Identification and Case Management in an HMO of Patients at Risk of Preterm Labor

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Abstract

We carried out a study of pregnant patients in a health maintenance organization to identify and provide case management of women at risk of preterm labor and to determine important risk factors for preterm labor in a managed care population. Data were collected on 794 women who completed an initial prenatal care visit at HealthAmerica of Pittsburgh between July 15, 1994, and March 31, 1995, and delivered at a local Pittsburgh hospital. The patients were assessed during an initial call to schedule their first prenatal visit and also at the 8- to 15-week and 24- to 28-week prenatal visits. Patients scoring 10 or higher on the risk assessment form were referred to a nurse case manager who provided education and support. Results of a logistic regression analysis suggest that the risk assessment tool was effective in identifying women at risk for preterm labor. "Physical/stressful work," as assessed by the patient, history of a prior preterm birth, and multiple gestation were all statistically significant predictors of preterm birth. Further research is needed to confirm the finding that physical or stressful work is a significant predictor of preterm births and to determine which aspects of the work may increase the patient's risk. This study was based on 8 months of data; however, additional program implementation is needed to evaluate fully the potential long-term benefits of the program.

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Despite progress in obstetric and prenatal care, preterm delivery and low birth weight continue to be major sources of mortality and long-term morbidity in the United States.[1-3] In 1993, 21 countries had lower infant mortality rates than the United States.[2] Because of advances in the care of critically ill neonates, many infants weighing as little as 750 grams are surviving.[4] However, this is not without significant long-term health and developmental morbidity.[3,5,6]

Many healthcare providers and researchers are attempting to prevent preterm labor by creating programs to assist women who are at risk of early delivery.[1,7-16] Two important problems exist in this area of research, namely, how to identify women at risk of preterm labor and their respective risk factors and how to identify interventions that lengthen the gestational period for women identified as high risk (ie, preventing preterm births).

A popular method used to identify women at risk for preterm labor was developed by Creasy et al.[11] The Creasy method is based on identifying and applying a scoring system to potential preterm birth risk factors. Risk factor categories include socioeconomic status, past obstetric history, daily activities, and medical conditions occurring during the current pregnancy. The risk factors have relative weights and cut-points based on clinical experience. The patient is categorized as high risk based on a composite scoring system in which a score of 10 or greater is considered high risk.

Decreasing preterm birth rates when the exact causes are unknown is difficult. Currently, researchers are looking at several new tests to predict preterm labor. These new tests consist of identifying infections such as bacterial vaginosis or the presence of fetal fibronection.[17-21]

The current study was conducted jointly by HealthAmerica, a health maintenance organization located in Pittsburgh, PA, and the department of Biostatistics at the University of Pittsburgh, Graduate School of Public Health. The study was designed to address the following objectives: (1) to identify women at risk of preterm labor; (2) to determine important risk factors for preterm labor; (3) to enroll high-risk women in an educational intervention program; and (4) to evaluate if this preterm labor inter-

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vention program would effectively reduce the number of preterm births. This study began as a preterm birth prevention program using nursing interventions and later evolved into a formal research project.

··· METHODS ···

Data were collected on 794 women who completed an initial prenatal care visit at HealthAmerica between July 15, 1994, and March 31, 1995, and delivered at Magee-Womens Hospital in Pittsburgh. The obstetric practice that participated in this study was comprised of 10 physicians and one nurse practitioner with offices throughout the surrounding Pittsburgh area.

Risk Assessment Tool

An adaptation of the Creasy et al[11] risk assessment tool used by Group Health Incorporated in Minneapolis, Minn,[7] was applied to this population (see Appendix). The Group Health's adaptation of the Creasy risk assessment tool was chosen because of the similarities between Group Health's and HealthAmerica's patient populations. In addition, the Group Health program had successfully reduced preterm births.

Before program implementation, all nursing and relevant support staff completed the March of Dimes Preterm Labor Module.[22] An initial screen was conducted when the patient called to schedule her first prenatal visit. The interviewer completed and scored the first 19 questions relating to obstetric and medical history (see Appendix). The patient also answered questions about daily living and work habits. The physician was responsible for completing questions 20 through 40 (clinical information) at the first prenatal visit, which usually occurred at the eighth to tenth week of pregnancy. If the woman's first prenatal visit was after 20 weeks' gestation, she was excluded from the study. The same risk factors were evaluated during the patient's visit at 24 to 28 weeks' gestation. A cervical examination was performed at the 24- to 28-week visit to determine premature cervical dilation.

Risk scores were tabulated from the risk assessment tool at both visits. Women with scores of 10 or greater at either visit were considered high risk. Some risk factors were weighted more heavily than others. For example, a pregnancy with multiple gestations was scored 10 points, which automatically placed the woman in the high-risk category. However, the majority of other variables were scored between one and five points. Therefore, in the absence of one of the major risk factors, a woman would need a combination of these other risk factors to be considered high risk.

Case Management

High-risk women were referred to the nurse case manager. The case manager sent them educational literature including the March of Dimes Preterm Labor Guide,[23] which describes signs of preterm labor, procedures to follow if the woman experiences any symptoms, and how to palpate and time contractions. Each woman was contacted by telephone to review the contents of the educational literature and the signs and symptoms of preterm labor and to discuss normal feelings of pregnancy. The telephone calls were made approximately every 2 to 4 weeks for patients who were not experiencing signs of preterm labor. Those who were prescribed bed rest or tocolytics were called more often, from once a week to daily.

The frequency of calls was determined by the case manager's assessment of the woman's understanding of preterm labor and her current relationship with the obstetrician and the medical staff. The patients were also given emergency telephone numbers to report any problems. The nurse case manager treated the contact as educational in an attempt to minimize the woman's concern and anxiety about her condition.

Home uterine monitoring was used on only two out of the 155 women enrolled. Generally, tocolysis was not used to inhibit labor in women who are 35 to 37 weeks' gestation. Some women required referrals to community resources to provide additional social support and care for the family. This was coordinated by the nurse case manager.

Patients were seen at intervals determined by the physician. Women who had experienced preterm labor were usually seen weekly by their physician. Expected delivery dates were confirmed by the date of last menstrual period and prenatal ultrasonography. Verification of laboratory tests and cervical examinations performed were confirmed by chart review after the patient had delivered.

Statistical Analysis

SAS statistical software (SAS Institute, Cary, NC) was used to obtain summary statistics, including means and standard deviations for all continuous variables. Frequency distributions were determined for categorical variables. Univariate comparisons of risk factors for women who delivered preterm versus those who did not were performed using chi-square and Fisher's exact tests. All statistical analyses were conducted as two-tail tests with a significance level of 0.05.

Logistic regression analysis was performed to determine if the risk assessment tool was effective

overall in detecting preterm birth and to evaluate if any single variables or combinations of variables were important predictors of preterm births.

··· RESULTS ···

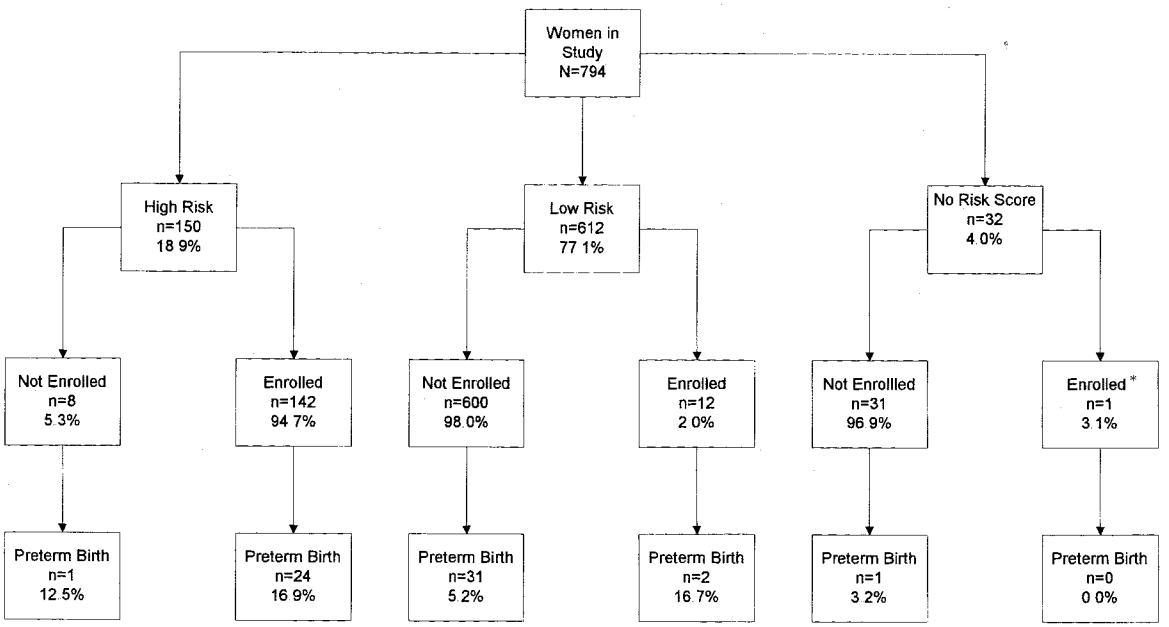
The enrollment and preterm birth rates are summarized in the figure. Of the 794 women in the study, 150 (18.9%) were determined to be high risk based on the risk assessment tool, 612 (77.1%) were identified as low risk, and 32 (4.0%) did not have a risk assessment tool completed. Some women entered the study too late to have a risk assessment tool completed, and in a few cases the physician neglected to complete the tool. The overall preterm birth rate for the 794 women screened was 7.4%, and the mean gestational age was 38.9 ± 2.2 weeks.

One hundred forty-two (94.7%) "high-risk" women were enrolled in the intervention program and 24 (16.9%) of these women delivered preterm with a mean gestational age of 32.1 ± 4.7 weeks. Of the eight high-risk women who were not enrolled, one (12.5%) delivered preterm with a gestational age of 35 weeks. Reasons for not being enrolled included refusals by women to participate in the intervention or lack of a completed risk as-sessment form.

Twelve (2.0%) of the "low-risk" women were enrolled in the intervention program because of other extenuating circumstance (ie, hospitalizations for preterm labor). Of these 12, two (16.7%) delivered preterm with a mean gestational age of 33.5 ± 3.5 weeks. Of the 600 women who were low risk and, therefore, not enrolled in the intervention, 31 (5.2%) delivered preterm with a mean gestational age of 34.3 ± 2.7 weeks. One of the 32 women who had no risk assessment form completed was enrolled in the program and delivered term.

Table 1 shows the preterm and term rates for women categorized as high and low risk by age, education level, work outside the home, physical or stressful work, and pregnancy losses before 14 weeks. Information on race was not available because the managed care organization did not routinely collect these data. The majority of women were between the ages of 20 and 40 years old, high school graduates, married, and working outside of the home. Although not statistically significant, approximately 10% of those in the low-risk preterm group who had one or two previous pregnancy losses or abortions (before 14 weeks) delivered preterm.

Figure. Summary of Enrollment and Preterm Births Based on a High-Risk Score at Either Visit



*The one person enrolled with no risk score was enrolled because of other circumstances.

Table 1. Maternal Demographic Information by Risk and Preterm Status*

	High-Risk Preterm		High-Risk Term		Low-Risk Preterm		Low-Risk Term	
	No.	%	No.	%	No.	%	No.	%
Age (years)								
<18	0	0.0	19	100.0	2	11.7	15	88.2
18-19 or >40	1	5.9	16	94.1	0	0.0	21	100.0
20-40	24	21.1	90	78.9	31	5.4	543	94.6
Education (grade)								
9-11	0	0.0	21	100.0	3	11.1	24	88.9
12+	25	19.4	104	80.6	30	5.1	555	94.9
Marital status								
Married	15	19.2	63	80.8	25	4.9	480	95.1
Single	10	13.9	62	86.1	8	7.5	99	92.5
Work outside the home								
No	5	15.2	28	84.8	4	2.4	162	97.6
Yes	20	17.1	97	82.9	29	6.5	417	93.5
Physical/stressful work								
No	13	17.3	62	82.7	15	3.4	422	96.6
Yes	12	16.0	63	84.0	18	10.3	157	89.7
Pregnancy losses or abortions <14 weeks								
0	13	15.3	72	84.7	24	5.8	392	94.2
1	7	15.9	37	84.1	7	4.9	135	95.1
2	2	20.0	8	80.0	2	4.8	40	95.2
3+	3	27.3	8	72.7	0	0.0	121	100.0

*Risk assessment form was not completed for 32 persons.

Table 2. Results of Logistic Regression Modeling: Outcome Variable Is Preterm Delivery (n=762)*

Variable†	Response	% Preterm	Odds Ratio	95% CI	*P* Value
Work	No	4.5	1.0		
	Yes	8.7	2.0	0.97-4.2	0.06
Physical work	No	5.5	1.0		
	Yes	12.0	2.4	1.4-4.0	0.002
Number of previous preterm births	0	7.1	1.0		
	1-2	17.1	2.7	1.07-6.8	0.04
Twins	No	6.5	1.0		
	Yes	81.8	64.4	13.6-306.2	<0.0001
Total risk	Low‡	5.4	1.0		
	High§	16.7	3.5	2.0-6.1	<0.0001

CI = confidence interval
*32 persons did not have a completed evaluation form.
†Only statistically significant risk factors are reported.
‡Total score is less than 10
§Total score is greater than or equal to 10.

Table 2 shows the results of the logistic regression analysis including odds ratios (OR), corresponding 95% confidence intervals (CI), and two-tail *P* values. The risk assessment tool appeared to be effective in detecting women at risk for preterm labor. The total risk score, dichotomized as high or low, was a statistically significant predictor of preterm births (OR = 3.5, $P < 0.0001$, 95% CI = 2.0-6.1).

The following variables were statistically significant predictors of a preterm birth: physical or stressful work (OR = 2.4, $P = 0.002$, 95% CI = 1.4-4.0), history of prior preterm labor (OR = 2.7, $P < 0.0001$, 95% CI = 1.07-6.8), and multiple gestation (OR = 64.4, $P < 0.0001$, 95% CI = 13.6-306.2). Multiple gestation is believed to be one of the greatest risk factors for preterm birth; therefore, the elevated odds ratio for this population was not unexpected. The variable, work outside the home, was borderline statistically significant (OR = 2.0, $P = 0.06$, 95% CI = 0.97-4.2).

Overall, there were 11 sets of twins born to women included in this study. Ten of the 11 women were enrolled in the intervention program. One mother of twins was not enrolled because she did not complete the second screening and, therefore, was not noted as a multiple gestation on the screening tool. Nine of the 10 women enrolled in the intervention program delivered preterm; however, their gestational ages were all 35 weeks or greater with the exception of one, which was 33 weeks. The gestational ages of the twins ranged from

31 to 40 weeks with a mean age of 36 weeks. Interestingly, the mother of twins who was not enrolled had the shortest gestational period (31 weeks).

··· DISCUSSION ···

The results of this study suggest that the modified version of the Creasy risk assessment tool[11] was useful for identifying women at high risk of preterm labor and their respective risk factors in a health maintenance organization. We successfully enrolled 95% of our high-risk patients into the educational intervention program. However, it was difficult to fully assess the effect of the intervention on preterm birth rates at this time. The studies conducted by Papiernik et al[24] suggest that there is a significant delay from the time a program is implemented until an improvement in outcome can be observed. In addition, they demonstrated a significant education impact that took a number of years before a decrease in the prematurity rate was detected.

The results of our study have been corroborated by other investigators. Papiernik et al[24] reported that questions regarding lifestyle and physical or stressful work; the woman's ability to recognize contractions; and pelvic examinations to determine cervical dilation are the most important parts of their risk assessment system. In France, this research has prompted physicians to prescribe a work leave at 34 weeks or earlier with full salary protection for women at high risk of preterm delivery.[21] Women who obtain prenatal care early are rewarded financially. Also, an extensive educational program on preterm labor has been instituted for all women and caregivers. Women at risk for delivering early are seen more frequently at home by a nurse midwife. Results have shown that the program has been effective in reducing preterm births in France.[25,26]

Our findings are similar to those reported by Mark et al[7] who used the same risk assessment tool. However, they found polyhydramnios to be a significant risk factor for preterm birth, but not physical or stressful work.

Other studies have suggested that physically stressful work can affect the outcome of a pregnancy.[27-29] Luke et al[30] found that preterm birth may be related to the number of hours per day or week worked. A limitation of our study is the lack of specific information about the patient's occupation. There is a potential reporting bias because physical work was based on the patient's perception rather than on an objective measure. More research is needed to determine the effects of physical or stressful work during pregnancy and preterm labor.

The reported success of various preterm labor prevention programs is inconsistent. Many preterm birth prevention programs report a statistically significant improvement in either preterm birth rates or neonatal outcome after implementing prevention efforts,[9,13-16] while many do not.[8,10,12,16] Educating high-risk women and increasing the frequency of patient visits to the physician have been shown to be successful interventions.[7,9,13,14] However, other studies such as the California North Coast Preterm Prevention Project reported no statistically significant decrease in preterm deliveries after implementing similar interventions.[8,10,12,16]

A weakness of the current study is the lack of a randomized control group. All high-risk women were eligible for enrollment in the intervention program. While this precluded a direct measure of the success of the program, comparisons were possible with a similar study conducted by Mueller-Heubach et al,[8] which applied the Creasy et al[11] tool to a population of women also delivering at Magee-Womens Hospital between September 1, 1984, and August 31, 1987. This study reported that 18.1% of their patients were scored as high risk and 21.9% of those women delivered preterm. These authors also reported an overall preterm birth rate of 10.1% and a low-risk preterm birth rate of 7.4%.

Our study reported that 18.9% of the patients were scored as high risk and only 16.7% of those women delivered preterm. In addition, we found an overall preterm birth rate of 7.4% and a low-risk preterm birth rate of 5.4%.

Because preterm birth rates are generally lower for patients treated in private practices compared to those seen in publicly funded clinics, Mueller-Heubach et al[8] studied a large group of private patients. Over a 3-year period the preterm birth rates for private practice patients were reported to be between 8.0% and 8.6%, which is still slightly higher than the overall rates reported in our study population. In addition, the Allegheny County, Pennsylvania, rates have been rising steadily since 1989 (from 8.0% to 9.7%); however, the overall preterm birth rate in our study was only 7.4%.

Without a randomized control population, the sensitivity and specificity of the risk assessment tool cannot be evaluated because the intervention was applied to all eligible high-risk women. Another concern is that women in this study may be subjected to the unnecessary stress of being incorrectly considered high risk. However, as reflected in a patient satisfaction survey, the majority of women in this study found it comforting to receive the additional education and support provided by the nurse case manager. The program benefited women who were reluctant to contact

their physicians with abnormal symptoms because they were encouraged to call for confirmation that they needed further assessment by the physician.

While the risk assessment tool significantly identified women at risk of preterm births, there is room for improvement. Of the 600 low-risk women who were not enrolled in the intervention, 31 (5.2%) still delivered preterm. Assuring that the risk assessment forms were completed and scored correctly was difficult. There was a need for constant follow-up with regards to form completion and referral information. A majority of the physicians felt the risk form to be very long and cumbersome. In future studies, simplification of the risk assessment tool could overcome some of these problems.

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Appendix. Patient Questionnaire

Patient Questionnaire (PLEASE ANSWER QUESTIONS 1-19 ONLY) SCREENING DATE:_____

					SCORE
1. What is your age? _____	❑ ≤ 17= 4		❑ 18 or 19 = 2	❑ > 40 = 2	
2. If you are not a high school grad, please check:	❑ 9th -11th grade = 1		❑ Less than 9th grade = 2		
3. Are you single?	❑ No		❑ Yes = 2		
4. Is your height less than five feet?	❑ No		❑ Yes = 3		
5. Was your pre-pregnant weight less than 100lbs.?	❑ No		❑ Yes = 3		
6. Do you work outside the home?	❑ No		❑ Yes = 1		
If yes, is your work physical or stressful?	❑ No		❑ Yes = 3		
7. Is your driving time to work one hour or more?	❑ No		❑ Yes = 3		
8. Do you smoke?	❑ No		❑ 1 1/2 packs/day or less = 1	❑ > 1 1/2 packs/day = 4	
9. Have you used drugs during this pregnancy? (cocaine, marijuana, etc.)	❑ No		❑ Yes = 5		
10. Have you had 2 or more alcoholic drinks per week during this pregnancy?	❑ No		❑ Yes = 2		
11. Do you live in a stressful social situation?	❑ No		❑ Yes = 2		
12. Have you delivered a baby within the last year?	❑ No		❑ Yes = 1		
13. How many preschoolers at home (include daycare)?	❑ 0 or 1		❑ 2 or 3 = 1	❑ 4 or more = 2	
14. Have you had any kidney (not bladder) infections?	❑ No		❑ Yes = 4		
15. Have you had a cone biopsy of your cervix?	❑ No		❑ Yes = 5		
16. How many pregnancy losses or abortions before 14 weeks?	❑ None	❑ 1 = 1	❑ 2 = 2	❑ 3 or more = 3	
17. How many pregnancy losses or abortions after 13 weeks?	❑ None		❑ 1 or 2 = 5	❑ 3 or more = 10	
18. Did your mother take DES when pregnant with you?	❑ No		❑ Don't know	❑ Yes = 10	
19. Do you have a prior history of premature labor?	❑ No		❑ Yes = # x 10		
			ANTEPARTUM SCORE / SCREENER'S INITIALS		

Provider Assessment

		(INITIAL VISIT) 8-15 WEEKS		24-28 WEEKS		UPDATE	
SCREENING DATE/#WEEKS GESTATION							
20. Bleeding > 12 weeks?	❑ Yes = 4						
21. Bacteriuria, chlamydia, GC this pregnancy?	❑ Yes = 2						
22. Fibroids ❑ Yes = 3 Previous myomectomy	❑ Yes = 10						
23. Uterine anomaly	❑ Yes = 5						
24. Surgery (abdominal) ≥ 18 weeks (or cerclage)	❑ Yes = 10	N/A					
25. Multiple pregnancy	❑ Yes = 10						
26. Febrile illness	❑ Yes = 3						
27. Weight gain at 22 weeks of < 7 lbs.	❑ Yes = 2	N/A					
28. Weight loss before 34 weeks of > 5 lbs	❑ Yes = 3						
29. Placenta previa at 26 weeks or more	❑ Yes = 5	N/A					
30. Uterine irritability before 34 weeks	❑ Yes = 4						
31. Presenting part engaged ≤ 32 weeks	❑ Yes = 3	N/A					
32. Cervical length < 1 cm at < 34 weeks	❑ Yes = 4	N/A					
33. Dilation ≥ 1 cm at < 34 weeks	❑ Yes = 4	N/A					
34. Oligohydramnios < 34 weeks	❑ Yes = 5						
35. Polyhydramnios < 34 weeks	❑ Yes = 5						
36. Urine protein ≥ 1+	❑ Yes = 2						
37. Hypertension (on medications)	❑ Yes = 2						
38. Autoimmune diseases (lupus, ↑ activated PTT)	❑ Yes = 5						
39. Positive BV	❑ Yes			N/A			
40. Positive Trich	❑ Yes			N/A			
SUBTOTAL/ANTEPARTUM SCORE							
TOTAL SCORE/SCREENER'S INITIALS							

(PA-1060)