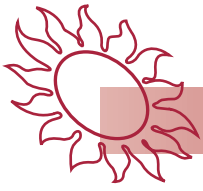

CHAPTER 4

Prevention of Low Birth Weight/Preterm Birth

By Orlando P. da Silva

4

Prevention of Low Birth Weight/Preterm Birth

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Prematurity is defined as gestational age less than 37 completed weeks at birth and low birth weight (LBW), as weight less than 2,500 g. Such infants may be premature, small for gestational age, or both. Social support alone is not effective in improving pregnancy outcome with respect to improving birth weight or gestational age at delivery in high-risk populations. The situation for multicomponent programs is less clear and the Task Force found the evidence available to evaluate them inconclusive. While diet supplementation in the prenatal period in pregnant women at high risk for undernutrition increases birth weight slightly and has been shown to be cost effective in one U.S. study, the evidence regarding its effectiveness in preventing preterm birth or improving fetal and infant survival is also inconclusive. Cessation of smoking in pregnancy is addressed in Chapter 3 and screening for preeclampsia (Chapter 13) do show some benefits with respect to LBW and they are recommended by the Task Force.

Burden of Suffering

Low birth weight is associated with about 75% of early neonatal mortality in both Canada and the U.S

LBW is associated with about 75% of early neonatal mortality in both Canada and the United States. A U.S. study of 349 neonatal deaths found that 83% of deaths were associated with delivery <37 weeks and 66% with delivery <29 weeks. LBW also contributes significantly to infant and childhood morbidity.<1> About 6% of infants born in Canada are of LBW. The cost of care for these babies is very high. The average cost per admission in the United States has been estimated to be over US$ 7,500 per infant. The burden on society is even greater when long-term costs are taken into account.

Cigarette smoking is the most important established risk factor for intrauterine growth retardation

In developed countries, cigarette smoking is the most important established factor with a direct causal impact on the rate of intrauterine growth retardation (defined as birth weight <2500 g and gestational age >37 weeks). Other important factors include poor gestational nutrition, low pre-pregnancy weight, primiparity, female sex and short stature.<1> Although most preterm deliveries are of unknown etiology, cigarette smoking, prior preterm delivery, spontaneous abortion and low pre-pregnancy weight, seem to play an important role in determining the rate of preterm births.<1> The rate

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of LBW deliveries also correlates directly with poverty, social disadvantage<1> and cocaine use.

Maneuver

The prevention of LBW and of preterm births using multicomponent programs was initially implemented in France;<2> programs vary considerably with respect to their components (see Table 1) and target populations. Some strategies are common to most programs, such as staff and patient education concerning the early signs and symptoms of preterm labour and the provision of ready access to health care personnel. All include changes in antenatal care: more frequent visits, longer visits and continuity of care. Most include serial cervical assessment, self-monitoring of uterine contractions and lifestyle modifications. The major feature that distinguishes the French programs from those in North America is their use of home visiting by nurse/midwives.

Effectiveness of Prevention

Several studies have evaluated multicomponent programs using a before-and-after design for both general and high risk patient populations.<2-8> While these studies tend to show significant improvement in preterm delivery rates (from 5.4-6.75% before to 2.4-5.8% after), they have significant methodological limitations (e.g. comparing different patient populations and inadequate controls).

Main *et al*<9> conducted a randomized trial in Pennsylvania of a preterm prevention program in an indigent, mainly black population of women at high risk for preterm birth. After risk scoring, patients were allocated to either an intervention (n=64) or control group (n=68). The intervention group was followed in a special clinic and received intensive education, frequent clinic visits and easy access to medical staff. The control group received standard care in a separate clinic. The demographic characteristics of the two groups were comparable. Outcomes were not significantly different in the two groups. Deliveries prior to 37 weeks occurred in 25% of the intervention group and 20.6% of the control group. The LBW rate was 21.9% in the study group and 19.1% in the controls.

Mueller-Heubach and colleagues<10> randomized patients after scoring them for risk of preterm labour and delivery. A major component of the study was the training and education of the medical staff in making high-risk patients more aware of the subtle signs and symptoms of preterm labour. All patients were seen in the same clinic. No difference in the rate of preterm birth (20.8% intervention group, 22.1% control group) was found. However, a steady decrease in the rate of premature birth was noted during the study period (statistically lower than historic rates from the same institution).

In a controlled, non-randomized trial in which patients attending a South Carolina Twin Clinic were compared with those attending a normal care high-risk clinic,<11> the intervention included regular evaluation of maternal symptoms and cervical status by a single, certified nurse-midwife, intensive education regarding the prevention of preterm birth, individualized modification of maternal activity, increased attention to nutrition and tracking of clinic non-attenders. There were no inter-group differences in demographic characteristics, adequacy of prenatal care or antepartum complications. Twin Clinic attenders had lower rates of birth weights <1500 g (6% vs. 26%; p<0.0001), neonatal intensive care unit admission (13% vs. 38%; p<0.0001), and perinatal mortality (1% vs. 8%; p<0.0002).

In an evaluation of the West Los Angeles Preterm Birth Prevention Project which served a predominantly Hispanic population, Goldenberg *et al*,<13> in 8 clinics were randomized to intervention or control groups.<12> High-risk patients were identified by a risk scoring system. Intervention groups received special education, more frequent visits and one of the following bed rest, social work, Provera or placebo (n=1,774). Controls received standard care (n=880). Preterm birth rates were 7.4% in the experimental group and 9.1% in controls (p=0.063). In multiple regression analysis, differences were significant (p<0.05) when preterm risk was taken into account (the experimental group had a lower proportion of Hispanic women, women who had not completed high school, and lower gravidity and parity).

Goldenberg *et al*,<13> in a prospective, randomized controlled trial in Alabama, evaluated the effectiveness of a program to prevent preterm birth in a predominantly black, low-socioeconomic population. The program consisted of risk scoring, intensive weekly observation including cervical examinations, and education of medical staff and patients about the signs and symptoms of preterm labour. Four hundred and ninety-one high-risk patients were allocated to the intervention group and 478 to the control group. The demographic distribution was similar in both groups, and the two groups received prenatal care at different sites to avoid “contamination”. The rate of premature delivery was similar in the intervention and control group (15.9% vs. 14.2%), as was the incidence of LBW (<2,500 g) delivery (12.9% vs. 12.2%).

McLaughlin *et al*,<14> in a prospective randomized, controlled trial, evaluated the effectiveness of comprehensive prenatal care for low-income women in reducing LBW. Two hundred and seventeen women were assigned to comprehensive care and 211 to standard care. The intervention consisted of care provided by a multidiscliplinary team that included nurse-midwives, social workers, a nutritionist, paraprofessional home visitors, and a psychologist. The team focused on psychosocial support for the mothers, education about self-care, and promotion of healthy behaviours during pregnancy

(good nutrition, avoidance of alcohol and drugs, and reduction of smoking). The demographic distribution of both groups was fairly similar, except for a higher percentage of single primiparas in the comprehensive care group (74% vs. 59.2%). The percentage of smokers was not described. The mean birth weight was not significantly different in the two groups. However when the subgroup of primaparas (comprehensive, n=86; standard, n=79) was analyzed separately, mean birth weight was significantly higher in the comprehensive care group (3,233 g vs. 3,089 g).

Heins *et al*<15> conducted a multicenter randomized controlled trial in South Carolina. They evaluated nurse-midwifery and a comprehensive preterm/LBW prevention program in women identified as being at high risk for LBW deliveries. The intervention, provided by nurse-midwives, included patient education to identify the signs and symptoms of preterm labour, activity counselling based on monitoring of the cervix through frequent visits to the prenatal clinic, stress reduction by enhanced social support, nutrition counselling with emphasis on adequate weight gain, counselling concerning substance abuse and around-the-clock access to medical staff. Women in the control group received standard care by obstetricians. The two groups of patients were seen at different clinic sites. Seven hundred and twenty-eight patients were randomly allocated to the nurse-midwifery intervention and 730 to the control group. The two groups were comparable in terms of race, education, marital status, age, gravidity, and smoking habits. The results showed a LBW rate of 19.0% in the intervention group compared to 20.5% in controls. A subset of the population consisting of black patients with very high-risk scores did show a significant decrease in the incidence of very LBW, when compared to the same population in the control group (odds ratio 0.35, 95% confidence interval (CI): 0.1-0.9).

In summary, randomized multicenter trials evaluating programs at health clinics designed to prevent preterm delivery and/or LBW have shown conflicting results in high-risk populations.

Health clinic programs designed to prevent preterm delivery and/or low birth weight have had contradictory results in high-risk populations

Aspirin for Women At Risk of Pregnancy-induced Hypertension

Meta-analysis of data from randomized controlled trials on the use of low-dose aspirin for the treatment and/or prophylaxis of women at risk for pregnancy-induced hypertension has shown that this intervention significantly reduces the rate of premature deliveries, with no change in perinatal death rate.<16> However, the trials included in the review were too small to provide reliable results. Two recent, large, multicentered trials<17,18> failed to show any benefit on perinatal outcome of low-dose aspirin for the prevention and treatment of pregnancy-induced hypertension (also see preeclampsia, Chapter 13). In an Italian study<17> babies born to women in the

treatment group had a 16 g increase in mean birth weight and a slightly lower rate of premature deliveries (1.7%). In a British study,<18> the average duration of pregnancy was 1 day longer and average birth weight 32 g heavier for babies born to women in the aspirin group compared to those in the placebo group; there was no significant difference in the rate of stillbirths or neonatal deaths. Although the results from the British study were statistically significant, the clinical significance of the differences is questionable. Given the currently available evidence, routine prophylactic or therapeutic administration of low-dose aspirin cannot be recommended for the prevention of LBW or premature delivery in women with pregnancy induced hypertension.

Programs With Greater Emphasis on Social Support

A randomized trial of prenatal nurse visiting was conducted in disadvantaged primiparous women,<19> i.e. teenage mothers, unmarried mothers or mothers of low socioeconomic status. Nurses made home visits to educate parents, enhance informal support, encourage smoking cessation, establish linkages with community services, and emphasize the pregnant woman's personal strengths. One hundred and eighty-nine patients were randomly allocated to the intervention group and 165 to the control group. The mean birth weight in both groups did not differ significantly (3,285 g vs. 3,262 g). The LBW rate was also similar as was the rate of preterm deliveries. However a subset of 21 teenage mothers enrolled in the intervention before mid-gestation had infants with higher birth weights (3,437 g) than did 11 comparable control mothers (2,922 g). This difference was significant (P<.001) after adjusting for height, weight, smoking, and length of gestation.

Spencer *et al*<20> conducted a randomized trial involving 1,227 women at risk for delivering a LBW baby, as identified by a broad risk assessment. The intervention group received home visits by lay workers whose goal was to reduce stress by providing social support. Assistance included acting as a confidante, helping patients obtain state benefits, provision of child care and help with domestic chores. No difference was found in the mean birth weight, or in the proportion of LBW and preterm births in the two groups. A subset of young primiparous women showed a trend toward fewer LBW and preterm babies in the intervention group, but this difference did not reach statistical significance.

Oakley *et al*,<21> in a randomized controlled trial, evaluated the impact of a social support intervention on pregnancy outcome. Five hundred and nine high-risk, socially disadvantaged women with a previous history of giving birth to a LBW baby, were randomly allocated to receive either a social support intervention in pregnancy

in addition to standard care (n=255) or standard care alone (n=254). The intervention consisted of home visiting by the midwives, who provided advice with regards to healthy behaviours, referrals to other health professionals and welfare agencies, a listening service and 24-hour telephone contact. They did not provide any clinical care. The demographic profile of the two groups was comparable. Mean birth weight in the intervention group was only 38 g higher than in the controls. Mothers in the intervention group experienced more vaginal deliveries, and had a positive response to the social experience.

Bryce and coworkers, in Australia,<22> conducted a randomized controlled trial of antenatal social support to prevent preterm birth (defined as gestational age between 20 and 36 weeks at birth) in a population of public and private care patients at high-risk for preterm birth. Women were eligible for the program if they had a previous history of preterm births, LBW, perinatal death, more than two first trimester pregnancy losses, one or more second trimester miscarriages, or antepartum hemorrhage in a previous pregnancy. The patients were randomized by block design prior to obtaining consent, and allocated to control (n=986) or intervention groups (n=981). The control group received standard perinatal care, while the intervention group was offered additional social support provided by midwives. The intervention consisted of frequent home visitation and telephone contact, aimed at providing a listening service, information, advice and material aid as well as acting as a confidante. Clinical care was not provided, except in emergency situations. The patient demographics were similar in both groups. The rate of preterm birth was 12.8% in the intervention group compared to 14.9% in controls. 12.5% of women in the program delivered a LBW infant, compared to 12.9% in the control group. In order to prevent one LBW infant 250 women would have had to receive the intervention. Forty-two women would have had to receive the intervention in order to prevent a single preterm delivery. This study had only 60% power to show a risk reduction greater than 25% in the rate of preterm deliveries in the intervention group.

In a recent, large, multicenter randomized controlled clinical trial of psychosocial support during high-risk pregnancies, Villar *et al*<23> studied 2,235 patients, in Latin America, randomized to an intervention (n=1,115) or control group (n=1,120). Patients were enrolled in early pregnancy (<22 weeks gestation) if they had one or more of the following risk factors for delivering a LBW infant: previous delivery of a LBW or preterm infant; previous fetal or infant death; maternal age <18 years; body weight ≥50 kg height ≥1.5 meters; low family income; less than three years of primary school; smoking or heavy drinking; and residence apart from the child's father.

The intervention was aimed at increasing social support and reducing stress and anxiety. Either specially trained social workers or obstetrical nurses carried out home visits during weeks 22, 26, 30, and

34 of gestation, with the option of two additional visits. The home visitor provided direct emotional support to the woman and helped her cope with problems related to medical recommendations or prenatal care. In addition, women in the intervention group had 24-hour access to a telephone line in each hospital. No medical care was provided during the home visits.

The control group was provided with the routine prenatal care available at each of the participating institutions. The rate of LBW was 8.7% in the intervention group and 9.4% in the controls. The rate of preterm delivery (<37 weeks) was 11.1% in the intervention group and 12.5% in the control group.

A meta-analysis<24> of trials involving 8,000 women in 9 countries has determined that psychosocial support interventions for at-risk women has not been associated with improvement in any medical outcomes for the index pregnancy.

In summary, the evidence is consistent in showing that social support alone is not effective in overriding the cumulative effects of social and biologic disadvantage in populations at risk for delivering a LBW and/or preterm infant.

Nutritional Supplementation

Over the past two decades a number of intervention studies have evaluated the impact of maternal nutritional supplementation on pregnancy outcome. In the U.S., results of evaluation of the Nutrition Supplementation Programs for Women, Infants, and Children (WIC), have been conflicting. A review of 22 WIC intervention studies by Rush and colleagues in 1988, concluded that the range of reduction in the rate of LBW was approximately 1-2%, while average birth weight increases ranged from 0 to 60 g.<25>

In a cost-benefit analysis of WIC participation in North Carolina,<26> however, a records linkage study indicated that women who received Medicaid benefits and prenatal WIC services had substantially lower rates of low and very LBW than women who received Medicaid but no prenatal WIC. For white women (8.4% vs. 10.8% <2,500 g; $p<0.001$ and 1.4% vs. 2.5% <1,500 g; $p<0.001$) and for black women (11.6% vs. 16.9% <2,500 g; $p<0.001$ and 1.8% vs. 4.1% <1,500 g; $p<0.001$) the differences were statistically significant. It was estimated that for each $1.00 spent on WIC services, Medicaid savings in costs of newborn medical care were $2.91. For those receiving some prenatal care, longer maternal participation in WIC was also associated with better birth outcomes and lower costs.

The Montreal Diet Dispensary Program was begun in the 1960s in order to improve pregnancy outcome in socially disadvantaged urban women. A recent evaluation of this program reported by Higgins *et al.*<27> in a sibling matched analysis demonstrated an average 107 g

increase in the birth rate of the second sibling when the mother had participated in the program during the pregnancy of the second born, but not the first born. The rate of LBW was also significantly decreased among intervention infants when compared to their siblings. These results should be interpreted with caution in view of the study design, and the fact that the Montreal Diet Dispensary Program included social support and suggestions for lifestyle improvements in addition to nutritional supplementation.

In a meta-analysis of randomized trials of balanced protein/energy supplementation in pregnancy,<28> Kramer found that supplementation was associated with a small but significant increase in mean birthweight (weighted mean difference 29.5 g; 95% CI: 0.7-58.3 gm) and a reduction (of borderline statistical significance) in the incidence of small for gestational age births. Mean gestational age was not affected; the available evidence was inadequate to permit conclusions concerning effects on preterm birth, fetal and infant survival, or maternal health.

Thus, specific nutritional supplementation programs have had varying degrees of success in increasing birth weight at term and have led to a small reduction in the incidence of LBW. The clinical significance of this difference is unclear. The wide range of benefit shown in different studies can be attributed to differences in the populations studied, in the supplements used, and in methodological quality of the study design.

Conclusions and Recommendations

There is level I evidence showing that social support alone is not effective in improving pregnancy outcome with regard to birth weight or gestational age at delivery, in high risk patient populations. These programs are not recommended (D Recommendation) to prevent LBW/preterm births. However, their effectiveness in preventing other conditions or problems was not evaluated.

The effectiveness of multicomponent programs in preventing LBW is less clearly defined, since results of randomized controlled trials are conflicting (C Recommendation). The body of information available suggests that they may be effective when applied to a wide population base, but studies conducted to date are methodologically weak, thus definite conclusions are not possible.

Nutritional supplementation has been shown to increase average birth weight, but only slightly. While the clinical significance of this difference can be questioned, the intervention has been shown to cost-effective in at least one U.S. setting. There appear to be no harmful effects but the evidence with regard to improving prevalence of preterm birth, fetal and infant survival and maternal health was inconclusive. Overall, the evidence regarding nutritional

supplementation programs for women at high-risk of undernutrition to prevent LBW is inconclusive (C recommendation).

Unanswered Questions (Research Agenda)

A trial to determine whether a comprehensive preterm prevention program decreases the rate of preterm birth and/or LBW in the general population and to determine the cost effectiveness of such programs in Canada, is indicated. Other approaches to prevention of preterm labour and LBW in high-risk women are needed.

Evidence

Articles were retrieved by a computerized search (Cochrane Collaboration Database on Pregnancy and Childbirth and MEDLINE from 1966 to January, 1994, using the following keywords: low birth weight, prematurity, prevention). Content experts were also consulted. Articles that evaluated a single intervention other than nutritional supplementation were excluded (eg. smoking cessation, cerclage, use of tocolytic agents). This review was initiated in January 1993 and recommendations were finalized by the Task Force in April 1994.

Acknowledgements

The Task Force thanks Graham W. Chance, MB, ChB, FRCPC, FRCP(Lond), Professor of Pediatrics and of Obstetrics and Gynecology, University of Western Ontario, London, Ontario and A. Ohlsson, MD, MSc, FRCPC, Associate Professor of Pediatrics, Division of Neonatology, University of Toronto, Toronto, Ontario for their valuable comments.

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Table 1: Components of multicomponent prevention programs

Risk assessment
Education
Staff
Patients
Public
Advice
Reduce paid work
Reduce housework and child care
Reduce smoking
Reduce stress
Reduce travel, commuting, moving house
Reduce/stop sexual activity
Improve nutrition
Bed rest at home
Self-monitoring of uterine activity
Antenatal care
Increased frequency of contact
Continuity of care
Facilitated access to hospital
Support systems
Home visiting nurses/midwives
Home help
Family help
Social worker assignment
Stress management classes
Specific obstetric interventions
Regular cervical examinations
Cervical suture
Bed rest in hospital
Progestogens
B-mimetics
Calcium antagonists

Prevention of Low Birth Weight/Preterm Birth

MANEUVER	EFFECTIVENESS	LEVEL OF EVIDENCE <REF>	RECOMMENDATION
Multicomponent education preterm birth/ low birth weight prevention programs	**General Population** Programs have shown some benefits in methodologically weak studies.	Before and after studies<2-8> (II-3)	Inconclusive evidence that programs for the general population or for high-risk pregnant women are effective (C)
	High-risk populations In most studies programs were not effective in improving pregnancy outcome with regards to birth weight or gestational age at delivery; twin clinic showed benefit and improvement of marginal statistical significance in one trial.	Randomized controlled trials<9-15> (I)	
Programs consisting exclusively of social support	Programs were not effective in improving pregnancy outcome.	Randomized controlled trials<19-23> (I)	Fair evidence that programs consisting exclusively of social support for high-risk populations do not prevent preterm birth (D)
Diet supplementation in the prenatal period in pregnant women at high-risk for undernutrition	Average increase in birth weight 29.5 gm.	Meta-analysis of randomized controlled trials<28> (I)	Inconclusive evidence regarding diet supplementation in high-risk women to prevent low birth weight (C)
	Maternal nutritional supplementation lowered rates of low birth weight for Medicaid recipients and was cost effective.	Cost-benefit analysis, cohort study<26> (II-2)	