

# The One Step test: The better diagnostic approach for gestational diabetes mellitus

It is time for the United States to reconsider its guidelines for screening for GDM

### Vincenzo Berghella, MD

Professor and Director  
Division of Maternal-Fetal Medicine and Fellowship Program  
Department of Obstetrics and Gynecology  
Sidney Kimmel Medical College of Thomas Jefferson University  
Philadelphia, Pennsylvania

### Gabriele Saccone, MD

Resident  
Department of Neuroscience  
Reproductive Sciences and Dentistry School of Medicine  
University of Naples Federico II  
Naples, Italy

**G**estational diabetes mellitus (GDM) generally is defined as any degree of glucose intolerance with onset or first recognition during pregnancy.<sup>1-14</sup> The best approach and exact criteria to use for GDM screening and diagnosis are under worldwide debate. In **TABLE 1** we present just some of the many differing suggestions by varying organizations.<sup>2,7-9,11,12,15-17</sup> The American College of Obstetricians and Gynecologists, for instance, suggests a Two Step approach to diagnosis.<sup>15</sup> We will make the argument in this article, however, that diagnosis should be defined universally as an abnormal result with the One Step 75-g glucose testing, as adopted by the World Health Organization, International Federation of Gynecology and Obstetrics, and others. Approximately 8% of all pregnancies are complicated by GDM by the One Step test in the United States.<sup>18-22</sup> The prevalence may range from 1% to 14% of all pregnancies, depending on the population studied and the diagnostic tests employed.<sup>1,19</sup>

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### Diagnostic options

Different methods for screening and diagnosis of GDM have been proposed by international societies; there is controversy regarding the diagnosis of GDM by either the One Step or the Two Step approach.<sup>6</sup>

**The One Step approach** includes an oral glucose tolerance test with a 75-g glucose load with measurement of plasma glucose concentration at fasting state and 1 hour and 2 hours post-glucose administration. A positive result for the One Step approach is defined as at least 1 measurement higher than 92, 180, or 153 mg/dL at fasting, 1 hour, or 2 hours, respectively.

**The Two Step approach** includes a nonfasting oral 50-g glucose load, with a glucose blood measurement 1 hour later. A positive screening, defined often as a blood glucose value higher than 135 mg/dL (range, 130 to 140 mg/dL), is followed by a diagnostic test with a 100-g glucose load with measurements at fasting and 1, 2, and 3 hours post-glucose administration. A positive diagnostic test is defined as 2 measurements higher than the target value.

### Why we support the One Step test

There are several reasons to prefer the One Step approach for the diagnosis of GDM, compared with the Two Step approach.

#### **Women testing negative for GDM with Two Step still experience complications pregnancy.**

Women who test positive for GDM with the One Step test, but negative with the Two Step test, despite having therefore a milder degree of glucose intolerance, do have a higher risk of experiencing several complications.<sup>23</sup> For the mother, these complications include gestational hypertension, preeclampsia, and cesarean delivery. The baby also can experience problems at birth (**TABLE 2**).<sup>23</sup> Therefore, women who test positive for GDM with the One Step test deserve to be diagnosed with and treated for the condition, as not only are they at risk for these complications but also treatment of the GDM decreases the incidence of these complications.<sup>18,19</sup>

**There is indeed an increased GDM diagnosis rate with the One Step (about 8%) compared with**

**TABLE 1** Criteria for gestational diabetes mellitus screening by selected societies<sup>2,7-9,11,12,15-17</sup>

Society	Test	No. of abnormal values required for diagnosis	Fasting glucose (mg/dL)	1 hour after loading (mg/dL)	2 hours after loading (mg/dL)	3 hours after loading (mg/dL)
ACOG 2017 <sup>15</sup> ; C&C <sup>16</sup>	Two Step 3-hr 100 g	≥2	95	180	155	140
ACOG 2017 <sup>15</sup> ; NDDG <sup>17</sup>	Two Step 3-hr 100 g	≥2	105	190	165	145
ADA 2017 <sup>7</sup> 75 g	One Step 2-hr 75 g	≥2	95	180	155	Not required
ADA 2017 <sup>7</sup> 100 g	Two Step 3-hr 100 g	≥2	95	180	155	140
CDA 2013 <sup>8</sup>	Two Step 2-hr 75 g	≥2	95	191	160	Not required
FIGO 2013 <sup>12</sup>	One Step 2-hr 75 g	≥1	92	180	153	Not required
IADPSG 2015 <sup>2,12</sup>	One Step 2-hr 75 g	≥1	92	180	153	Not required
NICE/RCOG 2015 <sup>9</sup>	One Step 2-hr 75 g	≥1	101	Not required	140	Not required
WHO 2013 <sup>11</sup>	One Step 2-hr 75 g	≥1	92	180	153	Not required

Abbreviations: ACOG, American College of Obstetricians and Gynecologists; ADA, American Diabetes Association; CDA, Canadian Diabetes Association; C&C, Carpenter and Coustan; FIGO, International Federation of Gynecology and Obstetrics; IADPSG, International Association of Diabetes Pregnancy Study Group; NICE, National Institute for Health and Care Excellence; RCOG, Royal College of Obstetricians and Gynecologists; NDDG, National Diabetes Data Group; WHO, World Health Organization.

**the Two Step test (about 4%).** Nonetheless, this increase is mild and nonsignificant in the meta-analysis of randomized controlled trials (RCTs),<sup>18,19</sup> is less than the 18% difference in diagnosis rate previously hypothesized, is consistent with the increased diabetes/prediabetes rates in the general population, and is linked to the increasing incidence of obesity and insulin resistance.

**Overall test adherence is better.** Five percent to 15% of patients, depending on the study, are not adherent with taking the second part of the Two Step test. Women indeed prefer the One Step approach; the second step in the Two Step approach may be a burden.

**Less costly.** The One Step process is cost-effective when postpregnancy diabetes mellitus prevention is considered.

**Better maternal and perinatal outcomes.** Probably the most

important and convincing reason the One Step test should be used is that meta-analysis of the 4 RCTs comparing the approaches (including 2 US trials) shows that diagnosing and treating mild GDM as per the One Step approach, compared with screening and treating using the Two Step approach, is associated with increased incidence of GDM (8% vs 4%) and with better maternal and perinatal outcomes.<sup>13,18,19</sup> In fact,

the One Step approach is associated with significant reductions in: large for gestational age (56%), admission to neonatal intensive care unit (51%), and neonatal hypoglycemia (48%). Tests of heterogeneity in the meta-analysis and of quality all pointed to better outcomes in the One Step test group.<sup>13,19</sup>

**The need for a second step in the Two Step approach delays diagnosis and treatment.** The One

**TABLE 2** Complication risks in pregnancies that are positive for GDM at the One Step test but negative at the Two Step test compared with pregnancies that are negative at the One Step test<sup>23</sup>

Maternal	Neonatal
Gestational hypertension	Preterm birth
Preeclampsia	Macrosomia/LGA
Cesarean delivery	Hypoglycemia
	Intensive care unit admission

Abbreviations: GDM, gestational diabetes mellitus; LGA, large for gestational age.

**TABLE 3** Benefits of the One Step approach, compared with the Two Step approach

- The increased GDM rate (8% with One Step vs 4% with Two Step) is consistent with the increased diabetes/prediabetes rates in the general population
- Better adherence, as patients may not be adherent with the second part of the Two Step test
- Milder GDM (positive One Step test, but negative Two Step) is associated with several maternal and perinatal adverse outcomes, compared with euglycemic women (see TABLE 2)<sup>23</sup>
- The One Step process is cost-effective when postpregnancy DM prevention is considered
- Meta-analysis of RCTs<sup>19</sup> shows that diagnosing and treating mild GDM as per the One Step approach, compared with screening and treating using the Two Step approach, is associated with several benefits, including less:
  - Preeclampsia<sup>a</sup>
  - Large for gestational age
  - Neonatal hypoglycemia
  - NICU admission
  - Neonatal death<sup>a</sup>
- The need for a second step in the Two Step approach delays diagnosis and treatment of GDM
- The One Step, 75-g, 2-hour OGTT is universally used outside of pregnancy

Abbreviations: GDM, gestational diabetes mellitus; DM, diabetes mellitus; NICU, neonatal intensive care unit; OGTT, oral glucose tolerance test; RCT, randomized controlled trial.

<sup>a</sup>Statistical trends.

Step approach is associated with an increase in GDM test adherence and earlier diagnosis,<sup>13</sup> which is another reason for better outcomes with the One Step approach. In the presence of risk factors, such as prior GDM, prior macrosomia, advanced maternal age, multiple gestations, and others, the One Step test should be done at the first prenatal visit.

### US guidelines should be reconsidered

The One Step, 75-g, 2-hour oral glucose tolerance test is universally used to diagnose diabetes mellitus outside of pregnancy. Given our many noted reasons (TABLE 3), we recommend universal screening of GDM by using the One Step approach. It is time, indeed, for the United States to reconsider its guidelines for screening for GDM. ●

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