CSIRO PUBLISHING
Australian Health Review, 2014, 38, 495–505
http://dx.doi.org/10.1071/AH14018

An evaluation of the quality of evidence underpinning diabetes management models: a review of the literature

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Abstract

Objective. There is a paucity of research on the quality of evidence relating to primary care workforce models. Thus, the aim of the present study was to evaluate the quality of evidence on diabetes primary care workforce models in Australia.

Methods. The National Health and Medical Research Council of Australia's (National Health and Medical Reseach Council; 2000, 2001) frameworks for evaluating scientific evidence and economic evaluations were used to assess the quality of studies involving primary care workforce models for diabetes care involving Australian adults. A search of medical databases (MEDLINE, AMED, RURAL, Australian Indigenous HealthInfoNet and The Cochrane Institute), journals for diabetes care (*Diabetes Research and Clinical Practice*, *Diabetes Care*, *Diabetic Medicine*, *Population Health Management*, *Rural and Remote Health*, *Australian Journal of Primary Health*, *PLoS Medicine*, *Medical Journal of Australia*, *BMC Health Services Research*, *BMC Public Health*, *BMC Family Practice*) and Commonwealth and state government health websites was undertaken to acquire Australian studies of diabetes workforce models published 2005–13. Various diabetes workforce models were examined, including 'one-stop shops', pharmacy care, Aboriginal services and telephone-delivered interventions. The quality of evidence was evaluated against several criteria, including relevance and replication, strength of evidence, effect size, transferability and representativeness, and value for money.

Results. Of the14 studies found, four were randomised controlled trials and one was a systematic review (i.e. Level II and I (best) evidence). Only three provided a replicable protocol or detailed intervention delivery. Eleven lacked a theoretical framework. Twelve reported significant improvements in clinical (patient) outcomes, commonly HbA1c, cholesterol and blood pressure; only four reported changes in short- and long-term outcomes (e.g. quality of life). Most studies used a small or targeted population. Only two studies assessed both benefits and costs of their intervention compared with usual care and cost effectiveness.

Conclusions. More rigorous studies of diabetes workforce models are needed to determine whether these interventions improve patient outcomes and, if they do, represent value for money.

What is known about the topic? Although health systems with strong primary care orientations have been associated with enhanced access, equity and population health, the primary care workforce is facing several challenges. These include a maldistribution of resources (supply side) and health outcomes (demand side), inconsistent support for teamwork care models, and a lack of enhanced clinical inter-professional education and/or training opportunities. These challenges are exacerbated by an ageing health workforce and general population, as well as a population that has increased prevalence of chronic conditions and multi-morbidity. Although several policy directions have been advocated to address these challenges, there is a lack of high-quality evidence about which primary care workforce models are best (and which models represent better value for money than current practice) and what the health effects are for patients.

What does this paper add? This study demonstrated several strengths and weaknesses of Australian diabetes models of care studies. In particular, only five of the 14 studies assessed were designed in a way that enabled them to achieve a Level II or I rating (and hence the 'best' level of evidence), based on the NHMRC's (2000, 2001) frameworks for assessing scientific evidence. The majority of studies risked the introduction of bias and thus may have incorrect conclusions. Only a few studies

described clearly what the intervention and the comparator were and thus could be easily replicated. Only two studies included cost-effectiveness studies of their interventions compared with usual care.

What are the implications for practitioners? Although there has been an increase in the number of primary care workforce models implemented in Australia, there is a need for more rigorous research to assess whether these interventions are effective in producing improved health outcomes and represent better value for money than current practice. Researchers and policymakers need to make decisions based on high-quality evidence; it is not obvious what effect the evidence is having on primary care workforce reform.

Additional keywords: economic evaluation, models of care, primary care, workforce.

Received 23 January 2014, 1 June 2014, published online 4 August 2014

Introduction

Although health systems with strong primary care orientations have been associated with improved access, equity and population health,[1] the primary care workforce is currently facing significant challenges. These include a mal-distribution of resources (supply-side) and health outcomes (demand-side), inconsistent support for teamwork care models and a lack of enhanced clinical inter-professional education and/or training opportunities. These challenges are exacerbated by an ageing health workforce and an ageing general population that has increased prevalence of chronic conditions and multi-morbidity.[2]

Novel health workforce models have been advanced as a way forward to address these challenges, and growing patient and wider health system demands through new roles (e.g. nurse practitioners), support roles (e.g. allied health assistants) which may substitute for current forms of service delivery, or enhanced roles (e.g. diabetes nurses). Approaches to improve the retention of primary healthcare workers through organisational policies, increase the efficiency of the current skills mix, or improve productivity through linking pay to performance have also been advanced. Although several policy directions have been advocated, there is a lack of evidence about which primary care workforce models are best and what the health effects are for patients.[3,4]

The lack of evidence to support these new directions in primary care is surprising, since it is widely acknowledged in medicine (and public health) that evidence-based medicine is essential to reduce the introduction of ineffective and expensive medical treatments.[5]

In this paper, we draw on the National Health and Medical Research Council (NHMRC: 2000, 2001) frameworks for assessing the quality of scientific evidence (and economic evaluations)[6,7] to evaluate the quality of evidence on primary care workforce models for diabetes care.

The NHMRC's[6,7] frameworks for evaluating the quality of scientific evidence with examples from primary care workforce models

To make a decision about whether to introduce a new care model it is important to be familiar with the quality of the evidence surrounding that model. In particular, whether the care model (intervention) is likely to achieve the aims of the intended model and whether it represents value for money.[6]

A set of criteria established by the NHMRC (2000, 2001) to assess medical and public health research is used in this paper to appraise diabetes primary care workforce models.[6,7] These criteria are summarised in Table 1. The first is whether the study states clearly what health outcomes may be achieved by the particular intervention, and whether these outcomes have been measured in appropriate units. For example, whether the new primary care model was intended to improve health outcomes or save money but produce no worse health outcomes

Table 1. A framework for assessing the quality of evidence relating to primary care workforce models
Data from NHMRC;[6,7] RCT, randomised controlled trial

Evidence	Purpose
Relevant and replicable	Did the study identify clinical outcomes that are appropriate and relevant? Is the study design stated clearly enough so that it could be replicated?
Theoretical framework	Is there a logical (scientific) reason why the primary care workforce model (intervention) will have the desired effect?
Strength of the evidence	Is it a robust study design? • Level I: Systematic reviews of RCTs • Level II: A well-designed RCT • Level III: Pseudo RCTs, comparative studies, case control studies, cohort studies • Level IV: Evidence from case series such as pre- and post- studies • Level V: Expert opinion
Size of the effect	Did the *P*-value or confidence interval reasonably exclude chance? Is the effect size clinically important?
Transferable and representative	What are the benefits and harms (costs) of the intervention and the comparator? Do they differ between patient groups? Is the study population representative of the population in which the primary care workforce model will be implemented?
Duration	Is the effect sustained over a relevant time horizon?
Value for money	Is the new primary care workforce model cost effective relative to standard care?

(non-inferiority). Additionally, the study needs to have a reasonable hypothesis and scientific explanation with evidence (and perhaps a theoretical model) underpinning it, information that can be used to explain why the desired effect is expected from the model.

The design of studies can vary markedly. The highest quality of evidence, as classified by the NHMRC, comes from systematic reviews of randomised controlled trials (RCTs; Level I). Systematic reviews determine whether a treatment effect can be replicated and, by pooling the results of RCTs, provides a best estimate of the magnitude of the effect.[7] The second level of evidence comes from a well-designed RCT, which has the strength of minimising bias (Level II). Pseudo RCTs, comparative studies, case control studies or cohort studies have the potential to introduce bias and are ranked as Level III. Case series (pre- and post-test studies) suffer from problems related to the lack of randomisation (e.g. non-comparability of control and treatment groups, different outcome measures for the two groups) and are ranked as Level IV. The lowest level, now excluded by the NHMRC, is expert opinion and consensus from expert committees because these sources do not have a scientific basis (Level V).

Although a study may report a statistically significant effect, it is important to ascertain whether the effect is clinically important. In relation to diabetes care, for example, we would want to know what the cut-off was for scale weight loss to be regarded as clinically important (i.e. losing how many kilograms would be considered as clinically significant). In this case, it would also be important to know whether the difference in this outcome was sustained over time or became insignificant between the intervention and control groups. Although studies may clearly state what the benefits (health outcomes) are for patients, it is important that they also state what the harms (costs) are for patients (and funders). Information on relevant benefits and costs of interventions are needed to undertake an overall (economic) evaluation.

As funding becomes increasingly scarce, due to governments continuously running deficits (as they try to cope with an ageing population) and external challenges (e.g. the Global Financial Crisis, GFC), ensuring that only new healthcare models which represent efficacy as well as efficiency are implemented is crucial.

Methods

Assessing the quality of evidence relating to diabetes primary care workforce models

An appraisal of primary care workforce models applied to diabetes care in Australia published in peer reviewed and 'grey' literature between 2005 and 2013 was undertaken. Three main areas were searched:

- key medical databases (MEDLINE, AMED, RURAL, Australian Indigenous HealthInfoNet and The Cochrane Institute)
- key academic peer review journals (*Diabetes Research and Clinical Practice*, *Diabetes Care*, *Diabetic Medicine*, *Population Health Management*, *Rural and Remote Health*, *Australian Journal of Primary Health*, *PLoS Medicine*, *Medical Journal of Australia*, *BMC Health Services Research*, *BMC Public Health*, *BMC Family Practice*) relating to diabetes models of care
- several key Australian (Commonwealth and state government) health websites (Australian Government Department of Health, http://www.health.gov.au/; Australian Government Department of Health and Ageing, http://www.yourhealth.gov.au/internet/yourhealth/publishing.nsf/content/home; Government of Western Australia Department of Health, http://www.health.wa.gov.au/home/; accessed 1 July 2014).

Key search terms were 'primary workforce', 'workforce models', 'diabetes', 'care models' and 'Australia'.

The NHMRC's[6,7] frameworks for assessing evidence (see Table 1) were applied to the studies we found involving primary care workforce models designed to improve the health of adults with diabetes. Of the 14 studies found, only five could be classified as RCTs or systematic reviews and thus correspond to the 'best' type of evidence (Level II or I). Nine studies constituted 'evidence from case series' or 'expert opinion' (Level IV or V). Of the higher-rated studies, one study incorporated an economic evaluation (cost-effectiveness analysis) within the RCT,[8] whereas another was a systematic review.[9] Note that the study by Graves *et al*.[8] is rated II* rather than simply II because it not only meets the NHMRC's (2000)[7] standard for Level II evidence (i.e. a properly designed RCT) but it also includes an economic evaluation.

Results

All studies provided some information about study design and expected outcomes; however, only three studies provided a replicable protocol or detailed information about intervention delivery.[8,10,11] Thirteen studies lacked a theoretical framework. Only four studies provided sufficient detail about the intervention to enable replication.[8,12–14] Only three studies clearly stated the types of changes in health outcomes that equated to 'clinically important' ones.[8,10,15]

Most studies identified, measured and valued the benefits of their particular intervention; however, only three studies identified, measured and valued the related costs.[8,16,17] Only two of these studies had collected the type of data required to undertake an economic evaluation and thus determine whether the intervention represented value for money compared with the comparator (usual care).[8,17]

Table 2 is a summary of the 14 studies found. The quality of each study was rated on the basis of the NHMRC's (2000, 2001) criteria for assessing evidence (see column 4). The diabetes primary care workforce models are grouped under five headings: one-stop shops, pharmacy models, Aboriginal services, telephone delivered interventions and systematic reviews, which characterise the models implemented. Of the 14 studies, 12 reported statistically significant improvements in several immediate health outcomes (e.g. HbA1c) of patients with diabetes. Only four studies assessed changes in both short- and long-term health outcomes.[8,10,16,17] Most studies used either a small (cut-off was $n \sim 100$) or very specific populations such as diabetic patients in a rural community.

The 'one-stop shop' or coordinated diabetes treatment

Of the seven studies in this group, five were given a quality rating of IV or IV* and two were given a rating of V. The first five studies analysed clinical data from interventions,[12,13,15,16,18,19] whereas the last two studies (WA Department of Health[20] and Foster

Table 2. Summary of primary level models of diabetes care

AHW, Aboriginal health worker; BMI, body mass index; CI, confidence interval; CVD, cardiovascular disease; DBP, diastolic blood pressure; DSS, Diabetes Support Service; ED, emergency department; ESRD, end-stage renal disease; FDS, Freemantle Diabetes Study; FPG, fasting plasma glucose; GGT, Greater Green Triangle; GP, general practitioner; HR-QOL, health-related quality of life; IHD, ischaemic heart disease; IQR, interquartile range; LDL-C, low-density lipoprotein–cholesterol; NA-HARP, Northern Alliance Hospital Admission Risk Program; NPV, net present value; POCT, point-of-care testing; QAAMS, quality assurance for Aboriginal medical services; QALE, quality-adjusted life expectancy; QOL, quality of life; RCT, randomised control trial; SBP, systolic blood pressure; SHDGP, Southern Highlands Division of General Practice; T2D, type 2 diabetes; TC, total cholesterol; TG, triglycerides

Model of care (study and brief description)	Relevant and replicable	Theoretical framework	Strength of evidence	Size of main effects	Transferable and representative	Effect time	Value for money
One-stop shop POCT: Shephard *et al.*[18] Standard 'disjointed and uncoordinated' care vs a multidisciplinary 'one-stop' GP, diabetes educator, podiatrist and nurse service	Provided few details of the intervention	–	IV: a before and after study of patients with diabetes	Mean (± s.d.) values at baseline and most recent GP visit were: HbA1c: 7.6 ± 1.6% and 7.1 ± 1.4%, respectively ($P = 0.03$); Cholesterol: 4.64 ± 1.0 and 4.28 ± 0.9 mM, respectively ($P = 0.01$); SBP 143 ± 21 and 134 ± 14 mmHg, respectively ($P = 0.004$); DBP 81 ± 21 and 76 ± 10 mmHg, respectively ($P = 0.09$).	Small sample size ($n = 54$) in seven rural communities	10 months	No economic evaluation
GGT diabetes prevention project: Laatikainen *et al.*[12] and Kilkkinen *et al.*[13] Patients recruited in GP clinics using the Diabetes Risk Score tool for six group counselling sessions with study nurses, dietician and physiotherapist.	Yes, the intervention was based on a Finnish implementation study The longitudinal study design used to examine changes in clinical outcomes was based on the design of a previous implementation trial	Yes, based on a Finnish implementation study	IV: a pre- and post-test study	Significant reductions after 12 months in mean weight (by 2.52 kg; 95% CI 1.85–3.19), waist circumference (by 4.17 cm; 3.48–4.87), mean FPG (by 0.14; mM 0.07–0.20), plasma glucose 2 h after oral glucose challenge (by 0.58 mM; 0.36–0.79), TC (by 0.29 mM; 0.18–0.40), LDL-C (by 0.25 mM; 0.16–0.34), TG (by 0.15 mM; 0.05–0.24) and DBP (by 2.14 mmHg; 0.94–3.33)	Patients aged 40–75 years, with at least moderate risk of T2D Three rural communities in south-east Victoria ($n = 237$)	12 months	No economic evaluation
SHDGP: McRae *et al.*[16] GPs used a database of SHDGP clinical data to coordinate care according to national guidelines.	Sufficient information to be replicated Changes in short-term (HbA1c, blood pressure, BMI, cholesterol) and long-term outcomes (e.g. QALE) examined Costs were also counted No formal control group	–	IV*: assessed costs and health outcomes	Found a small but significant improvement in mean HbA1c over 5 years (6.9% at registration vs 7.2% after 5 years; *P*-value not reported) Also found a significant reduction in lipid cholesterol level (6.1 mM at registration vs 5.1 mM after 5 years; *P*-value not reported)	Only used one database from one Division of General Practice in NSW	Projected outcomes to 40 years	Cost–impact analysis

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Table 2. (*continued*)

Model of care (study and brief description)	Relevant and replicable	Theoretical framework	Strength of evidence	Size of main effects	Transferable and representative	Effect time	Value for money
Multidisciplinary DSS clinic, Melbourne: Li Wai Suen *et al.*[19] The clinic was designed to support primary care by providing rapid assessment and management plans (2–3 visits per patient with an endocrinologist, a diabetes nurse educator and a dietician) and with other specialists (podiatry, nephrology and ophthalmology) if necessary.	Provided information about patient visits and type of health professionals seen at the diabetes support service clinic Only one clinical outcome considered (benefit) and no costs No randomisation No control group	–	IV: a retrospective audit of the DSS clinic	Reported a significant reduction in mean HbA1c of 1.5% for patients who visited the clinic after a mean follow-up period of 4.4 months (i.e. mean HbA1c at the time of admission to the service was 9.2% vs 7.7% at discharge; $P < 0.0001$)	Small sample, $n = 115$, complete medical records for patients who attended the DSS clinic at the Dandenong Hospital in Melbourne 2004–09	4.4. months (mean follow up)	No economic evaluation
NA-HARP: Rasekaba *et al.*[15] A multidisciplinary disease management program for patients with poorly controlled type 2 diabetes.	Study design outcomes were appropriate: HbA1c and HR-QOL Sufficient information to be replicated (specified minimum number of visits per patient, skills-mix of the care team, length of stay in program capped at 12 months) No costs, no randomisation (and thus no control group)	–	IV: design not stated	Reported significant improvements in mean (± s.d.) HbA1c (8.6 ± 1.9% at enrolment vs 7.3 ± 1.2% at 12 months; $P < 0.001$) and QOL measures for patients (251 patients (64%) had improved HR-QOL, 27 (7%) had no change and 114 (29%) had deteriorated QOL) after 12 months Overall, 68% of patients experienced improvements in HbA1c Mean utility scores improved by 0.11 ($P < 0.001$) after 12 months	545 patients who had HbA1c data at baseline and at 12 months The program provided care to a socioeconomically disadvantaged population living in a northern metropolitan region of Melbourne	12 months	No economic evaluation
WA Department of Health[20] The Endocrine Network's recommended diabetes model of care including GP-coordinated multidisciplinary care.	High level of program description The model is described in detail, including the roles of the WA government and Divisions of General Practice Intended outcomes are described (e.g. reduced rates of diabetes, complications, reduced ED presentations and hospital admissions)	–	V: a grey literature report.	Nothing reported	Potentially high if the study were conducted state wide	–	–

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Table 2. (*continued*)

Model of care (study and brief description)	Relevant and replicable	Theoretical framework	Strength of evidence	Size of main effects	Transferable and representative	Effect time	Value for money
Enhanced Primary Care: Foster *et al.*[14]	Medicare Enhanced Primary Care program Several potential adverse clinical outcomes of the program are identified, and illustrative hypothetical case studies claiming possible serious perverse incentives are discussed	–	V: a description of the Australian Government's initiative to introduce chronic disease management items on Medicare, including referrals to up to five allied health treatments	No real patients or health professionals in the study (and thus no clinical outcomes reported) Case studies were hypothetical	–	–	–
Pharmacy models							
FDS: Clifford and Davis[10] Pharmaceutical care patients with type 2 diabetes had face-to-face goal-directed medication and lifestyle counselling at baseline, 6 and 12 months and 6-weekly telephone assessments.	Defined protocol (RCT)	–	II: RCT	Significant and larger reductions in mean HbA1c for those in the intervention vs control group (–0.5% (95% CI –0.7 to –0.3) vs 0 (–0.2 to 0.2), respectively), SBP (–14 mmHg (–19 to –9) vs –7 (–11 to –2), respectively) and DBP (–5 mmHg (–8 to –3) vs –2 (–4 to 1), respectively; ($P \leq 0.043$) Reduction in the median (IQR) 10-year estimated risk of a first coronary heart disease event for patients in the intervention group (25.1% (15.6–36.2) to 20.3 (14.6–30.2); $n = 42$; $P = 0.002$) but not for those in the control group (26.1% (17.2–39.4) vs 26.4 (16.7–38.0); $n = 52$; $P = 0.17$)	198 patients with T2D from the FDS were randomised to pharmaceutical (92 patients) or usual care (88 patients)	12 months for Hb1Ac and blood pressure Projected first CVD event to 10 years	No economic evaluation
Pharmacy diabetes care program in four states Krass *et al.*[11] Intervention pharmacists attended a 2-day workshop and patients made five visits to the pharmacy over six months. Those in the control had one visit at the beginning and another at end of the study.	Defined protocol (RCT) Study examined changes in clinical outcomes and QOL measures for patients in intervention and control groups	–	II: multisite RCT	For patients in the intervention ($n = 149$), there was a significant reduction in mean blood glucose level over the 6-month study from 9.4 to 8.5 mM ($P < 0.01$) There was also a significantly greater improvement in glycaemic control in the intervention compared with control group (mean reductions in HbA1c	56 pharmacies (28 interventions and 28 controls) and 289 patients in four Australian states (urban and rural settings) were involved in the study	6 months	No economic evaluation

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Table 2. (*continued*)

Model of care (study and brief description)	Relevant and replicable	Theoretical framework	Strength of evidence	Size of main effects	Transferable and representative	Effect time	Value for money
		–		−0.97% (95% CI −0.8 to −1.14) and −0.27% (−0.15 to −0.39), respectively) Reductions also seen in SBP and DBP in the intervention group between baseline and follow-up, but when compared with the control group these decreases were not significant			
Aboriginal services							
Quality Assurance for Aboriginal Medical Services (QAAMS) Point of Care Testing Program Shephard.[21] Delivery involved doctors, pathologists, Aboriginal health workers (AHWs) and allied health professionals.	Brief description of this feasibility or acceptability study was given	–	IV: design not stated	Both clinicians and patients reported improved satisfaction with delivery or consumption of diabetes services A significant reduction in mean (± s.d.) HbA1c, from 9.3 ± 2.0% to 8.6 ± 2.0%, was found in 74 patients 12 months after commencing QAAMS point-of-care testing ($P = 0.003$)	Aboriginal rural communities	12 months	No economic evaluation
McDermott and Segal.[17] Direct costs and savings of new diabetes service implemented in 2000 were compared with usual care in the primary care setting from 2001 to 2006.	Discussed the type of health professionals delivering the new diabetes service, what patients were expected to experience Outlined the different cost components and health outcomes (hospitalisations among people with diabetes for infections and other acute complications, lower limb amputations, ESRD and CVD)	–	II: a costing study	Over the years 2000–05, a net present value cost of A$570 000 was estimated for the new service; this was equivalent to A$1800 for each major event avoided Showed that 4 years after initiation, annual cost savings exceed annual program delivery costs Estimated number of hospitalisations averted among patients with diabetes due to improved diabetes care: 253 fewer serious foot infections requiring hospitalisation and possible amputation At least 15 person-years on dialysis averted and 47 fewer serious CVD events (IHD and stroke) requiring hospitalisation	A district health service in remote northern Australia, with 9600 mainly Indigenous (Islander) residents, including 1000 adults with known diabetes served by 21 primary care centres	6 years (2000–05)	NPV calculated

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Table 2. (*continued*)

Model of care (study and brief description)	Relevant and replicable	Theoretical framework	Strength of evidence	Size of main effects	Transferable and representative	Effect time	Value for money
		–		Significant reductions in mean (± s.d.) SBP (39.40 ± 16.1 to 130.86 ± 19.1 mmHg; $P = 0.000$) and DBP (81.05 ± 9.3 to 75.97 ± 12.1mmHg; $P = 0.000$) found for patients during the period 2000–03			
Flinders model of self-management support for patients with type 2 diabetes, Battersby *et al.*[22] AHWs carried out patient-centred, self-management assessment and care planning with patients.	Good description of the roles of different health professionals involved in the program and outcomes measured	–	IV: a pilot study	A significant reduction in mean HbA1c after 12 months, dropping from 8.74% to 8.09% ($P < 0.01$) No significant change in mean blood pressure after 12 months AHWs found the program acceptable, as did their patients	60 Aboriginal Australians with T2D on Eyre Peninsular, SA	12 months	No economic evaluation
Telephone-delivered interventions							
A cost-effectiveness study of the Logan Healthy Living Program (RCT), Graves *et al.*[8] Telephone counselling vs usual care.	Study protocol provided Immediate (physical activity and diet) and final benefits (QALYs) and various costs (e.g. staff costs and services used by patients) included in the study	Intervention based on previous studies (cited)	II*: a cost-effectiveness modelling study using RCT data	Mean values and 95% Bayesian credible intervals of incremental cost and QALY outcomes for all comparisons were presented in the paper Choosing the telephone counselling intervention over usual care cost A$78 489 per QALY gained; choosing telephone counselling over the existing practice alternative (real control) cost A$29 375 per QALY gained; choosing usual care over existing practice alternative (real control) cost A$12 153 per QALY gained The modelling study showed that a decision to adopt a telephone counselling program over usual care had only a 38% probability of being cost-effective, whereas adopting the intervention over existing practice (real control) had a 100% probability	10 years	434 patients with T2D or hypertension in a low socioeconomic area of Qld (Logan)	Cost-effectiveness study

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Table 2. (*continued*)

Model of care (study and brief description)	Relevant and replicable	Theoretical framework	Strength of evidence	Size of main effects	Transferable and representative	Effect time	Value for money
				of being cost-effective (as shown in cost-effectiveness acceptability curves)			
RCTs or systematic reviews							
Chronic disease management in primary care, Dennis *et al.*[9]	Systematic review, but broad set of inclusion criteria	Yes, based on a chronic care model (reference provided)	I	Multidisciplinary team care, self-management interventions and adherence to guidelines positively related to health outcomes	Review of Australian and international studies of chronic disease (including diabetes) interventions	–	–

et al.[14]) were primary care policy papers.[14,20] The first five studies provided a sufficient amount of information regarding health outcomes (e.g. H1bA1c and quality of life) to conclude they were both appropriate and relevant. Only one (observational) study also provided information about costs;[16] however, this was limited to the intervention only (as there was no control group) and used to conduct a cost-impact analysis. All studies described the state of existing evidence on the effectiveness of similar interventions in different disease populations[19] or research demonstrating a link between their intervention and the desired effects in diabetic patients. Only the Greater Green Triangle (GGT) diabetes prevention project[12,13] provided details about an earlier implementation of their intervention (pilot). All studies reported changes in clinical outcomes that were statistically significant for patients in the intervention group. Foster *et al.*[14] only reported 'outcomes' on hypothetical case studies, that is, no patients actually experienced the incentives. The transferability of study findings is questionable, because these studies relied on small samples[18,19] or specific populations (i.e. rural communities, socioeconomically disadvantaged groups). Only one study projected the occurrence of health outcomes to several decades.[16]

Pharmacy diabetes care programs

Two studies of pharmacy diabetes care models were found. Both studies were given a high-quality rating: Level II. They shared many of the required criteria for a high rating, such as having a well-defined protocol for the RCT, enabling replication; reporting that the observed improvements in clinical outcomes were greater (and statically significant) in the pharmaceutical care group than in the control; and using a large sample. Clifford and Davis[10] also outlined the type of changes in health outcomes that could be seen as 'clinically important' ones for diabetic patients. In addition to assessing changes in immediate outcomes for patients, Clifford and Davis[10] estimated the long-term risk of first cardiovascular disease (CVD) event in patients. Although Clifford and Davis[10] noted the need for cost-effective programs in diabetes care, neither they nor Krass *et al.*[11] conducted an economic evaluation.

Aboriginal services

Three primary care workforce models for Aboriginal Australians with type 2 diabetes were found. Shephard[21] and Battersby *et al.*[22] were given a quality rating of IV, whereas McDermott and Segal[17] were given a rating of II. All studies provided a generous amount of information on their particular intervention. Health outcomes were appropriate for addressing the aims of the respective studies. Both immediate (e.g. HbA1c and blood pressure) and long-term clinical outcomes (e.g. avoidable diabetes-related hospitalisations and quality of life) were considered. The studies of Shephard[21] and Battersby *et al.*[22] are feasibility or acceptability studies and hence report on outcomes relevant to implementation, such as level of satisfaction assessed by patients and health workers. McDermott and Segal[17] conducted an economic evaluation of enhanced coordinated care for patients with diabetes in remote Australian Indigenous communities over a period of 6 years. Shephard[21] and Battersby *et al.*[22] only assessed changes in clinical outcomes for their patients at 12 months after the intervention; they did not assess the cost effectiveness of their intervention.

Telephone delivered interventions

Only one telephone delivered intervention was found.[8] That study is an economic evaluation of a telephone counselling intervention designed to improve the level of physical activity and diet of patients with type 2 diabetes or hypertension in a low socioeconomic area of Queensland. The cost-effectiveness modelling relied on data from a cluster-randomised trial comparing telephone counselling with usual care (brief intervention) and existing practice (real control) collected between 2005 and 2007. Health states were modelled for 10 years after recruitment.

Systematic reviews

Only one systematic review of international literature on chronic disease management in primary care was found.[9] Multidisciplinary team and self-management support interventions (and adherence to guidelines) were reported from January 1990 to February 2006 and found to have a significant effect on patients (clinical outcomes). A total of 141 studies and 23 systematic reviews were examined. The study included objective disease control measures, such as patient and practitioner satisfaction and adherence to guidelines. However, the review does not present a summary of cost effectiveness. The main limitation of the study was that it included a large number of models of care (e.g. organisational, professional and financial interventions) using different measures (health outcomes), applied to different patient groups and health conditions. To better assist decision makers, this review should have pooled the results of outcomes for specific patients receiving a well-defined intervention and reported on its relative effect and cost effectiveness over a particular comparator.

Discussion

The 14 studies of diabetes primary care workforce models appraised in this paper suggest there is an urgent need for more rigorous research on this topic in Australia, especially in relation to the cost effectiveness of new interventions. Only five studies were designed in such a way as to achieve a Level II or I rating, based on the NHMRC's (2000, 2001) frameworks for assessing scientific evidence. The majority of studies risked the introduction of bias and may have made incorrect conclusions. Several the diabetes primary care models were implemented in quite unique populations (i.e. small, culturally or socioeconomically defined) and hence it is difficult to say whether they (and the possible benefits they describe) could be transferred to the (general) population. Only a few studies described clearly what the intervention and the comparator were and thus could be successfully replicated. Only two studies assessed the cost effectiveness of their intervention compared with (formal) usual care.[8,17]

The Commonwealth government is currently piloting new approaches to diabetes management through general practice. It has recognised that benefits can be derived from well-coordinated, integrated, multidisciplinary diabetes care teams and, for this reason, in July 2011 the government committed $30.2 million over 3 to 4 years to a Coordinated Care for Diabetes Pilot in the primary care setting.[23] The pilot is testing a model of prepaid funding for coordinated care of patients with diabetes in general practice.[24] With a superior study design it could generate vital information about the relative merits of the intervention in relation to patient outcomes.

It is widely acknowledged that researchers and policymakers need to make decisions based on high-quality evidence;[25] however, it is not obvious what effect the evidence is having on primary care workforce reform.

Conclusions

Although there has been an increase in the number of primary care workforce models implemented in Australia, there is a need for more rigorous research to assess: (1) whether these interventions are effective in producing improved health outcomes; and (2) whether they represent better value for money than current practice.

Competing interests

The authors have no conflicts of interest to report.

Acknowledgements

None.

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