NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

QUALITY AND OUTCOMES FRAMEWORK (QOF) INDICATOR DEVELOPMENT PROGRAMME

Briefing paper

QOF indicator area: Diabetes – dietary review

Potential output: Recommendations for indicator development

Date of Primary Care QOF Indicator Advisory Committee meeting: 2 and

3 June 2010

The briefing paper is structured as follows:

- 1. Outline of the stakeholder topic suggestion
- 2. An overview of diabetes, including an epidemiological summary and its current management in primary care
- 3. Recommendations highly relevant to primary care from NICE clinical guideline 15, 66 and SIGN clinical guidelines 116 identified for indicator development and a summary of the evidence that informs the recommendations
- **4.** An assessment of current practice
- **5.** A summary of the key considerations

Introduction

This briefing paper presents an assessment of the suitability of NICE clinical guideline recommendations relevant to primary care and proposed by stakeholders to progress for QOF indicator development.

The QOF indicator area is diabetes and the recommendations and underlying evidence are taken from the following guidance:

'Type 1 diabetes in adults: national clinical guideline for diagnosis and management' (NICE clinical guideline 15). This guideline was issued by NICE in July 2004.

'Type 2 Diabetes. National clinical guideline for management in primary and secondary care (update)' (NICE clinical guidance 66). This guideline was issued by NICE in May 2008.

'Management of diabetes'. Scottish Intercollegiate Guidelines Network. (SIGN clinical guidance 116). This guideline was issued by SIGN in March 2010.

Stakeholder topic suggestion

The stakeholder submission(s) for this topic is dietary review which has been prioritised by the NICE team for consideration by the Advisory Committee.

Dietary review

Percentage of people with diabetes who have received a dietary review and assessment by a suitably competent professional in accordance with the relevant NICE guidance for type 1 or type 2 diabetes, in the last 15 months.

Overview of diabetes

Epidemiological summary

Definition

Diabetes is a chronic metabolic disorder caused by defects in insulin secretion and action. There are two main types of diabetes. Type 1 diabetes occurs because the insulin-producing cells of the pancreas have been destroyed by the body's immune system, and it typically develops in children and young adults. Type 2 diabetes is more commonly diagnosed in adults over the age of 40 years, but is also increasing in young people. In this condition, insulin is produced but is insufficient for the body's needs. There is also a degree of insulin resistance, where the cells in the body are not able to respond to the insulin that is produced.

Incidence and prevalence and evidence of variation by age, sex and ethnicity

Type 2 diabetes accounts for around 90% of all diabetes. Prevalence estimates vary from around 3.5 to 5.0%. The Health Survey for England 2003 suggests that 3.1% of men and 1.5% of women aged 35 and over have undiagnosed diabetes. The prevalence of diabetes varies with factors such as mix of ethnic groups and degree of social deprivation. People from minority ethnic groups have up to a six times higher than average risk of developing diabetes. The incidence and prevalence of type 2 diabetes are rising annually and are greater in areas of higher social deprivation.

Morbidity and mortality

Type 1 diabetes is fatal unless **treated with insulin**. Most people who develop type 1 are otherwise healthy. Untreated type 1 diabetes commonly leads to **coma**, often from **diabetic ketoacidosis**, which is fatal if untreated. Life expectancy is reduced by at least 15 years for someone with type 1 diabetes. In type 2 diabetes, which can be prevented in two-thirds of people who have it, life expectancy is reduced by up to 10 years. Most of the morbidity and increased mortality comes from coronary, cerebral and

peripheral arterial disease. Mortality attributed to people with diabetes is suggested as contributing to 4.2% of deaths in men and 7.7% of deaths in women in the UK, although the burden is likely to be greater since diabetes is strongly linked to coronary heart disease.

Impact on health services

Primary care

People with diabetes form a significant part of the general practice workload. More than 2000 people every week are being diagnosed with diabetes in England and the numbers of diabetic prescription items have risen by 55% over the last 5 years. In 2006, the cost of primary care prescribing in England for drugs to treat diabetes was over £500 million (The Information Centre, 2007). The reported 2008/09 QOF prevalence for diabetes is 5.1% in England, 4.6% in Wales, 3.9% in Scotland and 3.5% in Northern Ireland.

Secondary care

Many patients with type 1 diabetes attend secondary care clinics for their diabetes. Although type 2 diabetes is primarily managed in primary care, it is common for people with type 2 diabetes to experience related complications requiring hospital admission.

Current management in primary care

General Practitioners (GPs) play a crucial role in managing diabetes in primary care. Much of the management and monitoring of patients with type 2 diabetes is undertaken by GPs and members of the primary care team. Measures include encouraging a healthy lifestyle, modifying blood pressure and blood lipid levels, and lowering blood glucose in order to reduce the risk of complications. The NICE full guideline on diabetes states that an understanding of diabetes, informed choice of management opportunities, and the acquisition of relevant skills for successful self-management, play an important role in achieving optimal outcomes. This includes provision of good dietary advice and nutritional information, which may also be included as part of diabetes education and self-management programmes.

Current practice

People with diabetes have emphasised the value of access to dietary advice. Poor access to a dietitian or dietary advice was ranked fifth in a list of the top ten concerns received by Diabetes UK from people with diabetes between January and March 2009. A Diabetes UK survey of people with diabetes found 21% wanted better access to advice/appointments about their diet.

NHS priorities and timeliness for guidance

The NICE QOF team examined national clinical guidelines, policy documents and national strategies across the UK to assess timeliness of indicators in this topic area. The following were found to be of relevance to diabetes and indicate that diabetes is deemed an area of high priority for the NHS:

- Type 1 diabetes in adults: National clinical guideline for diagnosis and management in primary and secondary care. NICE clinical guideline 15. (Royal College of Physicians 2004).
- <u>Diabetes in pregnancy. Management of diabetes and its complications from pre-conception to the postnatal period</u>. NICE clinical guideline 63. (National Collaborating Centre for Women's and Children's Health 2008).
- Type 2 diabetes. National clinical guideline for management in primary and secondary care (update). NICE clinical guideline 66. (Royal College of Physicians 2008).
- Management of diabetes. A national clinical guideline. (Scottish Intercollegiate Guidelines Network 2010) no. 116
- <u>National service framework for diabetes: standards</u>. (Department of Health 2001)
- Scottish diabetes framework: Action plan. (NHS Scotland 2006)
- Diabetes follow-up reports. (NHS Quality Improvement Scotland 2006)
- A profile of long-term and chronic conditions in Wales. (Welsh Assembly Government 2006)
- Designed to improve health and the management of chronic conditions in Wales: an integrated model and framework. (Welsh Assembly Government 2005)

- Diabetes: national overview. (NHS Quality Improvement Scotland 2004)
- Scottish diabetes framework. (NHS Scotland 2002)
- Diabetes national services framework. (Welsh Assembly Government 2002)

Review of recommendations

Summary of NICE guideline recommendations

Four recommendations from NICE clinical guidelines 15, 66 and SIGN clinical guideline 116 have been identified as being potentially suitable for QOF indicator development.

NICE recommendation 1.8.3.1 (NICE CG15)

Nutritional information sensitive to personal needs and culture should be offered from the time of diagnosis of type 1 diabetes.

NICE recommendation 8 (NICE CG66)

Provide dietary advice in a form sensitive to the individual's needs, culture and beliefs being sensitive to their willingness to change, and the effects on their quality of life (type 2 diabetes).

SIGN recommendation 3.7.1 (SIGN 116)

People with type 2 diabetes can be given dietary choices for achieving weight loss that may also improve glycaemic control. Options include simple calorific restriction, reducing fat intake, consumption of carbohydrates with low rather than high glycaemic index, and restricting the total amount of dietary carbohydrate (a minimum of 50g per day appears safe for up to six months).

Clinical effectiveness

Dietary review – type 1 diabetes

The NICE guideline developers acknowledged a large body of evidence for improving diabetes care for people with type 1 diabetes through good dietary management. There was GDG consensus to support the provision of

nutritional information as recommended in recommendation 1.8.3.1 of the NICE clinical guideline for type 1 diabetes (CG15).

<u>Dietary review – type 2 diabetes</u>

The NICE guideline developers acknowledged that optimal dietary behaviour can contribute to maintaining blood glucose levels and blood pressure in the normal range or as close to normal as is safely possible, and to maintaining lipid levels to reduce the risk of vascular disease. The GDG noted that the major consensus-based recommendations from the UK and USA emphasise sensible and practical nutritional advice for people with type 2 diabetes. This consensus provides the basis to support the provision of nutritional information for people with type 2 diabetes as recommended in recommendation 8 (R8) of the full NICE clinical guideline (CG66).

The SIGN guideline developers acknowledged the importance of healthy eating as part of diabetes management. There is level 1 evidence (meta-analyses and/or RCTs) for relevant health outcomes, primarily achieving weight loss, that may also improve glycaemic control, to support provision of dietary choices for people with type 2 diabetes as recommended in 3.7.1 of the SIGN guideline for the management of diabetes.

It should be highlighted that the evidence reviewed supporting recommendation 3.7.1 investigated the efficacy of different diets to improve glycaemic control in people with type 1 and type 2 diabetes. No sub-analysis according to diabetes type was presented. The SIGN guideline developers noted that there is insufficient evidence to make a recommendation about specific diets for improving glycaemic control and the SIGN recommendation was extrapolated from level 1 studies.

Cost effectiveness

There is no cost-effectiveness evidence presented that is specific to the recommendations for the provision of nutritional information/dietary choice/dietary advice.

Assessment of recommendations against current practice

Health inequalities

Type 2 diabetes is more common in people of low socioeconomic status, in minority ethnic groups and in people aged 65 and older. The NICE full clinical guideline reports that maternal social deprivation is associated with poor pregnancy outcome for women with type 1 or type 2 diabetes but ethnicity is not. There is no evidence that these recommendations can directly impact health inequalities. [Relevance to health inequalities: medium/high]

Will implementation of these recommendations lead to cost-effective improvements in the delivery of primary care?

It is not clear to what extent the recommendations relating to dietary advice would represent a shift in practice in primary care.

Key considerations

The following key considerations summarise the key points made in the briefing paper and should be used by the Committee in its deliberations.

- Dietary review is considered feasible, is supported by evidence that is judged to be moderate-high and would be expected to lead to a moderate change in practice.
- NICE full clinical guideline 66 for type 2 diabetes recommends annual reinforcement and review following structured education which would cover dietary advice.
- The Committee may need to consider whether all forms of diabetes should be covered for the same dietary advice/review.
- Pre-conception care is considered feasible, is supported by evidence that is judged to be moderate-high, is likely to be cost effective and would be expected to lead to a moderate change in practice.

 There are likely to be similar issues identified and resolved as part of the development of the pre-conception epilepsy indicator that has been developed and is available on the NICE menu.

Assessment against NICE's prioritisation criteria

The condition is considered to have a population prevalence that is high and fully meets the criteria for diagnosis, treatment and monitoring in primary care (by GPs or directly employed practice staff).

The recommendations for **dietary review** are considered feasible. The evidence of clinical effectiveness has been assessed as moderate-high. There is no evidence of cost effectiveness available. The expected change in practice is considered to be moderate.

Appendix A: Evidence summary

Evidence summary of NICE clinical guidelines 15, 63 and 66 and SIGN clinical guideline 116 selected recommendations

	Recommendation	Level of evidence	Key outcomes considered	Specific considerations highlighted by guideline developers	Cost-effectiveness evidence				
Dietary manag	Dietary management (Type 1 diabetes)								
NICE clinical guideline 15, recommendation 1.8.3.1	Nutritional information sensitive to personal needs and culture should be offered from the time of diagnosis of Type 1 diabetes	Existing guidelines	n/a	The guideline developers acknowledged and cross referenced a body of evidence reviewed in existing guidelines showing clear health benefits from good dietary management and improved diabetes care for people with type 1 diabetes. As such the recommendations made by the guideline developers relating to dietary management relate to the emphasis and approach to management. The GDG noted a NICE technology appraisal on education models for people with type 1 diabetes (DAFNE).	No cost-effectiveness evidence presented specific to the recommendation for the provision of nutritional information				
Dietary advice	Dietary advice (type 2 diabetes)								

	Recommendation	Level of evidence	Key outcomes considered	Specific considerations highlighted by guideline developers	Cost-effectiveness evidence
NICE full clinical guideline 66, recommendation 8	Provide dietary advice in a form sensitive to the individual's needs, culture and beliefs being sensitive to their willingness to change, and the effects on their quality of life	Existing guidelines	n/a	In addressing the review question of different forms of dietary advice, the guideline developers concluded that there was little new evidence in this area and agreed that all the major consensusbased recommendations from the UK and USA emphasise sensible and practical nutritional advice for people with type 2 diabetes	No cost-effectiveness evidence presented specific to the recommendation for the provision of dietary advice
SIGN clinical guideline 116, recommendation 3.7.1	People with type 2 diabetes can be given dietary choices for achieving weight loss that may also improve glycaemic control. Options include simple calorific restriction, reducing fat intake, consumption of carbohydrates with low rather than high glycaemic index, and restricting the total amount of dietary carbohydrate (a minimum of 50g per	Meta- analyses of 11 RCTs	Weight reduction, metabolic control, improved glycaemic control, general well being	The guideline developers acknowledged evidence from UK PDS (prospective diabetes study), which demonstrated an association between diet and beneficial effects on weight, metabolic control and general well being. The guideline developers reviewed the evidence of one meta analysis of 11 RCTs, which investigated the effects of different diets on glycaemic control of people with type 1 and type	No cost-effectiveness evidence presented specific to the recommendation for the provision of dietary choices in people with type 2 diabetes

Recommendation	Level of evidence	Key outcomes considered	Specific considerations highlighted by guideline developers	Cost-effectiveness evidence
day appears safe for up to six months)			2 diabetes. Pooled data from six trials reported a statistically significant reduction in blood glucose for patients on low glycaemic index diets compared with higher glycaemic index diets. The guideline developers noted there was insufficient evidence to recommend specific diets for improving glycaemic control. Trials assessing low carbohydrate diets were also reviewed but it was noted that they reported high dropout rates and poor compliance. The guideline developers considered that this may suggest that such diets are not widely acceptable to some patients.	

Appendix B: Assessment of topic and recommendations against prioritisation checklist criteria status

This appendix provides assessment of the overall topic and recommendation that has been produced by the QOF programme team. This takes into account information presented in this briefing paper against the revised prioritisation checklist as agreed at the July 2009 Advisory Committee meeting.

Topic status

This topic meets the prioritisation criteria for prevalence, primary care management and disease severity as outlined in 1A, 1B and 1C below.

1A Population					
The condition is considered to have population prevalence that is high					
The condition is considered to have population	on prevalen	ce that is n	nedium		
The condition is considered to have population	on prevalen	ce that is lo	W		
1B Management					
		Fully meets criteria	Partly meets criteria	Doesn't meet criteria	
	Score:	[3]	[2]	[1]	
The condition is diagnosed in primary care*		\boxtimes			
The condition is treated in primary care*					
The condition is monitored in primary care*					
* by general practitioners or directly employed practice staff					
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1C Disease Severity			
Score	Scoring criteria		
1	Minor quality-of-life impact, no disability, limited morbidity impact		
2	Definite quality-of-life impact, no disability, limited morbidity impact		
3	Definite quality-of-life impact, some disability and/or intermediate morbidity impact		

4	Definite quality-of-life impact, significant disability and/or	
	significant morbidity impact	

Recommendation Status

The individual recommendations are assessed on feasibility, strength of clinical and cost effectiveness evidence and expected change in practice.

Feasibility of each recommendation		
Dietary review		
NICE recommendation 1.8.3.1 (NICE CG15)	Green	
NICE recommendation 8 (CG66)	Green	
SIGN recommendation 3.7.1 (116)	Green	

Scores for each recommendation					
	Evidence of clinical effectiveness	Evidence of cost effectiveness	Expected change in practice		
Dietary review					
NICE recommendation 1.8.3.1 (CG15)	Moderate-high	No data available	Moderate		
NICE recommendation 8 (CG66)	Moderate-high	No data available	Moderate		
SIGN recommendation 3.7.1 (116)	Moderate-high	No data available	Moderate		