

One-Step Approach to Identifying Gestational Diabetes Mellitus

Association With Perinatal Outcomes

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OBJECTIVE: To compare perinatal outcomes before and after a clinical guideline change from a two-step to a one-step approach to screening for gestational diabetes mellitus (GDM).

METHODS: We conducted a before–after cohort study of women with singleton live birth deliveries within Kaiser Permanente Washington, a mixed-model health plan in Washington state. We used Kaiser Permanente Washington electronic health data and linked birth certificates. We compared outcomes before (January 2009–March 2011) and after (April 2012–December 2014) the guideline change among women who received prenatal care from health care providers internal to Kaiser Permanente Washington (n=4,977 before, n=6,337 after).

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We made the same comparison among women who received prenatal care from external health care providers (not exposed to the guideline change; n=3,386 before, n=4,454 after) to control for time trends unrelated to the guideline change. Adjusted relative risks and 95% CIs were estimated using Poisson generalized estimating equations.

RESULTS: After the guideline change, receipt of the one-step approach became widespread among women cared for by Kaiser Permanente Washington internal providers (87%), and use of insulin increased 3.7-fold from 1.2% to 4.4%. Among women cared for by Kaiser Permanente Washington internal providers, GDM increased from 6.9% to 11.4%, induction of labor from 25.2% to 28.6%, neonatal hypoglycemia from 1.3% to 2.0%, and outpatient nonstress testing from 134.6 to 157.0 test days per 100 women. After accounting for background trends in outcomes (based on the women cared for by external providers), the guideline change was associated with increased incidence of GDM (relative risk [RR] 1.41, 95% CI 1.17–1.69), labor induction (RR 1.20, 95% CI 1.09–1.32), neonatal hypoglycemia (RR 1.77, 95% CI 1.14–2.75), and nonstress testing (RR 1.12, 95% CI 1.02–1.24% per 100 women). There was no association with other outcomes including cesarean delivery or macrosomia.

CONCLUSION: Adopting the one-step approach was associated with a 41% increase in the diagnosis of GDM without improved maternal or neonatal outcomes.

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Routine screening for gestational diabetes mellitus (GDM) is recommended in pregnancy^{1,2} because treatment reduces risks of adverse outcomes,^{3–5} but the best screening approach remains unclear. Traditionally, a two-step approach has been used: a 50-g screening glucose challenge test followed by a 100-g 3-hour oral glucose tolerance test (OGTT) in women



who screen positive.² In 2010, the International Association of the Diabetes in Pregnancy Study Groups recommended a one-step approach: a 75-g 2-hour OGTT for all women.⁶ This approach, which has a lower threshold for diagnosis, has not been widely adopted. No randomized trial has been published comparing outcomes of the two approaches. Results from observational studies comparing perinatal outcomes in one-step and two-step eras have been mixed^{7–11} with one study showing decreases in cesarean delivery and neonatal intensive care unit (NICU) admission⁷ and another increases in both.¹¹ These studies did not account for time trends in outcomes unrelated to changes in GDM testing.

Therefore, we conducted a before–after cohort study within Kaiser Permanente Washington, a health plan in which two thirds of members receive care internally from our own health care providers, and one third receive care from contracted (“external”) providers. In 2011, a new clinical guideline was issued for internal providers recommending the one-step approach. This guideline was not issued to external providers. We compared perinatal outcomes before and after the change among women receiving prenatal care from health care providers internal to Kaiser Permanente Washington. Women receiving prenatal care from external providers served as a concurrent control group allowing us to account for background trends in outcomes.

MATERIALS AND METHODS

We conducted a before–after cohort study of Kaiser Permanente Washington deliveries before and after a GDM clinical guideline change in 2011. All research activities were approved by the Kaiser Permanente Washington institutional review board.

The setting was Kaiser Permanente Washington, a mixed-model health care delivery system in Washington state with approximately 680,000 members. Data sources were Kaiser Permanente Washington electronic health data and Washington state birth certificates. Our electronic health data included enrollment information; and from insurance claims, diagnosis and procedure codes from health care encounters; and outpatient pharmacy dispensings. These data have been used extensively in perinatal health research, and validation studies have been conducted.^{12–14} Individual variables used in our study are described in Appendix 1, available online at <http://links.lww.com/AOG/B125>. Gestational age was ascertained from the clinical estimate from the birth certificate; because this estimate includes only

weeks of gestation, we assumed each delivery occurred midweek (4/7 days).

The study cohort comprised women enrolled at Kaiser Permanente Washington who delivered a live-born neonate from January 1, 2009, through December 31, 2014, and for whom linked neonatal records were available.¹⁵ We excluded deliveries for the following reasons: no linked birth certificate, maternal age younger than 15 years, multiple gestation, missing neonatal birth weight or gestational age, and pregestational diabetes. Women diagnosed with type 1 or 2 diabetes after the start of pregnancy were not excluded because they may have been identified as a consequence of the new guideline and thus excluding them could have led to bias. To ensure adequate data availability, we required women be enrolled from 12 weeks of gestation through 28 days after delivery.

Approximately two thirds of our members receive care within our health care system from Kaiser Permanente Washington health care providers who are part of our multispecialty group practice (“internal providers”), and approximately one third receive care externally from a contracted network of health care providers (“external providers”). For the most part, members receive prenatal care from external providers if they live in a geographic region without obstetric care providers employed by Kaiser Permanente Washington. We designated women as receiving prenatal care from internal providers if, during their pregnancy, the majority of their family practice or obstetrics and gynecology outpatient health care encounters was with a health care provider employed by Kaiser Permanente Washington. Otherwise, they were designated as receiving their prenatal care from external providers.

In March 2011, a new GDM clinical practice guideline was issued for internal providers, which directed them to switch from a two-step approach to identifying GDM (a screening test [50-g glucose challenge or fasting serum glucose test] followed by a 100-g 3-hour OGTT in women who screen positive) to the International Association of the Diabetes and Pregnancy Study Groups’ one-step approach (a 75-g 2-hour OGTT for all women plus routine screening of all women with the hemoglobin A_{1C} test at the first prenatal visit).⁶ The International Association of the Diabetes and Pregnancy Study Groups approach has a lower threshold for diagnosis than the two-step approach. Appendix 2, available online at <http://links.lww.com/AOG/B125>, provides details about the two approaches and additional changes made as part of the new guideline. These included lower blood



glucose thresholds for recommending medication and a strong emphasis on insulin as first-line medication. To facilitate uptake of the new guideline by internal providers, changes were made to the electronic medical record interface (eg, changing default options for glucose tolerance tests in the Epic SmartSet for pregnancy care). The new guideline applied only to internal providers; there was no mechanism in place to change care provided by external providers.

Maternal and neonatal outcomes before (January 2009–March 2011) and after (April 2012–December 2014) the guideline change were compared among women cared for by internal and external providers with the latter serving as a concurrent control group that was unexposed to the guideline change.^{16,17} A concurrent control group allowed us to control for changes in outcomes over the study period, which were unrelated to the change in GDM testing.^{16,17}

Risk estimates for women delivering during the 1-year transition period after the guideline change (April 2011–March 2012) were not computed because 1) some women delivering in this period would have received GDM testing when the old approach was in place and 2) we wanted to allow time for uptake of the new recommendations. We sought to evaluate the association between the guideline change and two types of outcomes: 1) diabetes-related processes of care and 2) maternal and neonatal outcomes (see Appendix 1 [<http://links.lww.com/AOG/B125>] for definitions). The processes of care outcomes allowed us to evaluate uptake of the new guideline. They included: receipt of the hemoglobin A_{1C} test before 16 weeks of gestation, receipt of one-step GDM testing, and use of diabetes medications during pregnancy.

Primary maternal and neonatal outcomes included a diagnosis of GDM, induction of labor, primary cesarean delivery, macrosomia (4,500 g or greater), large for gestational age (LGA), small for gestational age, admission to the NICU, and neonatal hypoglycemia. Neonates' birth weight for gestational age was calculated using Washington state sex-specific birth weight data to determine those in the greater than the 90th percentile (LGA) and less than the 10th percentile (small for gestational age).¹⁸ Secondary outcomes are listed in Appendix 1 (<http://links.lww.com/AOG/B125>). They included rare outcomes, different definitions of primary outcomes, and outcomes, which, although important, we did not hypothesize would be affected by the guideline change. These included cesarean delivery overall (combining primary and repeat cesarean),

vaginal delivery among women with a prior cesarean delivery, receipt of nonstress testing, preterm birth, shoulder dystocia, operative vaginal delivery (forceps or vacuum), preeclampsia, birth injury, and infant mortality (death within 365 days of birth).

We computed descriptive statistics comparing characteristics of women delivering before and after the guideline change according to prenatal care setting (ie, care from internal vs external providers). We applied the difference-in-differences approach to account for trends in the incidence of outcomes over the study period that were not related to the guideline change by including concurrent controls, that is, women not exposed to the new guideline.^{16,17} Specifically, we used a modified Poisson regression model for a binary outcome¹⁹ to evaluate the effect of the guideline change on the incidence of each outcome. To estimate separate incidences and relative risks (RRs) for each time period and prenatal care setting, we included main effects of time period (before, during, and after the guideline change) and prenatal care setting as well as their interaction terms in all models. We also adjusted for neonatal sex and the following maternal factors (categorized as shown in Table 1): maternal age, race–ethnicity, education, marital status, Medicaid insurance, smoking, prepregnancy body mass index (BMI, calculated as weight (kg)/[height (m)]²), chronic hypertension, and nulliparity. We used generalized estimating equations with an independent working correlation matrix and robust standard errors estimated through the sandwich estimator to account for correlation among births to the same woman over the study period.²⁰

For each of the time periods in each prenatal care setting, we computed the adjusted outcome incidences and 95% CIs using model coefficients and marginally standardized to a common distribution of neonatal sex and maternal characteristics among all eligible deliveries. We then estimated within each setting the adjusted RRs and 95% CIs comparing the incidence of each outcome after compared with before the guideline change (ie, deliveries before the change were the referent group). To remove the effect of background trends in outcomes, we computed the ratio of the RR for women receiving care from internal providers (RR_{Internal}) to the RR for women receiving care from external providers (RR_{External}), that is, RR_{Internal}/RR_{External}. This ratio, or “difference-in-differences RR,” is interpreted as the association between the guideline change and risk of the outcome beyond the effect of underlying trends in the outcome that were unrelated to the guideline change.^{17,21}



Table 1. Characteristics of Study Participants Before and After Kaiser Permanente Washington's Gestational Diabetes Guideline Change According to Prenatal Care Setting†**

Characteristic	Care Received From Internal Provider		Care Received From External Provider	
	Before (n=4,977)	After (n=6,337)	Before (n=3,386)	After (n=4,454)
Maternal age at delivery (y)				
Younger than 24	812 (16)	744 (12)	525 (16)	760 (17)
25–29	1,323 (27)	1,597 (25)	1,116 (33)	1,325 (30)
30–34	1,704 (34)	2,466 (39)	1,128 (33)	1,527 (34)
35 or older	1,138 (23)	1,530 (24)	617 (18)	842 (19)
Maternal race–ethnicity				
Hispanic	344 (7)	419 (7)	347 (10)	486 (11)
Non-Hispanic white	3,410 (69)	4,404 (70)	2,706 (80)	3,524 (79)
Non-Hispanic black or African American	384 (8)	433 (7)	60 (2)	88 (2)
Non-Hispanic Asian	751 (15)	971 (15)	226 (7)	259 (6)
Non-Hispanic other or unknown race	88 (0)	110 (1)	47 (2)	97 (2)
Education greater than 12 y	3,950 (80)	5,353 (85)	2,704 (80)	3,548 (80)
Married	3,933 (79)	5,155 (81)	2,863 (85)	3,617 (81)
Medicaid insurance	236 (5)	99 (2)	78 (2)	11 (0)
Smoked during pregnancy	239 (5)	217 (3)	143 (4)	180 (4)
Prepregnancy BMI (kg/m ²)				
Less than 25	2,506 (52)	3,189 (53)	1,636 (51)	2,060 (49)
25 to less than 30	1,227 (26)	1,554 (26)	832 (26)	1,095 (26)
30 or greater	1,069 (22)	1,323 (22)	711 (22)	1,028 (25)
Chronic hypertension	115 (2)	187 (3)	94 (3)	168 (4)
Parity				
Nulliparous	2,406 (49)	3,182 (50)	1,374 (41)	1,882 (42)
Parous	2,541 (51)	3,144 (50)	1,998 (59)	2,556 (58)
Gestational age at delivery (wk)				
Less than 39	1,250 (25)	1,533 (24)	972 (29)	1,269 (28)
39 or greater	3,727 (75)	4,804 (76)	2,414 (71)	3,185 (72)
Mean (SD)	39.0±1.9	39.1±1.7	38.9±1.7	38.8±1.8
Female sex	2,469 (50)	3,046 (48)	1,668 (49)	2,129 (48)

BMI, body mass index.

Data are n (%).

Column percentages may not add to exactly 100% as a result of rounding.

* Before the guideline change, January 2009–March 2011; after the change, April 2012–December 2014.

† Less than 5% of data was missing for all variables except for prepregnancy BMI, which was missing for 4–6% of deliveries depending on time period and prenatal care setting. Missing values were not included in the denominators of the percentages.

For two outcomes, receipt of nonstress testing and third-trimester ultrasonography, we estimated the average number of days in which each test was received per 100 women in each care setting and time period using the same statistical methods described previously. We conducted complete case analyses. All statistical tests were two-sided and a *P* value <.05 was considered statistically significant. Analyses were conducted using SAS 9.4.

RESULTS

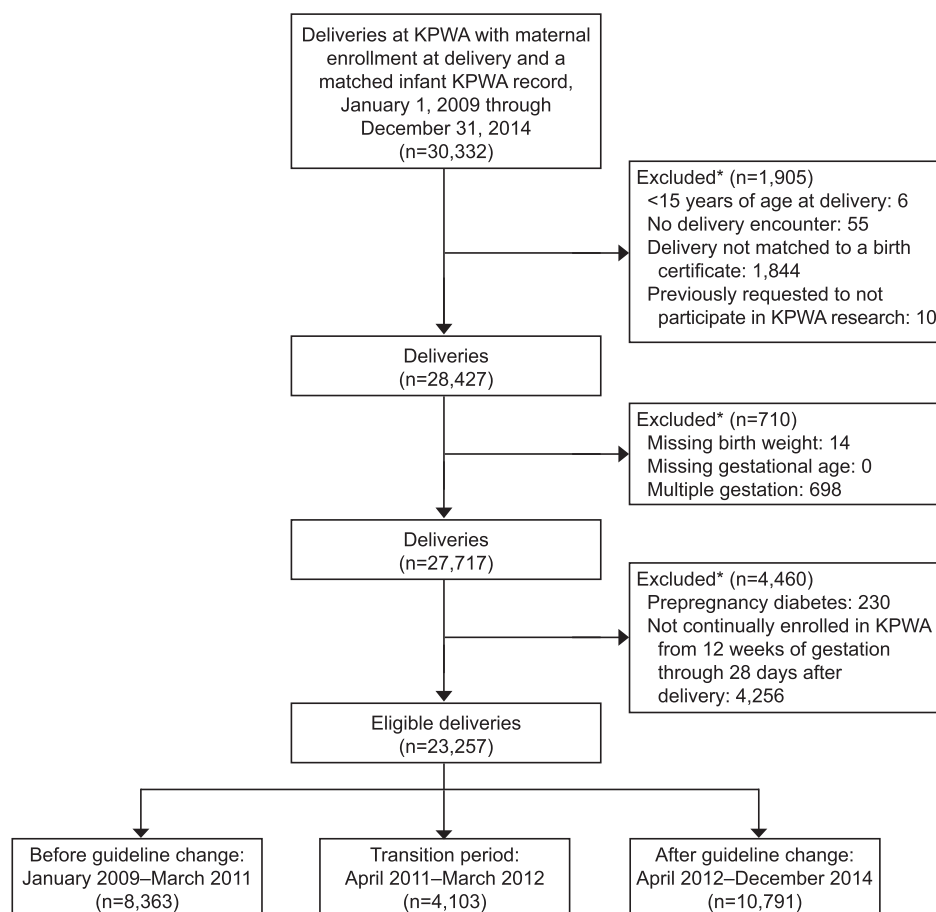
Our study population included 23,257 women and their neonates between January 1, 2009, and December 31, 2014. A total of 8,363 women delivered before the GDM guideline change (January 2009–March 2011) and 10,791 afterward (April 2012–December 2014), allowing for a 1-year transition period (April

2011–March 2012; n=4,103) (Fig. 1). Approximately 60% of women received prenatal care from health care providers internal to Kaiser Permanente Washington and 40% from external providers. Women receiving care from internal providers were slightly older, more educated, less likely to be white, Hispanic, or married, less likely to have a gestational age at delivery less than 39 weeks, and more likely to be nulliparous and have lower prepregnancy BMI than women receiving care from external providers (Table 1).

Among women cared for by internal providers, receipt of the one-step approach to identify GDM increased from 0.3% before the guideline change to 86.8% afterward; among women cared for by external providers, only 5.0% of women received the one-step



Fig. 1. Identification of the final study cohort. *Exclusion criteria are not mutually exclusive. KPWA, Kaiser Permanente Washington. Pocobelli. *Perinatal Outcomes and One-Step Testing for GDM. Obstet Gynecol* 2018.



approach after the change (Table 2). Similarly, among women cared for by internal providers, receipt of the hemoglobin A_{1C} test before 16 weeks of gestation increased from 5.5% before the guideline change to 89.4% afterward, and among women cared for by external providers, only 12.2% of women underwent hemoglobin A_{1C} testing after the change (Table 2).

Use of diabetes medication increased twofold among women cared for by internal providers after the guideline change, from 2.7% to 5.5% ($P<.001$), whereas, among women cared for by external providers, use increased more modestly (Table 2). The increase in use of diabetes medication among women cared for by internal providers was driven by a 3.7-fold increase in use of insulin ($P<.001$), whereas use of metformin was relatively stable and use of sulfonylureas (eg, glyburide) decreased approximately 50% (Table 2). Among pregnant women cared for by external providers, there was little change in use of the specific diabetes medications (Table 2).

The incidence of GDM among pregnant women cared for by internal providers increased from 6.9% before the guideline change to 11.4% afterward, an increase of 65% (adjusted RR 1.65, 95% CI 1.46–1.86;

Table 3). Among pregnant women cared for by external providers, GDM increased more modestly, from 9.6% to 11.3% after the guideline change (Table 3). Comparing the change among pregnant women cared for by internal providers with that occurring among pregnant women cared for by external providers yielded a difference-in-differences RR of 1.41 (95% CI 1.17–1.69), meaning the incidence of GDM went up 41% among pregnant women cared for by internal providers after accounting for background trends in GDM incidence (Table 3). Gestational diabetes mellitus was diagnosed on average approximately 1 week earlier in pregnant women cared for by internal providers after the guideline change (29 5/7 weeks before vs 28 4/7 weeks afterward [$P<.001$]), whereas, among pregnant women cared for by external providers, it remained stable at 29 6/7 weeks.

The incidence of labor induction increased among pregnant women cared for by internal providers, from 25.2% before the guideline change to 28.6% afterward, an increase of 13% (RR 1.13, 95% CI 1.06–1.21); among pregnant women cared for by external providers, it decreased from 31.1% to 29.4% (Table 3). The corresponding difference-in-differences



Table 2. Process of Care Outcomes Before and After Kaiser Permanente Washington's Gestational Diabetes Guideline Change According to Prenatal Care Setting*†

Process of Care Outcomes	Care Received From Internal Provider		Care Received From External Provider		<i>P</i> Comparing Change for Care From Internal vs External Providers
	Before (n=4,977)	After (n=6,337)	Before (n=3,386)	After (n=4,454)	
Receipt of hemoglobin A _{1c} testing before 16 wk	278 (5.5)	5,703 (89.4)	71 (1.9)	549 (12.2)	<.001
Receipt of the 2-step approach to GDM testing‡	4,635 (93.6)	369 (5.7)	2,868 (84.5)	3,626 (81.3)	<.001
Receipt of the 1-step approach to GDM testing‡	4 (0.1)	5,536 (86.5)	5 (0.1)	179 (4.2)	<.001
Use of any diabetes medication during pregnancy§	134 (2.7)	357 (5.5)	124 (3.9)	214 (4.7)	<.001
Use of insulin during pregnancy§	61 (1.2)	283 (4.4)	39 (1.3)	65 (1.4)	<.001
Use of metformin during pregnancy§	29 (0.6)	70 (1.0)	44 (1.5)	90 (1.9)	.353
Use of sulfonylureas during pregnancy§	66 (1.3)	46 (0.7)	62 (1.9)	110 (2.5)	<.001

GDM, gestational diabetes mellitus.

Data are n (%).

Bold indicates that the change in the adjusted incidence in the group receiving care internally vs externally was statistically significantly different ($P<.05$).

* Before the guideline change, January 2009–March 2011; after the change, April 2012–December 2014.

† Percentages and comparisons adjusted for maternal age, race–ethnicity, education, marital status, parity, prepregnancy body mass index, chronic hypertension, smoking during pregnancy, and Medicaid insurance; and neonatal sex. Unadjusted percentages and *P* values are very similar to adjusted ones across all outcomes.

‡ For 78 deliveries, the GDM testing method was neither the two-step or one-step approach and thus they did not contribute to the numerator of either testing strategy.

§ Use from 12 weeks of gestation through day before delivery among all women.

RR for labor induction was 1.20 (95% CI 1.09–1.32) (Table 3). Neonatal hypoglycemia also increased among the offspring of women cared for by internal providers from 1.3% before the guideline change to 2.0% afterward, an increase of 55% (RR 1.55, 95% CI 1.14–2.10) (Table 3). In comparison, among the offspring of women cared for by external providers, there was a slight decrease in neonatal hypoglycemia from 2.4% to 2.1%. The difference-in-differences RR for neonatal hypoglycemia was 1.77 (95% CI 1.14–2.75).

The guideline change was not associated with risk of primary cesarean delivery, which decreased slightly after the guideline change among both pregnant women cared for by internal (18.5–17.0%) and external providers (22.9–21.3%), but to a similar degree (difference-in-differences RR 0.99, 95% CI 0.87–1.12). The guideline change was also not associated with LGA. Incidence of LGA decreased slightly after the guideline change among the offspring of women cared for by internal (10.4–9.5%) and external providers (9.6–8.7%), again, to a similar degree (difference-in-differences RR 1.01, 95% CI 0.85–1.21) nor was the guideline change associated with small for gestational age or NICU admission (Table 3).

Results for secondary outcomes are provided in Appendix 3, available online at <http://links.lww.com/AOG/B125>. The only significant change was a 12% increase in receipt of outpatient nonstress testing after the guideline change (difference-in-differences RR 1.12, 95% CI 1.02–1.24). Among women cared for by internal providers it increased from 134.6 to 157.0 test days per 100 women. The guideline change was not associated with the other secondary outcomes.

We conducted a subgroup analysis of our primary outcomes, receipt of nonstress testing, and use of diabetes medication among deliveries to obese women (BMI greater than 30) (n=5,077), a group at relatively high risk of GDM. With the exception of neonatal hypoglycemia, which was no longer associated with the guideline change (difference in differences RR 1.04), our point estimates were similar to those in our main analysis.

DISCUSSION

After the GDM guideline change, Kaiser Permanente Washington internal providers nearly completely switched from the two-step to the one-step approach to GDM testing. This was associated with substantial increases in GDM diagnoses and use of diabetes



Table 3. Associations Between Perinatal Outcomes and Kaiser Permanente Washington's Gestational Diabetes Guideline Change According to Prenatal Care Setting

Perinatal Outcome	Before* [Incidence, % (95% CI)] [†]	After* [Incidence, % (95% CI)] [†]	Unadjusted RR vs Before (95% CI) [‡]	Adjusted RR After vs Before (95% CI) ^{††}	Difference-in- Difference [RR (RR _{Internal} / RR _{External}) (95% CI)] ^{†§}
Gestational diabetes					
Care from internal providers	6.9 (6.3–7.7)	11.4 (10.7–12.3)	1.67 (1.49–1.89)	1.65 (1.46–1.86)	1.41 (1.17–1.69)
Care from external providers	9.6 (8.3–10.7)	11.3 (10.4–12.3)	1.20 (1.05–1.38)	1.17 (1.02–1.34)	Reference
Induction of labor					
Care from internal providers	25.2 (24.1–26.5)	28.6 (27.5–29.8)	1.15 (1.08–1.22)	1.13 (1.06–1.21)	1.20 (1.09–1.32)
Care from external providers	31.1 (30.0–32.8)	29.4 (28.0–30.8)	0.98 (0.91–1.05)	0.94 (0.88–1.01)	Reference
Primary cesarean					
Care from internal providers	18.5 (17.5–19.7)	17.0 (16.2–18.0)	0.98 (0.90–1.06)	0.92 (0.85–1.00)	0.99 (0.87–1.12)
Care from external providers	22.9 (21.3–24.7)	21.3 (20.0–22.8)	0.97 (0.88–1.07)	0.93 (0.85–1.02)	Reference
Macrosomia (4,500 g or greater)					
Care from internal providers	2.5 (2.1–3.1)	2.1 (1.8–2.6)	0.85 (0.66–1.08)	0.84 (0.65–1.07)	0.84 (0.55–1.30)
Care from external providers	1.6 (1.2–2.1)	1.6 (1.3–2.0)	1.04 (0.74–1.45)	0.99 (0.70–1.41)	Reference
Large for gestational age					
Care from internal providers	10.4 (9.5–11.3)	9.5 (8.8–10.3)	0.94 (0.84–1.05)	0.92 (0.82–1.03)	1.01 (0.85–1.21)
Care from external providers	9.6 (8.7–10.7)	8.7 (7.9–9.6)	0.93 (0.81–1.06)	0.90 (0.79–1.04)	Reference
Small for gestational age					
Care from internal providers	6.5 (5.9–7.3)	7.0 (6.5–7.7)	1.02 (0.89–1.16)	1.07 (0.94–1.23)	1.11 (0.88–1.39)
Care from external providers	6.9 (6.1–8.0)	6.7 (6.0–7.6)	0.97 (0.81–1.15)	0.97 (0.81–1.16)	Reference
NICU admission (level 3–4)					
Care from internal providers	5.0 (4.5–5.7)	5.0 (4.5–6.0)	0.97 (0.83–1.14)	0.99 (0.84–1.16)	0.85 (0.67–1.08)
Care from external providers	6.4 (5.7–7.4)	7.4 (6.7–8.4)	1.14 (0.97–1.34)	1.16 (0.97–1.37)	Reference
Neonatal hypoglycemia					
Care from internal providers	1.3 (1.0–1.7)	2.0 (1.7–2.4)	1.66 (1.23–2.23)	1.55 (1.14–2.10)	1.77 (1.14–2.75)
Care from external providers	2.4 (1.9–3.1)	2.1 (1.7–2.6)	0.96 (0.71–1.30)	0.87 (0.64–1.20)	Reference

RR, relative risk; NICU, neonatal intensive care unit.

Counts of deliveries in the numerators and denominators are in Appendix 4, available online at <http://links.lww.com/AOG/B125>.

Bold indicates that RRs are statistically significantly different ($P < .05$) from 1.00.

* Before the guideline change, January 2009–March 2011; after the change, April 2012–December 2014.

[†] Adjusted for maternal age, race–ethnicity, education, marital status, parity, prepregnancy body mass index, chronic hypertension, smoking during pregnancy, and Medicaid insurance; and neonatal sex.

[‡] For each prenatal care setting, the reference group was women delivering before the guideline change (January 2009–March 2011).

[§] The “difference-in-differences” RR compares the RR of the outcome after vs before the guideline change among women receiving care from internal providers to the comparable estimate among those receiving care from external providers; that is, the denominator is the RR after vs before in those receiving care from external providers (eg, RR 1.17 for gestational diabetes).

^{||} Level 3–4 includes intermediate and intensive care.



medication, primarily insulin. After accounting for background trends in the outcomes, the guideline change was associated with increases in labor induction, neonatal hypoglycemia, and nonstress testing. It was not associated with improvement in other outcomes including cesarean delivery, macrosomia, and NICU admission.

The observed increase in incidence of GDM associated with the switch to the one-step approach (ie, a 65% increase [95% CI 46–86%] after vs before the guideline and a 41% increase [95% CI 17–69%] when taking into accounting background trends in GDM incidence) is consistent with prior studies with most showing a 40% or greater increase.²² An increase would be expected given the one-step approach's lower threshold for diagnosis.^{2,6} The increases in labor induction and nonstress testing are also both plausible given it is recommended that women with GDM, especially those taking insulin, receive antenatal fetal surveillance and be induced by a certain gestational age as a result of their increased risk of adverse outcomes.²

Diagnoses of neonatal hypoglycemia also increased after the guideline change (difference-in-differences RR 1.20, 95% CI 1.09–1.32). We recognize that criteria for testing for neonatal hypoglycemia may have varied over time and between hospitals and care settings. Because pediatric guidelines recommend routine screening in neonates born to women with GDM,^{23,24} the increase we observed may have simply been the result of a greater proportion of neonates being screened because more women were diagnosed with GDM with the one-step approach, as opposed to a true increase in risk. The increased incidence of hypoglycemia may also have been a consequence of the shift toward use of insulin after the guideline change. Women with GDM treated with insulin are 58% more likely than those treated with metformin to give birth to a neonate who develops hypoglycemia (RR 1.58, 95% CI 1.16–2.16).²⁵

Findings from prior studies evaluating a switch to the one-step approach have been mixed; some suggested overall benefit^{7,9,10} and others net harm.^{8,11} All compared two-step and one-step eras, but unlike the present study, none accounted for underlying time trends unrelated to the change in testing method. As well, patterns of diabetes medication use after the switch varied across studies, ranging from large increases in use of insulin⁷ or glyburide⁸ to substantial decreases in use of insulin.⁹ Evidence suggests that glyburide may be less effective in treating GDM than insulin.²⁶ Therefore, differences across studies in how

women with GDM were treated may have contributed to differences in study results.

Limitations of our study include the possibility of confounding. We did not have information on maternal diet and exercise, and some risk factors may have been underreported (eg, smoking). Study outcomes were ascertained using electronic data, which may have resulted in some misclassification. Our results may have been influenced by other changes in care included in the guideline such as lower blood glucose thresholds for recommending medication and an emphasis on insulin as first-line medication.

Strengths of our study include its large size, evidence of a highly effective implementation of the GDM practice change, a concurrent control group, and adjustment for maternal education, BMI, race, and ethnicity.

In conclusion, adoption of the one-step approach to GDM testing was associated with increased incidence of GDM along with increases in labor induction, neonatal hypoglycemia, and nonstress testing, and there was no apparent benefit regarding other maternal and neonatal outcomes. The International Association of the Diabetes and Pregnancy Study Groups' one-step approach was intended to have a beneficial effect by decreasing risks of adverse outcomes including LGA, macrosomia, and cesarean delivery through use of a more sensitive definition for GDM.^{6,27–29} However, the additional women identified with the one-step approach may be at lower risk of these outcomes and may not benefit from GDM treatment to the same degree as women diagnosed with the two-step approach.^{2,30} Overall, our findings do not suggest a benefit of adopting the one-step over the two-step approach. Kaiser Permanente Washington has revised their guidelines to return to a two-step process. We recommend that any health care system considering switching to the one-step approach incorporate a rigorous evaluation of changes in maternal and neonatal outcomes.

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