Transformed Healthy Start Program Evaluation Plan

PROGRAM DESCRIPTION

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 Healthy Start (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 is administered by the Division of Healthy Start and Perinatal Services (DHSPS) within the Maternal and Child Health Bureau (MCHB) at the Health Resources and Services Administration (HRSA). The program is authorized under Title III, Part D, Section 330H of the Public Health Service Act (42 USC 254 c-8) and was reauthorized in 2014. The grant period for the transformed HS program is September 2014 – May 2019.

While the program has existed for over 20 years, the HS program was transformed in 2014 to apply lessons from emerging research, past evaluation findings, and to act on national recommendations from the Secretary's Advisory Committee on Infant Mortality (SACIM) (http://www.hrsa.gov/advisorycommittees/mchbadvisory/InfantMortality/Correspondence/recommendationsjan2013.pdf). With an emphasis on standardized, evidence-based approaches, the goal of the new HS program is to improve maternal health outcomes and reduce disparities in 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 the first two years of life) and their families in geographically, racially, ethnically, and linguistically diverse low income communities with exceptionally high rates of infant mortality. Approximately half of all HS participants served are pregnant women. The five approaches are briefly described below.

1. **Improve women's health.** Facilitate and conduct outreach, screening and assessment, health education, insurance enrollment, and linkages to medical and other social resources for women before, during, and beyond pregnancy.
2. **Promote quality services.** Promote service coordination and systems integration across the life-course; conduct staff training to support core competencies and cultural competence; and use standardized and evidence-based curricula and interventions.
3. **Strengthen family resilience.** Address toxic stress and support trauma-informed care; provide linkages to mental and behavioral health; support healthy relationships and male involvement; and empower women and their families to meet child developmental needs and cope with adversity.
4. **Achieve collective impact.** Convene a community action network to spur community mobilization and transformation in systems, policies, and environments; build social capital; and serve as a community hub to provide leadership in the community.
5. **Increase accountability through quality improvement, performance monitoring, and evaluation.** Strengthen the monitoring and evaluation capacity and infrastructure of HS to track and measure efficiency, effectiveness, quality, performance, and other key

outcomes for accountability, quality improvement, and program improvement; and translate findings into practice to support sustainability of the program within the larger context of the health care delivery and social service system.

HS grantees engage in a number of activities including recruiting participants, conducting comprehensive screenings, enrolling participants in health coverage, developing reproductive life plans, providing health education and preventive services, providing case management and follow-up services, referring patients to primary health and social services, and promoting interconception care and male/father involvement. Grantee activities also include collective impact efforts such as connecting to national MCH organizations, creating strategic action/work plans, and coordinating community services and data systems. HS grants are provided at three levels with an increasing expectation of service delivery and impact. The majority of HS grantees (n=60) are Level 1, Community-based HS programs, serving a minimum of 500 program participants per year, and supporting implementation of essential activities under the five approaches. There are another 22 Level 2, Enhanced Services HS grantees, serving more participants (minimum 800) and engaging in Level 1 activities as well as additional activities to stimulate community collaboration. Lastly, there are 18 Level 3, Leadership and Mentoring HS grantees, serving the highest number of program participants (minimum 1,000), and engaging in activities under both Levels 1 and 2, as well as additional activities to expand maternal and women's health services, develop place-based initiatives, and serve as centers to support other HS projects and organizations working towards improving perinatal outcomes.

Logic Models

There are two logic models included in this evaluation plan. The first is a program logic model (Appendix A) that was developed in December 2014 in consultation with the HS Evaluation Technical Expert Panel (TEP), HRSA's Office of Research and Evaluation (ORE), and the HS contractor, JSI. The basis of the program logic model is the transformed HS program funding opportunity announcement (FOA). As noted in the program logic model, the HS program relies on a number of resources at the participant, program/organization, and community levels. For example, resources such as social networks and partnerships, provider and service networks, MCH evidence-based interventions and related research, capacity building assistance, community leaders and priorities, community infrastructure and resources (e.g., childcare, housing, transportation) and policies at the Federal, state, and local levels all are essential to the implementation and conduct of HS activities.

Implementation of the program's approaches and subsequent activities is expected to result in a number of outcomes. There are three levels of outcomes: 1) short-term; 2) intermediate; and 3) long-term/impact. Short-term outcomes can be observed within the first few years of project implementation, such as changes in knowledge, skills, motivation and health care utilization at the individual and family/social support levels and changes in access, systems development, and coordination at organizational, community, and systems levels. Intermediate outcomes occur after the program has matured, usually 2–3 years after implementation, and include changes in healthy behaviors; community, organizational, and systems capacity, quality, efficiency, and effectiveness; and active partnerships and networks. Long-term outcomes or impact often require more than 3-5 years to observe and are related to changes in health status (for example, morbidity and mortality), policies, and environment. The program logic model illustrates the specific components, pathways for change, and outcomes the program is expected to achieve.

The evaluation team did not update the program logic model because it is still reflective of the transformed HS program and its program guidance. However, to help communicate the

evaluation aims and the data collection and analysis activities of the current evaluation, the MCHB evaluation team worked with ORE to develop a logic model for the HS evaluation plan. The evaluation plan logic model can also be found in Appendix A. The evaluation plan logic model includes the data collection instruments, HS participants and partners, MCHB/HRSA staff and the HS Evaluation TEP as the inputs or resources. From here, the data collection instruments are linked to the three evaluation components (implementation, utilization, and outcome evaluations) and the analysis activities for each component. The outputs to be assessed by the evaluation (e.g., types of activities, interventions, and services; program and organizational factors; HS participant characteristics; and indicators of access to and use of HS services) are identified for the implementation and utilization evaluations. Additionally, the short, intermediate, and long-term outcomes to be assessed are identified for the outcome evaluation. Examples of outcomes include: Short-term Outcomes – enrollment in health insurance, use of social services, and development of reproductive life plans; Intermediate Outcomes – program alignment to the five HS approaches, differences in health behavior and health service utilization patterns, adoption of healthy behaviors; and finally Long-term Outcomes – decrease in low birthweight, infant mortality, and perinatal mortality. Throughout the evaluation, continuous quality improvement will take place to improve both the evaluation and programmatic activities.

Both the program and evaluation plan logic models are considered living documents and may be updated as new information about the program and the evaluation is revealed or the program or the evaluation focus shifts.

PURPOSE OF THE EVALUATION

To understand the implementation and overall impact of the newly transformed HS program, there is a need for a robust and comprehensive evaluation. MCHB will conduct an evaluation of the program's implementation, utilization of HS services, and outcomes. 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 participant satisfaction with the HS program, knowledge, behaviors, access to services, integration of services, and maternal health care utilization. However, the evaluations showed mixed evidence with respect to an association with improved longer-term perinatal health status 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.

The overarching goal of this national HS evaluation is to determine the effect of the transformed program on changes in participant-level characteristics (e.g., behaviors, HS services utilization, and health outcomes). This evaluation plan focuses only on participant- and program-/organizational-level outcomes. Depending on the availability of funding, a second phase of the national HS evaluation may assess how programs perform on community-level outcomes such as coordination and integration within and between systems, and the adoption of policies at the state and local levels to address social determinants.

The specific aims of the evaluation are:

Implementation Evaluation:

1. To document the implementation of the transformed HS program components (e.g., activities, type of services, intervention models) and their alignment with the five HS approaches.
2. To examine factors that help explain effective implementation of the transformed HS program.

Utilization Evaluation:

3. To assess how many women and infants participated in the transformed HS program.
4. To assess to what extent services were delivered to the highest risk target populations (women and infants), as intended.
5. To examine factors (personal, program, organizational) that help explain the volume of services used (e.g., high service delivery versus low service delivery programs).

Outcome Evaluation:

6. To assess the transformed HS program's impact on HS participants compared to non-HS controls.
7. To examine factors (program/organizational) of the transformed HS program that are associated with improved participant behaviors, utilization, and health outcomes.

Good implementation and utilization evaluations help to explain the findings of an outcome evaluation and distinguish program and utilization-related factors contributing to variation in performance. In combination, these three evaluation components enable us to determine whether HS is effective in impacting participant outcomes, as well as why and how so that we can spread and scale effective program components.

EVALUATION STAKEHOLDERS

The goal of the evaluation is driven by the needs of the primary HS stakeholders, which include MCHB/HRSA, HS grantees, participants, partners, and experts in maternal and child health (MCH). Each of these stakeholders brings a unique perspective to the evaluation, as they are the intended users of the evaluation results. They have been and will be engaged to best leverage their knowledge, expertise, and skills throughout the evaluation process to identify the priorities for evaluation and assess feasibility of implementation of the plan. Stakeholder engagement will also help to gain buy-in to facilitate data collection, improve data quality, address challenges encountered, and ensure use of results.

- **MCHB/HRSA:** This agency provides funding and oversight to support and lead implementation of the program and its evaluation. Its accountability for the program includes a responsibility to ensure that the program meets its legislative requirements. Because one purpose of the evaluation is to develop evidence to address HRSA's need for accountability, MCHB/HRSA staff have been engaged throughout the evaluation planning process and will continue to be involved throughout its implementation. Where possible, on-going feedback will be provided to MCHB/HRSA so they can monitor the program's implementation and make timely, informed decisions about the program, including modifying and/or improving activities and determining appropriate next steps.

- **Healthy Start grantees:** As implementers of the program in the community, grantees have a unique understanding of the population targeted by the program, the community factors that contribute to program successes and challenges, the availability of data, and the feasibility of data collection in the community. Therefore, they have been engaged in

the development of the data collection instruments and will continue to be engaged as the evaluation is implemented. The HS Collaborative Improvement and Innovation Network (CoIIN), which includes staff and representatives from a Level 1 and Level 2 grantee and all Level 3 HS grantees, has participated in multiple presentations regarding the evaluation plan and has provided feedback on the plan to MCHB/HRSA.

- **Healthy Start participants:** As participants are the direct beneficiaries of HS services, it will be important for the evaluation to include their input. The evaluation will include a HS participant survey to assess participants' experiences with the HS program and utilization of program services. Additionally, participants were engaged in pre-testing instruments to ensure that length and content are not fatiguing and flow logically.

- **Healthy Start partners:** Linkages and partnerships are central to the transformed HS model. As with participants, partners' input and their perspectives will be essential to understanding program implementation and outcomes. We engaged this group to pretest data collection instruments that pertain to them to ensure that modes of delivery and content are appropriate for the audience. They will continue to be engaged for data collection and insight into their uses and needs for evaluation results. HS partners may include Title V programs; Head Start; Special Supplemental Nutrition Program for Women, Infants, and Children (WIC); Maternal, Infant, and Early Childhood Home Visiting programs; the CoIIN to Reduce Infant Mortality; state health departments; community health centers and other providers; and other programs that deliver employment, housing, and social support to the HS target populations.

- **MCH experts:** HS has the potential to greatly enhance understanding of successful models to improve perinatal outcomes. MCH experts have knowledge of the existing evidence base as well as gaps in the field and will be consulted on a quarterly basis as the evaluation plan is implemented to ensure that targeted evaluation questions and related outcomes of interest are appropriate, and the design of the evaluation is rigorous.

- **Healthy Start Evaluation Technical Expert Panel (TEP)**: MCHB sought the input of an external committee to guide the design and implementation of the HS national evaluation. In October 2014, a TEP of maternal and child health researchers, practitioners, project directors and policy stakeholders was convened to discuss and recommend an evaluation design for the transformed HS program. The TEP strongly recommended building linkages to existing datasets such as vital records (birth and death certificates) and the Pregnancy Risk Assessment Monitoring System (PRAMS) to compare key benchmarks and outcomes of HS participants and non-participants. Additionally, the TEP and MCHB/HRSA staff in the Office of Epidemiology and Research (OER) recommended conducting process and utilization evaluations of the transformed HS program to assess how program activities are delivered, the quality of the program's implementation, who utilized the program, and to provide information to adjust and strengthen the effectiveness of program strategies and approaches.

  The TEP will serve as an external consultative committee and provide direction on the design and implementation of the evaluation (see Draft TEP Charter in Appendix B). The evaluation management team and DHSPS staff will meet quarterly with the TEP to continue to obtain their input and recommendations for the evaluation design, progress

and findings, and the final report. Table 1 below provides a list of the TEP members and their affiliations.

A contractor will be procured to support the implementation of the evaluation plan described here. This contractor's responsibilities will include coordinating and managing the quarterly meetings with the TEP.

Table 1. Technical Expert Panel Participants

Name	Affiliation
Patricia O'Campo, PhD	Director, Centre for Research on Inner City Health, St. Michael's Hospital and Professor, Dalla Lana School of Public Health Sciences, University of Toronto
Arden Handler, DrPH	Professor, Community Health Sciences & Director, Maternal and Child Health Program, University of Illinois at Chicago
Kenn L. Harris, LMin	Health Administrator, The Community Foundation for Greater New Haven
Leslie Lipscomb Harrison, MPH	Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention
Vijaya Hogan, DrPH	Clinical Professor, University of North Carolina Gillings School of Global Public Health
Milton Kotelchuck, PhD, MPH	Professor of Pediatrics, Harvard Medical School
Saba W. Masho, MD, MPH, DrPH	Associate Professor, Virginia Commonwealth University, Department of Family Medicine and Population Health, Division of Epidemiology
Jennifer E. Moore, PhD, RN	Director, Institute for Medicaid Innovation and Vice President of Policy & Research, Medicaid Health Plans of America
Diane L. Rowley, MD, MPH	Professor, University of North Carolina Gillings School of Global Public Health
Hamisu Salihu, MD, PhD	Professor, Baylor College of Medicine Professor, College of Public Health, University of South Florida

EVALUATION DESIGN

Overview

Each component of the national evaluation will answer a particular set of evaluation questions, but combined they will provide a more complete picture of the effects of the HS program. **The design components include the implementation evaluation, the utilization evaluation, and the outcome evaluation.** The implementation and utilization evaluations will primarily use descriptive analyses. The outcome evaluation will use a quasi-experimental method and benchmarking to compare characteristics and pregnancy-related outcomes among HS women and non-HS women. The quasi-experimental method involves 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; and (2) a matched individual comparison analysis of HS participants and non-participants by oversampling of 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.

The implementation evaluation will be based on data from the National Healthy Start Program Survey (NHSPS) and a participant survey, 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 may be used to interpret and explain program outcomes. Program and organizational factors that align with the five HS approaches will be identified.

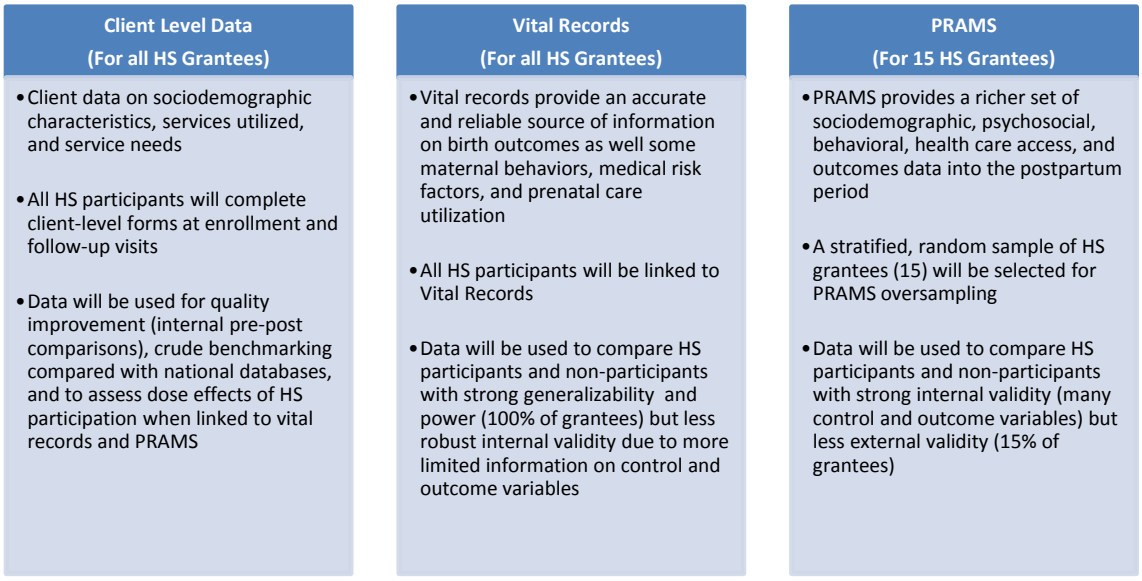
The utilization evaluation will link vital records and client-level program data. It will assess how many women and infants participated in the HS program and examine the characteristics of women and infants who utilized the program, their level of participation, and the characteristics of women and infants who did not utilize the program. It will also examine factors (personal, program, organizational) that differentiate high versus low service delivery programs.

The outcome evaluation will link the vital records, PRAMS survey, and client-level program data (see Figure 1). The 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.).

The outcome analysis will also consist of a 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. Not all grantees will be part of the sampling frame of PRAMS states.

Particularly for outcomes not available in vital records and PRAMS, benchmarking methods will also be used to compare individual-level outcomes related to behavior, utilization, and health outcomes 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 differ 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 crude and descriptive as a high-level performance comparison relative to national data.

Figure 1. Linked Datasets for the Outcome Evaluation



See a complete table of variables that will be used in the evaluation, by data source, in Appendix C.

Evaluation Questions and Data Sources

The HS evaluation will consider the evaluation questions in Table 2 below. The evaluation questions are designed to address variables at the participant and program/organizational levels. Community-level inputs and outcomes may be assessed in a second phase of the transformed HS evaluation at a later date.

Several data collection tools are needed to support the components of the evaluation design. Data will be collected from the NHSPS; a HS participant survey; the HS program's client-level assessment forms; vital records (birth and death certificates); and the PRAMS survey. The relevant key variables contained in each data source are provided in Table 2 below.

Table 2. HS Evaluation Questions, Data Sources, and Key Variables

Type of Evaluation	Evaluation Question	Data Source(s) and Key Variables
Implementation	1. What components (e.g., activities, services, interventions) did grantees implement in the transformed HS program and to what extent did the components align with the five HS approaches? 2. What factors (e.g., program and organizational) help explain effective implementation of the transformed HS program?	**NHSPS:** overview of services, staffing, outreach and retention; efforts across the 5 key approaches; and HS program achievements. **HS Participant Survey:** will assess participants' experiences with the HS program and utilization of program services (to be developed).

Utilization	3. How many women and infants participated in the transformed HS program? 4. To what extent were services delivered to the highest risk target populations (women and infants), as intended? 5. What factors (e.g., personal, program, and organization level) help explain the volume of services used?	**NHSPS:** overview of services, staffing, outreach and retention; efforts across the 5 key approaches; HS program achievements. **HS Participant Survey:** will assess participants' experiences with the HS program and utilization of program services (to be developed). **Client-level Assessment Forms:** socio-demographic characteristics, personal risk factors, services utilized, service needs. **Vital Records:** some maternal behaviors, medical risk factors, socio-demographics, and prenatal care utilization. **PRAMS:** socio-demographic, psychosocial, behavioral, health care access and outcomes data into the postpartum period.
Outcome	6. What impact did the transformed HS program have on HS participants when compared to non-HS controls? 7. What factors (program/organizational) of the transformed HS program are associated with improved participant behaviors, utilization, and health outcomes?	**NHSPS:** overview of services, staffing, outreach and retention; efforts across the 5 key approaches; HS program achievements. **Client-level Assessment Forms:** socio-demographic characteristics, personal risk factors, services utilized, service needs. **Vital Records:** birth outcomes, some maternal behaviors, medical risk factors, socio-demographics, and prenatal care utilization. **PRAMS:** socio-demographic, psychosocial, behavioral, health care access and outcomes data into the postpartum period.

Data Sources and Data Collection Strategies

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. 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 NSHSP is designed to be self-administered through a web-based application by HS staff.

MCHB conducted a pre-test of the survey with two HS programs. The purpose of pre-testing the survey instrument was to gain information on the average time it takes to complete the survey; grantees' understanding of the survey questions and ability to provide empirical responses; and to identify any questions that could be deleted or revised to improve clarity. The survey pre-test yielded several recommended changes to the instrument and provided important feedback about the clarity, flow, and timing of the questions. The recommended changes were implemented to: 1) substantially reduce the amount of time grantees take to complete the survey; 2) make the survey questions clearer to respondents; and 3) make the response options to multiple-choice items more robust.

Healthy Start Participant Survey

The HS Participant Survey is a new survey that will assess HS participants' experiences with the transformed HS program, services used in the program, and satisfaction with the program/services. In consultation with the MCHB/HRSA evaluation team, a contractor will develop and pre-test the survey instrument. The contractor may review previous surveys conducted by the HS program and/or its grantees to determine the type of questions to include and the best mode for survey administration. It is anticipated that the survey will include both open-ended and close-ended questions, but it should not take respondents longer than 30 minutes to complete. Currently, the survey is planned to be administered at all 100 HS grantee sites with a maximum of 30 randomly selected respondents per site. The survey will be designed to address the evaluation questions and minimize social desirability, recall, and other biases. Survey administration is anticipated for 2018 depending on receipt of OMB and IRB approval.

Client-level Assessment Forms (previously known as the Preconception, Pregnancy and Parenting Information Form (3Ps))

The client-level assessment forms were previously known as the Preconception, Pregnancy, and Parenting Information Form (3Ps). Working collaboratively, the HS CoIIN and MCHB/HRSA redesigned the 3Ps from one form into six forms. The six forms include:

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

The purpose of the redesign was to ensure that collected data was meaningful for monitoring and evaluation, as well as screening and care coordination, and to streamline previously separate data systems. The 3Ps Information Form was also redesigned to allow questions to be

administered in accordance with the participant's enrollment/service delivery status and perinatal period. In addition to redesigning the 3Ps Information Form, questions that were neither critical for evaluation nor programmatic purposes were deleted. Questions were also added to allow the forms to be used as an all-inclusive data collection instrument for MCHB and HS grantees. The additional questions extended and refined previously approved content, allowing for the collection of more granular and/or in-depth information on existing topics. Adding these questions allows HS grantees to better assess risk, identify needed services, provide appropriate follow-up activities to program participants, and improve overall service delivery and quality.

The redesigned client-level assessment forms still provide uniform information at the individual level about HS participants, their children (up to age 2), and families for monitoring and evaluation purposes. Data collected using the forms are a source for the utilization evaluation and for certain non-experimental benchmark comparisons within the outcome evaluation. The client-level 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 were created to serve both programmatic and evaluation purposes. The forms allow for assessment of grantee performance on a monthly basis and identification of technical assistance (TA) needs. They also facilitate aggregate or crude benchmarking and comparison with national databases on various health behaviors, health services received, and perinatal outcomes.

Due to grant regulations, DHSPS cannot require HS grantees to use the actual client-level assessment forms; however, grantees are required to report on the data elements in the client-level assessment forms. As such, collection of these data is expected to vary by grantee. For example, some grantees currently collect most or some of the data elements contained in the HS client-level assessment forms via their own program forms and will need to augment their current program forms to collect all of the required elements. Other programs that may not currently collect the required data elements will need to initiate new data collection efforts, either with their own forms or using the HS client-level forms. Further, survey mode and administration will vary at grantee sites because some grantees collect the required data elements using paper forms and others electronically; some grantees use staff to administer surveys while others use self-administered survey processes. Time frames for completing data collection are also expected to vary by program, as does the frequency with which participant records are updated with the necessary data elements. Finally, several other issues are unknown, including whether certain data elements (such as health behaviors, like smoking) are re-visited with clients and if so, with what frequency; what happens to the participant record when a participant leaves or graduates from the HS program; and if all of the data elements will be available from all grantees. Clarification regarding these issues is urgently needed in order to understand what data will be available from the forms, when, and how complete and systematic the data will be.

While several data collection issues need to be clarified, all HS grantees are expected to administer the client-level assessment forms or collect the required data elements during enrollment and throughout a client's participation in the program depending on her perinatal status. For grantees using the client-level assessment forms, the timeframes for data collection are specified for each form (see Table 3).

Table 3. HS Client-Level Assessment Forms Timeframes for Data Collection

Client-Level Data Collection Form	Timeframe for Collecting Data
Demographic Intake Form	To be completed with each participant at intake/enrollment.
Pregnancy Status/History	To be completed with all women when they seek to use HS services – this will most likely be at intake/enrollment.
Preconception	To be completed for women in the preconception period. This phase refers to the time period before becoming pregnant and more than 2 years postpartum.
Prenatal	To be completed for women in prenatal period. This phase refers to the time period from diagnosis of pregnancy to birth.
Postpartum	To be completed for women in postpartum period. This phase refers to the time period from birth to six months after the baby is born.
Interconception/Parenting	To be completed with women in the period beyond the immediate postpartum phase. This phase refers to the time period from six months to two years after delivery.

Once collected, HS grantees are required to report data on a monthly basis by uploading individual client data to the Healthy Start Monitoring and Evaluation Database (HSMED). Data will be submitted to MCHB/HRSA through a contractor in a web-based and/or electronic format. The data are expected to be uploaded in batches 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 (see details regarding linkages below).

Vital Records

United States (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 at all 100 HS grantee sites and to PRAMS data at 15 grantee sites 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 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:

[1] Pending action by OMB.

- 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.

The PRAMS sampling frame is population-based, using state birth certificate data to identify a sample of women with a recent live birth. Each participating state samples 1,500-3,500 women per year, and women from certain groups are oversampled, ensuring sufficient data are available for higher risk populations. Women selected from birth certificate data are contacted by mail, and if there is no response to repeated mailings, women are contacted by phone and interviewed. Instruments and data collection procedures are consistent to enable cross-state comparisons.

The PRAMS survey will be administered to all eligible HS participants at 15 HS grantee sites. The PRAMS data will then be linked to HS client-level data and vital records data for the outcome evaluation.

Data Linkage Procedures

Data Sharing/Transfer Agreements

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, Vital Records Office (VRO), PRAMS program, and MCHB/HRSA. MCHB/HRSA will use a contractor to 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.

Data Linkage Procedures for HS Participant Individual Identifiers and Vital Records

All 100 HS grantees will collect individual identifiers from eligible program participants (see proposed individual identifiers in Table 4). In April 2018, grantees will provide to state/jurisdiction VROs the linkage variables for each pregnant and postpartum HS participant with informed consent. The VROs will complete the linkage of HS participants to 2017 birth certificates and send the linked data file to MCHB/HRSA in May 2018. State/jurisdiction VROs will also provide birth certificate data for non-participant controls from the same city or county(s)

served by the HS grantee with geographic identifiers (census tract or zip code). In May 2019, 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. MCHB/HRSA will then link the vital records data to client-level information on service receipt within HS using the client ID to complete the evaluation analyses. This may continue annually for all HS grantees.

Through the existing Vital Statistics Cooperative Program, NCHS will distribute funds to state/jurisdiction VROs to accomplish the linkage between HS participant information and vital records for grantee locations upon receipt of a signed data sharing/transfer agreement.

MCHB/HRSA will work through its evaluation support contract to ensure that all 100 HS grantees deliver the HS participants' individual identifiers to their state/jurisdiction VROs to complete the linkage. The contractor will provide technical assistance (TA) regarding the HS grantees' ability to provide data to VROs in a timely manner. The contractor will also monitor birth certificate linkage rates and deliver a report on the overall success of the linkages. Based on communication with an experienced Vital Registrar, we have set linkage targets of ≥95% for a known delivery date in 2017 and ≥80% for those with an expected delivery date in 2017. Finally, the contractor will develop a reporting template(s) for HS participants' individual identifiers to be transferred to the VROs on an annual basis. The template may need to be modified to meet the specific requirements of HS grantees and/or VROs. The contractor will also develop a protocol to transfer vital records data to MCHB/HRSA.

VROs will transfer birth certificate 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: birth certificate data on linked participants with client ID number, date of enrollment, and geographic identifiers (census tract or latitude/longitude) and birth certificate data for non-participant controls from the same city or county(s) served by the HS grantee with geographic identifiers (census tract or latitude/longitude). MCHB/HRSA will use the unique client ID to link the vital records data to client-level 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 procedures.

Table 4. Proposed Individual Identifiers for Linkage to Vital Records

Mother's name (first, last, maiden)
Mother's date of birth (or age in years but exact date of birth is preferred)
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 # (provide a number 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*
Fathers name (first, last) (if known)
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.

Data Linkage Procedures for PRAMS Matched Comparison

The client-level data for each HS participant, linked to their vital records data, will be linked to PRAMS data, for 15 randomly selected grantees (Figure 2). This subset of 15 HS grantees will be oversampled so their HS participants can be included in the PRAMS survey sample. The birth certificate provides the sampling frame for PRAMS. After linking HS participants to the birth certificate, the VROs will note which individuals are HS participants and PRAMS offices will sample these individuals to take part in the PRAMS survey (2 to 9 months postpartum) for their respective states. Oversampling via PRAMS will require ongoing monthly linkage to identify HS participants for sampling. The HS participant data, along with non-participant data, will be transferred to MCHB/HRSA for analysis. State/jurisdiction VROs will also complete linkage of the PRAMS sample to subsequent infant death certificates and send the linked data file to MCHB/HRSA. Participant/client identification numbers will allow MCHB/HRSA to link client-level data to Vital Records/PRAMS; however, no personal identifiers will be transferred to MCHB/HRSA.

Linking the client-level data, vital records and PRAMS will allow the evaluation team to fully assess the type and frequency of services HS participants received and the impact these services had on important benchmark and outcome measures (e.g., breastfeeding and infant mortality). Further, oversampling via PRAMS will enable comparisons between HS participants and non-participants. The process for the various stages of linkage and data collection is outlined in Figure 2 and in more detail in the HS Evaluation Linkage Flowchart (Appendix D).

In March 2017, the 15 randomly selected HS sites will begin providing individual identifiers monthly to state/jurisdiction VROs for pregnant and postpartum women with informed consent. The first transferred file will include all pregnant and postpartum women served with an expected or known delivery date in January and beyond. Subsequent monthly transfers will add any new pregnant or postpartum enrollees or any updated information for previously submitted data. The state/jurisdiction VROs receiving the individual identifiers will complete linkage of HS participants to birth certificates monthly. VROs will identify HS participants with confirmed deliveries in calendar year 2017. State/jurisdiction VROs will transfer the birth certificate data with the HS participants' unique client ID and enrollment date (no other identifying information is needed in the files transferred to PRAMS) to PRAMS programs so that they know which individuals are HS participants. The PRAMS programs will then include the identified HS

participants in the PRAMS Phase 8 sample and will contact the HS participants for survey administration.

In September 2018, CDC/PRAMS will provide MCHB/HRSA with the full, uniformed PRAMS file of all PRAMS participants in the selected states (both HS participants and non-participants); including linked vital records with a geographic identifier (census tract or latitude/longitude) for analytic purposes. State/jurisdiction VROs will complete linkage of the PRAMS sample to infant death certificates and send the linked data file to MCHB/HRSA in May 2019. Using the client ID number, MCHB/HRSA will link to PRAMS data via client-level information (from the client-level assessment forms) on service receipt within HS to complete the evaluation analyses (in July 2018 and March 2019).

Randomized Site Selection for PRAMS Matched Comparison

The HS program currently has 86 grantees located in states that conduct the PRAMS survey. To improve the chances of evaluating an operational program early in the grant cycle, the TEP recommended restricting the PRAMS oversampling to continuing grantees (75 of 100 total grantees). Similarly, CDC PRAMS recommended restricting the sample to grantees in current PRAMS states (n=40) given the lack of capacity in potential new PRAMS Phase 8 states (funding available for up to 61 states/jurisdictions/tribes).Therefore, the HS Sampling Frame included 63 of 75 continuing grantees that are located in current PRAMS states.

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 listed below include cells categorized by Level (1, 2, 3), Project Service 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. The strata or categories for each level and the methodology for randomly selecting the 15 HS grantees sites can be found in Appendix E.

The selection of 15 HS grantees, shown below in Table 5, has not been finalized for all states. There are currently 11 PRAMS States/Jurisdictions. A Southern, Level 3, urban site and Level 1 border site need to be identified or replaced with the next randomly selected site. The current PRAMS states include: AL, CT, IA, LA, MO, NY, NYC, MI, OR, PA, and SC.

Table 5. 15 HS Grantees Selected for Participation in PRAMS Matched Comparison

Border Grantee

Grantee	*City*	*State*	*Region*	*Level*	*Serving*
				1	*Border*

AI/AN Grantee

Grantee	*City*	*State*	*Region*	*Level*	*Serving*

Inter-tribal Council of Michigan, Inc.	*Sault Sainte Marie*	*MI*	*Midwest*	*2*	*AI/AN*

Level 1: 2 Urban (1 Non-Western; 1 Western); 1 Rural

Grantee	***City***	***State***	***Region***	***Level***	***Serving***
Monroe County	*Rochester*	*NY*	*Northeast*	*1*	*Urban*
Multnomah County	*Portland*	*OR*	*West*	*1*	*Urban*
Health Care Coalition of Southern OR	*Medford*	*OR*	*West*	*1*	*Rural*

Level 2: 4 Urban (2 Midwest, 1 Northeast, 1 South); 1 Rural

Grantee	***City***	***State***	***Region***	***Level***	***Serving***
MCH Health Coalition	*Kansas City*	*MO*	*Midwest*	*2*	*Urban*
Visiting Nurse Services	*Des Moines*	*IA*	*Midwest*	*2*	*Urban*
Community Foundation	*New Haven*	*CT*	*Northeast*	*2*	*Urban*
Birmingham Healthy Start Plus, Inc.	*Birmingham*	*AL*	*South*	*2*	*Urban*
Office of Rural Health	*Lexington*	*SC*	*South*	*2*	*Rural*

Level 3: 5 Urban (1 Midwest, 2 Northeast, 2 South)

Grantee	***City***	***State***	***Region***	***Level***	***Serving***
Institute for Population Health	*Detroit*	*MI*	*Midwest*	*3*	*Urban*
Healthy Start Inc.	*Pittsburgh*	*PA*	*Northeast*	*3*	*Urban*
Northern Manhattan Perinatal Partnership	*Harlem*	*NYC*	*Northeast*	*3*	*Urban*
			South	*3*	*Urban*
City of New Orleans	*New Orleans*	*LA*	*South*	*3*	*Urban*

Approximately half of all HS participants are pregnant women. We estimate the sample to include:

Level 1: 250 births x 5 grantees = 1,250
Level 2: 400 births x 5 grantees = 2,000
Level 3: 500 births x 5 grantees = 2,500

Thus, the sampling design will result in a projected total of 5,750 HS mother-infant dyads selected for PRAMS sampling as well as at least 5,750 matched controls (K:1 matching may be pursued).

Administrative and Funding Support for Data Linkage

All 100 HS grantees and up to 39 state/jurisdiction VROs will receive TA support to link HS participant individual identifiers to vital records data. MCHB/HRSA will use the evaluation support contract to conduct the following TA activities:

- Outreach to HS grantees, VROs, and PRAMS programs (if participating in oversampling) to facilitate customization and signing of the model data sharing and transfer agreements developed by NAPHSIS for the 100 grantees;
- Promote and monitor the timeliness of data transfer from HS grantees to VROs;
- Provide TA to HS grantees regarding collection and transfer of individual identifiers, as needed;
- Provide TA to VROs regarding data linkage and transfer (e.g., software/hardware requirements, linkage protocols, transfer mechanisms and formats), as needed;
- Develop and implement a process to monitor birth and death certificate linkage rates overall and by available data (i.e., known versus estimated date of delivery); and
- Work with VROs and HS grantees to improve linkage rates, where necessary and possible.

For the 15 HS grantees participating in PRAMS oversampling, the contractor will also provide guidance on outreach activities to promote and improve HS participants' response rates to the PRAMS survey. Additionally, HS sites will receive a one-time disbursement of $1,500 for outreach, materials, and training to promote HS participants' response rates to PRAMS.

VROs participating in PRAMS oversampling will also receive a one-time disbursement of $6,000 per HS grantee selected in their state/jurisdiction. These funds may be used to cover staff time for the monthly record linkage, the initial alteration to and testing of the sampling program/algorithm to accommodate the oversample. Funds may also be used for any additional resources needed to support changes to the PRAMS sampling.

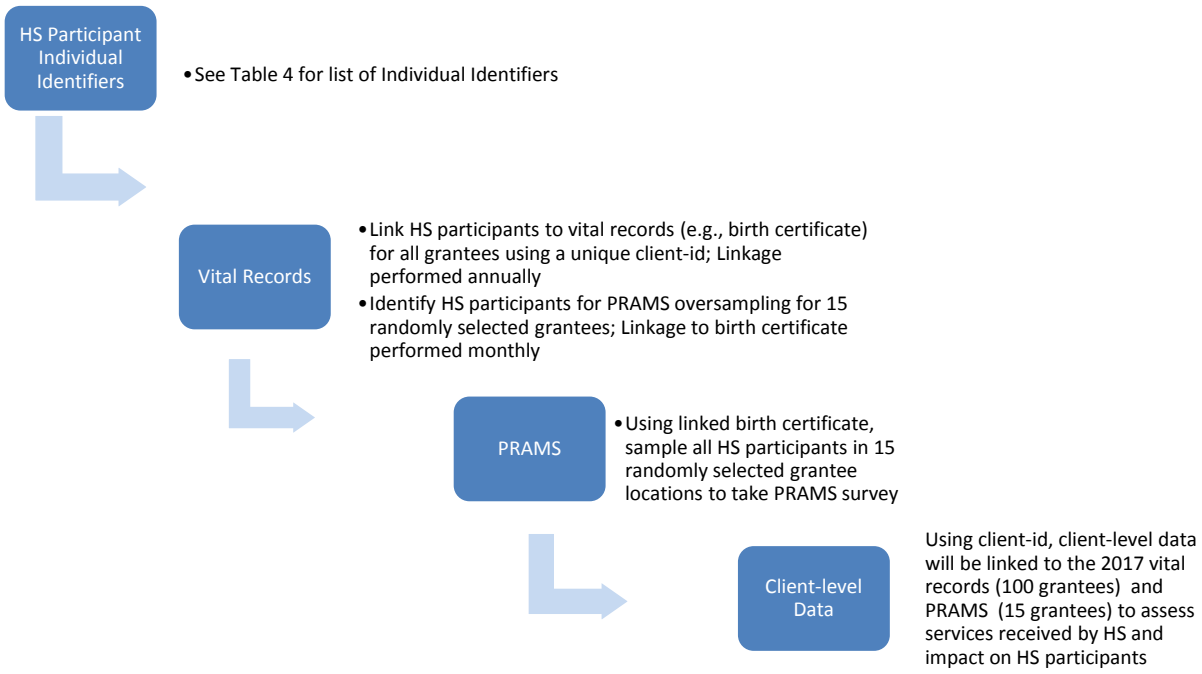
PRAMS state programs participating in the oversample will receive funds in the amount of $100 per birth/HS respondent to cover staff time for the additional interviews, survey printing, incentives, supplies, mailings, and the data entry required by the oversampling. Additionally, MCHB/HRSA, through an interagency agreement (IAA), will provide the CDC funds to hire a project coordinator to provide: ongoing project management and coordination; statistical support to develop and modify PRAMS sampling plans; and enhanced TA to PRAMS program managers selected to participate in the PRAMS oversampling. The CDC will also oversee the PRAMS oversampling in the 13 selected states/jurisdictions and lead the development of a transfer protocol for state PRAMS data to MCHB/HRSA.

Integrated Data Repository

The MCHB/HRSA evaluation team is exploring options to migrate the various data into one integrated data repository to include the linked HS client-level data, vital records and PRAMS data sets. A decision regarding database management is expected in fall 2016. The current plan is to have the evaluation support contractor receive data files from the HSMED for HS client-level data; state/jurisdiction VROs for all 100 HS grantees, including both HS participants and non-participants; and the CDC PRAMS program, including both HS participants and non-participants. Upon receiving the transferred data files, the contractor will clean the data and

prepare it for data analysis. Preparation may include creating relational databases to link together; performing rigorous quality control procedures and data verification checks; developing a common format, variable names and code book; and formatting the files for analysis in SAS/SUDAAN. The contractor will store all data on a secure server.

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



Data Analysis Plan

Implementation Evaluation

MCHB/HRSA will conduct an implementation evaluation of the transformed HS program to document and describe program activities, to understand the extent to which the program was implemented as intended, and to determine what factors explain effective implementation. The implementation evaluation is important to understand and establish linkages between the program and observed outcomes. The implementation evaluation is designed to answer the following questions:

- What components (e.g., activities, services, interventions) did grantees implement in the transformed HS program and to what extent did the components align with the five HS approaches?
- What factors (e.g., program and organizational) help explain effective implementation of the transformed HS program?

The transformed HS program does not have a set of defined intervention or evidence-based models each grantee is required to use. As such, the activities and intervention models will vary

across grantees and each program may be unique to that grantee only. While there is variation across grantee programs, all HS grantees are required to address key areas of activity for each of the five HS approaches. See Table 6 below for each approach's key areas of activity.

Table 6. Key Areas of Activity for the Five HS Approaches

HS Approach	Key Areas of Activity
Improve Women's Health	1. Outreach and enrollment in health coverage 2. Coordination and facilitation of access to health care services 3. Support for prevention, including clinical preventive services, interconception health and health promotion 4. Assistance with reproductive life planning
Promote Quality Services	1. Improve service coordination 2. Focus on prevention and health promotion (e.g., breastfeeding, immunization, safe sleep) 3. Apply core competencies for the HS workforce 4. Use standardized curricula and interventions
Strengthen Family Resilience	1. Address toxic stress and support trauma-informed care 2. Support mental and behavioral health 3. Promote father involvement 4. Improve parenting
Achieve Collective Impact	1. Level 1 Grantee: Actively participate in community collaboration, information sharing, and advocacy through Community Action Network which involves consumers and community leaders to engage consumers, providers and others in community change 2. Level 2 Grantee: Stimulate community collaboration to focus on working with the relevant partners to develop a common agenda, shared measurement approach, and coordinate resources 3. Level 3 Grantee: Provide leadership and structure for collective impact, including overall strategic direction, dedicated staff, coordination of communication and outreach, data collection and analysis, and mobilization of funding and other resources
Increase Accountability through Quality Improvement, Performance Monitoring, and Evaluation	1. Apply quality improvement 2. Conduct performance monitoring 3. Conduct local evaluation

Methods

The implementation evaluation includes quantitative assessment using the NHSPS and the HS Participant Survey. Description may include the number and types of people served and the types of services provided as outlined in the FOA. Because there is no set of defined intervention/evidence-based models required by the transformed HS program, the evaluation will first assess if grantees are conducting activities in the key areas and describe the activities of the grantee programs. Using data collected from the NHSPS, we will describe areas and activities that are common among grantees and those that differ across programs. The

description will outline the activities according to the 5 approaches and determine what percentage of grantees is adhering to the key program activities as outlined in the FOA. Additionally, NHSPS data will be used to examine the extent to which grantee programs address the key areas for each approach. Data will be assessed to track changes from the baseline NHSPS administered in 2016 and the follow-up survey to be administered in 2018. Lastly, we will use the HS participant survey to measure participants' engagement and involvement in, and overall satisfaction with the program and program services.

The implementation evaluation will examine the extent to which participants received promising and best practices and the challenges encountered by grantees when implementing activities and interventions. Specifically, the evaluation will assess how implementation is occurring across grantees and whether implementation is occurring as intended according to HS guidance. It will provide insight into factors that may be associated with implementation best practices, including characteristics of the organization delivering the HS program and of the program itself, such as age, program level, size, location, coverage, complexity of the program, and individuals delivering the program. This information will provide important contextual information to help interpret and explain program outcomes.

Analysis

Using program and participant survey data, metrics will be developed to assess more (versus less) effective implementation of HS services. Program goals and fidelity to implementing the 5 HS approaches will be analyzed by assessing, for example, number of participants enrolled in health coverage and methods used for enrollment, use of standardized curricula and interventions across grantee sites, and types of prevention education models used. We aim to identify program approaches/models considered to be key to effective implementation and identify metrics for assessing performance.

The analysis will also test the statistical significance of bivariate and multivariable associations between program- and organization-level factors and indicator(s) of effective implementation. Program-level factors may include the outreach strategies employed; number and types of referrals provided; the number and types of screenings provided; case management models utilized; caseloads maintained; and promotion of male involvement, among others. Organization-level factors will likely include the type of program (urban, rural, border); the HS program level (1, 2 or 3); the lead agency type; age of the program; staffing characteristics; and the type of approaches and services provided, among others.

Utilization Evaluation

The utilization evaluation will examine the characteristics of participants using HS services, the extent to which participants are making use of HS services, and the factors that explain the volume of services. This evaluation component is designed to answer the following questions:

- How many women and infants participated in the transformed HS program?
- To what extent were services delivered to the highest risk target populations (women and infants), as intended?
- What factors (e.g., personal, program, and organization level) help explain the volume of services used?

Methods

HS participants are defined as women who were enrolled in HS case management services and delivered a baby during calendar year 2017 for the vital records linkage and matched comparison. The utilization evaluation will assess the types of services utilized by HS participants, the extent to which the HS services were utilized, and the characteristics of HS participants compared to non-participants. Further, this analysis will provide insight into individual, program and organization-level factors associated with higher levels of HS service utilization. This information will provide important contextual information to help interpret and explain program outcomes.

Analysis

Descriptive analyses will include a summary of HS participants in terms of number of participants served during the preconception, pregnancy and postpartum periods within the target population, providing service dosage; individual characteristics, including socio-demographic indicators (e.g., age, race/ethnicity, income, education, insurance type, geographic area); health behaviors (e.g., smoking, alcohol use, drug use, breastfeeding); and health outcomes (e.g., low birth weight, preterm birth, infant mortality, maternal morbidity). Service or participation rates within the HS catchment areas will also be calculated and examined. As a precursor to the outcome evaluation, bivariate analyses will test for statistically significant differences in sociodemographic indicators, 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 include a summary of indicators of access to and utilization of HS services among HS participants, such as the number of available HS case management slots; number of filled case management slots; average number of days enrolled in case management; average caseload volume; the percent of clients who graduate from case management; the percent of clients lost to follow-up; and the type of HS services utilized.

Finally, bivariate and multivariable analyses will test for statistically significant associations between various program- and organization-level factors and level of utilization of HS services. Program-level factors may include the number of participants served during the preconception, pregnancy and postpartum periods; the outreach strategies employed; the number and types of referrals provided; the case management models utilized; the caseloads maintained; the number and types of screenings provided; if male involvement is promoted, among others. Organization-level factors will likely include the type of program (urban, rural, border); the HS program level (1, 2 or 3); the lead agency type; age of the program; staffing characteristics; and the type of approaches and services provided, among others.

Outcome Evaluation

The outcome evaluation is designed to measure the overall effect of the transformed HS program on participant outcomes and answer the following evaluation questions:

- What impact did the transformed HS program have on HS participants when compared to non-HS controls?

- What factors (program/organizational) of the transformed HS program are associated with improved participant behaviors, utilization, and health outcomes?

The evaluation seeks to assess the effect of the program on individual-level outcomes and provide MCHB/HRSA with reliable and generalizable results.

Methods

The outcome evaluation will employ aggregate benchmarking comparisons as well as an individually-matched quasi-experimental approach, 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; and

2. A matched individual comparison analysis of HS participants and non-participants by oversampling of the 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.

HS participants are defined as women who were enrolled in HS case management services and delivered a baby between a 12-month period (calendar year 2017).

Analysis for Benchmarks

The use of benchmarks is of particular interest to MCHB/HRSA, as it will place HS outcomes in a national context; the relevant outcomes are primarily those related to knowledge, behavior, risk, morbidity, and mortality. The transformed HS program established the following benchmarks, which will also be used for performance measures and reporting for all HS grantees.

1. Increase the proportion of Healthy Start women and child participants with health insurance to 90% (reduce uninsured to less than 10%).

2. Increase the proportion of Healthy Start women participants who have a documented reproductive life plan to 90%.

3. Increase the proportion of Healthy Start women participants who receive a postpartum visit to 80%.

4. Increase the proportion of Healthy Start women and child participants who have a usual source of medical care to 80%.

5. Increase the proportion of Healthy Start women participants that receive a well-woman visit to 80%.

6. Increase the proportion of Healthy Start women participants who engage in safe sleep practices to 80%.

7. Increase the proportion of Healthy Start child participants whose parent/caregiver reports they were ever breastfed or pumped breast milk to feed their baby to 82%.

8. Increase the proportion of Healthy Start child participants whose parent/caregiver reports they were breastfed or fed breast milk at 6 months to 61%.

9. Increase the proportion of pregnant Healthy Start participants that abstain from cigarette smoking to 90%.

10. Reduce the proportion of Healthy Start women participants who conceive within 18 months of a previous birth to 30%.

11. Increase the proportion of Healthy Start child participants who receive the last age-appropriate recommended well-child visit based on AAP schedule to 90%.

12. Increase the proportion of Healthy Start women participants who receive depression screening and referral to 100%.

13. Increase the proportion of Healthy Start women participants who receive intimate partner violence (IPV) screening to 100%.

14. Increase the proportion of Healthy Start women participants that demonstrate father and/or partner involvement (e.g., attend appointments, classes, etc.) during pregnancy to 90%.

15. Increase the proportion of Healthy Start women participants that demonstrate father and/or partner involvement (e.g., attend appointments, classes, infant/child care) with their child participant to 80%.

16. Increase the proportion of Healthy Start child participants aged <24 months who are read to by a parent or family member 3 or more times per week to 50%.

17. Increase the proportion of HS grantees with a fully implemented Community Action Network (CAN) to 100%.

18. Increase the proportion of Healthy Start grantees with at least 25% community members and Healthy Start program participants serving as members of their CAN to 100%.

19. Increase the proportion of HS grantees who establish a quality improvement and performance monitoring process to 100%.

HS communities are selected based on demonstrated population need for such interventions and will likely start out with much poorer outcomes than the average community in the U.S. Thus, it will be an achievement for HS to show progress toward or to reach the national average. This method compares prevalence and incidence of outcomes among HS participants with outcomes found in national data sources. Data available from all HS projects will be used to compare HS outcomes to that from secondary data sources. If particular data elements of interest to MCHB/HRSA are only available from the 15 HS projects selected for PRAMS oversampling, the benchmark analysis could be limited to a comparison between outcomes from those 15 projects to that from the secondary data source. Because all outcomes of interest are unlikely to be available from one secondary data source, multiple secondary data sources will likely have to be employed for the benchmark analysis. The eligibility criteria for inclusion in this type of method will be driven by the specifications of the secondary data source; for example, if a secondary data source includes a sample of women up to 6 months postpartum, and the women were surveyed during the first half of the calendar year, we would use data from HS women meeting these same criteria. The national comparison group can also be refined to

a low-income reference to be more comparable to the HS population.

Several factors will determine whether benchmarking data sources can provide a population similar to HS's, including available variables and sample size. If standard deviations can be calculated for benchmark rates, basic statistical tests (such as *t*-tests or chi-square tests) may be used to assess the significance of the difference between the HS and benchmark rate for an outcome—that is, whether the rate of the outcome among HS participants differs from the benchmark rate within a tolerable type-1 error (e.g. $p<0.05$). Although this benchmarking method places the outcomes of the HS program in a national context, it is unlikely to allow for attribution of any differences to HS program effects. It also does not control for what might have happened in the absence of HS in as rigorous a manner as the quasi-experimental method, which matches a comparison group based on a rich set of community- and individual-level variables and may assess changes in outcomes over time.

Analysis for Individually-Matched Comparisons (Vital Records and PRAMS)
The 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 (see examples of matching variables in Table 7) 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.

Table 7. Examples of Matching Variables to be Included in Multivariable Models

Variable	Vital Record	PRAMS
Age	X	
Race/Ethnicity	X	
Parity	X	
Plurality	X	
Education	X	
Marital status	X	
Neighborhood poverty rate*	X	
Body mass index	X	
Medical risk factors	X	X
WIC participation	X	X
Health insurance	X	X
Household income		X
Time of PRAMS survey completion		X
Physical abuse (before, during, and after pregnancy)		X
Stressful life events		X
Preconception visit		X
Pregnancy intention		X
Preconception health status		X

Postpartum depression		X

*From residential address geocoding

Individual-level matching would ensure that the comparisons in the evaluation involve similar women (with the exception that the participants have accessed the transformed HS program), and the evaluation produces estimates of the effects of HS on individual-level outcomes. A propensity score matching approach will be used to match participants and non-participants. The propensity score method uses the set of variables to compute the probability of being served by HS for each HS participant and nonparticipant using a logistic regression model. In other words, the demographic and risk factors (independent variables) are used to predict whether individuals are HS participants (dependent variable). The resulting propensity scores are the chances that each individual is a HS participant, or the predicted propensity to be a HS participant.

Given the general PRAMS sample size, however, non-participants will not be restricted to the same "community" in the PRAMS matched comparison. Thus, census tract or zip code-based poverty will likely be used to control for community characteristics. In the vital records comparison, however, participants will be able to be matched to non-participants in the same general geographic area (city/county) that is served by HS (e.g., same census tract service area or a census tract in the same city with similar rates of disadvantage as those served by HS). This will enhance MCHB/HRSA's ability to draw conclusions about the effectiveness of the program in influencing the key health outcomes of the transformed program. Given that there are likely to be many more non-HS participants in vital records than HS participants, the analysis could be statistically strengthened by a 1:N (3, 4) match. Subgroup analyses will also be explored to determine whether the effect of program participation is greater for certain high-risk groups (e.g., teens).

An important consideration to account for in the analysis is 'dose of HS intervention' received by HS participants as dose response effects improve causal inference. Due to the size and multi-faceted and changing nature of the HS program, it will be difficult to precisely measure "dose" of each HS intervention or the initiative as a whole. One strategy is the use of multiple comparison groups within the HS participant group in order to assess the effects of various levels of intervention 'dosage.' This may involve sub-group analyses by dose and/or separate propensity score models that predict each level of dose. See Table 8 below for possible characterizations of HS dose.

Table 8. Potential Characterizations of HS Intervention Dose

Healthy Start Case Management Dosage
Duration of enrollment (HS admit date, delivery date, discharge date)
Breadth of interventions - visit type: phone, home, office, other
Amount of contact time - Date of visit
HS provider (RN, SW, MH counselor, paraprofessional)
HS enrollment for a prior pregnancy

Finally, multivariable analyses of grantee-level propensity score-based effect estimates will be used to identify program- and organization-level factors that predict greater impact on behaviors, service receipt, and outcomes. Program-level factors may include the number of participants served during the preconception, pregnancy and postpartum periods; the outreach

strategies employed; the number and types of referrals provided; the case management models utilized; the caseloads maintained; the number and types of screenings provided; and if male involvement is promoted, among others. Organization-level factors will likely include the type of program (urban, rural, border); the HS program level (1, 2 or 3); the lead agency type; age of the program; staffing characteristics; and the type of approaches and services provided, among others.

Limitations of the Transformed Healthy Start Program Evaluation

Information Bias

The HS implementation evaluation encounters the limitations inherent in self-reported data from grantee reports and survey data. Such information is subject to desirability and recall bias, among other concerns. The design of this evaluation will address this concern by asking grantees and participants for their feedback close in time to their experience. The evaluation has also been designed to triangulate these data with other sources to address those concerns. Finally, this limitation applies equally to HS participants and non-participants.

The quality of the evaluation depends on accurate information from grantees, their staff, partners, and participants about the performance of the program. Inherently, data relying on perceptions are hard to verify. Therefore, to develop as accurate a picture as possible of implementation at any given grantee site, it may be necessary to gather information from multiple sources that represent various perspectives. High quality and complete program administrative data will also be critical for assessments of fidelity. For example, if grantee data systems do not collect and track the needed data elements to assess implementation (such as attendance, retention, frequency of services), the ability to conduct assessments of fidelity may be compromised due to lack of data.

Consistent data collection across all grantee sites is another possible limitation to the evaluation. HS grantees may use their own forms and methods to collect data and may collect information at varying time intervals. Using a method (such as the web-based application) that promotes consistent data collection and implementing procedures that support adherence to protocols across all sites will also help eliminate any biases that could be introduced through data collection. Incomplete and insufficient client-level data has been a limitation of previous HS evaluations. Although a client-level data monitoring and evaluation system has been developed, there remains a risk of incomplete and non-comparable data across grantees. A lack of complete and comparable client-level data would pose grave limitations to portions of the utilization and outcome evaluation in terms of dosage of services received. As a back-up plan, we've included the date of enrollment on the linkage to at least capture the timing of enrollment (prenatal, postpartum) and presumed length of enrollment to enable crude comparisons of service dose for both the utilization and outcome evaluation.

Selection Bias

PRAMS data will be restricted to 'continuing' HS sites, thus excluding any new grantees. While improving the likelihood of evaluating fully operational programs, restricting the analysis to more mature HS programs presents a challenge when attempting to assess the effects of the 'transformed HS program' on program participants, which only began in 2014. Future phases of the evaluation will need to account for differences in program design and developmental stages among grantees. Further, non-participation in the evaluation among some sites selected to be included in the PRAMS oversampling may result in selection bias. None of the declines, however, have been due to HS grantee issues so it may be possible to assume that the decision to participate in the evaluation is independent of HS grantee functioning. However, the implementation, utilization, and vital records based outcome evaluation will include all grantees

and carries an added benefit of geographically based controls despite having fewer available outcomes and covariates. Beyond grantee-level selection, non-participation in the evaluation among individuals who decline to consent may also introduce selection bias. Therefore, participation rates will be monitored closely with technical assistance provided to sites with low participation levels.

Omitted Variables Bias (Confounding)

A considerable weakness of the aggregate benchmarking method is the general inability to balance comparisons between participants and non-participants across the full range of observed covariates that may be related both to participation and outcomes. In addition, the timeliness and availability of the benchmark data will help determine the suitability of the data for comparisons to HS participants. Certain surveys or administrative data are collected and reported annually and are available for public use. Other data sources may have a cycle of several years, and access may require data use agreements. Old benchmark data may no longer be valid, as they reflect previous trends in the outcome (for example, new policies or science may have been introduced since the benchmark data were collected), and comparisons of HS outcomes to such benchmarks would lead to unreliable results.

Although individual propensity score matching across a range of observed covariates, gathered with the same instrument at the same time, represents a significantly improved approach, there may still be unobserved characteristics associated with the likelihood of participation in HS and health outcomes (for example, motivation). If the matched nonparticipants are different from the participants based on these unobserved characteristics, the estimated effects of the HS program could be biased due to self- selection. The PRAMS-based analyses contain more covariates that may be related to program participation and outcomes, offering an improvement to internal validity, but confounding by unobserved variables will always remain a limitation of a quasi-experimental versus true experimental approach.

Contamination

An additional challenge is the fact that similar efforts, whose goals overlap with those of HS, may be taking place both within and outside of HS communities (e.g., home visiting programs, state-based Healthy Start). This may make it difficult to attribute estimates of program impact solely to Healthy Start and/or diminish effect estimates by having controls that participate in similar programs. To mitigate these possibilities, we will solicit information on overlapping service receipt from grantees and may select geographic controls that are similarly served or not served by additional programs. For PRAMS-based comparisons that will not be geographically based, we will explore the addition of a question on participation in a case management or home visiting program to identify women who should be excluded from consideration as controls.

Quality Assurance Plan

To ensure the quality of the data and ultimately the analysis for the evaluation, several best practices will be used to guide the data collection and preparation activities: (1) when possible, data will be cross-checked against multiple sources; (2) when sources differ in data quality, the highest quality source will be used first; (3) pre-programmed and pre-formatted, detailed databases and forms/templates will be used for information capture; (4) quality and consistency checks will be performed on all tables before analysis takes place; and (5) the limitations of the method will be acknowledged and addressed where feasible. Additionally, data will be downloaded into pre-formatted and pre-programmed databases. Pre-programmed, automated queries will be used as part of a comprehensive process of quality assurance to help identify

problems or anomalies, and a second analyst will review data before analysis begins to ensure that the data are truly "clean".

Once individual components of data analysis described above are complete, the team as a whole will participate in triangulating the data to develop key findings and (as appropriate) develop recommendations or matters for consideration. Findings and recommendations will be discussed thoroughly with program staff and with the evaluation TEP as appropriate, to help ensure that all information and perspectives are considered and incorporated thoughtfully.

Clearance Requirements

The MCHB/HRSA evaluation team wants to ensure that all appropriate clearances are obtained to conduct the evaluation. For the protection of human subjects, Institutional Review Board (IRB) approval was sought for the following:

1. Participating in the HS evaluation;
2. Completing the HS client-level assessment forms;
3. Providing HS participant individual identifiers (Table 4) to state/jurisdiction 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.

The IRB package included the evaluation protocol and an informed consent form template describing the process and how the data will be utilized for the evaluation. HS grantees will be instructed to conduct the informed consent process when they enroll HS participants into the program and will administer the client-level assessment forms. Please note, participants with an expected delivery date in CY2017 and postpartum women that delivered in CY2017 are eligible to have their individual identifiers sent to VROs for linkage.

Grantees that currently provide informed consent are asked to update their informed consent forms to include language regarding the HS national evaluation. If grantees are not currently providing informed consent, they can begin to provide it using the MCHB/HRSA protocol and informed consent approved for the evaluation. HS grantees may tailor the informed consent template to their specific populations as long as they adhere to the approved evaluation protocol. Grantees using the MCHB/HRSA IRB approved informed consent language must fully comply with the MCHB/HRSA evaluation study protocol. All information collected during the evaluation will be kept confidential to the extent allowed by law. All information will be de-identified and presented in aggregate so that no individual is identifiable. Participants will be informed that their participation is voluntary and they have the right to not answer any or all questions.

Since personal identifiable information will be obtained on HS participants and sent to state/jurisdiction VROs to link participants to infants' vital records, HIPAA and other privacy issues are being considered and discussed with HRSA officials. Additionally, HIPAA compliance issues will also be assessed in the IRB review.

In addition to IRB and HIPAA clearance, MCHB/HRSA is seeking clearance through the Paperwork Reduction Act (PRA) from the Office of Management and Budget (OMB) for the client-level assessment forms and participant survey. The client-level assessment forms are adapted from the Preconception, Pregnancy, and Parenting (3Ps) form (which received OMB clearance) and screening tools developed by the HS CoIIN. The client-level assessment forms

will be submitted to OMB for a full clearance review as a Revision to the current Healthy Start OMB clearance (OMB No.: 0915-0338, Expiration Date: June 30, 2017). Along with the Revision, we are also seeking an extension of the current OMB clearance to extend the clearance for an additional 3 years, with an expiration date in 2019. The Revised HS OMB package identifies and provides a rationale for changes from the previously approved 3Ps form to the revised client-level assessment forms. It also includes the NHSPS, which received OMB approval in 2014 along with the original 3Ps.

We will also seek OMB clearance for the HS participant survey once it is developed. Depending on the nature of the participant survey questions, an expedited OMB review may be sufficient and OMB approval can be obtained in 1-3 months. If an expedited review is not granted, a full clearance for the participant survey will also be required, which may take 6-9 months for OMB approval.

EVALUATION MANAGEMENT

The HS evaluation management team consists of Ms. Jamelle Banks and Dr. Maura Dwyer. Ms. Banks is the MCHB Chief Evaluation Officer in the Office of Epidemiology and Research (OER) and will serve as the Lead Evaluator for the HS program evaluation. She has over 13 years of evaluation experience and 9 years of project management experience. She has led several evaluation projects for public and private sectors. Dr. Dwyer is Senior Health Policy Advisor and Program Director for the Maryland Health Enterprise Zones Initiative at the Maryland Department of Health and Mental Hygiene (DHMH). Dr. Dwyer has over 14 years' experience implementing and managing evaluation studies for large complex public health programs. An Intergovernmental Personnel Agreement (IPA) was established for Dr. Dwyer's time on this evaluation. Ms. Banks and Dr. Dwyer will work closely with the TEP, DHSPS staff, OER, MCHB/HRSA leadership, and other stakeholders to conduct the three evaluation components. They will both work at 0.5 level of effort for a total of 1 FTE on the evaluation.

In addition to the evaluation team, 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 and Washington, DC 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 the HS Participant survey; 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 TEP quarterly meetings; and providing administrative and coordination support to MCHB/HRSA staff managing previously-established activities to support data collection processes and activities. Ms. Banks will serve as the Contractor Officer Representative and will closely monitor the contract and its activities. Contractor support will also be provided for the process evaluation through DHSPS' current

contractor, JSI, who will administer the NHSPS. OER will analyze the NHSPS data and prepare a preliminary report of the findings.

Communication/Reporting

To ensure that the HS program evaluation achieves the greatest possible impact, the methods and results will be shared widely with HRSA Bureaus, on the MCHB/HRSA and HRSA internal and external websites, and through presentations at HRSA (e.g., EvalChat) as well as other federal meetings. The evaluation results will also be presented in a final report available on internal and external MCHB/HRSA and HRSA websites, as well as in HRSA reports to Congress. Information will also be shared via presentations and reports with MCH collaborators and stakeholders such as Title V programs, state health departments, and partnership organizations. All communications, reports, and presentations will be tailored to the interests of each audience as needed to maximize translation of findings to practice and implementation of proposed recommendations. Table 9 below presents a plan for disseminating the evaluation findings.

Table 9. HS Evaluation Dissemination Plan

Audience	Forum/Method	Product(s)
MCHB/HRSA leadership	Special meeting	PowerPoint presentation
Program staff	Special meeting	PowerPoint presentation
	Documents available on MCHB/HRSA internal and external web sites	Evaluation report, one page summary
		Full evaluation report
	Documents designed to address specific questions, not of general interest	Supplementary tables
Technical Expert Panel	Special meeting	PowerPoint presentation
Program stakeholders	Special meetings	PowerPoint presentation
	Scientific conference presentation	
	Documents available on MCHB/HRSA internal and external web sites	Evaluation report, one page summary
		Full evaluation report
HRSA Bureaus and Offices & Evaluation Community	HRSA EvalChat	PowerPoint presentation
	Documents available on MCHB/HRSA internal and external web sites	Evaluation report, one page summary
		Full evaluation report
HRSA OPAE	Documents available on MCHB/HRSA internal and external web sites	Evaluation report, one page summary
		Full evaluation report
MCHB/HRSA Policy/Legislative Office	HRSA reporting	Included in relevant reports prepared by HRSA (e.g., Congressional Justification)
MCH stakeholders	Publications	Peer reviewed journal articles (e.g., Maternal and Child Health Journal)

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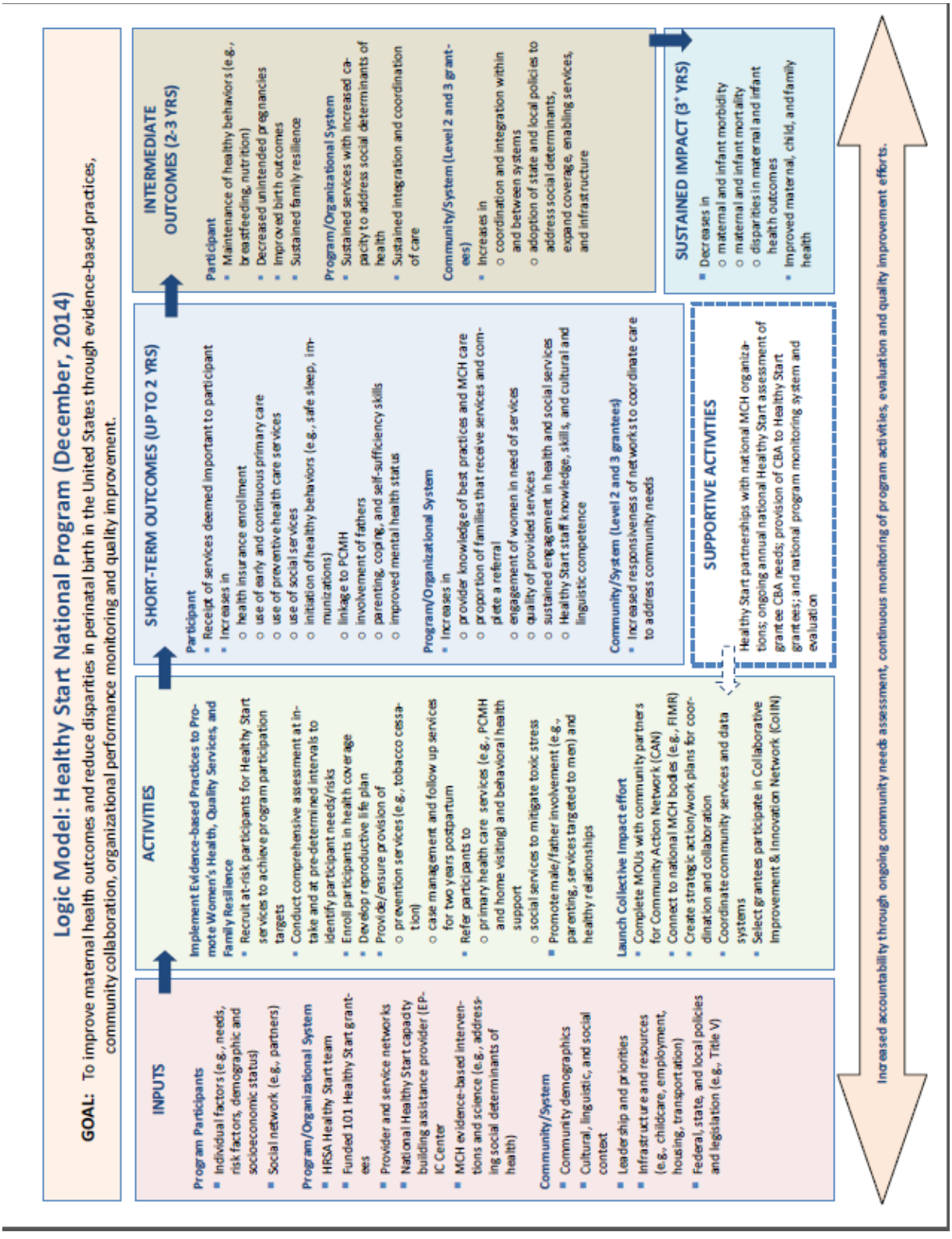
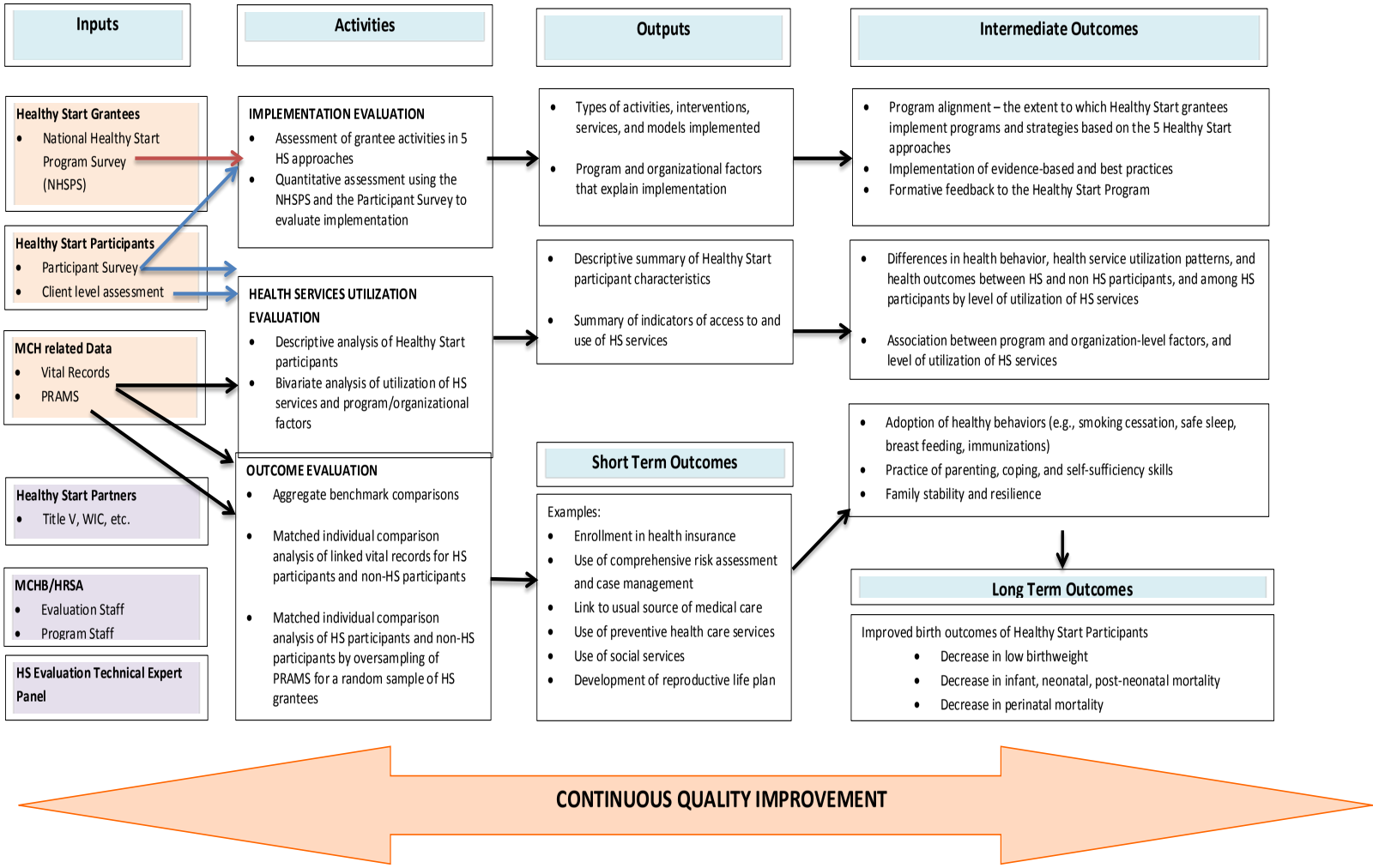
APPENDICES

Appendix A: Healthy Start National Program Logic Model, December 2014



Healthy Start (HS) Evaluation Plan Logic Model

Evaluation Goal: To determine the effect of the transformed Healthy Start Program on changes in participant-level characteristics (e.g., behaviors, health services utilization, and health outcomes).



Appendix B:

DRAFT

Health Resources and Services Administration

Maternal and Child Health Bureau

Evaluation of the Transformed Healthy Start (HS) Program

HS Evaluation Technical Expert Panel (TEP) Charter

Background

The Health Resources and Services Administration's (HRSA) Maternal and Child Health Bureau (MCHB) is charged with promoting and improving the health of the Nation's women and children by providing national leadership and by working in partnership with states, communities, public-private partners, and families. In support of this mission, the Division of Healthy Start and Perinatal Services (DHSPS) provides administrative oversight of the federal Healthy Start (HS) program which provides grants to communities to reduce infant mortality, health disparities, and improve perinatal health outcomes. HS has evolved from a demonstration project in 15 communities in 1991 to a national program in 100 communities across 37 states, and Washington, DC.

While the program has existed for over 20 years, the HS program was transformed in 2014 to apply lessons from emerging research, past evaluation findings, and to act on national recommendations from the Secretary's Advisory Committee on Infant Mortality. The goal of the new HS program is to improve maternal health and reduce disparities in 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 and children through their first two years, and their families in diverse, low income communities with exceptionally high rates of infant mortality. The five approaches include: improving women's health, promoting quality services; strengthening family resilience; achieving collective impact; and increasing accountability through quality improvement, performance monitoring, and evaluation.

To understand the implementation, utilization and overall impact of the HS program, a national program evaluation will be conducted. The evaluation's implementation is led by MCHB's Office of Epidemiology and Research (OER). The design of the evaluation strives to address the challenges and limitations noted in prior evaluations, such as a lack of consistently collected data on outcomes and the ability to identify an appropriate comparison group(s).

The national evaluation includes three components: 1) implementation; 2) utilization; and 3) outcome. The purpose of the implementation evaluation is to describe and examine program components that affect outcomes. The purpose of the utilization evaluation is to examine the characteristics of women and infants who did and did not utilize the program. The purpose of the outcome evaluation is to assess the program's performance and overall effectiveness with regard to producing expected outcomes among the target population. The data sources for the implementation evaluation are an OMB approved survey, the National Healthy Start Program Survey (NHSPS), and a HS Participant Survey (to be developed). The utilization and outcome evaluations will link state/jurisdiction vital records (e.g., infant birth and death certificates); the Centers for Disease Control and Prevention (CDC) Pregnancy Risk Assessment Monitoring System (PRAMS) survey; and participant level program data to compare HS participant and non-participant characteristics and outcomes. Key benchmarks and outcomes that can be examined with vital records include infant mortality, low birth weight, preterm birth, initiation and adequacy of prenatal care, breastfeeding initiation, and gestational weight gain. PRAMS also provides additional and enhanced data on psychosocial and demographic characteristics, health

behaviors and outcomes, and health care access into the postpartum period. The evaluation is designed to link HS participant data to vital records for all HS grantees and to PRAMS data for 15 randomly selected HS grantees. All HS grantees will be asked to provide individual identifiers (e.g., mother's name, mother's date of birth, infant sex, date of delivery, delivery hospital) for participants that give birth to state/jurisdiction Vital Records offices. The Vital Records offices will link the HS participants to infant birth certificates and any subsequent infant death certificates. For the 15 HS grantees selected for PRAMS oversampling, all HS participants that are linked to birth certificates—the PRAMS sampling frame—will be selected to receive a PRAMS survey. Evaluation findings are expected to inform program decisions and future program direction. Further, findings will enable not only a determination of whether HS is effective in impacting participant outcomes, but why and how, so that effective program components can be spread and scaled.

Purpose

The purpose of the HS Evaluation TEP is to engage the expertise of maternal and child health (MCH) and evaluation experts on the design, methods, and implementation of the transformed HS national evaluation. The TEP will serve as an external consultative committee that provides objective review, input, and recommendations regarding the evaluation design, data collection instruments, measures, and interim and final reports on the evaluation findings, and any related publications. The TEP will also assist in finalizing recommendations based on the overall evaluation findings and their applicability to HS participants and grantees, MCHB/HRSA, and other stakeholders.

Scope

The scope of the HS Evaluation TEP includes the planning, implementation, analysis, and final recommendation phases of the HS national evaluation. This scope applies to the individual TEP members charged with serving as consultants on the transformed Healthy Start program evaluation.

Duration and Time Commitment

The duration of the HS evaluation is 48 months. Each TEP member is requested to participate in up to 16 teleconference and/or in-person meetings and review various documents over the duration of the 48-month project. The time commitment is approximately 50 hours over the course of the evaluation.

Members

The table below provides a list of the TEP members and their affiliations:

Technical Expert Panel Members

Name	Affiliation
Patricia O'Campo, PhD	Director, Centre for Research on Inner City Health, St. Michael's Hospital and Professor, Dalla Lana School of Public Health Sciences, University of Toronto
Arden Handler, DrPH	Professor, Community Health Sciences & Director, Maternal and Child Health Program, University of Illinois at Chicago
Kenn L. Harris, LMin	Health Administrator, The Community Foundation for Greater New Haven
Leslie Lipscomb Harrison, MPH	Division of Reproductive Health, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention
Vijaya Hogan, DrPH	Clinical Professor, University of North Carolina Gillings School of Global Public Health
Milton Kotelchuck, PhD, MPH	Professor of Pediatrics, Harvard University Medical School
Saba W. Masho, MD, MPH, DrPH	Associate Professor, Virginia Commonwealth University, Department of Family Medicine and Population Health, Division of Epidemiology
Jennifer E. Moore, PhD, RN	Director, Institute for Medicaid Innovation and Vice President of Policy & Research, Medicaid Health Plans of America
Diane L. Rowley, MD, MPH	Professor, University of North Carolina Gillings School of Global Public Health
Hamisu Salihu, MD, PhD	Professor, Baylor College of Medicine Professor, College of Public Health, University of South Florida

Roles and Responsibilities

TEP members have been invited to offer their expertise to the transformed HS program evaluation. The roles and responsibilities of the TEP members are:

1) Attend TEP meetings;
2) Review program evaluation documents (e.g., evaluation plans, surveys, implementation plans, draft and final evaluation reports, publications);
3) Provide comments, edits, and recommendations on the program evaluation documents; and
4) Communicate with MCHB/HRSA staff and the evaluation team as needed regarding the transformed HS program evaluation.

TEP Meetings

The MCHB evaluation team and DHSPS staff will meet with the TEP on scheduled meeting dates according to their availability. The meetings are anticipated to occur quarterly. TEP members are asked to attend all meetings and actively participate in reviewing evaluation documents and providing input and recommendations regarding the evaluation design, progress and findings, interim and final reports, and related publications. TEP meetings will be scheduled in advance using scheduling software (e.g., Outlook calendar, Doodle polls). If a TEP member is not able to attend a meeting, they should inform the MCHB evaluation team in advance so the meeting can either be rescheduled or alternate plans can be made to accommodate the change.

The MCHB evaluation team will strive to provide agendas and draft documents to TEP members five business days prior to scheduled meetings. As resources permit, MCHB/HRSA will hold in-person meetings with the TEP once a year or every other year.

Document Review
TEP members are asked to provide comments to the MCHB evaluation team for review and collation of comments by the determined deadlines. TEP members are encouraged to make revisions, comments, and/or recommendations in writing using Track Changes, as applicable. Final revisions to evaluation instruments, reports, and publications will be made by the MCHB evaluation team and made available to the TEP within 5 business days of the TEP meetings or after receipt of all emailed comments.

Communication
The TEP will meet as a group with the MCHB evaluation team via teleconference and/or in person as they are able. The group will maintain communication via email as needed.

Supporting Resources
The MCHB evaluation team consists of the MCHB Chief Evaluation Officer in the Office of Epidemiology and Research (OER), who will serve as the Lead Evaluator for the HS program evaluation (at 0.5 FTE), with 0.5 FTE of support provided through an Intergovernmental Personnel Agreement (IPA). These individuals will work closely with the DHSPS staff, OER, MCHB leadership, and other stakeholders to conduct the evaluation. In addition to the evaluation team, MCHB has/will establish a Purchase Order, two Interagency Agreements (IAAs), and an Indefinite Deliverable Indefinite Quantity (IDIQ) contract to support data collection and evaluation implementation activities. The Purchase Order is with the National Association of Public Health Statistics and Information Systems (NAPHSIS) to develop model data sharing/transfer agreements between HS grantees, Vital Records offices, PRAMS programs, and MCHB/HRSA. The IAAs are with the CDC's National Center for Health Statistics (NCHS) and the CDC's Division of Reproductive Health (DRH) which oversees the PRAMS program. NCHS will ensure MCHB 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 and DC 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 HS Participant survey; providing technical assistance to HS grantees, state/jurisdiction Vital Records offices, 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 TEP quarterly meetings; and providing administrative and coordination support to MCHB 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, who will administer the NHSPS. OER will analyze the NHSPS data and prepare a preliminary report of the findings.

Appendix C: 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

Appendix D: Evaluation Linkage Flow Chart

Flowchart for Vital Records Linkage and PRAMS Oversampling
DRAFT: 3/30/16

Step	Activity	Timeframe	Questions/Comments
Vital Records Linkage for All HS Grantees			
1	Solicit feedback on grantee experiences with vital records linkage and issue guidance to HS grantees on identifying variables^ needed to complete a linkage to vital records	February - July 2016	We will send an email to HS grantees providing them with the list of individual identifiers and asking the feasibility of collecting and sending the information to Vital Records Offices (VRO). Individual identifiers should be collected at enrollment.
2	Model data sharing/transfer agreement developed and distributed by NAPHSIS for data transfer between HS grantees, VROs, and MCHB/HRSA	By August 2016	
3	HS grantees and VROs sign the data sharing/transfer agreement Upon receipt of a signed data sharing/transfer agreement, funds will be disbursed to VROs to complete this linkage through the Vital Statistics Cooperative Program (VSCP) contract with NCHS	By December 2016	VROs participating in PRAMS oversampling will receive extra funds in 2017 VSCP contract via 2017 IAA
4	HS grantees collect individual identifiers at enrollment (standard informed consent to be provided)	October 2016	This is planned to be ongoing for multiple years
5	All 100 HS grantees provide individual identifiers to state/jurisdiction VRO for annual linkage to birth certificate	April 10, 2018	
6	State/jurisdiction VRO complete linkage of HS participants to 2017 birth certificates and send linked data file to MCHB/HRSA (with unique client ID, date of enrollment, and census tract or zip code) and information on linkage rates by type of participant (known date of delivery in 2017, estimated date of delivery in 2017) VROs also provide birth certificate data for	May 2018	

	non-participant controls from the same city or county(s) served by HS grantee with census tract or zip code		
7	State/jurisdiction VROs update linkage of HS participants and controls to include any subsequent infant death certificates and send linked data file to MCHB/HRSA	May 2019	
8	MCHB links vital records data to client-level information on service receipt within Healthy Start using the client ID to complete evaluation analyses	June 2018, June 2019	
PRAMS OVERSAMPLING for 15 HS GRANTEES (Step 1-8 are the same as above; additional steps below)			
1	Beginning March 10, 2017, the 15 HS grantees selected for PRAMS oversampling shall provide participant individual identifiers to state/jurisdiction VROs ***monthly*** for pregnant and postpartum women	March 2017 – February 2018	This is lagged by over a month to capture all deliveries in the previous month.
2	State/jurisdiction VROs receiving individual identifiers complete linkage of HS participants to birth certificates ***monthly***. VROs will identify HS participants with confirmed deliveries in 2017 State/jurisdiction VROs transfer the birth certificate data with the HS participants' unique client-id and enrollment date (no other identifying information is needed in the files transferred to PRAMS) so PRAMS programs know which individuals are HS participants	March 2017 – February 2018	VROs will receive supplemental funding and technical assistance to support monthly linkage activities.
3	PRAMS programs include the identified HS participants in the PRAMS Phase 8 sample and contact HS participants for survey administration	April 2017 – March 2018	HS grantees will receive supplemental funds and technical assistance to promote the completion of the PRAMS survey. PRAMS grantees will receive supplemental funding to assist with costs associated with promoting and administering the survey to HS participants.

4	CDC PRAMS provides MCHB/HRSA with the full PRAMS file of all PRAMS participants in the selected states (both HS participants and non-participants)	September 2018	This assumes 6 months to provide the full PRAMS file.
5	VROs participating in PRAMS oversampling send any additional requested birth certificate items for PRAMS sample to MCHB/HRSA	September 2018	
6	State/jurisdiction VROs complete linkage of PRAMS sample to infant death certificates and send linked data file to MCHB/HRSA	May 2019	
7	MCHB links to PRAMS data from client-level information on service receipt within Healthy Start using the client ID to complete evaluation analyses	September 2018, May 2019	

^Proposed Individual Identifiers

- **Mother's date of birth (or age in years but exact date of birth is preferred)**
- 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 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., 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 through March of 2018, in the possible event of early delivery occurring in 2017. The annual linkage will include deliveries in 2017 and may be repeated on an annual basis. The monthly PRAMS linkage will include any deliveries –in calendar year 2017.

Appendix E: Strata and Methodology for Randomly Selecting 15 HS Grantees Sites for PRAMS Oversampling

Strata/Categories

- Select 1 of 2 Border grantees (both Level 1)
- Select 1 of 3 AI/AN grantees (mostly Level 1)
- Select 3 of 28 Level-1 grantees (serving 500+ clients per year):
    - 2 of 19 Urban grantees
        - 1 of 18 non-Western grantees
        - 1 of 1 Western grantees
    - 1 of 9 Rural grantees
- Select 5 of 17 Level-2 grantees (serving 800+ clients per year):
    - 4 of 14 Urban grantees
        - 2 of 5 Midwestern grantees
        - 1 of 4 Northeastern grantees
        - 1 of 5 Southern grantees
    - 1 of 3 Rural grantees (all South)
- Select 5 of 13 Level-3 grantees (serving 1,000+ clients per year; all Urban):
    - 1 of 2 Midwestern grantees
    - 2 of 6 Northeastern grantees
    - 2 of 5 Southern grantees

Methodology for Randomly Selecting 15 Grantee Sites within each Stratum

- Grantee lists were entered into different excel spreadsheets by the 5 primary strata listed above
- Within each stratum-specific spreadsheet, each grantee is given a random number between 0 and 1 (formula "=RAND()"), with values copied and pasted so that numbers do not regenerate
- The spreadsheets were sorted by random number (lowest to highest) and the top-listed grantees were selected according to primary and secondary stratum-specific criteria listed above
- Any grantee/state that refuses participation will be replaced by the next listed grantee/state within the particular stratum