Title: Stillbirth or Neonatal Death and Subsequent Short Inter-Pregnancy Interval Following an Early Preterm Birth

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Preterm birth is the leading cause of perinatal morbidity and mortality in the US with annual costs of tens of billions of dollars. There are major public health campaigns to reduce a range of associated risk factors (1, 2). Significant racial/ethnic and socio-economic disparities are also observed in the risk of both primary and repeat preterm birth, with African American women disproportionately affected by these outcomes (3, 4). Women who have a history of preterm births are more than twice as likely to have a subsequent preterm birth and efforts have been made to reduce repeat prematurity in this group (5-7). Short inter-pregnancy interval is another known risk factor for preterm birth; Inter-pregnancy intervals of less than 18 months are associated with a 6% higher risk of prematurity compared with intervals of greater than 18 months (8). Furthermore, there is evidence that short pregnancy intervals further increase the already elevated risk of repeat preterm birth (9-11). Plausible physiologic mechanisms have been proposed to explain these findings (12). Reducing the rate of pregnancies conceived within 18 months of a previous birth is a public health priority and a *Healthy People 2020* family planning objective (2).

Although preconception guidelines recommend targeting women with history of prematurity with interventions to reduce subsequent short inter-pregnancy interval, there is little evidence that these guidelines have influenced clinical practice and outcomes (13). Demographic and psychosocial factors have been associated with pregnancy intervals but potentially modifiable targets of public health intervention are not well described (3,14, 15). One known risk factor for short inter-pregnancy interval is stillbirth or neonatal loss; Pregnancy intervals for women following a stillbirth are on average 1 year shorter than for women without a loss (16, 17). This pattern has been described as

an effort by women who have experienced a stillbirth or neonatal death to “replace” the loss of their infant (18). On the healthcare delivery side of the equation, a range of studies suggest that the inter-conception care delivered to women following stillbirth or neonatal death is less effective at supporting recommended birth spacing than that delivered to women with live births. Reports of provider avoidance (19), a focus on grieving (20), and earlier discharge from the hospital (21) for women with these poor birth outcomes likely undermine usual support of healthy birth spacing. Surveys of obstetric providers also indicate that clinicians generally view repeat pregnancy within one year of a perinatal loss as safe and so are in conflict with public health guidelines (22). Authoritative and influential clinical guidelines on stillbirth also do not address birth spacing indicating a lack of attention to this issue (23).

In a recent analysis of women following an early preterm birth we found that women whose infant died within the first six months of life were eighteen times more likely to intend to become pregnant within one year compared with women who did not experience a loss (24). The objective of the current analysis was to determine whether stillbirth or neonatal death is associated with subsequent short inter-pregnancy interval among women following early preterm birth. To better inform the design of interventions to address this issue, we also wished to assess the extent to which the timing of subsequent pregnancies was accounted for by intention for short inter-pregnancy interval and contraceptive use in the immediate postpartum period. This is the first analysis that we are aware of that explores these possible linkages to short inter-pregnancy interval within the high-risk population of women who have just experienced an early preterm birth.

Methods

Study design and Population

This analysis utilized data from the Philadelphia Collaborative Preterm Prevention Project, a randomized trial designed to test risk modification strategies for several pro-inflammatory risk factors for repeat preterm birth: 1) periodontitis, 2) obesity, 3) major depression, 4) smoking, 5) infection and 6) common sources of stress (housing and low literacy). While more details about the study design can be found elsewhere, briefly, women with a preterm birth were recruited from 12 Philadelphia hospitals between November 2004 and August 2006, and randomized to one of two possible study conditions: 1) usual care, or 2) the intervention condition including a range of interventions to reduce risk factors listed above (25). No interventions targeted birth spacing or reducing risk of short inter-pregnancy interval. Eligibility criteria for the study included delivery of a singleton infant at < 35 weeks gestation, ability to speak English or Spanish, and Philadelphia residency. The participants completed an interview one month following birth and were interviewed every 6 months for a total of 24 months following the index birth.

The current analysis used data from enrollment interviews immediately following the index preterm birth and one month follow-up interviews, study records of pregnancy over the following 18 months, and linked birth certificates, which accounted for births within twenty-four months following the index birth. As shown in Figure 1, 70.9% (n=798) of the enrolled sample (n=1,126) was included in the analysis. Women were excluded if they: did not complete the one month follow-up assessment (n=298), did not

have birth records linked with study records of pregnancy (n=18), reported having an IUD (making the outcome of short inter-pregnancy interval highly unlikely) (n=1), or were missing key measures of birth control effectiveness (n=3), pregnancy intention (n=1), insurance status (n=1), homelessness (n=1), drug use (n=2), or marital status (n=3). All study procedures were approved by the involved institutions' institutional review boards.

Key Measures

Subsequent short inter-pregnancy interval. Birth record data provided by the Pennsylvania State Department of Health was used to determine if women had a subsequent live birth within 18 months following the index preterm birth through calculations based on birth date and gestational age. The occurrence of a subsequent pregnancy was also assessed every six months as part of the parent study evaluation procedures. Women were excluded when self-reported data or study notes suggesting potential pregnancy could not be confirmed with health department data. Stillbirth and neonatal death. Women with stillbirth between 20 weeks and 35 weeks gestation or a neonatal death, defined as an infant death within one month postpartum of the index PRETERM BIRTH, were identified by abstraction of medical records and analyzed as a dichotomous (yes/no) variable. Pregnancy intention. At one month follow-up, participants were asked, "When do you plan to become pregnant again?" Women who responded "right now", or "within the next year" were categorized as having intention for pregnancy within one year. Women who responded "one to two years from now", "three or more years from now," or "never" were categorized as not having an intention for pregnancy within one year. Given that this intention measure (one year) does not

correspond to the outcome of short inter-pregnancy interval (18 months), separate sensitivity analyses were performed in which those who responded “right now” or “within the next year” or “one to two years from now” were categorized as having a pregnancy intention. Using this measure of intention in the sensitivity analyses did not change the pattern of findings, and so only the first measure is presented in the results.

Contraception. Women were asked at one month follow-up about current use of a variety of birth control methods. Based on CDC guidelines for birth control effectiveness (25), women were categorized as using methods of low (no method reported, foam, jelly, or creams, withdrawal, rhythm method), medium (male or female condoms, diaphragm), or high (birth control pills, medroxyprogesterone acetate, patch) effectiveness. Women who reported using more than one method were categorized according to the most effective method reported. Previously published studies of this sample, which assessed birth control use at six months postpartum, also used self-reported consistency of contraceptive use during intercourse (every time, sometimes, rarely, other) to construct a birth control effectiveness measure (24). However, we chose not to include this measure of consistency in the current efficacy categorization because a large proportion of women are not yet sexually active or have just become active within one month postpartum and so the measure would not have meaning to the respondents (26).

Statistical analysis

A range of potential confounders were analyzed based on theoretical grounds including socio-demographic factors and psychosocial predictors (number of prior pregnancies, number of prior births, severe depressive symptoms, insurance status,

ever having been homeless, alcohol use in the past month, and marijuana use in the past month). Women were categorized as having severe depressive symptomatology if they scored 23 or greater on the Centers for Epidemiological Studies Depression Scale (CESD) (27). This cut point has been traditionally labeled as “likely depressed” and reflects greater likelihood of current major depressive disorder than the commonly used lower cut point of 16 or greater. Although breastfeeding, because it reduces fertility, can be a risk factor against short inter-pregnancy interval (15), it is not relevant for the sub-group of our sample who had a stillbirth or neonatal death and was not included in the current analyses. Although none of the interventions in the larger trial from which the current analysis was drawn targeted short inter-pregnancy interval or family planning, a dichotomous dummy variable representing assignment to treatment group (intervention versus control) was included to assess any potential influence of the interventions.

The majority of data on independent variables were collected at the one-month follow-up interview, although certain demographics were collected at the time of enrollment immediately following the index preterm birth. The analytic sample was compared to the excluded sample to test for possible selection bias as reflected by differences in socio-demographic factors. Bivariate associations between stillbirth or neonatal death, pregnancy intention, contraceptive effectiveness and short inter-pregnancy interval were initially examined using the chi-square statistic. Multiple regression analyses were then carried out to assess the relationship between short inter-pregnancy interval and stillbirth or neonatal death, controlling for potential confounders. Potential confounders were included in the regression analyses based on

the theoretical framework and if they showed a significant bivariate association with short inter-pregnancy interval at the p=0.25 level (28, 29).

Results

Women included or excluded in the analytic sample (Figure 1) did not differ significantly by race, age, education level, insurance, marital status, nativity, or having ever been homeless (p>0.05). However, women in the excluded group reported lower household income, and were more likely to have been assigned to the control condition for the randomized trial (not the subject of the current analyses). The latter difference is consistent with observed higher rates of attrition documented in the control condition (30), as completion of the first follow-up interview was an inclusion criterion for the current analysis.

As shown in Table 1 the majority of women in the study sample were African American (71.9%) and about half were under the age of 25 (52.9%). Roughly one third reported less than a high school degree (30.2%) and about one in five reported an annual household income of less than ten thousand dollars (21.9%). The majority of these women were insured by Medicaid (66.9%). Approximately 14% of women in the study experienced a stillbirth or neonatal death, 8% reported intention to become pregnant in the next year, and 21% had a short inter-pregnancy interval of <18 months.

Women who were 25 years old or younger were more likely to have short inter-pregnancy interval compared to women between the ages of 25 and 29, and women aged 30 years or older (24.9% vs. 19.3% vs. 12.5%, p=0.002). Rates of short inter-pregnancy interval were also higher among women with less than a high school degree

compared to women with a high school degree or some college (24.9% vs. 22.0% vs. 14.8%, p=0.017), among women with Medicaid compared to women with private insurance or no insurance (23.6% vs. 15.1% vs. 12.0%), and among women with severe depressive symptoms compared to those without (25.0% vs. 18.6%, p=0.038).

When stratified by birth outcome more than forty percent of women with stillbirth or neonatal death were pregnant again within 18 months, while less than twenty percent of women without stillbirth or neonatal death were pregnant again in that time period (43.2% vs. 17.0% p<0.0001; data not shown). Women who experienced a stillbirth or neonatal death were much more likely to report that they intended to become pregnant within the next year compared to women without a loss (37.0 vs.3.6%, p<0.0001, data not shown). Over forty percent of women with stated intention for repeat pregnancy within one year had a subsequent short inter-pregnancy interval compared with less than twenty percent of women without a stated intention to become pregnant in that time (42.2% vs. 18.7%, p <0.0001).

The results of logistic regression analyses are shown in Table 3. Model A shows that the unadjusted odds of short inter-pregnancy interval for women whose infant died was 3.71 times higher than for those whose infant survived (95% CI 2.43-5.68). The relationship between short inter-pregnancy interval and stillbirth or neonatal death was reduced but persisted even after adjusting for confounders (Model B). Finally, Model C shows that women who had a stillbirth or neonatal loss were 3 times more likely to have short inter-pregnancy interval than those who did not, even after controlling for intention for repeat pregnancy within one year and contraception efficacy (aOR=3.09: 95% 1.88-5.11). Both intention for short interval pregnancy and efficacy of

contraceptive method were themselves independently associated with short inter-pregnancy interval. Women who intended to become pregnant within the next year where nearly two and a half times more likely to have a subsequent short inter-pregnancy interval compared to women who did not express this intention (2.40, 95% CI1.24-4.65) and women using methods of “high efficacy” were about 50% less likely to have short inter-pregnancy interval compared to women using methods of “low efficacy” (aOR=0.53, 95% CI 0.35-0.81).

Discussion

In this sample of 798 women with early preterm birth about one in five was pregnant again within 18 months. The odds of short inter-pregnancy interval were nearly three times greater for women with a stillbirth or neonatal death than those whose infants lived beyond the first month after delivery even after adjusting for a range of socio-demographic and psychosocial variables known to be associated with risk of short inter-pregnancy intervals. We also found that the proportion of women with an intention to become pregnant within one year was ten-fold higher among women who had a stillbirth or a neonatal death than among women who did not experience this outcome. A corollary to this was the finding that the use of highly effective contraception method soon after delivery is protective against short inter-pregnancy interval. The overall rate of short inter-pregnancy interval we observe (21%) is lower than the national average of 35% (2).It is possible that short inter-pregnancy interval is less likely to follow an early preterm birth, as mothers are more likely to be caring for ill infants and may be less likely to be sexually active compared to women with full term births. Additional research is needed to further define the differences in birth spacing following full term versus

premature births as this has implications for efforts to reduce rates of short inter-pregnancy interval nationally.

Our findings are consistent with previous studies showing that the experience of a stillbirth or neonatal loss is strongly associated with increased risk of a short inter-pregnancy interval (3, 9, 11). In the current study we extend this observation to women with early preterm birth, a group of women who are already at heightened risk for repeat adverse outcomes. Over 40% of women with a stillbirth or neonatal death in this sample were pregnant again within 18 months. This is a vulnerable and sizeable population with approximately 20,000 women experiencing stillbirth following preterm birth every year (23).

The use of contraception with high effectiveness early after the preterm birth reduced the risk of short inter-pregnancy interval. This association was driven by the use of the long acting injectable form of medroxyprogesterone acetate in our sample. The reduction in risk of short inter-pregnancy interval was substantial and indicates a need for further research into both the factors associated with selecting this method and its potential role in efforts to reduce risk of short inter-pregnancy interval among women with preterm birth. We also found that only one woman in the current sample received an intrauterine device suggesting that long acting reversible forms of contraception could be better employed in this population.

Our findings of elevated risk of short inter-pregnancy interval and intention for a short inter-pregnancy interval are consistent with a range of previous studies suggesting that healthcare practice does not support recommended birth spacing adequately.

Although published guidelines for preconception counseling call for longer inter-pregnancy intervals, a recent survey of obstetricians showed that only 1/3 recommended that patients wait at least 6 months to attempt conception following stillbirth or neonatal death (22). Clinicians clearly need to address the emotions that accompany a mother's desired timing for future pregnancies, when the grief surrounding loss may complicate the counseling process. However it appears that greater awareness of the risks of short inter-pregnancy interval is needed among clinicians and their patients (20, 22). In fact it is reasonable to assume that women with poor perinatal outcomes will be receptive to counseling which focuses on reducing risk of poor outcomes for subsequent births. While influential clinical guidelines for management of stillbirth include recommendations for grief counseling, as well as clinical care guidelines for subsequent pregnancies whenever the next pregnancy occurs, they do not currently address family planning or spacing between stillbirths and subsequent pregnancies (32). This represents an important potential target for public health policy intervention.

The results of this paper have several limitations. First, the sample was primarily comprised of urban minority women with low income, and our results are not necessarily generalizable to other populations. However, risk of preterm birth is higher in low-income African American women than other populations so this study is highly relevant to efforts targeting the reduction of preterm birth. Second, many of our measures were limited to those that could be assessed at one month postpartum. Several of our measures such as pregnancy intention and contraceptive use could have changed before the 18-month marker of short inter-pregnancy interval. However, we

believe that this timing is particularly clinically relevant, because this is the time period when women are more likely to receive medical care, and are physically available for targeted interventions. We also believe that if our pregnancy intention measure biased the results, it should be biased conservatively and would actually underestimate any association between stillbirth or neonatal death and short inter-pregnancy interval. Our measure of contraception use was also recorded at one month postpartum, a time when many women are not sexually active, and may not be representative of later contraceptive practices. However, if interventions to decrease short inter-pregnancy interval include discussions of family planning and contraception, behaviors reported at one month following a birth are relevant to this planning.

In conclusion we found an increased risk of short inter-pregnancy interval in women with preterm birth who experienced a stillbirth or neonatal loss. The high proportion of women who intended to have a short inter-pregnancy intervals suggest that the increased risk of repeat poor outcomes is not adequately addressed for these women at particular risk for subsequent negative birth outcomes. Campaigns to reduce the risk of repeat preterm birth and short inter-pregnancy interval should pay greater attention to women with stillbirth and neonatal loss at the time of preterm birth. Promoting a longer inter-pregnancy interval with focus on reducing intention for this outcome and increasing the use of highly effective forms of contraception early after delivery are important targets of these efforts.

Table 1. Characteristics of the study sample

	All N (%) 798 (100)
Stillbirth or neonatal death	111 (13.9)
Intend pregnancy within 1 year	66 (8.3)
Effectiveness of birth control	
Low	349 (43.7)
Medium	111 (13.9)
High	338 (42.4)
Race	
Black	574 (71.9)
White	83 (10.4)
Hispanic/Other	141 (17.7)
Age	
<25	422 (52.9)
25-29	192 (24.1)
≥ 30	184 (23.1)
Education	
< HS	241 (30.2)
HS	313 (39.2)
Some college +	244 (30.6)
Insurance	
Non-Medicaid	239 (30.3)
Medicaid	534 (66.9)
Uninsured	25 (3.1)
Marital status	158 (19.8)
Ever homeless	121 (15.2)
Parity-0	371 (46.5)
Parity-1	201 (25.2)
Parity 2+	226 (28.3)
CES-D ≥ 23	256 (32.1)

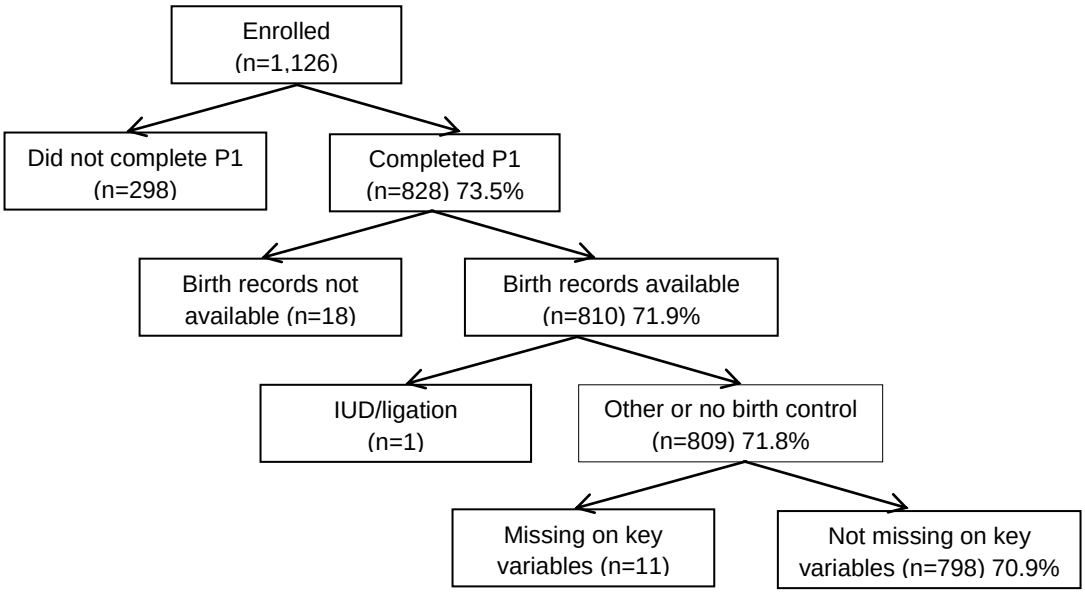
Table 2. Characteristics associated with short inter-pregnancy interval

Variable	Short inter-pregnancy interval(SHORT INTER-PREGNANCY INTERVAL)	p-value
Stillbirth or Neonatal death-No	117 (17.0)	0.000
Stillbirth of Neonatal death-Yes	48 (43.2)	
Pregnancy intention within 1 year-No	137 (18.7)	0.000
Pregnancy intention within 1 year-Yes	28 (42.2)	
Effectiveness of birth control-Low	83 (23.8)	0.097
Effectiveness of birth control-Medium	24 (21.6)	
Effectiveness of birth control-High	58 (17.2)	
Race-Black	126 (21.9)	0.181
Race-White	11 (13.3)	
Race-Hispanic/other	28 (19.9)	
Age <25	105 (24.9)	0.002
Age 25-29	37 (19.3)	
Age ≥ 30	23 (12.5)	
Education- < HS	60 (24.9)	0.017
Education- HS/GED	69 (22.0)	
Education- some college+	36 (14.8)	
Insurance-Private	36 (15.1)	0.014
Insurance-Medicaid	126 (23.6)	
Insurance-Uninsured	3(12.0)	
Marital status-Married	140 (21.9)	0.093
Marital Status-Single	25 (15.8)	
Ever homeless-No	135 (19.9)	0.225
Ever homeless-Yes	30 (24.8)	
Parity- first child	84 (22.6)	0.271
Parity-1	34 (16.9)	
Parity-2+	47 (20.8)	
CES-D ≤ 23	101 (18.6)	0.038
CES-D ≥ 23	64 (25.0)	

Table 3. Multivariate analyses assessing the relationship between stillbirth or neonatal death, pregnancy intention, and short inter-pregnancy interval (n=798)

Variable	OR	aOR	
	Model A	Model B	Model C
Stillbirth or neonatal death	3.71 (2.43-5.68)	4.06 (2.59-6.36)	3.09 (1.88-5.11)
Race			
Black		1.00	1.00
White		0.84 (0.41-1.74)	0.82 (0.39-1.73)
Hispanic/Other		0.84 (0.52-1.38)	0.71 (0.42-1.18)
Age			
≥ 30		1.00	1.00
25-29		1.72 (0.95-3.13)	1.94 (1.04-3.59)
<25		2.49 (1.37-4.52)	3.07 (1.65-5.71)
Education			
< HS		1.00	1.00
HS		0.86 (0.56-1.31)	0.84 (0.54-1.30)
Some college +		0.71 (0.41-1.22)	0.65 (0.37-1.13)
Insurance			
Non-Medicaid		1.00	1.00
Medicaid		1.46 (0.92-2.32)	1.50 (0.94-2.40)
Uninsured		0.79 (0.21-2.92)	0.78 (0.20-2.96)
Married		1.26 (0.72-2.17)	1.12 (0.64-1.97)
Ever homeless		1.38 (0.83-2.27)	1.46 (0.88-2.43)
Parity-first child		1.00	1.00
Parity-1		0.65 (0.40-1.04)	0.65 (0.40-1.06)
Parity-2 or more		1.13 (0.69-1.83)	1.20 (0.73-1.96)
Severe depressive symptoms		1.25 (0.86-1.84)	1.17 (0.79-1.73)
Intend pregnancy within 1 year			2.40 (1.24-4.65)
Effectiveness of birth control			
Low			1.00
Medium			0.80 (0.46-1.40)
High			0.53 (0.35-0.81)

Figure 1. Flow chart of study sample



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