

# Evaluating the Health Outcomes of the Healthy Women Healthy Babies Program in Delaware

Khaleel S. Hussaini<sup>1</sup> · Mawuna D. Gardesey<sup>2</sup> · George Yocher<sup>2</sup> · David A. Paul<sup>3,4</sup>

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# Abstract

**Objectives** The Delaware Healthy Women Healthy Babies Program (HWHB) was developed in response to increasing rates of infant mortality (IMR) and widening racial disparity. The primary aim of this study was to examine birth outcomes of enrolled and non-enrolled black and Hispanic women in the program whose payer was Medicaid.

**Methods** We utilized a retrospective cohort of linked birth certificate and HWHB program participant data during 2011–2015. Our primary outcome variables (dependent variables) of interest included cigarette use, low birth weight, preterm birth and neonatal mortality. We utilized inverse probability of treatment weighting (IPTW) and estimated crude odds ratios (COR) and adjusted odds ratio (AOR) with 95% confidence intervals (CI) using IPTW as a weight variable.

**Results** HWHB enrolled women were 10% less likely to smoke during pregnancy COR 0.89 (95% CI 0.82–0.96); were 9% less likely to deliver a low birth weight infant (AOR 0.91; 95% CI 0.84–0.99; p=0.023); were 15% less likely to deliver a preterm infant (AOR 0.85; 0.78–0.92; p<.0001) as compared with non-HWHB women. Infants delivered by HWHB enrolled women had 27% less likelihood (AOR 0.73; 95% CI 0.54–0.98; p=0.035) of experiencing a neonatal death (i.e., <28 days) as compared with infants of non-enrolled HWHB women.

**Conclusion** The primary goal of this evaluation was to assess the effectiveness of the HWHB program on modifiable risk factors of IMR among HWHB enrolled and non-enrolled women. We found that HWHB program is a promising practice in improving the outcomes of infants born to participating black and Hispanic mothers.

Keywords IPTW · Evaluation · LBW · Preterm · Infant mortality · Healthy women healthy babies

# Significance

This is the first statewide evaluation of a publicly funded program to understand the impact of the HWHB program on birth outcomes among high risk black and Hispanic women on Medicaid. The study utilizes propensity score weighting to estimate

Khaleel S. Hussaini khaleel.hussaini@delaware.gov

- <sup>1</sup> Delaware Department of Health and Social Services, Division of Public Health, 417 Federal Street, Dover, DE 19901, USA
- <sup>2</sup> Delaware Department of Health and Social Services, Division of Public Health, Center for Family Health Research and Epidemiology, 417 Federal Street, Dover, DE 19901, USA
- <sup>3</sup> Department of Pediatrics, ChristianaCare, Newark, USA
- <sup>4</sup> Sidney Kimmel Medical College at Thomas Jefferson University, Philadelphia, PA, USA

average treatment effects and reinforces the importance of comprehensive wraparound care in geographically diverse locations of the state. The HWHB program incorporates various elements of the life course—preconception, prenatal, and interconception care—as well as addresses some of the social determinants of health such as stress, food, and social exclusion.

# Background

The Delaware Healthy Women Healthy Babies Program (HWHB) was developed in response to increasing rates of infant mortality (IMR) and widening racial disparity in rates. The former Governor of Delaware, Ruth Ann Minner appointed an Infant Mortality Task Force (IMTF) in 2004 "to identify risk factors and implement practices to prevent infant mortality and reverse recent IMR increases in the state" (DE Thrives 2005). At the time of the IMTF report, Delaware had the sixth worst IMR in the U.S. In addition,

historical data on IMR from the Delaware Health Statistics Center (2018) for blacks and Hispanics have suggested persistent disparities as compared to non-Hispanic whites. For instance, in 2000–2004, the 5-year average IMR for blacks was 15.7 per 1000 births and for Hispanics it was 7.9 per 1000 births as compared with non-Hispanic whites (7.3 per 1000). As per the most recent data available from the Centers for Disease Control and Prevention (CDC), the 2017 IMR in the U.S. was 5.8, while the 2017 IMR for Delaware was 6.6 per 1000 live births (Centers for Disease Control and Prevention 2019). While the causes of infant mortality are multifactorial, low birth weight and preterm birth are among two preventable causes of infant mortality (Paneth 1995; Kramer 1987; Polyzos et al. 2009; Shah 2010; Shah and Olson n.d.; Grote et al. 2010; Pineless et al. 2016; Malley et al. 2017).

During the course of their charge, the IMTF identified that a life course approach to a woman's health was essential to improve birth outcomes. The proponents of a life course model (LCM) argue that health is a result of a complex interplay of biological, behavioral, psychological, and social protective and risk factors (Lu and Haflon 2003). While prenatal care provides the much-needed access to care during pregnancy; evidence suggests that prenatal care usually begins past the critical period of time that carries the most risk for fetal development (Atrash et al. 2006; Curtis 2008; Lu et al. 2006; Wise 2008). Preconception care is health care that optimizes the health of the mother prior to conception and can improve both reproductive health and birth outcomes (Centers for Disease Control and Prevention 2019). Keeping in view the evidence that underlie the life course approach, and consistent with the long-term goal of the IMTF, the aim of the HWHB program is to improve birth outcomes (i.e., low birth weight and preterm birth) across the state through preconception, prenatal, and interconception care.

#### **Healthy Women Healthy Babies**

Under the HWHB program, women of reproductive age are defined as women from ages 15 to 44 years old. The State of Delaware issues request for proposals (RFP), open to any entity within the state, detailing the requirements of the program. Priority populations that receive these services include black women, and other high-risk populations as determined by eligibility criteria. Some of these criteria include but are not limited to: women with a history of poor birth outcomes such as a previous low birth weight delivery ( $\leq 2500$  g); previous premature birth (< 37 weeks gestation); previous infant death (mortality at  $\leq 12$  months of age), or fetal death/stillbirth (weight of at least 350 g or if weight unknown, at least 20 weeks gestation at demise). Other risk factors can be found elsewhere (DE Thrives 2005, 2012). While the program is deemed state wide, the catchment areas of some facilities limit the geographic breadth of women in the program. Due to the inclusion criterion of black women (without any other eligibility criteria) along with two Federally Qualified Health Centers (FQHCs) who typically cover uninsured and underinsured populations in Delaware, Hispanic and black women comprise a large share of the HWHB women.

Six health care organizations and one social service organization that contract with the Delaware Division of Public Health provide services to HWHB participants. These healthcare providers conduct program outreach and enrollment and deliver service bundles. The following bundle descriptions are not exhaustive but highlight main components: Bundle A, designated for preconception care, includes medical examination, height and weight measurements, blood pressure, clinical breast examination, Papanicolau smear and pelvic exam, screening for chronic diseases and disease management, family planning, risk assessment (family violence, sexually transmitted infections, smoking, nutrition), health promotion (immunizations, breastfeeding, physical activity). Bundle B, designated for preconception women and pregnant women, includes psychosocial intervention covering mental health diagnosis and counseling, and medical social work. Bundle C, designated for pregnant women, includes enhanced prenatal care, which includes wrap-around services for high-risk women. Interconception visits at 2 weeks, 6 weeks and 6 months postpartum. Bundle D, designated for preconception women and pregnant women, covers nutritional assessment and counseling (DE Thrives 2005, 2012).

# **Study Aim**

Our evaluation study is an ongoing effort to understand the health outcomes of HWHB program participants. The primary aim of this study was to examine birth outcomes of enrolled non-Hispanic black and Hispanic women who indicated Medicaid as their payer as compared to non-Hispanic black and Hispanic women on Medicaid who were not enrolled in the program.

#### Methods

#### Design, Data and Sample

We utilized a retrospective cohort of the HWHB program participant dataset that contains unique identifiers (such as unique ids, name, date of birth, etcetera) of the program participants enrolled in any of the program bundles prior to a birth event during 2011–2015 and linked them to birth certificate data for the period 2011–2015. Our dataset contained 14,690 birth records in Delaware during 2011–2015 for 6208 HWHB (~42%) and 8482 non-HWHB (~58%) participants who were either non-Hispanic black or Hispanic and who indicated Medicaid as their payer. Missing data in both groups ranged between one-tenth of 1% to 2%, well-below the 5% missing data threshold to conduct any imputation (Schafer 1999; Tabachnick and Fidell 2012; Dong and Peng 2013; Jakobsen et al. 2017). Hence, listwise deletion was used for missing data.

Because participation (see King et al. 1998 for details on "authentic participation") in the HWHB program is voluntary, self-selecting into the HWHB program introduces potential selection bias. To reduce the threat of selection bias, propensity score analyses based on Neyman-Rubin's counterfactual framework was used (Morgan and Winship 2007; Guo and Fraser 2010). Counterfactuals are potential outcomes that happen in the absence of cause (Shadish et al. 2002; Morgan and Winship 2007; Guo and Fraser 2010). For HWHB program participants, a counterfactual is the potential outcome under the control condition (i.e., non-HWHB), and vice-versa. Stated in another way, propensity scores are the conditional probabilities of assignment to a particular treatment (intervention i.e., participating in HWHB) given a vector of observed covariates (Rosenbaum and Rubin 1983). We utilized inverse probability of treatment weighting (IPTW), which is one among several techniques available for propensity scoring in quasi-experimental and observational studies (Robins et al. 2000; Hirano and Imbens 2001; Hirano et al. 2003; Ye and Kaskutas 2009; Stürmer et al. 2014; Austin 2011a, b; Austin and Stuart 2015; Austin et al. 2017). We used multivariate propensity score weighting as it reduces the potential loss of participants by using weights in a weighted regression of the outcome on treatment and covariates and does not resample the data. In essence, it creates a synthetic sample in which treatment assignment is independent of the observed covariates, allowing IPTW to provide an unbiased estimate of average treatment effects (Robins et al. 2000; Hirano and Imbens 2001; Hirano et al. 2003; Lunceford and Davidian 2004; Austin 2011a, b; Austin and Stuart 2015; Austin et al. 2017).

Because we utilized secondary data and no human subjects were involved, the evaluation was deemed public health practice and exempt from IRB.

#### Measures

Our primary outcome variables (dependent variables) of interest included cigarette use, low birth weight (LBW i.e., <2500 g), preterm birth (PTB i.e., <37 weeks of gestation), and neonatal mortality (infant deaths <28 days). The primary exposure (intervention/treatment) variable of interest was maternal participation in the HWHB program. Our comparator was Medicaid HWHB enrolled women and Medicaid non-HWHB women. A priori variables available in birth certificate data such as maternal age, cigarette use, and previous poor birth outcome were utilized to adjust for any potential confounding for the 2011–2015 birth years.

#### **Analytic Procedures**

We first calculated propensity weights as the inverse of propensity scores using multivariable model logistic regression for the subset dataset described earlier. We used maternal age, mother's education, race and ethnicity (i.e., Black and Hispanics), and mother's county of residence as covariates and their interaction terms: maternal age and race and ethnicity; maternal age and education, maternal education and race and ethnicity, maternal education and county of residence, race and ethnicity and county of residence.

Second, we estimated crude odds ratios (COR) and adjusted odds ratio (AOR) with 95% confidence intervals (CI) using IPTW as a weight variable. Standardized differences before and after weighting was used to assess the reduction in bias (Austin and Stuart 2015; Austin et al. 2017). Model fit was assessed using the Hosmer and Lemeshow and c statistic, a measure of how well the model discriminates individuals experiencing the event from individuals who do not.

Third, we conducted sensitivity analyses using E-values (VanderWheele and Ding 2017). The E-value is "the minimum strength of association on the risk ratio scale that an unmeasured confounder would need to have with both the treatment and the outcome to explain away a treatment-outcome association" (VanderWheele and Ding 2017, p. 270).

## Results

Table 1 provides the characteristics of HWHB enrolled black and Hispanic and non-enrolled black and Hispanic women before propensity weighting as measured through standardized differences. It is evident that there are significant differences in HWHB enrolled and non-HWHB Medicaid Table 1Characteristics ofHWHB-enrolled in Medicaidand non-HWHB Medicaidwomen, in Delaware, 2011–2015

Characteristics of mothers whose delivery was paid by Medicaid <sup>a</sup>	Intervention/exposure $(n = 14,690)$		
	HWHB enrolled $(n=6208)$	Non-HWHB $(n = 8482)$	Absolute standard- ized difference (d) <sup>b</sup>
Age***	26.3 (±5.9)	26.3 (±5.8)	5.1
Race and ethnicity***			
Non-Hispanic Blacks	3108 (50.1%)	5997 (70.7%)	43.2
Hispanics	3100 (49.9%)	2485 (29.3%)	43.2
Mother's education***			
< 9 years of schooling	1295 (20.9%)	736 (8.7%)	34.8
9-11 years of schooling	1565 (25.2%)	1993 (23.5%)	3.8
High school graduate	2136 (34.4%)	3130 (36.9%)	5.5
1–3 years of college	988 (15.9%)	2135 (25.2%)	23.3
> 3 college graduate	197 (3.2%)	419 (4.9%)	9.1
Missing/unknown	27 (0.4%)	69 (0.8%)	
County of residence***			
Kent	413 (6.7%)	2093 (24.7%)	51.2
New Castle	4377 (70.5%)	4102 (48.4%)	46.3
Sussex	1418 (22.8%)	2287 (27%)	9.5

Continuous variables are represented as mean  $\pm$  standard deviation, while dichotomous and categorical variables are represented as N (%). Independent *t tests* continuous measures and chi-square tests for dichotomous and categorical variables

<sup>a</sup>Non-Hispanic Black and Hispanic women whose delivery was paid by Medicaid

<sup>b</sup>The standardized difference compares the difference in means and/or proportions in units of the pooled standard deviation and are not influenced by sample size and are used to compare balance in measured variables between "treated" (i.e., intervention—HWHB) and "control" subjects (i.e., non-intervention— non-HWHB). It is reported in percentage and therefore, a standardized difference in excess of 10% may be indicative of meaningful imbalance in covariates between treated and control subjects

\*\*\*p<.0001

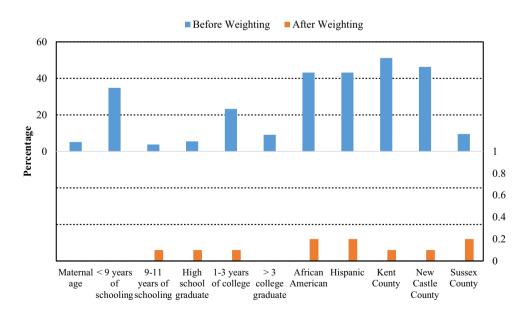


Fig. 1 Standardized differences<sup>a</sup> in the characteristics of Healthy Women Healthy Babies program and non-program participants before and after propensity weighting. <sup>a</sup>The standardized difference compares the difference in means and/or proportions in units of the pooled standard deviation and are not influenced by sample size and are used to compare balance in measured variables between "treated" (i.e., intervention—HWHB) and "control" subjects (i.e., non-intervention—non-HWHB). It is reported in percentage and therefore, a standardized difference in excess of 10% may be indicative of meaningful imbalance in covariates between treated and control subjects

women on a variety of characteristics. Figure 1 displays the reduction in bias after propensity weighting as measured through standardized differences for the variables above. The absolute standardized differences reduced bias by more than 95%.

Table 2 presents crude (COR) and adjusted odds ratios (AOR) for the primary outcomes of cigarette use, low birth weight, preterm birth, and neonatal death using propensity weights. As hypothesized, cigarette use was lower among HWHB enrolled non-Hispanic black and Hispanic women on Medicaid as compared with non-enrolled women. For instance, HWHB enrolled women were 10% less likely to smoke during pregnancy COR 0.89 (95% CI 0.82-0.96) as compared with non-HWHB women. Low birth weight, preterm birth and neonatal mortality rates of infants delivered by non-Hispanic Black and Hispanic HWHB enrolled women were lower as compared with non-enrolled HWHB women after adjusting for potential confounders and demographic covariates. For instance, HWHB women were 9% less likely to deliver a low birth weight infant (AOR 0.91; 95% CI 0.84–0.99; p=0.023) as compared non-HWHB. Similarly, HWHB women were 15% less likely to deliver a preterm infant (AOR 0.85; 0.78-0.92; p < 0.0001) as compared to non-HWHB women. Finally, infants of HWHB enrolled women had 27% less likelihood (AOR 0.73; 95% CI 0.54–0.98; p = 0.035) of experiencing a neonatal death (i.e., <28 days) as compared to infants of non-HWHB enrolled women. Hosmer and Lemeshow Goodness-of-Fit statistics also indicated good model fit for the adjusted models. In short, health outcomes for women enrolled in HWHB program was better as compared to non-HWHB women. We also conducted sensitivity analyses using E-values. Sensitivity analyses revealed that the E-value for LBW was 1.3; 1.4 for PTB; and 1.6 for neonatal death. The sensitivity analyses result suggests that an unmeasured confounder of exposure (i.e., being enrolled in HWHB) and outcomes such as LBW, PTB, and neonatal death by a risk ratio of 1.3, 1.4, and 1.6 respectively could potentially explain away the 'treatment' effect.

# Discussion

The main finding of our evaluation is that HWHB enrolled non-Hispanic black and Hispanic women whose birth was paid by Medicaid had reduced odds of smoking, low birth weight, preterm births, and their infants had lower neonatal mortality rates as compared with non-Hispanic Black and Hispanic women not enrolled in HWHB. The premise of the evaluation rests on choice of comparator, given the fact that racial and ethnic minority women enrolled in the HWHB program are theoretically at high risk and therefore, in the 'program.' While randomized control trials (RCTs) are the gold standard, use of RCTs are often unrealistic and may even be unethical (Shadish et al. 2002). In observational studies self-selection poses threats to the internal validity of a study (Morgan and Winship 2007; Guo and Fraser 2010; Robins et al. 2000; Hirano and Imbens 2001; Hirano et al. 2003; Ye and Kaskutas 2009; Stürmer et al. 2014; Austin 2011a, b; Austin and Stuart 2015; Austin et al. 2017). To minimize selection bias we utilized propensity scores and in particular, IPTW described earlier. Evaluation of the HWHB program in Delaware during 2011–2015, using propensity score weighted analyses provides promising evidence with regards to efficacy of the program among racial and ethnic minorities (i.e., Black and Hispanic women) whose delivery was paid by Medicaid.

To our knowledge, our study is the first to show that a specific statewide medical program can impact infant mortality and other important birth outcomes. From our study we are unable to determine the specific aspects of the program that contribute to its efficacy. For instance, it was difficult ascertain what combination of bundles (Bundle A i.e., screening for chronic disease, and chronic disease management, screening for family violence, counseling for

Table 2Outcomes of HWHB-enrolled in Medicaid and non-HWHB Medicaid women, inDelaware, 2011–2015

Outcomes <sup>a</sup>	Crude odds ratio (95% CI)	Adjusted odds ratio (95% CI)
Cigarette use during pregnancy	0.89 (0.82–0.96)	#N/A
Low birth weight (<2500 g)	0.92 (0.85-1.00)	0.91 (0.84–0.99) <sup>b</sup>
Preterm birth (<37 weeks)	0.86 (0.80-0.94)	0.85 (0.78–0.92) <sup>c</sup>
Neonatal death	0.74 (0.55–0.99)	0.73 (0.55–0.98) <sup>d</sup>

Propensity scores weighted crude odds ratio and adjusted odds ratio with 95% CIs. Adjusted models include propensity weights with covariates age, education, cigarette use, previous preterm birth, and county of residence

<sup>a</sup>Non-Hispanic Black and Hispanic women whose delivery was paid by Medicaid

<sup>b</sup>Hosmer and Lemeshow Goodness-of-Fit  $\chi^2(8) = 7.4047$ ; p=0.4937

<sup>c</sup>Hosmer and Lemeshow Goodness-of-Fit  $\chi^2(8) = 5.1608$ ; p=0.7403

<sup>d</sup>Hosmer and Lemeshow Goodness-of-Fit  $\chi^2(8) = 6.5511 \text{ p} = 0.5857$ 

smoking and nutrition, physical activity and Bundle C i.e., enhanced prenatal care that includes wraparound services or C and B i.e., nutritional assessment and counseling) and with what frequency and intensity (i.e., dose measure) contributed to the effect. We speculate that the success of the program is related to enrolling high-risk women, in geographically diverse locations of the state, while focusing on comprehensive wrap around services that are not typically available in most care settings. The HWHB program incorporates various elements of the life course-including preconception, prenatal, and interconception care-as well as addresses some of the social determinants of health such as stress, food, and social exclusion. As such, the complexity (Connelly 2007) of the HWHB program also acts as a double-edged sword: while it is sensitive to the life course approach and social determinants, and has adopted a multifaceted approach, it also blurs the distinction of 'intervention or treatment' that are often subject of evaluation in RCTs. Hence, any evaluation of the HWHB program including our study is limited by scope.

Further, to scale-up a HWHB intervention to attain 'large' population level effects and to reduce infant mortality rates and its antecedent causes of low birth weight and preterm birth, it is important to develop strategies and policies that "create social conditions that will ensure good health for the entire population" (Marmot 2005, p. 1103). The fact that the evidence for HWHB is promising as noted in this evaluation through reduction in cigarette use, LBW, PTB, and neonatal mortality, suggests that it is extremely critical to maintain the current efforts. Although our model provides a potential blue print for other statewide programs to improve birth outcomes, further research is needed to determine the generalizability of this approach.

Our study has several strengths and limitations. First, our study utilizes a subset of population data of black and Hispanics enrolled in HWHB on Medicaid with an optimal comparator of non-HWHB black and Hispanics on Medicaid providing greater specificity and generalizability to this population. Second, unlike many observational studies where causal inference and deciphering average treatment effects are limited, this study utilizes propensity weights to minimize selection bias and estimate average treatment effects.

Despite its strengths, the study is also limited in some aspects. First, while IPTW reduces bias, it only does so for what is measured. Despite the fact that the current HWHB program meets its intent, the variability in program eligibility, and fidelity of program implementation, pose challenges in measuring any potential confounders not available in our dataset.

Second, our evaluation is limited in the sense that it cannot clearly delineate the impact of different programmatic elements especially those that relate to bundles of care. As discussed earlier, the deliberate vision of the IMTF to utilize a life course approach to improve a woman's health is not over reaching. It is well-established within life course epidemiology that social determinants play a pivotal role in health. The "solid facts and the ten messages" within the domain of social determinants outlined by Marmot (2005): (1) the social gradient; (2) stress; (3) early life; (4) social exclusion; (5) work; (6) unemployment; (7) social support; (8) addiction; (9) food; and (10) transportation become all the more critical in today's population health programming. While one may reduce all poor health outcomes to 'poverty' as the root cause, Marmot elegantly argues that "income poverty provides, at best an incomplete explanation" (p. 1102).

# Conclusion

The primary goal of this evaluation was to assess whether non-Hispanic Black and Hispanic Medicaid women enrolled in HWHB had better health outcomes as compared to non-HWHB Black and Hispanic Medicaid women in Delaware. As hypothesized, we found that HWHB women had lower cigarette use, were less likely to deliver a low birth weight infant, have preterm infants, and their infants were less like to experience neonatal deaths. Notwithstanding the limitations noted previously, the evaluation findings have several implications for population-based programs that incorporate comprehensive wraparound services like HWHB in geographically underserved and diverse communities with persistent race and ethnic disparities. The findings also reinforce the continual need to support and maintain the current programmatic efforts while emphasizing the need for a high fidelity program through continuous quality improvement efforts.

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## **Compliance with Ethical Standards**

Conflict of interest The authors have nothing to disclose.

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