Gestational Diabetes Mellitus: NICE for the U.S.?

A comparison of the American Diabetes Association and the American College of Obstetricians and Gynecologists guidelines with the U.K. National Institute for Health and Clinical Excellence guidelines

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OBJECTIVE — To compare recent U.S. and U.K. guidelines on gestational diabetes mellitus (GDM).

RESEARCH DESIGN AND METHODS — The guidelines from the American Diabetes Association, the American College of Obstetricians and Gynecologists, and the National Institute for Health and Clinical Excellence (NICE) in the U.K. were collated and compared using a general inductive approach.

RESULTS — There are substantial differences in the recommendations between the U.K. and the U.S. guidelines. Of particular note are the reduced sensitivities of the early and later antenatal and postnatal screening and diagnostic criteria. NICE undertook a cost-effectiveness analysis using lower prevalence estimates and limited outcomes and still showed screening for GDM to be cost-effective.

CONCLUSIONS — The latest NICE recommendations appear to reduce access to proven, cost-effective management of GDM, an issue relevant in the current U.S. health care policy debate.

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In an age of increasing patient empowerment, the diagnosis of gestational diabetes mellitus (GDM) provides a woman with the knowledge that her baby has an increased chance of complications before, during, and after birth (including an increased chance of obesity and/or diabetes in the future); that she herself has an increased chance of future diabetes; and that future pregnancies are more likely to be complicated by diabetes (gestational or otherwise) (1). Such knowledge could be harmful if there were no opportunities to reduce these risks. However, there is now good evidence that there are fewer obstetric and neonatal complications with intensive management (2) and that future diabetes cases can be delayed and possibly avoided (3). There is even evidence that there may be fewer incidents of postnatal depression following the diagnosis and management of GDM than among untreated women (2). To further the recent debate on the screening and detection of GDM (4,5), we have compared the different approaches to the detection and management of GDM recommended by the American Diabetes Association (ADA) (6), the American College of Obstetricians and Gynecologists (ACOG) (7), and the National Institute for Health and Clinical Excellence (NICE) in the U.K. (8).

NICE is wholly funded by the U.K. government to provide "national guidance on promoting good health and preventing and treating ill health." NICE assessments are multidisciplinary and include both research and health economic considerations, the latter giving a National Health Service, rather than a societal, perspective. NICE clinical guidelines for diabetes in pregnancy (8) were initially published in March 2008 and revised in July 2008, and a brief critique was published in September 2008 (9).

RESEARCH DESIGN AND METHODS

— The guidelines from the three organizations were collated and compared using a general inductive approach. Each guideline category has been treated as a "theme."

RESULTS

— Table 1 compares the ADA, ACOG, and NICE guidelines for diabetes in pregnancy (6–8). There are substantial differences in the recommendations between the U.K. and U.S. guidelines in most categories.

Unlike NICE, the ADA and ACOG guidelines do not include a cost-effectiveness component. NICE used a single cost-effectiveness model addressing screening, diagnosis, and treatment, and the model was used to direct the guideline recommendations. Using the data from the Australian Carbohydrate Intolerance Study in Pregnant Women (ACHOIS) (2), NICE demonstrated that the screening, diagnosis, and treatment of GDM are cost-effective.

CONCLUSIONS

— This comparison of NICE, ADA, and ACOG guidelines has identified a number of key areas where the recommendations are markedly divergent. Of particular importance are:

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Table 1—*Comparison of NICE, ADA, and ACOG guidelines for GDM*

	ADA	ACOG	NICE
Who should be screened for GDM	Women at high risk of GDM should undergo GTT as soon as feasible. If found not to have GDM at initial screening, they should be retested between 24 and 28 weeks. Women of average risk should have testing undertaken at 24–28 weeks. Low-risk status requires no glucose testing.	Because only 10% of the population would be exempt from screening using the selective method, screen all pregnant women (universal screening) as a more practical approach.	BMI ≥30 kg/m^2, previous baby ≥4.5 kg, previous GDM, first-degree relative with diabetes, South Asian, black Caribbean, Middle Eastern. Not included are age, other high-risk ethnic groups, past IGT, polycystic ovarian syndrome.
What women should be told about screening and testing for GDM	Although uncomplicated GDM with less severe fasting hyperglycemia has not been associated with increased perinatal mortality, GDM of any severity increases the risk of fetal macrosomia.	Women with GDM are more likely to develop hypertensive disorders than women without GDM. GDM increases the risk of fetal macrosomia. In addition, women with GDM have an increased risk of developing diabetes later in life.	Most women respond to diet/exercise; some (10–20%) need other agents; if GDM is not detected, there is a small risk of birth complications such as shoulder dystocia; GDM may lead to more interventions.
How screening for GDM should occur	Women at high risk of GDM should undergo GTT as soon as feasible. If they are found not to have GDM at that initial screening, they should be retested between 24 and 28 weeks' gestation. Women of average risk should have testing undertaken at 24–28 weeks' gestation. Low-risk status requires no glucose testing.	Universal screening by two-step method. It involves an initial test after administration of 50-g glucose 1-h test followed by GTT to confirm the diagnosis for patients with an abnormal initial result.	75-g 2-h OGTT at 16–18 weeks if prior GDM; 24–28 weeks if risk factors
Criteria for GDM	100-g glucose: plasma glucose level (2 or more time points need to elevated): Fasting >5.3 mmol/l; 1-h >10.0 mmol/l; 2-h, >8.6 mmol/l (only 2 h if 75-g glucose used); 3-h, >7.8 mmol/l	100-g glucose: plasma glucose level (2 or more time points need to elevated): Fasting >5.3 mmol/l; 1-h >10.0 mmol/l; 2-h, >8.6 mmol/l; 3-h, >7.8 mmol/l	75-g glucose: plasma glucose level (1 or more time points need to elevated): Fasting 7.0 mmol/l; 2-h 7.8 mmol/l
Screening for undiagnosed type 2 diabetes	Women at high risk of GDM should undergo GTT as soon as feasible.	Diagnosis of diabetes recommended in the first half of pregnancy using 50-g 1-h screening test	Early testing of blood glucose or OGTT for women with a history of GDM and/or IGT (18–20 weeks)
Targets for blood glucose control	Fasting whole blood glucose ≤5.3 mmol/l 1-h postprandial whole blood glucose ≤7.8 mmol/l 2-h postprandial whole blood glucose ≤6.7 mmol/l	Plasma glucose level: Fasting, 5.3 mmol/l 1-h postprandial, ≤7.2 mmol/l	Fasting 3.5–5.9 mmol/l 1-h postprandial <7.8 mmol/l No A1C 2nd/3rd trimester
GDM antenatal management	All women with GDM should receive nutritional counseling. BMI >30 kg/m^2, a 30–33% calorie restriction to ~25 kcal/kg actual weight per day. Selection of pregnancies for insulin therapy can be based on measures of maternal glycemia with or without assessment of fetal growth characteristics. Inadequate information to recommend oral hypoglycemic agents.	Nutritional intervention in women with GDM should be designed to achieve normal glucose levels to avoid ketosis. Hypoglycemic therapy supported: further studies recommended for glyburide. Insulin therapy based on measures of maternal glycemia based on fasting, 1- and 2-h postprandial.	Low GI diet, calorie restriction if BMI ≥27 kg/m^2, moderate exercise, hypoglycemic therapy (including metformin) after 1–2 weeks if lifestyle insufficient or abdominal circumference >70th centile at diagnosis.
GDM intrapartum management	Delivery during the 38th week is recommended unless obstetric considerations dictate otherwise. Prolongation of gestation past 38 weeks increases the risk of fetal macrosomia without reducing cesarean rates.	The timing of delivery in GDM remains relatively open. If estimated fetal weight is 4,500 g or more, cesarean delivery may be considered.	Induce/elective cesarean after 38 weeks if normally grown fetus; glucose monitoring hourly target 4–7 mmol/l if higher intravenous dextrose/insulin

Table 1—*Continued*

	ADA	ACOG	NICE
GDM postpartum management	All patients with prior GDM should be educated regarding lifestyle modifications, including maintenance of normal body weight. Patients should be advised to seek medical attention if they develop symptoms of hyperglycemia.	Individuals at increased risk of type 2 diabetes (i.e., obesity, increased age at the diagnosis of GDM) should be counseled regarding diet, exercise, and weight reduction or maintenance to delay or prevent type 2 diabetes.	Women should have blood glucose tested before discharge, be reminded of symptoms of hyperglycemia, offered lifestyle advice, and be advised of risk of GDM in future pregnancy.
GDM postnatal testing	If glucose levels are normal postpartum, reassessment of glycemia should be undertaken at a minimum of 3-year intervals. Women with IFG or IGT in the postpartum period should be tested for diabetes annually.	All women with GDM should be screened at 6–12 weeks postpartum, either FBG or 75-g GTT. If GTT/FBG is normal, assess every 3 years. Consider metformin in IFG and IGT	FBG at 6 weeks (but not an OGTT) and annually thereafter

FBG, fasting blood glucose; GTT, glucose tolerance testing; IFG, impaired fasting glucose.

Screening

The recent point-counterpoint (4,5) comprehensively debated is in regards to whether screening for GDM should be selective (i.e., using risk factors) or universal (i.e., using blood tests). There was general agreement on the risk factors of importance, while the latter addressed the broader issues of complexity and long-term benefits. NICE recommendations exclude several risk factors, including some shown to be cost-effective. NICE cost-effectiveness analysis substantially understated the benefits of screening because the basic decision tree structure omitted many avoidable downstream costs including some maternal morbidity (e.g., preeclampsia), neonatal morbidity (e.g., hypoglycemia), long-term maternal morbidity (e.g., preventable complications by earlier diabetes diagnosis and intervention), and long-term offspring risk (e.g., fetal morbidity if undiagnosed diabetes in a subsequent pregnancy; possibly future obesity and diabetes) (10).

NICE cost-effectiveness analysis acknowledged that a large number of assumptions were made "owing to data limitations and methodological complexity" and that there was potential for underestimating the true costs and effects (by using a cohort excluding those with worse glucose control) (2). The published modeling showed that universal screening becomes more cost-effective as the disease prevalence increases and used a sensitivity analysis with prevalence estimates of GDM ranging from 2–5%; actual GDM prevalence is now running at least 5–8% (1).

Detecting undiagnosed type 2 diabetes

Women with undiagnosed type 2 diabetes are significantly more prone to have babies with malformations and may have established diabetic complications (e.g., nephropathy and retinopathy) requiring close follow-up to ensure prompt restoration of normoglycemia. NICE recommendations delay the time to testing and ignore important criteria (e.g., strong family history). Given the often asymptomatic nature of type 2 diabetes and its potential to cause severe pregnancy complications, we consider that testing should be undertaken early in those at high risk, ideally as part of the first antenatal contact.

Postnatal testing

NICE dependence on fasting plasma glucose screening without performing an oral glucose tolerance test (OGTT) has been shown to reduce the sensitivity of identifying postpartum diabetes and impaired glucose tolerance (IGT) by 38–60% (11–12). In another study, 83% of those with IGT and 56% of those with diabetes would have been missed (13). The follow-up of women with a history of GDM is becoming increasingly important because of their increased risk of progression to type 2 diabetes (1) and the secular trend for a shortening of time between GDM and the development of diabetes (14). Many of these women would have been diagnosed at OGTT on the 2-h glucose alone, avoiding the risk of undiagnosed diabetes at the next pregnancy (should one occur). Moreover, without an OGTT, IGT cannot be identified. This is particularly important given the clear evidence that progression to subsequent diabetes can be reduced by over 50% (3).

Among increasingly empowered, knowledgeable, and "Internet savvy" patients, clinicians run the risk of having their management undermined by conflicting guidelines, making the implementation of clinical care substantially harder and more time-consuming. NICE guidelines are a relatively new addition to the scene but appear to be the most minimalist in relation to screening and postnatal follow-up (1). Fortunately, the completion of the Hyperglycemia and Adverse Pregnancy Outcomes (HAPO) study (15) now provides a large observational cohort that is being used to redefine diagnostic criteria for GDM in relation to adverse outcomes.

In conclusion, the comparison between NICE, ADA, and ACOG guidelines has demonstrated significant differences in recommendations for the screening, diagnosis, and management of GDM. Cost-effective management is a major issue in the debate on health care reform in the U.S., and current NICE recommendations appear to reduce access to proven, cost-effective GDM management.

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