EVALUATION OF PARTICIPATION IN A
PRETERM BIRTH PREVENTION PROGRAM

by

B. Anthony Armson, MD, FRCS(C)

Submitted in partial fulfillment of the requirements for the degree of Master of Science

at

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ABSTRACT

Objectives:

1. To determine if participation in the Halifax County Preterm Birth Prevention Project (HCPBPP) by women at low and/or high risk for preterm labour resulted in a reduction in their risk of preterm labour.

2. To evaluate the degree to which specific components of the program contributed to preterm birth risk reduction.

Methods:

A case-control design was used to select Halifax County postpartum women during the final year of the HCPBPP for interviewer-administered questionnaires. Cases were defined as women who delivered preterm (<37 wks) and controls were full term parturients. Three controls per case were sequentially selected. The exposures of interest were overall participation and the effect of specific components of the program. Data analysis employed univariate and multivariate statistical methods.

Results:

Seventy cases and 210 controls were enrolled in the study. Although 82% of subjects participated in some aspect of the program, only 8% of high risk and 6% of low risk women complied fully with the program recommendations. Exposure to the project educational component and/or pelvic examinations alone or in combination provided no protective benefit for preterm birth in low or high risk women. However, compliance with prenatal care providers’ recommendation to restrict activity and/or monitor for uterine contractions by self-palpation was associated with a marked reduction in the risk of preterm birth in low risk women (OR 0.20, CI 0.08-0.50).

Conclusion:

Although full participation in the HCPBPP protocol was limited, activity restriction and uterine activity monitoring by self palpation may reduce the likelihood of preterm birth in women with no identifiable risk factors for prematurity.
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CHAPTER 1: INTRODUCTION

Preterm birth is the single most important determinant of perinatal mortality and morbidity in the industrialized world.\(^1\) The preterm birth rate in Canada had remained stable at approximately six percent for decades,\(^2\) but recent evidence indicates a steady increase in the incidence of prematurity in Canada similar to that observed previously in the United States.\(^3\)\(^4\) Obstetric management of prematurity has been directed primarily toward pharmacologic inhibition of uterine contractions. Although some tocolytic agents have been shown to delay delivery by 48 hours and to prolong gestation in selected cases, randomized control trials have failed to demonstrate overall reduction in preterm birth rates attributable to tocolytic therapy.\(^5\)\(^6\) The few medications which have been shown to arrest premature labour may cause significant and even life threatening complications to the mother and/or fetus.\(^7\)\(^8\)

Since the early 1980's, multiple intervention preterm birth prevention programs have been developed and evaluated in a variety of settings with variable results.\(^9\) Programs designed for women at increased risk for preterm birth have generally included specialized high-risk clinics, frequent antenatal visits, comprehensive education sessions, regular cervical exams, uterine activity monitoring, bedrest, and psychosocial support. With a few exceptions, randomized control trials of preterm birth prevention programs in high-risk obstetric populations have shown no reduction in preterm birth rates.\(^10\) Using a population-based approach, Papiernik and others have reported significant reductions in preterm birth rates in observational studies.\(^10\) Such programs provide education about prematurity and
their health care providers and encourage women to participate in the prevention of preterm birth through enhancement of self-managed early intervention. The encouraging results of these studies support further research into population-based preterm birth prevention strategies.

The effectiveness of preterm birth prevention programs is measured by the preterm birth rate. In most studies, participation in prevention programs by women and their health care providers has been assumed without confirmational evidence. Successful population-based prevention programs have employed multiple prevention strategies making it difficult to discern which of the interventions was responsible for observed beneficial effects. Although many of these interventions have been studied independently, there is very little information regarding the degree to which specific components of a population-based prevention program influence the preterm birth rate. The effect of participation on perinatal outcome in women at increased risk for preterm birth compared to women with no known risk factors has not been evaluated. In order to develop preterm birth prevention policies, the effectiveness of specific interventions of a population-based preterm birth prevention programs need to be evaluated.
CHAPTER 2: BACKGROUND INFORMATION AND LITERATURE REVIEW

2.1 Epidemiology of Preterm Birth

2.1.1 Definition

Preterm birth is defined by the World Health Organization as birth occurring before 37 completed weeks (<259 days) gestation.\textsuperscript{11} Low birth weight (LBW), which has been used as a proxy for preterm birth, indicates a birth weight of <2,500 g. Since such infants may be premature, small for gestational age, or both, low birth weight is not an accurate substitute for preterm birth. Infants weighing <1,500 g at birth are categorized as very low birth weight (VLBW) infants. Lower gestational age cut offs (28, 30, 32, or 34 weeks) are sometimes used to identify subgroups of premature infants who are at increased risk of neonatal mortality and morbidity.\textsuperscript{12} The lower limit of preterm birth is defined by birth weight (>500 g) in some areas and by various gestational ages in others. In Nova Scotia, preterm birth is defined as delivery occurring before 37 completed weeks' gestation with a birth weight >500 g or a gestational age of >20 completed weeks’ gestation.

The accuracy of the preterm birth rate is directly related to the accuracy of gestational age determination. Gestational age is calculated from the first day of the last menstrual period (LMP) which normally occurs two weeks prior to conception. In approximately 20 percent of pregnancies, the LMP is uncertain and in a smaller percentage of the remainder, the variable length of the menstrual cycle results in under or overestimation of gestational age. Although first and second trimester ultrasound has been helpful in improving the accuracy of gestational age determination, there is, as yet, no true “gold standard”.

3
2.1.2 Incidence

Despite significant advances in perinatal care over the past 20 years, there has been little change in the preterm birth rate in most industrialized countries. Prior to 1990, the incidence of preterm birth in Canada had remained stable at between 6 and 6.5% (25,000/year) for the previous 20 years. This increase appears to be due to changes in the frequency of multiple births, increases in obstetrical intervention, improved registration of early gestation births, and increased use of ultrasound-based estimates of gestational age. The incidence of low birth weight (less than 2500 grams) in Nova Scotia remained relatively unchanged between 1976 and 1995 at approximately 6% (Fig. 1). During the eight-year period between 1988 and 1995, the preterm live birth rate in Nova Scotia increased gradually from 5.34% to 5.89% (Fig. 2, unpublished data from the Nova Scotia Atl Lee Perinatal Database).

Although international comparisons of preterm birth rates are problematic because of differences in the completeness of registration of births, varying definitions of prematurity, and inconsistent ascertainment of gestational age, available data suggests that rates of preterm birth and low birth weight are higher in Canada and the United States than many other industrialized countries. In the United States, the incidence rose from 9.4% in 1981 to 10.7% in 1989. In Great Britain, the preterm birth rate declined only slightly from 5.4% in 1958 to 5.1% in 1970, then increased gradually to 6.3% in 1990. In Sweden, there has been a gradual increase in the preterm birth rate from 5.5% in 1973 to 6.1% in 1990. In contrast, the rate of preterm births in France has dropped from 8.2% in 1972 to 4.8% in 1989.
Figure 1. Low birth weight rate (500-2,499 g) in Nova Scotia from 1976 to 1995.
Figure 2. Preterm birth rate in Nova Scotia from 1988 to 1995.
2.1.3 Burden of Suffering

Prematurity continues to be the major cause of perinatal mortality and morbidity, accounting for 75 to 85% of neonatal deaths not associated with lethal abnormalities.\textsuperscript{17,18} Premature infants are more likely to utilize specialized neonatal intensive care resources for resuscitation and treatment of severe respiratory disorders, patent ductus arteriosus, sepsis, necrotizing enterocolitis, intraventricular hemorrhage, and bronchopulmonary dysplasia. In Canada, the estimated cost for these services is approximately 100 million dollars per year.\textsuperscript{19}

Data from the Neonatal Follow-up Program of Nova Scotia indicate that up to 50% of extremely preterm survivors (24-26 weeks gestation) will have a major disability. The probability of residual disability decreases with increasing gestational age, but remains significant for Nova Scotian infants born before 31 weeks gestation with a 15% incidence of major disability and 10% incidence of cerebral palsy. Children born prematurely are also more likely to require special education during their first year of primary school, may be disadvantaged in terms of cognitive ability in school performance, and use significantly more resources with a much lower health-related quality of life.\textsuperscript{20-22}

The economic consequences of prematurity are considerable. A conservative estimate based on Canadian data suggests that the lifetime cost for every surviving preterm infant with a birth weight of less than 2500 g averages more than $600,000.\textsuperscript{19} This estimate takes into account the use of neonatal intensive care, rehospitalization during the first year of life and the average lifetime cost of handicapped survivors.
2.1.4 Determinants of Preterm Birth

Although the etiology of preterm birth is unknown, the onset of premature uterine contractions appears to arise from multiple and diverse causes. The principal pathways leading to preterm birth are spontaneous preterm labour, preterm premature rupture of membranes (PROM), and medical intervention. Spontaneous preterm labour precedes approximately 40% to 50% of preterm deliveries and has been associated with premature cervical change and formation of gap junctions between uterine muscle fibers which promote contractions and an increase in oxytocin receptors. Preterm PROM is associated with 30% to 40% of preterm births and may be related to subclinical infection or weakening of the membranes secondary to subclinical uterine activity. Medically indicated or iatrogenic preterm birth represents early delivery because of either maternal or fetal complications and represents approximately 20% to 30% of preterm deliveries.

Numerous sociodemographic, historical, pregnancy-related, and maternal medical factors have been associated with preterm birth. Risk factors known to increase the likelihood of preterm birth include: previous preterm birth or low birth weight infant, multiple gestation, uterine abnormalities, multiple second trimester abortions, antenatal bleeding, placental abnormalities, polyhydramnios, abdominal surgery, fetal anomalies, black race, low socioeconomic status, cigarette smoking, and single marital status. Previous preterm birth and multiple gestation are the most common risk factors associated with prematurity. Socioeconomic status has been variously defined on the basis of education, occupation, and family income. Most investigators have found an increased risk of preterm
delivery in women of low socioeconomic status. However, educational level has not been clearly associated with prematurity.

Probable risk factors for preterm birth include: fetal growth retardation, urogenital infections, inadequate prenatal care, and seasonality. In North America, the probability of preterm birth increases during the late summer/early fall and mid to late winter.\textsuperscript{25,26} The reason for such secular trends are unclear, but may be related to seasonal variation and urogenital infection and/or reproductive hormonal levels.

Factors which have been weakly associated with preterm birth include: short interpregnancy interval, prior first trimester induced abortion, sexual activity during pregnancy, alcohol consumption, cocaine abuse, caffeine intake, maternal age, parity, maternal weight gain, dietary intake, and infant gender. Factors which remain inconclusive in the determination of preterm birth include: low pre-pregnancy weight, employment related physical activity, psychosocial stress, short stature, and anemia.

The influence of physical activity on preterm birth remains controversial. Numerous studies have reported that employed women either have no increased risk or a reduced risk of preterm birth when compared with women who are not employed.\textsuperscript{27-30} To the contrary, some studies have demonstrated that certain working conditions are associated with increased risk of preterm birth, particularly among women in occupational categories that involve prolonged standing, physically strenuous work, long working hours, or a physically uncomfortable environment.\textsuperscript{38,31-35}

In summary, many risk factors for prematurity have been identified with varying degrees of influence on pregnancy outcome. Even so, only 10 to 25% of preterm births
occur in women with known risk factors. Factors which significantly increase the risk of preterm birth include: previous preterm birth, second trimester abortion, uterine anomaly, fetal anomaly, multiple gestation, abdominal surgery, polyhydramnios, placenta previa, antepartum bleeding, premature cervical change, and premature uterine contractions.

2.2 Interventions for Prediction and Prevention of Preterm Birth

2.2.1 Risk-Scoring Systems

Identification of risk factors associated with preterm delivery has been promoted as a necessary component of preterm birth prevention programs. Since 1969, when Papiernik first proposed a coefficient of risk for preterm birth based on previous medical and social history, current pregnancy problems and lifestyle, numerous risk scoring systems have been developed. The ability of these risk assessment protocols to predict spontaneous preterm birth has been variable with sensitivities of 35-60% and positive predictive values of only 15-30%. However, when combined with other markers for prematurity such as uterine activity, premature cervical change, and markers of infection/inflammation and psychosocial stress, risk scoring has proven to be useful in identifying women at high risk for prematurity. Recent reports suggest that risk-scoring systems derived from one obstetric population may not be applicable to other patient populations. Consequently, the development of population-specific preterm birth assessment protocols has been recommended.

2.2.2 Education About Preterm Labour

In an effort to optimize the effectiveness of tocolytic therapy in women at increased risk for preterm birth, early recognition of preterm labour has been emphasized.
Education of high-risk women and their health care providers about the warning signs and symptoms of preterm labour, the importance of early intervention, health-related habits, and appropriate utilization of health services has been evaluated in several randomized controlled trials.\(^{51-54}\) Despite showing improvement in the early diagnosis of premature labour, a recent meta-analysis of preterm birth prevention programs in high-risk populations failed to show any benefit of education in reducing preterm birth rates in high risk populations.\(^{55}\) This disappointing finding may be due to the fact that risk factors for preterm birth such as previous preterm deliveries, multiple gestation, and uterine anomalies cannot be modified and, consequently, prevention of preterm birth in high-risk women may not be possible.\(^9\)

Education of all pregnant women and health providers as part of population-based preterm birth prevention programs appears, in observational studies, to be effective in reducing the preterm birth rate in populations where self-referral to health care facilities is promoted.\(^{56-58}\) Improvements in perinatal outcome are more likely when education is appropriate for women's reading abilities, cultural background, and intellectual capabilities.\(^{59}\) Since the majority of premature deliveries occur in women without identifiable risk factors, it seems likely that increased awareness of the signs and symptoms of premature labour would provide a beneficial effect. This premise has not yet been tested in a well designed, randomized controlled trial using a population-based approach.

### 2.2.3 Cervical Examination

Several investigators have shown that premature cervical change determined by digital examination is associated with a two to five fold increase in the rate of prematurity.\(^{46}\) Detection of premature cervical change and increased uterine activity have been used to
identify women at increased risk for preterm birth. In some areas, routine cervical examination has been promoted during pregnancy to identify women at risk for preterm delivery. However, a recent multinational, randomized controlled trial of routine cervical examinations in pregnancy, showed no benefit in terms of reduction in the preterm birth rate. The use of interventions recommended to reduce the likelihood of preterm delivery, such as bed rest and work leave, were similar in the experimental and control groups. This finding suggests that the additional information provided by cervical examination may not have been acted upon clinically, or that the interventions employed in conjunction with cervical examinations are of limited value in preventing preterm birth.

2.2.4 Activity Restriction

It has been suggested that heavy physical effort and prolonged standing during pregnancy are associated with an increased risk of preterm birth and intrauterine growth retardation. Using a scoring system developed by Mammelle, it is possible to compute an occupational fatigue index for pregnant women in the workplace. Women who work for more than 8 hours per day, 40 hours or 6 days per week, and/or stand for more than 3–4 hours per day are more likely to deliver preterm and have small-for-gestation-age (SGA) babies. In France, where prenatal work leave has been offered to all employed pregnant women from 32 weeks' onward since 1972, preterm birth rates between 1978 and 1981 were lower in women at risk for occupational fatigue who took pregnancy leave than those who did not (3.1% vs 8.1%). As pointed out by Papiernik, however, it is not possible to estimate the proportion of the reduction in preterm birth rates related to liberalized pregnancy leave separate from other simultaneous interventions. In a more
recent study from Mexico City, where working women are entitled to 6 weeks’ antenatal leave, women with no antenatal leave were much more likely to deliver prematurely. Nevertheless, the effectiveness of prenatal work leave has not been evaluated in a randomized controlled trial.

Bedrest is commonly recommended for women at increased risk for preterm birth, particularly in pregnancies complicated by multiple gestation, preterm labour, preterm premature rupture of membranes, or antenatal bleeding. The well-accepted association between maternal activity and uterine contractility is the physiologic basis for its prescription. The interpretation of this intervention ranges from a few hours per day resting at home to complete bedrest in hospital.

The effectiveness of hospital rest for preterm birth prevention has only been formally studied in twin pregnancies. Although one study suggested a modest reduction in preterm birth, systematic review of randomized trials indicated a slightly higher prematurity rate and worse perinatal outcome associated with hospitalized bedrest. In addition, no benefits were derived from hospital rest in twin pregnancies complicated by premature cervical change or in triplet pregnancies. Recent evidence suggests that the physical and psychosocial side effects of antepartum hospital rest may do more harm than good. Despite these findings, activity restriction has not been adequately evaluated for safety or beneficial effects.

2.2.5 Psychosocial Support

The relationship between maternal and fetal stress and preterm birth is suggested by higher prematurity rates among (1) unmarried and poor mothers, (2) women experiencing
major stressful events, and (3) women with objective and/or subjective evidence of depression and anxiety.\textsuperscript{75-79} Two mechanisms to explain this relationship have been proposed: (1) stress mediated glucocorticoid production increases the placental production of corticotrophin releasing hormone (CRH) which promotes prostanoid production in the decidua and fetal membranes, leading to increased uterine contractility, and (2) immune suppression resulting in an increased susceptibility to genital tract infection and subsequent premature labour.

Epidemiologic studies conducted during the past 30 years have provided convincing evidence that maternal psychosocial stress is a risk factor for prematurity and fetal growth retardation.\textsuperscript{18,80-85} Social support of low and high-risk women by health care providers, including home visits by nurses, midwives, and social workers, has provided little evidence of benefit in terms of birth weight or gestational age at delivery.\textsuperscript{86-90} On the other hand, programs designed to promote support by the partner, family, or neighbours, have been associated with reduction in preterm birth and improved perinatal outcomes.\textsuperscript{91} In addition, exercise and relaxation techniques have been shown to decrease the frequency and intensity of uterine contractions.\textsuperscript{78} In a recent study of women with symptoms of preterm labour, psychological support by a psychologist using a psychotherapeutic intervention resulted in a significant decrease in the preterm birth rate in experimental subjects compared to controls (12.3\% vs 25.7\%).\textsuperscript{92} Further evaluation of the role of psychosocial support in preterm birth prevention is warranted.
2.2.6 **High-Risk Prevention Programs**

A number of multiple intervention preterm birth prevention programs involving women at high risk for preterm birth have been evaluated. (Table 1)\(^{52-54, 88, 93-97}\) Various high-risk strategies have been utilized in these programs, but most have included specialized high-risk clinics, frequent antenatal visits, regular cervical examinations, uterine activity monitoring, comprehensive education sessions, and psychosocial support. Apart from a few exceptions, randomized controlled clinical trials targeted at high-risk obstetric populations have generally shown no significant reduction in preterm birth rates.\(^5\) The lack of effectiveness of prevention programs directed solely at high-risk populations is related to several factors. There is some evidence that risk factors for preterm birth, such as previous preterm deliveries, multiple gestation, and uterine anomalies can not be modified and, consequently, prevention of preterm birth in high-risk women may not be preventable.\(^9\) Since the underlying cause of spontaneous preterm delivery in most cases is unknown, the majority of preterm births can not be predicted.\(^98\) Only 15-30% of preterm deliveries occur in women known to be at increased risk with the majority of premature births occurring unexpectedly in women thought to be at low risk. Given the difficulties with accurate identification and prevention of prematurity in high-risk women, it is not surprising that interventions aimed at this population have not been effective in reducing the preterm birth rate for the larger obstetric population. Limitations in the current state of knowledge and available interventions makes the high-risk prevention strategy impractical.
Table 1: High-Risk Preterm Birth Prevention Programs

<table>
<thead>
<tr>
<th>Author</th>
<th>Location</th>
<th>Study Design</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Main&lt;sub&gt;52&lt;/sub&gt;</td>
<td>Philadelphia (1983-1985)</td>
<td>RCT</td>
<td>No difference</td>
</tr>
<tr>
<td>Konte&lt;sub&gt;93&lt;/sub&gt;</td>
<td>NW California (1984-1985)</td>
<td>Historical Comparison</td>
<td>No difference</td>
</tr>
<tr>
<td>Goldenburg&lt;sub&gt;53&lt;/sub&gt;</td>
<td>Alabama (1982-1986)</td>
<td>RCT</td>
<td>No difference</td>
</tr>
<tr>
<td>Mueller-Heubach&lt;sub&gt;94&lt;/sub&gt;</td>
<td>Pittsburgh (1984-1987)</td>
<td>RCT</td>
<td>No difference; ↓ PTB overall</td>
</tr>
<tr>
<td>Collaborative Group&lt;sub&gt;54&lt;/sub&gt;</td>
<td>USA (1983-1986)</td>
<td>Multi-centre RCT</td>
<td>No difference</td>
</tr>
<tr>
<td>Hobel&lt;sub&gt;96&lt;/sub&gt;</td>
<td>West Los Angeles (1983-1986)</td>
<td>RCT</td>
<td>↓ PTB Rate (9.1% vs. 7.4%)</td>
</tr>
<tr>
<td>Heins&lt;sub&gt;95&lt;/sub&gt;</td>
<td>South Carolina (1983-1987)</td>
<td>RCT</td>
<td>No difference</td>
</tr>
<tr>
<td>Villar&lt;sub&gt;88&lt;/sub&gt;</td>
<td>Latin America (1989-1991)</td>
<td>Multi Centre RCT</td>
<td>No difference</td>
</tr>
<tr>
<td>Moore&lt;sub&gt;97&lt;/sub&gt;</td>
<td>North Carolina (1992-1994)</td>
<td>RCT</td>
<td>No difference overall; ↓ PTB rate in subgroup of low-income black women</td>
</tr>
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RCT = randomized controlled trial; PTB = preterm birth
2.2.7 Population-Based Prevention Programs

There is some evidence supporting the effectiveness of population-based preterm birth prevention programs which provide support and education about prematurity for all pregnant women and their health care providers.\textsuperscript{4, 9, 10} Such programs encourage women to participate in preterm birth prevention through enhancement of self-managed early intervention and reinforcement of the desire to reach full term.

In 1985, Papiernik reported the results of the twelve-year preterm birth prevention program in Haguenau, France.\textsuperscript{56} The community-wide effort included the application of a risk-assessment system, use of midwives for home visits, and an education component including advice regarding activity restriction for women at risk. The goal of the program was to modify women's attitudes, lifestyles, and daily activities through self recognition and self management of the warning signs of premature labour. Liberal use of work leave and hospital self admission were encouraged. During the study period (1971-1982), the preterm birth rate decreased from 5.4\% to 3.7\%, a 30\% reduction. During the same time period, there was a 66\% decrease in the very preterm birth rate (rate ≤ 32 weeks) from 1.4\% to 0.5\%. No reduction was observed among high-risk women with a history of previous preterm birth (12.97-13.0\%).

France subsequently implemented a national program of preterm birth prevention.\textsuperscript{99} This resulted in raising national awareness and instilling a sense of personal responsibility in pregnant women to deliver at term. In addition, special education was provided to health professionals. At each prenatal visit, patients were questioned regarding warning signs for preterm labour and a vaginal examination for evidence of premature cervical change was
performed. Modification of the behaviour and/or lifestyle of pregnant women was enhanced when applied to the general population. As part of the French government's national perinatal policy, financial compensation was provided to women as an incentive to begin antenatal care in the first trimester. Other social measures included recommendations to limit physical activity with paid work leave when needed and home visits to advise rest in high risk women, reinforcing the educational message to both the woman and her family. Home domestic assistance was provided if deemed necessary by a social worker. The national preterm birth rate fell 27% between 1972 and 1981 (7.9% to 5.8%) with a further reduction of 29% by 1989 (4.1%). The very preterm birth rate (≤32 weeks) was reduced by 60% from 1.6% in 1972 to 0.7% in 1981 and to 0.5% by 1989. Despite the cost of implementing such a program, the reduction in pediatric care resulted in significant cost savings. Papiernik has estimated cost savings of approximately ten dollars for every dollar spent.

Several investigators have demonstrated similar results utilizing a population-based approach to prematurity prevention. (Table 2)\textsuperscript{57-58,100-102} To date, only observational study designs have been used to evaluate population-based preterm birth prevention programs. Further evaluation of a population-based approach to preterm birth prevention and reappraisal of the content of prenatal care is indicated.

2.3 Description of the Halifax County Preterm Birth Prevention Project

The Halifax County Preterm Birth Prevention Project (HCPBPP) was a population-based, multidisciplinary, health promotion pilot project which was made available to all pregnant women of Halifax County, Nova Scotia. The HCPBPP, which was funded by the
Table 2: Population-Based Preterm Birth Prevention Programs

<table>
<thead>
<tr>
<th>Author</th>
<th>Location</th>
<th>Study Design</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Papiernik</td>
<td>France (1971-1982)</td>
<td>Historical</td>
<td>PTB Rate (5.4%-3.7%)</td>
</tr>
<tr>
<td>Herron</td>
<td>San Francisco (1978-1979)</td>
<td>Historical</td>
<td>PTB Rate (6.8%-2.4%)</td>
</tr>
<tr>
<td>Goujon</td>
<td>Martinique (1980-1982)</td>
<td>Observational</td>
<td>PTB Rate Exposed (6.0%-4.4%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Controls (6.7%-7.5%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(10.0%-12.1%)</td>
</tr>
<tr>
<td>Meis</td>
<td>North Carolina (1984-1986)</td>
<td>Historical</td>
<td>LBW Rate (10%-6.5%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>VLBW Rate (1.3%-0.6%)</td>
</tr>
<tr>
<td>Yawn</td>
<td>Minnesota (1986-1988)</td>
<td>Historical</td>
<td>PTB Rate (3.2%-1.3%)</td>
</tr>
<tr>
<td>Fangman</td>
<td>Minnesota (1990)</td>
<td>Observational</td>
<td>PTB Rate Exposed (4.6%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Controls (8.3%)</td>
</tr>
</tbody>
</table>

PTB = preterm birth; LBW = low birth weight (< 2500 g); VLBW = very low birth weight (< 1500 g)
Grace Maternity Hospital Foundation, began subject recruitment in January, 1995 and continued through June, 1997.

Prior to the beginning of subject enrolment in January, 1995, an introductory education program was presented to all physicians and nurses who cared for pregnant women in Halifax County. Educational materials about the symptoms and management of preterm labour were made available to pregnant women in physician's offices, health care clinics, hospitals, pharmacies, community centres, and libraries in Metro Halifax and Halifax county. Information sessions were provided to women's groups and to prenatal class instructors in the area. The information and educational materials were also incorporated into the prenatal education program provided to childbearing women of Halifax County.

A population specific risk assessment tool developed previously by B.A. Armson and L. Dodds, was used by participating physicians to assess the risk of preterm birth for all pregnant women at the first prenatal visit and again at 20 to 24 weeks and 28 to 32 weeks gestation (Appendix 1). Participating women were educated about the warning signs of preterm labour at 20 to 24 weeks gestation and provided with a project pamphlet and wallet card. Pelvic examinations were also recommended for low risk women at 20 to 24 weeks and again at 28 to 32 weeks to screen for premature cervical change.

Women identified at increased risk for preterm birth at any time during their pregnancy were designated "High Risk". Physicians were encouraged to provide such women with project education materials and refer them to the project coordinator for an individual education session. High risk patients who participated in the program were seen weekly by their physician from 24 to 34 weeks gestation. Women who were felt to be at
increased risk because of uterine contractions or cervical change after 24 weeks gestation were seen weekly thereafter. On each of these weekly visits, warning signs of preterm labour were reviewed and a pelvic examination was performed to ascertain cervical dilatation and effacement, station of the presenting part, and thinning of the lower uterine segment. Patients in the high risk group were also encouraged to stop work from 24 weeks gestation and rest at home. Women referred to the project coordinator were instructed in self-palpation for uterine activity and contacted one to two times per week to provide information and support. The project protocol and educational materials are included as Appendix 2.

Preterm birth rates, adjusted for risk status, were evaluated over time in Halifax County and compared to non-Halifax County residents. There was no appreciable change in the overall (< 37 weeks) or early (< 34 weeks) preterm birth rates within or outside Halifax County during the intervention period compared to the pre-intervention period. The very PTB rate (< 30 weeks) in Halifax County decreased by 30% whereas no change was observed elsewhere in Nova Scotia. There was also a statistically significant decrease in early preterm births associated with spontaneous labour in Halifax County which was not observed in the rest of the province (Appendix 3).
CHAPTER 3: RESEARCH PROTOCOL

3.1 Objectives

The primary objective of this study was to determine if participation in the Halifax County Preterm Birth Prevention Project (HCPBPP) resulted in a reduction in the risk of premature delivery. Secondary objectives were to evaluate the degree to which specific components of the program contributed to preterm birth risk reduction and to determine if the effect of participation differed between women at low risk for preterm birth and those at high risk.

3.2 Hypotheses

The primary hypothesis of this study was that participation in a population-based preterm birth prevention program would be associated with a reduction in the risk of preterm birth.

The second hypothesis was that the effect of participation would vary according to the degree of compliance with specific program recommendations.

The third hypothesis was that participation in a population-based prevention program would have a different effect on perinatal outcome in women identified at low risk compared to those at high risk for preterm birth.

3.3 Overview of Study Design

A case-control design was used to select Halifax Country parturients during the final nine months of the Halifax County Preterm Birth Prevention Project for interviewer-administered questionnaires. Cases were defined as women who delivered preterm (<37
weeks' gestation) and controls were women who delivered full-term infants (≥37 weeks' gestation). Three controls per case were sequentially selected by identifying eligible term deliveries occurring immediately after each preterm birth. Information was collected from cases and controls pertaining to their participation in the Halifax County Preterm Birth Prevention Project.

3.4 Materials and Methods

3.4.1 Subjects

Subjects were selected from Halifax County residents who delivered babies at the IWK Grace Health Centre from November 1, 1996, to July 31, 1997. The Halifax County Preterm Birth Prevention Project remained fully operational until June 30, 1997. It was estimated that the effect of the prevention program would be measurable in pregnancies completed up to three months after the project officially ended (until September, 1997). The project coordinator continued to provide weekly telephone contact to high-risk women referred to her until August 31, 1997.

Halifax County contains the largest metropolitan area in Nova Scotia with a population of approximately 360,000. The population of Halifax County is relatively homogeneous and predominantly white. Only 20% of Halifax County residents live in rural settings. The average family income in Halifax County is similar to the Canadian national average, and only about 10% of the population come from low income families.103 The IWK Grace Health Centre, the major tertiary care perinatal centre in Nova Scotia, provides maternity services for all pregnant women of Halifax County. The annual live birth rate for
Halifax County residents is approximately 4,500. Approximately 6% of these babies (270 per year) are delivered preterm.

3.4.2 Recruitment

Childbearing women of Halifax County with singleton live births at the IWK Grace Health Centre during the study period were eligible for inclusion. In order to evaluate potentially preventable preterm births, women with pregnancies complicated by multiple gestation, congenital malformations, chorioamnionitis, abruptio placenta, placenta previa, or delivery for medical indications such as insulin dependent diabetes or pregnancy induced hypertension were excluded from enrolment in the study. Non-Halifax County residents transferred to the IWK Grace Health Centre for delivery were also excluded from the study. Exclusion criteria were applied to both potential cases and controls.

Women with preterm deliveries (cases) and three subsequent term controls were identified from the delivery log book on a daily basis by a research assistant. After reviewing each potential subject's chart for exclusion criteria, all eligible cases and controls were approached by a study research assistant and invited to participate in the study. Informed consent was obtained from all women recruited into the study (Appendix 4).

3.4.3 Procedures

An interviewer-administered questionnaire was used for each subject enrolled in the study (Appendix 5). Because of early discharge policies in place at the time of the study, interviews were usually conducted within 12 to 36 hours after delivery. Demographic data was collected from all participants including age, parity, ethnic background, educational level, income and occupation. Information about subjects' perceived level of stress and
physical activity in the workplace and at home (heavy physical labour, standing) was also collected. Risk status (high or low) for preterm birth was determined for all study participants using the risk assessment tool developed for the HCPBPP. Hence, study participants were retrospectively determined to be at low or high risk for preterm delivery by the research assistant through subject interview and chart review.

Subject participation in the Halifax County Preterm Birth Prevention Project was determined by asking a series of questions derived from the project protocol. Subjects were shown the project pamphlet and asked if they had seen or received any of the materials during their pregnancy. Women who recognized the educational materials were asked more specific questions, including where they first saw the material and if they had been provided with the project pamphlet and wallet card. Women who received the educational materials were asked at what gestational age they received them and who provided them. Subjects were also asked if they remembered the focus of the educational materials.

Subjects were asked if the warning signs of premature labour were discussed during their pregnancy. If so, further questions were asked to determine who discussed premature labour signs and symptoms and whether the information was retained and understood. Women who experienced warning signs of premature labour were asked what actions, if any, they took in response to these symptoms. Subjects were asked if they had pelvic examinations performed by their health care provider during their pregnancy and, if so, at what gestational age and how often the pelvic examinations were performed. Subjects were asked if their prenatal care provider advised them to reduce activity, reduce or stop housework, stop work, rest in bed or monitor for uterine contractions by self palpation and,
if so, to what degree they were able to do so. Subjects were also asked if they were referred to the project coordinator for an individual educational session and if they were contacted weekly by the project coordinator.

All data was entered into an Epi-Info study database and converted to SAS for subsequent analysis.

3.4.4 Assessment of Participation

The primary exposure of interest for this study was participation in the Halifax County Preterm Birth Prevention Project. Any participation was defined as participation in some aspect of the prevention program, including exposure to the project pamphlet, review of warning signs, pelvic examinations, recommendations to decrease activity or check for uterine contractions, or individual educational sessions and follow-up with the project coordinator. Exposure to the project pamphlet required that the subjects had read the pamphlet. Exposure to review of the warning signs of premature labour required review by a health care provider. Data was also collected on actions taken by subjects when they experienced warning signs. Exposure to pelvic examinations for low-risk women indicated pelvic examinations at 20-24 weeks and again at 28-32 weeks. For women at increased risk for preterm birth, exposure to pelvic exams implied weekly pelvic examinations from 24-34 weeks' gestation. Exposure to project recommendations indicated the recommendation by a prenatal care provider to either reduce activity, reduce/stop housework, stop work, rest in bed, or check for uterine contractions. Exposure to activity restriction implied the recommendation by a prenatal care provider to reduce activity, reduce/stop housework, stop work, or rest in bed. Exposure to the education session implied referral of women to the
project coordinator for an individual teaching session and subsequent weekly telephone contact. Exposure to prenatal risk assessment by subjects’ attending physicians could not be determined because the HCPBPP risk assessment sheets, when used, were kept on physicians’ office records and were not available for review.

For women determined to be at low risk for preterm birth, full participation required exposure to the project pamphlet, warning signs review and low-risk pelvic examination protocol. For women who were determined to be at high-risk for preterm birth and those who developed warning signs of premature labour, full participation in the high-risk protocol was defined as exposure to the project pamphlet, warning signs review, high-risk pelvic examination regimen, project recommendations and education session with the project research nurse.

3.4.5 Sample Size

The sample size was determined by estimating the recruitment rate among eligible women who had preterm birth during the time available for the study to be conducted (nine months). Since there are approximately 270 preterm births to Halifax residents per year at the IWK Grace Health Centre, it was estimated that there would be approximately 203 preterm births during the study period. It was assumed that approximately 20% of potential subjects would be ineligible because of the exclusion criteria leaving approximately 162 eligible cases for recruitment. Based on compliance rates from previous studies at the IWK Grace Health Centre, it was estimated that approximately 85% of eligible women would agree to participate in the study. Consequently, it was estimated that approximately 140 cases would be included in the study. With three controls per case selected, it was estimated that there would be 420 controls.
Assuming an alpha of .05, beta of 0.2, and an exposure prevalence of 80% (proportion of controls who had participated in the preterm birth prevention project), a sample size of 140 and a control:case ratio of 3:1, there would be an 80% probability that an odds ratio of 0.53 or smaller would be statistically significant.  \(^{104}\)

### 3.4.6 Data Analysis

Data analysis was performed using Statistical Analysis Systems (SAS) computer software. Cases and controls were compared with respect to sociodemographic information (e.g. age, parity) and potential risk factors (e.g. smoking) using the Chi square test for categorical variables and Student’s t-test for continuous variables. A value of \(p < 0.05\) was required for statistical significance.

The rate of participation in the Halifax County Preterm Birth Prevention Project was determined by calculating the proportion of subjects who participated in any aspect of the project. Participation rates were also calculated separately for women at increased risk for preterm birth and for those at low risk. Univariate odds ratios and confidence intervals using the Chi square test were calculated for any degree of participation among all subjects, as well as high and low-risk women separately to determine whether the risk of preterm birth was reduced among those who participated in the preterm birth prevention program at some level compared to those who had not. Odds ratios were assumed to approximate relative risk.

The effect of specific program components on the risk of preterm birth were then analyzed univariately using the Chi square test for high and low-risk groups separately. Exposure variables, as previously defined (project pamphlet, warning signs review, pelvic examinations, project recommendations, and individual education sessions) were subjected to univariate analysis among high-risk and low-risk women as per HCPBPP protocol.
Logistic regression analysis was performed for each participation variable in high-risk and low-risk groups controlling for potential confounders and co-interventions. Co-interventions were retained in the final logistic regression models for high-risk and low-risk groups as per protocol to control for the effect of the co-interventions within this multi-intervention prevention program. Using stepwise logistic regression modelling, potential confounders were removed from the model if the differences in the likelihood ratios between models were non-significant by the Chi square test and variation in the odds ratios of participation variables was less than 10%. Only potential confounders which remained significant were retained in final logistic regression models. Variables which remained in the regression model were further analyzed to determine if interactions existed between intervention and other significant variables. Adjusted odds ratios and confidence intervals were computed to establish whether any of the program interventions, individually or combined, were associated with reduction in the risk of preterm birth for high-risk and/or low-risk women.

3.4.7 Ethics

Potential subjects were approached by research assistants on the day following their delivery and asked to participate in a 10 to 15 minute interview at their convenience. Both research assistants involved in the study were nurses with experience in obstetrics who were sensitive to the needs of each subject and her family during the postpartum period, particularly women who had experienced a preterm birth. Care was taken during the interview to avoid any suggestion of responsibility of the mother or her health care provider for any adverse pregnancy outcomes.
The study was approved by the Research Ethics Committee of the IWK Grace Health Centre and the Human Investigation Committee of Dalhousie University. Written consent was obtained from each subject prior to enrolment in the study, including the voluntary nature of participation, the right to refuse or withdraw from the study at any time without affecting or compromising her medical care, and the confidentiality of the study. All information was handled by a coded unique number to maintain confidentiality. The code for the unique numbers was kept in a locked drawer. Subject names will not be used in any publication.
CHAPTER 4: RESULTS

During the study period there were 288 preterm births at the IWK Grace Health Centre. Women residing outside Halifax County, transferred for tertiary level perinatal care, accounted for 101 of the preterm deliveries. Ninety-five (50.8%) of the 187 women from Halifax County who delivered preterm were ineligible for recruitment because of the presence of one or more of the exclusion criteria [stillbirth (8), multiple gestation (18), abruptio placenta (15), placenta previa (7), chorioamnionitis (3), congenital malformation (6), medical indication (38)]. As shown in Table 3, of the 92 eligible cases, 22 (24%) were not recruited. Only four (4.3%) women refused to participate in the study, and another four (4.3%) had been discharged before being invited to participate by a research assistant. Although there was only one physician who refused to participate in the study, this accounted for the exclusion of 14 (15.2%) potential cases.

There were 270 potential controls who delivered subsequent to recruited cases. Thirty-eight (14.1%) were excluded for pregnancy complications associated with prematurity leaving 233 eligible term controls. Of these, 22 (9.4%) women were not recruited because of physician or patient refusal. Nearly half of these exclusions were patients of the one physician who refused to participate. After all exclusions, there were 70 cases (women who delivered preterm) and 210 term controls.

The sociodemographic characteristics of the study population are presented in Table 4. There was no difference between cases and controls in terms of mean age, marital status, ethnic origin, education, or income. Parity reached borderline statistical significance with
### Table 3: Exclusion of Eligible Subjects

<table>
<thead>
<tr>
<th>Reason for Exclusion</th>
<th>Potential Cases n=92</th>
<th>Potential Controls n=233</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. (%)</td>
<td>No. (%)</td>
</tr>
<tr>
<td>Physician Refusal</td>
<td>14 (15.2)</td>
<td>7 (3.0)</td>
</tr>
<tr>
<td>Patient Refusal</td>
<td>4 (4.3)</td>
<td>15 (6.4)</td>
</tr>
<tr>
<td>Early Discharge</td>
<td>4 (4.3)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>
39 (56%) primiparous cases compared to 93 (44%) primiparous controls. Although there was a higher percentage of single mothers and women of Western European origin in the preterm group than among term controls, neither factor reached significance. Overall, the study population consisted of women who were of Western European descent, married, reasonably well educated, and in the middle to upper income brackets.

Lifestyle and occupational characteristics of the case and control groups are presented in Table 5. Approximately 70% of study subjects worked during pregnancy, 50% had children at home and 26% smoked during pregnancy. Being a heavy smoker, (>10/day), appeared to be associated with an increased risk of preterm birth, whereas having children at home appeared to be protective. Neither factor reached significance, however. Increased perceived stress levels (5 on a 5-point scale), prolonged standing or increased activity levels (5 on a 5-point scale) at home or at work did not appear to influence the risk of preterm birth.

The occurrence of potential risk factors for preterm birth in case and control groups are shown in Table 6. The risk of preterm birth was increased in women designated as high risk by the risk assessment protocol and among women who reported warning signs of preterm labour with odds ratios of 1.9 and 2.0 respectively. Although few women (17%) reported experiencing “warning signs” of preterm labour, more than 70% of subjects reported experiencing one or more of the symptoms which may occur before progression into established preterm labour. The occurrence of these symptoms individually or combined did not appear to increase the risk of preterm birth, however. Antepartum bleeding, gestational diabetes, sexually transmitted diseases, increased perceived stress or activity level, and working outside the home did not appear to increase the risk of prematurity.
Table 4: Sociodemographic Characteristics of Study Population

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Case (n=70)</th>
<th>Control (n=210)</th>
<th>OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal Age (x)</td>
<td>28.6</td>
<td>28.9</td>
<td>1.03</td>
<td>0.96-1.09</td>
</tr>
<tr>
<td>Parity (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multiparous</td>
<td>44.3</td>
<td>55.7</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Primiparous</td>
<td>55.7</td>
<td>44.3</td>
<td>1.58</td>
<td>0.94-2.12</td>
</tr>
<tr>
<td>Marital Status (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>With Partner</td>
<td>75.7</td>
<td>83.8</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Single</td>
<td>24.3</td>
<td>16.2</td>
<td>1.66</td>
<td>0.86-3.21</td>
</tr>
<tr>
<td>Ethnic Origin (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Western European</td>
<td>82.5</td>
<td>70.9</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>17.5</td>
<td>29.1</td>
<td>0.52</td>
<td>0.25-1.10</td>
</tr>
<tr>
<td>Education (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; High School</td>
<td>72.5</td>
<td>69.5</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>≤ High School</td>
<td>27.5</td>
<td>30.5</td>
<td>0.87</td>
<td>0.47-1.59</td>
</tr>
<tr>
<td>Income (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&gt; $20,000</td>
<td>89.8</td>
<td>86.5</td>
<td>1.00</td>
<td></td>
</tr>
<tr>
<td>≤ $20,000</td>
<td>10.2</td>
<td>13.5</td>
<td>0.72</td>
<td>0.28-1.87</td>
</tr>
</tbody>
</table>

OR = odds ratio; 95% CI - 95% confidence interval; x = mean
Table 5: Lifestyle/Occupational Characteristics of Study Population

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Case (n=70)</th>
<th>Control (n=210)</th>
<th>OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. (%)</td>
<td>No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Working during Pregnancy</td>
<td>50 (72.5)</td>
<td>142 (68.3)</td>
<td>1.23</td>
<td>0.67-2.24</td>
</tr>
<tr>
<td>Prolonged Standing</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home</td>
<td>30 (42.9)</td>
<td>104 (49.5)</td>
<td>0.76</td>
<td>0.44-1.32</td>
</tr>
<tr>
<td>Work</td>
<td>28 (54.9)</td>
<td>93 (64.1)</td>
<td>0.68</td>
<td>0.36-1.30</td>
</tr>
<tr>
<td>Heavy Physical Work</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home</td>
<td>21 (30.0)</td>
<td>83 (39.5)</td>
<td>0.66</td>
<td>0.37-1.17</td>
</tr>
<tr>
<td>Work</td>
<td>29 (56.9)</td>
<td>89 (61.4)</td>
<td>0.83</td>
<td>0.43-1.58</td>
</tr>
<tr>
<td>Rarely Sit</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home</td>
<td>21 (30.0)</td>
<td>84 (40.0)</td>
<td>0.64</td>
<td>0.36-1.15</td>
</tr>
<tr>
<td>Work</td>
<td>23 (45.1)</td>
<td>84 (57.9)</td>
<td>0.60</td>
<td>0.31-1.13</td>
</tr>
<tr>
<td>Children at Home</td>
<td>32 (46.4)</td>
<td>118 (57.0)</td>
<td>0.65</td>
<td>0.38-1.13</td>
</tr>
<tr>
<td>Increased Stress</td>
<td>23 (32.9)</td>
<td>60 (28.6)</td>
<td>1.22</td>
<td>0.68-2.19</td>
</tr>
<tr>
<td>Smoking</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heavy Smoker (&gt;10/day)</td>
<td>21 (30.0)</td>
<td>51 (24.3)</td>
<td>1.34</td>
<td>0.73-2.44</td>
</tr>
<tr>
<td></td>
<td>13 (21.0)</td>
<td>22 (12.2)</td>
<td>1.92</td>
<td>0.90-4.09</td>
</tr>
</tbody>
</table>

OR = odds ratio; 95% CI = 95% confidence interval
<table>
<thead>
<tr>
<th>Factor</th>
<th>Case (n=70) No. (%)</th>
<th>Control (n=210) No. (%)</th>
<th>OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>High Risk Status</td>
<td>27 (38.6)</td>
<td>52 (24.8)</td>
<td>1.91</td>
<td>1.07-3.39*</td>
</tr>
<tr>
<td>PTL Symptoms</td>
<td>50 (71.4)</td>
<td>147 (70.0)</td>
<td>1.07</td>
<td>0.59-1.95</td>
</tr>
<tr>
<td>Contraction</td>
<td>22 (31.4)</td>
<td>55 (27.6)</td>
<td>1.19</td>
<td>0.63-2.25</td>
</tr>
<tr>
<td>Menstrual Cramps</td>
<td>20 (28.5)</td>
<td>55 (27.6)</td>
<td>1.13</td>
<td>0.59-2.16</td>
</tr>
<tr>
<td>Abdominal Cramps</td>
<td>16 (22.9)</td>
<td>45 (21.4)</td>
<td>1.09</td>
<td>0.54-2.18</td>
</tr>
<tr>
<td>Back Pain</td>
<td>16 (22.9)</td>
<td>56 (26.7)</td>
<td>0.81</td>
<td>0.41-1.62</td>
</tr>
<tr>
<td>Pelvic Pressure</td>
<td>35 (50.0)</td>
<td>98 (46.7)</td>
<td>1.14</td>
<td>0.64-2.05</td>
</tr>
<tr>
<td>Vaginal Discharge</td>
<td>19 (27.1)</td>
<td>98 (46.7)</td>
<td>0.87</td>
<td>0.45-1.66</td>
</tr>
<tr>
<td>PTL Warning Signs</td>
<td>18 (26.5)</td>
<td>30 (15.0)</td>
<td>2.04</td>
<td>1.05-3.96*</td>
</tr>
<tr>
<td>Antepartum Bleeding</td>
<td>9 (12.9)</td>
<td>18 (8.6)</td>
<td>1.57</td>
<td>0.67-3.68</td>
</tr>
<tr>
<td>STD</td>
<td>3 (4.3)</td>
<td>4 (1.9)</td>
<td>2.31</td>
<td>0.50-10.6</td>
</tr>
<tr>
<td>Gestational Diabetes</td>
<td>3 (4.3)</td>
<td>3 (1.4)</td>
<td>3.09</td>
<td>0.61-15.7</td>
</tr>
</tbody>
</table>

OR = odds ratio; 95% CI = 95% confidence interval; PTL = preterm labour; STD = sexually transmitted disease
*p < 0.05
As demonstrated in Table 7, 201 women had no identifiable risk factors for preterm birth, (low risk), and 79 women were designated as high risk by the risk assessment protocol. Among the women at low risk for preterm birth, the only factor that was significantly associated with preterm birth was having children at home, with an odds ratio of 0.49. None of the other suggested potential risk factors, including smoking, increased perceived stress or activity level, preterm labour symptoms, or perceived warning signs of preterm labour were associated with a statistically significant increased risk of preterm delivery. Among women at high risk for preterm birth, none of the potential risk factors evaluated were associated with a statistically significant risk of delivering preterm. High-risk women were more likely to report warning signs of preterm labour, but this factor was not associated with a statistically significant risk of prematurity. Among high-risk women, prolonged standing at work appeared to be protective with an odds ratio of 0.31.

Participation in some aspect of the Halifax County Preterm Birth Project was generally high (82%) for all subjects. However, this level of participation provided no benefit in terms of risk of prematurity by univariate analysis (OR=1.09; CI=0.53-2.22). After controlling for potential confounders (maternal age, parity, previous spontaneous abortion, marital status, education level, children at home, work outside the home during pregnancy, increased perceived stress level, smoking, preterm labour symptoms, and perceived warning signs of preterm labour) in a logistic regression model, the adjusted odds ratio and 95% confidence intervals was similar to the univariate values (OR=1.03; CI=0.50-2.11). Only parity remained in logistic regression models for any degree of participation for all subjects and for low-risk women whereas all potential confounders were eliminated from
Table 7: Potential Risk Factors for Preterm Birth by Risk Status

<table>
<thead>
<tr>
<th>Factor</th>
<th><strong>Women at Low Risk</strong></th>
<th></th>
<th><strong>Women at High Risk</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n=201) OR 95% CI</td>
<td>(n=79) OR 95% CI</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Working during Pregnancy</td>
<td>0.97 0.47-1.99</td>
<td>1.92 0.61-6.01</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prolonged Standing</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home</td>
<td>0.90 0.46-1.77</td>
<td>0.50 0.20-1.30</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Work</td>
<td>1.05 0.46-2.43</td>
<td>0.31 0.10-0.97*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heavy Physical Work</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home</td>
<td>0.71 0.34-1.46</td>
<td>0.53 0.20-1.43</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Work</td>
<td>0.72 0.32-1.63</td>
<td>1.01 0.33-3.08</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rarely Sit</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home</td>
<td>0.60 0.29-1.26</td>
<td>0.68 0.26-1.80</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Work</td>
<td>0.69 0.31-1.55</td>
<td>0.41 0.13-1.25</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Children at Home</td>
<td>0.49 0.25-0.99*</td>
<td>0.91 0.35-2.35</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increased Stress</td>
<td>0.89 0.41-1.92</td>
<td>1.80 0.70-4.71</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Smoking</td>
<td>1.17 0.53-2.54</td>
<td>1.45 0.54-3.89</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Heavy Smoker (&gt;10/day)</td>
<td>1.78 0.67-4.73</td>
<td>1.99 0.54-6.40</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PTL Symptoms</td>
<td>0.90 0.45-1.81</td>
<td>1.05 0.28-3.84</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PTL Warning Signs</td>
<td>0.90 0.24-3.34</td>
<td>2.27 0.86-6.01</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Antepartum Bleeding</td>
<td>1.21 0.05-30.2</td>
<td>1.03 0.38-2.77</td>
<td></td>
<td></td>
</tr>
<tr>
<td>STD</td>
<td>3.81 0.52-27.8</td>
<td>0.96 0.08-11.1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diabetes</td>
<td>3.74 0.23-61.0</td>
<td>2.00 0.27-15.1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

OR = odds ratio; 95% CI = 95% confidence interval; PTL = preterm labour; STD = sexually transmitted disease
*p < 0.05
logistic regression models for the high-risk subgroup. Interaction terms for any participation and parity for all subjects and for the low-risk subgroup were non-significant, indicating that there was no interaction between participation and parity in either model or that there was not enough power to detect a significant interaction.

Univariate and multivariate evaluation of the effect of exposure to project interventions on the risk of preterm birth among women at high risk are presented in Table 8. As demonstrated, none of the interventions of the preterm birth prevention project provided any benefit to women at high risk for preterm birth by either univariate or multivariate analysis. Odds ratios for most of the interventions, individually or combined, adjusted for potential confounders and co-interventions, suggest an increased risk of preterm birth for high-risk women exposed to the project interventions. Although exposure to the individual education session by a small number (9) of high-risk women was associated with a statistically significant (fivefold) increase in the risk of preterm birth by univariate analysis, this association became non-significant when adjusted for co-interventions. Full participation in the preterm birth prevention project by high-risk women was very low (8%).

To evaluate the effect of compliance with project recommendations, new variables, combining each recommendation and compliance level of 4 or greater on a 5-point scale, were created and evaluated in a univariate and multivariate analysis. As shown in Table 9, compliance with any of the project recommendations, individually or in combination, by women in the high-risk subgroup provided no beneficial effect. In fact, women who complied with the recommendation to rest in bed had a two-and-a-half-fold increase in the risk of preterm birth. Although compliance with project recommendations, individually or
Table 8: Effect of Participation among Women at High Risk (n=79)

<table>
<thead>
<tr>
<th>Intervention</th>
<th>n (%)</th>
<th>OR</th>
<th>95% CI</th>
<th>Adjusted OR†</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Pamphlet</td>
<td>54 (68)</td>
<td>1.51</td>
<td>0.54-4.25</td>
<td>1.28</td>
<td>0.40-4.07</td>
</tr>
<tr>
<td>Warning Signs Review</td>
<td>23 (29)</td>
<td>1.36</td>
<td>0.50-3.72</td>
<td>0.69</td>
<td>0.17-2.82</td>
</tr>
<tr>
<td>Pelvic Exams</td>
<td>21 (27)</td>
<td>1.26</td>
<td>0.45-3.57</td>
<td>0.78</td>
<td>0.20-3.05</td>
</tr>
<tr>
<td>Check for Contractions</td>
<td>28 (35)</td>
<td>2.29</td>
<td>0.87-6.01</td>
<td>1.45</td>
<td>0.43-4.86</td>
</tr>
<tr>
<td>Activity Restriction</td>
<td>55 (70)</td>
<td>2.53</td>
<td>0.82-7.79</td>
<td>2.07</td>
<td>0.62-6.92</td>
</tr>
<tr>
<td>Education Session</td>
<td>9 (11)</td>
<td>4.67</td>
<td>1.07-20.4*</td>
<td>2.99</td>
<td>0.49-18.4</td>
</tr>
<tr>
<td>Any Participation</td>
<td>70 (89)</td>
<td>4.73</td>
<td>0.56-40.0</td>
<td>4.65</td>
<td>0.55-39.4</td>
</tr>
<tr>
<td>Full Participation</td>
<td>6 (8)</td>
<td>4.35</td>
<td>0.74-25.5</td>
<td>4.46</td>
<td>0.76-26.2</td>
</tr>
<tr>
<td>Project Recommendations</td>
<td>58 (73)</td>
<td>2.79</td>
<td>0.83-9.36</td>
<td>2.48</td>
<td>0.69-8.89</td>
</tr>
</tbody>
</table>

OR = odds ratio; 95% CI = 95% confidence interval;
Activity Restriction = reduce activity, or reduce housework, or stop work, or bedrest;
Project Recommendations = activity restriction or check for contractions
† Co-interventions of high-risk protocol retained in final logistic regression model;
none of the potential confounders were statistically significant
*p < 0.05
Table 9: Effect of Compliance with Project Recommendations among Women at High Risk (n=79)

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>n (%)</th>
<th>OR</th>
<th>95% CI</th>
<th>Adjusted OR†</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Recommendations</td>
<td>56 (71)</td>
<td>2.33</td>
<td>0.76-7.19</td>
<td>1.99</td>
<td>0.61-6.52</td>
</tr>
<tr>
<td>Check for Contractions</td>
<td>27 (34)</td>
<td>1.97</td>
<td>0.75-5.19</td>
<td>1.11</td>
<td>0.32-3.86</td>
</tr>
<tr>
<td>Activity Restriction</td>
<td>53 (67)</td>
<td>2.19</td>
<td>0.75-6.35</td>
<td>1.81</td>
<td>0.57-5.75</td>
</tr>
<tr>
<td>Reduce Activity</td>
<td>43 (54)</td>
<td>1.70</td>
<td>0.66-4.40</td>
<td>1.34</td>
<td>0.47-3.84</td>
</tr>
<tr>
<td>Reduce Housework</td>
<td>36 (46)</td>
<td>1.85</td>
<td>0.72-4.72</td>
<td>1.51</td>
<td>0.50-4.56</td>
</tr>
<tr>
<td>Stop Work</td>
<td>30 (38)</td>
<td>1.91</td>
<td>0.74-4.95</td>
<td>1.66</td>
<td>0.60-4.60</td>
</tr>
<tr>
<td>Bedrest</td>
<td>32 (41)</td>
<td>2.57</td>
<td>0.99-6.69</td>
<td>2.38</td>
<td>0.83-6.78</td>
</tr>
<tr>
<td>Response to Warning Signs</td>
<td>30 (90)</td>
<td>1.75</td>
<td>0.14-21.4</td>
<td>1.44</td>
<td>0.10-19.9</td>
</tr>
</tbody>
</table>

OR = odds ratio; 95% CI = 95% confidence interval
† Co-interventions of high-risk protocol retained in separate final logistic regression models for each of the project recommendation variables; none of the potential confounders were statistically significant
in combination, appeared to increase the risk of preterm birth for high-risk women, none of the associations were statistically significant. Of the 33 high-risk women who reported experiencing warning signs of preterm labour, 30 reported following the recommendations promoted in the project pamphlet. Because of the small effective sample size and cell counts less than five, univariate and multivariate analysis of response to warning signs are unreliable.

Table 10 presents the effect of participation among women with no identifiable risk factors for preterm birth. Neither exposure to the project pamphlet, review of warning signs nor pelvic exams provided any benefit in preterm birth risk reduction among low-risk women. Parity was the only potential confounder and it remained in all final logistic regression models for project interventions among low-risk women. Interaction terms for each intervention and parity were all non-significant, ruling out interactions between parity and the various interventions. Participation in some aspect of the prevention program by low-risk women was relatively high (79%) but did not appear to reduce the risk of preterm birth. Assessment of full participation in the project by low-risk women required exposure to the project pamphlet, review of warning signs and pelvic examinations. As illustrated, full participation among women at low risk was extremely low (6%).

Although activity restriction and uterine activity monitoring was not part of the low-risk protocol, over 40% of women with no identifiable risk factors were instructed to restrict their activity level and/or check for contractions by their prenatal care providers. Since more than 70% of study subjects reported experiencing symptoms associated with premature labour, it follows that practitioners would be inclined to prescribe the project
Table 10: Effect of Participation among Women at Low Risk (n=201)

<table>
<thead>
<tr>
<th>Intervention</th>
<th>n (%)</th>
<th>OR</th>
<th>95% CI</th>
<th>Adjusted OR†</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Pamphlet</td>
<td>119 (59)</td>
<td>1.37</td>
<td>0.68-2.77</td>
<td>1.62</td>
<td>0.74-3.55</td>
</tr>
<tr>
<td>Warning Signs Review</td>
<td>32 (16)</td>
<td>1.03</td>
<td>0.41-2.58</td>
<td>0.79</td>
<td>0.29-2.16</td>
</tr>
<tr>
<td>Pelvic Exams</td>
<td>48 (24)</td>
<td>0.96</td>
<td>0.43-2.12</td>
<td>0.82</td>
<td>0.35-1.93</td>
</tr>
<tr>
<td>Any Participation</td>
<td>157 (79)</td>
<td>0.69</td>
<td>0.31-1.53</td>
<td>0.63</td>
<td>0.27-1.47</td>
</tr>
<tr>
<td>Full Participation</td>
<td>12 (6)</td>
<td>0.74</td>
<td>0.16-3.49</td>
<td>0.67</td>
<td>0.14-3.23</td>
</tr>
</tbody>
</table>

OR = odds ratio; 95% CI = 95% confidence interval
† Co-interventions of low-risk protocol retained in final logistic regression model; models adjusted for parity
recommendations to women who complained of warning signs of premature labour. As shown in Table 11, reduction of activity, work leave, and checking for contractions all provided a beneficial effect in prematurity risk reduction by univariate and logistic regression analysis. Exposure of low-risk women to any of the project recommendations resulted in a fivefold decrease in the risk of preterm birth. Exposure to one or more of the activity restriction recommendations was associated with more than a threefold reduction in risk. The recommendation to either reduce/stop housework or rest in bed also appeared protective for low-risk women but was not statistically significant.

For low-risk women, compliance with the project recommendations was associated with an 80% reduction in the risk of preterm birth (Table 12). Compliance with any of the activity restriction recommendations or any of the project recommendations also resulted in four to fivefold reductions in preterm birth risk. All 15 (7.5%) low-risk women who reported having experienced warning signs of preterm labour indicated that they had complied with the recommendations promoted in the project pamphlet. Consequently, it was impossible to evaluate the effect of compliance with recommendations for women experiencing warning signs in the low-risk group.
Table 11: Effect of Activity Restriction/Uterine Activity Monitoring among Women at Low Risk (n=201)

<table>
<thead>
<tr>
<th>Intervention</th>
<th>n (%)</th>
<th>OR</th>
<th>95% CI</th>
<th>Adjusted OR†</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Recommendations</td>
<td>86 (42)</td>
<td>0.28</td>
<td>0.13-0.62*</td>
<td>0.21</td>
<td>0.09-0.49*</td>
</tr>
<tr>
<td>Check for Contractions</td>
<td>34 (17)</td>
<td>0.31</td>
<td>0.09-1.06</td>
<td>0.34</td>
<td>0.09-1.31</td>
</tr>
<tr>
<td>Activity Restriction</td>
<td>77 (38)</td>
<td>0.30</td>
<td>0.13-0.68*</td>
<td>0.29</td>
<td>0.12-0.71*</td>
</tr>
<tr>
<td>Reduce Activity</td>
<td>50 (25)</td>
<td>0.33</td>
<td>0.12-0.89*</td>
<td>0.30</td>
<td>0.11-0.84*</td>
</tr>
<tr>
<td>Reduce Housework</td>
<td>38 (19)</td>
<td>0.37</td>
<td>0.13-1.12</td>
<td>0.36</td>
<td>0.12-1.10</td>
</tr>
<tr>
<td>Stop Work</td>
<td>52 (26)</td>
<td>0.31</td>
<td>0.12-0.84*</td>
<td>0.26</td>
<td>0.10-0.73*</td>
</tr>
<tr>
<td>Bedrest</td>
<td>24 (12)</td>
<td>0.30</td>
<td>0.07-1.34</td>
<td>0.30</td>
<td>0.07-1.37</td>
</tr>
</tbody>
</table>

OR = odds ratio; 95% CI = 95% confidence interval;
Activity Restriction = reduce activity, or reduce housework, or stop work, or bedrest
Project Recommendations = activity restriction, or check for contractions
† Co-interventions of low-risk protocol retained in separate final logistic regression models; parity remained in all models
*p < 0.05
Table 12: Effect of Compliance with Project Recommendations among Women at Low Risk (n=201)

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>n (%)</th>
<th>OR</th>
<th>95% CI</th>
<th>Adjusted OR†</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Project Recommendations</td>
<td>77 (38)</td>
<td>0.30</td>
<td>0.13-0.68*</td>
<td>0.20</td>
<td>0.08-0.50*</td>
</tr>
<tr>
<td>Check for Contractions</td>
<td>29 (14)</td>
<td>0.11</td>
<td>0.02-0.84*</td>
<td>0.11</td>
<td>0.01-0.88*</td>
</tr>
<tr>
<td>Activity Restriction</td>
<td>67 (33)</td>
<td>0.32</td>
<td>0.13-0.76*</td>
<td>0.28</td>
<td>0.11-0.72*</td>
</tr>
<tr>
<td>Reduce Activity</td>
<td>39 (19)</td>
<td>0.36</td>
<td>0.12-1.08</td>
<td>0.29</td>
<td>0.10-0.92*</td>
</tr>
<tr>
<td>Reduce Housework</td>
<td>31 (15)</td>
<td>0.35</td>
<td>0.10-1.21</td>
<td>0.31</td>
<td>0.09-1.09</td>
</tr>
<tr>
<td>Stop Work</td>
<td>46 (23)</td>
<td>0.38</td>
<td>0.14-1.02</td>
<td>0.33</td>
<td>0.12-0.91*</td>
</tr>
<tr>
<td>Bedrest</td>
<td>16 (8)</td>
<td>0.50</td>
<td>0.11-2.30</td>
<td>0.44</td>
<td>0.09-2.06</td>
</tr>
</tbody>
</table>

OR = odds ratio; 95% CI = 95% confidence interval
Activity Restriction = reduce activity, or reduce housework, or stop work, or bedrest
Project Recommendations = activity restriction, or check for contractions
† Co-interventions of low-risk protocol retained in separate final logistic regression models; parity remained in all models
*p < 0.05
DISCUSSION

5.1 Participation

Although participation in some aspect of the preterm birth prevention program was high (82% overall; 89% for high-risk; 79% for low-risk), full participation by women in this study was very low (8% for high-risk; 6% for low-risk). More than 60% of study subjects read the project pamphlet, but less than 20% reported having the warning signs of preterm labour reviewed by their prenatal care providers. Women who were identified to be at increased risk for preterm birth based on the clinical criteria of the risk assessment tool had higher levels of exposure to the interventions of the prevention protocol than did women with no identifiable risk factors for preterm birth. Apart from the recommendation to restrict activity, participation in other aspects of the project protocol was generally low among high-risk women. In particular, only 11% of women with identifiable risk factors were referred to the project coordinator for individual counseling and support. It is interesting to note that over 40% of women with no identifiable risk factors for preterm birth were advised to restrict their activity and/or monitor for uterine contractions by self palpation. It is unclear what motivated prenatal care providers to invoke these recommendations since they were not part of the prevention protocol for low-risk women. Presumably, they prescribed these lifestyle modifications in response to clinical signs or symptoms which did not alter the preterm birth risk status.

Although information regarding participation in the preterm birth prevention project was obtained from childbearing women, the choice to participate or not was actually made
by their attending physicians. Despite the enthusiastic response to the promotion of the prevention project by physicians, nurses and receptionists following teaching sessions in doctors' offices and at hospital rounds, the results of this study indicate that physicians did not generally incorporate the interventions of the preterm birth prevention project into their practice. The interventions which were employed were directed primarily toward women at increased risk for preterm birth where prevention strategies have traditionally been focused. Since the project pamphlet was made available to pregnant women of Halifax County in hospitals, pharmacies, community centers, libraries and through prenatal classes, exposure to this component of the prevention project was high.

The successful integration of recommendations into practice depends on the interaction of a number of factors, such as the characteristics of the change; state of readiness of health care providers; organizational/system support and assistance of staff; feedback systems among practitioners; as well as available evidence, experts and sources of information. The patient encounter is known to be time-limited, case-specific and action-oriented. During a patient visit, providers face the competing demands of patient/family; provider practice; and policy. These realities require consideration when introducing new recommendations into practice. Although recommendations to modify physician practice often predispose providers to consider implementing change, they often fall short of invoking it. This was highlighted in a recent study in Eastern Ontario which confirmed that most women were not educated about the prevention of preterm birth by their physicians or anywhere in the health care team despite promotion of practice guidelines by the regional perinatal education program.
Interventions are most successful when matched with, and designed for, a readiness for change of providers or organizations. Targeted, multi-pronged and phased interventions in a supportive environment using opinion leaders, educational material and social marketing are most effective.\textsuperscript{109} Evidence suggests that predisposing, enabling and reinforcing strategies in combination are often required to invoke change.\textsuperscript{110} Given the limited resources of the Halifax County Preterm Birth Prevention Project and the large number of practitioners providing prenatal care, it is not surprising that physician participation in the prevention project was limited.

5.2 Characteristics of the Study Population

Comparison of cases and controls for sociodemographic, lifestyle/occupational and potential risk factors for preterm birth were performed to identify potential confounders unequally distributed between the two groups rather than to determine risk factors for preterm birth. Determinants of prematurity have been identified in large epidemiologic studies.\textsuperscript{1} In this study, there was a higher proportion of primiparous women among those who delivered preterm relative to those who delivered at term. Parity has not been shown to play an important role in the occurrence of preterm birth\textsuperscript{1} so it is therefore more likely that this finding resulted from chance than from being a risk factor for preterm birth in this small sample. The unequal distribution of primiparity may explain the apparent, though nonsignificant, protective effect of having children at home since these factors are inversely related.

Factors which have been associated with preterm birth such as single marital status, low socioeconomic status and increased stress were not significantly associated with preterm
birth in this study. Although there was a suggestion of an increased risk of prematurity associated with working during pregnancy, prolonged standing, heavy physical work and excessive activity at home or at work appeared to provide a protective, though nonsignificant, effect. Although these findings may be due to chance, one explanation for an apparent protective effect of increased activity is that women who were at increased risk and delivered preterm would be more likely to have been advised to reduce activity than those who had no identifiable risk factors and delivered at term.

Established risk factors for preterm birth such as smoking, antepartum bleeding, sexually transmitted disease and gestational diabetes were more prevalent among women who delivered preterm than those who delivered at term. The lack of significance in these associations probably reflects insufficient power of the study sample size to demonstrate a significant difference. Predictably, high risk status and subjects’ recognition of warning signs of preterm labour were both significantly associated with an increased risk of preterm birth. Although approximately 70% of study subjects reported prenatal symptoms promoted as “warning signs” of preterm labour, less than 20% of interviewed women stated that they had actually experienced warning signs of preterm labour. This would suggest that women are selective in their interpretation of which symptoms constitute warning signs of preterm labour. It would also suggest that either women are capable of correctly identifying true warning signs of preterm labour or that the recognition of these warning signs occurs too late for interventions to be effective. Both explanations have been suggested previously.¹¹¹,¹¹²

When evaluated by risk status (low-risk and high-risk subgroups), associations between potential risk factors and the occurrence of preterm birth were similar to the
associations observed in the study population as a whole. The only factor which appeared to have a significant beneficial effect was having children at home among women at low risk for preterm birth. As suggested previously, this finding is related to the higher proportion of primiparous parturients who delivered preterm in this study.

5.3 Effect of Participation in the Halifax County Preterm Birth Prevention Project

5.3.1 Educational Component

The primary rationale for educating pregnant women and healthcare providers about the symptoms of premature labour is to increase early recognition and improve the effectiveness of preventive interventions. In this study, neither exposure to the project pamphlet nor education session with the project coordinator provided any benefit in terms of reducing the likelihood of preterm birth for women known to be at high risk. These findings are consistent with several randomized controlled trials of preterm birth educational programs for high-risk women. The few high-risk women who were referred for counseling and support by the project coordinator had an increased, though nonsignificant, risk of preterm birth. Since physicians tended only to refer women after assessment or admission for premature uterine contractions or cervical change they were at extreme risk for preterm birth. Consequently, individualized education and support was reserved for those least likely to benefit from the intervention.

There was also no evidence of a beneficial effect of exposure to the project pamphlet among women with no identifiable risk factors for preterm birth. As in the high risk group, there was a suggestion, though nonsignificant, of a reduction in the risk of prematurity among women whose healthcare providers reviewed the warning signs of preterm labour.
Given the small proportion of women exposed to this intervention and the relatively small sample size in this study, no conclusions can be drawn from this observation. One might speculate, however, that self-education about the warning signs of preterm labour is unlikely to be beneficial unless reinforced by prenatal healthcare providers.

5.3.2 Cervical Examination

Premature cervical change determined by digital examination has been shown to be a reliable predictor of preterm birth, particularly in women at increased risk. Pelvic examination is not a routine component of prenatal care in North America and acceptance of this practice as part of the preterm birth prevention protocol was limited among prenatal care providers of Halifax County. (27% for high-risk; 24% for low-risk) Although the adjusted odds ratios for this intervention in high and low-risk women suggested a protective effect, the 95% confidence intervals were wide and included the null value. This equivocal observation supports the conclusion of a randomized controlled trial of routine cervical examination in pregnancy which failed to show a reduction in the prematurity rate related to this intervention.

5.3.3 Self Palpation for Uterine Contractions

The association between increased uterine contractility and prematurity is well documented. Identification of increased uterine activity by self palpation has been promoted as a preventive strategy in women at risk for preterm birth. High-risk women in this study who were encouraged and complied with the recommendation to check for contractions derived no beneficial effect. On the other hand, women at low risk for preterm birth who were advised to monitor for uterine contractions appeared to have a reduced,
though nonsignificant, likelihood of delivering preterm. This beneficial effect was significant for those women who complied with the recommendation. These findings support the observation that the process leading to preterm birth in women at high risk cannot be modified following the recognition of increased uterine contractility. In contrast, recognition of premature uterine contractions by women with no identifiable risk factors for preterm birth may raise the concern of prenatal care providers and result in lifestyle modifications which reduce the risk of preterm birth.

5.3.4 Activity Restriction

Despite the lack of convincing evidence that bedrest reduces the risk of preterm birth, activity restriction is commonly recommended for women at increased risk for preterm birth, particularly in pregnancies complicated by multiple gestation, preterm premature rupture of membranes and premature uterine contractions. The widespread use of this intervention by prenatal care providers is based on promising results from multi-intervention preterm birth prevention programs in France and the United States. More convincing evidence on the beneficial effects of rest during pregnancy comes from well controlled studies of French and Mexican workers who are at increased risk for occupational fatigue. A significant reduction in preterm deliveries was found among women who took work leave for fatigue, without concurrent medical or obstetric problems, compared to their co-workers who did not opt for pregnancy leave.

In this study, activity restriction provided no benefit for women at high risk for preterm birth but resulted in a three-fold reduction in the risk of prematurity for women with no identifiable risk factors. As suggested previously, women with non-modifiable risk
factors do not appear to benefit from preterm birth prevention strategies whereas women presenting with idiopathic warning signs of preterm labour may benefit from these lifestyle modifications. The risk scoring algorithm used in this study does not include occupational risk factors. In addition, subjects were not evaluated with reliable measures of physical activity. As a result, it is not possible to draw more definitive conclusions from these interesting findings.

5.4 Limitations and Benefits of the Study

The major limitation of this study was its small sample size. The availability of women exposed to the Halifax County Preterm Birth Prevention Project was limited by the duration of the project which was in its final year of funding when this study was initiated. As a result, the effect size and power to demonstrate a significant difference between cases and controls were derived from a predetermined sample size estimate. As it turned out, the predicted enrolment of cases and controls during the study period was significantly overestimated. The main reason for this judgement error was the exclusion of women whose preterm deliveries were related to pregnancy complications believed to be non-preventable, such as multiple gestation, congenital malformations, chorioamnionitis, abruptio placenta, placenta previa or delivery for medical reasons. The exclusion criteria combined with a slightly lower preterm birth rate among Halifax County women and a lower recruitment rate than estimated resulted in a study sample which was 50% less than anticipated. The small sample size resulted in reduced power to demonstrate a difference when a difference was present. This limitation was illustrated by the lack of significant associations between established risk factors and the occurrence of preterm birth. The lower sample size
particularly influenced the results of sub-analyses for high risk and low-risk subgroups. Since the exclusion criteria were highly associated with prematurity, there was a much higher rate of exclusion of potential cases than controls (51% versus 14%). However, comparison of cases and controls for sociodemographic, lifestyle and occupational characteristics revealed that the study population was relatively homogeneous.

The case-control design, in any setting, is subject to several potential sources of bias that can distort or invalidate the results. The principal disadvantage of non-randomized studies of program efficacy is the possibility that individuals who choose to participate in a health promotion program will differ in the underlying risk for the outcome from those who are not exposed or who choose not to participate. Consequently, the exposed group may differ in prognosis from the unexposed group for reasons unrelated to the intervention. For interventions with a large component of patient and/or physician choice, differences between patients who choose to follow program recommendations and those who do not can distort associations between specific interventions and outcomes. In this study, participation in the Halifax County Preterm Birth Prevention Project depended primarily on whether or not a woman's physician decided to participate in the program. Based on unpublished survey information, physicians of Halifax County either agreed to participate or not, although the degree of participation varied. Physicians may not have consciously decided that some prenatal patients would participate and others would not, but they were more likely to employ project interventions in women with identified risk factors for preterm birth.

Another potential limitation of the case-control study is the potential for recall bias which must be considered for women who were only interviewed postpartum. Cases and
controls may differentially recall events which occurred prior to delivery. For example, in this study, women who experienced preterm birth may have remembered more about program materials, symptoms and internal examinations than controls. This differential recall would bias the results in the direction of increased risk associated with participation. Studies of congenital malformations designed to evaluate recall bias have provided little evidence of recall bias in mothers’ exposure reports.\textsuperscript{117, 118} Since pregnancy involves a relatively short time span, accurate recall of prenatal events by study subjects is more likely than in studies involving assessment of exposures occurring many years previously. Potential differences in recall of project interventions between high-risk and low-risk women were controlled for by separate analyses of these subgroups. In addition, prenatal records were available to validate some of the recalled information obtained from study subjects.

The case-control method has been applied extensively to the study of chronic diseases because of its advantage in cost and statistical power over other study designs.\textsuperscript{119} The case-control study is particularly useful in preliminary investigations, in situations where prospective randomized controlled trials are impractical or too extensive and when outcomes of interest are too infrequent to permit prospective studies. Several investigators have used case-control methodology to estimate program efficacy indirectly by comparing compliance with program recommendations as the exposure of interest, such as the use of bicycle helmets\textsuperscript{120} or oral hydration therapy\textsuperscript{121}. A direct assessment of efficacy may be achieved by comparing participation in a healthcare program in cases and controls, as in the evaluation of emergency services reported by Sampalis et al.\textsuperscript{122}
The case-control approach was the most feasible method to evaluate the impact of participation in the Halifax County Preterm Birth Prevention Project. This approach was particularly relevant to the outcome of interest, preterm birth, which has an incidence of between 5% and 6% in the study population. Since all of the deliveries in Halifax County occur at one hospital, the identification of cases and controls was greatly simplified. A cohort study, on the other hand, would have required the identification of prenatal patients seen throughout Halifax County by many practitioners in order to determine participation. The difference in cost to conduct a case-control study versus a cohort study in this population is obvious.

Although prospective randomized trials remain the preferred method for evaluation of program efficacy, it would have been difficult to impossible to conduct a randomized trial of a preterm birth prevention program from a single obstetric population given the potential for treatment contamination resulting in controls receiving similar treatment to the experimental group. This case-control study provides important information, including estimates of the effectiveness of preterm birth prevention interventions for high-risk and low-risk women where a randomized trial would have been impractical.

### 5.5 Conclusions

Participation in the Halifax County Preterm Birth Prevention Project was limited by the low level of integration of the project recommendations into the practice of prenatal care providers. Consequently, the ability to evaluate the effect of participation in the prevention program on preterm birth was suboptimal. Despite the limitations of the case-control design and the small sample size, there were a number of interesting and hypothesis-generating
findings in this study. As reported previously by others, multi-intervention prevention strategies appear to be ineffective when applied to women with established risk factors for preterm birth. On the other hand, women with no identifiable risk factors for preterm birth may benefit from activity restriction and uterine activity monitoring by self palpation. The precipitating factors and rationale which lead prenatal care providers to advise low-risk women to reduce their activity level are unclear. The effect of activity restriction and maternal stress reduction on pregnancy outcomes is not well understood. The results of this study provide stimulus for further research in this area.
PRETERM BIRTH RISK ASSESSMENT TOOL

<table>
<thead>
<tr>
<th>Major Factors</th>
<th>Minor Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>History</strong></td>
<td><strong>Current Pregnancy</strong></td>
</tr>
<tr>
<td>Previous PTB</td>
<td>Multiple Gestation</td>
</tr>
<tr>
<td>Uterine Anomaly</td>
<td>Preterm Labour</td>
</tr>
<tr>
<td></td>
<td>Cx Dilatation &gt; 1 cm</td>
</tr>
<tr>
<td></td>
<td>Cx Length &lt; 1 cm</td>
</tr>
<tr>
<td></td>
<td>Antepartum Bleeding*</td>
</tr>
<tr>
<td></td>
<td>Anemia &lt; 100g/L</td>
</tr>
<tr>
<td></td>
<td>Abdominal Surgery</td>
</tr>
</tbody>
</table>

High Risk = one major or two minor factors
PTB = preterm birth; Cx = cervical
* vaginal bleeding ≥ 20 weeks gestation
HALIFAX COUNTY PRETERM BIRTH PREVENTION PROJECT PROTOCOL

<table>
<thead>
<tr>
<th>Low Risk</th>
<th>High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>First Prenatal Visit</strong></td>
<td>Educational material provided</td>
</tr>
<tr>
<td>- risk assessment</td>
<td>Education session with project coordinator</td>
</tr>
<tr>
<td>- cervical exam</td>
<td>Modified bed rest at home</td>
</tr>
<tr>
<td><strong>20-24 Weeks</strong></td>
<td>Weekly prenatal visits (24-34 weeks)</td>
</tr>
<tr>
<td>- risk assessment</td>
<td>Weekly cervical exams (24-34 weeks)</td>
</tr>
<tr>
<td>- educational materials provided</td>
<td>Uterine activity monitoring by self-palpation</td>
</tr>
<tr>
<td>- warning signs reviewed</td>
<td>Weekly telephone contact with project coordinator</td>
</tr>
<tr>
<td>- cervical exam</td>
<td></td>
</tr>
</tbody>
</table>

**28-32 Weeks**
- risk assessment
- warning signs reviewed
- cervical exam
Halifax County Preterm Birth Prevention Project

FIRST PRENATAL VISIT

- Risk Assessment
  - HIGH RISK
  - LOW RISK

PRENATAL VISIT

@ 20-24 Weeks
- Educational material given to patient
- Warning signs reviewed

- Risk Assessment
- Pelvic exam
  - HIGH RISK
  - LOW RISK

@ 28-32 Weeks
- Warning signs reviewed

- Risk Assessment
- Pelvic exam
  - HIGH RISK
  - LOW RISK

Patient's Name: ____________________________
Nurse coordinator telephone: 420-3088

HIGH RISK
- Educational material given to patient
- Nurse coordinator contacted
- Weekly MD visits from 24-36 weeks including Pelvic exam

Risk Assessment Tool

<table>
<thead>
<tr>
<th>Cervical Length</th>
<th>Low Risk</th>
<th>High Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Visit</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20-24 Weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>28-32 Weeks</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

One major or two minor factors = HIGH RISK.

Major Factors
- History:
  - Previous Preterm Delivery
  - Uterine Anomaly
- This Pregnancy:
  - Multiple Gestation
  - Suspected Preterm Labour
  - Bleeding after 12 weeks
  - Anemia < 100g/L
  - Cervical Dilation >1cm
  - Cervical Length <1cm
  - Abdominal Surgery

Minor Factors
- Smoking during Pregnancy
- Polyhydramios (confirmed by ultrasound)
- Sexually Transmitted Disease (syphilis, gonorrhea, condyloma, mycoplasma, chlamydia, or active herpes).
- Gestational Diabetes

Halifax County Preterm Birth Prevention Project
Grace Maternity Hospital
Department of Obstetrics and Gynaecology
5980 University Avenue, Halifax, Nova Scotia B3H 4N1
Telephone: 420-3088
How To Check For Contractions
Place your fingertips on your uterus, like this –

If your uterus is tightening and softening, you can tell how often these contractions are happening by timing the number of minutes from the start of one tightening to the start of the next tightening.

Some tightenings feel harder or stronger than others.

It is normal for you to feel contractions at times during pregnancy, however, if you have 4 or more contractions per hour then you should contact your doctor or go to the hospital right away.

My Due Date: 

My Doctor's Number: 

Grace Maternity Hospital 
Early Labour 
Assessment Unit: 420-6672

Nurse Coordinator: 420-3088

Halifax County Preterm Birth Prevention Project ©
Grace Maternity Hospital
Dept. of Obstetrics and Gynaecology
5980 University Avenue, Halifax, Nova Scotia B3H 4N1
Telephone: 420-3088
• Project funded by Grace Maternity Hospital Foundation.
• Educational materials funded by N.S. Dept. of Health, Community Health Promotion Fund.
THE HALIFAX COUNTY PRETERM BIRTH PREVENTION PROJECT

ABSTRACT

Background: The Halifax County Preterm Birth Prevention Project was designed to determine the feasibility and effectiveness of a population-based preterm birth (PTB) prevention program in Nova Scotia.

Methods: The prevention program was made available to all pregnant women of Halifax County from January 1995 through June 1997. Education of prenatal patients and health care providers about the signs, symptoms, and management of preterm labour was provided. Risk assessment and cervical examination was recommended for women at low risk for preterm birth at the initial prenatal visit, 20-24 weeks, and 28-32 weeks. Prenatal care for high-risk women promoted rest and reduction of stress with close maternal surveillance for early indications of preterm labour. Preterm birth rates, adjusted for risk status, were evaluated over time in Halifax County and compared to non-Halifax County residents.

Results: There was no appreciable change in the overall (<37 weeks) or early (<34 weeks) PTB rates within or outside Halifax County during the intervention period compared to the pre-intervention period. The very PTB rate (<30 weeks) in Halifax County decreased by 30% (0.67%-0.46%) whereas no change was observed elsewhere in Nova Scotia (0.54%-0.60%). There was a statistically significant decrease in early preterm births (<34 weeks) associated with spontaneous labour in Halifax County (0.65%-0.35%) which was not observed in the rest of the province (0.50%-0.48%).

Interpretation: These results suggest that adoption of preterm birth prevention strategies in Nova Scotia may be effective in reducing the rate of very preterm and spontaneous early preterm births.
## Risk Factors in Study and Control Populations

<table>
<thead>
<tr>
<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 11,040</td>
<td>n = 10,326</td>
<td>n = 15,542</td>
<td>n = 14,246</td>
</tr>
<tr>
<td></td>
<td>No. (%)</td>
<td>No. (%)</td>
<td>No. (%)</td>
<td>No. (%)</td>
</tr>
<tr>
<td>High-Risk Status</td>
<td>1,931 (17.5)</td>
<td>1,652 (16.0)</td>
<td>2,126 (13.7)</td>
<td>2,041 (14.3)</td>
</tr>
<tr>
<td>Previous LBW</td>
<td>436 (4.08)</td>
<td>392 (3.85)</td>
<td>470 (3.12)</td>
<td>411 (2.97)</td>
</tr>
<tr>
<td>Uterine Anomaly</td>
<td>74 (0.67)</td>
<td>77 (0.75)</td>
<td>70 (0.45)</td>
<td>78 (0.55)</td>
</tr>
<tr>
<td>Multiple Gestation</td>
<td>147 (1.33)</td>
<td>139 (1.35)</td>
<td>144 (0.93)</td>
<td>133 (0.93)</td>
</tr>
<tr>
<td>Antepartum Bleeding*</td>
<td>894 (8.10)</td>
<td>626 (6.06)</td>
<td>945 (6.08)</td>
<td>1,004 (7.05)</td>
</tr>
<tr>
<td>Anemia &lt;100g/l</td>
<td>373 (3.38)</td>
<td>414 (4.01)</td>
<td>424 (2.73)</td>
<td>383 (2.69)</td>
</tr>
<tr>
<td>Abdominal Surgery</td>
<td>2 (0.02)</td>
<td>4 (0.04)</td>
<td>1 (0.01)</td>
<td>2 (0.01)</td>
</tr>
<tr>
<td>Smoking</td>
<td>2,779 (26.4)</td>
<td>2,583 (25.6)</td>
<td>4,871 (32.4)</td>
<td>4,176 (30.1)</td>
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<tr>
<td>Polyhydramnios</td>
<td>54 (0.49)</td>
<td>34 (0.33)</td>
<td>73 (0.47)</td>
<td>65 (0.46)</td>
</tr>
<tr>
<td>STD</td>
<td>413 (3.74)</td>
<td>326 (3.16)</td>
<td>183 (1.18)</td>
<td>157 (1.10)</td>
</tr>
<tr>
<td>Gestational Diabetes</td>
<td>275 (2.49)</td>
<td>235 (2.28)</td>
<td>489 (3.15)</td>
<td>456 (3.20)</td>
</tr>
</tbody>
</table>

High Risk = one major or two minor factors; LBW = low birth weight (<2500 g); STD = sexually transmitted disease (syphilis, gonorrhea, condyloma, mycoplasma, chlamydia, or active herpes) *vaginal bleeding ≥ 20 weeks’ gestation
### PRETERM BIRTH RATES DURING PRE-INTERVENTION AND INTERVENTION PERIODS

<table>
<thead>
<tr>
<th></th>
<th>Halifax County</th>
<th>Non-Halifax County</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 11,040</td>
<td>n = 10,326</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>No. (%)</td>
<td>No. (%)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preterm Birth (&lt;37 weeks)</td>
<td>599 (5.43)</td>
<td>592 (5.73)</td>
<td>1.09 (0.98, 1.21)</td>
<td>795 (5.12)</td>
<td>766 (5.38)</td>
</tr>
<tr>
<td>Early PTB (&lt;34 weeks)</td>
<td>149 (1.35)</td>
<td>126 (1.22)</td>
<td>0.90 (0.66, 1.24)</td>
<td>197 (1.27)</td>
<td>181 (1.27)</td>
</tr>
<tr>
<td>Very PTB (&lt;30 weeks)</td>
<td>74 (0.67)</td>
<td>47 (0.46)</td>
<td>0.71 (0.49, 1.01)</td>
<td>84 (0.54)</td>
<td>85 (0.60)</td>
</tr>
<tr>
<td>Spontaneous Labour PTB &lt;37 weeks</td>
<td>222 (2.01)</td>
<td>186 (1.80)</td>
<td>0.93 (0.77, 1.12)</td>
<td>343 (2.21)</td>
<td>336 (2.36)</td>
</tr>
<tr>
<td>PTB &lt;34 weeks</td>
<td>72 (0.65)</td>
<td>36 (0.35)</td>
<td>0.56 (0.38, 0.80)</td>
<td>77 (0.50)</td>
<td>68 (0.48)</td>
</tr>
<tr>
<td>PROM PTB &lt;37 weeks</td>
<td>229 (2.07)</td>
<td>248 (2.40)</td>
<td>1.19 (0.99, 1.42)</td>
<td>269 (1.73)</td>
<td>235 (1.65)</td>
</tr>
<tr>
<td>PTB &lt;34 weeks</td>
<td>41 (0.37)</td>
<td>52 (0.50)</td>
<td>1.42 (0.95, 2.13)</td>
<td>74 (0.48)</td>
<td>62 (0.44)</td>
</tr>
<tr>
<td>Medical Intervention PTB &lt;37 weeks</td>
<td>148 (1.34)</td>
<td>158 (1.53)</td>
<td>1.17 (0.94, 1.47)</td>
<td>183 (1.18)</td>
<td>195 (1.37)</td>
</tr>
<tr>
<td>PTB &lt;34 weeks</td>
<td>36 (0.33)</td>
<td>38 (0.37)</td>
<td>1.16 (0.74, 1.83)</td>
<td>46 (0.30)</td>
<td>51 (0.36)</td>
</tr>
</tbody>
</table>

Adjusted RR = relative risk adjusted for risk status; 95% CI = 95 percent confidence interval; PTB = preterm birth
<table>
<thead>
<tr>
<th></th>
<th>Halifax County</th>
<th>Non-Halifax County</th>
<th>RR (95% CI)</th>
<th>RR (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1993-1995 No. (%)</td>
<td>1995-1997 No. (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Singleton Pregnancy</td>
<td>(n = 10,893)</td>
<td>(n = 10,187)</td>
<td>(n = 15,398)</td>
<td>(n = 14,113)</td>
</tr>
<tr>
<td>PTB &lt;37 weeks</td>
<td>527 (4.84)</td>
<td>532 (5.22)</td>
<td>1.08 (0.96,1.21)</td>
<td>1.05 (0.94,1.16)</td>
</tr>
<tr>
<td>PTB &lt;34 weeks</td>
<td>126 (1.16)</td>
<td>110 (1.08)</td>
<td>0.93 (0.72,1.20)</td>
<td>1.05 (0.84,1.30)</td>
</tr>
<tr>
<td>Multiple Gestation</td>
<td>(n = 147)</td>
<td>(n = 139)</td>
<td>(n = 144)</td>
<td>(n = 133)</td>
</tr>
<tr>
<td>PTB &lt;37 weeks</td>
<td>72 (49.0)</td>
<td>60 (43.2)</td>
<td>0.88 (0.69,1.13)</td>
<td>1.12 (0.88,1.42)</td>
</tr>
<tr>
<td>PTB &lt;34 weeks</td>
<td>23 (15.7)</td>
<td>16 (11.5)</td>
<td>0.74 (0.41,1.33)</td>
<td>0.74 (0.43,1.25)</td>
</tr>
<tr>
<td>Low Risk</td>
<td>(n = 9,109)</td>
<td>(n = 8,674)</td>
<td>(n = 13,416)</td>
<td>(n = 12,205)</td>
</tr>
<tr>
<td>PTB &lt;37 weeks</td>
<td>336 (3.69)</td>
<td>341 (3.93)</td>
<td>1.07 (0.92,1.24)</td>
<td>1.10 (0.97,1.25)</td>
</tr>
<tr>
<td>PTB &lt;34 weeks</td>
<td>66 (0.72)</td>
<td>62 (0.71)</td>
<td>0.99 (0.70,1.39)</td>
<td>1.08 (0.80,1.44)</td>
</tr>
<tr>
<td>High Risk</td>
<td>(n = 1,931)</td>
<td>(n = 1,652)</td>
<td>(n = 2,126)</td>
<td>(n = 2,041)</td>
</tr>
<tr>
<td>PTB &lt;37 weeks</td>
<td>263 (13.6)</td>
<td>251 (15.2)</td>
<td>1.12 (0.95,1.31)</td>
<td>0.94 (0.81,1.09)</td>
</tr>
<tr>
<td>PTB &lt;34 weeks</td>
<td>83 (4.30)</td>
<td>64 (3.87)</td>
<td>0.90 (0.66,1.24)</td>
<td>0.91 (0.69,1.19)</td>
</tr>
</tbody>
</table>

**RR** = relative risk; **95% CI** = 95% confidence interval; **PTB** = preterm birth
Preterm Birth Rate
(< 37 weeks)

Percent


Halifax Co Non Halifax Co
Preterm Birth Rate
(< 34 weeks)

Percent


Halifax Co  Non Halifax Co
Preterm Birth Rate
(<30 weeks)

Percent


Halifax Co  Non Halifax Co
Preterm Birth Rate
(<30 weeks)

<table>
<thead>
<tr>
<th>Percent</th>
<th>1993 to 1995</th>
<th>1995 to 1997</th>
</tr>
</thead>
<tbody>
<tr>
<td>Halifax Co</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non Halifax Co</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Preterm Birth Rate
Spontaneous Labour (< 37 weeks)

Percent


Halifax Co Non Halifax Co
Preterm Birth Rate
Spontaneous Labour (< 34 weeks)

- Halifax Co
- Non Halifax Co
Preterm Birth Rate

Spontaneous Preterm Labour (<34 wks)

<table>
<thead>
<tr>
<th>Percent</th>
<th>0.8</th>
<th>0.6</th>
<th>0.4</th>
<th>0.2</th>
<th>0.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Halifax Co</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non Halifax Co</td>
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</tr>
</tbody>
</table>

1993 to 1995
1995 to 1997
Premature birth is when babies are born before 37 weeks' (8 ½ months) of pregnancy. This can happen no matter what you or your health care team does or doesn't do.

A study is being done at the IWK-Grace Health Centre to help us find out more about premature birth. We are asking you to answer some questions about your pregnancy, as well as some basic questions about yourself. We are asking mothers whose babies were born prematurely, as well as mothers whose babies were born near their due date to participate.

Someone from the study team will ask you some questions at a time which is good for you, and it should only take about 15 or 20 minutes. This person will also look at your chart for information about your pregnancy and delivery.

Thank you for your help in this research project. If you have any questions about this study, please contact either the nurse coordinator, at 420-3088, or Dr. Armson, principal investigator, at 420-6778.

My decision to take part in this study is my own choice. I understand that my health care will be the same if I choose to participate or not. I may ask questions or withdraw from the study at any time. Although this study does not affect my health, I know that I should contact my doctor if I have problems of any kind.

I understand that this study may not help me, but may help others. All of the answers to questions will be confidential and no one will be able to tell that they are my answers. The information will be identified by a number and kept in a locked cabinet. My name will not be used in any of the reports. I will be able to have a copy of any of the reports should I ask.

I have read the consent form and I have had all of my questions answered. I agree to participate in this study.

Date ___________________________ Signature ___________________________

Witness ___________________________
PREMATURE BIRTH STUDY

STUDY QUESTIONNAIRE
How many children do you have at home?

0 1 2 3 4 5 >6
☐ ☐ ☐ ☐ ☐ ☐ ☐

If you have children at home, what are their ages:

☐CHILDA1 0-2 ☐
☐CHILDA2 3-5 ☐
☐CHILDA3 6-9 ☐
☐CHILDA4 >10 ☐

Do you usually work outside the home?

Yes ☐ 1 No ☐ 2

Did you work outside the home during this pregnancy?

Yes ☐ 1 No ☐ 2

If yes, how many hours per week ______

What is your usual occupation? ____________________________________________
On a scale of 1 to 5, what was your usual level of physical activity while you were pregnant? (This does not apply to any time in your pregnancy when your doctor recommended restricted activity.)

<table>
<thead>
<tr>
<th>HOME</th>
<th>WORKPLACE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STAND1</strong></td>
<td><strong>STAND2</strong></td>
</tr>
<tr>
<td>I hardly stand at all = 1</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>I am constantly standing = 5</td>
<td>□ □ □ □ □</td>
</tr>
<tr>
<td><strong>PHYS1</strong></td>
<td><strong>PHYS2</strong></td>
</tr>
<tr>
<td>No physical demands = 1</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>Extremely physically demanding = 5</td>
<td>□ □ □ □ □</td>
</tr>
<tr>
<td><strong>SIT1</strong></td>
<td><strong>SIT2</strong></td>
</tr>
<tr>
<td>I am always sitting = 1</td>
<td>1 2 3 4 5</td>
</tr>
<tr>
<td>I never sit down = 5</td>
<td>□ □ □ □ □</td>
</tr>
</tbody>
</table>

**STRESS**

Prior to your labour and delivery, how would you rate your level of stress during your pregnancy? (On a scale of 1 to 5 with 1 being no stress and 5 being extreme stress.)

1 2 3 4 5
□ □ □ □ □

**BLEED**

Did you have any vaginal bleeding after the first three months of this pregnancy?

Yes □ 1  No □ 2
SURG
Did you have any abdominal surgery during this pregnancy?

Yes □ 1  No □ 2

SMOKE
Did you smoke during this pregnancy?

Yes □ 1  No □ 2

SMOKE1
If yes, how many cigarettes per day?

<10 □ 1  ≥10 □ 2

STD
Did you have any of the following sexually transmitted diseases during this pregnancy: chlamydia, genital herpes, genital warts or gonorrhea?

Yes □ 1  No □ 2

DIAB
Did you develop diabetes during this pregnancy?

Yes □ 1  No □ 2
Cases: Excluding the past week, did you experience any of the following symptoms in your pregnancy?

Controls: Prior to 36 weeks (8 months), did you experience any of the following symptoms in your pregnancy?

- **CONTR**
  Uterine contractions
  Yes □ 1  No □ 2

- **MCRAMP**
  Menstrual-like cramps
  Yes □ 1  No □ 2

- **BACK**
  Low dull backache, radiating to the front
  Yes □ 1  No □ 2

- **PRESS**
  Pelvic pressure
  Yes □ 1  No □ 2

- **ACRAMP**
  Abdominal cramps
  Yes □ 1  No □ 2

- **VAG**
  Change in vaginal discharge
  Yes □ 1  No □ 2
If yes to any of the above (symptoms, page 4):

■ CONDOC

Did you contact a doctor or nurse? Yes □ 1 No □ 2

■ SEEDOC

Were you seen by a doctor or nurse? Yes □ 1 No □ 2

■ REST

Were you told to reduce your activity or rest at home? Yes □ 1 No □ 2

■ HOSP

Were you admitted to hospital? Yes □ 1 No □ 2

■ OTHER

Other

If no to all of the above (symptoms, page 4):

■ RESTPL

Were you told to reduce your activity or rest at home because of suspected premature labour? Yes □ 1 No □ 2

■ HOSPPL

Were you admitted to hospital for suspected premature labour? Yes □ 1 No □ 2
### PAMP

Does this pamphlet look familiar to you?  
Yes [ ] 1  No [ ] 2

If yes,

#### PAMP1

Where did you first see it?  
- Doctor's Office [ ] 1  
- Prenatal Class [ ] 2  
- Pharmacy [ ] 3  
- Ultrasound/OP Lab [ ] 4  
- Friend [ ] 5  
- Library [ ] 6  
- Other [ ] 7  
- Don't Know [ ] 99

#### PAMP2

When in your pregnancy did you first see it? (weeks)  
Don't Know [ ] 99

#### PAMP3

Did you get your own pamphlet?  
Yes [ ] 1  No [ ] 2

#### PAMP4

Did you have a chance to read it?  
Yes [ ] 1  No [ ] 2

#### PAMP5

Did someone review it with you?  
Yes [ ] 1  No [ ] 2
PAMP6

If yes, who?

Doctor □ 1

Nurse □ 2

Prenatal Instructor □ 3

Kim Rinaldo, a special nurse at the IWK-Grace Health Centre □ 4

Other □ 5
Did you have any warning signs of premature labour during your pregnancy?

Yes □ 1   No □ 2   Don't Know □ 99

If yes: (check all that apply)

■ WARN1
Did you stop what you were doing?
Yes □ 1   No □ 2

■ WARN2
Did you drink 2-3 glasses of juice or water?
Yes □ 1   No □ 2

■ WARN3
Did you lie down and rest on your side?
Yes □ 1   No □ 2

■ WARN4
Did you check for contractions for one hour?
Yes □ 1   No □ 2

■ WARN5
Did you have four or more contractions in one hour or did the symptoms not go away after one hour?
Yes □ 1   No □ 2

■ WARN5A
If yes, what did you do next? (check all that apply)

Nothing □ 1
Continued to check for contractions □ 2
Called my doctor □ 3
Went to my doctor's office □ 4
Went to the hospital □ 5
Other □ 6
Did you have any internal (pelvic) examinations during your pregnancy?

Yes ☐ 1    No ☐ 2

If yes, when?: (check all that apply)

- PV1
  First prenatal visit
  Yes ☐ 1    No ☐ 2    Don't Know ☐ 99

- PV2
  20-24 weeks (5-6 months)
  Yes ☐ 1    No ☐ 2    Don't Know ☐ 99

- PV3
  28-32 weeks (7-8 months)
  Yes ☐ 1    No ☐ 2    Don't Know ☐ 99

- PV4
  Weekly any time between 24 weeks
  (6 months) and 36 weeks (8 1/2 months)
  Yes ☐ 1    No ☐ 2    Don't Know ☐ 99

- PV5
  Did your doctor tell you anything about
  your exam?
  Yes ☐ 1    No ☐ 2    Don't Know ☐ 99

- PV5A
  If yes, what? ________________________________
During your pregnancy, did a doctor or nurse recommend that you:

- **REDUC**
  - Reduce your activity
    - Yes □ 1
    - No □ 2

- **CHECK**
  - Check for contractions
    - Yes □ 1
    - No □ 2

- **BED**
  - Rest in bed
    - Yes □ 1
    - No □ 2

- **STHW**
  - Cut back or stop housework
    - Yes □ 1
    - No □ 2

- **STWK**
  - If working, did you cut back or stop work
    - Yes □ 1
    - No □ 2
    - Not Applicable □ 3

If yes, to what extent were you able to do what he/she recommended?

- **REDUC1**
  - 1
  - 2
  - 3
  - 4
  - 5

- **CHECK**
  - 1
  - 2
  - 3
  - 4
  - 5

- **BED1**
  - 1
  - 2
  - 3
  - 4
  - 5

- **STHW1**
  - 1
  - 2
  - 3
  - 4
  - 5

- **STWK1**
  - 1
  - 2
  - 3
  - 4
  - 5

**EDUC**

Did you have a one-to-one education session with Kim Rinaldo, a special nurse at the IWK-Grace Health Centre?

- Yes □ 1
- No □ 2

**TEL**

If yes, did she call you at home after you met with her?

- Yes □ 1
- No □ 2
Now I am going to ask you some basic questions about yourself?

DEM1

What is your current marital status?

- Single □ 1
- Married or with partner □ 2
- Separated/divorced □ 3
- Widowed □ 4
- Refused □ 88

DEM2

What is your ethnic origin?

(check all that apply)

- West European □ 1
- East European/Slavic □ 2
- Native Indian/Inuit □ 3
- African □ 4
- Caribbean □ 5
- East Indian/Pakistani □ 6
- Asian □ 7
- Central/South American □ 8
- Middle Eastern □ 9
- Other □ 10
- Don't Know □ 99
- Refused □ 88
DEM3

What was the highest level of education that you completed?

- Less than high school □ 1
- High school/equivalency □ 2
- Community/technical college □ 3
- University/polytechnic □ 4
- Graduate school or higher □ 5
- Refused □ 88

DEM4

What was your total family income last year?

- < 20,000 □ 1
- 20,000 - 39,000 □ 2
- 40,000 - 60,000 □ 3
- > 60,000 □ 4
- Don't know □ 99
- Refused □ 88
Data from Prenatal Record/Hospital Chart

Date | ___ | ___ | ___ |
     |     |     |     |
     | D   | M   | Y   |

Study No. | ___ | ___ | ___ | ___ |

Unit No. | ___ | ___ | ___ | ___ | ___ | ___ | ___ |

POST - Postal Code

AGE - Age

GRAV - Gravida (no. of pregnancies)

PAR - Parity (deliveries ≥ 20 weeks gestation)

ABORT - Abortions (< 20 weeks gestation)

GESTAGE - Gestational age at delivery (completed weeks)

Risk Assessment

One major or two minor factors = HIGH RISK

Major Factors

☐ previous preterm delivery
☐ uterine anomaly
☐ multiple gestation
☐ suspected preterm labour
☐ bleeding after 12 weeks
☐ anemia (<100 g/L)
☐ abdominal surgery during pregnancy

Minor Factors

☐ polyhydramnios
☐ smoking during pregnancy
☐ sexually transmitted disease during pregnancy
☐ gestational diabetes

HIGH

HIGH RISK

Yes ☐ 1

No ☐ 2
REFERENCES


77. Lockwood CJ. Recent advances in elucidating the pathogenesis of preterm delivery, the detection of patients at risk, and preventative therapies. Curr Opin Obstet Gynecol 1994; 6: 7-18.


114. Iams JD, Johnson FF, Hamm C. Uterine activity and symptoms as predictors of preterm labor. Obstet Gynecol 1990; 76 (1 suppl.):42S-6S.


