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Pregnancy and Birth Outcome Improvements for American Indians in the Healthy Start Project of the Inter-Tribal Council of Michigan, 1998–2008

Rebecca L. Coughlin · Elizabeth K. Kushman · Glenn E. Copeland · Mark L. Wilson

Abstract American Indians living in Michigan experience disproportionately high rates of infant mortality. This 11-year (1998–2008) cohort study evaluated impacts of a Healthy Start (HS) program administered by the Inter-Tribal Council of Michigan (ITCM) on perinatal outcomes. Women who enrolled in ITCM's HS program ("exposed") were compared with non-enrolled ("unexposed") for four outcomes: low birth weight (LBW), small for gestational age, preterm birth, and inadequate prenatal care. To classify exposed and unexposed women and their children, Michigan vital records data were linked with HS enrollment records to identify participants and non-participants among all American Indian births. Logistic regression was used to calculate odds ratios for the four outcomes of interest. Analyses were stratified for high and low access to care based on Medically Underserved Area (MUA) designation for a woman's county of residence. Of 4,149 American Indian births during the period, 872 were to women who enrolled prenatally in HS. Although unstratified analysis showed no differences between HS participants and non-participants, stratified analyses demonstrated that participants from MUA counties had decreased odds of LBW and inadequate prenatal care. Results suggest that in MUA counties where participants and non-participants are at similar risk for poor outcomes, HS may be reducing barriers and improving outcomes. In non-MUA counties participants had similar outcomes as non-participants. These results may reflect a wider disparity in risk factors between the two groups in non-MUA counties. The complex interplay among need, access, and benefit complicates analyses and suggests the importance of more in-depth and focused studies.

Keywords Healthy Start evaluation · Low birth weight · Inadequate prenatal care · American Indian · Medically Underserved Area

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Introduction

American Indians experience significant racial[1] disparities in rates of infant mortality and perinatal outcomes [1–6]. In Michigan, during 1998 through 2009, the infant mortality rate for American Indians ranged between 8.8 and 12.4 infant deaths/1,000 live births; 1.5–2.0 times greater than the White rate during the same time period [7]. Racial misclassification of American Indians is known to underestimate true counts [8–10] and vital records are likely to

[1] For the purposes of this study we use the terms "race" and "racial" in keeping with the United States Office of Management and Budget (OMB) 1997 guidelines for categorizing race and ethnicity [39], which are the standards used to categorize "race" and "ethnicity" in the Michigan vital records.

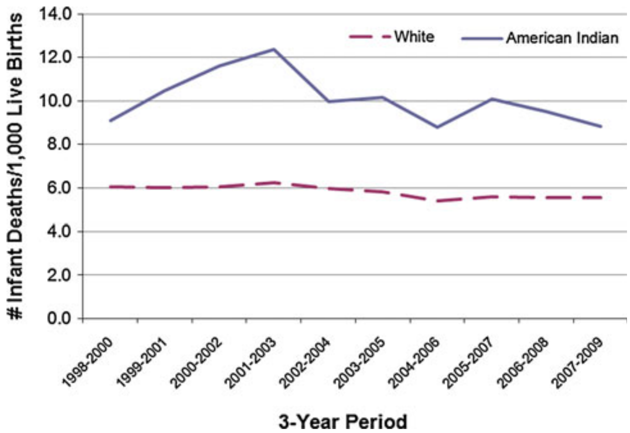

Fig. 1 Infant mortality rates, 3-year moving averages, Michigan 1998–2009. Data source: 1998–2009 live birth and death cohort matched infant death files, Michigan Department of Community Health

underestimate American Indian mortality rates [8–12], suggesting that this disparity is even greater than reported. These disparities are persistent and not decreasing over time (Fig. 1) [2, 7].

Healthy Start (HS) is a home visiting program that addresses racial disparities in infant mortality through community-driven and population-specific interventions. One aim is to improve birth outcomes in high-risk communities by emphasizing community involvement and a case management approach [13, 14]. The Healthy Start model consists of five core services: direct outreach and client recruitment, case management, health education, screening and referrals for maternal depression, and interconceptional continuity of care [14]. Central to HS is its community focus; each HS program is individually-tailored to fit its community, and uses community health workers to link participants with services [15]. Since it began in 1991, HS programs in diverse communities across the country have shown reductions in the incidence of low birth weight (LBW), very low birth weight (VLBW), and preterm births [15, 16].

Beginning in 1998, the Inter-Tribal Council of Michigan (ITCM) has implemented a HS program in six tribal locations, with a seventh added in 2001. Each HS site operates within a specific tribal service area, working with tribal and community leaders to tailor services to their communities. Services at each of the HS sites are locally managed by tribal health centers. ITCM's HS recruits women through referrals and word of mouth. All HS clients receive a one-on-one visit with a HS nurse to assess medical, social and basic needs, followed by individually-tailored education based on identified risks, referrals to needed services (e.g. Medicaid, WIC, prenatal care), and monthly home visits during pregnancy. Additional services vary by client and by site.

Our study evaluated the impacts of ITCM's HS project on clients (participants) who enrolled prenatally and gave birth between 1998 and 2008. The focus of ITCM's HS is on reducing infant mortality, but the number of infant deaths among ITCM's HS participants between 1998 and 2008 was too small to allow quantitative analyses. Our study instead analyzed program impacts on four outcomes targeted by the national HS program [14] using data available from live birth records: LBW, small for gestational age (SGA), prematurity, and inadequate prenatal care. We hypothesized that through delivering individually tailored and culturally relevant services to American Indian women, ITCM's HS would result in improved outcomes among participants.

In addition to evaluating program impacts on the participant group as a whole, this study explored differential impacts among participants residing in counties with different levels of access to healthcare. Living in locations with less access to healthcare is associated with adverse birth outcomes and reduced levels of prenatal care [17–19]. Michigan does not have a regionalized system of perinatal care and has large geographic disparities in access to perinatal care [20]. Unlike HS programs that operate in one community, ITCM's HS program operates in seven communities that vary in economic conditions and healthcare systems. These sites vary from a large city to rural and remote counties; differing in proximity to hospitals, Neonatal Intensive Care Units, and specialty care providers [21]. For many HS participants, HS services are a critical source of information and services in the prenatal period [15]. We hypothesized that HS would have different impacts for women living in counties with limited access to services and healthcare facilities compared to those with more access. We used Medically Underserved Area (MUA) designation as a proxy for county-level access to care, assuming that women living in counties designated entirely as an MUA would have less access to care than women from counties that were not entirely MUAs [22–24].

This study investigated the following two hypotheses: (1) HS participants had lower odds of LBW infants, SGA births, preterm births, and inadequate prenatal care than non-participants; and (2) the impacts of HS were different in counties designated as MUAs than in counties that were not MUAs.

Methods

Study Design and Participants

A retrospective cohort study design was used to analyze all American Indian births recorded in Michigan between

January 1, 1998 and December 31, 2008. The exposure of interest was whether the mother was prenatally enrolled in ITCM's HS project. Four outcomes of interest were investigated: LBW, SGA, preterm birth, and inadequate prenatal care. The protocol for this study was approved by the Michigan Department of Community Health Institutional Review Board (Log #: 761-LHAS) on December 22, 2009. The Institutional Review Boards of the University of Michigan and the Michigan Department of Community Health both exempted this project from further review, as only de-identified data were released for use in the analysis.

HS participants in this study were enrolled at seven HS sites in Michigan. Clients were recruited and served in accordance with each tribe's policy on service eligibility, which vary by site, but requires documentation of being an enrolled member of a federally recognized Indian tribe, being a descendant of the local tribe, or being an expectant mother of an infant who will be eligible for tribal services. The number of visits and intensity of contact with HS staff varied among individuals, averaging six visits in the prenatal period (ranging from one to >20 visits). Due to limitations in program data, it was not possible to evaluate number of visits.

Vital Records Data and Data Linking

Infants born to HS participants were identified by linking HS enrollment records with Michigan live birth records from 1998 through 2008. Project data and state vital records were linked through Registry Plus™ Link Plus 2.0 software [25] using available personal identifiers for the mother, father, and infant. Missing identifiers increased the likelihood that an individual would not be linked successfully to the birth records, but such records were not excluded from the linkage process based on missing data alone. All records were de-identified before leaving the Michigan vital records office and all statistical analyses were conducted on a de-identified data set. 41 duplicate records identified from birth record number were deleted after linking.

The resulting database consisted of Michigan live birth record variables for all live births with an additional variable identifying births as either belonging to a HS participant or not. Exposed infants were born to a HS participant mother, while unexposed infants were those born to non-participants. Inclusion criteria involved being an American Indian infant born to a mother residing in a county where at least 5 % of all American Indian births were to HS participants during the study period. These inclusion criteria ensured that unexposed and exposed participants lived in similar geographic contexts, thereby controlling for unmeasured geographic factors. An "American Indian infant" was defined as any infant with "American Indian" listed as the primary race or bridge race for the mother and/or father; or any individual enrolled in ITCM's HS, even if that infant's parent(s) were not listed as American Indian in the state birth records.[2] The sample was further restricted to singleton births. All American Indian singleton births residing in eligible counties during 1998 through 2008 were included in the final cohort.

The four outcomes were dichotomized as follows: low (<2,500 g) versus not low (≥2,500 g) birth weight, small for gestational age (SGA) versus not SGA, preterm birth (<37 weeks) versus not preterm (≥37 weeks), and inadequate prenatal care (Kotelchuck[3] Index = Inadequate) versus adequate prenatal care (Kotelchuck Index = Adequate Plus, Adequate, or Intermediate). SGA was defined as <10th percentile of weight for gestational age, using fetal growth curves based on United States births between 1999 and 2000 [26]. Covariates considered as potential confounders were: parity (mother's first birth, yes/no), infant's sex, number of maternal risk factors (0, 1, >1), mother's tobacco use during pregnancy (yes/no), source of payment for delivery (private, Medicaid, self), mother's age (years), and mother's education (years). Maternal risk factors included in the risk factor variable were: diabetes, incompetent cervix, previous birth ≥4,000 g, previous preterm or small birth, renal disease, RH sensitization, uterine bleeding, eclampsia, prenatal hypertension, chronic hypertension, anemia, cardiac disease, lung disease, genital herpes, hemoglobinopathy, drug abuse, HIV infection, and other. Overall, 10.2 % of the sample had one or more risk factor and also smoked during pregnancy. There was no association between maternal risk factors and tobacco use during pregnancy ($p = 0.25$).

[2] In Michigan birth records, an infant's race/ethnicity is identified as its mother's race/ethnicity, and state policy designates that the mother should provide her race/ethnicity information. However, if someone other than the mother identifies the mother and/or father's race/ethnicity, it is possible that the mother (and therefore the infant) will have the wrong race/ethnicity on their birth records [9, 10]. At each site, ITCM's HS enrolls mothers and infants if the mother and/or father is eligible to receive services from that tribal clinic. Therefore, we included in our definition of American Indian any infant with a mother or father who was American Indian. Additionally, we included in our sample as American Indian any infant enrolled in ITCM's HS regardless of the race/ethnicity listed on their birth certificate.

[3] The Kotelchuck Index measures the adequacy of prenatal care by combining the month prenatal care began and the number of visits between the first visit and delivery, then compares this actual number of visits with the expected number of visits based on recommendations from the American College of Obstetrics and Gynecology. The Kotelcheck Index was selected for this study because it assesses separately the month prenatal care began and compliance with recommended care after the first visit, and is recommended for evaluating programs intended to improve prenatal care use, including home visiting programs [40].

MUA Stratification

County-level Medically Undeserved Areas (MUAs) were identified using Health Resources and Services Administration (HRSA) definitions [27]. HRSA designates MUAs based on: ratio of primary medical care physicians per 1,000 population, infant mortality rate, population percentage with incomes below poverty level, and population percentage ≥65 years old [22]. For this study, two MUA-status strata were created, one with all women living in MUA-designated counties, and the other with women from non-MUA counties. Analyses were stratified by MUA status to determine if HS had different impacts in MUA versus non-MUA counties.

Statistical Methods

All analyses used SAS 9.2. Chi-square tests determined differences between exposed and unexposed groups for categorical covariates, with independent samples *t* tests used for continuous variables. Logistic regression models were developed to calculate odds ratios (ORs) and 95 % confidence intervals (CI) characterizing associations between HS exposure and each outcome. Change in estimate criteria was used to identify confounding variables; if the estimated *beta* coefficient for HS changed by >10 % upon addition of the potential confounder to the univariate logistic regression model, that variable was adjusted for in the final multivariable model. If addition of a variable produced a high standard error, it was removed from that model. Prenatal care was not included in models predicting LBW or preterm birth because prenatal care access was influenced by participation in HS and may thus be an intermediate variable in the pathway between HS participation and birth weight or gestational age.

Cell sizes of at least 5 counts were confirmed before performing statistical analyses. Missing data were dealt with by excluding observations that did not have complete data for all covariates in the models. Due to the large number of statistical tests, a p value of <0.001 was used as the cutoff to determine statistical significance for χ^2 and *t* tests.

To test the hypothesis that the HS program had different impacts in MUA versus non-MUA settings, the original analysis was then repeated in the two strata, MUA or not MUA. Limited sample sizes prevented further stratification. Stratification was used instead of including a variable for MUA in the models for two reasons. First, MUA is associated with several other covariates, thus creating a problem of collinearity when included in the models. Second, MUA is a county-level, not individual-level, designation, which would create a lack of independence among observations when included in the model.

Results

Of the 1,402 infants in the prenatal HS enrollment records during 1998–2008, 1,340 (95.6 %) were matched to a birth in the Michigan vital records. From these 1,340 matched HS births, 41 were duplicates, 13 were enrolled at a temporary HS site, and 361 were enrolled after the child was born. After excluding these cases, 966 HS cases were considered eligible and included in the final sample. There were 1,433,047 births in the state of Michigan from 1998 through 2008. Of these, 12,406 were singleton births to American Indian mothers and/or fathers. This sample was further restricted to births that were to women who resided in counties where >5 % of all American Indian births involved women enrolled in HS. The final sample analyzed 4,149 births, of which 872 were to women who enrolled prenatally in HS (Fig. 2).

Unstratified analysis of HS participants versus non-participants showed associations with hypothesized predictors that varied in extent and direction (Table 1). At the $p < 0.001$ level, there were no differences between HS participants and non-participants in infant birth weight, SGA, gestational age, adequacy of prenatal care, parity, sex, tobacco use during pregnancy, maternal age, or maternal education. Maternal participation in HS was associated with payment source for delivery, with participants having higher levels of private- or self-payment for delivery costs, and with non-participants having higher levels of Medicaid. (Note: Tribal coverage of delivery payment is sometimes recorded as private- or self-insurance.) Participating mothers had a greater number of maternal risk factors documented in their infant's birth record than non-participants, and more participants lived in counties designated as MUAs than non-participants. After stratifying by MUA, the differences between source of payment for delivery and number of maternal risk factors disappeared in the MUA stratum, but remained in the Non-MUA stratum (Table 2).

Low Birth Weight

Change in estimate criteria showed that number of maternal risk factors, delivery payment source, tobacco use during pregnancy, and mother's age all changed the β coefficient for HS status by >10 %, and thus were considered confounders of the association between HS participation and LBW. Adjusted and unadjusted odds ratios for LBW by HS participation status were calculated from a series of logistic regression models stratified by MUA. In the unstratified analysis, the odds of LBW did not differ between HS participants and non-participants, before or after adjusting for identified confounders. After stratifying by MUA status, HS participants had lower adjusted odds of LBW compared to non-participants in MUA counties

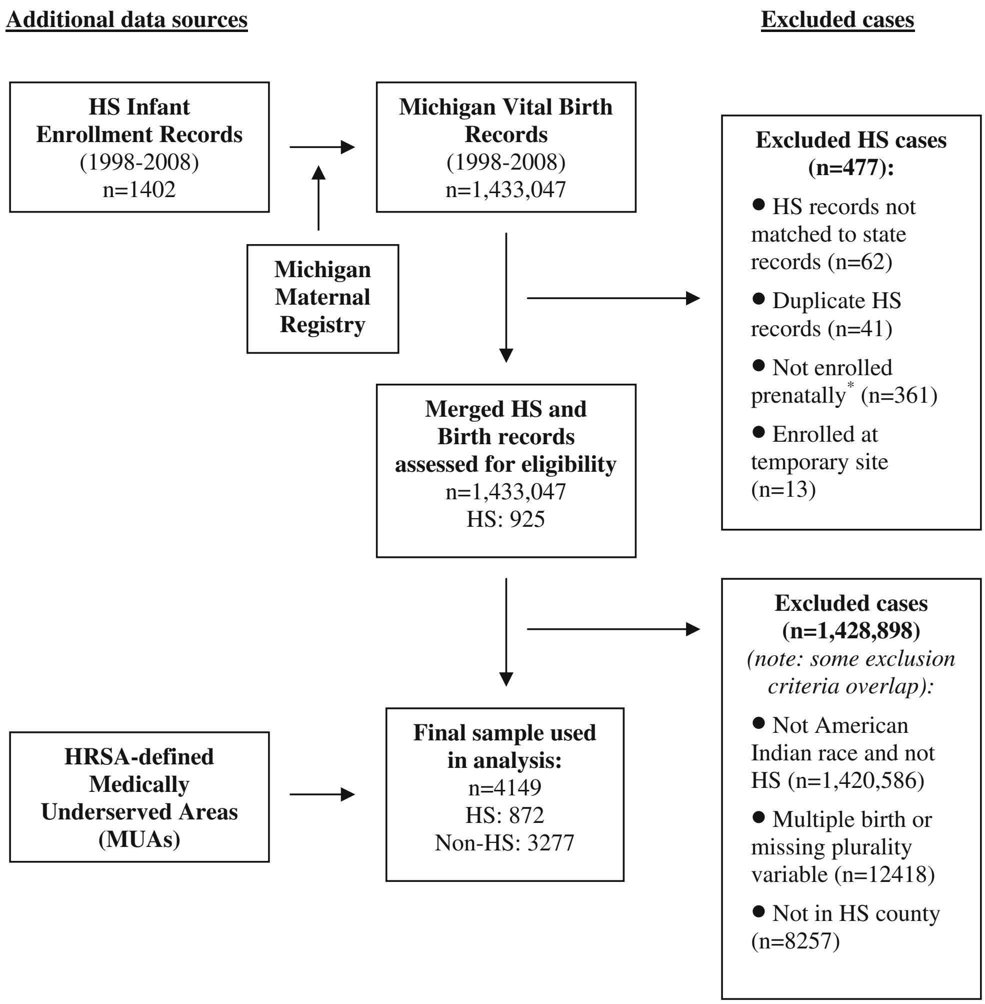

Fig. 2 Process used to create data set and select final sample for analysis. HS: ITCM healthy start project. * Indicated cases were not excluded from the study sample but were considered unexposed

(OR = 0.37, 95 % CI = 0.14, 0.96). There was no difference between participants and non-participants in non-MUA counties (Fig. 3).

Small for Gestational Age (SGA)

The delivery payment source, tobacco use during pregnancy, mother's age, and mother's education changed the *beta* estimate for prenatal HS (>10 %) and thus were controlled for in the adjusted models. Adjusted and unadjusted logistic regression models, also stratified by MUA, were used to calculate odds ratios for SGA by HS participation status. Neither unstratified nor MUA-stratified results showed statistically significant differences (Fig. 4).

Preterm Birth

The number of maternal risk factors and source of payment for the delivery were identified by change in estimate criteria as confounders of the association between HS participation and preterm birth. Adjusted and unadjusted logistic regression models, also stratified by MUA, were used to calculate odds ratios for preterm birth by HS participation status. Unstratified results and those stratified by MUA showed no statistically significant differences (Fig. 5).

Inadequate Prenatal Care

Because delivery payment source, tobacco use during pregnancy, mother's age, and mother's education confounded the association between HS participation and inadequate prenatal care, they were included in the final model. Adjusted and unadjusted odds ratios of inadequate prenatal care by HS participation status indicated that there was no difference in the odds of prenatal care between participants and non-participants in the unstratified model.

Table 1 Characteristics of the Michigan Inter-Tribal Council's Healthy Start participants and American Indian non-participants living in counties where at least 5 % of all American Indian births were enrolled in Healthy Start, Michigan, birth years 1998–2008. Full sample (n = 4149)

	Participants (n = 872) No. (%)	Non-participants (n = 3,277) No. (%)	*p* value*
Birth weight			
<2,500 g	44 (5.1)	164 (5.0)	0.96
≥2,500 g	828 (94.9)	3,111 (95.0)	
Small for gestational age (SGA)			
SGA	69 (7.9)	284 (8.7)	0.48
Not SGA	801 (92.1)	2,987 (91.3)	
Gestational age			
<37 weeks	71 (8.2)	241 (7.4)	0.43
≥37 weeks	800 (91.8)	3,034 (92.6)	
Prenatal care (Kotelchuck Index)			
Inadequate	95 (11.9)	381 (12.7)	0.55
Adequate plus, adequate, or intermediate	701 (88.1)	2,613 (87.3)	
Parity			
1st birth	266 (30.5)	1,025 (31.3)	0.66
Not 1st birth	606 (69.5)	2,252 (68.7)	
Infant sex			
Male	441 (50.6)	1,677 (51.2)	0.75
Female	431 (49.4)	1,600 (48.8)	
Source of payment for delivery			
Private	411 (48.3)	1,329 (41.6)	<0.0001
Medicaid	395 (46.5)	1,815 (56.9)	
Self	44 (5.2)	47 (1.5)	
Number of maternal risk factors			
0	498 (68.0)	1,970 (74.9)	0.0008
1	203 (27.7)	562 (21.4)	
>1	31 (4.2)	98 (3.7)	
Tobacco use during pregnancy			
Yes	344 (39.5)	1,219 (37.2)	0.22
No	527 (60.5)	2,054 (62.8)	
Reside in county designated as Medically Underserved Area			
MUA	333 (38.2)	394 (12.0)	<0.0001
Not MUA	539 (61.8)	2,883 (88.0)	
	Mean (SD)	Mean (SD)	*p* value**
Birth weight (g)	3,461.3 (635.9)	3,432.2 (595.1)	0.22
Gestational age (weeks)	38.8 (2.0)	39.0 (2.0)	0.020
Month prenatal care began	2.6 (1.7)	2.6 (1.7)	0.64
Number of prenatal care visits	11.1 (3.6)	11.3 (3.4)	0.20
Maternal age (years)	24.5 (5.4)	25.1 (5.7)	0.0015
Maternal education (years)	11.5 (3.1)	11.5 (3.3)	0.94

* *p* values calculated using χ^2 tests

** *p* values calculated using independent samples *t* tests

Table 2 Characteristics of the Michigan Inter-Tribal Council's Healthy Start participants and American Indian non-participants living in counties where at least 5 % of all American Indian births were enrolled in Healthy Start, Michigan, birth years 1998–2008. Stratified by residence in a county designated as a Medically Underserved Area (MUA) (n = 4149)

	Stratified: MUA			Stratified: not MUA		
	Participants (n = 333) No. (%)	Non-participants (n = 393) No. (%)	*p* value	Participants (n = 539) No. (%)	Non-participants (n = 2,882) No. (%)	*p* value*
Birth weight						
<2,500 g	12 (3.6)	26 (6.6)	0.069	32 (5.9)	138 (4.8)	0.26
≥2,500 g	321 (96.4)	367 (93.4)		507 (94.1)	2,744 (95.2)	
Small for gestational age (SGA)						
SGA	19 (5.7)	34 (8.7)	0.13	48 (8.9)	227 (7.9)	0.42
Not SGA	313 (94.3)	359 (91.4)		490 (91.2)	2,651 (92.1)	
Gestational age						
<37 weeks	19 (5.7)	34 (8.6)	0.13	52 (9.7)	207 (7.2)	0.047
≥37 weeks	313 (94.3)	360 (91.4)		487 (90.3)	2,674 (92.8)	
Prenatal care (Kotelchuck index)						
Inadequate	46 (15.3)	75 (21.4)	0.046	49 (9.9)	306 (11.6)	0.28
Adequate plus, adequate, or intermediate	255 (84.7)	276 (78.6)		446 (90.1)	2,337 (88.4)	
Parity						
1st birth	91 (27.3)	101 (25.6)	0.61	175 (32.5)	924 (32.1)	0.85
Not 1st birth	242 (72.7)	293 (74.4)		364 (67.5)	1,959 (68.0)	
Infant sex						
Male	163 (49.0)	199 (50.5)	0.68	278 (51.6)	1,478 (51.3)	0.89
Female	170 (51.0)	195 (49.5)		261 (48.4)	1,405 (48.7)	
Source of payment for delivery						
Private	122 (38.9)	123 (36.4)	0.79	289 (53.9)	1,206 (42.3)	<0.0001
Medicaid	186 (59.2)	209 (61.8)		209 (39.0)	1,606 (56.3)	
Self	6 (1.9)	6 (1.8)		38 (7.1)	41 (1.4)	
Number of maternal risk factors						
0	189 (70.5)	220 (67.9)	0.77	309 (66.6)	1,750 (75.9)	0.0001
1	67 (25.0)	87 (26.9)		136 (29.3)	475 (20.6)	
>1	12 (4.5)	17 (5.3)		19 (4.1)	81 (3.5)	
Tobacco use during pregnancy						
Yes	174 (52.4)	194 (49.4)	0.41	170 (31.5)	1,025 (35.6)	0.07
No	158 (47.6)	199 (50.6)		369 (68.5)	1,855 (64.4)	
	Mean (SD)	Mean (SD)	*p* value**	Mean (SD)	Mean (SD)	*p* value**
Birth weight (g)	3,457.5 (555.9)	3,386.2 (617.4)	0.11	3,463.6 (681.2)	3,438.5 (591.8)	0.42
Gestational age (weeks)	38.9 (1.8)	38.9 (2.2)	0.94	38.7 (2.2)	39.0 (2.0)	0.010
Month prenatal care began	2.7 (1.7)	2.9 (1.9)	0.13	2.6 (1.6)	2.6 (1.7)	0.58
Number of prenatal care visits	10.8 (3.6)	10.8 (4.0)	0.86	11.3 (3.5)	11.3 (3.3)	0.90
Maternal age (years)	24.3 (5.4)	25.1 (5.9)	0.088	24.5 (5.4)	25.1 (5.6)	0.024
Maternal education (years)	11.3 (3.3)	11.4 (3.2)	0.71	11.7 (3.0)	11.5 (3.4)	0.34

* *p* values calculated using χ^2 tests

** *p* values calculated using independent samples *t* tests

However, after stratification, MUA-county participants had lower odds of receiving inadequate prenatal care than non-participants (OR = 0.63, 95 % CI = 0.41, 0.96). There was no such difference in non-MUA counties (Fig. 6).

Discussion

By linking individual-level program participation data to state vital records, this study was able to quantify impacts

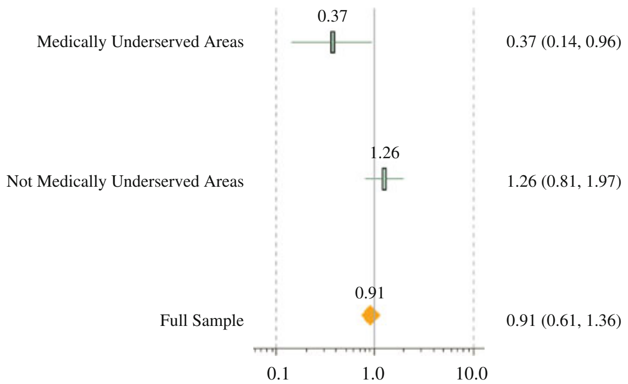

Fig. 3 Adjusted odds ratios of low birth weight and 95 % CI, comparing participants with non-participants, stratified by residence in a county-level Medically Underserved Area. Adjusted for number of maternal risk factors, delivery payment source, tobacco use during pregnancy, and mother's age

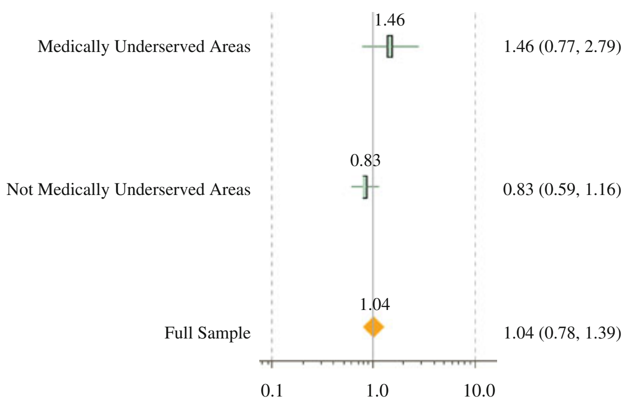

Fig. 4 Adjusted odds ratios of small for gestational age and 95 % CI, comparing participants with non-participants, stratified by residence in a county-level Medically Underserved Area. Adjusted for delivery payment source, tobacco use during pregnancy, mother's age, and mother's education

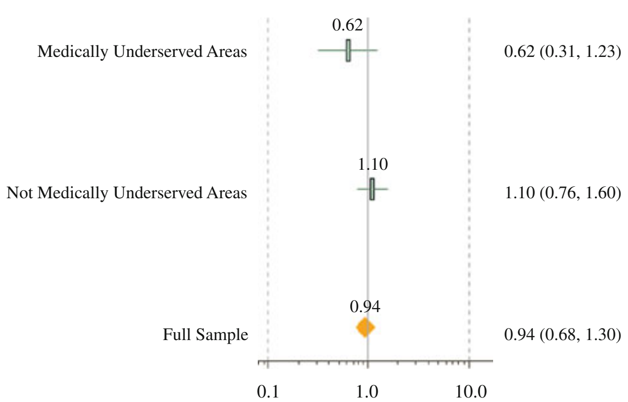

Fig. 5 Adjusted odds ratios of preterm birth and 95 % CI, comparing participants with non-participants, stratified by residence in a county-level Medically Underserved Area. Adjusted for number of maternal risk factors and delivery payment source

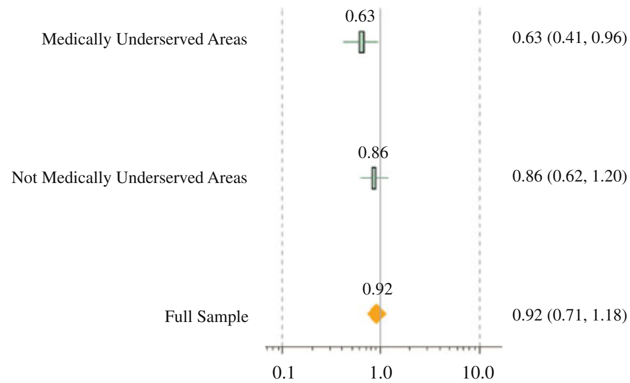

Fig. 6 Adjusted odds ratios of inadequate prenatal care and 95 % CI, comparing participants with non-participants, stratified by residence in a county-level Medically Underserved Area. Adjusted for delivery payment source, tobacco use during pregnancy, mother's age, and mother's education

of the Inter-Tribal Council of Michigan's Healthy Start program on its participants over an 11-year period. The study benefited from a large sample size and a high percentage of HS participants linked to the vital records, examining HS effects on LBW, SGA, preterm birth, and inadequate prenatal care. For each of these outcomes, the odds ratios comparing participants to non-participants were close to one, indicating that HS participants had similar outcomes compared to non-participants. After stratifying the sample by MUA status, HS participants living in counties designated as MUAs had decreased odds of LBW births and inadequate prenatal care as compared to non-participants living in those counties.

These results suggest that ITCM's HS is having a positive impact on participants in MUA counties, and that HS may be most effective in areas where access to care is limited. Other studies have attributed HS success to its community focus [28–30] and use of home visits by community health workers (CHWs) [28, 31]. Home visits and case management by both CHWs and registered nurses help engage and educate clients [15, 31], increase client self-efficacy [15, 29, 32] and address "non-medical" life stressors [16, 31, 33, 34]. By drawing on community knowledge, HS may effectively connect participants with care by empowering them to overcome access barriers and delivering information from trusted sources [15].

HS participants in non-MUA counties were different from non-participants (Table 2) in that they were more likely to have at least one maternal risk factor (Table 2). With higher levels of maternal risk factors in the absence of any intervention, one might expect participants to have higher odds of LBW, SGA, and preterm births. That participants and nonparticipants had similar odds of all four outcomes may actually be demonstrating a positive impact of HS. It is also possible that HS was unable to overcome the additional risk factors participants face as compared to non-participants in non-MUA communities. The non-MUA stratum includes ITCM's urban HS site, which is the only site not affiliated with a reservation. Urban participants may feel more cultural isolation as compared to other participants, which could present additional barriers to accessing healthcare, such as trust in providers and culturally-relevant care [35]. Furthermore, the small number of outcome events among participants in each stratum (Table 2) suggest that results should be interpreted cautiously. Although the data suggest that HS is impacting participants in MUA counties, additional studies with larger sample sizes are required, especially as we did not observe the same results for women living in non-MUA counties.

The selection and classification of the exposed sample represents an important consideration in interpreting results of this study. HS participation was not randomly assigned; in some cases women were referred due to elevated risk. As a result, the exposed (HS participants) and unexposed (non-participants) groups lack comparability on several levels. We attempted to control for these factors using adjusted logistic regression models, yet unmeasured variables may still have confounded results. Our analyses also lacked information concerning the amount of program contact participants actually experienced, which may have biased the odds ratios toward the null by diluting the effects of the program, and further prevented analysis of loss to follow up.

Misclassification of race may also have introduced bias. We found that 25.6 % of the HS participants did not have American Indian listed in the state birth records as a race for either parent (data not shown). HS participants were recruited through tribal centers, and met tribal health center service eligibility criteria, making us confident that these infants were correctly classified as American Indian. However, one quarter of infants could have been excluded from the unexposed sample, suggesting that our unexposed sample may be incomplete by excluding individuals who are American Indian but not identified as such in the birth records.

This study stretched over an 11-year time period, during which contexts changed. Between 1999 and 2008, Michigan's uninsured, non-elderly population rose from 10.7 to 13.3 % [36], the median annual income among American Indian households rose from $37,071 to $40,360, and the percent of American Indian children in Michigan living at or below poverty also rose from 22.1 to 24.8 % [37, 38]. Over the course of the study period six HS sites consistently provided service without interruption, and the seventh consistently provided service since it opened in 2001. To determine if HS had different impacts in the first half of the study period compared to the second half, we stratified the analysis by 1998–2002 versus 2003–2008, but did not detect significant differences (data not shown).

MUA status was used as a county-level proxy for access to healthcare, but individual variation in these variables within counties was not analyzed. In several non-MUA counties some census tracts were identified as MUAs. Lacking census tract-level information about participants, we were unable to analyze MUA at a finer geographic scale than county. In addition to MUA status, HRSA also identifies populations as medically underserved, based on financial or cultural barriers to accessing care [22]. Again, we were unable to identify individual women belonging to medically-underserved populations.

Finally, the causal pathway between exposure and outcome in this study is not straightforward. Tobacco use during pregnancy and source of payment for delivery were included in multivariable analyses as confounders of the association between HS participation and outcomes of interest, but both are specifically targeted by HS interventions. If they indeed lie on the pathway between HS participation and outcomes, they should not be controlled for as confounders, again suggesting that the observed associations may be biased towards the null.

Taken together, however, these results suggest that HS successfully helped to reduce the odds of LBW and inadequate prenatal care among mothers in MUA counties who face similar risks as non-HS mothers. Given the culturally-specific nature of HS projects, it is difficult to generalize these results to other HS projects. However, the fact that this home visiting program has an impact on LBW and prenatal care in some counties is notable and suggests that similar programs are likely to be worthwhile. In addition to assessing the impact of HS, our study described birth and health outcomes for American Indians in Michigan. The characteristics of the study population do not reflect all American Indians living in Michigan, but this study does add new insights about the health risks faced by this population. Future studies should consider impacts of HS on infant growth and survival after birth, when HS may have its largest opportunity to prevent infant deaths among American Indians living in Michigan.

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