Design for the
Mother and Infant Home Visiting Program
Evaluation—Strong Start

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Overview

Rates of infant mortality, preterm birth, low birthweight births, and other adverse birth outcomes in the United States are substantially higher than in most other developed countries. In an effort to improve birth outcomes and to mitigate their short- and long-term adverse health effects, the Centers for Medicare and Medicaid Services (CMS) developed the Strong Start for Mothers and Newborns initiative. CMS has identified home visiting as one of the promising prenatal interventions to be tested through the initiative. To understand the effects of this service strategy, CMS has partnered with the Administration for Children and Families and the Health Resources and Services Administration to implement the Mother and Infant Home Visiting Program Evaluation – Strong Start (MIHOPE-Strong Start). The study is being conducted by MDRC in partnership with Mathematica Policy Research, Johns Hopkins University, and James Bell Associates.

This document describes the design of MIHOPE-Strong Start. Some key features include:

- **Sampling plan.** The study aims to include 3,400 women who are no more than 32 weeks pregnant and at least 15 years old. Women are being randomly assigned to a program group that can receive home visiting services or to a control group that will receive referrals to other community services. The study includes local programs implementing one of two national home visiting models: Healthy Families America or Nurse-Family Partnership. The sample will be spread across 75 local home visiting programs in 17 states. MIHOPE-Strong Start will thus be the largest random assignment study of the effects of home visiting on birth outcomes ever conducted in the United States.

- **Impact analysis.** An impact analysis will estimate the effects of home visiting on prenatal health care use, birth outcomes, infant health, and health care use and costs using data from birth certificates and state Medicaid systems. Key outcomes include birth weight, preterm births, whether the baby is born small-for-gestational-age, adequacy of prenatal care, whether the infant was breastfed at the time of hospital discharge, the length of Medicaid enrollment, NICU use at birth, and the number and type of health care visits during the first 60 days of life and the first year of life.

- **Implementation research.** A broad literature suggests that program effects are associated with the quality of implementation, but there has been little systematic documentation of program implementation in home visiting. To help fill this gap, MIHOPE-Strong Start is collecting detailed information on program implementation at the local level to investigate how home visiting services and program characteristics such as staff qualifications and training are associated with service delivery and impacts on family outcomes. Of particular interest is to understand what "dosage" of home visiting would optimize program impacts and cost-effectiveness.

MIHOPE-Strong Start represents an important opportunity to learn whether and under what conditions home visiting affects maternal, prenatal, and infant health outcomes and health care use. By studying the variation in effects for different subgroups, different program dosages, and other implementation factors, MIHOPE-Strong Start is designed to provide information needed by states, communities, program developers, and program operators to build future programs that can best improve birth outcomes, prenatal care, and infant health care.

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Chapter 1

Home Visiting and Improving Adverse Birth Outcomes and Maternal and Infant Health

Despite notable declines in infant mortality over the past several decades, the infant mortality rate in the United States remains significantly higher than in other developed nations.[1] A sizable share of the higher infant mortality in the U.S. can be explained by the country's higher rates of adverse birth outcomes, including preterm births and low birth weight births.[2] In 2009, about 12 percent of infants born in the U.S. were born prematurely (before 37 weeks of gestation) and roughly 8 percent were classified as low birth weight (less than 2,500 grams).[3] In comparison, approximately 7 percent of children born in 34 developed countries (not including the U.S.) in 2009 were considered low birth weight.[4] Across a wider group of 180 countries, the United States ranked 54th in preterm births.[5]

In addition to the higher risk of infant mortality, preterm and low birth weight infants are at increased risk for numerous health, neurological, and developmental problems beginning during the first year of life.[6] Preterm newborns are more likely than full-term infants to experience complications such as respiratory distress, jaundice, anemia, and infection.[7] Similarly, low birth weight infants are at higher risk of illness and infection during the first six days of life.[8] Preterm and very low birth weight infants also have more hospital readmissions in the weeks following discharge,[9] which is often due to respiratory illnesses and lower-respiratory-tract infections, which are more common among preterm infants and infants born with lower birth weights.[10]

The health risks associated with poor birth outcomes are financially costly for families and the nation's health care system. For instance, preterm and low birth weight infants account for roughly half of all hospitalization costs for infants less than a year old.[11]

While the rates of preterm and low birth weight births are generally higher in the U.S. than in other developed countries, some portions of the U.S. population experience adverse birth outcomes at even higher levels. For instance, non-Hispanic blacks, Puerto Rican, and Native Americans experience disproportionately high rates of preterm deliveries and low birth weight

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[1]MacDorman and Mathews (2009).

[2]Goldenberg, Culhane, Iams, and Romero (2008); March of Dimes, PMNCH, Save the Children, and WHO (2012).

[3]Martin et al. (2011).

[4]Organization for Economic Cooperation Development (2011).

[5]March of Dimes, PMNCH, Save the Children, and WHO (2012).

[6]Eichenwald and Stark (2008); Goldenberg, Culhane, Iams, and Romero (2008); Institute of Medicine (2009); Jobe and Bancalari (2001).

[7]Centers for Disease Control and Prevention (2009).

[8]Centers for Disease Control and Prevention (2012).

[9]Lamarche-Vadel et al. (2004); Yüksel and Greenough (1994).

[10]Bird et al. (2010); Melamed et al. (2009); Seubert, Stetzer, Wolfe, and Treadwell (1999).

[11]Russell et al. (2007).

infants.[12] Such disparities early in life may contribute to persistent racial and ethnic disparities in adult health and well-being.[13] Poor birth outcomes are also influenced by the mother's broader familial and socio-economic resources, her social relationships, and her neighborhood environment.[14] Women who have low incomes or low educational attainment and who live in neighborhoods with high poverty and deprivation are more likely than others to be in poor health and are at greater risk of delivering a preterm or low birth weight infant.[15] For these reasons, the health of expectant mothers and their receipt of appropriate and adequate health care during pregnancy are important indicators of general maternal well-being and salient determinants of birth outcomes.[16]

In an effort to improve birth outcomes and to mitigate adverse health complications for low-income mothers and infants, the Centers for Medicare and Medicaid Services (CMS) developed the Strong Start for Mothers and Newborns (Strong Start) initiative. Strong Start is testing and evaluating enhanced prenatal care interventions for women enrolled in Medicaid or Children's Health Insurance Programs (CHIP) who are at risk for poor birth outcomes. The initiative focuses specifically on the impact of nonmedical prenatal interventions that, when provided in addition to routine obstetrical medical care, have the potential to improve birth outcomes for low-income women and their children. In addition to improving the health outcomes and health care use of pregnant women and newborns, Strong Start is also examining whether such interventions can decrease the anticipated total cost of medical care during pregnancy, delivery, and over the first year of a child's life.[17]

CMS has identified home visiting services as one of the promising prenatal interventions to be tested through Strong Start. Home visiting programs include a range of individualized in-home services for families, including direct education, screening and assessments, and referrals to community resources. To understand the effects of this service strategy, CMS has partnered with the Administration for Children and Families (ACF) and the Health Resources and Services Administration (HRSA) to implement the Mother and Infant Home Visiting Program Evaluation-Strong Start (MIHOPE-Strong Start). MIHOPE-Strong Start is meant to be integrated with the national evaluation of home visiting programs funded through the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) program, also referred to as the Federal Home Visiting Program.[18] That evaluation, called the Mother and Infant Home Visiting Program Evaluation (MIHOPE), is examining the effectiveness of the four evidence-based models that were selected by at least 10 states in their initial MIECHV plans: Early Head Start – Home-Based Option, Parents as Teachers, Healthy Families America (HFA), and Nurse-Family Partnership (NFP). As required by the legislation that created MIECHV, MIHOPE will examine impacts across a num-

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[12]Coughlin, Kushman, Copeland, and Wilson (2013); Giscombé and Lobel (2005); Landale and Oropesa (2001).

[13]Lu and Halfon (2003).

[14]Institute of Medicine (U.S.) Committee on Understanding Premature Birth and Assuring Healthy Outcomes (2007); Misra, Guyer, and Allston (2003); U.S. Department of Health and Human Services, Maternal and Child Health Bureau, and Health Resources and Services Administration (2008).

[15]Farley et al. (2006); Roberts (1997).

[16]Centers for Disease Control and Prevention (2013).

[17]For more information on the Strong Start for Mothers and Newborns Initiative, please visit: http://innovation.cms.gov/initiatives/strong-start/.

[18]The MIECHV program is designed to strengthen home visiting services in disadvantaged, underserved communities or areas with poor health outcomes by facilitating collaboration and partnership at the federal, state, and local levels to improve health and development outcomes for at-risk children, mothers, families, and communities.

ber of domains including birth outcomes, but also maternal and child health, parenting, child development, family economic self-sufficiency, domestic violence and crime, and referral and coordination of health and social services.[19]

This document describes the design of MIHOPE-Strong Start, a study of the effectiveness of home visiting services at improving birth outcomes for women who are enrolled or eligible to be enrolled in Medicaid or CHIP, as well as the effectiveness of these services at improving infant and maternal health, health care use, and use of prenatal care.[20] The study is being conducted by MDRC in partnership with Mathematica Policy Research, Johns Hopkins University, and James Bell Associates. MIHOPE-Strong Start will examine local programs that use either HFA or NFP, which are the two national home visiting models that, based on the Home Visiting Evidence of Effectiveness (HomVEE) review[21], meet HHS' criteria for evidence-based home visiting models, and for which previous research has found evidence of improved birth outcomes. In addition to estimating the impacts of home visiting services on prenatal care, birth outcomes, and infant health and health care, MIHOPE-Strong Start will investigate the features of home visiting programs that are associated with improvements in these outcomes.[22]

Both of the national home visiting models included in MIHOPE-Strong Start provide disadvantaged expectant mothers with individualized in-home services, including assessment of prenatal and postnatal risks to child well-being, referrals to needed health care or social services, and direct education of parents by home visitors on such topics as healthy prenatal behaviors, parenting, and child development. Both models serve many families across the U.S. and abroad. In April 2013, NFP had 1,588 home visitors serving 25,944 families in 43 states and the U.S. Virgin Islands.[23] HFA is even larger; in 2013, HFA programs had nearly 3,000 home visitors serving approximately 75,000 families across 40 states, several U.S. territories, and Canada.[24]

Improving Birth, Maternal, and Infant Health Outcomes: Key Features of NFP and HFA

As discussed earlier, birth outcomes are influenced by a variety of social, psychological, behavioral, environmental, and biological risk factors. Moreover, there are substantial racial and ethnic disparities in poor birth outcomes. It is likely that these differences are attributable in part to differences in socioeconomic status, maternal health behaviors, prenatal care, and psychosocial stress, as well as community-level disadvantage and structural factors such as neighborhood resources and residential segregation.[25] In addition, younger and older maternal age, single moth-

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[19]For more information about the design of MIHOPE, see Michalopoulos et al. (2013).

[20]The goal of the study is to include local home visiting programs that serve primarily women who will be enrolled in Medicaid or CHIP before they give birth.

[21]The legislation authorizing the MIECHV program requires that a majority of that program's grant funds be spent to implement "evidence-based" home visiting models. To determine which national models are evidence-based, HHS developed criteria and funded the HomVEE review to regularly review research on home visiting models and compare it to the criteria. For details on the HomVEE review and HHS criteria, go to http://homvee.acf.hhs.gov/

[22]Although some other evidence-based home visiting models also serve pregnant women, they have not looked at the effects of their programs on birth outcomes.

[23]Nurse Family Partnership (2012).

[24]Healthy Families America (2014).

[25]Lu and Halfon (2003); Mason et al. (2010).

erhood, involvement in abusive intimate relationships, low income, low educational attainment, and unstable employment have been associated with birth and infant health outcomes.[26]

The home visiting programs to be studied in MIHOPE-Strong Start have the potential to improve many of these behavioral and psychosocial factors, thereby reducing adverse birth outcomes and improving both maternal and infant health among Medicaid and CHIP beneficiaries. Both national models consider increased use of prenatal care and improved infant health to be among their priorities (Table 1.1). Home visitors in both programs actively work to increase use of prenatal care and encourage expectant mothers to take proper care of themselves during pregnancy. They also aim to increase access to primary care and appropriate infant health practices. Both also target families that are risk for poor birth outcomes, such as low-income status or single parenthood. Finally, both use techniques such as screening for risk factors, discussing those risks or other issues that might be affecting the family's achievement of program goals, providing information about prenatal health, and referring mothers to community resources.

While the two national models have some similarities, they differ in some key aspects.

- **Origins**. HFA was founded as a program to prevent child abuse. Over the years, it has evolved to focus on improving other aspects of child well-being, including preparing expectant mothers for healthy bonding and attachment and to improve birth outcomes. By comparison, NFP has deep roots in public health, and focuses its services more pointedly on birth outcomes.

- **Standardization.** HFA gives local programs flexibility in the curricula they choose, although HFA programs use a standardized assessment tool, screen families for the presence of various risk factors, and have home visitors provide direct education to parents or make referrals to community services, as appropriate. NFP provides a standard curriculum that all local programs are required to use. If a local program intends to adapt any of the national model elements, they must receive approval from the national office.

- **Target population**. NFP programs enroll all participants by their 28th week of pregnancy. By comparison, HFA programs enroll women throughout pregnancy and up to when their infants are three months old. However the study will only include expectant HFA enrollees who are up to 32 weeks along in their pregnancy.

- **Program intensity, duration, and staffing.** NFP offers services to clients until the child's second birthday, while HFA offers services until the child's fifth birthday. Both programs offer services weekly, biweekly, or monthly depending on the stage of pregnancy, the age of the child, and whether the family has reached particular milestones. NFP specifies that home visitors should be registered nurses; in contrast, HFA encourages programs to hire home visitors based on their ability to connect well with families in addition to having relevant education and experience.

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[26]Boy and Salihu (2004); Institute of Medicine (U.S.) Committee on Understanding Premature Birth and Assuring Healthy Outcomes (2007).

Table 1.1

Key Components of Service Models for MIHOPE-Strong Start

Service Model	Program Goals	Target Population/ Age at Enrollment	Program Intensity/Duration	Home Visitor Qualifications	Management Information System
Healthy Families America (HFA)	Systematically reach out to parents to offer resources and support Cultivate the growth of nurturing, responsive parent-child relationships Promote healthy childhood growth and development Build the foundations for strong family functioning	The program targets parents facing challenges such as single parenthood, low income, childhood history of abuse or adverse experiences, current or prior behavioral health issues, or domestic violence. Individual programs select the specific characteristics of the target populations they plan to serve. Families are enrolled prenatally or within the first three months after a child's birth.	Home visits typically a minimum of 60 minutes Minimum of weekly home visits for the first six months after a child's birth; frequency of the visits after six months based on family risk factors determined by local programs Services beginning prenatally or at birth and continuing through the first three to five years of life	There are no specific educational requirements for home visitors Home visitors should be selected based on personal characteristics and experience in working with families with multiple needs, experience working with or providing services to children and families, ability to establish trusting relationships, acceptance of individual differences, experience in working with culturally diverse communities, knowledge of infant and child development, and ability to maintain boundaries between personal and professional lives.	Prevent Child Abuse America developed the Program Information Management System (PIMS) to enable HFA sites to maintain and report on the community programs and participant services they provide. Program sites are encouraged but not required to utilize PIMS for tracking service delivery.

(continued)

Table 1.1 (continued)

Service Model	Program Goals	Target Population/ Age at Enrollment	Program Intensity/Duration	Home Visitor Qualifications	Management Information System
Nurse-Family Partnership (NFP)	Improve prenatal health and outcomes Improve child health and development Improve families' economic self-sufficiency and maternal life-course development	The program targets first-time, low-income mothers and their children. The first home visit must occur no later than the end of week 28 of pregnancy. Programs are recommended to begin conducting visits in the 2nd trimester (14 to 16 weeks of gestation).	Home visits typically 60 to 75 minutes Weekly home visits for the first month after enrollment, then every other week until baby is born Weekly home visits for the first six weeks after the baby is born and then every other week until the baby is 20 months; last four visits monthly until the child is 2 years old Visit schedule potentially adjusted to meet client needs	Home visitors must be registered professional nurses with a minimum of a bachelor's degree in nursing.	All programs are required to use the NFP Clinical Information System (CIS) for tracking information that is needed to monitor the quality of program implementation and the progress of enrolled families in attaining program goals.

SOURCES: Program model websites and the U.S. Department of Health and Human Services HomVEE website: http://homvee.acf.hhs.gov/programs.aspx.

- **Supports for model fidelity and implementation**. Historically, NFP has emphasized fidelity of local programs to the national model and has used its National Service Office, including regional clinical and quality support staff, as an intermediary to help support implementation. NFP also requires local programs to use their centralized web-based data system. HFA's philosophy, in contrast, is to provide affiliates with the principles of operating a HFA program but allow local discretion in meeting local community needs and allow individual home visitor's discretion in activities conducted with families. HFA recommends that programs collect particular data items and make a management information system available to their local programs but do not require that the local programs use it.

Prior Evidence on HFA and NFP

According to the HomVEE review, both NFP and HFA have produced some positive effects on birth outcomes in at least one rigorous, high-quality study. However, there are many remaining gaps in knowledge about how HFA and NFP, when scaled broadly, affect birth outcomes, maternal and infant health, and health care. These gaps are discussed below:

Effects on Birth Outcomes

Only a handful of rigorous studies have examined impacts of home visiting programs on birth outcomes, and effects have been inconsistent. One high quality study of HFA found that mothers who enrolled at least two months prior to giving birth in three New York communities were 5 percentage points less likely to deliver a low birth weight infant than mothers not receiving HFA.[27] However, the study did not find statistically significant impacts on premature births or the need for neonatal intensive care. NFP's randomized trial in Elmira, NY found improvements in birth outcomes, but only for subgroups of families. In particular, the study found reductions in preterm birth for adolescent mothers and smokers and reductions in low birth weight infants for adolescent mothers and older smokers.[28] However, these findings were not replicated in NFP's Memphis and Denver experiments, perhaps because 55 percent of sample members in Elmira were smokers while only 9 percent of those in Memphis and 25 percent in Denver were smokers.[29] Moreover, some of these studies are now somewhat dated, and each focused on a small number of locations. As discussed later in this document, MIHOPE-Strong Start is a rigorous evaluation with a sizable number of families across a large number of local programs, which will provide more reliable and updated information on the effects across birth outcomes and across the two models.

Evidence of Effectiveness in Subgroups

The HomVEE review found that many studies of home visiting programs used too few families to allow a precise analysis of effects for different groups of families. Examining effects for different families is an important goal of MIHOPE-Strong Start because some subpopulations of mothers are at significantly higher risk than others for poor outcomes in this domain, including minorities, smokers, and teen mothers. In addition, as mentioned above, the prior evidence

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[27]Lee et al. (2009).

[28]Olds, Henderson, Tatelbaum, and Chamberlin (1986).

[29]Olds et al. (1999); Olds et al. (2002).

suggests that NFP was most effective at reducing preterm birth for smokers and the impacts of HFA on low birth weight in New York were particularly pronounced for African American and Hispanic mothers. Concerns about having enough families for subgroup comparisons are particularly important in examining birth outcomes, since overall effects are likely to be small given the low incidence of adverse birth outcomes. Given these limitations of prior studies, the field would benefit from research that helps identify and clarify what works for different types of families.

Effects on Health Care Use

Home visiting programs could theoretically affect two types of health care use that are relevant to the Strong Start initiative's goal of improved outcomes at birth and in infancy: (1) maternal and infant preventive care (including maternal prenatal care, well child visits, and immunizations) and (2) treatment of acute conditions in infancy. First, concerning preventive care, several meta-analyses and literature reviews have concluded that in general, home visiting programs do not typically lead to an increase in the use services for mothers or for infants.[30] In addition, few statistically significant estimates of the effects of HFA and NFP on preventive care have been reported in studies rated high quality by the HomVEE review. MIHOPE-Strong Start includes more families than previous studies, though, which will help identify significant effects on use of preventive care, even if they are relatively small or specific to particular subgroups.

Second, home visiting could affect infant health care use by reducing acute conditions through improved birth outcomes, reduced infant injuries, or improved health-related practices by parents of infants. For example, NFP's studies in Elmira and Memphis showed reductions in child injuries and hospital visits and reduced health encounters for injuries and ingestions, particularly for parents with low psychological resources.[31] However, none of the moderate and high quality HFA studies reviewed by HomVEE that examined emergency department visits, sick child visits, injuries, or hospitalizations found statistically significant improvements in these outcomes. The field would benefit from research that systematically examines home visiting's impact on infant and child health care use across a range of outcomes and sub-groups.

Evidence on Home Visiting Program Implementation and its Links to Impacts

Prior studies of human service programs have found that program effects are associated with a number of implementation-related factors such as program maturity, clarity of program goals, and the extent to which services target specific outcomes.[32] For example, NFP programs in Pennsylvania did not affect the likelihood of a repeat pregnancy within a relatively short time interval (2 year span) until the programs had been operating for at least three years.[33] The clarity of a program's focus on a particular outcome has likewise been found to be related to the likelihood that the home visitor delivers services related to that outcome, and the program's impacts on that outcome.[34] Nevertheless, there has been very little systematic documentation of program implementation in studies of home visiting programs.

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[30]Gomby (2005).
[31]Haskins and Barnett (eds.) (2010).
[32]Fixsen et al. (2005).
[33]Rubin et al. (2011).
[34]Duggan, DeCelle, Burrell, and Hernandez (2012).

Of particular interest is to understand what "dosage" of home visiting would optimize program impacts and cost-effectiveness, and relatedly, whether program impacts vary depending on when in pregnancy the mother enrolls. Surprisingly, prior studies of home visiting programs have rarely presented information on dosage or its associations with program impacts. However, recent evidence from three randomized controlled trials of NFP found that that families received, on average, approximately 28-30 visits from pregnancy to the child's second birthday (45-62 percent of the intended visits), providing some initial evidence about the level of dosage that might be needed to achieve impacts in home visiting programs.[35]

To investigate the relationship between program implementation and program effects, MIHOPE-Strong Start is collecting detailed information on program implementation at the local level. The study is thus aiming to help inform the question of how program implementation features are related to impacts by systematically examining how dosage and other program characteristics such as staff qualifications and training are associated with service delivery and impacts both for mothers who enroll prenatally in NFP and HFA and for their children's birth outcomes.

MIHOPE-Strong Start represents an important opportunity to learn more about the extent to which, and under what conditions, HFA and NFP affect maternal, prenatal, and infant health outcomes and health care use. By measuring the effects of HFA and NFP as well as studying the variation in effects for different subgroups, different program dosages, and other implementation factors, MIHOPE-Strong Start is designed to provide information needed by states, communities, program developers, and program operators to build future programs that can best improve birth outcomes, prenatal care, and infant health care.

Overview of the Document

The remainder of the document presents the design for MIHOPE-Strong Start. Each chapter presents an aspect of the overall design:

- Chapter 2 discusses the basic design of the study, including the study's conceptual framework and the overarching research goals and questions.

- Chapter 3 discusses the sampling plan and presents details on the number of families and local programs that will be included as well as how the local programs will be chosen.

- Chapter 4 discusses the implementation study that will be included in MIHOPE-Strong Start.

- Chapter 5 presents the measurement and analytic plan for the impact study, including how the evaluation will assess the ability of home visiting programs to improve adverse birth outcomes.

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[35]Wasik, Mattera, Lloyd, and Boller (2013).

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Overview of the Proposed Design

This chapter presents a brief overview of the design of the Mother and Infant Home Visiting Program Evaluation-Strong Start (MIHOPE-Strong Start), which will be elaborated on in the remainder of the document. Specifically, this chapter presents a conceptual framework describing how home visiting programs may improve appropriate health care use and birth outcomes among at-risk families, the research questions that stem from this framework, and a synopsis of key components of the evaluation.

MIHOPE-Strong Start Conceptual Framework

The MIHOPE-Strong Start conceptual framework (Figure 2.1) has three broad aspects: (1) inputs (the factors influencing service delivery), (2) outputs (the services delivered) and (3) outcomes for families. It also shows the study's three major outcomes areas: maternal prenatal health and health care use, preterm births and other birth outcomes, and infant health and health care use.

Inputs that influence how services are provided to families are shown in the left half of the figure. Starting at the bottom of the figure, community resources provide a foundation from which programs operate. In particular, these determine the outside referral services available to home visiting programs and the opportunities available to families in both the program and control groups. Examples include prenatal care for low-income women, smoking cessation programs, substance abuse treatment, and other resources needed to produce healthy birth outcomes. By connecting pregnant women with these services, home visiting programs can change mothers' health care use, health behaviors, and health status, which in turn can lead to improvements in birth outcomes. Community resources also includes community characteristics that could affect norms toward use of social services and health care, or other influences on control group help-seeking and program group responses to home visiting programs. These contextual factors can affect program impacts in both positive and negative directions, as described further in Chapter 4.

Moving to the top of the figure, the service model defines the program plan and includes information such as the intended goals of the home visiting program; the expected frequency, duration, and content of home visits; and intended linkages with other services. The service model is defined by the national model (HFA or NFP) but can be refined or adapted by each local program. It is important to clearly understand how HFA and NFP define their models since these models showed efficacy in prior research. At the same time, local programs often deliberately adapt models to fit their local contexts. To the extent that the services families receive diverge from the national model's recommendations, it is important to understand whether local programs modified the national recommendations or failed to deliver services as the local program managers intended.

Figure 2.1

Conceptual Framework

Inputs (Factors for Service Delivery)	Outputs	Outcomes

Service model

Family attributes

Staff attributes

Organizational influences

Implementation system

Services Delivered

Maternal prenatal health, health behaviors, and health care use

Preterm birth and other birth outcomes

Infant health and health care use

Community resources
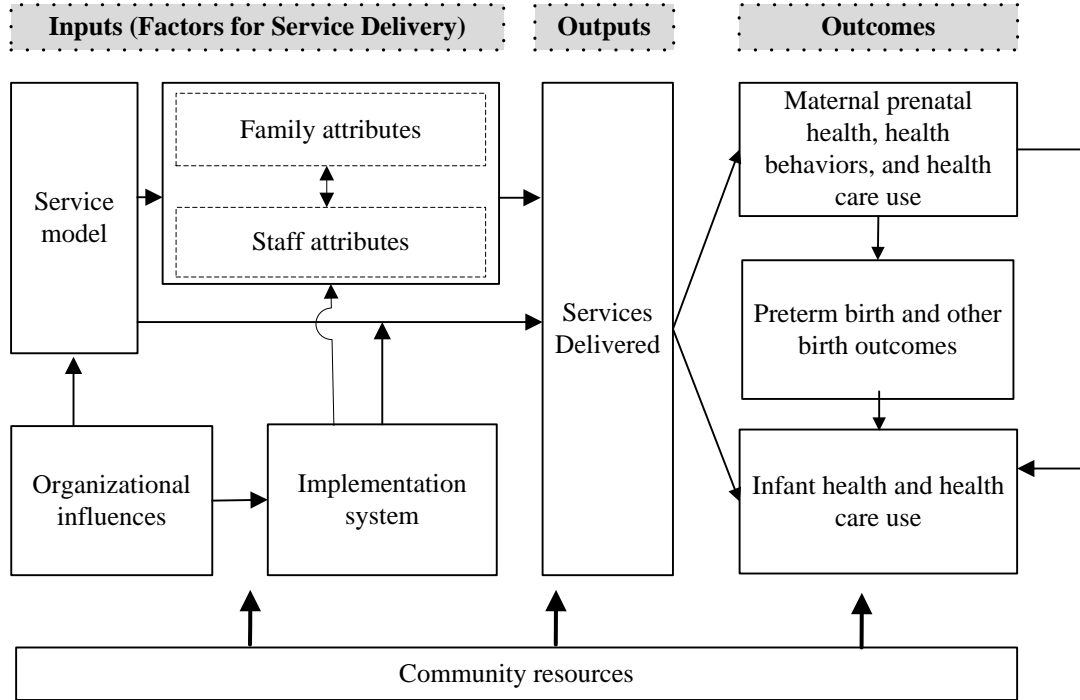
The implementation system includes the resources for carrying out the service model. It incorporates policies and procedures for staff recruitment, training, supervision and evaluation; assessment tools, protocols and curricula to guide service delivery; administrative supports such as management information systems; organizational climate regarding fidelity to and the use of evidence-based practices; available consultation to address issues beyond the home visitor's skills and expertise; and the program's relationships with other organizations to facilitate referral and service coordination. In fields outside of home visiting, there is evidence that as the adequacy of the implementation system increases, so does fidelity to the intended program model.[1]

As shown in Figure 2.1, multiple organizations influence a home visiting program's service model and implementation system. These influences include the local implementing agency, the training and technical assistance part of the national model that has been adopted, the state MIECHV grantee (if the local programs is participating in MIECHV), and community organizations with which the local agency collaborates. For example, if a state administrator emphasizes improving birth outcomes over other potential outcomes, local home visiting programs in that state might have stronger impacts on birth outcomes. The attributes of staff and families in a given program also affect the services it delivers. As noted in Chapter 1, NFP specifies that home visitors should be registered nurses with a minimum of a baccalaureate degree in nursing and NFP programs must submit a formal variance to get approval from the NFP National Service Office to employ staff that do not meet the staff qualification standards. HFA gives local programs

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[1]Carroll et al. (2007).

more discretion in this regard. Some local HFA offices might specify particular credentials, while others might not. In addition to background, home visitors' psychological well-being, such as whether they are depressed or experiencing burnout, can influence how they approach their work with families. Finally, staff may vary in their degree of focus, confidence, and competence in carrying out responsibilities with respect to particular outcomes. For example, a local program might provide staff with better training and supervision on screening and follow-up activities for some outcomes than for others.

With regard to family attributes, HFA and NFP specify the characteristics of families that their programs can serve, but local programs sometimes vary in the families they target because of community characteristics or because they vary in their processes for family recruitment. Attributes of families who enroll can, in turn, influence services because staff are expected to tailor services to the family's strengths, needs, and concerns; because families vary in their understanding of the program and the benefits they are likely to derive from it; and because parents vary in their capacity, whether psychosocial or because of material resources, to engage with the services offered.

These inputs – the service model, implementation system, and characteristics of home visitors and families – all affect the outputs, or the services that families receive. Because home visiting programs rely heavily on referrals to other community organizations to meet families' needs, outputs can include services provided directly by home visiting staff – such as screening for risk factors or education about maternal behaviors that can affect prenatal health – and referrals to other services – including services for intimate partner violence or mental health concerns. As an example of how inputs affect outputs, when and how a home visiting program addresses risk factors for prenatal health influence the services a family receives. Likewise, the availability of ancillary services in the community affects the services a family receives. Finally characteristics and risk status of families may affect the services that particular family receives.

The right side of the figure shows the outcomes that home visiting programs in MIHOPE-Strong Start are designed to affect. At the top are mothers' prenatal outcomes, including use of recommended levels of prenatal care, prenatal health behaviors related to birth outcomes such as smoking and use of alcohol or other substances, and mothers' prenatal health. These prenatal outcomes may influence birth outcomes and may also directly influence infant health outcomes. Birth outcomes may also directly affect infant health and health care use. Furthermore, home visiting services may indirectly improve infant health and health care use regardless of impacts on birth outcomes by improving parenting behaviors, such as promoting breastfeeding and use of preventive care.

Research Questions

The conceptual framework supports the following research questions for MIHOPE-Strong Start impact analysis[2]:

- What is the impact of evidence-based home visiting for Medicaid or CHIP-eligible pregnant women on birth outcomes, prenatal care, and infant health and health care use up to the first year postpartum?

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[2]The design is also intended to provide information that would allow actuaries at the Centers for Medicare and Medicaid Services (CMS) to estimate the effects of the programs on Medicaid costs.

- What are the impacts of each national home visiting model on birth outcomes, prenatal care, infant health, and health care use?

The implementation study for MIHOPE-Strong Start will document the key features of HFA's and NFP's service models and implementation systems that are expected to affect birth and health outcomes. The implementation study will answer the following questions:

- How is each evidence-based model — HFA and NFP — defined at the national level?

- How do local home visiting programs specify or adapt their service models relative to the national models with which they are affiliated?

- To what extent are local service models and implementation systems focused on preterm birth and related outcomes?

- What dosage of services do families actually receive in local programs and how much does it differ from the intended dosage?

- What kinds of referrals are provided to community services that could affect birth outcomes and the child's and mother's health?

- How do programs' inputs (such as the two service models, the extent of focus on birth outcomes, family characteristics, staff attributes, and community characteristics) relate to achieved outputs (in particular, the dosage of services received and referrals provided)?

Finally, the study will examine the intersection of impacts and implementation to address the following broad research questions:

- How do the home visiting models achieve their impacts?

- How is the level of dosage or enrollment length related to program impacts?

The Sampling Plan

To provide unbiased estimates of the effects of home visiting programs, families who are recruited into the study will be randomly assigned either to a program group that can receive home visiting services or to a control group that will receive referrals to other services available in the community. In choosing local programs for MIHOPE-Strong Start, the study team looked for places where the need for home visiting services far exceeds the capacity of local programs in most places, allowing for the ethical creation of a control group. When a program cannot serve all eligible families, a lottery is one way to allocate scarce slots, rather than, for example, accepting all families only until slots are full and then creating a waiting list. The study is adhering to all ethical standards and has undergone human subjects review by the MDRC Institutional Review Board, as well as a number of state and local Institutional Review Boards.

Initial discussions of the study design included much larger sample size estimates, based in part of the relative rarity of the birth outcomes of interest and in part on actuarial calculations of the sample size needed to detect reductions in Medicaid costs due to improved birth outcomes. However, it soon became clear that recruiting such a large sample in the time frame of the study would not be possible. Therefore, further analyses were conducted to determine a sample size that could be realistically obtained and still allow for key questions of interest to be examined.. Specifically, the study is seeking to include about 3,400 families in estimating the effects of home visiting programs on birth outcomes and maternal and infant health and health care. When

they enter the study, women will be no more than 32 weeks pregnant, at least 15 years old, and must be able to complete a short survey in either English or Spanish. The sample is expected to be spread across approximately 75 local home visiting programs.[3] To reduce the costs of recruiting local programs into the study, monitoring their activity in the research, and data collection, the study is operating in 17 states. All families who fall within the study's eligibility guidelines will be randomly assigned to a home visiting group or a comparison group that receives referrals to other services in the community, whether or not they participate in the research, to ensure that a family's willingness to participate in the study does not affect their likelihood of receiving program services.

In addition to allowing for the creation of a control group, local programs were chosen for the study based on several criteria. They must have existed for at least two years before starting enrollment into the study. Although, as noted previously, programs that have been running for at least three years are likely to be even more stable, limiting the study to programs in operation at least two years provided a larger number of potential local programs while maintaining the desire to include programs that have matured past their start-up phase. Local programs must also have been located in an environment with few other home visiting services available for control group members. They must also have demonstrated that a high percentage of the families they serve receive Medicaid or CHIP or are enrolled in Medicaid or CHIP prior to giving birth. They could not have evidence of severe implementation problems (for example, unstable funding or lack of connections to service providers) that would interfere with the site's ability to be in the study. To the extent possible, the study selected local programs that contribute to the diversity of families for purposes of estimating effects for important subgroups. Finally, local programs were not to be located in service areas where the families they serve are likely to have received services under other parts of the Strong Start Initiative.

Data Collection and Analysis Plan

An impact analysis will estimate the effects of home visiting on prenatal health care use, birth outcomes, infant health, and maternal and infant health care use until the infant is one year old. The analysis will start with an analysis for the full sample, by model (HFA and NFP), and for key subgroups. In all three cases, results will be presented for an "intent-to-treat" analysis that compares all program group members—regardless of whether they actually received home visiting services—with all control group members, some of whom may have received home visiting outside the MIECHV program. The study intends to analyze state Medicaid and vital records data for families enrolled in the study from each of the 17 states.

An implementation study, designed to complement the impact study, will collect information on community context, influential organizations, the service model, the implementation system, home visitors, families, and actual service delivery. As explained further in Chapter 4, MIHOPE-Strong Start will rely on multiple sources of data to understand how home visiting programs are implemented and what factors affect the quality of implementation. These data include information from each model's management information systems, and interviews with home visitors and program managers at local programs. Collecting basic implementation data

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[3]The number of states, local programs, and families include those enrolled in MIHOPE. Relevant data from MIHOPE will be combined with information collected for MIHOPE-Strong Start for all MIHOPE-Strong Start analyses.

across such a large number of local programs will enable MIHOPE-Strong Start to provide evidence about which program variations are most effective at improving birth outcomes and maternal and infant health care use. It will also provide information about how programs can be designed to best improve these outcomes in the future.

Sampling Plan

This chapter describes the number of families and local home visiting programs that will be included in the Mother and Infant Home Visiting Program Evaluation–Strong Start (MIHOPE-Strong Start), the statistical power of the sampling plan, and the principles underlying how local programs were prioritized and chosen.

Number of Local Home Visiting Programs and Families

The goal is for MIHOPE-Strong Start analyses to include information on approximately 3,400 families (including 2,450 families associated with NFP programs and 950 associated with HFA programs) in approximately 75 sites across 17 states. The large number of local programs was chosen for several reasons. First, many home visiting programs serve a small number of families, so a greater number of local programs is needed to obtain a sample large enough to detect program effects on the outcomes of interest. A large number of families are necessary to have enough power to detect effects because impacts on adverse birth outcomes are typically small. Second, having this many local programs will make it easier for the study to reflect the diversity of communities and families involved in home visiting nationally. Finally, including many local programs enhances the ability of the study to identify the features of local NFP and HFA programs that are associated with stronger program effects.

Minimum Detectable Effects

The statistical power of the sampling plan was assessed using a concept called "minimum detectable effect." A minimum detectable effect is one way of indicating how big an effect would have to be likely to provide reliable evidence that home visiting programs are improving outcomes for families. For purposes of the design, calculations were performed to find the smallest effects that would generate statistically significant findings in 80 percent of studies with a similar design, using two-tailed t-tests with a 10 percent significance level.[1] As noted, 60 percent of families recruited into MIHOPE-Strong Start will be assigned to the program group and 40 percent to the control group.[2]

Table 3.1 shows the minimum detectable effect of this sampling plan for the full sample, for each national model, and for differences in impacts across pairs of subgroups of families (for example, comparing impacts for younger women to those for older women).

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[1]Although many disciplines assess statistical significance at the 5 percent level, the design uses the 10 percent level for two reasons. First, conventions about statistical significance are not universal, and many prior studies have assessed significance at the 10 percent level. More important, for making policy decisions, it can be useful to know that a result is significant at a level between 5 percent and 10 percent. The study will report the exact significance of results using p-values or standard errors to minimize the importance of deeming one specific level as being "significant."

[2]Families who were recruited into MIHOPE and who meet the MIHOPE-Strong Start eligibility criteria will be combined with families recruited into MIHOPE-Strong Start for all analyses. In MIHOPE, 50 percent of families were assigned to each of the program and control groups.

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Table 3.1

Minimum Detectable Effects of Proposed Sampling Plan

	Full Sample	NFP	HFA
Full Sample			
Standard Deviation	0.086	0.101	0.163
Low birth weight (%)	0.025	0.029	0.047
Preterm birth (%)	0.028	0.033	0.053
Number of well-infant visits	0.033	0.039	0.062
Differences across two subgroups (standard deviations)			
50% in larger subgroup	0.172	0.203	0.325
60% in larger subgroup	0.176	0.207	0.332
70% in larger subgroup	0.188	0.221	0.355
80% in larger subgroup	0.215	0.254	0.406
Projected number of families	3,404	2,450	954

NOTES: Results are the smallest true impact that would generate statistically significant impact estimates in 80 percent of studies with a similar design using two-tailed t-tests with a 10 percent significance level.

No adjustment for multiple comparisons is assumed. Results are based on fixed effects estimates.

Follow-up data are assumed available for all families.

No covariate adjustment is assumed.

Pooled Sample

The minimum detectable effect would be 0.086 standard deviations for the full sample, 0.101 standard deviations for NFP, and 0.163 standard deviations for HFA. For example, if 9 percent of control group babies are born low birth weight, the design would have an 80 percent chance of finding a statistically significant estimated effect if the true effect were 2.5 percentage points (a reduction from 9 percent of the control group to 6.5 percent of the program group) for the full sample, 2.9 percentage points for NFP, and 4.7 percentage points for HFA. If 12 percent of control group babies are born preterm, the design would be likely to detect impacts if home visiting reduces preterm births by 2.8 percentage points (from 12 percent of the control group to 9.2 percent of the program group) for the full sample, 3.3 percentage points for NFP, and 5.3 percentage points for HFA.

These minimum detectable effects are similar to results from several previous studies. As noted earlier, a study of HFA in New York found a 5 percentage point decline in low birth weight births. The NFP study in Elmira found reductions in preterm births of nearly 8 percentage points among smokers.[3] However, these effects have not been found in all studies of HFA and NFP, and MIHOPE-Strong Start presents an opportunity to replicate those earlier findings. In

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[3]Olds, Henderson, Tatelbaum, and Chamberlin (1986).

addition, MIHOPE-Strong Start is larger than earlier studies of the effects of home visiting on birth outcomes and therefore presents an opportunity to obtain more precise information on its effects.

Subgroup Differences

The design also allows for investigation of whether home visiting has larger effects for some subgroups of families.[4] Since statistical power depends on the number of families in each subgroup, minimum detectable differences are presented for cases where 50, 60, 70, and 80 percent of the sample is in the larger of two subgroups (or in either subgroup if each has half of the study sample). Key subgroups might be defined by mother's age (in MIHOPE, nearly 40 percent of sample members are under age 20),[5] racial or ethnic minority status, or smoking status (about 20 percent of pregnant Medicaid recipients are expected to report that they are smokers).[6]

For a subgroup that divides the sample in half – for example, comparing those above and below the median gestational age at baseline – the minimum detectable differences in impacts across the two subgroups are double the minimum detectable effects for impacts for the pooled sample. So, for the sample size of 3,400 (2,450 NFP, 950 HFA), the minimum detectable effect is 0.172 standard deviations for differences in impacts across subgroups for the full sample, 0.203 standard deviations for NFP, and 0.325 standard deviations for HFA. For an outcome such as the percentage of preterm births, the design could detect differences in impacts across the subgroups of about 5.0 percentage points for the full sample (that is, including participants both models). These minimum detectable differences in impacts increase gradually as the proportion of families in one subgroup increases. For a comparison of smokers and nonsmokers (who are expected to be 20 percent and 80 percent of the sample, respectively), the minimum detectable differences in impacts across subgroups are 0.215 standard deviations for the full sample (or a difference of about 6.2 percentage points in the impact on preterm birth), 0.254 standard deviations for NFP, and 0.406 standard deviations for HFA.

Program Features

In addition to estimating the average effect of home visiting programs and effects by subgroup, the study will explore the relationship between program features and program impacts to answer the research question related to how programs achieve their impacts. Program features could include any aspect of the community context, implementation system, service models, organizational influences, or home visitor characteristics that are described in the conceptual framework. For example, this analysis could explore how program impacts vary with the background and training of home visitors, or how impacts vary depending on the emphasis of the local program on prenatal health or smoking cessation.

Because local programs would not be randomly assigned to have different program features, results of this analysis would be less rigorous than main results from the impact analysis. For example, a finding that local programs with higher intended dosage around prenatal care had

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[4]Bloom and Michalopoulos (2010).

[5]Michalopoulos et al. (2015).

[6]A recent CDC analysis of the National Health and Nutrition Examination Survey (NHANES) data found that 24 percent of pregnant Medicaid recipients were smokers (Dietz et al. (2011); Russell, Crawford, and Woodby (2004)) and an average misclassification rate at baseline of 26 percent, which would imply that about 20 percent of pregnant women would self-report that they are smoking.

larger effects on prenatal care than other local programs would not necessarily mean that higher intended dosage caused the larger effects. Instead, it is possible that other features of the local program or local implementation system are responsible. Thus, this type of analysis may suffer from the biases that can affect any regression framework, such as omitted variable bias — in which estimated effects are biased if important program features are omitted from the analysis — and selection bias.

The precision of the estimated relationships between program features and program impacts increases with the number of local programs and the precision of impact estimates within each site. The precision decreases with the number of program features to be investigated and how related the various program features are to one another.[7] As an example of the last point, it may be very difficult to distinguish the effect of planned duration of home visits from the effect of actual duration, since the two are likely to be closely related in a particular local program. Finally, the precision will increase with variation in characteristics across local programs. For example, it would be impossible to examine the influence of intended frequency of home visits if all programs use the same intended frequency. For that reason, final decisions about which features to include in this analysis will not be made until information on program implementation has been collected and compared across study sites.

Table 3.2 shows the minimum detectable effects of program features for a program feature that can be characterized by a binary indicator. For example, half of the local programs might plan to visit families weekly while half would visit only every other week. Results are presented depending on whether 10, 20, or 30 program features would be examined at one time. Results for each scenario are presented for three assumptions about how highly correlated various program features are with one another.

Consider the first row of Table 3.2, which shows the case where 10 program features are being examined simultaneously and there is a low correlation across them. The study would be able to detect differences of 0.314 standard deviations in impacts between local programs of one type and sites of another type (which translates, for example, into a difference in impacts on preterm births of about 10 percentage points across the two groups of local programs). The ability to detect an effect of a program feature is only slightly worse if more features are examined, but the minimum detectable effects increase markedly if the features are highly correlated with one another. As a result, the study would have little ability to distinguish the effects of several highly correlated features. With 10 highly correlated features, for example, the minimum detectable difference is nearly 1 standard deviation, which is quite large. One way to avoid this problem is to use factor analysis to characterize the local programs in terms of orthogonal factors (that is, those that are not correlated with one another). Final decisions about which program features will be included in this analysis will be made after investigating which program features show substantial variation across local programs.

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[7]Greenberg, Meyer, Michalopoulos, and Wiseman (2003).

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Table 3.2

Minimum Detectable Effects of Program Features

Number of Variables representing program features	Correlation across program features	Minimum Detectable Effect
10	Low	0.314
	Medium	0.444
	High	0.992
20	Low	0.351
	Medium	0.496
	High	1.109
30	Low	0.405
	Medium	0.573
	High	1.280

NOTES: Results are the smallest true impact that would generate statistically significant impact estimates in 80 percent of studies with a similar design using two-tailed t-tests with a 10 percent significance level.

No adjustment for multiple comparisons is assumed.

Results are based on fixed effects estimates.

The correlation across program features is based on the R^2 statistic when one program feature is regressed on all other program features.

For purposes of the calculations, a low correlation means the R^2 increases by .01 with every added feature, by .02 with every added program feature for a medium correlation, and by .03 for a high correlation.

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Implementation Study

This chapter describes the design of the implementation study of the Mother and Infant Home Visiting Program Evaluation–Strong Start (MIHOPE-Strong Start), which will examine what services are delivered to families, as well as how, and how often or to what degree they are delivered. This information, in turn, will inform the questions of how programs affect birth outcomes, prenatal care, infant health, and health care use, and how dosage or enrollment length is related to impacts. In addressing these objectives, the information in the implementation study can also provide insights into strengthening future home visiting programs.

Implementation Research Questions

Although some earlier studies of home visiting programs have found modest impacts on maternal and infant health and health care use – highlighting the potential of such programs to improve such indicators – not all studies have found positive effects. Differences in findings may be related to differences in how well the programs were implemented. This is consistent with a review of over 500 studies of prevention and health promotion programs for children and adolescents that found that effects were at least two to three times greater when programs were carefully implemented and free of serious implementation problems.[1]

To help understand the relationship between program implementation and program effectiveness, the implementation study for MIHOPE-Strong Start will document the key features of program models, implementation systems, and service delivery that are expected to affect birth outcomes and health care use, and how these vary across the two national models and across local programs. As outlined in Chapter 2, in addition to documenting intended services as defined at the national level and adaptions made by local programs, the implementation study will document the dosage of services families receive (and how that might differ from what is intended by the national home visiting model). This part of the study will also examine how program inputs (including the consistency of focus and strength of supports that local programs provide for key outcomes) and community characteristics relate to the services families receive.

Data Sources for the Implementation Study

The primary sources of data for the implementation study include reviews of national model documents, interviews with national model developers, management information systems, structured web-based surveys of program staff, and structured surveys of women when they enter the study (which is discussed later in Chapter 5). Table 4.1 lists the data sources for each set of inputs and outputs of interest.

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[1]Durlak and DuPre (2008).

**Mother and Infant Home Visiting Program Evaluation-Strong Start
(MIHOPE-Strong Start)**

Table 4.1

**Constructs and Data Collection Instruments for MIHOPE-Strong
Start Implementation Research**

Implementation Constructs	Data Collection Instruments
Community resources	
Service availability	Web-based surveys of managers and home visitors
Service coordination	Web-based surveys of managers
Organizational influences	Web-based surveys of managers
Service model	National model interviews and documents
	Web-based surveys of managers and home visitors
Implementation system	National model interviews and documents
	Web-based surveys of managers and home visitors
Staff attributes	Web-based survey of home visitors
Family attributes	Baseline family interview
Services delivered (outputs)	
Dosage	HFA and NFP management information systems
Referrals	HFA and NFP management information systems

The following sections describe the measurement strategy for each component of the implementation study. These include community resources, organizational-level factors, and staff characteristics that may affect delivery of services. They also include measurement of the actual services delivered. Measurement of family characteristics, which may also affect service delivery, is discussed in Chapter 5.

Community Resources

The communities in which home visiting programs operate can influence how programs function and their ability to affect outcomes. For example, home visiting programs operating in communities with a rich mix of services and resources should be better able to meet the needs of families through referrals. Home visiting programs with strong connections to community resources should likewise be better able to meet family needs. The conceptualization of community resources in MIHOPE-Strong Start includes two main constructs: service availability and service coordination.

Availability of relevant community services will be measured by surveying home visiting program staff about their experiences with services including: prenatal care, maternal preventive care, family planning services, mental health care and substance use treatment, services to address family violence, and pediatric primary care. Specifically, for various types of family service needs, program managers and home visitors are being asked whether there is at least one organization in the community that they can refer families to, whether they think it is easy or hard for families to get services from that organization, whether they perceive the organization to be effective in meeting their families' needs, and how well they are able to share information

about referred families with this organization. In addition, program managers are being asked whether organizations place families on waitlists, whether families experience difficulty accessing services, and to identify various reasons for those difficulties. This information will be used to create a measure of service availability for each outcome, as well as measures of service accessibility and coordination with the home visiting program.

Organizational-Level Factors

To offer lessons on how to improve the effectiveness of home visiting, MIHOPE-Strong Start will gather information on the factors underlying variation in service delivery. Two of the key inputs into service delivery are the service model – which defines the program plan – and the implementation system – which defines the policies, procedures, and resources to carry out that plan. Both the service model and implementation system are shaped and influenced by multiple organizations.

Organizational Influences

Organizations that can influence how a program delivers services and supports service delivery include the local program operator, the purveyor of the evidence-based model that has been adopted (HFA or NFP), the state MIECHV grantee (if the site is participating in MIECHV), and community organizations and partners with which the local agency collaborates. Through web-based surveys, program managers will be asked about the type of implementing agency operating their program, sources and the stability of funding, and how well the national model's goals fit with the needs and mission of their local program. As noted earlier, program managers will also be asked about their relationships with other community partners.

Service Model and Implementation System

MIHOPE-Strong Start will measure the service model and the implementation system from the perspectives of both the national model and the local home visiting program. Earlier implementation studies suggest that dosage and other aspects of actual services received by families vary considerably from program to program and family to family, and it is important to assess the sources of variation. Services may vary across programs because of deliberate changes to the service model by local programs to meet local needs; local programs or home visitors' exercising of discretion as intentionally afforded them in the national program model; or simply "drift" or unintentional divergence by home visitors from the service model. Thus, it is important to understand the service model from both perspectives.

To measure service models and implementation systems as defined at the national level, national model staff were interviewed by phone and the study team reviewed relevant national model developer documents. To measure the service models and implementation systems in local MIHOPE-Strong Start sites, program staff are completing Web-based surveys. For example, the local service model's degree of focus on birth outcomes is being assessed through surveying program managers about which outcomes are highest priority, how explicitly the program communicates this priority to staff through its policies about home visitors' roles and responsibilities with respect to birth outcomes, and how much structure and discretion staff are given in working with families. Web-based surveys will also assess home visitors' perceptions about their program's priorities, including the program's emphasis on improving birth outcomes and focus on prenatal and infant health.

Staff and Parent Characteristics Affecting Service Delivery

Home visiting services are directly affected by the characteristics of home visitors and parents. Both individual- and organizational-level theories of behavior suggest that a range of predisposing, reinforcing, and enabling factors will influence home visitors' activities and families' participation in home visiting. Data collection of home visitor characteristics relevant to program implementation are described here, while mothers' characteristics, collected through the family baseline survey, are discussed in the next chapter.

Home Visitor Predisposing Factors

Predisposing factors are characteristics of the individual that influence a behavior, such as demographics, educational and employment background, psychological well-being, and beliefs, attitudes, knowledge, and skills. As shown in Table 4.2, MIHOPE-Strong Start will measure home visitor predisposing factors through baseline web-based surveys of home visitors.

Demographics and Educational and Employment History

Web-based surveys will collect information on demographics, education, and employment history of home visiting staff using items drawn from existing large scale studies and prior home visiting research.

Psychological Well-Being

Earlier research has found that home visitors' psychological well-being can influence family engagement, home visit content, and their likelihood of leaving the job.[2] To measure depressive symptoms, MIHOPE-Strong Start is using a 10-item short form of the Center for Epidemiologic Studies Depression Scale (CES-D), which detects major or clinical depression in the general non-psychiatric adult population with a recall period of one week.[3]

Outcome- and Activity-Specific Beliefs, Perceptions and Self-Efficacy

Prior work suggests that that a home visitor's beliefs, attitudes, and self-efficacy concerning the specific activities and outcomes targeted during home visits will influence how she delivers services.[4] A home visitor will be more likely to carry out activities to achieve good birth outcomes, for example, if: a) she believes that her program views this as a top priority; b) she herself believes the outcome is important; c) she believes her program expects her to carry out the activity; and d) she believes she is competent to carry out the activity well, even in challenging situations. MIHOPE-Strong Start will measure these constructs for domains relevant to birth outcomes, using items from a survey of home visitors.

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[2]Burrell et al. (2009).
[3]Radloff (1977).
[4]Duggan (2011).

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Table 4.2

Measurement of Home Visitor Predisposing Factors for Service Delivery

Construct	Measure	Timing, Source, and Method
Demographics Employment history Educational history	Self-report items from other large-scale national studies and home visiting studies[a]	Baseline home visitor web-based survey
Psychological well-being:		
Depressive symptoms	Center for Epidemiologic Studies Depression Scale (CES-D), 10 items	Baseline home visitor web-based survey
For each outcome domain:		
Perceived importance to agency Personal belief of importance	Self-report items from home visitor surveys[a]	Baseline home visitor web-based survey
For specific activities to achieve outcomes:		
Perceived importance to agency Perceived competence to carry out activity Self-efficacy in challenging situations	Self-report items from home visitor surveys[a]	Baseline home visitor web-based survey
Capacity to make referrals:		
Knowledge of community resources Perceptions of community resources	Self-report items from home visitor surveys[a]	Baseline home visitor web-based survey

NOTE: [a]Self-report items adapted from studies such as the randomized trial of Hawaii's Healthy Start Program (Burrell, McFarlane, Tandon et al. 2009).

Capacity to Carry Out Referrals

A home visitor's capacity to perform an activity is likely to influence whether and how well she carries it out. In particular, it is hypothesized that a home visitor's knowledge of and attitudes toward the availability and accessibility of specific community resources will influence whether and how she makes referrals. Prior research has shown substantial variation in this capacity across programs and home visitors, and improvements with training and other implementation system enhancements.[5] The web-based survey will assess home visitors' knowledge and skills with regard to making referrals relevant to birth outcomes and appropriate use of health

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[5]Tandon et al. (2008).

care. The survey will also assess, as noted earlier, the home visitors' perceptions about the effectiveness of the referral organizations.

Home Visitor Reinforcing and Enabling Factors

Reinforcing factors are characteristics of interpersonal relations that follow a behavior and influence the individual's future repetition of it. For example, the supervision received by home visitors may support provision of certain behaviors over others. Enabling factors are attributes of the environment antecedent to a behavior that makes it easier or more difficult to carry out the behavior. Examples of enabling factors for home visitors include receipt of training about birth outcomes and availability of screening tools and education materials. Home visitor reinforcing and enabling factors are being measured through web-based surveys of home visitors as shown in Table 4.3. The specific enabling and reinforcing factors that are being measured in the implementation study are further described below.

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Table 4.3

Measurement of Home Visitor Reinforcing and Enabling Factors for Service Delivery

Construct	Measure	Timing, Source, and Method
Reinforcing Factors		
Ongoing supervision feedback		
Ratings of supervision received	Self-report from home visitor survey	Baseline home vistor web-based survey
Enabling Factors		
For each outcome domain:		
Home visitor training activities	Self-report from home visitor survey	Baseline home visitor web-based survey
Ratings of training adequacy		
For each outcome domain:		
Home visitor administrative supports	Self-report from home visitor survey	Baseline home visitor web-based survey
Usefulness of supports received		
Home visitor clinical supports		
Timeliness and usefulness of supports received		

Ongoing Supervision and Feedback

Home visitors are rating various aspects of the supervision that they have received, including attributes of their supervisor, such as communication style. Home visitors are also being asked to rate their supervisor's feedback in all the outcome domains.

Training Activities

Home visitors are rating the training they receive at their local program, reporting on how adequately prepared they feel to help mothers achieve outcomes from all domains.

Administrative Supports

Home visitors are being asked about their access to certain technology resources (such as computers, the Internet). They are also being asked a series of questions regarding how they document what happens in each home visit, including questions about their use of paper forms and electronic record systems for documentation, the ease with which they are able to complete this documentation, and the ease with which they can access their documentation as needed.

Clinical Supports

Home visitors are being asked to rate the timeliness and helpfulness of their supervisor's guidance in each outcome domain area. Additionally, home visitors are being asked about the availability, accessibility, and helpfulness of professional consultation for each outcome domain.

Services Delivered

As shown in the MIHOPE-Strong Start conceptual framework, the services that are actually received by families are the means by which a local program directly influences family outcomes. Thus, an important goal of the study is to understand the extent to which families receive the intended services. Service delivery can be characterized in terms of the quantity of services delivered (dosage), content and techniques, and referrals to other services and supports (Table 4.4).

MIHOPE-Strong Start focuses on understanding three aspects of service delivery that are fundamental to whether home visiting programs accomplish their goals – the dosage or frequency, intensity, and duration of services to which a family is exposed, the frequency and types of referrals that home visitors provide to outside services, and other aspects of visits such as the content delivered. Table 4.4 displays the approach for collecting information on service delivery in MIHOPE-Strong Start.

Dosage

National model and state-level management information systems are the primary source of information about dosage, specifically the intensity of services over time and the duration of program enrollment. Dosage is measured by indicators including the number of visits, the length of each visit, and the duration of family enrollment in the program. Fidelity measures will also be created and analyzed, such as the ratio of visits achieved to visits intended by the national service model and the local service model. Depending on data availability in the management information systems, reasons for client attrition may also be examined.

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Table 4.4

Measurement of Service Delivery

Construct	Measure	Source
Dosage		
Duration on enrollment	National, state, and site-level	MIS[a]
Number of home visits	policies and actual dosage	MIS[a]
Reasons for disenrollment		MIS[b]
For each visit:		
Date, length, distribution of time		MIS[a]
Content and techniques		
For each visit:		
Content/activities specified in theories of change for each relevant outcome domain	National, state, and site-level policies and actual content / techniques	MIS[b]
Referrals to other services and supports (for each visit)	National, state, and site-level policies and actual and referrals	MIS[a]

NOTES: [a]All MIHOPE-Strong Start sites for which the project is able to obtain management information system (MIS) data.

[b]Possible additional variables; use dependent on availability in MIS.

Referrals

While dosage and duration of enrollment are the key service delivery measures of interest in MIHOPE-Strong Start, the study will also examine referrals made by home visitors to other community services because these services would be a primary mechanism through which home visiting can affect birth outcomes and infant health and health care use. Referrals are a critical component of home visiting services, given the multiple risks faced by families. Service models may specify procedures for providing referrals for parents with particular high priority needs. For example, the model may specify that all mothers should be screened for substance use using a particular screening tool, and those who have symptoms of substance abuse should be referred for further evaluation. Because the evaluation has baseline measures of maternal and family risks, indices can be created to track how closely home visitors follow the service models' protocols for referrals for subgroups of parents who report particular baseline risks that are relevant to birth outcomes. A preliminary list based on the proposed MIHOPE-Strong Start logic models would include depression, substance use, intimate partner violence, smoking, and inadequate prenatal care.

Other Information on Actual Services Delivered

To contribute to greater understanding of how home visiting models achieve results for birth outcomes and infant health and health care use, additional information from management

information systems could be examined if it is widely available. This information might include the distribution of content during home visits (topics covered and approaches used), participants in home visits, and engagement and responsiveness of client during visits.

Analysis Plan for Program Implementation and Dosage

In order to understand how home visiting models achieve impacts on birth outcomes, infant health, and health care use, it is critical to understand how the programs are implemented and how, in turn, program impacts vary as program features vary. This section describes analyses that will be aimed at documenting aspects of program implementation that are fundamental to understanding the treatment that was delivered, understanding the factors that influenced service delivery, and interpreting the program's impacts on birth outcomes and health care use.

Analyses that address the implementation research questions outlined earlier will include descriptive analyses as well as tests of specific hypotheses about how particular inputs affect service delivery, to yield lessons for strengthening home visiting programs in the future. The first set of questions described earlier – including how HFA and NFP are defined, how local programs have adapted their service models, and the extent to which local service models and implementation systems are focused on preterm birth and related outcomes in a clear, coherent way – center on the inputs into the program: the national service model, the local service model, the implementation system, local community resources, and the program staff. For many program features, information will come from qualitative data sources (such as program documents from the national models and qualitative interviews with the national model developers) as well as quantitative data sources. Descriptive analyses will therefore require the construction of categorical and interval variables that reduce and simplify quantitative and qualitative data collected from multiple sources over the course of the evaluation. For many inputs, the data will be specific to each outcome domain that is relevant to birth outcomes. Thus, the analysis will not only describe overall site-level inputs (e.g., home visitor educational credentials) but also describe inputs as they relate to birth outcomes and to mediating outcomes like prenatal health, mental health, substance abuse, and smoking (e.g., the extent to which home visitors have received training in each of these domains).

The analyses of program model definitions, local sites' adaptations, and clarity and coherence of local implementation systems and service models on improving maternal and infant health outcomes and health care use will be primarily descriptive and comparative. For example, an analysis of the goals of the local programs will present information about how program managers and home visitors describe the local program goals on average and by national program model, the distribution of responses overall and by national program model, and a comparison between local program goals and the goals articulated by HFA and NFP. These facets of program implementation, traced and compared across program models and local sites, may be particularly relevant for understanding variation in dosage.

The next set of analyses will describe the amount of services that are directly received by families. It will be important not only to measure the dosage that is delivered but also to compare this with the dosage that was intended. One local program might provide visits less often than another one not because its services are poorer but because its service model calls for less intensive services. Thus, both absolute levels of dosage and fidelity of dosage (the extent to which

actual services conform to what is specified in the service model) could be associated with program impacts.[6] Fidelity of dosage can be measured in a straightforward way as the proportion of the intended dosage that was actually received by an individual or, in aggregate, provided by a local program or national model to its enrollees. MIHOPE-Strong Start might advance the field by studying the degree to which local programs deviate from intended dosage and the factors that are associated with unintended variability. For example, home visitor training and supervision may be related to unintended variability in dosage; programs that do not provide adequate training and supervision to home visitors but still hold them accountable for achieving outcomes may have higher turnover of both staff and families, which may lead to both lower dosage and lower fidelity of dosage. These kinds of analyses may suggest ways of limiting unintended variability and thus achieving more consistent effects across programs.

The last set of analyses will investigate how differences in inputs to local program models relate to differences in the services families receive, including dosage of services and referrals provided. Many factors are likely to be related to the intensity of services delivered to families, as discussed above. In addition to clarity and coherence of service models, family characteristics and risk factors may play a role in the number of actual services delivered. This analysis will investigate which program model characteristics, including family and staff characteristics, availability of community resources, service model and implementation system components, are the most salient for predicting "outputs" for families using a regression framework.

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[6]Dane and Schneider (1998); Mowbray, Holter, Teague, and Bybee (2003).

Chapter 5

Impact Study

A key objective of the Mother and Infant Home Visiting Program Evaluation – Strong Start (MIHOPE-Strong Start) is to systemically assess the effectiveness of home visiting to improve birth and infant health outcomes, as well as to promote adequate and appropriate health care use during pregnancy and after birth. Potential impacts of home visiting will be assessed for the overall sample, as well as for subgroups of families. The specific research questions to be addressed by the impact analysis of the evaluation are:

- What is the impact of evidence-based home visiting for Medicaid or CHIP-eligible pregnant women on birth outcomes, prenatal care, and infant health and health care use up to the first year postpartum?

- What are the impacts of each national home visiting model on birth outcomes, prenatal care, infant health, and health care use?

The study will also examine the intersection of impacts and implementation to address the following broad research questions:

- How do the home visiting models achieve these impacts?

- How is the level of dosage or enrollment length related to program impacts?

This chapter further describes the design for collecting and analyzing the data to address these research questions. Although the chapter presents many details of the analyses, final decisions for many parts of the analyses will be made only after more information is available. For example, final decisions about which outcomes will be included in the main impact analysis will be made after the team assesses the quality of data available from the U.S. Standard Certificate of Live Birth (henceforth referred to as the revised birth certificate) and state Medicaid systems, which the study will rely on for information on outcomes for families. Likewise, final decisions about which subgroups of families to examine will be made after more information is available about the characteristics of families who enroll in the study. Finally, decisions about linking local program features to impacts cannot be finalized until the team knows more about how local programs have been implemented. A final analysis plan for the impact study will be developed once these additional pieces of information are available, and before the impact analysis is conducted.

Measures for the Impact Study

Answering questions about the effectiveness of home visiting programs begins with choosing the right measures and data. The impact analysis will rely on several sources of information including health care use measured through State Medicaid and CHIP systems, birth outcomes recorded in state vital records systems, brief surveys with women when they enter the study, and home visiting management information systems.

Baseline Information for the Impact Study

Baseline data – information on families at the time they enter the study – will be used for three purposes: to describe the sample, to measure moderators of program impacts (such as maternal depression and smoking), and to increase the statistical precision of impact estimates.. Ta-

ble 5.1 shows the information that will be collected at baseline and which data sources will provide each piece of information.

Baseline Demographic and Family Economic Self-Sufficiency

The revised birth certificate includes information on demographics, including both parents' age, education, race, and ethnicity.[1] To ensure the study has consistent measurement in states that have adopted the revised birth certificate and have not, some questions about baseline demographics will also be collected in the family baseline survey.

As noted earlier, low income is strongly associated with poor birth outcomes. To measure income, the family baseline survey asks women about their earned income and their household's total income. The baseline family survey also obtains a household roster to determine household size and composition. Finally, the survey includes several questions to gauge food security, which has been found to lead to greater weight gain during pregnancy, which can further lead to complications during pregnancy.[2] Questions on food insecurity were taken from the National Health and Nutrition Examination Survey (NHANES)-Short Form, which is one component of the Centers for Disease Control and Prevention's National Center for Health Statistics data systems and surveys.

Baseline Maternal Health

Maternal physical and mental health and health behaviors such as smoking have been linked to birth outcomes in a number of ways. The revised birth certificate includes information on a number of these health-related risk factors. For example, it includes information on poor outcomes in prior births (such as preterm births, spontaneous losses, ectopic pregnancies, and perinatal death) and smoking behavior prior to and throughout pregnancy. Information on maternal health conditions such as gestational diabetes and hypertension will also be available from birth certificate data. Because reports of smoking on the birth certificate may be unreliable and may not indicate when smoking occurred, the family baseline survey also includes questions on smoking behavior.[3] In addition, information on diagnoses may be available from Medicaid claims data, which may also indicate whether such diagnoses occurred prior to study entry. Finally, information on maternal illness and health conditions during pregnancy (such as vaginal bleeding, kidney or bladder infection, hyperemesis, high blood pressure) will be obtained from the baseline survey.

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[1]The revised birth certificate is not universally used in all states; as of December 31, 2011, 38 states implemented the revised birth certificate (California, Colorado, Delaware, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Massachusetts, Michigan, Minnesota Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Washington, Wisconsin, and Wyoming). However the core set of measures are consistent across the 1989 (unrevised) and 2003 versions.

[2]Laraia, Siega-Riz, and Gundersen (2010).

[3]Neither birth certificate data nor self-reports are perfectly accurate (Allen et al. (2008)), and studies suggest lower reporting rates to clinical records (DiGiuseppe et al. (2002)). The study will compare the two sources of information to look for inconsistencies and to assess the possibility of supplementing or pooling the two sources.

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Table 5.1

Baseline Measures

Domain and constructs	Source	Proposed survey measures or sources
Demographics		
Maternal age, race, and ethnicity	BC, FBS	Mother's date of birth, race, and ethnicity
Maternal education	BC	Mother's education level
Paternal age, education, race, and ethnicity	BC	Father's date of birth, education level, race, and ethnicity
Family Self-Sufficiency		
Income: Maternal earned and household income in last month	FBS	Items from the Supporting Healthy Marriage (SHM) 12 month follow-up surveys
Housing and Household Composition: Age and relations of other members	FBS	Items from HtE-EHS and Supporting Healthy Marriage (SHM) follow-up surveys
Food Insecurity	FBS	National Health and Nutrition Examination Survey-Short Form
Maternal Health		
Prior preterm births and other poor birth outcomes	BC, FBS	Miscarriages, fetal death, or infant mortality in the year prior to becoming pregnant
Smoking during pregnancy	BC, FBS	Number of cigarettes smoked
Illnesses and health conditions during pregnancy (e.g., diabetes, gestational diabetes, gestational hypertension, other high-risk factors)	BC, MF, FBS	Problems during current pregnancy
Depression and anxiety	FBS	CES-D (Radloff 1977), GAD-7 (Spitzer et al. 2006).
Intimate Partner Violence		
Intimate partner violence	FBS	Conflict Tactics Scale (Straus et al. 1996), Women's Experience with Battering-Short Form (Smith, Smith, and Earp 1999)
Baseline Maternal Health Care Use		
Mother's Service Use: Use of prenatal care, hospitalizations, emergency department visits, having a usual source of care, and type of facility	BC, MF, FBS	Initiation of prenatal care and number of prenatal care visits

NOTE: BC = Birth Certificate; MF = Medicaid Files; FBS = Family Baseline Survey

Regarding maternal mental health, the family baseline survey includes several measures. First is a short form of the Center for Epidemiologic Studies Depression Scale (CES-D), which detects major or clinical depression in general non-psychiatric adult populations with a recall pe-

riod of 1 week.[4] The survey also assesses for anxiety using the Generalized Anxiety Disorder 7-item scale, which is designed to detect significant and severe anxiety.[5] Previous research has shown that individuals with high scores on this instrument have exhibited signs of sickness, including more doctor visits than those with low scores.[6]

Intimate Partner Violence

The survey includes questions from the Conflict Tactics Scale and Women's Experience with Battering to assess maternal experiences of physical and psychological intimate partner violence, which may serve as a potential moderator of home visiting program impacts.

Baseline Maternal Health Care Use

Medicaid claims may be a rich source of baseline information on the timing and frequency of prenatal care if health care providers are paid by Medicaid for each visit (rather than being paid once for a set of visits). Although the revised birth certificate also contains some information on these measures, Medicaid data may be more accurate (on number of prenatal care visits, for example) and may allow for distinguishing visits that happen before women enter the study from those that occur afterwards. Information on receipt of prenatal care and number of prenatal care visits will also be assessed in the baseline survey.

Outcomes for the Impact Study

As noted above, parent and child outcomes will be measured using two broad data sources: Medicaid and CHIP-reimbursed health care and birth certificates. Tables 5.2 to 5.4 list key outcomes to be used in MIHOPE-Strong Start, including information about data sources and potential variable definitions, for three areas: (1) birth outcomes, (2) maternal prenatal health care and health behaviors, and (3) infant health care and health status.

Birth Outcomes

Studies that assess the impact of interventions on birth outcomes typically focus on the likelihood of women giving birth to low or very low birth weight or preterm infants (Table 5.2). In addition, babies born small-for-gestational-age, which reflects restricted fetal growth, are at higher risk of health complications[7].

Each of these outcomes will be measured using information from birth certificates. In particular, the revised birth certificate includes information on infants' weight at birth, which can be used to classify infants as low birth weight and very low birth weight. It also includes information on the estimated gestational age at the time of birth, which will be used to determine if a baby was born pre-term and combined with birth weight to form a measure of small-for-gestational age.

A number of studies have examined the quality of these data and have generally concluded that the reliability and validity of the data are high with one exception: information on gesta-

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[4]Radloff (1977).
[5]Spitzer, Kroenke, Williams, and Löwe (2006).
[6]Paul et al. (2013).
[7]Chatelain (2000); Meas et al. (2008); Pallotto and Kilbride (2006); Saenger, Czernichow, Hughes, and Reiter (2007).

tional age exhibits fairly modest overreporting and underreporting.[8] However, there is reason to believe that the quality of gestational age reported on birth certificates will improve by the time the data are collected for MIHOPE-Strong Start as a variety of data-quality improvement efforts are underway at both the national and state levels.[9]

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Table 5.2

Key Measures of Birth Outcomes

Domain/Measure	Variables	Definition	Source
Birth Weight	Low birth weight	Binary indicator of birth weight <2,500 g	BC
	Very low birth weight	Binary indicator of birth weight <1,500 g	
Preterm Birth	Preterm birth	Binary indicator of gestation <37 weeks	BC
Fetal Growth	Small-for-gesational age	Binary indicator of birth weight below the 10th percentile for gestational age	BC

NOTE: BC = Birth Certificate; MF = Medicaid Files

In addition to these key outcomes, the study will examine alternative measures of birth weight, gestational age, and fetal growth as exploratory outcomes. Some of these alternative measures (for example, birth weight and gestational age as continuous variables) are of interest because they have been used in prior research. Others such as indicators of overly large babies may be of potential interest because of related health complications. In particular, overly large babies may experience birth injury and hypertension and are more likely to require cesarean delivery.[10] In addition, these babies are at increased risk of obesity and metabolic syndrome during childhood.[11] Alternative measures of gestational age will also be examined, including very premature birth (at or before 32 weeks) and early birth (less than 39 weeks gestation). Very preterm births, although relatively rare, are especially prone to poor outcomes and require extensive and expensive medical treatment. Near-term births are associated with high neonatal morbidity and neonatal intensive care unit (NICU) admission, and one of the overarching goals of the Strong Start initiative is to decrease the percentage of infants delivered before 39 weeks gestation.[12]

Prenatal and Maternal Health Care Use, Health Behaviors, and Health Outcomes

Home visiting programs that target expectant mothers may improve their access to and use of health care during pregnancy including accessing appropriate prenatal care. As discussed concerning baseline measures, data on prenatal health care use might be obtained from both Medicaid files and birth certificates, as shown in Table 5.3.

In the birth outcomes literature, adequate prenatal care is typically measured by an index that accounts for both early initiation of prenatal care (within the first 3 or 4 months of pregnan-

[8]Clayton et al. (2013); DiGiuseppe et al. (2002); Lain et al. (2012); Reichman and Schwartz-Soicher (2007).
[9]Martin et al. (2013).
[10]Spellacy, Miller, Winegar, and Peterson (1985).
[11]Boney, Verma, Tucker, and Vohr (2005); Schellong, Schulz, Harder, and Plagemann (2012).
[12]Sengupta et al. (2013).

cy) and whether the mother received regular care throughout her pregnancy as recommended by the American College of Obstetrics and Gynecology (ACOG). However, a comparison of adequacy indices underscores the need to distinguish women who appear to have more prenatal care visits than what is expected based on the ACOG recommendations, noting that these women often have high risk pregnancies, use health care services the most, and are more likely to have poor birth outcomes.[13] For this reason, the study intends to use a revised version of the Kotelchuck or Adequcy of Prenatal Care Utilization (APNCU) index, the APNCU 2-M (VanderWeele, Lantos, Siddique, and Lauderdale (2009)), because it accounts for initiation and the number of visits adjusted for gestational age, and has a separate category for women who appear to receive intensive services.[14] Information on the initiation of prenatal care from birth certificate data and number of visits estimated from the Medicaid claims data will be used to create this measure.

Most validation studies of prenatal care reports find fairly high levels of agreement (at least 80 percent) on month of initiation between birth certificate data and hospital medical records (the "gold standard;").[15] Medicaid claims data should be able to provide information on the number of reimbursed prenatal care visits, although this may be reported in categorical ranges for global billing patients in managed care plans. The extent to which this is possible for all states' Medicaid files in MIHOPE-Strong Start is unknown, and will thus need to be revisited once the data are further assessed. Sensitivity checks can also be done using the birth certificate data for both prenatal care initiation and number of visits, in order to see whether discrepancies in reports across data source changes the results.

Home visiting programs could influence the receipt of health care at birth. Therefore, it may be of interest to conduct additional exploratory analyses on the impact of home visiting on method of delivery, intensive care unit (ICU) stay during delivery, and length of hospital stay after delivery, which are all highly correlated outcomes. Over-use of cesarean delivery for low-risk nulliparous women is on the Institute of Medicine's (IOM) six aims for improvement in obstetric care. In addition, non-vaginal deliveries result in longer hospitalizations, resulting in increased healthcare costs. However, these outcomes are considered exploratory because there is very limited or mixed evidence regarding the effects of home visiting program.[16]

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[13]Alexander and Kotelchuck (1996).

[14]The original categories of the Kotelchuck or APNCU index include *no care*; *inadequate care* (women who either initiate late OR report visits that are less than 80 percent of the recommended number based on gestational age); *adequate care* (women who begin care in months 1 to 4 of pregnancy, and receive 80 to 109 percent of recommended visits); and *intensive care* or *adequate plus* (report visits that exceed 110 percent of that recommended by ACOG based on gestational age, regardless on when they initiated prenatal care).

A revision to this index, called APNCU 2-M, modifies the APNCU to allow for a stricter definition of "adequate plus," which is only designated if the actual to expected number of visits ratio exceeds 1.1 *and* if the difference between the actual number of visits exceeds the expected number of visits by two or more. It also classifies prenatal care as "adequate" on the visit scale provided that it does fall in the "intensive care" or "adequate plus" category and provided either that the actual to expected visit ratio is between 0.8 and 1.1 or that the actual number of visits is nine or greater. Finally, the APNCU 2-M combines the "inadequate" and "intermediate" categories because of the similarity between these categories and because once the modifications above are made, only a small share of pregnancies fall in the intermediate category VanderWeele, Lantos, Siddique, and Lauderdale (2009).

[15]Martin et al. (2013).

[16]Barth (1991); Kemp and Harris (2012).

Exploratory analyses will also be conducted on the impact of home visiting on pre- and postnatal maternal health care use, beyond adequacy of prenatal care. These outcomes include the number of emergency department visits and hospital admissions during pregnancy. An evaluation of the Michigan Maternal and Infant Health Program found that Medicaid beneficiaries enrolled in home visiting had higher odds of receiving an appropriately timed postnatal visit, although this study did not employ an experimental (random assignment) design.[17]

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Table 5.3

Key Measures of Prenatal Health Care Use and Maternal Behaviors

Domain/Measure	Variables	Definition	Source
Health Care Use			
Prenatal Care	Adequate prenatal care (APNCU Index)	Binary indicator of "adequate" prenatal care based on the Adequacy of Prenatal Care Use (APNCU) 2-M Index (Kotelchuck 1994; Vanderweele et al. 2009)	BC, MF
Maternal Behaviors			
Smoking during Pregnancy	Smoking anytime during pregnancy	Binary indicator	BC, FBS
	Smoking cessation during pregnancy	Binary indicator	BC
Breastfeeding	Attempted breastfeeding in hospital before discharge	Binary indicator	BC

NOTE: BC = Birth Certificate; MF = Medicaid Files; FBS = Family Baseline Survey

In addition to measures of women's healthcare use, home visiting programs' impacts on prenatal health behaviors will be examined using information found on the revised birth certificates. As summarized in Table 5.3, maternal behaviors that may be examined as outcomes of home visiting include smoking during pregnancy and attempted breastfeeding at hospital discharge. Maternal smoking is one of the best-documented risk factors for poor birth outcomes, and MIECHV-funded home visiting programs are required to report rates of maternal smoking during pregnancy. There is a dose-response relationship between smoking cigarettes and birth weight, in particular, but the relationship is not always found to be linear.[18] An epidemiological study of smoking during pregnancy and birth outcomes found that the sharpest declines in birth weight occur at low levels of tobacco exposure, and this pattern was found for both self-reports of smoking and urine cotinine levels.[19] This underscores the importance of quitting smoking (not just reducing) during pregnancy as a targeted area of improvement for tobacco users enrolled in

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[17]Meghea, Raffo, Zhu, and Roman (2013).
[18]England et al. (2001a); Hebel, Fox, and Sexton (1988); Wang et al. (1997).
[19]England et al. (2001a).

home visiting programs. As noted earlier, the revised birth certificate includes information about the number of cigarettes smoked during each trimester of pregnancy and smoking behavior during pregnancy will be assessed in the family baseline survey. The effects of home visiting on smoking cessation and any smoking during pregnancy will be examined. [20]

Some groups, such as pregnant women, may be more reluctant than others to admit that they are smoking because they are more apt to perceive smoking behavior as socially undesirable. This would suggest underestimation of smoking in the birth certificate data.[21] Validation studies (where self-reports are measured against another source, such as biomarkers) have indeed found underreporting of smoking behavior during pregnancy, although these studies also suggest that pregnant women who are college-educated, married, older than 30 years, employed full-time, planning to breastfeed, and who have insurance other than Medicaid are more likely to underreport smoking compared to other women.[22] Thus, the socio-demographic correlates of underreporting smoking are not likely to overlap strongly with the characteristics of the MIHOPE-Strong Start sample. In addition, an analysis of infant birth weight that examined self-reported measures of cigarettes smoked and urine cotinine found that both measures similarly explained variation in outcomes among the women in their sample.[23] Because information on smoking behavior will also be collected in the family baseline survey, sensitivity checks using these reports can be conducted.

The revised birth certificate also includes an indicator of whether the infant was breastfed at the time of hospital discharge. Prior research suggests that home visiting programs can encourage mothers to initiate breastfeeding.[24] Although early attempts at breastfeeding are not the strongest predictors of extended breastfeeding,[25] breast milk produced during the first few days after birth has the highest concentration of colostrum, which is thought to be among the most beneficial and non-replicable elements of breast milk.[26]

A comparison of birth certificate data and medical records from two states found that breastfeeding at discharge reports had very high agreement (91 percent and 96 percent, respectively).[27] However, there were also false discovery rates between 16 and 19 percent, which indicates that this information is more often reported on the birth certificate data than in medical records. There is also substantial variation by hospital in breastfeeding initiation, which may be explained by differences in population demographics as well as by differences in hospital practices.[28]

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[20]Ideally, smoking would be measured after random assignment. However, the birth certificate provides information on smoking only by trimester. Given that many women quit smoking when they become pregnant (and before enrolling in pregnancy-related services) (Yunzal-Butler, Joyce, and Racine (2010)), it will be difficult to tell whether women in their first trimester smoked before or after enrolling in the home visiting program. Therefore, this analysis would focus on whether women smoked in the third trimester of pregnancy, restricting the sample to women who began participating in home visiting programs in their first or second trimester.

[21]Florescu, Ferrence, Einarson, and Selby (2009).

[22]Allen et al. (2008); England et al. (2001b).

[23]England et al. (2001a).

[24]Kitzman et al. (1997).

[25]Lewallen (2006).

[26]Saint, Smith, and Hartmann (1984).

[27]Martin et al. (2013).

[28]Denk, Kruse, and Rotondo (2011).

The revised birth certificate also includes measures of maternal health that may be of interest. Specifically, it includes indicators of whether a woman developed gestational diabetes or hypertension (preeclampsia) during pregnancy and body mass index (BMI) (pre-pregnancy and at delivery), which can be used to determine whether the amount of weight a woman gained during pregnancy conformed to recommendations from the Institute of Medicine.[29] While one study has found a positive impact of home visiting on pregnancy-induced hypertension, maternal health conditions are perhaps better used as covariates in other analyses rather than outcomes, since these conditions are often not clearly attributable to modifiable behaviors amenable to home visiting interventions.[30] Because there is limited research available on whether home visiting programs can improve gestational weight gain and because there are concerns about the validity of BMI information from birth certificates, analyses of gestational weight gain will be considered exploratory.[31]

Medicaid Enrollment

One concern with the use of Medicaid records is that some parents may lose eligibility for benefits. Since both HFA and NFP aim to help the family achieve economic self-sufficiency, mothers in the program group may be more likely to return to work and therefore may be more likely to have income that makes them subsequently ineligible for Medicaid. Conversely, home visitors may help mothers continue to receive benefits, for example, by helping them become recertified for Medicaid benefits. As long as control group families receive care for their infants and remain eligible for Medicaid, it is likely that their health care providers will help them remain eligible for benefits. To explore whether home visiting increases the length of stay on Medicaid, the study will examine whether mothers are enrolled in the third trimester of pregnancy and the number of days of enrollment in the child's first year.

Infant Health and Health Care Use

Information on infant health and health care use will be obtained from both Medicaid files and birth certificates. Table 5.4 summarizes the key proposed outcomes and their data sources and variable definitions. In particular, Medicaid files and birth certificate data will provide information on NICU use at birth, and Medicaid files will provide information on the number and type of health care visits during the first 60 days of life and the first year of life.

Although there is limited evidence that home visiting may reduce NICU use after birth, it is considered a key outcome because it is an important consequence of improved birth outcomes and a potential source of savings for the Medicaid system. In addition, findings from a quasi-experimental study of home visiting indicate that women who received telephonic case management and periodic home visits during the prenatal period through the Partners in Pregnancy program were significantly less likely to have their babies admitted to the NICU and, on average,

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[29]Institute of Medicine (2009).

[30]Kitzman et al. (1997).

[31]An analysis by Joyce Martin and colleagues revealed that completeness of gestational weight gain on birth certificates varies widely across states (0.6-25.6 percent missing), with an average missing-ness rate of 4.5 percent. In addition, the standard birth certificate lacks information on maternal pre-pregnancy height and weight, preventing comparisons of gestational weight gain relative to pre-pregnancy BMI in states that have not adopted the revised birth certificate (Martin et al. 2013).

their infants had a shorter stay in the NICU than those of a comparison group who received care as usual.[32]

Regarding other aspects of infant health care, there is some evidence that home visiting programs increases the number of well-infant office visits in the first 60 days postpartum and over the course of the infant's first year which in turn, may increase the likelihood of receipt of adequate immunizations. Studies of three different home visiting programs (HFA, Early Start [NZ], and Healthy Steps) reported statistically significant estimated increases in the number of well-child visits.[33] However, an increase in the number of well-child visits may actually reflect poor infant health.[34] Thus, an alternative measure would include the proportion of children who had any well-child visits as opposed to frequency.[35] Because well-infant visits may be indistinguishable from Early Periodic Screening, Diagnosis, and Treatment (EPSDT) visits in the Medicaid claims data, a broad, inclusive measure of well-child visits (that includes EPSDT) will be analyzed. In addition, immunizations during infancy are linked to health status and access to health care, and will thus be examined as a key infant health care-related outcome.[36]

Finally, several studies have found statistically significant estimated impacts of home visiting services on the rate of immunizations in children's first and second years of life, although one study failed to find program effects on immunization rates.[37] In addition, although infant emergency department visits and hospitalizations have been widely studied, the findings have been inconsistent, with one NFP trial demonstrating reductions in emergency department visits in the child's first and second years of life, and one HFA study exhibiting increases in number of pediatric emergency department visits at year 3 follow-up.[38] There is stronger evidence for the impact of home visiting on decreasing the number of infant hospitalization days, although it is limited to evaluations of one model.[39] Despite the inconsistent findings, hospitalizations and emergency department visits in the infant's first year are considered important outcomes in MI-HOPE-Strong Start because of their tolls on the health care system, health care costs, and family well-being.

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[32]Jallo, Bray, Padden, and Levin (2009).

[33]Fergusson, Grant, Horwood, and Ridder (2006); Guyer et al. (2003); Landsverk et al. (2002).

[34]Fergusson, Horwood, Grant, and Ridder (2005); Guyer et al. (2003); Johnston et al. (2006); Landsverk et al. (2002).

[35]Another option is the American Academy of Pediatrics standard of care. Since that standard is very specific, however, few families are expected to meet it exactly.

[36]Whitney, Zhou, Singleton, and Schuchat (2014); Wood et al. (1995).

[37]Guyer et al. (2003); Johnston et al. (2004); Kitzman et al. (1997); Koniak-Griffin et al. (2002).

[38]Anisfeld, Sandy, and Guterman (2004); Olds, Henderson, Tatelbaum, and Chamberlin (1986).

[39]Koniak-Griffin et al. (2002).

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Table 5.4

Key Measures of Infant Health Care Use

Domain/Measure	Variables	Definition	Source
Neonatal intensive care unit (NICU) at birth	Required NICU admission	Binary indicator	MF, BC
	Length of NICU admission	Continuous measure	MF
Infant's health care use up to 60 days postpartum	Percent with emergency department (ED) visits	Continuous measure[a]	MF
	Percent with hospitalizations	Continuous measure[a]	MF
	Number of well-infant (EPSDT[b] and other preventive care) office visits	Continuous measure[a]	MF
Infant's health care use in first year of life	Percent with ED visits	Continuous measure[a]	MF
	Percent with hospitalizations	Continuous measure[a]	MF
	Number of well-infant (EPSDT and other preventive care) office visits	Continuous measure[a]	MF
	Any Medicaid-paid immunizations	Binary measure[a]	MF

NOTES: BC = Birth Certificate; MF = Medicaid Files

[a]For health care use measures, we will also calculate the percent of mothers/infants with any use (e.g., percent with one or more ED visits) in addition to the number of claims. When there is very little variation in the number of claims, we may also use categorical variables (e.g., three categories for 0, 1, or ≥ 2 hospitalizations)

[b]EPSDT, or the Early and Periodic Screening, Diagnosis, and Treatment program, is Medicaid's child health component.

Analytic Approach

Intent-to-Treat Impact Estimates

The starting point for the impact analysis is to estimate *intent-to-treat effects,* whereby all program group members — regardless of whether they actually received home visiting services — are compared with all control group members, some of whom may have received home visiting. Random assignment ensures that these estimates are the unbiased effects of assigning program group families to the home visiting programs.

Impact estimates will be regression adjusted, controlling for family baseline characteristics. Regression adjustment is intended to increase the precision of estimated impacts by reducing the unexplained variation in outcomes across families. Covariates will be chosen based on preliminary analyses exploring correlations with key outcomes, particularly birth outcomes. For example, obesity, poverty, maternal depression, and race and ethnicity have all been associated with poor birth outcomes.

Following the recommendations of Schochet (2009), a short list of key outcomes will be specified before the analysis begins to reduce the likelihood of a spurious finding of program ef-

fects.[40] These outcomes will fall into three broad areas: (1) birth outcomes, (2) infant health care use, and (3) maternal prenatal health care. To further reduce the chance of a false positive finding, results could be adjusted for having multiple outcomes using statistical methods that have been developed for this purpose.[41]

For each outcome, a regression adjusted mean will be presented for the program and control groups. The estimated impact will be the difference in means between the two groups. Two-tailed t-tests will be used to assess statistical significance. Although the list of key outcomes will be kept parsimonious, secondary analyses might be proposed, depending on what is found in the key outcome analysis. For example, if the key outcome impact analysis finds that home visiting programs significantly reduced the number of preterm births, secondary analysis could investigate the distribution of birth weight to see if there were effects on very low birth weight or on the distribution of birth weight.

Subgroup Estimates

Impacts will also be estimated for key subgroups of families to investigate whether home visiting programs have larger effects for some types of families than others. Subgroups will be chosen based on several factors: (1) prior research that indicates that birth outcomes differ according to personal characteristics or behaviors, or that the response to prenatal interventions differs according to those characteristics, (2) theory about who is more likely to benefit from home visiting programs, and (3) potential interest to policymakers. For MIHOPE-Strong Start, key subgroups might reflect risk factors, such as age, smoking status, and racial and ethnic minority status.

Estimates by National Model

To examine the impacts of each national home visiting model on birth outcomes and infant health and health care use, effects will be estimated separately for HFA and NFP and then compared. Presenting results for each model without comparing impacts for the two models could lead readers to inappropriate conclusions about the relative effectiveness of the two models. Of particular concern is the possibility that estimates for the two models will be similar, but one is marginally statistically significant while the other is not statistically significant by a very small margin. The correct interpretation for such a set of findings is that the two models work about equally well, but a focus on statistical significance levels for each model might lead some readers to conclude that only one of the models is effective.

Exploring the Relationship between Program Features and Impacts

In addition to basic intent-to-treat analyses, MIHOPE-Strong Start impact analyses will explore how features of local home visiting programs are related to impacts of those programs. As described earlier, because sites will not be randomized to have different program features, a finding that sites with certain program features had larger effects would not necessarily mean that those features are responsible for the larger effects. Instead, those program features might be related to aspects of the program that were not measured or not included in the analysis. Unbiased estimates generated through random assignment of the effects of home visiting at each site

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[40]Schochet (2009).
[41]Romano and Wolf (2005); Westfall (1993).

will be linked to program features of that site, but the associations uncovered through the analysis might not be causal. Therefore these findings will need to be interpreted carefully.

In investigating the link between program features and program impacts, a parsimonious set of factors will have to be considered in order to preserve statistical power. As discussed in Chapter 4, those features might include whether a goal of the local program was to improve prenatal health; whether a goal was to reduce tobacco, alcohol, and drug use during pregnancy; the clarity of those goals as stated by the local programs; the extent and quality of training that home visitors received related to those two goals; and frequency and quality of supervision. This analysis could also investigate how characteristics of the home visitors are associated with greater effects in some programs.

Because the statistical power of this analysis depends on how closely related program features are to one another, final decisions about the analysis are unlikely to be made until after some data are collected. If the data suggest that many program features are unrelated to one another, a more expansive analysis could be conducted. If, as is more likely, program features are highly related within a site, it will be important to prioritize which small number of features should be included in the analysis while minimizing the possibility that the results would be biased by the exclusion of important features. Alternatively, factor analysis could be used to develop a set of factors that are orthogonal to one another. This approach would increase the statistical power of the analysis, but the resulting factors might not yield findings that would translate into straightforward lessons for programs. The statistical power of this analysis depends on how much variation there is in features across local programs, and this information will be available only after data on program implementation are collected and examined.

Conclusion

This design report provides an overview of the intended data collection and analysis activities for MIHOPE-Strong Start. As the administrative and survey data become available over time, the MIHOPE-Strong Start research team will incorporate new information from the data collected to update our plans for both measurement and analysis. The project aims to provide information in the form of annual reports as data become available, culminating in a final implementation and impact report in late 2017. The study's first annual report, which was published in January 2014, summarized the study design and describes the two national models included in the evaluation. The study's second annual report, which was published in January 2015, described the study's efforts to acquire birth certificate and Medicaid data from states. The third annual report, which will be published in 2016, will describe the families and local home visiting programs that are participating in the study.

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