# Effect of a Computer-Guided, Quality Improvement Program for Cardiovascular Disease Risk Management in Primary Health Care The Treatment of Cardiovascular Risk Using Electronic Decision Support Cluster-Randomized Trial

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**Background**—Despite effective treatments to reduce cardiovascular disease risk, their translation into practice is limited. **Methods and Results**—Using a parallel arm cluster-randomized controlled trial in 60 Australian primary healthcare centers, we tested whether a multifaceted quality improvement intervention comprising computerized decision support, audit/ feedback tools, and staff training improved (1) guideline-indicated risk factor measurements and (2) guideline-indicated medications for those at high cardiovascular disease risk. Centers had to use a compatible software system, and eligible patients were regular attendees (Aboriginal and Torres Strait Islander people aged  $\geq$ 35 years and others aged  $\geq$ 45 years). Patient-level analyses were conducted using generalized estimating equations to account for clustering. Median follow-up for 38725 patients (mean age, 61.0 years; 42% men) was 17.5 months. Mean monthly staff support was <1 hour/site. For the coprimary outcomes, the intervention was associated with improved overall risk factor measurements (62.8% versus 53.4% risk ratio; 1.25; 95% confidence interval, 1.04–1.50; *P*=0.02), but there was no significant differences in recommended prescriptions for the high-risk cohort (n=10 308; 56.8% versus 51.2%; *P*=0.12). There were significant treatment escalations (new prescriptions or increased numbers of medicines) for antiplatelet (17.9% versus 2.7%; *P*<0.001), lipid-lowering (19.2% versus 4.8%; *P*<0.001), and blood pressure–lowering medications (23.3% versus 12.1%; *P*=0.02).

*Conclusions*—In Australian primary healthcare settings, a computer-guided quality improvement intervention, requiring minimal support, improved cardiovascular disease risk measurement but did not increase prescription rates in the high-risk group. Computerized quality improvement tools offer an important, albeit partial, solution to improving primary healthcare system capacity for cardiovascular disease risk measurement.

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Cardiovascular diseases (CVDs) are the greatest contributors to the global burden of disease, and finding ways to reduce this burden are a major challenge faced by health systems worldwide.<sup>1</sup> Most guidelines recommend that the decision to use vascular disease preventive drug therapy should be on the basis of a patient's overall or absolute cardiovascular risk.<sup>2</sup> The broader application of risk-based care with safe, effective treatments has the potential to reduce disease burden substantially

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# WHAT IS KNOWN

- Effective treatments to reduce cardiovascular disease risk exist, but their use in routine clinical practice is limited, and as few as 50% of people at high cardiovascular disease risk are prescribed appropriate treatments.
- Computerized clinical support tools are a promising strategy to improve healthcare quality.
- Clinical trials in this area are variable in quality, tend to lack data on clinical parameters, and are not scalable.

# WHAT THE STUDY ADDS

- This Australian cluster-randomized trial, involving >38 000 people and 60 health services, tested a decision support system, combined with audit and feedback strategies.
- The intervention results in a 10% absolute improvement in screening for cardiovascular disease risk.
- However, there were no significant improvements in prescribing recommended medicines to people at high cardiovascular disease risk although there were significant improvements in treatment escalation (new prescriptions or increased numbers of medicines) of recommended medicines.
- The findings suggest that computerized tools may play an important role in preventative treatments; however, there is an important opportunity to improve clinical management further.

and has been shown to be highly cost-effective.<sup>3,4</sup> However, there has been a failure to implement such a strategy adequately for both primary and secondary CVD prevention globally.<sup>5-7</sup> Even in high-income countries, the use of recommended medicines in people with established CVD may be as low as 50% after 6 months of therapy, with only around one third of people achieving treatment goals.<sup>8,9</sup> In Australian general practice and Aboriginal Community Controlled Health Service (ACCHS) settings,  $\approx$ 50% of routinely attending adults lacked sufficient recorded information to evaluate vascular risk and only  $\approx$ 40% to 50% of people at high CVD risk were prescribed optimal guideline-indicated medicines.<sup>10,11</sup>

Strategies to address these gaps in care are generally complex, multifaceted, and target barriers at the system, provider, and patient levels.<sup>12</sup> Quality improvement (QI) interventions can take many forms and most of the evidence about effectiveness is based on observational studies, which have major limitations. Two main strategies that have been more extensively evaluated are first, clinical decision support systems and second, audit and feedback systems. Although both systems have been demonstrated to confer modest improvements in practitioner performance,<sup>13-17</sup> few trials have targeted CVD risk management and most of these have focused on single risk factors with varying results and with little attention to patient outcomes or intervention costs.<sup>15,18</sup>

The Treatment of Cardiovascular Risk using Electronic Decision Support (TORPEDO) study was a cluster randomized trial that tested whether a computer-guided QI intervention comprising point-of-care electronic decision support, audit and feedback tools, and clinical workforce training improved CVD risk management when compared with usual care.

# Methods

# **Study Design**

Parallel arm cluster-randomized controlled trial in 60 Australian primary healthcare centers.

# **Included Patients and Health Services**

Health services were eligible to participate if there was exclusive use of 1 of the 2 compliant software systems to record risk factor information, pathology test results and prescribe medications and a willingness from all clinical staff to use the intervention. The eligible patient population was based on Australian guideline vascular risk screening recommendations<sup>19</sup> and defined as all Aboriginal and Torres Strait Islander people  $\geq$ 35 years and all others  $\geq$ 45 years (no upper age limit) who had attended the service  $\geq$ 3× in the previous 24-month period and at least once in the previous 6-month period. The outcome evaluation cohort included patients who met these criteria at both baseline and end of study data extractions.

#### **Study Setting**

General practices were recruited from the Sydney region with assistance from primary healthcare organizations known as Medicare Locals. ACCHSs were recruited through collaboration with 2 state representative bodies from NSW and Queensland and included urban, rural, and remote services. A \$500AUD reimbursement to all participating sites was made to assist with study-related activities. All license costs and technical support associated with the intervention were provided free to intervention sites. The costs associated with patient care occurred as per usual practice. Australia has a universal health insurance scheme (Medicare), which subsidizes primary healthcare consultations on a predominantly fee for service basis. General practices can charge patients above the Medicare rebate at their discretion. ACCHS do not charge above the rebate and receive additional state and federal funding for provision of other primary healthcare services beyond general practice care.

#### **Randomization and Allocation Concealment**

Randomization was in a 1:1 allocation to the intervention or usual care stratified at 3 levels: (1) ACCHS versus general practices; (2) service size (<500 patients meeting eligibility criteria versus  $\geq$ 500); and (3) current participation in a national or state QI program. Permuted block randomization was performed centrally, and outcome analyses were conducted blinded to randomized allocation. Participating services did not make any special provisions to advertise the trial and their allocation status to patients; however, it would be reasonable to assume that when the tools were used during a consultation patients may have been aware of the intervention.

# Intervention

Full details of the intervention have been published and are also summarized in the Appendix in the Data Supplement.<sup>20</sup> In brief, a single screening and management algorithm were developed and then validated, based on a synthesis of recommendations from several screening and management guidelines for CVD, kidney disease, and diabetes mellitus.<sup>21</sup> The algorithm interfaces with 2 clinical practice software systems that together comprise  $\approx 80\%$  of primary healthcare record systems in Australia. Data from the patient record prepopulate the tool. Point-of-care recommendations based on that patient's absolute CVD risk are provided. If the patient is receiving suboptimal screening or management, a series of traffic light prompts alert the practitioner to suggested recommendations. A risk communication tool also assists patients to understand their CVD risk, including how overall risk is affected by changes in individual risk factors.<sup>22</sup> Identification of screening and management gaps for the whole patient population was also built into a commonly used audit tool. This tool allows health services to audit health records, identify performance gaps, and establish recall/reminder prompts rapidly. It also allows for deidentified data to be exported to a Web-based portal where health services can view peer-ranked performance data benchmarked against other participating trial sites.

Clinical staff were trained in use of the tools and received access to a technical support desk. One face-to-face training visit was supplemented with ad hoc visits to resolve technical issues as required. Bimonthly Webinars were offered with a focus on the practical demonstrations of the tools. Sites allocated to the control arm continued usual care without access to the intervention tools or training. Services in both arms participating in existing QI initiatives continued with these programs at their discretion. Intervention was for a minimum of 12 months.

# **Data Collection**

Deidentified data extracts were obtained for all patients who met the eligibility criteria with an encrypted identifier code attached to each patient's data to allow for longitudinal comparisons. Data extraction was performed using a validated extraction tool at 1 month before randomization to check data quality, at randomization and at the end of the study.<sup>23</sup>

# Outcomes

Coprimary outcomes were defined as follows:

- The proportion of eligible patients who received appropriate screening of CVD risk factors by the end of study. This was defined as having recorded: smoking status at least once, systolic blood pressure (BP) in the previous 12 months, total cholesterol and highdensity lipoprotein cholesterol in the previous 24 months.
- The proportion of eligible patients defined at baseline as being at high CVD risk, receiving recommended medication prescriptions at the end of study. This was defined as (1) current prescription for ≥1 BP-lowering drugs and a statin for people at high risk without established CVD, (2) current prescription for ≥1 BP-lowering drugs and a statin and an antiplatelet agent (unless contraindicated by oral anticoagulant use) for people with established CVD, or (3) lowering of calculated 5-year CVD risk to ≤15%.

High CVD risk is defined in Australian guidelines as (1) history of CVD (diagnosis of coronary heart disease, cerebrovascular disease, peripheral vascular disease); (2) the presence of any guideline-stipulated clinically high-risk conditions (diabetes mellitus and age >60 years, diabetes mellitus and albuminuria, stage 3B chronic kidney disease, or extreme individual risk factor elevations: systolic BP ≥180 mm Hg, diastolic BP ≥110 mm Hg, total cholesterol >7.5 mmol [290 mg/dL])<sup>19</sup>; or (3) a calculated 5-year CVD risk of >15% using the 1991 Anderson Framingham equation.<sup>24</sup>

Secondary outcome measures included (1) measurements of individual CVD risk factors (smoking status, BP, lipids, body mass index, estimated glomerular filtration rate, and albuminuria); (2) escalation of drug prescription among patients at high CVD risk (either newly prescribed or additional numbers of antiplatelet, BP-lowering and lipid-lowering agents); (3) BP and serum lipid levels among people at high CVD risk; and (4) newly recorded CVD-related diagnoses.

#### Sample Size

Randomization of 60 services (30 per arm) was calculated to provide 90% power to detect a  $\geq 10\%$  absolute higher occurrence in each primary study outcome among services receiving the intervention. This assumed for the coprimary outcomes a 10% absolute improvement

in the control arm as a result of study participation, an average cluster size of 750 patients with 30% of these at high CVD risk, baseline rates of risk factor measurement and appropriate prescribing of 50%,<sup>10</sup> 2 $\alpha$ =0.05 and an intraclass correlation coefficient of 0.05. The intraclass correlation coefficient was based on data from 3 recent cross-sectional studies in Australian general practices and ACCHSs conducted by our group.<sup>10,11</sup>

#### **Data Analysis**

Patient-level data analysis was performed using SAS enterprise guide 5.1 (SAS Institute Inc, Cary, NC) on an intention-to-treat basis using generalized estimating equations with an exchangeable correlation structure to account for clustering of patients within services. The population defined for the primary analyses was a cohort of eligible patients whose health record data were extracted at both randomization and end-of-study periods. Analyses were conducted using Gaussian and log-binomial generalized estimating equation regressions for continuous and binary outcomes, respectively. The intervention effects are expressed as unadjusted rate ratios for binary end points and mean difference for continuous end points with 95% confidence intervals (CIs) and P values. Subgroup analyses were performed using the 3 randomization strata. For each subgroup, the primary analysis was repeated with the addition of the subgroup variable along with its interaction with treatment. Heterogeneity was assessed based on the significance of the interaction term. Although formal adjustments for multiple tests were not made, findings are interpreted in the light of the number of comparisons made and the level of significance of the result.25

#### **Ethical Considerations**

The study was approved by the University of Sydney Human Research Ethics Committee and the Aboriginal Health and Medical Research Council Human Research Ethics Committee. Individual consent waiver was granted, given data collection was based on deidentified extracts from the electronic health record system. Signed agreements with participating sites were obtained.

#### Results

# Recruitment

Sixty-four services were recruited from September 2011 to May 2012 (Figure 1) with 61 randomized (31 to intervention and 30 to usual care). One small intervention general practice site (n=152 eligible patients) withdrew from the study shortly after randomization. This left 60 randomized services and on outcome evaluation cohort of 38725 eligible patients that included 10308 patients defined as high CVD risk at baseline. Median follow-up for intervention and control arms was 17.3 and 17.7 months, respectively. Almost all intervention services (27 sites) used the audit tool to conduct data extractions and submissions to the Web portal  $\geq$ 50% of the time (ie, on average data were submitted at least bimonthly). Intervention practices received an average of 48-minute support per month comprising on-site training, remote clinical Webinars, and helpdesk services. A detailed description of this support is provided in the Appendix in the Data Supplement. Table 1 shows the service level characteristics, and Table 2 shows the baseline cardiovascular risk profile of the sample.

# **Primary and Secondary Outcomes**

During follow-up, patients in intervention sites were more likely to receive appropriate screening for CVD risk (62.8% versus 53.4% risk ratio [RR], 1.25; 95% CI, 1.04–1.50; *P*=0.02; Figure 2). Improvements were mainly driven by improvements in total/high-density lipoprotein cholesterol measurement and



Figure 1. Study flow diagram. ACCHS indicates Aboriginal Community Controlled Health Service; CVD, cardiovascular disease; GP, general practice; and IQR, interquartile range.

BP recording. There was a trend to heterogeneity of effect based on whether these risk factors were measured at baseline (Figure 3). For the high-risk cohort (n=10308), baseline

	Intervention (n=30; n=19385)	Usual Care (n=30; n=19340)					
Eligible population							
<500	15/30 (50%)	15/30 (50%)					
≥500	15/30 (50%)	15/30 (50%)					
Type of service							
ACCHS	10/30 (33%)	10/30 (33%)					
General Practice	20/30 (67%)	20/30 (67%)					
Current participation in a QI initiative							
No	17/30 (57%)	16/30 (53%)					
Yes	13/30 (43%)	14/30 (47%)					
Medical software used							
Best Practice	10/30 (33%)	11/30 (37%)					
Medical Director	20/30 (67%)	19/30 (63%)					
IT support							
Both local and external	5/30 (17%)	11/30 (37%)					
External	17/30 (57%)	14/30 (47%)					
Local	8/30 (27%)	5/30 (17%)					
Staff currently using data extraction tools							
Most	1/30 (3%)	1/30 (3%)					
Some	18/30 (60%)	19/30 (63%)					
None	11/30 (37%)	10/30 (33%)					

ACCHS indicates Aboriginal Community Controlled Health Service; IT, information technology; and QI, quality improvement.

prescription rates of recommended medications were 46.7% (intervention) and 52.8% (control; Table 2). At end-of-study comparison, there were no statistically significant improvements in prescription of recommended medications (56.8% versus 51.2%; RR, 1.11; 95% CI, 0.97–1.27; P=0.12). The intervention was most strongly associated with escalation of medications for patients at high risk (new prescriptions or increased numbers of medications) with respect to antiplatelet medications (17.9% versus 2.7%; RR, 4.80; 95% CI, 2.47–9.29; P<0.001), lipid-lowering medications (19.2% versus 4.8%; RR, 3.22; 95% CI, 1.77–5.88; P<0.001), and BP-lowering medications (23.3% versus 12.1%; RR, 1.89; 95% CI, 1.08–3.28; P=0.02).

For the intervention arm site that withdrew from the study, a sensitivity analysis was conducted assuming that there was no improvement in the coprimary outcomes at end of study for this site and this had negligible effect on the findings. Because of likely effect modification relating to initial levels of the coprimary outcome, we did not conduct adjusted analyses for baseline differences. As is more appropriate in the presence of effect modification, we interpreted the effect of the intervention based on stratified results.

In the high-risk cohort, there were no clear effects on mean systolic BP (-2.3 versus -1.5 mmHg; difference, -0.8 mmHg; 95% CI, -2.0 to 0.4; P=0.20) and low-density lipoprotein cholesterol (-0.14 versus -0.09 mmol/L; difference, -0.05 mmol/L; 95% CI, -0.12 to 0.01; P=0.08). There was a higher proportion attaining guideline BP targets in the intervention group versus control (61.0% versus 55.0%; RR, 1.10; 95% CI, 1.00-1.20; P=0.05). There were no differences in the proportion attaining lipid targets (P=0.61). There were also no significant differences in prescribing rates for BP, statin, and

#### Table 2. Baseline Patient Characteristics

	Intervention (Sites=30; n=19385)		Usual Care (Sites=30; n=19340)		
	Available Data	n (%) or Mean (SE)	Available Data	n (%) or Mean (SE)	<i>P</i> Value
Age, y, mean (SD)	19382	60.7 (12.4)	19339	61.3 (12.7)	0.66
Men	19377	7729 (40.0%)	19305	8536 (44.0%)	0.03
Aboriginal/Torres Strait Islander	19385	3624 (18.7%)	19340	3292 (17.0%)	0.66
Current smoker/ex-smoker in the past 12 mo	16539	3524 (21.4%)	16464	3537 (21.4%)	0.94
Systolic blood pressure, mm Hg, mean (SD)	17 497	129.9 (17.5)	18092	129.9 (16.4)	0.61
Total cholesterol, mmol, mean (SD)	16383	5.00 (1.08)	14544	5.00 (1.13)	0.40
High-density lipoprotein, mmol, mean (SD)	15422	1.40 (0.43)	12761	1.40 (0.41)	0.69
HbA1c for those with recorded diagnosis of diabetes mellitus, %, mean (SD)	3224	8.0 (4.6)	2942	7.5 (1.8)	0.16
Body mass index >30 kg/m <sup>2</sup>	12981	4949 (36.3%)	13647	4900 (37.8%)	0.32
Albuminuria*	3942	1025 (25.7%)	3996	1181 (30.0%)	0.79
Estimated glomerular filtration rate† <60 mL/min per 1.73 m <sup>2</sup>	16415	1476 (9.9%)	14876	1896 (11.6%)	0.87
Recorded diagnoses					
Coronary heart disease	19385	2170 (11.2%)	19340	1914 (9.9%)	0.31
Cerebrovascular disease	19385	570 (2.9%)	19340	525 (2.7%)	0.92
Peripheral vascular disease	19385	160 (0.8%)	19340	206 (1.1%)	0.51
Diabetes mellitus	19385	3555 (18.3%)	19340	3250 (16.8%)	0.95
Left ventricular hypertrophy	19385	34 (0.2%)	19340	95 (0.5%)	0.01
Atrial fibrillation	19385	724 (3.7%)	19340	657 (3.4%)	0.85
Heart failure	19385	354 (1.8%)	19340	287 (1.5%)	0.84
CVD risk information					
5-y CVD risk‡					
Missing information	19385	5678 (29.3%)	19340	7101 (36.7%)	0.19
<10%	19385	7197 (37.1%)	19340	6493 (33.6%)	0.40
10%–15%	19385	1118 (5.8%)	19340	830 (4.3%)	0.29
>15%	19385	505 (2.6%)	19340	398 (2.06%)	0.30
Clinically high risk condition§	19385	2249 (11.6%)	19340	2094 (10.8%)	0.94
Established CVD	19385	2638 (13.6%)	19340	2424 (12.5%)	0.61
Primary outcomes at baseline					
Patients with appropriate CVD risk screening	19385	10110 (52.2%)	19340	8558 (44.3%)	0.47
Patients at high CVD risk with appropriate medical management	5392	2516 (46.7%)	4916	2598 (52.8%)	0.17

HbA1c indicates glycated hemoglobin.

\*Urinary albumin:creatinine ratio >2.5 men and >3.5 women.

†Calculated using the Chronic Kidney Disease Epidemiology Collaboration formula.

‡Calculated using the 1991 Anderson Framingham risk equation.

Any of the following based on Australian guidelines: diabetes mellitus and age >60 year, diabetes mellitus and albuminuria, estimated glomerular filtration rate <45 mL/min per 1.73 m<sup>2</sup>, systolic blood pressure (BP) ≥180 mm Hg, diastolic BP ≥110 mm Hg, total cholesterol >7.5 mmol/L.

|Any of the following: coronary heart disease, cerebrovascular disease, and peripheral vascular disease.

antiplatelet medicines for those at low risk of CVD (<10% at 5-year risk; all *P*>0.55). There were no differences in the proportion with newly recorded CVD diagnoses (*P*=0.72).

There were greater improvements in risk factor screening in smaller when compared with larger health services (*P* interaction=0.02), but no other significant differences were observed for either primary outcome for any prespecified subgroup (Figure 3).

In a post hoc analysis, there was a significant heterogeneity of effect according to whether patients were prescribed recommended medicines at baseline (interaction P=0.03) with those

not prescribed medicines (n=5090) showing a large improvement (38.3% versus 20.9%; RR, 1.59; 95% CI, 1.19–2.13; *P*<0.001).

# Discussion

TORPEDO contributes new evidence on the effect of technology-assisted interventions to improve healthcare quality. It address a recent US Community Prevention Services Taskforce recommendation that multicomponent service delivery interventions, combining electronic health record– integrated decision support with performance feedback, are needed for CVD prevention.<sup>17</sup> TORPEDO demonstrated that a

	Intervention	Usual care	Favours Usual care	Favours Intervention	Risk ratio (95% Cl)	p value	ICC
CVD risk screening (n=38,275)							
Primary outcome							
Proportion receiving appropriate and timely measurement of CVD risk factors	12164/19385 (62.8%)	10317/19340	(53.4%)	\$	1.25 (1.04, 1.50)	0.02	0.08
Secondary outcomes							
Smoking status recorded	17596/19385 (90.8%)	17227/19340	(89.1%)		1.04 (0.96, 1.13)	0.35	0.08
Systolic BP recorded in previous 12 months	16433/19385 (84.8%)	15587/19340	(80.6%)		1.08 (0.99, 1.18)	0.09	0.05
Total & HDL cholesterol recorded in the previous 24 months	14641/19385 (75.5%)	12855/19340	(66.5%)		1.19 (1.03, 1.37)	0.02	0.09
BMI measurement in previous 12 months	9780/19385 (50.5%)	9559/19340	(49.4%)	-	0.97 (0.77, 1.23)	0.79	0.15
Urinary ACR measured in the previous 24 months	5196/19385 (26.8%)	4281/19340	(22.1%)	╞═─╴	1.23 (0.84, 1.80)	0.29	0.11
eGFR measured in the previous 24 months	16230/19385 (83.7%)	15494/19340	(80.1%)		1.06 (0.97, 1.15)	0.20	0.06
Medication management for people at high CVD risk (n=10,308)							
Primary outcome							
Proportion receiving guideline recommended medication prescriptions	3030/5335 (56.8%)	2483/4846	(51.2%)	Þ	1.11 (0.97, 1.27)	0.12	0.09
Secondary outcomes							
Current prescription for at least one BP lowering medicine and a statin for people at high risk without CVD	1571/2697 (58.3%)	1311/2422	(54.1%)	-	1.09 (0.97, 1.22)	0.16	0.06
Current prescription for at least one BP medicine, a statin and an antiplatelet medicine for people with CVD	1459/2638 (55.3%)	1172/2424	(48.4%)	-	1.14 (0.97, 1.35)	0.10	0.12
Escalation of antiplatelet medicines for people with CVD	470/2638 (17.8%)	65/2424	(2.7%)	<u> </u>	<b>-</b> 4.79 (2.47, 9.29)	<.001	0.57
Escalation of lipid-lowering medicines	1026/5335 (19.2%)	226/4846	(4.7%)		3.22 (1.77, 5.88)	<.001	0.49
Escalation of BP-lowering medicines	1243/5335 (23.3%)	586/4846	(12.1%)	_ <b></b>	1.89 (1.09, 3.28)	0.02	0.42
		1/	10	1	10		

Rısk ratio

Figure 2. Cardiovascular disease (CVD) risk factor screening and medication management end points. ACR indicates albumin:creatinine ratio; BMI indicates body mass index; BP, blood pressure; CI, confidence interval; eGFR, estimated glomerular filtration rate; HDL, high-density lipoprotein; and ICC, intraclass correlation coefficient.

computer-guided intervention comprising point-of-care decision support, audit and feedback tools, training and support improved cardiovascular risk factor screening. The intervention did not improve the prescription of appropriate preventive drugs in the overall high-risk cohort. The improvements identified in the high-risk individuals inadequately treated at baseline suggest that this is the group most likely to benefit from the intervention; however, this was a post hoc analysis. The escalation in guideline-based care indicates that the intervention was effective in reducing practitioner therapeutic inertia (the failure to initiate or increase therapy when treatment goals are not being met) although it must be emphasized that absolute rates of treatment remained unacceptably low.<sup>26</sup> The observed improvements in care were equally apparent in ACCHSs and in general practices; this is especially pertinent to addressing Indigenous health inequities in Australia, which are largely driven by excess CVD burden.

Despite more than a decade of CVD guidelines recommending medical management on the basis of overall cardiovascular risk, most implementation strategies have focused on the management of single risk factors and there are few strategies that have been shown to be effective in changing practitioner behavior toward risk-based management. The US Community Prevention Services Taskforce review of 44 randomized controlled trials on effectiveness of cardiovascular decision support systems found median absolute improvements of 3.2% for screening and 4.0% for test ordering.<sup>18</sup> In the area of audit and feedback, a systematic review of 49 studies (not CVD specific) found a median absolute improvement in performance of 4.3%.<sup>17</sup> TORPEDO demonstrated 3-fold greater improvements than these for screening and test ordering. Key features of the TORPEDO interventions that are known to be drivers of change included work flow integration, alignment with usual decision-making processes in the patient consultation, provision of treatment recommendations rather than just assessments, and repeated audit and feedback with explicit recommendations.<sup>14,17</sup>

Importantly, however, TORPEDO was less successful in shifting prescribing behavior, which is consistent with small intervention effect sizes found in the US Community Prevention Services Taskforce systematic review (only a 2%) absolute improvement).18 Consequently, there remains much scope for further improvements if such QI strategies are to translate into tangible health benefits. Berwick<sup>27</sup> has commented that QI is not a single, testable answer. Rather it is a complex process driven by a range of factors at the level of the patient, provider, health service, and the broader health system.<sup>28</sup> For diabetes mellitus care, QI strategies that have targeted both prescriber and patient behavior change in combination seem to be associated with greater success.<sup>29</sup> Similarly, for CVD risk management, patient-focused strategies may be a critically important additional element to improving outcomes. Despite the bold promise of consumer-focused technologies to increase patient engagement, few trials have been conducted

	Intervention	Usual care	Favours Usual care	Favours R Intervention	isk ratio (95% CI)	p-value interaction	ICC
CVD risk screening by so (Proportion receiving appr	ubgroup (n=38,275) opriate and timely measurer	ment of CVD risk facto	ors)				_
Type of service							
ACCHS	2904/4812 (60.4%)	1579/3459 (45.7%	)	1.29	(0.98, 1.70)	0.76	0.13
General Practice	9260/14573 (63.5%)	8738/15881 (55.0%	)	1.22	(0.97, 1.55)		0.07
Service size at baseline							
Small (<500)	2652/4436 (59.8%)	1620/4343 (37.3%	)	1.63	(1.17, 2.26)	0.02	0.14
Large (>=500)	9512/14949 (63.6%)	8697/14997 (58.0%	) 1	- 1.03	(0.87, 1.23)		0.06
Participation at baseline quality improvement pro	in a national						
No	7576/11839 (64.0%)	5113/9843 (52.0%	)	1.35	(1.00, 1.82)	0.41	0.11
Yes	4588/7546 (60.8%)	5204/9497 (54.8%	) .	<b>■</b> 1.16	(0.94, 1.43)		0.06
Medication management (Proportion receiving guide	t for people at high CVD riseline recommended medical	<b>sk (n=10,308) by suk</b> tion prescriptions)	group				
Type of service							
ACCHS	1112/1622 (68.6%)	787/1195 (65.9%	)	1.05	(0.97, 1.14)	0.45	0.01
General Practice	1918/3713 (51.7%)	1696/3651 (46.5%	)	<b>-</b> 1.14	(0.96, 1.35)		0.08
Service size at baseline							
Small (<500)	757/1315 (57.6%)	800/1390 (57.6%	) -	1.04	(0.86, 1.24)	0.35	0.05
Large (>=500)	2273/4020 (56.5%)	1683/3456 (48.7%	)	1.18	(0.98, 1.41)		0.09
Participation at baseline	in a QI program						
No	1583/3151 (50.2%)	1021/2209 (46.2%	) -	1.13	(0.92, 1.39)	0.91	0.09
Yes	1447/2184 (66.3%)	1462/2637 (55.4%	)	<b>-</b> 1.11	(0.98, 1.26)		0.07
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Figure 3. Screening and medication management end points by prespecified subgroups. ACCHS indicates Aboriginal Community Controlled Health Service; CI, confidence interval; CVD, cardiovascular disease; ICC, intraclass correlation coefficient; and QI, quality improvement.

to examine their effectiveness, costs, and optimal delivery mechanisms. New studies are required that combine such consumer-focused approaches with provider-focused approaches, each designed in a way that takes careful account of health service and system characteristics. Given the particularly large unmet need for quality improvement interventions in low- and middle-income countries, such regions should also be a major focus for attention.<sup>30</sup>

The strengths of this study include the pragmatic implementation of a randomized study within usual day-to-day practice, the large sample size, the clinical outcome data, scalable intervention components, and the low level of implementation support required. Another strength is the representativeness of participating general practices and ACCHSs. All general practices included in TORPEDO were recruited from urban settings (in which ≈70% of all Australian general practices are based) and had site characteristics that were broadly representative of general practice in Australia.<sup>31</sup> The ACCHSs represented urban, rural, and remote regions and comprised ≈20% of all ACCHSs that provide medical services in Australia. The TORPEDO ACCHS sites also demonstrated service characteristics that were similar to the sector at large.<sup>32</sup> Furthermore, the baseline rates for key outcome measures were similar to those found in previous Australian studies in both general practice and ACCHSs.<sup>10,11</sup>

The main study limitation is that it was not powered for clinical outcomes. This needs to be balanced against the pragmatic nature of the trial and a focus on increasing prescription of treatments of known efficacy, which is a critical first step in maximizing the full benefits of such treatments. Data linkage studies with national hospitalization and mortality databases are currently being planned and will help to ascertain the effect on hard outcomes. Although not a limitation per se, the intervention is ideally suited for implementation in settings where there are high adoption rates of electronic health records. Australia has among the highest rates of electronic health record adoption in the world (>90%); however, uptake is increasing internationally with the majority of high-income countries in Europe now achieving rates in excess of 80% and substantial implementation occurring in North America, spearheaded by the Medicare and Medicaid meaningful use program.33,34 Intervention programs such as that tested by TORPEDO are therefore well placed for large-scale implementation in high-income countries. Indigenous governed community health services operating within other high-income country settings, such as United States and Canada, may also be well suited to adopting this intervention. These findings may also have broader relevance to the management of cardiovascular risk in other resource-poor settings and in other rural and remote communities.

The implications of effective QI tools and strategies are substantial. Improving health system performance by even a small margin has the potential to make a major effect on disease burden if improvements can be delivered at scale. Taking a conservative estimate that 5% of people in Australia have at least a 20% 5-year CVD risk,<sup>35</sup> and using published data on risk reductions from treatment interventions,<sup>36-38</sup> a 2 mm Hg mean systolic BP reduction, 0.1 mmol low-density lipoprotein reduction, and a 10% increase in aspirin adherence together could lead to around a 10% relative risk reduction and ≈20000 fewer events >5 years. Such improvements highlight the great potential for the primary healthcare sector to make a larger contribution to reduction of the CVD burden. Scalable and effective systems that require minimal support to implement could make major improvements in primary healthcare system performance and health outcomes globally.

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# Disclosures

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