

# National Evidence Based Guideline for Patient Education in Type 2 Diabetes

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For the:  
Diabetes Australia Guideline Development Consortium

Approved by NHMRC  
on 12 June 2009



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## **Diabetes Australia Guideline Development Consortium**

The Diabetes Australia Guideline Development Consortium comprises Diabetes Australia; Australian Diabetes Society; the Australian Diabetes Educators' Association; the Royal Australian College of General Practitioners; and The Diabetes Unit, Menzies Centre for Health Policy, The University of Sydney.

A link to the guideline can be found on the Diabetes Australia website:  
[www.diabetesaustralia.com.au/For-Health-Professionals/Diabetes-National-Guidelines/](http://www.diabetesaustralia.com.au/For-Health-Professionals/Diabetes-National-Guidelines/)

## **The National Health and Medical Research Council**

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A link to the guideline can be found on the National Health and Medical Research Council website:  
[www.nhmrc.gov.au/publications](http://www.nhmrc.gov.au/publications).

## **Disclaimer**

This document is a general guide to appropriate practice, to be followed subject to the clinician's judgement and the patient's preference in each individual case. The guidelines are designed to provide information to assist decision-making and are based on the best evidence available at the time of development.

## **Suggested Citation**

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## Glossary of Accromyms

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ADDQOL	Audit of Diabetes-Dependent Quality of Life
BMI	Body Mass Index
BP	Blood Pressure
BRFSS	Behavioural risk factor Surveillance System
CCT	Controlled Clinical Trial
CEN	Certified Expert Nurse
CI	Confidence Interval
CINAHL	Cumulative Index to Nursing and Allied Health Literature
CV	Cardio Vascular
CVD	Cardio Vascular Disease
DESMOND	Diabetes Education and Self-Management in Ongoing and Newly Diagnosed
DQOL	Diabetes Quality of Life
DSME	Diabetes Self-Management Education
DSMT	Diabetes Self-Management Training
eGFR	Estimated Glomerular filtration Rate
FBG	Fasting Blood Glucose
FPG	Fasting Plasma Glucose
GHb	Glycohaemoglobin
HbA <sub>1c</sub>	Glycated Haemoglobin
HDL	High-Density Lipoprotein
HRQL	Health-Related Quality of Life
HTA	Health Technology Assessment
ICAN	Improving Control with Activity in Nutrition
IDF	
LDL	Low-Density Lipoprotein
MI	Myocardial Infarction
mM	Millimolar
NICE	National Institute for Clinical Excellence
NNT	Number Needed to Treat
NS	Not Significant
OHA	Oral Hypoglycaemic Agent
OR	Odds Ratio
QALY	Quality Adjusted Life Years
QOL	Quality of Life
RCT	Randomised Controlled Trial
RR	Relative Risk
SD	Standard Deviation
SDSCA	Summary of Diabetes Self-Care Activities
SIDEP	Structured Intensive Diabetes Education Program
SMBG	Self-Monitoring of Blood Glucose
SMD	Standard Mean Difference
SR	Systematic Review
WMD	Weighted Mean Difference

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# Diabetes Patient Education

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## **Aim of the guideline**

This guideline covers issues relating to patient education in adults with type 2 diabetes. Its aim is to inform and guide health care providers with evidence based information about what educational strategies and areas that have been shown to improve patient outcomes. The guideline targets health care professionals and all providers who deliver education to people with type 2 diabetes people, planners, policy makers and clinicians.

## **Methods**

In addition to the methods used to identify and critically appraise the evidence to formulate the guideline recommendations which are described in detail in the overview of *Methods and Processes* (Appendix 6), the Research Team reviewed and checked each step of the methods process and:

- repeated a selection of the searches
- double culled the yield from all the database searches
- double reviewed the majority of the articles used as evidence references
- checked all recommendations, evidence statements, evidence tables and search strategy and yield tables

## **Guideline Format**

Questions identified by the Expert Advisory Group (EAG) and from the literature as critical to the diabetes patient education for adults with type 2 diabetes are shown (next page). Each of these issues is addressed in a separate section in a format presenting:

- **Recommendation(s)**
- **Practice points** - including experts' consensus in absence of gradable evidence
- **Evidence Statements** - supporting the recommendations
- **Background** – discussing issues for the guideline
- **Evidence** - detailing and interpreting the key findings
- **Summary** - of major evidence found and gaps in research identified
- **Evidence tables** - summarising the evidence ratings for the articles reviewed

*For all issues combined*, supporting material appears at the end of the guideline and includes:

- **Summary of the literature** – Most of studies identified have reported more than one outcomes, therefore to avoid repeating study details under each section, a complete summary of those systematic reviews and primary studies have been included as appendices (see appendices 1 & 2)
- **Search Strategy and Yield Tables** documenting the identification of the evidence sources

## Questions for patient education

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1. Is structured diabetes patient education effective?
  
2. How should diabetes patient education be delivered?
  - i. group/individual
  - ii. duration of program/length of session
  - iii. setting
  - iv. delivery model/style
  - v. educators and training
  
3. Is diabetes patient education cost-effective and what are the socio-economic implications?

## Summary of Recommendations and Practice Points

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### Recommendations

1. All people with type 2 diabetes should be referred for structured diabetes patient education (Grade A)
2. Diabetes education should be delivered in groups or individually (Grade A)
3. Efforts to improve the cost-effectiveness of diabetes care should include patient education (Grade B)
4. Diabetes education should be culturally sensitive and tailored to the needs of socio-economically disadvantaged populations (Grade B)

### Practice Points

- Diabetes education, where possible, should be delivered by a multidisciplinary team.
- Education programs should be comprehensive and should include a component on physical activity
- People with diabetes should be encouraged to actively participate in goal setting and decision making
- Educational interventions should be followed by regular reinforcement

## Overview of Diabetes Patient Education

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Diabetes is a chronic complex illness that requires continuing clinical care and intensive self care. Type 2 diabetes is responsible for approximately 85% of all diabetes in Australia and by virtue of sheer numbers, accounts for the majority of the total public health and cost burden attributable to diabetes. In terms of personal suffering and hardship this burden is immeasurable. In financial terms, the direct and indirect cost of type 2 diabetes and its complications are staggering and will continue to rise (Colagiuri et al, 2003b; AIHW, 2008). In 2004-5, diabetes related complications added nearly \$1 billion to total health expenditure in Australia (AIHW, 2008)

Diabetes patient education has long been recognised as a vital and integral component of successful diabetes care. However, complex and daily requirements such as medication taking and adjustment, self-monitoring of blood glucose (SMBG), foot care, dietary modification and attendance for regular medical care place a psychological and financial burden on people with diabetes. HG Lawrence, the co-founder of the British Medical Association, himself a physician and a person with diabetes, is reputed to have stated that the person with diabetes must be his own doctor, nurse and lab technician. It has been pointed out that, while there have been many advances in the medical treatment of diabetes, their implementation puts enormous demand on people with diabetes and their carers (Strine et al, 2005; Clark, 2008). Self-management underpinned by patient education and support are paramount for acquisition of necessary knowledge and problem solving skills (Deakin et al, 2005; Clark, 2008).

According to a technical report published by Diabetes Australia (Colagiuri & Goodall 2004), there is a vast body of literature relating to education theory but no general agreement on how learning takes place. From their literature review of education theory, the authors conclude that while there is no one theory which can be used for all people in all situations, there is general agreement that the learner must be an active participant in the learning process and that there must be a variety of learning experiences for optimal learning to occur. However, there are major differences between the theories. For example, cognitive learning theory primarily deals with how the brain structures and organises what we learn. Learning is viewed as a developmental process and learners are considered to test new information against existing ideas, beliefs and experience. Constructivist theory considers that learners actively construct new ideas and theories from existing experience and the new ideas and concepts being presented. Humanism provides the core theoretical base for self-directed learning. Humanist theory considers that real learning is something that the learner discovers for him/herself, with a fundamental principle that learning must be based on learner-centred objectives identified by the learner(s)

The Diabetes Australia report (Colagiuri & Goodall 2004) cites educational theorists and researchers who propose that elements of each of these theories are necessary in the development of information and education for people with diabetes. Behaviourist theory provides tools and methods useful for teaching skills oriented tasks such as injecting insulin; cognitive theory explains the need to consider the prior experiences and beliefs of the person with diabetes and further, explains why education strategies that fail to do so are not perceived as relevant; constructivist theory also reinforces the need to take into account the prior experience and beliefs of the individual but goes further to demonstrate the need for learning to be realistic, based on and delivered in, settings that are relevant and meaningful to the individuals life experience. Humanist theory provides the basis for empowerment, with its emphasis on collaborative learning, including collaborative determination of what is to be

learned, how it is to be learned and how that learning is to be demonstrated. Humanist theory emphasises that for effective learning the learner must feel secure, respected, esteemed and empowered (Colagiuri & Goodall, 2004).

Early research into the impact of diabetes education has been criticised for focussing on assessing improvements in knowledge. Nonetheless, it is now widely agreed that, although knowledge alone is not sufficient to effect behaviour change, it is a vital prerequisite to such changes. The main goals of diabetes patient education have been expressed as promoting self-management that in turn may lead to long-term diabetes control to reduce associated morbidity and mortality, and to help people with diabetes balance short and long-term quality of life (QOL) against the burden of daily intensive self-management (Corabian & Harstall, 2001; Snoek & Visser, 2003). Several national and international reports have identified a lack of agreed benchmarks, standardised outcomes and indicators for diabetes patient education (Glasgow & Osteen, 1992; Fain et al, 1999; Home et al, 1999; Naqib, 2002; Colagiuri et al, 2003a; IDF, 2003; Colagiuri & Goodall, 2004). Further, (Colagiuri & Goodall, 2004) demonstrated that the needs of Australians with diabetes are not being adequately met in many areas of information and education and proposed that, without agreed aims and ‘yardsticks’, it is difficult to determine the reason for this.

To address the serious implications of these issues for patient outcomes and for the design and evaluation of educational interventions, Diabetes Australia commissioned the development of a National Consensus on Outcomes and Indicators for Diabetes Patient Education (Eigenmann & Colagiuri, 2007). This project identified the overarching goals of diabetes patient education as:

- Optimal adjustment to living with diabetes
- Optimal physical (health) outcomes
- Optimal (public and personal) cost-effectiveness

The key outcomes that can either be directly attributable to diabetes education, or in which diabetes education plays an important discernable role relate to the goal of ‘*optimal adjustment to living with diabetes*’ and were agreed to be:

- Knowledge and understanding (includes application of knowledge)
- Self-determination (includes confidence, empowerment and capacity for decision making)
- Self-management (includes skills, practices and behaviours)
- Psychological adjustment (includes well-being and QOL).

The National Consensus Report defined diabetes patient education as:

*“an interactive process that facilitates and supports the individual and/or their families, carers or significant social contacts to acquire and apply the knowledge; confidence; practical, problem-solving and coping skills needed to manage their life with diabetes to achieve the best possible outcomes within their own unique circumstances”.*

Diabetes education should have a documented curriculum with specific aims and learning objectives and should be delivered by a trained educator (UK DH and Diabetes UK, 2005). The variety and complexity of diabetes self-care is onerous and ongoing and is critically important to the avoidance of short and long-term diabetes complications. It is imperative that people with diabetes have access to opportunities to acquire the necessary information and skills to self-manage their condition (Diabetes UK, 2005) and numerous guidelines and

reports recommend that all people with diabetes should have access to information about self-management of their diabetes (Home et al, 1999; NICE, 2003; IDF, 2005).

Nonetheless, the evaluation of educational interventions is problematic. The traditional lack of well defined and clearly described inputs and standardised outcome measures hinders our ability to generalise about the impact of diabetes education and its contribution to the health and economic status of individuals and populations with diabetes (Peeples et al, 2001; Colagiuri et al, 2003a). This guideline sets out the best available evidence, from systematic reviews (SRs) and randomised controlled trials (RCTs), about what has been shown to be effective in diabetes patient education. It should be noted that the remit for this guideline was to identify and synthesise the evidence for educational interventions in people with type 2 diabetes.

### **Structure of the document**

The guideline is structured into three Sections according to the research questions or ‘issues’ identified by the Expert Advisory Group to guide the literature searches.

*Section 1* deals with what is known about the effectiveness of diabetes patient education

*Section 2* addresses how diabetes patient education should be delivered

*Section 3* looks at cost implications and the requirements of socio-economically disadvantaged group in relation to diabetes patient education

### ***Full literature review***

To avoid repetition resulting from the use of the large number of the studies that qualify as evidence across a number of the sub-questions examined in Sections 1 & 2, a full description of the studies used as evidence for these Sections has been provided in Appendix 1 & 2, with citations appearing in relation to specific sub-questions under the appropriate sub-headings throughout the textual account of the evidence within the Sections.

# Section 1: Effectiveness of diabetes patient education

---

## Question

Is structured diabetes patient education effective?

## Recommendation

All people with type 2 diabetes should be referred for structured diabetes patient education (Grade A)

## Evidence Statements

- Diabetes patient education for people with type 2 diabetes improves their knowledge and understanding of the condition  
*Evidence Level I*
- Diabetes education has a positive effect on changing dietary habits  
*Evidence Level I*
- Diabetes education may increase the frequency of physical activity in the short-term  
*Evidence Level I*
- Diabetes education improves foot care behaviours  
*Evidence Level I*
- Effect of diabetes education on adherence to medical treatment and care is inconclusive  
*Evidence Level I*
- Diabetes education has a positive short-term effect on self monitoring of blood glucose  
*Evidence Level I*
- Diabetes education is effective in helping smokers with type 2 diabetes quit smoking  
*Evidence Level I*

- Diabetes education is likely to improve glycaemic control as measured by HbA<sub>1c</sub> but evidence of its effect on lipids and blood pressure is mixed  
*Evidence Level I*
- Diabetes education is effective in helping people with type 2 diabetes improve body weight  
*Evidence Level I*
- Diabetes education improves health related quality of life including physical, psychological and social function  
*Evidence Level I*
- Diabetes education may have an effect in reducing depression and anxiety  
*Evidence Level I*
- Diabetes education may improve patients' self-efficacy/empowerment, psychological adjustment to diabetes, and enhance attitudes and beliefs about diabetes  
*Evidence Level I*
- Diabetes education is associated with a reduction in cardiovascular events and microvascular complications such as retinopathy and end stage nephropathy  
*Evidence Level I*
- Limited evidence suggests that diabetes education may reduce diabetes related hospital admissions  
*Evidence Level I*

## Background - Is structured diabetes patient education effective?

There is a large volume of international literature examining the impact of patient education on diabetes in relation to several outcomes including knowledge, self-management, behaviour, psychosocial outcomes, adherence to medication and medical care, glycaemic and metabolic control, and long-term complications.

Diabetes education has been consistently reported to improve knowledge and understanding of diabetes (Brown, 1992; O'Connor et al, 1992; Hitchcock Noel et al, 1998; Davies et al, 2001; Rickheim et al, 2002). Several researchers have argued that knowledge acquisition does not translate into behaviour change (Glasgow & Osteen, 1992; Maldonato et al, 1995; Krichbaum et al, 2003; Snoek & Visser, 2003). Corabian and Harstall (2001) claim that knowledge is necessary but not sufficient to ensure good diabetes control, reduce long-term morbidity and early mortality, or improve QOL. The value of assessing diabetes knowledge as an important measure of effectiveness of educational interventions (Tomky et al, 2000; Mulcahy et al, 2003; Funnell et al, 2007) vs the notion that knowledge is not sufficient for adequate self-regulation (Snoek & Visser, 2003) remains unresolved. However, Valk et al (2003) claim that the goals of health education are to improve both knowledge and behaviour. For the person with diabetes this can mean “optimising metabolic control, preventing acute and chronic complications, and optimising quality of life while keeping costs acceptable” (de Weerd et al, 1989).

According to Colagiuri & Goodall (2004), the long-term effects of information and education for people with diabetes are difficult to quantify and many questions about its effectiveness remain to be asked and answered by well designed and rigorously conducted research studies. However, there is more than sufficient evidence to justify its inclusion as an integral component of chronic disease care. The key challenge currently facing researchers and providers of diabetes care is not so much a matter of justifying the need for education but of measuring and ensuring its quality and effectiveness. This has traditionally been hampered by the lack of consensus about which are the most relevant measures of the effectiveness of diabetes patient education with some authors proposing that metabolic control and morbidity are the important outcomes to measure, while others claim that changes in attitudes and QOL are more proximal outcomes (Corabian & Harstall, 2001).

Several studies have demonstrated the importance of diabetes education in the promotion of health practices that could prevent or delay potential diabetes complications (Strine et al, 2005; Singh et al, 2005) and improve biomedical and overall psychosocial outcomes in patients with type 2 diabetes (Brown, 1999; Steed et al, 2003). For example, a behavioural risk factor surveillance system (BRFSS) survey conducted in 2001 and 2002 in 22,682 persons aged 18 years or older with type 2 diabetes in the US, Guam, Puerto Rico, and the Virgin Islands found that only 52% had attended a diabetes self-management education (DSME) program (Strine et al, 2005). The authors also reported that people who received DSME were significantly more likely than those who did not to be physically active, to have received a flu vaccine, to have checked their blood sugar daily, to have their feet checked for sores, and their HbA<sub>1c</sub> level have been assessed in the preceding year.

## Evidence – Is structured diabetes patient education effective?

This section of the guideline describes identified systematic reviews and recent primary studies that investigated the effectiveness of structured diabetes patient education in people with type 2 diabetes and met the inclusion criteria (Appendix 3) for this review.

The evidence addressing the question “*is structured diabetes patient education effective?*” is presented under sub-headings based on the indicator areas identified in the Australian National Consensus on Outcomes and Indicators for Diabetes Patient Education (Eigenmann & Colagiuri, 2007) as follows:

- Knowledge
- Self-management and behaviour change
  - dietary habits
  - physical activity
  - foot care
  - adherence to medical treatment and care
  - self monitoring of blood glucose
  - smoking
- Clinical outcomes
  - glycaemic control - HbA<sub>1c</sub>
  - lipid
  - blood pressure
  - body weight
- Psychological adjustment and self-determination
  - well-being
  - quality of life
  - depression and anxiety
  - empowerment
  - self-efficacy
- Long-term outcomes
  - mortality
  - complications (cardiovascular, end stage renal failure and retinopathy, foot ulceration and amputation)
- Health service utilisation
  - number and length of hospital admission
  - primary care
  - specialist services

Due to the large volume of studies addressing these issues, the systematic reviews used as evidence are summarised in Table 1 (alphabetically) and primary studies cited are summarised in Table 2 followed by a textual account of the evidence. A detailed description of all studies that were used as evidence can be found at Appendices 1 & 2.

**Table 1: Systematic reviews of patient education in people with type 2 diabetes**

Author, year, number and type of studies included	Intervention	Population characteristics	Outcome measurements	Main results
<p><b>Bazian Ltd, 2005</b> 1 SR 7 RCTs</p>	<p>Educational intervention that aims to prevent foot ulceration in any setting</p>	<ul style="list-style-type: none"> <li>- Adults over 18 years with type 2 diabetes (one included study-type not specified)</li> <li>- High and mixed risk of foot problems</li> </ul>	<ul style="list-style-type: none"> <li>- Foot Ulceration</li> <li>- Infections</li> <li>- Amputation</li> <li>- Foot care knowledge and behaviour</li> </ul>	<ul style="list-style-type: none"> <li>- Education does not have large effect in improving foot health</li> <li>- Education appears effective at improving knowledge of foot care and changing self-reported behaviour in the short-term</li> </ul>
<p><b>Conn et al, 2007</b> Meta-analysis of 103 studies (RCTs, comparative studies)</p>	<p>Diabetes self-management interventions that included recommendations to increase exercise</p>	<ul style="list-style-type: none"> <li>- Adults with type 2 diabetes</li> <li>- No inclusion criteria stated</li> </ul>	<ul style="list-style-type: none"> <li>- Metabolic control (change in HbA<sub>1c</sub>)</li> </ul>	<ul style="list-style-type: none"> <li>- Overall mean weighted effect size for two-group comparisons (54 studies) 0.29 (higher mean for treatment than control). This effect size is consistent with a difference in HbA<sub>1c</sub> means of 0.45% (7.38% for treatment subjects vs 7.83% for control subjects)</li> <li>- Lower effect sizes in studies with a greater proportion of female subjects</li> <li>- Bigger effect in studies that focused on exercise only (effect size 0.45) than interventions targeting multiple health behaviours (effect size 0.22)</li> </ul>
<p><b>Corabian and Harstall, 2001</b> Health Technology Assessment Report: 3 Meta-analyses 7 SRs 7 primary quantitative studies (3 RCTs, 1</p>	<p>Formalised outpatient diabetes education as a therapeutic tool for self-management</p>	<ul style="list-style-type: none"> <li>- Adults with type 2 diabetes (may include both type 1 and 2 adults)</li> <li>- Any age, sex, race</li> </ul>	<ul style="list-style-type: none"> <li>- Clinical (HbA<sub>1c</sub>)</li> <li>- Utilisation of health care services</li> <li>- Knowledge</li> <li>- Self-care behaviour</li> <li>- Psychosocial outcomes</li> <li>- QOL</li> </ul>	<ul style="list-style-type: none"> <li>- Mixed results in terms of improving metabolic control and reduced risk of diabetes complications in the long-term</li> <li>- Main findings from all meta-analyses (included type 1 diabetes) patient education is effective in producing beneficial outcomes for</li> </ul>

<b>Author, year, number and type of studies included</b>	<b>Intervention</b>	<b>Population characteristics</b>	<b>Outcome measurements</b>	<b>Main results</b>
prospective controlled, 3 prospective cohort with control or comparison group)			- Patient satisfaction	HbA <sub>1c</sub> , blood glucose, self-care behaviour, knowledge, and psychological status
<b>Deakin et al, 2005</b> Meta-analysis of 14 publications describing 11 studies (8 RCTs and 3 CCTs)	Group based diabetes self-management training	- Adults with type 2 diabetes - Any gender or ethnicity	- Glycaemic control (HbA <sub>1c</sub> , FBG) - Knowledge - QOL - Empowerment/self-efficacy - Weight, BMI - BP - Lipid - Diabetes complications - Diabetes related mortality - Lifestyle (diet, physical activity) - Treatment satisfaction - Intervention characteristics	At 12-14 months, group program compared to usual care have shown: - Reduction in HbA <sub>1c</sub> ; p<0.00001 - Improved knowledge p<0.00001 (meta-analysis of 3 RCTs) - Improved dietary intake - Conflicting results in terms of physical activity - Statistically significant improved foot care score and SMBG
<b>Duke et al, 2009</b> Systematic review and meta-analysis of RCTs and CCTs (nine studies)	Individual Patient Education	Adults with type 2 diabetes	- Metabolic control - Diabetes complications - Health service utilisation - Psychosocial outcomes - Diabetes knowledge	- In six studies comparing individual education to usual care, individual education did not significantly improve glycaemic control (WMD in HbA <sub>1c</sub> -0.1% (95% CI-0.3 to 0.1, p=0.33) over a 12 to 18 mth period. - Significant benefit of individual education on glycaemic control in a subgroup analysis of three studies

<b>Author, year, number and type of studies included</b>	<b>Intervention</b>	<b>Population characteristics</b>	<b>Outcome measurements</b>	<b>Main results</b>
				involving participants with a higher mean baseline HbA <sub>1c</sub> greater than 8% (WMD -0.3% to 0.1, p=0.0007)
<b>Ellis et al, 2004</b> Meta-analysis and meta-regression of 21 RCTs (=28 interventions)	Diabetes educational interventions	- Adults with diabetes (20 interventions included people with type 2 diabetes, 5 interventions type 1 only, 2 interventions type 1 and 2, 1 study type not specified)	- HbA <sub>1c</sub> - Effect of intervention variables on HbA <sub>1c</sub>	- Net HbA <sub>1c</sub> 0.32% lower in intervention compared to control group - Face-to-face delivery, cognitive reframing teaching method, exercise content more likely to improve HbA <sub>1c</sub> , collectively explain 44% of variance in glycaemic control
<b>Gary et al, 2003</b> 63 RCTs of which 19 were included in main meta-analysis	Educational and behavioural interventions	- Participants with type 2 diabetes - Mean age 57 years	- Glycaemic control - Weight	- Reduced standardised mean glycohaemoglobin of -0.43% (95%CI -0.71 to -0.14; p=0.003) - Weighted mean difference in weight -4.64 lb (95%CI -9.95 to 0.66)
<b>Loveman et al, 2008</b> HTA report 13 studies (11 RCTs, 2 CCTs) reporting education of multiple aspect of DSME , 8 studies (7 RCTs, 1 CCT) reporting education of one particular aspect of DSME	Education interventions	- Adults over 18 years with type 2 diabetes	- Diabetes control (HbA <sub>1c</sub> , BP, Lipids, BMI) - Diabetes end-points - QOL - Intervention characteristics	- Mixed results on diabetes control - Longer-term interventions with shorter interval to follow-up more positive effects
<b>Norris et al, 2002a</b> Meta-analysis of 31	DSME	- Adults with type 2 diabetes	- Glycaemic control	- Average decrease in GHb of 0.76% (95%CI 0.34 to 1.18) compared

Author, year, number and type of studies included	Intervention	Population characteristics	Outcome measurements	Main results
RCTs		<ul style="list-style-type: none"> <li>- English speaking</li> </ul>		<ul style="list-style-type: none"> <li>with control group at immediate follow-up, 0.26% (0.21 increase vs 0.73 decrease) at 1-3 months and 0.26% (0.05 to 0.48) at <math>\geq</math>4 months follow-up, respectively</li> <li>- A decrease of 1% for every additional 23.6hr (13.3 to 105.4) contact with educator</li> </ul>
<p><b>Norris et al, 2002b</b> 30 studies of all types of comparative study designs; of these educational settings included: 8 community gathering places 10 at home 10 camps 1 school 1 workplace</p>	DSME interventions in community settings (type 2 diabetes), workplace (type 1 and 2 diabetes) and camps (type 1 diabetes)	<ul style="list-style-type: none"> <li>- People with type 1 and 2 diabetes</li> <li>- Various ethnical backgrounds</li> </ul>	<ul style="list-style-type: none"> <li>- Glycaemic control</li> <li>- Knowledge</li> <li>- Skills</li> <li>- Psychosocial outcomes</li> <li>- Lifestyle (physical activity, diet, smoking)</li> <li>- QOL</li> </ul>	<p>DSME delivered in community gathering places showed:</p> <ul style="list-style-type: none"> <li>- Improvement in glycaemic control (GHb pooled estimate -1.9% 95%CI -2.4 to -1.18 and FBG median absolute effect size -2.0 range -1.3 to -4.0)</li> <li>- Improvement in knowledge; p=0.04 (1 RCT)</li> <li>- Median absolute effect size for total cholesterol -2.6 mg/dL range -54.0 to +6.0</li> <li>- No effect on QOL (1 RCT)</li> </ul>
<p><b>Norris et al, 2001</b> 72 RCTs published in 84 articles</p>	DSMT	<ul style="list-style-type: none"> <li>- People with type 2 diabetes</li> </ul>	<ul style="list-style-type: none"> <li>- Glycaemic control</li> <li>- Knowledge</li> <li>- SMBG</li> <li>- Dietary habits</li> <li>- Physical activity</li> <li>- Weight</li> <li>- Lipids</li> <li>- BP</li> <li>- Intervention characteristics</li> </ul>	<ul style="list-style-type: none"> <li>- Positive effects on knowledge, SMBG, dietary habits, glycaemic control in studies of 6 months follow-up</li> <li>- Variable effects on physical activity, weight, lipids, BP</li> <li>- Longer follow-up and regular reinforcement more effective in improving glycaemic control</li> <li>- Patient collaboration vs didactic more effective in improving glycaemic control, weight, lipids</li> </ul>

<b>Author, year, number and type of studies included</b>	<b>Intervention</b>	<b>Population characteristics</b>	<b>Outcome measurements</b>	<b>Main results</b>
<b>Sigurdardottir et al, 2007</b> 21 RCTs reporting 18 studies	Modification of provider-patient interaction and consultation style	<ul style="list-style-type: none"> <li>- People with type 2 diabetes</li> <li>- General practice and hospital outpatient settings</li> </ul>	<ul style="list-style-type: none"> <li>- Self-care and patient outcomes</li> </ul>	<ul style="list-style-type: none"> <li>- Delivery and teaching method not related to HbA<sub>1c</sub> pre- to post-intervention</li> <li>- Interventions on patient-provider interaction can improve patient behaviours</li> <li>- Most effective interventions support patient participation in self-care behaviours</li> </ul>
<b>Valk et al, 2002</b> 8 RCTs	Educational interventions (intensive vs. brief)	<ul style="list-style-type: none"> <li>- Adults over 18 years with type 2 diabetes (some studies unclear which type of diabetes)</li> <li>- High and mixed risk of foot problems</li> </ul>	<ul style="list-style-type: none"> <li>- Foot ulceration</li> <li>- Infections</li> <li>- Amputation</li> <li>- Foot care knowledge and behaviour</li> </ul>	Patient education may have positive but short-lived effects on foot care knowledge and behaviours and may reduce foot ulceration and amputations, especially in high-risk patients
<b>Van Dam et al, 2003</b> 8 RCTs	Modification of provider-patient interaction and provider counselling style	<ul style="list-style-type: none"> <li>- People with type 2 diabetes</li> </ul>	<ul style="list-style-type: none"> <li>- Patient diabetes self-care and diabetes outcomes</li> </ul>	Interventions focusing on patient behaviour are more effective than interventions focusing on provider behaviour in improving patient self-care and diabetes outcomes
<b>Vermeire et al, 2005</b> 21 studies (RCTs, CCTs and before and after epidemiological studies)	Interventions to improve adherence to treatment recommendations	<ul style="list-style-type: none"> <li>- People with type 2 diabetes</li> <li>- Primary care, outpatient settings, community and hospital settings</li> </ul>	<ul style="list-style-type: none"> <li>- HbA<sub>1c</sub>,</li> <li>- Weight</li> <li>- BP</li> <li>- Smoking cessation</li> </ul>	<p>Four studies reporting on diabetes education interventions found:</p> <ul style="list-style-type: none"> <li>- Reductions in systolic BP</li> <li>- No change or a reduction in HbA<sub>1c</sub> and weight</li> </ul> <p>Two studies reported positive effects on smoking cessation</p>
<b>Wens et al, 2008</b>	Education interventions to	<ul style="list-style-type: none"> <li>- People with type 2</li> </ul>	<ul style="list-style-type: none"> <li>- HbA<sub>1c</sub></li> </ul>	<ul style="list-style-type: none"> <li>- Face-to-face education (4 studies)</li> </ul>

Author, year, number and type of studies included	Intervention	Population characteristics	Outcome measurements	Main results
8 studies (RCTs, quasi randomised trials, controlled before-after, observational, and cohort studies)	improve adherence to treatment recommendations	diabetes in primary care, outpatient settings, community and hospital settings	<ul style="list-style-type: none"> <li>- FPG</li> <li>- Weight</li> <li>- BP</li> <li>- Total cholesterol</li> <li>- QOL</li> </ul>	<p>demonstrated significant reduction in HbA<sub>1c</sub> levels</p> <ul style="list-style-type: none"> <li>- Group education (2 studies) reported significant reduction in HbA<sub>1c</sub>, FPG, total cholesterol, systolic BP, weight, and waist-hip ratio</li> <li>- No direct measures of adherence reported</li> </ul>
<b>Zabaleta et al, 2007</b> 3 CCTs (of 21 selected for full review)	Structured group-based education in primary care	<ul style="list-style-type: none"> <li>- People with type 2 diabetes</li> <li>- Primary care setting (community or general practice)</li> </ul>	<ul style="list-style-type: none"> <li>- HbA<sub>1c</sub></li> </ul>	Only one study reported a clinically significant benefit in HbA <sub>1c</sub> (>0.5%) compared with the control group
<b>Zhang et al, 2007</b> 48 studies (12 RCTs, 4 non-randomised and 32 pre-post studies)	<ul style="list-style-type: none"> <li>- Diabetes education and behavioural modification</li> <li>- Pharmacotherapy</li> <li>- Surgery</li> </ul>	<ul style="list-style-type: none"> <li>- Adults with diabetes (type of diabetes not stated in 3 of 5 RCTs of educational interventions)</li> <li>- Aged ≥ 18 years</li> </ul>	<p>HRQL:</p> <ul style="list-style-type: none"> <li>- Physical function</li> <li>- Mental health</li> <li>- Bodily pain</li> <li>- Social function</li> <li>- Vitality</li> </ul>	<p>Diabetes education interventions: Data from 5 RCTs:</p> <ul style="list-style-type: none"> <li>- Improved physical function – pooled estimates 3.4 (95%CI 0.1 to 6.6) and mental health 4.2 (95%CI 1.8 to 6.6), and a decrease in bodily pain 3.6 (95%CI 0.6 to 6.7)</li> </ul> <p>Data from 5 pre-post studies:</p> <ul style="list-style-type: none"> <li>- Improved social function 5.8 (95%CI 2.0 to 9.6), vitality 3.0 (95%CI 1.6 to 4.4), and mental health 2.5 (95%CI 0.6 to 4.4), and a decrease in role limitations due to physical problems 4.3 (95%CI 0.1 to 8.4)</li> </ul>

BMI: Body Mass Index; BP: Blood Pressure; CCT: Controlled Clinical Trial; CI: Confidence Interval; DSME: Diabetes Self-Management Education; ES: Effect Size; FBG: Fasting Blood Glucose; FPG: Fasting Plasma Glucose; GHb: Glycated Haemoglobin; HRQL: Health-Related Quality of Life; QOL: Quality of Life; RCT: Randomised Controlled Trial; SMBG: Self-Monitoring of Blood Glucose; SR: Systematic Review

**Table 2: Randomised controlled trials of patient education in people with type 2 diabetes**

Author, year, country	Intervention	Population characteristics	Outcome measurements	Main results
<b>Adolfsson et al, 2007</b> Sweden	Empowerment group education program vs routine diabetes care	<ul style="list-style-type: none"> <li>- Adults with type 2 diabetes</li> <li>- Aged ≤75 yrs</li> <li>- Diet or OHAs</li> <li>- HbA<sub>1c</sub> 6.5-10%</li> <li>- Duration of diabetes ≥1 year</li> <li>- n=101</li> </ul>	<ul style="list-style-type: none"> <li>- HbA<sub>1c</sub></li> <li>- BMI</li> <li>- Weight</li> <li>- Confidence in diabetes knowledge</li> <li>- Self-efficacy</li> <li>- Satisfaction with daily life</li> </ul>	<p>At 1 year follow-up (intervention compared to control group):</p> <ul style="list-style-type: none"> <li>- Level of confidence in diabetes knowledge significantly higher (p&lt;0.05)</li> <li>- No significant differences in self-efficacy, satisfaction with daily life, BMI and HbA<sub>1c</sub></li> <li>- BMI and HbA<sub>1c</sub> maintained in both groups</li> </ul>
<b>Chen et al, 2008</b> Taiwan	Structured diabetes education (program 1- intervention) vs pamphlet (program 2 - control) before Chinese New Years holiday	<ul style="list-style-type: none"> <li>- Adults with type 2 diabetes</li> <li>- Aged 50 to 70 years</li> <li>- Treated with OHAs</li> <li>- n=102</li> </ul>	<ul style="list-style-type: none"> <li>- Fructosamine</li> <li>- FBG</li> <li>- HbA<sub>1c</sub></li> <li>- BP</li> <li>- Weight</li> <li>- Lipids</li> </ul>	<p>Post- holiday period (visit 3):</p> <ul style="list-style-type: none"> <li>- Mean FPG (mmol/L) in program 1: 11.1 (SD 2.9) vs program 2: 9.5 (SD 2.4) p=0.01</li> <li>- Fructosamine μmol/L: program 1: 354.0 (SD 66.3) vs program 2 331.2 (59.1) p=0.01</li> </ul> <p>At 12 months from pre-holiday</p> <ul style="list-style-type: none"> <li>- Mean HbA<sub>1c</sub> program 1: 7.95% (increased from 7.86% at baseline); program 2: 7.78% (decreased from 7.81% at baseline) - (<i>Data taken from graph</i>)</li> <li>- Mean change in HbA<sub>1c</sub> program 1 0.18% (95%CI -0.09% to 0.74%) vs -0.06 (95%CI -0.24% to 0.22%) for program 2 – NS</li> </ul>
<b>Davies et al, 2008</b> England and Scotland	Structured group education program (DESMOND) in primary practice vs routine care	<ul style="list-style-type: none"> <li>- Adults with type 2 diabetes</li> <li>- 207 general practices in 13 primary care sites</li> <li>- n=824 (people with type 2 diabetes)</li> </ul>	<ul style="list-style-type: none"> <li>- HbA<sub>1c</sub></li> <li>- BP</li> <li>- Weigh</li> <li>- Lipids</li> <li>- Smoking status</li> <li>- Physical activity</li> <li>- QOL</li> <li>- Illness beliefs</li> <li>- Depression and emotional</li> </ul>	<p>At 12 months follow-up:</p> <ul style="list-style-type: none"> <li>- HbA<sub>1c</sub> decreased by 1.49% in intervention and 1.21 in control group, after adjustment for baseline and cluster NS (0.05% (95%CI -0.1 to 0.20)</li> <li>- Weight loss -2.98kg (95%CI -3.54 to 2.41) in intervention vs 1.86kg (-2.44 to -1.28) in control group p=0.027</li> <li>- Odds of smoking 3.56 (95%CI 1.11 to 11.45) p=0.033</li> <li>- Illness belief score- greater changes in intervention</li> </ul>

Author, year, country	Intervention	Population characteristics	Outcome measurements	Main results
			impact of diabetes	<p>group (p=0.001)</p> <ul style="list-style-type: none"> <li>- Lower depression score in intervention group p=0.032</li> <li>- Positive association between perceived personal responsibility and weight loss (p=0.008)</li> <li>- Physical Activity: NS</li> </ul>
<b>Deakin et al, 2006</b> UK	Patient-centred, group-based self-management program (X-PERT)	<ul style="list-style-type: none"> <li>- Adults with type 2 diabetes</li> <li>- n=314</li> </ul>	<ul style="list-style-type: none"> <li>- HbA<sub>1c</sub></li> <li>- Weight</li> <li>- BMI</li> <li>- Waist circumference</li> <li>- Total cholesterol</li> <li>- Diabetes knowledge</li> <li>- Physical activity</li> <li>- Foot care</li> <li>- Fruit and vegetable intake</li> </ul>	<p>At 14 months follow-up:</p> <ul style="list-style-type: none"> <li>- Improved mean HbA<sub>1c</sub> (-0.6% vs +0.1%; p&lt;0.001), reduced cholesterol, weight, BMI and waist circumference</li> <li>- Reduced requirements for medication - NNT 7 (95%CI 5 to 11)</li> <li>- Increased consumption of fruit and vegetables</li> <li>- Improved knowledge, self-empowerment, self-management skills</li> </ul>
<b>Hörnsten et al, 2005</b> Sweden	Group sessions based on participants personal understanding of their illness vs conventional diabetes care	<ul style="list-style-type: none"> <li>- People with type 2 diabetes</li> <li>- Aged 40-80 years</li> <li>- Diagnosed within previous 2 years</li> <li>- n=257</li> </ul>	<ul style="list-style-type: none"> <li>- HbA<sub>1c</sub></li> <li>- Lipids</li> <li>- Treatment satisfaction</li> <li>- BMI</li> </ul>	<p>At 1 year follow-up (intervention vs control group):</p> <ul style="list-style-type: none"> <li>- HbA<sub>1c</sub> (treatment effect mean difference 0.94%; p&lt;0.05)</li> <li>- Triglycerides (mean difference 0.52 mmol/L; p=0.002)</li> <li>- HDL (mean difference 0.15 mmol/L; p=0.029)</li> <li>- Improved treatment satisfaction</li> </ul>
<b>Hörnsten et al, 2008</b> (follow-up of above 2005 study)	As above	- As above	- As above	<p>At 5 years follow-up</p> <ul style="list-style-type: none"> <li>- Mean HbA<sub>1c</sub> in intervention group 5.71% (SD 0.71) but increased to 7.07% in control group. Crude difference between groups 1.37 (p&lt;0.0001).</li> <li>- Total cholesterol HDL, LDL, triglycerides and BMI not statistically different.</li> </ul>
<b>Ko et al, 2007</b> North Korea	Structured inpatient	<ul style="list-style-type: none"> <li>- People with type 2 diabetes</li> </ul>	<ul style="list-style-type: none"> <li>- HbA<sub>1c</sub></li> <li>- Frequency of hospitalisation</li> </ul>	<ul style="list-style-type: none"> <li>- Significantly lower HbA<sub>1c</sub> (7.9 ± 1.2 SIDEV vs. 8.7 ± 1.6% control; p&lt;0.05)</li> </ul>

Author, year, country	Intervention	Population characteristics	Outcome measurements	Main results
	intensive group education (SIDEPE) vs conventional inpatient diabetes education (control)	<ul style="list-style-type: none"> <li>- Hospitalised</li> <li>- n=547</li> </ul>	<ul style="list-style-type: none"> <li>- Physical activity</li> <li>- Diet</li> <li>- Self blood glucose testing</li> </ul>	<ul style="list-style-type: none"> <li>- Frequency of hospitalisation related to diabetes per patient per year decreased significantly (<math>0.3 \pm 0.6</math> vs <math>0.8 \pm .9</math>; <math>p &lt; 0.05</math>) in SIDEPE vs control group</li> <li>- Self-care behaviours adherence significantly improved (SIDEPE vs control group over 4 years <math>p &lt; 0.05</math>)</li> <li>- People with longer duration of type 2 diabetes and those treated with insulin had poorer HbA<sub>1c</sub> at follow-up</li> </ul>
<b>Kulzer et al, 2007</b> Germany	Treatment arm: A = 4 didactic group sessions B = 12 group sessions focused on self-management/empowerment C = 12 more individualised sessions but including 6 group sessions, same delivery approach as B	<ul style="list-style-type: none"> <li>- People with type 2 diabetes</li> <li>- Aged 40-65 years</li> <li>- No insulin treatment</li> <li>- n=182</li> </ul>	<ul style="list-style-type: none"> <li>- HbA<sub>1c</sub></li> <li>- BMI</li> <li>- Lipids</li> <li>- Psychosocial variables</li> <li>- Behavioural variables</li> </ul>	<p>At 3 months follow-up:</p> <ul style="list-style-type: none"> <li>- HbA<sub>1c</sub> in individualised vs didactic group significantly different</li> </ul> <p>At 15 months follow-up:</p> <ul style="list-style-type: none"> <li>- HbA<sub>1c</sub> significantly lower in the group program compared with didactic education (<math>p = 0.017</math>)</li> <li>- HbA<sub>1c</sub> in the individualised treatment group higher than in the group treatment (<math>p = 0.729</math>)</li> <li>- Self-management training significantly higher medium-term efficacy than didactic diabetes education</li> <li>- Group sessions were more effective than individualised approach</li> <li>- Significant benefits in treatment B vs A in other medical (BMI and FBG), psychological (control, irritability and hunger dependency of eating behaviour, and trait anxiety) and behavioural (exercise) variables</li> <li>- No significant differences in triglyceride levels, HDL, diabetes-related knowledge, negative well-being, urine or blood glucose levels or foot care between any groups</li> </ul>
<b>Rachmani et al, 2005</b> Israel	Standard consultation (SC) or patient-participation program (PP)	<ul style="list-style-type: none"> <li>- High risk people with type 2 diabetes (hypertension, dyslipidaemia)</li> </ul>	<ul style="list-style-type: none"> <li>- BP</li> <li>- HbA<sub>1c</sub></li> <li>- eGFR</li> <li>- Albumin/Creatinine ratio</li> <li>- CV end-points (MI, stroke,</li> </ul>	<p>Over 8 years:</p> <ul style="list-style-type: none"> <li>- 80 CV events (eight deaths) in the SC group vs 47 events (five deaths) in the PP group (<math>p = 0.001</math>). RR for CV event in PP vs SC group 0.65 (95%CI 0.89 to 0.41)</li> </ul>

Author, year, country	Intervention	Population characteristics	Outcome measurements	Main results
		<ul style="list-style-type: none"> <li>- Referred to hospital clinic</li> <li>- n=167</li> </ul>	mortality)	<ul style="list-style-type: none"> <li>- 17 vs 8 cases of stroke in the SC and PP groups (p=0.05)</li> <li>- RR for stroke was 0.47 (95%CI 0.85 to 0.32)</li> <li>- Increased rate of overt nephropathy in SC vs PP group (p=0.05)</li> </ul> <p>Over seven years:</p> <ul style="list-style-type: none"> <li>- BP, LDL cholesterol, and HbA<sub>1c</sub> were significantly lower in the PP than in the SC patients</li> <li>- Reduced CV risk and slower progression of microvascular disease in PP group</li> </ul>
<b>Shibayama et al, 2007</b> Japan	One-on-one lifestyle education in an outpatient setting delivered by a Certified Expert Nurse (CEN) vs usual care	<ul style="list-style-type: none"> <li>- People with non-insulin-treated type 2 diabetes</li> <li>- Aged 20 to 75 years</li> <li>- n=309</li> </ul>	<ul style="list-style-type: none"> <li>- HbA<sub>1c</sub></li> <li>- BMI</li> <li>- BP</li> <li>- HRQL</li> <li>- Cognition</li> <li>- Behavioural modification</li> <li>- Satisfaction</li> <li>- Hospital visit</li> </ul>	<p>Over one year:</p> <ul style="list-style-type: none"> <li>- No significant differences in HbA<sub>1c</sub>, BMI, BP, serum lipids, or HRQL between the two groups</li> <li>- Modest favourable modification of cognition (p=0.004) and behaviour (p&lt;0.001) in intervention vs usual care group</li> </ul>
<b>Thoolen et al, 2007</b>	Self-management course based on theories of proactive coping, self-regulation and elements of anticipation, goal setting, planning, and problem solving vs	<ul style="list-style-type: none"> <li>- People with type 2 diabetes having received either intensive pharmacologic al or usual-care treatment since diagnosis</li> <li>- Aged 50-70 years</li> <li>- n=196</li> </ul>	<ul style="list-style-type: none"> <li>- HbA<sub>1c</sub></li> <li>- BMI</li> <li>- BP</li> <li>- Lipids</li> </ul>	<p>At 9 months follow-up (one year from baseline) intervention vs control participants and regardless of medical treatment:</p> <ul style="list-style-type: none"> <li>- Significant weight loss difference -0.77 kg/m<sup>2</sup> or 2.6kg; p&lt;0.001); net loss of - 0.39 kg/m<sup>2</sup> in intervention vs increase by + 0.38 kg/m<sup>2</sup> in control participants</li> <li>- Systolic BP reduced significantly (mean difference - 6.2 mmHg; p&lt;0.05)</li> <li>- No effect on HbA<sub>1c</sub> and lipid levels</li> <li>- Intensive medical treatment was also independently associated with lower BP, HbA<sub>1c</sub>, total cholesterol, and LDL before the course and further improvements</li> </ul>

Author, year, country	Intervention	Population characteristics	Outcome measurements	Main results
	usual care (receipt of self-management brochure)			in systolic BP (-4.7 mmHg)
<b>Trento et al, 2004</b> Italy	Systemic group education (intervention) vs individual education (control)	<ul style="list-style-type: none"> <li>- People with type 2 diabetes</li> <li>- Aged 60-69 years</li> <li>- Duration of diabetes 8.8 to 17.9 years</li> <li>- n=120</li> </ul>	<ul style="list-style-type: none"> <li>- Knowledge</li> <li>- Problem solving</li> <li>- QOL</li> <li>- HbA<sub>1c</sub></li> <li>- BMI</li> <li>- HDL cholesterol</li> </ul>	<p>At 5 years follow-up:</p> <ul style="list-style-type: none"> <li>- Statistically significant improvement in diabetes knowledge, problem solving ability, QOL and HbA<sub>1c</sub> (all p&lt;0.001)</li> <li>- NS for BMI and HDL cholesterol</li> </ul>
<b>Williams et al, 2005</b>	Patient activation intervention (I) vs passive education (C)	<ul style="list-style-type: none"> <li>- People with type 2 diabetes</li> <li>- HbA<sub>1c</sub> at least one point above upper limit of normal reference range</li> <li>- Mean age 54.7 years</li> <li>- n=232</li> </ul>	<ul style="list-style-type: none"> <li>- HbA<sub>1c</sub></li> <li>- Active participant involvement during practitioner visit</li> </ul>	<p>Rated active participant involvement predictive of improvement in glycaemic control</p> <p>At 12 months follow-up:</p> <ul style="list-style-type: none"> <li>- No significant difference in HbA<sub>1c</sub> between I and C</li> <li>- Significant effect of activation condition, on more questions asked (p&lt;0.01), and speaking a greater percentage of time (p=0.01)</li> </ul>
<b>Williams et al, 2007</b>	Patient-centred, computer assisted intervention vs control (handouts, computer assessment)	<ul style="list-style-type: none"> <li>- Adults with type 2 diabetes in primary care</li> <li>- Mean age 64 years</li> <li>- n=886</li> </ul>	<ul style="list-style-type: none"> <li>- HbA<sub>1c</sub></li> <li>- Lipids</li> <li>- Perceived competence</li> <li>- Perception of perceived autonomy support</li> <li>- Patient satisfaction</li> </ul>	<p>At 12 months follow-up:</p> <ul style="list-style-type: none"> <li>- Intervention increased patient perception of autonomy support relative to computer-based control condition (p&lt;0.05)</li> <li>- Change in perceived competence partially mediated effects of increased autonomy support on the change in lipids, diabetes distress, and depressive symptoms</li> <li>- The construct of autonomy support was found to be separate from that of patient satisfaction</li> <li>- Competence at 12 months was associated with 12-</li> </ul>

Author, year, country	Intervention	Population characteristics	Outcome measurements	Main results
				month outcomes, HbA <sub>1c</sub> , diabetes distress, and depressive symptoms

BMI: Body Mass Index; BP: Blood Pressure; CI: Confidence Interval; CV: Cardiovascular; DESMOND: Diabetes Education and Self-Management in Ongoing and Newly Diagnosed; eGFR: Estimated Glomerular Filtration Rate; FBG: Fasting Blood Glucose; FPG: Fasting Plasma Glucose; HDL: High-Density Lipoprotein; HRQL: Health-Related Quality of Life; LDL: Low-Density Lipoprotein; MI: Myocardial Infarction; mM: Millimolar; NNT : Number Needed to Treat; NS: Not Significant; OHA: Oral Hypoglycaemic Agents; QOL: Quality of Life; RR: Relative Risk; SD: Standard Deviation; SIDEPE: Structured Intensive Diabetes Education Program.

## 1. Knowledge

- **Diabetes patient education for people with type 2 diabetes improves their knowledge and understanding of the condition (*Evidence Level I*)**

### *Systematic reviews*

A Cochrane systematic review of group based training for self-management strategies in people with type 2 diabetes demonstrated that diabetes knowledge was significantly improved in three out of four studies at four to six months in the group-based, patient-centred training group compared with usual care. Due to high heterogeneity only three of six studies measuring knowledge at 12 and 14 months were included in a meta-analysis, which showed an improvement in favour of group-based diabetes education - Standardised Mean Difference (SMD) 1.0; 95%CI 0.7 to 1.2;  $p < 0.00001$ . Three other studies not included in the meta-analysis also reported significant improvements in knowledge. Two of these studies measured knowledge scores at 2 years and one study at 4 years follow-up. All three studies demonstrated significant better knowledge for the intervention groups (SMD 2.3; 95%CI 2.0-2.6; SMD 0.85; 95%CI 0.4-1.3; SMD 1.27; 95%CI 0.82 to 1.73, respectively) and all showed a statistically significant improvement at  $p < 0.00001$  compared with control groups (Deakin et al, 2005).

Similarly, a systematic review of 72 studies (describing 84 articles) of diabetes self-management training (DSMT) with follow-up of 6-12 months by Norris et al (2001), reported positive effects of patient education on knowledge. However, seven studies showed improved knowledge for both the intervention and control groups, suggesting possible contamination due to the lack of feasibility in blinding participants. Several studies showed that regular reinforcement of the intervention seemed to improve knowledge levels at variable length of follow-up. In a subsequent review by the same author only one of eight studies of DSMT in community gathering places examined the effect of the intervention on diabetes knowledge and showed a significant improvement ( $p = 0.04$ ) (Norris et al, 2002b).

Valk and colleagues (2002) conducted a systematic review to assess the effectiveness of patient education in preventing diabetic foot ulcers which reported conflicting outcomes. Two out of eight RCTs that evaluated intensive vs brief education interventions demonstrated significantly superior foot care knowledge at six months in one study ( $p < 0.001$ ) and at one year in another study (I:  $26.7 \geq 32.1$  vs C:  $26.1 \geq 29.2$ ;  $p = 0.004$ ). In the latter, knowledge was measured on a 19 item, three-choice questionnaire with total score ranging from 0-57. In a third study with a small sample size and high drop out rate, knowledge test scores were significantly worse in the intervention group compared with the control group at 6 months follow-up (I:  $9.1 \geq 10.0$  vs C:  $8.66 \geq 9.86$ ;  $p = 0.02$ ). While the authors identified one study reporting a statistically significant improvement in foot care knowledge at 6 months (I:  $62.2 \pm 1.7$  vs C:  $53.1 \pm 1.8$ ;  $p = 0.001$ ), a study with longer follow-up showed that positive knowledge effect disappeared at 7 years. Studies assessing intensive, tailored patient education vs usual care, also showed no effect at 1 year follow-up, although foot care behaviour improved significantly. The authors concluded that the evidence, while limited by poor methodological quality and conflicting results, suggests that patient education may have positive but short-lived effects on foot care knowledge and behaviour.

### ***Primary studies***

Findings from a recent RCT assessing the effectiveness of the Diabetes Education and Self-Management for Ongoing and Newly Diagnosed (DESMOND) program, highlighted the impact of patient education in increasing patients knowledge and understanding of diabetes (Davies et al, 2008). This study assessed the extent to which participants believe they understand their diabetes and their agreement with diabetes being a chronic condition and revealed that a structured group education program can positively affect participants understanding of their illness and its seriousness. Adjusted analysis showed that differences between intervention and control groups in four illness beliefs (coherence, timeline, personal responsibility and seriousness) were all highly significant ( $p < 0.001$ ).

Another RCT from Sweden demonstrated a significantly higher level of confidence in diabetes knowledge in participants attending an empowerment group education program compared with participants in the usual care group after 1-year follow-up ( $p < 0.012$ ). Confidence in diabetes knowledge was measured with a self-report 27-item questionnaire produced and validated specifically for the study (Adolfsson et al, 2007).

A patient-centred group-based education program (X-PERT) conducted in the UK showed that at 14-month follow-up, structured patient education significantly improved diabetes knowledge scores in participants randomised to the patient-centred group-based self-management program (+1.8) compared with participants in the control group (+0.8)  $p < 0.001$ , with a mean difference of -1.5 (95%CI -2.3 to -0.7) (Deakin et al, 2006).

Trento and colleagues (2004) used the 38-item questionnaire that was developed by the Education Study Group of the Italian Society for Diabetes to measure knowledge scores in a 5-year RCT of continuing system education delivered by group (intervention) vs individual diabetes care (control). At five years, diabetes knowledge scores improved in the intervention (+12.4; 95%CI 9.7 to 15.2) but worsened in the control group (-3.4; 95%CI -1.1 to -5.7), a difference which was statistically significant ( $p < 0.001$ ).

A recent RCT in Germany tested the efficacy of three education programs: (A) didactic-orientated intervention focusing on the acquisition of knowledge, skills and information about the correct treatment of diabetes; (B) self-management/empowerment approach focused on emotional, cognitive, and motivational processes of behaviour change; and (C) lessons in an individual and group setting with the same approach as (B). No significant differences in diabetes-related knowledge were found between any of the three groups (Kulzer et al, 2007).

## 2. Self-management and behaviour change

- **Diabetes education has a positive effect on changing dietary habits (*Evidence Level I*)**
- **Diabetes education may increase the frequency of physical activity in the short-term (*Evidence Level I*)**
- **Diabetes education improves foot care behaviours (*Evidence Level I*)**
- **Effect of diabetes education on adherence to medical treatment and care is inconclusive (*Evidence Level I*)**
- **Diabetes education has a positive short-term effect on self monitoring of blood glucose (*Evidence Level I*)**
- **Diabetes education is effective in helping smokers with type 2 diabetes quit smoking (*Evidence Level I*)**

### a) Dietary habits

#### *Systematic reviews*

Although not the focus of their systematic review, Deakin et al (2005) reviewed the evidence of the effect of group education programs on self-management skills. Six of the 11 included studies measured some aspect of self-management. Of those six RCTs, one RCT measured food intake with a validated food frequency questionnaire. At 4-month follow-up, participants allocated to group education had increased energy intake from carbohydrate (difference 4.1%; 95%CI 0.4 to 7.9;  $p=0.03$ ), total sugars (difference 5.1%; 95%CI 2.4 to 7.9;  $p<0.001$ ) and more fruit and vegetable portions per day (difference 1 portion; 95%CI 0.2 to 1.8;  $p=0.01$ ) compared with those in the control group. At 14-month follow-up, trends suggested that participants in the group education were consuming more percentage energy from carbohydrate (difference 3.3%; 95%CI 0.3 to 6.9;  $p=0.07$ ), more energy from total sugars (difference 6.6%; 95%CI 3.4 to 9.9;  $p<0.001$ ), less energy from total fat (difference 2.7%; 95%CI 0.3 to 5.6;  $p=0.08$ ), less energy from saturated fat (difference 1.1%; 95%CI 0.0 to 2.3;  $p=0.05$ ) and an extra two portions of fruit and vegetables per day (difference 2.2 portions; 95%CI 1.1 to 3.2;  $p<0.001$ ) compared with those in the control group. Deakin's review also identified similar findings from another study that showed positive improvement in stages of change with regards to: reduction of high fat foods ( $p=0.008$ ); consumption of five portions of fruit and vegetables ( $p<0.0001$ ); consumption of three meals daily ( $p=0.9$ ); and limitation of refined sugar intake to one product per day or less ( $p=0.001$ ). This confirms earlier findings from the systematic review by Norris and colleagues (2001) that also reported positive effects of self-management training on self-reported dietary habits, including improvements in dietary carbohydrate or fat intake, decreased caloric intake and increased consumption of low glycaemic index food.

Another systematic review by Norris et al (2002b) could not demonstrate statistically significant changes in dietary intake, measured as kcal/day, in both men and women from one study. However, they concluded that there is insufficient evidence of effectiveness of DSME in community settings on the outcome of dietary intake due to the small number of studies.

A Canadian Health Technology Assessment (HTA) report identified a German multicentre RCT that reported on dietary behaviours in people with type 2 diabetes. This study found a significant improvements in the ratio of polyunsaturated to saturated fatty acids in the intervention group as compared with the control group ( $p < 0.001$ ) but , efforts to reduce energy intake and fat consumption were unsuccessful (Corabian & Harstall, 2001). The main limitation of that review is that only one RCT was identified.

### ***Primary studies***

The X-PERT Study showed that at 14-months follow-up, subjects in the self-management program were more likely to have increased daily consumption of fruit and vegetables (-2.2; 95%CI -3.2 to -1.1;  $p = 0.008$ ), decreased percentage of energy from sugar (-6.6; 95%CI -9.9 to -3.4;  $p = 0.02$ ) and decreased percentage of energy from sucrose (-2.7; 95%CI -4.2 to -1.3  $p = 0.01$ ) compared with subjects in the control group. Percentage of energy from fat, saturated fat and carbohydrate did not show a statistically significant difference (Deakin et al, 2006).

Ko and colleagues (2007) reported similar findings from an RCT in North Korea. This study showed that at 1, 2, 3 and 4 years follow-up, participants who had attended an intensive diabetes education program had a statistically significant improvement in dietary habits (measured by self-reported questionnaire) compared with conventional education ( $p < 0.001$  for all time points).

## **b) Physical activity**

### ***Systematic reviews***

Evidence of improvement in physical activity following diabetes education are not consistent. One study in the Deakin and colleagues (2005) review measured self-management scores for physical activity using a validated questionnaire and found a positive effect at both 4 ( $p < 0.001$ ) and 14 months ( $p = 0.02$ ), whereas another study found no effect. Norris et al (2001) review also show improvement in physical activity in four studies, whereas five other studies found no change. The Norris et al (2001) review acknowledged that it was unclear what factors might contribute to success in some studies but not others. However, one study identified in a later review by the same author showed a significant improvement in minutes of walking ( $p < 0.001$ ) (Norris et al, 2002b). The reviewers concluded that there is insufficient evidence on the effectiveness of DSME in community settings on the outcome of physical activity due to the small number of studies (Norris et al, 2002b).

Corabian and Harstall (2001) cited findings from only one RCT included in their review that reported on physical activity and type 2 diabetes. This study demonstrated a significant increase in physical activity in the intervention group compared with the control group ( $p < 0.001$ ).

### ***Primary studies***

Evidence from more recent primary studies is more promising. The X-PERT study group found at 4 months follow-up, a statistically significant positive effect on frequency of physical activity completed within the preceding 7 days as measured by the Summary of Diabetes Self-Care Activities (SDSCA) score (mean difference in SDSCA score -0.9 [95%CI -1.6 to -0.3]) and at 14 months (mean difference in SDSCA score -0.9 [95%CI -1.6 to -0.1]) in the intervention compared with the control group (Deakin et al, 2006).

Similar results were reported from two other RCTs published in 2007. First, a Korean study showed a statistically significant improvement in frequency of physical activity per week at 1, 2, 3 and 4 years follow-up ( $p < 0.001$  for all time points) in the intervention group compared with the control. 59.4% of people in the intervention group performed physical activity 3-4 times/week compared with 30.6% in control group as measured on a five point scale (Ko et al, 2007). Second, a German study compared the efficacy of three education programs: (A) a didactic-orientated intervention focusing on the acquisition of knowledge, skills and information about the correct treatment of diabetes; (B) self-management/empowerment approach focused on emotional, cognitive and motivational processes of behaviour change; and (C) a combination of individual and group settings using the same approach as (B). This study showed that regular exercise was significantly increased among treatment B and C subjects compared with treatment A subjects; both  $p < 0.0001$ . Treatment C had a poorer effect on exercise than treatment B (Kulzer et al, 2007).

Recently, Davies et al (2008) measured physical activity using the international physical activity questionnaire. Participants in the intervention group showed a greater increase in physical activity (reported in the previous week) at 4, 8 and 12 months follow-up time points, with a significant increase at 4 months ( $p = 0.046$ ). Odds ratios (ORs) (95%CI), adjusted for baseline values and cluster effects at 4, 8 and 12 months were 2.17 (1.01 to 4.66), 1.18 (0.61 to 2.26) and 1.11 (0.47 to 2.65), respectively.

### **c) Foot care**

#### ***Systematic reviews***

One study in Deakin and colleagues' (2005) systematic review reported a significant increase in participants self-management scores for foot care ( $p = 0.008$ ) at 4 months following group education intervention, which remained significant at 14 months.

Six of seven RCTs included in a systematic review by Bazian Ltd (2005) measured behavioural outcomes. The authors concluded that at best, the available evidence suggests that education programs may have small effects on improving self-reported foot care practice in the short-term and that those at higher risk of ulceration and amputation will have higher absolute benefit from educational interventions. There is no evidence that these changes are lasting and very limited evidence that education has any effect on the incidence of foot problems.

A systematic review by Valk et al (2002) reported very similar findings from 8 RCTs, 6 of which had subsequently been reviewed by Bazian Ltd (2005). Four of the 6 studies that assessed behaviour (ie washing, applying cream, inspecting feet, cutting toenails, performing foot

gymnastics), showed significant improvements at 6 and 18 months after education. Nevertheless, Valk et al (2002) concluded that due to poor methodology of all RCTs and conflicting findings, these results need to be viewed with caution and good quality RCTs are warranted to establish the efficacy of patient education in preventing foot ulcerations.

### ***Primary studies***

Deakin et al (2006) reported a statistically significant difference in frequency of foot care within the past 7 days at 4-months follow-up measured by the SDSCA score (mean difference in SDSCA score -0.7, 95%CI -1.1 to -0.4) and at 14-months (mean difference in SDSCA score -0.6, 95%CI -1.0 to -0.2) in the intervention compared with the control group. In contrast, a subsequent German RCT reported non-significant improvements in foot care (measured by self-report questionnaire) in all three treatment groups (Kulzer et al, 2007).

### **d) Adherence to medical treatment and care**

In 2005, Vermeire et al (2005) published a Cochrane review of 21 RCT that assessed the effects of interventions for improving adherence to treatment recommendations in people with type 2 diabetes. These interventions included nurse led interventions, home aids, diabetes educations. This review included only two studies of diabetes education interventions that met their inclusion criteria and reported on adherence to treatment recommendation (Vermeire et al, 2005). The first study, a 9-month RCT compared quarterly visits to a diabetes educator vs usual care. This RCT demonstrated a small increase in self-reported medication compliance in both intervention and control groups. The second study, a 12-month telephone call program focusing on behaviour and lifestyle change, assessed subjective reports of adherence and measured utilisation of medical services. There were no differences in the perceived mean change score of medicine taking, of taking recommended medical tests or in the use of preventive health services. However, clinical quality process measures for patients in the intervention group showed more frequent testing of HbA<sub>1c</sub>, low-density lipoproteins (LDLs), microalbuminuria and diabetes retinopathy. Vermeire's review concluded that it was difficult to draw general conclusions from this review due to issues of methodological qualities of those studies identified.

Recently, Wens et al (2008) performed a sub-analysis of eight studies from the systematic review by Vermeire et al (2005). Wens and colleagues justified the reporting of metabolic parameters as indirect outcomes of adherence, but no direct outcomes of adherence, comparing intervention and control groups, were reported. Three of four studies of face-to-face education and two studies of group education showed significant reductions in HbA<sub>1c</sub> levels. Two studies found significant reductions in fasting plasma glucose (FPG), total cholesterol, systolic BP, weight, and waist-hip ratio while two other studies of distance education by telemedicine also showed statistically significant reductions in HbA<sub>1c</sub> but no change in QOL. One study also reported more frequent SMBG and foot inspection in the intervention group. Due to poor quality of study designs, a variety of heterogeneous outcome measures in different time intervals, unclear definitions of adherence, and difficulties in evaluating different aspects of education performed, a reliable quantitative synthesis could not be conducted and general conclusions about the effectiveness of diabetes education on adherence to treatment recommendations could not be drawn.

## e) Self monitoring of blood glucose

### *Systematic reviews*

A systematic review by Deakin et al (2005) include two RCTs that assessed the impact of group education on SMBG. The first RCT demonstrated that self-management scores for SMBG levels increased at 4-months follow-up ( $p=0.009$ ) in participants allocated to a group education program but there was no significant difference between the groups at 14 months ( $p=0.17$ ). The second study showed that the percentage of participants who carried out SMBG was significantly higher in the group allocated to education program at both 1 and 2 years ( $p<0.005$ ).

Earlier systematic review by Norris et al (2001) found positive effects of DSMT on frequency and accuracy of SMBG, demonstrated by decreased discrepancy between measurements by education provider and patient. They concluded that education interventions had a short-term (<6 months) positive effect on SMBG skills.

### *Primary studies*

The X-PERT study reported a statistically significant increase in frequency of self-blood testing (measured by the SDSCA score) within the past seven days in the intervention compared with the control group at 4 months follow-up (mean difference in SDSCA score  $-0.9$  (95%CI  $-1.6$  to  $-0.2$ ). However, this difference was not statistically significant at 14 months (mean difference in SDSCA score  $-0.5$  (95%CI  $-1.3$  to  $0.3$ ) (Deakin et al, 2006).

The Korean RCT by Ko and colleagues (2007) showed a statistically significant improvement in SMBG (measured by self-reported questionnaire) at all time points ie at 1, 2, 3 and 4 years follow-up in the intervention compared with control group ( $p<0.001$  for all). Comparable significant improvements were also demonstrated in the German study in the three education programs (Kulzer et al, 2007).

## f) Smoking

### *Systematic reviews*

Two studies reviewed by Vermeire and colleagues (2005) reported on smoking cessation. One study assessed the effectiveness of a 6-month nurse-led education and counselling program on smoking cessation, self-reported and verified smoking cessation as well as the change in mean number of cigarettes per day. Smoking cessation incidence was 17% in the intervention group compared with 2.3% in the usual care group, a difference of 14.7% (95%CI 8.2 to 21.3%). The second study assessed the effect of three structured education programs (traditional, video, educator) on smoking cessation and reported that 41% of the smoking participants had quit smoking over the period of the study.

### *Primary studies*

The DESMOND trial (Davies et al, 2008) also reported that the odds of not smoking were 3.56 (95%CI 1.11 to 11.45;  $p=0.033$ ) higher in the intervention group at 12 months compared with the control group.

### 3. Clinical Outcomes

- **Diabetes education is likely to improve glycaemic control as measured by HbA<sub>1c</sub> but evidence of its effect on lipids and blood pressure is mixed (*Evidence Level I*)**
- **Diabetes education is effective in helping people with type 2 diabetes reduces body weight (*Evidence Level I*)**

#### a) Glycaemic control - HbA<sub>1c</sub>

##### *Systematic reviews*

A recent systematic review and meta-analysis of RCTs and CCTs evaluated the effectiveness of individual patient education on metabolic control (Duke et al, 2009). This review included nine studies involving 1359 participants that met the review pre-specified inclusion criteria. Six studies compared individual education to usual care and three compared individual education to group education (361 participants). In the six studies comparing individual face-to-face education to usual care, individual education did not significantly improve glycaemic control (weighted mean difference (WMD) in HbA<sub>1c</sub> -0.1% (95% CI -0.3 to 0.1, p = 0.33) over a 12 to 18 month period. However, there did appear to be a significant benefit of individual education on glycaemic control in a subgroup analysis of three studies involving participants with a higher mean baseline HbA<sub>1c</sub> greater than 8% (WMD - 0.3% (95% CI -0.5 to -0.1, p = 0.007). In the studies that compared individual with group education, there was no significant difference in glycaemic control between individual or group education at 12 to 18 months with a WMD in HbA<sub>1c</sub> of 0.03% (95% CI -0.02 to 0.1, P = 0.22).

Loveman et al (2008) conducted a systematic review to update their 2003 HTA Report of clinical effectiveness of patient education models for adults with type 2 diabetes (Loveman et al, 2003). Consistent with the 2003 review, this recent review revealed that the effects of patient education on diabetes control are generally small, but relatively long-lasting. Reviewers identified 6 RCTs that reported statistically significant improvement of HbA<sub>1c</sub> in intervention groups compared with control groups (Table 3). On the other hand, this review identified seven studies that found no statistically significant differences in HbA<sub>1c</sub> between intervention and control groups, despite what seem to be relatively large differences in mean levels of HbA<sub>1c</sub> in some of the studies. However, the authors acknowledged that the studies lacked methodological rigor (such as no randomisation, lack of control group, or high attrition rates) and concluded that effectiveness of educational interventions for type 2 diabetes on metabolic control is inconclusive (Loveman et al, 2008).

**Table 3: HbA1c or HbA1 in studies of diabetes education in adults with type 2 diabetes**

Author/Study design	Time-point	Intervention Mean (SD)	Control Mean (SD)	Difference between groups
Ko et al, 2007 RCT	Baseline	9.4 (2.0) (n = 219)	9.2 (1.9) (n = 211)	NS
	1 year	7.9 (1.7) (n = 174)	8.1 (1.5) (n = 187)	NS
	2 years	7.9 (1.5) (n = 168)	8.2 (1.5) (n = 169)	NS
	3 years	7.8 (1.5) (n = 167)	8.4 (1.6) (n = 148)	p = 0.004
	4 years	7.9 (1.2) (n = 161)	8.7 (1.6) (n = 147)	p = 0.0001
Deakin et al, 2003, 2006 RCTs	Baseline	7.7 (1.6) (n=157)	7.7 (1.6) (n=157)	NS
	14 months change	7.1 (1.1) (n=150) -0.6	7.8 (1.6) (n=141) 0.1	p < 0.05 p < 0.001
Brown et al, 2002 RCT	Baseline 1 year	11.81 (30) (n=128) 10.89 (2.56) (n=112)	11.8 (3.02) (n=128) 11.64 (2.85) (n=112)	
Trento et al, 2001, 2002, 2004 RCT	Baseline	7.4 (1.4) (n = 56)	7.4 (1.4) (n = 56)	-
	2 year	7.5 (1.4) (n = 43)	8.3 (1.8) (n = 47)	p < 0.01
	5 years Change 0-5 years	7.3 (1.0) (n = 42) -0.1 (95%CI -0.5 to 0.4)	9.0 (1.6) (n = 42) 1.7 (95%CI 1.1 to 2.2)	- p < 0.01
*Sarkadi and Rosenqvist, 2004 RCT	Baseline	~6.5 (n = 39)	~6.5 (n = 38)	NS
	1 year	6.2 (95%CI 5.7 to 6.7) (n = 33)	6.4 (95%CI 5.8 to 7.0) (n= 31)	NS
	2 years	6.1 (95%CI 5.5 to 6.7) (n= 33)	6.6 (95%CI 6.0 to 7.2) (n= 31)	p < 0.01
#Raz et al, 1988 RCT	Baseline 1 year	10.0 (2.7) (n=25) 8.25 (n=23)	9.6 (2.6) (n=26) 9.6 (n=26)	- -
	Change	- 1.75	0	p < 0.05

\*Baseline means and all CI estimated from graph #All estimates from graph  
Adapted from Loveman et al (2008)

A meta-analysis of studies of DSME in people with type 2 diabetes by (Conn et al, 2007) showed conflicting results. On average, compared with control groups, those in intervention groups who received DSME that included exercise recommendations had a significant improvement in HbA<sub>1c</sub> (p<0.001). The overall mean weighted effect size for two-group comparisons (54 studies) was 0.29 (higher mean for treatment than control). This effect size is consistent with a difference in HbA<sub>1c</sub> means of 0.45% (eg 7.38% for treatment subjects vs 7.83% for control subjects). For single-group studies the overall mean weighted effect size was 0.32-0.34. Control group subjects experienced no improvement in metabolic control during participation in the studies. Interventions that targeted multiple health behaviours resulted in smaller effect size estimates (0.22) than interventions that focused only on exercise behaviours (0.45). Studies with a greater proportion of female subjects reported lower effect sizes. Baseline HbA<sub>1c</sub> and body mass index (BMI) were unrelated to metabolic outcomes despite considerable heterogeneity in the magnitude of the intervention effect. This meta-analysis suggests that DSME that includes exercise

recommendations may be effective in improving metabolic control, and adults of any age and any level of HbA<sub>1c</sub> may benefit from exercise interventions.

The Cochrane review by Deakin et al (2005) reported results of meta-analyses of: three studies that assessed HbA<sub>1c</sub> at 4-6 months (heterogeneity of I<sup>2</sup> = 36.7%); seven studies at 12-14 months (I<sup>2</sup> = 18%); and two studies at 2 years (I<sup>2</sup> = 0%), respectively. The results of these meta-analyses (Table 4) showed statistically significant reduced HbA<sub>1c</sub> levels in favour of group-based diabetes education compared with control groups. Of the four studies not included in the meta-analyses due to high heterogeneity, two studies also showed significant improvements at 4- and 6-months follow-up while two other studies showed no significant difference. However, this was reflecting the baseline HbA<sub>1c</sub> which differed substantially between intervention and control groups. Deakin and colleagues concluded that group-based patient education in people with type 2 diabetes is effective in improving HbA<sub>1c</sub>.

**Table 4: Results of meta-analysis: effect of group programs on HbA<sub>1c</sub> levels**

Follow-up time	Reduction in HbA <sub>1c</sub> %	95% confidence interval	p-value
4-6 months (3 studies)	1.4%	0.8-1.9	<0.00001
12-14 months (7 studies)	0.8%	0.7-1.0	<0.00001
2 years (2 studies)	1.0%	0.5-1.4	<0.00001

Adapted from Deakin et al (2005)

Eighteen of 63 articles included in a systematic review by Gary et al (2003) provided sufficient information for pooled estimates of glycohaemoglobin (total GHb, HbA<sub>1</sub>, or HbA<sub>1c</sub>), with an overall significant reduction in mean glycohaemoglobin of -0.43% (95%CI -0.71 to -0.14; p=0.003) in intervention groups compared with controls. When results were stratified by quality score, the standardised effect size was 0.50% for studies with the highest quality scores (p=0.001) and -0.38% for lower quality scores (non-significant). Studies with larger sample size (≥100) showed a larger decline (-0.65; p=0.016) compared with studies with smaller sample size (<100) (-0.31; p=0.048). When studies were weighted by sample size, fasting blood glucose (FBG) was reduced by 1.3 mmol/L. Gary and colleagues concluded that educational and behavioural interventions in type 2 diabetes have produced modest improvements in glycaemic control.

Positive effects of DSMT on glycaemic control in studies with short follow-up (<6 months) were found in a review by Norris and colleagues (2001). Fourteen studies reported an improvement in HbA<sub>1c</sub> in intervention groups compared with control groups. Percentage change in HbA<sub>1c</sub> ranged from -26% to + 4% in the intervention groups and from -33% to +15% in the control groups. In three studies, HbA<sub>1c</sub> decreased in the control group, though only significantly in one study. In contrast, 10 studies found no significant effects of DSMT despite regular patient contact. With longer follow-up, interventions that used regular reinforcement throughout follow-up were sometimes effective in improving glycaemic control. Educational interventions that involved patient collaboration may be more effective than didactic interventions in improving glycaemic control. However, the authors acknowledged limitations of studies such as performance, selection, attrition, and detection bias, and limited external generalisability. The authors

recommended further research to assess the effectiveness of self-management interventions on sustained glycaemic control. A second systematic review by Norris et al (2002b), highlighted that DSME is effective in community gathering places for adults with type 2 diabetes and reduced GHb (pooled estimate -1.9%; 95%CI -2.4 to -1.4) and FBG (median absolute effect size -2.0 mmol/L with a range of -1.3 to -4.0).

To ascertain the efficacy of DSME on GHb and identify the predictors of its effect in adults with type 2 diabetes, Norris et al (2002a) conducted a review and meta-analyses of RCTs and CCTs that focus on glycaemic control. This review follow their earlier work published in 2001 (Norries et al, 2001). On average, individuals who received DSME had reduced GHb by 0.76% (95%CI 0.34 to 1.18) more than the control group at immediate follow-up; by 0.26% (0.21% increase to 0.73% decrease) at 1-3 months of follow-up; and by 0.26% (0.05 to 0.48) at  $\geq 4$  months of follow-up. GHb decreased more with additional contact time between patient and educator, a 1% decrease was noted for every additional 23.6h (13.3 to 105.4) of contact. The authors concluded that self-management education improves GHb levels at immediate follow-up, with increased contact time improving the effect. The benefit declined at 1-3 months, suggesting that learned behaviours change over time.

A more recent systematic review demonstrated that initial HbA<sub>1c</sub> level is the single most important factor affecting improvements in glycaemic control in response to patient education (Sigurdardottir et al, 2007). When initial HbA<sub>1c</sub> levels were  $\geq 8\%$  the reduction was 0.8 to 2.5% and if initial HbA<sub>1c</sub> level was  $\leq 7.9\%$  the change ranged from +0.1 to -0.7%. The differences between intervention and control groups in HbA<sub>1c</sub> mean reduction according to high or low initial HbA<sub>1c</sub> level was statistically significant ( $t(33) = -2.82, p=0.008$ ) despite the control groups receiving more than standard care in at least seven studies. Seven of 18 RCTs achieved more than 10% reduction in HbA<sub>1c</sub> level and four of these achieved post intervention HbA<sub>1c</sub> levels of  $\leq 7.0\%$ . For the intervention groups the relative HbA<sub>1c</sub> level reduction was on average 6 to 7% compared with the control groups.

A Cochrane review to assess the effects of interventions for improving adherence to treatment recommendations in people with type 2 diabetes in primary care, outpatient settings, and community and hospital settings documented no change or a non-significant reduction in HbA<sub>1c</sub> in the intervention compared with the control groups in four studies reporting on diabetes education interventions. Due to insufficient quality and similarity between primary studies, the authors were not able to pool the data and undertook a descriptive synthesis of included studies (Vermeire et al, 2005)

Corabian and Harstall (2001) reviewed findings from four meta-analyses, one of which was an update of a previous review and showed mixed results ie some trials reported significant improvements on measures of diabetes control while others did not. No precise conclusion could be made due to methodological issues of primary studies included in this review such as inadequate description of: study design, sample characteristics, intervention content, sample size, follow-up, and outcome measures used. However, one meta-analysis reported only small improvement in metabolic control in patients groups with a mean age of over 55 years, while another meta-analysis showed that higher quality studies produced smaller effect size for HbA<sub>1c</sub>. Findings of these meta-analyses should be interpreted with caution as all four meta-analyses

included people with type 1 diabetes and no analysis was carried out separately for type 2 diabetes.

### ***Primary studies***

Evidence from individual primary studies was not consistent. For example, findings from the most recent DESMOND RCT by Davies et al (2008) did not show a statistically significant difference in glycaemic control between the intervention and the control group at 1 year follow-up. The HbA<sub>1c</sub> baseline level was higher in the intervention group compared with the control group (8.3% vs 7.9%). Despite a decrease in HbA<sub>1c</sub> levels at 12 months by 1.49% in the intervention group compared with 1.21% in the control group, after adjusting for baseline and cluster, the difference was not significant: (95%CI -0.10% to 0.20%; p=0.52). Similar findings were also reported by an earlier RCT from Sweden (Adolfsson et al, 2007). The between-group difference in HbA<sub>1c</sub> was -0.3% (95%CI: -0.7 to 0.2) with a mean HbA<sub>1c</sub> level of 7.3% (SD 1.3) in intervention and 7.4% (SD 1.1) in the control group at 1-year follow-up. Structured education for people with type 2 diabetes resulted in a small but non-significant reduction in HbA<sub>1c</sub> levels.

A study by a research group from Germany (Kulzer et al, 2007) aimed to test the efficacy of three education programs (A) a didactic-orientated intervention focusing on the acquisition of knowledge, skills and information about the correct treatment of diabetes; (B) self-management/empowerment approach focused on emotional, cognitive and motivational processes of behaviour change; and (C) lessons in an individual setting and group setting. This study showed a fall in HbA<sub>1c</sub> in treatment B at 3 months, 0.7% of which was sustained at 15-months follow-up. In treatment A, HbA<sub>1c</sub> was unchanged throughout. HbA<sub>1c</sub> was significantly lower in group B compared to group A (p<0.017). Further, and contrary to the authors' hypothesis, the individual approach of treatment C had no effect on HbA<sub>1c</sub> compared with treatment B. With the more individualised approach of treatment C, there was a fall in HbA<sub>1c</sub> at 3 but not 15 months (treatment B vs. treatment C; p=0.73).

Hörnsten et al (2005) conducted an RCT in Sweden to evaluate the effectiveness of an educational intervention, focusing on patients' personal understanding of their illness for diabetes care compared with standard care. Contrary to the above three RCTs, at 12-months follow-up, the intervention group showed lower HbA<sub>1c</sub> levels (mean difference 0.94%; p<0.05) than the control group. Significant changes were also seen within the groups regarding HbA<sub>1c</sub> levels at 12 months. The levels decreased from 5.7% to 5.4% (SD ± 0.7) in the intervention group, while the control group increased from 5.8% to 6.4% (SD ± 1.1). The differences remained when adjusting for age, gender, BMI or changed treatment during the intervention period. The authors concluded that patients' personal understanding of diabetes, was effective in improving metabolic control. A 5-year follow-up of the same study did not alter the authors' conclusions. The mean HbA<sub>1c</sub> in the intervention group was still 5.71% (SD 0.85), while it had increased to 7.08% (SD 1.71) among the controls. The crude difference in HbA<sub>1c</sub> was 1.37% (p<0.001). The adjusted difference with HbA<sub>1c</sub> in 2001 as covariate was also 1.37% (p<0.0001). Other variables that were used as covariate variables were treatment upgrade, BMI, total cholesterol, high-density lipoprotein (HDL), LDL and triglycerides at baseline. None of these influenced the difference in HbA<sub>1c</sub> (Hörnsten et al, 2008)

Chen et al (2008) conducted an RCT in Taiwan to compare quarterly routine diabetes health education (program one) with the delivery of an eight page holiday specific diabetes counselling

pamphlet (program two). The mean change in HbA<sub>1c</sub> levels at the end of the holiday period in program one was 0.34% (95%CI 0.03 to 0.85%) vs program two 0.09% (95%CI -0.23 to 0.42%). However, at 12 months the mean HbA<sub>1c</sub> level in program one (7.95%) was higher than program two (7.78%) (data taken from graph). There was no statistical difference in FPG at visit four (ie 1-2 months post Chinese New Year holiday). The authors concluded that this study demonstrated that patients receiving a holiday specific diabetes counselling pamphlet maintained better glycaemic control than patients receiving regular diabetes health education.

## **b) Lipids**

### ***Systematic reviews***

A high quality Cochrane review by Deakin et al (2005) did not find a significant difference between the intervention group (group-based education) and control group (usual care) with regard to total cholesterol and triglycerides. At 4-6 months follow-up, three studies (n=629 participants) that measured total cholesterol showed substantial heterogeneity ( $I^2 = 55.7\%$ ) and a meta-analysis was not performed, but at 12-14 months, three studies (n=552) with no heterogeneity ( $I^2 = 0\%$ ) showed no statistically significant differences between groups (0.09 mmol/L, 95%CI -0.09 to 0.26;  $Z = 0.95$ ;  $p=0.34$ ). However, of studies that measured triglycerides, three studies with a total of 628 patients ( $I^2 = 10.5\%$ ) were included in a meta-analysis and demonstrated a trend towards reduced triglyceride levels in favour of the group education program (0.24mmol/L; 95%CI -0.04 to 0.52;  $Z = 1.68$ ;  $p=0.09$ ) at 4-6 months follow-up. However, four studies (n=652) with a heterogeneity of  $I^2 = 15.1\%$  showed no statistically significant differences between groups (-0.14 mmol/L; 95%CI -0.41 to 0.13;  $Z = 1.01$ ;  $p=0.31$ ) at 12-14 months.

An earlier review by Norris et al (2001) showed mixed effects of DSMT on participant's lipid levels. Effects tended to be more positive with interactive, individualised or repetitive rather than didactic interventions. Five studies produced improvement in total cholesterol (range -0.9 to -0.07 mmol/L), and one study on LDL; -0.4 mmol/L and HDL; +0.1 mmol/L. Three studies found initial positive results but no significant difference from baseline at final follow-up. Eight studies showed no beneficial effects on lipids. A subsequent systematic review reported a median absolute effect size of -0.14 mmol/L (range -3.0 to +0.3) for total cholesterol in participants attending DSME in a community setting (Norris et al, 2002b). Two studies assessed LDL cholesterol with a reduction of -1.9mmol/L in one study and an increase of +0.39 mmol/L in another. Two other studies measured triglycerides showed a reduction of 2.2 and 1.1 mmol/L.

### ***Primary studies***

A recent RCT evaluated the effectiveness of structured patient education on total cholesterol, HDL cholesterol, and triglyceride levels (Davies et al, 2008). A significant reduction was only seen in triglyceride levels at 8 months FOLLOW-UP in participants attending the intervention group ( $p=0.008$ ), however at 12 months this difference was no longer significant (-0.15 mmol/L; 95%CI: -0.37 to 0.07,  $p=0.18$ ).

Similarly, a German RCT could not demonstrate significant differences with regard to triglyceride or HDL levels (Kulzer et al, 2007). In contrast, Hörnsten et al (2005) reported that at 1 year follow-up, patients in the intervention group (received educational intervention) had lower

triglycerides (mean difference 0.52 mmol/L;  $p=0.002$ ) and higher HDL (mean difference 0.15 mmol/L;  $p=0.029$ ) than the control group. However, at 5 year follow-up there were no differences in total cholesterol, HDL, LDL, triglyceride levels (Hörnsten et al, 2008).

### c) Blood Pressure

#### *Systematic reviews*

A Cochrane review by Deakin et al (2005) demonstrated evidence of short-term significant reductions in systolic blood pressure (BP). Two studies that measured systolic and diastolic BP at 4-6 months follow-up ( $n=399$  participants) with no heterogeneity between the studies for systolic BP ( $I^2 = 0\%$ ) and low heterogeneity for diastolic BP ( $I^2 = 28.3\%$ ) were identified. A meta-analysis showed that systolic BP was significantly reduced in patients allocated to group education programs (5 mmHg; 95%CI 1 to 10;  $Z = 2.53$ ;  $p=0.01$ ) and there was a trend towards reduced diastolic BP (3 mmHg; 95%CI -6 to 0;  $Z = 0.38$ ;  $p=0.08$ ). At 12-14 months follow-up two studies measured BP ( $I^2 = 0\%$ ) and a meta-analysis shows that there was a small non significant reduction in systolic BP (3 mmHg; 95%CI -7 to 2;  $Z = 1.24$ ;  $p=0.22$ ). A meta-analysis could not be performed for diastolic BP due to substantial heterogeneity between the two studies ( $I^2 = 67.9\%$ ). However, neither of the two studies reported significant differences between the intervention and control group for diastolic BP.

Earlier systematic reviews showed mixed results (Norris et al, 2001; Norris et al, 2002b). In the 2001 review, one study demonstrated a decrease in systolic BP (-4 mmHg) and four studies in diastolic BP (-3 to -8 mmHg), respectively, whereas four studies showed no significant changes (Norris et al, 2001). Two studies included in the 2002 review demonstrated an improvement in systolic BP (mmHg) (-12.3 and -8.6 ) and diastolic BP (- 5.2 and -1.0) (Norris et al, 2002b). These two reviews did not provide sufficient evidence of an effect of diabetes education on BP.

#### *Primary studies*

Recent RCTs did not demonstrate effectiveness of patient education on BP levels in patients with type 2 diabetes (Hörnsten et al, 2005; Davies et al, 2008). The most recent RCT measured systolic and diastolic BP in people with newly diagnosed type 2 diabetes at 4, 8 and 12 months (Davies et al, 2008) found clinical significant improvements in both the intervention and control groups. However, after adjusting for baseline and cluster values, the authors found no statistically significant difference between the groups in systolic or diastolic BP.

### d) Body Mass Index/Weight

#### *Systematic reviews*

The Cochrane review by Deakin et al (2005) highlighted that there is no evidence that group-based diabetes education programs had an impact on body weight or BMI at 4 to 6 months follow-up. A meta-analysis of four studies ( $n= 566$ ), with low heterogeneity ( $I^2 = 31.3\%$ ) showed an overall non-significant reduction in bodyweight in the intervention group compared with the control group (2.1 kg, 95%CI -0.5 to 4.7;  $Z = 1.62$ ;  $p=0.11$ ). Four studies ( $n=718$ ) assessed BMI ( $I^2 = 0\%$ ) also showed a non-significant difference between groups of 0.2 kg/m<sup>2</sup> in favour of group education (95%CI -0.7 to 1.0;  $Z = 0.37$ ;  $p=0.71$ ). However, at 12-14 months follow-up, Deakin's review suggested that there was some evidence in favour of the group education

programs improving body weight but not BMI. This has been demonstrated in a meta-analysis of five studies, involving 591 patients, assessed body weight ( $I^2 = 0\%$ ) with a difference between the group education and control group of 1.6 kg (95%CI 0.3 to 3.0;  $Z = 2.32$ ;  $p=0.02$ ). Nonetheless, another meta-analysis of four studies ( $n=751$ ) assessed BMI at 12-14 months ( $I^2 = 0\%$ ) showed no effect (difference 0.45 kg/m<sup>2</sup>; 95%CI -0.2 to 1.2;  $Z = 1.15$ ;  $p=0.25$ ). Only one study measured waist circumference at both 4 and 14 months found no significant difference between the two groups at 4 months (difference 1.3 cm; 95%CI -1.8 to 4.1;  $p=0.44$ ) but a favourable effect of the group education program at 14 months (difference 2.8 cm; 95%CI -0.3 to 5.6;  $p=0.06$ ).

An earlier systematic review by Norris et al (2001) found 13 studies that demonstrated positive effects of patient education on weight loss. The average weight loss for these studies was ~2 kg (range 1.3–3.1). Most studies with positive weight loss results involved regular contacts or reinforcement sessions (six studies) or very short follow-up periods (two studies), although four studies had follow-up periods of  $\geq 5$  months. All studies with follow-up of  $\geq 6$  months (from the end of the intervention) failed to demonstrate significant differences in weight loss between control and intervention groups. Only one of three studies involving didactic interventions showed a decrease in weight. A subsequent review and meta-analysis of six of eight studies by Norris et al (2002b) reported differences in weight in participants attending for self-management education in community settings. Median absolute effect size was -2.4kg, with a range of -4.1kg to +0.7kg. The authors, however, conclude from both reviews that this evidence of effectiveness was insufficient due to the few studies and inconsistent results.

A review by Gary and colleagues (2003) found the weighted mean difference (by precision) was small for weight as an outcome (-2.1kg, CI -4.5 to 0.3). The weighted mean difference (by sample size) was -1.4kg and the unweighted mean difference was -0.7kg, presenting a small difference between intervention and control group.

### ***Primary studies***

Mixed results of the effect of diabetes education on body weight were observed in more recent studies. In the DESMOND trial, participants with newly diagnosed type 2 diabetes attending a structured group education program (intervention) showed a greater weight loss: -2.98 kg (95%CI -3.54 to -2.41) compared with 1.86 kg (95%CI -2.44 to -1.28;  $p=0.027$ ) in the control group at 12 months (Davies et al, 2008).

No significant difference in BMI between the intervention and the control group at 1 year follow-up was reported by Adolfsson and colleagues (2007). Participants in the intervention group did not improve their BMI, and between-group differences in BMI were 0.8%. In contrast, Hörnsten and colleagues (2005) found improved BMI within the intervention group when looking within the groups. The BMI decreased after 12 months from 29.4 to 28.7 (S.D.  $\pm 4.6$ ) in the intervention group, while the control group remained stable. However, there were no significant differences in BMI between the groups ( $p=0.08$ ) at 1 and 5 years follow-up (Hörnsten et al, 2005; Hörnsten et al, 2008).

## 4. Psychological adjustment and self-determination

- **Diabetes education improves health related quality of life including physical, psychological and social function (*Evidence Level I*)**
- **Diabetes education may have an effect in reducing depression and anxiety (*Evidence Level I*)**
- **Diabetes education may improve patients' self-efficacy/empowerment, psychological adjustment to diabetes, and enhance attitudes and beliefs about diabetes (*Evidence Level I*)**

### a) Quality of Life

#### *Systematic reviews*

A systematic review assessed the effect of interventions for adults with diabetes on health-related quality of life (HRQL), as measured by the SF-36 questionnaire (Zhang et al, 2007). The mean changes and standardised mean differences between pre- and post-intervention were reported as outcome measures. Pooled estimates were obtained using random effects models. A total of 33 studies examining a wide range of interventions, including diabetes education and behavioural modifications (15 studies), pharmacotherapy (11 studies), and surgery (seven studies), were identified. Pooled effects from five RCTs of educational interventions demonstrated significantly improved physical function 3.4 (95%CI 0.1 to 6.6) and mental health 4.2 (95%CI 1.8 to 6.6), and a decrease in bodily pain 3.6 (95%CI 0.6 to 6.7). A pooled effect for five pre-vs-post educational interventions also showed significantly improved social function 5.8 (95%CI 2.0 to 9.6), vitality 3.0 (95%CI 1.6 to 4.4), and mental health 2.5 (95%CI 0.6 to 4.4), and a decrease in role limitations due to physical problems 4.3 (95%CI 0.1 to 8.4). It was concluded that a variety of interventions can improve HRQL among adults with diabetes, but the magnitude of effects varied with the interventions.

Two studies in the Deakin and colleagues (2005) review measured QOL at 4-6 months using different validated questionnaires. It was not possible to synthesise and summarise those statistically, as the scales were too dissimilar. One study found no improvement in overall QOL but in respect to the sub-scales there were highly significant improvements in participants allocated to the group education program: freedom to eat (difference 1.7; 95%CI 0.8 to 2.5;  $p<0.001$ ); enjoyment of food (difference 1.2; 95%CI 0.2 to 2.1;  $p=0.046$ ); and freedom to drink (difference 1.5; 95%CI 0.4 to 2.5;  $p=0.005$ ). The other study found that participants in both the intervention and control groups significantly improved their score on the SF-36 mental scale (group allocated to group education,  $p<0.01$ ; control group,  $p=0.04$ ), but there was no significant difference between the groups ( $p=0.82$ ). Neither group had a higher score for the SF-36 physical score at 6 months (intervention group  $p=0.63$ , control group  $p=0.93$ ) and there was no significant difference between the groups ( $p=0.69$ ). At 12-14 months two studies measured QOL, which used different validated questionnaires. It was not possible to synthesise and summarise these statistically because the scales were ranked in opposite directions. At 14 months the first of these studies reported similar results to those at 4 months, namely no significant improvement in overall QOL, but significant improvements for the sub-scales: freedom to eat (difference 1.1;

95%CI 0.2 to 2.1;  $p=0.04$ ); enjoyment of food (difference 1.1; 95%CI 0.1 to 2.0;  $p=0.05$ ); and freedom to drink (difference 1.5; 95%CI 0.5 to 2.6;  $p=0.01$ ). The second study did not find a significant difference in QOL at 12 months but reported a significant improvement in QOL at 2 years ( $p<0.001$ ) and at 4 years ( $p<0.009$ ). The authors concluded that there is some evidence that group-based education programs improve QOL.

In a recent HTA report a systematic review was performed on the clinical effectiveness of patient education models for adults with type 2 diabetes (Loveman et al, 2008). Two published trials were found that reported on QOL using a validated scale. In the first trial the Diabetes Quality of Life (DQOL) scale was used. This study reported results from 2 years follow-up from inception; however, educational sessions were conducted every 3 months throughout the 2 year period. At 2 years the intervention (group sessions) significantly improved participants' QOL compared with baseline (DQOL/Mod score  $55.6 \pm 15.9$  vs  $67.6 \pm 19.0$ ,  $p<0.001$ ), whereas a deterioration was seen in the control group (individual sessions) ( $80.8 \pm 31.5$  vs  $66.7 \pm 25.0$ ). This difference was statistically significant between intervention and control groups ( $p<0.01$ ). In a follow-up study at 5 years this trend continued, where the mean change in DQOL was  $-23.7$  (95%CI -30.0 to -17.3) in the intervention group compared with 19.2 (8.4 to 29.9) in the control group ( $p<0.001$ ). In the other trial no statistically significant difference in QOL as measured by the Audit of Diabetes-Dependent Quality of life (ADDQOL) was observed between the treatment group and control group after 14 months, although it appeared that the change in mean scores was greater in the treatment group than the control group. In this study, the intervention–evaluation interval was much larger as participants had a 6 week intervention and then were followed up at 14 months. The authors speculated that positive effects may be attributable to longer-term interventions with a shorter duration between the end of the intervention and the follow-up evaluation point.

Norris and colleagues (2001) systematically reviewed the effectiveness of DSMT in type 2 diabetes. Three studies were included which assessed QOL. One study noted an increase in QOL at 18 months for an intervention subgroup that received intensive counselling on both diet and physical activity. Two studies of brief interventions did not find an improvement in QOL. A subsequent review found only one study that reported the effect of DSME delivered in the home on QOL in adults with type 2 diabetes (Norris et al, 2002b). This study reported no significant change in QOL, however no data were reported.

Another systematic review by Vermeire et al (2005) to assess the effects of interventions for improving adherence to treatment recommendations in people with type 2 diabetes identified one study involving diabetes education which measured QOL. This study compared the effectiveness of education classes plus weekly nurse telemedicine 'home visit' vs usual care and found no significant changes on a DQOL scale or on the SF-36 scale.

### ***Primary studies***

A recent RCT evaluated the effectiveness of a structured group education program (DESMOND) on biomedical, psychosocial, and lifestyle measures (Davies et al, 2008). Adjusted analyses show that the groups did not differ significantly in any of the scores for six dimensions of QOL (two overall scores and four subscale scores for physical, psychological, social, and environmental). In addition, the groups did not differ significantly for emotional impact of diabetes at 8 and 12 months ( $p=0.97$  and  $p=0.91$ , respectively).

Shibayama et al (2007) conducted an RCT to examine whether one-on-one lifestyle counselling for people with non-insulin-treated type 2 diabetes (mean age 61 years) in an outpatient setting and delivered by a Certified Expert Nurse (CEN) can improve participants' health outcomes. Participants were randomly assigned to a one-year lifestyle intervention (n=67) or to a usual care group (n=67). Main outcome measures included changes from baseline in the score of health related QOL scales as measured with validated self report instruments (SF-36 and Problem Areas in Diabetes Scale). No significant differences in health related QOL over one year were found between the two groups (p values ranged from 0.24 to 0.81).

The Improving Control with Activity and Nutrition (ICAN) RCT by Wolf et al (2004) assessed the efficacy of a lifestyle intervention in 147 obese subjects (BMI  $\geq 27$  kg/m<sup>2</sup>) with type 2 diabetes (mean age 53 years) at 12 months. The lifestyle intervention consisted of individual and group education and support by registered dietitians. Participants in the usual care group received educational material and both groups received ongoing primary care. Results show a significant improvement in HRQL (as measured by the SF-36) in the lifestyle intervention group compared to usual care (p<0.001) over the intervention period. In seven of nine QOL domains the lifestyle intervention group showed significantly greater improvement than the usual care group (p<0.05) at 12 months. The authors concluded that dietitian-led lifestyle intervention programs may improve diverse health indicators, such as QOL, in obese people with type 2 diabetes.

## **b) Depression and Anxiety**

### *Systematic reviews*

In the systematic review by Norris and colleagues (2001) the effectiveness of self-management training in type 2 diabetes was evaluated. Three studies reported on psychological outcomes: one study noted a reduction in anxiety levels at 4 weeks (p<0.05), while no significant results were found in the other two.

### *Primary studies*

In the DESMOND study, the intervention group had a lower depression score (measured by the validated hospital anxiety and depression scale) at 12 months compared to the control group, with a mean difference of -0.50 (95%CI -0.96 to -0.04; p=0.032) (Davies et al, 2008).

## **c) Empowerment/self-efficacy/attitudes and beliefs**

### *Systematic reviews*

Deakin and colleagues (2005) located two studies which assessed the effect of diabetes education on empowerment/self-efficacy. Validated questionnaires were used in both studies to assess outcome variables. In the first study, at 4 months there was a significant difference in total empowerment score between the two groups in favour of the group education program (difference 0.3; 95%CI 0 to 0.6; p<0.001). That was also the case for the three sub scales: psychosocial adjustment to diabetes (difference 0.3; 95%CI 0 to 0.6; p=0.002); readiness to change (difference 0.4; 95%CI 0.2 to 0.5; p<0.001); and setting and achieving goals (difference 0.3; 95%CI 0.2 to 0.5; p<0.001). At 14 months, empowerment scores were still significantly higher amongst subjects allocated to the group education program: the total empowerment score was 3.5 for the group education program participants as opposed to 3.2 for the control group

(difference 0.3; 95%CI 0.04 to 0.6;  $p=0.006$ ); psychosocial adjustment to diabetes (difference 0.3; 95%CI 0.02 to 0.7;  $p=0.005$ ); readiness to change (difference 0.3; 95%CI 0.1 to 0.5;  $p=0.001$ ); and setting and achieving goals (difference 0.2; 95%CI 0.05 to 0.4;  $p=0.02$ ). The second study found that at 6 months, both the intervention and control groups significantly improved their psychological adjustment to diabetes ( $p<0.01$ ) but there was no statistical significance between the two groups ( $p=0.64$ ). It was concluded that there is some evidence that group-based education programs improve empowerment/self-efficacy, however, due to the limited number of studies further research is required.

### ***Primary studies***

Adolfsson et al (2007), conducted an RCT aimed to evaluate the impact of empowerment group education on the confidence of people with type 2 diabetes, in terms of their self-efficacy and satisfaction with daily life compared to the impact of routine diabetes care. At 1 year follow-up, no significant differences were found in self-efficacy ( $p=0.272$ ) and satisfaction with daily life ( $p=0.588$ ) between the intervention and control group.

In the DESMOND study, adjusted analyses show that compared with the control group, the intervention group had significantly greater changes in four illness belief scores (coherence, timeline, personal responsibility, and seriousness) ( $p=0.001$ ); directions of change were positive indicating greater understanding of diabetes and its seriousness (Davies et al, 2008).

## 5. Long-term health outcomes

- **Diabetes education is associated with a reduction in cardiovascular events and microvascular complications such as retinopathy and end stage nephropathy (Evidence Level I)**

### a) Mortality

#### *Systematic reviews*

Systematic reviews that reported on mortality rates as endpoints of diabetes education, showed no effect. In the systematic review by Deakin and colleagues (2005), group-based diabetes education did not show an effect on mortality rate (OR 1.2, 95%CI 0.3 to 5.6,  $Z = 0.29$ ,  $p=0.77$ ). Overall there were eight deaths in the intervention group and seven deaths in the control group over a 12-14 month outcome assessment period as reported from three studies ( $n=525$  participants) with low heterogeneity ( $I^2 = 36.3\%$ ).

One study included in a review by Norris et al (2001) did not find a significant difference in mortality 13 months after a 1 hour group didactic educational session.

### b) Complications

#### *Cardiovascular events*

#### *Systematic reviews*

Only one study included in the systematic review by Norris and colleagues (2001) examined cardiovascular disease (CVD) events. This study assessed the effects of a diabetes education intervention where people were followed-up every 3 months over 5 years. No significant differences in CVD events were found after 5 years follow-up. Similarly, a HTA report (Corabian and Harstall, 2001) concluded that the published literature shows mixed inconclusive results in terms of diabetes education reducing the risk of diabetes associated long-term complications including CVD.

#### *Primary studies*

A randomised, prospective study was undertaken by Rachmani et al (2005) in high risk individuals (including type 2 diabetes, hypertension, and hyperlipidemia). Patients were randomised to receive standard consultation (SC) or patient participation (PP). This study documented 72 CVD events in 45 patients of the SC group vs 47 in 31 patients in the PP group. The total number of CVD events was 80 vs 52, respectively ( $p=0.001$ ). The relative risk (RR) over 8 years for a cardiovascular event in the intervention (PP) vs the control (SC) group was 0.65 (95%CI 0.89 to 0.41;  $p=0.001$ ) (Table 5). There were 17 cases of stroke (fatal and non-fatal) in the SC vs 8 cases in the PP group ( $p=0.01$ ). RR for stroke was 0.47 (95%CI 0.85 to 0.32). There were also fewer coronary events and interventions in the PP than in the SC patients ie 56 vs 41 (fatal/nonfatal myocardial infarction [MI]/coronary artery bypass graft/percutaneous coronary intervention [PCI]), respectively ( $p=0.005$ ). Also, the participants of the PP program

had fewer bypass surgeries than their SC counterparts (3 vs 7). A Kaplan-Meier estimation of combined cardiovascular event-free survival in the SC vs PP group was statistically significant (p=0.004). It needs to be noted that although there was no direct pharmaceutical intervention and no prescriptions were issued by the consultation team in this study, patients in the intervention group were more likely to receive angiotensin-converting enzyme inhibitors or angiotensin II antagonists than those in the control group at both 4 and 8 years follow-up (p<0.05 for both time intervals). Also, at 4 and 8 years 81% and 96% of PP patients were prescribed lipid-lowering medication vs 34% and 59 % of the SC patients, respectively (p<0.05 for both time intervals). The prescribed daily doses of most of the antihypertensive agents and those of statins were higher in the PP than in the SC group. Glucose-lowering medications were not different in the two groups.

**Table 5: Eight-year Relative Risk reduction of CV parameters - intervention vs control groups**

Parameters	RR (95%CI)
MI	0.79 (1.0–0.45)
Stroke	0.47 (0.85–0.32)
CABG/PCI	0.70 (0.94–0.34)
Nonfatal CV events	0.65 (0.89–0.41)
CV mortality	0.62 (1.2–0.31)
Non-CV mortality	1.0

CABG: coronary artery bypass graft; CI: confidence interval; CV: cardiovascular; MI: myocardial infarction; PCI: percutaneous coronary intervention; RR: relative risk.  
Table adopted from Rachmani et al (2005)

### ***Retinopathy and end stage renal disease/nephropathy***

#### ***Systematic reviews***

Only one study reviewed by Deakin et al (2005) monitored the presence of diabetes complications. The study reported that at 2 years no significant differences between the group education participants and controls were seen with regard to diabetes retinopathy. However, at 4 years diabetes retinopathy had progressed more slowly amongst participants that had attended the group education program (p<0.009).

Retinopathy was assessed in one RCT that was included in the systematic review by Loveman et al (2008), but it showed no significant difference between intervention and control groups at 2 years follow-up.

#### ***Primary studies***

The RCT by Rachmani et al (2005) showed a greater average annual decline in estimated e-GFR in the control (SC) vs intervention (PP) groups (4.6 ± 2.1 vs 3.0 ± 1.8 ml/min per 1.73 m<sup>2</sup>, respectively) (p<0.01). Overt nephropathy (albumin/creatinine ratio >300 mg/g) developed in 14

(22%) patients in the control group vs 7 (12.5%) in the intervention group ( $p=0.01$ ). Four subjects in the intervention group and one in the control group developed end stage renal disease. No standard method was used to assess neuropathy. This study found that the relative risk reduction of microvascular complications in the intervention vs the control group was 0.57 (95%CI 0.91 to 0.28). However the authors noted that subjects in the intervention group were more likely to receive angiotensin-converting enzyme inhibitors or angiotensin II antagonists than those in the control group.

### ***Foot ulceration and amputation***

#### ***Systematic reviews***

In their HTA report, Loveman et al (2008) acknowledge the difficulty of performing long-term studies to specifically assess the effect of education on long-term end-points. Their review identified very few studies that included complications as outcomes, usually because the follow-up in the included studies was too short. One RCT evaluated the effect of patient education intervention on incidence of foot ulcers and reported that after 2 years follow-up there was no statistical difference between the two groups.

Two of four RCTs which measured clinical endpoints suggested that patient education reduces incidence of foot ulceration (Bazian Ltd, 2005). The first study involved an intensive, foot-specific education program delivered by nurse clinicians. The intervention did reduce the incidence of serious foot lesions ( $p<0.05$ ), but there was no significant effect on amputations (OR 0.32, 95%CI 0.05 to 1.86). The second study involved one hour foot care education, as part of a broader education, for people at very high risk of foot problems. The intervention significantly reduced the incidence of foot ulcers (15% vs 5%;  $p\leq 0.005$ ) and foot and limb amputations (12% vs 4%;  $p\leq 0.025$ ) at 26 months.

A previous review (Valk et al, 2002) reported similar findings from eight RCTs, six of which also later had been reviewed by Bazian Ltd (2005). Authors of both reviews concluded that due to poor methodology of all RCTs, and conflicting findings, results need to be viewed with caution and good quality RCTs are warranted to establish the efficacy of patient education in preventing foot ulcerations.

The systematic review by Deakin et al (2005) found one study reporting on foot ulcers at 2 years follow-up. There was no statistically significant difference between the group education participants and controls in this study.

Mixed results were reported from several studies that examined interventions focusing on foot lesions (Norris et al, 2001).

#### ***Primary studies***

Patients in the intervention group (PP) in a study conducted in Israel had fewer amputations than their SC counterparts (3 vs 7). It is not known, however, if this difference was significant as the authors did not provide this information (Rachmani et al, 2005).

## 6. Health service utilisation

- **Limited evidence suggests that diabetes education may reduce diabetes related hospital admissions (*Evidence Level I*)**

### a) Number and length of hospital stay

In a systematic review by Norris et al (2001) only one of five studies included in the review showed a decrease in emergency room visits 4 months after a short-duration patient education intervention ( $p=0.005$ ). Results from four other studies that reported on outcomes of admissions to emergency rooms and length of hospital stay found no significant difference between intervention and control groups.

Evidence from a recent RCT of a structured intensive diabetes education program (SIDEPE) by Ko et al (2007) reported that the frequency of admissions related to diabetes complications was significantly lower in the SIDEPE group compared with the control group during the 4 years observation period ( $p=0.005$ ). The most frequent cause of hospital admission in both groups was infection.

### b) Visits to specialist services

The percentage of patients with an eye examination was reported in one study reviewed by Norris et al (2002b). The OR of an eye examination in the prior 6 months was 4.3 in subjects receiving DSME in the home (home visits, computer-assisted instruction, and electronic communication with healthcare professionals). There was no significant decrease in the number of urgent care visits per person in two other studies. However, one of these studies included people with type 1 diabetes.

Similarly, Rachmani et al (2005) demonstrated in their RCT that over 8 years, participants in the intervention group initiated 826 additional visits to the consultation clinic, on average  $1.2 \pm 0.8$  additional consultations per annum compared to the standard consultation control group. The main reason given by the patients was a failure to meet one or more of the risk factor target values. In a Japanese study, participants in the intervention group (one-to-one lifestyle counselling by certified expert nurses) visited hospitals clinics more times than those in the control group ( $12 \pm 2$  times vs  $11 \pm 3$ ;  $p=0.03$ ) (Shibayama et al, 2007)

### c) Others (sick leave)

Only one of five studies in a review by Norris et al (2001) demonstrated more sick leave events per year for control compared with intervention subjects ( $p<0.05$ ). Results from four studies found no significant difference between intervention and control groups in number of sick days and duration of sick leave events. The authors conclude that most studies examining health care utilisation failed to demonstrate improvements in these parameters.

## Summary – Is structured diabetes patient education effective?

- A number of systematic reviews and RCTs have demonstrated that diabetes education for people with type 2 diabetes improves their knowledge and understanding of the condition; improves HbA<sub>1c</sub> and QOL at least in the short-term.
- While earlier systematic reviews reported conflicting results, more recent RCTs suggest diabetes education is effective in increasing physical activity and improving foot care and SMBG behaviour.
- Improved self-efficacy, empowerment, psychological adjustments to diabetes and enhanced attitudes and beliefs about diabetes have been reported in participants following diabetes education.
- Diabetes education may have an effect in lowering depression and reducing anxiety.
- There is inconclusive evidence and lack of primary studies on the effect of education on adherence to medical treatment, long-term outcomes and health service utilisation.
- Pooling of data has been hampered by the use of inconsistent assessment tools between studies, lack of description of education delivery and poor methodology of some RCTs reviewed in systematic reviews. Many authors point out the need for more standardised, well described education delivery models and the use of consistent outcome measurement tools.
- There is a need for good quality and long-term studies to quantify the effect of diabetes education on long-term endpoints

## Evidence Tables: Section 1

### Is Diabetes Patient Education Effective?

#### 1. Changing knowledge

Author, year	Evidence				
	Level of evidence		Quality rating	Magnitude of effect rating	Relevance rating
	Level	Study type			
Adolfsson et al, 2007	II	RCT	High	High	High
Davies et al, 2008	II	Multicentre cluster RCT	High	High	High
Deakin et al, 2005	I	Systematic review of RCTs and CCTs	High	High	High
Deakin et al, 2006	II	RCT	High	High	High
Kulzer et al, 2007	II	RCT	Medium	Low*	Medium
Norris et al, 2002b	I	Systematic review of all types of comparative study designs	Medium	N/A	High
Norris et al, 2001	I	Systematic review of RCTs	Medium	High	High
Trento et al, 2004	II	RCT	Medium	High	High
Valk et al, 2002	I	Systematic review of RCTs	Medium	High	High

\*Not significant ; N/A No results of pooled data available; results reported descriptively

## 2. Changing self-management behaviour

### a) Dietary habits

Author, year	Evidence				
	Level of evidence		Quality rating	Magnitude of effect rating	Relevance rating
	Level	Study type			
Corabian and Harstall, 2001	I	Systematic review meta-analyses RCTs	Medium	N/A	High
Deakin et al, 2006	II	RCT	High	High	High
Deakin et al, 2005	I	Systematic review of RCTs and CCT	High	High	High
Ko et al, 2007	II	RCT	Medium	High	High
Norris et al, 2001	I	Systematic review of RCTs	Medium	N/A	N/A
Norris et al, 2002b	I	Systematic review of all types of comparative study designs	Medium	High	High

N/A: No results of pooled data available; results reported descriptively

## b) Physical activity

Author, year	Evidence				
	Level of evidence		Quality rating	Magnitude of effect rating	Relevance rating
	Level	Study type			
Corabian and Harstall, 2001	I	Systematic review meta-analyses RCTs	Medium	N/A	High
Davies et al, 2008	II	Multicentre cluster RCT	High	Low	High
Deakin et.al, 2006	II	RCT	High	Medium	High
Deakin et al, 2005	I	Systematic review of RCTs and CCTs	High	Low	High
Ko et al, 2007	II	RCT	Medium	Medium	High
Kulzer et al, 2007	II	RCT	Medium	Medium	Medium
Norris et al, 2001	I	Systematic review of RCTs	Medium	N/A	N/A
Norris et al, 2002b	I	Systematic review of all types of comparative study designs	Medium	Low	High

N/A: No results of pooled data available; results reported descriptively

c) **Foot care**

<b>Author, year</b>	<b>Evidence</b>				
	<i>Level of evidence</i>		<i>Quality rating</i>	<i>Magnitude of effect rating</i>	<i>Relevance rating</i>
	<i>Level</i>	<i>Study type</i>			
Bazian Ltd, 2005	I	Systematic review of systematic reviews and RCTs	Medium	N/A	N/A
Deakin et.al, 2006	II	RCT	High	High	High
Deakin et al, 2005	I	Systematic review of RCTs and CCT	High	High	High
Kulzer et al, 2007	II	RCT	Medium	Low*	Medium
Valk et al, 2002	I	Systematic review of RCTs	Medium	N/A	High

\* Not significant, N/A: No results of pooled data available; results reported descriptively

**d) Adherence to medical treatment and care**

<b>Author, year</b>	<b>Evidence</b>				
	<i>Level of evidence</i>		<i>Quality rating</i>	<i>Magnitude of effect rating</i>	<i>Relevance rating</i>
	<i>Level</i>	<i>Study type</i>			
Vermeire et al, 2005	I	Systematic review of RCTs	Medium	N/A	Medium
Wens et al, 2008	I	Systematic review of RCTs and CCTs	Medium	N/A	Low

N/A: No results of pooled data available; results reported descriptively

e) **Self monitoring of blood glucose**

<b>Author, year</b>	<b>Evidence</b>				
	<i>Level of evidence</i>		<i>Quality rating</i>	<i>Magnitude of effect rating</i>	<i>Relevance rating</i>
	<i>Level</i>	<i>Study type</i>			
Deakin et.al, 2006	II	RCT	High	High	High
Deakin et al, 2005	I	Systematic review of RCTs and CCTs	High	High	High
Ko et al, 2007	II	RCT	Medium	High	Medium
Kulzer et al, 2007	II	RCT	Medium	Low*	Medium
Norris et al, 2001	I	Systematic review of RCTs	Medium	N/A	N/A

\* Not significant, N/A: No results of pooled data available; results reported descriptively

f) Smoking

Author, year	Evidence				
	<i>Level of evidence</i>		<i>Quality rating</i>	<i>Magnitude of effect rating</i>	<i>Relevance rating</i>
	<i>Level</i>	<i>Study type</i>			
Davies et al, 2008	II	Multicentre cluster RCT	High	High	High
Vermeire et al, 2005	I	Systematic review of RCTs	Medium	High	Medium

### 3. Improving clinical outcomes

#### a) Glycaemic control - HbA<sub>1c</sub>

Author, year	Evidence				
	Level of evidence		Quality rating	Magnitude of effect rating	Relevance rating
	Level	Study type			
Adolfsson et al, 2007	II	RCT	High	Low*	High
Chen et al, 2008	II	RCT	Medium	Low <sup>(-)</sup>	High
Conn et al, 2007	I	Meta-analysis	Medium	Low / Medium**	High
Corabian and Harstall, 2001	I	Systematic Review meta-analyses RCTs	Low	N/A	N/A
Davies et al, 2008	II	RCT	High	Low*	Medium
Deakin et al, 2005	I	Systematic review of RCTs and CCTs	High	High	High
Duke et al, 2009	I	Systematic review of RCTs and CCTs	High	Low*/ Medium <sup>#</sup>	High
Gary et al, 2003	I	Meta-analysis	High	High	High
Hörnsten et al, 2008	II	RCT	Medium	Medium	Medium
Hörnsten et al, 2005	II	RCT	Medium	High	High
Kulzer et al, 2007	II	RCT	Medium	Low	low
Loveman et al, 2008	I	Systematic review of RCTs and CCTs	High	Medium	High
Norris et al, 2002a	I	Meta-analysis of RCTs	High	High (<4 months) Low (> 4 months)	High
Norris et al, 2002b	I	Systematic review of comparative study designs	Medium	Low	Medium
Sigurdardottir et al, 2007	I	Systematic review of RCTs	High	High	High
Vermeire et al, 2005	I	Systematic review of RCTs and CCTs	Medium	Low*	Medium

\*Not significant; \*\*Medium when intervention focus on exercise; N/A No results of pooled data available; results reported descriptively; # high in subgroup analysis of three studies involving participants with a higher mean baseline HbA<sub>1c</sub> greater than 8%; (-) negative effect

**b) Lipids**

<b>Author, year</b>	<b>Evidence</b>				
	<i>Level of evidence</i>		<i>Quality rating</i>	<i>Magnitude of effect rating</i>	<i>Relevance rating</i>
	<i>Level</i>	<i>Study type</i>			
Davies et al, 2008	II	RCT	High	Low	N/A
Deakin et al, 2005	I	Systematic review of RCTs and CCTs	High	Low*	High
Hörnsten et al, 2008	II	RCT	Medium	High	High
Hörnsten et al, 2005	II	RCT	Medium	Low*	High
Kulzer et al, 2007	II	RCT	High	Low*	High
Norris et al, 2001	I	Systematic review of RCTs	Medium	Low	N/A

\*Not significant

c) **Blood pressure**

Author, year	Evidence				
	Level of evidence		Quality rating	Magnitude of effect rating	Relevance rating
	Level	Study type			
Davies et al, 2008	II	RCT	High	Low*	High
Deakin et al, 2005	I	Systematic review of RCTs and CCTs	High	Medium (<12 months) Low* (>12 months)	High
Hörnsten et al, 2005	II	RCT	Medium	Low*	High
Norris et al, 2002b	I	Systematic review of comparative study designs	Medium	Low	High
Norris et al, 2001	I	Systematic review of RCTs	Medium	Low	N/A

\*Not significant

**d) Body weight**

<b>Author, year</b>	<b>Evidence</b>				
	<i>Level of evidence</i>		<i>Quality rating</i>	<i>Magnitude of effect rating</i>	<i>Relevance rating</i>
	<i>Level</i>	<i>Study type</i>			
Adolfsson et al, 2007	II	RCT	High	Low*	Medium
Davies et al, 2008	II	RCT	High	High	High
Deakin et al, 2005	I	Systematic review of RCTs and CCTs	High	Low*	High
Gary et al, 2003	I	Meta-analysis	High	Medium	High
Hörnsten et al, 2008	II	RCT	Medium	Low*	Medium
Hörnsten et al, 2005	II	RCT	Medium	High	Medium
Norris et al, 2002b	I	Systematic review of comparative study designs	Medium	Medium	Medium
Norris et al, 2001	I	Systematic review of RCTs	Medium	High	High

\*Not significant

## 4. Improving the quality of psychological adjustment and self-determination

### a) Quality of life

Author, year	Evidence				
	Level of evidence		Quality rating	Magnitude of effect rating	Relevance rating
	Level	Study type			
Davies et al, 2008	II	RCT	High	Low*	High
Deakin et al, 2005	I	Systematic review	High	Medium	High
Loveman et al, 2008	I	Systematic review	High	Medium	High
Norris et al, 2002b	I	Systematic review	Medium	Low*	High
Norris et al, 2001	I	Systematic review	Medium	Medium	High
Shibayama et al, 2007	II	RCT	Medium	Low*	High
Vermeire et al, 2005	I	Systematic review	High	N/A	Low
Wolf et al, 2004	II	RCT	High	High	High
Zhang et al, 2007	I	Systematic review of RCTs and pre-post studies	Medium	High	High

\*Not significant ; N/A: No results of pooled data available; results reported descriptively

**b) Depression and anxiety**

<b>Author, year</b>	<b>Evidence</b>				
	<i>Level of evidence</i>		<i>Quality rating</i>	<i>Magnitude of effect rating</i>	<i>Relevance rating</i>
	<i>Level</i>	<i>Study type</i>			
Davies et al, 2008	II	RCT	High	High	High
Norris et al, 2001	I	Systematic review	Medium	Medium	High

**c) Empowerment/self-efficacy/attitudes and beliefs**

<b>Author, year</b>	<b>Evidence</b>				
	<i>Level of evidence</i>		<i>Quality rating</i>	<i>Magnitude of effect rating</i>	<i>Relevance rating</i>
	<i>Level</i>	<i>Study type</i>			
Adolfsson et al, 2007	II	RCT	High	Low*	High
Davies et al, 2008	II	RCT	High	High	High
Deakin et al, 2005	I	Systematic review	High	Medium	High

\* Not significant

## 5. Improving long-term health outcomes

### a) Mortality

Author, year	Evidence				
	Level of evidence		Quality rating	Magnitude of effect rating	Relevance rating
	Level	Study type			
Deakin et al, 2005	I	Systematic review of RCTs and CCTs	High	Low	High
Norris et al, 2001	I	Systematic review of RCTs	Medium	N/A	N/A

\*N/A: No results of pooled data available; results reported descriptively

## b) Complications

### *Cardiovascular events*

Author, year	Evidence				
	Level of evidence		Quality rating	Magnitude of effect rating	Relevance rating
	Level	Study type			
Corabian and Harstall, 2001	I	Systematic review meta-analyses RCTs	Low	N/A	N/A
Norris et al, 2001	I	Systematic review of RCTs	Medium	Low*	Medium
Rachmani et al, 2005	II	RCT	Medium	High	High

\*Not significant; N/A: No results of pooled data available; results reported descriptively

### *Retinopathy and end stage renal disease*

Author, year	Evidence				
	Level of evidence		Quality rating	Magnitude of effect rating	Relevance rating
	Level	Study type			
Deakin et al, 2005	I	Systematic review of RCTs and CCTs	High	Low	High
Loveman et al, 2008	I	Systematic review of RCTs and CCTs	High	Low*	N/A
Rachmani et al, 2005	II	RCT	Medium	High	High

\*Not significant

### *Foot ulceration and amputation*

Author, year	Evidence				
	Level of evidence		Quality rating	Magnitude of effect rating	Relevance rating
	Level	Study type			
Bazian Ltd, 2005	I	Systematic review of RCTs	Medium	Low	High
Deakin et al, 2005	I	Systematic review of RCTs and CCTs	High	Low*	High
Loveman et al, 2008	I	Systematic review of RCTs and CCTs	High	Low*	N/A*
Norris et al, 2001	I	Systematic review of RCTs	Medium	Low	N/A*
Valk et al, 2002	I	Systematic review of RCTs	Medium	Low	High
Rachmani et al, 2005	II	RCT	Medium	Low	High

\*Not significant

## 6. Improving health service utilisation

### a) Number and length of hospital stay

Author, year	Evidence				
	Level of evidence		Quality rating	Magnitude of effect rating	Relevance rating
	Level	Study type			
Ko et al, 2007	II	RCT	High	High	High
Norris et al, 2001	I	Systematic review of RCTs	Medium	Low	Low

### b) Visits to specialist service

Author, year	Evidence				
	Level of evidence		Quality rating	Magnitude of effect rating	Relevance rating
	Level	Study type			
Norris et al, 2002b	I	Systematic review of comparative study designs	Medium	Low	N/A
Norris et al, 2001	I	Systematic review of RCTs	Medium	Low	N/A
Rachmani et al, 2005	II	RCT	Medium	N/A	N/A
Shibayama et al, 2007	II	RCT	Medium	High	Medium

N/A: No results of pooled data available; results reported descriptively

## Section 2: Delivery of diabetes education

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### Question

How should education for people with diabetes be delivered?

### Recommendation

Diabetes education should be delivered in groups or individually (Grade A)

### Practice Points

- Diabetes education, where possible, should be delivered by a multidisciplinary team.
- Education programs should be comprehensive and should include a component on physical activity
- People with diabetes should be encouraged to actively participate in goal setting and decision making
- Educational interventions should be followed by regular reinforcement

### Evidence Statements

- Both group and individual diabetes patient education provided on a face-to-face basis has positive effects in increasing knowledge, life style changes and some aspects of psychological outcomes  
*Evidence Level I*
- Diabetes education that includes a focus on exercise may be more effective in improving HbA<sub>1c</sub>  
*Evidence Level I*
- Diabetes education based on active patient participation may increase its effectiveness  
*Evidence Level I*

- Educational interventions delivered over longer periods with a short follow-up and those with regular reinforcement have been shown to be more effective than one-off or short-term interventions

*Evidence Level I*

- Diabetes education delivered in primary care, hospital diabetes units, and community gathering places is effective.

*Evidence Level I*

- A variety of health care disciplines can successfully provide patient education (ie diabetes educators, nurses, dietitians, pharmacists, psychologists, podiatrists or physicians) but patient education delivered by a multi-disciplinary team may afford better opportunity for improving patient outcomes

*Evidence Level I*

## **Background – How should diabetes education be delivered?**

Diabetes education can be successfully delivered by various health care professionals, including physicians, dietitians, nurses, psychologists, social workers, pharmacists or other health professionals (Corabian & Harstall, 2001). However, comprehensive diabetes education is usually provided by diabetes educators - who have additional training in diabetes care and education in addition to basic training in their specific discipline.

A variety of settings including hospital in-patient wards and outpatient clinics, specialist diabetes centres, primary care practices and community locations are used to provide diabetes education. Australia has a network of specialist ambulatory care Diabetes Centres which are usually attached to metropolitan public hospitals but are increasingly found in major rural centres. These Centres provide comprehensive diabetes care including treatment and patient education delivered by a multidisciplinary team (Eigenmann & Colagiuri, 2007) and are the internationally dominant model of diabetes care. Other education settings, which seek to promote ease of access and which recognise the influence of community networks, include primary care, community centres, pharmacies and other community gathering places eg churches (Norris et al, 2006) with practice nurses being an increasingly common source of diabetes education in the community/primary care setting.

Diabetes education is believed to be most effectively delivered face-to-face although videos and web-based interventions can play an important role in augmenting face-to-face education (Krishna et al, 1997; Balas et al, 2004). Most of the available research establishing the effectiveness of diabetes education has studied group education ( Funnell, 2004; Loveman et al, 2008) However, a recent Cochrane systematic review provides evidence of the effectiveness of individual patient education for people with type 2 diabetes (Duke et al, 2009). Although both psychosocial and health outcomes have been improved through a variety of diabetes education programs, reinforcement and ongoing self-management support is vital if these benefits are to be sustained (Funnell, 2004; Duke et al, 2009)..

Over the last decade or two the focus of diabetes education has shifted from a doctor/nurse didactic information-giving style of education to a more patient-centred approach. Therapeutic patient-centred education has been promoted since the 1970s when Jean-Phillipe Assal first introduced the approach in the treatment of diabetes including medical, psychological and educational care (Maldonato et al, 1995). Since then, various learning and behaviour theories (eg health belief model, empowerment, self-efficacy, socio-behavioural model) have been tested and reported in the literature (Corabian & Harstall, 2001; Krichbaum et al, 2003; Funnell, 2004; Anderson et al, 2005).

Demonstrating comparative advantages of different education models, delivery modes, and settings is problematic due to inadequate description of interventions (Corabian & Harstall, 2001). This precludes reliable conclusions to which type of program or what components are most effective and lack of agreed goals and indicators (Muhlhauser & Berger, 2000; Eigenmann & Colagiuri, 2007). Evaluation is further complicated by factors such as the competence of the health care staff (Colagiuri et al, 1994) and it has, therefore, been difficult to determine the impact of educational interventions (Peeples et al, 2001).

Diabetes Australia's recent National Consensus on Outcomes and Indicators of Diabetes Patient Education was designed to address many of these issues (Eigenmann & Colagiuri, 2007). Previous attempts to increase consistency in the delivery and evaluation of diabetes education include curricula, standards, and competencies for diabetes educators such as those produced by the International Diabetes Federation, (DECS, 2002; 2003) the American Association of Diabetes Educators (Mensing et al, 2003) and the Australian Diabetes Educators Association (<http://www.adea.com.au>).

## Evidence – How should diabetes education be delivered?

Due to the small number of systematic reviews and primary studies exclusively in people with type 2 diabetes which addressed this question, we have included major relevant and recent (2000 to 2008) systematic reviews that did not separate type 1 and 2 in their analysis.

### 1. Group education and individual education

- **Both group and individual diabetes patient education provided on a face-to-face basis has positive effects in increasing knowledge, life style changes and some aspects of psychological outcomes (*Evidence Level I*)**

#### *Systematic Reviews*

Systematic reviews have not demonstrated a significant difference in HbA<sub>1c</sub> levels between group and individual education (Gary et al, 2003; Norris et al, 2002a). Gary et al (2003) conducted stratified analysis for pooled effect sizes for glycosylated haemoglobin based on method of delivery (individual vs group) and reported a similar effect sizes of -0.62% (p=0.005) and -0.70% (p=0.015), respectively for individual and group education. Norris et al (2002a) performed a meta-regression analysis, using the mean difference between intervention and control groups as dependent variables, to investigate treatment interactions of group vs individual intervention presentation and found no significant interaction.

The systematic review by Norris et al (2001) of the effectiveness of DSMT in type 2 diabetes reported that

- lifestyle interventions were generally effective in group settings with positive outcomes on weight loss (noted in 9 studies) and glycaemic control (demonstrated in 5 studies)
- both individual (evidence from 5 studies) and group lifestyle interventions (3 studies) have positive effects on diet and self-care behaviours and also seem equally effective for interventions that focus on knowledge and SMBG
- group programs are more cost-effective than individual education

A systematic review by Deakin et al (2005) found significant improvements in FBG levels, HbA<sub>1c</sub>, diabetes knowledge, reduction in systolic BP levels, body weight and reduced requirements for diabetes medication in participants of group-based training compared with routine care. However, no direct comparison between group vs individual was provided.

Another systematic review of provider-patient interaction included one RCT which demonstrated that group consultations over a two years period maintained stable diabetes control and improved blood lipids, BMI, diabetes health behaviour, diabetes knowledge and QOL scores compared with individual consultations (van Dam et al, 2003).

A recent Cochrane review (Duke et al, 2009) evaluated the effectiveness of individual education on metabolic control, diabetes knowledge and psychosocial outcomes. Nine studies involving 1359 participants met the inclusion criteria. The authors identified six studies that compared individual face-to-face education to usual care. Individual education did not significantly improve glycaemic control - WMD in HbA<sub>1c</sub> -0.08% (95%CI -0.25 to 0.08, p=0.33) over a six to twelve month period. There was also no significant improvement in BMI, blood pressure or total cholesterol in the short (6-9 months) and medium term (12-18

months). However, a subgroup analysis of three studies involving participants with a baseline HbA<sub>1c</sub> greater than 8%, showed a significant benefit of individual education on glycaemic control (WMD - 0.31% (95%CI -0.54 to -0.09, p=0.007). The authors also compared individual education with group education. Analysis of data from three studies did not demonstrate a significant difference in glycaemic control between group education compared with individual education at 12 - 18 months with a WMD in HbA<sub>1c</sub> of 0.03% (95%CI -0.32 to 0.08, p=0.22). However, at 6 - 9 months, group education appeared to have a greater impact on glycaemic control than individual education, with a WMD in HbA<sub>1c</sub> of 0.81% (95%CI 0.34 to 1.29, p=0.0007). There was no significant difference in the effect of individual education compared with group education on BMI, systolic or diastolic BP. A qualitative review suggested no difference in QOL, self-management skills or knowledge between group and individual education. The authors concluded that this meta-analysis suggests a benefit of individual education on glycaemic control when compared with usual care in a subgroup of those with a baseline HbA<sub>1c</sub> greater than 8%.

### **Primary studies**

A number of recent RCTs compared group education with standard care in people with type 2 diabetes. Davies et al (2008) evaluated the effectiveness of a structured group education program compared with usual care for established and newly diagnosed people with type 2 diabetes (DESMOND). At 12 months, HbA<sub>1c</sub> levels had decreased by 1.49% in the intervention group compared with 1.21% in the control group. After adjusting for baseline and cluster, the difference was not significant: 0.05% (95%CI -0.10% to 0.20%). The intervention group showed a greater weight loss: -2.98 kg (95%CI -3.54 to -2.41) compared with 1.86 kg (95%CI -2.44 to -1.28) (p=0.027) in the control group at 12 months. Self-reported physical activity in the previous week was significantly increased at 4 months OR=2.17 (95%CI 1.01 to 4.66, p=0.046) but showed no significant difference at 8 and 12 months between intervention and control groups. The odds of not smoking were 3.56 (95%CI 1.11 to 11.45, p=0.033) higher in the intervention group at 12 months. The intervention group showed significantly greater beneficial changes in illness belief scores (p=0.001) and a lower depression score at 12 months (mean difference -0.50, 95%CI -0.96 to -0.04, p=0.032). The authors conclude that structure group education programs that focus on behaviour change can successfully engage participants in commencing additional effective lifestyle changes sustainable over 12 months.

A German study by Kulzer et al (2007) assessed the efficacy of three education programs for people with type 2 diabetes - (A) a didactic-orientated group intervention focusing on the acquisition of knowledge, skills and information about the correct treatment of diabetes; (B) a self-management/ empowerment group approach and focusing on emotional, cognitive and motivational processes of behaviour change; (C) a combination of lessons in individual and group settings. Efficiency was measured at 3 (t1) and 15 months (t2) from baseline (t0). Results showed a fall in HbA<sub>1c</sub> in program B at 3 month which was sustained at 15 months (t0 8.1 ± 1.8%, t1 7.3 ± 1.7%, t2 7.4 ± 1.9%). In program A, HbA<sub>1c</sub> was unchanged throughout (t0 7.6 ± 1.5%, t1 7.5 ± 1.3%, t2 7.7 ± 1.7%; program A vs B; p<0.05). With the more individualised approach of program C, there was a fall in HbA<sub>1c</sub> at 3 month, but this was not sustained at 15 month (t0 7.8 ± 1.6%, t1 7.1 ± 1.3%, t2 7.6 ± 1.6%; program B vs C; p=0.73). There were also significant benefits in program B subjects compared with treatment A in other medical (BMI and FBG), psychological (control, irritability and hunger dependency of eating behaviour, and trait anxiety) and behavioural (exercise) variables.

Another RCT by Adolfsson et al (2007) in central Sweden, evaluated the impact of empowerment group education on the confidence of people with type 2 diabetes in diabetes knowledge, self-efficacy and satisfaction with daily life compared with the impact of routine diabetes care. The intervention group consisted of a 6 week empowerment group education program of 2 hours per week. The control group underwent the same routine diabetes care in their primary care centre which included usual visits to their diabetes specialist and specialist nurse and also individual counselling and recommendations based on biochemical and SMBG tests. At 1-year follow-up, the level of confidence in diabetes knowledge was significantly higher in the intervention group than in the control group ( $p < 0.012$ ). However, no significant differences were found in self-efficacy and satisfaction with daily life. BMI and HbA<sub>1c</sub> were not significantly different in the groups at one year.

A 5-year RCT of continued education delivered by group (intervention) vs individual diabetes education (control) was conducted in a hospital diabetes care unit in Italy ( Trento et al, 2004). Group sessions were held every three months with one or two physicians and an educator. The control group continued with traditional one-on-one consultation and education sessions. Results showed an improvement in diabetes knowledge, problem solving ability and QOL at 5 years follow-up in the group care but worsened in the control group ( $p < 0.001$  for all). QOL improved from year 2 with group but worsened in the individual diabetes care group ( $p < 0.001$ ). HbA<sub>1c</sub> increased in the control group (+1.7%; 95% CI 1.1 to 2.2) over the 5 years but not in the intervention group (-0.1%; 95% CI -0.5 to 0.4;  $p < 0.001$ ). BMI decreased in the group program (-1.4; 95% CI -2.0 to -0.7,  $p = 0.067$ ) and HDL increased (+0.14mmol/L; 95% CI 0.07 to 0.22, NS) compared with the control group. The authors concluded that a traditional one-on-one care including consultation and education sessions is associated with progressive deterioration of knowledge, problem solving ability and QOL. Educational procedures delivered in a group setting and tailored to participants needs can improve knowledge, glycaemic control and behaviour.

## 2. Education mode/approaches/styles

- **Education that includes a focus on exercise may be more effective in improving HbA<sub>1c</sub> (*Evidence Level I*)**

### a) Educational focus

#### *Systematic reviews*

The meta-regression analysis by Norris et al (2002a) examined the impact of the educational focus such as lifestyle, skills, knowledge, coping skills and revealed that the effect on HbA<sub>1c</sub> levels was not related to the educational focus. Although, most studies focusing on changes in lifestyle generally failed to show improvements in glycaemic control compared with control groups, a few studies showed improved glycaemic control in researcher-selected or volunteer populations with follow-up <6 months.

The results from the data mining analysis by Sigurdardottir et al (2007) were similar to those reported by Norris et al (2002a). The author reported that delivery and teaching methods, or content were not related to differences in HbA<sub>1c</sub> levels pre- to post-intervention. The most common delivery method was face-to-face (17 studies) and content was most often reported as teaching about basic diabetes knowledge and self-care skills such as diet and exercising, medication adherence, SMBG and psychosocial aspects. All interventions apart from one used collaborative teaching methods such as goal setting, problem solving and cognitive reframing.

In contrast, Gary et al (2003) conducted a stratified analysis and pooled effect sizes for glycohaemoglobin based on intervention topics (diet, exercise, medication and monitoring) and demonstrated that studies with a focus on medication adherence had the largest effect size (-0.72%; p=0.032), followed by exercise (-0.69%; p=0.007), diet (-0.51%; p=0.008) and SMBG (-0.20%; p<0.001).

Effect sizes of interventions that targeted exercise behaviour only were smaller in the review by Conn and colleagues (2007) (effect sizes 0.45) but did result in larger metabolic outcomes than those that attempted to change multiple self-management behaviours (effect sizes 0.22), despite considerable heterogeneity in the magnitude of the intervention effect. Conn et al (2007) suggested that interventions that emphasise exercise may be particularly effective in improving metabolic control. This conclusion was supported by the meta-regression analysis by Ellis et al (2004) that demonstrated a larger decrease in the post-intervention HbA<sub>1c</sub> in interventions which included exercise as a part of the content (the Coefficient -0.84, p=0.038; 95%CI: -1.63 to -0.05).

### b) Collaboration and patient involvement

- **Diabetes education based on active patient participation may increase its effectiveness (*Evidence Level I*).**

#### *Systematic reviews*

Norris and colleagues (2001) highlighted that patient education that involves collaboration and patient participation are more effective on glycaemic control than didactic approaches,

particularly if interventions were repetitive (results are presented under the ‘regular reinforcement subheading’). Norris et al (2002a) also demonstrated that interactive or individualised repetitive interventions were more likely to be positive on lipids and BP. These findings are consistent with findings from more recent reviews (van Dam et al, 2003; Loveman et al, 2008).

The systematic review of provider-patient interaction by Van Dam et al(2003) concluded that interventions that directly focus on enhancing patients’ participation in diabetes care proved to be the most powerful ones as evident from results of four studies included in their review. These were: an automated telephone management program (GHb of intervention group – 0.7%, control group -0.2%), a patient empowering group education (GHb of intervention group – 0.73%, control group -0.04%), a guided preparation for diabetes consultations (GHb of intervention group – 1.53%, control group -0.35%), and the group consultation experiment (GHb of intervention group +0.1%, control group +0.9%). One study showed that interventions that focused on change of provider behaviour were less effective, than the patient centred intervention. The authors advocate a shift from the traditional medical model (doctor, disease, and glucose level-centred model, blaming the patient for non-compliance), towards a patient participation, patient-centred, sharing, patient empowerment model.

Interventions which used a cognitive reframing teaching method, had a larger decrease in the post-intervention HbA<sub>1c</sub> as was demonstrated in the meta-regression analysis by Ellis et al (2004). This analysis suggested that 21% of study heterogeneity may be attributed to the use of the cognitive reframing teaching method. The authors define cognitive reframing teaching as “*providers suggesting alternate self-perceptions that are more advantageous to a person with diabetes’ self-management*”. They further postulate that educational models that employ cognitive reframing are likely to include a larger amount of psychosocial interaction and require the patient to become more engaged in the process.

### **Primary studies**

A research group from the Netherlands examined the effectiveness of a theory-driven self-management course in reducing cardiovascular risk in patients with screen-detected type 2 diabetes, taking ongoing medical treatment into account (Thoolen et al, 2007). The intervention group received a self-management course based on theories of proactive coping and self-regulation and emphasised the elements of anticipation, goal setting, planning, and problem solving to help participants move beyond the intentions to achieve optimal self-care. The control group received a brochure on self-management. Multi regression analysis showed that the self-management course significantly reduced BMI at the 9-months follow-up regardless of medical treatment with a difference of -0.77 kg/m<sup>2</sup> or 2.6kg (p<0.001). Intervention participants gradually lost weight with a net loss of – 0.39 kg/m<sup>2</sup> while control participants increased by + 0.38 kg/m<sup>2</sup>. Systolic BP also reduced significantly (mean difference -6.2 mmHg; p<0.05) up until the 9-month follow-up, regardless of medical treatment. The self-management intervention had no effect on HbA<sub>1c</sub> and lipid levels in either group. However, intensive medical treatment was also independently associated with lower BP, HbA<sub>1c</sub>, total cholesterol, and LDL before the course and further improvements in systolic BP (-4.7 mmHg). Patients receiving both intensive medical treatment and the self-management course therefore had the best outcomes. Authors concluded that a combination of behavioural and medical interventions is particularly effective in reducing cardiovascular risk in newly diagnosed patients.

A computer-assisted patient-centred intervention increased patient perception of autonomy support relative to the computer-based control condition ( $p < 0.05$ ) in a study by Williams et al (2007). Competence at 12 months was associated with 12-month outcomes, HbA<sub>1c</sub>, diabetes distress, and depressive symptoms. Separate ANOVA analyses were performed to test the hypothesis that the intervention would have a positive impact on the experience of provider autonomy support and on perceived competence, after controlling for baseline autonomy support and competence, and adjusting for age and number of chronic conditions. Patients in the intervention experienced greater autonomy support from their providers than did patients in the usual care condition, and this difference was significant at 12 months ( $p < 0.05$ ), but not at 6 months ( $p < 0.30$ ). There was a trend for the patients to experience greater perceived competence at 6 ( $p < 0.20$ ) and at 12 months ( $p < 0.10$ ), but neither increase in perceived competence was significant.

### c) **Theoretical models**

#### *Systematic reviews*

In a sub-group analysis of the systematic review by Deakin et al (2005), only 5 of the 11 included studies identified the theoretical model underpinning the group education program which was based on therapeutic patient education, patient activation and empowerment. Deakin et al (2005) concluded that based on patient education using the principles of empowerment, participation and adult learning group education programs have proved to be efficacious.

In contrast, Sigurdardottir et al (2007) demonstrated no statistically significant difference in reduction in HbA<sub>1c</sub> level between theory guided interventions and non-theory guided interventions ( $t(16) = -0.66$ ,  $p = 0.516$ ) as evident from 10 of 18 studies that were included in the data-mining analysis.

#### *Primary studies*

Two RCTs by Davies et al (2008) and Adolfsson et al (2007) both applied an empowerment approach to their group education interventions. Both RCTs showed no significant change in HbA<sub>1c</sub> in the longer term. However, some psychological parameter produced favourable outcomes compared to control groups as detailed above (under subheading group education and individual education).

Similarly, results from an earlier RCT from the USA (Williams et al, 2005), which compared an activation intervention to passive education, indicated that HbA<sub>1c</sub> was lowered significantly across the entire population. However, neither relative nor absolute HbA<sub>1c</sub> improved significantly more in the activation condition than in the education condition. The intervention effect was also tested by comparing the percentage of patients in the activation and education groups who achieved a 12-month criterion value of 'healthy' HbA<sub>1c</sub>, defined as one point above the upper limit of normal and no significant effect was found (Williams et al, 2005). Nonetheless, rated active involvement during the intervention visits was found to be significantly correlated with number of questions asked ( $r = 0.39$ ,  $P < 0.001$ ,  $n = 151$ ) and with percent time speaking ( $r = 0.67$ ,  $P < 0.001$ ,  $n = 151$ ). The clinical relevance of rated active involvement was reflected in its correlation with HbA<sub>1c</sub> at baseline ( $r = -0.18$ ,  $p < 0.05$ ). Further, simultaneous regression analyses revealed a significant effect of activation condition, such that patients experiencing the activation intervention were rated as asking more questions ( $p < 0.01$ ), and as speaking a greater percentage of time ( $p = 0.01$ ) than patients receiving passive education.

**d) Group size**

Two of the studies included in the systematic review by Deakin et al (2005) had larger groups comprising between 16 and 18 participants (and some carers) in each diabetes education program. A subgroup analysis did not show reduced effectiveness of the intervention with studies of large groups.

**e) Computer aided education**

*Systematic reviews*

Computers as an educational tool have shown mixed results in terms of impact on glycaemic control and knowledge. The systematic review by Norris et al (2001) identified three studies that reported positive effects and two studies did not report a statistically significant difference. Of those three studies that showed positive effects, one study (n=174; mean age 57 years) demonstrated at 4-6 months a decreased HbA<sub>1c</sub> of -1.3% (p<0.05) in the computer knowledge assessment program (KAP) with feedback compared with no intervention. In a second study participants (n=105; mean age 45 years) enrolled in an interactive computer program on diet (90min/month over 6 months) increased knowledge (p<0.0001) but no statistically significant difference was observed in the control group (wait list) at 12 months follow-up. The third study (n=40; mean age 57 years) demonstrated a statistically significant difference (p=0.001) in GHb between the intervention (computer assisted intervention of 4 x 1hr didactic session with some feedback and testing) and the control group (didactic group teaching) at 3 months follow-up with a relative GHb change of 11% in the intervention group and 14% in the control group).

### 3. Duration of intervention and length of session

- **Educational interventions delivered over longer periods with a short follow-up and those with regular reinforcement have been shown to be more effective than one-off or short-term interventions (*Evidence Level I*).**

#### *Systematic reviews*

A systematic review by (Norris et al, 2001) examined the effectiveness of DSMT in type 2 diabetes. The seventy-two studies identified in this review ranged from one hour individual education to a twelve month intervention. The author's found positive effects of DSMT on frequency and accuracy of SMBG, self-reported dietary habits and glycaemic control in interventions of less than 6 months follow-up (Norris et al, 2001). In interventions with longer follow-up, regular reinforcement was required to produce these outcomes.

In their systematic review, Loveman et al (2008) revealed that in general the educational programs that affected diabetes control were those delivered over longer intervals with a shorter duration between the end of the intervention and the follow-up evaluation point, although they found few interventions that did result in long-lasting effects on HbA<sub>1c</sub> despite longer intervals between the last point of contact with the educators and the point of outcome measurement. It was noted that interventions varied considerably in whether sessions were provided over a short interval or spaced out over time. In one of the longest studies the interventions were spread throughout a 4-year period but the timing varied among patients, while the briefest interventions lasted for 1 month.

Further evidence suggest that intensive education programs, with increased contact time between patient and healthcare provider may be more effective (Loveman et al, 2008; Conn et al, 2007; Bazian Ltd, 2005; Norris et al, 2002a). Loveman et al (2008) included 13 studies in their review with considerable variation in the number of hours of contact between the patients and providers for each intervention. This ranged from approximately 2.5 hours (in a 6-month intervention) to 52 hours (1-year intervention in two studies). Some interventions began with 2–4 intensive sessions of 90–120 minutes followed up with additional sessions at 3 and 6 months.

a review by Bazian Ltd (2005) concluded that increased contact time between patient and healthcare provider may be more effective than a one-off, home-based education session to prevent foot ulcers in people with diabetes. This evidence was highlighted also by Norris et al (2002a) who showed increased contact time improved the effect of DSMT on glycaemic control. HbA<sub>1c</sub> decreased more with additional contact time between patient and educator, with a 1% decrease for every additional 23.6h (13.3-105.4) of contact. Total contact time was reported in addition to the number of contacts in 15 studies, with a total of 21 HbA<sub>1c</sub> measurements.

A review by Conn et al (2007) showed a weak relation between the number of weeks' intervention and favourable metabolic outcomes for two group comparisons. The number of weeks' intervention was weakly related to metabolic outcomes for two group comparisons ( $\beta_1=0.168$  in terms of log (days) such that the predicted mean effect size increased with increasing duration of intervention. For example, a tenfold increase in intervention duration increases the predicted mean effect size by 0.168; doubling it increased predicted mean effect size by  $0.168 \times \log 2 = 0.051$ . However, duration per session was not significantly related to outcomes.

Other systematic reviews could not detect statistically significant associations between reduction in HbA<sub>1c</sub> level and attributes such as duration and intensity of interventions (Deakin et al, 2005; Sigurdardottir et al, 2007).

Duration of the program does not appear to alter the effectiveness of the education as was concluded by Deakin et al (2005). A subgroup analysis showed that the least intensive group education programs, delivered in two RCTs, incorporated only three to four hours of education during the first year had similar results with regard to HbA<sub>1c</sub> as those resulting from the most intensive program that delivered 52 hours of education and support in the same time period. No actual results were presented for this sub-analysis. Deakin et al (2005) did however observe that providing additional education sessions on an annual basis can result in long-lasting benefits to health and psychosocial outcomes. They further proposed that thorough analysis of educational concepts and methods for evaluation of qualitative analysis may be warranted.

#### 4. Setting

- **Diabetes education delivered in primary care, hospital diabetes units, and community gathering places is effective (*Evidence Level I*).**

##### *Systematic reviews*

Deakin et al (2005) identified three of the four studies included in the HbA<sub>1c</sub> meta-analysis at 4 to 6 months were delivered in primary care. They also identified one study in which the education delivered at a hospital diabetes unit (secondary care). When a subgroup analysis was performed on the primary care studies that had been included in the original meta-analysis, the significant reduction in HbA<sub>1c</sub> remained for group education participants (1.1%; 95%CI 0.6 to 1.6; Z=4.43; p<0.00001). When the studies based at a hospital diabetes unit were removed from the 12-14 month meta-analysis on HbA<sub>1c</sub> and a subgroup analysis was carried out on the studies delivered in primary care, the significant reduction in HbA<sub>1c</sub> remained (0.9%; 95%CI 0.8 to 1.0; Z =12.89; p<0.00001). Deakin et al (2005) concluded that there is no evidence to suggest that programs delivered in either primary or secondary care are more efficacious. This statement was mirrored by Loveman et al (2008), who also concluded that there is no conclusive evidence as to what intervention setting is most effective. Similarly, a 'mini-review' by Zabaleta and Forbes (2007) did not present sufficient evidence of the effectiveness of diabetes group education for type 2 diabetes patients when delivered in primary care. This review included only studies of group based education programs that were structured, had a documented curriculum and provided sufficient details of the exact nature of the intervention.

The systematic review by Norris et al (2002b) summarised findings from four studies and highlighted that DSME is effective in community gathering places (faith-based institutions, community centres, libraries, and private (non clinical) facilities) for adults with type 2 diabetes in terms of improving GHb (pooled estimate -1.9%, 95%CI -2.4 to -1.4).

## 5. Educators and training

- **A variety of health care disciplines can successfully provide patient education (ie diabetes educators, nurses, dietitians, pharmacists, psychologists, podiatrists or physicians) but patient education delivered by a multi-disciplinary team may afford better opportunity for improving patient outcomes (Evidence Level I).**

### *Systematic reviews*

The systematic review by Loveman et al (2008) included four studies in which patient education appears to have been provided by one person. The individual educators included diabetes research technician, diabetes nurse, physician, or physician assistant. This review also included eight published studies in which education training was provided by a team. The most frequent health professionals delivering diabetes education in teams were nurses (eight studies), dietitians (five studies), physicians (three studies), community workers (two studies), pharmacists (two studies), and educationalist and medical students (one study) were also involved in education delivery. Loveman et al (2008) found that five of the eight studies that demonstrated statistically significant improvement in HbA<sub>1c</sub> measures, were interventions delivered by a team of different professions, but two studies using such teams did not produce significant differences in HbA<sub>1c</sub>. Therefore, Loveman et al (2008) concluded that a multi-professional team delivering the educational program would give the best opportunities for patient outcomes improvements. Loveman identified only three published studies that mentioned that they trained educators. In two studies nurses and dietitians attended seminars on diabetes education and participated in a supervised clinical practicum with outpatients; and community workers with type 2 diabetes participated in an 8-week program on diabetes self-management. In the third study nurse trainers trained together, were provided with a training manual, and each ran a supervised pilot course to ensure standardisation of content and reduce potential treatment heterogeneity. However, the review did not present data from those studies.

A sub group analysis by Deakin et al (2005), of five studies with a total of 869 participants, demonstrated that the effect size of group education programs delivered by nurses and/or dietitians vs routine care on HbA<sub>1c</sub> levels was the same as that of the full meta-analysis (0.8% reduction; 95%CI 0.5 to 1.0; Z=7.04; p<0.00001) compared with 0.8% reduction (95%CI 0.7 to 1.0; Z= 9.63; p<0.00001) with no heterogeneity ( $I^2 = 0\%$ ) between the five studies. The authors concluded that there is no evidence to suggest that a group education program is more effective if delivered by a physician, dietitian or nurse as long as the health professional is trained to deliver a diabetes education program. Similarly, the meta-regression analysis on potential treatment interactions by Norris et al (2002a) found no significant association between who delivered the education intervention and HbA<sub>1c</sub> levels.

However, Gary et al (2003) performed a stratified analysis and pooled effect sizes for HbA<sub>1c</sub> based on interventionists (physician, nurse, dietitian) and demonstrated significant effect sizes of -0.71 for studies using nurses (p=0.022) and effect sizes of -0.88 for studies using dietitians (p=0.043), but no significant effect sizes for studies using a physician -1.80 (p=0.229). Due to a limited number of studies that included physicians and methodological issues, findings should be interpreted with caution.

Van Dam et al (2003) systematic review included four studies that focused on provider consulting behaviour modification. In one study, training of providers (GPs and nurses) for a more patient-centred consulting style did not improve patient self-care, lifestyle nor diabetes control (HbA<sub>1c</sub> of intervention group after 1 year 7.07%, of control group 7.17%). Van Dam and colleagues (2003) concluded that, although a shift from the traditional medical model (doctor, disease, and glucose level-centred model) towards a patient participation, patient-centred, patient empowerment model, is regarded as necessary to meet quality diabetes care standards in the 21st century, it appears to be very difficult for providers to adopt and maintain a more patient participatory consulting style, even when supported by special training programs. The authors proposed intensive and continuous support for health professionals to sustain such behaviour changes and suggested combining an intensive doctor-supportive program for organisational and medical improvements (prompting system, guidelines, feedback, and medical education) with support of doctor and patient behaviour to negotiate more realistic individualised treatment goals with patients. Bazian Ltd (2005) adds support to van Dam et al's (2003) findings by postulating that educating professionals and patients may improve partnerships in healthcare delivery and ultimately improve health outcomes in people with diabetes.

## Summary – How should diabetes patient education be delivered?

- There is limited evidence to identify the characteristics of successful patient education programs for people with type 2 diabetes and the studies identified in this review yielded inconsistent results. Most of these studies measured the effect of diabetes education on glycaemic control as measured by HbA<sub>1c</sub>.
- There is some evidence from a number of systematic reviews that increased contact time with an educator and more intense education sessions favourably affect participants' self-management behaviours and glycaemic control.
- The use of multidisciplinary teams to provide education may enhance its effectiveness.
- Diabetes patient education is a multi-faceted and complex intervention. Interpreting its impact and outcomes is difficult as demonstrated effects could be attributed to other factors such as medical treatment, settings, individual factors, socio-economic factors, or factors associated with the education provider.
- There are well documented limitations, and deficiencies, in the number and the quality of available studies from which recommendations about the best structure, components, and characteristics of education programs can be drawn for achieving optimal outcomes for individuals with type 2 diabetes.
- Rigorous research, including well designed large RCTs with longer duration, on the effectiveness of different methods and delivery modes of education is needed to guide resource allocation, program design and delivery and ensure cost-effectiveness of educational interventions

## Evidence Tables: Section 2

### How Should Diabetes Education Be Delivered?

#### 1. Group education and individual education

Author, year	Evidence				
	Level of Evidence		Quality Rating	Magnitude of effect Rating	Relevance Rating
	Level	Study Type			
Adolfsson et al, 2007	II	RCT	High	Low	Low
Davies et al, 2008	II	RCT	High	Low*	Low
Deakin et al, 2005	I	Systematic review of RCTs and CCTs	High	High	High
Gary et al, 2003	I	Meta-analysis	Medium	High	High
Kulzer et al, 2007	II	RCT	High	High	High
Norris et al, 2001	I	Systematic review of RCTs	Medium	N/A	N/A
Norris et al, 2002a	I	Meta-analysis	Medium	High	High
Trento et al, 2004	II	RCT	Medium	High	High
Van Dam et al, 2003	I	Systematic review of RCTs	Medium	N/A	N/A

\* Not significant; N/A: no results of pooled data available; results reported descriptively

## 2. Education mode/approaches/styles

Author, year	Evidence				
	Level of Evidence		Quality Rating	Magnitude of effect Rating	Relevance Rating
	Level	Study Type			
Adolfsson et al, 2007	II	RCT	High	Low*	Low
Conn et al, 2007	I	Meta-analysis of comparative study designs	Medium	Medium	Low
Davies et al, 2008	II	RCT	High	Low*	Low
Deakin et al, 2005	I	Systematic review of RCTs and CCTs	High	High	High
Ellis et al, 2004	I	Meta-analysis and meta-regression	High	High	High
Gary et al, 2003	I	Meta-analysis	Medium	High	High
Loveman et al, 2008	I	Systematic review of RCTs	High	N/A	N/A
Norris et al., 2001	I	Systematic review of RCTs	Medium	Low	N/A
Norris et al, 2002a	I	Meta-analysis	Medium	Medium	High
Sigurdardottir et al, 2007	I	Systematic review of RCTs	High	Low	High
Thoolen et al, 2007	II	RCT	High	High	High
Van Dam et al, 2003	I	Systematic review of RCTs	Medium	N/A	N/A
Williams et al, 2005	II	RCT	High	Medium	Low
Williams et al, 2007	II	RCT	Medium	Low	Low

\* Not significant; N/A: no results of pooled data available; results reported descriptively

### 3. Duration of intervention and length of session

Author, year	Evidence				
	Level of Evidence		Quality Rating	Magnitude of effect Rating	Relevance Rating
	Level	Study Type			
Bazian Ltd, 2005	I	Systematic review of RCTs	Medium	N/A	N/A
Conn et al, 2007	I	Meta-analysis of comparative study designs	Medium	Low	Low
Deakin et al, 2005	I	Systematic review of RCTs and CCTs	High	Low	High
Loveman et al, 2008	I	Systematic review of RCTs	High	N/A	N/A
Norris et al, 2001	I	Systematic review of RCTs	Medium	N/A	N/A
Norris et al, 2002a	I	Meta-analysis	Medium	Medium	High
Sigurdardottir et al, 2007	I	Systematic review of RCTs	High	Low	High

N/A: No results of pooled data available; results reported descriptively

## 4. Setting

Author, year	Evidence				
	Level of Evidence		Quality Rating	Magnitude of effect Rating	Relevance Rating
	Level	Study Type			
Deakin et al, 2005	I	Systematic review of RCTs and CCTs	High	High	High
Loveman et al, 2008	I	Systematic review of RCTs	High	N/A	N/A
Norris et al, 2002b	I	Systematic review of comparative study designs	Medium	N/A	N/A
Zabaleta and Forbes 2007	I	Systematic review of RCTs and CCTs	High	High	Low

N/A: No results of pooled data available; results reported descriptively

## 5. Educators and training

Author, year	Evidence				
	Level of Evidence		Quality Rating	Magnitude of effect Rating	Relevance Rating
	Level	Study Type			
Bazian Ltd, 2005	I	Systematic review of RCTs	Medium	N/A	N/A
Deakin et al, 2005	I	Systematic review of RCTs and CCTs	High	Low	High
Gary et al, 2003	I	Meta-analysis	Medium	High	High
Loveman et al, 2008	I	Systematic review of RCTs	High	High	N/A
Norris et al, 2002a	I	Meta-analysis	Medium	Low	High
Van Dam et al, 2003	I	Systematic review of RCTs	Medium	N/A	N/A

N/A: No results of pooled data available.

## Section 3: Cost-effectiveness and socio-economic implications

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### Questions

- a) Is structured diabetes patient education cost-effective?
- b) What are the socio-economic implications of diabetes patient education?

### Recommendation

Efforts to improve the cost-effectiveness of diabetes care should include patient education (Grade B)

Diabetes education should be culturally sensitive and tailored to the needs of socio-economically disadvantaged populations (Grade B)

### Evidence Statements

- Diabetes patient education is likely to be a cost-effective intervention  
*Evidence Level 1*
- Diabetes patient education may reduce health care cost  
*Evidence Level 1*
- Culturally tailored diabetes education has positive impacts on diabetes knowledge, self-management behaviours, and clinical outcomes among racial/ethnic minorities and socio-economically disadvantaged individuals with diabetes  
*Evidence Level 1*

## **Background – Cost-effectiveness and socio-economic implications**

### *Cost effectiveness*

Type 2 diabetes has become epidemic in Australia and worldwide. The direct and indirect costs of caring for people with type 2 diabetes and its complications are considerable and will continue to rise. In 2004-05 the AIHW, based on administrative data, estimated the direct health care expenditure on diabetes to be \$907 million (of which type 2 diabetes accounted for 81% at \$733 million), accounting for 1.7% of the total allocatable recurrent health expenditure for that year (AIHW, 2008). These figures almost certainly underestimate the true cost of diabetes. The DiabCo\$t study reported that the average total (direct plus indirect) health costs for an individual with type 2 diabetes was \$5360 per year (Colagiuri et al, 2003b). The costs per year for individuals with both macrovascular and microvascular complications was on average 2.4 times higher than for those with no complications (\$9625 vs. \$4020). Based on a diabetes prevalence of 7.4%, the total annual cost for people with type 2 diabetes in Australia was estimated to be \$2.2 billion, and if the cost of carers is included this figure rises to \$3.1 billion. In addition, people with type 2 diabetes receive \$5540 per year on average in Commonwealth benefits, increasing the total annual cost of diabetes to \$6 billion (Colagiuri et al, 2003b).

### *Socio-economic implications*

According to Colagiuri & Rutherford (2004) the burden of diabetes is often distributed unequally across society citing a clear socioeconomic gradient in the prevalence of type 2 diabetes, with a rate two and a half times higher in the lowest socioeconomic group compared with the highest (AIHW, 2002). They further point out that the 1999-2000 hospital separation rates for diabetes in Aboriginal and Torres Strait Islander people was five times the non-Aboriginal rate (NSW Health, 2002). Several other authors cite variations in diabetes prevalence in relation to socio-economic position and highlight increases in diabetes prevalence with increasing disadvantage (Carter et al, 1996; Fisher et al, 2002; Candib, 2007).

Colagiuri & Rutherford (2004) also point out that while the physical burden of diabetes complications has been well documented, until relatively recently the psychological burden has not, although there is a growing body of evidence about the effect of diabetes on mental health eg depression has been reported to be 2-3 times higher in people with diabetes. The international Diabetes Attitudes Wishes and Needs (DAWN) study focussed on psychological aspects of diabetes and highlighted the stress, anxiety and burn out experienced by people with diabetes. Of the Australian people with diabetes who participated in the DAWN study, 25% were on current treatment for a diabetes complication and one third were in poor well being with only 17% reporting good well being. Self reported anxiety, stress and worry were most commonly related to fears about worsening of the disease, future financial worries, and the risk of hypoglycaemic events (Rutherford et al, 2004).

In 2001, the prevalence of self-reported diabetes was almost twice as high in the most disadvantaged areas than in the least disadvantaged in Australia (AIHW, 2008). Across Australia, Aboriginal people have a significantly higher prevalence of diabetes than the general population (O'Dea et al, 1993; Hoy et al, 2007), and certain overseas-born Australians have a higher prevalence of diabetes than people born in Australia (Colagiuri et al, 2007; AIHW, 2008). It has been reported that people at most social disadvantage in NSW were significantly less likely to be under the care of a GP (adjusted OR = 0.41; 95%CI 0.40 to

0.41) or consultant physician (adjusted OR = 0.50; 95%CI 0.48 to 0.53), despite having the highest prevalence of diabetes (Overland et al, 2002) .

### ***Cultural factors***

In a review of diabetes prevention in culturally and linguistically diverse groups commissioned by NSW Health, Colagiuri et al (2007) propose that with one in four residents born overseas and over 190 languages spoken, Australia is one of the most culturally and linguistically diverse nations on earth. While this diversity brings cultural depth and richness to our society, it also poses significant barriers to the delivery of effective and equitable health services. Further, certain cultural groups are known to be at higher risk of diabetes and the stress and lifestyle changes associated with migration itself may be an additional risk for the development of chronic conditions such as diabetes.

Mitigating the physical and mental health consequences of diabetes, and the health consequences of migration and socio-economic disadvantage are important areas requiring the attention of researchers, planners, policy makers and service providers alike. In addition to the personal suffering and socio-economic disadvantage to individuals, diabetes imposes an ever increasing macroeconomic burden on national economies as a result of its impact on workforce participation and productivity, early retirement and increased use of pensions as well as health care costs.

# Evidence – Cost-effectiveness and socio-economic implications

## Cost analysis and cost-effectiveness

- **Diabetes patient education is likely to be a cost-effective intervention (*Evidence Level 1*)**
- **Diabetes patient education may reduce health care cost (*Evidence Level 1*)**

A recent study reported on the cost-effectiveness of two diabetes intervention strategies compared with usual hospital outpatient care in people with type 2 diabetes (Dijkstra et al, 2006). It includes both participant-related and intervention-related cost. In a clustered-RCT design, 13 Dutch general hospitals were randomly assigned to a control group (n=276; mean age 65 years), a professional-directed (n=248; mean age 63 years) or a patient-centred (n=240; mean age 64 years) implementation program. In the professional-directed group, professionals received feedback on baseline data, education and reminders. In the patient-centred group, participants received education and diabetes passports. In the control group, physicians continued with usual care. A validated probabilistic Dutch diabetes model and the UKPDS risk engine were used to determine lifetime disease outcomes and cost. Results show that HbA<sub>1c</sub> at 1 year decreased by 0.2% in the professional-directed group and by 0.3% in the patient-centred group, while it increased by 0.2% in the control group (p<0.001). Costs of primary implementation were <€5 per person in both intervention groups, but average lifetime costs of improved care and longer life expectancy in the professional-directed and the patient-centred group rose by €9389 and €9620, respectively. Life expectancy improved by 0.34 and 0.63 years, and quality-adjusted life years (QALY) by 0.29 and 0.59 respectively. Accordingly, the incremental cost per QALY was €32,218 for professional-directed care and €16,353 for patient-centred care compared with control, and €881 for patient-centred vs professional-directed care. It was concluded that both intervention strategies in secondary care are cost-effective compared with current care, by Dutch standards.

Ragucci and colleagues (2005) conducted a one year observational study to evaluate the effectiveness of pharmacist-administered diabetes education and management services on selected diabetes performance measures. Each of the 191 subjects with diabetes (mean age 55 years, 99% type 2 diabetes) was assessed for HbA<sub>1c</sub> values, BP, LDL levels, and aspirin use at baseline and at 1 year after enrolment. Average HbA<sub>1c</sub> was reduced by 1.7% from 9.5% at baseline to 7.8% at one year (p<0.05). Average BP decreased over the study period from 141/79 to 135/75 mmHg (p=0.007). LDL levels did not change significantly. Aspirin use increased significantly from 34% at baseline to 73% after one year (p<0.0001). Cost avoidance comparators were calculated for subjects (n=72) with reductions in HbA<sub>1c</sub> of at least 1%. Based on previously published estimated savings of US\$820 in mean total health care costs for each 1% decrease in HbA<sub>1c</sub>, cost avoidance was calculated as US\$59,040.

Wolf and colleagues (2004) performed a 12-month RCT to assess the efficacy of a lifestyle intervention in 147 obese subjects (BMI ≥27 kg/m<sup>2</sup>) with type 2 diabetes (mean age 53 years) in the 'Improving Control with Activity and Nutrition' study. The lifestyle intervention consisted of individual and group education, support and referral by registered dietitians at a cost of US\$350 per person. Participants in the usual care group received educational material and both groups received ongoing primary care. Over the intervention period, compared to usual care, the intervention resulted in greater weight loss (p<0.001), reduced waist

circumference ( $p < 0.001$ ), reduced HbA<sub>1c</sub> ( $p = 0.02$ ), reduced use of prescription medications ( $p = 0.03$ ), and improved health-related QOL ( $p < 0.001$ ). This study demonstrated that care costs for those in the intervention group were US\$3,586/year lower than for those in the control group. The authors concluded that moderate-cost dietitian-led lifestyle intervention programs may improve diverse health indicators, in obese people with type 2 diabetes.

In their HTA report, Loveman and colleagues (2003) performed a systematic review and economic evaluation to assess the clinical effectiveness and cost-effectiveness of educational interventions for people with diabetes, compared with usual care or other educational interventions. RCTs and CCTs were included if they fulfilled pre-specified criteria, among which was  $\geq 12$  months follow-up. Data were synthesised through a narrative review because the diversity of studies prevented a meta-analysis. Twenty-four studies (18 RCTs and six CCTs) that compared education with either a control group or with another educational intervention were included. The quality of reporting and methodology was generally poor. Three studies were identified with cost data in relation to patient education models for type 2 diabetes. These studies covered a variety of methodologies. Therefore, no generalisations were able to be made from these studies regarding the cost-effectiveness of patient education models. The first study reported findings from a prospectively controlled trial assessing the efficacy of a treatment and teaching program in people with type 2 diabetes in Austria. The intervention group consisted of 53 subjects undergoing a structured diabetes treatment and training program (DTTP) and the control consisted of 55 subjects without the program. The DTTP consisted of four weekly teaching sessions (90–120 minutes each) for groups of 4–8 subjects, with a 6 month follow-up. The DTTP reduced routine health care costs by an average of 594 Austrian schillings (UK £33) per person per year due to the reduced prescription of oral hypoglycaemic agents. The second study presented findings from an observational study in a 466 subjects with type 2 diabetes from 10 Latin American countries. The intervention comprised a structured educational model, incorporating four weekly teaching units (90–120 minutes each) and a reinforcement session at 6 months. Some findings on the costs associated with the intervention were presented, however estimates of the actual intervention costs were not reported. The third study evaluated the efficacy of a structured treatment and teaching program for non-insulin-treated people with type 2 diabetes in a primary care setting. It involved a survey of physicians, and their office staff, who had participated in a training course related to the delivery of patient education to people with diabetes. The study also describes a retrospective data analysis for people from 17 randomly selected physicians' records (physicians who participated in the training course). Limited data were presented on the costs of the education program. Remuneration data covered by health insurance for education program costs were reported. Education costs are reported at US\$49 per person (1992 costs), with an additional cost for self-monitoring of about US\$34 per person. Loveman et al (2003) identified only one study reporting cost-effectiveness results that considered the economic evaluation of education models for type 2 diabetes. This study evaluated the cost-utility of behavioural interventions in an experimental study of 76 adults with type 2 diabetes. A cost-utility estimate of US\$10,870 per well-year (1986 prices) was presented by the authors, where a 1-year benefit rate is calculated based on the difference between treatment and control groups at each assessment point (3, 6, 12 and 18 months) weighted by duration of stay (this calculated 1-year rate is reported to be 0.092 units of well-being).

Gozzoli and colleagues (2001) used a diabetes simulation model to analyse the long-term clinical and economic implications of implementing various interventions for secondary prevention in type 2 diabetes in the Swiss setting. Based on data from the literature, the short-term effects on clinical variables of multifactorial interventions, including screening for nephropathy and retinopathy, educational programs and control of cardiovascular risk profile

were assessed, and a cost-effectiveness analysis in comparison to standard care was performed. Total lifetime costs from the perspective of the health insurance payer were calculated using a long-term Markov simulation model. With an annual discounted rate of 3%, compared to standard care (CHF 68,418), an educational program (CHF 68,573) resulted in additional total lifetime costs per person (CHF 155) (1996 values). Extrapolation to the whole Swiss type 2 diabetes population (285,000) shows that over the lifetime the 3% discounted cumulative costs associated with the educational program, compared to standard care, was an additional CHF 44 million.

## Socio-economic implications

- **Culturally tailored diabetes education has positive impacts on diabetes knowledge, self-management behaviours, and clinical outcomes among racial/ethnic minorities and socio-economically disadvantaged individuals with diabetes (*Evidence Level 1*).**

### *Systematic reviews*

Khunti et al (2008) conducted a systematic review of the effectiveness of educational interventions for South Asians migrant with type 2 diabetes living in Western countries. A range of electronic databases including MEDLINE, CINAHL, EMBASE, and three Cochrane Library databases were searched up to the end of 2007. Nine studies, including five RCTs, met the inclusion criteria. The quality of reporting in some studies was limited, for example omitting detailed information about ethnicity. Selected studies included a range of group and one-on-one interventions with varied knowledge, psychological and biomedical outcome measures. The effectiveness of the interventions varied, and the low number and heterogeneity of studies made identification of factors linked to effectiveness difficult and meta-analysis inappropriate. Of three RCTs reporting HbA<sub>1c</sub> outcomes, two reported no change while the other demonstrated significant improvements in the short-term, which dissipated after long-term follow-up. Two studies reported significant improvements in total cholesterol, two studies reported increases in knowledge, one study found an improvement in systolic and diastolic BP, and two studies reported no impact on BMI. The authors suggested that improvements in knowledge may be easier to achieve than positive biomedical outcomes such as HbA<sub>1c</sub>. Their findings confirm the difficulty of designing, assessing and achieving an impact through educational interventions for migrant South Asians with type 2 diabetes and emphasize the need for good-quality studies in these high-risk populations, with a focus on tailored approaches.

Hawthorne and colleagues (2008) systematically reviewed the literature to assess the effectiveness of culturally appropriate diabetes health education in people with type 2 diabetes. The inclusion criteria was RCTs of culturally appropriate diabetes health education for people over 16 years with type 2 diabetes from named ethnic minority groups resident in upper-middle or high income countries. Eleven trials involving 1603 people were included, with 10 trials providing suitable data for entry into meta-analysis. None of the studies were long-term, and so clinically important long-term outcomes could not be studied. No studies included an economic analysis. The heterogeneity of studies made subgroup comparisons difficult to interpret with confidence. Results indicate that HbA<sub>1c</sub> showed an improvement following culturally appropriate health education at 3 months (data from 5 studies; WMD -0.3%, (95% CI -0.6 to -0.01), and at 6 months (6 studies; WMD -0.6%, (-0.9 to -0.4), compared with control groups who received usual care. This effect was not significant at 12 months post intervention (3 studies; WMD -0.1%, (-0.4 to 0.2). Knowledge scores also improved in the intervention groups at 3 months (4 studies; SMD 0.6, (0.4 to 0.7), 6 months (5 studies; SMD 0.5, (0.3 to 0.7) and 12 months (2 studies; SMD 0.4, (0.1 to 0.6) post

intervention. Total cholesterol levels at 1 year (3 studies) showed a significant improvement in the intervention groups (WMD -0.02 mmol/L, (-0.64 to -0.14), however no such improvement was found at 3 and 6 months. Other outcome measures both clinical (such as BP, HDL, LDL and triglyceride levels) and patient centred (QOL measures, attitude scores and measures of patient empowerment and self-efficacy) showed no significant improvement compared with control groups. The authors concluded that culturally appropriate diabetes health education has beneficial short-term effects on HbA<sub>1c</sub> and knowledge of diabetes and healthy lifestyles. It was suggested that there is a need for more long-term, standardised multi-centre RCTs to compare different types and intensities of culturally appropriate health education within specified ethnic minority groups.

Peek and colleagues (2007) undertook a systematic review to assess the effectiveness of health care interventions at improving health outcomes and/or reducing diabetes health disparities among racial/ethnic minorities with diabetes. Literature searching was conducted using multiple electronic databases (MEDLINE, Cochrane Register of Controlled Trials, PsycINFO, Cochrane Database of Systematic Reviews, ACP Journal Club, and CINAHL) for evaluation studies of interventions published from 1985 to 2006 that were designed to improve diabetes care for adult minority people with type 2 diabetes. Forty-three studies were identified that met the inclusion criteria. On average, the health care interventions improved the quality of care for racial/ethnic minorities, improved health outcomes (such as diabetes control and reduced diabetes complications), and possibly reduced health disparities in quality of care. Results indicate that diabetes programs that sought to improve health outcomes among racial/ethnic minority populations reduced mean HbA<sub>1c</sub> in the intervention group by 0.36% (95%CI 0.27 to 0.45) in absolute terms compared to the control group. There is evidence supporting the use of interventions that target patients (primarily through culturally tailored programs), providers (especially through one-on-one feedback and education), and health systems (particularly with nurse case managers and nurse clinicians). Seventeen studies were found that targeted patients within the health care organisation. The interventions in these studies were patient education programs that sought to improve dietary habits, physical activity, and/or self-management activities (ie glucose self-monitoring). Of these 17 patient-targeted interventions, six met the inclusion criteria for meta-analysis of HbA<sub>1c</sub> values, five of which were culturally tailored and one of which was a general patient intervention. Culturally tailored patient initiatives produced a mean HbA<sub>1c</sub> value in the intervention group that was 0.69% (95%CI 0.37 to 1.0) lower than the control group, while the general patient intervention resulted in a mean absolute reduction in HbA<sub>1c</sub> of 0.10% (95%CI -0.28 to 0.48) (non-significant). Interventions that involved peer support and one-on-one interactions more often reported positive results than those using computer-based patient education. Culturally tailored interventions reported positive impacts on health knowledge, behaviours, and outcomes, although they varied in which health outcomes were affected.

Eakin et al (2002) performed a literature review of DSME interventions in disadvantaged populations. An electronic literature search of the MEDLINE database for the years 1987-2001 identified five formative evaluations and 10 controlled DSME intervention trials focused on under-served (low-income, minority or aged) populations. The RE-AIM (Reach, Efficacy, Adoption, Implementation, Maintenance) evaluation framework was used to evaluate the controlled studies. Seven of the controlled studies focused on ethnic or racial minorities, with five targeting older adults. Eight of the studies focused solely on adults with type 2 diabetes; one included those with and at risk for type 2 diabetes and one focused on obese Pima Indian adults at risk for diabetes. The sample sizes ranged from 64 to 275 participants. All but one of the studies was conducted in the US. The methodological quality of the articles was generally good and the short-term results were encouraging, especially with regards to behavioural outcomes. Reach was reported in five of 10 controlled studies

and participation rates ranged from less than one-third to 90%, with a median of 68%. The representativeness of study participants, compared to the population from which they were recruited, was reported in only one of 10 studies. With regard to efficacy, due to insufficient information provided in the majority of studies, it was not possible to calculate effect sizes or number needed to treat (NNT) for the key outcome variables. The length of follow-up ranged from 8 weeks to 12 months, with nine of 10 studies reporting short-term (<12-month) outcomes and four reporting 12-month or greater outcomes. Concerning short-term physiological outcomes, five of nine studies reported a significantly greater reduction in weight in the intervention group compared to the control group. Three of nine studies reported significant reductions in one or more measures of blood glucose control. Regarding short-term behavioural outcomes, three of five studies reported significantly greater short-term positive changes in dietary patterns and/or physical activity for intervention compared to control conditions. Only two studies reported on short-term changes in diabetes knowledge, with neither reporting significant short-term increases. Short-term psychosocial outcomes were reported in 3 studies, with 1 reporting short-term significant differences between conditions in the hypothesized direction. With regard to adoption, neither the percentage of settings/providers willing to deliver the intervention (or participate in the study) or the representativeness of these settings/providers was reported in any study. In reference to implementation, an index of whether the intervention was delivered as intended was reported in only one of 10 studies, which had a positive result. In five of 10 studies that reported on participant adherence, overall session attendance ranged from 10-90%, with a median of 60%. Four of ten studies reported on maintenance at the individual level. Concerning physiological outcomes, three studies reported results on weight, with none finding significant long-term reductions in the intervention group. Four studies reported long-term results on various measures of blood glucose control, with two showing significant long-term effects. Regarding behavioural outcomes, two of three studies reported significant long-term improvements in diet and or/physical activity. One study reported on long-term changes in diabetes knowledge resulting in a non-significant change. Two studies reported on long-term psychosocial outcomes, with neither reporting significant effects. Two of the studies reported on systems level maintenance or continuation of the intervention following the evaluation, with both reporting that the program was ongoing. The authors conclude that studies evaluating alternative modalities to deliver DSME interventions are needed, particularly those targeting under-served populations. Studies that explicitly address the community context as well as multiple issues related to the public health impact of DSME interventions are recommended to improve long-term results.

In a systematic review of interventions to improve diabetes care in socially disadvantaged populations, Glazier and colleagues (Glazier et al, 2006) identified several features of interventions with the most positive effects. These features included cultural tailoring of the intervention, having community educators or lay people leading the intervention, one-on-one interventions with individualised assessment and re-assessment, incorporating treatment algorithms, focusing on behaviour-related tasks, and high-intensity interventions (>10 contact times) delivered over a long duration (≥6 months).

### ***Primary studies***

Clancy and colleagues (Clancy et al) conducted an RCT to evaluate group education visits in the management of medically and economically disadvantaged people with uncontrolled type 2 diabetes. One hundred and twenty eligible subjects (mean age 54 years) from the US were randomly assigned to receive care in groups (n=59) or continue usual care (n=61). The majority of subjects were under insured, only 23% reported working full- or part-time and the average years of education completed were 10.6, with an average reading level of approximately the 8<sup>th</sup> grade. The group visits were co-led by a primary care physician and a

diabetes nurse educator and consisted of education on topics guided by the desires of group members themselves. The group visits were scheduled monthly for 6 months, with each session lasting 2 hours. Feasibility, acceptability, and concordance with American Diabetes Association standards of care were evaluated. At the end of the 6 months both groups showed non-significant improvement in diabetes control (HbA<sub>1c</sub>, lipid and cholesterol levels) compared to baseline. Subjects in the intervention group showed improvement in American Diabetes Association standards of care ( $p < 0.001$ ), higher scores in the Trust in Physician Scale ( $p = 0.02$ ), and tended to report better coordination of care ( $p = 0.07$ ), better community orientation ( $p = 0.09$ ), and more culturally competent care ( $p = 0.09$ ). The authors concluded that group visits provide a promising model for the delivery of health care to this population.

## **Summary - Cost-effectiveness and socio-economic implications**

- In general, there are limited high quality cost-effectiveness studies of diabetes patient education. More importantly there are no Australian cost analyses or cost-effectiveness data.
- Overseas studies have shown that diabetes education is likely to be cost-effective in improving knowledge, self-management behaviour and clinical outcomes in people with type 2 diabetes. This is likely to reduce complications and related costs.
- Evaluations of diabetes education programs should report the cost of delivering patient education and cost-effectiveness.
- Tailored patient education programs including culturally appropriate diabetes education have a positive effect on knowledge and improving glycaemic control and self-management behaviour in low socio-economic populations including racial/ethnic minorities. No economic evaluation of these programs is available for people with type 2 diabetes.
- Good quality studies assessing the cost-effectiveness of different patient education models and approaches as well as cost analyses and cost-benefit studies in the Australian context are needed.

## Evidence Tables: Section 3

### Is Structured Diabetes Patient Education Cost-Effective?

Author, year	Evidence				
	<i>Level of Evidence</i>		<i>Quality Rating</i>	<i>Magnitude of effect Rating</i>	<i>Relevance Rating</i>
	<i>Level</i>	<i>Study Type</i>			
Dijkstra et al., 2006	II	RCT	Medium	Medium	Medium
Gozzoli et al., 2001*	No pooled data	Modelling	N/A	Low	Medium
Loveman et al., 2003	I	Systematic review	Medium	Medium	High
Ragucci et al., 2005	IV	Case series	Medium	High	High
Wolf et al., 2004	II	RCT	High	High	Medium

\* does not fit into any level -modelling

## What are the Socio-Economic Implications?

Author, year	Evidence				
	Level of Evidence		Quality Rating	Magnitude of effect Rating	Relevance Rating
	Level	Study Type			
Clancy et al., 2003	II	RCT	Medium	Medium	High
Eakin et al., 2002	I	Systematic review	High	Medium	Medium
Glazier et al., 2006	I	Systematic review	High	Medium	Medium
Hawthorne et al., 2008	I	Systematic review	High	High	High
Khunti et al., 2008	I	Systematic review	Medium	Medium	Medium
Peek et al., 2007	I	Systematic review	High	High	High

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# Appendices

## Appendix 1: Summary of systematic reviews of structured patient education in people with type 2 diabetes

(listed in alphabetical order)

Bazian Ltd (2005) conducted a systematic review to examine the effectiveness of diabetes education interventions in prevention of foot ulcers in people with type 2 diabetes. Studies included systematic reviews or RCTs where the intervention focused specifically on preventative foot care. Studies were included if they reported patient outcomes such as change in knowledge or self-care practice, or clinical end points such as incidence of foot ulceration, infection, and amputation in people with or without foot ulcers. Seven RCTs were included in the review. This review highlighted that education does not have large effects in improving foot health for people with diabetes, though, it is effective in improving knowledge of foot care, and changing self-reported behaviour in the short-term. However, there is no evidence that these changes are lasting. This review also highlighted that intensive education programmes with increased contact time between patient and healthcare provider and a means of motivating behaviour change (such as frequent follow-up by healthcare providers or cognitive motivational training) may be more effective than brief, one-off information-based sessions.

In 2007, Conn and colleagues conducted a meta-analysis to integrate the results of primary research testing the effect of diabetes self-management interventions that included recommendations to increase exercise on metabolic outcomes among adults with type 2 diabetes Conn et al (2007). Typical attributes included supervised exercise (s=45 studies) consisted of 1-hour sessions, two or three weekly sessions for a period of 3-4 months. Other strategies were social modelling (s=35) in which subjects observed others exercise, exercise self-monitoring (s=34), behavioural goal setting (s=29) and generating social support (s=26) to foster behaviour change. Extensive literature searching strategies identified published and unpublished intervention studies that measured HbA<sub>1c</sub> outcomes. Fixed- and random-effects meta-analytic procedures included moderator analyses. Data from 103 research reports including 10,455 subjects were synthesised. The overall mean weighted effect size for two-group comparisons was 0.29 (higher mean difference in metabolic control for treatment than control). This effect size is consistent with a difference in HbA<sub>1c</sub> means of 0.45% (eg 7.38% for treatment subjects vs 7.83% for control subjects). For single-group studies, the overall mean weighted effect size was 0.32–0.34. No improvement in metabolic control was found in control subjects during participation in the studies. Interventions targeting multiple health behaviours resulted in smaller effect size estimates (0.22) than interventions focused only on exercise behaviours (0.45). Funded studies reported greater improvements in metabolic control. Studies with a higher proportion of female subjects reported lower effect sizes. Baseline HbA<sub>1c</sub> and BMI were unrelated to metabolic outcomes. Findings from this review suggest that self-management interventions that include exercise recommendations improve metabolic control, despite considerable heterogeneity in the magnitude of the intervention effect. Interventions that emphasise exercise may be particularly effective in improving metabolic control. It is to be noted that Conn et al did not document inclusion criteria nor a definition of interventions included in their analysis, nor was it clear from the paper whether interventions include structured diabetes education. They explain in the online supplementary material to their paper that interventions to change diabetes self-management behaviours are not standardised in term of content, depth and breadth within the topics nor the

manner of educational delivery, although some diabetes educator groups have outlined key topics of diabetes education .

A Health Technology Assessment (HTA) report from Canada included a systematic review and a meta-analysis of the literature published from 1990 to 2000 that focused on the effectiveness of formal outpatient diabetes education as a tool to promote self-management in adults with type 2 diabetes in the long-term (Corabian & Harstall, 2001). The HTA report retrieved 3 meta-analyses, 7 systematic reviews, 7 primary quantitative studies and 7 Canadian RCTs. This report produced mixed results in terms of improved metabolic control and reduced risks for diabetes-associated complications in the long-term. The main findings from all the meta-analyses were similar in that patient education is effective in producing beneficial outcomes (HbA<sub>1c</sub>, blood glucose, self-care behaviour, knowledge, and psychological status). However, this report reviewed meta-analyses that did include people with type 1 diabetes and who did not analyse type 1 and type 2 diabetes separate.

Deakin et al. (2005) undertook a systematic review and meta-analysis of RCTs and CCTs to review the impact of group-based education in self management in terms of clinical, lifestyle, and psychosocial outcomes. Studies were retrieved from computerised searches of multiple electronic bibliographic databases, supplemented by hand searches of reference lists of articles, conference proceedings and consultation with experts in the field. This review included group-based education programs for adults with type 2 diabetes compared with routine treatment, waiting list control or no intervention. Studies were only included if the length of follow-up was six months or more and the intervention was at least one session with the minimum of six participants. A meta-analysis was performed if there were enough homogeneous studies reporting an outcome at either four to six months, 12-14 months, or two years, otherwise the studies were summarised in a descriptive manner. Researchers identified fourteen publications describing 11 studies involving 1532 participants. The results of the meta-analyses in favour of group-based diabetes education programs were: reduced HbA<sub>1c</sub> at four to six months (1.4%; 95% CI 0.8 to 1.9; p<0.00001), at 12-14 months (0.8%; 95% CI 0.7 to 1.0; p<0.00001) and two years (1.0%; 95% CI 0.5 to 1.4; p<0.00001); reduced FBG levels at 12 months (1.2 mmol/L; 95% CI 0.7 to 1.6; p<0.00001); reduced body weight at 12-14 months (1.6 Kg; 95% CI 0.3 to 3.0; p=0.02); improved diabetes knowledge at 12-14 months (SMD 1.0; 95% CI 0.7 to 1.2; p<0.00001) and reduced systolic BP at four to six months (5 mmHg; 95% CI 1 to 10; p=0.01). There was also a reduced need for diabetes medication (OR = 11.8, 95% CI 5.2 to 26.9; p<0.00001; RD = 0.2; NNT = 5). Therefore, for every five patients attending a group-based education program we could expect one patient to reduce diabetes medication. The authors concluded that group-based training for self-management strategies in people with type 2 diabetes is effective in improving FBG levels, HbA<sub>1c</sub>, diabetes knowledge and reducing systolic BP levels, body weight and the requirement for diabetes medication.

A recent systematic review and meta-analysis of RCTs and CCTs evaluated the effectiveness of individual patient education on metabolic control, diabetes knowledge and psychosocial outcomes (Duke et al, 2009). Multiple electronic bibliographic databases were searched, including The Cochrane Library, MEDLINE, Premedline, ERIC, Biosis, AMED, Psychinfo, EMBASE, CINAHL, APAIS-health, Australian Medical Index, Web of Science, dissertation abstracts and Biomed Central. The intervention was individual face-to-face patient education while control individuals received usual care, routine treatment or group education. Only studies

that assessed outcome measures at least six months from baseline were included. This review included nine studies involving 1359 participants that met the inclusion criteria. Six studies compared individual education to usual care and three compared individual education to group education (361 participants). There were no long-term studies and overall the quality of the studies was not high. In the six studies comparing individual face-to-face education to usual care, individual education did not significantly improve glycaemic control (weighted mean difference (WMD) in HbA<sub>1c</sub> -0.1% (95% CI -0.3 to 0.1,  $p = 0.33$ ) over a 12 to 18 month period. However, there did appear to be a significant benefit of individual education on glycaemic control in a subgroup analysis of three studies involving participants with a higher mean baseline HbA<sub>1c</sub> greater than 8% (WMD - 0.3% (95% CI -0.5 to -0.1,  $p = 0.007$ ). In the studies that compared individual to group education, there was no significant difference in glycaemic control between individual or group education at 12 to 18 months with a WMD in HbA<sub>1c</sub> of 0.03% (95% CI -0.02 to 0.1,  $P = 0.22$ ). There was no significant difference in the impact of individual versus usual care or group education on body mass index systolic or diastolic blood pressure. There were too few studies to perform a meta-analysis on the effect of individual education on dietary self management, diabetes knowledge, psychosocial outcomes and smoking habits. No data were available on the other main outcome measures of diabetes complications or health service utilisation and cost analysis in these studies. This systematic review suggests a benefit of individual education on glycaemic control when compared with usual care in a subgroup of those with a baseline HbA<sub>1c</sub> greater than 8%. However, overall there did not appear to be a significant difference between individual education and usual care. In the small number of studies that compared group and individual education, there was an equal impact on HbA<sub>1c</sub> at 12 to 18 months.

To assess and characterise the effect of patient education interventions on glycaemic control, Ellis and colleagues performed a meta-analysis and meta-regression of RCTs published in English between 1990 and December 2000 (Ellis et al. (2004). They identified 28 educational interventions that were performed in adults with diabetes, carried out primarily in an outpatient setting, and reported pre- and post- intervention HbA<sub>1c</sub> values. Any non-pharmacological intervention whose intent was to improve the health of patients with diabetes through physical, intellectual, or psychosocial means was recognised as an educational intervention. To describe each intervention, they collected the following variables: the setting (one-on-one, group, family, other), delivery method, teaching method, educational content, health care provider, tailoring of intervention to assessment, modifying the intervention in follow-up, intensity or dose of the intervention, and whether a baseline “supplement” was given ie both the control and intervention group had received basic diabetes education before randomisation. Net glycaemic change from baseline for the educational intervention group (pre–post experimental group HbA<sub>1c</sub> difference) minus the glycaemic change from baseline for the control group (pre–post control group HbA<sub>1c</sub> difference), at 3, 6 and 12 month follow-up where available. Meta-regression using STATA was performed on the net glycaemic difference between time period one values (3 to 15 months) and baseline HbA<sub>1c</sub> values to determine whether specific characteristics of the educational interventions could explain the heterogeneity among studies in HbA<sub>1c</sub> change from baseline outcomes. Twenty one RCTs (28 educational interventions and 21 controls;  $n=2439$ ) met all inclusion criteria. Study size ranged from 23 to 320 subjects. Twenty interventions included only persons with type 2 diabetes, five interventions included only persons with type 1 diabetes, two studies included persons with either type 1 or type 2 diabetes, and one study did not specify the type of diabetes. Age ranged from 24.6 to 67.2 years. The duration and number of

interventions ranged from 1 month to 1 year and from 1 to 36 episodes, respectively. The interventions varied in the techniques used for education from didactic teaching (23 interventions), dictated goal setting (10 interventions), goal setting negotiated teaching (12 interventions), situational problem solving (15 interventions), cognitive reframing interventions (involves providers suggesting alternate self-perceptions that are more advantageous to self-management; 4 interventions) and other teaching methods (13 interventions). Some studies employed multiple teaching methods. Twenty-five interventions used dietary content, 18 used exercises, 15 taught SMBG, 10 taught basic diabetes knowledge, 8 discussed medication adherence, 7 included psychosocial topics and 19 incorporated a topic other than those described, respectively. Fixed effects meta-analysis of the net glycaemic change (test for heterogeneity  $Q = 14$ ,  $df = 19$ ,  $p=0.78$ ) at the end of time period one was  $-0.320$  ( $-0.571$ ,  $-0.069$ ), indicating the post-intervention HbA<sub>1c</sub> change from baseline in the intervention group was  $0.320$  greater than that in the control group. The net change was  $-0.294$  ( $-0.680$ ,  $0.092$ ),  $-0.486$  ( $-0.923$ ,  $-0.049$ ), and  $-0.328$  ( $-0.756$ ,  $0.101$ ) at 12, 24, and 52 weeks, respectively. The time period one, net change of all the studies as well as the net change in those studies that measured HbA<sub>1c</sub> at 24 weeks achieved statistical significance (indicated by the 95%CI). Random effects meta-analysis of the glycaemic change from baseline in the intervention group revealed a drop in HbA<sub>1c</sub> of  $-1.136$  ( $-1.481$ ,  $-0.790$ ) at the end of time period one ( $Q = 132$ ,  $df = 27$ ,  $p<0.001$ ). At 12, 24, and 52 weeks the change from baseline was  $-1.238$  ( $-1.665$ ,  $-0.811$ ),  $-0.892$  ( $-1.428$ ,  $-0.356$ ), and  $-1.544$  ( $-2.26$ ,  $-0.828$ ), respectively all of which reached statistical significance. The authors also performed a meta-regression analysis on the post-intervention HbA<sub>1c</sub> change from baseline in the intervention group. Interventions that were performed face-to-face, which used a cognitive reframing teaching method, or which included exercise as a part of the content had a larger decrease in the post-intervention HbA<sub>1c</sub>. The meta-regression of face-to-face delivery on glycaemic change from baseline yielded a  $t^2 = 0.68$ , meaning approximately 27% ( $1-0.68/0.92$ ) of study heterogeneity can be attributed to between intervention differences in delivery methods. Similarly, approximately 21% of study heterogeneity may be attributed to the use of cognitive reframing teaching method and 14% of the heterogeneity may be attributed to the inclusion of exercise in the content of an intervention. A meta-regression model with all three covariates accounted for 44% of the heterogeneity ( $t^2 = 0.52$ ). The time to the post-intervention value (from 3 to 15 months) and the type of diabetes were included as covariates in the regression model and the results remained the same as above. The authors point out several limitations to their analysis. The power of this analysis, particularly the meta-regression, was limited by the relatively small number of studies as well as the imprecision of the measurement techniques. The regression analysis was not a controlled comparison hence there are most likely unmeasured variables that have important unrecognised effects on glycaemic control, in intervention and control groups. Nevertheless, the authors concluded that patient education has a modest improvement on glycaemic control in adults with diabetes and suggested several attributes of patient education that seem to predict improved glycaemic control ie face-to-face interaction, a cognitive reframing teaching method and inclusion of exercise content in educational interventions. The 'dose' or amount of intervention was not a sensitive indicator of an intervention's success or failure.

Gary et al (2003) conducted a meta-analysis to assess the effect of educational and behavioural interventions on body weight and glycaemic control in type 2 diabetes. Studies selected for analysis were published RCTs that evaluated educational and behavioural interventions (no drug interventions) in type 2 diabetes with a sample size  $\geq 10$ . The Medline and Cochrane Collaboration databases were searched, with data abstracted independently by two reviewers

adjudicated by consensus. Sixty three articles met the inclusion criteria, of which 18 provided sufficient information for pooled estimates of glycohaemoglobin (total GHb, HbA<sub>1c</sub>, or HbA<sub>1c</sub>), yielding a total of 2720 participants (sample sizes of 18 to 749). The studies were conducted between 1984 and 1997 with interventions ranging from 1 to 19 months and follow-up ranging between 1 and 26 months. Overall, glycohaemoglobin was significantly reduced by a mean of 0.43% (95% CI -0.71 to -0.14, p=0.003) in intervention groups compared with controls. When results were stratified by quality score, glycohaemoglobin was reduced by 0.51% (p=0.001) and 0.38% (non-significant) for high and low quality scores, respectively. When studies were weighted by sample size, FBG was reduced by 24mg/dL and weight by 3lbs. It was concluded that educational and behavioural interventions in type 2 diabetes produce only modest improvements in glycaemic control.

Loveman et al (2003) conducted a systematic review to assess the effects of specialist nurse care on outcomes for people with diabetes, compared with usual care in hospital clinics or primary care with no input from specialist nurses. A comprehensive literature search was performed using the Cochrane Library, MEDLINE and EMBASE databases to identify trials (Date of last search November 2002). RCTs and CCTs of the effects of a specialist nurse practitioner on short and long-term diabetic outcomes were included in the review. Three investigators performed data extraction and quality scoring independently; any discrepancies were resolved by consensus. Six trials (5 RCTs and 1 CCT) including 1,382 participants followed for six to 12 months were included. Two trials were in adolescents. Due to substantial heterogeneity between trials a meta-analysis was not performed. The main findings indicate that HbA<sub>1c</sub> in the intervention groups was not significantly different from the control groups over a 12 month follow-up period. One study demonstrated a significant reduction in HbA<sub>1c</sub> in the presence of specialist nurse care at 6 months. There were no significant differences overall in hypoglycaemic episodes or hyperglycaemic incidents. Where reported, emergency admissions and QOL were not found to be significantly different between groups. No information was found regarding BMI, mortality, long-term diabetic complications, adverse effects, or costs. It was concluded that the presence of a diabetes specialist nurse/nurse case manager may improve patients' diabetic control over short time periods, but from currently available trials the effects over longer periods of time are not evident.

Recently, Loveman and colleagues (2008) updated their previous systematic review for a HTA Report (Loveman et al, 2003) on the clinical effectiveness of patient education models for adults with type 2 diabetes. They searched electronic databases from 2002 to January 2007. The current review identified 13 published studies (including studies identified in the previous systematic review). Of those 13 studies, eight studies of education focused on a particular aspect of self-management. The quality of reporting and methodology of the studies was variable. Studies of multi-component educational interventions yielded mixed results. Some trials reported significant improvements on measures of diabetic control but others did not. Positive effects may be attributable to longer-term interventions with a shorter duration between the end of the intervention and the follow-up evaluation point. There may also be an effect of having a multi-professional team delivering the educational program. Studies of focused educational interventions did not yield consistent results. Some effects were shown on measures of diabetic control in studies that focused on diet or exercise alone. Although the effects shown were generally small, those that were present did appear to be relatively long-lasting. This updated review did not substantially alter the conclusions of the previous systematic review; for each

outcome, the proportion of studies that demonstrated significant effects of education was similar. The authors concluded that based on the evidence, it would seem that education delivered by a team of educators, with some degree of reinforcement of that education made at additional points of contact, may provide the best opportunity for improvements in patient outcomes and educators need to have time and resources to fulfil the needs of any structured educational program. They also identified the need for education to have a clear program at the outset. From the evidence reported it is unclear what resources would need to be directed at the educators themselves to ensure that they can deliver programs successfully. The authors also suggested that good-quality, longer-term studies would be desirable, but these would require careful consideration around the nature of any control group.

Norris et al. (2001) undertook a systematic review to determine the effectiveness of DSMT in type 2 diabetes while keeping costs acceptable. A total of 72 RCTs described in 84 articles published between 1980 and 1999 were identified through searching MEDLINE, Educational Resources Information Center (ERIC), and Nursing and Allied Health databases. This review included interventions in all settings, regardless of provider type, medium, individual or group-based interventions, intensity or duration of the intervention. Outcomes were classified as knowledge, attitude, lifestyle behaviours, psychological outcomes, QOL, metabolic outcomes and health service utilisation. Researchers found positive effects of DSMT on knowledge, frequency and accuracy of SMBG, self-reported dietary habits, and glycaemic control were demonstrated in studies with short follow-up (<6 months). Effects of interventions on lipids, physical activity, weight, and BP were variable. With longer follow-up, interventions that used regular reinforcement throughout follow-up were sometimes effective in improving glycaemic control. Educational interventions that involved patient collaboration may be more effective than didactic interventions in improving glycaemic control, weight, and lipid profiles. No studies demonstrated the effectiveness of self-management training on CVD-related events or mortality; no economic analyses included indirect costs; few studies examined health-care utilisation. While this review acknowledged several methodological issues in studies reviewed, including threats to internal validity (selection, performance, detection bias, and attrition), the heterogeneous population characteristics, and the generalisability of study results, the authors concluded that evidence supports the effectiveness of self-management training in type 2 diabetes, particularly in the short-term.

Norris et al. (2002a) Followed their earlier review by another systematic review and meta-analysis to evaluate the efficacy of DSME on glycaemic control in adults with type 2 diabetes. Literature searching for English language trials published between 1980 and 1999 was performed using MEDLINE, CINAHL, and ERIC databases. Studies were included if they were RCTs or CCTs published in English, tested the effect of self-management education on adults with type 2 diabetes and reported extractable data on the effect of the intervention of DSME on glycaemic control. A total of 31 studies of 463 initially identified articles met the inclusion criteria. On average the intervention reduced GHb by 0.76% (95% CI 0.34 to 1.18) compared with the control group at immediate follow-up, by 0.26% (0.21 increase to 0.73 decrease) at 1-3 months, and by 0.26% (0.05 - 0.48) at  $\geq 4$  months follow-up. GHb decreased more with additional contact time between patient and educator, with a 1% decrease for every additional 23.6h (13.3 -105.4) of contact. The authors concluded that DSME improves GHb levels at immediate follow-up, with increased contact time improving the effect. However, the benefit declines at 1-3 months, suggesting that learned behaviours change over time.

Norris et al. (2002b) published another systematic review of the literature on the effectiveness and economic efficiency of DSME interventions for people with diabetes. Literature searching was conducted using the MEDLINE, ERIC, CINAHL, Healthstar, CDP, and CHID databases through December 2000. Articles were included for review if they evaluated the effectiveness of DSME interventions delivered outside of traditional clinical settings, in community centres, faith institutions and other community gathering places, the home, the worksite, recreational camps, and schools. A total of 30 studies were included in the review. Data on glycaemic control provide sufficient evidence that DSME is effective in community gathering places for people with type 2 diabetes. There was insufficient evidence, however, to assess the effectiveness of DSME interventions at the worksite or in the home for type 2 diabetes. Physical activity (minutes of walking) improved significantly in one study reviewed by the authors ( $p < 0.001$ ) and dietary intake showed a non-significant increase in men and a non-significant decrease in women in another study. The authors of this review concluded that the available literature is applicable to people with type 2 diabetes of a wide range of ethnical backgrounds and in a variety of community settings. However, due to self-selection of the study population and high attrition rates and high baseline HbA<sub>1c</sub> levels applicability need to be reviewed with caution.

Sigurdardottir et al (2007) performed a systematic review to analyse which factors contribute to improved glycaemic control in educational interventions in type 2 diabetes reported in RCTs published in 2001–2005. Articles were extracted from the MEDLINE, SCOPUS and CINAHL databases using educational intervention and adults with type 2 diabetes as keywords. Data were analysed using a data-mining program. Of 464 titles extracted, 21 articles reporting 18 studies met the inclusion criteria. Data mining indicated that for initial HbA<sub>1c</sub> level  $\leq 7.9\%$  the diabetes education intervention achieved a small change in HbA<sub>1c</sub> level (from +0.1 to -0.7%). For initial HbA<sub>1c</sub>  $\geq 8.0\%$ , a significant drop in HbA<sub>1c</sub> level of 0.8–2.5% was found. Data mining indicated that duration, educational content and intensity of education did not predict changes in HbA<sub>1c</sub> levels. It was concluded that initial HbA<sub>1c</sub> level is the single most important factor affecting improvements in glycaemic control in response to patient education. Participation in educational interventions generally seems to benefit people with type 2 diabetes. However, diversity in conceptualisation of interventions and diversity of instruments used for outcome measurements could have hampered actual discovery of effective educational practices.

Valk et al. (2002) performed a systematic review to assess the effectiveness of patient education in preventing diabetic foot ulcers. Literature searching was performed using the Cochrane Controlled Trials Register (2001) and the Wounds Group Specialized Trials Register. The Wounds Group Specialized Trials register is a database of RCTs compiled from regular searches of the electronic databases of MEDLINE (1966–2001), EMBASE (1980–2001), AND CINAHL (1982–2000) and hand searching of journals that focus on wound care and relevant conference proceedings. Studies were included if they were RCTs that evaluated educational programs for the prevention of foot ulcers in people with diabetes mellitus. The methodological quality of the 8 included RCTs was poor. The internal validity score (range 0–10) of individual RCTs ranged from 2 to 4. Four trials compared the effect of intensive with brief educational interventions; 2 of these reported clinical endpoints. One study involving high-risk patients reported a reduction in ulcer incidence (OR = 0.28, 95% CI 0.13 to 0.59) and amputation rate (OR = 0.32, 95% CI 0.14 to 0.71) after 1 year. The other RCT did not find an effect for either outcome after 7 years of follow-up. Two trials showed that participants' foot care knowledge significantly improved with education; at 6 months in one and 1 year in the other. In one trial, foot care knowledge was

significantly worse at 6 months, although foot care behaviour improved significantly. One RCT, that compared patient foot care education as part of a general diabetes education program to usual care, showed no reduction in the risk of foot ulceration. In one RCT, patient education as part of a complex intervention targeted at both people with diabetes and doctors reduced the prevalence of serious foot lesions at 1 year (OR = 0.41, 95% CI 0.16 to 1.00) and improved foot care behaviour. Evidence from two RCTs comparing the effect of patient-tailored education in addition to usual care was conflicting. The authors concluded that the evidence, while limited by poor methodological quality and conflicting results, suggests that patient education may have positive but short-lived effects on foot care knowledge and behaviour of patients and may reduce foot ulceration and amputations, especially in high-risk patients.

Van Dam et al (2003) performed a systematic review to examine the effect of provider-patient interaction on patient self-care and outcomes in people with diabetes. Literature searching using MEDLINE, EMBASE, PSYCLIT/PSYCINFO and the Cochrane Library databases from 1980 through 2001 identified only eight publications based on well-designed studies involving RCTs – testing the effects of modification of provider-patient interaction and provider consulting style on patient diabetes self-care and diabetes outcomes, in general practice or hospital outpatient settings. Results indicate that interventions on the provider–patient interaction in primary and outpatient clinic diabetes care, can improve patient diabetes behaviour, patient self-care, and diabetes outcomes. It was found that the most effective interventions are those with a direct approach to support patient participation in diabetes care and self-care behaviour, while interventions which focus on change of provider behaviour are less effective. The latter proves hard to sustain, needs intensive support, and is not very effective in improving patient self-care and health outcomes when executed alone. Patient behaviour focused interventions show good efficacy and efficiency, and improve patient self-care and diabetes outcomes.

A Cochrane review to assess the effects of interventions for improving adherence to treatment recommendations in people with type 2 diabetes in primary care, outpatient settings, community and hospital settings was performed by a Belgium research group (Vermeire et al, 2005). Extensive literature searching was performed using multiple electronic bibliographic databases supplemented with hand searches of references. The last search was completed in November 2002. RCTs and CCTs, before-after studies and epidemiological studies, assessing changes in adherence to treatment recommendations, were included. Twenty-one studies were included in the review. The included studies are heterogeneous in terms of interventions, participants, settings, and outcomes. Nurse led interventions, home aids, diabetes education, pharmacy led interventions, adaptation of dosing and frequency of medication taking showed a small effect on a variety of outcomes including HbA<sub>1c</sub>. Studies reporting on diabetes education interventions documented no change or a reduction in HbA<sub>1c</sub> and weight, reductions in systolic BP and improvements in knowledge of diabetes in the intervention compared with the control groups. No data on mortality and morbidity or on QOL could be found. The authors concluded that current efforts to improve or to facilitate adherence of people with type 2 diabetes to treatment recommendations do not show significant effects or harms.

Wens et al (2008) performed a sub-analysis of eight articles from the systematic review by Vermeire et al (2005) to assess educational interventions aimed at improving adherence to medical treatment recommendations, other than lifestyle advice, in people with type 2 diabetes. Wens et al (2008) justified the reporting of metabolic parameters as indirect outcomes of adherence, but no results, comparing intervention and control groups, of direct outcomes of adherence were reported. Three of four studies of face-to-face education showed significant reductions in HbA<sub>1c</sub> levels. In addition, two studies indicated that group education significantly improve HbA<sub>1c</sub>, FPG, total cholesterol, systolic BP, weight, and waist-hip ratio. Two other studies of distance education by telemedicine also showed significant reduction in HbA<sub>1c</sub> but no change in QOL. One study reported more frequent glucose self-monitoring and foot inspection in the intervention group. Due to poor quality of study designs, a variety of heterogeneous outcome measures in different time intervals, unclear definitions of adherence, and difficulties in evaluating different aspects of education performed, a reliable quantitative synthesis could not be conducted and general conclusions about the effectiveness of diabetes education on adherence to treatment recommendations could not be drawn.

Zabaleta et al (2007) conducted a review to determine the effectiveness of structured group-based diabetes education programs in improving glycaemic control in adults with type 2 diabetes in primary care. A comprehensive literature search was performed using the Cochrane register of controlled trials, MEDLINE, EMBASE and CINAHL. The specific inclusion criteria for this review included that the education program had to be structured with a detailed curriculum; group-based in sessions other than usual consultation; held in a primary care setting; and covered topics designed to address diabetes self-care. Twenty one studies were selected for full review and only three of the 21 studies met the inclusion criteria. The results were mixed, with only one study reporting a clinically significant benefit of diabetes education in lowering HbA<sub>1c</sub> compared with the control group. In the second study the difference between the groups was neither clinically nor statistically significant. While the authors of the third study reported improvements in both groups, no comparison was possible as follow-up data were not reported. The authors concluded that there is not sufficient evidence on the effectiveness of diabetes group education for type 2 diabetes patients in primary care. The interventions reported in these three studies were heterogeneous in terms of the size of the groups and duration of the intervention. The authors stated that this review has a number of limitations. These include that the findings of one study could only be considered partially; and while cost-effectiveness might be a relevant factor in choosing group education over alternative therapies, this review was limited to the effectiveness of education in clinical terms.

Zhang et al (2007) conducted a systematic review to assess the effect of interventions for adults with diabetes on HRQL, as measured by the SF-36 questionnaire. The systematic review was conducted using the methods of the Cochrane Collaboration. Studies reporting SF-36 scores before and after an intervention focused on adults with diabetes were obtained from searches of multiple bibliographic databases between 1992 (when the SF-36 was first published) and 2006. The mean changes and standardised mean differences between pre- and post-intervention were reported as outcome measures. Pooled estimates were obtained using random effects models. A total of 33 studies examining a wide range of interventions, including diabetes education and behavioural modifications (15 studies), pharmacotherapy (11 studies), and surgery (7 studies) were identified. Interventions generally demonstrated improvement in HRQL. Pooled effects from 5 RCTs of educational interventions demonstrated significantly improved physical function

3.4 (95% CI 0.1 to 6.6) and mental health 4.2 (95% CI 1.8 to 6.6), and a decrease in bodily pain 3.6 (95% CI 0.6 to 6.7). A pooled effect for 5 pre-versus-post educational interventions significantly improved social function 5.8 (95% CI 2.0 to 9.6), vitality 3.0 (95% CI 1.6 to 4.4), and mental health 2.5 (95% CI 0.6 to 4.4). It was concluded that a variety of interventions can improve HRQL among adults with diabetes, but the magnitude of effects varied with the interventions.

## Appendix 2: Summary of randomised control trials of structured patient education in people with type 2 diabetes

(listed in alphabetical order)

Adolfsson et al. (2007) conducted An RCT at 7 primary care centres in central Sweden to evaluate the impact of empowerment group education on the confidence of people with type 2 diabetes in diabetes knowledge, self-efficacy and satisfaction with daily life compared with the impact of routine diabetes care. Other outcomes assessed were BMI, weight and glycaemic control. 101 patients were randomly assigned either to empowerment group education (intervention group) or to routine diabetes care (control group). Of these, 42 patients in the intervention group and 46 in the control group completed the 1-year follow-up. The intervention group consisted of a 6 week empowerment group education program of 2 hours per week. There were no significant differences in baseline characteristics between the two groups. A 27-item questionnaire produced and validated specifically for the study was used to measure three domains: confidence in diabetes knowledge, self-efficacy and satisfaction with daily life. At 1-year follow-up, the level of confidence in diabetes knowledge was significantly higher in the intervention group than in the control group ( $p < 0.05$ ). However, no significant differences were found in self-efficacy, satisfaction with daily life, BMI and HbA<sub>1c</sub> between the intervention and control group. Thus, BMI and glycaemic control were maintained in both groups over the one year study period.

A research team from Taipei undertook an RCT to compare the effects of regular diabetes health education vs a holiday specific pamphlet before the Chinese New Year holiday period on glycaemic control during the winter holidays among patients with type 2 diabetes (Chen et al, 2008). One hundred and two people with type 2 diabetes aged 50 to 70 years treated with oral hypoglycaemic agents from a Taipei Veterans General Hospital in Taiwan were randomised to program one or to program two. Program one (intervention) was a structured managed care system with regular diabetes health education comprising of individual counselling, which was performed quarterly through to December 2005. Dietitians provided nutrition recommendations, and diabetes educators provided information about diabetes and screened for diabetes complications. The processes included assessment of glycosylated hemoglobin levels, blood pressure and lipid tests, regular diabetes health education, and eye, renal, and foot screening at each visit. Subjects in program two (control) were given an eight-page holiday reminder pamphlet about diet, exercise, and travel and also received regular assessment of HbA<sub>1c</sub> levels, blood pressure and lipid tests, and eye, renal, and foot screening, but without the offer of regular diabetes health education. The Chinese New Year holiday period in this study was from February 6 to February 12, 2005, a total of 7 days, during which time most people did not work. Participants were seen preholiday (visit one to two); the holiday period (visit two to three), post-holiday period (visit three to four) then very four months until December 2005. Fructosamine, FPG, BP and weight were checked at visit one to four, HbA<sub>1c</sub> at visit one, four then at six and 12 months follow-up. Ninety-three subjects completed the first four visits during the Chinese New Year holidays, and 89 participants completed 12 months of the study. Fructosamine levels in program one participants increased during the preholiday period (mean (SD) 7.4 (5.2) while those in program two decreased mean (SD) -5.3 (8.3)  $\mu\text{mol/L}$ , with a statistically significant difference between the programs ( $p = 0.03$ ). Changes in fructosamine levels during the holiday

and post-holiday periods were similar in the two groups however at 5-6 months follow-up the difference remained statistically significant ( $p=0.05$ ). The mean change in HbA<sub>1c</sub> levels at the end of the holiday period in program one was 0.34% (95% CI 0.03 to 0.85%) vs program two 0.09% (95% CI -0.23 to 0.42%). However, at 12 months the mean HbA<sub>1c</sub> level in program one was higher (7.95% compared to program two 7.78% (Data taken from graph). There was no statistical difference in any of the other parameters measured (ie BP, FPG, body weight) at visit four (ie one-two months post Chinese New Year holiday). The authors concluded that this study demonstrated that patients receiving a holiday specific diabetes counselling pamphlet maintained better glycaemic control than patients receiving regular diabetes health education and suggest that that holiday reminder pamphlets be included in general diabetes education before some special events.

Davies et al. (2008) evaluated the effectiveness of a diabetes education and self-management for ongoing and newly diagnosed (DESMOND) structured group education program on biomedical, psychosocial, and lifestyle measures in people with newly diagnosed type 2 diabetes. 207 general practices were recruited from 13 primary care sites in the United Kingdom to participate in this multicentre cluster RCT. Randomisation occurred at practice level. In total 162 practices actively referred a total of participants 824 adults (55% men, mean age 59.5 years). The structured group education program was conducted by two trained healthcare professional educators over six hours delivered in a community setting. Control participants received usual care. Validated self-report measures were applied to assess lifestyle and psychosocial outcomes. Main outcome measures were HbA<sub>1c</sub> levels which at 12 months had decreased by 1.49% in the intervention group compared with 1.21% in the control group. After adjusting for baseline and cluster, the difference was not significant: 0.05% (95% CI -0.10% to 0.20%). The intervention group showed a greater weight loss: -2.98 kg (95% CI -3.54 to -2.41) compared with 1.86 kg (-2.44 to -1.28),  $p=0.027$  at 12 months. Self-reported physical activity (in the previous week) was significantly increased at 4 months -4.3 (-8.3 to -0.3)  $p=0.046$  but showed no significant difference at 8 and 12 months between intervention and control group. The odds of not smoking were 3.56 (95% CI 1.11 to 11.45),  $p=0.033$  higher in the intervention group at 12 months. The intervention group showed significantly greater changes in illness belief scores ( $p=0.001$ ); directions of change were positive indicating greater understanding of diabetes. The intervention group had a lower depression score at 12 months: mean difference was -0.50 (95% CI -0.96 to -0.04);  $p=0.032$ . A positive association was found between change in perceived personal responsibility and weight loss at 12 months ( $\beta=0.12$ ;  $p=0.008$ )(Davies et al, 2008).

Deakin et al (2006) developed a patient-centred, group-based self-management program (X-PERT), based on theories of empowerment and discovery learning. Deakin and colleagues conducted an RCT to assess the effectiveness of the X-PERT program on clinical, lifestyle and psychosocial outcomes in adults with type 2 diabetes ( $n=314$ ), living in Burnley, Pendle or Rossendale, Lancashire, UK. Sixteen general medical practices consented to take part in the study. Adults with type 2 diabetes were identified from practice registers. The X-PERT program was designed and delivered by a diabetes research dietitian who also acted in the role of a diabetes educator. The control group received usual care as well as face-to-face appointments with a dietitian (30min), a practice nurse (15min) and a general practitioner (10min). Baseline characteristics were similar with no significant differences between the intervention and control groups for either outcome or demographic variables. Validated self-report measures were used to assess QOL, knowledge, nutrition intake and diabetes self-care activities. Participants were

randomized to either individual appointments (control group) (n=157) or the X-PERT program (n=157). X-PERT patients were invited to attend six 2-h group sessions of self-management education. Outcomes were assessed at baseline, 4 and 14 months. One hundred and forty-nine participants (95%) attended the X-PERT program, with 128 (82%) attending four or more sessions. By 14 months the X-PERT group compared with the control group showed significant improvements in the mean HbA<sub>1c</sub> (- 0.6% vs. + 0.1%, repeated measures ANOVA, p<0.001). The number needed to treat (NNT) for preventing diabetes medication increase was 4 (95% CI 3 to 7) and NNT for reducing diabetes medication was 7 (95% CI 5 to 11). At 14 months, statistically significant improvements were also seen in the X-PERT patients compared with the control patients for body weight, BMI, waist circumference, total cholesterol, self-empowerment, diabetes knowledge, physical activity levels, foot care, fruit and vegetable intake, enjoyment of food and treatment satisfaction.

Hörnsten et al (2005) conducted a cluster RCT to evaluate whether an educational intervention focusing on patients' personal understanding of their illness was more effective than care given according to national guidelines for diabetes care in people with type 2 diabetes diagnosed within two years. A total of 15 primary health care centres (HCCs) in Sweden were eligible for randomisation. Four HCCs were randomised to the intervention group and four to the control group, equally distributed between rural and urban areas. Five diabetes nurses from each intervention and control group agreed to participate in the study. Patients were aged 40 to 80 years. The educational intervention consisted of 10 group sessions (of 2 hours each) over 9 months with a focus on people's personal understanding of their illness. The intervention was facilitated by trained diabetes nurses. An intervention group (n=44), with type 2 diabetes was compared with a control group (n=60), with HbA<sub>1c</sub> as the primary outcome. The normal level of HbA<sub>1c</sub> in Sweden is 3.5-5.3% and a level of <6.5% was the Swedish treatment target during the study period. Mean HbA<sub>1c</sub> at baseline was 5.71% (S.D. 0.76) in the intervention group and 5.78% (S.D. 0.71) in the control group. At 1-year follow-up the intervention group showed lower HbA<sub>1c</sub> levels (treatment effect mean difference 0.94%; p<0.05), lower triglycerides (mean difference 0.52 mmol/l; p=0.002) and higher HDL (mean difference 0.15 mmol/l; p=0.029) and treatment satisfaction than did the control group. The differences remained when adjusting for age, gender, BMI or changed treatment during the intervention period. At follow-up, significant changes were also seen within the groups with regard to HbA<sub>1c</sub> levels. The levels decreased from 5.7% to 5.4% (SD ± 0.7) in the intervention group, while the control group increased from 5.8% to 6.4% (SD ± 1.1). BMI and treatment satisfaction were also improved within the intervention group. At 5-years follow-up, Hörnsten and colleagues found that trends remained consistent with mean HbA<sub>1c</sub> in the intervention group still 5.71% (S.D. 0.85) while it had increased to 7.08% (S.D. 1.71) among the controls (Hörnsten et al, 2008). The crude difference in HbA<sub>1c</sub> was 1.37 (p<0.001). The adjusted difference with HbA<sub>1c</sub> in 2001 as covariate was also 1.37 (p<0.0001). Other variables used as covariate variables were treatment upgrade, BMI, total cholesterol, HDL, LDL and triglycerides at baseline. They did not influence the difference in HbA<sub>1c</sub>. In addition, the 5-year follow-up revealed that there were no differences in total cholesterol, HDL, LDL, triglycerides and BMI between intervention and control groups (Hörnsten et al, 2008)

Ko et al (2007) conducted an RCT in North Korea to examine the long-term effectiveness of a structured intensive diabetes education program (SIDEPE) for people with type 2 diabetes. People with type 2 diabetes (n= 547) hospitalised from December 1999 to December 2000 were

randomly assigned to two groups. Two hundred and nineteen patients took part in an inpatient SIDEPE and the remaining patients (n=218) received minimal conventional education. All patients were monitored regularly. Laboratory data were obtained, and adherence to self-care behaviour was determined on a five-point scale by questionnaires completed annually. It is unclear from the article whether these questionnaires were validated. Of the patients who completed the SIDEPE, 160 (73.1%) were followed up for more than 4 years. The mean HbA<sub>1c</sub> ( $7.9 \pm 1.2$  SIDEPE vs.  $8.7 \pm 1.6\%$  Control;  $p < 0.05$ ) and the frequency of hospitalization related to diabetes per patient per year ( $0.3 \pm 0.6$  vs.  $0.8 \pm 0.9$ ;  $p < 0.05$ ) were significantly lower in the SIDEPE group than in the control group. Self-care behaviours were more closely adhered to by the SIDEPE group compared with the control group over 4 years ( $p < 0.05$ ). People with longer duration of type 2 diabetes and those treated with insulin had poorer HbA<sub>1c</sub> at follow-up. The authors emphasised the importance of regular and sustained reinforcement with encouragement as a requirement for maintaining optimal glycaemic control, especially in insulin-treated patients.

A German RCT by Kulzer et al (2007) was undertaken to test the efficacy of three education programs for people with type 2 diabetes. The three programs consisted of (A) four didactic-orientated intervention focusing on the acquisition of knowledge, skills and information about the correct treatment of diabetes; (B) twelve self-management/empowerment approach and focused on emotional, cognitive and motivational processes of behaviour change; and (C) twelve more individualised sessions but including group sessions with the same approach as program B. All programs were conducted by four program trained health psychologists. One hundred and eighty-one people with type 2 diabetes (age  $55.6 \pm 6.3$  years, diabetes duration  $6.6 \pm 6.2$  years, HbA<sub>1c</sub>  $7.8 \pm 1.6\%$ , female 49.7%) not treated with insulin living around the city of Würzburg, Germany took part. No significant baseline differences were present between the three intervention groups. Efficiency was measured at 3 (t1) and 15 months (t2) from baseline (t0). Validation of the questionnaire for assessing self-care behaviours was not discussed whereas references were given for assessment instruments used to measure knowledge and psychological outcomes. Results showed a fall in HbA<sub>1c</sub> in treatment B at t1 was sustained at t2 (t0  $8.1 \pm 1.8\%$ , t1  $7.3 \pm 1.7\%$ , t2  $7.4 \pm 1.9\%$ ). In treatment A, HbA<sub>1c</sub> was unchanged throughout (t0  $7.6 \pm 1.5\%$ , t1  $7.5 \pm 1.3\%$ , t2  $7.7 \pm 1.7\%$ ; treatment A vs. treatment B;  $p < 0.05$ ). With the more individualized approach of treatment C, there was a fall in HbA<sub>1c</sub> at t1, but this was not sustained at t2 (t0  $7.8 \pm 1.6\%$ , t1  $7.1 \pm 1.3\%$ , t2  $7.6 \pm 1.6\%$ ; treatment B vs. treatment C;  $p = 0.73$ ). There were also significant benefits in treatment B subjects compared with treatment A in other medical (BMI and FBG), psychological (control, irritability and hunger dependency of eating behaviour, and trait anxiety) and behavioural (exercise) variables. There were no significant benefits of the more individualized treatment C compared with group treatment B. There were no significant differences in triglyceride levels, HDL, diabetes-related knowledge, negative well-being, urine or blood glucose levels or foot care between any groups. The authors concluded that DSMT had a significantly higher medium-term efficacy than didactic diabetes education. The group sessions were more effective than a more individualised education style.

Rachmani et al (2005) conducted a study to examine whether motivating patients to gain expertise and closely follow their risk parameters will attenuate the course of microvascular and cardiovascular consequences of diabetes. A randomised, prospective study was conducted of 165 patients with type 2 diabetes, hypertension, and hyperlipidaemia referred for consultation to a diabetes clinic in an academic hospital in Israel. Patients were randomly allocated to standard

consultation (SC) or to a patient participation (PP) program. Both groups were followed by their primary care physicians. The mean follow-up was 7.7 years. The SC group attended eight standard annual consultations, whereas the patients of the PP program were given two 2-h teaching sessions about ways to achieve tight control of the modifiable risk factors. This included an individualised plan of lifestyle modification and a fitness program, instruction to measure BP weekly, keep records of the results of the laboratory investigations, and urge their physicians to change or intensify treatment if the target values of BP (130/80 mmHg), LDL cholesterol (100 mg/dl), and HbA<sub>1c</sub> (7%) were not reached. These patients were encouraged to call their consultant if they felt that they needed advice. The PP patients initiated on average one additional consultation per year. There were 80 cardiovascular events (eight deaths) in the SC group versus 47 events (five deaths) in the PP group ( $p=0.001$ ). The relative risk (RR) over 8 yr for a cardiovascular event in the intervention (PP) versus the control (SC) group was 0.65 (95% CI 0.89 to 0.41). There were 17 versus eight cases of stroke in the SC and PP groups, respectively ( $p=0.05$ ). RR for stroke was 0.47 (95% CI 0.85 to 0.32). Fourteen patients in the SC group developed overt nephropathy (four end stage renal disease (ESRD) versus seven (one ESRD) in the PP group ( $p=0.05$ ). Over the seven year study period, BP, LDL cholesterol, and HbA<sub>1c</sub> were significantly lower in the PP than in the SC patients. Well informed and motivated patients in this study were more successful in achieving and maintaining good control of their risk factors, resulting in reduced cardiovascular risk and slower progression of microvascular disease. However, no details of who delivered the PP intervention were given by the authors of this study which would makes replication difficult.

Shibayama et al. (2007) examined whether one-on-one lifestyle counselling for people with non-insulin-treated diabetes in an outpatients setting and delivered by a Certified Expert Nurse (CEN) can improve patients' health outcomes. Participants were randomly assigned to a one-year lifestyle intervention ( $n=67$ ) or to a usual care group ( $n=67$ ). Main outcome measures were changes from baseline in: HbA<sub>1c</sub> and score of HRQL scales as measured with validated self report instruments (SF-36 and Problem Areas in Diabetes Scale). Cognitive/behavioural modification for one year and satisfaction in CEN counselling were other measures collected by minimally validated self-produced questionnaire. No significant differences in HbA<sub>1c</sub>, BMI, BP, serum lipids, or HRQL over one year were found between the two groups. Patients in the intervention group, however, showed modest but more favourable modification of cognition ( $p=0.004$ ) and behaviour ( $p<0.001$ ) than subjects in usual care group. The low attrition rate (9%), more frequent hospital visit ( $12 \pm 2$  times versus  $11 \pm 3$  times;  $p=0.03$ ) and high degree of satisfaction (95%) in the intervention group indicate feasibility of the monthly CEN counselling in the outpatient settings of Japanese hospitals.

A research group from the Netherlands examined the effectiveness of a theory-driven self-management course in reducing cardiovascular risk in patients with screen-detected type 2 diabetes, taking ongoing medical treatment into account (Thoolen et al, 2007). Participants (aged 50-70 years) were recruited from the Dutch arm of the ADDITION study (Anglo-Danish-Dutch Study of Intensive Treatment in People With Screen-Detected Type 2 Diabetes in Primary Care). A total of 196 screen-detected patients, receiving either intensive pharmacological or usual-care treatment since diagnosis (3–33 months previously), were subsequently randomised to a control or intervention condition (self- management course). The control group received a brochure on diabetes self-management. The intervention group received a self-management course lasting 12 weeks, including two one hour individual sessions and four two hour bi-weekly group meetings

(n= 6–8) lead by a trained nurse. The sessions were based on theories of proactive coping and self-regulation and emphasised the elements of anticipation, goal setting, planning, and problem solving to help participants move beyond the intentions to achieve optimal self-care. A 2 x 2 factorial design evaluated the behavioural intervention (self-management course versus control) nested within the medical treatment (intensive versus usual care), using multilevel regression modelling to analyse changes in patients' BMI, HbA<sub>1c</sub>, BP, and lipid profiles over 12 months, from the start of the 3-month course to 9-month follow-up. The self-management course significantly reduced BMI at the 9-months follow-up regardless of medical treatment with a difference of -0.77 kg/m<sup>2</sup> or 2.6kg; p<0.001. Intervention participants gradually lost weight with a net loss of -0.39 kg/m<sup>2</sup> while control participants increased by +0.38 kg/m<sup>2</sup>. Systolic BP also reduced significantly (-6.2 mmHg; p<0.05) up until the 9-month follow-up, regardless of medical treatment. Self-management intervention had no effect on lipid levels in either group. However, intensive medical treatment was also independently associated with lower BP, HbA<sub>1c</sub>, total cholesterol, and LDL before the course and further improvements in systolic BP (-4.7 mmHg). Patients receiving both intensive medical treatment and the self-management course therefore had the best outcomes. This self-management course was effective in achieving sustained reductions in weight and BP, independent of medical treatment. Authors concluded that a combination of behavioural and medical interventions is particularly effective in reducing cardiovascular risk in newly diagnosed patients.

Trento et al (2004) conducted a 5-year cluster RCT of continuing system education delivered by group (intervention) versus individual (control) diabetes education in a hospital diabetes care unit. The study was designed to assess knowledge, problem solving ability and QOL in people with non-insulin treated type 2 diabetes. One hundred and twenty participants were randomised, 8 did not start and 28 did not complete the study. Main outcomes were assessed at 1, 2, 3, 4, and 5 years and they were: knowledge, problem solving ability and quality, HbA<sub>1c</sub>, BMI and HDL cholesterol. Diabetes knowledge, problem solving ability and QOL were assessed with self-reported questionnaires which were checked for internal consistency, and validity. Results showed an improvement in diabetes knowledge, problem solving ability and QOL at 5 years follow-up in the group education but worsened in the control group (p<0.001 for all). QOL improved from year 2 with group but worsened in the individual diabetes care group (p<0.001). HbA<sub>1c</sub> increased in the control group (+1.7%, 95% CI 1.1 to 2.2) over the 5 years but not in the intervention group (-0.1% 95% CI -0.5 to 0.4) (p<0.001). Compared with the control group, BMI decreased in the group program (-1.4 95% CI -2.0 to -0.7) (p=0.067); and HDL increased (+0.14mmol/l 95% CI 0.07 to 0.22) but was not statistically significant.

Williams et al (2005) conducted a randomised attention-control trial of 232 patients with type 2 to determine whether a patient activation resulted in patients being rated as more active during practitioners visits and whether glycaemic control would improve in the intervention group. The activation intervention was modelled on the Expanding Patient Involvement in Care (EPIC) trials, and was compared to time-matched passive education viewing of video tapes. Active intervention was designed to encourage patients to become more involved in the management of their diabetes and to help them generate three to five care related questions during a practitioner visit. Patient demographics and clinical characteristics of their diabetes were assessed with questionnaires, active involvement was assessed via ratings of taped interactions between patients and providers, and serum samples were analysed for HbA<sub>1c</sub>. Of the 232 patients randomized to the condition, an intention to treat analysis was conducted on 197 (85%) people

with diabetes. Rated active involvement during the intervention visits was found to be significantly correlated with number of questions asked ( $r = 0.39$ ,  $p < 0.001$ ,  $n = 151$ ) and with percent time speaking ( $r = 0.67$ ,  $p < 0.001$ ,  $n = 151$ ). These results indicate that rated active involvement was reliably measured. The clinical relevance of rated active involvement is reflected in its correlation with HbA<sub>1c</sub> at baseline ( $r = -0.18$ ,  $p < 0.05$ ). Simultaneous regression analyses revealed a significant effect of activation condition, such that patients experiencing the activation intervention were rated as asking more questions  $\beta = 0.32$ ,  $F(1, 122) = 23.54$ ,  $p < 0.01$ , and as speaking a greater percentage of time ( $p = 0.01$ ) than patients receiving passive education. Results also indicate that HbA<sub>1c</sub> was lowered significantly across the entire population. Neither relative nor absolute HbA<sub>1c</sub> improved significantly more in the activation condition than in the education condition. The intervention effect was also tested by comparing the percentage of patients in the activation and education groups who achieved a 12-month criterion value of “healthy” HbA<sub>1c</sub>, defined as one point above the upper limit of normal and no significant effect was found. The authors summarized that this study provides evidence that rated patient active involvement can be increased by patient activation, and that patient active involvement relates to improved control of diabetes. The positive effect of the activation intervention on HbA<sub>1c</sub> such as in the EPIC trials was not replicated in this study, possibly because of the intensive level of care provided in the background of the trial

An RCT by Wolf et al. (2004) assessed the efficacy of a lifestyle intervention program in 147 obese subjects ( $BMI \geq 27 \text{ kg/m}^2$ ) with type 2 diabetes. Participants were randomised to lifestyle case management or usual care. Case management entailed individual and group education, support, and referral by registered dietitians at a cost of US\$350 per person. Individuals treated with usual care received educational material. Both groups received ongoing primary care. Outcomes were differences between groups for change in weight (kilograms), waist circumference (centimetres), HbA<sub>1c</sub>, fasting lipid levels, use of prescription medications, and health-related quality of life. Case management resulted in greater weight loss ( $p < 0.001$ ), reduced waist circumference ( $p < 0.001$ ), reduced HbA<sub>1c</sub> level ( $p = 0.02$ ), less use of prescription medications ( $p = 0.03$ ), and improved health-related quality of life ( $p < 0.001$ ) compared with usual care. The 12-month group difference in weight loss and waist circumference was 3.0kg (95%CI -5.4 to -0.6) and -4.2cm (-6.8 to -1.6). HbA<sub>1c</sub> differences were greatest at 4 months (-0.59%,  $p = 0.006$ ) but not significant by 12 months (-0.19%,  $p = 0.45$ ). Participants in the case management group lowered their use of medications, primarily diabetes medications, by 0.8 medications per day more than participants treated with usual care ( $p = 0.03$ ). In seven of nine quality-of-life domains, the case management group improved compared with usual care ( $p < 0.05$ ). The authors concluded that moderate-cost dietitian-led lifestyle intervention programs may improve diverse health indicators among obese people with type 2 diabetes.

Williams et al (2007) conducted an RCT to determine if a patient-centered, computer-assisted diabetes care intervention increased perceived autonomy support, perceived competence (from self-determination theory), patient satisfaction, glycaemic control (HbA<sub>1c</sub>), ratio of total to HDL cholesterol, diabetes distress, and depressive symptoms compared to a control group. The study recruited 866 adult with type 2 diabetes in heterogeneous primary care settings in Colorado. Self-determination theory proposes that when social surroundings support autonomy and competence, humans become more motivated to adopt recommended health behaviours. Intervention participants were asked to complete a touch screen computerised program to establish a self-management action plan related to dietary, physical activity, and/or smoking

behaviours. Control participants also used a touch screen computer but did not set self-management goals, meet with a care manager nor received follow-up phone calls as did the intervention group. Both autonomy support and perceived competence were measured with validated questionnaires (health care climate questionnaire (HCCQ); 4-item perceived competence scale (PCS), respectively. A series of statistical analyses (ANOVA, structural equation modeling, regression weights) were used to analyse and describe the data. The computer-assisted intervention increased patient perception of autonomy support relative to the computer-based control condition ( $p < 0.05$ ). Competence at 12 months was associated with 12-month outcomes, HbA<sub>1c</sub>, diabetes distress, and depressive symptoms. Separate ANOVA analyses were performed to test the hypothesis that the intervention would have a positive impact on the experience of provider autonomy support and on perceived competence, after controlling for baseline autonomy support and competence, and adjusting for age and number of chronic conditions. Patients in the intervention experienced greater autonomy support from their providers than did patients in the usual care condition, and this difference was significant at 12 months ( $p < 0.05$ ), but not at 6 months ( $p < 0.30$ ). There was a trend for the patients to experience greater perceived competence at 6 ( $p < 0.20$ ) and at 12 months ( $p < 0.10$ ), but neither increase in perceived competence was significant. Change in perceived competence partially mediated the effects of increased autonomy support on the change in lipids, diabetes distress, and depressive symptoms. The construct of autonomy support was found to be separate from that of patient satisfaction. Authors concluded that a patient-centred, computer-assisted intervention was effective in improving diabetes self-management outcomes and that these findings support the self-determination model for health behaviour change and the chronic care model.

## **Appendix 3: Inclusion and Exclusion Criteria**

### ***Generic Inclusion Criteria***

- Present original data or reviews of original data
- Focus on adults with type 2 diabetes or have a cohort of adults with type 2 diabetes
- Address one or more of the specified research questions
- Applicable to diabetes care or prevention in Australia
- Conducted in humans
- Conducted in appropriate population for the question being addressed

### ***Specific Inclusion Criteria***

- Published in the English language
- Articles published in peer-reviewed journals OR reports identified from an electronic database OR recommended by the EAG members
- Evaluate a diabetes education intervention which meets the definition of Structured Patient Education adopted for this review ie:  
It should:
  - have a documented curriculum
  - have documented specific aims and learning objectives
  - be delivered by a trained educator
- Published between 1980 and 2008
- Primary studies should have a minimum follow-up period of 12 months from baseline

### ***Generic Exclusion Criteria***

- Studies of inappropriate patient population/s
- Articles and reviews which present the author's opinion rather than evidence
- Small review articles where the material is covered more adequately by more recent reviews
- In vitro and animal studies

- Genetic studies that are not clinically applicable

### ***Specific Exclusion Criteria for Patient Education Guidelines***

- Studies of a non-dominant population to the country in which the study is conducted (eg a Hispanics population living in the USA)  
NOTE: this does not include studies where a small number of a minority population was included in a principally dominant population
- Studies that evaluate specialised psychological interventions, such as cognitive behavioural therapy or psychotherapy. However diabetes education interventions that incorporate a psychological component will be included.
- Studies in populations not relevant to the Australian population
- Multiple component interventions in which the education component is unable to be analysed separately

## Appendix 4: Guideline Search Strategy, Terms and Yield Tables

### Electronic databases searched

- Medline
- EMBASE
- Cochrane Library
- CINAHL
- NHS Economic Evaluation Database 3rd Quarter 2008, for question 3 (cost-effectiveness)

### Terms used to search the databases:

Search terms are detailed on the next page under in the search strategies used for Medline search. These search terms have been modified as appropriate for other databases.

### Search inclusion criteria

See general and specific inclusion and exclusion criteria (Appendix 3). Searches were limited by the publication years as follows:

- Systematic Reviews January 1980 to June 2008
- Randomised Controlled Trials January 2003 to August 2008

### Abbreviations and explanation of table headings

**Identified** = number of articles which matched the mesh terms listed or contained the text terms in each particular database

**Relevant** = those articles considered relevant to the questions being asked after viewing titles or abstracts

**Articles identified by other strategies** = including articles or reports suggested by the Expert Advisory Group or other experts or public submissions

**Total for Review** = those articles considered relevant to the question after viewing titles and abstracts, contained original data or were systematic reviews of original articles and met the inclusion/exclusion criteria

**Total No. reviewed and graded** = articles used to generate the evidence for the identified question . These articles have been summarised and graded

### Search Terms

*Systematic reviews for patient education in type 2 diabetes*

1 meta-analysis.pt.  
 2 (meta-anal\$ or metaanal\$).tw.  
 3 (quantitativ\$ review\$ or quantitativ\$ overview\$).tw.  
 4 (systematic\$ review\$ or systematic\$ overview\$).tw.  
 5 (methodologic\$ review\$ or methodologic\$ overview\$).tw.  
 6 review.pt. and medline.tw.  
 7 or/1-6  
 8 Education/  
 9 exp Patient Education as Topic/ or exp Health Education/ or Consumer Education/ or exp  
 Competency-Based Education/  
 10 ((diabet\$ or patient or health) and education\$).tw.  
 11 ((self-management or self-care) and (education\$ or train\$)).tw.  
 12 (train\$ or teach\$ or instruct\$ or counsel\$).tw.  
 13 ((diabet\$ or lifestyle or education\$) and (intervention\$ or program\$)).tw.  
 14 or/8-13  
 15 Diabetes Mellitus/ or exp Diabetes Mellitus, Type 2/  
 16 14 and 15  
 17 7 and 16  
 18 limit 17 to (english language and humans and yr="1980 - 2008")

***Randomised Controlled Trials for patient education in type 2 diabetes***

1 randomized controlled trials as topic/  
 2 randomized controlled trial.pt.  
 3 controlled clinical trial.pt.  
 4 Random Allocation/  
 5 Double Blind Method/  
 6 Single Blind Method/  
 7 or/1-6  
 8 animals/ not (animals/ and humans/)  
 9 7 not 8  
 10 clinical trial.pt.  
 11 exp Clinical Trials as Topic/  
 12 (clinic\$ adj25 trial\$).ti,ab.  
 13 Cross-over Studies/  
 14 (crossover or cross-over or cross over).tw.  
 15 ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj25 (blind\$ or mask\$)).ti,ab.  
 16 Placebos/  
 17 placebo\$.ti,ab.  
 18 random\$.ti,ab.  
 19 Research Design/  
 20 or/10-19  
 21 20 not 8  
 22 9 or 21  
 23 Education/

24 exp Patient Education as Topic/ or exp Health Education/ or Consumer Education/ or exp  
Competency-Based Education/  
25 ((diabet\$ or patient or health) and education\$.tw.  
26 ((self-management or self-care) and (education\$ or train\$)).tw.  
27 (train\$ or teach\$ or instruct\$ or counsel\$).tw.  
28 ((diabet\$ or lifestyle or education\$) and (intervention\$ or program\$)).tw.  
29 or/23-28  
30 exp Diabetes Mellitus/ or exp Diabetes Mellitus, Type 2/  
31 and/22,29-30  
32 limit 31 to (english and humans and yr="2003 - 2008")  
33 limit 31 to (english and humans and yr="1980 - 2008")

**Table 9: Literature search yield**

Questions		No. articles identified (all databases combined)	No. relevant articles	Articles identified by other strategies	Total for review	Total No. reviewed and graded	Level I	Level II	Level III	Level IV	Highest level of evidence
<b>Diabetes patient education and type 2 diabetes</b>		1198	134	3	80	32	57	30			I
<b>1</b>	<b>Is structured diabetes education effective?</b>						37	21			I
	- Knowledge						4	4	1		I
	- Self-management						9	4			I
	- Clinical outcomes						10	4			I
	- Psychological adjustment and self-determination						6	4			I
	- Long-term outcomes						6	2			I
	- Health service utilisation						2	3			I
<b>2</b>	<b>How should diabetes education be delivered?</b>						16	6			I
<b>3</b>	<b>Is structured diabetes patient education cost effective?*</b>						1	2			I
	<b>What are the socio-economic implications?</b>						5	1			I

\*One article (Gonzolli 2001)- doesn't fit into any level -modelling

## Appendix 5: NHMRC Evidence Statement Grading Form

Key question(s): Is structured diabetes patient education effective?		Evidence table ref: Section 1
<b>1. Evidence base</b> <i>(number of studies, level of evidence and risk of bias in the included studies)</i>		
	<b>A</b>	Several Level I or II studies with low risk of bias
	<b>B</b>	one or two Level II studies with low risk of bias or SR/multiple Level III studies with low risk of bias
	<b>C</b>	Level III studies with low risk of bias or Level I or II studies with moderate risk of bias
	<b>D</b>	Level IV studies or Level I to III studies with high risk of bias
<b>2. Consistency</b> <i>(if only one study was available, rank this component as 'not applicable')</i>		
	<b>A</b>	All studies consistent
	<b>B</b>	Most studies consistent and inconsistency can be explained
	<b>C</b>	Some inconsistency, reflecting genuine uncertainty around question
	<b>D</b>	Evidence is inconsistent
	<b>NA</b>	Not applicable (one study only)
<b>3. Clinical impact</b> <i>(Indicate in the space below if the study results varied according to some unknown factor (not simply study quality or sample size) and thus the clinical impact of the intervention could not be determined)</i>		
	<b>A</b>	Very large
	<b>B</b>	Moderate
	<b>C</b>	Slight
	<b>D</b>	Restricted
<b>4. Generalisability</b>		
	<b>A</b>	Evidence directly generalisable to target population
	<b>B</b>	Evidence directly generalisable to target population with some caveats
	<b>C</b>	Evidence not directly generalisable to the target population but could be sensibly applied
	<b>D</b>	Evidence not directly generalisable to target population and hard to judge whether it is sensible to apply
<b>5. Applicability</b>		
	<b>A</b>	Evidence directly applicable to Australian healthcare context
	<b>B</b>	Evidence applicable to Australian healthcare context with few caveats
	<b>C</b>	Evidence probably applicable to Australian healthcare context with some caveats
	<b>D</b>	Evidence not applicable to Australian healthcare context

**Other factors** *(Indicate here any other factors that you took into account when assessing the evidence base (for example, issues that might cause the group to downgrade or upgrade the recommendation))*

**EVIDENCE STATEMENT MATRIX**  
*Please summarise the development group's synthesis of the evidence relating to the key question, taking all the above factors into account.*

Component	Rating	Description
1. Evidence base	<b>A</b>	
2. Consistency	<b>B</b>	
3. Clinical impact	<b>B</b>	
4. Generalisability	<b>A</b>	
5. Applicability	<b>A</b>	

*Indicate any dissenting opinions*

<b>RECOMMENDATION</b> <i>What recommendation(s) does the guideline development group draw from this evidence? Use action statements where possible.</i>	<b>GRADE OF RECOMMENDATION</b> <b>A</b>
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All people with type 2 diabetes should be referred for structured diabetes patient education

**IMPLEMENTATION OF RECOMMENDATION**

*Please indicate yes or no to the following questions. Where the answer is yes please provide explanatory information about this. This information will be used to develop the implementation plan for the guidelines.*

Will this recommendation result in changes in usual care?	YES
	NO
Are there any resource implications associated with implementing this recommendation?	YES
	NO
Will the implementation of this recommendation require changes in the way care is currently organised?	YES
	NO
Are the guideline development group aware of any barriers to the implementation of this recommendation?	YES
	NO

## NHMRC Evidence Statement

Key question(s): How should diabetes patient education be delivered?		Evidence table ref: Section 2
<b>1. Evidence base</b> <i>(number of studies, level of evidence and risk of bias in the included studies)</i>		
	A	Several Level I or II studies with low risk of bias
	B	one or two Level II studies with low risk of bias or SR/multiple Level III studies with low risk of bias
	C	Level III studies with low risk of bias or Level I or II studies with moderate risk of bias
	D	Level IV studies or Level I to III studies with high risk of bias
<b>2. Consistency</b> <i>(if only one study was available, rank this component as 'not applicable')</i>		
	A	All studies consistent
	B	Most studies consistent and inconsistency can be explained
	C	Some inconsistency, reflecting genuine uncertainty around question
	D	Evidence is inconsistent
	NA	Not applicable (one study only)
<b>3. Clinical impact</b> <i>(Indicate in the space below if the study results varied according to some unknown factor (not simply study quality or sample size) and thus the clinical impact of the intervention could not be determined)</i>		
	A	Very large
	B	Moderate
	C	Slight
	D	Restricted
<b>4. Generalisability</b>		
	A	Evidence directly generalisable to target population
	B	Evidence directly generalisable to target population with some caveats
	C	Evidence not directly generalisable to the target population but could be sensibly applied
	D	Evidence not directly generalisable to target population and hard to judge whether it is sensible to apply
<b>5. Applicability</b>		
	A	Evidence directly applicable to Australian healthcare context
	B	Evidence applicable to Australian healthcare context with few caveats
	C	Evidence probably applicable to Australian healthcare context with some caveats
	D	Evidence not applicable to Australian healthcare context

**Other factors** *(Indicate here any other factors that you took into account when assessing the evidence base (for example, issues that might cause the group to downgrade or upgrade the recommendation))*

**EVIDENCE STATEMENT MATRIX**  
*Please summarise the development group's synthesis of the evidence relating to the key question, taking all the above factors into account.*

Component	Rating	Description
1. Evidence base	<b>A</b>	
2. Consistency	<b>B</b>	
3. Clinical impact	<b>B</b>	
4. Generalisability	<b>A</b>	
5. Applicability	<b>A</b>	

*Indicate any dissenting opinions*

<b>RECOMMENDATION</b> <i>What recommendation(s) does the guideline development group draw from this evidence? Use action statements where possible.</i>	<b>GRADE OF RECOMMENDATION</b> <b>A</b>
--	--

Diabetes education should be delivered in groups or individually

<b>IMPLEMENTATION OF RECOMMENDATION</b>	
<i>Please indicate yes or no to the following questions. Where the answer is yes please provide explanatory information about this. This information will be used to develop the implementation plan for the guidelines.</i>	
Will this recommendation result in changes in usual care?	YES
	NO
Are there any resource implications associated with implementing this recommendation?	YES
	NO
Will the implementation of this recommendation require changes in the way care is currently organised?	YES
	NO
Are the guideline development group aware of any barriers to the implementation of this recommendation?	YES
	NO

## NHMRC Evidence Statement

4. Key question(s): Is diabetes patient education cost-effective and what are the socio-economic implications?		Evidence table ref: Section 3
1. Evidence base <i>(number of studies, level of evidence and risk of bias in the included studies)</i>		
	A	Several Level I or II studies with low risk of bias
	<del>B</del>	one or two Level II studies with low risk of bias or SR/multiple Level III studies with low risk of bias
	C	Level III studies with low risk of bias or Level I or II studies with moderate risk of bias
	D	Level IV studies or Level I to III studies with high risk of bias
2. Consistency <i>(if only one study was available, rank this component as 'not applicable')</i>		
	A	All studies consistent
	<del>B</del>	Most studies consistent and inconsistency can be explained
	C	Some inconsistency, reflecting genuine uncertainty around question
	D	Evidence is inconsistent
	NA	Not applicable (one study only)
3. Clinical impact <i>(Indicate in the space below if the study results varied according to some unknown factor (not simply study quality or sample size) and thus the clinical impact of the intervention could not be determined)</i>		
	A	Very large
	<del>B</del>	Moderate
	C	Slight
	D	Restricted
4. Generalisability		
	A	Evidence directly generalisable to target population
	<del>B</del>	Evidence directly generalisable to target population with some caveats
	C	Evidence not directly generalisable to the target population but could be sensibly applied
	D	Evidence not directly generalisable to target population and hard to judge whether it is sensible to apply
5. Applicability		
	A	Evidence directly applicable to Australian healthcare context
	<del>B</del>	Evidence applicable to Australian healthcare context with few caveats
	C	Evidence probably applicable to Australian healthcare context with some caveats
	D	Evidence not applicable to Australian healthcare context

**Other factors** *(Indicate here any other factors that you took into account when assessing the evidence base (for example, issues that might cause the group to downgrade or upgrade the recommendation))*

**EVIDENCE STATEMENT MATRIX**  
*Please summarise the development group's synthesis of the evidence relating to the key question, taking all the above factors into account.*

Component	Rating	Description
1. Evidence base	<b>B</b>	
2. Consistency	<b>B</b>	
3. Clinical impact	<b>B</b>	
4. Generalisability	<b>B</b>	
5. Applicability	<b>B</b>	

*Indicate any dissenting opinions*

<b>RECOMMENDATION</b> <i>What recommendation(s) does the guideline development group draw from this evidence? Use action statements where possible.</i>	<b>GRADE OF RECOMMENDATION</b> <b>B</b>
--	--

Efforts to improve the cost-effectiveness of diabetes care should include patient education

**IMPLEMENTATION OF RECOMMENDATION**

*Please indicate yes or no to the following questions. Where the answer is yes please provide explanatory information about this. This information will be used to develop the implementation plan for the guidelines.*

Will this recommendation result in changes in usual care?	YES
	NO
Are there any resource implications associated with implementing this recommendation?	YES
	NO
Will the implementation of this recommendation require changes in the way care is currently organised?	YES
	NO
Are the guideline development group aware of any barriers to the implementation of this recommendation?	YES
	NO

## NHMRC Evidence Statement

5. Key question(s): Is diabetes patient education cost-effective and what are the socio-economic implications?		Evidence table ref: Section 3
1. Evidence base <i>(number of studies, level of evidence and risk of bias in the included studies)</i>		
	A	Several Level I or II studies with low risk of bias
	B	one or two Level II studies with low risk of bias or SR/multiple Level III studies with low risk of bias
	C	Level III studies with low risk of bias or Level I or II studies with moderate risk of bias
	D	Level IV studies or Level I to III studies with high risk of bias
2. Consistency <i>(if only one study was available, rank this component as 'not applicable')</i>		
	A	All studies consistent
	B	Most studies consistent and inconsistency can be explained
	C	Some inconsistency, reflecting genuine uncertainty around question
	D	Evidence is inconsistent
	NA	Not applicable (one study only)
3. Clinical impact <i>(Indicate in the space below if the study results varied according to some unknown factor (not simply study quality or sample size) and thus the clinical impact of the intervention could not be determined)</i>		
	A	Very large
	B	Moderate
	C	Slight
	D	Restricted
4. Generalisability		
	A	Evidence directly generalisable to target population
	B	Evidence directly generalisable to target population with some caveats
	C	Evidence not directly generalisable to the target population but could be sensibly applied
	D	Evidence not directly generalisable to target population and hard to judge whether it is sensible to apply
5. Applicability		
	A	Evidence directly applicable to Australian healthcare context
	B	Evidence applicable to Australian healthcare context with few caveats
	C	Evidence probably applicable to Australian healthcare context with some caveats
	D	Evidence not applicable to Australian healthcare context

**Other factors** *(Indicate here any other factors that you took into account when assessing the evidence base (for example, issues that might cause the group to downgrade or upgrade the recommendation))*

**EVIDENCE STATEMENT MATRIX**

*Please summarise the development group's synthesis of the evidence relating to the key question, taking all the above factors into account.*

Component	Rating	Description
6. Evidence base	<b>A</b>	
7. Consistency	<b>B</b>	
8. Clinical impact	<b>B</b>	
9. Generalisability	<b>B</b>	
10. Applicability	<b>B</b>	

*Indicate any dissenting opinions*

**RECOMMENDATION**

*What recommendation(s) does the guideline development group draw from this evidence? Use action statements where possible.*

**GRADE OF RECOMMENDATION**

**B**

Diabetes education should be culturally sensitive and tailored to the socio-economic needs of populations to which it is delivered

<b>IMPLEMENTATION OF RECOMMENDATION</b>	
<i>Please indicate yes or no to the following questions. Where the answer is yes please provide explanatory information about this. This information will be used to develop the implementation plan for the guidelines.</i>	
Will this recommendation result in changes in usual care?	YES
	NO
Are there any resource implications associated with implementing this recommendation?	YES
	NO
Will the implementation of this recommendation require changes in the way care is currently organised?	YES
	NO
Are the guideline development group aware of any barriers to the implementation of this recommendation?	YES
	NO

## **Appendix 6: Overview of Guideline Development Process and Methods**

# **National Evidence Based Guidelines for the Prevention and Management of Type 2 Diabetes**

## **Overview of Guideline Development Process and Methods**

**Prepared by  
The Diabetes Unit  
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**for the  
Diabetes Australia Guideline Development Consortium**

Last updated 5 May 2009



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# Purpose and Structure of the Document

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## Purpose

This 2008-9 series of guidelines for type 2 diabetes updates and builds on the original suite of evidence based diabetes guidelines which were initiated in 1999 under funding from the Department of Health and Ageing (DoHA) to the Diabetes Australia (DA) Guideline Development Consortium. Under the initial diabetes guideline project, six evidence based guidelines for type 2 diabetes were endorsed by the NHMRC. The purpose of the initial guidelines and the current guidelines is to provide systematically derived, objective guidance to:

1. Improve quality and consistency of care and reduce inappropriate variations in practice by assisting clinicians' and consumers' understanding of and decisions about treatment and management options
2. Inform fund holders and health service planners about the effectiveness and feasibility of the various options
3. Assist researchers and research authorities to highlight i) areas of diabetes prevention and care for which there is inconclusive evidence and ii) areas of deficiency in the evidence which require further or definitive research.

The specific purpose of this current project which commenced in early 2008 was to update two of the previous guidelines - Primary Prevention, and Case Detection and Diagnosis – and to develop three new guidelines, one for Blood Glucose Control, one for Chronic Kidney Disease and one for Patient Education.

## Structure

This *Overview of the Guideline Development Process and Methods* outlines the rationale for the guidelines and the organisational structure, methods and processes adopted for the Type 2 Diabetes Guideline project, including the Blood Glucose Control Guideline. The guidelines are structured to present the recommendations, practice points, evidence statements, documentation of search strategies and search yield and a textual account of the evidence underpinning each recommendation.

## Final format and implementation

The contract between the DoHA and the DA Guideline Development Consortium makes provision for locating and synthesising the available evidence on the five index areas into guideline recommendations and describing the objective justification for the recommendations. Thus, the contract covers the development of the guidelines up to and including endorsement by the NHMRC but does not include implementation of the guidelines.

However, following endorsement by the NHMRC there will need to be an independent process of consultation with potential guideline users to determine the final format of the guidelines for wide dissemination to clinicians and consumers. Once this format has been agreed, an implementation strategy to encourage and facilitate the widespread uptake of the guidelines in everyday practice will need to be developed and actioned at national and state

and territory level. It is our understanding that the DoHA has developed an implementation plan and strategies and is currently obtaining internal sign-off on these before enacting them.

# 1.0 Introduction and Overview

---

## 1.1 Diabetes as a health burden

Results of the national diabetes prevalence survey, AusDiab (Dunstan et al, 2002), which was conducted on representative sample of some 11,000 people across Australia, found a prevalence of diabetes of 7.4% in people aged 25 years or older. Another 16.4% of the study population had either impaired glucose tolerance or impaired fasting glucose. AusDiab also confirmed that there is one person with undiagnosed diabetes for every person with diagnosed diabetes. Findings from the second phase of AusDiab, a 5-year follow-up survey of people who participated in the baseline study, have indicated that every year eight out of every 1,000 people in Australia developed diabetes (Barry et al, 2006). This, together with the increasing number of new cases of pre-diabetes, obesity, the metabolic syndrome, and kidney disease, has demonstrated that abnormal glucose metabolism is exerting a major impact on the health of Australians (Magliano et al, 2008).

Diabetes has a demonstrably high health and cost burden (Colagiuri et al, 2003; AIHW, 2008) resulting from its long term complications which include:

- heart disease and stroke
- foot ulceration, gangrene and lower limb amputation
- kidney failure
- visual impairment up to and including blindness
- erectile dysfunction

The health burden of diabetes is described in more detail throughout the guideline series but to put these complications in perspective, it is worth noting here that, in Australia, diabetes is the most common cause of:

- blindness in people under the age of 60 years
- end stage kidney disease
- non-traumatic amputation

Diabetes is heavily implicated in deaths from cardiovascular disease (CVD) but, due to death certificate documentation deficiencies; this link is believed to be substantially under reported. At a global level, diabetes is predicted to increase dramatically in the next decade or two (IDF, 2006). With an ageing and increasingly overweight and physically inactive population, and a cultural mix comprising numerous groups known to be at high risk of type 2 diabetes, Australia is a prime candidate for realising the projected increases.

Due to sheer numbers, the major proportion of the total diabetes burden is attributable to type 2 diabetes which is the most common form of diabetes and accounts for approximately 85% of all diabetes in Australia. Type 2 diabetes occurs predominantly in mature adults with the prevalence increasing in older age groups. However, in high risk populations such as Aboriginal and Torres Strait Islander people it may become manifest much earlier.

These guidelines focus exclusively on type 2 diabetes in non-pregnant adults. Like type 1 diabetes, type 2 diabetes is characterised by high blood glucose levels. However, unlike type 1 diabetes, the key feature of type 2 diabetes is insulin resistance rather than insulin deficiency. Consequently, its treatment does not necessarily require insulin and in many people, particularly in the initial years following diagnosis, type 2 diabetes can be successfully

managed with dietary and general lifestyle modification alone or in combination with oral anti-diabetic medications. Insulin therapy may be required if and when oral medication becomes ineffective in lowering and maintaining the blood glucose within an acceptable range. Assiduous attention to the management of elevated blood pressure, lipid problems and overweight is also required as these common features of type 2 diabetes markedly increase the risk of long term complications.

## 1.2 Key components and principles of diabetes care

### Key components of care

In 1995, the NSW Health Department identified three key components of diabetes care, stating that .... ‘there is consensus supported by published literature that diabetes care and outcomes can be improved by providing access for all people with diabetes to:

- information about their condition and self care education
- ongoing clinical care to provide optimal metabolic control
- screening for and appropriate treatment of complications’ (Colagiuri R et al, 1995).

These and the principles of care below were included in the initial suite of guidelines for type 2 diabetes and remain as valid now as they were then.

### Principles of care

The particular expression of the universally accepted diabetes care principles set out below was abbreviated from those developed by the UK Clinical Advisory Group (CSAG, 1994) and later summarised by the NSW Health Expert Panel on Diabetes (New South Wales (NSW) Department of Health, 1996) and was further adapted for this project:

- People with diabetes should have access to timely and ongoing care from a diabetes team. This should ideally include a doctor, nurse and dietitian with specific training and experience in the management of diabetes. Additional expertise, for example in podiatry, social work, behavioural psychology and counselling, should be available as required as should referral access to specialist services for the management of identified complications
- People with diabetes are entitled to access to opportunities for information, education and skills acquisition to enable them to participate optimally in their diabetes management
- People with diabetes are entitled to access high quality health services regardless of their financial status, cultural background, or place of residence
- For people with diabetes from community groups who may have special needs eg people from Aboriginal, Torres Strait Islander or culturally and linguistically diverse backgrounds and the elderly, diabetes care should be specifically tailored to overcoming access barriers and providing opportunities for optimising diabetes care and outcomes
- Diabetes teams should routinely evaluate the effectiveness of the care they provide

## 1.3 Rationale for the Guidelines

The magnitude of the impact of diabetes on individuals and society in Australia is manifest in its status as a National Health Priority Area since 1996 and the current attention directed to it by the Council of Australian Governments' National Reform Agenda which seeks to address and avert a greater impact on productivity than already exists as a result of diabetes.

For tangible and lasting benefits, evidence based information is required which synthesises new and existing evidence to guide primary prevention efforts and assist clinicians to identify and treat modifiable primary risk factors, accurately diagnose type 2 diabetes, assess metabolic control, provide effective routine care, and make appropriate and timely referrals.

Since the initial suite of NHMRC diabetes guidelines was released there has been a vast improvement in both the volume and quality of the evidence about preventing type 2 diabetes which is detailed in the Primary Prevention Guideline. Nonetheless, there remain grave concerns that the rapidly increasing prevalence of obesity combined with decreasing levels of physical activity will continue to impact negatively on the incidence and prevalence of diabetes unless addressed as a matter of urgency. Consequently, the Primary Prevention Guideline also cites some of the emerging evidence about environmental influences on food consumption and physical activity.

Type 2 diabetes represents a complex interaction of patho-physiological factors and its prevention and successful management requires clinicians and public health practitioners to maintain a thorough understanding of these interactions especially since there is now irrefutable evidence that both the onset of diabetes and the onset of its complications can be prevented or significantly delayed. Given the typically long pre-clinical phase of type 2 diabetes and that half of all people with diabetes are undiagnosed, the Case Detection and Diagnosis Guideline is an important component of this suite of guidelines.

Integral to the successful management of diabetes is self care knowledge and skills, and the capacity of the person with diabetes to adapt their lifestyle to optimise their physical and psychological well being. The Patient Education Guideline presents evidence addressing these issues.

The care of type 2 diabetes is predominantly carried out by general practitioners, often under 'shared care' arrangements with local Diabetes Centres and/or private endocrinologists. In remote Australia, and even in more densely settled rural regions, the population base is insufficient to support specialist diabetes teams and the general practitioner may not have local access to specialist referral and support. Regardless of geographical factors, standards of diabetes clinical care in Australia are known to be variable. The Chronic Kidney Disease Guideline sets out diagnostic criteria and therapies for achieving the treatment targets to guide the identification, prevention and management of kidney disease in people with diabetes.

Microvascular complications (retinopathy, nephropathy and neuropathy) and the increased risk of macrovascular complications (ischemic heart disease, stroke and peripheral vascular disease) are associated with reduced life expectancy and significant morbidity in type 2 diabetes. Using therapeutic interventions to lower blood glucose and achieve optimal HbA1c levels is critical in preventing diabetes complications and improving the quality of life. The Blood Glucose Control Guideline examines the evidence and the relationships among these issues.

## 1.4 Funding source

The Type 2 Diabetes Guidelines project is funded by the DoHA under a head contract with DA as convener of the Guideline Development Consortium. The development of the guidelines is managed in partnership with DA by The Diabetes Unit at the University Sydney under the direction of A/Professor Ruth Colagiuri.

## 1.5 The Guideline Development Consortium

The Guideline Development Consortium led by DA comprises organisations representing consumers, specialist diabetes practitioners and primary care physicians and includes:

- The Australian Diabetes Society (ADS)
- The Australian Diabetes Educators Association (ADEA)
- The Royal Australian College of General Practitioners (RACGP)
- The Diabetes Unit – Menzies Centre for Health Policy (formerly, the Australian Health Policy Institute), the University of Sydney.

Additionally there are a number of collaborators:

- The NSW Centre for Evidence Based Health Care (University of Western Sydney)
- The Cochrane Renal Review Group (Westmead Children's Hospital)
- The Cochrane Consumer Network
- The Caring for Australians with Renal Impairment Guidelines Group (CARI),
- Kidney Health Australia.

## 1.6 The scope of the Guidelines

The brief for the Guideline Development Project was to prepare a set of evidence based guidelines for type 2 diabetes to NHMRC standard.

The Type 2 Diabetes Guidelines target public health practitioners, clinicians (medical, nursing and allied health), diabetes educators and consumers and were designed to be appropriate for use in a wide variety of practice settings. The guidelines focus on care processes and interventions that are primarily undertaken in the non-acute setting ie they do not deal with highly technical procedural interventions such as renal dialysis.

## 1.7 Use of the Guidelines

Guidelines are systematically generated statements which are designed to assist health care clinicians and consumers to make informed decisions about appropriate treatment in specific circumstances (Field MJ & Lohr, 1990).

Guidelines are not applicable to all people in all circumstances at all times. The recommendations contained in these guidelines are a general guide to appropriate practice and are based on the best information available at the time of their development. The clinical guidelines should be interpreted and applied on an individual basis in the light of the health care practitioner's clinical experience, common sense, and the personal judgments of consumers about what is appropriate for, and acceptable to them.

## **1.8 Review date**

New information on type 2 diabetes is continually and rapidly becoming available. The Project Management Team and Steering Committee recommend that these guidelines are reviewed and revised at least every three years after publication. We anticipate this will be June 2012.

## **1.9 Economic analysis**

Assessment of economic impact i.e., analysing the cost implications of recommendations has become a mandatory component of guideline development.

## **1.10 Socio-economic impact**

The Expert Advisory Groups for each guideline were encouraged to adopt a framework that is recommended by the NHMRC to identify, appraise and collate evidence of the impact of socioeconomic position and other markers of interest eg income, education, occupation, employment, ethnicity, housing, area of residence, lifestyle, gender.

## 2.0 Organisational structure and staffing

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The organisational structure of the Guideline Development Project (Figure 1) comprises:

- A Steering Committee
- Project Management Team
- Expert Advisory Groups
- Guidelines Assessment Register Consultant
- Research Officers
- Research team

*The Steering Committee* consists of a representation from each of the Consortium members, the Guideline Project Medical Advisor, and the DoHA. Refer to Appendix i for Terms of Reference. The Project Steering Committee provides guidance and directions to the project and to the DoHA via DA. The main role was to oversee the project progress and timeline.

*Expert Advisory Groups (EAGs)* were established for each of the five guideline areas. They have a core composition of a consumer, a general practitioner, content experts nominated by the Australian Diabetes Society and the Australian Diabetes Educators Association, and other representation as appropriate. Consumers on the expert advisory groups were provided by Diabetes Australia as being representative of people with type 2 diabetes who are experienced in acting as consumer representatives and who had a detailed understanding of issues affecting people with diabetes. Terms of Reference of the EAGs is provided in Appendix ii. Lists of the individual members of each of the EAGs are provided in each guideline.

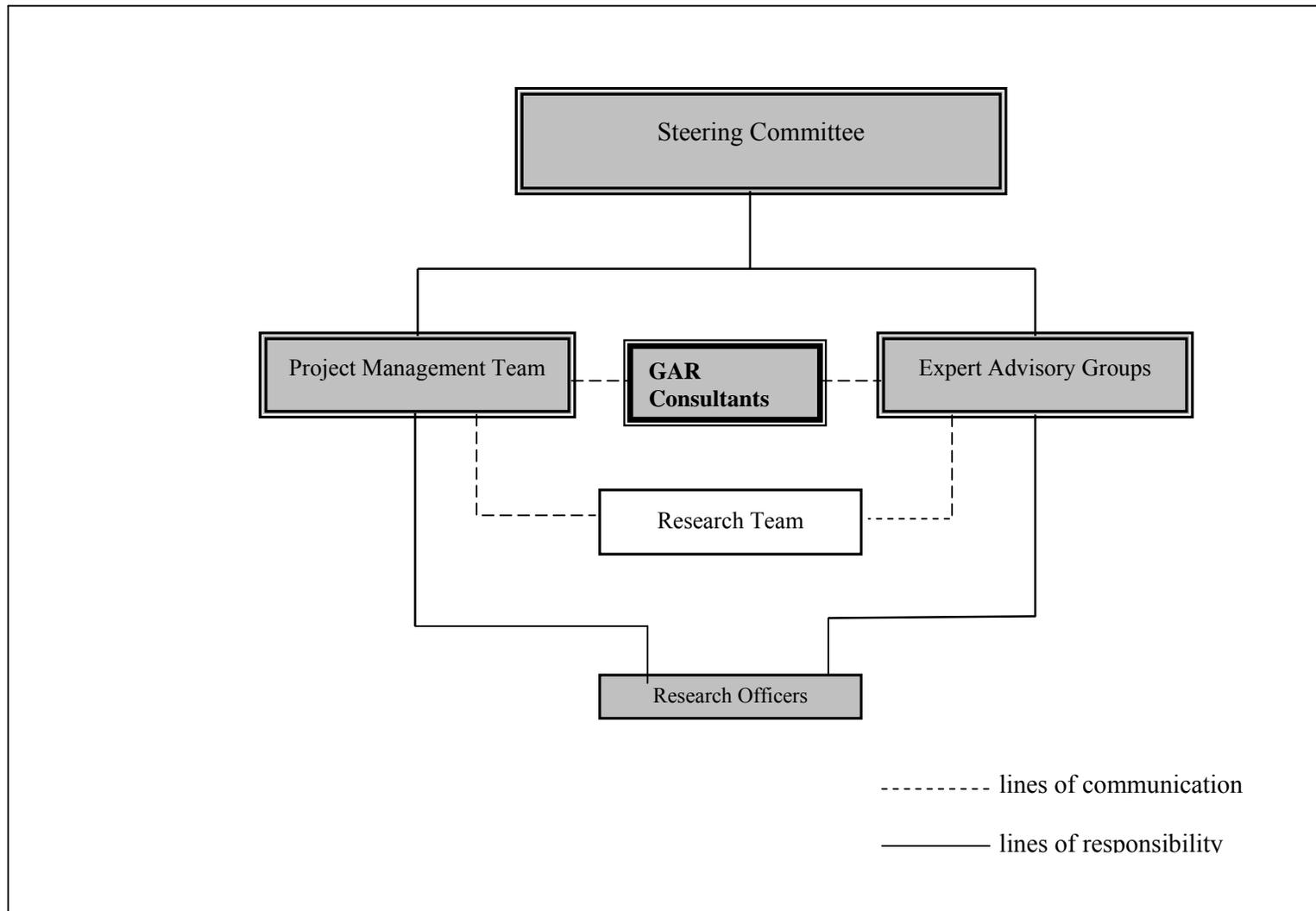
*The Project Management Team.* The Diabetes Unit, at Menzies Centre for Health Policy (formerly, the Australian Health Policy Institute), University of Sydney was subcontracted by DA to manage the project on behalf of the Consortium. The Diabetes Unit provides guidance on methods, technical support, data management, co-ordinates the input of the EAGs and supervises the project staff on a daily basis. The Project Management Team consists of the Director of the Diabetes Unit, the CEO of Diabetes Australia and the project's Medical Advisor.

*Guidelines Assessment Register (GAR) consultants.* The NHMRC nominated a GAR consultant for each guideline (except the Blood Glucose Control guideline) to provide guideline developers with support in relation to utilising evidence-based findings and applying the NHMRC criteria. Specifically, the GAR consultants provided advice on evaluating and documenting the scientific evidence and developing evidence-based recommendations based on the scientific literature and NHMRC procedures.

*Research Officers* were recruited or seconded from a variety of research and health care disciplines and given additional training to conduct the literature searches, and review, grade and synthesise the evidence under the supervision of the Senior Research and Project Manager, Dr Seham Girgis, the Chairs of the EAGs and the Project Management Team.

*Research Team* refers to the Project Director, Senior Project Manager, Research Officers, and the project's Medical Advisor.

**Figure 1: Organisational Structure**



## 3.0 Methods

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### 3.1 Development of Protocols

At the beginning of the project, a Methods Manual was developed for the EAGs and project staff. The Manual was based on the NHMRC *Standards and procedures for externally developed guidelines* (NHMRC, 2007) and the series of handbooks on the development, implementation and evaluation of clinical practice guidelines published by the NHMRC from 2000–03. The NHMRC Standards and procedures document (NHMRC, 2007) introduced an extended set of levels of evidence and an approach to assessing a body of evidence and grading of recommendations. These standards and handbooks have superseded *A guide to the development, implementation and evaluation of clinical practice guidelines* (NHMRC, 1999), which formed the basis of the initial suite of NHMRC guidelines for type 2 diabetes.

The NHMRC has introduced a requirement for guidelines to consider issues related to cost-effectiveness and socioeconomic impact. Two publications in the NHMRC toolkit for developing clinical practice guidelines have been used to address these issues - how to compare the costs and benefits: evaluation of the economic evidence (NHMRC, 2001) and using socioeconomic evidence in clinical practice guidelines (NHMRC, 2003).

The Methods Manual developed for the project contains definitions, procedures and protocols, descriptions of study type classifications, checklists and examples of steps and methods for critical appraisal of the literature. It also includes the revised level of evidence and the minimum requirements for formulating NHMRC evidence based guidelines.

### 3.2 Guideline Development Process

From the literature and expert opinion the following steps were identified as central to the process of identifying sources of rigorously objective, peer reviewed information and reviewing, grading, and synthesising the literature to generate guideline recommendations:

1. Define specific issues and generate clinically relevant questions to guide the literature searches for each guideline topic.
2. Search the literature systematically using a range of databases and search strategies.
3. Sort the search yield on the basis of relevance to the topic area and scientific rigour.
4. Document the search strategy and the search yield.
5. Critically review, grade and summarise the evidence.
6. Assess the body of evidence according to the published NHMRC standard and formulate guideline statements and recommendation/s in accordance with the evidence.
7. Formulate the evidence statements and recommendations.
8. Conduct quality assurance throughout all these steps.

## Step 1: Defining issues and questions to direct the literature searches

Each EAG was asked to define key issues for the guideline and to generate a set of questions focusing on clinically relevant issues to guide the literature searches. These critical clinical issues also formed the focus of the guideline recommendations and accompanying evidence statements. A generic framework was developed and centred on issues such as:

- What are the key treatment/management issues for this area?
- What anthropometric, clinical or behavioural parameters need to be assessed?
- Should everyone be assessed or are there particular risk factors which warrant selective testing or preventative treatment?
- What assessment techniques should be used?
- How often should the assessment be done?
- How should the results be interpreted?
- What action should follow from the results (if abnormal) e.g., management, further investigation, referral?
- What are the overall costs of using the intervention? (particularly in relation to changes in costs if changes to management are recommended)
- What is the impact of socioeconomic position and other markers of interest e.g., income, education, occupation, employment, ethnicity, housing, area of residence, lifestyle, gender.

EAGs were also advised to frame each question using the ‘**PICO**’ elements as follows: **P**opulation **or** **P**roblem; **I**ntervention (for a treatment intervention question), **or** **I**ndicator or exposure (for a prognosis or aetiology or question), **or** **I**ndex test (for a diagnostic accuracy question); **C**omparator; and **O**utcome.

The resulting questions developed by each EAG are presented at the beginning of each guideline and again in the Search Strategy and Yield Table.

## **Step 2: Searching the literature**

NHMRC clinical practice guidelines are required to be based on systematic identification and synthesis of the best available scientific evidence (NHMRC, 2007). A number of systematic strategies were used in this project to identify and assess scientific information from the published literature. The search strategies were designed to reduce bias and ensure that most of the relevant data available on type 2 diabetes were included in the present review and were similar to those detailed in the Cochrane Collaboration Reviewers Handbook (Higgins JPT et al). Several strategies were used to identify potentially relevant studies and reviews from the literature such as:

### ***Electronic Databases***

Searches were carried out using the following databases:

- Medline
- Cochrane Library: Databases of Systematic Reviews, DARE, Controlled Trials Register, Central, HTA.
- Additional databases searched where indicated included:
  - Embase
  - Cinahl
  - Psycho Info
  - Eric
  - Other (where appropriate) such as Internet, Expert sources, Hand searching of reference lists at the end of relevant articles.

### ***Key words***

The key words (MeSH terms and some free text terms) used when searching these electronic databases are presented in detail in the Search Strategy and Yield Table at the end of each guideline topic. The EAGs limited their searches through a number of methods including:

- specification of temporal constraints (e.g. 1999-2008 for the updated guideline)
- language constraints (English only)
- where there were overwhelming amounts of literature or if there was a large volume of poor quality research, some groups imposed limits by experimental design to exclude the less rigorous forms of research.

Details of specific inclusion criteria for the EAG are also presented, together with the key words, at the end of each individual guideline.

### ***Consultation with colleagues***

The EAGs were encouraged to gather relevant information/articles from other experts and colleagues. The Project Management Team collated the questions developed by each EAG to direct the literature searches and highlight overlapping questions and requested EAGs and Research Officers to send any articles identified as applicable to other guideline topics to the EAG.

### **Step 3: Sorting the search yield**

Two or more members of each EAG were responsible for sorting through the search results by scanning the lists of titles and abstracts generated by the electronic database searches, highlighting potentially relevant articles and requesting printed full articles. Full articles were retrieved and those which were relevant were assessed for quality. Articles were considered relevant if they provided direct or indirect information addressing one or more of the specified 'clinical issues' questions and were applicable to diabetes care or prevention in Australia.

#### ***Sorting according to study design***

Articles with original data were sorted according to study design. Articles with the most rigorous experimental designs were reviewed in the first instance. Articles conducted to other study designs were included if they added new information not found in the papers of highest levels of evidence. Relevant papers were sorted as follows:

- Meta-analysis, systematic review of randomised controlled trials (interventions)
- Randomised controlled trials (RCT)
- Cohort studies
- Case control studies
- Case series, pre-post or post studies

#### ***Exclusion criteria***

Articles were not included for review if it was apparent that their relevance to formulating a guideline recommendation was non-existent or negligible. Examples of reasons for non review included criteria such as:

- Studies of inappropriate patient population(s) for the question being addressed (epidemiology, specific diet)
- Hypothesis/mechanism/in vitro study/animal studies
- Genetic studies that are clinically inapplicable
- Non-systematic reviews which presented the author's opinion rather than evidence

## **Step 4: Documenting the search strategy and its yield**

The search strategy (terms and limits) and yield were documented and are available for viewing in a table at the end of each guideline. In brief, the Search Strategy and Yield Table recorded details about the:

1. Questions being investigated
2. Electronic databases searched
3. MeSH terms and key words used to search the database
4. Methods for limiting the searches
5. Number of articles identified by each search
6. Number of articles relevant from that search
7. Number of relevant articles identified through other search processes
8. Number of articles obtained for review
9. Number of relevant articles which were systematic reviews, RCTs or well designed population based studies, quasi-experimental and other (these were documented in the tables according to the updated NHMRC Evidence Levels I–IV).
10. Number of articles reviewed
11. Highest level of evidence found for each question

## Step 5. Critically reviewing, grading and summarising the evidence

All relevant articles were reviewed and critically assessed using checklists recommended by the NHMRC (2000) (NHMRC, 2000a; NHMRC, 2000b). The NHMRC checklist sets out an explicit standardised approach to reviewing and incorporating scientific evidence into clinical practice guidelines.

In addition, Research Officers were asked to construct tables to summarise extraction of data and to provide a brief summary of the key results for each article.

### *Overall assessment of individual studies*

At the conclusion of reviewing each article, the reviewers rated the evidence in a summary form as shown in (Table 1) using the following criteria:

- *Levels of evidence*  
The 'interim' NHMRC levels of evidence (NHMRC, 2007) was used in this project to assess levels of evidence for a range of study designs (Appendix iv).
- *Quality rating*
- *Magnitude of effect*
- *Relevance rating*

Criteria for quality of evidence, magnitude of effect, and relevance of evidence were based on those provided by the NHMRC (2000a &b). These criteria are presented in Appendix iv.

**Table 1: Example of an Overall Assessment Report**

Assessment Category	Rating			
	Value	Low	Medium	High
Level of evidence				
Quality rating				
Magnitude of effect				
Relevance rating				

These assessments were then used in the evidence tables which summarises basic information about **Each Study** reviewed, including an overall assessment of the evidence (Table 2).

**Table 2: Example of an evidence table with overall study assessment**

Author, Year	Evidence				
	<i>Level of Evidence</i>		<i>Quality Rating</i>	<i>Magnitude of Effect Rating</i>	<i>Relevance Rating</i>
	<i>Level</i>	<i>Study Type</i>			
Author X (1999)	III-2	Cohort	High	Low	High

## Step 6. Assessing the body of evidence and formulating guideline evidence statements and recommendations

In addition to considerations of the rigour of the research providing the evidence (Tables 1 and 2), principles for formulating guideline evidence statements and recommendations were derived consistent with the NHMRC recommended standard *'The NHMRC Standards for External Developers of Guidelines'* (NHMRC, 2007).

For each identified clinical question, evidence statements are based on an assessment of all included studies for that question (**the Body of Evidence**). The NHMRC considers the following five components in judging the overall body of evidence (NHMRC, 2007) as specified in the *'NHMRC Body of Evidence Matrix'* (Table 3):

- The evidence base, in terms of the number of studies, level of evidence and quality of studies (risk of bias).
- The consistency of the study results.
- The potential clinical impact of the proposed recommendation.
- The generalisability of the body of evidence to the target population for the guideline.
- The applicability of the body of evidence to the Australian healthcare context.

Based on the body of evidence, recommendation/s was formulated to address each of the identified clinical questions for the area. Recommendation/s was written as an action statement.

### *Principles for formulating the guideline recommendation/s*

In the course of the face-to-face meetings of the EAGs, and from published sources, principles were identified re-affirming the need for guideline recommendations to:

- Be developed systematically and objectively by synthesising the best available evidence.
- Have potential to improve health and related outcomes whilst minimising possible harms.
- Be clinically relevant and feasible.
- Take account of ethical considerations, and acceptability to patients.
- Centre on interventions which are accessible to those who need them.
- Propose activities within the scope of the role of those expected to use the guidelines e.g., interventions which could be expected to be conducted in routine general practice.

### *Grading of recommendation/s*

The grading of each recommendation reflects the strength of the recommendation (Table 4) and is based on *'The NHMRC Standards for External Developers of Guidelines'* (NHMRC, 2007).

In face-to-face meetings, the EAG, initially graded each of the five components of the NHMRC Body of Evidence Matrix (Table 3) for each recommendation and then determined the overall grade for the body of evidence by summing the individual component grades (Appendix v).

Cost effectiveness analyses that were based on modelling, could not be evaluated using the NHMRC 'Body of Evidence Matrix'. Hence, cost-effectiveness recommendations were not graded.

**Table 3: NHMRC Body of Evidence Matrix**

<b>Component</b>	<b>A</b>	<b>B</b>	<b>C</b>	<b>D</b>
	<b>Excellent</b>	<b>Good</b>	<b>Satisfactory</b>	<b>Poor</b>
<b>Evidence base</b>	several level I or II studies with low risk of bias	one or two level II studies with low risk of bias or a SR/multiple level III studies with low risk of bias	level III studies with low risk of bias, or level I or II studies with moderate risk of bias	level IV studies, or level I to III studies with high risk of bias
<b>Consistency</b>	all studies consistent	most studies consistent and inconsistency may be explained	some inconsistency reflecting genuine uncertainty around clinical question	evidence is inconsistent
<b>Clinical impact</b>	very large	substantial	moderate	slight or restricted
<b>Generalisability</b>	population/s studied in body of evidence are the same as the target population for the guideline	population/s studied in the body of evidence are similar to the target population for the guideline	population/s studied in body of evidence different to target population for guideline but it is clinically sensible to apply this evidence to target population	population/s studied in body of evidence different to target population and hard to judge whether it is sensible to generalise to target population
<b>Applicability</b>	directly applicable to Australian healthcare context	applicable to Australian healthcare context with few caveats	probably applicable to Australian healthcare context with some caveats	not applicable to Australian healthcare context

**Table 4: Definition of NHMRC grades of recommendation**

<b>Grade of recommendation</b>	<b>Description</b>
<b>A</b>	Body of evidence can be trusted to guide practice
<b>B</b>	Body of evidence can be trusted to guide practice in most situations
<b>C</b>	Body of evidence provides some support for recommendation(s) but care should be taken in its application
<b>D</b>	Body of evidence is weak and recommendation must be applied with caution

## Step 7. Articulate the guidelines

For each guideline, clinical questions identified by EAGs are addressed in separate sections in a format presenting:

- *Recommendation(s)* - including grading.
- *Practice Point (s)* – including expert consensus in absence of gradable evidence.
- *Evidence Statements* - supporting the recommendations.
- *Background* - to issues for the guideline.
- *Evidence* - detailing and interpreting the key findings.
- *Evidence tables* - summarising the evidence ratings for the articles reviewed.

At the end of the guideline, references and Search Strategy and Yield Tables documenting the identification of the evidence sources were provided.

To ensure consistency between the guidelines, a template was designed for writers to use when drafting the guidelines.

## **Step 8. Methods for Quality Assurance across the project**

To ensure optimal accuracy and consistency within and between guideline areas, the Project Management Team conducted a range of quality assurance activities throughout the project:

### ***Quality Assurance, Procedures and Protocols***

- The provision of a Methods Manual which provides written instructions to the Chairs of the EAGs and research staff identifying the steps and processes to be followed.
- The provision to the EAGs of a selection of key published resource material relevant to the development of the guidelines (NHMRC tool kit 2000-2003; NHMRC, 2007).
- Specification and training of research staff on the search process.

### ***Quality Assurance, Methods***

- The appointment of a Senior Research Officer to the Project Management Team to advise on research methods, and provide a resource and support service to the research staff.
- The establishment of a Methods Advisory Group.
- The development of questions based on key clinical issues for each guideline topic to focus and guide the literature searches and the formulation of the guideline recommendations. As previously indicated, these are listed at the beginning of each guideline and the Search Strategy and Yield Table at the end of the guideline.
- The Project Management Team collated and reviewed the questions and undertook a Delphi - like process with the Chairs of EAGs to refine these questions. In addition, all EAGs and the Project Management Team reviewed the combined questions during one of the three face-to-face meetings.
- The design and provision to Chairs of EAGs and Research Officers of standardised forms documenting aspects of the search strategy used, the search yield, and the inclusion and exclusion of articles for review. A completed Search Strategy and Yield Table follows each guideline topic.
- The Senior Research Officer reviewed:
  - all search terms used to ensure that the searches were comprehensive and that the approach was similar across groups.
  - the documentation of the search process.
- The GAR Consultants worked closely with the Senior Research Officer and EAGs. The GAR Consultants provided advice on evaluating and documenting the scientific evidence, developing evidence-based recommendations based on the scientific literature, and NHMRC procedures.

- Double culling of the search yield for each guideline topic by project staff and members of the EAG.
- Double reviewing of a sample of completed reviews for each guideline topic by the Senior Research Officer or an experienced Research Officer, or by a member of the relevant EAG.
- Review of the completed recommendations and written description of the literature review for each guideline area was undertaken to check for:
  - appropriate use of references
  - accurate application of evidence ratings
  - congruence between the recommendations and evidence statements
  - consistency between recommendations
  - clarity of the literature review findings

## 4.0 Consultation Process

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The organisational structure for the Type 2 Diabetes Guidelines Development Project was designed to involve and ensure consultation between the Guideline Development Consortium (DA, ADS, ADEA, RACGP) and the Diabetes Unit. A number of other strategies were employed to ensure wide consultation with a range of stakeholders and interested groups and individuals.

### **Initial Consultation**

Prior to commencement of the project, initial consultation included contacting relevant professional organisations to discuss the guideline development and to seek nomination of content experts.

### **Internal Consultation**

The internal communication and interaction between the Project Management Team and the research officers included fortnightly meetings, email communications, and regular telephone contact. In addition, for each guideline, there was individual informal meetings between the research officers and their project managers.

### **The Project Steering Committee**

The Project Steering Committee comprised representatives from various organisations (who should be consulting with their colleagues in that organisation) include:

- Diabetes Australia (Mr Matt O'Brien)
- Medical Advisor (Professor Stephen Colagiuri)
- Australian Diabetes Society (Dr Maarten Kamp)
- Australian Diabetes Educators Association (Ms Jane Giles)
- Royal Australian Collage of General Practice (Professor Mark Harris)
- Department of Health and Ageing (Ms Suzanne Prosser)
- The Diabetes Unit, Menzies Centre for Health Policy (Associate Professor Ruth Colagiuri)

During the course of the project, DA convened two face-to-face meetings and three teleconferences of the Project Steering Committee members to provide guidance and direction to the project.

### **Expert Advisory Groups**

The EAGs consulted formally through the inclusion of specific interest groups on the individual EAG. Examples include dietitians, clinicians, educators, researches, and consumers.

Communication strategies with EAG members included:

- Face-to-face meetings
  - an initial meeting to scope the coverage of the guideline and view the processes required to develop it, identify and agree on the roles of the EAG.
  - a final meeting to review and grade the recommendations and body of evidence form.

- Email communication seeking advice on research questions and search terms and requesting review of material developed.
- Chairs and individual members of EAGs, consulted with additional content experts regarding approaches and clinical/content issues as required.

### **Consultation with Guidelines Assessment Register (GAR) Consultants.**

The GAR consultant for each guideline provided guideline developers with support in relation to utilising evidence-based findings and applying the NHMRC criteria. GAR consultants attended face-to-face meetings with EAGs. They provided advice on evaluating and documenting the scientific evidence and developing evidence-based recommendations based on the scientific literature and NHMRC procedures.

### **Consultation with Consumers**

Consumer representatives were selected and appointed by Diabetes Australia for each EAG to ensure the consideration of people with type 2 diabetes with respect to their acceptability of the proposed guideline recommendations.

### **Public Consultation**

All guidelines went through a formal public consultation process. This process was as follows:

- The guidelines were released for public consultation by Diabetes Australia through the NHMRC designated public consultation process between August and October 2008.
- The call for submissions was advertised in the national public press and a front page website advertisement was placed on the Diabetes Australia website, which linked to a full website advertisement.
- The NHMRC also advertised the draft guidelines in their ‘bulletin’.
- Key stakeholder organisations (Appendix vi) were notified directly by email of the availability of the guidelines for public review and requested to comment. The emailed notice provided a link to the advertisement on the Diabetes Australia website.
- As a result of public consultation, submissions were received and referred to the Project Management Team:
  - six submissions relating to the Primary Prevention Guideline
  - four submissions relating to Case Detection and Diagnosis Guideline
  - two submissions relating to Patient Education
  - two submissions relating to Chronic Kidney Disease
  - five submissions relating to Blood Glucose Control
  - one submission did not relate to any of the guidelines but made comments on the overall process of the guideline development which was subsequently referred to the Diabetes Australia Guideline Consortium Steering Committee.

- The issues raised in these submissions were considered and consulted about internally and externally by the guideline developers and were reviewed by the Project Management and Research Teams, the Medical Advisor, the relevant EAG, and the GAR Consultant.
- Key issues from the submissions for each guideline were summarised into table form and corresponding responses addressing each issue were presented in separate documents entitled “*Response to Public Consultation on ...* ” and accompanied the guideline drafts presented to independent review by the NHMRC.
- Changes to the guidelines as a result of public consultation and as a result of independent review by the NHMRC were incorporated into the revised final guidelines.

### **Informal Consultation**

Further consultation occurred throughout the project with a wide variety of groups and individuals in response to particular issues and needs. For example, the Chronic Kidney Disease Guideline has been reviewed by the CARI peer reviewers and presented at the Dialysis, Nephrology Transplant 2009 Workshop, Lorne Victoria. Comments from the peer reviewers and from the workshop have been incorporated into the subsequent revision of the draft guideline.

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# APPENDICES

## **Appendix i: Terms of Reference of Steering Committee**

### **Type 2 Diabetes Guidelines Project**

#### **1. Scope**

The Steering Committee is a composite body which provides guidance and direction to the project and advice in relation to the project to the Department of Health and Ageing via Diabetes Australia.

#### **2. Function**

The role of the Steering Committee is to oversight and monitors the project progress and timelines.

#### **3. Membership**

The Steering Committee will comprise representatives from the following organisations:

- Diabetes Australia
- The Diabetes Unit, Australian Health Policy Institute
- Australian Diabetes Society
- Australian Diabetes Educators Association
- Royal Australian College of General Practitioners
- Medical Advisor
- Consumer – person with type 2 diabetes nominated by Diabetes Australia.

The Department of Health and Ageing (the Department) will be represented in an advisory role.

The final composition of the Steering Committee, the operating procedures and the Chair of the Committee will be agreed by the Department.

If a representative is unable to attend a meeting/teleconference they may nominate a proxy representative from their own organisation.

#### **4. Quorum and Voting**

The quorum for Steering Committee meetings is to be 50% of membership plus one additional member.

The Steering Committee shall always attempt to achieve consensus. In the event of decisions requiring a vote, each member of the Committee shall exercise a single vote. Decisions will be by a majority and the Chair shall have a casting vote.

#### **5. Communication**

The Steering Committee will communicate directly with Diabetes Australia who in turn will liaise with the Department. Communication between the Steering Group and other teams and groups is essential and will be facilitated by the Chair of the Committee.

**Frequency of Meetings**

The Steering Committee will meet on at least five occasions throughout the contract period. These meetings will comprise two face-to-face meetings and three teleconferences, throughout the contract period.

**6. Executive and Operational Support**

The Steering Group Secretariat will be provided by Diabetes Australia. The Secretariat will provide support in writing minutes and co-ordinating meetings

**7. Funding**

The costs of travel, accommodation, meeting location (or teleconference) expenses and other activities proposed by the Steering Committee will be agreed and borne by Diabetes Australia.

## **Appendix ii: Terms of Reference for Expert Advisory Groups**

### **Type 2 Diabetes Guidelines Project**

#### **Purpose**

The Expert Advisory Groups (EAGs) for the National Evidence Based Guidelines for Type 2 Diabetes are convened by The Diabetes Unit, Menzies Centre for Health Policy (formerly Australian Health Policy Institute), The University of Sydney under the head agreement between Diabetes Australia and the Department of Health and Ageing to support the development of the guidelines by providing:

1. Overall technical and content advice and critical comment
2. Input into the development or revision of research questions to guide the literature reviews
3. Guidance on search terms and for the literature review
4. Review of drafts of the guidelines and recommendations at critical points along the continuum of their development
5. Perspectives on the feasibility and applicability of the guidelines from the perspective of their own disciplines and their peers and colleagues

#### **Duration**

The EAGs are convened for the duration of the project. It is anticipated this will cover approximately 18 months up to end 2008.

#### **Frequency of Meetings**

It is anticipated that there will be three meetings of the EAGs mainly by teleconference with one face-to-face meeting at commencement.

The EAG members may also be asked to comment on emailed information from time to time.

#### **Expenses**

Reasonable expenses for travel to meeting will be reimbursed on presentation of original receipts

#### **Conflict of Interests**

EAG members are asked to declare any/all perceived conflict/s of interest

**Appendix iii: NHMRC Evidence Hierarchy, designations of ‘levels of evidence’ according to type of research question**

<b>Level</b>	<b>Intervention</b>	<b>Diagnostic accuracy</b>	<b>Prognosis</b>	<b>Aetiology</b>	<b>Screening Intervention</b>
I	A systematic review of level II Studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies	A systematic review of level II studies
II	A randomised controlled trial	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among consecutive persons with a defined clinical presentation	A prospective cohort study	A prospective cohort study	A randomised controlled trial
III-1	A pseudorandomised controlled trial (i.e. alternate allocation or some other method)	A study of test accuracy with: an independent, blinded comparison with a valid reference standard, among non-consecutive persons with a defined clinical presentation	All or none	All or none	A pseudorandomised controlled trial (i.e. alternate allocation or some other method)
III-2	A comparative study with concurrent controls: <ul style="list-style-type: none"> <li>▪ Non-randomised, experimental trial</li> <li>▪ Cohort study</li> <li>▪ Case-control study</li> <li>▪ Interrupted time series with a control group</li> </ul>	A comparison with reference standard that does not meet the criteria required for Level II and III-1 evidence	Analysis of prognostic factors amongst persons in a single arm of a randomised controlled trial	A retrospective cohort study	A comparative study with concurrent controls: <ul style="list-style-type: none"> <li>▪ Non-randomised, experimental trial</li> <li>▪ Cohort study</li> <li>▪ Case-control study</li> </ul>
III-3	A comparative study without concurrent controls: <ul style="list-style-type: none"> <li>▪ Historical control study</li> <li>▪ Two or more single arm study</li> <li>▪ Interrupted time series without a parallel control group</li> </ul>	Diagnostic case-control study	A retrospective cohort study	A case-control study	A comparative study without concurrent controls: <ul style="list-style-type: none"> <li>▪ Historical control study</li> <li>▪ Two or more single arm study</li> </ul>
IV	Case series with either post-test or pre-test/post-test outcomes	Study of diagnostic yield (no reference standard)	Case series, or cohort study of persons at different stages of disease	A cross-sectional study or case series	Case series

(Source: NHMRC 2007)

## Appendix iv: Study Assessment Criteria

### I. Study quality criteria

#### ***Systematic reviews***

1. Were the questions and methods clearly stated?
2. Is the search procedure sufficiently rigorous to identify all relevant studies?
3. Does the review include all the potential benefits and harms of the intervention?
4. Does the review only include randomised controlled trials?
5. Was the methodological quality of primary studies assessed?
6. Are the data summarised to give a point estimate of effect and confidence intervals?
7. Were differences in individual study results adequately explained?
8. Is there an examination of which study population characteristics (disease subtypes, age/sex groups) determine the magnitude of effect of the intervention?
9. Were the reviewers' conclusions supported by data cited?
10. Were sources of heterogeneity explored?

#### ***Randomised controlled trials***

1. Were the setting and study subjects clearly described?
2. Is the method of allocation to intervention and control groups/sites independent of the decision to enter the individual or group in the study ?
3. Was allocation to study groups adequately concealed from subjects, investigators and recruiters including blind assessment of outcome?
4. Are outcomes measured in a standard, valid and reliable way?
5. Are outcomes measured in the same way for both intervention and control groups?
6. Were all clinically relevant outcomes reported?
7. Are factors other than the intervention e.g. confounding factors, comparable between intervention and control groups and if not comparable, are they adjusted for in the analysis?
8. Were >80% of subjects who entered the study accounted for at its conclusion?%
9. Is the analysis by intention to intervene (treat)?
10. Were both statistical and clinical significance considered?
11. Are results homogeneous between sites? (Multi-centre/multi-site studies only).

#### ***Cohort studies***

1. Are study participants well-defined in terms of time, place and person?
2. What percentage (%) of individuals or clusters refused to participate?
3. Are outcomes measured in a standard, valid and reliable way?
4. Are outcomes measured in the same way for both intervention and control groups?
5. Was outcome assessment blind to exposure status?
6. Are confounding factors, comparable between the groups and if not comparable, are they adjusted for in the analysis?
7. Were >80% of subjects entered accounted for in results and clinical status described?
8. Was follow-up long enough for the outcome to occur
9. Was follow-up complete and were there exclusions from the analysis?
10. Are results homogeneous between sites? (Multicentre/multisite studies only).

#### ***Case-control studies***

1. Was the definition of cases adequate?

2. Were the controls randomly selected from the source of population of the cases?
3. Were the non-response rates and reasons for non-response the same in both groups?
4. Is possible that over-matching has occurred in that cases and controls were matched on factors related to exposure?
5. Was ascertainment of exposure to the factor of interest blinded to case/control status?
6. Is exposure to the factor of interest measured in the same way for both case and control groups in a standard, valid and reliable way (avoidance of recall bias)?
7. Are outcomes measured in a standard, valid and reliable way for both case and control groups?
8. Are the two groups comparable on demographic characteristics and important potential confounders? and if not comparable, are they adjusted for in the analysis?
9. Were all selected subjects included in the analysis?
10. Was the appropriate statistical analysis used (matched or unmatched)?
11. Are results homogeneous between sites? (Multicentre/multisite studies only).

***Diagnostic accuracy studies***

1. Has selection bias been minimised
2. Were patients selected consecutively?
3. Was follow-up for final outcomes adequate?
4. Is the decision to perform the reference standard independent of the test results (ie avoidance of verification bias)?
5. If not, what per cent were not verified?
6. Has measurement bias been minimised?
7. Was there a valid reference standard?
8. Are the test and reference standards measured independently (ie blind to each other)
9. Are tests measured independently of other clinical and test information?
10. If tests are being compared, have they been assessed independently (blind to each other) in the same patients or done in randomly allocated patients?
11. Has confounding been avoided?
12. If the reference standard is a later event that the test aims to predict, is any intervention decision blind to the test result?

(Sources: adapted from NHMRC1999, NHMRC 2000a, NHMRC 2000b, Liddle et al 96; Khan et 2001)

**Study quality – Rating**

The following was used to rate the quality of each study against the study type criteria listed above.

**High:** all or all but one of the criteria were met

**Medium:** 2 or 3 of the criteria were not met

**Low:** 4 or more of the criteria were not met

## II. Classifying magnitude of the effect

Ranking	Statistical significance		Clinical importance of benefit
<b>High</b>	Difference is statistically significant	AND	There is a clinically important benefit for the full range of estimates defined by the confidence interval.
<b>Medium</b>	Difference is statistically significant	AND	The point estimate of effect is clinically important BUT the confidence interval includes some clinically unimportant effects
<b>Low</b>	Difference is statistically significant	AND	The confidence interval does not include any clinically important effects
	OR Difference is not statistically significant (no effect) or shows a harmful effect	AND	The range of estimates defined by the confidence interval includes clinically important effects.

(Source: adapted from the NHMRC classification (NHMRC 2000b))

## III. Classifying the relevance of the evidence

Ranking	Relevance of the evidence
<b>High</b>	Evidence of an effect on patient-relevant clinical outcomes, including benefits and harms, and quality of life and survival <i>Or</i> Evidence of an effect on a surrogate outcome that has been shown to be predictive of patient-relevant outcomes for the same intervention
<b>Medium</b>	Evidence of an effect on proven surrogate outcomes but for a different intervention <i>Or</i> Evidence of an effect on proven surrogate outcomes but for a different intervention and population
<b>Low</b>	Evidence confined to unproven surrogate outcomes.

(Source: adapted from the NHMRC classification (NHMRC 2000b))

## Appendix v: NHMRC Evidence Statement Form

Key question(s):		Evidence table ref:
<b>1. Evidence base</b> <i>(number of studies, level of evidence and risk of bias in the included studies)</i>		
	A	Several Level I or II studies with low risk of bias
	B	one or two Level II studies with low risk of bias or SR/multiple Level III studies with low risk of bias
	C	Level III studies with low risk of bias or Level I or II studies with moderate risk of bias
	D	Level IV studies or Level I to III studies with high risk of bias
<b>2. Consistency</b> <i>(if only one study was available, rank this component as 'not applicable')</i>		
	A	All studies consistent
	B	Most studies consistent and inconsistency can be explained
	C	Some inconsistency, reflecting genuine uncertainty around question
	D	Evidence is inconsistent
	NA	Not applicable (one study only)
<b>3. Clinical impact</b> <i>(Indicate in the space below if the study results varied according to some <u>unknown</u> factor (not simply study quality or sample size) and thus the clinical impact of the intervention could not be determined)</i>		
	A	Very large
	B	Moderate
	C	Slight
	D	Restricted
<b>4. Generalisability</b>		
	A	Evidence directly generalisable to target population
	B	Evidence directly generalisable to target population with some caveats
	C	Evidence not directly generalisable to the target population but could be sensibly applied
	D	Evidence not directly generalisable to target population and hard to judge whether it is sensible to apply
<b>5. Applicability</b>		
	A	Evidence directly applicable to Australian healthcare context
	B	Evidence applicable to Australian healthcare context with few caveats
	C	Evidence probably applicable to Australian healthcare context with some caveats
	D	Evidence not applicable to Australian healthcare context

**Other factors** *(Indicate here any other factors that you took into account when assessing the evidence base (for example, issues that might cause the group to downgrade or upgrade the recommendation))*

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**EVIDENCE STATEMENT MATRIX**  
*Please summarise the development group's synthesis of the evidence relating to the key question, taking all the above factors into account.*

Component	Rating	Description
1. Evidence base		
2. Consistency		
3. Clinical impact		
4. Generalisability		
5. Applicability		

*Indicate any dissenting opinions*

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<p><b>RECOMMENDATION</b>  <i>What recommendation(s) does the guideline development group draw from this evidence? Use action statements where possible.</i></p>	<p><b>GRADE OF RECOMMENDATION</b></p>	
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<b>IMPLEMENTATION OF RECOMMENDATION</b>	
<i>Please indicate yes or no to the following questions. Where the answer is yes please provide explanatory information about this. This information will be used to develop the implementation plan for the guidelines.</i>	
Will this recommendation result in changes in usual care?	YES
	NO
Are there any resource implications associated with implementing this recommendation?	YES
	NO
Will the implementation of this recommendation require changes in the way care is currently organised?	YES
	NO
Are the guideline development group aware of any barriers to the implementation of this recommendation?	YES
	NO

## **Appendix vi: Key stakeholder organisations notified of public consultation**

- Diabetes Australia State and Territory member organisations including:
  - Australian Diabetes Society
  - Australian Diabetes Educators Association
  
- University Schools of Nursing, Medicine, Podiatry, Nutrition/ Dietetics
- Australian Podiatry Association
- Australian Podiatry Council
- Eyes on Diabetes
- Cooperative Centre for Aboriginal Health
- Australian Centre for Diabetes Strategies
- Public and private Diabetes Centres throughout Australia (for which we were able to obtain email addresses)
- State and Federal health departments