Prenatal Care Interventions and Pregnancy Outcomes:
Evidence from the IMPLICIT program

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ABSTRACT

The IMPLICIT program is a network of 13 family medicine residency programs that uses specific clinical protocols to minimize pre-term birth (PTB) and low birth weight (LBW). Data files were analyzed for over 3000 mothers who received prenatal careand had infants with known birth weight and/or gestational age. IMPLICIT mothers disproportionately possess racial, ethnic, socioeconomic, and educational characteristics associated with higher than ordinary risks of LBW and/or PTB.

Overall LBW rate was 7.9%, with higher rates in mothers who were black, Hispanic, less than 18 years old, without a high school degree, and/or eligible for medical assistance. PTB rate was also 7.9%, with the highest rates in Hispanics and very young mothers. Nearly all those whose demographic status was unknown or missing had higher rates of adverse outcomes. Previous PTB or LBW delivery significantly increased the odds for another LBW or PTB delivery. A significant association was found between smoking and LBW; and between a diagnosis of depression and PTB. Smoking cessation and treatment for depression reduced the odds for LBW and PTB.

The overall rates of adverse pregnancy outcomes in these IMPLICIT mothers were lower than expected for this population, but some favorable bias may have been introduced by several sites transferring identifiably 'high risk' cases to specialized obstetrical care.

Evidence examined here suggests that the screening and intervention protocols used at IMPLICIT sites have some effectiveness in reducing pre-term birth and low birth weight, especially when there is a strong communicative relationship between an expectant mother and her clinical care provider(s).

INTRODUCTION

The IMPLICIT program (**I**nterventions to **M**inimize **P**reterm and **L**ow-birth weight **I**nfants through **C**ontinuous **I**mprovement **T**echniques) is a multi-site initiative to improve adherence to clinical standards in the provision of pre-and-post-natal care. Other investigators have analyzed the program's success in increasing the utilization of specific interventions designed to mitigate the adverse effects of maternal risk factors,[1] but they have not examined the actual impact of this program on the incidence of low birth weight (LBW) and pre-term birth (PTB). We examine here these pregnancy outcomes together with the full set of data describing expectant mothers treated within the IMPLICIT network, in order to understand the effects of both the overall program and the specific interventions in the program's protocols.

The IMPLICIT network comprises thirteen family medicine residency programs located in Pennsylvania (10), New York (2), and Connecticut (1). Five maternal care focus areas were selected based on: a) published evidence for their association with an increased risk of adverse pregnancy outcomes; and b) the practicality of implementing effective interventions.[2-4] Physicians and nurses at these sites provided screening and intervention for smoking, asymptomatic bacteriuria,[5-7] asymptomatic bacterial vaginosis,[8-13] depression,[14-18] and inter-pregnancy interval.[19-21]

METHODS

DATA

Since September of 2005, clinicians at IMPLICIT sites have been charged to complete a 66 item "Prospective Abstract Form," which compiles demographic information about each expectant mother, plus screening and intervention information recorded during her prenatal care visits at 15 and 30 weeks of gestation. Information about the pregnancy outcome as well as further screening and interventions undertaken at the postpartum visit is also recorded. Because of heavy patient volume, two of the sites use a stratified random sample in collecting and reporting these data; data from the other eleven sites are derived from a full census.

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Demographic elements include information about the expectant mother's age, race, ethnicity, educational attainment, insurance coverage, and obstetric history. Other data record whether the patient was screened in accordance with project protocols, the diagnoses resulting from such screenings, any interventions or treatments offered, and whether those treatments were accepted and were successful. (IMPLICIT protocols call for each patient to receive all screenings and to be offered appropriate interventions based on the outcomes of those screenings, with the exception of bacterial vaginosis, for which only women with a previous low birth weight or preterm delivery are screened.)

Information about the outcome of pregnancy includes delivery status (live birth, stillborn or fetal death), birth weight, and gestational age at delivery. We define LBW conventionally as a birth weight of less than 2500 g and PTB as delivery prior to 37 full weeks of gestation.

The master data set is housed at Lancaster General Hospital in Lancaster, PA. This paper's results are based on that data set as it existed at the end of September 2009. The data collection and research project from which these results are derived has received IRB approval at each of the IMPLICIT sites.

STATISTICAL ANALYSIS

The full data set includes 4,114 cases, but approximately one-quarter of them do not report sufficiently specific information about birth weight and/or gestational age. A small number of cases reported as stillbirths or fetal deaths were also eliminated to arrive at a data file of 3,089 cases of live births with known birth weight (BW) and another file of 3,283 cases of live births with known gestational age (GA). The statistical results reported below are derived from these two data sets. Statistical significance is defined as a 95% confidence level ($p < 0.05$). All computations were performed using STATA/IC 10.0 for Macintosh; StataCorp, College Station, TX.

RESULTS

As reported in Table 1,[iii] white women account for about 45% of the cases in each data set, with black or African American women accounting for about 32%. Of the approximately 20% whose race is recorded as "other" or is missing, a sizable portion are likely Hispanics, who often self-identify as of a race other than black or white.[22-23] Women specifically identified as Hispanic in fact account for approximately 18% of each sample.

About 83% of the women in these data sets are from 18 to 34 years of age, with roughly equal percentages falling into the older and younger age categories. The mean age is 24.

While more than one-quarter of the cases have no information as to educational attainment, among those for whom such information is recorded fewer than 7% have obtained a post-high school degree and approximately 27% have not completed high school. Finally, women who are covered by private insurance or who are 'self-payers' make up only 22% of the total, while those covered by medical assistance account for almost three-quarters of the cases.

Taken together, the demographic characteristics of this group of women identify them as of relatively high risk for adverse pregnancy outcomes. They are generally poorer, less educated, and more likely of minority status than the general population of expectant mothers in the United States.[24]

Low birth weight occurred in 7.9% of all cases in the BW sample (244/3089) where the mean birth weight is 3254 g. Infants born prematurely account for 7.9% of the GA sample as well (259/3283). Mean gestational age was in the 39th week, roughly 5 days prior to due date. Taking these results together, it can be said that expectant mothers treated at IMPLICIT sites experience relatively favorable rates of adverse pregnancy outcomes, particularly with respect to preterm birth.

The LBW rate experienced by white mothers is significantly lower (6.0% vs. 10.1%) than that recorded among black mothers, whose infants have a mean birth weight 133 grams less than that of infants delivered by white mothers. For PTB, the black-white gap is smaller at 1.3 percentage points and not significant. Mothers of Hispanic ethnicity have an LBW rate of 8.4%, only 0.8 percentage points higher than that seen for non-Hispanics. Though their 9.5% PTB rate is more than 2 percentage points higher than the 7.2% observed for non-Hispanic mothers, the difference is not significant.

Mothers less than 18 years of age have the highest LBW and PTB rates of any of the identified demographic groups included in Table 1 (11.1% and 9.6%, respectively).

An unexpected result is that mothers with a post-high school degree (e.g., trade or military training certification, Associate's degree, Bachelor's degree, or beyond) tend to have a higher rate of PTB than do those with less education, although the difference is not significant. Mothers without a high school degree do tend to have a higher LBW rate but a lower PTB than those who've graduated from high school, though not significantly so.

Among mothers who are eligible for medical assistance, the LBW rate tends higher while the PTB rate is lower than those observed for women who are covered by private insurance or who are self-payers. In all cases except one, mothers whose demographic information is unknown or unrecorded have higher rates of LBW and PTB, often by a considerable and even significant margin (see Table 1).

INFLUENCE OF DEMOGRAPHIC FACTORS

Table 2 reports odds ratios that test the significance of demographic factors in explaining the incidence of LBW and PTB. In comparison with all white mothers, African American mothers have a statistically significant odds ratio for LBW of 1.75. In comparison with white, non-Hispanic mothers, Hispanic mothers have LBW and PTB odds ratios of 1.41 and 1.42 respectively, which fall just short of statistical significance.

In comparison with mothers from 18 to 34 years of age, younger mothers likewise show a nearly significant odds ratio for LBW of 1.53. In the cases where educational attainment and/or insurance coverage groups are compared, none of the odds ratios are significantly different from 1.00.

There is no evidence in these data that multiparity exerts any significant effect upon LBW or PTB; nor is there any evidence here of an adverse impact associated with an inter-pregnancy interval of less than one year. However, mothers with one or more previous LBW or PTB pregnancies are at significantly greater risk for recurrence of each of these outcomes.

EFFECT OF INTERVENTIONS

Table 3 reports odds ratios associated with the IMPLICIT program's focus areas and intervention protocols. In comparison with women who never smoked, those who were smoking at either their 15 week or 30 week prenatal visit have significant odds ratios for LBW (1.74 and 1.75 respectively) but not for PTB. Of particular note, women who were documented at their 30 week visit as having followed advice to stop smoking are significantly less likely to experience either an LBW or a PTB delivery than those documented as not having followed that advice (ORs: 0.44 and 0.39, respectively).

Women with a positive diagnosis of Asymptomatic Bacteriuria show an odds ratio of 1.30 for PTB. Among those with a positive diagnosis, women who received treatment (versus those who did not) have a PTB odds ratio of 0.62. However, each of these odds ratios falls short of achieving statistical significance.

Among women with a previous adverse pregnancy outcome who were screened for Bacterial Vaginosis, neither a positive diagnosis, nor treatment for it, has a statistically significant effect with respect to LBW or PTB.

Expectant mothers with a positive diagnosis of depression at the 15 or 30 week visit show significant odds ratios for PTB, 1.56 and 1.60 respectively. Those so diagnosed who accepted recommended treatment via medication and/or counseling were observed in all cases to have odds ratios less than 1.00 (in comparison with those who refused treatment). However, only the lower odds for LBW among mothers who accepted counseling approached statistical significance.

The IMPLICIT program's fifth focus area is aimed at reducing the likelihood of a subsequent pregnancy that follows too soon after the current pregnancy. The related intervention calls for discussion between clinicians and expectant mothers about planning for post-partum contraception. Approximately 77 percent of cases in both the BW (birth weight) and the GA (gestational age) files are identified as having documentation of such a discussion as of the 30 weeks visit. Among expectant mothers who are black, the number is somewhat lower at 74 percent while for Hispanics it is considerably higher at 87 percent.

DISCUSSION

Using CDC data for the counties in which IMPLICIT sites are located, we calculated 'expected' LBW and PTB rates for the BW and GA samples (using a weighted average based on the percent of total cases from each site). Even without having accounted for the demographic factors that identify IMPLICIT mothers in general as at relatively high risk for adverse pregnancy outcomes, we found an 'expected' LBW rate of 8.3%, which is above the 7.9% LBW rate observed among the BW sample (although within its 95% confidence interval); the 'expected' PTB rate, at 11.6%, is more than 3.5 percentage points higher than the GA sample's 7.9% rate.

The superior pregnancy outcomes observed for expectant mothers who received treatment at the IMPLICIT sites at least in part reflects the fact that some of these programs refer identifiably high-risk cases to specialized obstetrical care rather than continuing to deliver care within the family medicine program. Such cases therefore may become "lost to follow up" or otherwise excluded from the BW and GA samples. On the other hand, some part of the favorable results may also reflect the quality of treatment provided to IMPLICIT patients as well as the effectiveness of interventions undertaken in the fulfillment of program protocols. We are skeptical, however, that such improvements could be as large as the differences reflected in this comparison, particularly in the case of PTB. Ideally, IMPLICIT records would include pregnancy outcome information for all cases in which prenatal care was initiated within the program. Absent this, we cannot quantify the favorable selection effect of 'high risk' patients being transferred out to specialized practices, or the loss to follow up of patients who defect from the program.

For those cases with complete information as to birth weight and/or gestational age, our statistical analysis found the following demographic factors significantly associated with higher risk: for LBW, black race, mother's age less than 18, and a previous pregnancy that resulted in an adverse outcome; for PTB, while the Hispanic ethnicity odds ratio fell just short of achieving statistical significance, only the status of having experienced a previous adverse pregnancy outcome is fully significant at the 95% confidence level.

Although the demographic factors we have identified above as significant have already been established in the existing literature as associated with greater risk, our findings reinforce the need to pay particular attention to the prenatal care received by these populations. That these factors are primarily significant for LBW in our sample suggests that tailoring interventions specifically to address fetal growth would be most apt to yield beneficial results in a similar such population of expectant mothers.

The following behavioral and/or health status variables were found to have significant odds ratios with respect to LBW or PTB: current smoker at the 15 week and/or 30 week visit, and positive diagnosis of depression at either the 15 or 30 weeks visit. A diagnosis of asymptomatic bacteriuria was nearly significant. Although this study has not addressed the mechanisms by which these factors affect LBW and/or PTB, our findings support the importance of rigorous screening for smoking, depression, and bacterial infection to identify women at high risk of adverse pregnancy outcomes.

The IMPLICIT program's intervention protocol regarding smoking is statistically associated with significantly improved birth outcomes. Current smokers at the 15 weeks visit who were documented at the 30 weeks visit as having followed advice to quit were less than half as likely as those who continued to smoke to experience either a LBW or a PTB delivery. And while expectant mothers diagnosed with asymptomatic bacteriuria were more likely to experience a PTB, those so diagnosed who received treatment tended to have lower odds for a premature delivery than did those who were not treated, but not significantly so.

Among women who were diagnosed as positive for depression, those who accepted a recommended treatment were in all cases less likely to experience an adverse pregnancy outcome than those who did not, although never within the parameters of conventional statistical significance. Similarly, women who were treated for bacterial vaginosis had considerably lower odds for PTB than those with a positive diagnosis who did not receive treatment, but the cohort was too small to establish significance.

An intriguing result not reported above is that women for whom there is documentation of a clinician-patient discussion regarding post-partum contraception planning are significantly less likely to have experienced a subsequent low birth weight and/or pre-term delivery than those for whom there is no documentation of same (ORs [p-values] for LBW and PTB, respectively: 0.60 [0.001]; 0.64 [0.002]). Similarly, mothers who propose a "breast only" feeding plan at discharge—versus those with an alternative feeding plan—show significantly lower odds of having delivered a low birth weight infant (OR [p-value]: 0.60 [0.002]).

What is to be made of such findings? Clearly, *planned* behavior, which is only to be enacted in the period following a current pregnancy, cannot have affected that pregnancy's delivery outcome. On the other hand, the existence of a plan and/or the specific content of such a plan may be correlated with unobserved maternal behaviors past and present (during the current pregnancy) that do have an effect on the current pregnancy's outcome. Furthermore, the existence of such plans and/or the clinician-patient interactions that may have prompted them can reflect the superior quality of the broad communicative relationship between an expectant mother and her prenatal care provider(s).

Indeed, we interpret our findings as suggesting that such forces are at work in effecting beneficial pregnancy outcomes. The generally positive treatment effects observed above may also reflect, in part at least, the prior differences between women who accepted the IMPLICIT program's recommended treatments and those who did not.

The IMPLICIT program appears to have been successful in mitigating adverse pregnancy outcomes among a group of relatively "high risk" expectant mothers. Its efficacy might be further improved by strenuous efforts to ensure the fullest possible exchange of information between patients and prenatal care providers.

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