

## MONITORING WOMEN AT RISK FOR PRETERM LABOR

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**ABSTRACT**

**Background** Preterm birth is a major cause of perinatal morbidity and mortality. Whether the rate of preterm birth can be reduced by frequent contact between nurses and pregnant women or home monitoring of uterine activity is not known.

**Methods** We randomly assigned 2422 pregnant women with known risk factors for preterm labor (including 844 women who were pregnant with twins) to receive education and to have one of the following: weekly contact with a nurse, daily contact with a nurse, or daily contact with a nurse and home monitoring of uterine activity. The nurses elicited the women's own assessments of their symptoms and signs of preterm labor. The primary end point was the incidence of birth at less than 35 weeks' gestation. Secondary end points included cervical status at the time preterm labor was diagnosed and birth weight.

**Results** There were no significant differences among the groups in the incidence of birth at less than 35 weeks (14 percent in the weekly-contact group, 13 percent in the daily-contact group, and 14 percent in the home-monitoring group), in the mean amount of cervical dilatation at the time preterm labor was diagnosed (1.8 cm, 1.5 cm, and 1.4 cm, respectively), or in such neonatal outcomes as birth weights of less than 1500 g or less than 2500 g. However, daily contact with a nurse increased the mean number of unscheduled visits to obstetricians (1.2 in the weekly-contact group, 1.8 in the daily-contact group, and 2.3 in the home-monitoring group) and the proportion of women who received prophylactic tocolytic drugs (12 percent, 14 percent, and 19 percent, respectively).

**Conclusions** Women who have daily contact with a nurse, with or without home monitoring of uterine activity, have no better pregnancy outcomes than women who have weekly contact with a nurse. (N Engl J Med 1998;338:15-9.)

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**P**RETERM birth is the main cause of perinatal mortality and morbidity.<sup>1</sup> Early detection of preterm labor is important, because tocolytic therapy is most effective when given soon after labor starts and before advanced cervical dilation has occurred. Traditionally, programs for the prevention of preterm delivery have emphasized the identification of high-risk pregnancies, patient education, self-palpation for uterine contractions, and frequent cervical examinations.<sup>2</sup>

Home monitoring of uterine activity may increase

the early detection of preterm labor, but the results of randomized, controlled trials of its efficacy have been inconsistent. In some small studies, it facilitated earlier detection of preterm labor, resulting in lower rates of preterm birth,<sup>3-6</sup> whereas in other studies there was no benefit.<sup>7,8</sup> Recently, concern has arisen about the design of these studies, including the way withdrawals were handled, the restriction of analysis to subgroups, and the appropriateness of the end points.<sup>9-11</sup>

We undertook this study to determine whether adding home monitoring of uterine activity to daily contact with a nurse would improve clinical outcomes and whether daily contact with or without the use of a monitor would be more effective than weekly contact for pregnant women at increased risk for preterm labor. Our primary end point was the incidence of preterm birth at less than 35 weeks' gestation.

**METHODS****Study Subjects**

All women receiving prenatal care at 30 Kaiser Permanente clinics in northern California were routinely screened for 14 risk factors for preterm labor, and those with at least 1 risk factor were eligible for the study. In addition, women were eligible if they had no preterm labor or premature rupture of membranes during the current pregnancy before enrollment, the gestational age was confirmed by ultrasonography by 24 weeks' gestation, they had access to a telephone, they were willing to comply with the study protocol, and they were at least 14 years old. The women with preexisting risk factors for preterm labor were enrolled between 24 and 30 weeks' gestation, and the women with risk factors that developed during the current pregnancy were enrolled before 33 weeks' gestation. The study protocol was approved by the Central Research Committee of the Kaiser Permanente Medical Care Program, Northern California, and by the Institutional Review Board of Kaiser Foundation Research Institute. Informed consent was obtained from all the participating women.

**Randomization**

After enrollment, the women were assigned to one of three treatment groups in a ratio of 1:1:1 with the use of a computer-generated randomization sequence. Randomization was stratified according to whether the women were pregnant with twins or at-risk singletons. The women who had preterm labor received care at eight tertiary centers. To control for possible differences in treatment philosophy, the randomization was also stratified according to treatment center.

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### Study Design

The treatment groups were those who had weekly contact with a nurse (the weekly-contact group), those who had daily contact with a nurse (the daily-contact group), and those who had daily contact plus home monitoring of uterine activity (the home-monitoring group). All the women received education about the symptoms and signs of preterm labor, such as changes in vaginal discharge, cramping, and backache; about the importance of early diagnosis and treatment; and about the way to palpate themselves for uterine contractions. An excessive number of contractions was defined for the women with singleton pregnancies as four or more contractions per hour and for the women with twin pregnancies as six or more contractions per hour. The women were asked to record their symptoms and signs as well as the number of contractions in a daily log. These 30-to-45-minute educational sessions followed a standard outline and used a teaching checklist.

The women in the weekly-contact group were asked to assess themselves for symptoms and signs of preterm labor and to palpate themselves for uterine contractions for one hour twice daily. The women who reached or exceeded their contraction thresholds or had symptoms or signs of preterm labor were asked to lie down, keep themselves hydrated, and palpate for another hour. If the symptoms or signs persisted or the contractions continued at or above the threshold, the women were told to call their obstetricians or labor-and-delivery units for evaluation. A nurse from a perinatal-service center called the women weekly to review their daily logs and to reinforce the importance of assessing their symptoms and palpating themselves for uterine contractions.

A nurse from a perinatal-service center called the women in the daily-contact group each day to review their symptoms and signs and the results of their twice-daily self-palpations for uterine contractions. These women were instructed to call the center if their symptoms or signs persisted or if their contractions continued to exceed their thresholds. The perinatal nurse then helped the women contact their obstetricians or labor-and-delivery units for evaluation.

The women in the home-monitoring group were each given a device (Corometrics 600, Corometrics Medical Systems, Wallingford, Conn.) that monitors uterine activity, stores the monitored information, and transmits it to a central receiver through telephone lines. The women were asked to use the device for one hour each morning and evening and to transmit the information after each session. The tracings were reviewed immediately, and any woman whose number of contractions per hour exceeded her threshold was called immediately. All the women were called daily to review their tracings and any symptoms or signs. The women were asked to call the center any time they had persistent symptoms or signs or wished to send emergency tracings. The perinatal nurse then helped the women contact their obstetricians or labor-and-delivery units for evaluation.

The women's obstetricians or nurse practitioners were aware of and consented to the women's participation in the study but were not informed of the group to which the women were assigned. The women and the perinatal-service nurses were instructed not to inform the obstetricians of the group assignments. The women and the perinatal-service nurses were also instructed not to divulge the method of detecting uterine activity (i.e., by palpation or monitoring device) when they reported increased uterine activity to the obstetricians.

### Obstetrical Care

The women received care from their primary obstetricians or nurse practitioners, who were asked to follow broad care guidelines. These guidelines encouraged examinations of the cervix every 2 weeks, suggested specific criteria for the diagnosis of preterm labor, and recommended aggressive use of tocolytic drugs for preterm labor at less than 35 weeks' gestation, but they discouraged the prophylactic administration of tocolytic drugs (defined as the administration of tocolytic drugs to women with or without symptoms who did not meet the criteria for preterm labor). The criteria for preterm labor were regular contractions ( $\geq 6$  per hour) and ei-

ther progressive effacement or dilatation of the cervix or cervical dilatation of  $\geq 2$  cm. The use of tocolytic drugs and glucocorticoids was left to the discretion of the obstetrician.

The women were followed according to their group assignments until either preterm delivery or 36 weeks' gestation. The guidelines of the initial group assignments were used to continue observing those who had preterm labor, except for 20 women whose obstetricians requested a specific change in services, such as providing home monitoring of uterine activity or daily contact that had not been initially assigned.

### Statistical Analysis

Birth at less than 35 weeks' gestation was the primary study end point. Other end points were cervical dilatation at the time preterm labor was diagnosed, the change in the amount of cervical dilatation from the time of the previous examination to the time preterm labor was diagnosed, the number of unscheduled visits to an obstetrician, and surrogate markers for neonatal morbidity, such as birth weight, admission to an intensive care nursery, the number of days of oxygen or ventilator therapy, and the length of time the infant remained in the hospital.

For data analysis, preterm labor was diagnosed if regular contractions persisted with progressive effacement or dilatation of the cervix or if the cervix was dilated  $\geq 2$  cm. Women given a tocolytic drug for symptoms or signs that did not meet the criteria for preterm labor were considered to have received a prophylactic tocolytic drug after symptoms appeared. Unscheduled visits were defined as visits other than those scheduled for prenatal care.

Statistical analyses were performed on both an intention-to-treat and a completion-of-protocol basis. We present only the former because the results of the two analyses were similar. We also analyzed the data on at-risk singleton pregnancies and twin pregnancies separately. Additional analyses were then performed for the at-risk singleton pregnancies according to risk factor. All the data were analyzed by personnel of the Kaiser Permanente Division of Research using the chi-square test and Student's *t*-test. Wilcoxon's rank-sum test was used for the variables of cervical dilatation at the time preterm labor was diagnosed and the change in cervical dilatation. Because each treatment group was compared with two other groups, a *P* value of 0.025 was considered to indicate statistical significance.

Twin pregnancies were analyzed as if they had a single outcome. For continuous variables, such as birth weights, the mean of the two twin-pregnancy values represented the pregnancy outcome. For discrete variables, such as admissions to an intensive care nursery, if either infant had the outcome the pregnancy was considered to have had that outcome. To ensure the patients' safety, the results of the study were analyzed in a blinded fashion after each quartile of the required sample of 2154 women had given birth.<sup>12</sup>

## RESULTS

Between July 1992 and August 1996, we identified 3455 women as being eligible for the study. Their obstetricians recommended that 348 women (10 percent) not participate, and an additional 627 women (18 percent) declined to participate. Thus, 2480 women (72 percent) were enrolled in the study. After enrollment but before randomization, 58 women (2 percent) either gave birth or withdrew their consent. Thus, 2422 women were randomly assigned to one of the three treatment groups. All completed the study, but 93 women (4 percent of those randomized) did not receive the surveillance to which they had been assigned.

The characteristics of the 2422 women are shown in Table 1, and the distribution of risk factors for preterm labor among the three groups is shown in

Table 2. There were no significant differences in demographic characteristics or risk factors among the three groups.

There were no significant differences among the three groups in the incidence of preterm birth at less than 37, less than 35, or less than 32 weeks' gestation for either all the women or those with twin pregnancies (Table 3). Similarly, there were no intergroup differences in mean birth weight, in the percentage of women having a baby weighing less than 1500 g or less than 2500 g, or in any surrogate markers for neonatal morbidity, such as the percentage of infants admitted to neonatal intensive care units, the number of days of oxygen or ventilator therapy, or the length of time the infant remained in the hospital. The incidence of neonatal mortality was also similar in the three groups (5.6 percent in the weekly-contact group, 3.7 percent in the daily-contact group, and 5.4 percent in the home-monitoring group).

The number of unscheduled visits to obstetricians was lowest in the weekly-contact group, higher in the daily-contact group, and highest in the home-monitoring group (Table 3). Before any symptoms of preterm labor appeared, 1.1 percent of the women received prophylactic tocolytic drugs; the proportions were similar in the three groups. However, the proportions of women who received tocolytic drugs prophylactically after symptoms of preterm labor appeared varied significantly, being lowest in the weekly-contact group and highest in the home-monitoring group (Table 3).

Preterm labor at less than 35 weeks' gestation was diagnosed slightly more often in the home-monitoring group ( $P=0.06$ ). Among the women who had preterm labor at less than 35 weeks' gestation, there were no intergroup differences in mean cervical dilatation or in the change in cervical dilatation from that at the previous examination (Table 4). There also were no differences in the percentages of women with cervical dilatation of  $\leq 2$  or  $\leq 3$  cm.

For women who had preterm labor at less than 35 weeks' gestation, there were no differences in neonatal outcomes among the three groups. The mean gestational ages at the time preterm labor was diagnosed and at delivery, the mean numbers of days gained (numbers of days from diagnosis of preterm labor to delivery), and the percentages of women who delivered at more than 35 weeks' gestation were similar in the three groups. Therefore, outcomes in the daily-contact and home-monitoring groups did not improve despite more unscheduled visits to obstetricians and greater use of tocolytic drugs.

In the women with singleton pregnancies, there were no differences in the incidence of preterm birth at less than 35 weeks' gestation or in cervical status at the time preterm labor was diagnosed among the three groups. In addition, no differences in outcomes were evident in the largest subgroup of

**TABLE 1.** CHARACTERISTICS OF THE WOMEN IN THE WEEKLY-CONTACT, DAILY-CONTACT, AND HOME-MONITORING GROUPS.\*

CHARACTERISTIC	WEEKLY CONTACT (N=798)	DAILY CONTACT (N=796)	HOME MONITORING (N=828)
Maternal age (yr)	30±6	29±6	29±6
Maternal gravidity	3±2	3±2	3±2
Maternal parity	1±1	1±1	1±1
Nulliparity (%)	31	32	32
Race or ethnic group (%)			
White	52	53	53
Black	14	14	15
Hispanic	18	17	17
Asian	7	7	8
Other	9	9	7
Non-English-speaking (%)	5	4	5
Education level (%)†			
<High-school graduation	9	9	9
High-school graduation	24	21	23
Some college	41	41	40
College degree	27	29	27
Single parent (%)	14	12	13
Cocaine use (%)‡			
During pregnancy	1	1	1
Before pregnancy	13	16	16

\*There were no significant differences in any characteristic among the three groups. Plus-minus values are means ±SD.

†Because of rounding, the percentages do not all total 100.

‡Data were self-reported.

**TABLE 2.** NUMBERS OF WOMEN ENROLLED ACCORDING TO RISK FACTOR AND TREATMENT GROUP.

RISK FACTOR	WEEKLY CONTACT	DAILY CONTACT	HOME MONITORING
	no. of women		
Twin gestation	280	277	287
Prior preterm birth at <34 wk	154	149	164
Prior preterm labor at <34 wk	138	142	135
Incompetent cervix with cerclage in place	40	36	43
Nullipara			
Uterine anomaly	14	16	23
Diethylstilbestrol exposure	7	8	16
Cone biopsy — no subsequent term delivery	50	34	37
≥2 Second-trimester abortions	26	30	18
Abdominal surgery at >18 wk	5	4	2
Cocaine or amphetamine use continuing in current pregnancy*	11	11	15
Cervix dilated >1 cm at <32 wk	19	20	21
Cervix <1 cm long at <32 wk (digital examination)	32	34	40
Polyhydramnios	10	11	9
Uterine irritability	85	92	81

\*Data were self-reported.

**TABLE 3. OUTCOMES OF PREGNANCY IN THE WEEKLY-CONTACT, DAILY-CONTACT, AND HOME-MONITORING GROUPS.**

OUTCOME	ALL WOMEN (N=2422)			WOMEN WITH TWIN PREGNANCIES (N=844)		
	WEEKLY CONTACT (N=798)	DAILY CONTACT (N=796)	HOME MONITORING (N=828)	WEEKLY CONTACT (N=280)	DAILY CONTACT (N=277)	HOME MONITORING (N=287)
Preterm birth (%)						
<37 wk	30	31	30	49	54	51
<35 wk	14	13	14	22	24	24
<32 wk	4	5	4	7	9	6
Birth weight						
<1500 g	4	4	4	6	8	9
<2500 g	26	26	28	52	55	59
No. of unscheduled visits*†	1.2±1.5	1.8±2.0	2.3±2.3	1.3±1.5	1.9±2.0	2.5±2.4
Prophylactic tocolytic-drug therapy (%)‡	12‡	14‡	19‡	8‡	11	16‡
Preterm labor <35 wk (%)	23	22	27	35	34	40

\*Plus-minus values are means ±SD. P<0.002 for all comparisons between treatment groups.

†Therapy was given after symptoms appeared but before the criteria for preterm labor were met.

‡P<0.01 for the comparisons between the weekly-contact or the daily-contact and the home-monitoring groups for all the women and between the weekly-contact and home-monitoring groups for the women with twin pregnancies.

**TABLE 4. OUTCOMES OF PREGNANCY IN WOMEN WITH PRETERM LABOR AT <35 WEEKS IN THE THREE TREATMENT GROUPS.\***

OUTCOME	ALL WOMEN (N=582)			WOMEN WITH TWIN PREGNANCIES (N=304)		
	WEEKLY CONTACT (N=184)	DAILY CONTACT (N=176)	HOME MONITORING (N=222)	WEEKLY CONTACT (N=97)	DAILY CONTACT (N=93)	HOME MONITORING (N=114)
Cervical dilatation (cm)	1.8±2.0	1.5±1.2	1.4±1.2	1.8±1.7	1.7±1.3	1.4±1.2
Change in dilatation from previous examination(cm)	1.6±2.0	1.2±1.1	1.2±1.1	1.5±1.7	1.4±1.2	1.2±1.1
Dilatation category (%)						
≤2 cm	77	77	82	75	76	80
≤3 cm	89	93	92	92	90	92
Gestational age (days)						
At preterm labor	217±20	217±19	215±21	217±20	219±19	213±22
At delivery	243±23	245±21	246±23	238±20	242±20	243±22
Mean no. of days gained	26±26	28±24	31±25	22±22	23±20	29±26
Delivery at <35 wk (%)	46	51	56	41	46	50

\*Plus-minus values are means ±SD. There were no significant differences in outcome in the women with preterm labor among the three groups (P>0.025 in all cases).

women with singleton pregnancies — i.e., those with previous preterm deliveries — despite their having made more unscheduled visits and used more tocolytic drugs prophylactically after symptoms appeared. This study had a power of more than 95 percent to detect a 1-cm difference between groups in cervical dilatation at the time of preterm-labor diagnosis for all study participants, for women with twins, and for women with at-risk singletons.

The women in the home-monitoring and daily-contact groups complied with the requirement of at least one daily session of monitoring uterine contractions 86 percent of the time, as compared with

79 percent in the weekly-contact group. No woman reported adverse effects of participating in this study; however, 24 (1 percent) had complications resulting from tocolytic-drug therapy, including pulmonary edema, chest pain, and hyperglycemia.

### DISCUSSION

Much of the controversy about the efficacy of home monitoring of uterine activity results from the inconsistent levels of care received by the control groups with which the home-monitoring groups in other studies have been compared. Most studies reporting a benefit of home monitoring<sup>4,6,13</sup> have com-

pared women receiving this intervention with women who attended one educational session on the symptoms and signs of preterm labor and received some instruction on self-palpation of the uterus. Although these studies have suggested that the monitoring device can facilitate early diagnosis of preterm labor, they have not addressed whether more frequent contact between nurses and pregnant women could accomplish the same goal.

We found that adding the monitoring device to daily contact with a nurse did not improve either the early detection of preterm labor or the outcome of pregnancy, a finding consistent with the results of all previous studies comparing home monitoring with frequent contact with a nurse (five to seven days per week).<sup>7,8,14,15</sup> We therefore ask, how much education and contact with a provider is necessary to achieve results similar to those of home monitoring? In our study, we found no difference in cervical status at the time preterm labor was diagnosed or in pregnancy outcome between the women contacted weekly and those contacted daily.

We think the similarity in outcome between our weekly-contact group and the other two groups resulted from three factors. First, educational consistency was ensured by the use of a standard outline and a teaching checklist. Second, women were asked to palpate their uteruses for contractions routinely and keep a daily log of contractions and the symptoms and signs of preterm labor. Third, each woman was scheduled for weekly contact with a designated nurse who reviewed her daily logs and reminded her to seek help if she suspected preterm labor. Health-education studies suggest that frequent reinforcement of desired behavior alters patients' behavior more effectively than a single educational session.<sup>16,17</sup>

The incidence of preterm labor diagnosed at less than 35 weeks' gestation was slightly but not significantly higher in the home-monitoring group than in the weekly-contact group. However, the significant, progressive intergroup increase in the number of unscheduled visits to obstetricians suggests that more intensive surveillance promoted more unscheduled visits. Increased surveillance was also accompanied by greater prophylactic use of tocolytic drugs in women who had some symptoms of preterm labor and contractions but who did not meet the criteria for a diagnosis of preterm labor. The additional unscheduled visits and use of tocolytic drugs did not improve clinical outcomes.

This study had a power of more than 95 percent to detect a 1-cm difference in cervical dilatation at the time preterm labor was diagnosed in the three major analysis groups (all women, women carrying twins, and women carrying at-risk singletons). Without at least a 1-cm difference in mean cervical dilatation at the time of preterm-labor diagnosis, improvement in the perinatal outcome would be highly unlikely.

In conclusion, for both at-risk singleton and twin pregnancies, we found that neither daily contact with a nurse nor home monitoring of uterine activity provided additional benefit in terms of preventing preterm delivery, as compared with education, daily uterine self-palpation, and weekly contact with a nurse, among culturally diverse, well-educated, and predominantly middle-class women. In fact, adding daily contact or home monitoring increased the number of unscheduled visits and the prophylactic administration of tocolytic drugs without improving outcomes.

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