

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

QUALITY AND OUTCOMES FRAMEWORK (QOF) INDICATOR DEVELOPMENT PROGRAMME

Briefing paper

QOF indicator area: Diabetes: pregnancy, conception and contraception advice

Potential output: Recommendation for indicator development

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Introduction

This briefing paper presents an assessment of the suitability of measures derived from NICE quality standards, relevant to primary care, to be progressed for Quality and Outcomes Framework (QOF) indicator development. The QOF indicator area is diabetes. The NICE quality standard on diabetes was published in March 2011:

<http://publications.nice.org.uk/diabetes-in-adults-quality-standard-qs6>

The relevant quality statement (statement 7) and underlying recommendation and evidence is taken from the following guidance:

'Diabetes in pregnancy. Management of diabetes and its complications from preconception to the postnatal period' (NICE clinical guideline 63, 2008)

This paper is based on the evidence presented in NICE clinical guideline 63 and no update searches have been performed.

Topic selection

Diabetes quality standard (QS6)

Quality Standards

NICE quality standards are sets of specific, concise statements and associated measures. They set out aspirational, but achievable, markers of high-quality, cost-effective patient care, covering the treatment and prevention of different diseases and conditions.

Derived from the best available evidence, such as NICE guidance and other evidence sources accredited by NICE Evidence, they are developed independently by NICE in collaboration with NHS and social care professionals, their partners and service users. Quality standards address clinical effectiveness, patient safety and patient experience, and are central to supporting the government's vision for an NHS focused on delivering the best possible outcomes for patients.

Review of the diabetes quality standard and identification of possible QOF indicators

The diabetes quality standard was reviewed to identify potential areas for further development as QOF indicators.

Statement 7 in the diabetes quality standard was considered to be an appropriate area for potential QOF indicator development:

Women of childbearing age with diabetes are regularly informed of the benefits of preconception glycaemic control and of any risks, including medication that may harm an unborn child. Women with diabetes planning a pregnancy are offered preconception care and those not planning a pregnancy are offered advice on contraception.

The associated process measures are:

- The proportion of women of childbearing age with diabetes who are regularly informed about the benefits of preconception glycaemic control and of any risks including medication that may harm an unborn child.
- The proportion of women of childbearing age with diabetes planning a pregnancy who are offered preconception care from an appropriately trained healthcare professional.
- The proportion of women of childbearing age with diabetes not planning a pregnancy who are offered advice on contraception.

Proposed indicators

Provisional approval for the development of indicators on diabetes care was given by the chair of the QOF Advisory Committee in July 2012. The following indicators have been progressed for indicator development:

1. *The percentage of women with diabetes under the age of 55 years who have been given information and advice about pregnancy, conception or contraception tailored to their pregnancy and contraceptive intentions recorded in the preceding 15 months.*

2. *The percentage of women with diabetes under the age of 55 years who have a record of information and counselling about contraception, conception and pregnancy in the preceding 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 major 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 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.

Adverse pregnancy outcomes in women with diabetes (both type 1 and type 2) include factors such as fetal congenital abnormality, perinatal mortality and stillbirth. These can arise from the interaction between diabetes and pregnancy; social and lifestyle factors and as a result of the adverse effects of medications used to treat the complications of diabetes.

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

Type 2 diabetes accounts for around 90% of all diabetes. Type 2 diabetes is rising annually. The prevalence of doctor-diagnosed diabetes in the 2011 Health Survey for England was higher in men (7%) than in women (4.9%). Prevalence has increased significantly between 1994 and 2011 - from 2.9% to 7.0% among men and from 1.9% to 4.9% among women, and this is a pattern seen in almost all age groups. Incidence and prevalence of diabetes is greater in areas of higher deprivations.

The prevalence of diabetes varies with factors such as mix of ethnic groups and degree of social deprivation. People from minority ethnic communities have up to a six times higher than average risk of developing diabetes.

The Confidential Enquiry into Maternal and Child Health (CEMACH) survey (2005) found that the maternal ethnic origin of pregnant women with type 1 and type 2 diabetes (considered together) was not significantly different to the general maternity population of England. However, a much higher proportion of women with type 2 diabetes were of Black, Asian or Other Ethnic Minority origin compared to women with type 1 diabetes (48.5% versus 8.5%). The CEMACH data also suggested that ethnicity was not associated with poorer pregnancy outcome for women with type 1 or type 2 diabetes. However, women from ethnic minority groups are more likely to develop gestational diabetes. They are also more likely to have unplanned pregnancies and less likely to have a measure of long-term glycaemic control in the 6 months before pregnancy.

Morbidity and mortality

Type 1 diabetes is fatal unless treated with insulin. Most people who develop type 1 diabetes 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 fifteen 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. Most of the morbidity and increased mortality comes from coronary, cerebral and peripheral arterial disease. Mortality attributed to people with diabetes is suggested as 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.

Pregnancy can affect the control and complications of diabetes. Pregnancy in diabetics may result in an increased frequency of hypoglycaemia with a reduction in hypoglycaemic awareness; disruption of blood glucose control due to nausea and vomiting, which if severe can lead to ketoacidosis; progression of diabetic retinopathy and accelerate progression to end stage renal disease in women with moderate/advanced diabetic nephropathy.

Women with type 1 and type 2 diabetes are at increased risk of losing a baby during pregnancy, having a baby with a congenital anomaly or the baby dying during the first year of life. The CEMACH report into maternity services for women with diabetes (2004) found that when compared to the general maternity population women with diabetes have a fivefold increased risk of stillbirth, a threefold increased risk of perinatal mortality and a twofold increased risk of fetal congenital abnormality. This can be due to the teratogenic effect of drugs for diabetes on pregnancy.

Women with pre-existing complications of diabetes are also more likely to have a poor pregnancy outcome than women without.

Impact on health services

Primary care

People with diabetes form a significant part of the general practice workload. The reported 2011/12 QOF prevalence for diabetes is 5.8% in England.

In 2006, the cost of primary care prescribing in England for drugs to treat diabetes was over £500 million. The Health and Social Care Information Centre (HSCIC) reports that the net ingredient costs (NIC) of prescribing for diabetes in 2009/10 accounted for 7.7% of the total cost of all primary care prescribing. This has increased from 5.8% in 2004/05. Both the NIC and number of items prescribed have risen by over 40% in that period, as drugs become more expensive and the incidence and identification of diabetes increases.

The Audit Commission report on costing care pathways: Understanding the cost of the diabetes care pathway (2011) found that the average PCT spend per patient on prescriptions varies from £214 to £344. Insulins, oral anti-diabetics and blood glucose monitoring equipment accounted for more than 99% of spend on drugs used in 2009/10.

Secondary care

Many people 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 and people with diabetes are admitted to hospital for both elective and emergency care. The Diabetes UK, Key Statistics on Diabetes report (2010) has estimated that diabetes costs £9 billion per year, accounting for 10% of all NHS spending.

The 2011 National Diabetes Inpatient Audit (NaDIA) found that 9.0% of in-patients with diabetes in England and 11.2% in Wales were admitted specifically for the management of their diabetes. The audit also showed that people with diabetes are more likely to be admitted as an emergency compared to the general population - 84.5% of people with diabetes were admitted to hospital as an emergency in England, compared to 80.8% of all people in hospital. The NHS Diabetes briefing - Improving Emergency and Inpatient Care for People with Diabetes, reported that people with diabetes stay in hospital longer, whatever the cause of admission.

The Audit Commission report on costing care pathways: Understanding the cost of the diabetes care pathway (2011) found that although average inpatient spending varies from £19 to £175 per diabetic patient, over half of PCTs spent within £26 per patient of one another. The report also found that the biggest driver of costs is diabetes medication which accounts for three quarters of the total cost of diabetes care.

Current management in primary care

Provision of pre-conception care and advice for women with epilepsy has been included in the QOF since 2011 and forms part of current practice in primary care with a 90% achievement rate in 2011/12.

General Practitioners (GPs) play a crucial role in managing diabetes in primary care. People diagnosed with diabetes are recorded on general practices' QOF diabetes registers. Much of the management and monitoring of patients with Type 2 diabetes is undertaken by general practitioners and members of the primary care team. These include encouraging a healthy lifestyle, modifying levels of blood pressure and lipids, and lowering blood glucose in order to reduce the risk of complications.

There are known teratogenic effect of drugs prescribed to people with diabetes. ACE inhibitors and ARBs (angiotensin-II receptor antagonists) should be avoided throughout pregnancy because of the possible risk of congenital malformations. However, the benefits of continuing with ACE inhibitors until discontinuation of contraception for the purposes of protecting renal function should be considered. For women with microalbuminuria, the risk of progression to macroalbuminuria in the preconception period is thought to be small while the risk of pre-eclampsia is greatly increased. Calcium-channel blockers should be avoided throughout pregnancy because of the risk of disruption to labour and fetal hypoxia. However, the risk to the fetus should be balanced against the risk of uncontrolled maternal hypertension in deciding whether to discontinue nifedipene. It would be the role of the GP to advice about contraception and the interaction between drugs for women with diabetes considering pregnancy.

The NICE full clinical 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 preconception care and preparation for pregnancy as a vital part of improving outcomes for women with type 1 and type 2 diabetes.

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 relevant to diabetes and indicate that diabetes is deemed as an area of high priority for the NHS:

- In progress: NICE clinical guideline [Diabetes in pregnancy: management of diabetes and its complications from preconception to the postnatal period](#) clinical guideline update (publication date TBC)
- NICE (2011) [Diabetes in pregnancy Pathway](#) (updated January 2013)
- NICE public health guidance (2010) [Dietary interventions and physical activity interventions for weight management before, during and after pregnancy](#)

- NICE clinical guideline (2008) [Antenatal care](#)
- NICE clinical guideline (2008) [Diabetes in pregnancy: Management of diabetes and its complications from preconception to the postnatal period](#)
- clinical guideline (2005) [Long-acting reversible contraception](#)
- NHS Diabetes [Preconception care for women with diabetes Pathway](#)
- Map of Medicine (2012) [Diabetes in pregnancy](#)
- Clinical Knowledge Summaries (2012) [Pre conception advice and management](#)
- NHS Diabetes (2011) [Commissioning pregnancy and diabetes care](#)
- Diabetes UK (2011) [Preconception care for women with diabetes](#)
- Skills for Health (2010) [National Occupational Standard: Diab PD01 Provide advice and information on planning pregnancy to all women with diabetes of childbearing age](#)
- Skills for Health (2010) [National Occupational Standard: Diab PD02 Agree care plans to help women with diabetes prepare for a safe and healthy pregnancy](#)
- Skills for Health (2010) [National Occupational Standard: Diab PD03 Support and review care plans to help women with diabetes prepare for a safe and healthy pregnancy](#)
- Clinical Knowledge Summaries (2010) [Diabetes Type 1](#)
- Clinical Knowledge Summaries (2010) [Diabetes Type 2](#)
- Department of Health (2010) [Six Years On: delivering the Diabetes National Service Framework](#)
- Scottish Government (2010) [Diabetes Action Plan 2010: Quality care for diabetes in Scotland](#)
- Welsh Government (2008) [Designed for the Management of Adults with Diabetes Mellitus across Wales: Consensus Guidelines](#)
- Diabetes UK (2008) [Recommendations for the management of pregnant women with diabetes \(including Gestational diabetes\)](#)
- Confidential Enquiry into Maternal and Child Health (2007) [Diabetes in pregnancy: are we providing the best care?](#) Findings of a National Enquiry. England, Wales & Northern Ireland
- Scottish Executive (2006) [Scottish Diabetes Framework: action plan](#)

- Scottish Executive (2004) [Diabetes in Scotland: current challenges and future opportunities: reviewing the Scottish Diabetes Framework](#)
- Scottish Government (2002) [Scottish Diabetes Framework](#)
- Welsh Government (2002) [National Service Framework for Diabetes](#)
- Department of Health (2001) National Service Framework for Diabetes

Review of recommendations

Summary of NICE guideline recommendations

The quality standard on diabetes statement 7 was informed by NICE clinical guideline 63. The following recommendations from this guideline informed the basis for the development of this statement, and are therefore presented below.

To provide further context to the recommendations presented, selected recommendations from the NICE clinical guideline 63 relating to pregnancy, conception or contraception and relevant to primary care are provided in appendix B.

NICE recommendation 1.1.1.2

Women with diabetes who are planning to become pregnant should be informed that establishing good glycaemic control before conception and continuing this throughout pregnancy will reduce the risk of miscarriage, congenital malformation, stillbirth and neonatal death. It is important to explain that risks can be reduced but not eliminated.

NICE recommendation 1.1.8.1

Women with diabetes should be informed about the benefits of pre-conception glycaemic control at each contact with healthcare professionals, including their diabetes care team, from adolescence.

Evidence summary

This is a summary of the evidence supporting the recommendations presented above. This section relates to the evidence summary table in appendix A of this briefing paper.

Clinical effectiveness

NICE recommendation 1.1.1.2

This recommendation was based on the GDG's expert view of what information should be offered to women with pre-existing diabetes before pregnancy to support and explain the guideline's substantive recommendations regarding management options before, during and after pregnancy, both in terms of maternity care and management of diabetes during these periods and to reinforce the recommendations of the NSF for diabetes.

NICE recommendation 1.1.8.1

The GDG noted evidence showing that women with diabetes (including young women) lack awareness of the importance of planning pregnancy and the role and purpose of preconception care. To overcome barriers to preconception care information about the importance of planning pregnancy and achieving good glycaemic control in the periconceptual period should be reinforced at each contact between women with diabetes who are of childbearing age and their healthcare professionals, including the diabetes care team, and the woman's intentions regarding pregnancy in the immediate future or longer term should be discussed.

Cost effectiveness

An economic model constructed for the purposes of the guideline suggested that some form of preconception care and advice is likely to be cost-effective in reducing major malformations, but not specific to these recommendations.

Assessment of recommendations against current practice

Current practice

Women with diabetes of childbearing age are routinely seen in primary care for contraceptive advice and other health needs. However, the 2004 CEMACH report which was based on a survey from 2002-2003 examining standards of care in pregnancy in women with diabetes in England, Wales and Northern Ireland found that preconception care tended to be poor and uncoordinated and recommended a need for better clinical care and diabetes management before, during and after pregnancy. The study found only 38.2% of women with type 1 diabetes and 24.8% of women with type 2 diabetes had pre-pregnancy counselling documented.

The 2007CEMACH report identified the following social and lifestyle factors associated with poor pregnancy outcomes:

- Suboptimal glycaemic control before and during pregnancy
- Lack of contraceptive use in the 12 months before pregnancy
- Suboptimal preconception care and approach to managing diabetes
- Suboptimal maternity and diabetes care during pregnancy

The CEMACH report found two-thirds of women had suboptimal glycaemic control before and during early pregnancy, and this was associated with poor pregnancy outcome. Only one-third of women with diabetes had a recorded assessment of glycaemic control in the 6 months prior to pregnancy, noting that up to 40% of pregnancies in women with diabetes may be unplanned.

Planned pregnancy rates were similar for both type 1 and type 2 diabetes but women with type 2 diabetes were less likely to have evidence of contraceptive use in the 12 months before pregnancy.

These findings suggest that women's preparation for pregnancy, glycaemic control, and the standard of preconception and pregnancy care need to be improved if better pregnancy outcomes are to be achieved for women with diabetes. This is the most relevant recent source of information identified for baseline practice.

Health inequalities

Type 2 diabetes is more common in people of low socioeconomic status, in ethnic minorities and in people aged 65 and above. 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. However, women from ethnic minority groups are more likely to have unplanned pregnancies and less likely to have a measure of long-term glycaemic control in the 6 months before pregnancy. There is no evidence that these recommendations can directly impact health inequalities.

[Relevance to health inequalities: moderate/high]

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

Recommendations 1.1.1.2 and 1.1.8.1 would be expected to lead to a moderate shift in practice and the NICE QOF team consider that some form of preconception care and advice is likely to be cost-effective in reducing major malformations.

Initial feasibility assessment

A feasibility assessment was carried out as part of a workshop involving topic experts. The experts considered that there may need to be a definition of what constitutes 'information and advice' and that practices may need to link the advice code to the appropriate pregnancy intention code.

The experts noted that the second indicator mirrored the 2012/13 QOF epilepsy indicator around pre-conception care and advice¹.

Key considerations

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

¹ The percentage of women under the age of 55 years who are taking antiepileptic drugs who have a record of information and counselling about contraception, conception and pregnancy in the previous 15 months

- Indicators on pregnancy, conception and contraception care and advice are already included in the QOF for women with epilepsy and this forms part of current practice.
- Indicators on pregnancy, conception and contraception care and advice are under consideration of the Committee for women with serious mental illness
- Effective pre-conception care and pregnancy planning can help to reduce the risks of a poor pregnancy outcome. However, there is evidence to suggest that women with diabetes are less well prepared for pregnancy and are less likely to describe their pregnancy as planned when compared to the general maternity population.
- Indicators on pregnancy, conception and contraception care and advice are considered feasible, are supported by expert opinion, are likely to be cost effective and would be expected to lead to a moderate change in practice.

Assessment against NICE's prioritisation criteria

The condition is considered to have population prevalence that is high and fully meets the criteria for diagnosis, treatment and monitoring in primary care (by general practitioners or directly employed practice staff). The recommendations selected are considered feasible. The recommendations are based on expert opinion and evidence on the increased need for information around pregnancy, conception and contraception. The recommendations selected are likely to be cost effective. The expected change in practice is considered to be moderate.

References

Audit Commission (2011) Costing care pathways: Understanding the cost of the diabetes care pathway. Available online: <http://archive.audit-commission.gov.uk/auditcommission/nationalstudies/health/financialmanagement/Pages/costingcarepathways.aspx.html>

Confidential enquiry into maternal and child health (2004) Maternity services in 2002 for women with type 1 and type 2 diabetes. London: CEMACH.

Available online: <http://www.hqip.org.uk/assets/NCAPOP-Library/CMACE-Reports/31.-2004-Maternity-services-in-2002-for-women-with-type-1-and-type-2-diabetes.pdf>

Confidential Enquiry into Maternal and Child Health (2005) Pregnancy in women with type 1 and type 2 diabetes 2002-2003 England, Wales and Northern Ireland. London: CEMACH. Available online:

<http://www.hqip.org.uk/assets/NCAPOP-Library/CMACE-Reports/29.-2005-Pregnancy-in-women-with-type-1-and-type-2-diabetes-2002-2003.pdf>

Confidential Enquiry into Maternal and Child Health (2007) Diabetes in pregnancy: are we providing the best care? Findings of a national enquiry: England, Wales and Northern Ireland. London: CEMACH. Available online:

<http://www.hqip.org.uk/assets/NCAPOP-Library/CMACE-Reports/25.-February-2007-Diabetes-in-Pregnancy-are-we-providing-the-best-care-Findings-from-a-national-project-March-2002-February-2003.pdf>

Diabetes UK (2010) Diabetes in the UK 2010: Key Statistics on Diabetes.

Health Survey for England (2011), Trend tables Publication date: December 20, 2012 Available online: <http://www.ic.nhs.uk/article/2021/Website-Search?productid=10152&q=health+survey+for+england&sort=Relevance&size=10&page=1&area=both#top>

The Health and Social Care Information Centre (2011) National Diabetes Inpatient audit. Available online: <http://www.hscic.gov.uk/diabetesinpatientaudit>

NHS Diabetes (2008) Improving Emergency and Inpatient Care for People with Diabetes. Available online:

http://www.diabetes.nhs.uk/our_publications/reports_and_guidance/inpatient_and_emergency/

The Health and Social Care Information Centre (2010) Prescribing for Diabetes in England: 2004/5 to 2009/10

Appendix A: Evidence Summary

Evidence summary of NICE clinical guideline CG63 selected recommendations

| | Recommendation | Level of evidence | Key outcomes considered | Specific considerations highlighted by guideline developers | Cost-effectiveness evidence |
|--|--|--------------------|-------------------------|---|--|
| Diabetes: Pregnancy, conception and contraception care and advice | | | | | |
| Recommendation 1.1.1.2 | Women with diabetes who are planning to become pregnant should be informed that establishing good glycaemic control before conception and continuing this throughout pregnancy will reduce the risk of miscarriage, congenital malformation, stillbirth and neonatal death. It is important to explain that risks can be reduced but not eliminated. | GDG expert opinion | N/A | <p>No systematic searches were conducted specifically for recommendations relating to the section of the guideline on “Outcomes and risks for the woman and baby” and the evidence used to underpin recommendation 1.1.1.2 was drawn from publications identified in searches for other sections.</p> <p>The GDG acknowledged evidence from the CEMACH survey of pregnant women with diabetes (2004), which shows women with type 1 and type 2 diabetes have an increased risk of adverse pregnancy outcomes, including miscarriage, fetal congenital anomaly and perinatal death.</p> <p>The GDG also acknowledged evidence from the final report of the CEMACH national</p> | <p>The GDG considered some form of preconception care and advice was likely to be cost-effective in reducing major malformations, but not specific to these recommendations.</p> <p>The GDG noted that preconception care and advice can take many different forms and some of this heterogeneity was reflected in the meta-analysis undertaken to assess the cost-effectiveness of self-management programmes.</p> <p>The GDG acknowledged the uncertainty on the effectiveness of different forms of preconception care and advice, and assessed the robustness of baseline results using threshold analyses. These showed that the reduction in major congenital malformations needed for</p> |

| | Recommendation | Level of evidence | Key outcomes considered | Specific considerations highlighted by guideline developers | Cost-effectiveness evidence |
|------------------------|--|--|--|---|---|
| | | | | <p>survey (2007) that certain social and lifestyle factors have also been shown to be associated with poor pregnancy outcome such as unplanned pregnancy and lack of contraceptive use in the 12 months prior to pregnancy.</p> <p>The GDG noted that a sub-optimal approach to diabetes, specifically a lack of local glycaemic control targets, before and during pregnancy were also associated with poor pregnancy outcome.</p> <p>It was of the GDG's expert view that information should be offered to women with pre-existing diabetes before pregnancy.</p> | <p>preconception care and advice to be considered cost effective was much lower than reported in a meta-analysis of cohort studies of preconception care and advice.</p> <p>These also showed that cost-effectiveness of preconception care and advice relative to no preconception care and advice was not very sensitive to the costs of preconception care and advice or the 'downstream' costs associated with major congenital malformations.</p> <p>The GDG did not recommend a specific form of preconception care and advice in light of the fact that differing methods of delivery and variation in resource cannot really be compared in terms of their incremental cost effectiveness ratios (ICERs) due to issues using existing data and the inherent limitations of this kind of analysis.</p> |
| Recommendation 1.1.8.1 | Women with diabetes should be informed about the benefits of pre-conception glycaemic control at each contact with healthcare professionals, including | Prospective and retrospective cohort studies | Glycaemic control before pregnancy (improvements in HbA1c) to reduce the incidence of miscarriages | The GDG noted evidence illustrating that that some women with diabetes (including young women) lack awareness of the importance of planning pregnancy and the role and purpose of preconception care. | |

| | Recommendation | Level of evidence | Key outcomes considered | Specific considerations highlighted by guideline developers | Cost-effectiveness evidence |
|--|--|--------------------------|--------------------------------|--|--|
| | their diabetes care team, from adolescence | | and congenital abnormalities. | <p>The studies reviewed found an association between good glycaemic control and the risk of adverse pregnancy outcomes, such as miscarriage and congenital abnormalities.</p> <p>The GDG also noted that good glycaemic control before conception puts the woman at an increased risk of hypoglycaemia, and women may be attempting to achieve optimal glycaemic control for several months until conception occurs. The GDG noted that targets for blood glucose monitoring should be agreed with the individual taking into account the risk of hypoglycaemia.</p> | The GDG used the phrase 'preconception care and advice' (rather than 'preconception counselling') to emphasise that this is not care needing to be specifically provided by trained counsellors. |

Appendix B: Selected recommendations from the NICE clinical guideline 63 relating to pregnancy, conception or contraception and relevant to primary care

The two recommendations highlighted in grey are included in the main part of the briefing paper for consideration for indicator development.

Outcomes and risks for the woman and baby

Recommendation 1.1.1.1

Healthcare professionals should seek to empower women with diabetes to make the experience of pregnancy and childbirth a positive one by providing information, advice and support that will help to reduce the risks of adverse pregnancy outcomes for mother and baby.

Recommendation 1.1.1.2

Women with diabetes who are planning to become pregnant should be informed that establishing good glycaemic control before conception and continuing this throughout pregnancy will reduce the risk of miscarriage, congenital malformation, stillbirth and neonatal death. It is important to explain that risks can be reduced but not eliminated.

Recommendation 1.1.1.3

Women with diabetes who are planning to become pregnant and their families should be offered information about how diabetes affects pregnancy and how pregnancy affects diabetes. The information should cover:

- the role of diet, body weight and exercise
- the risks of hypoglycaemia and hypoglycaemia unawareness during pregnancy
- how nausea and vomiting in pregnancy can affect glycaemic control
- the increased risk of having a baby who is large for gestational age, which increases the likelihood of birth trauma, induction of labour and caesarean section

- the need for assessment of diabetic retinopathy before and during pregnancy
- the need for assessment of diabetic nephropathy before pregnancy
- the importance of maternal glycaemic control during labour and birth and early feeding of the baby in order to reduce the risk of neonatal hypoglycaemia
- the possibility of transient morbidity in the baby during the neonatal period, which may require admission to the neonatal unit
- the risk of the baby developing obesity and/or diabetes in later life.

The importance of planning pregnancy and the role of contraception

Recommendation 1.1.2.1

The importance of avoiding unplanned pregnancy should be an essential component of diabetes education from adolescence for women with diabetes.

Recommendation 1.1.2.2

Women with diabetes who are planning to become pregnant should be advised:

- that the risks associated with pregnancies complicated by diabetes increase with the duration of the diabetes
- to use contraception until good glycaemic control (assessed by HbA_{1c}) has been established
- that glycaemic targets, glucose monitoring, medications for diabetes (including insulin regimens for insulin-treated diabetes) and medications for complications of diabetes will need to be reviewed before and during pregnancy
- that additional time and effort is required to manage diabetes during pregnancy and that there will be frequent contact with healthcare professionals. Women should be given information about the local arrangements for support, including emergency contact numbers.

Removing barriers to the uptake of pre-conception care and when to offer information

NICE recommendation 1.1.8.1

Women with diabetes should be informed about the benefits of pre-conception glycaemic control at each contact with healthcare professionals, including their diabetes care team, from adolescence.

Recommendation 1.1.8.2

The intentions of women with diabetes regarding pregnancy and contraceptive use should be documented at each contact with their diabetes care team from adolescence.

Recommendation 1.1.8.3

Pre-conception care for women with diabetes should be given in a supportive environment and the woman's partner or other family member should be encouraged to attend.

Self-management programmes

Recommendation 1.1.9.2

Women with diabetes who are planning to become pregnant should be offered pre-conception care and advice before discontinuing contraception.

Appendix C: Related QOF indicators

Related existing QOF indicators from 2013/14 indicator set

Diabetes is part of the existing QOF clinical domain as defined in the 2013/14 GMS contract guidance. QOF indicators for England for this domain are outlined below. Indicators for Scotland, Wales and Ireland can be found from the relevant countries web pages.

QOF domain 2013/14: Diabetes

| Indicator | Points | Achievement thresholds |
|--|---------------|-------------------------------|
| Records | | |
| DM001. The contractor establishes and maintains a register of all patients aged 17 or over with diabetes mellitus, which specifies the type of diabetes where a diagnosis has been confirmed <i>NICE 2011 menu ID: NM41</i> | 6 | |
| Ongoing management | | |
| DM002. The percentage of patients with diabetes, on the register, in whom the last blood pressure reading (measured in the preceding 12 months) is 150/90 mmHg or less <i>NICE 2010 menu ID: NM01</i> | 8 | 53-93% |
| DM003. The percentage of patients with diabetes, on the register, in whom the last blood pressure reading (measured in the preceding 12 months) is 140/80 mmHg or less <i>NICE 2010 menu ID: NM02</i> | 10 | 38-78% |
| DM004. The percentage of patients with diabetes, on the register, whose last measured total cholesterol (measured within the preceding 12 months) is 5 mmol/l or less | 6 | 40–75% |
| DM005. The percentage of patients with diabetes, on the register, who have a record of an albumin:creatinine ratio test in the preceding 12 months <i>NICE 2012 menu ID: NM59</i> | 3 | 50–90% |
| DM006. The percentage of patients with diabetes, on the register, with a diagnosis of nephropathy (clinical proteinuria) or micro-albuminuria who are currently treated with an ACE-I (or ARBs) | 3 | 57-97% |
| DM007. The percentage of patients with diabetes, on the register, in whom the last IFCC-HbA1c is 59 mmol/mol or less in the preceding 12 months <i>NICE 2010 menu ID: NM14</i> | 17 | 35-75% |

| | | |
|--|----|--------|
| DM008. The percentage of patients with diabetes, on the register, in whom the last IFCC-HbA1c is 64 mmol/mol or less in the preceding 12 months | 8 | 43-83% |
| DM009. The percentage of patients with diabetes, on the register, in whom the last IFCC-HbA1c is 75 mmol/mol or less in the preceding 12 months | 10 | 52-92% |
| DM010. The percentage of patients with diabetes, on the register, who have had influenza immunisation in the preceding 1 September to 31 March | 3 | 55-95% |
| DM011. The percentage of patients with diabetes, on the register, who have a record of retinal screening in the preceding 12 months | 5 | 50–90% |
| DM012. The percentage of patients with diabetes, on the register, with a record of a foot examination and risk classification: 1) low risk (normal sensation, palpable pulses), 2) increased risk (neuropathy or absent pulses), 3) high risk (neuropathy or absent pulses plus deformity or skin changes in previous ulcer) or 4) ulcerated foot within the preceding 12 months <i>NICE 2010 menu ID: NM13</i> | 4 | 50–90% |
| DM013. The percentage of patients with diabetes, on the register, who have a record of a dietary review by a suitably competent professional in the preceding 12 months <i>NICE 2011 menu ID: NM28</i> | 3 | 40-90% |
| DM014. The percentage of patients newly diagnosed with diabetes, on the register, in the preceding 1 April to 31 March who have a record of being referred to a structured education programme within 9 months after entry on to the diabetes register <i>NICE 2011 menu ID: NM27</i> | 11 | 40-90% |
| DM015. The percentage of male patients with diabetes, on the register, with a record of being asked about erectile dysfunction in the preceding 12 months <i>NICE 2012 menu ID: NM51</i> | 4 | 40-90% |
| DM016. The percentage of male patients with diabetes, on the register, who have a record of erectile dysfunction with a record of advice and assessment of contributory factors and treatment options in the preceding 12 months <i>NICE 2012 menu ID: NM52</i> | 6 | 40-90% |

Related indicators from the NICE menu of indicators

All diabetes related indicators on the NICE menu have been negotiated into the 2013/14 QOF and listed above.

Related indicators under consideration by the Advisory Committee

The committee is asked to consider the briefing paper on diabetes care plans and serious mental illness - pregnancy, conception and contraception advice.

Appendix D: 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.

Topic Status

This topic meets the prioritization 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 | <input checked="" type="checkbox"/> |
| The condition is considered to have population prevalence that is medium | <input type="checkbox"/> |
| The condition is considered to have population prevalence that is low | <input type="checkbox"/> |

| 1B Management | | | |
|---|-------------------------------------|--------------------------|--------------------------|
| | Fully meets criteria | Partly meets criteria | Doesn't meet criteria |
| | Score: [3] | [2] | [1] |
| The condition is diagnosed in primary care* | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| The condition is treated in primary care* | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| The condition is monitored in primary care* | <input checked="" type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| <i>* by general practitioners or directly employed practice staff</i> | | | |

| 1C Disease Severity | | |
|---------------------|---|--------------------------|
| Score | Scoring criteria | |
| 1 | Minor quality-of-life impact, no disability, limited morbidity impact | <input type="checkbox"/> |
| 2 | Definite quality-of-life impact, no disability, limited morbidity impact | <input type="checkbox"/> |
| 3 | Definite quality-of-life impact, some disability and/or intermediate morbidity impact | <input type="checkbox"/> |

| | | |
|---|--|-------------------------------------|
| 4 | Definite quality-of-life impact, significant disability and/or significant morbidity impact | <input checked="" type="checkbox"/> |
|---|--|-------------------------------------|

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 | |
|---|-------|
| <i>Preconception Care</i> | |
| NICE recommendation 1.1.1.2 (CG63) | Green |
| NICE recommendation 1.1.8.1 (CG63) | Green |

| Scores for each recommendation | | | |
|---------------------------------------|---|---------------------------------------|------------------------------------|
| | Evidence of clinical effectiveness | Evidence of cost effectiveness | Expected change in practice |
| <i>Preconception Care</i> | | | |
| NICE recommendation 1.1.1.2 (CG63) | Low | Likely cost effective | Moderate |
| NICE recommendation 1.1.8.1 (CG63) | Low | Likely cost effective | Moderate |