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Evaluation Protocol to Assess Maternal and Child Health Outcomes Using Administrative Data: A Community Health Worker Home Visiting Program

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Contributors: All authors contributed equally. Dr. Sabo, Dr. Butler and Ms. Rumann conceptualized the original study protocol. Dr. Wightman and Mr. Pilling conducted data analysis and contributed greatly to the preparation of the analytic methods and data management protocol sections. Dr. Sabo, Ms. McCue and Ms. Rumann led all protocol writing and editing. Mr. Celaya provided ongoing edits to early and late stage drafts.

ADHS will oversee the study and 1) provide input to study design, conduct, data analysis and interpretation of results and review of draft manuscripts; 2) conduct monthly meetings and conference calls to discuss the evaluation impact study, challenges and barriers; and 3) provide Heath Start Program data, documents and data results, program training and policies manuals as needed.

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Abstract

Introduction: Emerging evidence suggests Community Health Workers (CHWs) delivering preventive maternal and child health (MCH) interventions through home visiting improve several important maternal and child outcomes. Globally and in the US, CHW MCH home visiting interventions are associated with several primary prevention MCH outcomes including the initiation of any, early and adequate prenatal care, healthy birthweight, and the uptake and completion of childhood immunizations.

Methods and analysis: The Arizona Health Start Program is an individual-level, behavioral-based home visiting intervention based in the community which utilizes CHWs to improve MCH outcomes through health education, referral support, and advocacy services for at risk pregnant and postpartum women and families with children up to age two. We aim to objectively test our central hypothesis that mothers and children exposed to this intervention will experience positive health outcomes in the areas of (1) newborn health; (2) maternal health and care utilization; and (3) child health and development. This is a retrospective, propensity score-matched observational study over the period 2006 to 2015, 15,576 unique mothers utilizing administrative data. We use propensity score matching to generate a statistically similar synthetic control group. Our analytic sample size is sufficient to detect meaningful program effects from low-frequency events, including preterm births, low and very low birthweights, maternal morbidity, and differences in immunization and hospitalization rates over a relatively long period of time.

Ethics and dissemination: This work is supported through an inter-agency contract from the Arizona Department of Health Services and is approved by the University of Arizona Research Institutional Review Board (Protocol 1701128802), approved 25 January 2017. Research will contribute to determination of Health Start as an evidence-based practice home visiting model by the US Department of Health and Human Services, Home Visiting Evidence of Effectiveness program.

Strengths and Limitations of the study:

- A retrospective, propensity score-matched observational study of CHW MCH home visiting intervention over a 10-year period (2006-2015).
- Size and diversity of unique mothers in the intervention group (9,665) matched to one or more characteristically similar mothers in the comparison group.
- Less than 1% of intervention participants were involved in other CHW and/or home visiting programs.
- Analysis may have limited external validity for populations who differ along socioeconomic status, race, and ethnicity.

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Introduction

Background and rationale

Over the last decade, the community health worker (CHW) workforce has been recognized by the World Health Organization and several US entities as an evidence-based approach to address health disparities (1-3). In the US, the CHW workforce has gained increased recognition and visibility, as evidenced by the creation of a US Department of Labor Standard Occupational Classification (21-094) in 2010, to include CHWs as a health profession in the Patient Protection and Affordable Care Act (ACA). According to the American Public Health Association, a CHW is defined as: *A frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served. This trusting relationship enables the worker to serve as a liaison/link/intermediary between health/social services and the community to facilitate access to services and improve the quality and cultural competence of service delivery* (4). Here we describe a retrospective comparative evaluation using propensity score matching to assess the impact of a long-standing community health worker maternal and child health home visiting program called Health Start.

Operating in Arizona, this statewide program employs CHWs to engage at-risk, low income and racially and ethnically diverse mothers to improve maternal and child outcomes. CHWs share the language, socioeconomic status and life experiences of the community members they serve and are recognized as integral to reducing health inequalities among disenfranchised groups (5). Barriers to care among disenfranchised mothers have important public health implications. It is widely recognized that late prenatal care (PNC) is associated with preterm and low birthweight births and infant mortality. In 2015, 61% of Arizona mothers initiated PNC by the first semester, a decrease from 81% in 2013 (6). In 2014, 9% of babies born in Arizona were premature and 7.2% were low birthweight (6). Historically, low-income mothers have experienced higher rates of premature birth and low birthweight in Arizona (7) and nationally (8). Preterm and low birthweight baby delivery costs have been shown to be 25 times more than uncomplicated newborns (9). The difference in costs of maternal delivery, medical care through age five, special education and early intervention is estimated to be approximately $70,000 per low birthweight child (10). Low birthweight has been found to decrease long-term educational attainment and earnings (11). The documented difference in birthweight along socioeconomic status in Arizona and nationally contributes to the strong observed correlation of economic standing across generations (12).

Emerging evidence suggests CHWs delivering preventive maternal and child health (MCH) interventions through home visiting improve several important maternal and child outcomes (13, 14). Globally, CHW home visiting interventions are associated with several primary prevention efforts that promote the initiation of any, early and adequate prenatal care (15, 16), initiation of any and exclusive breastfeeding (14, 17-20), reduction of maternal morbidity and perinatal mortality (21), and the uptake and completion of childhood immunizations (14, 22). In the US, CHW home visiting interventions are associated with several MCH outcomes, including decreased incidence of preterm birth (16, 23-25) and low birth weight (16, 23-29), and increases in up-to-date immunizations among newborns and toddlers (30). Moreover, CHWs are recognized as integral contributors in collaborative health- and community-based teams and in providing comprehensive care, including attention to the social determinants of health that contribute to health improvements and cost savings (31, 32). As the CHW workforce continues to gain traction as an essential part of the public health and health care systems (33), our goal is to describe the research protocol to assess the impact of a long standing CHW home visiting perinatal support program serving women and children of Arizona on multiple maternal, infant, and child health outcomes.

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Arizona launched "Un Comienzo Sano/A Healthy Beginning" in 1984, when Arizona ranked among the lowest five states for the number of women receiving any or adequate prenatal care (34). In 1992, the Arizona Health Start Program (HSP) was administered by the Arizona Department of Health Services (ADHS), Bureau of Women's and Children's Health (BWCH) (35). In 1994, the Arizona State Legislature passed the Arizona Children and Families Stability Act, A.R.S. § 36-697, which formalized and expanded HSP and articulated the purpose, requirements and administration of the program. Health Start is a community-based outreach program that identifies, screens and enrolls pregnant women early in their pregnancies and assists them with obtaining early and consistent prenatal care, provides prenatal and postpartum education, information and referral services, advocacy and emphasizes timely immunizations and developmental assessments for their children. Since its inception, Arizona Health Start Program's mission has been "*to educate, support and advocate for families at risk by promoting optimal use of community-based family health care services and education services through the use of community health workers (CHWs) who live in and reflect the ethnic, cultural and socioeconomic characteristics of the community they serve.*" (35)

HSP is significant in that it is one of the longest standing programs in Arizona and employs CHWs in 14 distinct Arizona counties to engage at-risk, low income mothers in order to improve birth outcomes (Figure 1). CHWs serve as the primary interventionist and home visitors for the intervention. In 2016, Health Start CHWs provided services to 2,534 unduplicated clients, conducted 16,698 home visits, facilitated 461 classes, installed 346 infant seats and 630 convertible car seats with education on the proper use, and provided 157 Pack n Plays for clients who needed a safe sleep environment for their child (35). For over 25 years the Arizona Health Start has focused CHW home visitation strategies to improve life course health of mothers, newborns, and children in Arizona. Retrospective evaluation of the HSP will illuminate existing strengths in MCH services and outcomes and areas for development and improvement.

Objectives

We plan to objectively test our central hypothesis that mothers and children exposed to the Arizona Health Start Program from 2006-2015 will experience positive health outcomes in the areas of 1) newborn health; 2) maternal health and care utilization; and 3) child health and development (Table 1). Broadly, the goal for the study is to meet the federal Home Visiting Evidence of Effectiveness (HomVEE) standard for evidence-based effectiveness. We employ a matched comparison group design study that meets the published standard for HomVEE's 'Moderate' rating (36).

Study Design

This is a retrospective, propensity score-matched observational study over the period 2006 to 2015 for the state of Arizona utilizing administrative Arizona Department of Health Services data.

A previous evaluation of Health Start Program by Hussaini et al (2011) utilized state vital records data from 2007 to identify non-participant mothers with at least one medical risk (as reported on their birth certificate) in order to create a comparison cohort (28). They found that Health Start participation was associated with a reduction in the likelihood of a low birthweight outcome. We propose to build upon the Hussaini study in a number of ways.

First, based on observed covariates, the Hussaini study matching process did not result in baseline equivalence across the two groups. For example, the comparison group was on average four years older (28.2 vs. 24.3) than the Health Start mothers. Additionally, Hussaini et al matched to comparison

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mothers on ex post medical risks which likely created a bias in favor of finding a positive Health Start effect. We employ propensity score matching (PSM) to generate a comparison group that achieves baseline equivalence of observed covariates, which is required to receive a 'Moderate' HomVEE study rating, qualifying the study as an 'evidence-based' intervention. Second, we explicitly match on socioeconomic status variables as required by the HomVEE-published standard for matched comparison group design studies (36). Specifically, we match on two individual measures of socioeconomic status (SES): maternal education and indicators for primary payer for the birth procedure, which, in the case of Medicaid, serves as an indicator of mean-tested assistance. Similarly, the absence of any payer is also a significant indicator of SES. While these variables satisfy HomVEE's documented standard for measuring socioeconomic status for Group Design studies with a 'Moderate' rating, we also utilize the maternal zip code of residence to include a measure of mean household income by zip code which is obtained from the American Community Survey in the matching process. Third, we propose to build on the scope of the original study in two significant ways: 1) by expanding the number and time frame of the outcomes considered, including maternal and child outcomes over time, i.e. following birth; and 2) by performing a number of sub-group analyses that investigate program impacts based on when in the course of the pregnancy the Health Start intervention began, mother's country of origin, and maternal age (i.e. teen mothers). Fourth, the Hussaini study compared 484 women enrolled in Health Start in 2007 to almost 5,000 women not enrolled in Health Start (non-Health Start). We are evaluating ten (10) years of Health Start Program data from 2006-2015, thereby increasing our sample size to 15,576 unique Health Start enrollees.

Methods: participants, interventions and outcomes

Study Setting

Arizona is the sixth largest state in the nation, with a population of 6.8 million people. Arizona is unique, as it shares an international border with Mexico and is home to 21 federally recognized American Indian Tribes and Nations. In 2015, nearly a quarter of the population lived in rural areas, where the poverty rate reached 30%, nearly double that of the national poverty rate (6). Arizona is a racially and ethnically diverse state with a higher proportion of Latino (30.9%) and American Indian (5%) residents compared nationally (17.8% and 1%, respectively) and a comparatively smaller proportion of African American residents (5% compared to 13% nationally) (6).

Approximately 20% of Arizona families with children live below the federal poverty line, compared to 18% nationally. Poverty disparately effects Arizona's Latino (36%) and American Indian (46%) families and children (6). Arizona ranks the fifth highest US state for adult female poverty rate in the country, with more than one quarter of Arizona families headed by single-mother households (6). The initial framework for the Health Start Program as a promising practice approach model was developed in 1994, over 24 years ago, to address the social determinants associated with the steady increase in the rate of women receiving inadequate or no prenatal care associated with high rates of preterm and low birthweight births. At that time, Arizona was ranked 45th lowest in the nation for the number of women receiving adequate prenatal care. In the most recent Arizona Title V Maternal and Child Health Needs Assessment (2017), approximately 73.8% of pregnant women received prenatal care beginning in the first trimester, and 7.9% had no prenatal care. There were disparities among mothers by race/ethnicity who received prenatal care, notably American Indian mothers having the highest rates of 'inadequate' prenatal care (25%) compared to all women in Arizona (15%) (6). There are also apparent racial disparities for birth outcomes in Arizona. Preterm birth rates are highest among Black (12.2%), American Indian (9.4%), and Latino (9.2%) compared to all preterm births (9.1%) in the state. Preterm births increase the risk of low birthweight; similar trends persist with the highest rates of low birthweight

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among Black residents (10.32%) compared to White residents (5.36%) and the total Arizona population (7.2%) (6). Although prenatal care and birth outcomes in Arizona have improved over the years, many under-resourced women continue to experience significant challenges and barriers to obtaining health care services.

Inclusion Criteria

Women who participated in Health Start during the 10-year observation period self-selected the 'intervention'. Per the HSP manual, women are eligible to enroll in HSP if they 1) live in the targeted service area, 2) are pregnant or postpartum with a child under age two, and 3) have one or more risk factors. Risk factors are divided into *social risks*, including marital status, living situation, race and ethnicity, education level, income, and insurance type, and *medical risks*, including previous preterm birth or labor, low birthweight, miscarriage, birth defect, chronic disease, maternal BMI, and maternal age. Women and families can be of any age and there are no income requirements. All enrolled clients during the 10-year observation period of 2006-2015 are included in this study if their records were identified and linked from the Health Start database to vital records birth database (VRBD).

Exclusion Criteria

A comparison group of women not exposed to the Health Start Program (non-HSP) was created using a matching technique to enhance equal representation of subjects in each group, derived from VRBD.

Intervention

This section is organized by the Template for Intervention Description and Replication (TIDR) checklist (37). The Health Start Program is an individual-level, behavioral-based home visiting intervention situated in the community which utilizes CHWs to provide health education, referral support, and advocacy services for at-risk pregnant and postpartum women and families with children up to age two (2) with the goal of improving five primary maternal and child health outcomes (Table 2).

Health Start Intervention

Health Start identifies, screens and enrolls pregnant women early in their pregnancies and assists them with obtaining early and consistent prenatal care, provides prenatal and postpartum education, information and referral services, advocacy and emphasizes timely immunizations and developmental assessments for their children (Table 2). HSP home visiting is generally guided by an asset-based approach (38) and two theories of behavior change, the Trans Theoretical Model of Behavior Change (TTM) (39) and the Social Cognitive Theory (SCT) (40). These two behavioral change theories assume, respectively, that behavior modification in individuals is a multistage process in which people move through stages of readiness for change, and that they do so in the context of reciprocal relationships with their environment, behavior and cognition. As trusted members of the community served, sharing both lived experience and cultural knowledge of the population, a Health Start CHW is well positioned as a knowledgeable, trusted and supportive role model and guide for Health Start clients. SCT and TTM guide each CHW home visiting sessions which involve assessment, education, goal planning, referral, advocacy and follow up activities. Such trusted interactions overtime, promote personal agency and self-efficacy to engage in the activities and systems promotive of Health Start programmatic goals.

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Behavioral theories are further coupled with meaningful adult learning models which acknowledges the agency of adult learners to integrate new knowledge into what is already known and create a cognitive structure that makes sense of their own surroundings and situations (41). Through TTM, SCT and adult learning models Health Start CHWs privilege the co-construction of knowledge among all participants, assumes all are co-learners and encourages critical thinking about self-sufficiency, empowerment, and personal agency related to the five Health Start goals.

Health Start CHW Core Competencies, Roles and Training

According to the Health Start policy and procedure manual, CHWs must 1) live and work in the service area, 2) reflect the ethnic, cultural and socioeconomic characteristics of the communities they serve, 3) are able to read and write English, 4) have a high school diploma or General Educational Development, and 5) have a background check. It is highly recommended that CHWs have post high school training and education in maternal and child health, early childhood development education, family studies, social work, nursing or closely related field, although not required (35). Before a CHW can initiate unsupervised outreach or home visits, they must complete 40 hours of training in both the 10 CHW Core Competencies set forth by the CHW Core Consensus Project (42) and recognized by the Arizona state legislature HB 2324 Voluntary CHW Certification (43) and in the Health Start Program Core Training (35) and 8 hours of home visit shadowing with a senior CHW.

Nationally recognized, the CHW 10 core competencies include: 1) Cultural and Systems Mediation; 2) Culturally Appropriate Health Education; 3) Care Coordination and Case Management; 4) Coaching and Social Support; 5) Advocacy; 6) Capacity Building; 7) Direct Service; 8) Individual and Community Assessments; 9) Outreach; and 10) Research and Evaluation (42). HSP Core Training covers: 1) Essential Health Start Information (Health Start Basics, Health Start Visits, Community Outreach); 2) Communication and Emotional Support; 3) Nutrition and Physical Activity (family nutrition and physical activity, infant nutrition and physical activity); 4) Health Education (healthy pregnancy, prenatal care, discomforts during pregnancy, labor and delivery, postpartum care and family planning, early childhood development and parenting skills, infant health and child health); 5) Safety (home safety for infants and children, child abuse and domestic violence) (35). CHWs are required to complete 12 hours of continuing education per year.

CHWs connect clients to prenatal care and increase client's continuity of care during and after pregnancy. CHW home visiting sessions include assessment, education, and goal setting, which, overtime, promote personal agency and self-efficacy to engage in the activities that promote positive health change and improved health outcomes for clients and their families (44). CHWs encourage self-sufficiency and empowerment by acting as an advocate and connecting clients to resources and opportunities that help overcome the barriers to personal agency. Although not an exhaustive list, Table 3 outlines the primary intervention activities conducted by the CHW.

Outcomes

Primary Outcome

As a primary prevention intervention to improve maternal and child health outcomes among at-risk, racially and ethnically diverse, rural and urban mothers and children of Arizona, we will conduct a retrospective, propensity score-matched observational study over the period 2006 to 2015 for the state of Arizona utilizing administrative Arizona Department of Health Services data (Table 4). We employ four Arizona Department of Health Services administrative data sets to evaluate Specific Aims 1-3

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including: Health Start Programmatic Data, Vital Records Birth Data, Hospital Discharge Data, and Arizona State Immunization Information System.

Methods: Data Collection, Intervention Assignment, Data Management and Analysis

Data Collection

Health Start administrative data from 2006 to 2015 was used to identify HSP enrollees. These individuals were then matched to birth certificate information from the vital records birth database administered by ADHS. Mothers were matched on the mother's date of birth and first name, with the last name also taken into consideration. In order to be a candidate for a match, the mother's date of birth had to be an exact match while her first name had to be at least 95% similar, using Jaro-Winkler (JW) similarity (45). JW percentages were generated for the mother's last name as well, but not used to certify matches because of possible changes due to marriage. The information for the matched mothers included a unique ID, last name similarity percentage, first name similarity percentage, HSP enrollment date, status, and closure (i.e. program completion) data, the reason for closure, and the child's (children's) birthdate. Using the process described above, 15,576 unique births to Health Start enrollees were identified in the VRBD.

Sample Size

Of the initial 15,576 records identified as HSP matches 5,911 fell outside of the 24-month (either before or after) Health Start enrollment window and are excluded from all subsequent analysis. The resulting 9,665 HSP-associated births constitute the basis of this study (Figure 2). Because Health Start participants can enroll before or after birth, we limit the analysis for Specific Aims 1 and 2 to those births where the mother is enrolled prior to the child's birth. This final criterion results in 6,493 HSP-attributed births for the evaluation of these Aims. Specific Aim 3 is evaluated using the larger set of 9,665 HSP-associated births. The data for this evaluation is the universe of Health Start enrollment (within 24 months of the date of birth of the child) and the universe of births occurring in Arizona over the study period. Due to the respective sizes of these populations lack of statistical power is not a significant issue for this project.

Comparison Sample

After identifying our study population we use propensity score matching (PSM) to generate a statistically similar synthetic control group that has, on average, the same observable pre-program characteristics as the Health Start mothers (46). The pool of potential comparators comes from the universe of Arizona births that occurred over the study period (2006-2015). This process was guided by HomVEE standards requiring that the covariates used to balance the treatment and control groups be associated with both treatment status and the outcomes of interest (47). Because the Health Start eligibility criteria focus on social and medical risks, we prioritized these types of measures in the PSM model, in addition to including characteristics that have been shown to have strong associations with our outcomes of interest in previous empirical and theoretical work.

We employed radius matching to identify comparison group mothers across the common support region (48). Measures used in in the PSM model include mother's birth year, mother's age at birth, county of residence and indicator variables for the following: child's birth order, maternal educational attainment, health insurance payer (Medicaid being a proxy for low-income status), race, ethnicity, availability of

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information for the father on the birth certificate, maternal country of birth, previous history of preterm or hypertension. We also included median household income by zip code of residence, from the American Community Survey. In addition to these demographic and socio-economic characteristics, we restricted potential comparators to mothers within the same fiscal years in order to account for economic conditions and any potentially shifting program parameters. Imposing within-year matches allows us to analyze the program's efficacy over time by cohort. Comparator mothers were limited to three of the "nearest neighbors" (based on the propensity score) of each Health Start mother, with ties being broken according to the (randomly generated) unique IDs assigned to each mother in the VRBD. Moreover, comparison mothers may match to more than one Health Start mother again, based on the propensity score. These factors resulted in a synthetic comparison group of nearly 23,000 non-Health Start mothers.

Data management

An honest broker process was established to securely access and protect several datasets from ADHS including health start data, vital records birth data, hospital discharge data, and Arizona state immunization information system. The Center for Biomedical Informatics and Biostatistics Biomedical Informatics Services (CB2 BIS) at the University of Arizona maintains protected health information anonymization and HIPAA-compliance computer servers, and was designated as Honest Brokers to facilitate the de-identification, transfer, and management of data for this study. In this role, they will utilize personally identifiable information administrative data (e.g., name, DOB) to identify Health Start participating mothers and their children in the other sets of data.

CB2 BIS employs a group of IT professionals who have been designated as Honest Brokers to facilitate the de-identification and transfer of data to researchers in a compliant manner. CB2 BIS has established a Secure Analysis Server (Server) which is running 64 bit RedHat Linux, with 16 cores, 64 GB Ram and 1 TB of disk space. The Server is running in a virtualized environment which will permit expansion of cores, ram and disk space as needed. Authentication will be performed using the University's Centralized CATNET Active Directory. Authorization to access data sets will be performed utilizing groups (roles) locally on the Server. Users of the server will be given access to the minimum necessary data sets required for their projects. In order to ensure availability of the computational resources of the server, scheduling software has been installed which will queue long running analyses.

Statistical methods

Once we have proper covariate balance between the treatment and matched-control groups, point estimates of the treatment effects will be estimated by comparing outcomes using Stata version 15 software and specifically the effects command (49). Following Abadie and Imbens (50, 51), this command (as opposed to other similar commands available in Stata and other statistical software packages) considers the fact that the propensity scores (i.e. the parameter that determines the comparison population) are estimated when calculating the standard errors and thus generates confidence intervals. We do not intend to include the propensity scores as a covariate in traditional regression analysis as this approach has been shown to have two important disadvantages compared to the relatively non-parametric approach outlined here. First it is less effective in forcing baseline equivalence as it allows non-matched mothers to be included in the comparison, and second, this functional form imposes the assumption that the relationship between the score (the mechanism that determines comparability between the treatment and control groups) and the outcome is linear (46).

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Because the data for our evaluation comes from administrative sources missing data is not anticipated. Of some potential concern, in the absence of a single unique identifier, is the possibility of incorrect matches across the different sources. To address this, in addition to limiting potential matches to those that are no less than 95% similar, the honest broker will include measuring of match quality in the limited data sets made available to the researchers. We will use this information to determine the extent to which match quality impacts our results in a series of sensitivity analyses, e.g. including these variables in regressions, and limited comparisons to individuals at different levels of similarity.

Our analytic sample size is sufficient to detect meaningful program effects from low-frequency events, including preterm births, low and very low birthweights, maternal morbidity, and differences in immunization and hospitalization rates over a relatively long period of time.

Patient and public involvement
No patient involved

Methods: monitoring

Data monitoring

The honest brokers matched the Health Start database to the VRBD, generated a comparison group, and matched both the Health Start and non-Health Start groups to Hospital Discharge Data (HDD) and the Arizona State Immunization Information System (ASIIS) databases using PII (e.g., name, DOB, social security number). Honest brokers then created a separate de-identified "limited data set" for our analyses to compare the mean outcomes of Health Start mothers to the comparison group mothers.

Ethics and dissemination

Protocol amendments

This article refers to the protocol 1701128802 dated 25 January 2017.

Consent

Data are collected by the Arizona Department of Health Services for surveillance and monitoring. A waiver of informed consent was approved by the University of Arizona Research Institutional Review Board (Protocol 1701128802).

Confidentiality

Protocol complies with the University of Arizona Biomedical Informatics Service (BIS) group information security policies including, Information Security Policy (IS-100), Computer and Network Access Agreement (IS-700), Acceptable Use of Computers Policy (IS-701), Electronic Privacy Statement Policy (IS-1000), Data Classification and Handling Standard (IS-2321) (52).

Access to data

All access to data will be logged on the University of Arizona server at the file level and will be monitored regularly to ensure compliance with Server utilization policies. Disk-based backup of the Server is implemented with data from the Server being isolated from other data to facilitate easy destruction of the data per any data use agreements. Because this is a one-time request for

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retrospective data, a limited dataset cannot be shared beyond project personnel without the explicit permission by the Arizona Department of Health Services. Identified data will reside on the Server three years after the evaluation of Specific Aims 1-3 has been completed and the results have been published in peer-reviewed journals. At that time, all data will be destroyed from the BIS Server.

Dissemination

On completion of the study, we will engage major dissemination strategies, including; (1) peer-reviewed publications in targeted journals; (2) scholarly presentations at scientific conferences and public health governance meetings; (3) interactive web-based promotional and training materials and (4) strategic informational and planning meetings. Published journal articles will be submitted in collaboration with Arizona Department of Health Services to Mathematica Policy Research for review for determination of Health Start as a HomVEE evidence-based practice home visiting model. We will identify local and national forums for dissemination of preliminary results. Findings will be shared with ADHS leadership, Arizona Health Care Cost Containment System (Arizona Medicaid), Arizona Public Health Association (AzPHA), American Public Health Association (APHA), City MatCH and other MCH conferences and professional forums, as well as the Arizona Association of federally qualified community health center, Association of Health Plans, CHW Workforce Coalitions, and Maternal, Infant, and Early Childhood Home Visiting (MIECHV).

Funding: Funding for the study is provided by the Arizona State Lottery through the Arizona Department of Health Services for the time period of: July 1, 2017 - June 30, 2022. Health Resources Services Administration (HRSA) Maternal, Infant, Early Childhood Home Visiting (MIECHV) provided 17 months of additional federal funding through the Arizona Department of Health Services during the study period.

Data Sharing: At the conclusion of our study, de-identified data may be available upon request.

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Figures and Tables Legend

Figure 1. Arizona Health Start Program Service Area Map, 2018. ***(Page 6).*** Map demonstrates the Arizona Health Start Program service areas within 14 counties across the state. CHWs conduct regular home visits to underrepresented pregnant women and their families in rural and urban communities.

Table 1. Health Start Program evaluation aims and measurable outcomes. ***(Page 6).*** Our study will analyze the listed outcomes in order to test our central hypothesis, that mothers and children exposed to the Arizona Health Start Program from 2006-2015 will experience positive health outcomes. Results from this study may be used as evidence to support the Arizona Health Start Program as a recognized HomVEE evidence-based effectiveness program.

Table 2. Arizona Health Start Program Goals and Primary Intervention Strategies. ***(Page 8).*** Five (5) maternal and child health goals guide the Arizona Health Start Program CHW activities. CHWs undergo training in order to provide health education, referral support, and advocacy services for at-risk pregnant and postpartum women and families with children up to age two (2).

Table 3. Selected Health Start Program intervention activities performed by Health Start CHWs and hypothesized client actions evaluated via measurable aims (non-exhaustive). ***(Page 9).*** CHWs provide support and services to meet the individual needs of their clients. This list includes general activities provided by CHWs during home visiting sessions that promote self-sufficiency, empowerment, positive health change and improved health outcomes for clients and their families.

Table 4. Data Sources and Outcome Measures by Study Aim. ***(Page 9).*** Our retrospective, propensity score-matched observational study pulls data from four (4) sources: Health Start Programmatic Data, Vital Records Birth Data, Hospital Discharge Data, and Arizona State Immunization Information System. Data were confined to 2006 to 2015, and serve to evaluate maternal and child health outcomes among at-risk, racially and ethnically diverse, rural and urban mothers and children of Arizona.

Figure 2: Flow chart of intervention participant inclusion and exclusion criteria. ***(Page 10).*** 9,665 Health Start Program births constitute the basis of this study. 15,576 records were initially identified as Health Start Program matches; however, 5,911 records were excluded because the child's birth fell outside of the 24-month (either before or after) enrollment window. We evaluate Aims 1 & 2 with a subgroup: records for mothers enrolled in HSP prior to the child's birth (6,493 births). We evaluate Aim 3 using the larger set of 9,665 HSP-associated births.

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Tables

Table 1. Health Start Program evaluation aims and measurable outcomes	
Evaluation Aims	**Measurable Outcomes**
Aim 1: Assess the impact of the HSP on newborn health	Preterm birth (gestational age) Birthweight (birthweight, low birthweight <2500 grams, very low birthweight <1500 grams, and small size for gestational age) Newborn hospital length of stay and 30-day hospital charges
Aim 2: Assess the impact of the HSP on maternal health and care utilization	Month pregnancy care initiated Total number of prenatal visits Method of delivery (e.g. first-time Cesarean delivery) Maternal morbidity (e.g. uterine rupture) Inter-pregnancy intervals
Aim 3: Assess the impact of the HSP on child health and development	Probability of a child being on schedule for immunizations Utilization of Emergency Room (ER) visits and Inpatient (IP) stays at through ages 1, 3, and 5 Any charges associated with ER and IP utilization

Table 2. Arizona Health Start Program Goals and Primary Intervention Strategies	
Program Goals	**Program Strategies**
1. Increase prenatal services to pregnant women. **2. Reduce the incidence of very low birthweight babies.** **3. Reduce the incidence of children affected by childhood diseases.** **4. Increase the number of children receiving age appropriate immunizations by two (2) years of age.** **5. Increase awareness by educating families on the importance of good nutritional habits, developmental assessments, and preventative health care.**	• Identify pregnant women and postpartum mothers in the CHWs' neighborhood or community, and enroll them into HSP. • Conduct monthly prenatal and postpartum home visits and provide case management through the enrolled child's second birthday. • Connect mothers to prenatal care providers and on-going education and social support services related to fetal development and health behaviors that can impact birth outcomes. • Screen and refer for postpartum depression. • Provide information about inter-conception health. • Educate parents about child development, immunizations, home safety, and vehicle safety. • Assist clients and their family with access to various

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	health-promoting opportunities including a medical home, early childhood education programs, financial assistance, transportation, employment services, and referral services.

Table 3. Selected Health Start Program intervention activities performed by Health Start CHWs and hypothesized client actions evaluated via measurable aims (non-exhaustive)

CHW Input	Process Indicator	Outcomes Indicator
Perinatal home visits including education on pregnancy, labor, delivery, nutrition, and inter-conception.	Increased knowledge of and engagement in pregnancy process, delivery options, and activities to promote a healthy pregnancy.	Increased number of prenatal care visits; Reduced rates of preterm birth and low birthweight; Decreased maternal morbidities; Decreased hospital length of stay.
Screening, education, assistance and follow up with access and enrollment to continuous perinatal care.	Initiate prenatal care earlier in pregnancy and attend more prenatal care visits.	Increased number of prenatal care visits; Reduced rates of preterm birth and low birthweight.
Screening, education, assistance and follow up with child wellbeing services.	Timely completion of all immunizations for children.	Increased immunization rates; Reduced hospital encounters and stays.
Screening, education, assistance and follow up for mood and anxiety disorders, alcohol/tobacco/drug cessation, and domestic violence.	Increase knowledge of available services, completed assistant referrals, increased access to services.	Decreased maternal morbidities; Reduced rates of preterm birth and low birthweight.

Table 4. Data Sources and Outcome Measures by Study Aim

Data Source (Years)	Outcome Measures	Aim
Health Start Program Data (2006-2015)	• Intervention Enrollment • Month pregnancy care began • Total number of prenatal visits	1, 2, 3

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Vital Records Birth Data (2006-2015)	• Month pregnancy care began • Preterm birth (gestational age) • Birthweight (birthweight, low birthweight <2500 grams, very low birthweight <1500 grams, and small size for gestational age) • Total number of prenatal visits • Method of delivery (first-time Cesarean delivery) • Maternal morbidity (e.g. uterine rupture) • Inter-pregnancy intervals	1 & 2
Hospital Discharge Data (2006-2015)	• Newborn hospital length of stay and 30-day hospital charges • Utilization of emergency room visits and Inpatient stays at through ages 1, 3, and 5 • Any charges associated with emergency room and inpatient utilization	3
Arizona State Immunization Information System (2006-2015)	• Probability of a child being on schedule for immunizations	3

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Figure 1: Arizona Health Start Program Service Area Map, 2018

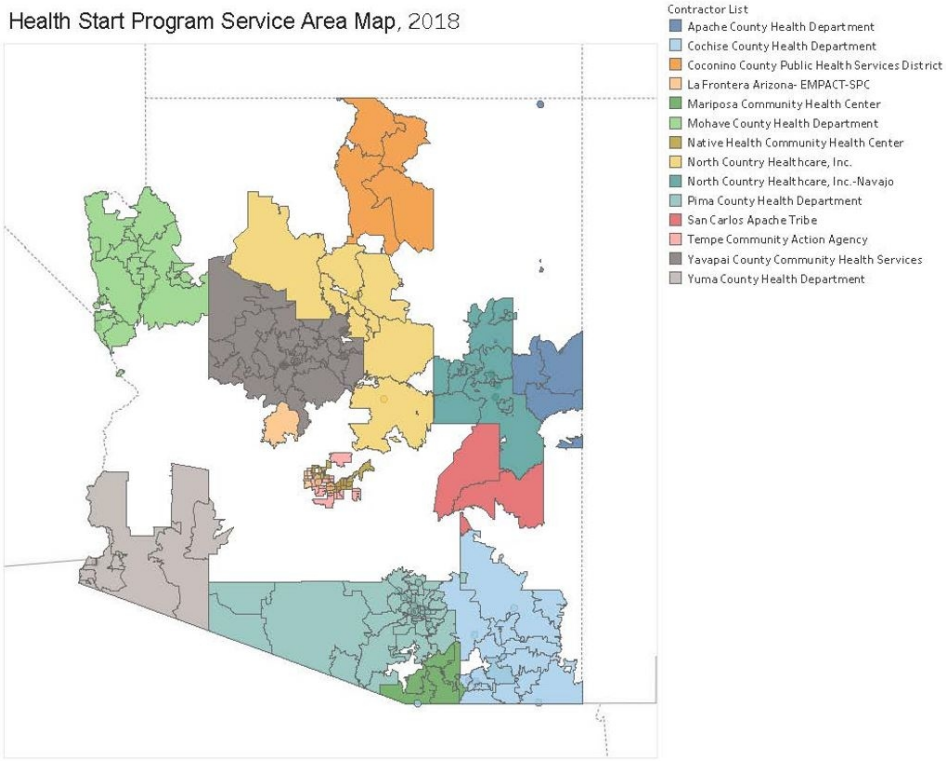

Figure 1. Arizona Health Start Program Service Area Map, 2018.

284x231mm (96 x 96 DPI)

Figure 2: Flow chart of intervention participant inclusion and exclusion criteria

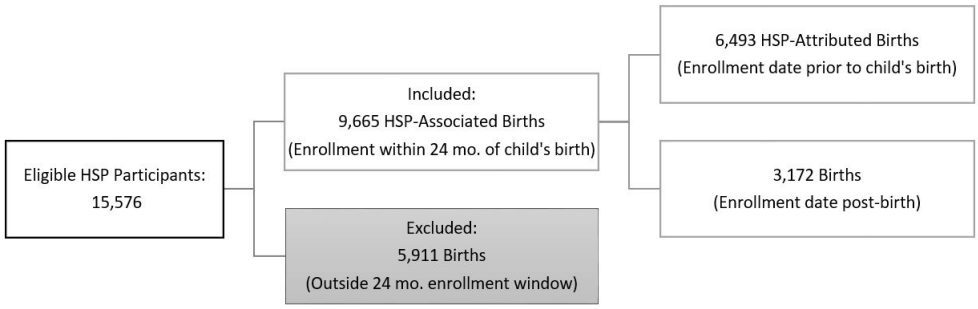

Figure 2: Flow chart of intervention participant inclusion and exclusion criteria.

330x128mm (96 x 96 DPI)

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Status	Section/item	ItemNo	Description
	Administrative information		
DONE	Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
NA, non RCT	Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry
NA, non RCT		2b	All items from the World Health Organization Trial Registration Data Set
DONE	Protocol version	3	Date and version identifier
DONE	Funding	4	Sources and types of financial, material, and other support
DONE	Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors
		5b	Name and contact information for the trial sponsor
DONE		5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
		5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
	Introduction		
DONE	Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
DONE		6b	Explanation for choice of comparators
DONE	Objectives	7	Specific objectives or hypotheses
DONE	Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)
	Methods: Participants, interventions, and outcomes		
DONE	Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
DONE	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will

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			perform the interventions (eg, surgeons, psychotherapists)
DONE	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
NA, non RCT		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
NA, non RCT		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
NA, non RCT		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
DONE	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
DONE	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
DONE	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
NA, non RCT	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size
	Methods: Assignment of interventions (for controlled trials)		
NA, non RCT	Allocation:		
NA, non RCT	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions
NA, non RCT	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
NA, non RCT	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
NA, non RCT	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
NA, non		17b	If blinded, circumstances under which unblinding is

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RCT			permissible, and procedure for revealing a participant's allocated intervention during the trial
	Methods: Data collection, management, and analysis		
DONE	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
DONE		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
DONE	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
DONE	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
DONE		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
DONE		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)
	Methods: Monitoring		
NA, non RCT	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed
NA, non RCT		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
NA, non RCT	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
NA, non RCT	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
	Ethics and dissemination		
DONE	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
DONE	Protocol amendments	25	Plans for communicating important protocol modifications

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			(eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
DONE	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
DONE	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
DONE	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
DONE	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
NA, non RCT	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
DONE	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
NA		31b	Authorship eligibility guidelines and any intended use of professional writers
DONE		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code
	Appendices		
NA, non RCT	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
NA, non RCT	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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BMJ Open

Evaluation Protocol to Assess Maternal and Child Health Outcomes Using Administrative Data: A Community Health Worker Home Visiting Program

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Manuscripts

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Conflicts of interest: None of the authors has conflicts of interest to declare.

Contributors: All authors contributed equally. Dr. Sabo, Dr. Butler and Ms. Rumann conceptualized the original study protocol. Dr. Wightman and Mr. Pilling conducted data analysis and contributed greatly to the preparation of the analytic methods and data management protocol sections. Dr. Sabo, Ms. McCue and Ms. Rumann led all protocol writing and editing. Mr. Celaya provided ongoing edits to early and late stage drafts.

ADHS will oversee the study and 1) provide input to study design, conduct, data analysis and interpretation of results and review of draft manuscripts; 2) conduct monthly meetings and conference calls to discuss the evaluation impact study, challenges and barriers; and 3) provide Heath Start Program data, documents and data results, program training and policies manuals as needed.

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Abstract

Introduction: Emerging evidence suggests Community Health Workers (CHWs) delivering preventive maternal and child health (MCH) interventions through home visiting improve several important health outcomes. Globally and in the US, CHW MCH home visiting interventions are associated with several primary prevention MCH outcomes including the initiation of any, early and adequate prenatal care, healthy birthweight, and the uptake and completion of childhood immunizations.

Methods and analysis: The Arizona Health Start Program is an individual-level, behavioral-based home visiting intervention, which utilizes CHWs based in the community. The goal of the program is to improve MCH outcomes through health education, referral support, and advocacy services for at risk pregnant and postpartum women and families with children up to age two. We aim to objectively test our central hypothesis that mothers and children exposed to this intervention will experience positive health outcomes in the areas of (1) newborn health; (2) maternal health and healthcare utilization; and (3) child health and development. This is a retrospective, propensity score-matched observational study over the period 2006 to 2015, utilizing administrative data for 15,576 unique mothers. We use propensity score matching to generate a statistically similar synthetic control group. Our analytic sample size is sufficient to detect meaningful program effects from low-frequency events, including preterm births, low and very low birthweights, maternal morbidity, and differences in immunization and hospitalization rates over a relatively long period of time.

Ethics and dissemination: This work is supported through an inter-agency contract from the Arizona Department of Health Services and is approved by the University of Arizona Research Institutional Review Board (Protocol 1701128802, approved 25 January 2017). This research will contribute to determination of the Health Start Program as an evidence-based practice home visiting model by the US Department of Health and Human Services, Home Visiting Evidence of Effectiveness program.

Strengths and Limitations of the study:

- A retrospective, propensity score-matched observational study of CHW MCH home visiting intervention over a 10-year period (2006-2015).
- Size and diversity of unique mothers in the intervention group (9,665) matched to one or more characteristically similar mothers in the comparison group.
- Less than 1% of intervention participants were involved in other CHW and/or home visiting programs.
- Analysis may have limited external validity for populations who differ along socioeconomic status, race, and ethnicity.

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Background

Over the last decade, the community health worker (CHW) workforce has been recognized by the World Health Organization and several US entities as an evidence-based approach to address health disparities (1-3). In the US, the CHW workforce has gained recognition and visibility, as evidenced by the creation of a US Department of Labor Standard Occupational Classification (21-094) in 2010, to include CHWs as a health profession in the Patient Protection and Affordable Care Act (ACA)(4). According to the American Public Health Association, a CHW is defined as: *A frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served. This trusting relationship enables the worker to serve as a liaison/link/intermediary between health/social services and the community to facilitate access to services and improve the quality and cultural competence of service delivery* (5).

Emerging evidence suggests CHWs delivering preventive maternal and child health (MCH) interventions through home visiting improve several important maternal and child outcomes (6, 7). Globally, CHW home visiting interventions are associated with several primary prevention efforts that promote the initiation of any, early, and adequate prenatal care (8, 9), initiation of any and exclusive breastfeeding (7, 10-13), reduction of maternal morbidity and perinatal mortality (14), and the uptake and completion of childhood immunizations (7, 15). In the US, CHW home visiting interventions are associated with decreased incidence of preterm birth (9, 16-18) and low birth weight (9, 16-22), and increases in up-to-date immunizations among newborns and toddlers (23)**.** CHWs share the language, socioeconomic status and life experiences of the community members they serve and are recognized as integral to reducing health inequalities among disenfranchised groups (24). Moreover, CHWs are recognized as integral contributors in collaborative health- and community-based teams and in providing comprehensive care, including attention to the social determinants of health that contribute to health improvements and cost savings (25, 26).

Arizona launched the first iteration of the Health Start Program (HSP) in 1984, when Arizona ranked among the lowest five states for the number of women receiving any or adequate prenatal care (27). HSP is a statewide program that employs CHWs to engage at-risk, low income and racially and ethnically diverse mothers to improve maternal and child outcomes. HSP has been managed by the Arizona Department of Health Services (ADHS), Bureau of Women's and Children's Health since 1992 (28). In 1994, the Arizona State Legislature passed the Arizona Children and Families Stability Act, A.R.S. § 36-697, which formalized and expanded HSP and articulated the purpose, requirements and administration of the program. HSP is a community-based outreach program that identifies, screens and enrolls pregnant women early in their pregnancies and assists them with obtaining early and consistent prenatal care. The program also provides prenatal and postpartum education, information and referral services, client advocacy, and emphasizes timely immunizations and developmental assessments for their children. Since its inception, Arizona Health Start Program's mission has been "*to educate, support and advocate for families at risk by promoting optimal use of community-based family health care services and education services through the use of community health workers (CHWs) who live in and reflect the ethnic, cultural and socioeconomic characteristics of the community they serve."* (28)

Study Setting

Arizona is the sixth largest state in the nation, with a population of 6.8 million people. The state shares an international border with Mexico and is home to 21 federally recognized American Indian Tribes and Nations, making it uniquely racially and ethnically diverse. Arizona has a higher proportion of Latino

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(30.9%) and American Indian (5%) residents compared to the nation (17.8% and 1%, respectively) and a comparatively smaller proportion of African American residents (5% compared to 13% nationally) (29).

In 2015, nearly a quarter of the population lived in rural areas, where the poverty rate reached 30%, nearly double that of the national poverty rate (29). Approximately 20% of Arizona families with children live below the federal poverty line, compared to 18% nationally. Poverty disparately effects Arizona's Latino (36%) and American Indian (46%) families and children (29). Arizona ranks as the fifth highest US state for adult female poverty rate in the country, with more than one quarter of Arizona families headed by single-mother households (29). The initial framework for the HSP was developed in the 1980s and 1990s to address the social determinants associated with the steady decrease in the rate of women receiving early or any prenatal care. In the most recent Arizona Title V Maternal and Child Health Needs Assessment (2017), approximately 74% of pregnant women initiated prenatal care in the first trimester (compared to 61% in 2015 and 81% in 2013), and 7.9% had no prenatal care (29). There were disparities among mothers by race/ethnicity who received prenatal care, notably American Indian mothers having the highest rates of 'inadequate' prenatal care (25%) compared to all women in Arizona (15%) (29).

It is widely recognized that late prenatal care is associated with preterm birth, low birthweight, and infant mortality. In 2014, 9% of babies born in Arizona were premature and 7.2% were low birthweight (29). Historically, low-income mothers have experienced higher rates of premature birth and low birthweight in Arizona (30) and nationally (31). There are also apparent racial disparities for birth outcomes in Arizona. Preterm birth rates are highest among Black (12.2%), American Indian (9.4%), and Latino (9.2%) compared to all preterm births (9.1%) in the state. Preterm births increase the risk of low birthweight; similar trends persist with the highest rates of low birthweight among Black residents (10.32%) compared to White residents (5.36%) and the total Arizona population (7.2%) (29). Preterm and low birthweight baby delivery costs have been shown to be 25 times more than uncomplicated newborn deliveries (32). Although prenatal care and birth outcomes in Arizona have improved over the years, many under-resourced women continue to experience significant challenges and barriers to obtaining health care services.

Objectives

Our goal is to describe the research protocol for a retrospective comparative evaluation to assess the impact of Arizona's Health Start Program, a CHW home visiting perinatal support program, on multiple maternal, infant, and child health outcomes. Broadly, the goal for the study is to meet the federal Home Visiting Evidence of Effectiveness (HomVEE) standard for evidence-based effectiveness. We will use a matched comparison group design study that meets the published standard for HomVEE's 'Moderate' rating (note: 'High' rating is reserved for randomized controlled trials) (33).

Specific Aims

We plan to objectively test our central hypothesis that mothers and children exposed to Arizona's Health Start Program (HSP) during the study period of 2006 to 2015 will experience positive health outcomes in the areas of newborn, maternal, and child health (Table 1). Specifically, our aims include:

- Aim 1: Assess the impact of HSP on newborn health
- Aim 2: Assess the impact of HSP on maternal health and care utilization
- Aim 3: Assess the impact of HSP on early child health and development

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Methods: Intervention, Participants, & Outcomes

Health Start Program Intervention

HSP is significant in that it is one of the longest standing programs in Arizona and employs CHWs in 14 distinct Arizona counties to engage at-risk, low income mothers in order to improve birth outcomes (Figure 1). CHWs serve as the primary interventionist for the program. In 2016, Health Start Program CHWs provided services to 2,534 unduplicated clients, conducted 16,698 home visits, and facilitated 461 classes (28). Women are eligible to enroll in HSP if they 1) live in the targeted service area, 2) are pregnant or postpartum with a child under age two, and 3) have one or more social or medical risk factors. Social risks can include but are not limited to: single-parent status, underserved racial or ethnic group, education equal to or less than high school level, income less than $40,000, and Medicaid or no insurance. Medical risks are broad and can include previous preterm birth, low birthweight, chronic disease, high maternal BMI, and substance use. Women can be of any age and there are no income requirements to participate.

CHWs connect clients to prenatal care and increase client's continuity of care during and after pregnancy. CHWs identify, screen and enroll eligible women, provide prenatal and postpartum education, information and referral services, advocacy, and emphasize timely immunizations and developmental assessments for their children. Although not an exhaustive list, Table 2 outlines the primary intervention activities conducted by the CHW. HSP CHW home visits are guided by an asset-based approach (34) and two primary theories of behavior change, the Trans Theoretical Model (35) and the Social Cognitive Theory (36). These two behavioral change theories assume, respectively, that behavior modification in individuals is a multistage process in which people move through stages of readiness for change. These stages occur in the context of reciprocal relationships between the person's environment, their behavior and their cognition. As trusted members of the community served, sharing both lived experience and cultural knowledge of the population, CHWs are well positioned to support HSP clients. Each CHW home visiting session is structured to promote behavior change through assessment, goal planning, referral, advocacy, and follow up activities, coupled with education through meaningful adult learning models. These interactions are designed to encourage personal agency of adult learners to integrate new knowledge and create a cognitive structure that makes sense of their own surroundings and situations (37). Through behavior change theories and adult learning models, the Health Start Program CHWs privilege the co-construction of knowledge among all participants, assume all are co-learners, and encourage critical thinking about self-sufficiency, empowerment, and personal agency related to the five HSP goals (Table 1).

Health Start Program CHW Core Competencies, Roles and Training

According to the HSP policy and procedure manual, CHWs must 1) live and work in the service area, 2) reflect the ethnic, cultural and socioeconomic characteristics of the communities they serve, 3) be able to read and write in English, 4) have a high school diploma or General Educational Development, and 5) pass a background check. It is highly recommended (though not required) that CHWs have post high school training and education in maternal and child health, early childhood development education, family studies, social work, nursing or closely related field (28). Before a CHW can initiate unsupervised outreach or home visits, they must complete 40 hours of training in both the *10 CHW Core Competencies* set forth by the CHW Core Consensus Project (38), which are recognized by the Arizona state legislature HB 2324 Voluntary CHW Certification (39), and the *Health Start Program Core Training* (28). An additional 8 hours of home visit shadowing with a senior CHW is required.

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Nationally recognized, the *10 CHW Core Competencies* include: 1) Cultural and Systems Mediation; 2) Culturally Appropriate Health Education; 3) Care Coordination and Case Management; 4) Coaching and Social Support; 5) Advocacy; 6) Capacity Building; 7) Direct Service; 8) Individual and Community Assessments; 9) Outreach; and 10) Research and Evaluation (38). *HSP Core Training* covers: 1) Essential Health Start Information (Health Start Basics, Health Start Visits, Community Outreach); 2) Communication and Emotional Support; 3) Nutrition and Physical Activity (family nutrition and physical activity, infant nutrition and physical activity); 4) Health Education (healthy pregnancy, prenatal care, discomforts during pregnancy, labor and delivery, postpartum care and family planning, early childhood development and parenting skills, infant health and child health); and 5) Safety (home safety for infants and children, child abuse and domestic violence) (28). CHWs are required to complete 12 hours of continuing education per year.

Intervention Cohort

HSP administrative data from 2006 to 2015 were used to identify HSP enrollees. All enrolled Health Start clients during the 10-year observation period of 2006-2015 will be included in this study if their records were identified and linked from the HSP database to the vital records birth database (VRBD). HSP enrollee records were linked to birth certificates based on the mother's date of birth and first name. In order to be a candidate for the HSP study cohort, the mother's date of birth had to be an exact match while her first name had to be at least 95% similar, using Jaro-Winkler (JW) similarity (40). JW percentages were also generated for the mother's last name; however, this criterion was excluded for possible changes due to marriage. Information collected for the HSP study cohort mothers included a unique ID, first name similarity percentage, last name similarity percentage, HSP enrollment date, program closure information (i.e. program completion, reason for closure), and the child's birthdate. Using the process described above, 15,576 unique births to HSP enrollees were identified in the VRBD.

Intervention Cohort Sample Size

Of the initial 15,576 records identified through the HSP-to-VRBD data link, 5,911 fell outside of the 24-month (either before or after) HSP enrollment window and will be excluded from all subsequent analysis. The resulting 9,665 HSP-associated births constitute the basis of this study (Figure 2). Because HSP participants can enroll before or after birth, we will limit the analysis for Specific Aims 1 and 2 to those births for which the mother was enrolled prior to the child's birth. This final criterion results in 6,493 HSP-attributed births for the evaluation of these Aims. Specific Aim 3 will be evaluated using the larger set of 9,665 HSP-associated births. Our evaluation will include all HSP participants enrolled (within 24 months of the date of birth of the child), and all births occurring in Arizona over the study period 2006-2015. Due to the respective sizes of these populations, lack of statistical power is not a significant issue for this project.

Synthetic Comparison Group

A comparison group of women not exposed to the Health Start Program (non-HSP) will be created using a propensity score matching approach and all other births that occurred in Arizona (derived from VRBD) over the study period to balance representation of subjects in each group. After identifying our study population we will use propensity score matching (PSM) to generate a statistically-similar synthetic control group that has, on average, the same observable pre-program characteristics as the HSP

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mothers (41). The pool of potential comparators will come from all Arizona births that occurred over the study period (2006-2015). This process will be guided by HomVEE standards requiring that the covariates used to balance the treatment and control groups be associated with both treatment status and the outcomes of interest (42). Because the HSP eligibility criteria focus on social and medical risks, we will prioritize these types of measures in the PSM model, in addition to characteristics that have been shown to have strong associations with our outcomes of interest in previous empirical and theoretical work.

We will employ radius matching to identify comparison group mothers across the common support region (43). We will use the following measures in the PSM model: mother's birth year, mother's age at birth, county of residence. Additional indicator variables include: child's birth order, maternal educational attainment, health insurance payer (Medicaid being a proxy for low-income status), race, ethnicity, availability of information for the father on the birth certificate, maternal country of birth, previous history of hypertension, and median household income by zip code of residence. In addition to these demographic and socioeconomic characteristics, we will restrict potential comparators to mothers within the same fiscal years in order to account for economic conditions and any potentially shifting program parameters. Imposing within-year matches will allow us to analyze the program's efficacy over time by cohort.

Comparison mothers may match to more than one HSP mother, based on the propensity score. Preliminary efforts to identify matches resulted in a potential synthetic comparison group of nearly 23,000 non-HSP mothers.

Outcomes

Primary Outcomes

HSP is a primary prevention intervention to improve maternal and child health outcomes among at-risk, racially and ethnically diverse, rural and urban mothers and children of Arizona. We will use four Arizona Department of Health Services administrative datasets to evaluate Specific Aims 1-3 including Health Start programmatic data, Vital Records Birth Data, Hospital Discharge Data, and Arizona State Immunization Information System data. Aim 1 (HSP impact on newborn health) will be measured by preterm birth, birthweight, and newborn hospital length of stay and associated charges. Aim 2 (HSP impact on maternal health) will be measured by prenatal care initiation and frequency, method of delivery, maternal morbidities, and inter-pregnancy intervals. Aim 3 (HSP impact on child health) will be measured by uptake of age-appropriate immunizations, and emergency room and inpatient encounters and charges (Table 3).

Methods: Data Management, Monitoring, & Statistical Analysis

Data management

We established an honest broker process to securely house the four datasets that will be accessed for this study. We designated the Center for Biomedical Informatics and Biostatistics' Biomedical Informatics Services at the University of Arizona as the honest broker to facilitate the de-identification, transfer, and management of data, as well as maintain protected health information anonymization and HIPAA-compliance. In this role, the honest broker can identify individuals overlapping between relevant

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databases, and assign de-identified study codes that would enable cross-linking individuals between the systems.

Data monitoring

The honest brokers will link the HSP database to the Vital Records Birth Data (VRBD) to generate a comparison group. They will match both the HSP and non-HSP groups to Hospital Discharge Data (HDD) and the Arizona State Immunization Information System (ASIIS) databases using personally identifiable information (e.g., name, DOB, social security number). The honest brokers will create a separate de-identified "limited data set" for our analyses to compare the mean outcomes of Health Start Program mothers to the comparison group mothers.

Statistical Analysis

The motivation for using PSM to create a synthetic comparison group is to be able to "observe" the "counterfactual" to HSP participation, that is, what would have happened in the absence of the program. We will explore this by comparing outcomes between HSP mothers and those "matched" to them by the propensity score. More specifically, the average treatment effect (ATE) generated by PSM will estimate the impact of the program on the population of both HSP mothers and those who "look like" HSP mothers by taking the difference in outcomes between HSP mothers and their matches, and vice-versa.

Our analytic population is of sufficient size to detect meaningful program effects from low-frequency events, including preterm births, low and very low birthweights, maternal morbidity, and differences in immunization and hospitalization rates over a relatively long period of time. This is also true for specific subgroups served by HSP (e.g. Hispanics, Native Americans, economically disadvantaged).

Once we establish proper covariate balance between the intervention and matched-control groups, point estimates of the treatment effects will be estimated by comparing outcomes using Stata version 14 software and specifically the teffects command (44). Following Abadie and Imbens (45, 46), this command considers the fact that propensity scores (i.e. the parameter that determines the comparison population) are estimated when calculating the standard errors and thus generates confidence intervals. The propensity scores will not be used as a covariate in traditional regression analysis because it is less effective in forcing baseline equivalence and assumes the relationship between the score and the outcome is linear (41).

Both the HSP enrollment information and VRBD are administrative data sources, established and maintained for public health monitoring purposes. As such, we do not anticipate missing data to be a significant issue. We assume that such instances (as we find them) are very likely to be the result of human error and not any systematic issues with the data collection and/or reporting processes. Where missing-ness does occur in the variables that make up the propensity score model, we will control for these using dummy variables in place of the missing observations. In the case of missing outcome variables, we will restrict the analytic sample to the non-missing observations, and inspect to control variables to verify that there are no systematic differences.

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Discussion

Our evaluation will build upon a previous evaluation of HSP conducted by Hussaini et al (2011), which found that HSP participation was associated with a reduction in the likelihood of a low birthweight outcome (21).

The Hussaini study used data from 2007 and compared 484 HSP enrollees to almost 5,000 non-HSP women; our study compares 9,665 unique HSP enrollees to approximately 23,000 non-HSP women spanning 10 years of service. Based on observed covariates, the Hussaini study matching process did not result in baseline equivalence across the two groups. For example, the comparison group was on average four years older (28.2 vs. 24.3) than the HSP mothers. Additionally, Hussaini et al matched to comparison mothers on ex post medical risks, which likely created a bias in favor of finding a positive HSP effect. Our propensity score matching (PSM) model will generate a comparison group that achieves baseline equivalence of observed covariates. Additionally, we explicitly match on socioeconomic status variables as required by the HomVEE-published standard for matched comparison group design studies (33). Specifically, we match on two individual measures of socioeconomic status (SES): maternal education and indicators for primary payer for the birth procedure. While these variables satisfy HomVEE's documented standard for measuring socioeconomic status for Group Design studies with a 'Moderate' rating, we also utilize the maternal zip code of residence to include a measure of mean household income. Finally, we will build on the scope of the original study in two significant ways: 1) by expanding the number of the outcomes considered, including maternal and child outcomes over time, and 2) by performing a number of sub-group analyses that investigate program impacts based on when in the course of the pregnancy the HSP intervention began, mother's country of origin, and maternal age (i.e. teen mothers).

Limitations

The primary limitation is the identifying assumption that selection into the HSP is driven by observable characteristics. This is a limitation common to most PSM analyses. Attenuation bias is a possibility, to the extent that HSP mothers are incorrectly identified and linked to state birth certificate data. However, the effect of this would be to underestimate (in absolute value) the magnitude of the resulting coefficients, meaning the true effect is likely to be larger (ceteris parabis). In addition, the analysis may have limited external validity for populations who differ along socioeconomic status, race, and ethnicity.

Ethics and dissemination

Patient and public involvement

Patients and the public were not involved in the design or planning of the study.

Protocol amendments

This article refers to the protocol 1701128802 dated 25 January 2017.

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Consent

Data are collected by the Arizona Department of Health Services for surveillance and monitoring. A waiver of informed consent was approved by the University of Arizona Research Institutional Review Board (Protocol 1701128802).

Confidentiality

Protocol complies with the University of Arizona Biomedical Informatics Service group information security policies including, Information Security Policy (IS-100), Computer and Network Access Agreement (IS-700), Acceptable Use of Computers Policy (IS-701), Electronic Privacy Statement Policy (IS-1000), Data Classification and Handling Standard (IS-2321) (47).

Access to data

All access to data will be in a controlled and monitored environment maintained by the University of Arizona Biomedical Informatics Service group. Because this is a single-use request for retrospective data, limited datasets cannot be shared beyond project personnel without the explicit permission by the Arizona Department of Health Services.

Dissemination

On completion of the study, we will initiate major dissemination strategies, including; (1) peer-reviewed publications in targeted journals; (2) scholarly presentations at scientific conferences and public health governance meetings; (3) interactive web-based promotional and training materials and (4) strategic informational and planning meetings. Published journal articles will be submitted in collaboration with Arizona Department of Health Services to Mathematica Policy Research for review for determination of the Health Start Program as a HomVEE evidence-based practice home visiting model. We will identify local and national forums for dissemination of preliminary results. Findings will be shared with ADHS leadership, Arizona Health Care Cost Containment System (Arizona Medicaid), Arizona Public Health Association (AzPHA), American Public Health Association (APHA), City MatCH and other MCH conferences and professional forums, as well as the Arizona Association of federally qualified community health center, Association of Health Plans, CHW Workforce Coalitions, and Maternal, Infant, and Early Childhood Home Visiting (MIECHV).

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Figures and Tables Legend

Table 1. Health Start Program evaluation aims and measurable outcomes. Five (5) maternal and child health goals guide the Arizona Health Start Program CHW activities to support at-risk pregnant and postpartum women and families with children up to age two. Our study aligns 3 aims with the HSP goals and will analyze the listed outcomes in order to test our central hypothesis, that mothers and children exposed to the Arizona Health Start Program from 2006-2015 will experience positive health outcomes. Results from this study may be used as evidence to support the Arizona Health Start Program as a recognized HomVEE evidence-based effectiveness program.

Figure 1. Arizona Health Start Program Service Area Map, 2018. Map demonstrates the Arizona Health Start Program service areas within 14 counties across the state. CHWs conduct regular home visits to underrepresented pregnant women and their families in rural and urban communities. Map courtesy of and permission by Arizona Health Start Program, Arizona Department of Health Services. This map is not under copyright.

Table 2. Selected Health Start Program intervention activities performed by Health Start Program CHWs and hypothesized client actions evaluated via measurable aims (non-exhaustive). CHWs provide support and services to meet the individual needs of their clients. This list includes general activities provided by CHWs during home visiting sessions that promote self-sufficiency, empowerment, positive health change and improved health outcomes for clients and their families.

Figure 2: Flow chart of intervention participant inclusion and exclusion criteria. 9,665 Health Start Program births constitute the basis of this study. 15,576 records were initially identified as Health Start Program matches; however, 5,911 records were excluded because the child's birth fell outside of the 24-month (either before or after) enrollment window. We evaluate Aims 1 & 2 with a subgroup: records for mothers enrolled in HSP prior to the child's birth (6,493 births). We evaluate Aim 3 using the larger set of 9,665 HSP-associated births.

Table 3. Data Sources and Outcome Measures by Study Aim. Our retrospective, propensity score-matched observational study pulls data from four (4) sources: Health Start Programmatic Data, Vital Records Birth Data, Hospital Discharge Data, and Arizona State Immunization Information System. Data were confined to 2006 to 2015, and serve to evaluate maternal and child health outcomes among at-risk, racially and ethnically diverse, rural and urban mothers and children of Arizona.

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Table 1. Description of Health Start Program goals, evaluation aims and measurable outcomes available through administrative data sources

Program Goals	Evaluation Aims	Measurable Outcomes
1. Reduce the incidence of very low birthweight babies.	Aim 1: Assess the impact of the HSP on newborn health	• Preterm birth (gestational age) • Birthweight (birthweight, low birthweight <2500 grams, very low birthweight <1500 grams, and small size for gestational age) • Newborn hospital length of stay and 30-day hospital charges
2. Increase prenatal services to pregnant women.	Aim 2: Assess the impact of the HSP on maternal health and care utilization	• Month prenatal care initiated • Total number of prenatal visits • Method of delivery (e.g. first-time Cesarean delivery) • Maternal morbidity (e.g. uterine rupture) • Inter-pregnancy intervals
3. Reduce the incidence of children affected by childhood diseases. **4.** Increase the number of children receiving age appropriate immunizations by two (2) years of age.	Aim 3: Assess the impact of the HSP on child health and development	• Probability of a child being on schedule for immunizations • Utilization of Emergency Room (ER) visits and Inpatient (IP) stays at ages 1, 3, and 5 • Any charges associated with ER and IP utilization
5. Increase awareness by educating families on the importance of good nutritional habits, developmental assessments, and preventative health care.	Not evaluated by this study	N/A

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Table 2. Selected Health Start Program intervention activities (non-exhaustive) performed by Health Start Program CHWs and hypothesized client actions (indicators) evaluated via measurable aims

Evaluation Aims	CHW Input	Process Indicator	Outcomes Indicator
Aim 1: Assess the impact of the HSP on newborn health	Prenatal home visits. Education on pregnancy, labor, delivery, nutrition, inter-conception. Screening, education, and assistance for mood and anxiety disorders, substance cessation, and domestic violence.	Increased knowledge of and engagement in pregnancy process and activities to promote a healthy pregnancy. Increase knowledge of available services, completed assistant referrals, increased access to services.	• Reduced rates of preterm birth • Reduced rates of low birthweight • Reduced newborn hospital length of stay and 30-day hospital charges
Aim 2: Assess the impact of the HSP on maternal health and care utilization	Perinatal home visits. Assistance with access and enrollment to continuous perinatal care. Education on pregnancy, labor, delivery, inter-conception.	Initiate prenatal care earlier in pregnancy and attend more prenatal care visits. Increased knowledge of and engagement in pregnancy process, delivery options, and activities to promote a healthy pregnancy.	• Increased number of prenatal care visits • Reduced first-time Cesarean delivery • Reduced maternal morbidity • Increased inter-pregnancy intervals
Aim 3: Assess the impact of the HSP on child health and development	Perinatal home visits. Screening, education, and assistance with child wellbeing services.	Timely completion of all immunizations for children.	• Increased immunization rates for children • Reduced utilization of ER at ages 1, 3, and 5 • Reduced charges associated with ER

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Table 3. Data sources and outcome measures by study aim		
Data Source (Years)	**Outcome Measures**	**Aim**
Health Start Program Data (2006-2015)	• Intervention enrollment • Month prenatal care began • Total number of prenatal visits	1, 2, 3
Vital Records Birth Data (2006-2015)	• Preterm birth (gestational age) • Birthweight (birthweight, low birthweight <2500 grams, very low birthweight <1500 grams, and small size for gestational age) • Month prenatal care began • Total number of prenatal visits • Method of delivery (first-time Cesarean delivery) • Maternal morbidity (e.g. uterine rupture) • Inter-pregnancy intervals	1 & 2
Hospital Discharge Data (2006-2015)	• Newborn hospital length of stay and 30-day hospital charges • Utilization of ER visits and IP stays at ages 1, 3, and 5 • Any charges associated with ER and IP utilization	1 & 3
Arizona State Immunization Information System (2006-2015)	• Probability of a child being on schedule for immunizations	3

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Figure 1: Arizona Health Start Program Service Area Map, 2018

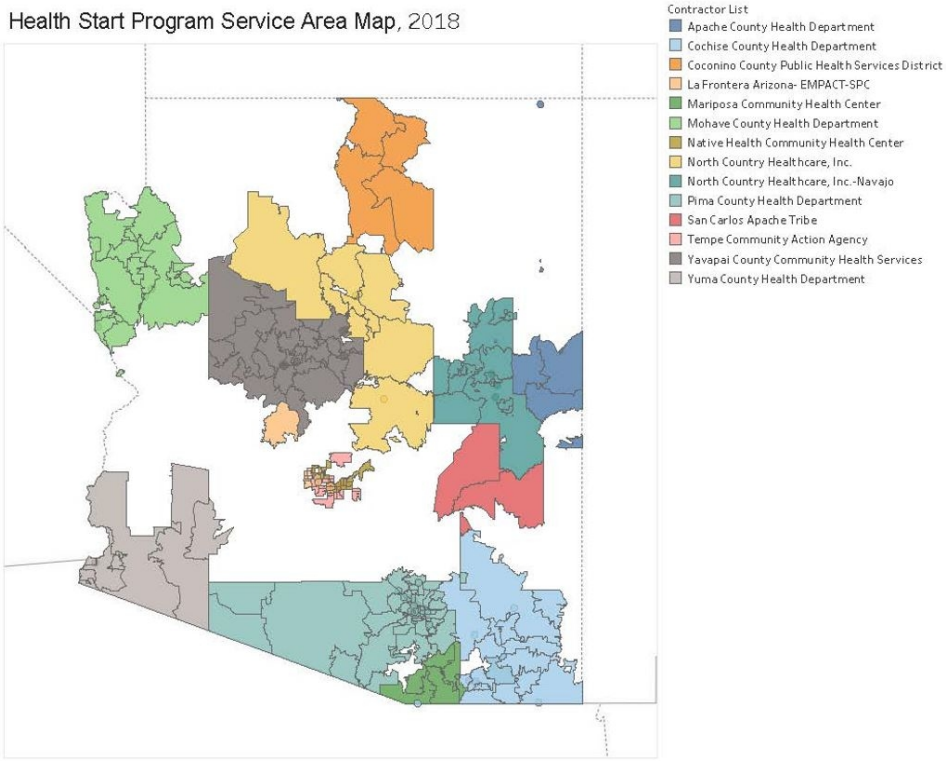

Figure 1. Arizona Health Start Program Service Area Map, 2018.

284x231mm (96 x 96 DPI)

Figure 2. Flow chart of intervention participant inclusion and exclusion criteria

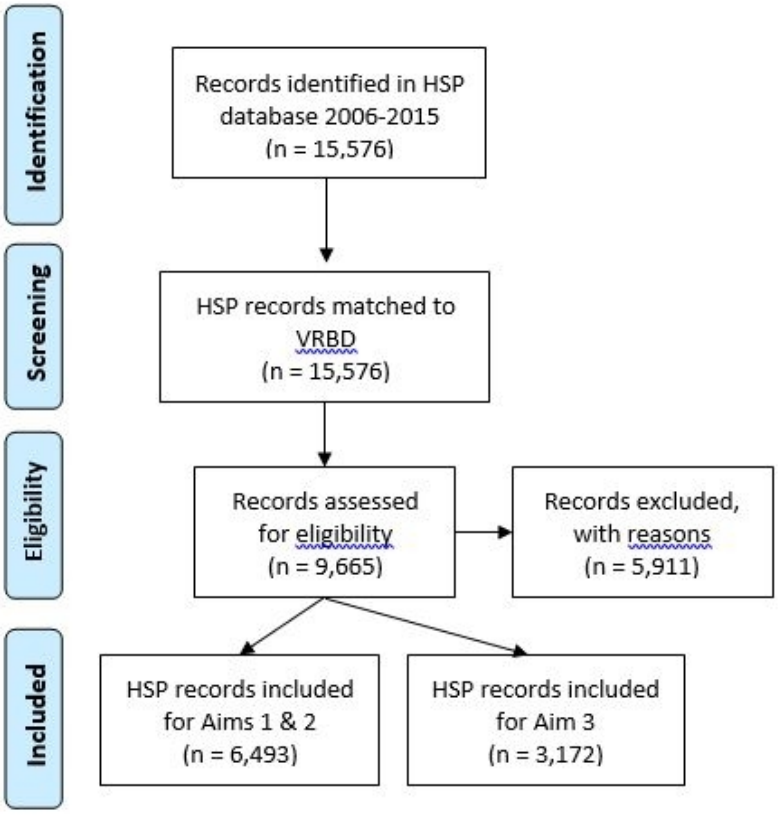

Figure 2: Flow chart of intervention participant inclusion and exclusion criteria.

146x141mm (96 x 96 DPI)

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Status	Section/item	ItemNo	Description
	Administrative information		
DONE	Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
NA, non RCT	Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry
NA, non RCT		2b	All items from the World Health Organization Trial Registration Data Set
DONE	Protocol version	3	Date and version identifier
DONE	Funding	4	Sources and types of financial, material, and other support
DONE	Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors
		5b	Name and contact information for the trial sponsor
DONE		5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
		5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
	Introduction		
DONE	Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
DONE		6b	Explanation for choice of comparators
DONE	Objectives	7	Specific objectives or hypotheses
DONE	Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)
	Methods: Participants, interventions, and outcomes		
DONE	Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
DONE	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will

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			perform the interventions (eg, surgeons, psychotherapists)
DONE	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
NA, non RCT		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
NA, non RCT		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
NA, non RCT		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
DONE	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
DONE	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
DONE	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
NA, non RCT	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size
	Methods: Assignment of interventions (for controlled trials)		
NA, non RCT	Allocation:		
NA, non RCT	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions
NA, non RCT	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
NA, non RCT	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
NA, non RCT	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
NA, non		17b	If blinded, circumstances under which unblinding is

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RCT			permissible, and procedure for revealing a participant's allocated intervention during the trial
	Methods: Data collection, management, and analysis		
DONE	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
DONE		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
DONE	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
DONE	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
DONE		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
DONE		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)
	Methods: Monitoring		
NA, non RCT	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed
NA, non RCT		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
NA, non RCT	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
NA, non RCT	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
	Ethics and dissemination		
DONE	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
DONE	Protocol amendments	25	Plans for communicating important protocol modifications

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			(eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
DONE	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
DONE	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
DONE	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
DONE	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
NA, non RCT	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
DONE	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
NA		31b	Authorship eligibility guidelines and any intended use of professional writers
DONE		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code
	Appendices		
NA, non RCT	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
NA, non RCT	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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BMJ Open

Evaluation Protocol to Assess Maternal and Child Health Outcomes Using Administrative Data: A Community Health Worker Home Visiting Program

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Manuscripts

Title: Evaluation Protocol to Assess Maternal and Child Health Outcomes Using Administrative Data: A Community Health Worker Home Visiting Program

Protocol: Approved by the University of Arizona Research Institutional Review Board (Protocol # 1701128802), dated January 25, 2017.

Funding: The Arizona Department of Health Services (ADHS) funds the study, from July 1, 2017 through June 30, 2022. Health Resources Services Administration (HRSA) Maternal, Infant, Early Childhood Home Visiting (MIECHV) provided 17 months of additional federal funding through ADHS during the study period.

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Conflicts of interest: None of the authors has conflicts of interest to declare.

Contributors: All authors contributed equally. SS, MB and SR conceptualized the original study protocol. PW and VP conducted data analysis and contributed greatly to the preparation of the analytic methods and data management sections. SS, KM and SR led all protocol writing and editing. MC provided ongoing edits to early and late stage drafts.

ADHS will oversee the study and 1) provide input to study design, conduct, data analysis and interpretation of results and review of draft manuscripts; 2) conduct monthly meetings and conference calls to discuss the evaluation impact study, challenges, and barriers; and 3) provide Heath Start Program data, documents and data results, program training, and policies manuals as needed.

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Abstract

Introduction: Emerging evidence suggests community health workers (CHWs) delivering preventive maternal and child health (MCH) interventions through home visiting improve several important health outcomes, including initiation of prenatal care, healthy birthweight, and uptake of childhood immunizations.

Methods & Analysis: The Arizona Health Start Program is a behavioral-based home visiting intervention, which utilizes CHWs to improve MCH outcomes through health education, referral support, and advocacy services for at-risk pregnant and postpartum women with children up to age two. We aim to test our central hypothesis that mothers and children exposed to this intervention will experience positive health outcomes in the areas of (1) newborn health; (2) maternal health and healthcare utilization; and (3) child health and development. This paper outlines our protocol to retrospectively evaluate Health Start Program administrative data from 2006 to 2015, equaling 15,576 enrollees. We will use propensity score matching to generate a statistically similar control group. Our analytic sample size is sufficient to detect meaningful program effects from low-frequency events, including preterm births, low and very low birthweights, maternal morbidity, and differences in immunization and hospitalization rates.

Ethics & Dissemination: This work is supported through an inter-agency contract from the Arizona Department of Health Services and is approved by the University of Arizona Research Institutional Review Board (Protocol 1701128802, approved 25 January 2017). Evaluation of the three proposed outcome areas will be completed by June 2020.

Strengths & Limitations:

- A 10-year retrospective observational study of a CHW home visiting intervention using propensity score matching.
- Size and diversity of mothers in the intervention group (9,665) will be matched to one or more characteristically similar mothers in the comparison group.
- Less than 1% of intervention participants were involved in other home visiting programs.
- Analysis may have limited external validity for populations who differ along socioeconomic status, race, and ethnicity.

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Background

Over the last decade, the community health worker (CHW) workforce has been recognized by the World Health Organization and several United States entities as an evidence-based approach to address health disparities (1-3). In the US, the CHW workforce has gained recognition and visibility, as evidenced by the creation of a US Department of Labor Standard Occupational Classification (21-094) in 2010, to include CHWs as a health profession in the Patient Protection and Affordable Care Act (ACA)(4). According to the American Public Health Association, a CHW is *a frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served. This trusting relationship enables the worker to serve as a liaison/link/intermediary between health/social services and the community to facilitate access to services and improve the quality and cultural competence of service delivery* (5).

Emerging evidence suggests CHWs delivering preventive maternal and child health (MCH) interventions through home visiting improve several important maternal and child outcomes (6, 7). Globally, CHW home visiting interventions are associated with several primary prevention efforts that promote the initiation of any, early, and adequate prenatal care (8, 9), initiation of any and exclusive breastfeeding (7, 10-13), reduction of maternal morbidity and perinatal mortality (14), and the uptake and completion of childhood immunizations (7, 15). In the US, CHW home visiting interventions are associated with decreased incidence of preterm birth (9, 16-18) and low birthweight (9, 16-22), and increases in up-to-date immunizations among newborns and toddlers (23)**.** CHWs share the language, socioeconomic status, and life experiences of their clients, making them a fundamental asset to reducing health inequalities among disenfranchised groups (24). Moreover, CHWs are recognized as integral contributors in collaborative health- and community-based teams by improving comprehensive care and addressing the social determinants of health that contribute to health improvements and cost savings (25, 26).

Arizona launched the first iteration of the Health Start Program (HSP) in 1984, when Arizona ranked among the lowest five states for the number of women receiving any or adequate prenatal care (27). HSP is a statewide program that employs CHWs to engage at-risk, low income, and racially and ethnically diverse mothers and improve maternal and child outcomes. HSP has been managed by the Arizona Department of Health Services (ADHS), Bureau of Women's and Children's Health since 1992 (28). In 1994, the Arizona State Legislature passed the Arizona Children and Families Stability Act, A.R.S. § 36-697, which formalized and expanded HSP and articulated the purpose, requirements, and administration of the program. HSP is a community-based outreach program that identifies, screens, and enrolls pregnant women early in their pregnancies and assists them with obtaining early and consistent prenatal care. The program also provides prenatal and postpartum education, information and referral services, client advocacy, and emphasizes timely immunizations and developmental assessments for their children. Since its inception, Arizona Health Start Program's mission has been "*to educate, support and advocate for families at risk by promoting optimal use of community-based family health care services and education services through the use of community health workers (CHWs) who live in and reflect the ethnic, cultural and socioeconomic characteristics of the community they serve."* (28)

Study Setting

Arizona is the sixth largest state in the nation, with a population of 6.8 million people. The state shares an international border with Mexico and is home to 21 federally recognized American Indian Tribes and Nations, making it uniquely racially and ethnically diverse. Arizona has a higher proportion of Latino

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(30.9%) and American Indian (5%) residents compared to the nation (17.8% and 1%, respectively) and a comparatively smaller proportion of African American residents (5% compared to 13% nationally) (29).

In 2015, nearly a quarter of the population lived in rural areas, where the poverty rate reached 30%, almost double that of the national poverty rate (29). Approximately 20% of Arizona families with children live below the federal poverty line, compared to 18% nationally. Poverty disparately affects Arizona's Latino (36%) and American Indian (46%) families and children (29). Arizona ranks as the fifth highest US state for adult female poverty rate in the country, with more than one quarter of Arizona families headed by single-mother households (29). The initial framework for the HSP was developed in the 1980s and 1990s to address the social determinants associated with the steady decrease in the rate of women receiving prenatal care. In the most recent Arizona Title V Maternal and Child Health Needs Assessment (2017), approximately 74% of pregnant women initiated prenatal care in the first trimester (compared to 61% in 2015 and 81% in 2013), and 7.9% had no prenatal care (29). There were disparities among mothers by race/ethnicity who received prenatal care, notably American Indian mothers having the highest rates of 'inadequate' prenatal care (25%) compared to all women in Arizona (15%) (29).

It is widely recognized that late prenatal care is associated with preterm birth, low birthweight, and infant mortality. In 2014, 9% of babies born in Arizona were premature and 7.2% were low birthweight (29). Historically, low-income mothers have experienced higher rates of premature birth and low birthweight in Arizona (30) and nationally (31). There are also apparent racial disparities for birth outcomes in Arizona. Preterm birth rates are highest among Black (12.2%), American Indian (9.4%), and Latino (9.2%) compared to all preterm births (9.1%) in the state. Preterm births increase the risk of low birthweight; similar trends persist with the highest rates of low birthweight among Black residents (10.32%) compared to White residents (5.36%) and the total Arizona population (7.2%) (29). Preterm and low birthweight baby delivery costs have been shown to be 25 times more than uncomplicated newborn deliveries (32). Although prenatal care and birth outcomes in Arizona have improved over the years, many under-resourced women continue to experience significant challenges and barriers to obtaining health care services.

Objectives

Our goal is to describe the research protocol for a retrospective comparative evaluation to assess the impact of Arizona's Health Start Program, a CHW home visiting perinatal support program, on multiple maternal, infant, and child health outcomes. Broadly, the goal for the study is to meet the federal Home Visiting Evidence of Effectiveness (HomVEE) standard for evidence-based effectiveness. We will use a matched comparison group design that meets the published standard for HomVEE's 'Moderate' rating, defined by HomVEE as: "1) baseline equivalence established on tested outcomes and demographic characteristics and controls for baseline measures of tested outcomes, if applicable; and 2) no confounding factors; must have at least 2 participants in each study arm and no systematic differences in data collection methods". (Note: a 'High' rating is reserved for randomized controlled trials) (33).

Aims

We plan to objectively test our central hypothesis that mothers and children exposed to HSP during the study period of 2006 to 2015 will experience positive health outcomes in the areas of newborn, maternal, and child health (Table 1). Specifically, our aims include:

- Aim 1: Assess the impact of HSP on newborn health

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- Aim 2: Assess the impact of HSP on maternal health and care utilization
- Aim 3: Assess the impact of HSP on early child health and development

Methods: Intervention, Participants, & Outcomes

Health Start Program Intervention

HSP is significant in that it is one of the longest-standing programs in Arizona and employs CHWs in 14 distinct Arizona counties to engage at-risk, low-income mothers in order to improve birth outcomes (Figure 1). CHWs serve as the primary interventionist for the program. In 2016, HSP CHWs provided services to 2,534 unduplicated clients, conducted 16,698 home visits, and facilitated 461 classes (28). Women are eligible to enroll in HSP if they 1) live in the targeted service area, 2) are pregnant or postpartum with a child under age two, and 3) have one or more social or medical risk factors. Social risks can include but are not limited to: single-parent status, underserved racial or ethnic group, education equal to or less than high school level, annual income less than $40,000, and Medicaid or no insurance. Medical risks are broad and can include previous preterm birth, low birthweight, chronic disease, high maternal BMI, and substance use. Women can be of any age and there are no income requirements to participate.

CHWs connect clients to prenatal care and increase client's continuity of care during and after pregnancy. CHWs identify, screen, and enroll eligible women; provide prenatal and postpartum education; provide referral and advocacy services; and emphasize timely immunizations and developmental assessments for children. Although not an exhaustive list, Table 1 outlines the primary intervention activities conducted by the CHW. HSP CHW home visits are guided by an asset-based approach and two primary theories of behavior change, the Trans Theoretical Model and the Social Cognitive Theory. Identifying assets acknowledges and supports the existing strengths and capabilities of individuals and resources to promote community-driven development and positive change (34). The Trans Theoretical Model assumes that behavior modification in individuals is a multistage process in which people move through stages of readiness for change (35), and Social Cognitive Theory states that stages occur in the context of reciprocal relationships between the person's environment, their behavior, and their cognition (36). CHWs are a community asset and well positioned to support HSP clients; they share both lived experiences and cultural knowledge of the community they serve. The home visiting sessions promote behavior change through assessment, goal planning, referral, advocacy, and follow up activities, coupled with education through meaningful adult learning models. These interactions are designed to encourage personal agency of adult learners to integrate new knowledge and create a cognitive structure that makes sense of their own surroundings and situations (37). Through behavior change theories and adult learning models, the Health Start Program CHWs privilege the co-construction of knowledge among all participants, assume all are co-learners, and encourage critical thinking about self-sufficiency, empowerment, and personal agency related to the five HSP goals (Table 1).

Health Start Program CHW Core Competencies, Roles, & Training

According to the HSP policy and procedure manual, CHWs must 1) live and work in the service area, 2) reflect the ethnic, cultural and socioeconomic characteristics of the communities they serve, 3) be able to read and write in English, 4) have a high school diploma or General Educational Development, and 5) pass a criminal history background check within the Department of Public Safety records to be eligible to

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work for the state-funded program. It is highly recommended (though not required) that CHWs have post high school training and education in maternal and child health, early childhood development education, family studies, social work, nursing or a closely related field (28). Before a CHW can initiate unsupervised outreach or home visits, they must complete 40 hours of training in both the *10 CHW Core Competencies* set forth by the CHW Core Consensus Project (38), which are recognized by the Arizona state legislature HB 2324 Voluntary CHW Certification (39), and the *Health Start Program Core Training* (28). An additional 8 hours of home visit shadowing with a senior CHW are required.

Nationally recognized, the *10 CHW Core Competencies* include: 1) Cultural and Systems Mediation; 2) Culturally Appropriate Health Education; 3) Care Coordination and Case Management; 4) Coaching and Social Support; 5) Advocacy; 6) Capacity Building; 7) Direct Service; 8) Individual and Community Assessments; 9) Outreach; and 10) Research and Evaluation (38). *HSP Core Training* covers: 1) Essential Health Start Information (HSP basics, visits, and community outreach); 2) Communication and Emotional Support; 3) Nutrition and Physical Activity (family nutrition and physical activity, infant nutrition and physical activity); 4) Health Education (healthy pregnancy, prenatal care, discomforts during pregnancy, labor and delivery, postpartum care and family planning, early childhood development and parenting skills, infant health and child health); and 5) Safety (home safety for infants and children, child abuse and domestic violence) (28). CHWs are required to complete 12 hours of continuing education per year.

Intervention Cohort

HSP administrative data from 2006 to 2015 is the primary source for identifying the retrospective intervention group. All Health Start clients enrolled during the 10-year observation period will be included in this study if their records are identified and linked from the HSP database to the vital records birth database (VRBD). Records will be linked based on the mother's date of birth and first name. In order to be a candidate for the HSP study cohort, the mother's date of birth must be an exact match while her first name must be at least 95% similar, using Jaro-Winkler (JW) similarity (40). Mother's last name may change due to marriage; therefore, this criterion is not required to identify the intervention cohort. We will obtain the following information for each HSP study cohort mother: a unique ID, first name similarity percentage, last name similarity percentage, HSP enrollment date, program closure information (i.e. program completion, reason for closure), and the child's birthdate. Using the process described above, 15,576 HSP records were linked to the VRBD.

Intervention Cohort Sample Size

Of the initial 15,576 records identified through the HSP-to-VRBD data link, 5,911 fall outside of the 24-month (either before or after) HSP enrollment window and will be excluded from all subsequent analysis. The resulting 9,665 HSP-associated births constitute the basis of this study (Figure 2). Because HSP participants can enroll before or after birth, we will limit the analysis for Aims 1 and 2 to those births for which the mother was enrolled prior to the child's birth. This final criterion results in 6,493 HSP-attributed births for the evaluation of Aims 1 and 2. Aim 3 will be evaluated using the larger set of 9,665 HSP-associated births. Our evaluation will include all HSP participants enrolled (within 24 months of the date of birth of the child), and all births occurring in Arizona over the study period 2006-2015. Due to the respective sizes of these populations, lack of statistical power is not a significant issue for this project.

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Synthetic Comparison Group

A comparison group of women not exposed to the Health Start Program (non-HSP) will be created using a propensity score matching approach and all other births that occurred in Arizona (derived from VRBD) over the study period to balance representation of subjects in each group. After identifying our study population we will use propensity score matching (PSM) to generate a statistically-similar synthetic control group that has, on average, the same observable pre-program characteristics as the HSP mothers (41). The pool of potential comparators will come from all Arizona births that occurred over the study period (2006-2015). This process will be guided by HomVEE standards requiring that the covariates used to balance the treatment and control groups be associated with both treatment status and the outcomes of interest (42). Because the HSP eligibility criteria focus on social and medical risks, we will prioritize these types of measures in the PSM model, in addition to characteristics that have been shown to have strong associations with our outcomes of interest in previous empirical and theoretical work.

We will employ radius matching to identify comparison group mothers across the common support region (43). We will use the following measures in the PSM model: mother's birth year, mother's age at birth, county of residence. Additional indicator variables include: child's birth order, maternal educational attainment, health insurance payer (Medicaid being a proxy for low-income status), race, ethnicity, availability of information for the father on the birth certificate, maternal country of birth, previous history of hypertension, and median household income by zip code of residence. In addition to these demographic and socioeconomic characteristics, we will restrict potential comparators to mothers within the same fiscal years in order to account for economic conditions and any potentially shifting program parameters. Imposing within-year matches will allow us to analyze the program's efficacy over time by cohort.

Comparison mothers may match to more than one HSP mother, based on the propensity score. Preliminary efforts to identify matches resulted in a potential synthetic comparison group of nearly 23,000 non-HSP mothers.

Patient & Public Involvement

Patients and the public were not involved in the design or planning of the study.

Outcomes

Primary Outcomes

HSP is a primary prevention intervention to improve maternal and child health outcomes among at-risk, racially and ethnically diverse, rural and urban mothers and children of Arizona. We will use four Arizona Department of Health Services administrative datasets to evaluate Aims 1-3 including Health Start programmatic data, Vital Records Birth Data, Hospital Discharge Data, and Arizona State Immunization Information System data. Aim 1 (HSP impact on newborn health) will be measured by preterm birth, birthweight, and newborn hospital length of stay and associated charges. Aim 2 (HSP impact on maternal health) will be measured by prenatal care initiation and frequency, method of delivery, maternal morbidities, and inter-pregnancy intervals. Aim 3 (HSP impact on child health) will be measured by uptake of age-appropriate immunizations, and emergency room and inpatient encounters and charges (Table 2).

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Methods: Data Management, Monitoring, & Statistical Analysis

Data Management

The four datasets that will be accessed for this study will be securely stored and protected through an honest broker. We designated the Center for Biomedical Informatics and Biostatistics' Biomedical Informatics Services at the University of Arizona as the honest broker to facilitate the de-identification, transfer, and management of data, as well as maintain protected health information anonymization and HIPAA-compliance. In this role, the honest broker can identify individuals overlapping between relevant databases, and assign de-identified study codes that would enable cross-linking individuals between the systems.

Data Monitoring

The honest brokers will link the HSP database to the Vital Records Birth Data (VRBD) to generate a comparison group. They will match both the HSP and non-HSP groups to Hospital Discharge Data (HDD) and the Arizona State Immunization Information System (ASIIS) databases using personally identifiable information (e.g., name, DOB, social security number). The honest brokers will create a separate de-identified "limited data set" for our analyses to compare the mean outcomes of Health Start Program mothers to the comparison group mothers.

Statistical Analysis

The motivation for using PSM to create a synthetic comparison group is to be able to "observe" the "counterfactual" to HSP participation, that is, what would have happened in the absence of the program. We will explore this by comparing outcomes between HSP mothers and those "matched" to them by the propensity score. More specifically, the average treatment effect (ATE) generated by PSM will estimate the impact of the program on the population of both HSP mothers and those who "look like" HSP mothers by taking the difference in outcomes between HSP mothers and their matches, and vice-versa.

Our analytic population is of sufficient size to detect meaningful program effects from low-frequency events, including preterm births, low and very low birthweights, maternal morbidity, and differences in immunization and hospitalization rates over a relatively long period. This is also true for specific subgroups served by HSP (e.g. Hispanics, Native Americans, economically disadvantaged).

Once we establish proper covariate balance between the intervention and matched-control groups, point estimates of the treatment effects will be estimated by comparing outcomes using Stata version 14 software and specifically the *teffects* command (44). Following Abadie and Imbens (45, 46), this command considers the fact that propensity scores (i.e. the parameter that determines the comparison population) are estimated when calculating the standard errors, and thus generates confidence intervals. The propensity scores will not be used as a covariate in traditional regression analysis because it is less effective in forcing baseline equivalence and assumes the relationship between the score and the outcome is linear (41).

Both the HSP enrollment information and VRBD are administrative data sources, established and maintained for public health monitoring purposes. As such, we do not anticipate missing data to be a significant issue. We assume that such instances (as we find them) are very likely to be the result of human error and not any systematic issues with the data collection and/or reporting processes. Where

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missing-ness does occur in the variables that make up the propensity score model, we will control for these using dummy variables in place of the missing observations. In the case of missing outcome variables, we will restrict the analytic sample to the non-missing observations, and inspect to control variables to verify that there are no systematic differences.

Discussion

Our evaluation will build upon a previous evaluation of HSP conducted by Hussaini et al (2011), which found that HSP participation was associated with a reduction in the likelihood of a low birthweight outcome (21).

The Hussaini study used data from 2007 and compared 484 HSP enrollees to almost 5,000 non-HSP women; our study compares 9,665 HSP enrollees to approximately 23,000 non-HSP women spanning 10 years of service. Based on observed covariates, the Hussaini study matching process did not result in baseline equivalence across the two groups. For example, the comparison group was on average four years older (28.2 vs. 24.3) than the HSP mothers. Additionally, Hussaini et al matched to comparison mothers on *ex post* medical risks, which likely created a bias in favor of finding a positive HSP effect. Our propensity score matching (PSM) model will generate a comparison group that achieves baseline equivalence of observed covariates. Additionally, we explicitly match on socioeconomic status variables as required by the HomVEE-published standard for matched comparison group design studies (33). Specifically, we match on two individual measures of socioeconomic status (SES): maternal education and indicators for primary payer for the birth procedure. While these variables satisfy HomVEE's documented standard for measuring socioeconomic status for Group Design studies with a 'Moderate' rating, we also utilize the maternal zip code of residence to include a measure of mean household income. Finally, we will build on the scope of the original study in two significant ways: 1) by expanding the number of the outcomes considered, including maternal and child outcomes over time, and 2) by performing a number of sub-group analyses that investigate program impacts based on when in the course of the pregnancy the HSP intervention began, mother's country of origin, and maternal age (i.e. teen mothers).

Limitations

The primary limitation is the identifying assumption that selection into the HSP is driven by observable characteristics. This is a limitation common to most PSM analyses. Attenuation bias is a possibility if HSP mothers are incorrectly identified and linked to state birth certificate data. However, the effect of this would be to underestimate (in absolute value) the magnitude of the resulting coefficients, meaning the true effect is likely to be larger (*ceteris paribus*). In addition, the analysis may have limited external validity for populations who differ along socioeconomic status, race, and ethnicity.

Ethics & Dissemination

Consent & Confidentiality

Data will be collected by the Arizona Department of Health Services for surveillance and monitoring. The University of Arizona Research Institutional Review Board (Protocol 1701128802) approved a waiver of informed consent. Protocol complies with the University of Arizona Biomedical Informatics Service group information security policies including, Information Security Policy (IS-100), Computer and

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Network Access Agreement (IS-700), Acceptable Use of Computers Policy (IS-701), Electronic Privacy Statement Policy (IS-1000), Data Classification and Handling Standard (IS-2321) (47).

Dissemination

On completion of the study, we will initiate major dissemination strategies, including (1) peer-reviewed publications in targeted journals; (2) scholarly presentations at scientific conferences and public health governance meetings; (3) interactive web-based promotional and training materials and (4) strategic informational and planning meetings. In collaboration with Arizona Department of Health Services, we aim to submit published journal articles to Mathematica Policy Research for consideration of the Health Start Program as a HomVEE evidence-based practice home visiting model. We will identify local and national forums for dissemination of preliminary results. Findings will be shared with ADHS leadership, Arizona Health Care Cost Containment System (Arizona Medicaid), Arizona Public Health Association (AzPHA), American Public Health Association (APHA), MCH-specific conferences and professional forums, the Arizona Association of Federally Qualified Community Health Centers, Association of Health Plans, CHW workforce coalitions, and Maternal, Infant, and Early Childhood Home Visiting (MIECHV).

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Figures and Tables Legend

Table 1. Health Start Program goals, CHW activities (non-exhaustive), predicted client actions, study aims, and measurable outcomes. Five (5) maternal and child health goals guide the Arizona Health Start Program CHW activities to support at-risk pregnant and postpartum women and families with children up to age two. CHWs provide support and services to meet the individual needs of their clients during home visiting sessions that promote self-sufficiency, empowerment, positive health change, and improved health outcomes. Our three study aims align with the HSP goals, which we will analyze via the listed outcomes.

Figure 1. Arizona Health Start Program service area map, 2018. Map demonstrates the Arizona Health Start Program service areas within 14 counties across the state. CHWs conduct regular home visits to underrepresented pregnant women and their families in rural and urban communities. Map courtesy of and permission by Arizona Health Start Program, Arizona Department of Health Services. This map is not under copyright.

Figure 2: Flow chart of intervention participant inclusion and exclusion criteria. 9,665 Health Start Program births constitute the basis of this study. 15,576 records were initially identified as Health Start Program matches; however, 5,911 records were excluded because the child's birth fell outside of the 24-month (either before or after) enrollment window. We evaluate Aims 1 & 2 with a subgroup: records for mothers enrolled in HSP prior to the child's birth (6,493 births). We evaluate Aim 3 using the larger set of 9,665 HSP-associated births.

Table 2. Data sources and outcome measures by study aim. Our retrospective, propensity score-matched observational study pulls data from four (4) sources: Health Start Programmatic Data, Vital Records Birth Data, Hospital Discharge Data, and Arizona State Immunization Information System. Data were confined to 2006 to 2015, and serve to evaluate maternal and child health outcomes among at-risk, racially and ethnically diverse, rural and urban mothers and children of Arizona.

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Table 1. Description of Health Start Program goals, CHW activities (non-exhaustive), predicted client actions, study aims, and measurable outcomes				
Program Goals	**CHW Input**	**Process Indicator**	**Evaluation Aims**	**Measurable Outcomes**
1. Reduce the incidence of very low birthweight babies.	• Prenatal home visits. Education on pregnancy, labor, delivery, nutrition, inter-conception. • Screening, education, and assistance for mood and anxiety disorders, substance cessation, and domestic violence.	• Increased knowledge of and engagement in pregnancy process and activities to promote a healthy pregnancy. Increase knowledge of available services, completed assistant referrals, increased access to services.	Aim 1: Assess the impact of the HSP on newborn health	• Preterm birth (gestational age) • Birthweight (birthweight, low birthweight <2500 grams, very low birthweight <1500 grams, and small size for gestational age) • Newborn hospital length of stay and 30-day hospital charges
2. Increase prenatal services to pregnant women.	• Perinatal home visits. Assistance with access and enrollment to continuous perinatal care. • Education on pregnancy, labor, delivery, inter-conception.	• Initiate prenatal care earlier in pregnancy and attend more prenatal care visits. • Increased knowledge of and engagement in pregnancy process, delivery options, and activities to promote a healthy pregnancy.	Aim 2: Assess the impact of the HSP on maternal health and care utilization	• Month prenatal care initiated • Total number of prenatal visits • Method of delivery (e.g. first-time Cesarean delivery) • Maternal morbidity (e.g. uterine rupture) • Inter-pregnancy intervals
3. Reduce the incidence of children affected by childhood diseases. **4.** Increase the number of children receiving age appropriate immunizations	• Perinatal home visits. Screening, education, and assistance with child wellbeing services.	• Timely completion of all immunizations for children.	Aim 3: Assess the impact of the HSP on child health and development	• Probability of a child being on schedule for immunizations • Utilization of Emergency Room (ER) visits and Inpatient (IP) stays at ages 1, 3, and 5 • Any charges associated with ER and IP utilization

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by two (2) years of age.				
5. Increase awareness by educating families on the importance of good nutritional habits, developmental assessments, and preventative health care.	Not evaluated by this study	Not evaluated by this study	Not evaluated by this study	N/A

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Table 2. Data sources and outcome measures by study aim		
Data Source (Years)	**Outcome Measures**	**Aim**
Health Start Program Data (2006-2015)	• Intervention enrollment • Month prenatal care began • Total number of prenatal visits	1, 2, 3
Vital Records Birth Data (2006-2015)	• Preterm birth (gestational age) • Birthweight (birthweight, low birthweight <2500 grams, very low birthweight <1500 grams, and small size for gestational age) • Month prenatal care began • Total number of prenatal visits • Method of delivery (first-time Cesarean delivery) • Maternal morbidity (e.g. uterine rupture) • Inter-pregnancy intervals	1 & 2
Hospital Discharge Data (2006-2015)	• Newborn hospital length of stay and 30-day hospital charges • Utilization of Emergency Room (ER) visits and In Patient (IP) stays at ages 1, 3, and 5 • Any charges associated with ER and IP utilization	1 & 3
Arizona State Immunization Information System (2006-2015)	• Probability of a child being on schedule for immunizations	3

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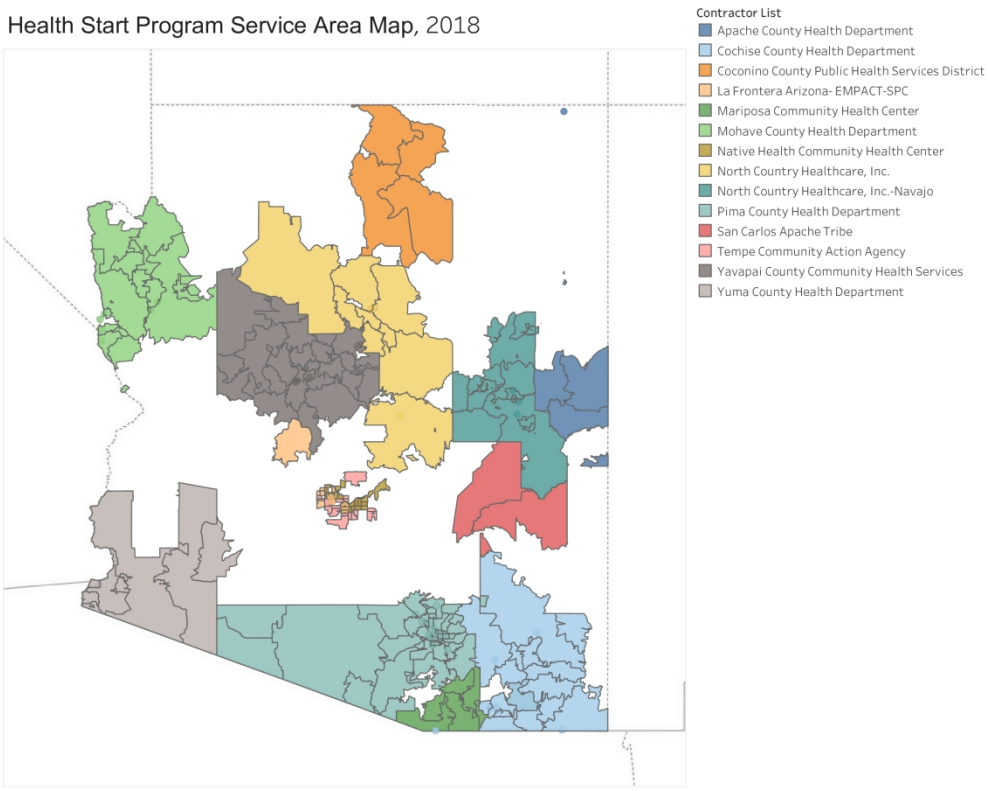

Figure 1. Arizona Health Start Program service area map, 2018. Map demonstrates the Arizona Health Start Program service areas within 14 counties across the state. CHWs conduct regular home visits to underrepresented pregnant women and their families in rural and urban communities. Map courtesy of and permission by Arizona Health Start Program, Arizona Department of Health Services. This map is not under copyright.

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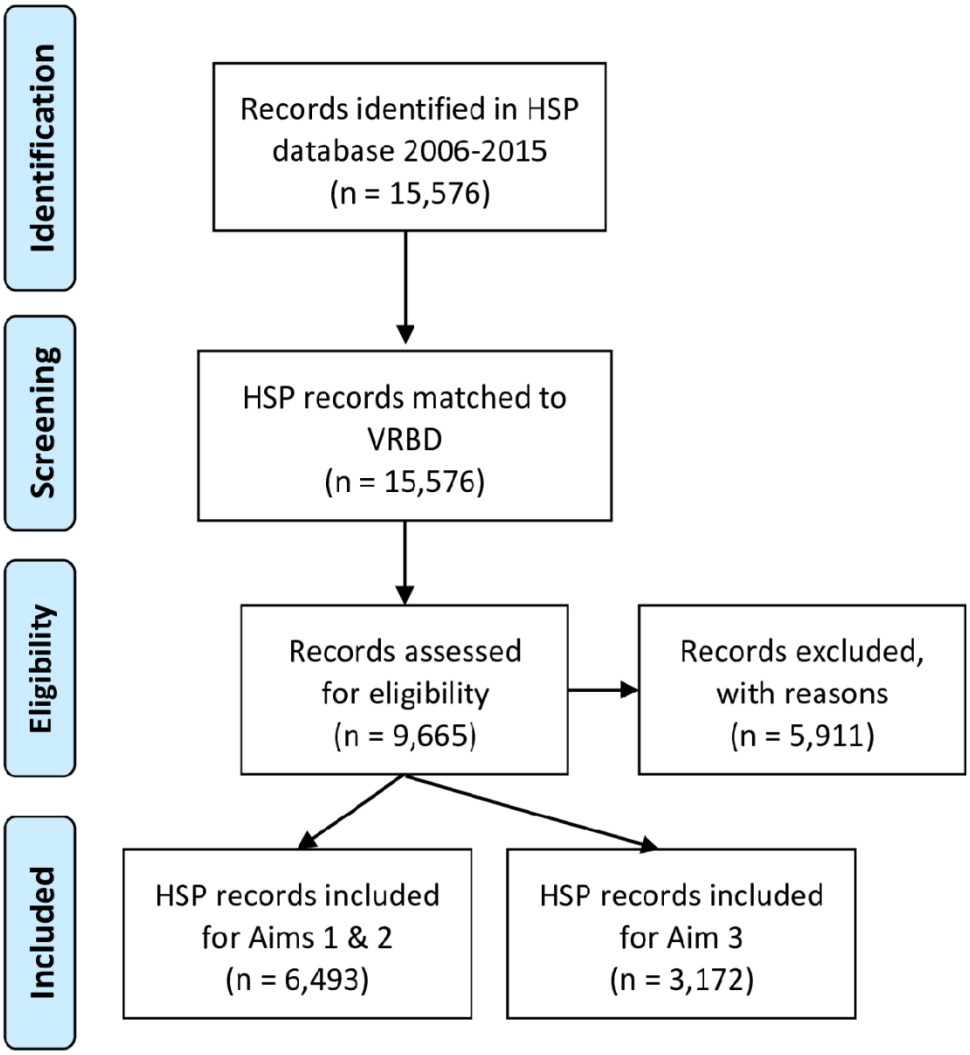

Figure 2: Flow chart of intervention participant inclusion and exclusion criteria. 9,665 Health Start Program births constitute the basis of this study. 15,576 records were initially identified as Health Start Program matches; however, 5,911 records were excluded because the child's birth fell outside of the 24-month (either before or after) enrollment window. We evaluate Aims 1 & 2 with a subgroup: records for mothers enrolled in HSP prior to the child's birth (6,493 births). We evaluate Aim 3 using the larger set of 9,665 HSP-associated births.

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SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Status	Section/item	ItemNo	Description
	Administrative information		
DONE	Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym
NA, non RCT	Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry
NA, non RCT		2b	All items from the World Health Organization Trial Registration Data Set
DONE	Protocol version	3	Date and version identifier
DONE	Funding	4	Sources and types of financial, material, and other support
DONE	Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors
		5b	Name and contact information for the trial sponsor
DONE		5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities
		5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)
	Introduction		
DONE	Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention
DONE		6b	Explanation for choice of comparators
DONE	Objectives	7	Specific objectives or hypotheses
DONE	Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)
	Methods: Participants, interventions, and outcomes		
DONE	Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained
DONE	Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will

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			perform the interventions (eg, surgeons, psychotherapists)
DONE	Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered
NA, non RCT		11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)
NA, non RCT		11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)
NA, non RCT		11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial
DONE	Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended
DONE	Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)
DONE	Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations
NA, non RCT	Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size
	Methods: Assignment of interventions (for controlled trials)		
NA, non RCT	Allocation:		
NA, non RCT	Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions
NA, non RCT	Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned
NA, non RCT	Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions
NA, non RCT	Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how
NA, non		17b	If blinded, circumstances under which unblinding is

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RCT			permissible, and procedure for revealing a participant's allocated intervention during the trial
	Methods: Data collection, management, and analysis		
DONE	Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol
DONE		18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols
DONE	Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol
DONE	Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol
DONE		20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)
DONE		20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)
	Methods: Monitoring		
NA, non RCT	Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed
NA, non RCT		21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial
NA, non RCT	Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct
NA, non RCT	Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor
	Ethics and dissemination		
DONE	Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval
DONE	Protocol amendments	25	Plans for communicating important protocol modifications

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			(eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)
DONE	Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)
		26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable
DONE	Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial
DONE	Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site
DONE	Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators
NA, non RCT	Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation
DONE	Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions
NA		31b	Authorship eligibility guidelines and any intended use of professional writers
DONE		31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code
	Appendices		
NA, non RCT	Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates
NA, non RCT	Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

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BMJ Open

Evaluation Protocol to Assess Maternal and Child Health Outcomes Using Administrative Data: A Community Health Worker Home Visiting Program

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Keywords:	community health worker, maternal and child health, home visiting, propensity score matching

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Manuscripts

Title: Evaluation Protocol to Assess Maternal and Child Health Outcomes Using Administrative Data: A Community Health Worker Home Visiting Program

Protocol: Approved by the University of Arizona Research Institutional Review Board (Protocol # 1701128802), dated January 25, 2017.

Funding: The Arizona Department of Health Services (ADHS) funds the study, from July 1, 2017 through June 30, 2022. Health Resources Services Administration (HRSA) Maternal, Infant, Early Childhood Home Visiting (MIECHV) provided 17 months of additional federal funding through ADHS during the study period.

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Conflicts of interest: None of the authors has conflicts of interest to declare.

Contributors: All authors contributed equally. SS, MB and SR conceptualized the original study protocol. PW and VP conducted data analysis and contributed greatly to the preparation of the analytic methods and data management sections. SS, KM and SR led all protocol writing and editing. MC provided ongoing edits to early and late stage drafts.

ADHS will oversee the study and 1) provide input to study design, conduct, data analysis and interpretation of results and review of draft manuscripts; 2) conduct monthly meetings and conference calls to discuss the evaluation impact study, challenges, and barriers; and 3) provide Heath Start Program data, documents and data results, program training, and policies manuals as needed.

Acknowledgements: We would like to acknowledge the Arizona Department of Health Services (ADHS) and the several ADHS Offices who have supported this partnership, including ADHS Office of Women and Children's Heath and the Health Start Program, ADHS Immunization Program, and ADHS Vital Statistics. We deeply appreciate their commitment to participating in this study designed to improve the health of women and children of Arizona. We also acknowledge the members of the University of Arizona and Northern Arizona University - ADHS Steering Committee for continued guidance in data sharing and data protection and security. We acknowledge the several Health Start Programs and hundreds of the Health Start Program CHW workforce who have worked tirelessly to improve maternal and child health equity among thousands of mothers, babies, and children.

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Abstract

Introduction: Emerging evidence suggests community health workers (CHWs) delivering preventive maternal and child health (MCH) interventions through home visiting improve several important health outcomes, including initiation of prenatal care, healthy birthweight, and uptake of childhood immunizations.

Methods & Analysis: The Arizona Health Start Program is a behavioral-based home visiting intervention, which utilizes CHWs to improve MCH outcomes through health education, referral support, and advocacy services for at-risk pregnant and postpartum women with children up to age two. We aim to test our central hypothesis that mothers and children exposed to this intervention will experience positive health outcomes in the areas of (1) newborn health; (2) maternal health and healthcare utilization; and (3) child health and development. This paper outlines our protocol to retrospectively evaluate Health Start Program administrative data from 2006 to 2015, equaling 15,576 enrollees. We will use propensity score matching to generate a statistically similar control group. Our analytic sample size is sufficient to detect meaningful program effects from low-frequency events, including preterm births, low and very low birthweights, maternal morbidity, and differences in immunization and hospitalization rates.

Ethics & Dissemination: This work is supported through an inter-agency contract from the Arizona Department of Health Services and is approved by the University of Arizona Research Institutional Review Board (Protocol 1701128802, approved 25 January 2017). Evaluation of the three proposed outcome areas will be completed by June 2020.

Strengths & Limitations:

- A 10-year retrospective observational study of a CHW home visiting intervention using propensity score matching.
- Size and diversity of mothers in the intervention group (9,665) will be matched to one or more characteristically similar mothers in the comparison group.
- Less than 1% of intervention participants were involved in other home visiting programs.
- Analysis may have limited external validity for populations who differ along socioeconomic status, race, and ethnicity.

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Background

Over the last decade, the community health worker (CHW) workforce has been recognized by the World Health Organization and several United States entities as an evidence-based approach to address health disparities (1-3). In the US, the CHW workforce has gained recognition and visibility, as evidenced by the creation of a US Department of Labor Standard Occupational Classification (21-094) in 2010, to include CHWs as a health profession in the Patient Protection and Affordable Care Act (ACA)(4). According to the American Public Health Association, a CHW is *a frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served. This trusting relationship enables the worker to serve as a liaison/link/intermediary between health/social services and the community to facilitate access to services and improve the quality and cultural competence of service delivery* (5).

Emerging evidence suggests CHWs delivering preventive maternal and child health (MCH) interventions through home visiting improve several important maternal and child outcomes (6, 7). Globally, CHW home visiting interventions are associated with several primary prevention efforts that promote the initiation of any, early, and adequate prenatal care (8, 9), initiation of any and exclusive breastfeeding (7, 10-13), reduction of maternal morbidity and perinatal mortality (14), and the uptake and completion of childhood immunizations (7, 15). In the US, CHW home visiting interventions are associated with decreased incidence of preterm birth (9, 16-18) and low birthweight (9, 16-22), and increases in up-to-date immunizations among newborns and toddlers (23)**.** CHWs share the language, socioeconomic status, and life experiences of their clients, making them a fundamental asset to reducing health inequalities among disenfranchised groups (24). Moreover, CHWs are recognized as integral contributors in collaborative health- and community-based teams by improving comprehensive care and addressing the social determinants of health that contribute to health improvements and cost savings (25, 26).

Arizona launched the first iteration of the Health Start Program (HSP) in 1984, when Arizona ranked among the lowest five states for the number of women receiving any or adequate prenatal care (27). HSP is a statewide program that employs CHWs to engage at-risk, low income, and racially and ethnically diverse mothers and improve maternal and child outcomes. HSP has been managed by the Arizona Department of Health Services (ADHS), Bureau of Women's and Children's Health since 1992 (28). In 1994, the Arizona State Legislature passed the Arizona Children and Families Stability Act, A.R.S. § 36-697, which formalized and expanded HSP and articulated the purpose, requirements, and administration of the program. HSP is a community-based outreach program that identifies, screens, and enrolls pregnant women early in their pregnancies and assists them with obtaining early and consistent prenatal care. The program also provides prenatal and postpartum education, information and referral services, client advocacy, and emphasizes timely immunizations and developmental assessments for their children. Since its inception, Arizona Health Start Program's mission has been "*to educate, support and advocate for families at risk by promoting optimal use of community-based family health care services and education services through the use of community health workers (CHWs) who live in and reflect the ethnic, cultural and socioeconomic characteristics of the community they serve."* (28)

Study Setting

Arizona is the sixth largest state in the nation, with a population of 6.8 million people. The state shares an international border with Mexico and is home to 21 federally recognized American Indian Tribes and Nations, making it uniquely racially and ethnically diverse. Arizona has a higher proportion of Latino

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(30.9%) and American Indian (5%) residents compared to the nation (17.8% and 1%, respectively) and a comparatively smaller proportion of African American residents (5% compared to 13% nationally) (29).

In 2015, nearly a quarter of the population lived in rural areas, where the poverty rate reached 30%, almost double that of the national poverty rate (29). Approximately 20% of Arizona families with children live below the federal poverty line, compared to 18% nationally. Poverty disparately affects Arizona's Latino (36%) and American Indian (46%) families and children (29). Arizona ranks as the fifth highest US state for adult female poverty rate in the country, with more than one quarter of Arizona families headed by single-mother households (29). The initial framework for the HSP was developed in the 1980s and 1990s to address the social determinants associated with the steady decrease in the rate of women receiving prenatal care. In the most recent Arizona Title V Maternal and Child Health Needs Assessment (2017), approximately 74% of pregnant women initiated prenatal care in the first trimester (compared to 61% in 2015 and 81% in 2013), and 7.9% had no prenatal care (29). There were disparities among mothers by race/ethnicity who received prenatal care, notably American Indian mothers having the highest rates of 'inadequate' prenatal care (25%) compared to all women in Arizona (15%) (29).

It is widely recognized that late prenatal care is associated with preterm birth, low birthweight, and infant mortality. In 2014, 9% of babies born in Arizona were premature and 7.2% were low birthweight (29). Historically, low-income mothers have experienced higher rates of premature birth and low birthweight in Arizona (30) and nationally (31). There are also apparent racial disparities for birth outcomes in Arizona. Preterm birth rates are highest among Black (12.2%), American Indian (9.4%), and Latino (9.2%) compared to all preterm births (9.1%) in the state. Preterm births increase the risk of low birthweight; similar trends persist with the highest rates of low birthweight among Black residents (10.32%) compared to White residents (5.36%) and the total Arizona population (7.2%) (29). Preterm and low birthweight baby delivery costs have been shown to be 25 times more than uncomplicated newborn deliveries (32). Although prenatal care and birth outcomes in Arizona have improved over the years, many under-resourced women continue to experience significant challenges and barriers to obtaining health care services.

Objectives

Our goal is to describe the research protocol for a retrospective comparative evaluation to assess the impact of Arizona's Health Start Program, a CHW home visiting perinatal support program, on multiple maternal, infant, and child health outcomes. Broadly, the goal for the study is to meet the federal Home Visiting Evidence of Effectiveness (HomVEE) standard for evidence-based effectiveness. We will use a matched comparison group design that meets the published standard for HomVEE's 'Moderate' rating, defined by HomVEE as: "1) baseline equivalence established on tested outcomes and demographic characteristics and controls for baseline measures of tested outcomes, if applicable; and 2) no confounding factors; must have at least 2 participants in each study arm and no systematic differences in data collection methods". (Note: a 'High' rating is reserved for randomized controlled trials) (33).

Aims

We plan to objectively test our central hypothesis that mothers and children exposed to HSP during the study period of 2006 to 2015 will experience positive health outcomes in the areas of newborn, maternal, and child health (Table 1). Specifically, our aims include:

- Aim 1: Assess the impact of HSP on newborn health
- Aim 2: Assess the impact of HSP on maternal health and care utilization

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- Aim 3: Assess the impact of HSP on early child health and development

Methods: Intervention, Participants, & Outcomes

Health Start Program Intervention

HSP is significant in that it is one of the longest-standing programs in Arizona and employs CHWs in 14 distinct Arizona counties to engage at-risk, low-income mothers in order to improve birth outcomes (Figure 1). CHWs serve as the primary interventionist for the program. In 2016, HSP CHWs provided services to 2,534 unduplicated clients, conducted 16,698 home visits, and facilitated 461 classes (28). Women are eligible to enroll in HSP if they 1) live in the targeted service area, 2) are pregnant or postpartum with a child under age two, and 3) have one or more social or medical risk factors. Social risks can include but are not limited to: single-parent status, underserved racial or ethnic group, education equal to or less than high school level, annual income less than $40,000, and Medicaid or no insurance. Medical risks are broad and can include previous preterm birth, low birthweight, chronic disease, high maternal BMI, and substance use. Women can be of any age and there are no income requirements to participate.

CHWs connect clients to prenatal care and increase client's continuity of care during and after pregnancy. CHWs identify, screen, and enroll eligible women; provide prenatal and postpartum education; provide referral and advocacy services; and emphasize timely immunizations and developmental assessments for children. Although not an exhaustive list, Table 1 outlines the primary intervention activities conducted by the CHW. HSP CHW home visits are guided by an asset-based approach and two primary theories of behavior change, the Trans Theoretical Model and the Social Cognitive Theory. Identifying assets acknowledges and supports the existing strengths and capabilities of individuals and resources to promote community-driven development and positive change (34). The Trans Theoretical Model assumes that behavior modification in individuals is a multistage process in which people move through stages of readiness for change (35), and Social Cognitive Theory states that stages occur in the context of reciprocal relationships between the person's environment, their behavior, and their cognition (36). CHWs are a community asset and well positioned to support HSP clients; they share both lived experiences and cultural knowledge of the community they serve. The home visiting sessions promote behavior change through assessment, goal planning, referral, advocacy, and follow up activities, coupled with education through meaningful adult learning models. These interactions are designed to encourage personal agency of adult learners to integrate new knowledge and create a cognitive structure that makes sense of their own surroundings and situations (37). Through behavior change theories and adult learning models, the Health Start Program CHWs privilege the co-construction of knowledge among all participants, assume all are co-learners, and encourage critical thinking about self-sufficiency, empowerment, and personal agency related to the five HSP goals (Table 1).

Health Start Program CHW Core Competencies, Roles, & Training

According to the HSP policy and procedure manual, CHWs must 1) live and work in the service area, 2) reflect the ethnic, cultural and socioeconomic characteristics of the communities they serve, 3) be able to read and write in English, 4) have a high school diploma or General Educational Development, and 5) pass a criminal history background check within the Department of Public Safety records to be eligible to work for the state-funded program. It is highly recommended (though not required) that CHWs have

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post high school training and education in maternal and child health, early childhood development education, family studies, social work, nursing or a closely related field (28). Before a CHW can initiate unsupervised outreach or home visits, they must complete 40 hours of training in both the *10 CHW Core Competencies* set forth by the CHW Core Consensus Project (38), which are recognized by the Arizona state legislature HB 2324 Voluntary CHW Certification (39), and the *Health Start Program Core Training* (28). An additional 8 hours of home visit shadowing with a senior CHW are required.

Nationally recognized, the *10 CHW Core Competencies* include: 1) Cultural and Systems Mediation; 2) Culturally Appropriate Health Education; 3) Care Coordination and Case Management; 4) Coaching and Social Support; 5) Advocacy; 6) Capacity Building; 7) Direct Service; 8) Individual and Community Assessments; 9) Outreach; and 10) Research and Evaluation (38). *HSP Core Training* covers: 1) Essential Health Start Information (HSP basics, visits, and community outreach); 2) Communication and Emotional Support; 3) Nutrition and Physical Activity (family nutrition and physical activity, infant nutrition and physical activity); 4) Health Education (healthy pregnancy, prenatal care, discomforts during pregnancy, labor and delivery, postpartum care and family planning, early childhood development and parenting skills, infant health and child health); and 5) Safety (home safety for infants and children, child abuse and domestic violence) (28). CHWs are required to complete 12 hours of continuing education per year.

Intervention Cohort

HSP administrative data from 2006 to 2015 is the primary source for identifying the retrospective intervention group. All Health Start clients enrolled during the 10-year observation period will be included in this study if their records are identified and linked from the HSP database to the vital records birth database (VRBD). Records will be linked based on the mother's date of birth and first name. In order to be a candidate for the HSP study cohort, the mother's date of birth must be an exact match while her first name must be at least 95% similar, using Jaro-Winkler (JW) similarity (40). Mother's last name may change due to marriage; therefore, this criterion is not required to identify the intervention cohort. We will obtain the following information for each HSP study cohort mother: a unique ID, first name similarity percentage, last name similarity percentage, HSP enrollment date, program closure information (i.e. program completion, reason for closure), and the child's birthdate. Using the process described above, 15,576 HSP records were linked to the VRBD.

Intervention Cohort Sample Size

Our evaluation intervention group will include all HSP participants enrolled within 24 months of the date of birth of the child during 2006-2015. Of the initial 15,576 records identified through the HSP-to-VRBD data link, 5,911 fall outside of the 24-month (either before or after) HSP enrollment window and will be excluded from all subsequent analyses. The resulting 9,665 HSP-associated births constitute the basis of this study (Figure 2). Because HSP participants can enroll before or after birth, we will limit the analysis for Aims 1 and 2 (newborn and maternal health outcomes) to those births for which the mother was enrolled during pregnancy. This final criterion results in 6,493 HSP-attributed births for the evaluation of Aims 1 and 2. Aim 3 (child health outcomes) will be evaluated using the larger set of 9,665 HSP-associated births.

Synthetic Comparison Group

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A comparison group of women not exposed to the Health Start Program (non-HSP) will be created from all births occurring in Arizona during 2006-2015 (derived from VRBD). After identifying our study population we will use propensity score matching (PSM) to generate a statistically-similar synthetic control group that has, on average, the same observable pre-program characteristics as the HSP mothers (41). The pool of potential comparators will come from all Arizona births that occurred over the study period (2006-2015). This process will be guided by HomVEE standards requiring that the covariates used to balance the treatment and control groups be associated with both treatment status and the outcomes of interest (42). Because the HSP eligibility criteria focus on social and medical risks, we will prioritize these types of measures in the PSM model, in addition to characteristics that have been shown to have strong associations with our outcomes of interest in previous empirical and theoretical work.

We will employ radius matching to identify comparison group mothers across the common support region (43). We will use the following measures in the PSM model: mother's birth year, mother's age at birth, county of residence. Additional indicator variables include: child's birth order, maternal educational attainment, health insurance payer (Medicaid being a proxy for low-income status), race, ethnicity, availability of information for the father on the birth certificate, maternal country of birth, previous history of hypertension, and median household income by zip code of residence. In addition to these demographic and socioeconomic characteristics, we will restrict potential comparators to mothers within the same fiscal years in order to account for economic conditions and any potentially shifting program parameters. Imposing within-year matches will allow us to analyze the program's efficacy over time by cohort.

Comparison mothers may match to more than one HSP mother, based on the propensity score. Preliminary efforts to identify matches resulted in a potential synthetic comparison group of nearly 23,000 non-HSP mothers. Due to the respective sizes of the intervention and comparison populations, lack of statistical power is not a significant issue for this project.

Patient & Public Involvement

Patients and the public were not involved in the design or planning of the study.

Outcomes

Primary Outcomes

HSP is a primary prevention intervention to improve maternal and child health outcomes among at-risk, racially and ethnically diverse, rural and urban mothers and children of Arizona. We will use four Arizona Department of Health Services administrative datasets to evaluate Aims 1-3 including Health Start programmatic data, Vital Records Birth Data, Hospital Discharge Data, and Arizona State Immunization Information System data. Aim 1 (HSP impact on newborn health) will be measured by preterm birth, birthweight, and newborn hospital length of stay and associated charges. Aim 2 (HSP impact on maternal health) will be measured by prenatal care initiation and frequency, method of delivery, maternal morbidities, and inter-pregnancy intervals. Aim 3 (HSP impact on child health) will be measured by uptake of age-appropriate immunizations, and emergency room and inpatient encounters and charges (Table 2).

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Methods: Data Management, Monitoring, & Statistical Analysis

Data Management

The four datasets that will be accessed for this study will be securely stored and protected through an honest broker. We designated the Center for Biomedical Informatics and Biostatistics' Biomedical Informatics Services at the University of Arizona as the honest broker to facilitate the de-identification, transfer, and management of data, as well as maintain protected health information anonymization and HIPAA-compliance. In this role, the honest broker can identify individuals overlapping between relevant databases, and assign de-identified study codes that would enable cross-linking individuals between the systems.

Data Monitoring

The honest brokers will link the HSP database to the Vital Records Birth Data (VRBD) to generate a comparison group. They will match both the HSP and non-HSP groups to Hospital Discharge Data (HDD) and the Arizona State Immunization Information System (ASIIS) databases using personally identifiable information (e.g., name, DOB, social security number). The honest brokers will create a separate de-identified "limited data set" for our analyses to compare the mean outcomes of Health Start Program mothers to the comparison group mothers.

Statistical Analysis

The motivation for using PSM to create a synthetic comparison group is to be able to "observe" the "counterfactual" to HSP participation, that is, what would have happened in the absence of the program. We will explore this by comparing outcomes between HSP mothers and those "matched" to them by the propensity score. More specifically, the average treatment effect (ATE) generated by PSM will estimate the impact of the program on the population of both HSP mothers and those who "look like" HSP mothers by taking the difference in outcomes between HSP mothers and their matches, and vice-versa.

Our analytic population is of sufficient size to detect meaningful program effects from low-frequency events, including preterm births, low and very low birthweights, maternal morbidity, and differences in immunization and hospitalization rates over a relatively long period. This is also true for specific subgroups served by HSP (e.g. Hispanics, Native Americans, economically disadvantaged).

Once we establish proper covariate balance between the intervention and matched-control groups, point estimates of the treatment effects will be estimated by comparing outcomes using Stata version 14 software and specifically the *teffects* command (44). Following Abadie and Imbens (45, 46), this command considers the fact that propensity scores (i.e. the parameter that determines the comparison population) are estimated when calculating the standard errors, and thus generates confidence intervals. The propensity scores will not be used as a covariate in traditional regression analysis because it is less effective in forcing baseline equivalence and assumes the relationship between the score and the outcome is linear (41).

Both the HSP enrollment information and VRBD are administrative data sources, established and maintained for public health monitoring purposes. As such, we do not anticipate missing data to be a significant issue. We assume that such instances (as we find them) are very likely to be the result of human error and not any systematic issues with the data collection and/or reporting processes. Where

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missing-ness does occur in the variables that make up the propensity score model, we will control for these using dummy variables in place of the missing observations. In the case of missing outcome variables, we will restrict the analytic sample to the non-missing observations, and inspect to control variables to verify that there are no systematic differences.

Discussion

Our evaluation will build upon a previous evaluation of HSP conducted by Hussaini et al (2011), which found that HSP participation was associated with a reduction in the likelihood of a low birthweight outcome (21).

The Hussaini study used data from 2007 and compared 484 HSP enrollees to almost 5,000 non-HSP women; our study compares 9,665 HSP enrollees to approximately 23,000 non-HSP women spanning 10 years of service. Based on observed covariates, the Hussaini study matching process did not result in baseline equivalence across the two groups. For example, the comparison group was on average four years older (28.2 vs. 24.3) than the HSP mothers. Additionally, Hussaini et al matched to comparison mothers on *ex post* medical risks, which likely created a bias in favor of finding a positive HSP effect. Our propensity score matching (PSM) model will generate a comparison group that achieves baseline equivalence of observed covariates. Additionally, we explicitly match on socioeconomic status variables as required by the HomVEE-published standard for matched comparison group design studies (33). Specifically, we match on two individual measures of socioeconomic status (SES): maternal education and indicators for primary payer for the birth procedure. While these variables satisfy HomVEE's documented standard for measuring socioeconomic status for Group Design studies with a 'Moderate' rating, we also utilize the maternal zip code of residence to include a measure of mean household income. Finally, we will build on the scope of the original study in two significant ways: 1) by expanding the number of the outcomes considered, including maternal and child outcomes over time, and 2) by performing a number of sub-group analyses that investigate program impacts based on when in the course of the pregnancy the HSP intervention began, mother's country of origin, and maternal age (i.e. teen mothers).

Limitations

The primary limitation is the identifying assumption that selection into the HSP is driven by observable characteristics. This is a limitation common to most PSM analyses. Attenuation bias is a possibility if HSP mothers are incorrectly identified and linked to state birth certificate data. However, the effect of this would be to underestimate (in absolute value) the magnitude of the resulting coefficients, meaning the true effect is likely to be larger (*ceteris paribus*). In addition, the analysis may have limited external validity for populations who differ along socioeconomic status, race, and ethnicity.

Ethics & Dissemination

Consent & Confidentiality

Data will be collected by the Arizona Department of Health Services for surveillance and monitoring. The University of Arizona Research Institutional Review Board (Protocol 1701128802) approved a waiver of informed consent. Protocol complies with the University of Arizona Biomedical Informatics Service group information security policies including, Information Security Policy (IS-100), Computer and

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Network Access Agreement (IS-700), Acceptable Use of Computers Policy (IS-701), Electronic Privacy Statement Policy (IS-1000), Data Classification and Handling Standard (IS-2321) (47).

Dissemination

On completion of the study, we will initiate major dissemination strategies, including (1) peer-reviewed publications in targeted journals; (2) scholarly presentations at scientific conferences and public health governance meetings; (3) interactive web-based promotional and training materials and (4) strategic informational and planning meetings. In collaboration with Arizona Department of Health Services, we aim to submit published journal articles to Mathematica Policy Research for consideration of the Health Start Program as a HomVEE evidence-based practice home visiting model. We will identify local and national forums for dissemination of preliminary results. Findings will be shared with ADHS leadership, Arizona Health Care Cost Containment System (Arizona Medicaid), Arizona Public Health Association (AzPHA), American Public Health Association (APHA), MCH-specific conferences and professional forums, the Arizona Association of Federally Qualified Community Health Centers, Association of Health Plans, CHW workforce coalitions, and Maternal, Infant, and Early Childhood Home Visiting (MIECHV).

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Figures and Tables Legend

Table 1. Health Start Program goals, CHW activities (non-exhaustive), predicted client actions, study aims, and measurable outcomes. Five (5) maternal and child health goals guide the Arizona Health Start Program CHW activities to support at-risk pregnant and postpartum women and families with children up to age two. CHWs provide support and services to meet the individual needs of their clients during home visiting sessions that promote self-sufficiency, empowerment, positive health change, and improved health outcomes. Our three study aims align with the HSP goals, which we will analyze via the listed outcomes.

Figure 1. Arizona Health Start Program service area map, 2018. Map demonstrates the Arizona Health Start Program service areas within 14 counties across the state. CHWs conduct regular home visits to underrepresented pregnant women and their families in rural and urban communities. Map courtesy of and permission by Arizona Health Start Program, Arizona Department of Health Services. This map is not under copyright.

Figure 2: Flow chart of intervention participant inclusion and exclusion criteria. 9,665 Health Start Program births constitute the basis of this study. 15,576 records were initially identified as Health Start Program matches; however, 5,911 records were excluded because the child's birth fell outside of the 24-month (either before or after) enrollment window. We evaluate Aims 1 & 2 with a subgroup: records for mothers enrolled in HSP prior to the child's birth (6,493 births). We evaluate Aim 3 using the larger set of 9,665 HSP-associated births.

Table 2. Data sources and outcome measures by study aim. Our retrospective, propensity score-matched observational study pulls data from four (4) sources: Health Start Programmatic Data, Vital Records Birth Data, Hospital Discharge Data, and Arizona State Immunization Information System. Data were confined to 2006 to 2015, and serve to evaluate maternal and child health outcomes among at-risk, racially and ethnically diverse, rural and urban mothers and children of Arizona.

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Table 1. Description of Health Start Program goals, CHW activities (non-exhaustive), predicted client actions, study aims, and measurable outcomes				
Program Goals	**CHW Input**	**Process Indicator**	**Evaluation Aims**	**Measurable Outcomes**
1. Reduce the incidence of very low birthweight babies.	• Prenatal home visits. Education on pregnancy, labor, delivery, nutrition, inter-conception. • Screening, education, and assistance for mood and anxiety disorders, substance cessation, and domestic violence.	• Increased knowledge of and engagement in pregnancy process and activities to promote a healthy pregnancy. Increase knowledge of available services, completed assistant referrals, increased access to services.	Aim 1: Assess the impact of the HSP on newborn health	• Preterm birth (gestational age) • Birthweight (birthweight, low birthweight <2500 grams, very low birthweight <1500 grams, and small size for gestational age) • Newborn hospital length of stay and 30-day hospital charges
2. Increase prenatal services to pregnant women.	• Perinatal home visits. Assistance with access and enrollment to continuous perinatal care. • Education on pregnancy, labor, delivery, inter-conception.	• Initiate prenatal care earlier in pregnancy and attend more prenatal care visits. • Increased knowledge of and engagement in pregnancy process, delivery options, and activities to promote a healthy pregnancy.	Aim 2: Assess the impact of the HSP on maternal health and care utilization	• Month prenatal care initiated • Total number of prenatal visits • Method of delivery (e.g. first-time Cesarean delivery) • Maternal morbidity (e.g. uterine rupture) • Inter-pregnancy intervals
3. Reduce the incidence of children affected by childhood diseases. **4.** Increase the number of children receiving age appropriate immunizations	• Perinatal home visits. Screening, education, and assistance with child wellbeing services.	• Timely completion of all immunizations for children.	Aim 3: Assess the impact of the HSP on child health and development	• Probability of a child being on schedule for immunizations • Utilization of Emergency Room (ER) visits and Inpatient (IP) stays at ages 1, 3, and 5 • Any charges associated with ER and IP utilization

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by two (2) years of age.				
5. Increase awareness by educating families on the importance of good nutritional habits, developmental assessments, and preventative health care.	Not evaluated by this study	Not evaluated by this study	Not evaluated by this study	N/A

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Table 2. Data sources and outcome measures by study aim		
Data Source (Years)	**Outcome Measures**	**Aim**
Health Start Program Data (2006-2015)	• Intervention enrollment • Month prenatal care began • Total number of prenatal visits	1, 2, 3
Vital Records Birth Data (2006-2015)	• Preterm birth (gestational age) • Birthweight (birthweight, low birthweight <2500 grams, very low birthweight <1500 grams, and small size for gestational age) • Month prenatal care began • Total number of prenatal visits • Method of delivery (first-time Cesarean delivery) • Maternal morbidity (e.g. uterine rupture) • Inter-pregnancy intervals	1 & 2
Hospital Discharge Data (2006-2015)	• Newborn hospital length of stay and 30-day hospital charges • Utilization of Emergency Room (ER) visits and In Patient (IP) stays at ages 1, 3, and 5 • Any charges associated with ER and IP utilization	1 & 3
Arizona State Immunization Information System (2006-2015)	• Probability of a child being on schedule for immunizations	3

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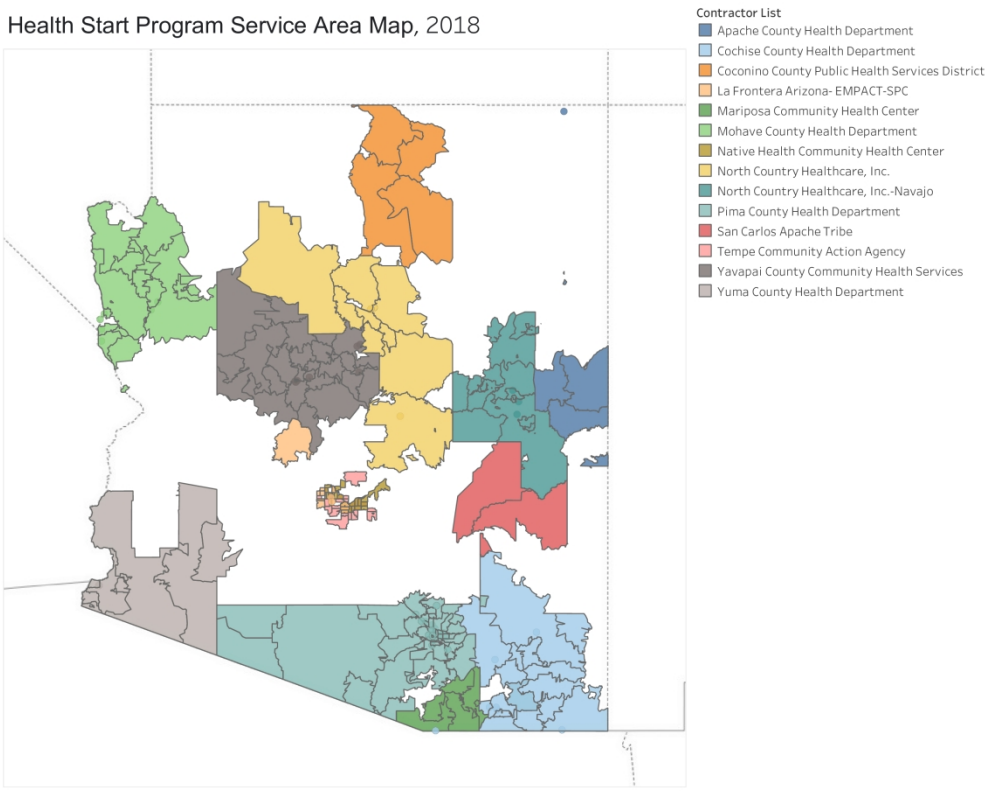

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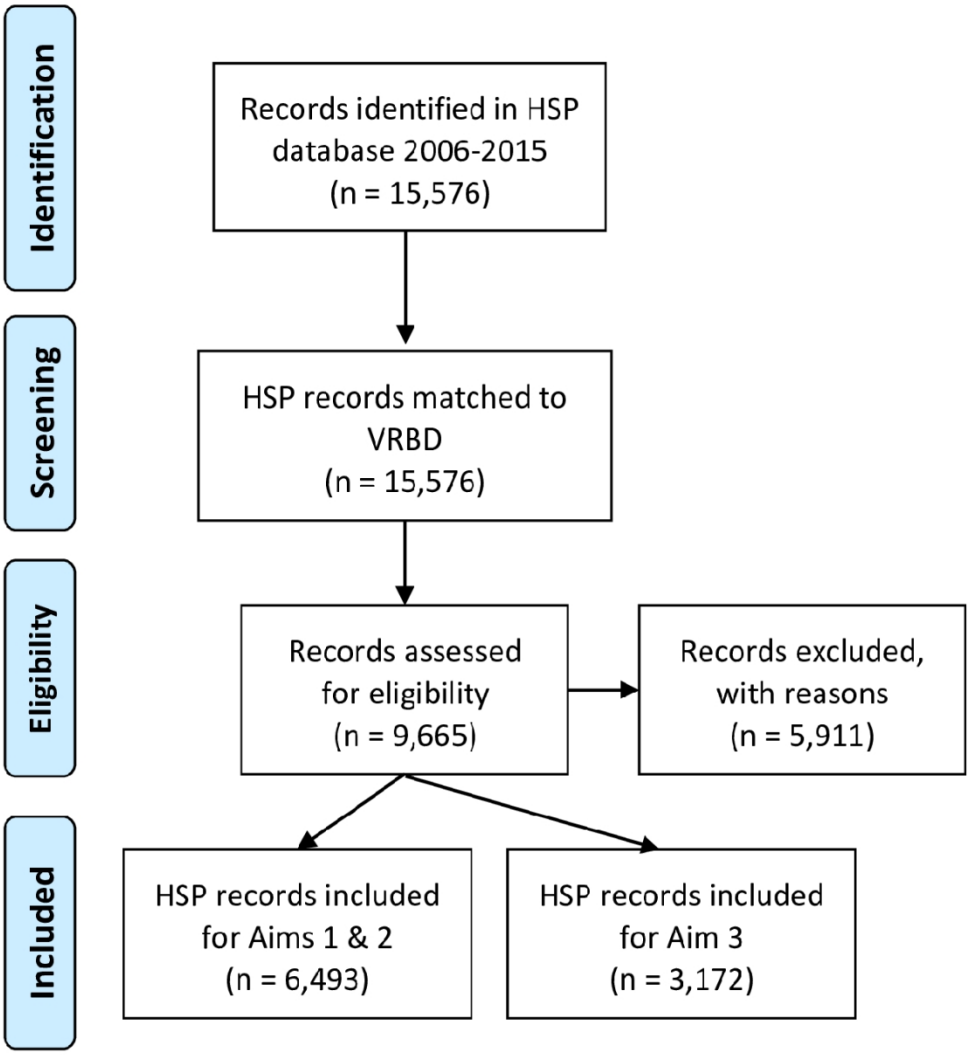

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