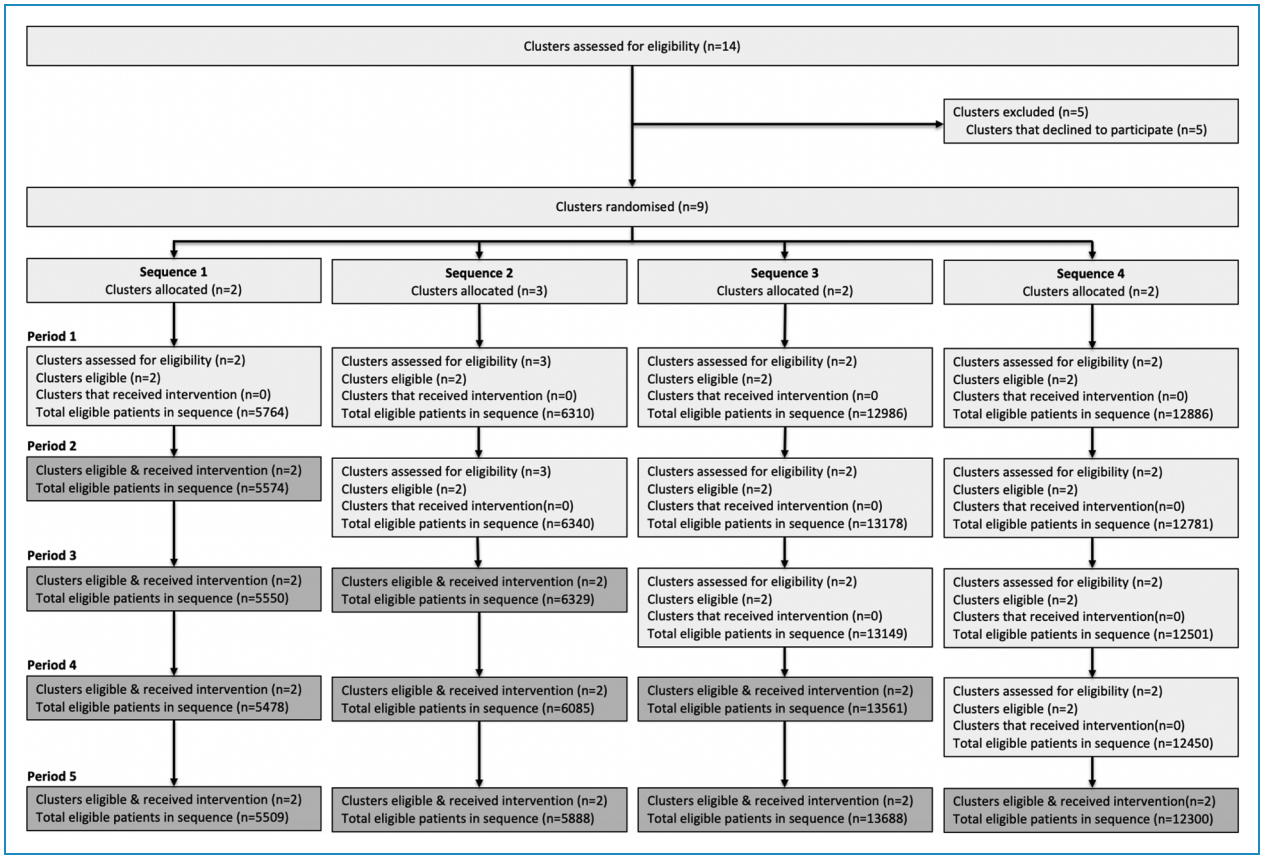

Figure 2. Participant flow diagram.

Diagnostic testing in those at risk

There was increased diagnostic testing in people at risk of CKD with a kidney health check (consisting of all of: eGFR, uACR and blood pressure testing) with an odds ratio (95% credible interval [CI]) of 1.34 (1.26–1.42) and number needed to treat (NNT) (95% CI) of 19 (13–72). There was also increased diagnostic testing (with either fasting blood glucose or HbA1c levels) in people at risk of T2D with an odds ratio of 1.15 (1.08–1.23) and NNT of 34 (21–102). See Figure 4.

Table 3. Aggregated raw data prior to intervention (April 2017) and after all clusters received intervention (July 2018).

Variable (n = total assessed) (Outcomes reaching statistical significance with generalised linear mixed model analysis presented in Bold)	April 2017 raw number/ denominator (proportion)	July 2018 raw number/ denominator (proportion)
Risk factors assessed as per guideline recommendations		
Smoking status recorded	34,059/37,946 (90%)	33,882/37,385 (91%)
Lipid profile recorded	12,156/17,616 (69%)	12,880/17,396 (74%)
Body mass index recorded	11,025/37,946 (29%)	11,049/37,385 (30%)
Blood pressure recorded	15,175/35,506 (43%)	16,526/35,050 (47%)
Aboriginal or Torres Strait Islander status recorded	32,384/37,946 (85%)	32,536/37,385 (87%)
Risk factors present		
Risk factor/s present for chronic kidney disease (CKD)	18,698/36,237 (52%)	18,217/35,208 (52%)
Risk factor/s present for type 2 diabetes (T2D)	12,180/35,231 (35%)	12,286/34,620 (35%)
Risk factor/s present for cardiovascular disease (CVD)	23,055/35,346 (65%)	23,449/34,889 (67%)
Obesity (body mass index $\geq$ 30 kg/m^2)	9409/37,946[a] (25%)	9640/37,385[a] (26%)
Coded hypertension	7561/37,946[a] (20%)	7455/37,385[a] (20%)
Hypertensive reading with no coded hypertension diagnosis	4522/37,946[a] (12%)	5001/37,385[a] (13%)
Daily smoking	5384/37,946[a] (14%)	4965/37,385[a] (13%)
Aboriginal or Torres Strait Islander	476/37,946[a] (1.3%)	433/37,385[a] (1.2%)
Diagnostic testing completed as per guideline recommendations		
CKD diagnostic testing in those at risk	**3630/18,698 (19%)**	**4532/18,213 (25%)**
T2D diagnostic testing in those at risk	**4143/12,180 (34%)**	**6141/12,286 (50%)**
Tests suggestive of diagnosis but no diagnosis coded		
Tests indicating possible CKD but no coded diagnosis	2300/36,237 (6.3%)	2053/35,208 (5.8%)
Tests indicating possible diabetes but no coded diagnosis	558/35,231 (1.6%)	578/34,620 (1.7%)
Tests indicating possible familial hypercholesterolaemia (FH) but no coded diagnosis	125/37,920 (0.33%)	133/37,350 (0.36%)
Coded diagnosis present		
Coded CKD diagnosis	**1709/37,946 (4.5%)**	**2177/37,385 (5.8%)**
Coded T2D diagnosis	2715/37,946 (7.2%)	2765/37,385 (7.4%)
Coded peripheral vascular disease (PVD) diagnosis	199/37,946 (0.52%)	211/37,385 (0.56%)
Coded ischaemic stroke (IS) diagnosis	793/37,946 (2.1%)	777/37,385 (2.1%)

(continued)

Table 3. Continued.

Variable (n = total assessed) (Outcomes reaching statistical significance with generalised linear mixed model analysis presented in Bold)	April 2017 raw number/ denominator (proportion)	July 2018 raw number/ denominator (proportion)
Coded ischaemic heart disease (IHD) diagnosis	1703/37,946 (4.5%)	1609/37,385 (4.3%)
Coded heart failure (HF) diagnosis	415/37,946 (1.1%)	402/37,385 (1.1%)
Coded atrial fibrillation (AF) diagnosis	863/37,946 (2.3%)	867/37,385 (2.3%)
Coded FH diagnosis	26/37,946 (0.06%)	35/37,385 (0.09%)
Chronic disease managed as per guideline recommendations		
CKD and prescribed statin	953/1709 (56%)	1253/2177 (58%)
CKD and prescribed angiotensin-converting-enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB)	1105/1709 (65%)	1440/2177 (66%)
T2D and estimated glomerular filtration rate (eGFR) within 12 months	2202/2715 (81%)	2211/2765 (80%)
T2D and urine albumin creatinine ratio (uACR) within 12 months	**1508/2715 (56%)**	**1809/2765 (65%)**
T2D and glycated haemoglobin (HbA1c) within 12 months	2205/2715 (81%)	2199/2765 (80%)
T2D and foot exam within 12 months	1073/2715 (40%)	965/2765 (35%)
T2D and eye exam within 24 months or within 12 months in Aboriginal or Torres Strait Islander peoples	**1046/2715 (39%)**	**1008/2765 (36%)**
PVD and prescribed statin	139/199 (70%)	150/211 (71%)
PVD and prescribed antiplatelet	120 /199 (60%)	134/211 (64%)
IS and prescribed statin	521/793 (66%)	542 /777 (70%)
IS and prescribed antiplatelet or anticoagulant	629/793 (79%)	621/777 (80%)
IHD and prescribed statin	1339/1703 (79%)	1305/1609 (81%)
IHD and prescribed beta blocker	772/1703 (45%)	740/1609 (46%)
IHD and prescribed antiplatelet	1256/1703 (74%)	1221/1609 (81%)
IHD and prescribed ACEI/ARB	1155/1703 (68%)	1106/1609 (69%)
HF and prescribed beta blocker	221/415 (53%)	215/402 (53%)
HF and prescribed ACEI/ARB	263/415 (63%)	256/402 (64%)
AF with CHA2DS2-VASc score[b] >1 in males or >2 in females and prescribed anticoagulant	468/676 (69%)	497/686 (72%)
FH and prescribed statin	19/26 (73%)	25/35 (71%)

[a]When assessing the presence of risk factors, the whole study population has been used as a denominator, not just people with up-to-date tests, as we have included those at risk based on older test results as well. We have assumed that all patients with no data recorded do not have the outcome of interest.
[b]Risk-based score to determine requirement for anticoagulation in patients with AF: congestive heart failure (1 point); Hypertension (1 point); Age ≥75 years (2 points); Diabetes (1 point); history of Stroke/TIA/systemic thromboembolism (2 points); Vascular disease (1 point); Age 65–74 years (1 point); Sex – female (1 point).

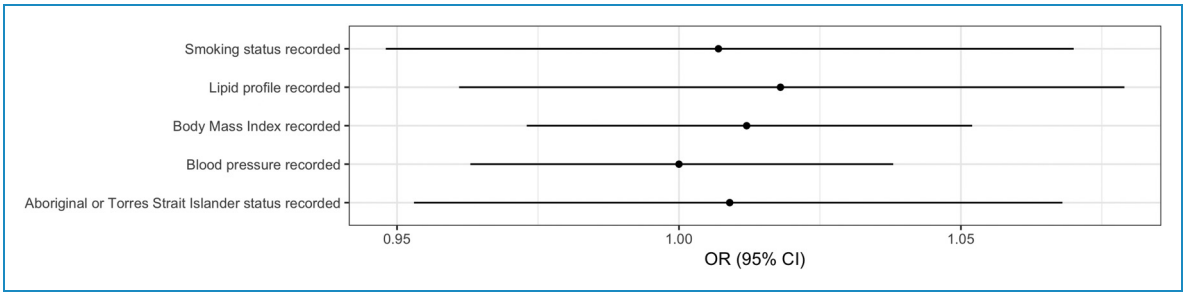

Figure 3. Risk factor assessments recorded as per national recommendations.

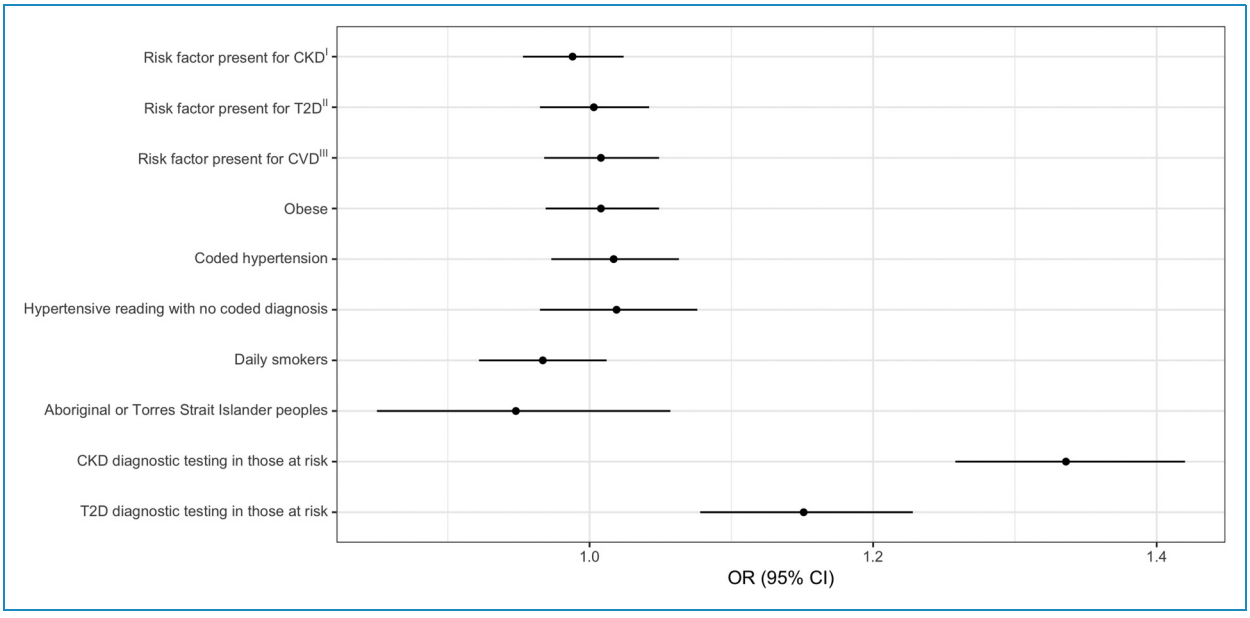

Figure 4. Risk factor presence and disease testing in those at risk.
[I] Chronic kidney disease. [II] Type 2 diabetes. [III] Cardiovascular disease.

Chronic disease diagnosis

There was an increased coded diagnosis of CKD with an odds ratio of 1.18 (1.09–1.28) and NNT of 125 (24–1777) but no statistically significant changes for the other chronic diseases. See Figure 5.

Chronic disease management (including disease monitoring)

For people with T2D there was increased uACR testing with an odds ratio of 1.79 (1.55–2.05) and NNT of 8 (6–18), but there was no statistically significant difference in HbA1c testing, eGFR testing or eye examinations. There was a reduction in documented eye examinations within 24 months (or within 12 months as recommended for patients of Aboriginal or Torres Strait Islander Origin) in patients with T2D with an odds ratio of 0.85 (0.77–0.96) and number needed to harm of 39 (17–410). There were no significant changes in other management variables (see Figure 6).

Ancillary analysis

A sensitivity analysis excluding a practice with outlying data (so that only seven practices were included) did not change any of the significant outcomes (see Supplementary Materials Table S2). An analysis to account for heterogeneity of the intervention found none of the outcomes that were significant in the original analysis remained statistically significant. An analysis to account for time-on-intervention effect found increased diagnostic testing for CKD in those at risk, increased coded diagnoses of CKD and increased uACR testing in T2D all remained significant while the increased diagnostic testing for T2D in those at risk was no longer statistically significant and eye examinations for

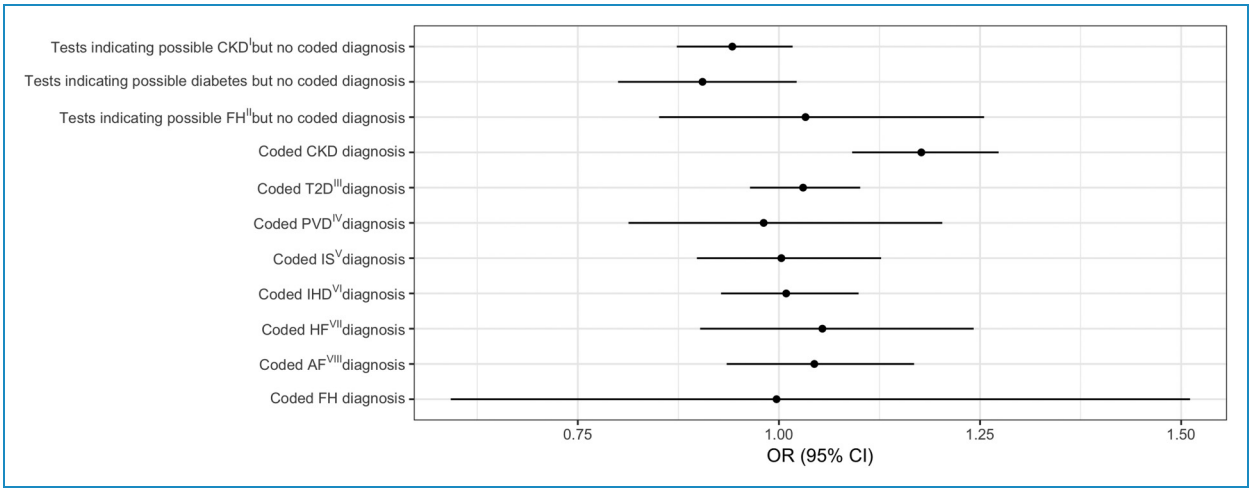

Figure 5. Chronic disease presence.
[I] Chronic kidney disease. [II] Familial hypercholesterolaemia. [III] Type 2 diabetes. [IV] Peripheral vascular disease. [V] Ischaemic stroke. [VI] Ischaemic heart disease. [VII] Heart failure. [VIII] Atrial fibrillation.

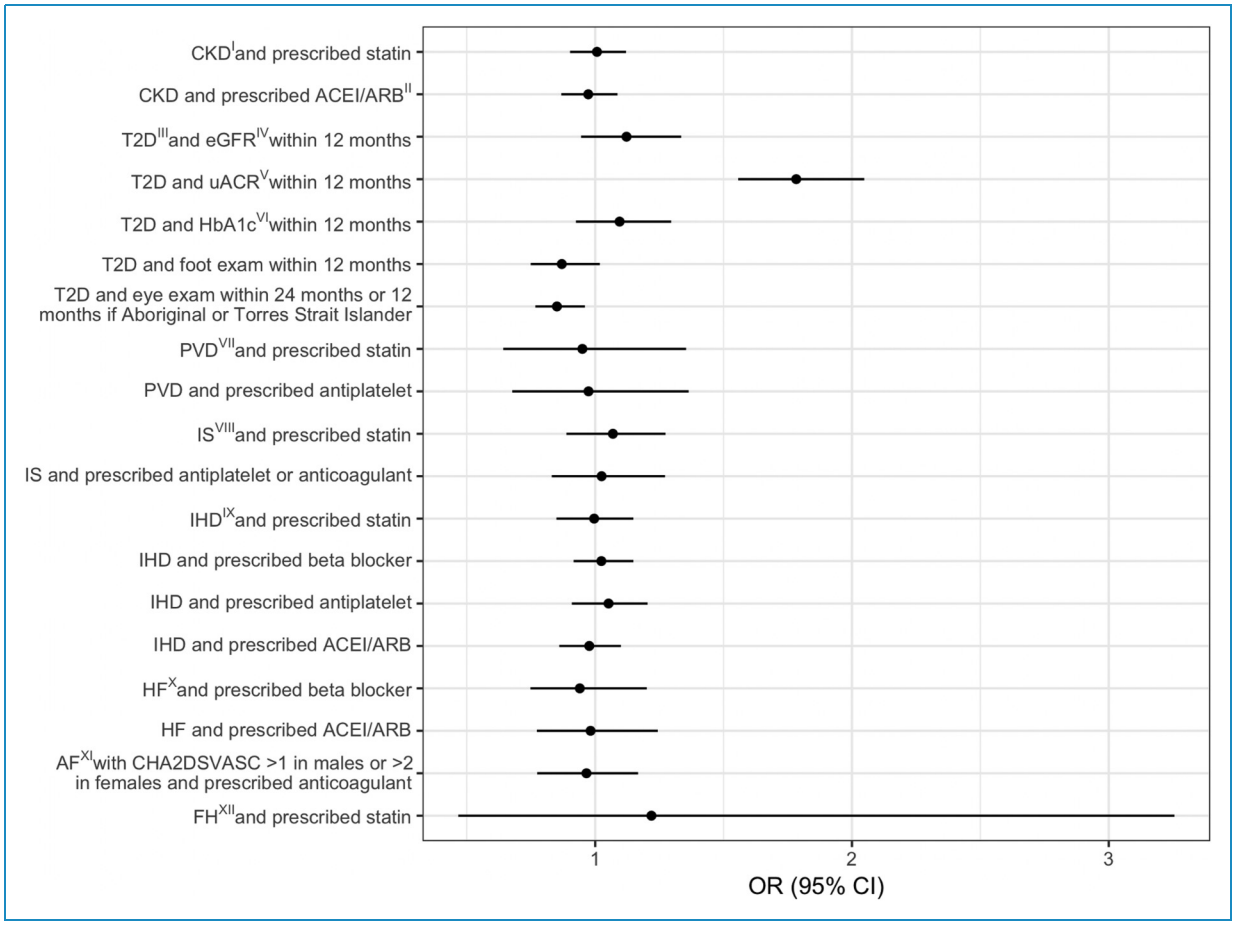

Figure 6. Chronic disease management.
[I] Chronic kidney disease. [II] Angiotensin-converting enzyme inhibitor or angiotensin receptor blocker. [III] Type 2 diabetes. [IV] Estimated glomerular filtration rate. [V] Urine albumin:creatinine ratio. [VI] Glycated haemoglobin. [VII] Peripheral vascular disease. [VIII] Ischaemic stroke. [IX] Ischaemic heart disease. [X] Heart failure. [XI] Atrial fibrillation.

people with T2D at the recommended frequency had changed to a non-statistically significant increase in examinations. An analysis to account for presumed decay in intra-cluster correlation found the increased diagnostic testing for CKD in those at risk and increased uACR testing in T2D remained statistically significant, but the increased coded diagnoses of CKD and increased diagnostic testing in T2D were not statistically significant and eye examinations at the recommended frequency for people with T2D had changed to a non-statistically significant increase in examinations. Details of these analyses are provided in Supplementary Materials Tables S3–S6.

Discussion

This real-world stepped wedge trial demonstrated that electronic-technology-based interventions in general practice to facilitate practice audit can help to improve chronic disease diagnostic testing, diagnosis documentation and disease management. It found improvements in some but not all chronic diseases, with improved diagnostic testing for CKD and T2D in those at risk and increased coded diagnoses of CKD and increased uACR testing in patients with T2D. There were no improvements seen in documented risk factor assessment, documented risk factor presence, coded disease diagnosis or management of CKD or CVD.

These improvements have significant implications. Improved diagnostic testing may lead to improved disease detection thereby offering the opportunity to institute management strategies in a timely manner. Improvements to coding of diagnoses in the EMR are important as people with uncoded diagnoses are less likely to receive guideline recommended care[43] and coded diagnoses can trigger treatment recommendations with electronic chronic disease solutions. The increase in uACR testing seen in patients with T2D has the potential to enable earlier detection of CKD. Early CKD diagnosis facilitates appropriate referral to nephrologists which is associated with slowed progression to end stage kidney disease (ESKD) and improved survival.[44] Late referral to nephrologists is associated with increased mortality, lower rates of renal transplantation,[45] a lack of vascular access creation prior to starting dialysis[46] and increased chance of commencing dialysis with vascular catheters that are associated with multiple complications and increased mortality.[46]

Three of the four significant improvements associated with the intervention related to CKD. Many practices chose to address CKD-related parameters in their audit, and this may in part be due to the CKD-focused education from a nephrologist that all practices received. Some practices chose to receive FH-focused education from a lipid specialist, but no practices elected to receive education on other aspects of CVD or on T2D, perhaps because they have had received education in these areas more recently. Practices received the CKD-focused education prior to developing their audit plans, and it is quite likely that this influenced their choice of audit targets. It is possible that if all practices had received education sessions from each of the disease specific specialties prior to developing their audit plans, that there would have been a more even distribution of improvements across the different diseases. Further research assessing electronic-technology tool-based interventions targeting multiple chronic diseases could ensure all practices received an education session covering all chronic diseases, however attendance at multiple education sessions may be logistically challenging, given the busy schedules of general practice staff and of the non-general practice specialists providing the sessions.

For the data extraction software to detect that an eye examination or foot examination had been performed, these data needed to be entered into the EMR by the practitioner in a specific manner. It is likely that many of these examinations were performed but were not captured because of this issue, making these variables more a reflection of clinical data entry rather than an indication of actual performance of these examinations. It is also possible that a change in government funding with cessation of the diabetes service incentive fee announced in the federal budget in May 2017[47] may have affected documentation of these examinations.

This study sought to offer a tool for general practice to facilitate the translation of guidelines into practice across multiple conditions, rather than focusing on a single condition. Practices had discretion as to which areas they would target in their audits. It is to be expected that it would be difficult to make changes across many areas at once and this study only found improvements in some of the domains that it targeted. Given that general practice is tasked with the challenge of managing more than one disease at a time, it is worth undertaking further investigation into strategies facilitating the detection and management of multiple conditions in primary care. Clinical decision support tools that support practitioners at point-of-care offer some advantages over clinical audit tools that requires patients to be recalled in order to action any recommended investigations or management strategies, and tools that support both audit and point-of-care clinical decision support may be even more effective. However, there is a need for more research into electronic-technology tools, such as clinical decision support interventions, that adequately address multimorbidity.[48] Qualitative research has identified that barriers to clinical decision support tool use include tools with inadequate consideration of multimorbidity, failure to take into account the multiple clinical guidelines that apply to a patient's care, poor integration with the EMR and alert burden, which can lead to practitioners overriding prompts that become intrusive[49]; enablers include tools that promote structured chronic disease care and provide immediate relevant information.[49] Future tools incorporating both clinical audit and clinical decision support that take these barriers and enablers

into consideration offer great promise and such a tool,[50] co-designed with practice staff and patients has been developed by authors of this study and is being assessed with a clinical trial. General practices in Australia are currently eligible for up to $50,000 AUD per annum via the Quality Improvement Practice Incentives Program.[51] In many cases, this funding may not cover the costs to practices of undertaking the quality improvement. Also, practices are required to focus their improvements on a limited selection of ten areas outlined by the government[52] which at this stage only cover some of the areas addressed by our study. Additional funding dedicated to quality improvement programs in general practice covering a broader range of chronic disease may assist with the translation of chronic disease guidelines into practice.

Strengths of this study include its randomised-controlled study design and its 'real-world' setting. Many of the practices were located in areas with a high proportion of people from culturally and linguistically diverse backgrounds and were located in areas of relative socio-economic disadvantage. The intervention was able to make an impact in a population who likely had lower health literacy which presents additional challenges in healthcare provision. The study population incorporated a large number of patients and included practices from both metropolitan and non-metropolitan areas. This study assessed an intervention addressing the interrelated chronic vascular diseases together, offering a more holistic approach than interventions targeting a single condition.

Limitations of this study include the risk of selection bias associated with practices being selected as a convenience sample from within one state. This may have led to the selection of practices that were more engaged with quality improvement activities than had practices been selected at random, affecting generalisability. Given this study was seeking to assess the impact of the intervention on multiple chronic diseases, a single prespecified primary outcome was not selected and there were many outcomes (some of which were interdependent, e.g. diagnostic testing and diagnosis) assessed in this study, with an associated risk of type one error. Sample size calculation was not performed prior to study commencement due to limited available sample size calculation tools for stepped wedge trials in 2016, at the time of study commencement, post hoc sample size calculation has been performed and is included in Supplementary Materials Figure S4. This study offered much flexibility to general practices to target areas that interested them, making it harder to detect changes if areas were only targeted by a small number of practices. Stepped wedge study design with 16-week periods meant that changes to study variables could only be attributed to the intervention if present at 16 weeks from time of intervention commencement, potentially too short a time for change. Exploratory studies investigating the length of time required to identify change following a similar intervention would be of interest to inform subsequent studies.

Conclusion

The interrelated chronic vascular diseases cause great morbidity and mortality and general practice is well placed to identify and support patients at risk of, and with, these diseases. This study showed improvements in testing for CKD and T2D in those at risk, documented diagnosis of CKD and in monitoring of patients with T2D with uACR testing. Further investigation into the length of time required for the intervention to fully take effect would be beneficial to inform future studies. This intervention addressed the interrelated chronic vascular diseases together, rather than focusing on just one disease at a time in recognition of shared risk factors and management strategies. Despite the benefits of such a holistic approach, the multitude of options for practices to focus on may have diluted the effect, making it more difficult to detect changes made. Research assessing similar interventions on a larger scale with more practices and longer periods to assess intervention effect in order to better assess its effects would be valuable. Despite its limitations, this study has shown the potential of an electronic-technology-based-intervention in general practice promoting clinical audit to improve testing of those at risk of disease, documentation of disease and disease management. This highlights areas for potential improvements in individual practices and offers patients an opportunity for earlier intervention, thereby potentially improving disease outcomes. Future electronic-technology tools incorporating both clinical audit and point-of-care features that seek to seamlessly integrate with existing EMRs may be able to achieve greater improvements in chronic disease care. This study can help to inform other interventions and the studies to assess their efficacy to continue the goal of facilitating the translation of evidence-based guidelines into practice, thereby improving the trajectory of people at risk of and with chronic disease.

Abbreviations

ACEI	angiotensin-converting-enzyme inhibitor
AF	atrial fibrillation
ARB	angiotensin receptor blocker
CHA2DS2-VASc score	Risk-based score to determine requirement for anticoagulation in patients with AF which considers: Congestive heart failure (1 point); Hypertension (1 point); Age ≥75 years (2 points); Diabetes (1 point); history of Stroke/TIA/systemic thromboembolism (2 points); Vascular disease (1 point); Age 65–74 years (1 point); Sex – female (1 point)

Chronic Disease IMPACT	Chronic Disease early detection and Improved Management in PrimAry Care ProjecT
CI	credible interval
CKD	chronic kidney disease
CVD	cardiovascular disease
DBP	diastolic blood pressure
eGFR	estimated glomerular filtration rate
EMRs	electronic medical records
FBG	fasting blood glucose
FH	familial hypercholesterolaemia
HbA1c	glycated haemoglobin
HF	heart failure
IHD	ischaemic heart disease
IS	ischaemic stroke
NNT	number needed to treat
Pen CAT	Pen Computer Systems Clinical Audit Tool
PVD	peripheral vascular disease
RBG	random blood glucose
RACGP	Royal Australian College of General Practitioners
RCTs	randomised-controlled trials
SBP	systolic blood pressure
T2D	type 2 diabetes
uACR	urine albumin creatinine ratio

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Data availability statement: Data are available upon reasonable request. Datasets generated and analysed in this study are not available to the public as per the agreement within the ethics committee approval, but are available upon reasonable request to the corresponding author subject to ethics approval.

Declaration of conflicting interests: The authors declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Multiple authors have been involved in a further study, Future Health Today which builds upon the concepts explored within this study but uses a quality improvement platform which differs from this one. CLN and J-AM-N are lead investigators on the Future Health Today program and EDJ, PSH, JLJ and NL are investigators.

J-AM-N is an investigator in the Data for Decisions research initiative www.gp.unimelb.edu.au/datafordecisions which uses the GRHANITE research data collection tool.

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