NICE Clinical Guideline: Diabetes in pregnancy (partial update)

Stakeholder scoping workshop notes

Scope – overall

- Preconception care is not addressed in scope but also acknowledged that there may not be any new evidence in this area. A possible topic to look at in relation to preconception care could be information about changes to diabetes medications
- The main clinical concern is women with type 1 diabetes
- The scope does not cover the management of *hypoglycaemia in pregnant women and this is an important issue for mother and baby – need a whole new section on this in the guideline to cover centralised specialist teams, (see N. Ireland and Danish data) where care is provided, how it is integrated with normal care, access to DAPHNE, driving etc
- Implementation of *GDM screening varies: some of the NHS only screen above 35 body mass index (BMI) because of resources,
- *Need to detect type 2 early in pregnancy and then accelerate care to avoid risks/harm. Covered in ADA guidelines with fasting blood glucose.
- *All pregnant women with diabetes need rapid access to retinal screening
- *Type 1 pump therapy - wide variation in provision. Need for specialist teams, and volume of patients to ensure confidence in delivering care.
- *Women cannot access enough testing strips from GPs to allow them to manage their diabetes and avoid risks to their babies.
- *Make up of specialist teams: Obstetricians, Physicians, dieticians; care to include pumps and carbohydrate counting
- *Specialist diabetic midwives
- *GDM need post natal screening
- *All DiP women need care tailored to their needs and *an individualised care plan for antenatal care (ANC) and labour, for women and baby, which is integrated with normal care. If they are sent into London for pumps how can they still access normal ANC care?
- *Integrated high quality ANC – women complain about the number of appointments and locations
- Pregnant women with diabetes women need hand held notes for that are integrated with their normal ANC care
- Preconception care needs to happen in paediatric services. There are cultural issues with some communities regarding this as not appropriate for their young people.

- Obesity in pregnancy needs consideration
- A key question is what percentage of the population is considered to have gestational diabetes (GDM). Some would argue that it is much higher than 5% but this is a subject of much debate
- The scope is almost entirely devoted to GDM and this does not reflect the population who have the worst outcomes

***** *denotes potential areas for Quality Standard for diabetes in pregnancy*

Guideline development group – draft constituency

- Include healthcare professionals involved in preconception care (GP (possibly with specialist interest)/dietician)
- If there are to be two obstetricians, it would be best if they came from different settings so they have a variety of experiences
- Consider having two midwives for the same reason
- That said, ensure there is diabetes specialist midwife and nurse representation (replace nurse practitioner with diabetes specialist nurse)
- Query whether neonatologist is necessary; consider nurse practitioner working in neonatology instead or recruiting this person as an expert advisor rather than a full member for questions where neonatal outcomes are important
- Add dietician, preferably specialist dietician because normal dieticians may not have the specific skills/experience that are most relevant to these women e.g. carb counting
- It might be helpful to have a paediatric diabetologist to reflect the young women covered by the guideline who have not yet transferred to adult care. Again this person could be an expert advisor
- Lay members – include a woman who has had diabetes in pregnancy and consider diversity in terms of ethnicity and lifestyle
- Antenatal care representation – suggest a non- specialist midwife (i.e. one who deals with normal pregnancies) or a senior midwife with a supervisory roll covering all aspects of midwifery

Population

- Suggest separate out care for women so that type 1, type 2 and GDM are considered separately – they have different issues and risks eg type 2 should not be put on satins and ace inhibitors**,** Type 1 diabetes it is very difficult to get good glycaemic control and this group of women need a lot more help, GDM is a big and important group within the overall population
- Query whether other types of diabetes (for example Maturity Onset Diabetes of the Young – MODY) will be covered
- Preconception care, this is being transferred to the community – yet some of these women (eg those with type1) need specialist care in preconception period

- Women with complications of diabetes – this is a small but important group should be considered separately if evidence allows
- Women who do not fit into the conventional risk factor categories should be considered separately if evidence allows – it would be important to give such women information about why they get gestational diabetes
- Women with language difficulties, as part of a broader consideration of women who find it difficult to access care, should be considered separately if evidence allows
- Query whether women with high BMI should be considered as a separate sub-group
- Query why women with comorbidities are being excluded agree that the management of these conditions is outside of the scope but the way it is written suggests that these women will be excluded entirely. This is especially relevant to women with infertility who are likely to be using metformin before pregnancy - IVF clinics treat women without regard for HBA1c and it's causing harm. A referral threshold would be helpful e.g. women referred to IVF clinics need HBAIC of less than… (new 2012 paper re pre existing diabetes)
- Population does not reflect the fact that all pregnant women need to be screened

Equalities

- Consider asylum seekers, women with language other than English, other vulnerable women (i.e. those with socially complex pregnancies)
- Be aware that some women come to the UK to receive treatment for diabetes
- People that are most vulnerable are often in hard to reach groups. Suggested solution for this is to increase preconception care and education in schools (because school attendance is compulsory) through, for example the use of videos such as 'Ready Girls'.
- One stakeholder identified a particularly high risk group as young women who do not know they have diabetes and do not know they are pregnant. This situation might be particularly likely to occur in cultures where pre-marital sex is discouraged/unacceptable and therefore discussing the possibility of pregnancy with young women may be less common
- Some evidence that white social group 5 have the worst outcomes
- Being very prescriptive about the timing of screening might create equalities issue as the more vulnerable women are less likely to attend clinic at specified times. Suggest that wording be amended to something broader such as 'first antenatal visit'
- Query whether women with high BMI should be considered separately as BMI can respond to interventions unlike other risk factors such as family history
- Query whether the list of ethnic groups in the draft risk factor question (see chair's presentation) is comprehensive – black

African and Chinese women should be considered

Health Care setting
• This should be expanded to all healthcare settings

Topics for update
Topic a) Risk factors present at the 8 week antenatal visit that are highly predictive of the later development of GDM.
• 8 week antenatal visit is inaccurate. Statuary obligation is to do it by 12+6 weeks. 6-12 or 8-12 weeks would be better • Change '8 week' to 'first contact about pregnancy' • Remove the 8 week specification – this is not important to the question and distracting • Timescales are different for women with pre-existing diabetes. They should be referred to diabetes in pregnancy pathway as soon as they are known to be pregnant • Polycystic ovaries should be considered as a risk factor • There is another question missing here about screening/diagnosis in the first trimester for previously undiagnosed type 2 diabetes
Topic b) Effectiveness of screening procedures to detect women with GDM between 24 -28 weeks.

• Increased frequency of transfers (e.g. within hospitals) is leading to problems/confusion for women with diabetes
  ○ Different settings use different sets of risk factors /screening tests/diagnostic tests and thresholds
  ○ Current recommendation that uses World Health Organization (WHO) criteria is not implemented everywhere
  ○ Different screening strategies are used according to whether local prevalence rate for GDM is low/high
  ○ Standardisation of diagnostic thresholds is more important than local variations in screening practice
  ○ Query who pays for testing primary/secondary care (although agree this question was beyond remit of a clinical guideline)
  ○ Testing for recurrent gestational diabetes at 16 weeks needs to be included in update (not implicitly/explicitly excluded)
  ○ All of the above issues should be considered/apply to all the topics b, c, d, e and g
• Screening for GDM is not sufficient. The scope also needs to consider universal screening for previously undiagnosed type 2 diabetes in the first trimester (or as early as possible). A random blood glucose test should be used for this type of universal

screening (as in Scotland). The identified women then need a pathway of accelerated care, eg how to monitor, screening etc • Add HbA1c to list of screening tests to be used at 24-28 weeks • Gycosuria testing still occurs even though this was a do not do recommendation last time. One stakeholder said that glycosuria testing had doubled GDM pick-up rate • 50g OGTT is actually the 'glucose challenge test' – revise wording • 100g OGTT is not used in the UK and should not be included
Topic c) The most effective (including safety and cost-effectiveness) intervention (alone or in combination) for women with GDM
• Lifestyle interventions are very important to women with gestational diabetes – reinforce the existing recommendation by emphasising continuous/ongoing active intervention in lifestyle and diet. Need for dietician on GDG was reiterated at this point • OK but also noted that obesity in pregnancy (with or without diabetes) would also benefit from lifestyle interventions – i.e. if a woman is obese but not diagnosed with diabetes in first trimester (see above), giving 'preventative' lifestyle interventions could reduce likelihood of GDM developing. • Use of metformin to prevent GDM in women at high risk? • This is not specific to GDM but for type 1 and 2 as well • Effectiveness of individual interventions is less interesting than the effectiveness of different models of care relating to intensity of intervention and monitoring. Consideration should be given to personnel, location, frequency and what works for which women. It might be necessary to look at a non-pregnancy specific evidence base for this.
Topic d) Diagnostic criteria used to diagnose GDM in pregnant women between 24 – 28 weeks.
• Timeframe does not reflect current practice for women who have a history of GDM who are tested at 16 weeks • This is an important topic but again specific timing of test should be removed because this is not important to the question and distracting • See also comments on Topic b
e) Diagnostic tests alone, or in combination, for GDM
• See comments on Topic b
Topic f) The effectiveness of continuous glucose monitoring in pregnant women with diabetes when compared with

	intermittent capillary blood glucose monitoring
	• Continuous glucose monitoring (CGM) is important and should be included. Cost and interpretation of the monitoring results are important considerations. Cost effectiveness in women with gestational diabetes (even through limited period use in such women approximately 10 weeks (after 29 week detection)) should be included – i.e. this topic is relevant to women with gestational diabetes as well as those with type 1 or type 2 • Acceptability to the woman is an important outcome • There is variation in practice currently in women with pre-existing diabetes. There is new research on this topic but practice has not changed. • Still need provision for calibration with intermittent testing – i.e. women will still need to use intermittent testing as well as GCM on some occasions to check that CGM readings are accurate • Other new technologies are available including computerised monitoring and 'therapeutic suggestions' (smart meters) for insulin • Education package – check in pregnancy that all women with pre-exising diabetes have received a structured education package, such education is recommended for all people with type 1 and type 2 diabetes and because good glycaemic control is so important in the preconception period and during pregnancy healthcare professionals should ensure that it has taken place • CGM can be used both continuously and intermittently and questions should reflect this • There is lots of hypoglycaemia in pregnancy and therefore pump therapy and preconception care is even more important. Access to machines and strips is a major concern – need enforceable guidance on how often women need to test and the equipment provided to do so. • Hypoglycaemia needs its own section in the guideline • This should cover preconception monitoring for women with pre-existing diabetes as well as monitoring during pregnancy • The pregnancy specific evidence base is limited (1 known RCT) and it is questionable as to whether data from non-pregnancy population can be extrapolated
Topic g)	***The comparative effectiveness of tests in the detection of type 2 diabetes after pregnancy in women who have had gestational diabetes***
	• The current recommendation is not being implemented because many women do not come to the 6 week appointment so it needs to be changed - need to review when, how and where would be best to improve access for women. • The post-natal check is an important opportunity to give further preconception advice for the future

- Southampton data used in existing guideline is not typical
- See also comments on Topic b

Topic h) The optimal timing of the first test after delivery to identify type 2 diabetes in women who have had gestational diabetes?

- Query whether this means immediately (72 hours) after birth or at the 6 week post natal visit
- There is variation in uptake of the 6-week post natal visit, what test is used and when
- Number of visits and appointments is an issue for women
- Wording should be changed from 'delivery' to 'birth'
- See also comments on topic g

Additional topics suggested by stakeholders

- Cost effectiveness and safety of insulin analogues, particularly long acting ones such as insulin detemir
- Induction of labour and planned c-section - current recommendation about use of steroids in green top guideline may not be appropriate for women with diabetes
- Are there any factors (other than risk factors) about the profile of women or the model of care that is delivered that can impact on neonatal and maternal outcomes such as still birth/diabetes related outcomes
- Retinal screening for women with GDM
- See also suggestions above (screening and diagnosis for undiagnosed diabetes in the first trimester, management of hypoglycaemia)
- Preconception/ongoing care came up as recurrent issue during discussion

Areas not included for update

- Topics identified are reasonable exclusions
- Interventions after post-natal care to prevent type 2 diabetes are not for this guideline (although this conflicts with comment made at outset that preconception care should be prioritised)
- If currently included topics had to be dropped the lowest priority would be Topic a (risk factors) followed by Topic g (timing of post-natal test)
- Query the exclusion of intrapartum care in relation to induction of labour as current guideline is at odds with recommendations for non-diabetic pregnant women and this may not be appropriate to some women with GDM

- See also comments on scope overall

Outcomes

- Neonatal outcomes:
  - 'Admission to intensive care' should be changed to 'admission to a unit requiring separation from mother'
  - Macrosomia should also include intrauterine growth restriction (IUGR)
  - 'Neonatal hypoglycaemia' should be changed to 'neonatal hypoglycaemia requiring active management'
  - Small for gestational age should be added
  - Birth weight should be added
  - Birth trauma e.g. shoulder dystocia should be added
  - Respiratory distress and neonatal jaundice can be dropped
- Maternal outcomes:
  - preterm birth should split into two categories 34 weeks and 37 weeks.
  - 'Need for change in treatment' can be changed to 'third party care for diabetes'.
  - Intrapratum intervention rate, neonatal death, congenital abnormalities should be priority outcomes
  - Caesarean section rate should be added
  - Long term outcomes such as BMI, mental health (e.g. post-natal depression) in women with pre-existing diabetes and GMD should be added
  - How many women would be prepared to repeat experience should be added
  - 'Fear of hypoglycaemia' (validated QoL scale) should be added
  - Time spent in hypo/hyperglycaemia/area under the curve, HbA1c should be added
- Diabetic complications, intrapartum complications in the unborn baby and diabetes control can be dropped

Scope –section 3

- Note that among women with diabetes in pregnancy, what are the populations of type 1, type 2 and gestational diabetes and how is this changing