NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

QUALITY AND OUTCOMES FRAMEWORK (QOF) INDICATOR DEVELOPMENT PROGRAMME

Briefing paper

QOF indicator area: Diabetes

Potential output: Recommendations for indicator development

Date of Primary Care QOF Indicator Advisory Committee meeting: 16 June 2009

Note: The content of this document is derived from the previous QOF process and the work of the NICE external contractor. It has been put into a NICE template to allow for consistency in reviewing proposed QOF indicators.

Introduction

The QOF indicator area is type 2 diabetes, and the recommendations and evidence reviews from 'Type 2 diabetes: the management of type 2 diabetes' (NICE clinical guideline 87), published in 2009, 'Type 2 diabetes: prevention and management of foot problems' (NICE clinical guideline 10), published in 2004, and 'Guidance on the use of patient-education models for diabetes' (NICE technology appraisal 60) published in 2003, form the basis of this paper.

The briefing paper is split into two sections:

- An overview of type 2 diabetes, including an epidemiological summary and its current management in primary care.
- A review of the proposed indicators and a summary of the evidence that informs the indicators.

Overview of diabetes

Epidemiological summary

Definition

Diabetes is a chronic metabolic disorder caused by defects in insulin secretion and action.

The criteria for diagnosis were agreed by the World Health Organization in June 2000: diabetic symptoms with random venous glucose concentration greater than 11.1 mmol/litre or fasting BM greater than 7.0 mmol/litre or 2-hour BM greater than 11.1 mmol/litre after 75 g glucose tolerance test.

Patients should be classified by pathological type (type 1 or type 2 diabetes) and then by stage, for example whether they are insulin dependent or not.

Type 1 diabetes is caused by the body's failure to produce insulin. Insulin is a hormone released by the pancreas to help control levels of sugar in the blood. It is sometimes called juvenile diabetes or early-onset diabetes because it usually appears before the age of 40 years.

Type 2 diabetes is caused by the body not producing enough insulin or not using what it produces effectively. It is the most common form of diabetes, and accounts for around 90% of all cases of diabetes.

Incidence, prevalence and variation by age, sex and ethnicity

The age-standardised prevalence of diagnosed diabetes is estimated to be 2.23 per 100 males and 1.64 per 100 females.

Not all diabetes is diagnosed. The ‘Health Survey for England 2003’ suggests that 3.1% of men and 1.5% of women aged 35 years and over have undiagnosed diabetes.

The proportion of people with diabetes increases with age. The ‘Health Survey for England 2006’ suggests that around 1% of men aged 16 to 34 years have diagnosed diabetes compared with 13.5% of those aged 75 years and over. This pattern is similar in women, although rates are slightly lower at most ages than for men.

People from minority ethnic communities have up to a six times higher than average risk of developing diabetes.

Morbidity and mortality

Diabetes significantly increases the risk of coronary heart disease (CHD). Men with type 2 diabetes have a two- to four-fold greater annual risk of CHD. Women with type 2 diabetes face an even higher risk, with a three- to five-fold greater annual risk of CHD (Garcia et al. 1974). Diabetes also magnifies the other risks factors for CHD such as raised cholesterol levels, raised blood pressure and obesity. The INTERHEART study estimated that 15% of heart attacks in Western Europe are due to diagnosed diabetes, so diabetes sufferers are at three times the risk of heart attack (Yusuf et al. 2004).

The World Health Organization Global Burden of Disease Project estimates that in established market economies such as the UK, 3% of years of life lost in disability are due to diabetes. This is only slightly lower than the years of life lost in disability due to cancer at 4% (Murray and Lopez 1996). There are 33,000 deaths each year due to diabetes. Life expectancy is reduced by at least 15 years for someone with type 1 diabetes. In type 2 diabetes, which is preventable in two thirds of people who have it, life expectancy is reduced by up to 10 years. Mortality rates from diabetes are higher in people from lower socioeconomic groups.

Impact on health services

Primary care

The proposed indicators will increase workload in primary care.

Secondary care

The proposed indicators may increase workload for secondary care, particularly in terms of referral for ulcers and foot care.

Current management in primary care

Primary care has a pivotal role in ensuring that all people with diabetes receive effective care. This is recognised by the inclusion of clinical indicators for diabetes in

the QOF. Many patients with diabetes are now managed solely or mainly in primary care.

NHS priorities and timeliness for guidance

The diabetes national service framework (NSF) standards, published in 2001, set out the first ever set of national standards for the treatment of diabetes. The NSF's 12 standards cover all aspects of diabetes care and prevention and, together with the delivery strategy (2003), set out a 10-year programme of change and improvement. Diabetes indicators were introduced to the QOF in 2004. There are currently 17 diabetes indicators (more than any other clinical domain) worth 101 points (out of a possible 1000 within the wider framework).

Review of proposed indicators

Proposed indicator 1

The percentage of patients with diabetes aged 17 or over with a record of the findings of testing of foot sensation using a 10 g monofilament or vibration (using biothesiometer or calibrated tuning fork), palpation of foot pulses and inspection for any foot deformity in the previous 15 months.

Evidence summary

Clinical effectiveness

Foot problems are a common complication of diabetes. They can include damage to the nerves, muscles and sweat glands, and poor circulation in the feet and legs. Therefore, it is very important that testing for sensory neuropathy is carried out correctly.

The foot inspection and assessment should include:

- identifying the presence of sensory neuropathy (by the loss of the ability to feel a monofilament, vibration or sharp touch) and/or the abnormal build up of callus

- identifying when the arterial supply to the foot is reduced (by the absence of foot pulses, signs of tissue ischaemia or symptoms of intermittent claudication)
- identifying deformities or problems of the foot (including bony deformities, dry skin or fungal infection) that may put it at risk
- identifying other factors that may put the foot at risk (which may include reduced capacity for self care, impaired renal function, poor glycaemic control, cardiovascular and cerebrovascular disease, or previous amputation).

Foot care advice should include:

- discussing with the patient their individual level of risk and agreeing plans for future surveillance
- initiating appropriate referrals for expert review of those with increased risk
- advising on action to be taken in the event of a new ulcer or lesion arising
- advising on the use of footwear that will reduce the risk of a new ulcer or lesion
- advising on other aspects of foot care that will reduce the risk of a new ulcer or lesion.

Evaluation of skin, soft tissue, musculoskeletal, vascular and neurological condition on an annual basis is important for the detection of feet at raised risk of ulceration. Both vibration perception threshold measurement using a biothesiometer and sensation threshold measurement using a 10 g monofilament accurately predict patients with neuropathy who are at increased risk of foot ulceration. Longevity and recovery testing suggests that each monofilament will survive use on approximately 10 patients before needing a recovery time of 24 hours (to restore buckling strength) before further use. Identification of neuropathy based on insensitivity to a 10 g monofilament is simple, convenient and appears cost-effective.

Updating this indicator to include the main components of foot examination in a systematic way will remind clinicians of the importance of holistic assessment of the feet of people with diabetes.

Proposed indicator 2

Classify feet as at low current risk of foot ulcers (normal sensation, palpable pulses), at increased risk (neuropathy or absent pulses or other risk factor), at high risk (neuropathy or absent pulses plus deformity or skin changes or previous ulcer) or ulcerated foot.

Evidence summary for proposed indicator

Clinical effectiveness

'Type 2 diabetes: prevention and management of foot problems' (NICE clinical guideline 10) advises that foot risk should be classified as:

- at low current risk
- at increased risk
- at high risk
- ulcerated foot.

The NICE guidance recommends that everyone with diabetes should have an annual assessment of the risk of foot ulceration. Including this in the QOF is achievable and will encourage practitioners to consider what further action is needed for those with increased risk of ulceration.

The two proposed foot indicators would replace DM 9 and DM 10.

Proposed indicator 3

DM 150/90 (higher level BP target) and 140/80

Evidence summary for proposed indicator

Clinical effectiveness

Current QOF indicator DM 12 is the percentage of patients with diabetes in whom the last blood pressure (BP) is 145/85 mmHg or less.

The new indicator proposes splitting the current BP indicator into a target for people without retinopathy, microalbuminuria or cerebrovascular disease of 140/80 mmHg (as recommended by NICE) and a target for people with retinopathy, microalbuminuria or cerebrovascular disease who cannot manage this of 150/90 mmHg .

- The cohort analysis of the United Kingdom prospective diabetes study (UKPDS) data suggests that risk of ‘adverse’ events increases more or less linearly with blood pressure levels, and important risk reductions can be achieved by lowering blood pressure by 10 mmHg across the whole range of blood pressure values, i.e. no threshold for risk or treatment benefit exists. It is therefore important that the QOF indicator should encourage reductions in blood pressure for those with high readings, as well as for those whose blood pressure is near the target.
- Evidence for target setting comes from the Hypertension optimal treatment (HOT) study and favours lower targets for people with diabetes than others with hypertension. People with diabetes comprised around 8% of participants and formed a pre-specified subgroup in the analysis of the trial. There was a 51% reduction in major cardiovascular events in people with diabetes assigned to the 80 mmHg target compared with the 90 mmHg target (p for trend = 0.005) (Hansson et al. 1998).
- Setting an additional blood pressure target at a higher level, but expecting most patients to have blood pressures below this, will encourage practitioners to address the needs of the minority of patients whose blood pressure is hard to control and avoid the possibility of perverse incentives to focus efforts away from those at highest absolute risk.
- ‘Type 2 diabetes: the management of type 2 diabetes’ (NICE clinical guideline 87) advises a blood pressure target of below 140/80 mmHg for people with type 2 diabetes or below 130/80 mmHg for people with type 2 diabetes and kidney, eye or cerebrovascular disease.
- Practitioners are already familiar with the idea of staging the incentives, because this is already done for glycaemic control.

Proposed indicator 4

The percentage of patients within 24 months of diagnosis who have completed or attended a structured education programme, which has been locally accredited as meeting the criteria developed by the Department of Health and Diabetes UK joint Patient Education Working Group.

Evidence summary for proposed indicator

This is a summary of the evidence supporting the proposed new indicator.

Clinical effectiveness

This indicator is based on the NICE guidance on type 2 diabetes (NICE clinical guideline CG87) which offers six detailed recommendations on patient education of which the two most relevant to this proposed indicator are:

1.1.1 Offer structured education to every person and/or their carer at and around the time of diagnosis, with annual reinforcement and review. Inform people and their carers that structured education is an integral part of diabetes care.

1.1.2 Select a patient-education programme that meets the criteria laid down by the Department of Health and Diabetes UK Patient Education Working Group.

The full guideline offered the following commentary (in the 'from evidence to recommendations' section) on the evidence base, which was drawn from the Health Technology Assessment (HTA) report 'The clinical effectiveness of diabetes education models for Type 2 diabetes: a systematic review' (2008) commissioned by the NHS R&D HTA programme on behalf of the National Collaborating Centre for Chronic Conditions:

'The HTA commissioned for the current review (2008) included 14 studies, of which eight appeared to have been conducted since 2003, and most were for people with established (rather than newly diagnosed) Type 2 diabetes. The NICE Guideline Development Group (GDG) noted that, as expected, some studies showed effects on HbA1c, others improved body weight and other lifestyle changes, some improved quality of life or knowledge, and yet others changed health beliefs or reduced depression. This diversity was often simply a reflection of study aims and design.

The HTA review acknowledged that health psychology approaches and some methods of health promotion have a good evidence base, but little is incorporated into studies of structured education, even though addressing health beliefs and motivating individuals to change behaviour is a cornerstone of any educational programme. Reported training for diabetes educators was poorly detailed in most studies.

The GDG was concerned that only three studies were UK-based. As cultural issues, patient health beliefs and attitudes are likely to differ from one country to another, applicability of the others may be limited. The GDG noted that the UK Diabetes Education and Self Management for Ongoing and Newly Diagnosed (DESMOND) study found changes in health beliefs, reduction in depression, and increases in self-reported physical activity, reduction in weight and improvement in smoking status. In people with established diabetes there was useful evidence from the Expert Patient Education Versus Routine Treatment (X-PERT) programme with improvements in HbA1c, reduced diabetes medication, body weight, waist circumference, total serum cholesterol, diabetes knowledge and increase in self-reported physical activity and treatment satisfaction.

Cost effectiveness

The GDG agreed that well-designed and well-implemented structured education programmes were likely to be effective and cost-effective interventions for people with type 2 diabetes, in line with the HTA For those people for whom education delivered in a group setting is appropriate, it is likely to be more cost effective.

Assessment of indicators against current practice

Reduction of health inequalities

These indicators may address some aspects of health inequalities. Diabetes prevalence is related to socioeconomic position. In the ‘Health Survey for England 2003’, men and women in managerial and professional and intermediate households had a lower prevalence of diagnosed diabetes than those from other households. In women, for example, the prevalence was around twice as high for those living in manual compared with non-manual households. Data from the ‘Health Survey for England 2006’ showed that women living in households with the highest incomes

had the lowest prevalence of diagnosed diabetes, although there was no similar pattern among men.

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

No evidence was identified to directly show that the recommendations may lead to cost-effective improvements in the delivery of primary healthcare.

Feasibility assessment

A summary of the initial feasibility assessment incorporating advice and expert opinion is provided below. This includes comments from the National Primary Care Research and Development Centre (NPCRDC) and NICE.

Proposed indicators one to three received a high consensus score, and it is the view of the NPCRDC that they are feasible.

The fourth proposed indicator did not go through the expert panel consensus process, and it is the view of NPCRDC that it would benefit from further feasibility testing through a piloting process.

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