



Published in final edited form as:

*Matern Child Health J.* 2008 July ; 12(4): 461–468. doi:10.1007/s10995-007-0279-z.

## Interpregnancy primary care and social support for African-American women at risk for recurrent very-low-birthweight delivery: a pilot evaluation

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### Abstract

**Objectives**—Very-low-birthweight (VLBW) delivery accounts for the majority of neonatal mortality and the black-white disparity in infant mortality. The risk of recurrent VLBW is highest for African-Americans of lower socioeconomic status. This study explores whether the provision of primary health care and social support following a VLBW delivery improves subsequent child spacing and pregnancy outcomes for low-income, African-American women.

**Methods**—This pilot study of mixed prospective-retrospective cohort design enrolled African-American women who qualified for indigent care and delivered a VLBW infant at a public hospital in Atlanta from November 2003 through March 2004 into the intervention cohort ( $n_1 = 29$ ). The intervention consisted of coordinated primary health care and social support for 24 months following the VLBW delivery. A retrospective cohort was assembled from consecutive women meeting the same eligibility criteria who delivered a VLBW infant during July 2001 through June 2002 ( $n_2 = 58$ ). The number of pregnancies conceived within 18 months of the index VLBW delivery and the number of adverse pregnancy outcomes for each cohort was compared with Poisson regression.

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**Results**—Women in the control cohort had, on average, 2.6 (95% CI: 1.1 – 5.8) times as many pregnancies within 18 months of the index VLBW delivery and 3.5 (95% CI: 1.0 – 11.7) times as many adverse pregnancy outcomes as women in the intervention cohort.

**Conclusions**—This small, pilot study suggests that primary health care and social support for low-income, African-American women following a VLBW delivery may enhance achievement of a subsequent 18-month interpregnancy interval and reduce adverse pregnancy outcomes.

### Keywords

birth intervals; preconception care; pregnancy outcomes; primary care; very low birth weight infant

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## Introduction

Very low birth weight (VLBW; < 1500 grams) delivery accounts for greater than 50% of infant mortality (1). Additionally, two-thirds of the racial disparity in infant mortality is attributable to the nearly four-fold higher rate of VLBW and two-fold higher rate of low birth weight (LBW; < 2500 grams) delivery among African-Americans (2). Poor pregnancy outcomes, such as VLBW, are more common among women with poor underlying health status and poor access to quality healthcare (3).

The best predictor of a woman having a VLBW delivery is her history of a previous one; the risk of recurrence is highest for African-American and teen mothers (4). Women with a VLBW delivery are also at increased risk of subsequently delivering a stillborn infant (5). The reasons for the increased occurrence and recurrence of adverse pregnancy outcomes are not well understood, but growing data link such adverse outcomes to the poor health of women (6-17), chronic stress and depression (17,18), and short interpregnancy intervals (19,20). Unaddressed health, social, and behavioral factors that may have contributed to the first VLBW delivery likely persist and affect subsequent pregnancies, particularly if the interpregnancy interval is short.

There is no evidence that existing prenatal strategies influence the probability that a woman will have her first preterm infant (21-23). For women with a previous preterm delivery, there is some evidence that the prenatal administration of 17-alpha-hydroxyprogesterone acetate (24,25) and antibiotics for the treatment of bacterial vaginosis (26-31) may decrease the risk of a subsequent preterm delivery.

There is one published study evaluating a preconception strategy for the prevention of recurrent adverse pregnancy outcomes. This randomized controlled trial of the administration of antibiotics in the interpregnancy period for women with spontaneous preterm delivery found no reduction in subsequent preterm delivery, but rather a possible association with lower gestation age and birth weight (32).

The purpose of this study is to explore the effect of interpregnancy care (IPC), defined as care received from the delivery of one neonate until conception of the next, on child-spacing and subsequent adverse pregnancy outcomes for women with a previous VLBW delivery. The IPC intervention for this study involves the provision of coordinated primary healthcare

in conjunction with social support, similar to the conceptual model of the Patient Outcomes Research Team on Low Birth Weight, which recognizes that successful prevention of LBW demands an interdisciplinary, multi-intervention approach (33). The recommendations of the Select Panel on Preconception Care specify that the interconception period should be used to provide interventions to women who have had a previous adverse pregnancy outcome to ameliorate medical, social, and behavioral risks indicated by the prior adverse pregnancy outcome (34).

## Methods

### Study Design

This pilot study compared the subsequent reproductive outcomes of two cohorts of women with a VLBW delivery: (1) a prospective cohort provided with the IPC intervention; and (2) a retrospective cohort that delivered prior to initiation of the IPC program. This study was approved by the Emory University Institutional Review Board, and all procedures were in accordance with prevailing ethical principles.

### Setting and Participants

The study was performed at Atlanta's Grady Memorial Hospital, a county-supported tertiary care hospital. Women who deliver at the hospital are typically from economically-disadvantaged census tracts with VLBW rates up to four times that of more affluent communities in the metropolitan area (35).

Eligibility criteria for enrollment in the IPC intervention cohort included: (1) African-American race; (2) qualification for indigent care status; and (3) delivery of a VLBW (defined as infant birth weight from 500 to 1499 grams) stillborn or liveborn infant between November 2003 and March 2004 (the pilot enrollment period during which time we expected to enroll 30 participants). During the enrollment period, 38 women met eligibility criteria and were invited to enroll during their delivery admission. Nine of the 38 eligible women declined enrollment; the remainder ( $n_1 = 29$ ) were enrolled in the intervention cohort. The census tracts of enrolled women were determined by entering the home address at the time of delivery into the American FactFinder software program (U.S. Census Bureau, 2004; available at <http://factfinder.census.gov/home/saff/main.html>).

A control cohort was constructed from a perinatal data base containing the demographic information of women with a VLBW delivery at the hospital from July 2001 through June 2002. Using the American FactFinder software program, the census tracts of women in this data base was determined. The first two retrospectively consecutive women meeting the same eligibility criteria as those in the intervention cohort and restricting to the same census tracts were selected for the control group. Twice as many controls as intervention group subjects were selected ( $n_2 = 58$ ).

### Intervention

The IPC intervention program provided coordinated primary health and dental care with nurse case management, facilitated group visits, and social support starting within 6 weeks

of the index delivery and continuing for 24 months or until a subsequent pregnancy. Clinical services were delivered by a family physician and a nurse midwife in consultation with a maternal-fetal medicine specialist; a periodontist; and a nurse case manager. Social support services were delivered by a Resource Mother, a layperson trained by the local health department to facilitate life skills. A complete description of the content of the IPC program has been published (36).

Women in the IPC cohort had the initial Resource Mother home visit within 2 weeks of discharge. The initial IPC clinical evaluation took place within 6 weeks postpartum, and involved the traditional elements of the postpartum visit and the development of a care plan that addressed seven areas epidemiologically linked to adverse pregnancy outcomes: (1) Family planning including the statement of a reproductive plan addressing pregnancy intentions, child-spacing, and contraception; (2) Management of chronic disease through the promotion of self-care and adherence to scheduled outpatient appointments; (3) Screening and treatment for nutritional deficiencies and multivitamin supplementation; (4) Prevention, screening, and treatment for reproductive tract infections; (5) Treatment and referral for substance abuse; (6) Screening and treatment for depression, psychosocial stressors, and domestic violence; (7) Prevention, screening and treatment for periodontal disease.

Subsequent IPC visits were scheduled every 1-3 months, depending upon the woman's health issues. Primary care was provided during facilitated group visits with education, support and health care components incorporating the elements of Centering Pregnancy group prenatal care (37), and by individual appointments as indicated. Resource Mother support was scheduled at least twice monthly through home visits and telephone contact.

## Measures and Outcomes

The main reproductive outcomes of interest were the average number of pregnancies conceived within 18 months of the index delivery and the average number of adverse pregnancy outcomes (for pregnancies conceived within 18 months of the index delivery). An interpregnancy interval of 18 months was chosen because intervals shorter than 18 months are associated with an increased risk of adverse perinatal outcomes (20). Interpregnancy interval (in months) was calculated by subtracting the date of the index VLBW delivery from the date of the subsequent delivery, minus the estimated gestational age of the subsequent delivery, divided by 30. Estimated gestational age was determined from mothers' medical record review. An adverse pregnancy outcome was defined as a pregnancy ending in late spontaneous abortion (12 - 20 weeks' gestation), stillbirth, ectopic or molar pregnancy, or a liveborn infant weighing < 2500 grams. This definition was chosen because there are established modifiable risk factors for each of these pregnancy outcomes (38-43) addressed as part of the interpregnancy care plan.

Data related to women's past medical and obstetrical history, outcomes of the index delivery and subsequently conceived pregnancies were collected by medical record review at the public hospital. For women in the IPC cohort, additional data were collected from records maintained by the IPC team, including diagnosis and treatment for acute and chronic conditions (IPC provider notes); reproductive plans (standard questionnaire based on the

Behavioral Risk Factor Surveillance System) (44); housing, employment, and educational status (Resource Mother notes).

## Data Analysis

Baseline social, medical, and obstetrical characteristics of eligible women in each cohort were compared using Fisher's exact test or the t-test. The proportions of women in each cohort who became pregnant within 9- and 18-months of the index delivery were compared using Fisher's exact test. The average number of pregnancies experienced within 18 months of the index delivery and the average number of adverse outcomes of pregnancy was calculated using the formula for the expected value of a discrete random variable:  $E(X) = \sum x_i Pr(X = x_i)$ , where  $x_i$ 's are the values the random variable assumes with positive probability,  $Pr$  (45). The effect of the intervention was evaluated using Poisson regression to compare counts of events that can occur more than once to a given woman when the counts of those events are considered 'uncommon' (46). The effect of potential confounders (maternal age, number of prior term and preterm deliveries, whether prenatal care was obtained, whether labor was induced or spontaneous, and multiple gestation) was investigated with multivariable Poisson regression. Data analyses were done using SAS Version 9.1.3 (SAS Institute Inc., Cary, NC, 2002-2005).

## Results

Compared with women who enrolled in IPC, the 9 women who declined enrollment were more likely to have had no documented prenatal care (66% vs. 21%;  $p = 0.02$ ) and a stillborn index VLBW (40% vs. 11%;  $p = 0.04$ ). There was no significant difference between enrollees and nonenrollees with respect to age, tobacco or substance abuse, chronic diseases, marital status, parity, or birthweight. Baseline characteristics of the women in the IPC and the control cohorts and their index VLBW infants (Table 1) were similar except for primiparity and multiple gestation, which were both significantly higher in the IPC cohort.

Twenty-one of 29 women (72%) in the IPC cohort completed 12 of the planned 24 months of the intervention. Sixteen of 29 women (55%) completed all planned 24 months. During the 24-month intervention period, the average number of outpatient visits to hospital system was 7 (median 6; range 4 - 10) and the average outpatient charges per woman was \$2,397 (median \$2,104).

Of the 21 women in the IPC cohort who had at least 2 IPC visits during the first 12 months of care, 7 (33%) women were identified as having significant chronic disease that was previously unrecognized or poorly managed, including hypertension, diabetes, asthma, sickle cell disease, depression and anxiety disorders, systemic lupus erythematosus, valvular heart disease, and prolactinoma. Reproductive tract infections were diagnosed and treated in 15/21 (71%) women, and iron-deficiency anemia was diagnosed and treated in 5/21 (24%) women. Fifteen of 21 women took part in dental evaluation and treatment; seven of 15 (47%) women had dental infections or periodontal disease that required treatment.

Of the 21 women in the IPC cohort who had at least 2 IPC visits during the first 12 months of care, 18/21 (86%) were without a high school diploma/GED upon entry. Of these, 13/18

(72%) were assisted by the Resource Mother in enrolling for a diploma/GED (8 earned a diploma/GED). Five women were assisted in completing other technical training. The Resource Mother assisted 12/21 (57%) women achieve part- or full-time employment by aiding in completing resumes and applications, preparing for job interviews, and acquiring telephone skills.

All 21 women in the IPC cohort who had at least 2 IPC visits during the first 12 months of care developed a personal reproductive plan in conjunction with their provider. None of the 29 women in the IPC cohort became pregnant within 9 months of the index VLBW delivery, in comparison with 18/58 (31%) women in the control cohort (Fisher's exact p-value < 0.001). Five of 29 (17%) women in the IPC cohort became pregnant within 18 months in comparison with 29/58 (50%) of women in the historical control cohort (p-value = 0.003).

There was a 61% reduction in the average number of pregnancies conceived within 18 months of the index VLBW delivery for women in the IPC intervention cohort (Table 2). Using Poisson regression, the average number of pregnancies conceived within 18 months was significantly lower ( $p = 0.02$ ) for women in the IPC cohort. Women in the control group had on average 2.6 (95% confidence interval: 1.1 – 5.8) times as many pregnancies within 18 months of the index VLBW delivery.

The outcomes of the pregnancies conceived within 18 months of the index delivery for women in the IPC and control cohorts are given in Table 3. There was a 72% reduction in the average number of adverse outcomes of pregnancy experienced by women in the IPC compared to the control cohort (Table 4). Using Poisson regression, the average number of adverse outcomes of pregnancy was significantly lower ( $p = 0.04$ ) for women in the IPC cohort. Women in the control group had on average 3.5 (95% confidence interval: 1.0 – 11.7) times as many adverse pregnancy outcomes.

There is no evidence that confounders are leading us to overstate the treatment effect, considering that a 5-10% decrement in effect would typically be considered important (47). For the outcome of number of pregnancies conceived within 18 months, all potential confounders considered together led to an increase in the perceived treatment effect size (+7.3%). For the outcome of number adverse outcomes of pregnancy, all potential confounders considered together also led to an increase in the perceived treatment effect size (+33.2%).

## Discussion

This small pilot study suggests that for low-income, African-American women, participation in a program of coordinated primary health care and social support following a VLBW delivery may be associated with the achievement of an 18-month interpregnancy interval and a reduction in the number of subsequent adverse pregnancy outcomes. Participation in the program of coordinated primary care and social support also seems to be linked to the following benefits for women: (1) the identification and management of conditions epidemiologically-linked to adverse pregnancy outcomes; (2) the development of a personal reproductive plan; (3) the acquisition of life skills to promote vocational success.

The design and size of this exploratory study does not allow us to determine which specific aspect of the IPC intervention may have been the most influential factor. Future research on an expanded population should focus on answering this question.

Significant limitations of this study, including its small sample size and the potential for selection bias in constructing the comparison group in a non-randomized fashion from non-contemporaneous controls, limit the conclusions that can be drawn. By using retrospective controls, women who might not have given their consent to participate in the study were included in the comparison group, but not in the intervention group. It is generally accepted that non-participants possess characteristics associated with having worse health outcomes than participants. We cannot ensure that the study's findings were not influenced by this phenomenon. However, as part of another IRB-approved protocol, we were able to ascertain that 2/9 (22%) of the eligible women who opted out of the intervention cohort became pregnant within 9 months of the index VLBW delivery: one delivered a term infant of normal birth weight, and one delivered a stillborn VLBW infant. If the outcomes of the 9 women who opted out of the study were included in the intervention cohort our conclusions based on Fisher's and Poisson analyses would remain unchanged.

Another study limitation is that ascertainment of reproductive outcomes for both cohorts was limited to medical record review at the delivering hospital. It is possible that women in either cohort could have conceived a pregnancy and sought care or delivered at another hospital. If care-seeking at outside hospitals were greater for one cohort or another, this could systematically bias our inter-cohort comparisons. As it would seem that women in the retrospective control cohort would be more likely to seek care at outside hospitals than would women in the intervention cohort (given their participation in the intervention), this would likely bias our findings toward the null.

A final limitation is that we are unable to exactly measure the 'exposure' status of women in the control cohort with regard to the primary care and social support they received following the index VLBW delivery. During their follow-up, there was no existing program to coordinate the delivery of primary care or social support for women with a VLBW delivery. From medical record review, we can ascertain that 26/58 (45%) of women in the control cohort accessed medical or gynecological clinic services in the hospital system in the 24 months following the index VLBW delivery (range = 1-10 visits; median = 2 visits).

In spite of the noted limitations, this pilot study is the first study suggesting that interventions administered between pregnancies may positively impact subsequent reproductive outcomes for women at known risk for recurrence of VLBW delivery. Because of its limitations, the findings from this pilot study should be seen as hypothesis-generating.

Medicaid is the primary mechanism for extending health care coverage to women of low income who do not have health insurance. In most states, low-income women of reproductive age do not have access to primary health care between pregnancies, as Medicaid coverage typically ends 60 days postpartum and resumes only after conceiving a subsequent pregnancy. Since 1995, a total of 22 states have used their federal waiver authority to extend family planning services to women who do not otherwise qualify for

Medicaid through family planning waivers. Some states also offer Medicaid coverage to women who lose coverage after the birth of a baby or starting a job, whereas others offer services based on income status alone (48,49).

The initiation of prenatal care once a pregnancy is identified has proven to be too late to reduce the occurrence and recurrence of low birth weight and preterm delivery (35,50). Findings from this study support the examination of the impact of continuation of Medicaid coverage – to include primary health care and family planning services – for women who have experienced a poor pregnancy outcome (35,51). Rather than discontinuing funding for medical care 60 days after delivery, women who have experienced a poor pregnancy outcome (especially a VLBW delivery) could retain coverage to promote pregnancy intendedness, optimum child-spacing, and improved health status prior to the next pregnancy.

## Acknowledgments

We gratefully acknowledge Ms. Michelle McIntosh and Ms. Patricia Ward who served as the nurse case manager and Resource Mother for this study.

Funding and support for the conduct of this research study was provided by Vasser-Woolley Foundation, Grady Memorial Hospital, Healthcare Georgia Foundation, Centers for Disease Control and Prevention, Rockdale Foundation, March of Dimes, and the General Clinical Research Center at Emory University funded by the National Center for Research Resources (NCRR M01-RR00039).

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**Table 1**

Baseline Characteristics of Women in IPC and Control Cohorts.

Characteristic	IPC Cohort (n <sub>1</sub> = 29)	Control Cohort (n <sub>2</sub> = 58)	p-value*
Teenagers (< 20 y)	7 (24%)	12 (21%)	0.78
Advanced age (≥ 35 y)	4 (14%)	3 (5%)	0.22
Primiparous	15 (52%)	14 (24%)	<b>0.02</b>
Previous term	12 (41%)	36 (62%)	0.11
Previous preterm	12 (41%)	20 (35%)	0.64
Previous abortion	15 (52%)	30 (52%)	0.99
Preeclampsia/Eclampsia	4 (14%)	18 (31%)	0.12
Hypertension	2 (7%)	5 (9%)	0.99
Diabetes	1 (3%)	3 (5%)	0.99
Connective Tissue Disease	1 (3%)	2 (3%)	0.99
Single (marital status)	27 (93%)	55 (95%)	0.99
Illicit substance abuse	8 (28%)	14 (24%)	0.80
Tobacco abuse	4 (14%)	6 (10%)	0.73
No prenatal care	9 (31%)	18 (31%)	0.99
Multiple gestation	7 (24%)	3 (5%)	<b>0.01</b>
Stillbirth	4/37 infants (11%) <sup>a</sup>	4/61 infants (5%) <sup>b</sup>	0.47
Birth weight, mean (range)	944 g (520-1490)	1023 g (520-1480)	0.25**

\* refers to p-value for Fisher's exact test unless otherwise specified;

\*\* refers to p-value for Student's t-test;

<sup>a</sup> 3 macerated stillbirth; 1 non-macerated with acute hypoxic changes (prolapsed cord);

<sup>b</sup> 3 macerated stillbirth; 1 non-macerated with acute hypoxic changes (entrapped breech).

**Table 2**

Distribution of pregnancies conceived within 18-months of the index VLBW.

No. of pregnancies conceived within 18-months	Number of women in each cohort experiencing 0, 1, or 2 pregnancies within 18-months	
	IPC Intervention (n <sub>1</sub> = 29)	Control (n <sub>2</sub> = 58)
0	24	29
1	3	22
2	2	7
Sample mean	0.24*	0.62*

\* p-value for Poisson regression = 0.02

**Table 3**

Outcomes of pregnancies conceived within 18 months of the index VLBW delivery.

Outcome of pregnancies conceived within 18-months	IPC Intervention: 7 pregnancies	Control: 36 pregnancies
Adverse pregnancy outcome	3 (43%): <ol style="list-style-type: none"> <li>1 liveborn, LBW</li> <li>2 spontaneous abortions</li> </ol>	21 (58%): <ol style="list-style-type: none"> <li>7 liveborn, LBW</li> <li>3 liveborn, VLBW</li> <li>4 stillborn, VLBW</li> <li>3 spontaneous abortions</li> <li>3 ectopic pregnancies</li> <li>1 molar pregnancy</li> </ol>
Liveborn, > 2500 grams	3 (43%)	8 (22%)
Elective abortion	1 (14%)	6 (17%)
Unknown	-	1 (3%) <sup>a</sup>

<sup>a</sup> Delivery at outside institution; outcome unknown.

**Table 4**

Distribution of adverse outcomes of pregnancies for pregnancies conceived within 18-months of the index VLBW.

No. of adverse pregnancy outcomes	Number of women in each cohort experiencing 0, 1, or 2 adverse pregnancy outcomes	
	IPC Intervention (n = 29)	Control (n = 58)
0	27	41
1	1	13
2	1	4
Sample mean	0.10*	0.36*

\* p-value for Poisson regression = 0.04