

Neonatal Outcomes After Implementation of Guidelines Limiting Elective Delivery Before 39 Weeks of Gestation

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OBJECTIVE: To evaluate the association of a new institutional policy limiting elective delivery before 39 weeks of gestation with neonatal outcomes at a large community-based academic center.

METHODS: A retrospective cohort study was conducted to estimate the effect of the policy on neonatal outcomes using a before and after design. All term singleton deliveries 2 years before and 2 years after policy enforcement were included. Clinical data from the electronic hospital obstetric records were used to identify outcomes and relevant covariates. Multivariable logistic regression was used to account for independent effects of changes in characteristics and comorbidities of the women in the cohorts before and after implementation.

RESULTS: We identified 12,015 singleton live births before and 12,013 after policy implementation. The overall percentage of deliveries occurring before 39 weeks of gestation fell from 33.1% to 26.4% ($P < .001$); the greatest difference was for women undergoing repeat cesarean delivery or induction of labor. Admission to the neonatal intensive care unit (NICU) also decreased significantly; before the intervention, there were 1,116 admissions (9.29% of term live births), whereas after, there were 1,027 (8.55% of term live births) and this difference was significant ($P = .044$). However, an 11% increased odds of birth weight greater than 4,000 g (adjusted odds ratio 1.11; 95% confidence interval [CI] 1.01–1.22) and an

increase in stillbirths at 37 and 38 weeks, from 2.5 to 9.1 per 10,000 term pregnancies (relative risk 3.67, 95% CI 1.02–13.15, $P = .032$), were detected.

CONCLUSION: A policy limiting elective delivery before 39 weeks of gestation was followed by changes in the timing of term deliveries. This was associated with a small reduction in NICU admissions; however, macrosomia and stillbirth increased.

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LEVEL OF EVIDENCE: III

The gestational age distribution of live births in the United States has declined over recent years resulting in an average gestational age of 39 weeks.^{1,2} Much of the shift has been attributed to the more active role of the obstetrician in the early initiation of the parturition process through induction of labor or timing of planned cesarean deliveries.^{2,3} Although such strategies lead to improved outcomes among women with growth-restricted fetuses and other appropriate indications, there is substantial evidence that a portion of induced labors is not medically indicated according to the American College of Obstetricians and Gynecologists guidelines, and many elective deliveries are initiated before 39 weeks.^{4–6}

Although all deliveries at 37 or more weeks of gestation are categorized as term births, recent observational studies have documented progressive improvement in neonatal outcomes with each completed week of gestation until 39 weeks.^{4–8} These findings have stimulated a national effort to reduce elective delivery before 39 weeks through increased adherence to the American College of Obstetricians and Gynecologists recommendations.⁹ The Joint Commission recently adopted rate of elective delivery before 39 weeks as a institutional quality measure.¹⁰

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Several investigators report success at shifting the timing of elective delivery at individual hospitals and large regions after implementation of guidelines.^{11–15} However, the effect of these policies on neonatal outcomes remains to be fully evaluated. The purpose of this study is to estimate the effect of the policy, on both obstetric practice and key neonatal outcomes, at a large regional medical center.

MATERIALS AND METHODS

We used retrospective cohort data to perform an analysis of outcomes for term deliveries before and after implementation of the new policy at a large regional academic medical center. The medical center is the dominant obstetric provider in the region, delivering 85% of all births. The policy change included education about American College of Obstetricians and Gynecologists guidelines for elective delivery before 39 weeks followed by the institution of the new policy. Beginning April 9, 2007, all planned inductions were required to meet the American College of Obstetricians and Gynecologists indications for medical reasons. The list included placental abruption, chorioamnionitis, fetal death, gestational hypertension (elevated blood pressure, hypertension), premature rupture of membranes, maternal medical conditions (such as prepregnancy or gestational diabetes, hypertensive disorder of pregnancy, chronic hypertension, renal disease, kidney stones, chronic pulmonary disease, cholestasis of pregnancy), fetal compromise (such as intrauterine growth restriction, isoimmunization), nonreassuring antenatal testing (such as oligohydramnios, fetal abnormality, single umbilical artery), aneuploidy, and post dates. No elective inductions using preinduction cervical-repinning agents were permitted. Exceptions required preapproval by the department chair, cochair, or chief of maternal-fetal medicine. There was no educational effort provided by the department to communicate this change in policy to patients who planned to deliver at the institution. The policy was implemented during 2007 and thus we considered 2007 to be a transitional year and data for those births were not included in the analysis. The 2 years before the guideline (2005–2006) constitute the “before” period; the 2 years that followed the transitional year (2008–2009) are considered the “after” period. The analysis was limited to the 5-year period to minimize unrelated changes in medical practice that might significantly affect outcomes. There were no changes in neonatal intensive care unit (NICU) admission policies during the 5-year period and no notable staff changes in the NICU or in the obstetrics provider

community. The study was approved by the Christiana Care Health System institutional review board.

Data were derived from the clinical electronic obstetrical record completed during labor and delivery by trained nursing staff. This system has been in place at the institution for more than 10 years. These data have been used in several other studies and have recently been described and validated in detail.^{3,16,17}

All singleton deliveries 37 or more completed gestational weeks during the periods of interest were included. Any fetal death was considered a stillbirth; all others were considered live births and were analyzed separately. Each stillbirth was verified and cause of death determined by review of the hospital medical record by the study investigators. Apgar scores missing in the data warehouse were obtained from the medical record and the reason for any missing score was identified. Cases with missing data were included in all analyses except regression models in which that variable was required.

We assessed change in obstetric practice by determining the percentage of neonates delivered during the early term if the delivery was at 37 or 38 weeks compared with full term if the delivery was 39 or more completed weeks. The total difference in the percentages of deliveries during the early term period, before when compared with after, was determined for the cohort overall as well as for inductions (all and elective) and repeat cesarean deliveries.

We had three primary neonatal outcomes for this study: admission to the NICU for at least 24 hours, fetal macrosomia, and stillbirth. Neonatal intensive care unit admission reflected at least a 24-hour stay. There is no intermediate care unit or level II NICU at this institution. We defined fetal macrosomia as a birth weight greater than 4,000 g but also reported incidence of birthweight 4,500 g or more.¹⁸ To estimate the stillbirth rate, we used the fetuses at risk approach in which the denominator is the number of ongoing pregnancies entering each gestational age in weeks.¹⁹ This analysis was predicted to be underpowered to detect a significant change in stillbirth rate; however, as a result of its importance, this outcome was explored. In addition, 1-minute and 5-minute Apgar scores were explored.

Covariates in the analysis included the maternal demographic characteristics and medical risk factors available in the electronic record and known to be associated with the outcomes of interest. Gestational age at delivery was the best clinical estimate as determined by the obstetrical provider. Diagnoses of prepregnancy diabetes, gestational diabetes, chronic hypertension, and hypertension during pregnancy



were recorded in the medical record as diagnosed by the patient's obstetrical provider. Hypertension during pregnancy represented a combination of gestational hypertension and pre-eclampsia as indicated by the physician caring for the patient. Method of delivery and the use of labor induction were recorded in the electronic obstetric record by the clinical care team at the time of the delivery.

Univariable comparisons of outcomes before implementation compared with after were tested using the chi-square test of independence and the Student's *t* test for categorical and continuous data, respectively. Wilcoxon rank sum was used to compare the differences in Apgar scores because these data are not normally distributed. Changes in the sample characteristics were considered to pose the main potential bias between the before and after periods. Multivariable logistic regression was used to adjust for these characteristics and covariates. The potential interactions of insurance type (Medicaid compared with private), parity (nulliparous compared with multiparous), and race and ethnicity were explored using interaction terms within the regression model and then through stratified analysis. Data were analyzed using SAS 9.

RESULTS

We identified 12,015 term singleton live births before the guidelines were implemented (2005 and 2006) and 12,013 after (2008 and 2009); these cohorts are described in Table 1. In addition, there were seven singleton stillbirths before and 17 singleton stillbirths after. Data for prepregnancy weight were missing in 247 cases (1.03%); height was missing for 633 (2.63%). Apgar score was missing for 11 live births, all out-of-hospital deliveries. The large sample size led to statistically significant differences in many maternal characteristics between the cohorts. The greatest differences were an increase in the number women reporting African American race, women who were unmarried, received Medicaid or were uninsured, and who were multiparous in the after group when compared with before. The incidence of both gestational diabetes and gestational hypertension decreased.

Figure 1 presents the gestational age distributions before and after as a measure of the changes in obstetric practice. As seen in Figure 2, the overall percentage of deliveries during the early term fell from 33.1% to 26.4% ($P<.001$) after the guidelines were introduced when compared with before. This changed for the cohort overall and for both cesarean and vaginal deliveries. The magnitude of the change

Table 1. Characteristics of Study Cohorts Before (2005 and 2006) and After (2008 and 2009) Implementation of Guidelines

	Before (n=12,022)	After (n=12,030)	<i>P</i>
Sociodemographic characteristics			
Patient type			
Private	9,503 (79.0)	9,780 (81.3)	<.001
Service	2,519 (21.0)	2,250 (18.7)	
Insurance type			
Medicaid or uninsured	4,170 (34.7)	4,485 (37.3)	<.001
Private Insurance	7,852 (65.3)	7,545 (62.7)	
Marital status			
Unmarried	4,191 (34.9)	5,010 (41.6)	<.001
Married	7,831 (65.1)	7,020 (58.4)	
Race or ethnicity			
White	7,233 (60.2)	6,706 (55.7)	<.001
African American	2,581 (21.5)	3,026 (25.2)	
Hispanic	1,414 (11.8)	1,423 (11.8)	
Asian	604 (5.0)	658 (5.5)	
Age group (y)			
Younger than 20	952 (7.9)	1,035 (8.6)	.13
20–34	9,071 (75.5)	9,043 (75.2)	
35 and older	1,999 (16.6)	1,952 (16.2)	
Stillbirths	7 (0.06)	17 (0.14)	.06
Multiparous	7,173 (59.7)	7,745 (64.5)	<.001
Pregnancy risk factors			
Prepregnancy diabetes	111 (0.92)	165 (1.37)	<.002
Chronic hypertension	332 (2.76)	334 (2.78)	.94
Body mass index (kg/m ²)	25.9±6.0	26.2±6.2	<.001
Pregnancy complications			
Excess weight gain (40 lb or more)	3,585 (29.8)	3,429 (28.5)	.025
Gestational diabetes	806 (6.70)	592 (4.92)	<.001
Gestational hypertension	846 (7.04)	564 (4.69)	<.001

Data are n (%) unless otherwise specified.

was greater for those women with an induced labor and repeat cesarean delivery; the change was greatest for those undergoing an elective induction of labor. These findings demonstrate the changes in practice expected with implementation of the new policy.

Multivariable logistic regression showed the odds of a term delivery occurring at 39 weeks or more was 38% higher after guideline enforcement when compared with before (adjusted odds ratio [OR] 1.38, 95% confidence interval [CI] 1.30–1.47) adjusted for patient age, type, insurance, race, marital status, obesity, gestational weight gain, parity, a diagnosis of prepregnancy diabetes, gestational diabetes, chronic hypertension, and hypertension during pregnancy. Tests of



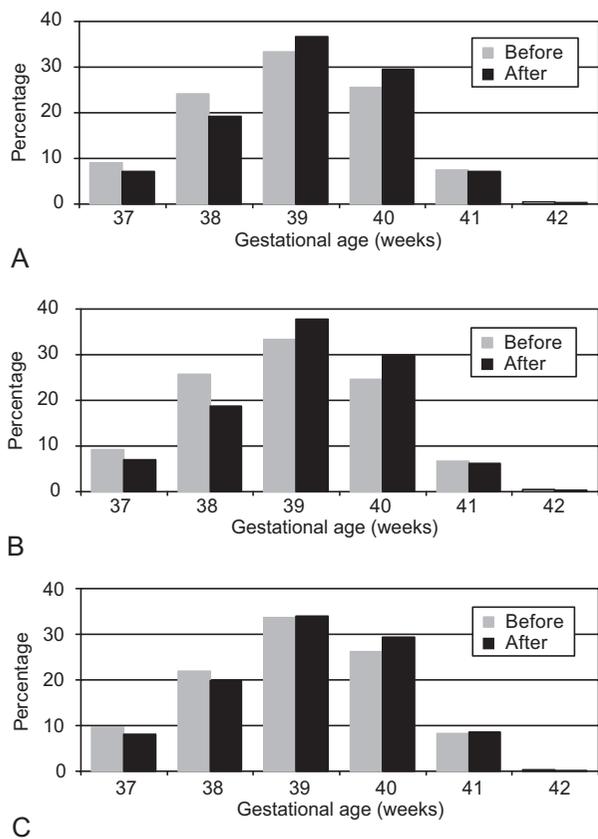


Fig. 1. Gestational age distribution before and after implementation of the guidelines for (A) all births, (B) births to women reporting white race, and (C) births to women reporting African American race. Differences in the distribution of completed gestational weeks were significant for all births ($P<.001$), deliveries to white women ($P<.001$), and for deliveries to African American women ($P=.02$).

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interaction identified significant differences by parity, insurance type, and race and ethnicity.

Stratified analysis, adjusting for the same factors, showed that the odds of a term delivery increased more for multiparous women (adjusted OR 1.47, 95% CI 1.37–1.58) than for nulliparous women (adjusted OR 1.22, 95% CI 1.11–1.35). There was also a greater magnitude of change for patients with private insurance (adjusted OR 1.50, 95% CI 1.40–1.62) than for women who were uninsured or receiving Medicaid (adjusted OR 1.18, 95% CI 1.07–1.30). The stratified analysis by race showed the differences after implementation were greatest for white women (adjusted OR 1.56, 95% CI 1.44–1.68) than for African American women (adjusted OR 1.17, 95% CI 1.04–1.32) and no different for women reporting Hispanic race or ethnicity (adjusted OR 1.0; 95% CI 0.83–1.19).

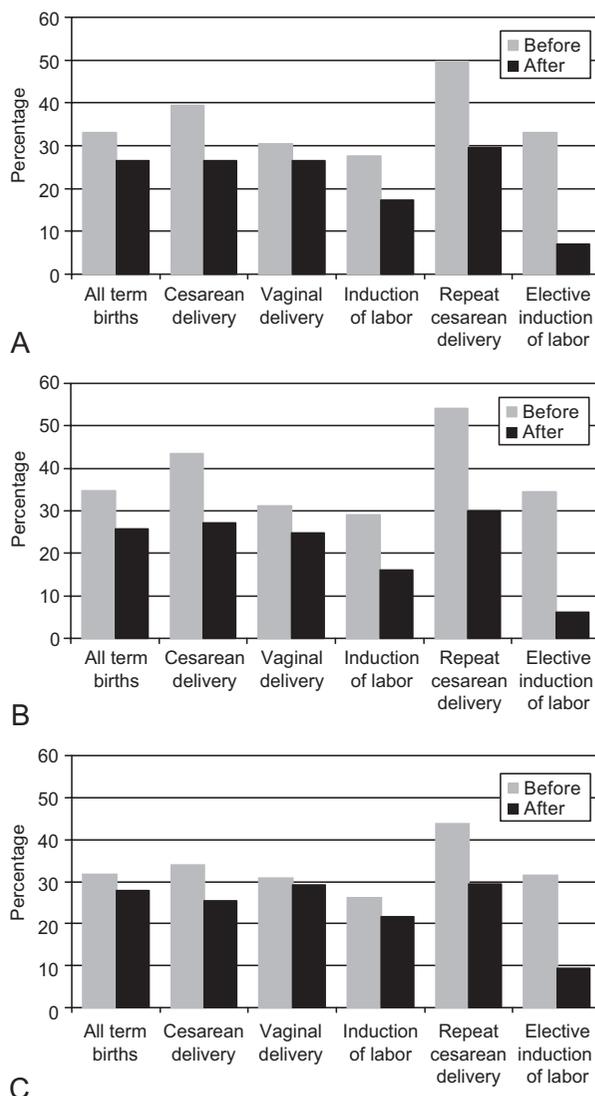


Fig. 2. The percentage of (A) all term births, (B) births to women reporting white race, and (C) births to women reporting African American race delivered at 37 or 38 weeks of gestation before and after implementation of the guidelines. The differences between the periods in each delivery group was significant for all births ($P<.05$), births to white women ($P<.05$), and births to African American women ($P<.05$), except those with a vaginal delivery ($P=.31$).

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Table 2 describes overall neonatal characteristics before and after. Among live births, the median 1- and 5-minute Apgar scores were significantly lower after the intervention, when tested using the Wilcoxon rank sum test ($P<.001$ for 1 minute; $P=.023$ for 5 minute). The percentage of neonates with 5-minute Apgar scores of 3 or less did not change ($P=.39$).



Table 2. Neonatal Outcomes for All Live Births Before (2005 and 2006) and After (2008 and 2009) Implementation of Guidelines

Outcome for Live Births	Before (n=12,015)	After (n=12,013)	P
Gestational age (wk)			
37 and 38	3,975 (33.1)	3,172 (26.4)	<.001
39 or more	8,040 (66.9)	8,841 (73.6)	
Birth weight (g)	3,393±459	3,399±463	.33
1,500–2,500	266 (2.2)	251 (2.1)	.60
2,500–4,000	10,668 (88.8)	10,626 (88.5)	
4,000–4,499	928 (7.7)	975 (8.1)	
4,500 or more	153 (1.3)	161 (1.3)	
5-min Apgar score	13 (0.11)	9 (0.07)	.39
3 or less			

Data are n (%) or mean±standard deviation unless otherwise specified.

The overall rate of admission to the NICU was significantly different between the two periods; before the intervention, there were 1,116 admissions (9.29% of term live births), whereas after, there were 1,027 (8.55% of term live births) and this difference was significant ($P=.044$). Multivariable logistic regression revealed a reduced odds of a NICU admission (adjusted OR 0.92, 95% CI 0.84–1.01) after the intervention. There were significant interaction effects with race. The results of the multivariable logistic regression stratified by maternal race are shown in Table 3, indicating the change was significant only for those neonates born to women reporting white race.

No statistically significant difference in the mean birth weight between the periods was identified. There

was an increase in the fraction of neonates with a birth weight 4,000 g or more and 4,500 g or more, but neither were statistically significant ($P=.22$ and $P=.65$, respectively). The multivariable logistic regression, accounting for changes in the characteristics of the cohort, gave an increased adjusted OR for a neonate 4,000 g or more (adjusted OR 1.11, 95% CI 1.01–1.22) after the intervention when compared with before. Analysis stratified by maternal race is shown in Table 3. The increase in macrosomia was statistically significant for neonates of women reporting white race; the point estimate for neonates of African American women was greater than 1 but failed to reach significance, possibly as a result of the smaller sample size. Neonates born to Hispanic women had reduced odds of macrosomia.

Table 4 provides a detailed accounting of the stillbirths identified; seven were identified before and 17 after. Two of the stillbirths after the intervention had congenital anomalies and were eliminated from the statistical analysis. The overall rate of stillbirth of nonanomalous fetuses differed between the periods with an overall increased risk of stillbirth after the intervention (relative risk 2.14, 95% CI 0.87–5.26, $P=.06$); this overall increase was not statistically significant. However, stratification by gestational age group of the stillbirth revealed the increased risk in the after group was limited to stillbirths before 39 weeks, which increased from 2.5 to 9.1 per 10,000 term pregnancies (relative risk 3.67, 95% CI 1.02–13.15, $P=.032$), whereas there was no change in risk of stillbirth at 39 weeks or more (relative risk 0.91, 95% CI 0.23–3.64, $P=.896$).

Table 3. Crude and Adjusted Odds of Neonatal Intensive Care Unit Admission and Macrosomia Overall and Stratified by Race and Ethnicity for All Live Births After (2008 and 2009) When Compared With Before (2005 and 2006) Implementation of Guidelines

Outcome	Characteristic (n)	Crude OR	95% CI	Adjusted OR	95% CI
NICU admission*					
Overall	24,028	0.91	0.84–1.00	0.92	0.84–1.01
White	13,927	0.89	0.79–1.00	0.88	0.78–1.00
African American	5,602	0.97	0.82–1.16	1.02	0.85–1.23
Hispanic	2,832	0.90	0.70–1.16	0.95	0.72–1.26
Macrosomia†					
Overall	24,028	1.06	0.97–1.15	1.11	1.01–1.22
White	13,927	1.16	1.05–1.29	1.17	1.05–1.31
African American	5,602	1.24	0.97–1.58	1.22	0.93–1.58
Hispanic	2,832	0.73	0.56–0.96	0.75	0.57–0.99

OR, odds ratio; CI, confidence interval; NICU, neonatal intensive care unit.

* Multivariable logistic regression adjusted for patient type (private compared with service), insurance type (private compared with Medicaid and uninsured), marital status, nulliparity, maternal age 35 years or older, diabetes, gestational diabetes, hypertension, gestational hypertension, body mass index category, weight gain 40 pounds or more, cesarean delivery, and labor induction.

† Multivariable logistic regression adjusted for patient type (private compared with service) and insurance type (private compared with Medicaid and uninsured), marital status, nulliparity, maternal age 35 years or older, diabetes, gestational diabetes, hypertension, gestational hypertension, and body mass index category, weight gain 40 pounds or more.



Table 4. Stillbirths, Stillbirth Rate, and Relative Risk of Stillbirth by Gestational Age Group After (2008 and 2009) When Compared With Before (2005 and 2006) Implementation of Guidelines

Gestational Age (wk)	Before			After			Relative Risk (95% CI)	P
	Stillbirths	Ongoing Pregnancies	Rate*	Stillbirths	Ongoing Pregnancies	Rate*		
Early term							3.67 (1.02–13.15)	.032
37	3	12,022	0.249	6	12,028	0.498		
38	0	10,939	—	5	11,153	0.448		
Full term							0.91 (0.23–3.64)	.896
39	2	4,018	0.249	2	4,406	0.226		
40	1	3,079	0.248	1	3,550	0.225		
41	1	944	1.06	1	885	1.29		

CI, confidence interval.

Data are n unless otherwise specified.

* Rate is stillbirths per 1,000 ongoing pregnancies or “fetuses at risk” at the start of the gestational week.

The authors carefully reviewed the medical records of each stillbirth to identify cause of death and the presence of a maternal risk factor; these findings are shown in Table 5. No definitive cause-of-death pattern emerged. We reviewed the characteristics of the women who delivered stillborn fetuses during each period to identify maternal factors that might be indications for delivery. Of the women who delivered before the intervention, four women were

white, two Hispanic, and one Asian; one woman was older than 35 years. Of the 17 women who delivered stillborn fetuses after the intervention, nine (53%) were white, five African American (29%), and two Hispanic (12%); nine women (53%) had risk factors related to advanced age or medical diagnosis. Findings related to results of antenatal testing completed before hospital admission for delivery were not available.

Table 5. Stillbirths at Term Before and After Implementation of Guidelines

Period	Gestational Age (Completed wk)	Fetal Cause of Death	Maternal Risk Factor(s)
Before	37	Cord accident	None
		Cord accident	None
		Unexplained	None
	39	Cord accident	None
		Unexplained	AMA
	40	Cord accident, two-vessel cord	None
41	Placental insufficiency	Postdates	
After	37	Fetal infection, intrapartum death	Corrected congenital heart disease
		Intrauterine growth restriction	Cocaine, AMA
		Major congenital anomaly*	Gestational diabetes
		Unexplained	Gestational diabetes
		Unexplained	Chronic hypertension
		Unexplained	None
	38	Unexplained	None
		Abruption	AMA
		Cord accident	None
		Cord accident	None
		Unexplained	None
		Unexplained	None
	39	Chromosomal abnormality*	AMA
		Cord accident, two-vessel cord	Gestational diabetes, AMA
		Unexplained	Prepregnancy diabetes
		Unexplained	None
	40	Abruption	None
	41	Infection, chorioamnionitis	Postdates

AMA, maternal age 35 years or older at the time of delivery.

* The two cases of major congenital anomalies were not included in Table 4 because outcome was not likely to be affected by timing of birth.



DISCUSSION

Using data derived from perinatal obstetric records, we found implementation of delivery guidelines at a large community-based hospital system led to a significant decrease in the fraction of term singleton births delivered at 37 or 38 weeks of gestation. Important contributors to this change were a decline in the fraction of repeat cesarean deliveries and elective inductions performed before 39 weeks. The shift was greatest for patients who were privately insured, multiparous, or white.

The change in obstetric practice was associated with differences in the three neonatal outcomes we examined for the population. We found a small decrease in the rate of NICU admissions for neonates born at term. This difference was of marginal statistical significance after adjusting for changes in the characteristics of the women between the two time periods. The magnitude of the effect was greatest for neonates born to white women. This is consistent with the finding that this was the group of women who showed the greatest reduction in the fraction of neonates born at 37 or 38 weeks after the guidelines were introduced. Rates of admission to the NICU at this institution were high for this gestational age group, potentially because there is no intermediate care nursery, but there was no indication that there were changes in the policy that occurred over the time period studied.

We found evidence to suggest potential adverse outcomes associated with the reductions in 37- and 38-week elective deliveries. There was a small increase in the percentage of neonates whose birth weight was 4,000 g or more. This could be an expected result of the extended duration of pregnancy and the limitations of clinical assessment of fetal macrosomia.¹⁸ We were unable to estimate the clinical consequences of this finding using the currently available data. Given the well-established morbidities associated with macrosomia, including shoulder dystocia, this small increase is of potential importance on a population level.

Also of concern is the increase in the number of stillbirths at term of sufficient magnitude to be detected in this analysis. By including only singleton pregnancies, we eliminated the possibility that the change was the result of a decrease in multiple gestation pregnancies, a group at higher risk for stillbirth. The excess in stillbirths occurred at 37 or 38 weeks, raising the concern that earlier delivery might have produced different outcomes. Although the numbers are too small to draw conclusions, they call

for the monitoring of trends in stillbirth rates, especially among women with the common risk factors such as age 35 years and older and any type of diabetes or hypertension.

The successful change in obstetric practice observed in this large community hospital is consistent with the experiences of other institutions and regions that have modified obstetric practice through the use of guidelines and monitoring.¹¹⁻¹⁵ The differential effect by race is an interesting and new finding, which might reflect a reversal of the historical trend of greater obstetric intervention at term for white, insured women in this community.¹⁶

Prior studies have not reported adverse effects on neonatal outcomes associated with similar changes in obstetric practice. Two earlier studies also observed a decline in NICU admission, and neither detected an increase in stillbirth after implementation of guidelines.^{11,14} An elevation in the risk of macrosomia also has not been observed, but careful accounting for changes in the maternal characteristics associated with that outcome was not conducted.¹⁴ The differences in these findings may be the result of differences in the characteristics of the populations studied or potentially related to our ability to adjust for confounding factors.

There are important limitations that should be considered when interpreting the results of this study. Errors in the estimates of gestational age could have led to misclassification of stillbirths, although our chart review suggests this was unlikely. It is also possible that other factors influenced obstetric care, perinatal outcomes, or both over the time periods studied that are independent of the guidelines and account for the changes in obstetric or neonatal outcomes we have observed. For example, the decision to admit a neonate to the NICU could be affected by changes in neonatal care and might not reflect differences in clinically important outcomes of the neonate. We attempted to account for these possibilities by limiting the time period studied and through a careful adjustment for changing characteristics of the populations. Moreover, our findings represent the experience of a single center and may not accurately predict experience at centers where obstetric practices differ or where there are differences in the patient population. Importantly, although the findings are statistically significant, their association with the intervention may not be causal and could be simply the result of chance.

We believe there are several strengths to this study design. The before and after approach is often used in the evaluation of interventions such as this



that cannot be applied randomly to a population. The use of clinical data provided more reliable outcome measures than those available from administrative or vital statistics data. Because these data are derived from the institutional data warehouse, they could be validated by review of the individual patient medical record. Of further importance, the clinical data also included pertinent covariates allowing adjustment for changes in the characteristics of the obstetric population. This helps to reduce the largest threat to the validity of the study findings that might result from differences in the cohorts between the two periods. The large size of the population provided sufficient power to detect changes in low-frequency events such as stillbirth.

The findings of this and other studies demonstrate that large institutions are able to enforce evidence-based guidelines and affect the clinical practice of community providers. These changes have occurred in a setting of increased attention by the National Committee for Quality Assurance and other organizations responsible for assessing quality of care and may have been an important motivator for the institution. The change in practice was associated with a lower rate of admission to the NICU, which remained of marginal significance after adjusting for changes in the characteristics of the cohort. The finding that changes in obstetric outcomes varied by race, and other maternal factors, suggests these characteristics need to be considered carefully when evaluating the effectiveness of these recommendations when applied to populations.

The detection of an increase in the rate of macrosomia and stillbirth is of concern. Macrosomia is well established to be associated with greater risk of shoulder dystocia, neonatal hypoglycemia, and hyperbilirubinemia.¹⁸ With national trends showing increased rates of diabetes and other causative factors, this would be an important outcome to monitor in different geographic and ethnic populations. The higher rate of stillbirth before 39 weeks is of course what we are all concerned about when we delay delivery. Our current data suggest that this may have involved women with medical risk factors and point to a need for surveillance of stillbirth rates, especially in the growing population of at-risk women.

We are in the midst of a national effort to eliminate elective delivery during the early-term period to optimize neonatal outcomes.^{20,21} This effort is guided by consistent findings from observational studies conducted in a variety of settings. However, none of these data are derived from randomized controlled trials. It is therefore critically important that the

clinical outcomes resulting from the broad application of these practice guidelines be monitored carefully in large population-based settings to ensure there are no unintended adverse consequences. The study of outcomes after implementation of guidelines at institutions across the country is needed to generate sufficient power to detect changes in outcomes and to generate the evidence needed to tailor clinical care. Only then can the balance of the risks and benefits associated with the implementation of guidelines limiting elective delivery before 39 weeks be debated.

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