Guidelines for change: Pregnancy and more

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In February 2015, NICE published *Diabetes in pregnancy: management of diabetes and its complications from preconception to the postnatal period* (NICE, 2015). An exploration of the key elements of this for primary care clinicians is provided in an article starting on page 88.

The St Vincent Declaration (St Vincent Declaration Working Group, 1990) set a goal of ensuring that pregnancy outcomes in women with diabetes matched those of women without diabetes. Sadly this has not yet been achieved. Miscarriages, congenital abnormalities, still-births and infant deaths remain more common than in those without diabetes. One in 20 UK pregnancies are complicated by diabetes – either pre-existing type 1 or type 2 diabetes or gestational diabetes. In 2013, nearly 45% of pregnant women with pre-existing diabetes had type 2 diabetes; 10 years earlier only 27% had type 2 diabetes (Health and Social Care Information Centre [HSCIC], 2014). These changing demographics have implications for primary care, since we will be providing all the care for the majority of these women with type 2 diabetes, including any pre-conception advice. How good are we at delivering this?

The National Pregnancy in Diabetes Audit audit (HSCIC, 2014), discussed by Su Down in her comment piece on page 62, highlighted that preparation for pregnancy in women with pre-existing diabetes in the UK remains poor. Only 33% of women were taking folic acid 5 mg and only 25% of those with type 1 diabetes and 45.9% of those with type 2 diabetes achieved the previous NICE-recommended conception HbA_{1c} of 53 mmol/mol (7%), despite our knowledge of the importance of these in reducing risk.

A Clinical Practice Research Datalink study found similar pregnancy losses (20%) in women with type 1 and type 2 diabetes (McGrogan et al, 2014) and another UK study identified that 30.5% of first pregnancies in those with diabetes ended in serious adverse outcomes (6.4% congenital anomalies and 24.1% additional fetal or infant deaths; Tennant et al, 2015). Although adverse outcomes overall were halved in second pregnancies, serious events remained equally common in those with first pregnancy adverse outcome. Sadly there was no evidence of inter-pregnancy preparation following adverse outcomes.

This NICE guideline highlights an urgent need for us to identify women of child-bearing potential with diabetes, to ensure they understand the importance of planned pregnancy, discussion regarding medication changes, tightening pre-conception glycaemic control, initiating folic acid supplementation, and more frequent retinopathy and renal checks while trying to conceive. All will need self-monitoring of blood glucose and 3-monthly HbA_{1c} measurement, while for many of those with type 2 diabetes, initiation of insulin will become necessary as other drugs unsuitable during pregnancy are withdrawn. Many will be taking angiotensin-converting enzyme inhibitors, angiotensin receptor blockers, statins or other drugs contraindicated in pregnancy; these will need to be stopped or switched prior to conception. All of this will necessitate lengthy and complex discussions, and provision of written information for review, reflection and further discussion will be needed. In addition, delivering this care in the most appropriate way for multicultural and vulnerable women will take some thought.

So how might we identify the people who need pre-conception care? Opportunistically raising the topic at every contact, waiting-room posters and TV-screen messages will help identify motivated women. Encouraging these women to use safe and effective contraception while planning their pregnancy will be harder, and helping them tighten their control may require help from secondary care colleagues. Whatever it takes, this is now an agenda that we need to tackle, and identifying many of these women is something that only we can do.

NICE also provides more stringent diagnostic criteria for gestational diabetes, resulting in an increased prevalence, translating into growing numbers of women considered at high risk of type 2 diabetes. As well as active encouragement to reduce their risk and annual monitoring for type 2 diabetes, many will need pre-conception counselling and help with weight reduction to reduce risk in their next pregnancy.

There is a possible protective effect of breast-feeding (Kim, 2014), particularly when lasting longer

Finkelstein S et al (2013) Breastfeeding in women with diabetes: lower rates despite greater rewards: A population-based study. *Diabet Med* **30**: 1094–1101

Handelsman et al (2015) American Association of Clinical Endocrinologists and American College of Endocrinology Clinical Practice Guidelines for developing a diabetes mellitus comprehensive care plan – 2015. *Endocr Pract* **21**(Suppl 1): 1–87

Health and Social Care Information Centre (2014) *National Pregnancy in Diabetes Audit, 2013*. HSCIC, Leeds. Available at: http://bit.ly/1Et0pzl (accessed 30.04.15)

Inzucchi S et al (2015) Management of hyperglycemia in Type 2 diabetes, 2015: A patient-centered approach. *Diabetes Care* **38**: 140–9

Kim C (2014) Maternal outcomes and follow-up after gestational diabetes mellitus. *Diabet Med* **31**: 292–301

McGrogan A et al (2014) Pregnancy losses in women with type 1 or type 2 diabetes in the UK: an investigation using primary care records. *Diabetes Care* **31**: 357–65

NICE (2015) *Diabetes in pregnancy: Management of diabetes and its complications from preconception to the postnatal period* (NG3). NICE, London. Available at: http://www.nice.org.uk/ng3 (accessed 30.04.15)

St Vincent Declaration Working Group (1990) Diabetes mellitus in Europe: a problem at all ages in all countries, a model for Prevention and Self Care. *G Ital Diabetol* **10**(Suppl): 1–143

Tennant P et al (2015) Risk and recurrence of serious adverse outcomes in the first and second pregnancies of women with preexisting diabetes. *Diabetes Care* **38**: 610–9

Zeigler A et al (2012) Long-term protective effect of lactation on the development of Type 2 diabetes in women with recent gestational diabetes mellitus. *Diabetes* **61**: 3167–71

than 3 months following a pregnancy complicated by gestational diabetes. During follow-up of one prospective study, women with gestational diabetes who breast-fed had a median time to diabetes of 12.3 years compared with 2.3 years in those who did not (Zeigler et al, 2012); interestingly this did not seem to be mediated solely through weight reduction. However, an important related finding is that women with pre-gestational or gestational diabetes appear to be less likely to breast-feed (Finkelstein et al, 2013).

Updated European and US guidance

Updates to the American Diabetes Association (ADA) and European Association for the Study of Diabetes (EASD) position statement on hyperglycaemia in type 2 diabetes (Inzucchi et al, 2015) and the American Association of Clinical Endocrinologists (AACE) and American College of Endocrinology (ACE) guideline for type 2 diabetes (Handelsman et al, 2015) were published in January and April 2015, respectively. Building on previous recommendations for personalised care, individualised targets and treatment strategies, both continue their strong focus on lifestyle interventions alongside medication, and both incorporate sodium–glucose cotransporter 2 (SGLT2) inhibitors in treatment recommendations.

Two emerging treatment strategies are highlighted. Firstly, both recommend initiating therapy with two drugs, usually a combination of metformin and another drug, in those with poor control at diagnosis. The AACE–ACE guidance recommends considering this when HbA_{1c} is ≥59 mmol/mol (7.5%) while the ADA–EASD guidance recommends this in those with an HbA_{1c} ≥75 mmol/mol (9%). As an alternative, the latter recommends initiating monotherapy with early treatment intensification, usually within 3 months. This reflects the benefits of tight early control of hyperglycaemia and the ensuing "legacy effect", and it may be quite different from early treatment decisions and inertia in UK practice. Secondly, both updates highlight the benefits of combining basal insulin and glucagon-like peptide-1 (GLP-1) receptor agonists to tighten control, as a simpler and safer alternative to intensification of insulin, both for people with diabetes and prescribers. The rationale for this approach and practical guidance on how to implement this are discussed in the article by Gwen Hall and Colin Kenny starting on page 80.

In stark contrast to the recent draft NICE guideline on type 2 diabetes (see page 67), the AACE–ACE guidance encourages initiation with dipeptidyl peptidase-4 inhibitors, GLP-1 receptor agonists, SGLT2 inhibitors or alpha-glucosidase inhibitors in those intolerant of metformin, stating: "A TZD, sulfonylurea or glinide may be considered as alternative therapies but should be used with caution due to side effect profiles." The AACE–ACE guidance also emphasises that minimising the risk of hypoglycaemia and weight gain are priorities and, when discussing the treatment algorithms, stresses: "Safety and efficacy should be given higher priorities than initial acquisition cost of medications per se since cost of medications is only a small part of the total cost of care of diabetes. In determining the cost of a medication, consideration should be given to monitoring requirements, risk of hypoglycaemia and weight gain etc."

Quality and Outcomes Framework

As we go to press, Quality and Outcomes Framework changes for 2015–16 are becoming clearer (see http://bit.ly/1GJQOYe [accessed 30.04.15]). There are no changes to the diabetes domain in England, with planned threshold changes deferred for a year. The value of each point is raised slightly. In Scotland, the agreement to delay major changes until 2017 remains in place. In Northern Ireland, 102 points are removed, including those for albumin–creatinine ratio measurement and referral for structured education in the diabetes domain, releasing £5.2 million, which is partly transferred into the global sum and partly used to raise the value of each point. In Wales, 102 points go back into the global sum, including four diabetes indicators, worth 18 points. Influenza immunisation moves to a new public health indicator, and the erectile dysfunction indicators and the ≤64 mmol/mol (8%) glycaemia indicator are retired, leaving only the ≤59 mmol/mol (7.5%) indicator, with 40–72% targets. The three glycaemic indicators remain in England and Scotland, while Northern Ireland retains the ≤64 mmol/mol indicator only.

To meet the increasing needs of women with, or at high risk of, diabetes in our practices, it is clear we are going to have to work smarter and really "make every contact count". We will include practical guidance on gestational diabetes in a future edition. ■