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 subsequent significant reduction in expenses.

Key words: cost, evaluation, preterm labor


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. However, approximately 50-80% of patients who require hospital admission are discharged eventually and ultimately deliver at term. 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 hospital 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 al and Hedriana and Bliss, 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 chorioamnionitis, 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-
sion with attending staff, and review of hospital course.

The historical comparison group was comprised of patients who had been admitted 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-
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 measurement (40%), because no cervical 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
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 delivery has been validated previously by Schmitz et al, 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.

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 ± 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

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**FIGURE 3**

Patient triage

Diagrammatic representation of delivery timing.


**TABLE 2**

<table>
<thead>
<tr>
<th>Evaluation</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preterm delivery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;7 days</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Positive</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Negative</td>
<td>1</td>
<td>135</td>
</tr>
<tr>
<td>Preterm delivery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;14 days</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Positive</td>
<td>0</td>
<td>5</td>
</tr>
<tr>
<td>Negative</td>
<td>3</td>
<td>133</td>
</tr>
</tbody>
</table>

tuitively we believe that the implementa-

tion of this protocol on a national scale
would likely result in a substantial de-
crease in hospital admissions and conse-
quent reduction in health care expendi-
tures, the magnitude of this effect would
be dependent on its adoption by individ-
ual obstetrics practices.

With the current focus on contain-
ment of health care costs, evidence-
based practices that improve efficiency
while retaining quality of care are as-
suming increasing importance. Formal
standardization of evaluation is also ad-
vantageous from the perspective of pro-
moting homogeneity of practice among
multiple house staff and faculty physi-
cians, which would lead to a more coop-

Erative work unit. Although specific du-
ration of triage use is not tracked at our
institution, the potential brevity of triage
examination should translate into an im-
provement in efficiency. An additional
benefit, although not recorded as a for-
mal metric, was improvement in house
staff proficiency with cervical length im-
aging technique. This study was under-
taken in an academic tertiary care center;
however, given the frequency of occur-
rence of suspected preterm labor, it is
broadly applicable to obstetrics practice
regardless of locale.

ACKNOWLEDGMENT
We acknowledge the contributions of Amy
Weaver, MS, for assistance with statistical inter-
pretation.

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Approximately 9% of patients require
admission for a diagnosis of preterm la-
br, with 38% delivering during their
initial hospitalization. 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 evalu-

ation. Extrapolating theoretic financial
effects with the use of electronically pub-
lished Centers for Disease Control data
for the year 2006: (1) total births in the
United States (4,265,555) × 5.6% =
238,018 patients who were admitted for
preterm labor and ultimately dis-
charged; (2) estimated costs (based on
48-hour hospitalizations at $2100/
day) would be 238,018 × $4200 =
$999,675,600.

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