Transformed Healthy Start Program Evaluation Plan

Study Proposal

Purpose and Origins of Study

The overarching goal of this national Healthy Start (HS) evaluation is to determine the effect of the *transformed* HS program (which was initiated in 2014) on changes in participant-level characteristics (e.g. health services utilization, preventive behaviors, and health outcomes).

Objectives

The national HS evaluation includes three components: 1) implementation; 2) utilization; and 3) outcome. The purpose of the implementation evaluation is to describe HS programs and strategies and to identify program factors that are associated with effective implementation. The purpose of the utilization evaluation is to examine the characteristics of participants and non-participants and factors that help explain differential penetration, or service rates. The purpose of the outcome evaluation is to assess the overall effectiveness of the program with regard to producing expected outcomes among the target population and factors that help explain variation in the program's impact on individual level outcomes. The outcome evaluation will employ a quasi-experimental method, which will include two types of comparisons:

1. A matched individual comparison analysis of linked vital records for HS participants and non-participants in the same general geographic service area for all 100 HS grantees, which maximizes generalizability and will allow for assessment of the key outcome of interest, infant mortality, with adequate statistical power.
2. A matched individual comparison analysis of HS participants and non-participants by oversampling of the Pregnancy Risk Assessment and Monitoring Survey (PRAMS) for a random sample of 15 HS grantees. This component of the evaluation data collection strategy will maximize internal validity with a broader set of outcomes and control or matching characteristics that can influence selection into the program.

Background

Improving pregnancy outcomes for women and children is one of the nation's top priorities. The infant mortality rate (IMR) is a widely used indicator of the nation's health. In 2013, the U.S. IMR was 5.96 infant deaths per 1,000 live births. However, racial-ethnic disparities persist and in the same year, the IMR for infants born to non-Hispanic black mothers was 11.11, more than double the non-Hispanic white IMR of 5.06 (Matthews, et al. 2015). The HS program was created to address factors that contribute to the high IMR, particularly among African-American and other minority groups. The program began in 1991 as a demonstration project with 15 grantees and has expanded over the past two decades to 100 grantees in 37 states and Washington, DC.

The HS program was transformed in 2014 to apply lessons from emerging research, past evaluation findings, and to act on national recommendations from the Report of Secretary's Advisory Committee on Infant Mortality (Secretary's Advisory Committee on Infant Mortality 2013). With an emphasis on standardized, evidence-based approaches, the goal of the redesigned HS program is to improve maternal and infant health and to reduce disparities in adverse perinatal outcomes in the US through evidence-based practices, community collaboration, organizational performance monitoring, and quality improvement. To achieve this

goal, the HS program employs five community-based approaches to service delivery and facilitates access to comprehensive health and social services for high-risk pregnant women, infants, children through their first two years, and their families in geographically, racially, ethnically, and linguistically diverse low-income communities with exceptionally high rates of infant mortality. The five approaches include: (1) improving women's health; (2) promoting quality services; (3) strengthening family resilience; (4) achieving collective impact; and (5) increasing accountability through quality improvement, performance monitoring, and evaluation.

Implementation of the program's approaches and subsequent activities is expected to result in a number of outcomes. Short-term outcomes include changes in knowledge, skills, motivation and health care utilization. Intermediate outcomes include changes in healthy behaviors, community, organizational, and systems capacity, quality, efficiency, effectiveness, active partnerships and networks. Long-term outcomes are related to changes in health status (for example, morbidity and mortality), policies, and environment.

To assess implementation and understand the overall impact of the newly transformed HS program, there is a need for a robust and comprehensive evaluation. Prior evaluations of HS (Devaney et al. 2000; Brand et al. 2010; Drayton et al. 2015; Health Resources and Services Administration 2006; Howell and Yemane 2006; Rosenbach et al. 2010) demonstrated some positive program impact on access to services, integration of services, maternal health care utilization, knowledge, and behaviors, as well as high participant satisfaction with the HS program. However, the evaluations showed mixed evidence with respect to an association with improved longer-term perinatal outcomes, such as rates of infant mortality, preterm birth, low birthweight and very low birthweight. These evaluations were limited by data quality issues, including inconsistency in the definition and source(s) of some measures; lack of verification of some measures; and missing and incomplete data. Further, the lack of a matched individual comparison analysis prevented strong inference regarding the impact of HS participation on perinatal outcomes.

Methodology

Evaluation Design

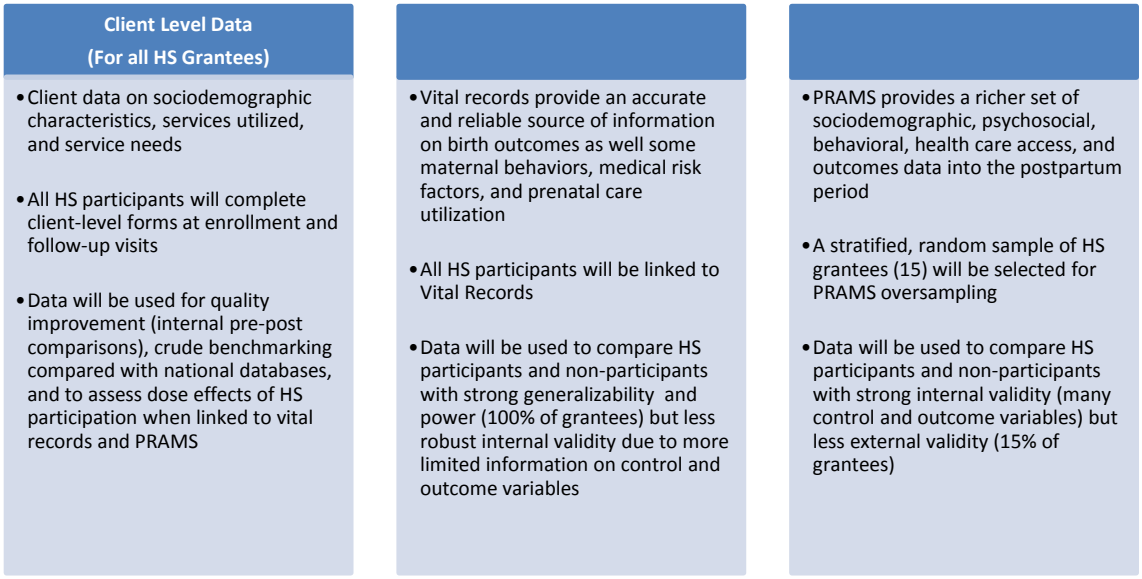
The implementation evaluation will be based on data from the National Healthy Start Program Survey (NHSPS) and will have both formative and summative purposes. Formative purposes include using the implementation evaluation findings to fine-tune the program. Summative uses include making a judgment about the extent to which the intervention was implemented as planned. This information can be used to interpret and explain program outcomes.

The utilization evaluation will link vital records (birth and death records) and client-level program data. It will assess how many women and children participated in the HS program and examine the characteristics of women and children who utilized the program, their level of participation, and the characteristics of women and children who did not utilize the program.

The outcome evaluation will link the PRAMS survey, vital records and client-level program data (see Figure 1). The primary outcome analysis will consist of the matched individual comparison analysis by oversampling the PRAMS for 15 randomly sampled grantees and will increase

internal validity with a quasi-experimental inference and rich set of outcomes and control characteristics that can influence selection into the program.

Figure 1. Linked Datasets for the Outcome Evaluation



Not all grantees will be part of the sampling frame of PRAMS states. Therefore, a secondary outcome analysis will consist of a vital records linkage and matched comparison for all HS grantees. A vital records analysis maximizes generalizability and will facilitate studying the ultimate outcome of infant mortality with adequate power. Further, the vital records analysis will enable multiple comparison groups to ensure robust results (e.g., within and outside of service areas, dose-response effect estimates among those with some level of HS participation, etc.).

For outcomes not available in vital records and PRAMS, benchmarking methods will also be utilized to compare individual level outcomes related to knowledge, behavior, risk, morbidity, and mortality among HS participants to data available from other sources or benchmarks. The benchmarking method compares the prevalence or incidence of an outcome among HS participants (such as smoking during pregnancy or use of a family planning method) to data available from other sources or benchmarks. However, the degree of consistency in the benchmark definition and study population can vary from HS depending on the data source. Therefore, an attempt will be made to choose data sources and populations most similar to HS but comparisons will be high-level performance comparisons relative to national data and thus crude and descriptive.

MCHB/HRSA is seeking IRB approval for the following:

1. Participating in the HS evaluation;
2. Completing the HS client-level assessment forms and providing the information to MCHB/HRSA;
3. Providing HS participant individual identifiers to state/jurisdiction Vital Records Offices (VROs);
4. Linking client-level data to vital records (e.g., infant birth and death certificates) for all 100 HS grantees;

5. Linking client-level data to other data sources such as PRAMS survey data for 15 randomly selected HS grantee sites; and
6. Sharing linked (e.g., vital records and PRAMS), de-identified data with MCHB/HRSA.

PRAMS and vital records have their own IRB clearances and protocols that apply to their data and data linkage activities. The data will be securely stored at VROs and PRAMS program offices.

Data Sources

National Healthy Start Program Survey (NHSPS)

The NHSPS is an OMB approved survey instrument designed to collect information about the implementation of the HS program across the five key approaches for monitoring and evaluation purposes. Survey data will be used to identify and describe program components and intervention models that may explain program outcomes. The information will be used to assess services offered and provided, intervention models used by projects, aggregated outcomes for the population served, and achievements at the grantee and national levels. HS grantees will be asked to complete the survey two times—at the end of the second and fourth grant years, and each time it will be open for a two-month period. The survey is designed to be self-administered through a web-based application by HS staff. Once they complete the survey, they will click on a submit button and MCHB/HRSA will be informed that the grantee completed the survey. JSI, Inc. was contracted to administer and analyze the NHSPS. JSI will monitor grantee response rates and conduct outreach to grantee sites to promote survey completion. JSI will also clean and analyze the survey data and provide the de-identified data and completed analysis (consistent with the HS evaluation analysis plan) to MCHB/HRSA. The NHSPS was reviewed by HRSA's Office of Research and Evaluation and received IRB exemption as it was determined to be non-research (please see email notification in Appendix A from Lydie A. Lebrun-Harris, PhD, MPH Office of Research and Evaluation, HRSA Office of Planning, Analysis and Evaluation. Dr. Lebrun-Harris's review pertained only to the NHSPS).

Client-level Assessment Forms

The client-level data provides uniform information at the individual level about HS participants, their children (up to age 2) and families for monitoring and evaluation purposes. The client data is the primary data source for the outcome evaluation. The client data provides information on individual-level socio-demographics, service needs, services received, and follow-up visits and enables DHSPS to understand the HS population and to track outcomes and progress at the participant level. The client-level assessment forms do not constitute a survey or census of the HS program; rather, HS is a national program and all HS grantees are participating in the program evaluation. The client-level assessment forms were created to serve both programmatic and evaluation purposes. There are six (6) forms, including:

1. Demographic Intake Form
2. Pregnancy Status/History
3. Preconception
4. Prenatal
5. Postpartum; and
6. Interconception/ Parenting

All HS grantees will administer the client-level assessment forms or collect the data contained in the forms during enrollment and throughout participation in the program. The assessment forms will be administered by Healthy Start program staff with various levels of training and education, including Family Services Managers, Home Visitors, High Risk Home Visiting Nurses, Public Health Assistants and Community Health Workers. The Demographic and Pregnancy History forms will be administered to all program participants upon enrollment in HS case management services following informed consent. The remaining assessment forms will be administered when relevant: Prenatal (from diagnosis of pregnancy to birth if the participant is or becomes pregnant), Postpartum (from birth to 6 months after delivery if the participant delivers a baby), and Interconception/Parenting (from 6 months to 2 years after delivery).

All HS program staff have received or will receive training on the use of the assessment forms and have access to additional training material through the HS EPIC Center (technical assistance contractor for the HS program). All program staff have been trained to handle clients in immediate danger and/or those experiencing traumatic events. Each Healthy Start program has procedures in place to handle clients in immediate danger (see sample Depression Screening flowchart in Appendix B), which includes the following:

1. Each Healthy Start program staff provides the client with instructions for handling medical and non-medical emergencies independent of program staff.
2. The Healthy Start program reviews options and resources for addressing non-medical emergencies with the client at the initial visit.
3. During the initial visit, the Healthy Start program instructs the client to contact their health care provider or call 911 for medical and non-medical emergencies.
4. The Healthy Start program documents the instructions given in the client's record.
5. The message on the Healthy Start program phones includes instructions for clients to hang up and dial 911 if they are dealing with an emergency situation during business hours. The message on Healthy Start program phones provides instructions for clients to hang up and dial 911 or go to the nearest emergency room, if the call is placed after hours or on weekends. The message also includes instructions for non-emergency care on the weekends and after hours.
6. HS program staff also have an Emergency Plan that provides instructions for clients to address non-emergencies and emergencies after hours or on weekends (see sample Violence Screening Decision Tree in Appendix C).

Additionally, Healthy Start staff are trained in the Health Insurance Portability and Accountability Act (HIPPA) and Patient Privacy policies. Healthy Start staff adhere to HIPAA protocols regarding client information. Healthy Start clients complete an Acknowledgment and Receipt of Notice of Privacy Practices or Informed Consent if applicable. No data is shared unless there is a signed informed consent on file. Every effort is made to ensure confidentiality at multiple levels. The Healthy Start programs will continue to follow established Protected Health Information (PHI)/HIPPA policy. All local regulations for PHI and HIPPA compliance are adhered to including data storage, client identifiers, data transfer, and confidentiality within and outside of each agency.

Healthy Start programs provide grief support to clients that have had a loss (see sample procedures for fetal/infant death in Appendix D). The Healthy Start program also works with several other programs that offer grief support, as well as provide clients with a list of grief resources. Services are provided to assure the client and their families are linked to ongoing services for grief support. Healthy Start program staff build relationships with their participants before, during, and after pregnancy. Their regular conduct is focused on caring for the mother and working with her to build resiliency and overcome life's challenges. In this regard, Healthy Start program staff meet with participants postpartum and into parenthood, and would reach out to offer support in the event of infant death. Staff have access to trained mental health therapists who are able to conduct appropriate counseling to grieving clients. Additionally, staff receive ongoing training on client engagement, trauma, rapport/trust building, and handling sensitive issues.

Once collected, data will be submitted to HRSA. The data are expected to be uploaded in batches (at yet-to-be-determined intervals) by HS grantees starting in October 2016[1]. The client-level data will be used to assess the reach of the program and services provided to HS participants. The client-level data will be collected and stored via the HS Monitoring and Evaluation System (HSMES) Database. This database is maintained by a contractor (DSFederal) who will ensure secure storage of the client-level data and protect potentially personal identifiable information using standard HHS procedures (http://www.hhs.gov/ocio/securityprivacy/).

Non-English speaking Hispanic mothers are allowed to enroll in HS. Thus the instruments and materials will be translated into Spanish. The client-level assessment forms are currently being piloted by the HS program and there may be subsequent changes to the instruments. Translation of the instruments and related materials (e.g., contact script, informed consent) will be completed once the instruments have been finalized. Any revised instruments and any Spanish language instruments and materials will be submitted for ERB review at that time.

Vital Records

U.S. vital statistics data are provided by the National Vital Statistics System (NVSS), through state and local collection and registration of birth and death events. The Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) administers the NVSS through contracts with each jurisdiction. Over 99% of births in the U.S. are registered. Data are pulled directly from medical records, providing birth and mortality information, including socio-demographic and medical data. Data from vital records provide information on birth rates, infant mortality rates, leading causes of death, and risk factors for adverse pregnancy outcomes. Vital records data will be linked to HS client-level data (for all 100 HS grantees) and PRAMS (for 15 grantees only) for the utilization and outcome evaluations.

Pregnancy Risk Assessment Monitoring System (PRAMS)

The PRAMS program was initiated in 1987 by the CDC for the surveillance of low birth weight and infant mortality. PRAMS collects data 2-9 months after delivery by surveying or interviewing mothers on their attitudes and experiences before, during, and shortly after pregnancy, as well as multi-dimensional prenatal risk factors. The PRAMS questionnaire has two

[1] Pending action by OMB.

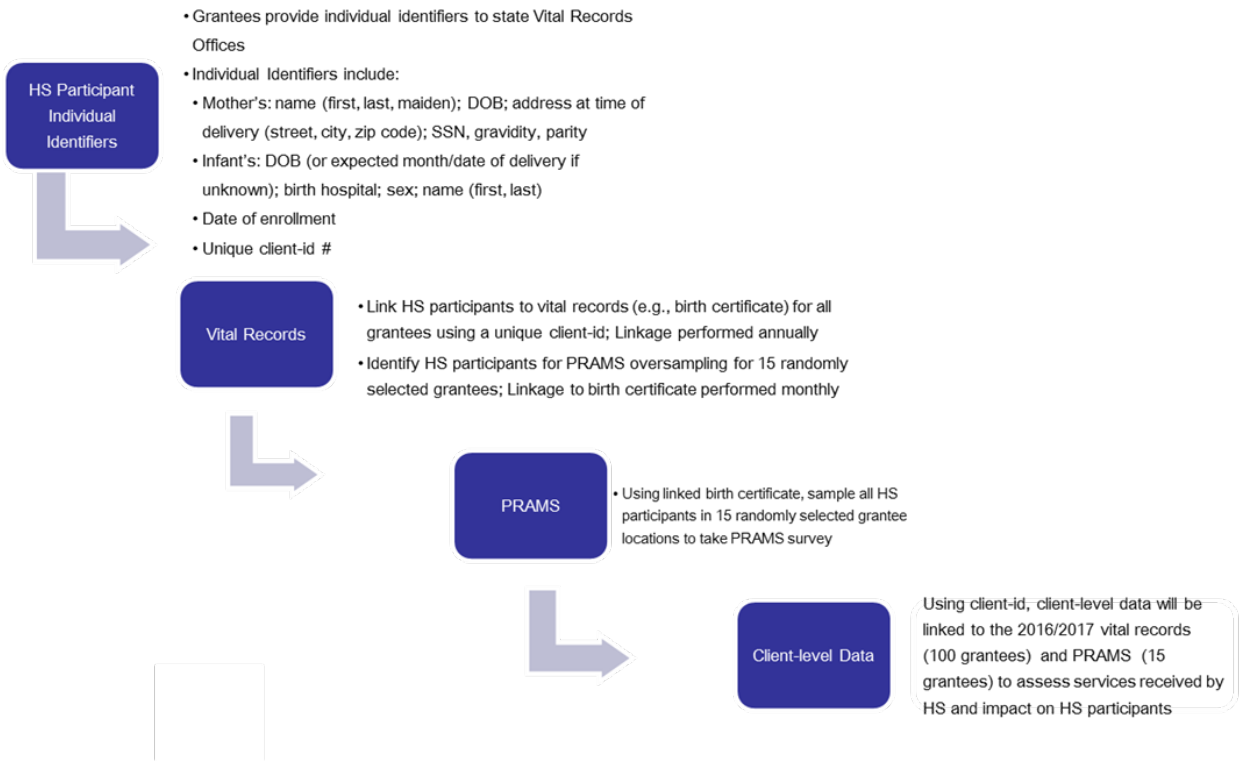
parts: core questions that are asked by all states and state-specific standard questions. The core portion of the questionnaire includes questions about the following:

- Attitudes and feelings about the most recent pregnancy;
- Content and source of prenatal care;
- Maternal alcohol and tobacco consumption;
- Physical abuse before and during pregnancy;
- Pregnancy-related morbidity;
- Infant health care;
- Contraceptive use; and
- Mother's knowledge of pregnancy-related health issues, such as adverse effects of tobacco and alcohol; benefits of folic acid; and risks of HIV.

The second part of the questionnaire includes questions that are chosen from a pretested list of standard questions developed by the CDC or developed by states on their own. As a result, each state's PRAMS questionnaire is unique.

Data Linkages: Vital Records, PRAMS and Client-Level Program Data (Figure 2)
The HS program currently has 86 grantees located in states that conduct the PRAMS survey. To improve the chances of evaluating an operational HS program early in the grant cycle, the PRAMS oversampling was restricted to continuing grantees (75 of 100 total grantees). Similarly, CDC PRAMS recommended restricting the sample to grantees in states which currently field PRAMS (n=40) given the potential lack of capacity in new PRAMS Phase 8 states (up to 61 states/jurisdictions/tribes). Therefore, the HS Sampling Frame for the PRAMS oversampling included 63 of 75 continuing grantees that are located in current PRAMS states.

Figure 2. Data Linkage Process for HS Participant Individual Identifiers, Vital Records and PRAMS



Based on available funding and CDC support services, it was determined that 15 HS grantees could be selected for PRAMS oversampling. To ensure scientific integrity, the 15 HS grantees were randomly selected within strata determined to be of importance to the program. The strata include cells categorized by Grantee Level (1, 2, 3)[2], Service Area Focus (Urban, Rural, Border, AI/AN), and Region (Midwest, Northeast, South, West). Within the sampling frame, there were only 3 grantees located in the Western Region (all Level 1 grantees in NM and OR). Given that most Western HS grantees are Urban (7 of 12); a Western Urban Level-1 grantee was selected with certainty. To ensure geographic representation of the remaining regions, Level-2 and Level-3 grantees were selected in the general proportion of these grantees by region.

Beginning in fall 2016, the 15 randomly selected HS grantees will send linkage variables (Table 1) for pregnant and postpartum HS participants to their state/jurisdiction VROs. The VROs will link to the birth certificate and note which individuals are HS participants. The VROs will not retain the individual identifiers after the linkage is completed. PRAMS offices in the randomly selected states will sample these individuals to take part in the PRAMS survey (2 to 9 months postpartum). Oversampling via PRAMS will require ongoing monthly linkage to identify HS

[2] Level 1 Community-based HS programs serve a minimum of 500 participants per year and implement activities under the five approaches; Level 2 Enhanced Services grantees serve a minimum of 800 participants and engage in Level 1 activities as well as activities to stimulate community collaboration; Level 3 Leadership and Mentoring HS grantees serve a minimum 1,000 participants and engage in activities under Level 1 and 2, as well as activities to expand maternal and women's health services, develop place-based initiatives, and serve as centers to support other HS and similar programs.

participants for monthly batch sampling. The CDC will provide MCHB/HRSA with the full PRAMS file of all PRAMS participants in the selected states (both HS participants and non-participants), including linked vital records and geographic identifiers for analytic purposes. State/jurisdiction VROs will then transfer any subsequent infant death certificate data for the PRAMS sample to MCHB/HRSA. Finally, MCHB/HRSA will link client-level program information on service receipt within HS to PRAMS and vital records data, using the client ID number, to complete evaluation analyses. This will allow the evaluation team to fully assess the type, dose, and frequency of services HS participants received and the impact these services had on important benchmark and outcome measures. Further, oversampling via PRAMS will enable comparisons between HS participants and non-participants. The initial selection of 15 HS grantees includes 13 PRAMS States/Jurisdictions (AL, CT, IA, LA, MD, MO, NM, NY, NYC, MI, OR, PA, and SC).

Table 1. Proposed Individual Identifiers for Linkage to Vital Records

Mother's date of birth (or age in years but exact date of birth is preferred)
Mother's name
Mother's address at time of delivery (street, city, zip code, county)
Mother's social security number
Mother's race
Mother's ethnicity
Mother's Medicaid status (yes/no)
Mother's gravidity (# previous pregnancies)
Mother's parity (# previous live births)
Mother's date of enrollment
Mother's Unique Client ID # that can be used to anonymously identify the HS participant and subsequently link back to any client-level information that is provided to MCHB/HRSA
Infant date of birth* (or expected month or date of delivery if unknown)
Infant birth hospital*
Infant sex*
Infant name (first, last)*
Infant birth weight*
Bold = required elements

*May not be available if participant is lost to follow-up (e.g., participant moves, stops participating, etc.) or has not yet delivered; regardless of the number of available individual identifiers, annual linkage will be attempted for all pregnant and postpartum women with a known delivery in calendar year 2017 and all pregnant women with an expected delivery in 2017 or through March of 2018, in the possible event of early delivery occurring in 2017. The linkage may be repeated on an annual basis. The monthly PRAMS linkage will include any deliveries from October 2016 - September 2017.

Data Linkages: Vital Records and Client-Level Program Data

All 100 HS grantees will provide the required linkage variables (Table 1) for each pregnant and postpartum HS participant with a known or expected delivery during the evaluation study period. The VROs will complete the linkage of HS participants to birth certificates and will then transfer the data to MCHB/HRSA without personally identifiable information for all linked HS participants and non-participants in the same county/city to facilitate analytic comparison. These

data will include birth certificate data on linked participants with client ID number, date of enrollment as well as birth certificate data for non-participant controls from the same city or county with geographic identifiers (census tract or zip code). The VROs will not retain the individual identifiers after the linkage is completed. MCHB/HRSA will use the unique client ID to link the vital records data to the client-level assessment forms and identify the services received by HS participants, which will allow the evaluation team to fully assess the type, dose and frequency of services HS participants received, and the impact these services had on important benchmark and outcome measures. Finally, the VROs will update the linkage of HS participants and controls to include any subsequent infant death certificates and send the linked data file to MCHB/HRSA. Data received by MCHB/HRSA will not contain personal identifiers but may still be potentially identifiable through a combination of demographic and medical characteristics, such as race/ethnicity, census tract of residence, and experience of infant death. Therefore, as an added level of precaution, MCHB/HRSA will maintain secure storage of vital records data and protect potentially personal identifiable information using standard procedures. This linkage is expected to continue annually for all HS grantees.

Analysis

The HS program funding announcement includes several benchmarks through which the program's performance will be measured. The program also has several performance measures required for reporting by grantees. These benchmarks and performance measures are the key outcomes for assessment under the evaluation (Table 2). Benchmarks and performance measures indicate the progress of the program towards its objectives and the outcomes that the program should be impacting, such as low birthweight. Other outcomes may be examined, including those related to risk, health care access and utilization, health knowledge and behaviors, delivery and birth outcomes, and child health.

Table 2. Evaluation Metrics by Data Source

	Vitals	PRAMS Core Phase 8	Participant Level HS Data	HSPS	Other
Benchmarks					
Health insurance (preconception, pregnancy, postpartum)	Partial	X	X		
Well woman visit (preconception)		X	X	Track	NHIS; BRFSS
Postpartum visit		X	X	X	HEDIS
Safe sleep behaviors		X	X		
Ever breastfed	X	X	X	X	NIS
Cigarette smoking (preconception, pregnancy, postpartum)	Partial	X	X		
Interpregnancy interval <18 months	X	X	X		
Well child visits		X	X	Track	HEDIS
Perinatal depression screening (preconception, pregnancy, postpartum)		X	X		
Intimate partner violence screening (preconception, pregnancy)		X	X		
Additional outcomes and/or characteristics					
Infant mortality	X			X	
Low birth weight	X		X	X	
Preterm birth	X		X	X	
Current breastfeeding		X		Track	
Initiation of prenatal care	X	X	X	Track	
Adequacy of prenatal care	X				
Gestational weight gain	X	X	X	Track	
Weight management counseling (preconception, pregnancy, postpartum)		X	X		
Alcohol use screening		X	X		
Physical activity (preconception, pregnancy, postpartum)		X			
Maternal morbidity	X				
Pregnancy-related complications	X	X	X		
Cesarean section among low-risk first births	X				
Home visiting		X			
Screening or counseling for breastfeeding (pregnancy and postpartum)		X	X		
Screening or counseling for birth control (preconception, pregnancy, and postpartum)		X	X		
Screening for smoking (preconception, pregnancy, postpartum)		X	X		
Screening for drug use (pregnancy)		X	X		
Flu shot receipt and counseling		X	X	Track	
Dental visit		X	X		
Content of postpartum visit		X			
Benchmarks not covered by PRAMS-Core or VITALS	**Vitals**	**PRAMS Core Phase 8**	**Participant Level HS Data**	**HSPS**	**Other**
Breastfed at 6 months		Partial	X	X	NIS
Follow-up services for perinatal depression			X		
Read daily to child			X		NSCH
Documented reproductive life plan			X	X	
Father and/or partner involvement during pregnancy			X		
Father and/or partner involvement with child 0-24 months			X		
Fully implemented CAN				X	
At least 25% HS participant membership on their CAN membership			X		
QI and performance monitoring process				X	
Healthy Start Case Management Dosage					
Duration of enrollment (HS admit date, delivery date, discharge date)			X		
Breadth of interventions - visit type: phone, home, office, other			X		
Amount of contact time - Date of visit			X		
HS provider (RN, SW, MH counselor, paraprofessional)			X		
HS enrollment for a prior pregnancy			X		

Track = The HS Survey asked respondents if these items were tracked. BRFSS = Behavioral Risk Factor Surveillance System
DGIS = Discretionary Grant Information System
HEDIS = The Healthcare Effectiveness Data and Information Set NIS = National Immunization Survey
NSCH = National Survey of Children's Health

Analysis of the implementation evaluation will include descriptive analyses to test the statistical significance of bivariate associations between program and organization level factors and indicator(s) of effective program implementation. Program factors may include the size and scale of the program; outreach strategies employed; number and types of referrals provided; case management models utilized; caseloads maintained; the number and types of screenings provided; and promotion of male involvement, among others. Organization level factors may include the geographic service area or focus (urban, rural, border); the HS program level (1, 2 or 3); the lead agency type; age of the program; and staffing characteristics, among others.

Analysis of the utilization evaluation will include descriptive analyses of HS participants in terms of a number of individual characteristics, including socio-demographic indicators, health behaviors, utilization of non-HS health services and health outcomes. Bivariate analyses will test for statistically significant differences in health behaviors, health service utilization patterns, and health outcomes between HS and non-HS participants and among HS participants, by level of utilization of HS services. Descriptive analyses will also examine service or penetration rates by intended target characteristics (e.g., % of uninsured or Medicaid-insured served) and summarize utilization levels among participants at the grantee level.

The outcome evaluation analysis will estimate the effect of program participation by comparing outcomes of HS participants and non-participants using multivariable techniques. Individual-level propensity score matching will ensure that outcome comparisons between participants and non-participants are balanced with respect to observed characteristics. Multiple comparison groups, including internal references among program participants, will be used to test the sensitivity of results and promote causal inference (e.g. postpartum versus prenatal enrollees, dose-response effects). Analyses will also examine variation in effects by program and organizational characteristics to identify critical practices that can be spread and scaled to maximize impact across grantees.

Data Use Agreement

Prior to HS client-level data, vital records and PRAMS data being linked, all agencies will be required to develop and sign a data sharing/transfer agreement. Through a subcontract with JSI, the National Association of Public Health Statistics and Information Systems (NAPHSIS) will develop a model data sharing/transfer agreement to be adapted and signed for each HS grantee, VRO, PRAMS program and MCHB/HRSA. The evaluation support contractor (to be awarded in September 2016) will monitor the signing and receipt of data sharing/transfer agreements and provide assistance to all entities to modify the model data sharing agreement to fit the needs and requirements of all involved agencies. Data sharing/transfer agreements may include language pertaining to the tasks and responsibilities of each agency, how files are provided (e.g., format), and the timing of submissions. The contractor will also assist agencies in obtaining the appropriate signatures from agency representatives by following up on the status of the agreements and providing assistance when needed to obtain signatures. The contractor will ensure the receipt of the signed data sharing/transfer agreements for HS grantees, VROs, PRAMS programs, and MCHB/HRSA.

Request for Waiver of HIPAA Authorization

We request a waiver of HIPAA authorization for HS grantees (the 'providers' in this scenario) to send the data file containing protected health information from the client-level assessment forms (i.e. HS participant individual identifiers) to state/jurisdiction VROs, linking the HS participant individual identifiers to vital records and PRAMS, and sharing the linked, de-identified data with MCHB/HRSA. These data will contain personal identifiable information and protected health information about HS participants, including demographic information (e.g., zip code, date of birth, infant's date of death), health conditions, and utilization of health care services (including dates of service). Such data could be used to identify individuals, particularly if triangulated with other variables. However, the personal identifiable information will be collected and stored at the HS grantee locations, VROs and state PRAMS programs. MCHB/HRSA and its contractors will only receive de-identified coded information.

The protected health information included in the data files involves no more that minimal risk to the privacy of the individuals. HRSA has strong protections in place to protect any identifiers or potential identifiers from disclosure or improper use. VROs and PRAMS programs will transfer data to MCHB/HRSA without personally identifiable information for all linked HS participants and non-participants in the same geographic area to facilitate analytic comparison, including birth certificate data on linked participants with client ID number, date of enrollment, geographic identifiers (census tract or latitude/longitude) and birth certificate data for non-participant controls from the same city or county with geographic identifiers (census tract or latitude/longitude). MCHB/HRSA will use the unique client ID to link the data to client-level program data and identify the services received by HS participants. However, data may still be potentially identifiable through a combination of demographic and medical characteristics, such as race/ethnicity, census tract of residence, and experience of infant death. Therefore, as an added level of precaution, MCHB/HRSA will maintain secure storage of vital records data and protect potentially personal identifiable information using standard HHS procedures.

We will ask all agencies to follow the security guidelines and policies for HHS, as well as what they have to follow for their agencies. All of this information will be outlined in the data sharing and transfer agreement. The Vital Records offices will not hold onto the individual identifier data once they link it. It will only be used to link to the Vital Records (infant birth certificate and subsequent death certificates). From there, PRAMS programs will use the infant birth certificate as a sampling frame to identify HS participants to survey and the vital records and PRAMS data will be linked to program data using the HS participants' unique client-id/code. Further, the VROs and PRAMS programs have experience handling confidential data and will be careful to ensure the data they have from the Healthy Start grantees is kept confidential while in their possession. All agencies participating in the evaluation may also specify in the data sharing agreement that the VROs will not keep any data once they send the linked data to HRSA.

Informed Consent

Two separate informed consent forms and a participant contact script have been developed for this evaluation study (see Appendix E):

1. One for pregnant/postpartum women enrolled in HS case management services (during the study period), for participation in the vital records portion of the evaluation; and

2. One for pregnant/postpartum women enrolled in HS case management services (during the study period), for participation in the PRAMS oversampling portion of the evaluation.

Both consent forms also include consent for completion of the HS client-level assessment forms for any individual enrolled in HS case management services, and sending the de-identified client-level assessment information to MCHB/HRSA.

The informed consent forms have been tested for readability. The informed consent form for completion of the HS client-level assessment forms was determined to be at an 8th grade reading level. The informed consent forms for the vital records linkage and the PRAMS oversampling were determined to be at 9th grade reading levels. The form is above an 8th grade reading level due to the names of the agencies, data sets, and methods involved. Every effort was made to address literacy issues in the development of the informed consent forms.

Research Partners

MCHB/HRSA has/will establish a subcontract, two Interagency Agreements (IAAs), and an Indefinite Deliverable Indefinite Quantity (IDIQ) contract to support data collection and evaluation implementation activities. The subcontract is with NAPHSIS to develop model data sharing/transfer agreements between HS grantees, VROs, PRAMS programs, and MCHB/HRSA. The IAAs are with the CDC's NCHS and the CDC's Division of Reproductive Health (DRH) which oversees the PRAMS program. NCHS will ensure MCHB/HRSA receives calendar year vital records data (birth and death certificates) for HS participants and non-HS participants within the cities/counties from the 37 states, DC, and NYC that have currently funded HS projects. The IAA with DRH will support a new project coordinator as well as a limited amount of statistical support and technical assistance from existing PRAMS staff to PRAMS sites and HS grantees. The IDIQ contract is anticipated to be awarded in September 2016. The IDIQ contract will support the implementation of the HS evaluation. Contract activities will include developing and administering a survey to HS participants; providing technical assistance to HS grantees, state/jurisdiction VROs, and PRAMS programs to support linkage processes; overseeing and monitoring the data collection, processing, cleaning, and management processes; analyzing evaluation data; preparing interim and final evaluation reports; coordinating the Technical Expert Panel (TEP) quarterly meetings (the external committee to guide the design and implementation of the evaluation); and providing administrative and coordination support to MCHB/HRSA staff managing previous established activities to support data collection processes and activities. Contractor support will also be provided for the process evaluation through DHSPS' current contractor, JSI. JSI will administer the NHSPS and conduct analysis of the responses. OER may also provide support for the survey analysis.

Publications

It is anticipated that findings from the evaluation will be published in peer-reviewed journals. These findings will include aggregated data only and will not include any identifiable data. Standard NCHS protocols of not reporting any tabulations with a numerator less than 10 and flagging any with a numerator 10-19 as unreliable will be followed.

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