



# The role of primary health care in primary and secondary prevention of diabetes

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## Acronyms

AIHW	Australian Institute of Health and Welfare
APCC	Australian Primary Care Collective
AUSDRISK	Australian Diabetes Risk Tool
BEACH	Bettering the Evaluation and Care of Health
BMI	Body mass index
BSDS	Brisbane South Complex Diabetes Service
CCM	Chronic Care Model
CDC	Centre for Disease Control and Prevention
CDM	Chronic Disease Management
CDPS	Chronic disease prevention and screening
CHF	Congestive Heart Failure
CQI	Continuous Quality Improvement
CVD	Cardiovascular disease
DAFNE	Dose Adjustment For Normal Eating
DESMOND	Diabetes Education and Self-Management for Ongoing and Newly Diagnosed Type 2 diabetes
DPP	Diabetes Prevention Programme (US)
DPS	Diabetes Prevention Study (Finland)
DSME	Diabetes self-management education
ELP	Enhanced lifestyle programme
EMR	Electronic medical record
FPG	Fasting Plasma Glucose
GDM	Gestational Diabetes Mellitus
GP	General Practitioner
HARP	Hospital Admission Risk Programme
HbA1c	Glycated haemoglobin (reflects average glycaemia over the preceding two months)
HEALD-PCN	Healthy Eating and Active Living in Diabetes
HF	Heart Failure
HRQL	Health Related Quality of Life
ICDMS	Inala Chronic Disease Management Service
IGT	Impaired glucose tolerance
LCD	Low calorie diet
LWWD	Living Well with Diabetes (LWWD)
MAGDA-DPP	Mothers After Gestational Diabetes in Australia Diabetes Prevention Programme
MDPS	Melbourne diabetes prevention study
MDT	Multidisciplinary team
MeSH	Medical Subject Heading
MI	Myocardial infarction
MVPA	Moderate-to-vigorous-intensity physical activity
NZ	New Zealand
OGTT	Oral Glucose Tolerance Testing
PCN	Primary Care Network
PCS-CAT	Pen Clinical Systems Clinical Audit Tool
PDSA	Plan-do-study-act
PHC	Primary Health Care

PN	Practice nurse
PoCT	Point of care testing
PREVIEW	PREvention of diabetes through lifestyle Intervention
QIC	Quality Improvement Collaboratives
RADICAL	Rural Australian Diabetes – Inspiring Control Activity & Lifestyle model
RCT	Randomised Controlled Trials
SDPP	Sydney diabetes prevention Programme
T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus
TLC	Telephone-Linked Care
UACR	Urinary microalbumin:creatinine ratio
UK	United Kingdom
USA	United States of America
X-PERT	A UK patient centered, group-based self-management programme for diabetes

# Executive summary

## Policy context

In Australia, diabetes represents a major burden in both human and financial terms, drawing heavily on limited health care resources including trained staff and carers. In contrast to many other health conditions, evidence suggests that many aspects of the burden imposed by diabetes could be avoided through preventive measures. Type 1 diabetes mellitus (T1DM) is a genetically linked autoimmune disease and there is currently no known prevention. However, the risk for complications associated with T1DM can be reduced by optimal management of blood glucose levels. Type 2 diabetes mellitus (T2DM) accounts for over 85 per cent of all diabetes in Australia. Obesity is a major contributor to the development of T2DM and weight loss has been shown to reduce the incidence of T2DM in people with impaired glucose tolerance (IGT). Therefore, primary prevention of T2DM has generally focused on weight loss and lifestyle interventions, while secondary prevention to reduce the risk of diabetes-related complications centres on use of pharmacotherapy in addition to diet and lifestyle interventions to manage surrogate markers of complication risk (e.g. blood glucose levels, blood pressure, and lipid levels). The aim of this research is to examine diabetes programmes reporting outcome data and used in general practice settings to identify and proactively manage individuals at high risk for developing diabetes; or where diabetes is diagnosed, at risk for development of, or deterioration in, diabetes-related complications. Comparison of programme structure with published evidence is used together with outcome data to assess programmes.

## Key findings

Based on our review of the literature we found that for **primary prevention of diabetes**:

- T1DM
  - There is currently no evidence-based method to prevent T1DM; thus current guidelines do not recommend screening or preventive treatment outside of defined clinical studies
  - Current ongoing efforts to identify prevention measures for T1DM are generally based on preserving pancreatic beta cell function and this has shown some promise in small sub-cohorts of patients with a family history of T1DM
  - Ongoing trials in the Australian setting include TrialNet.
  
- T2DM
  - T2DM can be prevented through sustained weight loss in people who are overweight or obese, adequate physical activity, reduced fat intake and increased fibre intake
  - Adherence to a Mediterranean diet has also been consistently associated with a significant reduction in the risk of developing T2DM despite minimal weight loss but this has not been adopted in current prevention programmes in Australia
  - The AUSDRISK diabetes score is used to identify high risk individuals in T2DM prevention programmes in Australian primary health care (PHC) settings
  - Intervention programmes aimed at reducing the incidence of T2DM largely draw on targets defined in the Finnish Diabetes Prevention randomised controlled trial (RCT) study, which included the following targets:
    - sustained weight loss of five per cent or more
    - increased physical activity to at least four hours per week
    - improved dietary patterns
  - Based on RCTs, weight loss of five per cent or more is associated with a 58 per cent reduction in incidence of T2DM



- Most diabetes prevention programmes in the clinical setting are based on lifestyle interventions but to date these have not demonstrated weight loss comparable to that achieved in RCTs
- Currently most programmes implemented in the clinical setting lack sufficient follow-up time to observe any impact on incidence of T2DM
- Cost-effectiveness analyses based on outcomes from the US Diabetes Prevention Programme (DPP) and Finnish Diabetes Prevention Study (DPS) RCTs may over-estimate the effectiveness of lifestyle interventions compared with 'real-world' interventions
- Lay community members may be as effective at motivating weight loss as PHC professionals and this is likely to have a major impact on the scalability and economic sustainability of diabetes interventions
- Australian prevention programmes demonstrating moderate but significant improvement in outcomes in the PHC setting include the *Life! Taking action in diabetes (Life!)* programme and the *Sydney Diabetes Prevention Programme (SDPP)*
- International programmes demonstrating significant improvement in outcomes include the UK-based *Counterweight* and US-based *SHINE* programmes
- Ongoing trials in the Australian setting, but currently lacking outcome data, include the *Mothers After Gestational Diabetes in Australia (MAGDA)* diabetes prevention programme trial for gestational diabetes mellitus (GDM) prevention, and the international *PREvention of diabetes through lifestyle Intervention (PREVIEW)* study for T2DM prevention.

Based on our review of the literature we found that for **secondary prevention of diabetes complications**:

- General practice-based programmes are particularly important for people with T2DM, and for those with T1DM and unable to readily access diabetes specialist services (e.g. rural and remote residents)
- Both T1DM and T2DM secondary prevention centres on modifying surrogate markers for risk of diabetes complications: achieving good glycaemic, blood pressure and lipid control
- Systematic reviews have identified key components of effective T2DM diabetes management programmes as:
  - **Team changes.** *Changes to the structure or organisation of the primary health care teams e.g. upskilling for GPs, or adding nurse specialists in diabetic care*
  - **Patient education.** *Interventions designed to promote greater understanding of the disorder or to teach specific prevention or treatment strategies.*
  - **Case management.** *Any system for coordinating diagnosis, treatment, or routine management of patients by a person or multidisciplinary team in collaboration with, or supplementary to, the primary-care clinician.*
  - **Facilitated relay of information to primary clinician.** *Clinical information collected from patients and transmitted to clinicians by means other than the existing medical record e.g. referral systems, patient passports*
- All of the programmes identified in the current review included team changes and patient education, with some of the most promising programmes including social or mental health professionals in those teams
- Programmes demonstrating significant improvement in outcomes for people with T1DM and/or T2DM in the rural Australian PHC setting include the *Rural Australian Diabetes – Inspiring Control Activity & Lifestyle (RADICAL)* and the Point of Care Testing (PoCT) *Mallee Track* programmes

- Australian programmes demonstrating significant improvement in outcomes for people with T2DM include the integrated primary-secondary care for complex diabetes model, and the *Northern Alliance HARP* programme
- The Canadian *St Josephs integrated care* model has demonstrated significant improvement in glycaemic control after just six months
- Ongoing trials in the Australian setting, but currently lacking published outcome data, at the time of writing include the *Diabetes Care Project*, which is due to be completed in 2014.

## Policy considerations

**Primary prevention** of T1DM is not possible currently, but ongoing research is required to assess the feasibility of pancreatic preservation through dietary and environmental control.

**Primary prevention** of T2DM has been demonstrated under controlled trial conditions. However, implementation of lifestyle interventions in PHC clinical settings has failed to achieve similar levels of improvement in established, surrogate markers for diabetes risk. Longer term studies are required in the clinical setting to assess the impact of these more modest improvements in weight and physical activity on the incidence of T2DM, as well as the impact of alternative strategies such as pharmacotherapy and surgery on modifying the surrogate markers. There is some evidence to suggest that delivery of primary prevention interventions by lay-people achieves similar outcomes to delivery by PHC professionals, this is likely to have a major impact on scalability and economic feasibility of lifestyle modification programme delivery.

Cost analyses in the clinical setting are often centred on model based projections utilising data from RCTs, but this is likely to overestimate cost-effectiveness because ‘real-world’ outcomes are more modest. Inclusion of in-trial/programme economic analyses should be encouraged in the future to gain a more accurate assessment of the cost of delivering lifestyle modification programmes. In response to the more modest improvements observed in clinical settings among those at risk for T2DM, it has been controversially suggested that in the US, national policies aimed at reducing overall consumption of food in the general population might have greater benefit than lifestyle programmes specifically targeting those at risk for diabetes. In view of the strong link between T2DM and obesity this suggestion has some merit, but would depend on the scalability and cost of broad-based lifestyle modification programmes, and /or the potential of other measures to achieve a general reduction in food consumption.

**Secondary prevention** of diabetes-related complications in T1DM and T2DM in the PHC setting has shown considerable success based on modification of surrogate markers of risk (HbA1c, blood pressure, lipid levels). Programme structure varies in line with patient needs and clinical setting, and this is consistent with calls for individualised patient-centred care to achieve optimal management of diabetes. It is unlikely that a single or limited number of programmes will meet the needs of all Australians with diabetes. However, programmes reporting significant impact are generally based on care provided by multidisciplinary teams (including social and/or mental health professionals) and targeted education of patients and professional staff. The expanded team of care providers will attract increased salary costs but these may be offset by improved glycaemic control and hence reduced cost of complications such as diabetic foot amputation, cardiovascular disease and renal disease.

## Methods

A thorough (non-systematic) review of Australian and international literature was undertaken to search academic and grey literature sources for relevant material published between 2008 and September 2014. The databases searched included PubMed, Google Scholar, Scopus, PHCRIS PHC search filter; and publicly accessible websites of relevant companies and organisations including Diabetes Australia, Royal Australian College of General Practitioners, Australian Institute of Health and Welfare. Two specific programme areas were targeted in this review:

- **Primary prevention** of diabetes among those without diagnosed diabetes
- **Secondary prevention** of incident or progression of diabetes-related complications among those with diagnosed diabetes.

Where possible, a distinction was made between diabetes type: T1DM, T2DM, gestational diabetes mellitus (GDM); and where possible on the basis of target population (e.g. general, Indigenous, high-risk populations). International programmes were only included if they were directly applicable to the Australian setting (i.e. Canadian, UK or New Zealand programmes).

## Background

Diabetes is a complex, chronic disease that represents a serious burden in both human and financial terms. At least one million people in Australia have some form of diabetes (AIHW, 2014b). Under normal conditions, insulin secreted from pancreatic beta cells regulates metabolism by controlling the uptake of glucose. In people with diabetes, insulin is either absent or inadequate levels are produced, and/or cells are resistant to the action of insulin. A direct consequence of this is disrupted cell metabolism and accumulation of high levels of glucose in the blood. Type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM) are the most prevalent forms of diabetes; and T2DM accounts for approximately 85.3 per cent of diabetes in Australia (ABS, 2012), and 90 per cent of all diabetes worldwide (Diabetes Australia, 2012, Colagiuri et al., 2009). In addition to the almost one million Australians with known diabetes, for every four adult cases there is an adult with undiagnosed diabetes (AIHW, 2014a). A population-based survey in 2000 showed that when those with pre-diabetes (and at high risk of developing T2DM) are taken into consideration the prevalence of abnormal glucose tolerance is almost 25 per cent (Dunstan et al., 2002). It is estimated that by 2033 approximately 3.4 million Australians will have diagnosed T2DM (Vos et al., 2007). Beyond this is the considerable personal burden to individuals and their carers, and the impact on communities of high-risk populations such as Aboriginal and Torres Strait Islander peoples. Indigenous Australians are three times more likely to report diabetes than non-Indigenous people (ABS, 2013). Contributing to the more than \$6 billion annual health care costs of all diabetes in Australia are the average per person cost of \$3,468 (T1DM) and \$4,025 (T2DM) where there are no diabetes-related complications, increasing to as much as \$16,698 in people with both micro- and macrovascular complications (Diabetes Australia, 2012). A recent audit of inpatients at Melbourne hospitals found a diabetes prevalence ranging from 15.7 to 35.1 per cent in different hospitals ( $P < 0.001$ ), and complication rates of 71.4 per cent for any microvascular complication, 52.2 per cent for any macrovascular complication and 82.2 per cent for any complication (Bach et al., 2014). The cost and resource implications of this are substantial.

### Type 1 diabetes mellitus

Due to a chronic autoimmune process involving the development of autoantibodies that mediate immune destruction of pancreatic beta-cells, people with T1DM progressively lose pancreatic function including the loss of insulin production to the point that they require insulin injections to control blood sugar levels (Bluestone et al., 2010). The incidence of T1DM varies among countries, and although Australia showed 'intermediate' or 'high' incidence levels (1990-1999) in the World Health Organization (WHO) DIAMOND study (Multinational Project for Childhood Diabetes), the AIHW has reported a slightly lower incidence at 11 cases per 100,000 people (2011) and state that this has remained stable between 2000 and 2011 (Tuomilehto, 2013, AIHW, 2014b). Genetic factors are known to contribute to the development of T1DM, and the incidence increases with age up to puberty (DIAMOND Project Group, 2006). There is currently no known way to prevent T1DM. A major aim of T1DM prevention research is stopping the destruction of beta cells. However, current trials targeting treatment in periods prior to the development of autoimmunity, after autoantibodies are found, and after diagnosis, have largely met with no or limited success (Wherrett, 2014, Atkinson et al., 2014). In established T1DM, failure to control blood glucose levels with insulin injections exposes individuals to an increased risk for microvascular complications affecting small blood vessels (retinopathy, nephropathy, and neuropathy) and macrovascular complications affecting larger blood vessels (including stroke, acute myocardial infarction) (Atkinson et al., 2014). Intensive insulin treatment provided in the long-term *Epidemiology of Diabetes Interventions and Complications (EDIC)* trial demonstrated a significant reduction (58%) in the risk of cardiovascular disease events in T1DM. This trial was an extension of the original Diabetes Control and Complications Trial (DCCT) in

which treatment was associated with a 35-76 per cent reduction in microvascular complications (The Diabetes Control and Complications Trial Research Group, 1993, Nathan, 2014). Intensive insulin treatment to control blood glucose levels and optimise metabolic regulation remains the cornerstone of T1DM care (Atkinson et al., 2014).

## Type 2 diabetes mellitus

Characterised by insulin resistance, with or without impaired insulin secretion, risk factors for T2DM include genetic predisposition, high blood pressure, overweight and obesity, and insufficient physical activity (Noble et al., 2011). Prevention of T2DM has been demonstrated in RCTs where intervention directly addressed those risk factors that could be modified (e.g. weight gain, blood pressure and physical activity) (Knowler et al., 2002, Knowler et al., 2009, Li et al., 2008, Lindstrom et al., 2013, Pan et al., 1997, Tuomilehto et al., 2001, Uusitupa et al., 2009). People with T2DM have an increased risk for microvascular and macrovascular complications. The landmark randomised United Kingdom Prospective Diabetes Study (UKPDS) demonstrated that control of blood glucose levels was associated with a significantly reduced risk for microvascular complications in people with newly diagnosed T2DM (Stratton et al., 2000). More specifically, the UKPDS established that there is a direct relationship between the risk of complication of diabetes and glycaemia over time, each one per cent reduction in HbA1c was associated with a 37 per cent reduction in risk for microvascular complications (Stratton et al., 2000). A follow-up study for UKPDS found that, after 10 years, blood glucose levels were again similar in the intensive management and usual care cohorts, but the intervention cohort had a significantly reduced risk of micro- and macrovascular complications compared with the control group (Holman et al., 2008). This is known as the ‘legacy effect’, a sustained impact due to improvements at the time of treatment even though those improvements (e.g. better glucose control) are not maintained (Chalmers and Cooper, 2008). Largely based on these findings, blood glucose control has been the cornerstone of T2DM management. However, it is also recognised that aiming for good glycaemic control, defined as HbA1c  $\leq$  53mmol/mol (7%), must be balanced against the potential conflict between this and patient priorities depending on their circumstances (e.g. limited life expectancy, advanced complications or a history of severe hypoglycaemia) (RACGP and Diabetes Australia, 2014-15). This is particularly so among the elderly where the benefits of intensive management of HbA1c may be outweighed by the risk of severe hypoglycaemia; or where there is potential for dangerous drug interactions because of renal impairment or polypharmacy (RACGP and Diabetes Australia, 2014-15). In addition to elevated blood glucose levels, the risk of microvascular and macrovascular complications is influenced by changes in blood pressure (e.g. systolic blood pressure, SBP) and lipid levels (e.g. Total cholesterol (Tc), Low-Density-Lipoprotein (LDL) cholesterol). All of these biological markers are referred to as surrogate markers for the hard endpoints of microvascular and macrovascular disease. “A surrogate marker is measurable, recordable and often changes more rapidly and more sensitively than the hard end point in response to interventions” (Weston, 2008, p S6).

## Pre-diabetes

Pre-diabetes (impaired fasting glucose or impaired glucose tolerance) refers to the condition where blood glucose levels are above normal but not sufficiently high to be classified as diabetes. Analysis of control group patients in the long-term Finnish Diabetes Prevention Study (DPS) projected that approximately 50 per cent of people with impaired glucose tolerance will develop diabetes over a 10 year period when no lifestyle intervention is applied. (Lindström et al.)

## Gestational diabetes mellitus (GDM)

Named for the fact that it first occurs during pregnancy, there is currently no internationally consistent definition of gestational diabetes mellitus (GDM). However, a recent, renewed call for an international consensus statement on diagnosis of GDM suggests that achieving this would “allow useful comparisons regarding treatment and longer-term outcomes for this population group” (McIntyre et al., 2014). Given that the risk factors for GDM and T2DM are similar, global increases in prevalence of T2DM are likely to be mirrored in increases in GDM (McIntyre et al., 2014). For Australian GPs, as noted in a recent review of the care of women during and after a pregnancy affected by GDM, there are currently three sets of guidelines that are similar (including use of 75g oral glucose tolerance test, OGTT, in the first trimester), but not identical and this can impact on implementation (Wilkinson et al., 2014). GDM typically disappears when the baby is born, but the mother is then at high risk for T2DM over the next 10-15 years (Diabetes Australia, 2012, Bellamy et al., 2009). In addition to this, the landmark Hyperglycaemia and Adverse Pregnancy Outcome (HAPO) study established the existence of a continuous relationship between maternal oral glucose tolerance test (OGTT) values and adverse outcomes including clinical neonatal hypoglycaemia, neonatal hyperinsulinaemia, foetal adiposity, preeclampsia and large-for-gestational-age babies (HAPO Study Cooperative Research Group, 2002). Although GDM is a strong predictor of T2DM, prevention during a pregnancy involves a major focus on tightly controlled blood glucose levels rather than on the weight loss goals targeted among non-pregnant individuals at risk for T2DM (Wilkinson et al., 2014).

## Primary care based prevention and management of diabetes

General practitioners (GPs) have a major role to play in diabetes care (Thepwongsa et al., 2014). For most people, GPs are the first contact point in the Australian health care system, and in 2009-10 approximately 83 per cent of the Australian population claimed at least one GP service from Medicare (Britt et al., 2013). Approximately 10 per cent of all patients attending a GP in Australia have diabetes (Britt et al., 2013). Based on the Better Evaluation and Care of Health (BEACH) study, it was estimated that patients with T2DM visited a GP an average of eight times per year in 2013, with almost half of these visits being to manage their diabetes (Britt et al., 2013). Despite this, only minor improvements have been reported across Australia since 2007 for average blood glucose levels (Michaelides and Daja, 2010, Diabetes Australia, 2012). Further, a small survey of 78 Australian GPs in 2010 found that the overall application rate of the T2DM screening tool, AUSDRISK, in general practice is low (Wong et al., 2011). In a review of the role of Australian PHC in the prevention of chronic disease, Harris and Lloyd (2012) identified evidence for gaps in preventive care in practice, including under-utilisation of practice nurses, allied health providers and group programmes.

## Policy context

Obesity predisposes people to T2DM and in the decade between 2003-04 and 2012-13, the prevalence of overweight/obese adults visiting GPs increased from 57 per cent to 61 per cent (Britt et al., 2013). Australia is one of very few countries to have had a national incentivised diabetes prevention policy including referral to Lifestyle Modification Programmes to reduce weight. The current prevention arrangement includes incentives for screening of people aged 40-49 years (MBS items 701, 703, 705, 707) and referral to community-based physical activity and healthy eating programmes. For four years from 2009/10, many such programmes received funding grants from a pool of \$71.8 million made available by the Australian Government under the Healthy Communities Initiative (HCI) (Noble et al., 2011, Australian Government Department of Health). With an ever-increasing number of people presenting to general practice for diabetes care, it is essential that the delivery of care is both adequate and effective. For people with diagnosed diabetes, management is

supported through the practice incentives programme (PIP) orientated around completion of the annual cycle of care (Australian Government Department of Health, 2014). However, in 2009-10 Medicare claims showed a relatively low uptake, with only 18 per cent of Australians with diabetes completing an annual cycle of care (AIHW, 2013).

## Aim

This *Policy Issue Review* aimed to identify key elements of effective programmes of diabetes prevention and care, and provide an overview of selected programmes currently implemented or being trialled in general practice with published outcomes related to primary and/or secondary prevention. Where possible, distinction between programmes will be made on the basis of diabetes type: T1DM, T2DM, GDM; and where possible on the basis of target population: e.g. mainstream, Indigenous, high risk.



## Methods

A thorough (though not systematic) review of Australian and international literature was undertaken to search academic and grey literature sources including, but not restricted to: PubMed, Trove, Google Scholar, Scopus, PHCRIS PHC search filter; and publicly accessible websites of relevant companies and organisations including Diabetes Australia, Royal Australian College of General Practitioners, Australian Institute of Health and Welfare.

Keywords applied in the searches included the following terms (and synonyms or derivatives of the terms): diabetes; prevention; management; primary health; primary care; general practice; community health; family practice; family medicine. Due to the limited timeframe for this review (8 weeks), searches and critical appraisal of the literature were pragmatic rather than systematic. In order to obtain the most relevant material quickly, the combinations of search terms varied across different databases. Therefore, replication of this review may result in a different literature base.

For the purposes of this review:

- **Primary prevention** is defined as prevention of diabetes onset
- **Secondary prevention** is defined as reducing the rate of diabetes progression or reducing the development of diabetes-related complications in those with diagnosed diabetes.

Searches were restricted to English language, and Australia, New Zealand, UK and Canada; and the search period restricted to articles published in the past five years (i.e. since 2008), although older articles cited in newer articles may be included as appropriate. Only programmes delivered by general practice and with published outcomes data are included in this review. Articles that included high-risk populations, including Aboriginal and Torres Strait Islander peoples, people with disabilities and multimorbidities, those living in rural and remote areas, culturally and linguistically diverse populations or those with low socioeconomic status are included, but due to time and resource constraints, specific searches for different high-risk groups was not undertaken.

A total of 2,470 peer reviewed articles were captured through the database searches, and this was added to by 'snowballing' and grey literature searches on the internet.

## Findings

### Primary prevention programmes for diabetes in general practice

#### *Type 1 diabetes*

No trial has successfully demonstrated prevention of T1DM (Australasian Paediatric Endocrine Group and the Australian Diabetes Society, 2011). Australian guidelines for T1DM in children and adolescents currently recommend that “in the absence of a proven intervention to prevent progression to T1DM, screening or intervention in the preclinical phase should be confined to defined clinical studies” (Australasian Paediatric Endocrine Group and the Australian Diabetes Society, 2011).

However, there have been a number of trials (and some are underway) aimed at preserving pancreatic function to prevent or delay onset of T1DM (Wherrett, 2014, Skyler, 2013). Efforts to prevent or cure T1DM are generally via large collaborative networks, with rigorous mechanistic assays and uniform protocols (Atkinson et al., 2014). Australian researchers are currently involved in at least one collaborative primary prevention trial for T1DM: the international TrialNet collaboration, which comprises a series of studies to determine whether new treatments (e.g. use of oral insulin) can delay or prevent the onset of T1DM in those at risk (TrialNet, 2014).

#### *Type 2 diabetes*

Primary prevention of T2DM, defined as prevention of diabetes onset, has been demonstrated under trial conditions through lifestyle modifications, pharmacotherapy, and surgical approaches to reduce obesity (Colagiuri et al., 2009). Current Australian guidelines (published in 2009) state that progression to T2DM can be prevented; Evidence level I (Colagiuri et al., 2009). Three landmark trials have contributed to this evidence: the Finnish Diabetes Prevention Study (DPS), the US-based Diabetes Prevention Programme (DPP), and the Da-Qing Study in China (Knowler et al., 2002, Knowler et al., 2009, Li et al., 2008, Lindstrom et al., 2013, Pan et al., 1997, Tuomilehto et al., 2001, Uusitupa et al., 2009). Lifestyle and dietary strategies have also been employed among women with GDM or at risk for developing GDM and, although there is a need for better-designed studies, there appears to be some evidence of benefit (Chasan-Taber, 2014, Oostdam et al., 2011).

#### **Evidence base of Type 2 diabetes prevention programmes**

In the DPS, overweight subjects with impaired glucose tolerance (IGT) were randomised to either a usual care control group or an intensive lifestyle intervention (Uusitupa et al., 2009, Lindstrom et al., 2013, Lindstrom et al., 2003). In the first year, mean weight loss with intervention was approximately five per cent (4.5kg), reducing to four per cent after three years. Based on observed T2DM incidence after three years, the risk of T2DM was reduced by 58 per cent in the intervention group compared to controls; and it was also noted that high-risk individuals did not develop diabetes during the initial trial period if they reached at least four of five predefined lifestyle targets:

- weight loss greater than five per cent
- intake of fat less than 30 per cent of energy
- intake of saturated fats less than 10 per cent of energy
- increase dietary fibre to equal or greater than 15g/1,000 kcal
- increase physical activity to at least 4h/week.

A post-intervention follow-up study demonstrated that after three years the incidence rate per 100 person-years was 8.4 in participants who did not achieve any of the goals compared to 2.0 among

those who achieved at least four, and over seven years the relative reduction in diabetes incidence for the intervention group was 43 per cent (Lindström et al., 2006).

In the US population-based DPP study, a randomised trial design was used to compare lifestyle intervention versus placebo or pharmacotherapy with the hypoglycaemic agent metformin among people with IGT (Knowler et al., 2002, Knowler et al., 2009). The aim of the intervention was to achieve and maintain seven per cent weight loss and 150 minutes or more per week of moderate-intensity physical activity (Knowler et al., 2009). The lifestyle intervention was more effective than metformin, leading to a mean weight reduction of almost six kg (5.9%) after 2.8 years, compared to 2.1kg with metformin over the same period (after 24 weeks the weight reductions were 6.8kg and 2.5kg respectively) (Knowler et al., 2002, Knowler et al., 2009, Tuomilehto et al., 2011). After 2.8 years, the rate of T2DM in the DPP was 11.0, 7.8, and 4.8 cases per 100-person years in the placebo, metformin, and lifestyle groups respectively. An analysis of diabetes incidence after three years of follow-up demonstrated that, after adjustment for diet and activity, for every kilogram of weight loss there was a 16 per cent reduction in risk (Hamman et al., 2006).

The Da Qing Study examined the effects of a 6-year diet and exercise intervention in Chinese subjects with IGT, and found that diet alone was associated with a 31 per cent reduction in the risk of developing T2DM compared to a 46 per cent reduction with exercise alone (combining exercise plus diet did not affect outcomes, 42 per cent reduction) (Li et al., 2008, Pan et al., 1997). The long-term benefits of lifestyle interventions suggests a 'legacy' or carry-over effect with a risk reduction of 43 per cent after 20 years follow-up in the Da-Qing study; and similarly 43 per cent in the DPS after seven years; and 34 percent in the DPP after ten years (Tuomilehto et al., 2011).

In a systematic review of nine RCTs, including both the DPP and DPS, the positive impact of lifestyle interventions on reducing the incidence of T2DM was confirmed (Gillett et al., 2012). However, it was also noted that many participants did not succeed, and others succeeded in the first six months but not in the longer term (Gillett et al., 2012). A systematic review and meta-analysis of 71 studies aimed at prevention of T2DM found that overall study quality was poor, but the evidence indicated significant efficacy for antidiabetic drugs, physical activity with diet, diet alone, physical activity or education, antihypertensive drugs, and lipid-lowering drugs, but higher effectiveness of bariatric surgery among the morbidly obese (Merlotti et al., 2014). These outcomes suggest that there may be several strategies for prevention of T2DM (Merlotti et al., 2014). The need for individualised care in optimising management of diagnosed diabetes is widely recognised, and the availability of different diabetes prevention strategies would enable a similar approach to prevention.

With respect to GDM, a meta-analysis of prevention programmes published between 1980 and March 2011 identified 19 eligible RCTs and, although most of the studies were considered to be of very low quality, it was concluded that dietary counselling, advice on a low glycaemic index (LGI) diet, or an exercise programme could be beneficial and probiotics might be promising (Oostdam et al., 2011). Similarly, a recent Cochrane review found insufficient evidence to determine if screening for GDM, or what types of screening, can improve maternal and infant health outcomes (Tieu et al., 2014).

### **Mediterranean diet**

Although we were unable to identify any diabetes prevention programmes within PHC specifically recommending use of the Mediterranean diet (MeDiet) there is consistent, good quality evidence documenting its association with a significant reduction in the incidence of T2DM (Salas-Salvadó et al., 2011, Kastorini et al., 2011, Martínez-González et al., 2008, Esposito et al., 2010, Itsiopoulos et al.,

2011, Salas-Salvadó et al., 2014, Koloverou et al., 2014). Composition of the MeDiet varies but is based primarily on high consumption of vegetables, legumes, grains, fruits, nuts, and olive oil, moderate consumption of fish and wine, and low consumption of white meat, eggs and whole-fat dairy products, and limited consumption of red meat (Bach-Faig et al., 2011). Of note, a recent, good quality meta-analysis, which included one clinical trial and nine prospective studies accounting for almost 137 thousand participants, found a significant 23 per cent reduction in the risk of developing T2DM for those most adherent to a MeDiet compared to the least adherent (Koloverou et al., 2014). This is less than the 52 per cent reduction demonstrated in the only RCT of MeDiet and T2DM prevention, but likely reflects heterogeneity in study setting, MeDiet content, and participant characteristics across the studies. Hence is potentially more relevant to expected impact with 'real-world' implementation (Salas-Salvadó et al., 2011). Currently RACGP guidelines for T2DM recommend the MeDiet for those at high risk for CVD (RACGP and Diabetes Australia, 2014-15). Although weight loss is relatively minor with the MeDiet (<1kg in the RCT), the diet is well tolerated and adherence is reportedly high. Moreover, the significant reductions in development of T2DM were also achieved in the absence of energy restriction or promotion of physical activity (Salas-Salvadó et al., 2011). Further investigation of the MeDiet is required with respect to T2DM prevention, including the value of combination with increased physical activity and the relative contributions of different food types, as well as the potential benefit across the age and risk spectrum. However, there is currently sufficient evidence to recommend this as an alternative dietary plan for those at risk for T2DM, particularly for those less adherent to the low-fat diets prescribed in the DPS and DPP based programs.

### **Risk assessment for T2DM**

Use of the ten item Australian Diabetes Risk assessment tool (AUSDRISK) is recommended in Australian T2DM prevention guidelines to identify those at high risk (Colagiuri et al., 2009, RACGP, 2012). The risk factors included in the AUSDRISK tool are: age, gender, country of birth, family history of diabetes, history of high blood glucose, hypertension, smoking status, fruit and vegetable intake, physical activity levels and waist circumference (Wong et al., 2011, Chen et al., 2010). A score of 12 or more is defined as high risk in the RACGP clinical guidelines for preventive activities in general practice, although a score of 15 or more is used in the 2009 National Evidence Based guideline (RACGP, 2012, Colagiuri et al., 2009). AUSDRISK was not designed to identify IGT. The recommended action for those identified as being at high risk for T2DM is lifestyle modification interventions implemented at the level of routine clinical practice (RACGP, 2012, Colagiuri et al., 2009).

In contrast, despite identifying 145 published risk prediction models and scores for T2DM, Noble et al. (2011) noted that, internationally, there is limited evidence demonstrating the application of these models as part of a formal health policy. Australia's scheme to pay GPs for measuring risk of diabetes in adults was cited as one exception to this finding (Noble et al., 2011). Noble et al. (2011) included the Australian T2DM risk assessment tool, AUSDRISK, in a list of seven validated diabetes risk scores judged to be the most promising for use in clinical or public health practice.

### **Real-world implementation of primary prevention of T2DM**

Translating trial-based outcomes to real-world settings is complicated by greater patient diversity and limited resources. The challenge is to identify those at greatest risk, and to deliver and achieve engagement with interventions to sustain lifestyle changes primarily leading to weight loss and increased physical activity (Johnson et al., 2013). A high quality, systematic review of 28 US-based translation studies implementing the DPP in real-world settings found that clinically significant weight loss (by 4-5% of body weight) was achieved over nine months of follow-up (Ali et al., 2012). However, this finding should be interpreted with caution as the quality of many of the included

studies was poor. Ali et al. (2012) also noted that comparable weight change was observed in studies using medical and allied health professionals versus lay community educators, and that programme costs were driven by the cost of glucose-based eligibility testing and salaries for intervention staff (Ali et al., 2012). Although the poor quality of studies warrants caution when interpreting these results, this suggests that use of lay community educators following GP referral could potentially reduce the cost of lifestyle intervention without compromising intervention efficacy.

Expanding on the study of Ali et al. (2012), a review of community-based interventions found that weight loss after 12 months was about the same as that achieved in the later years of the major trials (approximately 4.2kg) (Kahn and Davidson, 2014). Specifically, in the DPP, the mean reported weight loss after 12 months was 7kg with lifestyle intervention; but after three years the difference compared to baseline had declined to approximately 4kg, which was more consistent with the weight loss reported after 12 months in community-based interventions (Knowler et al., 2009). In the US, based on their findings of reduced impact in 'real-world' studies, Kahn and Davidson (2014) questioned the use of public funds for national prevention initiatives that used lifestyle modification to prevent diabetes; suggesting instead that there may be more benefit to be gained from national policies designed to reduce our overall consumption of food. Similarly, a systematic review and meta-analysis of 12 mostly good quality studies that evaluated diabetes risk and physical activity/nutrition interventions in routine clinical practice found that translation to routine practice leads to significant, but modest, weight loss but no significant change in metabolic indicators of diabetes risk (FPG or OGTT) (Cardona-Morrell et al., 2010). At 12 months, mean weight reduction was 1.82kg greater with intervention compared to controls, and it was noted that loss-to-follow-up varied greatly between five and 57 percent (Cardona-Morrell et al., 2010).

The recently reported three year follow-up of the *Health Information, Nutrition and Exercise (SHINE)* implementation of a DPP-based programme for adults with metabolic syndrome, warrants mention here because it was not included in those meta-analyses and it was delivered in the PHC setting (Trief et al., 2014). The *SHINE* intervention was delivered over two years via telephone either individually (IC) or in groups via conference call (CC) with all participants sending logged diet/activity/weight to educators on a monthly basis. There was no intervention in the third year. Educators (primary care practice staff) and coaches (registered dietitians) delivered the intervention weekly for the first five weeks and thereafter on a monthly basis, with educators and coaches alternating. At the three-year follow-up, mean weight loss was similar to outcomes at year two and significant at -6.4kg for CC versus -2.35kg for IC (Table 1). This translated into approximately 51 per cent of CC participants and 29 per cent of IC achieving weight loss of at least five per cent over the three year period. Interestingly, with respect to proportion achieving at least five per cent weight reduction, there was no difference between study completers and non-completers at three years for the CC group (51% vs 50%, respectively) but a significant difference for the IC group (37.8% vs 5.6%, respectively). Although both groups recorded improvement in HDL cholesterol, only IC participants experienced significant increases in blood pressure over the three year period, and there was no mention of any impact on physical activity or diet for either group.

### **Selected examples of primary prevention programmes for T2DM relevant to the Australian setting and reporting outcomes data**

All of the primary prevention programmes for T2DM, which were identified in the current review as being relevant to the Australian setting, targeted weight loss and physical activity as described in the DPS programme. Specifically, programmes targeted weight loss of five per cent or more of body weight, as well as increase in physical activity to four hours or more per week, and improved diet. Screening for T2DM was based on application of the AUSDRISK tool in Australian lifestyle modification programmes. However, it is interesting to note that the *Australian Primary Care*

*Collaborative Programme (APCCP)*<sup>i</sup> reported in February 2014 that just two per cent of eligible patients were screened with the AUSDRISK tool (Australian Primary Care Collaborative, 2014). In the following section, we provide an overview of key outcomes from relevant primary prevention programmes reporting outcomes data, and in Table 1 these are highlighted and compared to the DPP and DPS. More detailed summaries are provided in the Appendices.

Two high-profile, group-based, diabetes prevention programmes, *Life! Taking action in diabetes (Life!)* and the *Sydney Diabetes Prevention Programme (SDPP)*, were trialled in the Australian clinical setting and have met with similar levels of moderate success (Colagiuri et al., 2010, Davis-Lameloise et al., 2013, Dunbar et al., 2014, Laws et al., 2012, Vita et al., 2013, Cardona-Morrell, 2011). Approximately 25 per cent of participants completing the *Life!* and *SDPP* programmes recorded weight loss greater than five per cent, but only *Life!* participants reported improved physical activity (Table 1). Mean weight loss was also very similar between programmes at 2-2.4kg (<5%) for completers, although for those attending five *Life!* sessions (completers and non-completers), mean weight loss was less at 1.4kg (Dunbar et al., 2014). Reporting outcomes only for completers (as opposed to Intention-To-Treat (ITT) analyses including all participants enrolled at baseline) has been criticised because programme costs are also incurred for those who do not complete and this can impact on programme scalability (McCombie et al., 2012). Based on reference to the DPP and DPS reported reductions in diabetes incidence, it was proposed that the almost three per cent mean weight loss in the *Life!* study might correspond to a 21-32 per cent reduction in diabetes incidence (Dunbar et al., 2014).

In both *Life!* and *SDPP*, people at high risk for T2DM were identified using the AUSDRISK tool and a cut off score of 15<sup>ii</sup> or more (DPP and DPS entry was based on confirmed IGT). However, there were also important differences between the Australian programmes: entry into *Life!* was via multiple entry points (GP referral, *Life!* Provider and facilitator referral, workplace and social media-based recruitment); entry into *SDPP* was via GP referral only. This could potentially result in participants with lower risk being included in the *Life!* study. Further, *Life!* was a motivational programme delivered by certified health professionals with input from dietitians and physiotherapists for two sessions and working across community sectors including public and private; whereas the *SDPP* was delivered by Lifestyle Officers with scheduled GP consultations at 4 and 12 months, and participants were encouraged to attend local community-based lifestyle programmes to help achieve the physical activity and dietary goals. In addition, *Life!* participants were more likely to be socioeconomically disadvantaged than *SDPP* participants (53% versus 3%). Adaptation of the *Life!* programme to meet the Indigenous community's needs, and development of the *MAGDA* programme for women with a history of GDM demonstrates the utility of this model in meeting the sometimes very different needs and priorities of people with diabetes. However, reporting of outcomes is now required to determine the efficacy of these adaptations.

The success of lifestyle intervention is dependent on adherence to the programme and retention of participants; and this remains a challenge (Vita et al., 2013). Retention in the complete *Life!* programme was just 37 per cent for attendance at six sessions. However, this was in part due to the financial incentive payment structure whereby course providers may not have offered the sixth session. In contrast, 78 per cent of participants attended five *Life!* sessions, and this is similar to the 82 per cent retention rate in the *SDPP*. Optimisation of these programmes for those not achieving lifestyle targets and to further improve retention is now required, as are economic analyses and long-term data on diabetes incidence.

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<sup>i</sup> See the secondary prevention section in this review for more information.

<sup>ii</sup> The AUSDRISK score for *Life!* entry has since been reduced to 12 or more.

It is important to note that weight loss in the *Life!* and *SDPP* were substantially lower than the weight loss reported from the DPS and DPP randomised trial studies after 12 months. However, these outcomes are comparable to the 'real-world' UK based *Counterweight* lifestyle intervention, see Table 1. The *Counterweight* programme is an evidence- and theory-based intervention for weight management delivered through general practice and shown to be highly cost-effective using the NICE obesity health economic model in the UK setting (and cost saving in most scenarios modelled) (Laws, 2004, McQuigg et al., 2008, Trueman et al., 2010). The core *Counterweight* model involves patient attendance at six individual or group sessions over a 3-month period with follow-up at three quarterly support visits (Ross and Counterweight project team, 2012, Laws, 2004). Based on an evaluation conducted between 2000 and 2005, mean weight loss at 12 months was 2.96 kg among attenders, with 45 per cent of participants completing 12 months and 31 per cent meeting the target of greater than five per cent weight loss (2008). Approximately one third of participating practices were located in socially deprived areas. The *Counterweight* programme is currently being trialled in Australia in both Sydney and Adelaide.

A comparative review of *Life!* and *SDPP* highlighted the success of social marketing strategies in the former and suggested that limiting prevention programmes to the PHC setting results in limited impact (Vita et al., 2013). However, it should be noted that GPs referred approximately one third of *Life!* participants despite differences in incentive payments with GPs receiving \$20 for each referral and an additional \$30 upon completion of the introductory session; compared to programme facilitators being paid \$400 per participant that they take through the programme (Dunbar et al., 2014, Lifeprogram, 2014). In contrast, workplace recruitment accounted for less than six per cent of referrals, and this outcome was due in part to the difficulty of ensuring an individual's privacy.

The *SDPP* encouraged participants to access local community-based lifestyle programmes. In line with the Healthy Communities Initiative (HCI), which was funded for four years from 2009/10, a number of community-based lifestyle interventions are currently available with or without GP referral and generally at no cost. A selection of these are listed in Table 2, but published outcomes data were not located for most of them (Australian Government Department of Health). One community-based programme with published outcome data is the *Healthy Eating Activity and Lifestyle (HEAL™)* programme, an eight-week programme based on an hour of supervised exercise and an hour of healthy lifestyle education each week (Hetherington and Borodzicz, 2013). Based on data from more than 1,700 participants over a three year period, at programme end participants recorded a mean weight reduction of one kg, a 13 per cent increase in physical activity, a mean change in systolic blood pressure (SBP) by -3.1 mmHg, and a programme retention rate of 61 per cent. Follow-up data obtained at five months indicated that weight loss and physical activity continued to increase, while improvements in healthy eating were maintained. The impact of the *HEAL* intervention on cardiovascular risk factors such as blood pressure is particularly encouraging and should prompt further investigation and implementation. It will be of interest to observe whether the weight loss at 12 months approaches that reported by *Life!* and *SDPP*.

Generating outcome data from all of these programmes and ongoing trials such as *Mothers After Gestational Diabetes in Australia Diabetes Prevention Programme (MAGDA-DPP)* and the international *PREvention of diabetes through lifestyle Intervention, PREVIEW study*, will be very important for future funding decisions given evidence of variability in retention rates and the impact of intervention on important surrogate markers such as weight loss, physical activity and blood pressure. Extrapolation from observed weight loss to changes in T2DM incidence based on DPP and DPS findings will be required until sufficient follow-up time has elapsed to report on actual incidence of T2DM, but efforts to confirm this with actual incidence data should be encouraged.

### **Cost-effectiveness of diabetes prevention programmes**

In an extensive and detailed systematic review of literature published before January 2012, Gillett et al. (2012) concluded that it is difficult to reach a definitive conclusion regarding the cost-effectiveness of lifestyle interventions for the prevention of diabetes. Their conclusion was based on conflicting results from economic modelling studies. Several studies used Markov-type economic modelling to predict that lifestyle interventions that delayed diabetes “would provide good value for money” (p 71). However, using a “more complex model not widely used in health-care decision modelling” (Archimedes Diabetes Model), and outcomes from the DPP, predictions indicated that lifestyle interventions to prevent diabetes were not cost-effective. Although Gillett et al. (2012) noted that estimated cost-effectiveness was particularly sensitive to changes in intervention cost and participant adherence (and hence maintenance of intervention effectiveness), they also found agreement between the different models with respect to the significant impact of maintenance of lifestyle changes and weight loss on the risk of developing diabetes and its associated complications. More recently, an extensive review of 46 studies modelling the economics of T2DM prevention concluded that there is a need to develop more flexible models that incorporate multivariate risk equations for T2DM, and include diabetes-related complications and co-morbidities (Watson et al., 2014). This is an area in need of further development.

Nevertheless, two cost-effectiveness modelling studies have been reported where ‘real-life’ scenarios were created to more closely reflect likely events in routine care (Gillett et al., 2012, Palmer and Tucker, 2012). That is, people not adhering to the programme were switched to metformin pharmacotherapy after 12 months. This approach addresses criticism of programme promotion based only on data from ‘completers’, since those who discontinue also generate costs (McCombie et al., 2012). Based on this approach, it was predicted that in the Australian and UK settings, lifestyle intervention strategy would be at least cost-effective and potentially cost saving in certain scenarios (Gillett et al., 2012, Palmer and Tucker, 2012). However, although incorporating treatment changes and any associated side-effects is likely to more closely reflect ‘real-world’ scenarios, use of outcome data from RCTs (e.g. weight loss as reported in the DPP or DPS), may overestimate the impact of treatment in a clinical setting as discussed above; and therefore the projected cost-effectiveness may be overestimated. Thus, it is important that economic analyses include (and publish) extensive and rigorous sensitivity analyses that project outcomes based on uncertainty in key parameters (e.g. use of 95% confidence limits, where possible); and where evidence exists, they should reflect ‘real-world’ expectations particularly with respect to weight loss.



**Table 1 Summary of reported outcomes for selected Type 2 diabetes prevention programmes**

Programme	Risk assessment	n	Clinical impact on surrogate markers at 12 months <sup>^</sup>	Retention rate (%)	Impact on incidence of diabetes
<b>Finnish Diabetes prevention study (DPS) (Uusitupa et al., 2009, Lindstrom et al., 2013, Lindstrom et al., 2003)</b>	IGT	522	Mean weight loss 4.5kg (5.2%)  At three years, approximately 46% achieved a 5% or greater weight loss goal 14% achieved four or five goals (vs 6% for control), 10% did not achieve any of the goals(vs 27% for control)	NR	58% reduction
<b>US Diabetes Prevention study (DPP) (Knowler et al., 2002, Knowler et al., 2009)</b>	IGT	3,819	Mean weight loss 6.8kg (7.2%) with lifestyle Mean weight loss 2.5kg (7.2%) with metformin  50% achieved 7% or greater weight loss goal at 24 weeks 74% achieved physical activity goal at 24 weeks	NR	58% reduction with lifestyle 31% reduction with metformin
<b>Life!Taking action in diabetes (Dunbar et al., 2014)</b>	AUSDRISK	6,632	Mean weight loss 2.4kg (2.8%) for study completers Moderate change in physical activity (baseline 11.3% vs 17.6% for study completers) Moderate change in diet (baseline 31% vs 65.1% for study completers)	37*	NR
<b>Sydney Diabetes Prevention Programme (SDPP)# (Cardona-Morrell, 2011)</b>	AUSDRISK	1,250	Mean weight loss 2kg , approximately 2% (1.8kg at two years, and 2kg at three years) No change in physical activity  Approximately 24% of study completers achieved a 5% weight loss goal Only 11.5% achieved four goals and 1% five goals, 20% did not achieve any of the goals	82.3	NR

Programme	Risk assessment	n	Clinical impact on surrogate markers at 12 months <sup>^</sup>	Retention rate (%)	Impact on incidence of diabetes
<b>Healthy Eating Activity and Lifestyle (HEAL™) (Hetherington and Borodzicz, 2013)</b>	GP referral	1,500	Weight loss 1.0kg after 2 months Physical activity increase by 13% after 2 months SBP decrease by 2% (3.1mmHg) Also Improved diet, 6-min walk, reduced sitting	61	NR
<b>Counterweight (2008, Laws, 2004, Ross and Counterweight project team, 2012)</b>	GP assessment and BMI ≥30 kg/m <sup>2</sup> or ≥28 kg/m <sup>2</sup> with co-morbidity	1,906	Mean weight loss for completers (n=1,419) at 12 months was 2.96kg (3%) and at 24 months 2.3kg (n=825)  Approximately 31% of study completers (14% of all patients) achieved a 5% weight loss goal at 24 months	45	NR
<b>Building on Existing tools to Improve chronic Disease Prevention and Screening in Family Practice (BETTER) (Grunfeld et al., 2013)</b>	No specific risk calculator but screening includes blood pressure, lipid levels, waist circumference, BMI assessment.	789	Referral for weight control increased (51.4% vs 62.2%) <sup>§</sup> Physical activity >90min/week increased (49.7% vs 52.2%) <sup>§</sup> Healthy diet score increased (8.2% vs 9.6%) <sup>§</sup> Referral for nutrition counselling increased (8.2% vs 9.6%) <sup>§</sup>	NA	NR
<b>Support, Health Information, Nutrition and Exercise (SHINE) (Trief et al., 2014)</b>	Metabolic syndrome based on IDF criteria and BMI ≥30 kg/m <sup>2</sup>	257	Mean weight loss for individual call based intervention (IC) - 2.35 kg; for group call based intervention (CC) -6.44 kg <sup>β</sup> Proportion achieved a 5% or greater weight loss goal: 28.6% (IC) and 50.7% (CC) <sup>β</sup> HDL cholesterol approximately +2.84 mg/dL for IC, +5.47 for CC.	90	NR

IGT=Impaired glucose tolerance;NR= Not Reported; NA= Not applicable; GP=General Practitioner; ^ based on Intention-To-Treat cohort unless otherwise indicated; <sup>§</sup>percent improvement for prevention practitioner group compared to control group; \*Retention rate potentially biased because this is based on attending six sessions, but in some cases the sixth session was not offered; <sup>§</sup> based on control and prevention practitioner comparison only; <sup>β</sup> outcomes at 36 months (1 year after last intervention session).

**Table 2 Selected community based Type 2 diabetes prevention and lifestyle modification programmes currently implemented but without published outcomes data**

<b>Programme</b>	<b>Availability</b>	<b>Overview</b>	<b>Publications and/or website</b>
<b>Active measures</b>	WA	A free, 16-week community-based weight loss programme with self- or GP-referral. Based on an exercise programme and dietary education by a dietitian including review (0, 3, 6 months), the aim is to gradually improve fitness levels and reduce weight.	<a href="http://www.baml.com.au/health-professional/chronic-disease-hp/ac/">http://www.baml.com.au/health-professional/chronic-disease-hp/ac/</a>
<b>Beat it – Physical activity program</b>	NSW, QLD, SA, TAS, VIC, WA	A 10-12 week physical activity and education programme including healthy eating and lifestyle advice. Aimed to assist with increasing physical activity levels and improving healthy lifestyle behaviours to prevent or manage diabetes and other chronic conditions in a safe and supportive environment; and to ensure participants are competent to exercise independently following programme completion.	<a href="http://www.health.gov.au/internet/healthyactive/publishing.nsf/Content/healthy-comm-lgag-att_c-toc-healthy-comm-lgag-att_c-beatit">http://www.health.gov.au/internet/healthyactive/publishing.nsf/Content/healthy-comm-lgag-att_c-toc-healthy-comm-lgag-att_c-beatit</a>
<b>Lift for Life</b>	ACT, NSW, VIC, WA, QLD, NT, SA	Lift for Life is a unique resistance training programme designed for adults with (or at risk of developing) T2DM and other chronic conditions. Delivered in 3 eight-week programmes of up to 12 people attending 2-3 sessions per week. Referral forms available for GP use.	<a href="http://www.liftforlife.com.au">http://www.liftforlife.com.au</a>
<b>Heartmoves</b>	ACT, NSW, NT, QLD, SA, TAS, VIC, WA	The Heart Foundation’s Heartmoves offers “a gentle physical activity programme suitable for anyone who hasn’t done any exercise in a while”. It aims to provide a friendly atmosphere where people can exercise “at your own pace”	<a href="http://www.heartmoves.org.au/program">http://www.heartmoves.org.au/program</a>
<b>Heart Foundation Walking</b>	ACT, NSW, NT, QLD, SA, TAS, VIC, WA	Free community-based walking groups led by volunteer community members.	<a href="http://www.heartfoundation.org.au/active-living/walking/Pages/welcome.aspx">http://www.heartfoundation.org.au/active-living/walking/Pages/welcome.aspx</a>
<b>Healthy Lifestyle Programme</b>	WA	GP referral is required for this 12-month programme. A Dietician provides advice on maintaining a healthy diet. A Diabetes Educator advises clients with T2DM about how to manage their condition. An Exercise Physiologist tailors a structured exercise routine to suit individual clients’ needs.	<a href="http://www.baml.com.au/health-professional/chronic-disease-hp/healthy-lifestyle-program/">http://www.baml.com.au/health-professional/chronic-disease-hp/healthy-lifestyle-program/</a>
<b>Lift for Life</b>	ACT, NSW, NT, QLD, SA, TAS, VIC, WA	An evidence-based resistance training program for people with, or at risk of, T2DM or other chronic diseases. It is available to adults of all ages, and Lift for Life is licensed to private health and fitness businesses.	<a href="http://www.heartfoundation.org.au/active-living/walking/walking-groups/Pages/WA-Walking-Groups.aspx">http://www.heartfoundation.org.au/active-living/walking/walking-groups/Pages/WA-Walking-Groups.aspx</a>

## Secondary prevention programmes for diabetes in general practice

For people with diabetes, the consequences of uncontrolled blood glucose levels, blood pressure and lipids are the progressive development of microvascular (including retinopathy, nephropathy and neuropathy) and macrovascular (cardiovascular disease including myocardial infarction and stroke) complications. In the current review, secondary prevention is defined as any measures initiated to reduce the rate of diabetes progression or to reduce the development or further exacerbation of diabetes-related complications in those with diagnosed diabetes. Based on the landmark United Kingdom Prospective Diabetes Study (UKPDS) for T2DM and the Diabetes Control and Complications Trial (DCCT) for T1DM, it has been established that control of blood glucose and blood pressure can significantly reduce the incidence of diabetes-related complications (Nathan, 2014, Stratton et al., 2000, The Diabetes Control and Complications Trial Research Group, 1993). Therefore, an important aim of diabetes management programmes for those with diagnosed diabetes is to reduce the risk of complications or further exacerbation of existing complications by controlling these modifiable risk factors. Insulin treatment is essential in T1DM and management of diet and insulin dose is a central part of effective control. Although early management strategies for T2DM focus on lifestyle and dietary changes, pharmacotherapy is also a key element of treatment (Furler et al., 2013). The requirement for a broader, more inclusive management programme that incorporates all of these elements and addresses broader patient-centred needs, such as education and self-management skills, is recognised in diabetes management guidelines (RACGP and Diabetes Australia, 2014-15, Colagiuri et al., 2009). For patients with T2DM across the spectrum, structured care programmes that are easy to implement, are well-supported and meet the needs of the individual are required (RACGP and Diabetes Australia, 2014-15). These programmes bring together healthcare teams, evidence-based guidelines, useful support tools and good systems to support patients throughout their journey.

According to the latest Royal Australian College for General Practitioners (RACGP) guidelines for T2DM, the Chronic Care Model (CCM), developed by the MacColl Institute, identifies the fundamental elements of a healthcare system that supports high-quality chronic disease care (RACGP and Diabetes Australia, 2014-15):

- health system (organisation and mechanisms)
- delivery system design
- decision support
- clinical information systems
- self-management support
- the community.

### *Key elements of diabetes management programmes identified in systematic reviews*

Numerous diabetes management and quality improvement programmes have evolved, and a recent meta-analysis of 48 RCTs highlights key aspects of published quality improvement strategies for diabetes that positively impact on patient-level surrogate outcomes of glucose levels, blood pressure, and lipid levels that, in turn, are known to influence the risk for diabetes-related complications (see Table 3) (Tricco et al., 2012). The five programme features associated with chronic disease management (CDM)-related reductions in HbA1c, LDL, SBP, and DBP were:

- **Promotion of self-management.** Established goals or a written self-management plan, provision of equipment (e.g. home glucose meters) or access to resources (e.g. system for electronically

transmitting home glucose measurements and receiving insulin dose changes based on those data) to promote self-management.

- **Team changes.** Changes to the structure or organisation of the primary health care teams (e.g. additional members, multidisciplinary teams, expansion or revision of professional roles)
- **Patient education.** Interventions designed to promote greater understanding of the disorder or to teach specific prevention or treatment strategies.
- **Case management.** Any system for coordinating diagnosis, treatment, or routine management of patients by a person or multidisciplinary team in collaboration with, or supplementary to, the primary-care clinician.
- **Facilitated relay of information to primary clinician.** Clinical information collected from patients and transmitted to clinicians by means other than the existing medical record (e.g. pharmacist issued structured diaries for patients to record self-monitored glucose values or web-based methods for patients to provide self-care data, which were then taken to review with primary care physician)<sup>iii</sup>

Although 49 per cent of the studies included in Tricco et al.'s (2012) meta-analysis were US-based, an independent review of systematic reviews investigating programmes for improved quality of care for persons with diabetes concurred with these outcomes (Worswick et al., 2013). More specifically, based on 50 high quality reviews, Worswick et al. found evidence for the importance of patient education, team changes, and telemedicine interventions for improving glucose control. Strong evidence was also found for a positive role of team change on blood pressure and cholesterol levels. However, there was insufficient evidence to determine the role of organisational changes such as general practice versus hospital care, or the impact of shared decision-making on glycaemic control (Worswick et al., 2013).

Furthermore, in a survey of 38 Primary Care networks in Alberta, Canada, Campbell et al. (2013) found that the two most commonly used CDM strategies for patients with diabetes were team changes and patient education, despite the fact that team changes were among the most resource-intensive strategies. It was also found that many primary care networks in Alberta employ several CDM strategies concurrently in the management of patients with diabetes, likely reflecting the diversity of patients from newly diagnosed through to those with more advanced disease and complications.

These more recent findings are in line with an earlier review of CDM in primary care where the interventions most likely to be effective in the context of Australian primary care were self-management support through education and training of GPs and practice nurses and through linkage to multidisciplinary team support (Dennis et al., 2008).

Despite all of this, a recent review of diabetes primary care workforce models in Australia, was prompted by the “inconsistent support for teamwork care models and a lack of enhanced clinical inter-professional education and/or training opportunities” (Schofield et al., 2014, p 1). Although 14 studies primarily focused on secondary prevention or diabetes management were identified in that review, Schofield et al. concluded that there was a general lack of rigour, and the majority of studies risked the introduction of bias. Studies offering coordinated diabetes treatment rated poorly, achieving only IV or V on the NHMRC framework scale for assessing the level of evidence. According to Schofield et al. (2014), there is a need for more rigorous research to assess whether programmes

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<sup>iii</sup> If the results of routine visits with a pharmacist were sent in a letter to the primary-care physician, the use of routine visits with a pharmacist would count as a “team” change but the intervention would not also be counted as “facilitated relay”.

are effective in producing improved health outcomes and whether they represent better value for money than current practice.

**Table 3 Post-intervention reductions in biological markers associated with specific features of diabetes management programmes**

<i>Programme feature</i>	<i>Reduction in HbA1c (%)</i>	<i>Reduction in LDL mmol/l</i>	<i>Reduction in SBP(mmHg)</i>	<i>Reduction in DBP(mmHg)</i>
Promotion of self-management	0.57	0.18	3.69	1.89
Team changes	0.57	0.17	4.32	1.75
Case management	0.50	0.11	4.62	0.93
Patient education	0.48	0.14	4.02	2.25
Facilitated relay	0.46	0.16	4.31	0.82
Electronic patient register	0.42	0.09	3.35	0.78
Patient reminders	0.39	0.01	1.82	0.76
Audit and feedback	0.26	0.03	2.52	0.68
Clinician education	0.19	0.11	2.56	1.13
Clinician reminders	0.16	0.14	0.65	1.11
Financial incentives	0.10	NR	2.00	none
Continuous quality improvements	none	none	1.00	NR

Based on Tricco et al. (2012). For a full description of programme feature definitions see Appendices. NR= Not Reported

### *Monitoring diabetes management in primary care*

Monitoring general practice management of diabetes in Australia has been a difficult task due to the lack of national level reporting. Current data sources are often limited by the type of data collected, cohort size, or relevance of the data to the general diabetes population (Erny-Albrecht and Bywood, 2014). Use of the Pen Computer Systems Clinical Auditing Tool (PCS CAT) auditing tool may represent an approach that could be widely implemented to generate the information required to monitor diabetes prevalence; and patient management outcomes such as completion of Annual cycle of Care (ACC), HbA1c, blood pressure, uptake of preventive health activities offered through the Medicare benefits scheme and so forth (Ghosh et al., 2013, Ghosh et al., 2014). Recent pilot studies have demonstrated use of the PCS CAT system to monitor chronic disease prevalence and its associated risk factors among general practice attendees and at a local level (Ghosh et al., 2013, Ghosh et al., 2014). In addition to promoting the use of the AUSDRISK Tool to identify people at risk for T2DM, the *Life!* diabetes prevention programme coordinators also highlight the value of using PCS CAT to assist with systematic diabetes prevention and management (*Life!* program, 2014).

### *Examples of diabetes management programmes relevant to the Australian setting and reporting outcomes data*

Management of T1DM and T2DM shares many parallels including the central role of achieving good glycaemic control, but also some very important differences including the range of affected age groups, the potential of lifestyle interventions, and the choice and timing of pharmacotherapy. However, since T2DM accounts for 85-90 per cent of prevalent cases in Australia, diabetes management programmes for T2DM predominated in the current literature review. A limited number of programmes identified in this review targeted only T1DM, or both T1DM and T2DM, although people with T1DM made up less than 10 per cent of those enrolled in combined studies

(Reichert et al., 2014, Knight et al., 2012, Rasekaba et al., 2012b). In the following section, features of selected, secondary prevention programmes reporting clinical outcomes are summarised, but more detail about the individual programmes can be found in the Appendices.

### **Type 1 Diabetes secondary prevention programmes**

According to Australian guidelines, most people with T1DM will receive care from an endocrinologist or diabetes specialist; however, they may also access GPs for routine monitoring of HbA1c and blood pressure, and other requirements such as vaccination against influenza (Australasian Paediatric Endocrine Group and the Australian Diabetes Society, 2011). Since 2005, GPs across Australia have been able to refer T1DM patients in need of help with self-managing their diabetes to the one-week long *Dose Adjustment For Normal Eating (DAFNE)* programme to learn how to estimate and balance diet and insulin injections, as well as how to better manage exercise, illness and alcohol consumption (McIntyre et al., 2010). An audit of patients at seven Australian diabetes centres after participation in *DAFNE* showed moderately improved glycaemic control, reduced weight and a reduced incidence of severe hypoglycaemia (McIntyre et al., 2010). An adolescent version of *DAFNE* has also been developed and this is promoted as TEAM T1.

In rural and remote areas, access to specialist services may be limited and GPs are likely to be the main provider of primary care for T1DM. In this case, access to specialists and services within regional centres might be facilitated via telemedicine (Australasian Paediatric Endocrine Group and the Australian Diabetes Society, 2011). In response to the sometimes limited access to diabetes specialists for people with T1DM, a number of general practice-based programmes have been developed, and examples with reported outcome measures are briefly summarised here and described in more detail in the Appendices.

The *Rural Australian Diabetes – Inspiring Control Activity & Lifestyle (RADICAL)* general practice-based T1DM programme was launched in 2007 (Goss et al., 2010). Based on a co-located core multidisciplinary team (GP, diabetes educator, mental health nurse/counsellor) and on-site HbA1c testing, the *RADICAL* programme provides proactive child and family emotional support and promotes insulin regimes that aim to match patient lifestyle, especially insulin pump therapy. This is consistent with most of the key programme features identified by Tricco et al. (2012) as discussed above: promotion of self-management, team changes, patient education and case management. Over a two-year period, implementation of the *RADICAL* model resulted in a significant increase in the annual number of contacts with credentialed diabetes educators, and reductions in HbA1c for children and adolescents, as well as improved patient satisfaction and quality of life. Notably, in the year before *RADICAL* was launched, approximately six per cent of 48 patients achieved an HbA1c  $\leq 7.5$  per cent, and this increased to 36 per cent of 50 patients in 2009; and emergency department attendance and admissions to hospital for diabetes-related issues decreased from 23 per cent to eight per cent in 2008 (Goss et al., 2010). According to the study group, an important contributor to the success of *RADICAL* was the inclusion of a counsellor as part of the core team, as this was of benefit to the patient and their support network alike.

A second example of GP-based diabetes management programmes in rural regions is the *Diabetes Management Along the Mallee Track*, which incorporated community risk assessment and point-of-care testing (PoCT) to manage patients with diagnosed diabetes (T1DM and T2DM) in partnership with local GPs, allied health and community health nurses (Shephard et al., 2005). This service was offered irrespective of diabetes type and after 10 months the percentage of people achieving good glycaemic control (HbA1c < 8%) increased from 59 per cent to 91 per cent. PoCT diabetes management programmes have been implemented in a number of rural and urban settings,

including Aboriginal communities, and an accreditation programme has been established for ongoing implementation (Shephard, 2006). Patient and GP satisfaction with PoCT programmes is high, and significant improvement in diabetes management is consistently observed. However, a systematic review found that a lack of good quality, long-term follow-up studies prevented overall conclusions being drawn on the effectiveness of PoCT in the general practice setting (Gialamas et al., 2010). Again, key features of this programme were team changes and case management, but further studies documenting outcomes and programme requirements are needed.

### **Type 2 Diabetes secondary prevention programmes**

A number of secondary prevention programmes for T2DM were identified as being relevant to the Australian PHC setting; however, this review is limited to those with published outcomes data. In line with the different target populations, variability in the approach taken was evident, although most programmes focused on similar targets including HbA1c, blood pressure and lipid levels. Most programmes implemented changes through the use of multidisciplinary teams and upskilling of staff. Many of the other key criteria highlighted in Tricco et al.'s (2012) systematic review outlined above were also evident in programme design and these are briefly discussed in the following section. The individual programmes are presented in more detail in Appendices.

Although clinical markers like HbA1c are only proxy/surrogate measure for diabetes management and risk for diabetes-related complications, HbA1c was the most common primary outcome to assess programme efficacy for diabetes management across the programmes reviewed. This is consistent with the evidence for a direct relationship between reductions in HbA1c and reduced rates of diabetes-related complications as demonstrated in the landmark UKPDS study (Stratton et al., 2000). Despite the availability of a large pool of different therapeutic options for diabetes, it is noteworthy that a large number of patients with diabetes fail to reach optimal glycaemic targets.

While most programmes reported modest improvements in HbA1c of less than one per cent, many reported significant improvements in the proportion of people reaching glycaemic targets (Table 4). The rural *Diabetes Management Along the Mallee Track* programme reported a substantial improvement in those reaching target, increasing from 59 to 91 per cent, and, similarly, both the *Australian Primary Care Collaboratives* and *Integrated primary-secondary care for complex diabetes* programmes increased the proportion from approximately 20 to 40 per cent. Moderate improvement in mean HbA1c was reported in the Canadian *St Joseph's Primary Care Diabetes Support Programme*, where intensive diabetes management with education for self-management provided by an expanded care team including a social worker, resulted in significant improvements in HbA1c by 1.1 per cent for T1DM and 0.87 per cent for T2DM over a period of six months. Longer term follow-up is needed to determine whether this level of control is maintained. The importance of mental/social health professionals in diabetes management was also noted in the *RADICAL* T1DM management programme outlined above. A similar level of HbA1c improvement was also observed in the Victorian *Northern Alliance HARP diabetes programme*, with mean improvements by 1.3 per cent after 12 months, based on multidisciplinary care and individualised education. Although in that programme specific mention of mental/social health workers was not made, the provision of individualised education may have provided people with additional support that resulted in improved self-management and coping. However, team changes and education per se are not sufficient to produce these improvements in HbA1c, with a number of programmes reporting more modest changes despite implementing similar but not identical programmes. Programme efficacy will also depend on the potential for improvement, people with good control are less likely to achieve major changes in HbA1c, and many studies reported better outcomes in those with poorest control.



Measurement of outcomes that can be modified is an important consideration. In addition to providing effective targets to reduce the risk for complications, modifiable risk factors like diet, physical activity, smoking, and alcohol consumption, could be utilised to understand why a programme is effective and which elements may be the biggest contributors. Further development of effective health behaviour education and/or self-management approaches requires evidence from existing programmes to show how much they contribute to observed changes.

**Table 4 Summary of outcomes reported for secondary prevention programmes in diabetes**

<b>Programme</b>	<b>Change in HbA1c at 12 months (%)</b>	<b>Proportion with HbA1c ≤ 7%</b>	<b>Workforce</b>
<b>RADICAL (Goss et al., 2010)</b>	-1.5% (over 3 years)	36% (versus 6% a baseline)	GP, diabetes educator, mental health nurse/counsellor
<b>Diabetes Management Along the Mallee track (Shephard et al., 2005)</b>	-0.5%	63% (10 mo, versus 33% at baseline)	GP, allied health and community health nurses
<b>Integrated primary-secondary care for complex diabetes (Askew et al., 2010, Jackson et al., 2010)</b>	-0.8%	42% at 12 months versus 21% at baseline	GP Clinical Fellow, endocrinologist, diabetes educator, as needed dietician, psychologist, podiatrist
<b>Australian Primary Care Collaboratives (Australian Primary Care Collaborative, 2014)</b>	NR	40% (versus approximately 25% at programme start)	GP, Expert review panel
<b>Australian TLC Diabetes programme(Williams et al., 2012)</b>	-0.8% (versus -0.2% in control group)	20% (versus 15% in control group)	Automated telephone response
<b>Northern Alliance HARP(Rasekaba et al., 2012a, Rasekaba et al., 2012b)</b>	-1.3%	NR	Multidisciplinary team (endocrinologists, diabetes educators, dietitians)
<b>Logan Health Living(Eakin et al., 2013, Eakin et al., 2014)</b>	No change (but 1.4% weight loss)	NR	Nutritionist provides telephone based advice
<b>Diabetes, Your Life, Your Journey(Krebs et al., 2013)</b>	-0.4% at 6 mo, but no change at 9 mo	NR	Dietitian and practice nurse or diabetes nurse specialist
<b>Healthy Eating and Active Living in diabetes(Johnson et al., 2009)</b>	NR, but mean weight loss 1%	NR	Exercise specialist
<b>TeamCare model (Johnson et al., 2012a)</b>	-0.56%	NR	Nurse care manager and GP
<b>St. Joseph's Primary Care diabetes support Programme (Reichert et al., 2014)</b>	-1.15% for T1DM (6 mo) -0.87% for T2DM (6 mo)	NR	Expanded care team including GPs, nurse practitioners, dietitians, social worker
<b>Intermediate Care Clinics for Diabetes (Halfyard et al., 2010, Sharp, 2010)</b>	-1.5%	NR	GP, specialists, community services including podiatry and dietetics

NR= Not Reported; GP=General Pratictioner; T1DM=type 1 diabetes mellitus

### **Team changes**

There is a large diversity in team arrangements across programmes. This is often dictated by the context and resources available. Several programmes identify the importance of upskilling; especially for nurses in the role of nurse practitioners or diabetes specialist nurse. Similarly, GPs specialising in diabetes management (GP with Special Interest) (Russell et al., 2013, Jackson et al., 2010) are central to many programmes identified in this review. In addition to these fundamental roles, allied health professionals and specialists play a vital role as part of the expanded care teams, most frequently including endocrinologists, podiatrists, psychologists (health and clinical), dietitians/nutritionists, optometrists/ophthalmologists and exercise specialists. The inclusion of specialists in the team allows for early identification of potential complications (e.g. eye and foot screening) and therefore early intervention to prevent further deterioration (Russell et al., 2013, Zhang et al., 2013). For populations that are not well connected to PHC providers, the addition of a social worker has also been identified as being beneficial (Reichert et al., 2014).

### **Case management**

Programme fidelity is the extent to which delivery of an intervention adheres to the protocol or programme model originally developed (Kramer et al., 2009). Fidelity measurement has increasing significance for evaluation, treatment effectiveness research, and service administration in order to understand how transferable it is across a variety of settings and circumstances. With regard to context, the programmes described in this review suggest that population requirements influence the programme outcomes. For example, co-location strategies where team care is coordinated from one community-based location could be recommended for populations that are not strongly affiliated with a GP (TeamCare-PCN) (Johnson et al., 2012a). On the other hand, in urban settings, hub and spoke approaches can be considered (Wilson et al., 2014). Programmes that are more effective at improving clinical markers tend to have well-integrated primary/secondary models of care (Wilson et al., 2014, Russell et al., 2013). This type of horizontal integration requires relationships between organisations, professionals and patients. The *Australian Primary Care Collaboratives* programme is one of the few to address acceptability and capacity issues at the organisational level which may stall or enhance implementation (Knight et al., 2012).

### **Promotion of self-management and patient education**

Programmes identified in this review provide limited detail on the patient education and self-management aspects of the programmes. However, education for health professionals, (including upskilling), and referral to health professionals and organisation staff appears to be just as important as developing education for patients (Knight et al., 2012). Where education programmes have been developed, findings suggest they need to be personalised and well-integrated into community-based care (Wilson et al., 2014) and, importantly, they need to be culturally sensitive (Krebs et al., 2013). There is a strong role for allied health professionals (i.e. health psychologists, exercise physiologists, dietitians etc.) in secondary prevention programmes, including an increased focus on biopsychosocial assessment and behaviour change strategies.

Education and self-management approaches are frequently undertaken in a group setting (Johnson et al., 2009, Krebs et al., 2013) and delivered in community settings. Often there is a dilution of effect over time and renewed awareness of the effective programme elements across a team of health professionals would be beneficial post-programme (Krebs et al., 2013).

### **Cost considerations**

The NA-HARP hospital-based programme was the only approach that assessed the cost of providing the diabetes service (i.e. staffing costs). Cost data (staff annual salaries) or hourly rates (salary plus 15% on-costs) for each staff member working in the diabetes service were obtained from

administrative data (Rasekaba et al., 2012b). Further cost modelling by the authors indicates that if diabetes management programmes are able to decrease admissions for vascular complications of diabetes, the potential for cost savings can be realised. The Brisbane *Integrated secondary-primary care for complex diabetes management programme*, which is based on upskilled GPs and multidisciplinary teams, reported an increase in the proportion of people achieving good glycaemic control (HbA1c<7%) from 21 to 42 per cent, but for just one-fifth the cost of usual care provided by a hospital outpatient clinic.

### **Acceptance and implementation of programmes**

For policy and practice application of programmes like those identified in this review, scalability and cost need to be considered. However, very few programmes presented information on the cost of implementation. Programmes targeting diabetes management often measure efficacy, focusing on the internal validity of high-intensity health interventions in a controlled setting with a homogenous sample. It has been argued that this narrow focus does little to help understand what is effective in the real world (Wozniak et al., 2012) to assess health interventions. With this in mind, Canadian researchers have proposed and applied an expanded RE-AIM framework (Wozniak et al., 2012) to assess health interventions for diabetes and to identify facilitators, challenges, opportunities and lessons learned to be used in further programme development and implementation. The five dimensions are listed in Table 5.

**Table 5 RE-AIM framework**

<p><b>R</b>each into the target population, this refers to the ability to identify and target populations at an organisational level including the absolute number, proportion and representativeness of individuals willing to participate in said intervention</p> <p><b>E</b>ffectiveness of the intervention</p> <p><b>A</b>doption by target settings, institutions and staff</p> <p><b>I</b>mplementation, including consistency and cost of delivery</p> <p><b>M</b>aintenance of intervention effects over time.</p>
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Adapted from Wozniak et al. (2012)

## Summary and Discussion

Primary prevention of T2DM and secondary prevention of diabetes-related complications in T1DM and T2DM are based on very different strategies, but both have been demonstrated to be feasible in clinical trials and to a varied extent in clinical practice.

Primary prevention of T1DM is currently not possible and, although there is an intensive effort currently underway to identify interventions to delay pancreatic destruction and a number of genetic markers for T1DM have been identified, there is no recommendation for screening or intervention. In contrast, primary prevention of T2DM has been demonstrated in RCTs through the use of lifestyle interventions, and to a lesser extent pharmacotherapy, to target weight loss of five per cent or more of body weight together with improved diet and physical activity. However, translation of these findings in clinical practice has proven difficult because weight loss equivalent to that achieved in RCTs has only been demonstrated in less than 25 per cent of 'real-world' programme participants. Retention rates in clinical practice are also variable, although both the *Life!* and *SDPP* studies conducted in Australia reported good levels of retention compared to the UK *Counterweight* programme. Optimisation of current programmes to address reasons for this reduced efficacy and to further improve programme retention rates are now needed. However, longer-term follow-up of current programmes may reveal reductions in T2DM incidence in the future despite achieving only modest weight loss. The cost-effectiveness analyses based on modelling of 'real-world' scenarios, such as switching to pharmacotherapy when lifestyle programmes prove ineffective, are likely to provide a more realistic evaluation; but within programme/study economic analyses should also be encouraged to provide accurate costs and outcome data. Use of outcomes in cost-effectiveness analyses reported from RCTs, specifically from the DPP and DPS trials, are likely to overestimate the cost-effectiveness of programmes modelled in a clinical setting because of the lower weight loss achieved in the clinical setting.

Secondary prevention in T1DM and T2DM refers to management strategies aimed at reducing the rate of diabetes progression and/or the development of diabetes-related complications. While HbA1c is by far the most common outcome used to measure improvement in diabetes management and risk for complications, and this reflects the level of evidence behind this relationship, increasingly it is being combined with other clinical markers including blood pressure, and cholesterol parameters, as a combined indicator. Outcomes that can be modified can be incorporated into an effective management programme.

Team changes and self-management are commonly employed in the programmes reviewed here, and this is in line with findings of systematic reviews. Although a number of key programme elements have been identified, it should be noted that most programmes are specifically designed and refined to meet the needs of local populations and this may affect transferability. For example, co-location strategies where team care is coordinated from one community-based location could be recommended for populations that are not strongly affiliated with GP (TeamCare-PCN) (Johnson et al., 2012a). On the other hand, in urban settings, hub and spoke (Wilson et al., 2014) approaches can be considered.

There is very little discussion in the literature about the acceptability of these programmes, not only for organisations and practices to undertake, but also for patients to participate. More effective programmes at improving clinical markers have well-integrated primary/secondary models of care (Wilson et al., 2014, Russell et al., 2013). This type of horizontal integration requires relationships between organisations, professionals and patients. The *Australian Primary Care Collaboratives*

*programme* is one of the few to address acceptability and capacity issues at the organisational level which may stall or enhance implementation (Knight et al., 2012). Programmes targeting diabetes management often measure efficacy, focusing on the internal validity and high-intensity health interventions in a controlled setting with a homogenous sample. It has been argued that this narrow focus does little to improve our understanding of what is effective in the real world.

## Conclusions

Primary prevention of T1DM is currently not possible, and hence despite the identification of a number of genetic markers screening is currently not recommended. Ongoing research is focused on preventing or delaying deterioration of the pancreas by targeting diet and environmental factors.

Despite very strong evidence indicating that T2DM can be prevented, primary prevention programmes in the clinical setting and targeting those at high risk have not achieved equivalent or sustained weight loss in the majority of people enrolled. Further analyses of current programmes are required to identify facilitators and barriers to success, as well as the potential of more moderate weight loss to impact on future risk for diabetes.

In line with the evidence, secondary prevention of incident complications and progression of established complications in T1DM and T2DM remains focused on improvement of glycaemic control. In a number of cases, PHC-based management programmes tailored to the individual and based on a multidisciplinary team approach have reported significant improvements. The success of programmes where teams include social or mental health professionals suggest that a holistic approach to care may be an important contributor to achieving care targets. Although numerous programmes were identified, for most it was not possible to identify data on outcomes. In view of the resource and cost consequences of primary and secondary prevention programmes for diabetes, generating appropriate data on which to evaluate programmes is essential and should be a future priority.

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## Appendices

### Definition of quality improvement strategies targeting health systems

The following definitions are as applied in Tricco et al.'s (2012) the meta-analysis and more detail is available from the publication.

#### *Case management*

Any system for coordinating diagnosis, treatment, or routine management of patients (e.g. arrangement for referrals, follow-up of test results) by a person or multidisciplinary team in collaboration with, or supplementary to, the primary-care clinician. For a RCT to qualify, the case management had to happen more than once.

#### *Team changes*

Changes to the structure or organisation of the PHC team were defined as present if they met certain criteria:

- Adding a team member or shared care—e.g. routine visits with people other than the primary physician (including physician or nurse specialists in diabetic care, pharmacists, nutritionists, podiatrists).
- Use of multidisciplinary teams—i.e. active participation of professionals from more than one discipline (e.g. medicine, nursing, pharmacy, nutrition) in the primary, routine management of patients.
- Expansion or revision of professional roles (e.g. nurse or pharmacist has a more active role in monitoring of the patient or adjusting drug regimens).

#### *Electronic patient registry*

General electronic medical record system or electronic tracking system for patients with diabetes.

#### *Facilitated relay of information to clinicians*

Clinical information collected from patients and transmitted to clinicians by means other than the existing medical record, including, passports, referral systems, and dietary information (vs purely clinical information). In general, the patient should be facilitating the relay. To be included, the information must get to someone with prescribing or ordering authority.

#### *Continuous Quality Improvement*

Interventions explicitly identified as involving the techniques of continuous quality improvement (CQI), total quality management, or plan-do-study-act, or any iterative process for assessing quality problems, developing solutions to those problems, testing their effects and then reassessing the need for further action.

#### *Audit and feedback*

Summary of clinical performance of health care delivered by an individual clinician or clinic over a specified period, which was then transmitted back to the clinician (e.g. the percentage of a clinician's patients who achieved a target HbA1c concentration or who underwent dilated-eye examinations with a specified frequency).

#### *Clinician education*

Interventions designed to promote increased understanding of principles guiding clinical care or awareness of specific recommendations for a target disorder or population of patients. Subcategories of clinician education included conferences or workshops, distribution of educational materials (written, video, or other), and educational outreach visits (i.e. academic detailing).

#### *Clinician reminders*

Paper-based or electronic systems intended to prompt a health professional to recall patient-specific information (e.g. most recent HbA1c value) or to do a specific task (e.g. foot examination).

#### *Financial incentives*

Interventions with positive or negative financial incentives directed at providers (e.g. linked to adherence to some process of care or achievement of some target outcome).

### **QI strategies targeting patients**

#### *Education of patients*

Interventions designed to promote greater understanding of a target disorder or to teach specific prevention or treatment strategies, or specific in-person education (e.g. individual or group sessions with diabetes nurse educator; distribution of printed or electronic educational materials). Interventions with education of patients were included only if they also included at least one other strategy related to clinician or organisational change.

#### *Promotion of self-management*

Provision of equipment (e.g. home glucose meters) or access to resources (e.g. system for electronically transmitting home glucose measurements and receiving insulin dose changes based on those data) to promote self-management. Interventions promoting self-management were included only if they also included at least one other strategy related to clinician or organisational change.

#### *Reminder systems*

Any effort (e.g. postcards or telephone calls) to remind patients about upcoming appointments or important aspects of self-care. Interventions with reminders were included only if they also included at least one other strategy related to clinician or organisational change.

## Primary prevention programmes

### Life! Taking action in diabetes

*Life! Taking action in diabetes (Life!)* is the systematic, full-scale T2DM prevention programme launched across the state of Victoria in 2007 with funding from the Victorian government (Dunbar et al., 2014). The *Life!* programme structure is based on the Finnish DPS, the greater green Triangle (GGT) diabetes prevention programme, and the good Ageing in Lahti region (GOAL) Implementation trial. A *Life!* pilot study known as the *Melbourne Diabetes Prevention Study (MDPS)* was reported in 2012, and a larger, randomised MDPS sub-study aimed at evaluating the effectiveness and cost-effectiveness of the *Life!* programme delivered as an individual session plus five group sessions is ongoing (Davis-Lameloise et al., 2013, Janus et al., 2012). The widely implemented *Life!* programme is composed of six pre-defined group intervention sessions (8-15 people) provided over an eight-month period, with programme quality control measures and participant tracking of personal progress (Dunbar et al., 2014). Patient referral is via one of four pathways: 1) referrals generated through *Life!* providers or facilitators; 2) family physician/health professional; 3) social marketing via telephone/web support systems; and 4) workplace-generated recruitment. Of these, pathways one to three contributed 36.2, 30.2, and 28.2 per cent respectively of programme participants by June 2011, and 14,819 referrals had been received with 57 per cent commencing the first session and 37 per cent completing the programme (Dunbar et al., 2014). General practices are encouraged to refer eligible patients into the *Life!* programme via the General Practice Case-Finding Funding Initiative (<http://www.lifeprogram.org.au/for-health-professionals>), receiving: \$20 for each eligible patient referred; and \$30 when the patient completes the introductory session.

*Life!* service providers then deliver the *Life!* intervention programme. *Life!* service providers are paid \$400 per participant to cover programme and participant-related resources (as two instalments after sessions one and five), and therefore this acts as an incentive to actively promote uptake and retention (Dunbar et al., 2014).

*Life!* programme goals are based on the DPS:

1. No more than 30 per cent of energy consumed from fat
2. No more than 10 per cent of energy from saturated fat
3. At least 15g fiber/1,000 kcal
4. At least 30min/day of moderate-intensity physical exercise
5. At least 5 per cent weight reduction.

### Risk assessment

The Australian diabetes risk tool AUSDRISK is used to assess individual risk for developing T2DM. Programme entry is currently dependent on the AUSDRISK score and personal history satisfying one or more of the following (Dunbar et al., 2012):

- aged 50 years and over, AUSDRISK score of 12 or more (revised down from a score of 15 in the original programme)
- aged 18 years or older, indigenous Australians of Aboriginal and Torres Strait Islander descent who are at very high risk, AUSDRISK score of 12 or more
- aged 18 years or older, Aboriginal and Torres Strait Islander descent or previously diagnosed with high-risk conditions such as GDM or atherosclerosis-related CVD. (reflects revisions to programme eligibility criteria in 2010)
- aged 18-39, AUSDRISK score of 12 or more, and having received an occupational health assessment.

### Outcomes

Based on 6,632 participants, the following significant ( $p < 0.001$ ) changes were noted between sessions one and five (in brackets corresponding outcomes are provided for those completing sessions one to six):

- approximately 7.9 (25.3) per cent of the cohort recorded weight loss greater than five per cent
- compared to a baseline level of 28.8 (31.0) per cent, 59.5 (65.1) per cent reached dietary goals (intake of fat  $< 30\%$  of energy; intake of saturated fats  $< 10\%$  of energy; increase of dietary fibre to equal or greater than 15g/1,000 kcal)
- compared to a baseline level of 10.3 (11.3) per cent, 15.8 (17.6) per cent achieved an increase of physical activity to at least 4h/week.

### Risk reduction

The primary endpoint of diagnosed diabetes has not been reported to date. However, based on linear interpolation from the DPS, reported 58 per cent reduction in diabetes risk over four years for an average weight loss of approximately five per cent of body weight, the average weight loss reported for those completing six sessions (i.e. 2.3kg or 2.8% of body weight in *Life!*) equates to a 32 per cent reduction in diabetes risk over four years.

### Role of technology

Social marketing and use of website promotion and a 24-h telephone help line (13 RISK) facilitated recruitment of high risk individuals. Participants were provided with a manual to record lipid, blood pressure and blood glucose levels plus their individualised goals and outcomes; but there was no indication that this was an electronic device or based on entry of information via computer based technology. As a condition for payment, *Life!* facilitators (persons employed by non-profit, public sector, or private agencies and having completed a *Life!* training course) are required to enter data for performance measurement, continuous quality improvement, and evaluation.

### **Aboriginal Life! Taking action on diabetes**

The *Aboriginal Life!* programme launched in 2009 is an extension of the *Life! Taking action on diabetes programme*. The core model is based on the 'Road to good health' course developed and piloted by Goulburn Valley Division of General Practice together with Rumbalara health workers and services (HealthInfoNet, 2014). As with the *Life!* project outlined above, *Aboriginal Life!* comprises six interactive group sessions tailored to each group's needs. Adaptation of the model to meet Indigenous needs included (Alexander, 2013):

- Providing information and education that relates to 'real life'. Being aware of current behaviour among Aboriginal peoples helps understand their information needs, so pragmatic strategies can be provided which can be put into action immediately and implemented locally.
- The use of clear and simple language and incorporation of visual resources.
- Encouraging a conversational approach, rather than an emphasis on a 'reading and listening' approach and dependence on written material.
- The social context was taken into account, fostering group support by encouraging family and community members to take part in the programme. Messages emphasised maintaining good health for one's family or community, rather than focus on an individual.
- It was recommended not to call it a diabetes prevention programme. The community accepted the name Road to Good Health and helped design a logo.

### **Sydney Diabetes Prevention Programme (SDPP)**

The *SDPP* (also known as Prevent Diabetes Live Life Well) is a diabetes prevention programme initiated in three Divisions of General Practice in NSW, Australia, and delivered in a community setting. *SDPP* was delivered to 1,550 participants, including 100 Indigenous, 100 Arabic speaking, and 100 Chinese speaking people, between 2008 and 2011. (Colagiuri et al., 2010) The five aims of the *SDPP* were based on the DPS: at least 30min/day of moderate to vigorous intensity physical activity, reduction in the intake of energy from total fat to less than 30 per cent, fibre intake of at least 15g/1,000 kcal, a weight reduction of five or more per cent at 12 months. The *SDPP* placed particular emphasis on specifying use of resistance training. Following an individual session, participants attend three two-hour group sessions held over a six to eight week period. Material for Indigenous participants was modified to take account of cultural issues.

An adaptation of the *SDPP* was developed for the Prevent diabetes live life well programme managed by the Tharawal Aboriginal Medical service in NSW.

#### Risk assessment

Risk was assessed using the AUSDRISK tool. Individuals with an AUSDRISK score of 15 or more were invited to participate.

#### Risk reduction

After completion of the 12-month lifestyle modification programme of the *SDPP*, the mean weight loss at one-year follow-up was approximately 2kg or two per cent of body weight based on a preliminary study evaluation (Cardona-Morrell, 2011). However in a three-year follow-up, weight losses of 3.8kg, and 1.8kg at two years, and 2kg at three years were reported (Vita and Colagiuri, 2013). Participants reported eating less fat and more fibre, but physical activity did not change. Predictors of five per cent weight loss were lower saturated fat intake at baseline, high education and higher number of contacts with the lifestyle officer (Cardona-Morrell, 2011). A post-study analysis of the *SDPP* cohort found significant predictors of enrolment into the lifestyle programme to be physical inactivity, family history of diabetes, and history of high blood glucose levels (Laws et al., 2012). Individuals who smoked, were born in a country with high diabetes risk, were taking blood pressure-lowering medications, or consumed little fruit and vegetables were significantly less likely to enrol (Laws et al., 2012).

#### Role of technology

For those not able to attend, the same material was presented via telephone. At three, six, and nine months, participants were telephoned to enquire about progress and provide assistance with behaviour change as required. Individual assessments were conducted at 12 months.

### **Healthy Eating Activity and Lifestyle (HEAL™)**

The *HEAL™* programme is a group-based, 8-week, education and lifestyle modification programme designed to support people at risk for obesity-related conditions of cardiovascular disease and T2DM, but also for those requiring help to manage their weight, established T2DM, heart disease or metabolic condition (Hetherington and Borodzicz, 2013). GPs are encouraged to monitor participant progress at six and nine months after starting the programme, and to be eligible, patients must be referred from their GP and either have T2DM and a GP management plan, be at high risk of developing T2DM, have two or more CVD risk factors, or a BMI greater than 30.

### Risk assessment

GP referral.

### Risk reduction

Over a three-year period 1,737 people completed the *HEAL™* programme, with a retention rate of 61 per cent. Outcomes for 1,500 people were available for evaluation and demonstrated the following changes at 8 weeks: weight reduction by one kilogram (1% change), waist circumference reduction by 2.4cm, physical activity increased by 36.8 minutes per week, average daily sitting reduced by one hour (17% reduction), SBP reduced by 3.1 mmHg, DBP reduced by 2.4 mmHg, improved dietary intake, 6-minute walk (11%), and 30-second chair rise (18%). A five-month post-programme follow-up demonstrated maintenance of all improvements and continued improvement in physical activity and weight loss.

### Role of technology

The role of technology is unknown.

## **UK Counterweight Programme**

The *Counterweight* programme is an evidence- and theory-based intervention for weight management delivered through general practice and shown using the NICE obesity health economic model in the UK setting to be highly cost-effective (and cost saving in most scenarios modelled) (Laws, 2004, McQuigg et al., 2008, Trueman et al., 2010). First launched in the UK in 2000, the core model is based on four phases: 1) practice audit and needs assessment; 2) practice support and training; 3) practice nurse-led patient intervention; and 4) evaluation. Programme refinement is an ongoing process; however, the core model involves patient attendance at six individual or group sessions over a 3-month period with follow-up at three quarterly support visits (Ross and Counterweight project team, 2012, Laws, 2004). In phase one, structured interviews with GPs and practice nurses (PNs) are used to determine approaches used to manage obese patients and the equipment available for this. Then in phase two, a one-hour workshop provides feedback on the audit results and training for GPs and PNs. The GP's role is to raise the issue of weight, the benefits of weight loss and to screen for programme suitability using a flip-chart based set of tools. PNs undertake a 6-8 hour training programme on delivery of the lifestyle intervention; the course is delivered by weight management advisers who continue to mentor PNs for approximately six months or until competency reached. Average total general practice time to deliver the programme was 130 minutes per patient (Haslam, 2010). Based on an evaluation between 2000 and 2005, mean weight loss at 12 months was -2.96 kg among attenders, with 45 per cent of participants completing 12 months and 31 per cent meeting the target of greater than five per cent weight loss (2008). A subsequent evaluation of the programme implemented across 13 Health boards in Scotland between 2006 and 2010 demonstrated similar weight loss and retention rates in 6,715 attenders, except for the 12-month retention rate which was lower at 28 per cent (Ross and Counterweight project team, 2012). The programme now offers two additional models: *Counterweight plus*, a year-long programme with or without pharmacotherapy for severe and complicated obesity; and *Counterweight families*, recognising the importance of influence from within a family unit on behaviour change. A feasibility study of the *Counterweight plus* programme demonstrated an average weight loss of 12.4 kg (-9.1%) based on all participants, and a retention rate of 64 per cent (Lean et al., 2013). *Counterweight* is currently being trialled in studies based on Sydney and Adelaide. (<http://compare-phc.unsw.edu.au/content/counterweight-trial-sydney>)

### Risk assessment

Patients are initially identified by the GP, and then screened by PNs based on calculation of BMI and administering a 'Dieting Readiness' test to assess a patient's suitability for the *Counterweight* programme. Patients are prioritised for *Counterweight* if they have BMI  $\geq 30$  kg/m<sup>2</sup> or BMI  $\geq 28$  kg/m<sup>2</sup> with co-morbidities; others at lower risk are encouraged to use self-help and commercial programmes.

### Risk reduction

Assessment of obesity-related disease markers or risk factors has been difficult because the programme has insufficient funds and there is no control group for comparison.

### Role of technology

There was no mention about the role of technology, with the programme focusing more on changes to staff roles after attending workshops to upskill GPs and PNs.

## **Support Health Information, Nutrition and Exercise (SHINE) study**

The aim of the randomised US-based *SHINE* study was to compare delivery of the Diabetes Prevention Programme (DPP) using individual telephone sessions (IC) versus group telephone sessions (CC) (Weinstock et al., 2013).

Although outcomes from a three-year long follow-up of *SHINE* have been very recently published we were unable to identify any non-trial accounts for implementation of this programme in PHC. However, the *SHINE* programme is specifically designed to be delivered within the PHC setting by diabetes educators (in the trial this included registered nurses, family practice nurses, licensed practice nurses and a medical office assistant) and coaches (dietitians). The programme is based on a 16-session core curriculum covering goal-setting, self-monitoring, diet/activity modification and problem-solving; and this is further enriched with group diet and fitness classes. Participants are asked to keep a log to quantify diet and activity behaviours which they send to their educator and coach every month and give to the relevant primary care providers. Reported outcomes from the trial were collected at six, 12, and 24 months, and recently a 36-month follow-up was reported to assess outcomes one year after the programme had finished (Trief et al., 2014). At the three-year follow-up, mean weight loss was similar to outcomes at year two and significant at -6.4kg for CC versus -2.35kg for IC. In terms of the pre-defined endpoint, approximately 51 per cent of CC participants and 29 per cent of IC achieved weight loss of at least five per cent over the three year period. Interestingly, with respect to the proportion of participants achieving at least five per cent weight reduction, there was no difference between study completers and non-completers at three years for the CC group (51% vs 50%, respectively) but a significant difference for the IC group (37.8% vs 5.6%, respectively). Although both groups also recorded improvement in HDL cholesterol, there was no mention of any impact on physical activity or diet for either group. It was also notable that the IC group, but not the CC group, reported an increase in blood pressure over this time period.

### Risk assessment

Participants for the *SHINE* trial were selected based on being aged 18 years or older, having a BMI of  $\geq 30$ kg/m<sup>2</sup>, and presence of metabolic syndrome according to the International Diabetes Federation criteria of: triglyceride level  $\geq 150$  mg/dl or triglyceride treatment, HDL-cholesterol  $< 40$  mg/dl (males) and  $< 50$  mg/dl (females) or HDL treatment, elevated blood pressure (systolic  $\geq 130$  or diastolic  $\geq 85$  mmHg) or treatment of diagnosed hypertension, and high fasting plasma glucose ( $\geq 100$  mg/dl). Diagnosed diabetes or presence of severe medical problems that might interfere with participation were grounds for exclusion.



### Risk reduction

The study was not designed to assess the hard endpoint of diabetes prevention but relied on achieving weight loss  $\geq 5$  per cent of initial body weight. This is similar to the DPP target of seven per cent or greater weight loss which was associated with reduced risk for T2DM.

### Role of technology

Apart from use of telephone conference call for the group sessions, no other mention of technology was noted in the published accounts. However, it would of interest to know how log book entries were made and whether this was, or could be, implemented through use of electronic technology.

## **Building on Existing tools to Improve chronic Disease Prevention and Screening in Family Practice (BETTER)**

The aim of the Canadian *BETTER* randomised trial was to improve uptake of clinically effective chronic disease prevention and screening (CDPS) actions for primary prevention of heart disease and diabetes, screening for colorectal, breast and cervical cancers, and relevant lifestyle factors through a multifaceted intervention in primary care (Campbell-Scherer et al., 2014, Grunfeld et al., 2013, Manca et al., 2014). Although not designed specifically to prevent diabetes, the list of CDPS actions included increased physical activity, weight control referral, and blood sugar screening.

The *BETTER* RCT (n=789) compared use of usual care versus practice-level intervention with a practice facilitator who supported GPs with respect to using the electronic medical record (EMR) based algorithm to guide care and monitor actions, and/or a patient-level intervention with a practitioner (upskilled nurse practitioner, nurse or dietitian) from within the practice who spent one hour with intervention patients to develop personalised 'prevention prescription' and direct them to relevant practice or community resources. After 12 months, the effect on CDPS actions of the prevention practitioner intervention was significant (improved by 32.5% vs control) but the prevention facilitator was not. In addition, there was an indication that physical activity improved by 12.6 per cent and healthy diet by 7.2 per cent, with no impact on weight control or smoking cessation (Grunfeld et al., 2013). However, it should be noted that the study was not designed or powered to test the effect of the intervention on each action separately and this requires verification. The *BETTER* study was based in urban settings, and a second study, *BETTER2*, is assessing outcomes in rural settings and further refining the *BETTER* pathways.

### Risk assessment

With respect to the diabetes-specific pathways included in *BETTER*, no specific risk calculator is indicated. However, screening includes blood pressure, lipid levels, waist circumference, and BMI assessment.

### Risk reduction

The impact of *BETTER* on diabetes incidence has not been reported to date. However, as noted above, improvements in activity and diet were observed after 12 months.

### Role of technology

Optimal use of EMR with integrated algorithms for care is the core technology of the *BETTER* programme. Based on a comprehensive search of existing tools and guidelines (including international sources), evidence based algorithms were developed for primary prevention of diabetes and coronary artery disease (Campbell-Scherer et al., 2014). Recommendations for patients aged 40-65 were reformatted into algorithms to facilitate clinical decision-making and encourage implementation.

## *Ongoing primary prevention programme trials without outcomes data*

### **MAGDA**

The *Mothers After Gestational Diabetes in Australia diabetes Prevention Programme (MAGDA-DPP)* is a randomised, postnatal prevention study aimed at assessing the effectiveness of an adaptation of the *Life!* programme in women with a diagnosis of GDM in their most recent pregnancy (Shih et al., 2013, Shih et al., 2014). Intervention goals are as described for *Life!*, and programme delivery is achieved via a one-to-one first session followed by five group sessions with an emphasis being placed on content tailored to the participants (e.g. postnatal depression, sleep deprivation). A minimum number of 430 participants are required, and recruitment commenced in Melbourne in 2011 and Adelaide in 2012. To date, a total of 340 women have given consent and 134 have been randomised to either the intervention or the control group (Shih et al., 2013). Primary endpoints for *MAGDA* are as follows: 12-month change in diabetes risk as determined by changes in fasting plasma glucose level, weight, or waist circumference. Secondary endpoint changes in 2-hour OGTT, lipids, blood pressure, depression, quality of life, physical activity and diet.

### **PREVIEW**

*PREvention of diabetes through lifestyle intervention, PREVIEW*, is an international five-year study to determine the best lifestyle strategies for weight loss and prevention of T2DM.

(<http://preview.ning.com/>) A total of 15 partner organisations (mostly European) are taking part in the trial including Sydney University and the University of Auckland. The dietary regimen is based on previous research demonstrating that low glycaemic index foods and moderately high protein diets are associated with sustained weight loss (Larsen et al., 2010). “As of the end of March 2014, a total of 7,400 subjects have been pre-screened, 2,450 have been screened, and 1,050 subjects found eligible for the clinical trial. The average age of the eligible subjects so far is 52 y, divided into 735 females and 315 males. During the initial LCD<sup>iv</sup> phase (using Cambridge Weight Plan LCD products), a total of 80 per cent of the subjects have achieved the target weight loss as hypothesized in the *PREVIEW* concept” (<http://preview.ning.com/profiles/blogs/some-good-news-recruitment-in-the-preview-intervention-study-is>)

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<sup>iv</sup> LCD = low calorie diet.

## Australian secondary prevention programs

### **Integrated primary-secondary care for complex diabetes in the community**

This programme is a community-based model of care led by a general practitioner with advanced skills and an endocrinologist partnership. The programme is based on the *Brisbane South Complex Diabetes Service (BSDS)* Programme (Jackson et al., 2010) and the *Inala Chronic Disease management Service (ICDMS)* (Askew et al., 2010).

A prospective open controlled trial was undertaken comparing the programme delivered by GPs with advanced skills to usual care delivered via the hospital diabetes outpatient department. Outcomes included primarily HbA1c concentration at 12 months, but also serum lipids and blood pressure. The mean change in HbA1c concentration in the intervention group was -9mmol/mol (-0.8%) at 12 months and in the usual care group it was -2mmol/mol (-0.2%) (95% CI -5.1). The percentage of patients in the intervention group achieving the HbA1c target of  $\leq 53$  mmol/mol (7%) increased from 21 to 42 per cent ( $P < 0.001$ ); for the usual care group, there was a one per cent increase to 39 per cent of patients attaining this target ( $P = 0.99$ ). There were some differences across the intervention group that may have influenced results, including age, gender, country of birth and education level. Clinically, the intervention group had higher baseline HbA1c concentration and lower blood pressure, neuropathy rates, amputation rates and serum creatinine concentration, which may have influenced the results.

Cost per visit calculation based on Medicare and state health costing (excluding pathology), has shown that the intervention model is delivered at approximately one-fifth of the cost per visit compared with that of the usual care group, allowing a greater number of patient follow-up visits whilst still delivering clinic activity at a lower cost than usual outpatient department care (Russell et al., 2013).

A RCT, which builds on the promising results described above but in a larger, more robust research design and addressing key methodological issues identified in their study, is currently underway (Zhang et al., 2013).

### Self-management

All patients were offered a self-management course, usually around weight loss, conducted by the allied health team, although attendance was poor at six weeks and three months (Zhang et al., 2013, Russell et al., 2013).

### Team changes

Initial assessment was undertaken by a credentialed diabetes educator care coordinator. Attending the clinic are two GPs with special interests known as 'GP Clinical Fellows', a GP training registrar, an endocrinologist, a diabetes educator and, as needed, a dietitian, psychologist and podiatrist. Medical care is led by a GP Clinical Fellow in partnership with an endocrinologist. During the 'Diabetes Clinic', the plan is discussed with the attending endocrinologist, who then briefly co-consults with the patient and Clinical Fellow together to finalise the approach. This co-management model allows the endocrinologist to attend 2–3 times the number of patients per clinic than is possible via the traditional specialist outpatient department model.

### Patient education

'Diabetes clinic' consists of a single four-hour session involving 2-3 GPs with Special Interest in diabetes management, the diabetes educator and podiatrist. Additional time with the diabetes educator is usually organised during the same clinic. The education programme adopted National and International guidelines, including the clinical targets relevant at that time. Case-based education sessions were also offered to referring GPs and practice nurses.

### Case management

Comprehensive screening assessment is undertaken by a credentialed diabetes educator care coordinator including medication, diabetic history, retinal photographs, foot assessment, depression screen, and appropriate blood and urine testing. At the ICDMS diabetes clinic, the patients would see the GP Clinical Fellow, who reviewed and extended the diabetes nurse educator screening assessment and developed a patient-specific management plan. The GP Clinical Fellow would briefly consult the endocrinologist to review the management plan and then both would co-consult with the patient to finalise the management approach.

This screening assessment is prior to attending a 'Diabetes clinic'. All patients at clinic are first assessed by one of the Clinical Fellows, who clarify the history and medications, examines the patient, interprets the retinal photographs and pathology results, and drafts a management plan addressing glycaemic control, blood pressure, lipids, lifestyle, diabetes complication management and patient priorities. Additional time with the diabetes educator is usually arranged for the same clinic, and other allied health appointments at a time convenient for the patient. Patients initiating or altering insulin were enrolled in the Insulin Stabilisation Service, where patients are contacted by telephone twice weekly by the diabetes educator regarding insulin adjustment, according to defined protocols. The diabetes educator contacts all patients by telephone or, if attending the clinic in person, at six weeks and three months to assess progress, motivate and problem-solve any barriers to diabetes management.

### Facilitated relay of information to primary clinician

Evidence based guidelines inform all management planning. The patient's GP is kept closely informed of care management (currently by letter but this is expected to change to a shared web-based record). The patient's latest GP Management Plan or Team Care Arrangement is included with the booking visit, and to ensure patients have been appropriately assessed and supported by diabetes education and dietary and lifestyle advice before referral. The management plan is sent to the patient's usual GP within one week, with expectations of the service, patient and GP clearly outlined. GPs are provided with a direct contact number at the service for queries, concerns and rapid reassessment of patients if required. Patients were discharged back to their referring GP once glycaemic, lipid and blood pressure targets were achieved, or after 12 months if it was felt no further improvement could be achieved. The GP is advised to continue the usual cycle of care and is given some parameters for future re-referral of that individual patient.

### **Australian Primary Care Collaboratives Programme**

Quality improvement collaboratives (QIC) are multifaceted interventions that bring together a range of strategies including case management, team changes, patient education, care algorithms and information technology changes. The *Australian Primary Care Collaboratives (APCC)* is a model for improvement based on implementing change in small manageable cycles and identifying where a change actually leads to an improvement (Australian Primary Care Collaborative, 2014). A panel of experts is tasked with identifying evidence on a topic including measures and change principles, and developing strategies and ideas for implementing change.

Divisions of General Practice were invited to recruit a number of health services to the programme. Eight hundred and eleven small teams from health services, usually comprising a GP and one other, attended a series of workshops, including orientation describing the programme. Health services that went on to commit to the collaborative programme (n = 743) received additional support to collect baseline data across several waves including diabetes, coronary heart disease and access. Teams attended three learning workshops separated by activity periods of three months. The two-day interactive workshops addressed change principles, the evidence behind them and quality improvement. Health services that produced good results were used in subsequent workshops as exemplars. Ideas, successes and failures were shared between health services. Plan-do-study-act (PDSA) cycles were taught. During activity periods, teams used this approach to implement change principles, submit outcome measures and monthly PDSA cycle reports. Support was provided to reinforce the messages of the workshop and advise teams on how to meet challenges as well as help with software installation. Health services received monthly feedback on their progress compared with their wave and assistance was provided to reflect on the wave. Currently, there are more than 1,500 Australian general practices in the APCC programme (Australian Primary Care Collaborative, 2014).

#### Outcomes

Based on data for 1,850 patients in the year between May 2013 and February 2014, recording of HbA1c has improved and the proportion with HbA1c  $\leq 7$  per cent has increased from 30 per cent to 40 per cent over that time. However, the proportion with HbA1c  $> 10$  per cent has remained relatively unchanged over that same period at approximately three per cent. It should be noted that the evidence goal for the QIC method is not to determine whether the method is universally 'effective' or 'ineffective' across diverse setting and quality problems.

The QIC programme measures for improvement identify indicators at the organisational level and specify the number of patients on the register; and also context-specific clinical outcomes; for example, the percentage of patients with diabetes with a last recorded HbA1c  $\geq 7$  within the last 12 months, percentage of patients with diabetes with a last measured low-density lipoprotein cholesterol (LDL-C)  $< 2$  mmol/litre, percentage of patient with diabetes with a last recorded BP reading of  $\leq 130/80$  within the last 12 months. Consideration is given at the outset about the measures chosen to reflect best evidence. Capacity gaps are also identified as concepts: for example, disease registers, disease coding, team care and population management were unfamiliar to many practices in this study.

#### Self-management

No detail available.

#### Team Changes

For the health professionals working in these practices, existing expertise was commissioned to create software that could search clinical record systems to collect outcome measures electronically. Educational experts were involved to design interventions to teach quality improvement.

#### Patient Education

No detail available.

#### Case management

No detail available.

#### Facilitated Relay of Information to primary physician (information technology)

The APCC programme uses the Pen Clinical Systems Clinical Audit Tool (PCS CAT) system to collect the measures from practices' clinical software, and this can also be used to provide feedback and alerts for patient management within the practice. In addition, the APCC programme has a web portal known as qiConnect where participating practices lodge their monthly data electronically and can review their progress over time. This is a secure network with a unique log-in. The PCS CAT system is compatible with the following clinical software:

- Medical Director 2
- Medical Director 3
- Best Practice
- Genie
- Zedmed
- practiX
- Communicare
- Medinet
- MedTech32.

#### **Australian TLC Diabetes programme**

*Telephone-Linked Care (TLC) Diabetes* system (Williams et al., 2012) is an automated interactive telephone system, developed collaboratively by the Australian research team and researchers at the Medical Information Systems Unit, Boston University, USA.

A RCT of patients with poorly controlled diabetes has been undertaken to assess the efficacy of the *TLC* telephone coaching programme (Varney, 2013). Williams et al. (2013) reported a statistically significant difference in HbA1c at six months between the usual care and *TLC Diabetes* arms. HbA1c significantly decreased from 8.7 per cent (8.8%) to 7.9 per cent (8.0%) in the *TLC Diabetes* arm, compared with 8.9 per cent (9.0%) to 8.7 per cent (8.9%) in the usual care arm. There was some evidence that the difference in HbA1c at six months between study arms increased with baseline HbA1c ( $p=0.09$ ) for the interaction term in regression model. This suggested that the difference in six-month HbA1c between *TLC* and usual care patients was greater in patients with high baseline HbA1c values (i.e. those with poorer control) than in patients with low values. Of participants in the intervention arm, 20 per cent achieved HbA1c levels of 7.0 per cent or lower (95% CI 9.6-29.7), compared with 15 per cent (95% CI 4.4-24.7) in the usual care arm ( $p=0.32$ ).

Psychological wellbeing as measured by mental health-related quality of life (mental HRQL) improved in the *TLC Diabetes* group, compared with those in the usual care group where mental HRQL decreased marginally. No differences were observed in physical HRQL between the usual care and intervention arms ( $p=0.7$ ).

The mean number of completed calls for the Australian *TLC Diabetes* participants during the six-month intervention was 18 ( $\pm 6$ ), ranging between two and 27 calls, with a mean call duration of 11 minutes ( $\pm 1$ ). The mean percentage of completed calls out of the expected weekly calls for all individuals in the intervention condition was 76 per cent ( $\pm 22$ ).

### Self-management

The Australian *TLC Diabetes* system has been designed to improve diabetes management by targeting the following key self-management behaviours: blood glucose testing, nutrition, physical activity and medication-taking. Participants were requested to make weekly calls to the system over six months, with calls lasting five to 20 minutes, depending upon the call content and participant responses.

### Team changes

Automated responses have been developed through a MDT, however delivery is via pre-recorded information.

### Patient education

Different topics covered each week. Blood glucose monitoring was the first topic covered in each weekly call. It was followed by one of three other topics, including medication-taking, physical activity or healthy eating (calls 9-12 and 21-24). When diabetes medication was not prescribed, the medication-taking topic was replaced with physical activity. When clearance for physical activity was not provided by the patient's treating physician, physical activity was replaced by medication-taking. In cases when there was no clearance for physical activity and no pharmaceutical treatment of diabetes, the participant did not hear a second topic on some calls.

### Case management

Case management is not a focus of this programme. However the system is designed to support care currently being received by patients from their General Practitioner and/or other health professionals involved in diabetes management.

### Facilitated relay of information to primary clinician (role of technology)

Automated- *TLC's* responses, including feedback and encouragement, were tailored according to information entered in the *TLC* database at the start and the answers that it received from participants during all calls.

Clearance for certain topic discussion (i.e. physical activity) was provided by the patient's treating physician but it was unclear how this information was relayed to the service.

## **Northern Alliance Hospital Admission Risk Programme**

The outer northern metropolitan region of Melbourne is a major suburban growth corridor. In recognition of the high prevalence of diabetes in this area, the *Northern Alliance Hospital Admission Risk Programme (NA-HARP)* established a chronic disease management programme for patients with poorly controlled diabetes (Rasekaba et al., 2012b).

Patients eligible for this service were defined as patients with: an HbA1c > 8.0 per cent; the presence of diabetes-related complications; or hospitalisation for diabetes management in the past 12 months. The majority (90%) of clients enrolled in *NA-HARP* diabetes management have T2DM and an estimated 10 per cent have T1DM. Over a four year period, 967 patients were enrolled, and based on 56 per cent of those, mean change in HbA1c after 12 months was 1.3 per cent (8.6% versus 7.3%) (Rasekaba et al., 2012a). In addition, significant improvements in HRQL measures were reported.

For cost analyses, data were obtained from retrospective administrative records from 357 patients with diabetes who attended the *NA-HARP* for diabetes management between 1 September 2007 and

31 May 2008. The majority of patients who enrolled in the programme accessed the Northern Hospital for acute hospital services (emergency and inpatient admissions). Hospital utilisation by the cohort was compared in the 12 months pre-enrolment, during programme enrolment and in the 12 months post-completion of the programme. The cost of providing the diabetes service predominantly relates to staffing costs. Costs pertaining to staff annual salaries or hourly rates (salary plus 15% on-costs) for each staff member working in the diabetes service were obtained from administrative data.

Cost outcomes: hospital utilisation related to primary diabetes and associated complications, as these episodes of care were more likely to be influenced directly by the diabetes programme. Of particular focus was the effect of a diabetes disease management service on acute care admission costs for patients with T2DM. The programme's service delivery of 1,474 hours over nine months (4 hrs per patient) delivered a low per-patient cost (\$463 per patient). In contrast, the overall inpatient costs for the management of diabetes and related conditions were high and did not decrease significantly following programme completion. The major acute care cost drivers were surgical interventions for advanced peripheral vascular disease and the management of cardiovascular events. The cost modelling indicates that if diabetes management programmes are able to decrease admissions for vascular complications of diabetes the potential for cost savings can be realised.

#### Self-management

The service has integrated a self-management coaching approach into its model of care to assist clients in making the psycho-behavioural changes necessary to improve the control and management of their diabetes.

#### Team changes

Patients enrolled in the programme undergo a comprehensive, multidisciplinary team (MDT) assessment. Patients are provided with expert care from endocrinologists and allied health professionals including diabetes educators and dietitians.

#### Patient education

Individualised education is provided by diabetes educators and dietitians.

#### Case management

Based on the MDT assessment an individualised care plan is developed in consultation with the patient.

#### Facilitated relay of information to primary clinician (role of technology)

No details currently available.

### **Logan Healthy Living Programme**

*Living Well with Diabetes (LWWD)* is a telephone-delivered weight loss and physical activity intervention designed for real-world delivery to Australian primary care patients with T2DM (Eakin et al., 2010, Eakin et al., 2013, Eakin et al., 2014). A RCT design was used to evaluate the LWWD over an 18-month period, followed by a six-month non-contact maintenance follow-up period. Delivered entirely over the telephone, intervention combined increasing physical activity, reducing energy intake, and behavioural therapy through a maximum of 27 telephone calls over an 18-month period. Programme targets were  $\geq$  five per cent weight loss,  $\geq 210$  min/week moderate-to-vigorous-intensity physical activity (MVPA) and  $\geq 2$  MJ energy reduction. Primary outcomes were weight, accelerometer-derived MVPA, and HbA1c level. After 18 months intervention, modest but significant



improvements in weight loss (-1.42% of baseline body weight) and MVPA (42% higher than usual care), and more modest but significant changes in dietary quality and waist circumference were recorded. However, HbA1c, energy intake, cholesterol, triglyceride levels and blood pressure were not altered. After 18 months, 21 per cent of intervention and 13.2 per cent of usual care groups achieved the weight loss target; 34.8 per cent and 27.8 per cent, respectively, achieved the MVPA; and 22.8 per cent and 18.8 per cent achieved the energy reduction target. In the 6-month non-contact maintenance follow-up (24-months), only MVPA remained significantly changed from baseline, with a 44 per cent greater MVPA or 38.95 min/week. Participation rates were lower than expected, with approximately 40 per cent of the intervention group discontinuing with the telephone calls and/or the study, and only half of those who continued receiving the intervention took 75 per cent or more of scheduled intervention calls.

#### Self-management

Participants were given a detailed workbook with guidelines on exercise sessions and options for progression to greater levels of activity than the minimum target. In addition to encouragement for generally increased levels of movement, a resistance band was given to members of the intervention group together with detailed photographs and instructions in the workbooks for completing resistance exercise sessions. Self-monitoring 'trackers' were also provided to monitor daily physical activity and food intake, with encouragement for daily self-weighing. The first six months focussed on initiating behavioural change and then the next 12 months on maintenance of change.

#### Team changes

Following identification of eligible patients through general practice medical records, qualified nutritionists delivered the telephone-based consultations and nurses performed the baseline, 6-month, 18-month, and 24-month assessments.

#### Patient education

All patient education is conducted via telephone. Collaborative goals for weight, physical activity and dietary change were set with the telephone counsellor; the emphasis was placed on achievability and measurability.

#### Case management

All telephone counsellors have at least bachelor's level training in nutrition and dietetics; some have also completed a dual-degree in exercise physiology. To the extent possible, the same telephone counsellor remains with participants throughout the duration of the intervention to facilitate rapport and continuity of care. Each telephone contact produces a behaviourally-specific action plan specifying what is to be done and when, barriers and supports are identified, confidence is assessed and problem-solving discussed as appropriate.

#### Facilitated relay of information to primary clinician (role of technology)

GPs were sent brief summaries of their patients' assessment results. There was no information about the role of technology in the relay of this information.

### **RADICAL**

The *Rural Australian Diabetes – Inspiring Control Activity & Lifestyle' (RADICAL)* general practice based T1DM programme was launched in 2007 to provide proactive child and family emotional support (Goss et al., 2010). The *RADICAL* programme promotes insulin pump therapy and matching of therapy to the individual patient's lifestyle. Over a two-year period, implementation of the *RADICAL* model resulted in a significant increase in annual number of contacts with credentialed diabetes educators, and reductions in HbA1c for children and adolescents, as well as improved

patient satisfaction and quality of life. In the year before *RADICAL* was launched, approximately six per cent of 48 patients achieved an HbA1c  $\leq 7.5$  per cent, and this increased to 36 per cent of 50 patients in 2009; and emergency department attendance and admissions to hospital for diabetes-related issues decreased from 23 per cent to eight per cent in 2008 (Goss et al., 2010).

#### Self-management

In addition to promoting the use of insulin pumps, the *RADICAL* team supported patient use and self-management.

#### Team changes

The *RADICAL* model is based on a co-located core multidisciplinary team (GP, diabetes educator, mental health nurse/counsellor). According to the study group, an important contributor to the success of *RADICAL* was the inclusion of a counsellor as part of the core team. With expertise in child behaviour, family loss, grief, and trauma counselling, their role was to address the psychosocial needs of the child and family.

#### Patient education

Not indicated.

#### Case management

Patients were organised into three monthly 20-minute clinic appointments with team case meetings on each individual patient taking place on the same day.

#### Facilitated relay of information to primary clinician (role of technology)

Not indicated.

### **Diabetes Management Along the Mallee Track**

The *Diabetes Management Along the Mallee Track* incorporates community risk assessment and point-of-care testing (PoCT) to manage rural patients at risk for or with diagnosed diabetes (T1DM and T2DM) in partnership with local GPs, allied health and community health nurses (Shephard et al., 2005). This service was offered irrespective of diabetes type and after 10 months the percentage of people achieving good glycaemic control (HbA1c < 7%) increased from 33 to 63 per cent; and achieving adequate control (HbA1c < 8%) increased from 59 per cent to 91 per cent. PoCT diabetes management programmes have been implemented in a number of rural and urban settings, including Aboriginal and Torres Strait Islander communities, and an accreditation programme has been established for ongoing implementation (Shephard, 2006). This study was based on only 55 people and should be interpreted with caution.

#### Self-management

Not described.

#### Team changes

GPs were assisted by allied health and community health nurses. This included locally engaged podiatrists and visiting diabetes educators.

#### Patient education

Educational training and resources were provided by the Flinders' community Point of Care services for community health nurses, but no mention was made of patient education.

Case management

Follow-up for people identified at greatest risk for diabetes (and presumably diabetes-related complications) was flagged as a key challenge.

Facilitated relay of information to primary clinician (role of technology)

A central register of programme participants was established and maintained by the Flinders' community Point-of-Care services unit and electronically updated and made available to local GPs.

## International secondary prevention programmes

### **Diabetes, Your Life, Your Journey programme**

The *Your Life Your Journey* programme is a structured, group-based diabetes self-management education (DSME) programme for people, families and whanau with T2DM in New Zealand (Krebs et al., 2013). An observational study design was employed to assess outcomes at baseline, three, six and 12 months following programme delivery. The primary outcome was HbA1c with other outcome measures including: lipid profile, blood pressure, weight, smoking status and urinary microalbumin:creatinine ratio (UACR).

Routine clinical data were collected from the PHC records at baseline, three, six and nine months (Krebs et al., 2013). Glycaemic control improved between baseline and six months (HbA1c 64.9±20.0mmol/mol to 59.9±13.9mmol/mol ( $p<0.05$ ) (baseline 8.07%±1.80, 6 months 7.62%±1.25)), but was no different to baseline at nine months. Systolic BP reduced from 131.9±16.4 to 127.4±18.2mmHg ( $p<0.05$ ) at six months, but increased to baseline levels by nine months. Diastolic BP, triglycerides and UACR were significantly reduced at three, six and nine months.

The dilution of improvements after six months suggests a refresher course at that time may be beneficial. Results are based on an observational study design, with no control group.

#### Self-management

Self-management was group-based, and included family/whanau<sup>v</sup>. The programme is based on three accredited diabetes education programs developed in the UK (see EMIS), the *Dose Adjustment for Normal Eating (DAFNE)*, *Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND)*, and the *X-PERT* programmes. The NZ programme has been tailored for the unique social and ethnic environment of New Zealand using concepts from internationally developed programmes.

#### Team changes

The programme does not require a great deal of team changes but it is able to be delivered in a primary care or community setting. Sessions were delivered by a dietician, with either a practice nurse from primary care or diabetes nurse specialist from primary or secondary care.

#### Patient education

This programme focuses on group-based education for self-management. All sessions include a range of interactive activities, visual aids and demonstrations. At each session, participants are asked to set a goal and this is reviewed at the beginning of each session.

Over six weeks, eligible patients undertake an introduction to diabetes including defining what diabetes is and how it is managed with the use of emotion cards and hyperglycaemia symptoms to discuss diagnosis (week 1); and discussion on the balance between food, activity, medication and the health care team. Information on food classification activities, carbohydrate and glycaemic index; the influence of food on blood lipids, weight management, label reading, alcohol, diet review, and activity (weeks 2/3) is also covered. One session allows exploration of things patients have control over including physical activity, smoking, blood pressure, cholesterol, blood glucose levels, medications including insulin, urine tests and healthy coping approaches (week 4). Management of poor health or 'sick days' is discussed (week 5) including hyper- and hypo-glycaemia and what can be done to prevent complications. A summary and review session concludes the programme (week 6).

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<sup>v</sup> Whanau is a Maori language word meaning extended family or family community.

### Case management

There is very little case-management in this programme apart from identification of eligibility and referral to the programme.

### Facilitated relay of information to primary clinician (role of technology)

There were no formal arrangements for the relay of information between programme and other health professionals. Participants were recruited through primary care networks, community diabetes organisations and through secondary care specialist diabetes nurses and physicians.

## **Healthy Eating and Active Living in Diabetes**

*Healthy Eating and Active Living in Diabetes (HEALD-PCN)* is a pedometer-based walking programme. The programme consists of two 12-week phases with an emphasis on physical activity (walking).

The *HEALD-PCN* intervention is based on a previously pilot-tested self-management programme in a small (N = 41) RCT (Johnson et al., 2009). The primary outcomes for this study were *steps-per-day*. Secondary outcomes included energy intake, weight, BMI and systolic and diastolic blood pressure and resting pulse rate. Participants were randomized to either basic lifestyle programme or an enhanced lifestyle programme (ELP). Assessment after 12 weeks indicated a statistically significant increase in average total daily steps of 1,562 (95% confidence interval: 303–2821, p = 0.02) regardless of group allocation. Weight (mean change -0.9 kg, approximately 1.0%), BMI and systolic (mean change -6.0 mmHg) and diastolic blood pressure (mean change -5.2 mmHg) also improved for all participants. No changes were observed for energy intake. At week 24, those in the ELP had a lower resting PR (71 ± 12 bpm.) compared with those in the basic lifestyle programme (78 ± 12 bpm.). No group differences were observed for total daily steps or glycaemic control.

A study is currently underway (Johnson et al., 2012b) to assess efficacy in a larger sample of people with T2DM. The primary outcome will be physical activity determined by self-report using questions from the International Physical Activity Questionnaire and pedometers. Secondary outcomes include HbA1c, lipid profile, glucose, resting heart rate, blood pressure and BMI. Measure of nutrition behaviour was also recorded using a food frequency questionnaire.

### Self-management

Key features of *HEALD-PCN* include the provision of information in a group setting by an exercise specialist on increasing the amount and intensity of physical activity (i.e. walking), the glycaemic index and individual goal setting. As part of phase 1, during weeks 1 and 2, participants attend a 30-minute, group-based meeting, including a supervised walking session, facilitated by the Exercise Specialist, and located in facilities in the community. A pedometer, a resource manual and step logbook is provided at the first meeting as a means to facilitate goal setting and to record the total number of steps/day.

### Team changes

Exercise specialist.

### Patient education

Pacing techniques are taught during phase 2. In weeks 13 and 14, participants attend two more group-based meetings at the same community-based facility, where they are taught by the Exercise Specialist how to increase their walking speed by 10 per cent during a 30-minute walk. The participants are then asked to incorporate this faster walking pace for 30 minutes/day on three days/week on their own, until the end of the study period. For example, if a participant's self-selected walking pace was 90 steps/minute, they will be encouraged to increase his or her pace to approximately 100 steps/minute. Participants will be asked to perform their faster walking in bouts lasting no less than 10 minutes, and will be given a second pedometer and a stopwatch to help them.

### Case management

Not applicable

### Facilitated relay of information to primary clinician (role of technology)

Not applicable.

## **TeamCare model**

The *TeamCare model (TeamCare-PCN)* (Johnson et al., 2012a) is a collaborative team-based, depression case management intervention. It was initiated in four Primary Care Networks in Northern Alberta, Canada. Key features of *TeamCare-PCN* include coordinated care by a nurse care manager to direct active patient follow-up, treat-to-target principles and specialist (i.e. psychiatrist and internists/endocrinologists) consultation.

This programme has been evaluated in a RCT of participants with chronic conditions. It has been trialled in participants with poorly controlled diabetes, coronary heart disease or both, coexisting with depression. At 12 months, patients in the intervention group had significantly greater overall improvement compared with controls with respect to HbA1c (-0.56 % vs control), LDL cholesterol (-9.1 mg/dl vs control), systolic blood pressure (-3.4 mmHg vs control); and telephone interviews were undertaken at six month intervals to assess depression symptoms, health risk behaviour and satisfaction with care of depression and diabetes/coronary heart disease or both (Katon et al., 2010).

A study is currently underway (Johnson et al., 2012a) based on the Katon et al. (2010) trial. Primary outcomes target depressive symptoms and a multivariable, scaled marginal model for the combined outcome of global disease control (i.e. HbA1c, systolic blood pressure, LDL cholesterol) and chronic disease-related clinical outcomes. Process indicators will include the number of visits with PCN care providers, including case manager, family physicians, specialists' consults, referrals for mental health care, and use of medications and psychotherapeutic sessions. The time spent with patients, adjustments to medications and adherence to treatments will also be assessed.

This programme has three phases: depression management; stepped care/treat to target; and patient education.

- 1) Improving depressive symptoms, Depression management with antidepressants and/or psychotherapy. Direct referral to the care of a psychiatrist will occur only on failure of two separate trials of antidepressants, or one trial of antidepressant in combination with psychotherapy. When patients have reached remission, the case manager and patient work

together towards a relapse prevention plan to help the patient identify when and where to seek help with future depressive symptoms or renewed problems for disease control.

- 2) Improving blood glucose, blood pressure and cholesterol, cardio-metabolic diabetes management (Stepped care/treat-to-target algorithms). Recommended treatments have been based on algorithms that were developed in collaboration with the PCNs by compiling various guidelines and sources, such as extant clinical practice guidelines and consulting experts in the field. Phase 2 includes working with the care manager in analogous fashion to Phase 1, but with a focus on reaching individualised targets for HbA1c, lipids and blood pressure measures.
- 3) Improving lifestyle behaviours. Lifestyle modifications (algorithms based on local and national guidelines). Phase 3 involves patient education to address lifestyle behaviours such as diet and exercise. Locally developed educational materials and existing PCN support programmes will be available for patient referrals.

### Self-management

The intervention combines support for self-care with pharmacotherapy to control depression, hyperglycaemia, hypertension, and hyperlipidaemia. Patients worked collaboratively with nurses and primary care physicians to establish individualised clinical and self-care goals.

### Team changes

Nurse care managers guide the patient-centred care with family physicians and consultant physician specialists to monitor progress and develop tailored care plans.

A two-day training session for case managers and consultant specialists was scheduled at the beginning of the project, with an annual one-day booster session. Case managers were provided with basic training in three psychotherapeutic techniques: problem-solving therapy, behavioural activation, and motivational interviewing.

### Patient education

Education is a large part of this programme. The case manager's role is to partner with the patient to develop a shared definition of problems, provide education, support, negotiated specific targets/goals and to develop an individualised action plan. In particular, Phase 3 involves patient education to address lifestyle behaviours such as diet and exercise. Locally developed educational materials and existing PCN support programmes will be available for patient referrals.

### Case management

A two-hour baseline appointment with the case manager for a bio-psychosocial semi-structured assessment (reviewing medical history, previous treatments for depression and diabetes), patient education, potential treatment options (antidepressant medications and/or psychotherapy) and developing a personalised care plan.

Structured visits in each patient's primary care clinic every two to three weeks, where nurses monitor patient progress with respect to management of depression (according to the PHQ-9<sup>vi</sup> score), control of medical disease, and self-care activities. Treatment protocols guided adjustments of commonly used medicines in patients who did not achieve specific goals.

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<sup>vi</sup> Patient health questionnaire is a self-administered screening and diagnostic tool for mental health disorders.

### Facilitated relay of information to primary clinician (role of technology)

Nurse care managers actively follow up with patients by telephone or in person one to two times per month to re-assess symptoms, and assist and support patients in achieving treatment goals. The care manager will also have weekly meetings with the consulting specialists to review new cases and patient progress, and then communicate team treatment recommendations to the primary care physician. This includes a visit with the care manager or follow-up by phone; and a meeting with consulting specialists and family physician on a weekly basis or as needed.

### **The St. Joseph's Primary Care Diabetes Support Programme**

The *St. Joseph's Primary Care Diabetes Support Programme (SJHC PCDSP)* (Reichert et al., 2014) is part of the Ontario Diabetes Strategy-funded Diabetes Education Programme in London, Ontario. The programme was developed with the main objective of providing diabetes management for a variety of patients (over 90% T2DM) including those with multimorbidities (CVD, heart disease, stroke, myocardial infarction, transient ischemic attacks, neuropathy, nephropathy, fatty-liver and amputation), complex social determinants of health not well served by usual care (i.e. poverty, psychiatric medical histories, no health coverage, language barriers, multiple stressors and mobility issues), and individuals with no family physician.

The primary outcome measured was HbA1c, which was at baseline on average, 9.36 per cent and 8.61 per cent for patients with T1DM and T2DM, respectively. However, by six months, HbA1c was lowered by 1.15 per cent for patients with T1DM and by 0.87 per cent for patients with T2DM. Other important health outcomes, including blood pressure, dyslipidaemia and weight, are also routinely examined, and results revealed improvements over time.

### Self-management

Weekly contacts are established for insulin titration when a patient starts on insulin or a new medication that may require follow-up. Staff schedules reserve a number of these 15-minute spots to complete this work. Principles of self-management are reinforced during these encounters as patients are often taught how to test with purpose or to make connections between insulin action and dietary choices.

Remote support allows patients to communicate either by e-mail, phone or fax with allied health staff.

### Team changes

The main feature of this programme which is considered unique beyond patient self-management skills, as offered in traditional Diabetes Education Programmes, is the active medical management provided by an expanded care team that includes primary care physicians and nurse practitioners specialised in primary care and diabetes management. Patients have access to a variety of healthcare professionals, including three physicians, two full-time nurse practitioners, two part-time nurses, two dietitians and one social worker.

### Patient education

The social worker facilitates a behaviour-modification group focused on eating behaviours called "Craving Change", while volunteer undergraduate and master's programme kinesiology students offer weekly exercise group programmes.



### Case management

All nurses and dietitians are certified diabetes educators. The nurse practitioners have an extended class license allowing them to prescribe and manage a subset of patients independently.

### Facilitated relay of information to primary clinician (role of technology)

Physically co-located within the same building as a family health team, it serves patients referred from the family health team, and community referrals from a variety of providers and practice settings (i.e. post-hospital discharge, emergency departments, walk-in clinics, other health-care providers such as chiropractors, and patient self-referrals).

Further relay of information if supported by all assessments are structured using a standardised EMR-supported format. All electronic encounter notes are read and verified by the physician of the day. A case-management approach with relevant physician input ensures that patients have providers most knowledgeable about their care and the opportunity to involve additional expertise as required during any given visit.

Clinical care is supported by WebDR, a unique EMR developed for diabetes outpatient clinics. It was built after determining that commercial EMR vendors did not offer an EMR that fully suited practice demands. All relevant clinical data are housed in the EMR which, in turn, promotes team-based care. It can also be used as a searchable database and now houses more than 15,000 unique patient records.

### **Intermediate Care Clinics for Diabetes**

*Intermediate Care Clinics for Diabetes (ICCD)* are integrated diabetes service in a 'hub and spoke' model between primary and specialist services to utilise the specialist expertise economically and provide opportunity for regular 'up skilling' the knowledge of primary care practitioners (Sharp, 2010, Halfyard et al., 2010). These are community based, MDTs, working closely with general practices.

A pragmatic two-arm cluster RCT in three English PCTs (Wilson et al., 2014) has been undertaken in an urban setting of the East and West Midlands of the UK. Adults were aged 18 years or over, diagnosed with T2DM, with no severe cognitive impairment, no severe mental illness and not receiving terminal care.

Outcomes: Combined control (reaching all targets HbA1c, BP and total cholesterol), individual risk factors (HbA1c, BP and cholesterol). Secondary outcomes comprised the proportion of participants reaching targets for individual factors (HbA1c, BP and total cholesterol), HRQL and the incremental cost of the programme was estimated.

At follow-up (12 months post discharge from the clinic) 14.3 per cent of patients in the intervention group compared with 9.3 per cent in the control group achieved combined control. Intervention group patients were more likely to achieve control of HbA1c (mean change 1.5%) and total cholesterol at follow-up. The total cost of care per patient (including diagnostic tests and hospital inpatient stay) was higher in the intervention group, but did not reach statistical significance. Quality of life was not impacted.

The recruited sample for this study had poor HbA1c control at baseline (mean HbA1c 10.1%)  
Sharing information: In PCTs 1 and 2, an active 'case finding' approach was used in which members of the *ICCD* team searched GP records to identify those with suboptimal risk factor control who may benefit from referral. Although the *ICCD* service in PCT 3 visited practices to promote the clinics, it

relied on primary care practitioners identifying suitable patients for referral. Two intervention practices refused access for follow-up assessment and including these, a total of 528 patients were lost to follow-up (intervention–324; control–204). A further 189 patients were excluded from analysis (intervention–89; control–100) due to incomplete data. Thus, data from 68 per cent of the control group (636/940) and 61 per cent of the 644/1057) intervention group were available for final analyses.

#### Self-management

Emphasis on self-management.

#### Team changes

Clinics work closely with hospital-based specialist teams and community services, including podiatry and dietetic services. The community-based MDT is led by a diabetes specialist nurse, consultant or GP with specialist interests. Investigation has been recommended into organisational structure and ideal scale of *ICCD* services as they are linked to skill levels of the general practitioners involved (Wilson et al., 2014).

#### Patient education

Emphasis on education and direct work with patients and practice education.

#### Case management

Proactive ‘case finding’ approach used in two and use of MDTs in all three PCTs represent first steps towards case management. Patients were managed by the *ICCD* team until control of risk factors was achieved and then referred back to primary care. Teams worked to NICE guidelines on targets for HbA1c, lipids, and blood pressure.

#### Facilitated relay of information to primary clinician (role of technology)

Triaged hospital referrals. Providing practices with access to an *ICCD* service led to an increase in the proportion of patients achieving targets for control as assessed by a primary outcome measure. However without a ‘case-finding’ approach (i.e. predictive risk model) there is a risk that *ICCD* services may be under-utilised. The current arrangement relies on strong relationships with local practices to promote the use of the service(s).

## Ongoing secondary prevention programme trials without outcomes data

### Diabetes Care Project

The *Diabetes Care Project* (Leach et al., 2013) is a three-year, pragmatic, cluster RCT designed to evaluate the impact of two interventions on diabetes care delivered to adults in general practice:

1. Access to the online CDMt network (cdmNet) and access to training and capability building
2. Access to cdmNet with the addition of patient risk stratification, provision of a care facilitator, access to training and capability building, new funding model including rewards for improvement and care facilitator support.

Developed by a consortium of 20 organisations from across Australia, the programme features were based on published evidence for interventions shown to improve glycaemic control and, in line with this, change in HbA1c is the primary endpoint for the trial. In group 2, care delivery is based on a MDT including GPs and the care facilitator, and other professionals depending on patient needs. All carers use the cdmNet tool to coordinate deliver of care. Risk stratification affects the care plan that is generated for a patient, the risk categories are: not complex and within range; complex and within range; not complex and out of range; complex and out of range. Out of range refers to the level of control for HbA1c, SBP, and serum cholesterol.

The new funding model includes a number of innovations (Cheng): flexible funding for GP care planning; flexible funding for Allied Health Professional services; pay-for-performance payments to general practice for improvement in patient outcomes and meeting defined levels of patient experience and clinical processes; and funding to support organisation development such as training and resourcing.

The trial commenced in 2012, and a total of 150 practices have been enrolled and the planned end date for the trial is June 2014. No outcome data are currently available.