Matern Child Health J
DOI 10.1007/s10995-008-0400-y

Healthy Start Program and Feto-Infant Morbidity Outcomes: Evaluation of Program Effectiveness

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Abstract *Objective* We evaluate the impact of the Healthy Start intervention program on feto-infant morbidity within a community setting. *Methods* Prospective data from 2002 to 2007 within the ongoing Federally funded Healthy Start intervention project in Central Hillsborough County were merged with corresponding birth outcomes data from the Florida Department of Health. The impact of the project on the following feto-infant morbidity indices was assessed among service recipients: low birth weight (LBW), very low birth weight (VLBW), preterm, very preterm, small for gestational age (SGA) and a composite feto-infant morbidity outcome. Program effectiveness and impact were measured using odds ratios from logistic regression models and number needed to treat (NNT). *Results* The risk for low birth weight (OR = 0.7; 95% CI = 0.5–1.0), preterm (OR = 0.7; 95% CI = 0.5–0.9) and the composite feto-infant morbidity outcome (OR = 0.8; 95% CI = 0.6–0.9) was reduced among service recipients ($N = 536$) as compared to non-recipients ($N = 2{,}815$). A clinically important level of risk reduction was also noted for very low birth weight (OR = 0.5; 95% CI = 0.2–1.1) and very preterm (OR = 0.6; 95% CI = 0.3–1.2) although these did not reach statistical significance. The adjusted NNT was lowest for the composite feto-infant morbidity outcome (18), preterm birth (21) and low birth weight (24), and highest for very preterm (86) and very low birth weight (74) events. *Conclusions* In a disadvantaged community setting, the Healthy Start intervention program was found to reduce the risk for very low birth weight and preterm births by about one-third.

Keywords Healthy Start · Program effectiveness · Preterm · Low birth weight · NNT

Introduction

The federal government has set national health objectives to be achieved over the first decade of the century, designated as Healthy People 2010. A priority goal of Healthy People 2010 is the reduction in morbidity and mortality among disadvantaged populations, with calls for the eventual elimination of health disparities among subgroups of the US population [1]. An important reproductive health area in which disparities among US populations have been most disturbing and persistent is that of infant morbidity and mortality [2–4], a major public health concern for which several initiatives and strategies have been formulated. One of the most widely known programs that attempts to reduce disparities in infant morbidity and mortality is the nationwide Federal Government Healthy Start Project implemented through the Maternal and Child Health Bureau's Healthy Start Initiative.

The Central Hillsborough Healthy Start Project (CHHS) is one of the community-based programs in the State of Florida funded by the Federal Government through the Maternal and Child Health Bureau's Healthy Start Initiative. Implemented by the Lawton and Rhea Chiles Center for Healthy Mothers and Babies at the University of South Florida, the CHHS project functions as a community/university partnership to narrow racial disparities in maternal and infant health outcomes in urban Tampa neighborhoods (Florida) where the Black infant mortality and morbidity

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rates are more than double those among Whites [Low birth weights = 7.2% vs. 15.2% for whites and blacks, respectively; Infant mortality rates = 5.2/1000 vs. 22.7/1000 for whites and blacks, respectively] (unpublished data from the Florida Department of Health). In these neighborhoods most of the births are to mothers who are Black, many of whom are young, unmarried, undereducated, and Medicaid eligible [5].

Pre- and post-natal risk reduction services are provided by the project within the local perinatal healthcare system framework, the Central Hillsborough Healthy Start (CHHS) and a complementary state system, the Florida Healthy Start Program. The Florida Department of Health and the Healthy Start Coalition of Hillsborough County work collaboratively, thereby integrating local and state efforts in a complementary manner. Unique to Florida, all pregnant women and newborn infants are offered risk screens (Table 1) to identify those who would benefit most from risk reduction services. Mothers who voluntarily accept the screen and express interest in services are referred to local Healthy Start Programs. In Hillsborough County, women living in select East Tampa zip codes (33602, 33603, 33605 and 33610) who need services are referred to the CHHS Program for those services. This study evaluates the effectiveness of services rendered by the CHHS to recipients of services within this locale.

There are three main components to the risk reduction service delivered within the framework of the project according to needs identified through screening and further assessment, and these include (see also Table 2 for a time line):

(1) *Initial contact*: This is the point-of-entry into healthy start care coordination and other services. It is attempted within 5 days after screening or referral. At the initial contact, the risk status of the client is explained, the ability to assess health care and the need for further services are determined; the opportunity is used to review with the client risk factors for adverse pregnancy outcomes, concerns and priorities of the clients, and issues related to resource identification and utilization during the prenatal period.

(2) Initial assessment occurs within ten days after initial contact. It is the point where face-to-face contact is made with the client. At this stage, professional assessment of health and social–environmental risks are performed to determine if assistance is needed in overcoming the identified risk; in-depth health education is offered at this stage (education on nutrition, child spacing, fetal development, normal and abnormal pregnancy, signs and symptoms of preterm labor and what to do when they occur, etc.). A detailed need assessment is performed, and the available resources and how clients could qualify for these resources are discussed. Finally, the client is offered assistance on a comprehensive plan for pregnancy-related activities to ensure a smooth course till delivery.

(3) Care co-ordination is a comprehensive prenatal assessment and care utilization package that targets risk-appropriate care to address the identified risks

Table 1 Screening items

Variables	Categories	Points
Questions answered by mothers		
Your age	<18	1
	>39	1
Your race	Black	2
	White	0
	Others	0
Are you married?	Yes	0
	No	1
You graduated from high school or received a GED	Yes	0
	No	1
Your weight before pregnancy	<110	1
Do you have any problems which prevent you from keeping your health care or social services appointments?	Yes	1
Have you moved more than three times in the last 12 months?	Yes	1
Do you feel unsafe where you live?	Yes	1
Do you or any member of your household go to bed hungry?	Yes	1
In the last 2 months, have you used any form of tobacco?	Yes	1
In the last 2 months, have you used drugs or alcohol (including beer, wine, mixed drinks)?	Yes	1
If you could change the timing of this pregnancy, would you want it …	(a) Earlier	0
	(b) Later	0
	(c) Not at all	1
	(d) No change	0
Questions answered by health care provider		
Did patient's last pregnancy result in a miscarriage, stillbirth, a baby less than 5 1/2 pounds, a baby born more than 3 weeks early, or a baby that stayed in the hospital after the patient went home?	Yes	1
Does patient have any illness that requires continuing medical care? Specify illness:	Yes	1
Trimester of entry at first prenatal visit	Second trimester	1

Points are totaled for each patient. A total score of 4 or more is considered a positive screening

A total score of 3 or less is considered a negative screening

Table 2 Time line

Screening/ referral:	5 days	10 days	
Point of entry:	Initial contact	Initial assessment	Care coordination
	Explain risk status	Professional assessment	Comprehensive assessment
	Discuss available assessment	Identify factors	Care utilization
	Discuss available service	Health education	
		Discuss resources planning	

and prevent poor health and adverse birth outcomes. At this point, assistance is also offered to provide them with access to appropriate and needed care that will address specific risks identified during initial contact and initial assessment encounters.

It is now well established that in order to prevent mortality, a logical and tactically sound approach is to reduce the levels of morbidity or pre-cursors of mortality [6–8]. Low birth weight and its component, preterm birth have been known to be the main mechanisms through which feto-infant death occurs [6–8]. Few non-pharmacological interventions have shown promise in reducing preterm birth in a randomized controlled setting [9, 10] and several others have generally failed to demonstrate improvement in feto-infant morbidity [11–15]. Although a preliminary descriptive study [16] has noted the possibility of potential benefits in feto-infant health as a result of community-based interventions through the Federal Healthy Start programs, actual data on effectiveness of these interventions in reducing feto-infant morbidity burden based on scientifically rigorous approaches are lacking. Evaluation at this time is imperative and timely because the Healthy People 2010 projected year for achieving its stated goal is fast approaching, and there is a dire need to know whether formulated policies, strategies and actions have been effective or not in achieving desired objectives.

In this paper, we seek to evaluate the effectiveness of the Central Hillsborough Federal Healthy Start program in reducing birth outcomes related to feto-infant morbidity (low birth weight, very low birth weight, preterm, very preterm and small for gestational age, SGA) among the 3,351 women enrolled into the program in a socio-economically disadvantaged community in Hillsborough County, Tampa, Florida. It is now well established that fetal programming processes in utero influence subsequent adult-onset morbidity and mortality, a concept widely described as the Barker's hypothesis [17–20]. The manifestations of sub-optimal fetal programming in utero include a spectrum of sub-optimal fetal growth and development (feto-infant morbidity) which impacts subsequent survival and quality of life. It is therefore, important to prevent these consequences of altered/abnormal fetal programming processes in order to reduce later disease and mortality burden in the population. Accordingly, we sought to assess the impact of the Central Hillsborough Healthy Start on feto-infant morbidity occurrence among recipients of services. We hypothesized á priori that community intervention activities offered in the form of prenatal program services conducted among high-risk mothers by the local Federal Healthy start program (known as the Central Hillsborough Healthy Start or CHHS) have been effective in reducing feto-infant morbidity levels among service recipients.

Materials and Methods

The study covers the period from January 2002 through September 2007. Although the project received its initial funding in 1997, community-wide activity data on program enrollees were not routinely and systematically entered into an electronic data entry format until the end of 2001 when a data entry system equipped with automated validation processes that ensure accurate data entry and appropriate data modification procedures was installed. We subsequently linked pregnancy and birth information on the vital statistics records from the Florida State Department of Health with the CHHS program data for the purpose of analyses relating to birth outcome measures.

In this paper, we evaluate the effectiveness of the program in impacting the levels of feto-infant morbidity among women enrolled in the program. Mothers receiving service are defined as those that had initial assessment or care coordination or both prenatally. Mothers that were enrolled in the program prenatally but had none of the three components or had initial contact only but none of the other two components are considered to have received no service and comprise our internal control for the analyses in this paper.

We selected two comparison groups; an internal and external control for this purpose. The internal control (or control 1) comprises clients who were enrolled but did not receive services as defined above. In the majority of cases, the reason for non-receipt of services were due to prenatal screening scores that were below the recommended 4.0 screening score recommended as the cut-off point for delivery of risk reduction services. Florida's universal screening of pregnant women and infants includes a series of questions that focus on medical, environmental,

and psychosocial factors that identify a patient as at-risk (Table 1). The score is determined by summing the contributing items, each worth one point except for race, which contributes two points. The following 15 variables comprise the components of the screening score: Black race; maternal age below 18 or above 39; unmarried; less than high school education; low maternal weight (<110 pounds); problems keeping appointments; moving more ≥3 times in the past year; feeling unsafe; going to bed hungry; tobacco use in the past 2 months; use of drug or alcohol in the past 2 months; unwanted pregnancy; current maternal illness; seeking prenatal care in the second trimester; and history of poor outcomes or no previous pregnancy experience. The external control (or control 2) consists of pregnant women resident within the specified catchments zip code areas of CHHS and who delivered in Hillsborough County but were not enrolled in the CHHS program.

We considered only live viable births (≥20 weeks of gestation). The outcomes of interest in this study were the risk for feto-infant morbidities, and those examined were: low birth weight (<2,500 g), very low birth weight (<1,500 g), preterm (<37 weeks), very preterm (<33 weeks) and SGA. SGA was defined as <10th percentile of birth weight for gestational age using population based national reference curves [21]. Gestational age was computed in weeks while birth weight was measured immediately after birth and reported in grams. Gestational age was largely based on the interval between the last menstrual period and the date of delivery of the baby (95% cases). When the menstrual estimate of gestational age was inconsistent with the birth weight (e.g., very low birth weight at term), a clinical estimate of gestational age on the vital records was used instead [22]. The accuracy of using gestational age as reported on the US birth certificate has previously been validated [23]. In that validation study, the authors assessed the concordance between date of last menses (DLM) reported among case (very low birth weight infants or neonatal deaths) and those randomly selected from a non-case population. There was a good agreement (84.2%) with medical records. Clinical estimate of gestation in completed weeks was 79.0% concordant for recipients of services, and 94.0% for controls. This has recently been found to be consistent with an anticipated ±2 weeks variation in DLM [24]. Hence, gestational age as used in this study is reasonably valid.

In addition, we constructed a composite variable that we refer to as feto-infant morbidity, for simplicity. This composite variable is defined in this study as the occurrence of at least one of the following: low birth weight, very low birth weight, preterm, very preterm or SGA.

The following information on maternal characteristics for each woman was examined to assess any differences in socio-demographic features between service recipients and controls: maternal age (categorized as <35 or ≥35 years), gravidity, defined as total number of pregnancies experienced (primigravid or multigravid), race (Black non-Hispanic, White, non-Hispanic, Hispanic and others), marital status (married or unmarried), educational status (<12 or ≥12 years), obese (body mass index (BMI ≥ 30) or non-obese (BMI < 30), cigarette smoking during pregnancy (yes or no), and adequacy of prenatal care (adequate or inadequate). Height, measured at the first prenatal visit, and prepregnant weight, as reported at the first prenatal visit, were used to calculate prepregnant body mass index. BMI computation and comparison was only possible for the years 2004–2007 since prior to that period the information for height and pre-pregnancy weight was not routinely collected on the birth certificate. Adequacy of prenatal care was assessed using the revised graduated index algorithm, which has been found to be more accurate than several others, especially in describing the level of prenatal care utilization among groups that are high-risk [25]. This index assesses the adequacy of care based on the trimester prenatal care began, number of visits, and the gestational age of the infant at birth.

Statistical Analysis

We applied Chi-square tests to determine differences in socio-demographic characteristics and in the frequency of feto-infant morbidity indices between service recipients and controls. The association between program performance and levels of feto-infant morbidity was quantified by means of odds ratios generated from logistic regression models. We constructed the regression models and assessed goodness-of-fit using the −2 log likelihood ratio test. We estimated the significance of main effects by means of the Wald test [26].

We compared feto-infant indices for service recipients (numerator) against those for non-recipients (denominator) to determine program effectiveness. We defined à priori program effectiveness (in %) as the value derived from the following formula:

$$(1 - \mathrm{OR}) * 100$$

where OR = adjusted odds ratio. Positive values point to reduction of feto-infant indices while negative values denote increment.

We computed the number needed to treat (NNT), defined in this study as the number of mothers that would have to receive services offered by the program prenatally to prevent one case of a feto-infant morbidity outcome as compared to non-receipt of services. This was derived from adjusted odds ratios and computed thus [27, 28]:

$$\mathrm{NNT} = 1 \div [(1 - \mathrm{OR}) \times I_0]$$

where I_0 is the frequency of the feto-infant morbidity outcome among controls. We also computed adjusted probabilities from adjusted odds of the composite feto-

infant morbidity outcome from logistic regression models. We then constructed comparative curves for recipients and non-recipients of service using these estimates across prenatal screening scores.

All tests of hypothesis were two-tailed with a type 1 error rate fixed at 5%, and SAS version 9.1 (SAS Institute, Cary, NC, USA) was used to perform all analyses. This study was approved by the Office of the Institutional Review Board at the University of South Florida.

Results

Over the entire study period (2002–2007), 3,351 births to mothers enrolled in the program were recorded. Of these, 536 (16.0%) received services while the remaining 2,815 (84.0%) did not. Over the entire period, 804 of the births (24.0%) were to teen mothers and 263 (7.9%) were to women advanced for age (≥35 years of age). The mean gestational age at initial contact was 17.9 weeks (±0.4 weeks) but there was no difference between service recipients and non-recipients [(Mean ± SE) = 17 weeks ± 0.6 vs. 18 weeks ± 0.4); $P = 0.6$]. A summary of the differences in common maternal socio-demographic characteristics between service recipients and controls is given in Table 3.

External controls had more women of advanced maternal age than service recipients. By contrast, the proportion of teen pregnancies was similar for service recipients and internal controls but significantly greater as compared to external controls. Non-Hispanic blacks comprised the majority in the sample. As compared to both internal and external controls, service recipients had more non-Hispanic blacks and were less likely to have completed high school education. Service recipients were also less likely to be married and received lower levels of adequate prenatal care as compared to external controls. Service recipients were more likely to be multiparous than internal controls. The prevalence of smoking was 6.2% for all mothers enrolled in the program (service recipients and internal controls combined) but there were no differences across the three groups with respect to the prevalence of smoking during pregnancy, and that of obesity.

Of the 536 infants born to mothers that received services, 62 (11.6%) were of low birth weight, 8 (1.5%) had very low birth weight, 65 (12.1%) were preterm, 11 (2.1%) were very preterm and 76 (14.2%) were SGA. A breakdown of these rates according to recipients of services and controls (internal and external controls) is illustrated in Fig. 1.

Table 4 summarizes adjusted estimates for the relationship between receipt of services through the CHHS program and risk of feto-infant morbidity. The crude estimates were similar to the adjusted analyses using either internal or external controls. Compared to both internal and controls, infants born to mothers who were recipients of services had lower odds for all feto-infant morbidity indices although risk reduction was only found to be significant

Table 3 Comparison of service recipients to controls according to selected socio-demographic characteristics

	Service recipients ($N = 536$) %	Internal control ($N = 2,815$) %	*P*-value	External control ($N = 3,833$) %	*P*-value
Maternal age (in years)					
≥35	6.0	8.1	0.1	10.9	0.0008
<20	21.7	24.6	0.1	14.8	<0.0001
Gravidity					
>1	68.3	62.1	0.0009	70.7	0.2
Race/ethnicity					
Black NH	67.7	53.0	<0.0001	41.2	<0.0001
White NH	14.2	22.4		20.6	
Hispanic	11.1	13.0		21.6	
Others	7.0	11.2		16.6	
Married					
Yes	24.7	28.5	0.08	35.7	<0.0001
Education					
≥high school	55.3	62.2	0.003	65.4	<0.0001
Obesity[a]					
Yes	26.0	23.0	0.3	22.9	0.2
Smoking					
Yes	4.4	6.8	0.45	3.6	0.3
Adequate prenatal care					
Yes	12.8	12.9	0.98	19.5	0.0002

[a] Information available as from 2004, and hence, comparison restricted to that period

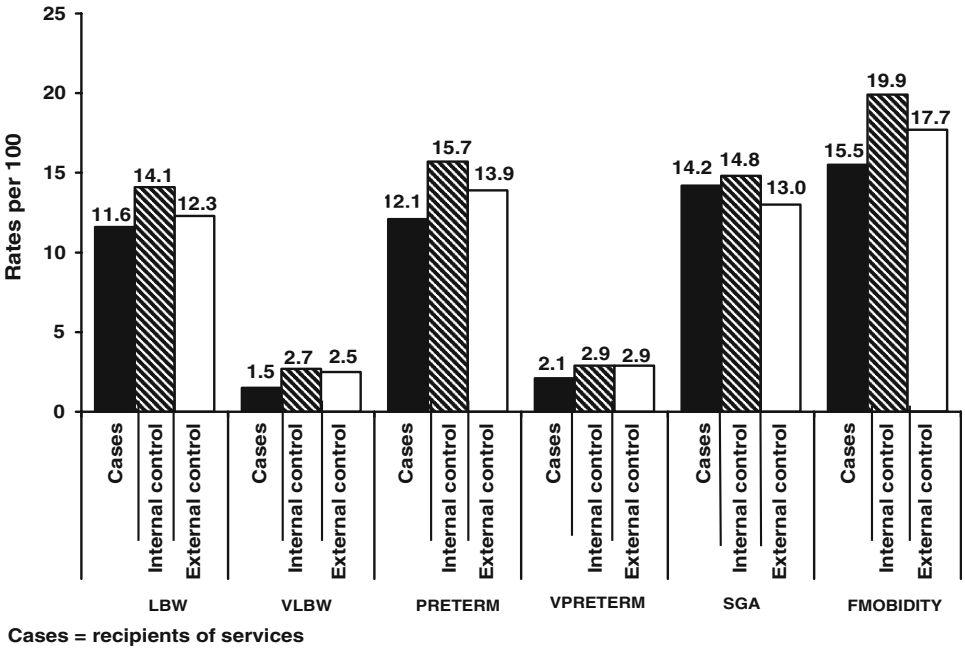

Fig. 1 Rates of feto-infant morbidity for mothers that received services compared to internal and external controls (LBW = low birth weight, VLBW = very low birth weight, VPRETERM = very preterm, SGA = small for gestational age, FMOBIDITY = feto-infant mobidity)

Table 4 Adjusted odds ratios (OR) for the association between receipt of services and feto-infant morbidity

	Internal control		External control	
	Crude OR	Adjusted OR	Crude OR	Adjusted OR
Low birth weight	0.8 (0.6–1.1)	0.7 (0.5–1.0)*	0.9 (0.7–1.3)	0.8 (0.6–1.0)*
Very low birth weight	0.6 (0.3–1.2)	0.5 (0.2–1.1)	0.7 (0.3–1.3)	0.5 (0.2–1.1)
Preterm	0.7 (0.5–1.0)*	0.7 (0.5–0.9)	0.9 (0.7–1.1)	0.7 (0.5–0.9)
Very preterm	0.7 (0.4–1.3)	0.6 (0.3–1.2)	0.8 (0.4–1.4)	0.6 (0.3–1.2)
Small for gestational age	1.0 (0.7–1.3)	0.9 (0.7–1.2)	1.1 (0.9–1.5)	1.0 (0.7–1.3)
Feto-infant morbidity (Composite)	0.8 (0.7–1.0)	0.8 (0.6–0.9)	0.9 (0.7–1.1)	0.8 (0.7–1.0)*

Adjusted estimates were obtained after controlling for the confounding effects of maternal age, gravidity, race/ethnicity, marital status, education, obesity, smoking status and adequacy of prenatal care

* P-value < 0.05

for low birth weight, preterm and the composite variable of feto-infant morbidity. The adjusted risk for low birth weight and preterm birth was 30% lower while the composite feto-infant morbidity was 20% lower among service recipients as compared to internal controls. Similarly when compared to external controls, mothers that received services had 20% lower likelihood for low birth weight and the composite feto-infant morbidity outcome, and 30% risk reduction for preterm birth. There were no significant differences between the two groups with respect to the other indices of feto-infant morbidity.

Mothers enrolled in the program could have received prenatal services from the program without having been screened, or for other reasons despite low screening scores, and this could have impacted our results. In addition, our inability to document those mothers that received services from other providers in the County could have confounded the results; however, this threat was minimal since both groups (control and comparison) are equally likely to be affected. We therefore, proceeded to determine whether there was any association between a high score ($\geq$4) at prenatal screening and subsequent feto-infant morbidity at birth. The analyses were restricted to about 75.0% of program enrollees with screening scores. Figure 2 illustrates clearly that mothers with high scores were at significantly elevated risks for low birth weight, very low birth weight, preterm, very preterm, SGA and the composite feto-infant morbidity outcome ($P < 0.0001$ in all cases).

There was also an association between receipt of services and prenatal screening scores. Mothers that received services were about twice as likely to have high screening scores prenatally as compared to non-recipients of services (42.1% vs. 26.7%; $P < 0.0001$). Adjusted risk estimates obtained from re-analysis of the data restricted to mothers

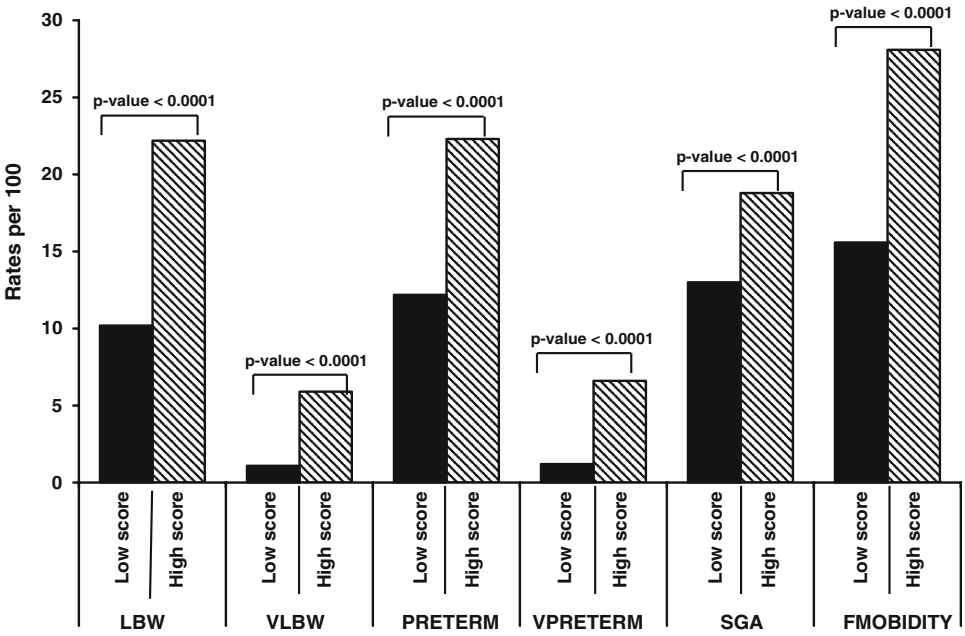

Fig. 2 Rates of feto-infant morbidity indices among program enrollees stratified by low and high screening scores (LBW = low birth weight, VLBW = very low birth weight, VPRETERM = very preterm, SGA = small for gestational age, FMOBIDITY = feto-infant mobidity)

with prenatal screening scores only yielded results not different from those displayed in Table 4.

The disparity in the risk for feto-infant morbidity across prenatal screening scores for recipients versus non-recipients of services is illustrated in Fig. 3. It demonstrates that at lower screening score values the disparity was relatively narrow. However, as the prenatal screening score increased the risk gap for feto-infant morbidity between service recipients and non-recipients widened tremendously. For instance, at the score value of three the adjusted probability of feto-infant morbidity was about 5% for service recipients versus 20% for non-recipients for an absolute risk difference of 15%. By contrast, at a screening score of 12, the corresponding adjusted probabilities were about 25% vs. 80%, yielding an absolute risk difference of 55%. This clearly indicates that the program services were more beneficial with ascending risk status.

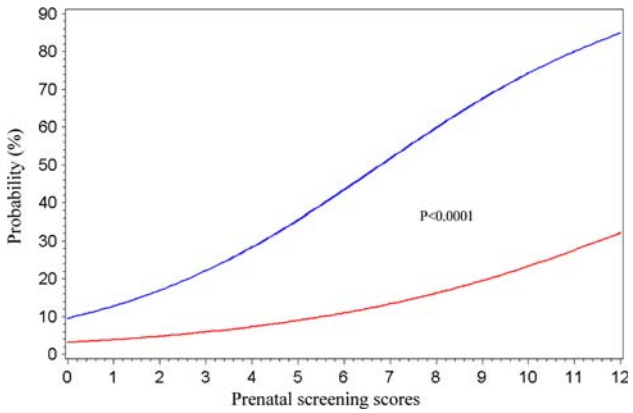

Fig. 3 Adjusted probability estimates for the likelihood of feto-infant morbidity based on prenatal screening scores among service recipients (*red or lower curve*) versus non-recipients (*blue or upper curve line*)

We further computed the number of mothers that would have to receive services offered by the program to prevent one case of a feto-infant morbidity outcome as compared to non-receipt of services. The results are shown in Table 5. The NNT (number needed to treat) was lowest for the composite feto-infant morbidity outcome, low birth weight and preterm births, and highest for very low birth weight and very preterm events.

Discussion

The major finding of this evaluation study is that the Central Hillsborough Federal Healthy Start program did reduce the level of low birth weight and preterm delivery by about 30% among service recipients as compared to non-recipients. These results bear important implications for care providers and health policy makers within the perinatal health care system where the study was conducted. Although we also noted a 50% and 40% risk reduction for very low birth weight and very preterm births, respectively, the results failed to reach statistical significance. Our inability to detect this comparatively large and clinically important magnitude of a difference for very low birth weight and very preterm might be attributable to insufficient sample size. Assuming a type 1 and a type 2 error rate of 5% and 20%, respectively, and a similar level of very low birth weight in both service recipients and non-recipients as found in this study, would require a total

Table 5 Program effectiveness and number needed to treat using internal and external controls as referent categories

	Program effectiveness-1 (%)	Program effectiveness-2 (%)	Number needed to treat-1 (%)	Number needed to treat-2 (%)
Low birth weight	30	20	24	41
Very low birth weight	50	50	74	91
Preterm	30	30	21	25
Very preterm	40	40	86	99
Small for gestational age	10	0	68	–
Feto-infant morbidity (Composite)	20	20	18	21

Program effectiveness = [1-adjusted odds ratio (OR)] × 100; number needed to treat was computed thus $1 \div [(1 - \text{OR}) \times I_0]$; where OR = adjusted odds ratio and I_0 is the frequency of the outcome among controls

Program effectiveness-1 uses internal controls as referent and Program effectiveness-2 uses external controls as referent. Number needed to treat-1 uses internal controls as referent and number needed to treat-2 uses external controls as referent

sample size of about 9,192 to detect the difference in very low birth weight between the two groups as observed in this study. This is approximately three times the current sample size used in this analysis.

A likely explanation for the observed risk reduction in low birth weight and preterm birth is that mothers who did not receive services were perhaps at a higher risk threshold for adverse pregnancy outcomes, a situation that could be the reason for a greater burden of feto-infant morbidity in that group as compared to service recipients. We tested this likelihood by comparing the two groups using an acceptable risk level measure that is universally utilized in the State of Florida, the prenatal screening score. Mothers that were recipients of services did comparatively poorly on this score and were about twice as likely to achieve higher values, and therefore at greater risk, than non-recipients of services. Since a higher prenatal screening score is related to adverse birth outcomes as well as non-receipt of services, it represents a confounding factor that had the effect of limiting our ability to detect program effectiveness where there was one. The observation of reduction in risk for adverse birth outcomes despite this limiting factor is additional convincing evidence that the Health Start Program was truly effective.

Another logical explanation for the observed risk reduction for low birth weight and preterm birth among service recipients is a shared global risk reduction occurring during the study period in the entire locality, and not restricted to program service recipients only. The external controls provided a reasonably acceptable comparison group to test this alternative explanation. The observation of a similar level of risk reduction using external control strengthens our initial findings. Additionally, the use of a comparison group within the same locale (external controls) permitted to a reasonable extent simultaneous control for confounding characteristics imposed by the environment (e.g., socio-economic status, neighborhood factors and geographical access to care) since individuals living in the same zip codes are likely to share similar environmental factors.

A significant point revealed in this study is that low birth weight seems to be a heterogeneous entity as previously suggested [29]. The program being evaluated was clearly effective in reducing preterm birth by a magnitude of about 30% but ineffective in impacting the other component of low birth weight, namely, SGA. This distinction in program effectiveness supports the widely held assumption that etiological differences/pathways exist between preterm and SGA. Given this premise, it therefore implies that the potent ingredient in the Healthy Start Program has been effective in reducing preterm but not SGA. An in-depth understanding regarding the specificity of the effective program component is needed in order to enhance our ability to refine and improve its potency and replication elsewhere, and this should represent one of the future study goals of the program.

Although the biological pathways linking program services to risk reduction in low birth weight and preterm births may not be clearly elucidated in this study, one could reasonably speculate reduction in overall psychosocial stress to be the mediator. It has been suggested that increases in levels of psychosocial stressors contribute to the occurrence of spontaneous preterm births [30, 31]. Depressive symptoms [32] and pregnancy-related anxiety [33] have been shown to be positively correlated with spontaneous preterm births in a prospective study setting. Much research has also shown that social support acts as a protector or a buffer for stress and stressful events, thereby reducing their impact on mental health [34–36].

It is highly probable that the information, counseling, health education and emotional support provided by CHHS staff might have contributed to a reduction in stress levels among their clients contributing to the reduced risk of preterm birth among service recipients in this study.

The public health implications of the findings in this study are obvious. Low birth weight and preterm births are

well-established precursors for subsequent death in infancy and childhood [6, 8, 37]. In addition, preterm infants that survive suffer disproportionately from severe morbidity (e.g., cerebral palsy) in later life leading to poor quality of life and enormous cost burden to affected families and the society in general [38, 39]. Attempts to reduce preterm birth have not been generally successful but remain a top priority. This underscores the significance and importance of the findings in this study. The policy implication of our findings is that the Healthy Start project is potentially beneficial in reducing feto-infant morbidity in a disadvantaged community such as the one in this study. It is, therefore, essential that Government support, especially in terms of financial infusion, be maintained and increased to support the program so that the persistent health disadvantages suffered by Black infants right from birth could be reduced over time. Another potential area emergent from our results is the utilization of robust statistical approaches in assessing frameworks that combine psychosocial and biomedical management concepts and practices, an approach that promises to be innovative and useful in other population settings.

Acknowledgements This work was supported in part by project H49MC00090 from the Maternal and Child Health Bureau (Title V, Social Security Act), Health Resources and Services Administration (HRSA), US Department of Human and Health Services. The funding agency did not play any role in any aspect of the analyses.

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