

## FREQUENCY OF UTERINE CONTRACTIONS AND THE RISK OF SPONTANEOUS PRETERM DELIVERY

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### ABSTRACT

**Background** The measurement of the frequency of uterine contractions has not been useful for reducing the rate of preterm delivery in randomized trials. Nonetheless, ambulatory monitoring of contractions continues to be used in clinical practice.

**Methods** We assessed the frequency of uterine contractions as a predictor of the risk of spontaneous preterm delivery before 35 weeks of gestation. We enrolled women with singleton pregnancies between 22 and 24 weeks of gestation. The women used a contraction monitor at home to record contraction frequency twice daily on 2 or more days per week from enrollment to delivery or 37 weeks of gestation.

**Results** We obtained 34,908 hours of successful monitoring recordings from 306 women. Although more contractions were recorded from women who delivered before 35 weeks than from women who delivered at 35 weeks or later, we could identify no threshold frequency that effectively identified women who delivered preterm infants. The sensitivity and positive predictive value of a maximal hourly frequency of contractions of four or more between 4 p.m. and 3:59 a.m. were 9 percent and 25 percent, respectively, at 22 to 24 weeks and 28 percent and 23 percent at 27 to 28 weeks. Other proposed screening tests, such as digital and ultrasound evaluations of the cervix and assays for fetal fibronectin in cervicovaginal secretions, also had low sensitivity and positive predictive value for preterm labor.

**Conclusions** Although the likelihood of preterm delivery increases with an increased frequency of uterine contractions, measurement of this frequency is not clinically useful for predicting preterm delivery. (N Engl J Med 2002;346:250-5.)

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**A**SSESSMENT of the frequency of uterine contractions has been suggested as a screening method to identify pregnant women with an increased risk of preterm delivery (i.e., delivery before 35 weeks of gestation)<sup>1,2</sup> and as a diagnostic test to detect preterm labor in its earliest stages.<sup>3</sup> Although an increase in the frequency of uterine contractions would be expected to precede

preterm delivery, the clinical value of this measure has been unclear. The clinical use of ambulatory monitoring of contractions continues, despite randomized clinical trials that have indicated that measurement of the frequency of contractions as a screening or diagnostic test has not been useful for reducing the rate of preterm delivery.<sup>4-8</sup>

We therefore performed an observational study to assess the frequency of uterine contractions as a predictor of spontaneous preterm delivery. We considered other variables that could affect the frequency of contractions, including the duration of gestation,<sup>2,9</sup> the time of day,<sup>9,10</sup> and the woman's history with respect to preterm delivery. We also compared contraction frequency with other proposed markers of the risk of preterm delivery, including the results of digital and ultrasound evaluations of the cervix and the presence or absence of fetal fibronectin in cervicovaginal secretions.<sup>11-14</sup>

### METHODS

#### Study Population

The study, which was initiated by the National Institute of Child Health and Human Development Network of Maternal-Fetal Medicine Units, was conducted at 11 network sites between 1994 and 1996 and was approved by the human-subjects review board at each institution. All women provided written informed consent.

To enroll a population with an increased likelihood of preterm delivery, we recruited women with singleton pregnancies who had a history of spontaneous preterm delivery between 20 and 36 weeks of gestation or bleeding in the second trimester of the current pregnancy — both risk factors for preterm delivery. We also enrolled a limited number of women without any risk factors to

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allow comparison of the frequency of contractions in women with and without risk factors for preterm delivery. The sample size was based on a univariate comparison of the mean hourly contraction rate at any given time between women delivering their infants before term and those delivering at term. We calculated that, for an assumed preterm-delivery rate between 10 percent and 15 percent, a sample of 300 would give the study approximately 80 percent power to detect a difference of 0.5 standard deviation (e.g., a difference of one contraction per hour if the standard deviation was no more than two contractions per hour<sup>9</sup>). Because it contained patients at high risk, this sample of 300 was likely to include women delivering before 35 weeks, when neonatal morbidity is increased. The goal was to recruit 50 to 70 women at low risk and 230 to 250 women at high risk.

The women were screened for eligibility before 22 weeks of gestation. All women underwent an ultrasound examination before enrollment to confirm or establish the duration of gestation. Women who had received or were scheduled to receive an ambulatory monitor or tocolytic medication or to undergo cerclage were not eligible, nor were women whose pregnancies were complicated by placenta previa or a major fetal anomaly detected by ultrasonography. Women who did not have telephones were not enrolled, because the transmission of data collected by the monitoring system required a telephone.

### Assessments

Once enrolled, women were evaluated every two to three weeks at outpatient visits so investigators could reinforce compliance with study protocols, perform examinations with a speculum to collect swabs of cervicovaginal fluid for the measurement of fibronectin, and perform digital and transvaginal ultrasound assessments of the cervix. Fetal fibronectin is an extracellular-matrix protein normally found at the interface between the fetal membranes and the maternal decidua; its presence in cervicovaginal secretions has been related to an increased risk of preterm delivery.<sup>11,13</sup> The risk of preterm delivery has also been related to cervical length as measured by ultrasonography<sup>12</sup> and to the Bishop score for digital examination of the cervix.<sup>14</sup> The Bishop score is a composite measure of cervical length, dilatation, position, consistency, and the degree of descent (station) of the presenting part of the fetus. The results indicate the degree of readiness for labor; values from 0 to 4 indicate not ready for labor, and values from 9 to 13 indicate ready for labor. These procedures were performed by study personnel according to previously established protocols.<sup>11-14</sup>

The visits were scheduled to collect data at 22 to 24 weeks (visit 1), 25 to 26 weeks (visit 2), 27 to 28 weeks (visit 3), 29 to 30 weeks (visit 4), 31 to 32 weeks (visit 5), and 33 weeks or later (visit 6). Swabs of cervicovaginal fluid for detection of fibronectin were collected at all six visits. Digital and ultrasound assessments of the cervix were performed only at visits 1, 3, and 5.

### Monitoring of Uterine Contractions

Research nurses at each center were trained in the use of a home contraction monitor (Healthdyne System 37, Matria, Marietta, Ga.). Monitors and assistance with data collection were provided by the manufacturer under a contract chosen by competitive bidding in accordance with guidelines of the Department of Health and Human Services.

A research nurse visited each woman at home to instruct her in the use of the monitor and transmission of data. Women were asked to record uterine activity for a minimum of one hour at least twice daily in two sessions at least two hours apart, one between 4 a.m. and 3:59 p.m. and the other between 4 p.m. and 3:59 a.m., on 2 or more days per week from enrollment to 28 weeks. After 28 weeks, two additional monitoring sessions per week were required. Data were transmitted immediately after collection to a dedicated computer system at the data-coordinating center at the

George Washington University Biostatistics Center. Compliance with the protocol, including the time, date, and quality of the recordings for each woman, was monitored weekly. Data collected from medical records, interviews, and ultrasound examinations were transmitted weekly to the center.

The enrolled women were followed to delivery. The duration of pregnancy and the reasons for preterm delivery, if it occurred, were recorded. The health care providers, investigators, and patients were blinded to the results of testing. None of the tests included in the analysis were performed outside the study.

### Analyses of Recordings

The recordings of uterine activity were analyzed according to a standard protocol by four research nurses. Any session lasting at least 30 minutes that produced a satisfactory tracing was reviewed. A research nurse first screened each recording to identify those that showed no contractions. All recordings with one or more contractions were read jointly by two nurses who were unaware of the outcome of the pregnancy. A contraction was defined as a deflection that occurred from a clear base line and that had a rounded peak and lasted from 40 to 120 seconds. The guiding principle in formulating this definition was that it include all deflections that any experienced obstetrician or obstetrical nurse would easily agree to identify as a contraction. Inverted, "double-peak," and "camel-back" contractions were included. "Possible" contractions — that is, those that were subtle, had a variable base line, had a flat peak, or were accompanied by an artifact that obscured the above criteria — were not considered contractions. Regular audits, in which a sample of recordings with contractions was reanalyzed, were conducted throughout the study to ensure consistent interpretation. Although discordant interpretation occurred in 14 to 28 percent of recordings, the discrepancy was never greater than one contraction per hour and was evenly distributed between increased and decreased numbers of contractions. Ten percent of recordings with no contractions were also reviewed again as a quality-control measure; the rate of discordance among observers was 1.4 percent for these recordings.

### Statistical Analysis

Analyses of uterine activity were performed to identify relations with the duration of gestation, the time of day (4 a.m. to 3:59 p.m. [designated as daytime] vs. 4 p.m. to 3:59 a.m. [designated as nighttime]), risk status (high vs. low), and the timing of delivery (term delivery vs. spontaneous preterm delivery at less than 35 weeks of gestation, after preterm labor or preterm rupture of the membranes). Hourly contraction rates were calculated for each woman and for each week of gestation and were analyzed by a repeated-measures, random-effects model. Because each woman could contribute data only as long as her pregnancy continued, more data were collected for women who did not deliver prematurely. Contraction-frequency data from women who delivered their infants after 35 weeks were therefore compared with data collected between 24 weeks 0 days and 28 weeks 6 days for women who delivered between 29 weeks 0 days and 32 weeks 6 days, and with data collected between 24 weeks 0 days and 32 weeks 6 days for women who delivered between 33 weeks 0 days and 34 weeks 6 days.

The maximal daytime and nighttime contraction rates per hour for each interval of weeks (22 to 24, 25 to 26, 27 to 28, 29 to 30, 31 to 32, and 33 or more weeks) were evaluated as predictors of preterm delivery by logistic regression.

To compare uterine activity with the results of other tests as predictors of preterm delivery, we determined the sensitivity, specificity, and predictive values of each test at each gestational interval for spontaneous preterm delivery before 35 weeks of gestation. The results were dichotomized for the Bishop score (according to published criteria),<sup>14</sup> cervical length ( $\leq 25$  vs.  $> 25$  mm),<sup>12</sup> and cervicovaginal fibronectin ( $< 50$  vs.  $\geq 50$  ng per mil-

liliter).<sup>13</sup> Contraction frequency was dichotomized as less than four or four or more contractions per hour, as previously described.<sup>3</sup>

We performed multivariate logistic-regression analyses that included maximal uterine-contraction frequency, presence or absence of fetal fibronectin in cervicovaginal secretions, cervical length, and Bishop score as dichotomous variables. Evaluation of collinearity, including the standard errors and the correlation of the parameter estimates, indicated that correlations between the results of the screening tests did not cause a problem with the logistic-regression analyses.

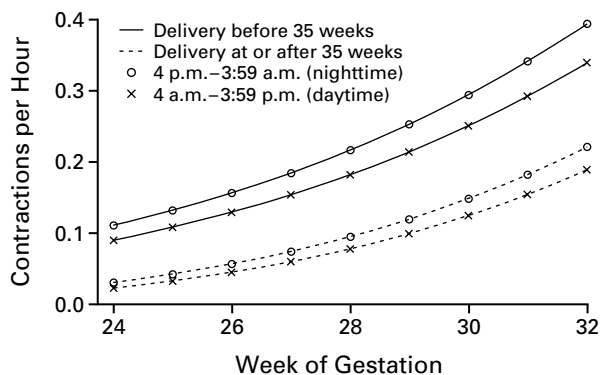
Receiver-operating-characteristic curves were constructed for each test for each two-week gestational interval. The curves were compared by calculating the area under the curve with use of a nonparametric approach based on the theory developed for generalized U statistics.<sup>15</sup>

## RESULTS

We screened 2205 women. Informed consent was not obtained from 545, and 1206 were ineligible (400 who did not have a telephone, 252 who were beyond 24 weeks of gestation, 94 with twin gestations, and 460 who had one or more of the other exclusion criteria listed above). There were 454 women with singleton pregnancies who met the inclusion criteria and consented to enroll. A total of 146 women (32 percent) did not comply with monitoring, and 2 delivered within one week of enrollment. The study group consisted of the remaining 306 women, for all of whom complete information was available.

The mean ( $\pm$ SD) age of the 306 women was  $26.2 \pm 5.8$  years, and the mean parity was  $1.8 \pm 1.3$ . Seventy-four percent had 12 or more years of education, 60 percent were black, and 26 percent smoked cigarettes. Of 254 women who were at increased risk for preterm delivery, 194 (76.4 percent) had one previous preterm delivery, 57 (22.4 percent) had two or more prior preterm deliveries, and 8 (3.1 percent) had second-trimester bleeding. Some women had more than one risk factor for preterm delivery. One hundred six women (35 percent) delivered their infants before 37 completed weeks of gestation, 48 (16 percent) before 35 weeks, and 18 (6 percent) before 32 weeks.

We obtained 34,908 hours of successful monitoring recordings, of which 21 percent (7268 hours) contained recordings of contractions. Because the frequency of contractions was not related to the historical risk of preterm delivery ( $P=0.22$ ), data from the low-risk and high-risk women were combined in subsequent analyses. The mean frequency of contractions increased significantly with the duration of gestation and was higher during nighttime hours (4 p.m. to 3:59 a.m.), regardless of the week of gestation at delivery (Fig. 1). Analyses were performed separately for daytime and nighttime contraction data. After the week of gestation at the time of monitoring had been controlled for, women who delivered their infants before 35 weeks of gestation had more contractions, as measured both during the daytime ( $P=$



**Figure 1.** Relation of the Week of Gestation, Time of Day, and Timing of Delivery (before 35 Weeks of Gestation or at 35 Weeks or More of Gestation) to the Frequency of Contractions between 24 and 32 Weeks.

The mean hourly contraction rates for both daytime and nighttime recordings were calculated with use of a repeated-measures random-effects model.

0.09 for 24 weeks 0 days to 28 weeks 6 days and  $P=0.03$  for 24 weeks 0 days to 32 weeks 6 days) and during the nighttime ( $P<0.001$  for 24 weeks 0 days to 28 weeks 6 days and  $P=0.02$  for 24 weeks 0 days to 32 weeks 6 days) than did women who delivered at or after 35 weeks.

In univariate analyses, the maximal frequency of contractions was inconsistently related to spontaneous delivery before 35 weeks of gestation (Table 1). Because the logistic-regression models for maximal morning and nighttime contraction frequency had slightly better fit than that for mean contraction frequency, the maximal frequency was used in subsequent analyses.

The strength of the relation between the frequency of contractions and preterm delivery relative to other factors associated with preterm delivery is shown in Table 2. These comparisons are limited to the three study visits at which the Bishop score and the presence or absence of fetal fibronectin in cervicovaginal secretions were determined and cervical ultrasonography was performed. In univariate analyses (data not shown), cervicovaginal fibronectin levels of at least 50 ng per milliliter, a cervical length of 25 mm or less, a Bishop score of 4 or more at all three visits, and a maximal nighttime contraction frequency of 4 or more per hour at 27 to 28 weeks were related to a greater risk of preterm delivery. In multivariate analyses (Table 2), maximal nighttime contraction frequency at 27 to 28 weeks, cervical length at all three visits, Bishop

**TABLE 1.** ODDS RATIO FOR SPONTANEOUS DELIVERY AT LESS THAN 35 WEEKS, ACCORDING TO THE MAXIMAL DAYTIME AND NIGHTTIME FREQUENCY OF CONTRACTIONS.

WEEK OF GESTATION	NO. OF WOMEN	ODDS RATIO (95% CI)*	
		DAYTIME (4 a.m.–3:59 p.m.)	NIGHTTIME (4 p.m.–3:59 a.m.)
22–24	270	0.9 (0.6–1.3)	1.3 (1.0–1.6)†
25–26	301	1.2 (1.0–1.5)‡	1.2 (1.0–1.4)‡
27–28	294	1.0 (0.8–1.2)	1.2 (1.1–1.4)§
29–30	288	1.1 (0.9–1.2)	1.1 (1.0–1.2)
31–32	281	1.0 (0.8–1.3)	1.1 (0.9–1.3)
≥33	266	0.8 (0.6–1.2)	1.1 (0.9–1.4)

\*CI denotes confidence interval.

†P=0.02.

‡P=0.03.

§P=0.003.

score at 22 to 24 weeks, and cervicovaginal fibronectin at 31 to 32 weeks were significantly related to an increased likelihood of preterm delivery.

Receiver-operating-characteristic curves were used to evaluate each measure as a predictor of spontaneous preterm delivery by means of pairwise compari-

sons of areas under the curve. At 22 to 24 weeks (data not shown), cervical length was a significantly better predictor than the other measures. At 27 to 28 weeks (Fig. 2), cervical length had the greatest area under the curve, but no test was superior to any other. At 31 to 32 weeks (data not shown), cervical length and Bishop score were both significantly better than the frequency of contractions in predicting preterm delivery. The sensitivity, specificity, and predictive values for maximal daytime and nighttime contraction frequency, presence or absence of cervicovaginal fibronectin, cervical length, and Bishop score to predict delivery before 35 weeks are shown in Table 3. No test had both good sensitivity and a high positive predictive value, but a contraction frequency of four or more per hour was a particularly weak predictor of preterm delivery. At 22 to 24 weeks, the sensitivity of the frequency of contractions to predict preterm delivery was below 10 percent, as compared with 35 to 45 percent for digital or ultrasound assessment of the cervix. Maximal nighttime contraction frequency had higher sensitivity at later weeks of gestation, but it continued to have poor sensitivity and positive predictive value.

### DISCUSSION

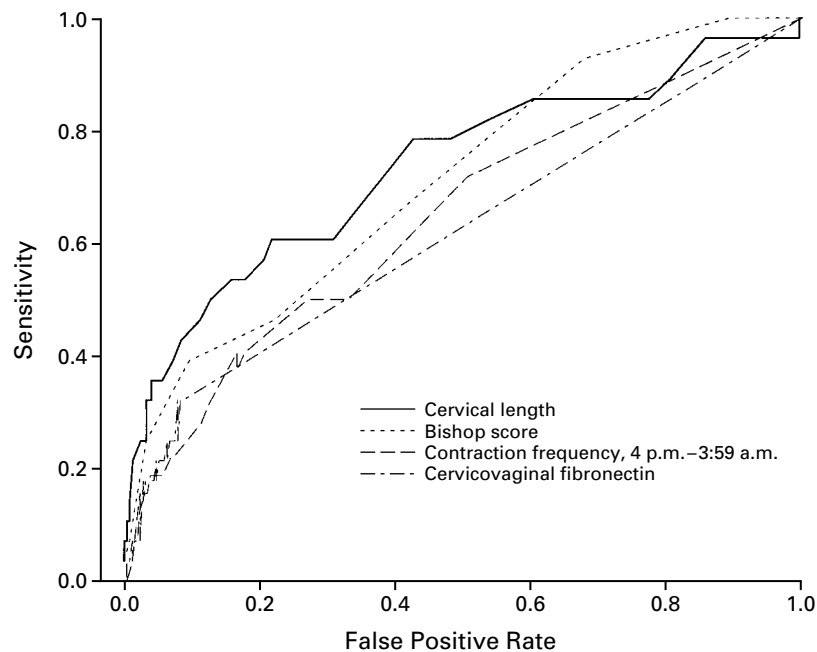
Because increased uterine-contraction frequency has been considered to lead to preterm labor and de-

**TABLE 2.** RELATION OF TEST RESULTS TO THE LIKELIHOOD OF SPONTANEOUS DELIVERY AT LESS THAN 35 WEEKS, ACCORDING TO MULTIVARIATE LOGISTIC REGRESSION.

TEST*	WEEK OF GESTATION AT TIME OF TESTING		
	22–24	27–28	31–32
Maximal nighttime contraction frequency ≥4/hr			
Odds ratio (95% CI)	3.0 (0.6–14.6)	3.0 (1.0–8.7)	1.3 (0.3–5.2)
P value	0.18	0.04	0.74
Maximal daytime contraction frequency ≥4/hr			
Odds ratio (95% CI)	3.2 (0.3–33.6)	1.6 (0.4–6.2)	0.5 (0.1–3.2)
P value	0.34	0.54	0.49
Cervicovaginal fibronectin ≥50 ng/ml			
Odds ratio (95% CI)	2.3 (0.6–8.2)	2.0 (0.6–6.9)	3.8 (1.1–13.2)
P value	0.22	0.25	0.04
Cervical length ≤25 mm			
Odds ratio (95% CI)	5.9 (12.6–13.7)	4.0 (1.6–10.2)	7.5 (1.9–29.7)
P value	<0.001	0.003	0.004
Bishop score ≥4†			
Odds ratio (95% CI)	4.2 (1.7–10.6)	1.7 (0.7–4.2)	3.1 (0.8–12.7)
P value	0.002	0.26	0.12

\*CI denotes confidence interval.

†The Bishop score is a composite measure of cervical length, dilatation, position, consistency, and the degree of descent (station) of the presenting part of the fetus. The results indicate the degree of readiness for labor; values from 0 to 4 indicate not ready for labor, and values from 9 to 13 indicate ready for labor.



**Figure 2.** Receiver-Operating-Characteristic Curves for Cervical Length, Bishop Score, Frequency of Contractions between 4 p.m. and 3:59 a.m., and Presence or Absence of Fetal Fibronectin in Cervicovaginal Secretions at 27 to 28 Weeks in the Prediction of Spontaneous Preterm Delivery (Less Than 35 Weeks).

livery, strategies for early detection and suppression of contractions have been advocated to reduce the incidence of premature delivery.<sup>3,4</sup> However, the preponderance of evidence from randomized clinical trials indicates that these strategies do not reduce the rate of prematurity.<sup>4-8</sup> Our results help to explain these observations. We found that frequency of contractions is significantly related to preterm delivery, but this measure has low sensitivity and low positive predictive value as a screening test for impending preterm delivery in asymptomatic women. This was true even in women at increased risk for preterm delivery. We found a relatively small difference in the frequency of contractions between women who subsequently delivered a preterm infant and those who gave birth at term. Not only was the difference small, but its discriminative value was low, so that the frequency of contractions had a low positive predictive value for preterm delivery. Because our data and those of others<sup>9,16</sup> show that the frequency of contractions is increased in the afternoon and evening<sup>9</sup> and with increased duration of gestation,<sup>9,16</sup> increased frequency of contractions in any individual woman is more likely

to reflect advancing gestation or diurnal variation than occult preterm labor.

Our results also confirm previous reports<sup>11-14</sup> of significant associations between prematurity and cervical length, Bishop score, and fibronectin in cervicovaginal secretions. However, our results indicate that these tests are not useful as screening tests for preterm delivery in asymptomatic women. Cervical length of 25 mm or less as measured by transvaginal ultrasonography was the most sensitive and consistent predictor of delivery before 35 weeks, but this test had a positive predictive value below 40 percent, even among women at increased risk for preterm delivery. The measurement of fetal fibronectin had lower sensitivity in this study than has previously been reported<sup>11,13</sup>; this low sensitivity may reflect the low incidence of delivery before 28 weeks in our study population, as compared with the incidence in prior trials.<sup>11,13,17</sup> Measurements of cervical length and fetal fibronectin in cervicovaginal secretions have been reported to be clinically useful in ruling out preterm labor among symptomatic women,<sup>17,18</sup> a group we did not study. Our data indicate that ambulatory

**TABLE 3.** VALUE OF TESTS IN PREDICTING SPONTANEOUS DELIVERY AT LESS THAN 35 WEEKS.

TEST	WEEK OF GESTATION AT TIME OF TESTING		
	22-24	27-28	31-32
	percent		
Maximal nighttime contraction frequency $\geq 4$ /hr			
Sensitivity	8.6	28.1	27.3
Specificity	96.4	88.7	82.0
Positive predictive value	25.0	23.1	11.3
Negative predictive value	88.3	91.1	93.0
Maximal daytime contraction frequency $\geq 4$ /hr			
Sensitivity	0	12.9	13.6
Specificity	98.4	93.9	84.9
Positive predictive value	0	20.0	7.1
Negative predictive value	87.0	90.2	92.1
Cervicovaginal fibronectin $\geq 50$ ng/ml			
Sensitivity	18.9	21.4	41.2
Specificity	95.1	94.5	92.5
Positive predictive value	35.0	30.0	30.4
Negative predictive value	89.4	91.6	95.2
Cervical length $\leq 25$ mm			
Sensitivity	47.2	53.6	82.4
Specificity	89.2	82.2	74.9
Positive predictive value	37.0	25.0	20.9
Negative predictive value	92.6	94.1	98.1
Bishop score $\geq 4$ *			
Sensitivity	35.1	46.4	82.4
Specificity	91.0	77.9	61.8
Positive predictive value	35.1	18.8	14.7
Negative predictive value	91.0	92.9	97.8

\*The Bishop score is a composite measure of cervical length, dilatation, position, consistency, and the degree of descent (station) of the presenting part of the fetus. The results indicate the degree of readiness for labor; values from 0 to 4 indicate not ready for labor, and values from 9 to 13 indicate ready for labor.

monitoring of uterine contractions does not identify women destined to have preterm delivery, and they thus explain the failure of this method to reduce the risk of preterm delivery in clinical practice.

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## APPENDIX

Institutions and staff members participating in the National Institute of Child Health and Human Development Network of Maternal-Fetal Medicine Units were as follows: *National Institute of Child Health and Human Development* — C. Catz, M. Klebanoff, and S. Yaffe; *University of Alabama at Birmingham* — J.C. Haut and R. Copper; *University of Chicago* — P. Jones and M. Lindheimer; *University of Cincinnati* — N. Elder and T. Siddiqi; *George Washington University Biostatistics Center* — A. Das and J. Zachary; *Ohio State University* — M.B. Landon; *University of Oklahoma* — J.C. Carey and A. Meier; *University of Pittsburgh-Magee Women's Hospital* — M. Cotroneo, J.H. Harger, and J.M. Roberts; *University of Southern California* — B. Kovacs and Y. Rabello; *Medical University of South Carolina* — B.A. Collins and J.P. Van Dorsten; *University of Tennessee* — B. Mercer and R. Ramsey; *Wake Forest University* — P. Meis and M. Swain; *Wayne State University* — G.S. Norman and Y. Sorokin.

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**CORRECTION**

**Frequency of Uterine Contractions and the Risk of Spontaneous Preterm Delivery**

Frequency of Uterine Contractions and the Risk of Spontaneous Preterm Delivery . In Table 2 on page 253, the lower limit of the confidence interval for the odds ratio associated with a cervical length of less than or equal to 25 mm at 22 to 24 weeks of gestation should have been 2.6, rather than 12.6, as printed.