The GDM Network presents

“Diagnosing and Screening for Gestational Diabetes: Still a Controversy? Still a Challenge?”

June 18, 2013
1:30-3:00 PM

Speakers include:
Robert Silver, MD, NIH GDM Panelist
Neil Murphy, MD International Pregnancy and Diabetes Study Groups criteria user
followed by
A Panel of Collaborative Partners

Sponsored by National Association of Chronic Disease Directors
and
The National Gestational Diabetes Network
in Collaboration with
US Office on Women’s Health,
The Centers for Disease Control and Prevention Divisions of
Diabetes Translation and Reproductive Health
The Gestational Diabetes Network Webinar presents “G Diabetes: Still a Controversy? Still a Challenge?” The webinar is scheduled for Tuesday, June 18, 2013 from 1:30 to 3:00 PM EST. This webinar discusses the recent NIH Consensus Conference on Diagnosing Gestational Diabetes recommendations, the utilization of the International Association of Diabetes and Pregnancy Study Groups diagnostic criteria, and several states will respond on the how and why of using which diagnostic criteria.

After attending this interactive webinar, you will:

- understand current GDM screening and diagnostic methods, and the implications for quality of care
- discuss the difference between the Carpenter/Coustan (ACOG) criteria and International Association of Diabetes and Pregnancy Study Groups diagnostic criteria
Diagnosing Gestational Diabetes
NICHD Consensus Development Conference

Bob Silver
University of Utah
Salt Lake City, Utah
Gestational Diabetes

- Carbohydrate Intolerance first recognized during pregnancy
- Varying prevalence
- U.S.: 5 – 6% (current criteria)
- 240,000 births / year
- Increasing with increase in risk factors such as obesity
Gestational Diabetes
Maternal Outcomes

- Gestational hypertension
- Preeclampsia
- Subsequent type 2 diabetes
- Cesarean delivery
- Subsequent CV disease
Gestational Diabetes
Fetal Outcomes

- Preterm birth (preeclampsia)
- Macrosomia
- Shoulder dystocia
- RDS
- Neonatal metabolic complications
Gestational Diabetes Standard Screening

- Two steps
- 50 gram GCT (1 hour – 1 test)
- 100 gram GCT (3 hours – 4 tests)
- 14 – 23% require second step
  - Varies by threshold
- Recommended by ACOG
Gestational Diabetes Controversies

- Value of routine screening
- Most appropriate method
- Most appropriate thresholds
- IADPSG advocates one step testing (FBS, 1 hour and 2 hour) with GDM requiring 1 abnormal
- May increase GDM by 2 – 3 fold
- Impetus for consensus conference
Gestational Diabetes Controversies

• Key issue:

  - Should criteria for diagnosis of GDM be changed??????
Gestational Diabetes

Question 1

• What are the current screening and diagnostic approaches for GDM, what are the glycemic thresholds for each approach, and how were these methods chosen?
Gestational Diabetes Current approaches

- Two-step approach (NDDG and Carpenter- Coustan)
- 50 gram GCT (not fasting)
- Threshold (130 – 140 mg/dL)
- 100 gram GCT (fasting)
- FBS and 1, 2, 3 hours (2 abnormal)
- Canadian: Modified 2 step with 75 gram GCT as second step
Gestational Diabetes
Current approaches

• One step approach
  • WHO and IADPSG
• 75 gram GCT (fasting)
• FBS and 1, 2 hours or 2 hours
• One abnormal
• Thresholds based on 1.75 fold increased risk in adverse pregnancy outcomes
Gestational Diabetes
Question 2

• What are the effects of various diabetes mellitus screening / diagnostic approaches for patients, providers, and U.S. healthcare system?
Adopting IADPSG criteria:

- All women would have FBS / GCT
- Increase proportion of GDM
- Diagnosis of GDM increases cost / time to patient, provider, healthcare
- Dietician, educator, clinic visits, NSTs, ultrasounds
- Childcare, transportation, missed work
Gestational Diabetes
Effect of approaches

- Adopting IADPSG criteria:
  - Clinic workload would increase by 30%
  - 450,000 more education visits
  - 1,000,000 more clinic visits
  - 1,000,000 more prenatal testing visits
  - Increase in U.S. cost for GDM from 636 million to 2 billion
  - Quality cost-effectiveness data lacking
In the absence of treatment, how do health outcomes of mothers who meet various criteria for gestational diabetes mellitus and their offspring compare with those who do not?
Gestational Diabetes
Health Outcomes

- Maternal outcomes – increased:
  - Cesarean delivery
  - Preeclampsia
  - Gestational hypertension
  - Subsequent diabetes and metabolic syndrome
Fetal outcomes – increased:

- Macrosomia
- Shoulder dystocia (rarely brachial plexus injury)
- Hypoglycemia
- Hyperbilirubinemia
- Potential increase in subsequent obesity
Gestational Diabetes Health Outcomes

- HAPO study
  - 25,505 women, 15 centers
  - Glucose tolerance 24 – 32 weeks
  - Observational cohort
    - Traditional GDM identified
      - FBS > 105; 2 hour > 200; random > 160
    - “Mild” GDM - blinded
Gestational Diabetes

Health Outcomes

- HAPO study
  - Increasing glucose levels
    - Increased birth weight
    - Increased infant body fat
    - Increased cord C peptide
    - Increased primary CS
    - Increased risks for preterm birth, preeclampsia, shoulder dystocia, hyperbilirubinemia
• Does treatment modify the health outcomes of mothers who meet various criteria for gestational diabetes mellitus and their offspring?
Gestational Diabetes
Health Outcomes

- Few data available (maternal)
- Treatment (using 2 step approach)
  - Reduces hypertensive disorders (40%)
  - Reduces shoulder dystocia (60%)
  - Absolute risk decreased 3.5 to 1.5%
  - No change in cesarean delivery!
  - Inconsistent data regarding weight gain, induction, other outcomes
Gestational Diabetes
Health Outcomes

• Few data available (fetal)
• Treatment (using 2 step approach)
  – Reduction in macrosomia (50%)
  – Absolute difference: 150 grams
  – No difference in neonatal hypoglycemia!
  – No data regarding prematurity, NICU admits, mortality, long term outcomes
Gestational Diabetes Health Outcomes

• Caution!
  – Studies may not apply to real world
    • Motivated, closely monitored women
  – Many confounding treatments today (e.g. oral hypoglycemics)
  – Varied criteria for GDM
    • Milder GDM may not have same benefits
What are the harms of treating gestational diabetes, and do they vary by diagnostic approach?
Gestational Diabetes
Harms of Increased Dx

- Patient anxiety
- Lower sense of well being
- Loss of personal control
- Potential increase in false positive results (with one vs two step test)
- Risks of oral hypoglycemic agents and insulin
Gestational Diabetes
Harms of Increased Dx

- Increased risk of induction
- Increased antenatal testing
- Increased ultrasound
- Increased cesarean delivery
- Increased neonatal care
- Increased cost
- All of these concerns are “theoretical”
• Given all of the above, what diagnostic approach(es) for GDM should be recommended, if any?
Gestational Diabetes
Recommended Approach

- Current two step approach
  - 5-6% GDM
  - Originally used to predict type 2 DM
  - Recent evidence that this IDs adverse maternal and fetal outcomes
  - Most women do not need to fast
Gestational Diabetes Recommended Approach

• Newly proposed one step approach:
  – IDs increased risk of maternal and perinatal morbidities
  – 15 – 20% GDM
  – Some operational advantages
    • One visit instead of two
    • Faster Dx and Rx
  – Consistency throughout the world
Gestational Diabetes Recommended Approach

- Criteria to justify change to one step
  - The additional women identified with GDM have an increase in morbidity
  - These morbidities can be reduced by interventions in the additional subgroup of women
  - The benefits of the decrease in morbidity is greater than potential harms
Gestational Diabetes Recommended Approach

- Criteria to justify change to one step
  - The additional women identified with GDM have an increase in morbidity
    - True! However, no clear threshold
  - Also, many outcomes are surrogate markers of true morbidity
  - No clear decrease in brachial plexus injury, perinatal mortality, preterm birth, subsequent obesity or metabolic disease
Gestational Diabetes
Recommended Approach

- Criteria to justify change to one step
  - These morbidities can be reduced by interventions in the additional subgroup of women
  - Not true! Results of RCTs in mild GDM cannot be generalized to IADPSG criteria
  - Major morbidities such as composite neonatal morbidity, CS, and long term maternal and infant outcomes are not improved
Gestational Diabetes
Recommended Approach

- Criteria to justify change to one step
  - The benefits of the decrease in morbidity is greater than potential harms
  - Not true!
  - Increased costs and burden on patients, clinicians and health care systems
  - Anxiety / psychosocial burden
  - Medical harms (CS / inductions)
Gestational Diabetes
Recommended Approach

- Conclusions
  - Not enough data to justify change
  - Still are potential benefits to IADPSG
    - More research is needed
  - Single standard for two step approach should be adopted
What are the key research gaps in the diagnostic approach of gestational diabetes mellitus?
Gestational Diabetes Research Gaps

• Develop a U.S. approach that is consistent with the world.
  – Perhaps using RR 2.0 in HAPO
  – Would allow one step approach
  – Avoid increase in Dx
Gestational Diabetes Research Gaps

- Determine if additional women with GDM based on IAPDSG criteria can benefit from diagnosis and treatment
  - RCTs needed
  - Need to assess important outcomes
Gestational Diabetes Research Gaps

- Cost / benefit analyses
- Patient burden / preferences
- Real world impact of GDM Dx and Rx
- Lifestyle interventions in pregnancy
- Long term impact: more pregnancies
- Long term impact: mother and child
- Interventions to improve long term impact
Six step vs the 1.25 step test

Neil Murphy MD
Southcentral Foundation
Alaska Native Medical Center
The ideal system in 2013: NIH

- Involves multiple handoffs
- Routinely loses highest risk pts to FU
- Designed for 2nd trimester, but used in all trimesters
- You pick GST cutoff prn: 130, 135, 140 mg/dL
- You pick OGTT criteria prn: CC, NDDG
Ideal system in 2013

• If a patient has one abnormal OGTT value they are still treated......

......just not diagnosed

Hold this thought
Current system

• Screens ‘high risk’ patients in 1\textsuperscript{st} trimester
• Screens again ‘routinely’ 24-28 wks
• Screens again at 32 wks, if the above ABN

• If pt got OGTT after each ABN GST, then she had to take 6 tests
....but there’s more...

- Dx’d if just a GST >185 or >200
- Mix and match GST and OGTT criteria
100 gm OGTT Criteria

- Carpenter / Coustan
  - Fasting: 95
  - 1 hr: 180
  - 2 hr: 155
  - 3 hr: 140
- NDDG
  - Fasting: 105
  - 1 hr: 195
  - 2 hr: 165
  - 3 hr: 145
- 2 ABN values
- 2 ABN values
Ideal system recap: NIH

Screening test only validated in 2nd trimester

Screening test has 3 cutoffs, de jour

Diagnostic test(s) have 8 cutoffs, de jour

...remember - still treats if one abnormal value
Don’t need to be screened

- Age < 25 yrs
- Not a member of a racial or ethnic group with high prevalence of diabetes (eg, Hispanic, African, Native American, South or East Asian, or Pacific Islands ancestry)
- BMI < of 25
- No history of abnormal glucose tolerance
- No previous history of adverse pregnancy outcomes usually associated with GDM
- No known diabetes in first degree relative
Revolutionary OGTT criteria

- Carpenter and Coustan
  - Fasting: 95
  - 1 hr: 180
  - 2 hr: 155

- ADA / IADPSG
  - Fasting: 92
  - 1 hr: 180
  - 2 hr: 153

- Two abnormal values
- One abnormal value
What is the ideal rate of GDM?

• 2 - 5%

• ACOG Practice Bulletin No. 30, 2010
What is the ideal rate of GDM?

• Are we the same population that Drs. O’ Sullivan and Mahan screened in 1964?

• Have there been any changes in our collective body composition in last 52 yrs?

• Diabetes. 1964 O'SULLIVAN JB, MAHAN CM
Trends by State 1985-2010

During the past 20 years, there has been a dramatic increase in obesity in the United States and rates remain high. In 2010, no state had a prevalence of obesity less than 20%. Thirty-six states had a prevalence of 25% or more; 12 of these states (Alabama, Arkansas, Kentucky, Louisiana, Michigan, Mississippi, Missouri, Oklahoma, South Carolina, Tennessee, Texas, and West Virginia) had a prevalence of 30% or more.

The animated map below shows the United States obesity prevalence from 1985 through 2010.

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**Download the Maps**

The prevalence of obesity is depicted in a PowerPoint slide presentation format. (31 slides total, PPT-3Mb)

This is also available as a text-only Acrobat file. (PDF-472K)
Trends by State 1985-2010

During the past 20 years, there has been a dramatic increase in obesity in the United States and rates remain high. In 2010, no state had a prevalence of obesity less than 20%. Thirty-six states had a prevalence of 25% or more; 12 of these states (Alabama, Arkansas, Kentucky, Louisiana, Michigan, Mississippi, Missouri, Oklahoma, South Carolina, Tennessee, Texas, and West Virginia) had a prevalence of 30% or more.

The animated map below shows the United States obesity prevalence from 1985 through 2010.
Ignoring the obesity epidemic

- Doesn’t make it go away
Landon 2009

- Mean birth weight
- Neonatal fat mass
- LGA
- > 4000 g
- Shoulder dystocia
- Cesarean delivery
- Preeclampsia / GHTN

N Engl J Med. 2009 Oct 1;361(14)
Crowther 2005

- Death
- Shoulder dystocia
- Bone fracture
- Nerve palsy
- Maternal depression
- Improved maternal quality of life

NIH Conference: Cost analysis

- Only charges for 2 steps
- Concerned about cost of nonstress tests
- Concerned about costs of MFM consults
- Shoulder dystocia = free
Reality based

- Mild GDM managed by CNMs, APNs, Primary Care providers
- Group visits
- Case managers
- Nutrition aides
- Shoulder dystocia = $ 750,000+
ADA (aka 1.25 step test)

• First prenatal labs
  Hgb A1c and RBS / FBS

Overt DM
Hbg A1c ≥ 6.5 %
FBS ≥ 126 mg/dL
RBS ≥ 200 mg/dL*

GDM
FBS ≥ 92 mg/dL

*needs confirmation
ADA (aka 1.25 step test)

- 24 – 28 wks only
  - 2 hr 75 gm OGTT
  - One abn value
Change in prevalence

- ADA GDM criteria: 17.8%
- ANMC: 9% -> 14%
- US Baseline:
  - DM: 11.3% (CDC)
  - Prediabetes: 35% (NIDDK)
  - Obesity: 35.7% (CDC)
The Emperor’s new clothes

Neil Murphy MD
Southcentral Foundation
Alaska Native Medical Center
Reality

- ACOG / NIH Dx system is deeply flawed
- ACOG system ignores obesity epidemic
- ACOG system ignores Tx one ABN value
- Cost analysis deeply flawed
- ACOG / NIH emphasis on short term
OR = 3.0 = Nirvana

- ADA OR = 1.75

....but ACOG/NIH system is no better than a hand waving argument
- ....any of 3 GST cutoffs
- ....GST in any trimester inappropriately
- ....highest risk = lost to FU
- ....2 sets of Dx criteria
- ....treats 1 ABN value, or if GST high
Reality

- ADA system is simple, data driven
- ADA prevalence c/w obesity epidemic
- ADA system admits Tx one ABN value
- Shoulder dystocia = not free
- ADA system c/w long term
Short term vs Long term

• If you believe that the obesity epidemic has occurred....

• Long term behavioral changes
• Family based changes
• Early intervention
Suggestions

• If you have started ADA system – keep with it....and monitor your results

• Innovative system-based approaches

• Improve post partum follow-up
Local Public Health Perspective

Diana Curran, MD
Medical Director
Henderson County Health Department
North Carolina
Local Public Health Perspective

- High-Incidence of GDM—9.4% in our clinic population (2008)
  - Ethnic risks—about 50% Hispanic
  - Obesity risks—about 30% of pregnant women
- MFM Consultant Recommendation
  - Urged all prenatal providers in our region to adopt ADA guidelines as standard of care for GDM testing
- Impact on Child Obesity
  - GDM is associated with child obesity
  - Good control reduces risk
    - OR 1.8-1.9 of obesity by age 5-7 years with untreated GDM
    - OR 1.3-1.38 if GDM well controlled.
One-Step Test is Patient-Centered

1-Step test more convenient
- One-step test done in office lab
  - Rapid turn-around-time
  - Diagnosed during the visit
- Combine with the 28-week visit
  - Long visit already due to 3rd trimester education and depression/violence/drug abuse Screening
  - All blood work done in one visit (HIV, Syphilis, CBC)

2-Step test less convenient
- F/u testing delays diagnosis and intervention
  - Difficult to schedule time for 3-hr test for lab and patients
  - Patients refuse to drink Glucola again
  - Patients no-show for 3-hr test appointments
GDM
WHY AR CHOSE ADA GUIDELINES

David Grimes MD, MPH
FACOG, FACPM
MCH Director
Arkansas Department of Health
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- Charity Lowdermilk, BSN, RN, CDE
  DSME Nurse Consultant
Why the interest now?

- The Diabetes Primary Prevention Trial (1990s) provided evidence that type 2 diabetes can be delayed by lifestyle changes.

- The Hyperglycemia and Adverse Pregnancy Outcomes Study (HAPO) (2000s) evidence to change the diagnostic criteria for GDM.


HAPO STUDY

- Pregnancy is the best “diabetes stress test” we have
- Maternal hyperglycemia and adverse fetal and neonatal outcomes are a direct linear correlation not a threshold amenable to “cut offs”
Identifying “mild” GDM allows treatment during pregnancy to decrease fetal and neonatal adverse outcomes.

Most importantly it allows identification of the most significant subgroup of IGT and provides the best chance for education and treatment to prevent progression to Type II DM for mother and family.
Diabetes Prevention Program (DPP)

- 4 year study to see if Impaired Glucose Tolerance (IGT) patients could be prevented or delayed from developing DM
  - Lifestyle
  - Metformin
DPP

YES

- **Lifestyle**------------------ 58% reduction
  - Diet—low fat; low calories
  - Exercise---150 min/wk
  - Goal—lose and maintain 7% wt. loss

- **Metformin**------------------ 30% reduction
10 Year F/U

- Lifestyle still had a 43% reduction in progression to DM
- One very disturbing point
  - 8% of IGT patients developed eye disease without developing “Type II DM”
GDM Screening and Diagnosis

One of the reasons for the lack of screening integrated into practice is that we lack consensus on screening guidelines

- 5 national and global sources provide screening guidelines
- Timing as to when to screen varies
- Diagnostic values differ
- Glucose load differ
GDM Screening and Diagnosis

- International Diabetes Federation Recommendations - Gestational Diabetes (2009)
- American College of Obstetrics and Gynecology Guidelines (2011)
- American Diabetes Association Recommendations and Guidelines (2011)
- Summary of Recommendations The U.S. Preventive Services Task Force (2010-2011)
KISS

- HAPO and DPP have a better fit with ADA
- Less than 50% of women with GDM obtain a postpartum glucose test
- Linkages between obstetric care and primary care are often missing
More complex and varied screening requirements result in “missed opportunities” compared to universal screening.

We have universal screening for syphilis and HIV during pregnancy that have a much lower population prevalence than diabetes.
CDC on Screening

- “Don’t screen for something you can not do anything about”
- Screening for and treating GDM lowers the risk of macrosomia, CD, and neonatal hypoglycemia
- Most importantly it allows a 50% reduction in progression to Type II DM with DSME
Why Gestational Diabetes?

- Diabetes has a unique and profound effect on women and their health, especially during pregnancy.
- Gestational diabetes is a public health concern because of adverse outcomes that may occur for the baby and the mother:
  - Including increased infant birth weight, birth trauma, and increased risk for preeclampsia.
- **GDM puts both mom and baby at life-long risk for developing diabetes**
Problem and Background

- Women with gestational diabetes mellitus (GDM) have a 70-100% risk of developing Type II diabetes within 10-20 years after delivery.

- The ADH APN Protocol includes referral to a lifestyle support program following GDM, but no diabetes prevention program exists through ADH and DSME is unavailable in most of the rural parts of the state.

- Thus, many patients lack a resource for a lifestyle education component to reduce diabetes risk.
Gestational Diabetes Mellitus (GDM)

- Defined by glucose intolerance with onset during pregnancy
- Presents a significant challenge to the health of the mother and her infant

American Diabetes Association Standards of Medical Care in Diabetes—2011, Diabetes Care, volume 34, Supplement 1, January 2011
When Should You Screen for DM?

- To **prevent** birth defects, reproductive age women need to be screened and treated for Type II DM **before** they get pregnant
  - 1/3 Type II diabetics are currently undiagnosed
  - FBS and/or A1C at well women or urgent visit
- Screening “high risk” pregnant women at their 1\textsuperscript{st} prenatal visit allows you to diagnosis previously undiagnosed Type II DM and begin early treatment
Figure 2—Cumulative incidence of type 2 diabetes by ethnicity and length of follow-up, adjusted for retention. Studies using local criteria or WHO criteria for GDM diagnosis are not illustrated.
Why the interest now?

- Recent studies suggest that the offspring of women experiencing GDM are also at greater risk for developing type 2 diabetes.
- 7.76 times the risk of developing diabetes later in life especially if that offspring is overweight or obese.

Top Strategy

- Keep women with GDM from developing Type II DM
- Make women aware that GDM means they have almost a 100% chance of developing Type II DM unless they take action now
  - Diet Changes
  - Exercise
  - DSME
  - Yearly F/U
Gestational diabetes screening for women 24 to 28 weeks pregnant and at initial visit for those at high risk of developing gestational diabetes* Follow-up screen post partum- if within normal range-yearly screens. If IGT follow up in 3 months. DSME while they are still pregnant. Monitor quarterly if not meeting goals, annually if meeting glycemic goals.
Questions?