Statewide Evaluation of Maternal and Infant Health Projects in Ohio

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Executive Summary

PROJECT OVERVIEW: The Center for Child Health and Policy (CCHP) at Rainbow Babies & Children's Hospital, Case Western Reserve University conducted an evaluation of the implementation and outcomes of five maternal and infant health programs across Ohio. These programs included the Southeast Community HUB (SE HUB), the Improve Maternal and Infant Health Outcomes among Disadvantaged Minority Populations in Ohio (IMIH) programs and Strong Start Ohio (SSO) Holzer, SSO Adena, and SSO Summa.

METHODS: The evaluation team used a mixed methods approach that included a quantitative analysis that used Medicaid claims data linked to vital statistics outcomes and qualitative interviews of program staff and participants. To the extent that they were available we used internal programmatic databases to describe several aspects of programs. We evaluated 730 women enrolled in 5 programs- the SE HUB and 4 SSO programs (as one SSO program employed two distinct models of intervention). Data for the IMIH program were not available to the evaluation team and thus not presented here.

KEY FINDINGS INCLUDE:

1. Each of the **programs was successful at identifying women who were at higher risk and at enrolling such high risk women**. Even so, there were large numbers of high risk women available for control groups for the evaluation, illustrating that there remains substantial unmet need for high risk women in each region. The capacity of these maternal and infant health programs was not sufficient to meet the needs of their region.
2. There were delays in program initiation and participant enrollment that reduced the number of women in each program. **The power of the quantitative evaluations to inform public policy would have been strengthened had more women been enrolled**. While there is something intuitively attractive to begin and evaluate a small scale short term project, such a strategy may not yield the desired benefits or insights and may not be the optimal use of public resources. Agencies funding future projects are encouraged to recognize the substantial time and effort needed to set up these complex programs.
3. The capacity to capture lessons learned from **future maternal infant health evaluations would benefit from having pre-specified design and evaluation criteria**, a large proportion of which that are uniform across the sites.
4. The qualitative analyses added critical insights. Both program staff and participants found participation in these enhanced prenatal care projects to be beneficial. Each of the **programs succeeded in connecting with high risk women, and in connecting those women with additional resources** to address underlying social determinants of health.
5. The **quantitative analyses did not demonstrate a reduction in any of the primary outcomes of low birth weight, preterm delivery, or maternal readmission**. We note that the number of women enrolled in each program was not sufficient to allow this evaluation to identify all meaningful or even important impacts. Even in aggregate, the total number enrolled remained too small to allow precise estimates of effect sizes or to reliably identify statistically significant differences between those receiving any intervention and those who did not. It would take thousands of women enrolled over longer periods of time, preferably also including between pregnancies, to demonstrate an impact on these outcomes.

Acronyms

AHRQ - Agency for Healthcare Research and Quality

CC - Care coordinator

CGC - Centering Group Care

CCHP – Center for Child Health and Policy

CHAP - Community Health Access Project

CHW - Community Health Workers

CMMI - Center for Medicare and Medicaid Innovation

CP - CenteringPregnancy

CPCCC - Centers for Pathways Community Care Coordination

FFS – Fee-for-service

GRC - Government Resource Center

HMG - Help Me Grow

HMO - Health Maintenance Organization

IMIH - Improve Maternal and Infant Health Outcomes among Disadvantaged Minority Populations in Ohio

IPAC - Integrating Professionals for Appalachian Children

MaCH - Maternity Care Home

MIH - Maternal Infant Health

MMC - Medicaid managed care

NICU- Neonatal intensive care unit

NW HUB - Northwest Ohio Pathways HUB

OA - Opiate addicted

OA-CGC - Opiate-addicted Centering Group Care

PCHI - Pathways Community HUB Institute

RR - Risk ratio

SE HUB - Southeast Ohio Community HUB

SGA - Small for Gestational Age

SSO - Strong Start Ohio

WIC - Women, Infants, and Children

1 Introduction

As a state, Ohio has suffered considerably higher rates of infant mortality than the national average (6.9 per 1,000 live births vs. 6.0) resulting in a national rank of #39 (CDC, 2016). The specific causes of infant mortality in the population are unclear but likely represent a complex interplay between social, genetic, behavioral and environmental determinants (Hogan, 2011). Preterm birth (defined as birth prior to 37 weeks gestation) is the most significant driver of infant mortality, morbidity and healthcare costs for infants. In Ohio, approximately 50% of infant mortality is due to preterm birth and low birth weight (Martin, 2011). The five leading causes of infant mortality in Ohio in order are prematurity, birth defects, diseases related to maternal health conditions, sleep related deaths, and injury (Ohio Department of Health, 2016). Wide variations in infant mortality rates can be seen between counties in Ohio as well as at the neighborhood level (ODH, 2014). In addition, marked health disparities exist with black infants experiencing over two times the risk of dying in the first year of life when compared to white infants (Collins, 2009; Lu, 2010).

In this report we present the findings from our evaluation of projects intended to reduce infant mortality and improve maternal child health in their respective catchment areas. The **Southeast Ohio Community HUB (SE HUB)**, **Improve Maternal and Infant Health Outcomes among Disadvantaged Minority Populations in Ohio (IMIH),** and **Strong Start Ohio (SSO),** the latter at Summa, Adena, and Holzer Health. Each program was tasked to advance the Ohio Department of Medicaid goal to improve the health of Medicaid and Medicaid-eligible mothers and infants. These projects each use their specified intervention models and protocols with the common feature that all identify pregnant women at high risk for poor birth outcomes and seek to address underlying social and health challenges this population faces in order to produce healthier pregnancies and pregnancy outcomes.

The Center for Child Health and Policy at University Hospitals Rainbow Babies & Children's Hospital and Case Western Reserve University was subcontracted by the Ohio Colleges of Medicine Government Resource Center (GRC) to evaluate the effectiveness and efficiency of these maternal and infant health interventions, describing their success in:

1. Identifying and enrolling pregnant women at high-risk of poor birth outcomes,
2. Improving quality of health care, including access to care, utilization, and patient satisfaction,
3. Improving perinatal health outcomes for mothers and babies, and
4. Improving cost-efficiencies in the coverage of this high-risk population

2 Overview of Models of Care

The three Ohio Maternal and Infant Programs discussed in this report adopted one or more of three models of care 1) Centering Group Care 2) Maternal Care Home or 3) Pathways. The following provides an overview of each model.

Centering Group Care

Centering Group Care (CGC), also referred to as "CenteringPregnancy" (CP), is a model of group care that integrates three major components: health assessment, education, and support. CP was developed in the 1990s by Yale-educated Certified Nurse Midwife, Sharon Schindler Rising. It was conceived as a method of collaborative practice that could increase patient satisfaction and patient volume while also improving outcomes. It is currently practiced at 300 sites worldwide.

As developed, each CP group consists of eight to twelve women of similar gestational ages and two health care clinicians. They meet jointly for 10 sessions beginning in the second trimester through the early postpartum period following the traditional obstetric care schedule (DeCesare, 2014). The women learn care skills, participate in a facilitated discussion, and develop a support network with other group members. Clinicians complete standard physical health assessments for each participant within the group space.

As described by the Centering Healthcare Institute (2016), CP benefits women, babies, and clinicians through:

- **Better health outcomes**, which lead to healthier babies and reduced racial disparities in preterm birth.
- **Self-care**, with women more engaged in their healthcare and health information.
- **More time with clinician** – 10 fold more time than traditional care.
- **Knowledge and self-confidence**, leading to women who are better prepared for labor, delivery and infant care, and reducing after-hour calls and emergency room visits.
- **Community building**, with women experiencing support and friendship of others going through a similar experience.
- **Greater likelihood of behavior change**, with active engagement and peer discussion influencing women to make positive lifestyle changes.

Maternity Care Home

The Maternity Care Home (MaCH) model is an adaptation of the Patient-Centered Medical Home, a model of care in which the primary care physician coordinates care to ensure that patients access necessary treatment and understand their care. MaCH seeks to provide coordinated prenatal and postpartum care to pregnant women. MaCH frequently moves beyond traditional prenatal care to provide women with additional psychosocial support, education, and health promotion (Centers for Medicare & Medicaid Services, 2016). This model has existed in informal ways in various settings, locally in community health centers and birth centers, at state-level through public-private partnerships (for example, Community Care of North Carolina), and nationally, through grant-funded opportunities, such as Strong Start for Mothers and Newborns (Hill et al., 2016). MaCH is one of three implementation approaches in the national Strong Start Initiative funded under the Affordable Care Act by the Center for Medicare and Medicaid Innovation (CMMI) of the Centers for Medicare and Medicaid Services (Hill et al., 2016).

Since standard-setting bodies and recognition programs for Maternity Care Homes do not yet exist, it is difficult to define specific attributes that designate a practice a MaCH; however, there are several overarching features (Romano, 2012):

- **Continuity of care from a primary clinician** who accepts responsibility for providing and/or **coordinating all health care and related social services** during a woman's pregnancy, childbirth, and postpartum period.
- **Commitment to continuous quality improvement**, patient safety, and evidence-based practice.
- **Commitment to woman-centeredness** and a positive experience of care.
- **Timely access** to appropriate care and information.

The MaCH model of care is relatively new and research into the effectiveness of the model is limited. (Anum, Retchin, & Strauss III, 2010). The national Strong Start for Mothers and Newborns Initiative hopes to provide the much needed

evidence-base for this model of care through an evaluation of more than one hundred sites implementing the MaCH model (Hill et al., 2016).

Pathways Community HUB

The Pathways HUB Model is a community-based delivery system for care coordination that seeks to move from a focus on what they refer to as activity-based health systems towards outcomes. The Pathway HUB concept evolved from observation of Community Health Workers (CHW) in Alaska who significantly improved infant mortality. This model was further developed and piloted by the Community Health Access Project (CHAP) in 2004 in Richland County, Ohio where client data (n> 300) showed a significantly lower rate of low birth weight babies than was previously recorded in the county. (Community Health Access Project).

FIGURE 2.1 PATHWAYS COMMUNITY HUB MODEL (ROCKVILLE INSTITUTE, 2016)

The HUB model is designed to identify at-risk individuals and connect them to evidence-based services to improve outcomes. It incorporates various elements addressing care coordination, including incentives, enhanced communication, and collaboration among care coordinators (CC), payers and providers/clinicians.

The main principles of the model are:

- **Find: Identify individuals at greatest risk** and provide assessment of health, social behavioral risk factors
- **Treat: Ensure that all risk factors have a specific 'Pathway'** to address interventions needed
- **Measure: Confirm completion of 'Pathway'** when risk factors have been successfully addressed

The model is designed with three central components: 1) Core Pathways 2) the HUB itself, and 3) payments linked to outcomes (Zeigler, Redding, Leath, Carter, & Russell, 2014).

Pathways: A pathway is defined by the program as a standardized and ordered set of activities designed to address a specific issue postulated to affect an individual health outcomes. The pathway provides an opportunity to measure how far along the intended path a client advances. It is intended to promote timely intervention towards risk reduction and to allow the CC to track progress. Table 1.1 provides an example of the steps described by the program for the Pregnancy Pathway.

TABLE 2.1 STEPS IN THE PREGNANCY PATHWAY

Initiation step	Action steps	Completion step
Enroll a woman confirmed to be pregnant through a pregnancy test	1. Provide health education, following up on prenatal appointments at least monthly.	Birth of a healthy baby (at least 2500 grams)
	2. Schedule a 1st prenatal appointment, providing an estimated due date, and identifying any concerns	
	3. Follow up on prenatal appointments at least monthly	

(Pathways Community HUB Institute, 2016)

The Pathways Community HUB Institute (PCHI), Community Care Coordination Learning Network (2016) offers more examples of standardized Pathways in its "Quick Start Guide to Developing Community Care Coordination Pathways".

Twenty standardized Pathways have been developed to respond to many issues related to health outcomes including behavioral health, developmental screening, employment, family planning, health insurance, housing, immunization, medical referral, and pregnancy (PCHI, 2016). Standardized Pathways allow for comparison of outcomes across CC, agencies, communities, regions, and states. Standardization also allows the development of universal billing codes to tie payment to outcomes. Each client may be enrolled in one or many such pathways depending on issues identified by a care coordinator during intake or follow up. Pathways that are not successfully completed are documented as closed.

The HUB: The HUB is described as a regional "clearing house" that connects care coordinating agencies, providers, and payers to individuals in the community (Figure 2.2). The HUB collects and monitors 1) individual health outcomes and cost data from individual CC and stakeholder agencies, 2) community performance data evaluating the network of agencies providing care coordination, and 3) population data to track broader health improvements and cost saving. This tracking through the HUB is intended to eliminate duplicative care (such as repeat testing and blood work) and provides standard quality measurements. By comparing completed pathways (i.e., desired outcomes) to the total number of opened/closed pathways by issue and agency, the HUB can also describe regional performance.

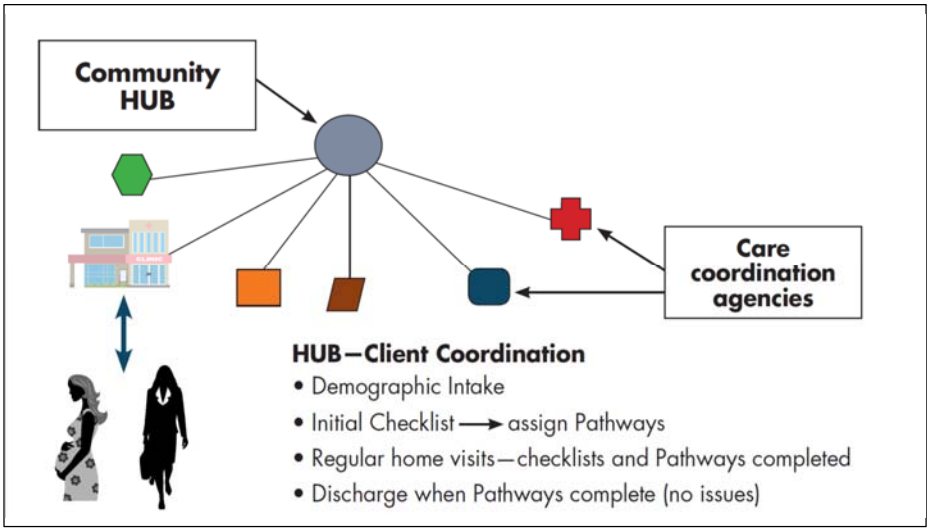

FIGURE 2.1 COMMUNITY HUB (PCHI, 2016)

Payments linked to outcomes (incentives for outcomes): Payers reimburse the HUB based on individual client outcomes with payments to CC and agencies linked to completion of pathways and positive patient-centered outcomes, described as improved health, reduced disparities, and lower costs. The intention is to incentivize value versus volume. Specific benchmarks along the pathway may yield incentives, with care coordinating agencies receiving the highest payment for

completed pathways that produce the desired outcome. The pathways data collection provides a mechanism to link incentives with performance.

A recently established Pathways Community HUB national certification process requires HUBs to demonstrate cultural competence and a business model approach, utilize standard Pathways, ensure comprehensive assessment and documentation, and verify that 50% or more of their funding is linked to specific health or social outcomes. To date, three HUBs have provisional certification with six more in process (PCHI, 2016).

3 Methods

The Center for Child Health and Policy used a mixed methods approach for evaluation of the programs. Primary data for qualitative analyses were collected during site visits and from interviews of staff and participants. A secondary quantitative analysis was performed upon those data made available to the team.

Our evaluation sought to describe the extent to which each program succeeded at:

1. Identification and enrollment of pregnant women at high-risk of poor birth outcomes,
2. Quality improvement including access to care, utilization, and patient satisfaction, and
3. Improvement of perinatal health outcomes for mothers and babies.

The evaluation team was prepared to conduct a cost-effectiveness or similar analysis. As cost data were not made available for analysis, this was not possible.

All aspects of this study were approved by the Case Western Reserve University Institutional Review Board.

Program Descriptions

To understand program content and context within which the programs operate, the team conducted site visits and reviewed web and print materials made available to them by the individual program sites. In consideration of logistical and resource constraints, site visits were conducted in person on site for three sites and via conference calls for two sites (Table 3.1)

TABLE 3.1 SITE VISIT DATES AND TYPE

Program	Date	Type
Southeast Community HUB	2/24/2015	On site
IMIH	4/9/2015	On site
Strong Start Ohio Holzer	4/14/2015	Conference call
Strong Start Ohio Summa	4/30/2015	On site
Strong Start Ohio Adena	5/5/2015	Conference call

Quantitative Analyses

Overview

This section describes the methods used to accomplish the quantitative analysis of the maternal-infant health programs. The quantitative analyses relied upon two key data sources:

1. Medicaid claims data linked to birth certificate data from the state of Ohio. These data were made available by the Ohio Colleges of Medicine Government Resource Center (GRC) at the Ohio State University. Linkages and processing of the data incorporated standard protocols and were performed by the GRC, who made preprocessed data available to the evaluation team for further analysis.
2. Data on mothers and infants collected directly by the Southeast HUB and each of the three Strong Start Ohio programs, collectively known at programmatic data.

Incorporated into the GRC data are demographic, geographic, socioeconomic, and health behavior data on both the programs' participants and a control group of women from the same geographic area. The GRC data are standardized across programs and we considered the GRC data to be generally reliable, valid and of high quality. Neither the design of the programmatic data (e.g., variables, definitions) nor the data collection were standardized, resulting in numerous potential opportunities for data error. The completeness, reliability and validity of these programmatic data could not be assessed in the context of this evaluation and we do not make assumptions about their quality.

Data Sources and Linkage

Table 3.2 below provides additional detail regarding the quantitative data.

TABLE 3.2 DESCRIPTION OF QUANTITATIVE DATA SOURCES

Data source	Description of data
Medicaid claims and eligibility data covering the period that the programs were in effect	• Covered an approximate 11-month time interval from the last menstrual period through the first 60 post-natal days for each woman in the program. • Available from birth through 60 days of age for infant claims. • Provided information on maternal risk factors, as well as health care utilization data on both the mother (prenatal and postpartum) and the infant.
Birth certificate data from the Ohio Department of Health	• Provided demographic data, maternal risk factors, delivery-related complications or trauma, and infant health indicators.
Programmatic data derived by each site	• Collected by the program staff at the time of enrollment, during program participation and follow-up visits. • Provided information on the utilization and completion of the various interactions with the participants.

The GRC conducted probabilistic matching to link mothers and infants Medicaid and birth certificate data, using The Link King – a public domain SAS-based software (see Appendix A). Program files were used to identify Medicaid numbers for enrollees. After preprocessing that included the removal of sensitive identifiers the data were provided to the research team. The resulting data set included one record per pregnancy. For women with multiple pregnancies during the study period, only the first pregnancy was included. The exclusion of multiple births and subsequent pregnancies was done to enhance the validity of the findings as an evaluation of these programs. Subsequent pregnancies would challenge the capacity to quantify and standardize the extent of exposure to the program. Multiple gestation pregnancies are prone to prematurity and low birth weight.

Study Population

Our study population consisted of women enrolled in Southeast Ohio Community HUB (SE HUB), Strong Start Ohio (SSO) Holzer, SSO Adena, and SSO Summa. Our study evaluated participant births from January 1, 2012, to September 30, 2015 (Table 3.3). Participant births after September 30, 2015 were excluded because complete data was not available due to the lag time for accurate and linked data to be made available. The comparator group ("controls") consisted of propensity-matched Medicaid enrollees not receiving services through the aforementioned programs.

The comparator group for each program was selected from a pool of Medicaid-enrolled women that resided in catchment areas, as identified by individual programs, who gave birth during the same time period as the cases. The evaluation team was provided 10 times the number of intended controls from which to derive propensity-matched 'controls'. Our propensity score matching algorithm matched each case to a single control without replacement, as described below. In some instances, the county of residence listed on the Medicaid record was outside the program catchment area for cases. In these instances, a participant was matched to a control from a geographically nearby, preferably adjacent, county.

TABLE 3.3 QUANTITATIVE STUDY POPULATION

Program	Enrolled participants[1]	Study Population[2] N (%)
IMIH[3]	unknown	unavailable
SE HUB	307	250 (81)
SSO Adena	234	68 (29)
SSO Holzer	531	326 (61)
SSO Summa (CGC)	76	45 (59)
SSO Summa (MaCH)	69	41 (59)

[1] based on programmatic data
[2] limited to participants with births prior to 9/30/2015 with available birth certificate and Medicaid claims data
[3]unable to complete quantitative or qualitative evaluation as no data was provided by GRC

Variables of interest

Outcome variables:

The maternal outcomes we analyzed included pre-term labor, post-partum hemorrhage, and maternal admission to a hospital or emergency department (ED) within 60 days of postpartum period, all of which were captured from Medicaid claims data. Cesarean section delivery was another outcome of interest, derived from birth certificate data.
The infant outcomes were all derived from birth certificates and included low birthweight (< 2500 grams), pre-term delivery (<37 weeks gestation), infant admission to the neonatal intensive care unit (NICU), and small for gestational age (SGA; calculated from gestational age and birthweight).

Predictor variables:

The maternal variables retrieved from birth certificates included: age at delivery, county of residence, race, education, marital status, height and weight prior to pregnancy and at delivery, chlamydia, gonorrhea, and/or syphilis infection present at delivery, prenatal and gestational diabetes and hypertension, tobacco use, prior pregnancy history and outcomes, admission to intensive care unit (ICU), cesarean section delivery, blood transfusion, uterine rupture, perineal trauma, and unplanned hysterectomy.

Maternal variables retrieved from claims data include: HIV infection present at delivery, drug use during pregnancy including opiates, receipt of prenatal and postpartum care, transfer during birthing process, length of birth stay, admission (or readmission) to hospital or emergency department during first 60 days of postpartum period, and post-partum hemorrhage.

Infant variables retrieved from birth certificates include: gestational age, birth weight, breastfed at discharge, transfer within 24 hours of delivery, and admission to NICU. Variables retrieved from claims data were: length of birth stay, and admission and/or readmission to hospital.

Maternal race was categorized as white or non-white. Education was categorized into four groups – less than high school education, high school diploma or GED, any college, and unknown. As some enrollees had a recorded residence outside of the program area, we assigned each of these to the nearest county in the program. Tobacco use and dependence was characterized in two ways due to data availability: in SE HUB, we used the number of cigarettes smoked prior to and during pregnancy to create the variable; however in SSO, we were provided the variable based on claims data and ICD-9 codes.

Programmatic descriptive data:

Programmatic data from SE HUB included: Pathway enrollment and completion status.Programmatic data from SSO included: gestational age at enrollment, gestational age at birth, number of sessions attended, number of visits postpartum, and clinically diagnosed opiate addiction.

Statistical Analyses

Descriptive Statistics

Descriptive statistics were calculated pre- and post-match for all variables included in the analysis. Univariate comparisons were made using the Fisher's exact test for categorical variables and t-test for continuous variables.

Missing Values

We used multiple imputation to handle missing values in our covariate variables before propensity score matching, using the Fully Conditional Specification (FCS) method (VanBuuren, Brand, Groothuis, & Rubin, 2006) as implemented in SAS Proc MI. First, some variables had missing data only among those in the control pool, including alcohol use, drug abuse, opiates, prior birth outcomes, and risk factors. Removing these records (6.5% of control pool) took care of most of the missing values in the data. For the remaining missing data we used multiple imputation to create 10 datasets with imputed values for missing variables. We used 15 burn-in iterations for each of the 10 datasets. The FCS method imputed missing binary variables using logistic regression, continuous variables using linear regression, and categorical variables with 3 or more levels using a discriminant function.

Propensity Score Analysis

We used 1:1 optimal matching on the linear propensity score which estimated propensity for program participation based on independent variables. First, we calculated the propensity score using a multiple logistic regression model with case/control indicator as the dependent variable and all of the variables described above as the independent variables. This was done separately for each of the 10 imputed datasets, yielding 10 estimated logistic propensity score models. We then took the mean of the 10 linear predicted values obtained from the ten models for each subject and used this as the propensity score (Mitra & Reiter, 2016). Subjects were then matched using an optimal matching algorithm that minimizes the sum of the differences in propensity scores between cases and controls (Austin, 2011). A caliper of 0.1 times the standard deviation of the propensity score was required for a case and control to be considered a match. We assessed the propensity score matching in terms of covariate balance using plots of standardized differences (Love, 2002) and a set of rules proposed by Rubin which assess the appropriateness of regression-style models for the adjusted population comparisons (Rubin, 2001).

After propensity matching, a generalized estimating equations marginal model with log link function and exchangeable working correlation matrix was used to examine the effects of program enrollment (participant/control) on the outcome (Hardin & Hilbe, 2012). All analyses were performed using SAS version 9.3 for Unix. Optimal matching was performed using the VMATCH, DIST, and NOBS macros (Bergstrahl, Kosanke, & Jacobsen, 1996).

Meta Analysis

For each of the three primary outcomes (low birthweight, preterm delivery, and maternal admission postpartum), a random effects meta analysis (DerSimonian & Laird, 1986) was carried out to obtain an estimated risk ratio comparing program enrollment to controls, pooling across programs. A chi-square test for heterogeneity in risk ratios across studies was also performed, and the I-square statistic (Higgins and Thompson, 2002), which represents the percentage of variation across studies that is due to heterogeneity rather than chance, was calculated.

For each of the three primary outcomes, relative risks comparing program enrollment to controls were estimated for each of the three programs (Maternity Care Home, Centering Group Care, and Pathways HUB), using a generalized estimating equations marginal regression model with log link function. A Wald test was used to test whether the risk ratios differed according to program type.

Descriptive Programmatic Analysis

Analysis on Southeast HUB programmatic data was performed to determine the number of participants in each program Pathway and the percentage of completion within each Pathway. Additionally, frequencies of outcomes among those who did and did not complete each Pathway were also examined.

A descriptive analysis on select programmatic data from the SSO (Holzer, Adena, Summa) sites was conducted.

Qualitative Evaluation

Overview

The purpose of the qualitative study was to understand the experiences of staff who implemented and women who participated in one of the four maternal and infant health initiatives across the State of Ohio (Southeast Ohio Community HUB / Pathways, Strong Start Ohio Summa Akron, Strong Start Ohio Holzer Athens, Strong Start Ohio Adena Chillicothe). The study involved semi-structured phone interviews with 17 staff and 59 program participants. All interviews were completed between June 2015 and March 2016. This study produced findings that demonstrate the importance of these programs for low-income, rural, and in some cases, opiate-addicted populations

Interview Protocols

Two semi-structured interview protocols, one for staff and one for participants, were developed by the lead authors, with input from the larger research team and the funder. Each protocol consisted of less than ten primary questions with several probes per question for follow-up information to be used at the discretion of the interviewer (see Appendix A). The primary purpose of the interviews was to understand staff and participants' experiences in one of four prenatal care programs throughout the State of Ohio.

Procedures and Recruitment

Staff contact information and participant mailing address information was received from the GRC. The GRC derived participant mailing addresses from Medicaid Administrative data. For three of the four sites, contact information was only provided for participants who delivered a live born infant and were also enrolled in the program at the time of delivery. There was insufficient information in one site's records (which was no longer in operation) to determine if a participant was enrolled at the time of delivery. One of the four sites reviewed mailing addresses and updated them where necessary. We received 759 unique addresses with many participants having multiple addresses.

Participant phone numbers were provided to the GRC by program delivery staff. Staff from one site only shared phone numbers for participants who gave their consent for the research team to contact them for a phone interview. In total, the research team received contact information for 474 participants (101 for Adena, 29 from Holzer, 262 from SE HUB, and 82 from Summa).

The research team sent emails (with an informed consent document attached) to program staff requesting their participation in a phone interview. Staff interviews were also scheduled via email. The research team sent invitation letters via United States Postal Service (USPS) to every participant mailing address received from the GRC in February 2016 (see Appendix C.1); 226 letters were unable to be delivered and returned to sender. For 58 of the returned letters, the address constituted the only address we had for that participant. All other letters were sent to multiple addresses. The invitation letter explained why program participants were being contacted, the purpose of the interview, the anticipated duration and content of the interview as well as the voluntary nature of participation. The invitation letter also contained an informed consent document that explained the research study in greater detail (see Appendix C.2). Participants were invited to call the research team using a toll-free number. Nineteen women who received the letter called us first to complete their interview (32.2% of women interviewed). Approximately one week after letters were mailed, the research team began calling participants.

One Ph.D.-level researcher conducted the 17 interviews with program staff (5 from Adena, 3 from Holzer, 5 from SE HUB, 4 from Summa). The same researcher, along with two other master's level social work researchers, conducted the participant phone interviews. Before calling participants, led by the Ph.D.-level researcher, interviewers reviewed the informed consent document and consent procedure, the interview protocol, the greeting and voicemail scripts, and the safety protocol should a participant be in imminent danger (as no participant was in imminent danger, the protocol was never implemented). Interview questions were discussed at length, and given their level of training and experience, master's level interviewers went directly to the interviewing phase.

The lead created four unduplicated lists of participant contact information, one for each site, and then used a random digit generator to create a random call order. The goal was to interview 25 participants from each site for a total of 100

interviews; however, one site only provided contact information for 29 participants. The research team called all participants three times, in the order determined by the random digit generator. When possible, the research team left voicemail messages, inviting participants to return our call using a toll-free number. Some participants had as many as three phone numbers; interviewers called all available numbers. Across sites, 112 numbers were unusable (27 from Adena, 4 from Holzer, 59 from the SE HUB, and 22 from Summa); that is, when called they were disconnected or out of service. All phone calls were made Monday-Friday between 10am and 6pm. Calls began at the end of the month, however, given the income level of participants, those who were not reached received a second or third call at the beginning of the following month in anticipation of cell phone minutes being available.

Interviews ranged in length from less than 10 minutes to more than 30 minutes with the majority lasting approximately 15 minutes. All phone interviews were audio recorded with permission. Program staff received a $25 Amazon electronic gift card for their time. Participants received a thank you letter and a $20 Walmart gift card via USPS mail for participating in the study. (See Figure 3.1, Enrollment diagram)

Data Analysis

Audio recordings were transcribed by a master's level social worker. Once transcription was complete, the lead qualitative researcher reviewed the written text, while listening to the recording, for quality and accuracy. Program staff and participant transcripts were analyzed separately. Transcriptions were parceled by interview question into separate primary documents and uploaded into ATLAS.ti for analysis. For training purposes, under the auspices of the lead author, the research team (the two master's level researchers who conducted the interviews and the master's level social worker who transcribed the interviews) independently coded the first interview question searching for both latent and manifest content. The coding process began by re-reading the unique transcribed responses to each question. Then, through an inductive process, coders created in vivo codes with the objective of staying as close to the responses as possible. Next, the team came together with their codes, written on separate slips of paper, for collective sorting. In this step, similar codes were grouped into higher-order axial level categories. The group atmosphere allowed for discussion of individual and then collective thought processes, and rationale for in vivo coding. Once trained, two team members coded each of the remaining questions following the same protocol.

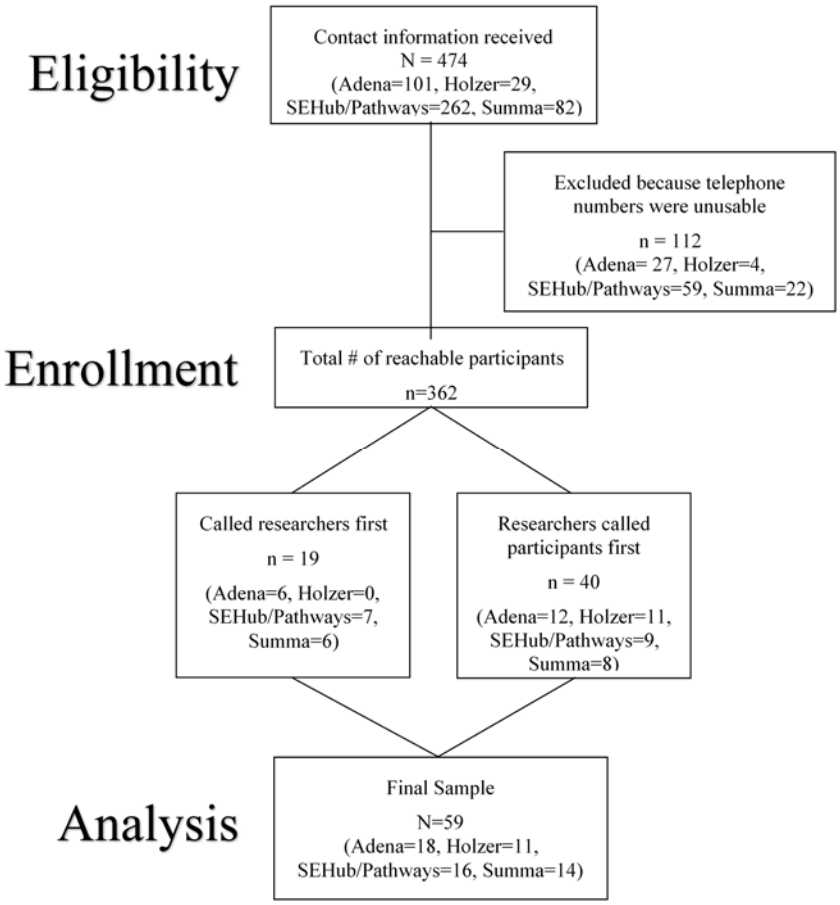

FIGURE 3.1 QUALITATIVE ENROLLMENT DIAGRAM

The research team utilized an inductive coding process. Thus, a codebook with a priori codes was not developed. Once all questions were coded and axial categories were determined, the team reviewed the larger research literature on similar programs to ensure all emergent themes were indeed captured. Themes were defined as patterns in the data that were relevant and shared in ways that extended beyond mere answers to the questions posed.

4 Program Descriptions

The evaluated programs and their catchment areas are shown below in Figure 4.1. They are Southeast Ohio Community HUB (SE HUB), Improve Maternal and Infant Health Outcomes among Disadvantages Minority Population in Ohio (IMIH), and Strong Start Ohio (SSO) Adena, Holzer, and Summa. Information in this section was obtained through site visits, phone interviews with projects and through secondary data sources (see References).

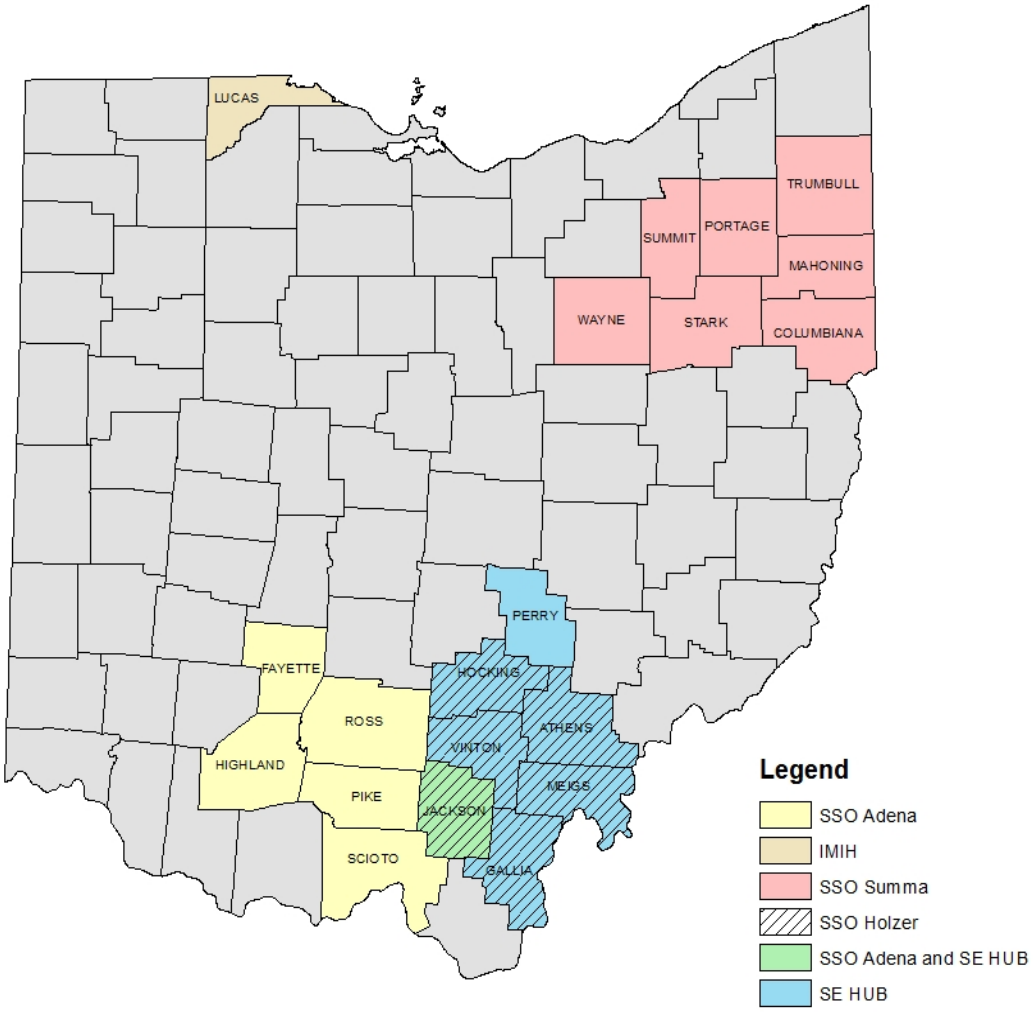

FIGURE 4.1 CATCHMENT COUNTIES FOR STATEWIDE INFANT AND MATERNAL HEALTH PROGRAMS

TABLE 4.1. PROGRAM AND MODEL

Program	Model
IMIH	Pathways Community HUB
SE HUB	Pathways Community HUB
SSO Adena	Centering Group Care (CGC), also known as CenteringPregnancy
SSO Holzer	Maternity Care Home (MaCH)
SSO Summa	CGC and MaCH

Improve Maternal and Infant Health Outcomes among Disadvantaged Minority Populations in Ohio (IMIH)

IMIH, also known as Northwest Ohio Pathways HUB, was formed as a community partnership in 2006 and began enrolling women in 2007. The program is the first focus area of the Northwest Ohio Pathways HUB which falls under the Hospital Council of Northwest Ohio (Three local hospital systems working under one umbrella). Its goal is to reduce preterm and low birth weight births in Lucas County by increasing early initiation of prenatal care and access to other social and medical services in high-risk pregnant women. The program initially relied only on grant funds but since 2010 has contracted with Medicaid Managed Care Organizations which pay for care coordination services for high-risk pregnant women based on improved outcomes.

According to its 2015 update, the initiative is now primarily funded by pay-for-performance Medicaid managed care (MMC) contracts. IMIH has served more than 1,800 at-risk pregnant women (1,400 births) since its inception with an anticipated enrollment of 500 women in 2015. Clients refer to the program simply as 'Pathways' after its model of care.

Client enrollment is done by CC in a variety of locations including community clinics, low income housing units, social service agencies, laundromats, Walmart, etc. IMIH receives referrals from clinics and MMC but often the CC find the women. These CC act as translators, assisting the clients to navigate the health system and access care. They are the program's face-to-face contact with clients. CCs average 50 clients per year, but their caseload varies from 35-65 at any given time. Case load depends on timing of enrollment before the birth as well as severity of the cases.

In 2014, 69% of clients were people of color. The average number of risk factors for clients is 7.4. Most clients are <100% of poverty level with some <200% poverty level. Client age is between 11-40. They are uninsured or on Medicaid. Significant issues include lack of transport, mental illness, and domestic violence. Administrators believe that the number of high-risk moms annually in the catchment area is approximately 1000. Their program is on track to serve 500 this year.

As a way to encourage agencies to hire a care coordinator, IMIH provides the start-up costs for approximately one year for the care coordinator. After the initial year the organization assumes the cost with the expectation that the CC salary will be generated through MCO outcomes payments. IMIH has also assisted organizations to cover unexpected costs such as paid sick/maternity leave that were not in their budgets. There are currently seven care coordination sites in Lucas County with a concentration of these in Toledo. These include Adelante Inc., East Toledo Family Center, Mercy, Neighborhood Health Association, The Providence Center, Toledo Hospital, and Toledo-Lucas County Health Department.

Southeast HUB (SE HUB)

SE HUB is a population-based maternal and infant health program that aims "to improve health and preventive care for high-risk mothers and children" by replicating the Community Pathways Model in the Appalachian region of Southeast Ohio. SE HUB was formed in 2012 through a $350,000 grant from the Governor's Office of Health Transformation awarded to Integrating Professionals for Appalachian Children (IPAC). Founded in 2002, IPAC is a network of 19 community agencies in Athens, Hocking, Meigs, and Vinton County. It includes several Ohio University departments and clinics.

This multi-county effort was conceptualized to involve several Managed Care Organizations and Partners for Kids affiliated with Nationwide Children's Hospital. As in the Pathway model, the HUB registers and tracks at-risk pregnant women to assure that their biological, psychological, and social needs are met. The aim is to provide quality assurance, lessen duplication, lower costs, reduce disparities, and improve health status. SE HUB was asked to track the following pathways: medical home, social service referral, health insurance referral, pregnancy, postpartum, family planning, development screening, and immunizations.

IPAC credits the community HUB model with moving health and social service providers to work collaboratively to connect those at greatest risk to evidence-based interventions focusing on prevention and early treatment.

Data collection and contracts with managed care organizations proved to be challenges for SE HUB. The database constructed for the project made tracking of pathways difficult resulting in incomplete and duplicate data. Despite its efforts, SE HUB was only able to contract with Partners for Kids and one managed care organization, CareSource. This affected sustainability with enrollment tapered by spring 2013 and the program closing once grant funding ended.

Strong Start Ohio (SSO)

SSO is a collaborative effort funded by Ohio Department of Medicaid and administered by Ohio College of Medicine Government Resource Center to reduce preterm births, improve birth outcomes, and lower health care cost for high-risk pregnant women enrolled in Medicaid. The effort was funded at three sites, Adena, Holzer, and Summa, as an 18 month learning collaborative and implementation phase.

Adena Health System

This initiative developed from a small-scale start-up project funded by a $5000 CareSource grant. Pregnant women addicted to opiates were provided with a modified Centering Pregnancy program and received medication (Subutex and later Suboxone) to treat their addiction. Based on the success of this pilot program, Adena applied and was named an SSO site.

Adena utilized the Centering Group Care (CGC) model (known as Centering Pregnancy in expectant mothers) for high-risk women, both with and without addiction. Women meet monthly and follow a standardized curriculum. For women with addiction, the program follows the monthly curriculum but they also meet three other weeks a month for additional, focused content. Blood pressure and weight is measured weekly, along with random drug screening and medical consultation with a physician when results indicate a need for additional care. Licensed prescribers provide the opiate addicted (OA) women with a Suboxone prescription weekly which they fill at the Adena pharmacy on their group care day. This coordination has promoted regular program attendance. If a woman misses her CP group, she must come for a urine screen before she is given her prescription.

For all women, SSO Adena provides additional supplementary information by connecting women to lactation consultants, Women Infants and Children (WIC), Baby and Me Tobacco Free, safe sleep, and Help Me Grow, while women attend their group meeting. Addicted women may also complete a case plan with Children's Services and be connected with the ADAMHS (Alcohol, Drug Addiction and Mental Health Services) Board.

Holzer Health System

Holzer Health system's intervention utilizes the Maternity Care Home Model (MaCH). After intake, clients are connected to various services via the patient navigator who is responsible for follow-up and coordination of referral services for all clients. Patient data is a mix of Electronic Medical Records and paper charting with the patient navigator tracking client referrals and follow-up. Staff describe the intervention as collaborative care with the patient navigator providing a "warm handoff" to referral services. Patients can access the navigator by cell phone at any time via voice or text message, though this service has been underutilized. At times, women will text and the navigator will have difficulty identifying the client since she does not store numbers due to PHI on the phone. The navigator visits and communicates with clients and providers to ensure enrolled women are receiving necessary services. A counselor assists women with needs related to housing, previous mental health diagnoses, and drug and alcohol abuse.

This is a pilot grant and is not sustainable without funding at this stage. The grant covers staff salaries and mileage. Practices provide no financial support for services provided. High-risk patients average 15 visits plus additional phone call follow-up. This is a 50% increase in prenatal visits covered by Medicaid basic care coverage. Practices are reimbursed based on services rendered not outcomes. Practices can bill Medicaid for an additional necessary visits but lactation, nutritionist and certain diagnostic testing must be covered by the grant funds. The program also provides for two post-partum visits (before 4 weeks and at 4-6 weeks) but Medicaid only reimburses for one. The $450 per client of grant funds do not cover the average cost gap per client.

Summa Health System

Summa Health System utilizes both the Maternity Care Home Model and Centering Group Care.

The MaCH model was implemented weekly during the typical high-risk clinic time for maternal and fetal medicine at the Women's Health Center at Akron City Hospital. Enrolled women come for their prenatal visit and receive care from a team of providers to meet their medical and social needs. These include a care coordinator, dietician, resident physician, legal aid, a behavioral health specialist, dental, family medicine physician, WIC and Jobs and Family Services staff. Childcare services are provided at the YMCA.

Summa's Centering Group Care occurred at Akron City Hospital (for opiated-addicted women) and Summa Barberton Hospital (for non-addicted, high-risk pregnant women). Women follow a prescribed curriculum together over the course of their pregnancy and have shared appointments with brief individual time with the provider. Lunch is provided. Summa's website states that Centering Group Care (CGC) has existed since 2006 with benefits that include: on-time appointments, opportunity to socialize with other expectant mothers, and convenience of one location for all appointments along with additional learning on topics related to goal setting, proper exercise, relaxation, nutrition, and breastfeeding tips.

The Summa catchment area has seen an increase in deliveries by opiate-addicted women from 25 in 2011 to a projected 200+ in 2015. While the Barberton CGC groups follow a prenatal schedule according to gestational age, the opiate-addicted CGC (OA-CGC) groups at Akron City meet every two weeks due to the need for additional support and a Subutex prescription to compliant women every 14 days. They otherwise follow the same Centering curriculum with add-ins specific to the population (e.g. how to keep your baby, what happens to a baby in withdrawal, shaken baby syndrome, safe sleep).

The Maternal-Fetal Medicine specialist along with residents complete the clinical part of the visit. Women meet as a group with the Care Coordinator and Nurse Case Manager. The OA-CGC program collaborates with addiction physicians and hopes to add an on-site addiction MD fellow to the program. For the OA-CGC, no children or support people are allowed due to security and space. Police are aware of the timing of centering for safety and security reasons.

All enrolled women (CGC and MaCH) receive a $10 Target card per visit (Target was selected since cigarettes are not sold there). Transportation is covered by Medicaid for prenatal visits. Those who drive are provided a parking pass at each visit. Completers receive additional incentives (e.g. cribs).

A care coordinator (CC) sees all women at every visit to make sure all medical and social needs are met. The CC follows up on unmet needs and makes sure that care coordination occurs with family medicine as well to encourage that all women have a primary care doctor for themselves and their child after the pregnancy and the program have ended. Approximately 30% of the women and babies are patients of Family Medicine.

For additional medical visits beyond standard prenatal care or additional ultrasound, SSO Summa provides transportation through Thomas Limousines Sedan Services since typical Medicaid transport providers require advance notice.

The Medicaid Technical Assistance and Policy Program (MEDTAPP) funding has been used to begin the MaCH model and jumpstart the CGC program again. The hope is that this pilot will help practitioners and residents to see the value in these models. These models could then be implemented in other specifically high-risk populations. If the practitioner feels supported by Summa and sees MaCH or CGC as adding value to standard care, then the model of care will continue. Staff shared that, based on Akron City Hospital's success with the CGC model, the Women's Health Clinic was interested in providing CGC for economically high-risk patients.

5 Quantitative Results

Southeast HUB (SE HUB)

The study population consisted of 244 SE HUB program participants, and 4,193 Medicaid-enrolled controls. The SE HUB participants were younger (mean age 23.3 vs 24.9, p< 0.001), a higher percentage were not married (81.1% vs 64.2%, p<.001), and had not finished high school (28.7% vs 19.2%, p< 0.001) compared to controls. A much higher percentage of SE HUB women also had claims indicating drug abuse (49.2% vs 26.0%, p< 0.001) or opiate abuse (22.5% vs 8.5%, p< 0.001), and more women indicated tobacco use during pregnancy (52.9% vs 38.3%, p< 0.001) compared to the control group. The descriptive analysis of the study population can be found in Table 5.1.

TABLE 5.1 DESCRIPTIVE ANALYSIS OF SE HUB STUDY POPULATION

	SE HUB		Control		
Characteristic	**N**	**%**	**N**	**%**	**p-value**
Total Subjects	244	100.0%	4,193	100.0%	
Race					0.102
Non-white	11	4.5%	111	2.6%	
White	233	95.5%	4,082	97.4%	
Marital status					< 0.001
Married	46	18.9%	1,499	35.8%	
Single, widowed, divorced	198	81.1%	2,694	64.2%	
Education					0.001
Less than high school	70	28.7%	803	19.2%	
High school	92	37.7%	1,701	40.6%	
Some college	81	33.2%	1,681	40.1%	
HMO vs FFS					0.090
FFS	6	2.5%	214	5.1%	
HMO	233	95.5%	3,974	94.8%	
Previous pre-term birth	16	6.6%	165	3.9%	0.064
Prior pre-term labor	50	20.5%	603	14.4%	0.012
Previous poor pregnancy outcome	9	3.7%	214	5.1%	0.449
Previous C-section	30	12.3%	557	13.3%	0.770
Pre-pregnancy hypertension	4	1.6%	87	2.1%	0.641
Pre-pregnancy diabetes	1	0.4%	23	0.5%	0.999
Gestational hypertension	13	5.3%	278	6.6%	0.506
Gestational diabetes	25	10.2%	290	6.9%	0.054
Drug addiction (including opiate)	120	49.2%	1,092	26.0%	<0.001
Opiate addiction	55	22.5%	355	8.5%	<0.001
Hepatitis C	12	4.9%	101	2.4%	0.032
Chlamydia	9	3.7%	130	3.1%	0.570
Tobacco use prior to pregnancy	150	61.5%	1,957	46.7%	< 0.001
Tobacco use during pregnancy	129	52.9%	1,608	38.3%	< 0.001
	Mean	**SD**	**Mean**	**SD**	**p-value**
Age	23.3	4.4	24.9	5.1	< 0.001
BMI	27.3	7.7	27.0	7.4	0.619

Note. Statistical tests were Fisher's exact test for categorical variables and t-test for continuous variables. BMI data was missing for 469 controls, and 44 cases. Education data missing 8 controls, 1 cases.

Before propensity score matching or risk-adjustment, the analysis showed no statistical difference between the SE HUB participants and the controls for any of the three primary outcomes: low birth weight, pre-term delivery, or maternal readmission postpartum. The SE HUB participants did have a higher risk of postpartum hemorrhage, infant admission to

the NICU, and a small for gestational age infant (Table 5.2). There was no statistically significant difference for the other secondary outcome measures of pre-term labor and Caesarean delivery.

TABLE 5.2 RISK RATIO OF SELECTED OUTCOMES IN SE HUB PARTICIPANTS COMPARED TO CONTROLS (BEFORE MATCHING)

Outcome Measure	Risk Ratio (95% CI)	p-value	Percentage with Outcome	
			SE HUB	Control
Primary				
Low birth weight (< 2500 g)	1.21 (0.81 - 1.81)	0.360	9.4%	7.8%
Pre-term delivery (< 37 weeks)	1.15 (0.78 - 1.69)	0.479	10.3%	8.9%
Maternal admission postpartum	0.77 (0.24 - 2.43)	0.655	1.2%	1.6%
Secondary				
Pre-term labor	1.13 (1.00 - 1.28)	0.052	52.5%	46.4%
Post-partum hemorrhage	1.81 (1.18 - 2.79)	0.007	8.6%	4.8%
C-section delivery	0.94 (0.76 - 1.15)	0.538	28.3%	30.2%
Admission to NICU	2.11 (1.39 - 3.19)	<.001	9.4%	4.5%
Small for gestational age	1.36 (1.03 - 1.79)	0.031	18.0%	13.3%

Note. Risk ratio and 95% confidence interval derived from a generalized linear model for a binary outcome with log link function.

All SE HUB participants were successfully matched to a comparable control within the specified caliper. After propensity score matching, the covariate balance improved in that no variable had a greater than 20% difference in the standardized mean between the two groups, and in fact all were 10% or less (See Appendix B, Figure B.1). Conditional logistic regression and paired t-tests revealed no significant difference in any categorical or continuous variables, respectively. The matching algorithm satisfied all three of Rubin's rules indicating the propensity score matching performed well in creating balance between cases and controls (Appendix B,Table B.1).

There was no significant difference in the risk of pre-term delivery, low birth weight, or maternal readmission between the SE HUB participants and controls after propensity score match adjustment (Table 5.3). There was also no significant difference in any of the secondary outcomes of interest including pre-term labor, post-partum hemorrhage, Caesarean delivery, NICU utilization, and small for gestational age status.

TABLE 5.3 RISK RATIO OF SELECTED OUTCOMES IN SE HUB PARTICIPANTS COMPARED TO CONTROLS (AFTER MATCHING)

Outcome Measure	Risk Ratio (95% CI)	p-value	Percentage with Outcome	
			SE HUB	Control
Primary				
Low birth weight (< 2500 g)	1.15 (0.65 - 2.03)	0.631	9.4%	8.2%
Pre-term delivery (< 37 weeks)	0.83 (0.49 - 1.40)	0.493	10.3%	12.3%
Maternal admission postpartum	1.00 (0.20 - 4.95)	0.999	1.2%	1.2%
Secondary				
Pre-term labor	1.02 (0.85 - 1.21)	0.859	52.5%	51.6%
Post-partum hemorrhage	1.11 (0.61 - 1.99)	0.739	8.6%	7.8%
C-section delivery	1.10 (0.83 - 1.45)	0.527	28.8%	25.8%
Admission to NICU	1.21 (0.68 - 2.15)	0.526	9.4%	7.8%
Small for gestational age	1.00 (0.69 - 1.45)	0.999	18.0%	18.0%

Note. Risk ratio and 95% confidence interval derived from GEE binomial regression model using robust standard errors, and associated p-value is derived from Wald Test. The frequency each outcome occurs is shown in the right side of the table with p-value from Fisher's exact test.

The number of women who participated in each pathway (i.e. program component) among those enrolled in the SE HUB are shown in Figure 5.1. Nearly all women were enrolled in the Pregnancy Pathway. The next most common pathways were the family planning and postpartum pathways, followed by the social service, and medical referral pathways. Other pathways were less common (< 20%) and are not shown. The completion rate for each varied from 39% (Pregnancy Pathway) to 57% (Social Service Pathway).

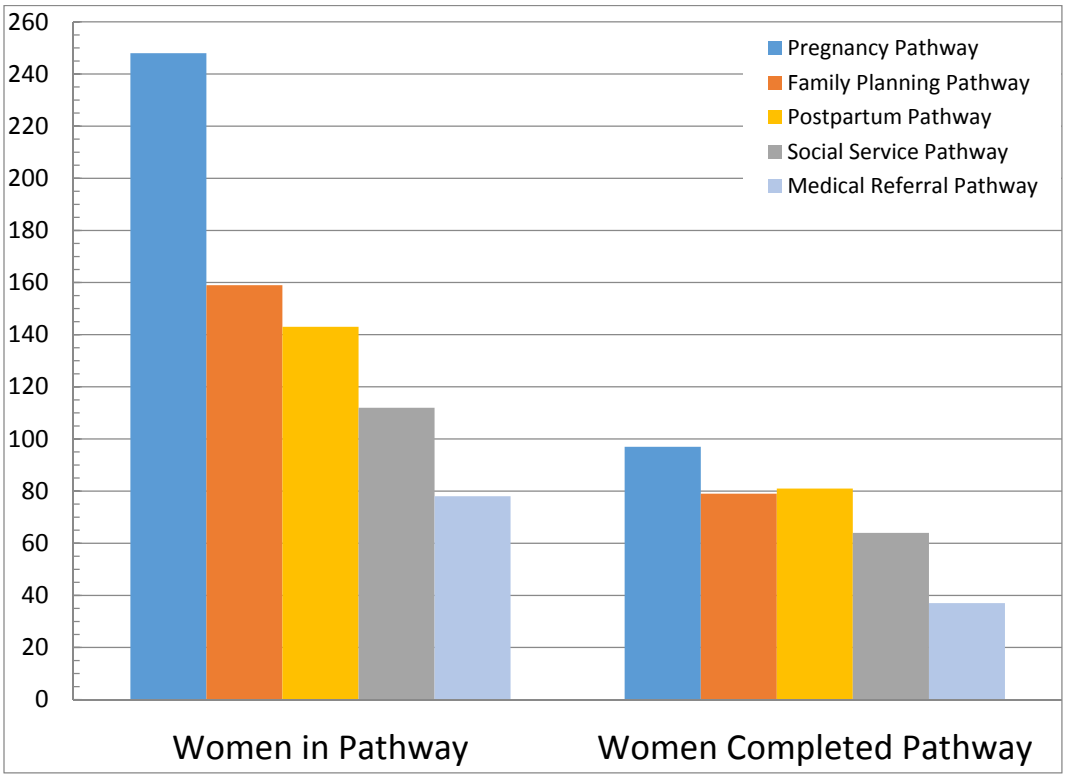

FIGURE 5.1 NUMBER OF SE HUB PARTICIPANTS ENROLLED AND PERCENTAGE COMPLETING EACH PATHWAY

Outcomes were not significantly different between women whom completed pathways and those whom did not (See Appendix B,Tables B.2-B.6).

Strong Start Ohio: Holzer Health System (Holzer)

The study population consisted of 325 Holzer program participants, and 1,263 Medicaid-enrolled controls. The groups were similar in terms of age and BMI. Compared to controls, a higher percentage of the Holzer participants were racial/ethnic minorities (7.4% vs 3.2%, p<.001). Holzer participants were more likely to have a history of pre-term labor (24.0% vs 18.9%, p=.04) and previous poor pregnancy outcomes (11.1% vs 6.1%, p<.001) compared to controls. Opiate abuse was lower among Holzer participants (9.8% vs 16.5%, p=.01), but non-opiate drug abuse was similar. Tobacco use was higher during pregnancy in the Holzer participants compared to controls (51.7% vs. 37.5%, p<.001). The descriptive analysis of the study population can be found in Table 5.4.

TABLE 5.4 HOLZER STUDY POPULATION BEFORE PROPENSITY SCORE MATCHING

	Holzer		Control		
Characteristic	**N**	**%**	**N**	**%**	**p-value**
Total Subjects	325	100.0%	1,263	100.0%	
Race					0.001
Non-white	24	7.4%	40	3.2%	
White	301	92.6%	1,223	96.8%	
Marital status					0.730
Married	108	33.2%	407	32.2%	
Single, widowed, divorced	217	66.8%	856	67.8%	

	Holzer		Control		
Characteristic	**N**	**%**	**N**	**%**	**p-value**
Education					0.083
Less than high school	78	24.0%	240	19.0%	
High school	134	41.2%	517	41.0%	
Some college	113	34.8%	504	40.0%	
HMO vs FFS					0.165
FFS	15	4.6%	38	3.0%	
HMO	310	95.4%	1,225	97.0%	
Previous pre-term birth	16	4.9%	87	6.9%	0.254
Prior pre-term labor	78	24.0%	239	18.9%	0.043
Previous poor pregnancy outcome	36	11.1%	77	6.1%	0.003
Previous C-section	28	8.6%	174	13.8%	0.012
Pre-pregnancy hypertension	3	0.9%	25	2.0%	0.243
Pre-pregnancy diabetes	1	0.3%	12	1.0%	0.486
Gestational hypertension	18	5.5%	91	7.2%	0.326
Gestational diabetes	25	7.7%	105	8.3%	0.821
Drug addiction (non-opiate)	45	13.9%	176	13.9%	0.999
Opiate addiction	32	9.8%	208	16.5%	0.002
Hepatitis C	15	4.6%	76	6.0%	0.422
Chlamydia	19	5.8%	31	2.5%	0.004
Tobacco use or dependence	168	51.7%	473	37.5%	< 0.001
Alcohol dependence or withdrawal	8	2.5%	29	2.3%	0.837
	Mean	**SD**	**Mean**	**SD**	**p-value**
Age	25.0	5.6	25.4	5.1	0.29
BMI	28.0	7.4	27.2	7.5	0.12

Note. Statistical tests were Fisher's exact test for categorical variables and t-test for continuous variables. BMI data was missing for 177 controls, and 18 cases. Education data missing 2 controls, 0 cases.

Before propensity score matching or any other risk-adjustment, the analysis showed that Holzer participants had 0.60 (0.35 – 1.04) times lower risk of low birth weight and 0.61 (0.37 – 1.01) times lower risk of pre-term delivery compared to controls. Holzer participants had a 1.19 (1.03 – 1.37) times higher risk of preterm labor. There was no statistical difference between the Holzer participants and the controls for any of the other primary or secondary outcomes: maternal readmission, postpartum hemorrhage, infant admission to the NICU, and small for gestational age status (Table 5.5).

TABLE 5.5 RISK RATIO OF SELECTED OUTCOMES IN HOLZER PARTICIPANTS COMPARED TO CONTROLS (BEFORE MATCHING)

Outcome Measure	Risk Ratio (95% CI)	p-value	Percentage with Outcome	
			Holzer	Control
Primary				
Low birth weight (< 2500 g)	0.60 (0.35 - 1.04)	0.067	4.3%	7.2%
Pre-term delivery (< 37 weeks)	0.61 (0.37 - 1.01)	0.052	5.2%	8.6%
Maternal admission postpartum	0.65 (0.19 - 2.19)	0.484	0.9%	1.4%
Secondary				
Pre-term labor	1.19 (1.03 - 1.37)	0.020	43.4%	36.6%
Post-partum hemorrhage	1.14 (0.70 - 1.85)	0.588	6.2%	5.4%
C-section delivery	0.95 (0.78 - 1.16)	0.612	27.1%	28.5%
Admission to NICU	0.71 (0.39 - 1.29)	0.259	3.7%	5.2%
Small for gestational age	0.81 (0.58 - 1.13)	0.221	11.4%	14.0%

Note. Risk ratio and 95% confidence interval derived from a generalized linear model for a binary outcome with log link function.

Of the 325 Holzer participants, 318 (98%) were successfully matched to a comparable control within the specified caliper. After propensity score matching, the covariate balance improved in that no variable had a greater than 20% difference in the standardized mean between the two groups, and only two (tobacco use and hepatitis C) were greater than 10% (Appendix B, Figure B.2). Conditional logistic regression and paired t-tests revealed no significant difference in any categorical or continuous variables, respectively. The matching algorithm satisfied all three of Rubin's rules indicating the propensity score matching performed well in creating balance between cases and controls (Appendix B, Table B.1).

After propensity score matching, the Holzer participants showed lower risk of low birth weight and pre-term delivery compared to controls; however it was no longer statistically significant (Table 5.6). There was no significant difference in any of the other outcomes of interest.

TABLE 5.6 RISK RATIO OF SELECTED OUTCOMES IN HOLZER PARTICIPANTS COMPARED TO CONTROLS (AFTER MATCHING)

Outcome Measure	Risk Ratio (95% CI)	p-value	Percentage with Outcome	
			Holzer	Control
Primary				
Low birth weight (< 2500 g)	0.70 (0.36 - 1.36)	0.296	4.4%	6.3%
Pre-term delivery (< 37 weeks)	0.77 (0.42 - 1.41)	0.399	5.4%	6.9%
Maternal admission postpartum	1.50 (0.25 - 8.98)	0.657	0.9%	0.6%
Secondary				
Pre-term labor	1.03 (0.86 - 1.24)	0.750	42.8%	41.5%
Post-partum hemorrhage	0.95 (0.52 - 1.76)	0.876	6.3%	6.6%
C-section delivery	1.06 (0.84 - 1.33)	0.608	27.0%	25.5%
Admission to NICU	0.92 (0.40 - 2.08)	0.835	3.5%	3.8%
Small for gestational age	0.77 (0.52 - 1.15)	0.205	11.6%	15.1%

Note. Risk ratio and 95% confidence interval derived from GEE binomial regression model using robust standard errors, and associated p-value is derived from Wald Test. The frequency each outcome occurs is shown in the right side of the table with p-value from Fisher's exact test.

Strong Start Ohio: Adena Health System (Adena)

The study population consisted of 68 Adena program participants and 2,707 Medicaid-enrolled controls. The groups were similar in terms of BMI, however Adena participants were on average 1.3 years older (26.6 vs 25.3, p=.048). Compared to controls, a higher percentage of the Adena participants were unmarried (80.9% vs 69.2%, p=<.001). Adena participants were more likely to have a history of pre-term labor (32.4% vs 18.3%, p=0.007). Opiate addiction (38.2% vs 11.3%, p<.001), non-opiate drug abuse (36.7% vs. 12.3%, p<.001), tobacco use during pregnancy (63.2% vs. 40.7%, p<.001), alcohol consumption (8.8% vs. 2.8%, p=.013) and were all higher among Adena participants compared to controls. The descriptive analysis of the study population can be found in Table 5.7.

TABLE 5.7 ADENA STUDY POPULATION BEFORE PROPENSITY SCORE MATCHING

	Adena		Control		
Characteristic	**N**	**%**	**N**	**%**	**p-value**
Total Subjects	68	100.0%	2,707	100.0%	
Race					0.325
Non-white	4	5.9%	101	3.7%	
White	64	94.1%	2,606	96.3%	
Marital status					0.045
Married	13	19.1%	835	30.8%	
Single, widowed, divorced	55	80.9%	1,872	69.2%	
Education					0.311
Less than high school	18	26.5%	541	20.1%	
High school	31	45.6%	1,207	44.8%	
Some college	19	27.9%	947	35.1%	
HMO vs FFS					0.849
FFS	2	2.9%	91	3.4%	
HMO	66	97.1%	2,616	96.6%	
Previous pre-term birth	5	7.4%	195	7.2%	0.815
Prior pre-term labor	22	32.4%	495	18.3%	0.007
Previous poor pregnancy outcome	2	2.9%	164	6.1%	0.434
Previous C-section	10	14.7%	372	13.7%	0.858
Pre-pregnancy hypertension	3	4.4%	53	2.0%	0.156
Pre-pregnancy diabetes	0	0.0%	26	1.0%	0.999
Gestational hypertension	5	7.4%	177	6.5%	0.802
Gestational diabetes	9	13.2%	162	6.0%	0.014
Drug addiction (non-opiate)	25	36.7%	331	12.3%	<.001
Opiate addiction	26	38.2%	306	11.3%	<.001
Hepatitis C	11	16.2%	121	4.5%	<.001
Chlamydia	2	2.9%	92	3.4%	0.999
Tobacco use or dependence	43	63.2%	1,101	40.7%	<.001
Alcohol dependence or withdrawal	6	8.8%	75	2.8%	0.013
	Mean	**SD**	**Mean**	**SD**	**p-value**
Age	26.6	5.7	25.3	5.1	0.048
BMI	27.5	7.6	27.0	7.3	0.609

Note. Statistical tests were Fisher's exact test for categorical variables and t-test for continuous variables. BMI data was missing for 146 controls, and 6 cases. Education data missing 12 controls, 0 cases.

Before propensity score matching or any other risk-adjustment, the analysis showed no statistical difference between the Adena participants and the controls for any of the three primary outcomes: low birth weight, pre-term delivery, or maternal readmission postpartum (Table 5.8). The Adena participants did have a 2.81 (1.36 – 5.83) times higher risk of postpartum hemorrhage and 1.90 (0.97 – 3.69) times higher risk of pre-term labor compared to controls. There were no statistically significant differences for the other secondary outcome measures.

TABLE 5.8 RISK RATIO OF SELECTED OUTCOMES IN ADENA PARTICIPANTS COMPARED TO CONTROLS (BEFORE MATCHING)

Outcome Measure	Risk Ratio (95% CI)	p-value	Percentage with Outcome	
			Adena	Control
Primary				
Low birth weight (< 2500 g)	1.18 (0.54 -2.56)	0.675	8.8%	7.5%
Pre-term delivery (< 37 weeks)	0.69 (0.26 - 1.79)	0.442	5.9%	8.6%
Maternal admission postpartum	1.08 (0.15 - 7.73)	0.942	1.5%	1.4%

Outcome Measure	Risk Ratio (95% CI)	p-value	Percentage with Outcome	
			Adena	Control
Secondary				
Pre-term labor	1.84 (1.45 - 2.34)	<.001	51.5%	28.0%
Post-partum hemorrhage	2.81 (1.36 - 5.83)	0.005	10.3%	3.7%
C-section delivery	1.30 (0.95 - 1.79)	0.102	37.3%	28.7%
Admission to NICU	1.90 (0.97 - 3.69)	0.060	11.8%	6.2%
Small for gestational age	0.72 (0.33 - 1.56)	0.411	8.8%	12.2%

Note. Risk ratio and 95% confidence interval derived from a generalized linear model for a binary outcome with log link function.

Of the 68 Adena participants, 67 (99%) were successfully matched to a comparable control within the specified caliper. After propensity score matching, the covariate balance improved in that only one variable (chlamydia) had a greater than 20% difference in the standardized mean between the two groups (See Appendix B, Figure B.3). Conditional logistic regression and paired t-tests revealed no significant difference in any categorical or continuous variables, respectively. The matching algorithm satisfied all three of Rubin's rules indicating the propensity score matching performed well in creating balance between cases and controls (Appendix B, Table B.1).

After propensity score matching, the Adena participants still showed higher risk of pre-term labor (RR: 1.79 [1.18 – 2.71]) and post-partum hemorrhage (2.33 [0.60 – 9.02]) compared to controls, however the latter was not statistically significant (Table 5.9). The maternal readmission relative risk was not calculable due to 0% having the outcome among controls, but a difference in proportion test showed it was not significant (1.5% vs 0%, p=0.999). The birth outcome of small for gestational age was less likely in the Adena participants (RR: 0.40 [0.16 – 0.98]). There was no significant difference in any of the other outcomes of interest.

TABLE 5.9 RISK RATIO OF SELECTED OUTCOMES IN ADENA PARTICIPANTS COMPARED TO CONTROLS (AFTER MATCHING)

Outcome Measure	Risk Ratio (95% CI)	p-value	Percentage with Outcome	
			Adena	Control
Primary				
Low birth weight (< 2500 g)	0.67 (0.24 - 1.87)	0.442	9.0%	13.4%
Pre-term delivery (< 37 weeks)	0.67 (0.22 - 2.07)	0.483	6.0%	9.0%
Maternal admission postpartum	---	---	1.5%	0.0%
Secondary				
Pre-term labor	1.79 (1.18 - 2.71)	0.006	50.8%	28.4%
Post-partum hemorrhage	2.33 (0.60 - 9.02)	0.220	10.5%	4.5%
C-section delivery	0.85 (0.61 - 1.19)	0.351	37.9%	44.8%
Admission to NICU	1.40 (0.49 - 3.99)	0.529	10.5%	7.5%
Small for gestational age	0.40 (0.16 - 0.98)	0.046	9.0%	22.4%

Note. Risk ratio and 95% confidence interval derived from GEE binomial regression model using robust standard errors, and associated p-value is derived from Wald Test. The frequency each outcome occurs is shown in the right side of the table with p-value from Fisher's exact test.

Strong Start Ohio: Summa Health System (Summa CGC)

The study population consisted of 45 Summa CGC program participants, and 5,540 Medicaid-enrolled controls. The groups were similar in terms of age, however BMI was lower in the Summa participants (27.1 vs 25.0, p=.031). Compared to controls, a higher percentage of the Summa CGC participants were white (84.4% vs 62.2%, p=0.002). Summa CGC participants were more likely to have a history of pre-term labor (53.3% vs 25.9%, p<.001) and to have hepatitis C (26.7% vs. 1.3%, p<.001). Opiate addiction (55.6% vs 4.3%, p<.001), non-opiate drug abuse (48.9% vs. 10.9%, p<.001), and tobacco use during pregnancy (71.1% vs. 36.2%, p<.001) were all higher among Summa CGC participants compared to controls. The descriptive analysis of the study population can be found in Table 5.10.

TABLE 5.10 SUMMA CGC STUDY POPULATION BEFORE PROPENSITY SCORE MATCHING

	Summa CGC		Control		
Characteristic	**N**	**%**	**N**	**%**	**p-value**
Total Subjects	45	100.0%	5,540	100.0%	
Race					0.002
Non-white	7	15.6%	2,094	37.8%	
White	38	84.4%	3,446	62.2%	
Marital status					0.154
Married	6	13.3%	1,287	23.2%	
Single, widowed, divorced	39	86.7%	4,253	76.8%	
Education					0.847
Less than high school	9	20.0%	1,195	21.6%	
High school	17	37.8%	1,945	35.1%	
Some college	17	37.8%	2,358	42.6%	
HMO vs FFS					0.403
FFS	0	0.0%	174	3.1%	
HMO	45	100.0%	5,366	96.8%	
Previous pre-term birth	2	4.4%	231	4.2%	0.712
Prior pre-term labor	24	53.3%	1,435	25.9%	< 0.001
Previous poor pregnancy outcome	2	4.4%	133	2.4%	0.297
Previous C-section	5	11.1%	757	13.7%	0.619
Pre-pregnancy hypertension	1	2.2%	128	2.3%	0.999
Pre-pregnancy diabetes	0	0.0%	64	1.2%	0.999
Gestational hypertension	4	8.9%	351	6.3%	0.530
Gestational diabetes	1	2.2%	281	5.1%	0.727
Drug addiction, non-opiate	22	48.9%	609	10.9%	< 0.001
Opiate addiction	25	55.6%	238	4.3%	< 0.001
Hepatitis C	12	26.7%	73	1.3%	< 0.001
Chlamydia	1	2.2%	271	4.9%	0.725
Tobacco use or dependence	32	71.1%	2,007	36.2%	< 0.001
Alcohol dependence or withdrawal	2	4.4%	196	3.5%	0.673
	Mean	**SD**	**Mean**	**SD**	**p-value**
Age	26.8	4.0	26.1	5.4	0.252
BMI	25.0	6.2	27.1	7.3	0.031

Note. Statistical tests were Fisher's exact test for categorical variables and t-test for continuous variables. BMI data was missing for 178 controls, and 2 cases. Education data missing 42 controls, 2 cases.

Before propensity score matching or any other risk-adjustment, the analysis showed that Summa CGC participants had 2.41 (1.39 – 4.19) times higher risk of low birth weight, 2.26 (1.30 – 3.93) times higher risk of pre-term delivery, and 4.04 (1.02 - 16.01) times higher risk of maternal readmission compared to controls. Summa participants also had a 1.55 (1.17 – 2.04) times higher risk of preterm labor, and 3.56 (2.04 – 6.20) times higher risk of NICU admission. There was no statistical difference between the Summa CGC participants and the controls for any of the other secondary outcomes (Table 5.11).

TABLE 5.11 RISK RATIO OF SELECTED OUTCOMES IN SUMMA CGC PARTICIPANTS COMPARED TO CONTROLS (BEFORE MATCHING)

Outcome Measure	Risk Ratio (95% CI)	p-value	Percentage with Outcome	
			Summa CGC	Control
Primary				
Low birthweight (< 2500 g)	2.41 (1.39 - 4.19)	0.002	22.2%	9.2%
Pre-term delivery (< 37 weeks)	2.26 (1.30 - 3.93)	0.004	22.2%	9.8%
Maternal admission postpartum	4.04 (1.02 -16.01)	0.047	4.4%	1.1%
Secondary				
Pre-term labor	1.55 (1.17 - 2.04)	0.002	53.3%	34.5%
Post-partum hemorrhage	0.71 (0.10 - 4.94)	0.727	2.2%	3.1%
C-section delivery	1.16 (0.77 - 1.76)	0.473	33.3%	28.6%
Admission to NICU	3.56 (2.04 - 6.20)	<.001	22.2%	6.3%
Small for gestational age	0.64 (0.25 - 1.64)	0.357	8.9%	13.8%

Note. Risk ratio and 95% confidence interval derived from a generalized linear model for a binary outcome with log link function.

All 45 Summa CGC participants were successfully matched to a comparable control within the specified caliper. After propensity score matching, the covariate balance improved but five variables had a greater than 20% difference in the standardized mean between the two groups (Appendix B, Figure B.4). Conditional logistic regression and paired t-tests revealed no significant difference in any categorical or continuous variables, respectively. The matching algorithm satisfied all three of Rubin's rules indicating the propensity score matching performed well in creating balance between cases and controls (Appendix B, Table B.1).

After propensity score matching, the Summa CGC participants had 2.00 (0.74 – 5.43) times higher risk of low birth weight and 1.43 (0.61 – 3.32) times higher risk of pre-term delivery, but results were not significant (Table 5.12). The maternal readmission relative risk was not calculable due to 0% having the outcome among controls, but a difference in proportion test showed it was not significant (4.4% vs 0%, p=0.49). There was no significant difference in any of the other outcomes of interest.

TABLE 5.12 RISK RATIO OF SELECTED OUTCOMES IN SUMMA CGC PARTICIPANTS COMPARED TO CONTROLS (AFTER MATCHING)

Outcome Measure	Risk Ratio (95% CI)	p-value	Percentage with Outcome	
			Summa CGC	Control
Primary				
Low birth weight (< 2500 g)	2.00 (0.74 - 5.43)	0.174	22.2 %	11.1%
Pre-term delivery (< 37 weeks)	1.43 (0.61 - 3.32)	0.408	22.2%	15.6%
Maternal admission postpartum	---	---	4.4%	0.0 %
Secondary				
Pre-term labor	1.41 (0.92 - 2.16)	0.110	53.3%	37.8%
Post-partum hemorrhage	1.00 (0.06 -15.99)	0.999	2.2%	2.2%
C-section delivery	1.36 (0.67 - 2.79)	0.396	33.3%	24.4%
Admission to NICU	2.00 (0.80 - 5.02)	0.139	22.2%	11.1%
Small for gestational age	0.50 (0.19 - 1.33)	0.166	8.9%	17.8%

Note. Risk ratio and 95% confidence interval derived from GEE binomial regression model using robust standard errors, and associated p-value is derived from Wald Test. The frequency each outcome occurs is shown in the right side of the table with p-value from Fisher's exact test.

Strong Start Ohio: Summa Health System (Summa MaCH)

The study population consisted of 41 Summa MaCH program participants, and 5,540 Medicaid-enrolled controls. The Summa MaCH participants were older (28.6 vs 26.1, p=0.004) and had a higher mean BMI (30.0 vs 27.1, p=.05). Compared to controls, a higher percentage of the Summa MaCH participants were racial/ethnic minorities (53.7% vs 37.8%, p=.037). Summa MaCH participants were more likely to have a history of pre-term labor (68.3% vs 25.9%, p<.001), and a history of pre-term birth (29.3% vs 4.2%, p<.001). Other risk factors that were higher in the Summa MaCH participants included pre-pregnancy hypertension (9.8% vs. 2.3%, p=.015) and pre-pregnancy diabetes (9.8% vs 1.2%, p=.002). Opiate addiction (12.2% vs 4.3%, p=.031), non-opiate drug abuse (34.2% vs. 10.9%, p<.001), and tobacco use during pregnancy (63.4% vs. 36.2%, p<.001) were all higher among Summa MaCH participants compared to controls. The descriptive analysis of the study population can be found in Table 5.13.

TABLE 5.13 SUMMA MACH STUDY POPULATION BEFORE PROPENSITY SCORE MATCHING

	Summa MaCH		Control		
Characteristic	**N**	**%**	**N**	**%**	**p-value**
Total Subjects	41	100.0%	5,540	100.0%	
Race					0.037
Non-white	22	53.7%	2,094	37.8%	
White	19	46.3%	3,446	62.2%	
Marital status					0.853
Married	10	24.4%	1,287	23.2%	
Single, widowed, divorced	31	75.6%	4,253	76.8%	
Education					0.540
Less than high school	11	27.5%	1,195	21.7%	
High school	15	37.5%	1,945	35.4%	
Some college	14	35.0%	2,358	42.9%	
HMO vs FFS					0.639
FFS	0	0.0%	174	3.1%	
HMO	41	100.0%	5,366	96.9%	
Previous pre-term birth	12	29.3%	231	4.2%	< 0.001
Prior pre-term labor	28	68.3%	1,435	25.9%	< 0.001
Previous poor pregnancy outcome	1	2.4%	133	2.4%	0.999
Previous C-section	10	24.4%	757	13.7%	0.064
Pre-pregnancy hypertension	4	9.8%	128	2.3%	0.015
Pre-pregnancy diabetes	4	9.8%	64	1.2%	0.002
Gestational hypertension	1	2.4%	351	6.3%	0.516
Gestational diabetes	7	17.1%	281	5.1%	0.005
Drug addiction, non-opiate	14	34.2%	606	10.9%	<0.001
Opiate addiction	5	12.2%	238	4.3%	0.031
Hepatitis C	2	4.9%	73	1.3%	0.104
Chlamydia	7	2.4%	271	4.9%	0.722
Tobacco use or dependence	26	63.4%	2,007	36.2%	<0.001
Alcohol dependence or withdrawal	6	14.6%	196	3.5%	0.003
	Mean	**SD**	**Mean**	**SD**	**p-value**
Age	28.6	5.3	26.1	5.4	0.004
BMI	30.0	8.9	27.1	7.3	0.052

Note. Statistical tests were Fisher's exact test for categorical variables and t-test for continuous variables. BMI data was missing for 178 controls, and 2 cases. Education data missing 42 controls, 1 cases.

Before propensity score matching or any other risk-adjustment, the analysis showed that Summa MaCH participants had 2.64 (1.53 - 4.56) times higher risk of low birth weight and 2.98 (1.84 - 4.83) times higher risk of pre-term delivery compared to controls. Summa MaCH participants also had a 1.91 (1.53 - 2.39) times higher risk of preterm labor, 3.11 (1.21

– 7.97) times higher risk of post-partum hemorrhage, and 3.12 (1.66 - 5.87) times higher risk of NICU admission. There was no statistical difference between the Summa MaCH participants and the controls for the other outcomes (Table 5.14).

TABLE 5.14 RISK RATIO OF SELECTED OUTCOMES IN SUMMA MACH PARTICIPANTS COMPARED TO CONTROLS (BEFORE MATCHING)

Outcome Measure	Risk Ratio (95% CI)	p-value	Percentage with Outcome	
			Summa MaCH	Control
Primary				
Low birth weight (< 2500 g)	2.64 (1.53 - 4.56)	<.001	24.4%	9.2%
Pre-term delivery (< 37 weeks)	2.98 (1.84 - 4.83)	<.001	29.3%	9.2%
Maternal admission postpartum	2.22 (0.31 -15.60)	0.425	2.4%	1.1%
Secondary				
Pre-term labor	1.91 (1.53 - 2.39)	<.001	65.9%	34.5%
Post-partum hemorrhage	3.11 (1.21 - 7.97)	0.018	9.8%	3.1%
C-section delivery	1.36 (0.93 - 2.00)	0.115	39.0%	28.6%
Admission to NICU	3.12 (1.66 - 5.87)	<.001	19.5%	6.3%
Small for gestational age	1.06 (0.50 - 2.23)	0.878	14.6%	13.8%

Note. Risk ratio and 95% confidence interval derived from a generalized linear model for a binary outcome with log link function.

All 41 Summa MaCH participants were successfully matched to a comparable control within the specified caliper. After propensity score matching, the covariate balance improved in that only four variables had a greater than 20% difference in the standardized mean between the two groups (Appendix C, Figure C.5). Conditional logistic regression and paired t-tests revealed no significant difference in any categorical or continuous variables, respectively. The matching algorithm satisfied all three of Rubin's rules indicating the propensity score matching performed well in creating balance between cases and controls (Appendix B, Table B.1).

After propensity score matching, the Summa MaCH participants had a 2.00 (0.90 - 4.45) times higher risk of pre-term delivery, however it was not statistically significant (Table 5.15). This may be due to the loss in power that occurs after matching since most controls are dropped from the analysis. The risk of pre-term labor was higher among Summa MaCH participants (RR: 1.80 [1.16 - 2.78]). There was no significant difference in any of the other outcomes of interest.

TABLE 5.15 RISK RATIO OF SELECTED OUTCOMES IN SUMMA MACH PARTICIPANTS COMPARED TO CONTROLS (AFTER MATCHING)

Outcome Measure	Risk Ratio (95% CI)	p-value	Percentage with Outcome	
			Summa MaCH	Control
Primary				
Low birth weight (< 2500 g)	1.43 (0.61 - 3.32)	0.408	24.4%	17.1%
Pre-term delivery (< 37 weeks)	2.00 (0.90 - 4.45)	0.090	29.3%	14.6%
Maternal admission postpartum	0.50 (0.13 - 2.00)	0.327	2.4%	4.9%
Secondary				
Pre-term labor	1.80 (1.16 - 2.78)	0.008	65.9%	36.6%
Post-partum hemorrhage	2.00 (0.37 -10.92)	0.423	9.8%	4.9%
C-section delivery	1.14 (0.62 - 2.11)	0.670	39.0%	34.2%
Admission to NICU	1.14 (0.48 - 2.72)	0.763	19.5%	17.1%
Small for gestational age	2.00 (0.59 - 6.79)	0.266	14.6%	7.3%

Note. Risk ratio and 95% confidence interval derived from GEE binomial regression model using robust standard errors, and associated p-value is derived from Wald Test. The frequency each outcome occurs is shown in the right side of the table with p-value from Fisher's exact test.

Pooled Analyses

Results of the analysis examining the three primary outcomes by model of care found no significant differences between participants and controls for any of the three programs. (Table 5.16).

TABLE 5.16 ANALYSES OF OUTCOMES BY MODEL OF CARE

Low Birth weight

Program	RR	Lower 95%CI	Upper 95 % CI	p-value
Maternity Care Home	0.89	0.54	1.48	0.66
Centering Group Care	1.14	0.57	2.29	0.71
Pathways HUB	1.15	0.65	2.03	0.63

Relative risks did not differ among the programs (p = 0.76)

Pre-term Delivery

Program	RR	Lower 95%CI	Upper 95 % CI	p-value
Maternity Care Home	1.04	0.65	1.64	0.88
Centering Group Care	1.08	0.55	2.09	0.83
Pathways HUB	0.83	0.49	1.40	0.49

Relative risks did not differ among the programs (p = 0.77)

Maternal Readmission

Program	RR	Lower 95%CI	Upper 95 % CI	p-value
Maternity Care Home	1.00	0.30	3.32	0.99
Centering Group Care*	---	---	---	---
Pathways HUB	1.00	0.20	4.95	0.99

Relative risks did not differ among the programs (p = 0.999)

Note. *RR for Centering Group Care model could not be calculated because there were zero events in the matched controls.

A meta-analysis of the primary outcomes pooling across all program sites (Appendix B, Table B.7) found no significant differences between participants and controls. These analyses also did not find significant heterogeneity in relative risks among sites for any of the three primary outcomes, although power to detect heterogeneity was not high due to the small number of sites.

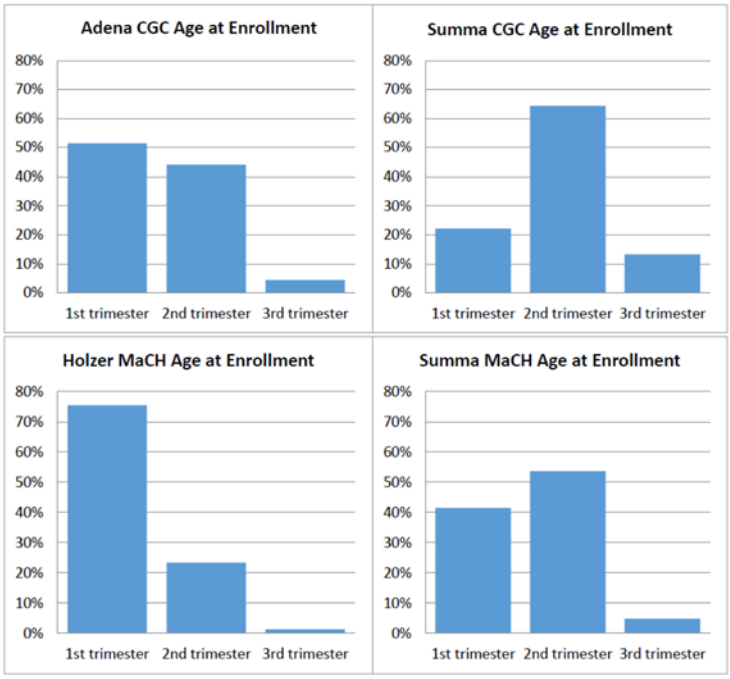

FIGURE 5.2 SSO TRIMESTER OF PROGRAM ENROLLMENT

TABLE 5.17 SSO, NUMBER OF PROGRAM SESSIONS ATTENDED

	Holzer MaCH		Summa MaCH		Adena CGC		Summa CGC	
Mean, SD	12.8	3.0	13.6	3.0	5.6	1.7	7.1	2.4
Median, IQR	13	11 - 15	14	12 - 16	5	5 - 7	8	6 - 9

Results for selected variables from the SSO programmatic data are shown in Figure 5.2 and Table 5.17. Holzer and Adena enrolled the majority of participants in the first trimester (75% and 52%). The number of sessions attended was similar between programs using similar models of care (Holzer MaCH vs Summa MaCH and Adena CGC vs Summa CGC).

6 Qualitative Interview Results

Semi-structured phone with 17 staff and 59 program participants were conducted to understand the experiences of staff and participants in one of four maternal and infant health initiatives across the State of Ohio (Southeast Ohio Community HUB / Pathways, Strong Start Ohio Summa Akron, Strong Start Ohio Holzer Athens, Strong Start Ohio Adena Chillicothe). Only 13 participants contacted indicated they were not interested in an interview. Interviews ranged in length from less than 10 minutes to more than 30 minutes with the majority lasting approximately 15 minutes. All interviews were completed between June 2015 and March 2016. Program staff and participant responses are summarized below by interview question. Participant responses are additionally described thematically.

Program Staff

What do you think works well for enrolling and retaining the women you serve?

In terms of enrollment, staff talked about the importance of cultivating collaborative relationships with other entities providing services in the community, in addition to medical professionals, in order to reach women as early as possible in their pregnancies, ideally the first trimester. Active recruitment of women who may not appear for prenatal care until late in their pregnancies was seen as essential. Staff said that collaborative relationships with medical professionals and community agencies were also helpful when program participants stopped coming to their maternity home or CenteringPregnancy appointments. For example, staff talked about the transient nature of many of their clients and how it was often difficult to keep in touch. When staff had not seen a client in a while, they could reach out to other professionals in the community who may be working with the same woman for help to reengage her in the program.

Program staff reported that the individualized attention participants received from consistent staff interaction, as well as the positive relationships they formed with other service providers and clients, contributed to participant retention. However, staff from all four programs said that retaining participants was difficult. The services they delivered, which included comprehensive education and access to needed resources, had to meet clients' needs to keep them engaged. For programs serving an opiate-addicted population, staff felt that women continued to return in part because of the Subutex prescriptions they received from addiction fellows at each appointment. At least one program offered gift cards to participants at each appointment. Staff reported that they felt participants really needed the gift cards and therefore, they continued to participate for them. Unfortunately, staff reported that simply offering helpful services was not always enough to keep participants coming back. Programs had to address all the other challenges in participants' lives that acted as barriers to continued enrollment.

Lastly, several staff members with whom we spoke talked about the need to do more to retain women after they delivered their babies. They suggested breastfeeding support groups or parenting classes would be helpful. We discuss this issue in greater detail in the next section.

In your opinion, how well has your program integrated health and social services? Are there particular services that are still needed at the table?

Across sites, staff reported that care coordination was best accomplished when social service partners were seamlessly integrated into the maternal and infant health programs in a 'one-stop-shopping' fashion. Relying on participants to follow-up with referrals on their own increased the likelihood that they would not get the help they needed given limited access to transportation, erratic employment schedules, and general stressful life circumstances. One program provided office space for WIC at the same location as the prenatal care program; participants could sign up for WIC after their CenteringPregnancy appointment. The WIC office was open to all women, not just those in the program, which encouraged women from the community to see the hospital as not just a place to visit when sick. Other CenteringPregnancy programs invited social service partners to present during the educational component of each session.

Staff also talked about the importance of matching participants' needs with staff skill and expertise. With limited time and resources, it was important to quickly assess and determine what types of problems could be addressed by program staff and what types of problems needed a more specific level of expertise (e.g., legal aid).

In terms of programming still needed at the table, staff reported a great need for program services to extend beyond delivery. For all programs, the goal was to connect mom with postpartum services delivered by other agencies (e.g., Help Me Grow) after she delivered her baby. However, staff talked about how the postpartum period is an inopportune time for forming new relationships; women may be struggling with postpartum depression or consumed by caring for a newborn. They are often not interested in establishing a new relationship with a 'stranger.' Therefore, program staff felt it would be better to retain moms through the postpartum period, as they have already established trusting relationships. Handing participants over to new agencies increases the likelihood that participants will drop out.

Staff reported great difficulty getting women to quit smoking during their pregnancies. Several staff members reported that they needed better programming for smoking cessation. While they had a hotline to refer, not all women had a phone they could use or cell phone minutes for the call. Staff from several programs also talked about the need for an on-site lactation consultant.

I wanted to learn more about barriers (logistical, staffing, etc.) your program faced or is currently facing. To what extent do you think your program meets current demand for services?

Staff from each site talked about multiple barriers that impacted their ability to meet participants' needs. At the most basic level, staff talked about the importance of ensuring that 'all players' needed to implement the program (e.g., hospital administration, floor nurses, reception, other medical providers in the community, etc.) have bought into the prenatal care model and are willing to collaborate. Staff from two programs said they spent a great deal of time convincing hospital administration and OBGYNs about the need for the program. They said that the culture at their hospitals was one of competition, where medical providers feared CenteringPregnancy would 'take away their clients.' One program administrator we interviewed talked about how cost savings estimates helped to sway reluctant hospital administrators, as did securing respected community figures to champion the program.

According to program staff, participants also need to be open and willing to participate. Though rare, program staff talked about women who declined to enroll in CenteringPregnancy or who dropped out after the first or second session. Relatedly, staff reported that participants brought a variety of issues with them to the programs that interfered with program delivery and uptake if not immediately addressed. Before being able to address women's prenatal care needs, staff had to address the other, more immediate issues (e.g., homelessness, pending eviction, unemployment, lack of transportation, etc.). These needs had to be met in order for women to be able to become fully engaged in the program.

Staff spoke about other barriers including a lack of resources, capacity, time, and funding. Some staff felt that they did not always have accessible resources for participants. For example, an absence of smoking cessation programming was mentioned several times. In terms of capacity and funding barriers, staff from one program reported that some participants required a nurse-level of care coordination given their level of need, but that nurse-level care was not available because of its high price tag. Staff serving rural communities reported that inconsistent information and staff training was a significant barrier. They saw a need for greater collaboration among medical professionals in pediatrics, OBGYN, and labor and delivery. In rural areas, a lack of transportation was also reported as a problem. For example, staff said that in some cases women lived close to a satellite facility where they could receive traditional prenatal care, but not CenteringPregnancy. While staff thought these women could benefit from the group model, they could not travel to the main campus to participate in the group. Or, Medicaid transport did not provide enough rides given the frequency with which they needed to see their medical provider.

Staff from one program talked about a funding limitation that they felt interfered with their ability to serve participants more intensely. Staff from the SE HUB said that moms could not be enrolled in their Pathways program and Help Me Grow (HMG) home visiting at the same time because it was considered a duplication of service. Staff reported that this regulation was particularly problematic when participants delivered and Pathways services ended. Staff felt that HMG engagement would have been higher if they could have introduced participants to their home visitor before the baby arrived, as women were often struggling with postpartum depression, sleep deprivation, or new motherhood and uninterested in forming a relationship with a stranger.

Lastly, across programs, staff reported a great need for their services. They were enthusiastic about expanding and serving more women in their communities.

In general, would you say you're satisfied with the way your program operates?

All but one staff member with whom we spoke was satisfied with the way their program operated. The one individual who expressed reservations was concerned that CenteringPregnancy did not afford the medical professional enough time with medically high-risk pregnant women. She felt that women with high-risk health conditions were better served by a maternity home model of care where the medical professional could spend more time with the mother and thoroughly review her medical history and present status.

I want to talk about the benefits of your program to the women you serve. What do you think women get out of being in your program? What is the greatest unmet need among the participants you serve?

In terms of the benefits of participation, staff across programs talked about how women gained self-esteem, self-confidence, and a sense of empowerment. Importantly, staff felt that giving women the confidence to use their voice to speak up and advocate for themselves and their children had long-lasting effects that would produce positive outcomes far beyond those associated with their current pregnancy. According to staff, a significant portion of the women they served carried considerable trauma histories. They had been witness to and/or victims of violence and abuse; many used drugs and alcohol, perhaps to cope with their trauma or mental health issues. In general, their clients had low levels of education and were used to just doing what they were told. Staff felt that both CenteringPregnancy and Maternity Care Home models contributed to participants' confidence because they facilitated the development of trusting, respectful, and unconditionally supportive relationships. Staff said that the women appreciated having a safe, supportive place where they could ask any question about anything and not be judged. In the CenteringPregnancy groups, staff reported that women encouraged and supported one another; for many women, this was the first time in their lives that they'd developed healthy relationships.

The staff members with whom we spoke also talked about how the programs helped raise awareness of and access to services in the community that participants desperately needed. Programs operating in rural communities served many isolated women living in extreme poverty. There was great need for healthy food, stable and affordable housing, and employment. Staff helped participants navigate the systems governing these resources.

We heard about three very significant unmet needs: access to long-acting, reversible contraceptives, education, and mental health services. Women don't have internet access and don't have transportation to libraries.

What words of advice would you offer to a new program just starting up? What else do you think is needed to improve birth outcomes for mothers and babies in your community?

It was very apparent that staff had learned a lot in the process of implementing their maternal and infant care program. Most importantly, staff encouraged other communities that were considering whether to adopt these programs to thoughtfully consider the local context in which it would operate. Doing so required thinking about several key aspects of implementation. According to the staff we interviewed, hiring the 'right' people to manage and facilitate these programs was important. The 'right' person for the job depended on the local context in which the program was being implemented. In rural communities, staff said it was very important for staff to be 'locals,' or insiders, who hailed from the very communities they were going to serve. Staff said participants were generally skeptical and distrustful of 'outsiders.' For programs serving an opiate-addicted population, staff reported that it was necessary to hire nonjudgmental, open-minded individuals who would treat participants with the utmost respect. These staff members had to be willing to welcome participants back to the programs if they relapsed.

Staff also suggested that communities considering implementing one of these programs needed to thoughtfully consider whether participants would be able to get to the program site. In rural communities with little or no public transportation, some staff members felt that home visiting programs would have been more appropriate.

In addition, staff recommended thinking through the extent to which other medical providers and public service agencies are willing to support the program. Because these partners are critical for successful recruitment and enrollment, it is important that they are willing to collaborate. Having the 'right' players at the table based on the population you are trying to serve, in large part, determines the success of the program. In addition, programs working with opiate-addicted clients need addiction specialists involved in program delivery.

Another important consideration when developing a program is the availability of ample financial resources to compensate staff for the services they deliver. New programs should consider whether they have sufficient financial resources to hire support staff. One position staff said they wished they had was an in-house, highly trained mental health professional. As staff pointed out, primary care providers do not typically have enough time to attend to participants' mental health needs in addition to their prenatal needs.

Lastly, staff reiterated that in order to better improve birth outcomes, it would be ideal if the program could extend longer post-pregnancy particularly for women with a history of drug addiction.

Program Participants

Participants from each of the maternal and infant health programs surveyed spoke in overwhelmingly positive terms about their experiences in the programs. Across programs, women talked primarily about the instrumental and emotional support they received as well as the significant amount of learning that occurred. Below, we summarize participant responses to each of the eight questions posed.

Why did you decide to participate in this program? What issues were you dealing with? What did you need help with?

Women reported joining the prenatal care programs for a variety of reasons, all of which were related to the desire to reduce stress and anxiety around pregnancy. The majority of women reported joining a program because they were looking for information and resources. In terms of the information sought, women reported wanting to learn about breastfeeding, labor and delivery, hospital policies, current 'best practices,' how to maintain a healthy pregnancy, nutrition, vaccines, and how to be a mom (or a 'better' mom). A few women spoke about high-risk pregnancies (either previous or current) and participated to learn about how to manage their chronic conditions (e.g., diabetes, high blood pressure). Women also reported participating because they "realized they didn't have it all together" and needed help accessing resources related to housing, transportation, food, employment, and education. For these women, programs with on-site legal assistance proved particularly helpful as one-stop-shopping increased their ability to and likelihood of accessing services.

Surveyed participants also frequently reported the need for emotional support and connection to other women. Many women said they decided to participate because they did not work outside the home, had male partners who did not offer emotional support, were single, or were surrounded by family and 'friends' who were not leading healthy lifestyles. This was particularly true for women who were opiate-addicted at the time of their pregnancy. For opiate-addicted women, the CenteringPregnancy model of care offered an opportunity to connect with other women in 'the same situation;' women who 'got it,' and understood where they were coming from.

Reasons for joining the maternal and infant care programs, as reported above, exist on a continuum of need from continuous or ongoing to situational or temporary. The continuous needs existed before the woman became pregnant and, in many instances, would extend beyond her pregnancy. For example, some women saw their CenteringPregnancy appointments as a "mom's day out" that provided needed social interaction and connection. As one mother stated, *"I'm a stay-at-home mom, so it was just nice to have a little bit of company."* Another woman said, *"…um mainly, it was just someone to talk to that wasn't, you know my four-year-old son or my boyfriend, you know."* These ongoing needs, which sparked women's willingness to participate and were overwhelming met while engaged in the programs, likely exist, perhaps even to a larger extent, after the baby is born. For women who joined the program because of continuous needs, engagement in service post-delivery is an important continuation of care, a point to which we return later. Other women reported joining for temporary or situational needs. These women joined because they were pregnant and wanted to learn something very specific related to their pregnancy or becoming a mother. As one mother put it*, "I just wanted things to be*

right." These women were looking for something more concrete, a resource to connect with, a book to read about breastfeeding, or a person to explain how to care for a newborn baby.

Situating women's reasons for joining the programs along this continuum of need suggests there could be an assessment of and plan for the resources that would be needed at the end of the program to continue to support family wellbeing. As we discuss later, some women reported that they would have liked to have continued their participation in CenteringPregnancy after delivering their baby. Though many women were offered Help Me Grow home visiting once the program ended and they had delivered their babies, relatively few reported engaging with this service. While right for some, the implication is that a one-sized-fits-all approach fails to acknowledge the unique circumstances of each woman's life and incorporate her specific wants going forward.

What was your experience with program staff?

Participants spoke very highly of program staff. They spoke highly of staff members especially their interpersonal skills, helpfulness, and willingness to 'go above and beyond' for clients. In terms of interpersonal skills, participants reported that staff were friendly, easy to talk to, good listeners, warm, gentle, caring, nice, supportive, relatable, thoughtful, understanding, sympathetic, nonjudgmental, respectful, and positive. Staff's willingness to listen was mentioned frequently. For example, one woman said, *"I mean, they wouldn't just talk. They would listen to you."* And another reported, *"I felt like people actually listened to me and that's a big issue in my life, I feel like nobody listens, you know."*

Woman also talked extensively about how helpful staff were. Participants clearly appreciated staff's resourcefulness and their ability to get clients the services they needed. Women reported how staff helped them set up appointments and arranged transportation to and from prenatal care. Women found staff incredibly knowledgeable and willing to ask others when they themselves did not have the answer. One woman dealing with a high-risk pregnancy stated:

> *I was having twins and they helped me cope with that and I was on bed rest. I was upset I had to quit my job and couldn't make my own money. [The program] gave me something to do to keep my mind off having to stay home all the time.*

Lastly, participants talked about how staff were willing to 'go above and beyond' for them and that they were not just 'there for a paycheck.' One mother said:

> *When I had her [daughter], they all came to visit me. I actually had her on Mother's Day and they brought in flowers and everything. It was great! They were great!*

Another mother talked about how staff would call her to check up on her or just to see how things were going. Participants really felt that staff "had their best interests at heart." Participants said some staff gave out their personal cell phone numbers so women could call at any time with anything. Perhaps most importantly, 'they followed through on what they said they would do.' As one woman stated*:*

> *They [staff] treated you as a best friend, one of their own, their child. That was especially helpful because my mom lived 500 miles away. They treated you with respect. They never looked down on you.*

What did you find most useful about participating in this program?

When asked about what aspects of the program women found most useful, participants referred to the information and education offered, the resources provided, and the social support, responses which were consistent with why women said

they decided to participate in the programs in the first place. The connection between why women joined and what they found most useful suggests that many women found these programs relevant to their needs.

In terms of the women who cited the information and education offered as the most useful aspect of the program, many talked specifically about learning about postpartum depression, birth control, breastfeeding, baby care basics, and healthy nutrition. Even women who had other children talked about how helpful they found the information. For example, one mother said, *"I am a parent of three. This was my third pregnancy. But, still with the new information coming, it was very helpful in making sure that I did everything correctly, to the new and improved methods."* Another woman commented, *"They did a lot of important stuff…I wish I would have known the first time around."*

Women who found the resources most useful talked about the healthy snacks offered, transportation assistance, the gift cards provided at each session, legal aid to assist with housing, pamphlets and books, and an onsite WIC office (at Summa). In addition to resources, many of the women cited social support as a key aspect of the service, even women who participated in the Maternity Care Home model as opposed to the group-based CenteringPregnancy approach. These women again talked about their relationship to staff and how much they appreciated their advice, calming presence, and nonjudgmental nature. As one woman said:

> *When I've been down as low as I have and my family went from literally living out of a car to where we are today that is the greatest thing you could have, someone you hardly know, but actually cares and worries about you. That's an amazing feeling.*

In some cases, being around other women was the very reason for joining the program, in others it was an unexpected, but welcomed benefit. Among the opiate-addicted population, some women openly discussed social support in tandem with their challenges with addiction before and during pregnancy:

> *Honestly, I think that what was most helpful for me was just the females that were there and being able to express myself, and it was almost like an AA meeting but for pregnant women. So I think, you know, because you go through a lot when you're in recovery and you go through a lot when you're pregnant and going to have a kid and it was nice to be able to have them…*

In some instances we asked women to think about whether and how their pregnancy might have been different had they not participated in these programs. About half the women interviewed said that they did not think that their pregnancy would have been different. Among those who noted a potential difference, the majority talked about feeling more anxious, nervous, or unaware of what to expect. As one mother put it:

> *I think I would have been more stressed out. I think it released a lot of stress and stuff and to see people to um, my baby's dad is not in the picture and I was kind of going at it alone and to have the Centering girls, some of them have been through that or worse, it kind of helped me put stuff in my life into perspective.*

Again, this women's experience was consistent with why many women said they joined the programs in the first place, to ease anxiety around pregnancy. A handful of women cited specific negative outcomes that they reported might have occurred had they not participated. These included going to jail, buying drugs off the streets, being depressed, having a drug dependent baby, and losing rent money. One mother said:

Um, I probably would've had a drug-addicted baby that was taken from me. I probably would've been in jail. I know because I've been there and I know what can happen because it's happened to me before.

Is there anything that would have made your program experience better?

The vast majority of participants reported an overall positive program experience and said that there really was not anything that could have made their program experience better. A lesser number or women provided suggestions focused on improving program delivery. Recommendations emerged around staff improvement, the length of the program, and resources offered throughout the course of the program. In regard to staff improvement, one participant explained how some staff members came across as less than knowledgeable, *"…maybe if the teachers were more informed. For some of them were the first time conducting the class, so they were learning as we were learning."*

Participants who spoke to the length of the program mentioned wanting to start the program earlier in their pregnancy and continue programming post-birth. As one woman stated:

It would be nice if there was still a program after the babies were born. It could really help the parents. The program should be focused on the parents after the babies are born. Have to try to meet parents' needs as well. I didn't have post-partum but many women do and don't recognize the signs. If they had someone who could bring this up in a nice way that would be helpful.

Another participant mentioned issues with the schedule of the group program and suggested changing meeting times to meet the needs of those who could not attend all sessions.

A number of women also remarked that the availability of specific resources would have enhanced their program experience. This included both material resources (i.e. diapers, gift cards) and resources for improving their future (education, housing).

Lastly, a few women who participated in the CenteringPregnancy model of care reported a lack of privacy during the belly checks and would have preferred to have been in a private room rather than behind a screen in one large room during that portion of the class. In addition, two women in the opiate-addicted CenteringPregnancy program had concerns about the Subutex medication they received. One woman reported that she left the program early and stopped taking her dose of medication because she did not want her baby to be born opiate-dependent and she felt like the staff did not seem concerned by this. On the other hand, another woman felt she was being weaned off the medication too quickly and she was concerned she might relapse because of it. Clearly, for opiate-addicted pregnant women, medication regimentation is a complex issue that likely requires significant conversation with a medical team to determine what is best for each woman.

Did you have any needs that the program wasn't able to meet?

The majority of participants reported that the programs met all of their needs. Participants stated that due to the nature of the wrap-around services that were provided, they received help in many ways. As one participant said, *"I mean they helped me with anything I needed help with."* Another participant said:

I don't recall there being anything specific that the program wasn't able to address or guide me in the right direction. If they couldn't specifically address it they'd find help for me. You know, I think it is well-rounded.

A few participants said it would have been helpful if the programs provided more material resources, such as diapers, clothes, baby wipes, or gift cards. As one mother stated, *"Diapers and wipes and stuff like that, I mean, that's always helpful for a mother."* Among women who mentioned getting gift cards for attending sessions, all reported using the gift cards to purchase diapers.

In general, are you happy you participated in the program?

All of the women interviewed stated that they were happy they participated in the programs and that they would (or already had) recommended the program to a friend. Additionally, many women said that if they were pregnant again, they would want to participate in the same or a similar program. The very high rate of positive response to the program and the willingness to recommend the program to others further demonstrates the ability to meet women's needs and provide support through the challenges of pregnancy.

Is there anything you need right now to maintain your health and your baby's health and wellness?

When participants were asked if they currently needed anything to maintain their own health or their child's health and wellbeing, most stated they had no current needs. We suspect this is due to the fact that we interviewed women long after they delivered their babies and completed these programs. Had we asked this question within the first weeks of caring for their newborns, we think we would have heard a greater need for ongoing material, instrumental, and social support. Some women, however, did report needs and these ranged considerably. A few women mentioned needing material goods such as diapers and books to read to their children. One woman stated, *"A couple sacks of hundred dollar bills"* would be helpful. One woman said she needed a place to live. Another reported:

> *We live in a trailer, um, and we're actually buying the trailer, so everything's our responsibility if something breaks or whatever. But, the windows in the trailer, almost all of them are broken, so a lot of them have duct tape over them and the one in the kitchen has plastic on it year round. We need help getting windows and doors.*

Several other women talked about the need for social and emotional support. While many women were involved in Help Me Grow (HMG) after they delivered their babies, others indicated that they would have liked to participate in something, but not HMG. For example, one woman reported a negative experience with HMG for her older child, another woman said a friend had a bad experience with the home visiting program, and another woman gave it a try but found them to be 'too persistent.' One woman who was interested in HMG said her full-time job made it impossible to stay engaged after she returned to work. One respondent who was not interested in HMG said she would have wanted to participate in a breastfeeding support group. In speaking with staff from each site, we heard that some but not all sites did offer a breastfeeding support group but that they were not well attended.

Is there anything else you would like to share about your experience in the program?

When asked whether there was anything else they would like to share about their program experience, the overwhelming majority of women reiterated that they had a very positive experience. Some women said they were grateful such programs exist and hope they expand to serve more women. As one woman said, *"I wish the program was bigger. We need more people to help and more people hired."* Another woman reiterated that her pregnancy *"would have been a lot more difficult without them guiding me through everything."*

Thematic Analysis

Next, we considered participants' interview responses in their entirety rather than question by question. A holistic, more comprehensive lens allowed for the emergence of overarching themes that transcended individual questions and interviews. What emerged was the notion, in some cases, of pregnancy as a transformational experience in a woman's life that can present an opportunity for change. This theme is best illustrated by the following excerpt from an interview with a woman who participated in CenteringPregnancy. When asked why she joined the program, she said:

> *To be honest, I have been addicted. I have been using opiates off and on since I was a freshman at high school. I had a son prior to having this son here and I had him almost 4 years before and I was still using. I wasn't all the way, um, I didn't feel like I had it together so I went through an adoption agency and adopted him out and it was a really hard decision but I knew my life on the streets. I knew that I wasn't ready to change and a child would have changed me and I knew that. Whenever I got pregnant [this most recent time], I knew there was something different in me. You know. So I talked to [my doctor] and told her that I knew I was pregnant. And I told her that the pain pills in my system wasn't prescribed and I was using and she said she could help me out. And that's how I got into the group.*

This woman's story, comparing and contrasting a previous pregnancy that resulted in adoption with her most recent pregnancy for which she participated in CenteringPregnancy, illustrates the transformational moment pregnancy can, but does not always, provide. While this example is perhaps the most impactful, the essence of it was conveyed across programs by multiple women.

Two patterns emerged once women enrolled in the programs: either they had a list of specific issues they needed help with or they really did not know what they needed. The following interview excerpts illustrate the latter pattern:

> *The only plan I had if I didn't go into that program was me having her early and me having to sit in the hospital. I'm really glad that they got to me before I could go further in my pregnancy without knowing I was high-risk. There was a lot of things I didn't know that I should have known a long time ago. Like about the baby's weight, what the baby eats, and how to hold the baby. And about stress management and stuff like that. A lot of those things I didn't know. They taught me every time I went there.*

Once women enrolled in the programs, the services offered had to be helpful and match defined needs (when those existed) in order for a relationship between the provider and participant to begin. For many women, prenatal care was neither their first, nor most urgent, perceived need. If staff were able to meet women's needs, trust began to develop. In the safety of a trusting, supportive relationship, many women began to develop their sense of confidence as mothers, the very thing they were looking for when they joined the program. Recall from our summary of results for Question 1, that women joined the programs to reduce stress and anxiety around pregnancy. Through the provision of information and resources in the context of a safe and nurturing relationship, many women began to feel more confident in their abilities to care for a baby.

Yet, the majority of women still needed support when the programs ended. Unfortunately, the warm hand-off to Help Me Grow after women delivered their babies was unsuccessful in many instances. We think this may be because many women were not interested in forming new relationships with 'strangers' in the weeks following the birth of a new child, an

incredibly stressful period of time. It might be fruitful to consider extending relationships between new mothers and prenatal care staff for several months after delivery, or to nurture the development of a new relationship well before women deliver.

Though this larger developmental process was occurring between staff and participants, we also heard about substantial adult development within women who participated in these programs, which, in a sense, mirrored the rapid physical development that was occurring for their unborn baby. When women discovered they were pregnant, a process of readying for the baby began. This typically started with the desire to gain knowledge and resources to ease the stress and anxiety of the unknown or create a more stable, secure environment in which to welcome the new baby. After securing this immediate need, women began to form new relationships, often their first healthy relationships in life. Through those relationships and their internalization of becoming a mother emerged a redefined sense of self.

7 Discussion

This statewide evaluation of maternal and infant health programs in Ohio demonstrated several key features among the programs individually and as a whole.

Successful enrollment of high-risk pregnant women

The level of risk among the targeted population for poor birth outcomes is high. The women enrolled in the programs, regardless of program site, structure or model all demonstrated higher likelihoods of well-known factors associated with undesirable birth outcomes than the general population of women in the program catchment areas. This would suggest that the individual programs did indeed target some of the most vulnerable women and children in their areas. Of note however, as demonstrated by our propensity score matching, despite effectively targeting some of the high-risk women in the areas, many remained. As a result, we were easily able to identify other high-risk women in the population, suggesting that an at-need population still exists. Qualitative interviews with program staff appear to support this notion, as many emphasized the high degree of at risk women in their program catchment areas- both those served and unserved.

Given the high number of risk factors noted among program participants, in particular the opiate addicted women, a need seems to exist for further resources related to behavioral health and addiction. Among the evaluated programs the incidence of opiate addition was as high as 20-50% of enrolled women. For programs serving an opiate-addicted population, detox management via Suboxone or another medication is an additional complexity that staff and participants must negotiate together and revisit throughout the duration of program involvement and beyond.

Improved experiences with pregnancy and access to needed resources

The programs we evaluated provided the majority of women with whom we spoke with much more than 'just' prenatal care. Despite this fact, the quantitative analysis did not demonstrate significant differences either between programs in outcomes or between participants and matched controls. Participants however cited both the learning components as well as the friendships the programs afforded. The programs helped at risk women navigate the complicated bureaucracies governing health, education, housing, employment and social systems, systems which offer important safety net services to families during difficult times.

Interestingly, though not necessarily surprisingly, while the mode or model of prenatal care delivery dominates in the research literature, participants spoke less about program structure and more about the consistency and quality of program staff. While some participants did talk about activities they particularly enjoyed or aspects of program structure that they disliked, comments regarding the personal interactions between staff and other participants were far more prevalent. Given the extensive trauma histories carried by the women we interviewed (for which we have only anecdotal information), it is understandable that relationships would offer the greatest opportunity for healing and transformation. Therefore, regardless of program model, staff must be able to develop and facilitate positive, trusting human interactions within the confines of prescribed operations.

Among other identified areas of need for high-risk women was access to care. Despite Medicaid coverage, a gap still exists in these women being able to access health services even while enrolled in programs designed to facilitate better access to care. Staff and participants stressed the need for better assistance with basic needs such as transportation to receive services, prenatal care or to fulfill basic needs such as access to diapers, formula or medications. Individual medical issues such as hypertension or diabetes mellitus, in addition to increased health needs during pregnancy accentuate these transportation needs. Women living in rural areas were particularly vulnerable to transportation issues according to program staff and required a great deal of time and energy that may be better spent.

The rich nature of the qualitative data presented in this evaluation on participant and staff experiences in MIH programs in Ohio are not without limitations, most notably the nature of the sample and the time lag between program participation and data collection. While the goal was never to sample an entirely representative selection of participants, the relatively small, convenience sample likely represents some but certainly not all of what we would have heard had we drawn a larger, representative sample. In addition, participants were asked to reflect on an experience that occurred potentially several

years ago and many noted that they could not recall the specific details. These limitations suggest a degree of caution when considering the largely positive experiences collected in this report. In addition, nearly a third of respondents called to volunteer for the interview. These women most likely represent a group who despite a potential time lag, have had non-characteristic experiences with the program most likely highly positive.

Unclear impact on measured health outcomes for mothers and babies

In this evaluation, we were unable to provide in depth analysis of an important downstream effect of maternal health and efficacy of the programs- the ongoing health of the child. Due to both the nature of the maternal-child linking process, as well as the relatively short follow-up period, only a few short-term outcomes could be assessed. These outcomes, such as prematurity and low birth weight may be better indicators of maternal pre-pregnancy health than of the pregnancy period. In addition, the timing and dosage of exposure to maternal and infant health (MIH) programs was difficult to measure and unlikely to intervene on pre-existing health conditions and social determinants of health that were much more deep seated. A life course approach to health would suggest that the foundations of health and disease are laid at critical points of development including the fetal life. The infants would therefore constitute an important cohort of children to follow after the program interventions are completed. Participants emphasized the continued need for services for themselves and their children beyond the delivery/postpartum period. Although a handoff was initiated with many of the programs, according to participants this was not enough and a need still existed for services afterwards.

The quantitative analysis did not suggest a benefit for the women who participated in the MIH programs. Overall, the linked data from the birth certificates and claims data demonstrated no appreciable difference in the pre-specified outcomes we analyzed. However, we recognize that an absence of effect may be due to multiple factors. First, our sample size was incredibly low. Programs evaluated had at most several hundred individuals to assess. While we anticipated some difficulty in demonstrating differences, issues related to data lag further lessened the statistical power of our analysis. As programs all encountered slow enrollment, the ability to collect postpartum data in the timeframe of this evaluation was limited to participants who delivered by September 2015. So, although the program may have enrolled their intended number of women, we were unable to evaluate them all.

As previously mentioned, the short, transitory nature of these funded programs presents a limitation for evaluating the effectiveness of MIH programs intended to make an impact on key issues such as postpartum health, prematurity and infant mortality. Many of the programs found startup to be a much longer and more difficult process than they intended. Staff noted that their ability to actually 'do' what was intended during the length of the funding period was challenging. These sentiments are in line with the research suggesting that these maternal child health issues are trans-generational and entrenched in the social determinants of health. Pregnancy, while a potentially transformative stage, is short in the context of overall health. Many of the issues that made women eligible for these programs, such as high-risk medical conditions or behavioral health/addiction were present long before their first interactions with program staff. As such it is not surprising that we were unable to see statistically significant differences in outcomes in the period of these funded projects. However, this may also suggest that other metrics may perform better when evaluating MIH programs as the qualitative analysis suggested. Programs such as the IMIH program appear to have improved maternal and child health in Lucas County; however, their program has been functioning for nearly 10 years.

Lessons learned & recommendations

The results of this evaluation demonstrate the need for practical, meaningful and standardized metrics built into any future MIH program. One of the most common themes we heard from staff during site visits and interviews was the challenges related to the data collection software. Variables collected were non-standardized and data was unable to be easily retrieved to ensure data integrity. Even amongst the SSO programs, which did collect standardized data, the programmatic data was only modestly informative. Many of the variables collected could be obtained from other sources more reliably, such as birth certificate or claims data. Of particular interest would be the collection of variables that allow for evaluation of the process by which the programs operated and their fidelity to the intended model. For the Pathways programs, there are recommended process measures from the certification body that could be collected and standardized, as well as suggested database software (Rockville Institute, 2016; Zeigler, 2016). There is a clear need however for some

adaptability to data collection that must inherently be built into the programs. Data monitoring for completeness, quality and usefulness should be performed at regular intervals. Any changes to data collection should be undertaken after a careful consideration of the potential impact on future ability to interpret these results.

Clarity in the implementation process and process measures would provide better insight into the efficiency and cost effectiveness of MIH programs. In addition, clarity in the program protocols allows for the ability to disseminate best practices and lessons learned and replicate successes. A clearer description of how individual projects adhere to the program model would make the evaluation process more straightforward. Specifically, we recommend that all programs construct a logic model to illustrate how the specific aims of the programs fit into the contextual nature of the community.

Short term funding of maternal and infant health projects may not be the most strategic use of public resources. As was discussed in the qualitative analysis, program start up and initial enrollment were a struggle for all of the programs. The majority of time and monies were spent in the initial establishment of the programs, enrollment was slow and many of the programs needed more time to reach their target enrollment numbers. These delays in program initiation and participant enrollment reduced the number of women in each program and weakened the conclusions that can be drawn from this evaluation. The quantitative analyses did not demonstrate a reduction in any of the primary outcomes of low birth weight, preterm delivery, or maternal readmission. It should be noted that the number of women enrolled in each program was not sufficient to allow this evaluation to identify small but potentially important impacts of the programs. Even when the programs are aggregated together the number enrolled remained too small to allow an effective evaluation. Thousands of women enrolled over longer periods of time including the intra-pregnancy interval would have been needed to demonstrate an impact on these outcomes. Future evaluations of MIH programs should be conducted on larger scale projects with more established histories such as the IMIH program that might be expected to see meaningful changes in key outcomes for Ohio such as preterm birth, low birth weight and infant mortality.

While fidelity to an evidence-based, outcome driven model to improve maternal-infant health is important, just as important are the particular needs of the community which it will ultimately serve. The semi-structured interviews demonstrated that both program staff and participants found participation in these enhanced prenatal care projects to be beneficial. Regardless of the program approach each was successful in connecting women with additional resources to address underlying social determinants of health. The participants and staff emphasized the importance of meeting the needs of the women in the catchment areas, such as those with special needs such as opiate addiction. Neither of the models of MIH care that we evaluated demonstrated a superiority over the others- each program served the individual needs of its community. Additionally, the geographic structure and community resources may make a certain model of care more or less successful in meeting the high-risk women's needs. For example, a CenteringPregnancy model may have difficulty recruiting and retaining patients in rural areas where distances between providers and participants are great and available transportation is sparse. However, a Pathways model may not be the most efficient delivery of care in some urban areas where there are larger numbers of participants in a smaller geographic area who have access to transportation. Although, a cost analysis was not possible in this study, issues such as the cost to operate a particular MIH model and the sustainability in a community should play a role in determining which program is best.

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Program Specific Secondary Resources

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Summa IRB application.

9 Appendices

Appendix A - Probabilistic Matching Protocol for Medicaid Claims to Birth Certificates

Updated 05/2015

OSU-GRC uses a public domain SAS-based software application for record linkage. The application, called The Link King, was developed at Washington State's Division of Alcohol and Substance Abuse and draws on a probabilistic algorithm developed by MEDSTAT for the Substance Abuse and Mental Health Services Administration. Testing of the linkage process suggests that The Link King produces claim-level match rates that compare favorably with match results from custom-designed linkage software.

OSU-GRC begins with an annual file of Medicaid babies and then use the software to match Ohio birth records for the same year to the Medicaid babies, resulting in a linked file including the baby's Medicaid ID and birth certificate number. Similarly, an annual file of Medicaid mothers are matched to Ohio birth records to produce a linked file for mothers. A common birth record number will then be used to link the results for babies to the results for mothers, creating a master table of all available identifiers, which may include the birth record number, the baby's Medicaid ID, and the mother's Medicaid ID. OSU-GRC uses first name, middle name, last name, gender, date of birth, race/ethnicity, and residential zip code to perform the matching process.

Data provided by the Ohio Department of Health (ODH) will be individually linked to maternal and infant Medicaid claims, encounter, and eligibility data using a variety of reliable linking indicators that may include but are not limited to: medical record number, delivery date, and maternal name, date of birth and race. Linkages will be further iterated by other socio-demographic variables provided through the vital statistics information.

The reliable core personal identifiers used in the initial linkage between the vital statistics datasets and Medicaid administrative data are commonly called the "match key" (Gomatam, Carter, Ariet, & Mitchell, 2002). The probabilistic linkage process will utilize a stepwise deterministic strategy (SDS) in which a first-pass comparison will link a subset of personal identifiers specified in the match key between datasets that meet a critical positive probability threshold of a true positive link between datasets, and any residual or duplicate comparisons that do not meet or exceed the probability threshold will be excluded until the next comparison of a new subset of personal identifiers (Gomatam, Carter, Ariet, & Mitchell, 2002; Blakely & Salmond, 2002).

The current manual process involves visual examination of 100% of the Link-Plus matches which have propensity scores below a critical positive score threshold. There are typically less than 2000 matches that have to be checked manually on a population size of approximately 60,000 Medicaid births. The largest number of these questionable matches is when the maiden name of the mother is the surname on Medicaid eligibility, and the married name is the surname on birth certificate data. Investigators visually compare fields in the datasets that are not being used in the probabilistic match to supplement the matching process. This would include data elements that are in both datasets, such as address, date of last menses, and birth weight. Upon multiple iterations of the probabilistic linkage process, the Medicaid and vital statistics datasets should be linked with reasonable accuracy.

Appendix B. Additional Quantitative Materials

TABLE B.1 ASSESSMENT OF PROPENSITY SCORE MATCHING USING RUBIN'S RULES

	Rule #1	Rule #2	Rule #3: Residuals Variance Ratios				
	Mean Diff.	Var. Ratio	<0.50	0.50 - 0.80	0.80 - 1.25	1.25 - 2.0	>2.0
SE HUB	-0.001	0.996	0%	10%	70%	20%	0%
Holzer	0.002	1.006	0%	10%	75%	10%	5%
Adena	0.000	1.001	5%	15%	60%	15%	5%
Summa CGC	0.000	1.002	15%	30%	45%	0%	10%
Summa MaCH	0.000	1.000	10%	15%	50%	15%	10%

Rubin (2001) suggested three tests to assess the appropriateness of regression-style models for the adjusted population comparisons. Rule #1 assesses whether the difference in means of the linear propensity scores across groups is near zero. Rule #2 assesses whether the variances in linear propensity scores across groups is similar (so that the variance ratio is near 1). Rule #3 involves regressing each individual covariate on the linear propensity score, and ensuring that the resulting regression residuals have similar variance across the treatment groups.

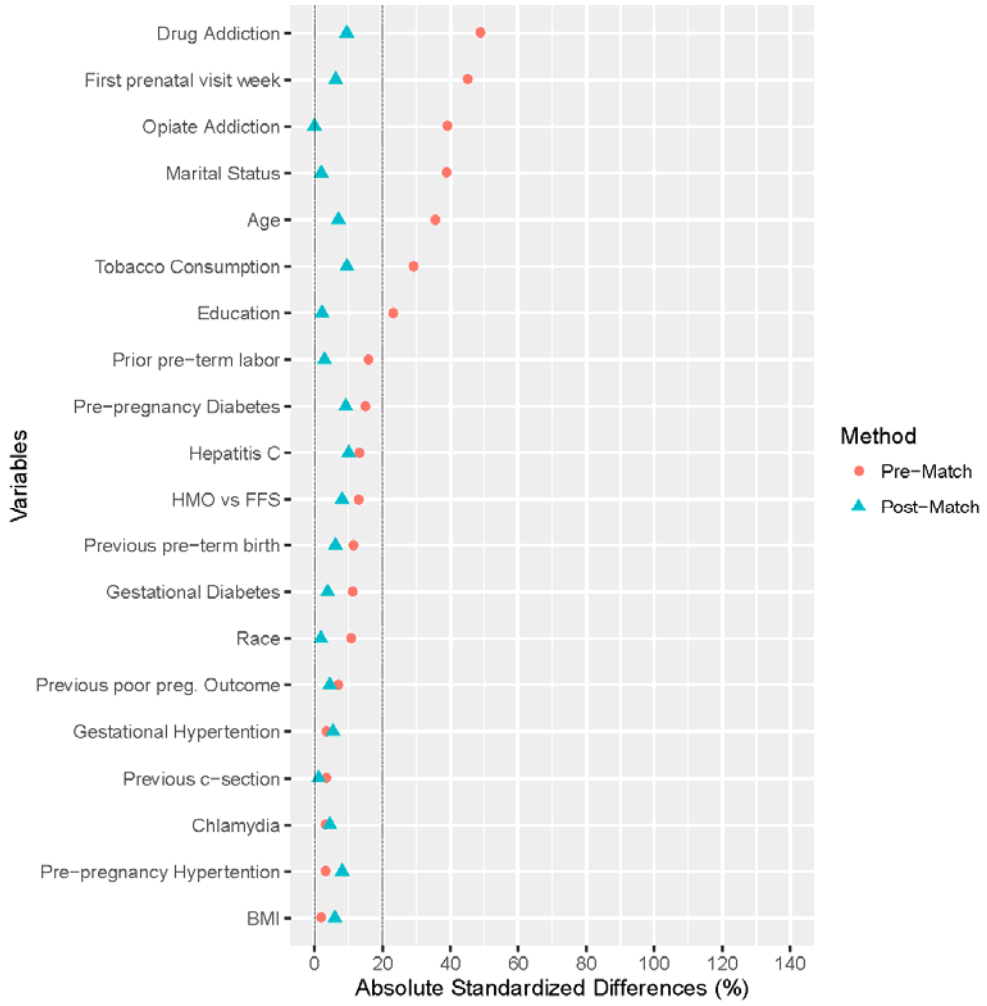

FIGURE B. 1 COVARIATE BALANCE BEFORE AND AFTER PROPENSITY SCORE MATCHING - SE HUB

Figure assesses the covariate balance between SE HUB participants and controls before and after propensity score matching. An absolute standardized mean difference score of <20% is considered to be trivial.

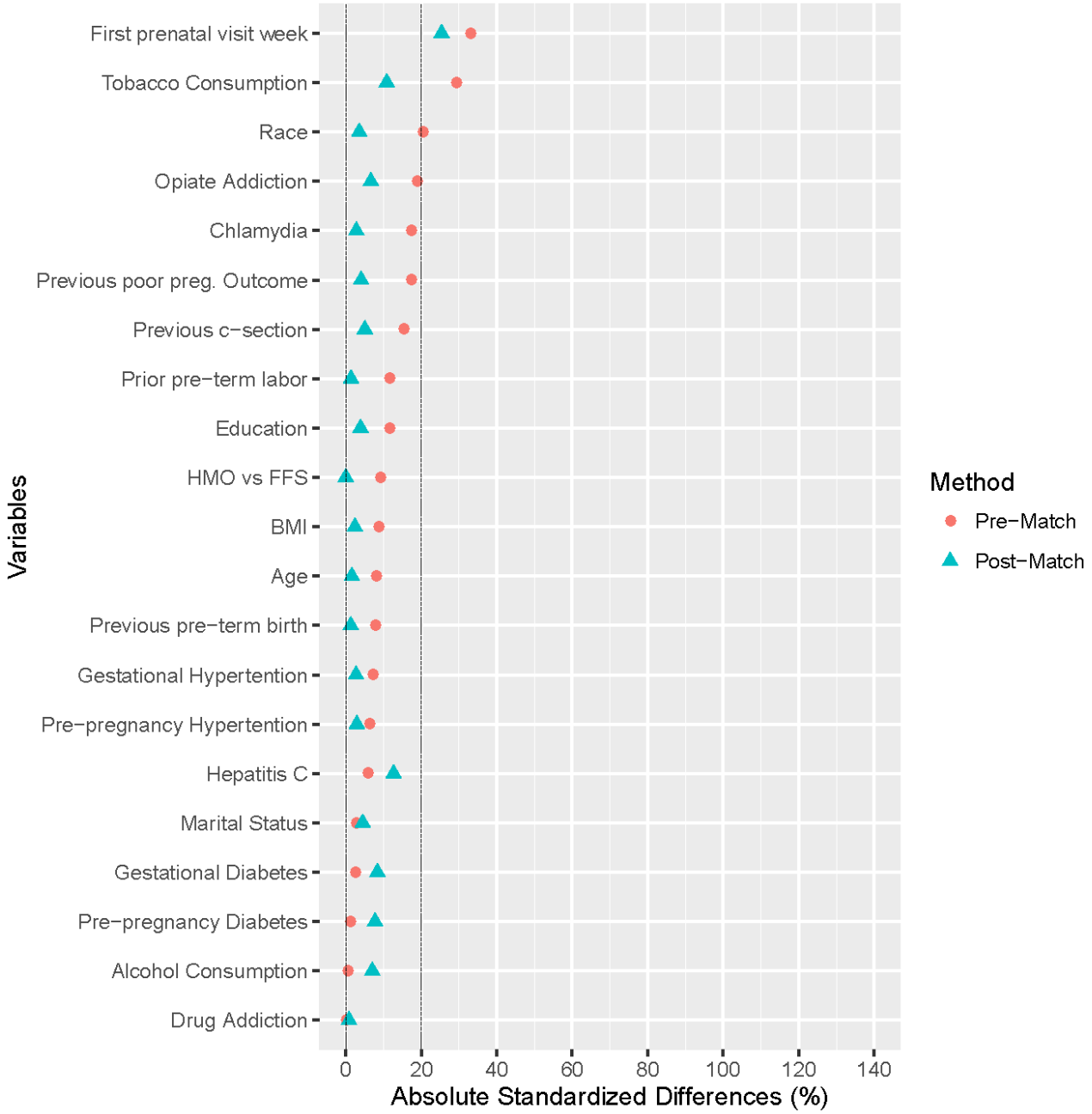

FIGURE B. 2 COVARIATE BALANCE BEFORE AND AFTER PROPENSITY SCORE MATCHING - HOLZER

Figure assesses the covariate balance between Holzer participants and controls before and after propensity score matching. An absolute standardized mean difference score of <20% is considered to be trivial.

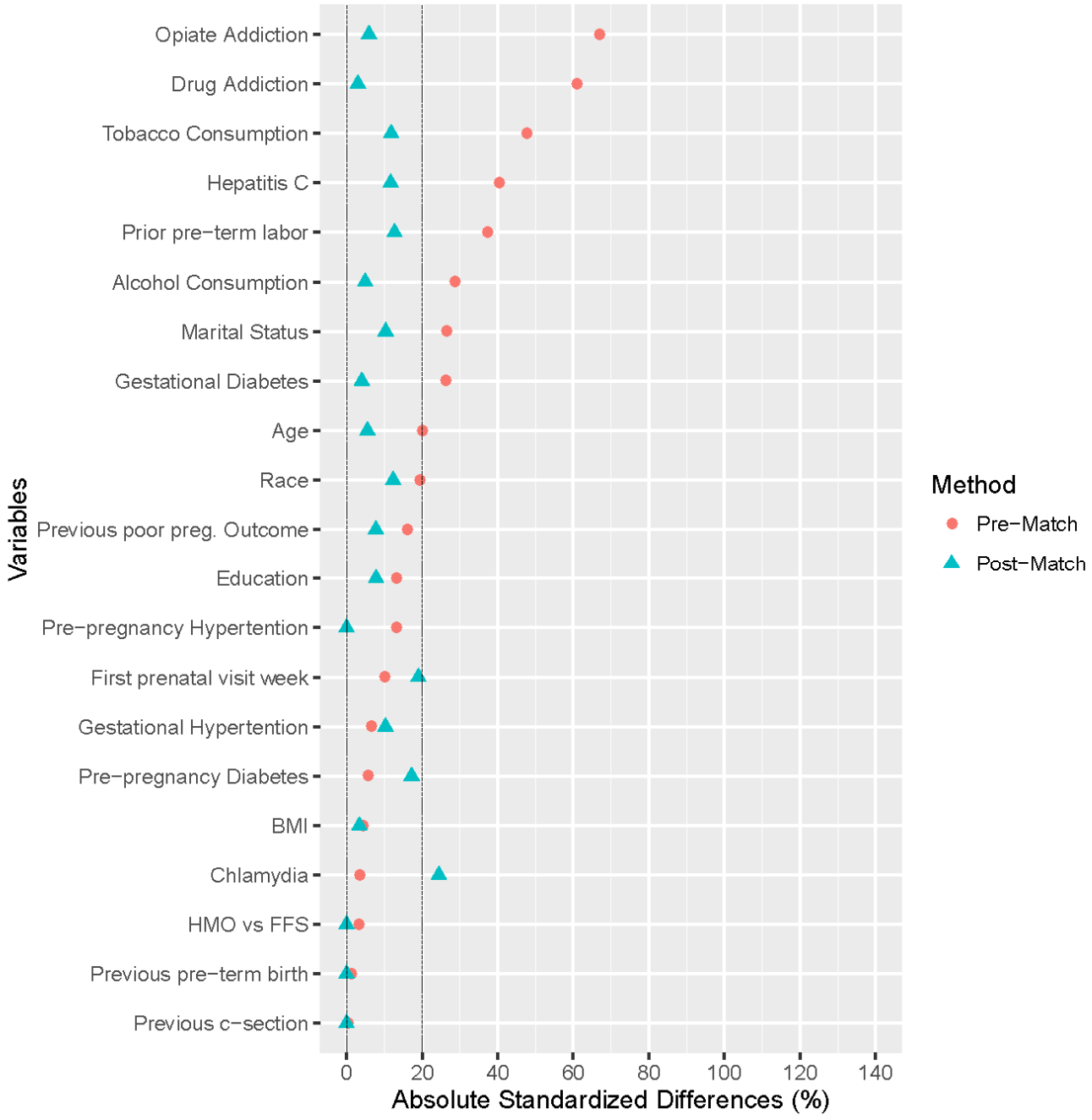

FIGURE B. 3 COVARIATE BALANCE BEFORE AND AFTER PROPENSITY SCORE MATCHING – ADENA

Figure assesses the covariate balance between Adena participants and controls before and after propensity score matching. An absolute standardized mean difference score of <20% is considered to be trivial.

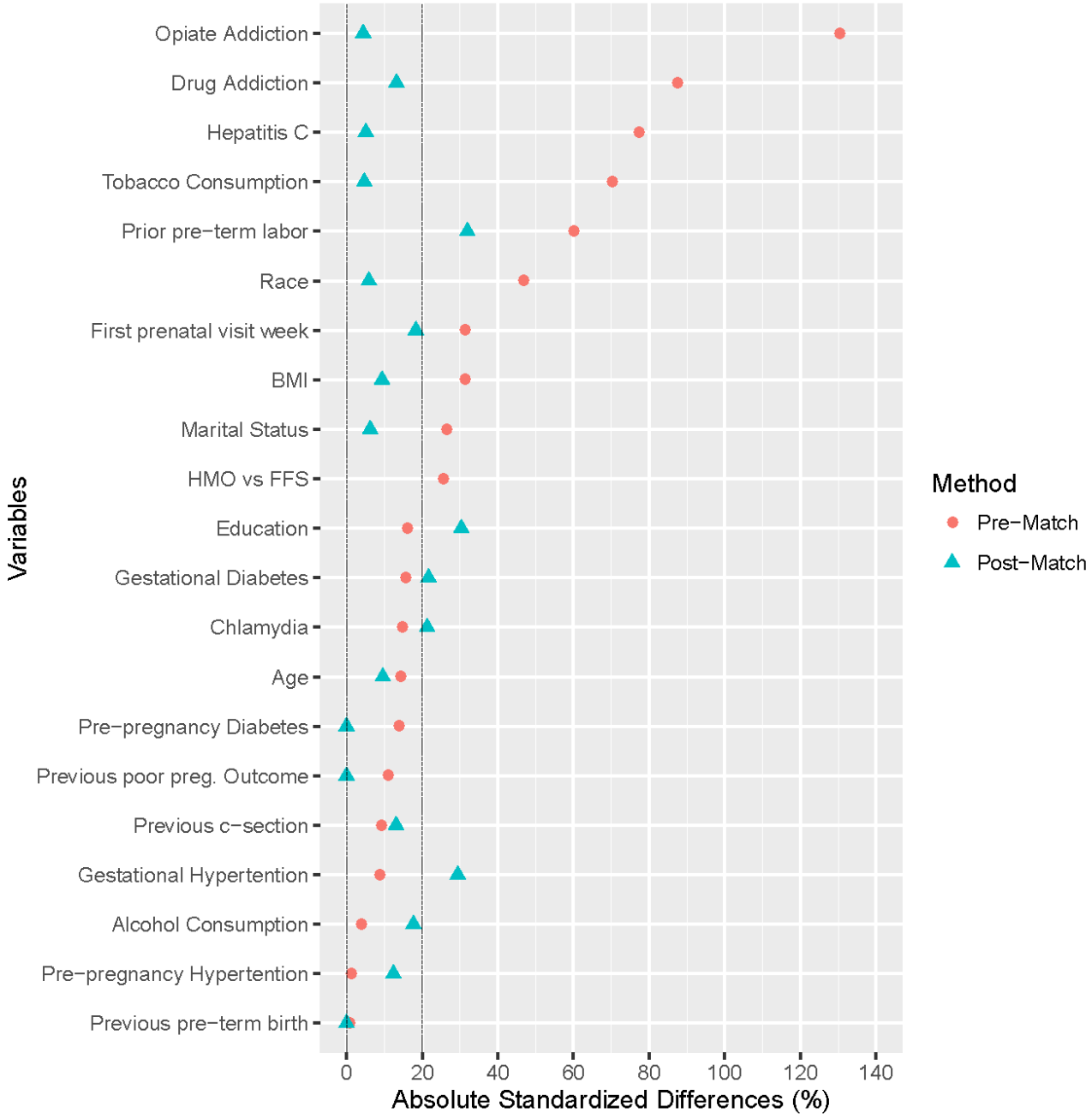

FIGURE B. 4 COVARIATE BALANCE BEFORE AND AFTER PROPENSITY SCORE MATCHING – SUMMA CGC

Figure assesses the covariate balance between Summa CGC participants and controls before and after propensity score matching. An absolute standardized mean difference score of <20% is considered to be trivial.

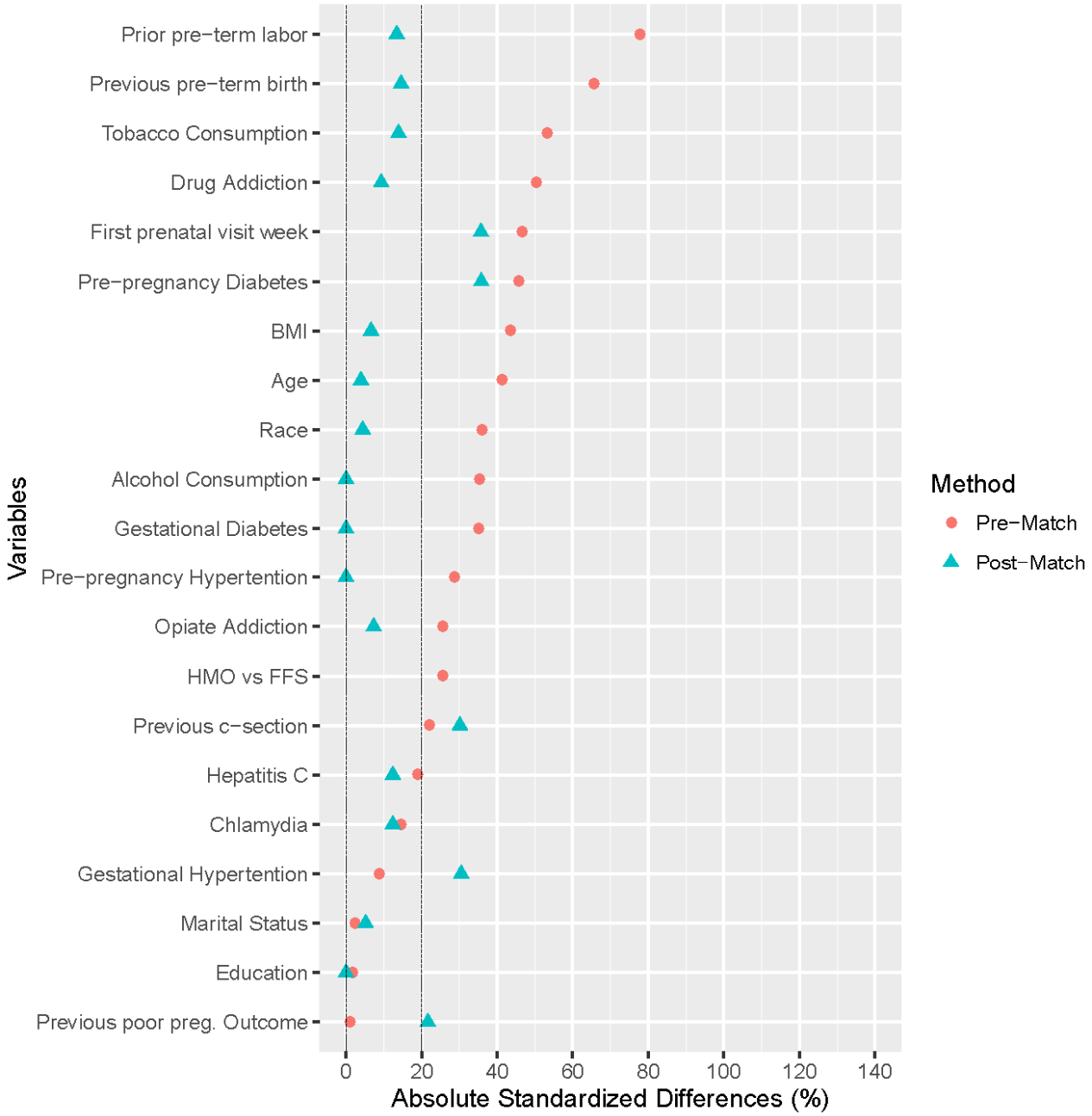

FIGURE B. 5 COVARIATE BALANCE BEFORE AND AFTER PROPENSITY SCORE MATCHING – SUMMA MACH

Figure assesses the covariate balance between Summa MaCH participants and controls before and after propensity score matching. An absolute standardized mean difference score of <20% is considered to be trivial.

TABLE B.2 COMPARISON OF OUTCOMES BETWEEN SE HUB PARTICIPANTS WITH COMPLETE AND INCOMPLETE PREGNANCY PATHWAYS

	Pregnancy Pathway (n = 250)				
	Complete (n = 98)		Incomplete (n = 152)		
Outcome	N	Column %	N	Column %	p-value
Primary					
Low birthweight (< 2500g)	11	11.3%	13	8.6%	0.48
Pre-term delivery (< 37 weeks)	12	12.4%	13	8.6%	0.34
Maternal admission postpartum	0	0.0%	3	2.0%	0.28
Secondary					
Pre-term labor	57	58.8%	70	46.4%	0.09
Post-partum hemorrhage	6	6.2%	15	9.9%	0.27
C-section deliver	26	26.8%	42	27.8%	0.86
Admission to NICU	9	9.3%	14	9.3%	1.00
Small for gestational age	18	18.6%	28	18.5%	1.00

TABLE B.3 COMPARISON OF OUTCOMES BETWEEN SE HUB PARTICIPANTS WITH COMPLETE AND INCOMPLETE SOCIAL SERVICE PATHWAY

	Social Service Pathway (n = 112)				
	Complete (n = 64)		Incomplete (n = 48)		
Outcome	N	Column %	N	Column %	p-value
Primary					
Low birthweight (< 2500g)	5	7.8%	3	6.3%	0.99
Pre-term delivery (< 37 weeks)	6	9.4%	3	6.3%	0.73
Maternal admission postpartum	0	0.0%	1	2.1%	0.43
Secondary					
Pre-term labor	35	54.7%	26	54.2%	0.96
Post-partum hemorrhage	7	10.9%	3	6.3%	0.51
C-section deliver	18	28.1%	9	18.8%	0.27
Admission to NICU	4	6.3%	6	12.5%	0.32
Small for gestational age	14	21.9%	7	14.6%	0.46

TABLE B. 4 COMPARISON OF OUTCOMES BETWEEN SE HUB PARTICIPANTS WITH COMPLETE AND INCOMPLETE MEDICAL REFERRAL PATHWAY

	Medical Referral Pathway (n = 78)				
	Complete (n = 37)		Incomplete (n = 41)		
Outcome	N	Column %	N	Column %	p-value
Primary					
Low birthweight (< 2500g)	3	8.1%	6	14.6%	0.49
Pre-term delivery (< 37 weeks)	3	8.1%	6	14.6%	0.49
Maternal admission postpartum	0	0.0%	1	2.4%	1.00
Secondary					
Pre-term labor	19	51.4%	20	48.8%	0.82
Post-partum hemorrhage	3	8.1%	5	12.2%	0.71

C-section deliver	8	21.6%	14	34.1%	0.22
Admission to NICU	3	8.1%	6	14.6%	0.49
Small for gestational age	9	24.3%	11	26.8%	0.80

TABLE B.5 COMPARISON OF OUTCOMES BETWEEN SE HUB PARTICIPANTS WITH COMPLETE AND INCOMPLETE FAMILY PLANNING PATHWAY

	Family Planning Pathway (n = 159)				
	Complete (n = 79)		Incomplete (n = 80)		
Outcome	**N**	**Column %**	**N**	**Column %**	**p-value**
Primary					
Low birthweight (< 2500g)	11	13.9%	5	6.3%	0.12
Pre-term delivery (< 37 weeks)	11	13.9%	5	6.3%	0.12
Maternal admission postpartum	1	1.3%	1	1.3%	1.00
Secondary					
Pre-term labor	42	53.2%	40	50.0%	0.75
Post-partum hemorrhage	7	8.9%	8	10.0%	0.79
C-section deliver	17	21.5%	25	31.3%	0.16
Admission to NICU	9	11.4%	6	7.5%	0.40
Small for gestational age	16	20.3%	15	18.8%	0.81

TABLE B.6 COMPARISON OF OUTCOMES BETWEEN SE HUB PARTICIPANTS WITH COMPLETED COMPLETE AND INCOMPLETE POSTPARTUM PATHWAY

	Postpartum Pathway (n = 143)				
	Complete (n = 81)		Incomplete (n = 62)		
Outcome	**N**	**Column %**	**N**	**Column %**	**p-value**
Primary					
Low birthweight (< 2500g)	9	11.1%	4	6.5%	0.39
Pre-term delivery (< 37 weeks)	10	12.3%	6	9.7%	0.62
Maternal admission postpartum	0	0.0%	2	3.2%	0.19
Secondary					
Pre-term labor	47	58.0%	26	41.9%	0.07
Post-partum hemorrhage	8	9.9%	3	4.8%	0.35
C-section deliver	19	23.5%	20	32.3%	0.24
Admission to NICU	10	12.3%	5	8.1%	0.41
Small for gestational age	16	19.8%	11	17.7%	0.76

TABLE B.7 META-ANALYSIS OF OUTCOMES BY PROGRAM

Low Birth weight

Program	RR	Lower 95%CI	Upper 95 % CI	p-value
Holzer	0.70	0.36	1.36	0.30
Adena	0.67	0.24	1.87	0.44
Summa CGC	2.00	0.74	5.43	0.17
Summa MaCH	1.43	0.61	3.32	0.41
SEHUB	1.15	0.65	2.03	0.63
Pooled	1.05	0.74	1.51	0.77

Test for heterogeneity: chi-square=4.38, 4 df, p=0.36
I-squared=0.09

Preterm delivery

Program	RR	Lower 95%CI	Upper 95 % CI	p-value
Holzer	0.77	0.42	1.41	0.40
Adena	0.67	0.22	2.07	0.48
Summa CGC	1.43	0.61	3.32	0.41
Summa MaCH	2.00	0.90	4.45	0.09
SEHUB	0.83	0.49	1.40	0.49
Pooled	1.01	0.70	1.47	0.96

Test for heterogeneity: chi-square=5.24, 4 df, p=0.26
I-squared=0.24

Maternal admission postpartum

Program	RR	Lower 95%CI	Upper 95 % CI	p-value
Holzer	1.50	0.25	8.98	0.66
Adena	.	.	.	.
Summa CGC	.	.	.	.
Summa MaCH	0.50	0.13	2.00	0.33
SEHUB	1.00	0.20	4.95	1.00
Pooled	0.82	0.33	2.02	0.67

Test for heterogeneity: chi-square=1.00, 2 df, p=0.61
I-squared=0.0

Appendix C. Additional Qualitative Materials

Appendix C.1 Invitation Letter

<<Participant name>>
<<Participant address>

Date
Hello, Ms. <<last name>>!

My name is Elizabeth Anthony. I am a part of a research team from Rainbow Babies & Children's Hospital and Case Western Reserve University in Cleveland, Ohio. We are studying women's experiences in maternal and infant health programs in Ohio. This project is funded by the State of Ohio. I am contacting you because you received prenatal care from <<agency1>>.

I am writing to you to invite you to participate in a one-time phone interview. I would like to talk to you about your experience in the maternal and infant health program, but you do not have to be in this study; your participation is completely voluntary. I have also enclosed an Informed Consent document that explains the study in more detail. The phone interview would last about 20 minutes and you would receive a $20 Walmart gift card as a thank you for your time.

You can be interviewed in one of two ways:

1. You can call me at toll free at 1-800-490-3282 and we can schedule a time to talk

   OR,

2. You can call the staff person from your program (listed below) and find a time to use the phone at the program site.

If I don't hear from you, I may call you within the next few weeks to see if you are interested in talking to me.

If you have any questions about the study or why you are being contacted, you can call me at 1-800-490-3282. If you would prefer to talk to a staff person from the program you participated in, you can call <<contact>> at <<contact#>> from <<agency2>>.

I hope to hear from you soon!

Sincerely,
<<insert signature image>>
Elizabeth R. Anthony, Ph.D.
Research Assistant Professor

Appendix C.2 Informed Consent Document

Qualitative Interview of Maternal and Infant Health Program Participants

You are being asked to be in a research study about your involvement in a program designed to improve birth outcomes and maternal health. You were selected as a possible participant because you participated in a maternal and infant health program. We will be interviewing a total of 100 women. Please read this consent form, which contains important information about the study, and ask any questions that you may have before agreeing to be interviewed. We will provide a copy of this form for your records.

Background Information
The purpose of this research study is to understand women's experiences in one of four maternal and infant health projects in Ohio: 1) Southeast Ohio Community HUB; 2) Strong Start Ohio Holzer; 3) Strong Start Ohio Summa; and 4) Strong Start Ohio Adena.

Procedures
If you agree to be interviewed by phone, we will ask you to do the following things: 1) Read this document and provide your verbal assent to participate in this study to the interviewer over the phone; 2) Participate in one 20 minute interview during which we will ask you questions about your experience in the program; 3) Allow us to audio record this interview discussion. The audio recording will only be used to help the interviewer fill in gaps in her notes. If you would prefer we not audio record the interview, then we will just take notes. During this study you will only interact with the interviewer.

Risks and Benefits to Being in this Study
This research has no foreseeable risks. You many skip any question that you would prefer not to answer or end the interview at any time without penalty. There are no known benefits to you from being in this study; however, programs intended to improve maternal and infant health outcomes my benefit from the knowledge gained from learning about your experience.

Compensation
You will receive a $20.00 gift card to Walmart for participating in this interview. If you end your participation early or skip questions, you will still receive the gift card in its entirety. The interviewer will mail you the gift card by U.S. mail after the interview.

Confidentiality
What you tell the interviewer will be kept private, except in the following two instances: 1) Should you reveal information that causes the interviewer to suspect child abuse or neglect, Ohio law requires that the researchers conducting this study report their concern to the county division of child welfare; 2) If there are indications you are in imminent danger the interviewer will contact staff from your program and 9-1-1 to get you immediate help.

In any report we might release, we will not include any information that will make it possible to identify you individually. Interview notes will be kept on password and firewall protected computers in a locked research office. Access will be limited to the researchers, the University review board responsible for protecting human participants, regulatory agencies, sponsors and funding agencies. If you allow us to audio record the interview, we will only use this recording to create a written summary of your comments. In the written summary we will omit any names or identifying information that may be

included in the audio recording. Audio files will be stored on password protected computers. The recordings will be destroyed within 120 days after the date of the interview.

Voluntary Nature of the Study

Your participation in this interview is completely voluntary. If you choose not to participate, it will not affect your current or future relations with your program, Case Western Reserve University or Rainbow Babies & Children's Hospital, or any other entity.

Contacts and Questions

The researchers conducting this study are Elizabeth R. Anthony, Ph.D. and Robert L. Fischer, Ph.D. You may ask any questions you have now. If you have additional questions, concerns or complaints about this study you may contact Dr. Anthony at exa136@case.edu / (216) 368-2734 or Dr. Fischer at fischer@case.edu / (216) 368-2711.

If the researchers cannot be reached, or if you would like to talk to someone other than the researchers about: 1) questions, concerns or complaints regarding this study; 2) research participant rights; 3) research-related injuries; or 4) other human subjects issues, please contact Case Western Reserve University's Institutional Review Board at (216) 368-6925 or write: Case Western Reserve University, Institutional Review Board, 10900 Euclid Ave., Cleveland, OH 44106-7230.

You will be given a copy of this form for your records.

Statement of Consent

I have read the above information. I have received answers to the questions I have asked. I am at least 18 years of age.

Do you verbally consent to participate in this study?

Do you verbally consent to being audio recorded, or would you prefer not to be audio recorded?

Appendix C.3 Semi-Structured phone interview questions for program staff

Thank you for participating in this interview. Please answer my questions as honestly as you can. If you have questions or are not sure what I'm asking, please stop me and ask. At any point during the interview, you can skip a question for any reason – just let me know.

****If participant gave permission for audio recording****

Please remember that I will be audio taping the interview so that I can refer back to your answers when reviewing my notes. If at any point during our conversation you would like me to stop recording, just let me know.

At the end of our conversation, I will recap what we talked about to make sure I heard you correctly and am not misrepresenting what you said.

Do you have any questions before we get started?

---

1. I'd like to start by talking about enrollment into your program. What do you think works well for enrolling and retaining the women you serve?
   - Have you tried some things in the past that didn't work so well?
   - What's needed to reach women earlier in their pregnancies?
   - What's needed to retain women longer after they deliver?
   - Do you have specific strategies to reach particular target populations?

2. Ok, let's talk a little bit about care coordination. In your opinion, how well has your program integrated health and social services?
   - What processes facilitate care coordination?
   - Is there anything that you tried in the past that didn't work?
   - Are there particular services that are still needed at the table?

3. This question piggybacks on the previous one. I want to learn more about barriers (logistical, staffing) your program faced or is currently facing.
   - What gets in the way of meeting your program's objectives?
   - What's needed to overcome these barriers?
   - To what extent do you think your program meets current demand for services?

4. So in general, would you say that you're satisfied with the way your program operates?
   - Why or why not?

5. Ok, I want to switch gears a little bit here and talk about the benefits of your program to the women you serve. What do you think women get out of being in your program?
   - What aspects of your program do you believe are most important to the women you serve and produce positive outcomes?

- Is there anything that you think could make their experience even better? Improve their outcomes?
- What is the greatest unmet need among the participants you serve?
- What aspect(s) of your program hinder participant success?

6. Just two more sets of questions. Let's talk a little bit about some of the lessons learned from your project. What words of advice would you offer to a new program just starting up?

- Is there anything you would change about your program?
- What was not successful in meeting the goals of the program?
- What is the greatest threat to the success of your program?
- What else do you think is needed to improve birth outcomes for mothers and babies in your community?

7. Alright. The last thing I'd like to talk about is your advice for how to access and engage participants for this study. First, do you think participants would be more comfortable with a one-on-one interview or focus group format?

- Should the one-on-one interview be in-person or over the phone?
- How would you suggest we recruit participants to learn about their experience in your program?
- Who should make the initial contact?
- How should participants be contacted?
- Where should interviews be held?
- What would you anticipate to be barriers to participation (transportation, child care, food, compensation)?

Appendix C.4 Semi-Structured phone interview questions for program participants

Thank you for participating in this interview. Please answer the questions as best as you can, there are no 'right' answers. If you have questions or are not sure what I'm asking, please stop me and ask. At any point during the interview, you can skip a question for any reason – just let me know.

****If participant gave permission for audio recording…****

Please remember that I will be audio taping the interview so that I can refer back to your answers when reviewing my notes. If at any point during our conversation you would like me to stop recording, just let me know.

Do you have any questions before we get started?

---

1. I'd like to start by asking you why you decided to participate in _____ (name of specific program)?
    a) What issues were you dealing with?
    b) What did you need help with?

2. What was your experience with program staff?

3. What did you find most useful about participating in the program?
    a) Do you think you would have gotten this if you weren't in the program?
    b) If you weren't in this program, how do you think your pregnancy would have been different?

4. Is there anything that would have made your program experience better? If so, please explain.

5. Did you have any needs that the program wasn't able to meet?
    a) If yes, what did you need to address those needs?

6. In general, are you happy you participated in the program? Why or why not?
    a) Would you recommend the program to a friend? Why or why not?
    b) If your friend was on the fence about participating in the program, what would you tell her?

7. Is there anything you need right now to maintain your health and your baby's health and wellness?
    a) Would you have liked to stay involved with the program after your pregnancy? Why or why not?

8. Is there anything else you would like to share about your experience in the program?