

Cost-effective standardization of preterm labor evaluation

Carl H. Rose, MD; Dennis T. McWeeney, DO; Brian C. Brost, MD; Norman P. Davies, MBBS; William J. Watson, MD

OBJECTIVE: The purpose of this study was to determine the effect of a standardized evidence-based protocol for preterm labor evaluation on resource use and obstetrics outcomes.

STUDY DESIGN: We conducted a retrospective 12-month observational study of patients with symptoms of preterm labor at the Mayo Clinic. All patients underwent triage evaluation per a standardized protocol with a combination of cervical length measurement with contingent fetal fibronectin assay.

RESULTS: Of 201 patients who underwent evaluation, 3 women delivered within 7 days, and only 1 woman delivered after a negative evaluation.

Mean gestational age at evaluation was 29 weeks 1 day, and delivery was at 38 weeks 3 days of gestation, with an average interval of 57.4 days until delivery. The rate of hospital admission was reduced by 56%, compared with the previous year; an estimated annual cost saving was \$39,900.

CONCLUSION: Implementation of a standardized protocol for evaluation of preterm labor reduces the rate of unnecessary hospital admissions for observation with consequent significant reduction in expenses.

Key words: cost, evaluation, preterm labor

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With the increasing national emphasis on containment of health care costs, standardization of medical evaluation can be an effective method for simultaneously reducing hospital expenditures while ensuring quality of patient care. Preterm labor consistently has proved to be a major concern in clinical obstetrics, with approximately 12% of all pregnancies delivering at <37 weeks' gestation.¹ However, approximately 50-80% of patients who require hospital admission are discharged eventually and ultimately deliver at term.² Because of the heterogeneity in diagnosis and management in our institution, the evaluation of preterm labor was identified prospectively as an area in which the incorporation of newer diagnostic modalities could realize a reduction in hos-

pital expenses while improving efficiency of the clinical practice. The purpose of this study was to implement an objective strategy for the assessment of patients with symptoms of preterm labor and determine subsequent pregnancy outcomes and potential cost savings.

MATERIALS AND METHODS

All patients examined at Rochester Methodist Hospital Obstetrics Triage between December 2007 and November 2008 (inclusive) underwent evaluation according to a standardized protocol (Figure 1) as validated by Schmitz et al³ and Hedriana and Bliss,⁴ who were endorsed by both the March of Dimes and the Society for Maternal-Fetal Medicine. Briefly, after gestational age was confirmed and contraction frequency was established, a speculum examination was performed to obtain routine data on gonorrhea, chlamydia, and group B streptococcal cultures and fetal fibronectin. This was followed by a digital cervical examination and cervix length measurement with transvaginal ultrasound scanning; subsequent obstetrics decisions regarding management, corticosteroid administration, and hospitalization for tocolysis were based on these parameters. If the cervix length measurement was ≥ 3 cm, cultures and fetal fibronectin were discarded; if there was not clinical concern for abruptio placentae or cho-

rioamnionitis, the patient was discharged. All patients who were transported from an outlying facility were admitted for a 23-hour observation period. Obstetric demographic characteristics, incidences of deviation from protocol, hospital admissions, gestational age at both evaluation and delivery, and interval elapsed time between evaluation and delivery were recorded for all patients. This study was approved by the Mayo Clinic Institutional Review Board under protocol #10-000887.

After an initial 30-day introductory period, the protocol was implemented as the exclusive method for the triage of patients with symptoms of preterm labor. All patients who were transferred to our institution from outlying facilities underwent a similar evaluation; although the women would be admitted for 23-hour observation, for clinical purposes they were treated identically. All clinical examinations were performed by both house staff and faculty.

All patient triage visits (approximately 4500 per year) were reviewed prospectively by the primary author (C.H.R.), and pregnancy outcome data were retrieved from the electronic medical record where available. Protocol violations were recorded, and the responsible physicians were contacted directly for verbal case review. Final appropriateness of hospital admission was determined after review of admission criteria, discus-

From the Division of Maternal-Fetal Medicine, Department of Obstetrics and Gynecology, Mayo Clinic, Rochester, MN.

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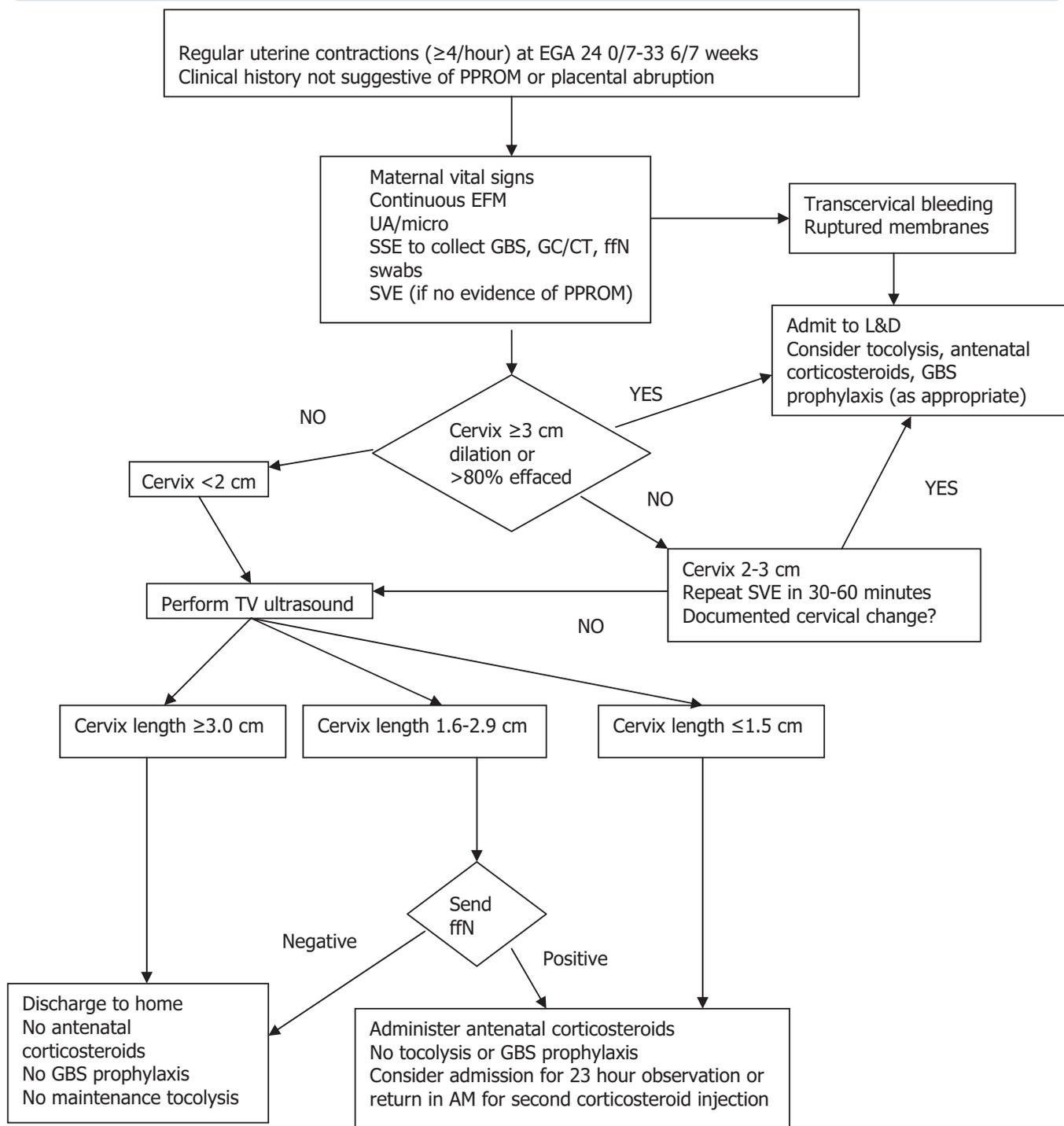
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FIGURE 1
Triage of patients with preterm labor symptoms



AM, morning; EFM, external fetal monitor; EGA, estimated gestational age; ffN, fetal fibronectin; GBS, Group B streptococcal culture; GC/CT, gonococcus/chlamydia trachomatis assays; L&D, labor and delivery; micro, microscopy; PPROM, preterm premature rupture of membranes; SSE, saline solution enema; SVE, sterile vaginal examination; TV, transvaginal; UA, umbilical artery.

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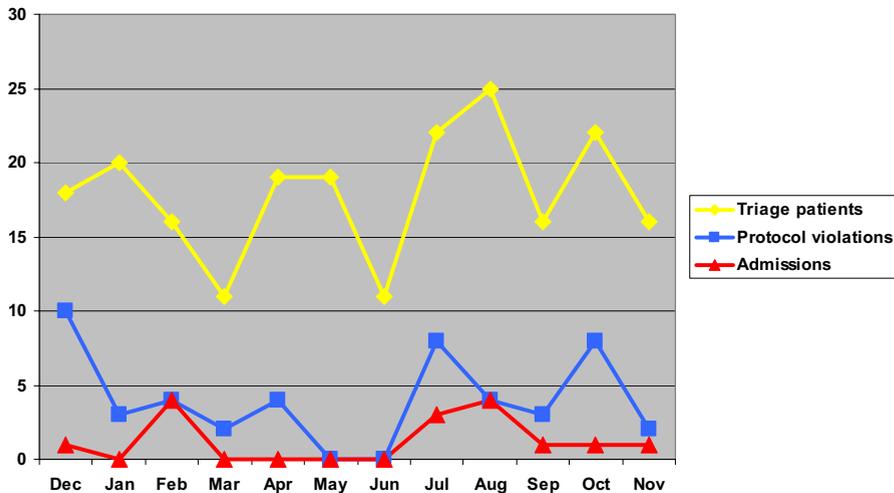
sion with attending staff, and review of hospital course.

The historical comparison group was comprised of patients who had been ad-

mitted from January 1 to December 31, 2006, who were treated with conventional methods for the exclusion of preterm labor (ie, continuous electronic

monitoring with serial cervical examinations). Decisions regarding hospitalization were individualized and left to the discretion of individual attending physi-

FIGURE 2
Protocol violations



Deviations from study protocol strategy.

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cians. Numeric admission data were obtained for comparative purposes, and costs of hospitalization were based on the estimated duration of hospitalization of 48 hours at a charge of \$2100 per day.

RESULTS

During the initial 12-month study interval, 201 patients had 215 visits to Obstetrics Triage for suspected preterm labor. Protocol violations occurred in 48 instances (22%) because fetal fibronectin was sent before cervix length measure-

ment (40%), because no cervix length measurement was available (27%), because neither cervix length nor fetal fibronectin was performed (27%), or because of other reasons (6%; Figure 2). Outcome data were unavailable for 21 patients (10%), primarily because of transport status and subsequent delivery at their respective referring institutions. Mean gestational age at delivery was 38 weeks 3 days, with an average interval of 57.4 days between evaluation and delivery (Table 1). Fifteen patients were admitted over the study interval, compared with 34 patients during preceding year; however, 11 of these 15 patients met criteria for admission according to the protocol. Only 3 patients (1.5%) delivered within 7 days of evaluation (Figure 3), with the following characteristics:

The protocol was followed: One patient had preterm contractions at 27 weeks of gestation; the cervix length measurement was 4.8 cm, and she was discharged with precautions. She returned later the same day with vaginal bleeding and fetal bradycardia and underwent emergent cesarean delivery for placental abruption.

Protocol was not followed: (1) one patient who was admitted at 33 weeks 5 days of gestation for a positive fetal fibronectin result experienced preterm

premature rupture of membranes and underwent elective induction of labor. (2) One patient delivered at 32 weeks 4 days of gestation 24 hours after clinical evaluation with serial digital cervical examinations.

In the final analysis, there were 141 patients who did not sustain a protocol violation for whom full obstetrics outcome data were available. All of the patients, except 1 with multiple visits, had initial negative evaluations that remained unchanged. The overall rate of preterm delivery was 17.0% (24/141 women). One patient delivered within 7 days; however, this patient had a negative evaluation that yielded a protocol sensitivity of 0%. Of the remaining 140 patients who delivered after 7 days, 5 patients had a positive evaluation, and 135 patients had a negative evaluation. The specificity of this testing strategy in our sample was 96.4% (95% confidence interval [CI], 91.9–98.8%), and the negative predictive value was 99.2% (95% CI, 96.0–100%; Table 2). These results were similar with either inclusion or exclusion of twin pregnancies (data not shown).

When extending the analysis to patients who delivered within 2 weeks after evaluation, in addition to the 3 patients who delivered within 7 days, 3 patients delivered within 14 days:

Protocol was followed: (1) one patient with monochorionic/diamniotic twins underwent induction of labor at 32 weeks 6 days of gestation for twin-twin transfusion syndrome 9 days after a negative evaluation. (2) One patient delivered spontaneously at 34 weeks 5 days of gestation after a negative evaluation 12 days previously.

Protocol was not followed: one patient was admitted (without following protocol), was discharged, and returned at 27 weeks 1 day of gestation and delivered consequent to a placental abruption.

The performance of the protocol at 14 days remained similar to that at 7 days, with specificity of 96.4% (95% CI, 91.8–98.8%) and negative predictive value of 97.8% (95% CI, 93.7–99.5%; Table 2).

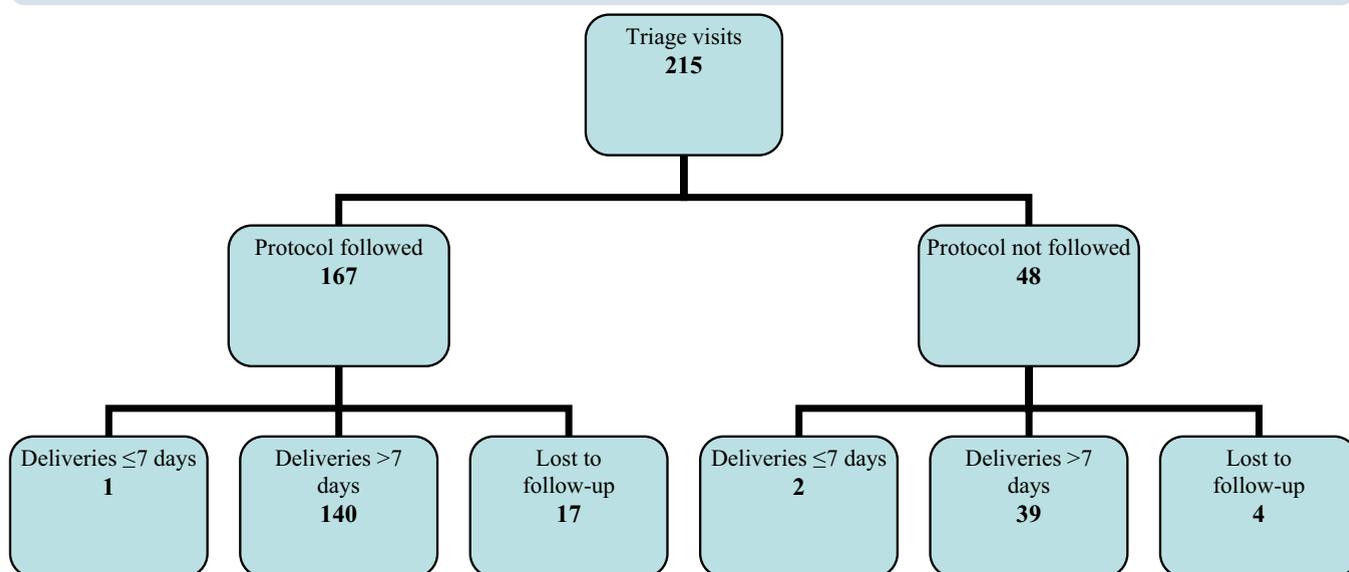
For comparative purposes, 34 patients were admitted to the antepartum unit during the previous year with a diagnosis of preterm labor, which represented a

TABLE 1
Study outcome data

Variable	Measure
Patients included, n	201
Protocol violations, n	48
Outcome data unavailable, n	21
Patients admitted, n	15
Delivery within 7 days of evaluation, n	3
Delivery within 14 days of evaluation, n	6
Mean gestational age at delivery, wk	38 4/7
Mean duration between evaluation and delivery, d	57.4

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FIGURE 3
Patient triage



Diagrammatic representation of delivery timing.

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56% reduction in admission rate after protocol implementation, with concurrent reduction of an estimated \$39,900 in health care expenditures.

COMMENT

Given the previous heterogeneity in criteria for hospital admission, implementation of a standardized protocol for the evaluation of suspected preterm labor resulted in a low rate of preterm delivery after negative evaluation. The protocol that integrated fetal fibronectin and sonographic cervical length measurement for the prediction of preterm deliv-

ery has been validated previously by Schmitz et al,³ with a low risk of delivery within 7 days of a negative evaluation. Although the current study was not designed for this specific purpose, only 1 of 141 patients (0.7%) with a negative evaluation delivered within 7 days, which had a negative predictive value of 99.2%. Studies that used either both cervix length and fetal fibronectin or blindly collected fetal fibronectin with omission of the sonographic examination have likewise shown similar results.⁵⁻⁷

Crucial to effective implementation of this protocol was dedicated outcomes tracking (ie, review of all medical records for patients examined in our triage unit). If on review of the medical record the protocol was not adhered to, then the responsible providers were contacted (either in person or by phone or email) to inquire about extenuating circumstances that were not reflected in the electronic documentation. If it was found that deviation from protocol was not supported by clinical factors, providers were reminded politely that this protocol was a formal departmental policy. Although not actually tabulated, it is the authors' opinion that this was required only on >1 occasion. Delivery numbers

at our institution have remained relatively constant (2300 deliveries per year \pm 2%) over the study interval with unchanged referral patterns; thus, this reduction is probably reflective of more objective decisions on the part of the house staff and faculty.

Inherent limitations of the present study are multiple and are related primarily to sample size, frequency of protocol violations, and loss of patients to follow-up evaluation. Prospective data regarding specific indications for hospitalization were not collected until this protocol was implemented. The protocol deviation rate of 22% suggests significant individual house staff and faculty noncompliance with departmental guidelines, despite practice-specific data. Outcomes of patients who required admission but who ultimately delivered elsewhere was unavailable for 10% of patients. The estimated reduction in expenditures is likely conservative, because specific hospital charges for each patient are difficult to ascertain. Four patients were admitted outside of protocol, which suggests a potential for even greater cost reduction with strict adherence to guidelines. However, cognizant of these limitations, this study suggests realization of a significant cost

TABLE 2
Statistical analysis

Evaluation	Yes	No
Preterm delivery <7 days		
Positive	0	5
Negative	1	135
Preterm delivery <14 days		
Positive	0	5
Negative	3	133

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saving without compromise of patient care.

Relatively few studies have examined the economic impact of standardized preterm labor assessment. In the only randomized trial to date, Grobman et al⁸ found no significant difference with the introduction of fetal fibronectin assays, because this did not appear to influence clinical management. Several smaller trials, which were conducted primarily in New Zealand and Canada, found a non-significant reduction in health care costs when obstetrics management decisions were based on fetal fibronectin results.^{9,10} A potential for cost savings through the prevention of transport to tertiary medical centers was described by Giles et al.¹¹ Although several theoretic analyses have been published, no studies of cost expenditures of cervical length measurement with contingent fetal fibronectin screening have yet been performed.^{12,13}

Approximately 9% of patients require admission for a diagnosis of preterm labor, with 38% delivering during their initial hospitalization.¹⁰ The remaining cohort of 62% of patients (5.6% of all pregnancies) would be anticipated not to be in active labor and thus potentially would be candidates for protocol evaluation. Extrapolating theoretic financial effects with the use of electronically published Centers for Disease Control data for the year 2006: (1) total births in the United States (4,265,555) \times 5.6% = 238,018 patients who were admitted for preterm labor and ultimately discharged; (2) estimated costs (based on 48-hour hospitalizations at \$2100/day) would be 238,018 \times \$4200 = \$999,675,600.

Reducing this rate by 56% would result in a cost saving of \$559,818,335 or as an estimate \$560 million.¹⁴ Although intuitively we believe that the implementa-

tion of this protocol on a national scale would likely result in a substantial decrease in hospital admissions and consequent reduction in health care expenditures, the magnitude of this effect would be dependent on its adoption by individual obstetrics practices.

With the current focus on containment of health care costs, evidence-based practices that improve efficiency while retaining quality of care are assuming increasing importance. Formal standardization of evaluation is also advantageous from the perspective of promoting homogeneity of practice among multiple house staff and faculty physicians, which would lead to a more cooperative work unit. Although specific duration of triage use is not tracked at our institution, the potential brevity of triage examination should translate into an improvement in efficiency. An additional benefit, although not recorded as a formal metric, was improvement in house staff proficiency with cervical length imaging technique. This study was undertaken in an academic tertiary care center; however, given the frequency of occurrence of suspected preterm labor, it is broadly applicable to obstetrics practice regardless of locale. ■

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REFERENCES

1. Muglia LJ, Katz M. The enigma of spontaneous preterm birth. *N Engl J Med* 2010; 362:529-35.
2. McPheeters ML, Miller WC, Hartmann KE, et al. The epidemiology of threatened preterm labor: a prospective cohort study. *Am J Obstet Gynecol* 2005;192:1325-9.
3. Schmitz T, Maillard F, Bessard-Bacquaert S, et al. Selective use of fetal fibronectin detection after cervical length measurement to predict spontaneous preterm delivery in women with

preterm labor. *Am J Obstet Gynecol* 2006; 194:138-43.

4. Hedriana HL, Bliss MC. Preterm labor assessment toolkit: March of Dimes 2006. Available at: http://www.marchofdimes.com/prematurity/21326_23788.asp. Accessed July 20, 2010.
5. Skoll A, St. Louis P, Amiri N, Delisle MF, Lalji S. The evaluation of the fetal fibronectin test for prediction of preterm delivery in symptomatic patients. *J Obstet Gynaecol Can* 2006;28: 206-13.
6. Rozenberg P, Goffinet F, Malagrida L, et al. Evaluating the risk of preterm delivery: a comparison of fetal fibronectin and transvaginal ultrasonographic measurement of cervical length. *Am J Obstet Gynecol* 1997;176:196-9.
7. Roman AS, Koklanaris N, Paidas MJ, Mulholland J, Levitz M, Rebarber A. "Blind" vaginal fetal fibronectin as a predictor of spontaneous preterm delivery. *Obstet Gynecol* 2005;105: 285-9.
8. Grobman WA, Welshman EE, Calhoun EA. Does fetal fibronectin use in the diagnosis of preterm labor affect physician behavior and health care costs? A randomized trial. *Am J Obstet Gynecol* 2004;191:235-40.
9. Musaad SM, Melson LC, Boswell RD. Fetal fibronectin assay may reduce management cost of preterm labour: an interval analysis. *Pathology* 2006;38:473-4.
10. Abenhaim HA, Morin L, Benjamin A. Does availability of fetal fibronectin testing in the management of threatened preterm labour affect the utilization of hospital resources? *J Obstet Gynaecol Can* 2005;27:689-94.
11. Giles W, Bisits A, Knox M, Madsen G, Smith R. The effect of fetal fibronectin testing on admissions to a tertiary maternal-fetal medicine unit and cost savings. *Am J Obstet Gynecol* 2000;182:439-42.
12. Honest H, Forbes CA, Durée KH, et al. Screening to prevent spontaneous preterm birth: systematic reviews of accuracy and effectiveness literature with economic modelling. *Health Technol Assess* 2009;13:1-627.
13. Vis JY, Wilms FF, Oudijk MA, et al. Cost-effectiveness of fibronectin testing in a triage in women with threatened preterm labor: alleviation of pregnancy outcome by suspending tocolysis in early labor (APOSTEL-I trial). *BMC Pregnancy Childbirth* 2009;9:38.
14. Martin JA, Hamilton BE, Sutton PD, et al. Births: final data for 2006. National vital statistics reports 2009. Available at: http://www.cdc.gov/nchs/data/nvsr/nvsr57/nvsr57_07.pdf. Accessed July 20, 2010.