

What Works to Save Babies' Lives? Reviews of Interventions to Reduce Mortality among African American and Rural Community Infants

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This draft is presented in one document with two parts. The first section focuses on African American infants, complete with all references. The second section focuses on rural infants, complete with all references.

The following reviews of literature have been completed for the Maryland Health Care Commission, pursuant to legislation (2018 Md. Laws, Chap. 83), requiring the Commission to conduct a study of infant mortality rates for African American infants and infants in rural area, which includes “thorough literature reviews on innovative and effective programs to reduce infant mortality with a specific focus on programs targeting rural and African American infants, and the use of pregnancy navigators and community health workers.” The reviews that follow address the first two of these three subjects, while some of the reviewed studies do involve care coordinators and community health workers.

The reviews of interventions to address African American infant mortality and rural infant mortality are presented here sequentially. This document includes four sections: (I) the introduction/background; (II) methods/procedures; (III) a thorough review of programs that target African American infant mortality; (IV) a thorough review of programs that target rural infant mortality. The end of the third and fourth sections each contain a brief summary of our findings. Sections I and II apply to both reviews, as we used the same approach and methods for both reviews.

I. Background

The United States continues to experience higher rates of infant mortality –babies born alive who die before their first birthday – than any other developed country in the world. This statistical reality persists despite the country’s wealth and world-leading health care systems. For example, the U.S. infant mortality rate in 2018 was an estimated 78% more than that of France (5.7 per thousand infants vs. 3.2 per thousand infants).¹ The country’s current infant mortality

rate is only the 55th best in the world, ranking between that of the United Arab Emirates and Serbia.²

It would be a good guess to assume that a few states with unusually high poverty rates are responsible for most of this gap. But the truth is more complicated. While Mississippi *does* have one of the highest percentages of people living in poverty among all states (19.5% between 2015 and 2017) and the highest infant mortality rate (8.6/1000 in 2017), other states with comparable proportions of residents living in poverty have infant mortality rates at about the national average. For example, in New Mexico, 18.7% of the population lived in poverty between 2015 and 2017, but the state's infant mortality rate of 5.9/1,000 live births in 2017 was very close to the national average. Similarly, California had a relatively high percentage of its population living in poverty (13.4 percent compared to the national average of 12.8 percent) and had the third lowest infant mortality rate in the country (4.2/1,000 live births) in 2017. These figures illustrate what researchers have long known, on a global level: poverty alone cannot explain infant mortality rates.³

Maryland's situation perhaps most clearly exemplifies this complicated reality. The state has one of the lowest percentages of the population living in poverty among all the states (8.2% between 2015 and 2017 – second only to New Hampshire). And yet the state had the 17th *worst* infant mortality rate in 2017 (and had the 15th worst in 2016). Translated into raw numbers, this meant that 460 babies born alive in Maryland in 2017 died before turning one, and 480 died in 2016. Considering that each child likely has multiple family members, such deaths have affected thousands of Marylanders. If Maryland had achieved the infant mortality rates of Japan or Slovenia (countries with some of the lowest infant mortality rates in the world), 651 Maryland babies' lives could have been saved in these two years alone.⁴ The state's high infant mortality

rate is all the more surprising given that Maryland is home to many of the nation's leading medical and public health research and clinical institutions, including the National Institutes of Health, Johns Hopkins University, the University of Maryland, and Uniformed Services University of the Health Sciences (USIS).

In Maryland, as in many other states, the African American infant mortality rate remains more than two times the white infant mortality rate, and is substantially higher than the Hispanic infant mortality rate.⁵ Genetic differences between blacks and whites, once thought to underlie these differences, have been ruled out as a cause.⁶ Studies that have compared infant mortality rates among foreign-born black women and those born in the U.S. found that the foreign-born black women had much lower rates of infant mortality than U.S. born black women. In other words, African American mothers are not losing babies at higher rates because of some inherited African genetic difference, but rather from factors in their social and physical environment that resulted from their being born and growing up Black in the U.S.⁷ Researchers have hypothesized that these factors include the stresses of racism, which may even be passed down from generation to generation through epigenetics – changes in the way that DNA is folded and activated.⁸

Rural populations are also disproportionately affected by infant mortality. On a national level, infant mortality in rural counties in 2015 was 25% higher than in large urban counties. These data on rural vs. urban infant mortalities is not broken down by state. But a recent analysis indicates that this disparity has persisted across time, as similar disparity had existed in 2007.⁹

Which interventions can best address these disparities in infant mortality? Prenatal care would seem like the most obvious place to intervene. In the 1980s, when health and political

leaders first realized that U.S. infant mortality rates were the worst in the developed world despite our leadership in medical advances, the U.S. began coordinated efforts to expand prenatal care. This “prenatal care revolution,” led to a dramatic increase in the proportion of U.S. women receiving prenatal care, and to a focus on making sure as many women as possible receive early prenatal care, in their first 12 weeks of pregnancy.¹⁰ Prenatal home visiting programs for mothers deemed at high risk became a focus of this effort, partly due to comparisons between the reproductive health care systems of the U.S. and other countries with lower infant mortality rates. A 1998 review article by the American Academy of Pediatrics, explained:

In most countries, home health visiting is free, voluntary, not income-related, and embedded in comprehensive maternal and child health systems. Although a causative link has not been demonstrated conclusively, countries with extensive home visitor programs generally have lower infant mortality than does the United States.¹¹

This AAP article cited Denmark as the pioneer country, having instituted universal home visiting in 1937, while the United Kingdom and France both instituted home visiting programs by trained nurses or midwives. The U.K program involves follow-up visits until the child is five years old, and the French model includes both prenatal care and education on nutrition and avoidance of smoking and substance use, as well as referrals to social services including housing.¹¹ However, in the U.S., this universal approach has been viewed as prohibitively expensive and unnecessary for women who have access to physicians through private insurance, so a more focused effort on extending home visiting to the most high-risk, low income women has been pursued.

Healthy Start, a federally funded program of grants for local and state programs begun in 1991 by the Maternal and Child Health Bureau of the U.S. Health Resources Administration (MCHB), is the capstone of efforts to expand prenatal care and home visiting.¹² The program, which originally involved 15 urban and rural demonstration projects in areas with infant mortality rates between 1.5 and 2.5 times the national average, aimed primarily to reduce infant mortality by 50% in these communities within four years. A national evaluation of the original 15 Healthy Start programs, published in 2000, found that rates of low birthweight (LBW) and very low birthweight (VLBW), pre-term birth (PTB) were significantly reduced in numerous Healthy Start program sites, but not in the majority; and that access to prenatal care significantly improved in the majority of sites.¹³ The programs also succeeded in developing effective case management, but experienced significant challenges in timely implementation and community involvement.¹³ Even though the original goal of substantially decreasing infant mortality was not met, the program became recognized as “an integral, though often unrecognized, part of the nation’s health care safety net.”¹⁴ Currently, over 100 federally funded Healthy Start programs exist in 37 states, targeting women in low-income areas with the highest infant mortality rates. Most provide monthly home visits by a nurse or community health workers, prenatal and postpartum health education, as well as case management including referrals to other service providers.¹⁵

Since the 1980s, the percentage of U.S. women receiving prenatal care has sharply increased. In fact, in 2016, a thorough analysis conducted by the U.S. Centers for Disease Control and Prevention, which included all births in 50 states and the District of Columbia, found that 98.4% of women in the U.S. received *some* prenatal care, and that 77.1% received early prenatal care (prenatal care in the first three months of pregnancy).¹⁶ While it is impossible

to compare these figures precisely to earlier incomplete data, the overall trend is clear: a greater proportion of women in the U.S. than ever before are receiving early prenatal care—and the U.S. is on track to meet the Healthy People 2020 goal of 77.9% of all pregnant women receiving early prenatal care.^{16,17}

However, there remains plenty of room for improvement in access to *adequate* prenatal care, particularly among African Americans and other groups. Overall, 75.6 % of U.S. women received adequate prenatal care in 2016, defined as prenatal care begun by the fourth month of pregnancy and including at least 80% of the recommended number of visits, but only 66.4% of black women received this adequate care. In Maryland overall, only 68.2% of women received adequate prenatal care – 10% lower than the national average, and only 72.0% began care in the first trimester – also below the national average.¹⁶ Specific percentages are not known for African American and rural women in Maryland; however, fewer African American women than white women in the U.S. overall received adequate prenatal care (66.4% vs 80.5%) or care beginning in first-trimester (66.5% vs. 82.3%), so such a racial gap in prenatal care would be expected in Maryland as well.¹⁶ There is less information on the rural-urban gap, although rates of first-trimester initiation of prenatal care have historically been lower for rural than urban women due to limited access to prenatal care in rural areas.¹⁸

Meanwhile, over the past two decades, experts have increasingly emphasized that it is necessary to reach women before they become pregnant in order to continue to improve infant mortality rates. For many women “early prenatal care is too late,” the March of Dimes declared in a 2002 publication.¹⁹ Researchers supporting this new, wider focus, explained: “By the time a pregnant woman makes it to her first early prenatal visit, most fetal organs are already formed, and many interventions to prevent birth defects or adverse maternal and infant outcomes come

too late to have any effect.”¹⁰ In preconception visits, a woman and her health care provider can address her chronic health conditions that may put her and the infant at heightened risk of mortality, such as diabetes, high blood pressure, or asthma; as well as infectious diseases such as HIV and other sexually transmitted infections (STIs); the woman’s current use of medications that could harm a developing fetus; behavioral health factors such as eating patterns and obesity, substance use, and smoking; and her own reproductive health concerns related to planning pregnancy and birth outcomes. Some Healthy Start programs, once only involved in providing prenatal and immediate postnatal care, have expanded to the preconception or inter conception (between pregnancies) period. At a national level, Healthy Start now lists, as its first strategic approach, to “improve women’s health before, during, and after pregnancy,” and seeks to assess families’ needs comprehensively, including their physical and behavioral health, their employment and housing status, and their domestic violence risks, as well as other factors. The program has also aimed to strengthen local health systems and community participation, with mixed success.^{12,15} In 2012, Harvard Maternal and Child Health expert Milton Kotelchuck, a key proponent of these improvements to Healthy Start, also noted in a presentation, “Healthy Start continues to lack a strong science base and an over-riding strategic conceptual framework.”¹² Kotelchuk has proposed rigorous evaluation and improvement of Healthy Start programs, but he and others also acknowledge that these programs at their current funding levels are not sufficient to address heightened levels of infant mortality.²⁰

In recent years, public health innovators at the state and local levels have been experimenting with many alternative approaches to intervention. In this two-part review, we examine the published literature that scientifically evaluates the effectiveness of programmatic interventions to reduce infant mortality in 1) African American, and 2) rural community infants

in the U.S. We consider literature that reviews Healthy Start and other home visiting programs, as well as other clinical, behavioral, community-based, and technology-intensive programs. We include programs that aim to improve key antecedents of infant mortality, as well as behaviors associated with infant mortality, along with those that directly measure their impact on infant mortality itself.

II. What We Did and How We Did It (Methods and Procedures)

In these literature reviews, we followed a systematic approach to identify published evaluations of interventions addressing infant mortality among African Americans and rural Americans. We developed a structured process of identifying, selecting and reviewing articles in consultation with the University of Maryland's Public Health librarian. This process was informed by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Our process allowed for rapid identification of intervention approaches that have been implemented in the United States, and evidence of effectiveness and scalability.

Given the project's scope and timeframe, we confined our analysis to programs with published evaluations and some evidence regarding their effectiveness, as this information is necessary to determine what programs are useful. We limited the review to the published literature. While this approach may not capture programs reported in the "grey literature" (non peer-reviewed, white papers and presentations produced by non-profits or health departments, for example), and those that have not yet been evaluated, we anticipate that interviews with key informants and other experts in another phase of the larger study will identify promising practices not identified in the literature review.

Additionally, this literature review focuses only on interventions implemented in the United States, as these interventions are most relevant to the project’s long-term goal of providing information to guide recommendations to address infant mortality in Maryland. While evaluated programmatic interventions conducted outside the United States may be thoroughly examined in a future review, the applicability of these interventions will need to be considered in light of important differences between the U.S. and other countries in demography, racial, ethnic, and class histories, health care systems, and political structures. As mentioned in the introduction to this review, many other developed countries have long incorporated universally available clinical and behavioral interventions to address pregnant women and new mothers into their public health care systems, and there may be limited applicability of these approaches to the fragmented, public-private and federalized system that has developed in the U.S.

<p>P Population or Participants Who/what is affected or involved?</p> <ul style="list-style-type: none"> • African Americans/ Black Americans • Rural Americans 	<p>I Intervention(s) or Indicator What is the action? What characteristics are indicated?</p> <ul style="list-style-type: none"> • Program Evaluation • Health Promotion • Community-Based Interventions • Prevention
<p>C Comparison or Control Are there opposing/ alternate actions?</p> <ul style="list-style-type: none"> • Matched controls • Population controls • Randomized controls not assigned intervention • Other 	<p>O Outcome What is the impact? Is there a change in knowledge, behaviour, or condition?</p> <ul style="list-style-type: none"> • Infant Mortality/Death • Preterm Birth
<p>Figure 1. PICO criteria for article inclusion</p>	

The two databases utilized for the article search in these reviews were PubMed and Embase. PubMed is maintained by the National Center for Biotechnology Information (NCBI) at the US National Library of Medicine (NLM) of the National Institutes of Health (NIH), and

contains over 29 million citations relevant to biomedicine and health, including the life sciences and behavioral sciences.²¹ Embase has over 32 million records, including both journal articles and conference abstracts.

Our search strategy followed the PICO framework (Figure 1), identifying the populations, interventions, comparison groups, and outcome of interest. Initial search strings were determined by the PI for this project [Moser Jones] by pre-searching PubMed to identify key search terms. Following an iterative process, search strings were refined by the co-investigator [Shelef], in consultation with both the PI and authors of the complementary review on risk factors for infant mortality. Search strings were developed for PubMed using both key words and MeSH (Medical Subject Headings) terms, and similar strings were used in Embase.

We searched PubMed and Embase for articles published since January 1, 2008, using a combination of Medical Subject Heading (MeSH) terms and Title/Abstract searches to identify articles of interest. Search terms included: “population, rural,” “populations, rural,” “community, rural,” “communities, rural,” “African American(s),” “black(s),” “infant mortality,” “infant death,” “mortality, infant,” “preterm birth,” “birth, preterm,” “program evaluation(s),” “intervention studies,” “intervention,” “prevention,” “health promotion(s),” “community based,” or “program.” A full list of the search strings and results are included as an attachment to this report.

Once the initial searches were completed in PubMed and Embase, we removed articles if they were not in English or not based in the United States. This yielded a total of 410 articles; with duplicates removed 257 articles were eligible for abstract review.

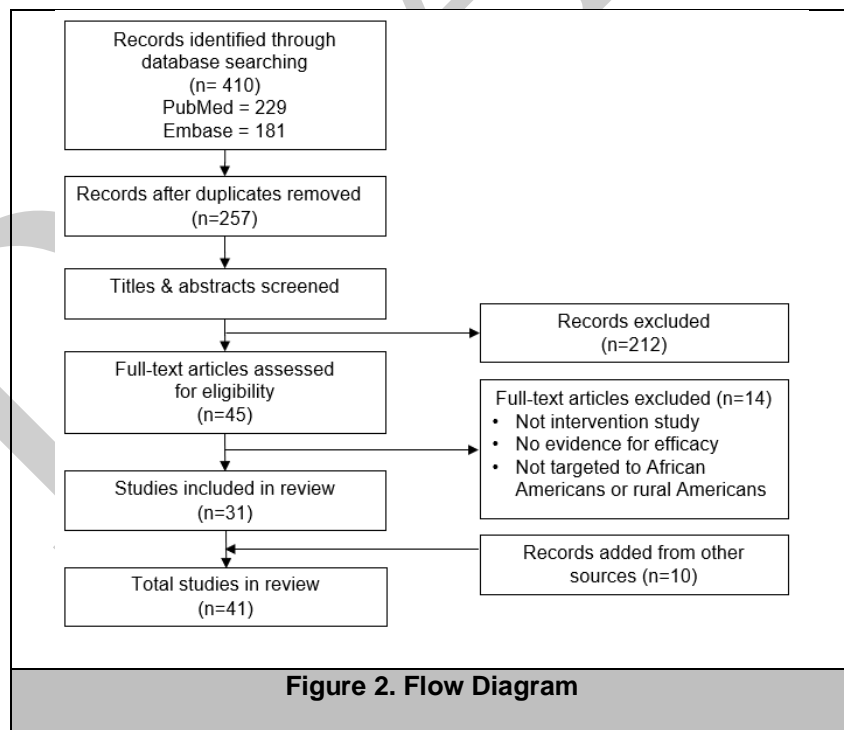
Two reviewers independently applied inclusion and exclusion criteria to the abstracts, identifying which articles would be reviewed in full. This process was conducted in blinded

fashion by two co-investigators [Shelef and Gleason] using Rayyan, a web-based application specifically developed to facilitate systematic reviews.²² In the review for African American infant mortality interventions, articles were selected for inclusion if they provided evidence of a programmatic intervention specifically targeting African American mothers, infants or families. Articles that described interventions but did not provide evidence of evaluations were flagged for further investigation. We followed the same approach with the rural infant mortality review. Studies included by both reviewers were advanced to full-text review. Studies with discordant decisions were discussed and resolved by consensus. A total of 212 articles were excluded at this stage: 179 studies based on the study design (not studies evaluating interventions), 66 for not focusing on the outcome of interest, and 24 for not targeting the populations of interest. In addition, 7 articles were determined to be duplicates. This exclusion process yielded 45 articles for full-text review.

Key information from each of the 45 articles was extracted into a table by two reviewers [Shelef and Katz] following an approach developed together with the principal investigator. Extracted information included the study design, target population(s), funding source, intervention(s), outcomes, and limitations. The principal investigator then reviewed all of the articles in full and excluded 14 articles that did not have evidence for efficacy, did not report on an intervention, or did not provide information on how rural or African American mothers and infants were affected. Articles that did not include direct measurement of infant mortality as an intervention outcome were still included if they measured key antecedents of infant mortality, such as low birthweight (LBW < 2500 grams or <5.5 lbs.), very low birthweight (VLBW < 1500 g or 3lbs. 4 Oz); preterm birth, (PTB < 37 weeks); and very preterm birth (VPTB 28-32 weeks);

or unsafe sleep practices associated with Sudden Infant Death Syndrome (SIDS), suffocation, and other infant sleep deaths.²³ This yielded 31 articles for inclusion in the report.

Additional articles were identified for inclusion in the review from two sources. The reference lists of included articles were reviewed for relevant citations, yielding an additional seven eligible studies. Also, a separate review of the literature on evaluated programs using community health workers to reduce infant mortality among African American and rural infants was conducted by another team member, and three additional articles were identified that met our qualifications for inclusion in this review. The final table of 41 articles is included as an attachment to this report. Some of these articles involved programs that addressed factors related to infant mortality in both African American and rural infants and are analyzed in both literature reviews. Figure 2 illustrates the progression from the initial search strategy to the final selection of articles for inclusion in this review.



III. Interventions to Reduce Infant Mortality among African American Infants

Our search strategies resulted in a final set of 34 recent articles on programmatic interventions that related to improving infant mortality or reducing adverse birth outcomes among African American infants. To analyze the efficacy, efficiency, scalability and feasibility of the interventions described and evaluated in these articles, we categorized them by type of intervention. After in-depth review, we found that the articles could be most logically separated into the following categories: analyses of a) programs that involved enhanced prenatal and postnatal (perinatal) care, including a1) Healthy start and other home visiting or coordination of care programs, a2) Centering Pregnancy/group prenatal care programs that targeted African American women at heightened risk for infant mortality, and a3) the Women, Infants and Children (WIC) program of the U.S. Department of Agriculture's food and nutrition service; b) behavioral interventions – those seeking to change African American women's behaviors to reduce their known risk factors for poor birth outcomes or infant mortality; c) community-based/grassroots interventions to increase social support for African American women during pregnancy and/or improve their knowledge of how to have a healthy pregnancy and reduce the risk of infant mortality; and d) MHealth (mobile health) or telehealth interventions that used phone-based intervention to address risks for infant mortality. A detailed description and discussion of these programs follows.

A. Perinatal care interventions

a1) Healthy Start and other Home Visiting Programs

Perinatal home visiting programs have been in use for over 100 years as a means to reduce infant mortality in vulnerable groups.²⁴ While in many nations, prenatal home visiting programs have long been universal, the U.S. in recent decades has limited home visiting

programs, including Healthy Start and state- or locally- funded interventions, on the women perceived to be of greatest need.¹¹ Opponents expanding home visiting have cited insufficient evidence for the efficacy of these programs in improving outcomes.¹¹ Moreover, until recently few rigorous evaluations have been conducted of home visiting programs, fostering a circular logic that limits further expansion or improvement of these programs.²⁵ Such programs have also varied widely in scope, training of staff, content, and implementation.²⁵

Our review found fourteen articles published since 2008 which rigorously evaluated interventions involving Healthy Start, home visiting and similar enhancements of perinatal care, and specifically examined their impact on birth outcomes among black women. Overall, articles evaluating the effect of Healthy Start participation on reducing infant mortality were consistent with the results of the prior national evaluation.¹³ They showed evidence of efficacy in assuring that women received adequate prenatal care, but limited or no effect on infant mortality; while those evaluating home visiting and care coordination programs outside the Healthy Start program showed overall substantial effects.

Eight of these articles evaluated Healthy Start programs, either on a nationwide (1) or county/local (7) level. These studies showed consistently that Black women who participated in Healthy Start had higher rates of adequate prenatal care than others, but other outcomes were inconsistent. While two of these studies found that Black women in Healthy Start had lower rates of preterm birth than comparable African American women^{26,27} two found higher rates of PTB.^{28,29} Similarly, while three of the six found that Black women participants in Healthy Start had lower rates of LBW infants^{27,30} or heavier weight infants than comparable non-participants,³¹ two others found that they had higher rates of LBW than comparable Black women in the overall population.^{28,29} Additionally, one study found that participation in Healthy Start mitigated the

negative effect of air pollution on LBW, VLBW and PTB in Black pregnant women.³² In the single nationwide study, which surveyed 821 women who participated in Healthy Start at eight sites throughout the U.S., Black women participants (34% of the total) reported a higher rate of breastfeeding (61%) and putting their infant to sleep on their back (69%) than the African American low-income women overall (46% breastfeeding and 47% infant to sleep on back). Since both breastfeeding and putting an infant to sleep on his or her back (rather than on the belly or side) are both associated with lower rates of infant mortality, this study provides some indirect evidence for the efficacy of these programs in reducing key antecedents of African American infant mortality. Furthermore, the authors of this study²⁸ shed some light on the elevated rate of LBW and PTB found in some of the evaluations. They noted that it might not be an apples-to-apples comparison to measure rates of LBW in Black Healthy Start participants in relation to those in low-income Black women overall, “given the program’s outreach to high risk women with multiple medical and social risk factors.”²⁸ Otherwise stated, the LBW rate might have been higher in this highest-risk group without Healthy Start.³³ Overall, these seven articles add to the weight of evidence for the continued importance of Healthy Start as a component of efforts to reduce black-white disparities in maternal and child health, but also point to the need for additional and alternative approaches.

In our review, we found five other home visiting programs that have been evaluated for their impact on infant mortality or its predictors among Black women. Of these, four showed promising results in improving birth outcomes among Black women, while one did not.

Two of the programs involved home visits by nurses. The first, the Black Babies Start More Infants Living Equally Healthy (SMILE) program, which targeted African American pregnant women in Montgomery County, Maryland, involved monthly home visits by nurses to

eligible African-American women.³⁴ In addition to monitoring the women, the nurse discussed educational topics including "the stages of pregnancy, signs of preterm labor, breast feeding and child development." Participants could opt in through self-referral, physician referral, or referral from another community service program. Although the program, funded by the NIH National Institute on Minority Health and Health Disparities, did not appear to effect birthweight, women who received these home visits were 0.37 times less likely to have a preterm delivery than comparable women.³⁴ Similarly, participation in the Michigan Infant Health Program (MIHP), where nurses and licensed social workers visit Medicaid-eligible pregnant women and their infants until age 1, was associated in a statewide analysis with a significant reduction in infant mortality among Black infants as well as other infants. These reductions were greatest among those women who were enrolled by the end of the second pregnancy trimester.³⁵ A second analysis of this program showed that Black women enrolled in MIHP had lower chances of VLBW and very preterm birth (VPTB) than those who were not enrolled. If they had 3 or more MIHP contacts, then they also had lower rates of LBW and PTB: this was true for all races not just Black women.³⁶ The program involved comprehensive risk screening and referral to programs to address these risks, such as smoking cessation, coordinating different types of care, and other interventions as well as activities to promote healthy pregnancies and positive birth outcomes.³⁶

Three other programs involved home visits by Community Health Workers (CHW), trained laypersons with ties to the local community in which they are working. The Community Health Access Project (CHAP), utilized trained Community Health Workers (CHW) to target women in census tracts of an urban Ohio county with the worst infant health outcomes (67.8% of participants were African American) and deliver home visits as well as coordinated care. The

evaluation found that participation in the program significantly reduced the odds of having a LBW baby. The CHW in this program was tasked with identifying pregnant women who were “at risk of having poor birth outcomes, connect[ing] them to health and social services, and track[ing] each identified issue to a measurable completion.” This meant ensuring that the client actually received the needed service for as long as necessary (prenatal care, finding a medical home, continued successful participation in a smoking cessation program) and obtaining documented evidence of this delivery. The authors of the CHAP study suggested that the program reduced LBW through factors other than increasing access to prenatal care. Since the CHW connected the client to other needed services, this may have addressed social determinants of prenatal and postnatal health that affect birth outcomes.³⁷ By contrast, participation in the Ohio Infant Mortality Reduction Initiative (OIMRI), another Ohio home visiting program for pregnant black women that utilized CHWs, did not appear to significantly impact birth outcomes.³⁸ The researchers analyzing this program’s results suggested that many participants might have enrolled too late in the program for it to effect birth outcomes, particularly PTB. However, participation in Healthy Families New York (HFNY) a third program that utilized trained CHWs at three sites in New York State, appeared to significantly reduced LBW among black infants, even when mothers enrolled at 30 weeks’ gestation.²⁵ This program was evaluated in a randomized controlled trial, in which pregnant women and pregnant adolescent girls living under 200% of the Federal Poverty line, who scored high on an assessment scale for risk of child maltreatment, were randomly assigned to a control group that received ordinary prenatal care, or to an intervention group that received biweekly home visits. Black mothers comprised 41.5% of the treatment group and 47.9% of the control group. The trained home visitors, who lived in the community and shared cultural and language backgrounds with the participants, built trust with

the participants; helped them strategize for stress reduction strategies; provided information on healthy nutrition and risk behaviors such as smoking, alcohol and drug use; encouraged them to keep medical appointments and follow medical advice; and linked them to a consistent medical provider (a medical home) along with needed social services such as WIC or food stamps. The authors of the evaluation noted that psychosocial interventions have not previously been shown to reduce prematurity, so its insignificant effect on PTB was unsurprising. But the program did show a dose-response effect for LBW, with those participants who entered before 24 weeks of pregnancy having an even greater reduction in risk.

A single article examined the Maternity Care Coordination (MCC) program in North Carolina – which incorporates elements of home visiting by seeking to help pregnant women receiving Medicaid navigate the complexities of the health care system, using trained nurses, social workers and trained “paraprofessionals.”³⁹ These workers provide health education; facilitate access and utilization of prenatal care; refer clients to community resources such as housing and transportation; refer clients to community agencies for information on pregnancy and newborn care; and refer to counseling services to address underlying issues that cause pregnant women stress or worry. When researchers compared birth outcomes in 2,255 mothers who received at least one MCC service to those outcomes in 4,869 women who were eligible but did not receive services, they found that the PTB was significantly lower in MCC mothers, although participation in the program did not significantly influence birthweight.³⁹

Finally, an article reported the results of the Magnolia Project, an inter-conception and preconception program operated under the umbrella of the Jacksonville, Florida (Duval County) Healthy Start program.⁴⁰ This program, which targeted a group of women at high risk for poor birth outcomes, 92.8% of whom were black, sought to reduce the impact of the social

environment and social class on birth outcomes. Women of childbearing age who were not pregnant were eligible if they had three or more of the following risk factors – a previous fetal or infant loss, or LBW baby; a birth as a young teenager; lack of access to regular healthcare source; substance abuse, a history of psychosocial or mental health problems; a history of casual sexual relationships or, “high-risk” unprotected sex.⁴⁰ These women were provided with case management that addressed their risk behaviors, care coordination for well woman care, and health education at a clinical site. Among the participants who gave birth within the study period, the researchers found an 11% decrease in LBW, and a 45.6% drop in infant mortality. These decreases were not statistically significant, but effects were more difficult to measure due to the small number of women in the study. The researchers also tested women’s perceived stress levels, social support, self-efficacy, and their goals and future orientation before and after participation in the program, but the small sample size precluded effective pilot testing of the measurement of these outcomes.⁴⁰ Still, this one program shows promising outcomes that suggest expanding Healthy Start’s scope to the interconception and preconception period would be useful and effective in improving birth outcomes.

Overall, these articles on Healthy Start, home visiting programs, and care coordination demonstrate that programs utilizing nurses, social workers, or community health workers to reach out to pregnant women at greatest risk of poor birth outcomes, and offer education as well as coordination of care and assistance in navigating the fragmented health care and social service systems can be effective in reducing the antecedents and correlates of infant mortality – and sometimes even are directly associated with drops in infant mortality among Black infants. These analyses are generally unable to pinpoint which aspects of the home visiting programs are most effective, and also indicate that program efficacy varies widely between models.²⁵ It may also be

difficult to measure success if the program is reaching women who are at heightened risk of preterm birth, low birthweight, and infant mortality in comparison to other low-income groups.²⁸

Finally, the issue of cost has not been discussed in most of this literature. Home visiting programs employing professionals are expensive, take time to implement successfully through active outreach in the community, and not easily scalable to wider groups of women who may be at risk. Among the programs analyzed above, the CHAP program is the only one for which an evaluation of cost and savings was presented. The researchers estimated that the cost of providing community care coordination via CHW home visiting to each pregnant client was \$751 (in 2001-2004) and that the program prevented 1 LBW birth per 11.5 participants. Based on the Institute of Medicine's estimate for the additional medical costs of a LBW baby in the first year of life, the researchers estimated that they saved \$3.36 for each dollar invested in this year, and \$5.59 over the longer term.³⁷ A broader analysis of the cost effectiveness of "targeted spending" on Healthy Start, WIC, and other related MCH programs to address racial disparities in infant mortality found that Black infant mortality rates were more responsive to this spending than overall infant mortality rates: they fell by 4.04 percent for each 10 percent increase in targeted spending.⁴¹ Given that a CHW-based model of home visiting and care coordination is less expensive than one employing professionals, and also may build greater trust among women at risk than other models, this model shows promise as a scalable and feasible approach to improving birth outcomes among African American women and other vulnerable groups.

a2) Group Prenatal Care/Centering Pregnancy

Centering Pregnancy, a form of group prenatal care with a trademarked and accredited curriculum, has been adopted in over 585 clinical practice sites within the U.S. since first being introduced in the 1990s. It currently is offered at nine leading Maryland healthcare institutions

from the University of Maryland Women's Center and Johns Hopkins Bayview to Walter Reed National Military Medical Center, according to Centering Healthcare, the organization that accredits this form of healthcare.⁴² In a 2007 Randomized Clinical Trial, in which 1,047 pregnant women were randomly assigned to either standard individual prenatal care or group care following the Centering Pregnancy model, the group prenatal care was associated with a 33% drop in the rate of PTB overall, and a 41% drop among Black women.⁴³ A more recent (2012) retrospective cohort study conducted on a low-income population of women in South Carolina found that Centering Pregnancy significantly reduced PTB in the population, and eliminated the black-white disparity in PTB.⁴⁴

The curriculum in Centering Pregnancy involves bringing women with low risk pregnancies at the same gestational age together in groups, where 10 prenatal visits are conducted by a certified nurse midwife or physician in the second and third trimesters of pregnancy.⁴² Each visit is between 90 minutes and two hours, and involves a one-on-one visit with the healthcare provider, women working together for self-assessment of blood pressure, weight, and other health data, along with a provider-facilitated group discussion of “nutrition, common discomforts, stress management, labor and delivery, breastfeeding, and infant care” along with other topics important to the group.

In this review, we found two articles that specifically examined the efficacy of Centering Pregnancy interventions on birth outcomes in African American women. These articles, analyzing program outcomes in South Carolina and Southwest Georgia, respectively, found that the program participants had reduced rates of PTB compared to the overall population, and the South Carolina program reported a statistically significant reduction in levels of PTB, which was

strongest among Black women in group care, and persisted across a number of practice locations.^{45,46}

Centering Pregnancy offers a promising approach to reducing poor birth outcomes among African American women. Some recent analyses also show that it is as cost effective or more cost effective than individual traditional prenatal care, although cost savings may accrue downstream, to the healthcare system overall, while initial investments are required at the level of the practice, in scheduling and organizing groups.⁴⁷ However, the limits of this approach include the fact that it is only offered at certain locations, and that not all “group prenatal care” models adhere to the guidelines established by the Centering Healthcare Institute. Also, of note, the model is only available to women with low-risk pregnancy, and specifically excludes women with obesity, hypertension (high blood pressure), heart disease, or kidney disease – all of which are present at higher levels among African American women than white women.⁴⁸ While an intervention like Healthy Start home visiting may disproportionately reach women with the highest risk pregnancies, as previously discussed, this intervention specifically excludes them – a major limitation.

a3) WIC Participation

The federal government’s Special Supplemental Nutrition Program for Women, Infants and Children (WIC) program provides grants to states to offer low-income women who are pregnant or postpartum, as well as their infants and young children, supplemental foods, referrals to health care and social services, education, and nutrition. The program estimates that it serves 53 percent of all infants born in the United States, and over 8 million women and children each year. It operates 1,900 local agencies, 10,000 clinic sites in all states and U.S. territories, the District of Columbia, as well as through 34 Indian Tribal Organizations.⁴⁹ In Maryland, the

program served over 135,000 women, infants and children in each month of 2017, and operates at 29 locations in all 23 counties and Baltimore City.⁵⁰

Three articles in our review – all large-scale studies using state vital statistics data-- examined the effectiveness of WIC participation on improving birth outcomes among African American women. One study of WIC participants in Hamilton County, Ohio found that African American women who participated had much lower rates of infant mortality than African American women who did not participate, but that WIC participation did not significantly affect the rate of PTB.⁵¹ A second study, however, of WIC participants in Kansas did not find a statistically significant difference in infant mortality rates between Black mothers who received WIC and those who did not.⁵² Lastly, a study of WIC participants in South Carolina, found that WIC participation was associated with increased birthweight, and that this increase was larger in Black mothers. It also found that it reduced the likelihood of LBW by 3.4%, and PTB by 3.8% in Black mothers, and decreased the probability that infants would be admitted to the Neonatal Intensive Care Unit (NICU) by 1.7%.⁵³ Overall, these studies suggest that expanded WIC participation may be helpful in reducing infant mortality and improving birth outcomes among Black women, but that it is not a sufficient strategy.

B. Behavioral Health Interventions

In addition to interventions that target perinatal care, three interventions in our review addressed risky maternal behaviors that are associated with LBW, PTB, and infant mortality. Overall programs were more successful when they incorporated validated psychosocial interventions with education.

Two interventions sought to reduce bed-sharing and increase safe sleep practices among families at highest risk of SIDS and sleep-related infant deaths. Both targeted African American

families because the majority of sleep-related infant deaths have been shown to occur among African Americans.⁵⁴ However, one of these interventions also included American Indian-Alaska Natives (another high-risk group for sleep related deaths), and targeted families with other risk factors: low-income (<150% of the federal poverty level), no crib in the home, maternal smoking, PTB or LBW, and/or the sibling of a SIDS infant.⁵⁵ This three-jurisdiction intervention, Bedtime Basics for Babies, provided over 3,300 qualifying families in Washington, D.C., Indiana, and Washington State with free cribs as well as crib sheets, a wearable blanket and sheet, wearable blanket and pacifier, and educational materials on how to prevent SIDS and sleep-related infant death, as well as breastfeeding. Surveys were conducted prenatally, postnatally, and then 1-3 months after the postnatal survey. The survey responses indicated that parents' knowledge of the recommended infant sleep position improved from 76% to 94% after they received the crib. Furthermore, while 38% of parents said in the postnatal survey that they had bed-shared the night before, only 16% did in the follow-up survey after receipt of the crib. Rates of reported infant sleeping in the crib rose from 51% postnatally to 90% after the intervention.⁵⁵ Over 42% of parents in this study were African American; these parents had the lowest rates of placing their infants on their back in the postnatal survey, but the researchers did not analyze how the pattern of bed-sharing differed by race after the receipt of the crib. Still, the study's overall results indicate that it was effective in reducing bed-sharing – a behavioral risk for infant mortality – and improving safe sleep practices. A program that provided “enhanced” health messaging to African American mothers about safe sleep practices to reduce Sudden Infant Death Syndrome (SIDS) and prevent suffocation was less effective.⁵⁴ Participants were assigned randomly into the group that provided the enhanced messaging – a brochure with information about preventing suffocation and strangulation, as well as SIDS, or to a control

group that received a brochure with standard messages provided by the American Academy of Pediatrics about SIDS prevention.⁵⁶ Analysis showed that the brochure intervention did not change mothers' bed-sharing practices.

Another type of behavioral intervention has targeted prenatal risk factors for infant mortality, such as smoking, environmental tobacco smoke exposure in the home ("second-hand smoke"), depression, and Intimate Partner Violence (IPV). One program recruited pregnant African American women in Washington, D.C. who each had at least one of these risk factors. After being assessed for these factors using commonly accepted screening tools, participants were randomly assigned to ordinary prenatal care or to an additional "integrated behavioral intervention" run by a team of psychologists and social workers trained to assess each mother's stage of change (psychological readiness to change her behavior) and tailor the intervention to her. Women who were assessed as depressed participated in cognitive behavioral therapy that addressed their negative thinking patterns and relationships, and stressed managing their mood and increasing positive social interaction. Women who the intervention team identified as experiencing IPV were provided with information on types of abuse, the cyclical nature of domestic violence, how to assess their levels of danger and develop a plan for their personal safety, as well as lists of community resources. Smokers were provided with a validated smoking cessation intervention, and those exposed to ETS were provided with an intervention in which they learned strategies to eliminate or minimize their exposure to ETS through role plays and practice negotiating with household members who smoked.^{57,58} All three of these behavioral programs were based on previously tested and validated models. Several studies analyzing this program showed that these interventions reduced smoking, depression, and IPV among the women who participated.⁵⁷⁻⁵⁹ A second study found that the integrated behavioral intervention

significantly reduced VPTB among the women in the intervention group, and discussed the possible “catalytic effect”—the way that multiple, sometimes not statistically significant reductions in multiple risk factors can effect birth outcomes.⁵⁸

This multi-pronged behavioral intervention comprised one small component of the National Institutes of Health-DC Initiative to Reduce Infant Mortality in Minority Populations, an 18-year (1992-2010), congressionally mandated research program. This three-phase program included several behavioral interventions focused on reducing parents’ and infants’ exposure to smoking and other risk factors; several parenting and teen pregnancy prevention interventions, cohort studies of risk factors for poor birth outcomes and barriers to prenatal care utilization, a study on women’s acknowledgement of alcohol use during pregnancy, and enhanced surveillance of childhood injuries.⁵⁹ Researchers involved in this sprawling program reported learning several lessons from it: 1) Make participation in interventions convenient for participants by integrating it with prenatal care; in some circumstances this can include home visits but in others, such as behavioral intervention to reduce infants’ exposure to ETS, participants viewed home visits as an invasion of privacy; 2) use computers, personal audio devices, and other technology (rather than face-to-face questionnaires) to ask participants about behaviors that they “may be hesitant to disclose,” from smoking and other substance use to IPV and sexual behaviors; 3) integrate education with behavioral risk reduction counseling to reduce risk behaviors for poor birth outcomes (as in the above program); and 4) involve family members in interventions. Women whose significant other supported their efforts to limit their exposure to ETS during pregnancy, for example, were more successful in doing so; while a program to educate caregivers on safe sleep enjoyed more success when other family members also learned about this practice.⁵⁹

Overall, this limited review indicates behavioral interventions to reduce infant mortality among African Americans appear to be successful when they are multi-faceted, accessible, and address the underlying family or structural reasons for the behavioral risk factors – i.e. no crib, family dynamics that prevent a safe prenatal or postnatal environment - and do not just involve a single educational protocol.

C. Community-based/grassroots interventions

Another type of intervention has sought to overcome some of the limits of top-down, one-way educational models delivered by professionals, by seeking to involve the community in improving birth outcomes. These community-based interventions focus on involving members of minority communities and engaging pregnant women in education about how to reduce the risks for infant mortality, while also building social support for pregnant women. In one such intervention, Sisters United, the Arkansas Department of Public Health partnered with African American sororities, whose members provided mini-trainings to African American women on how to reduce their risks for infant mortality through practices including taking folic acid prenatally to reduce birth defects, getting flu shots, infant safe sleep practices, and breastfeeding. The program surveys showed that the trainings did increase participants' knowledge of these factors, but did not measure whether they put these suggestions into practice.⁶⁰ In another similar intervention, "A Healthy Baby Begins with You," African American health professionals held community baby showers for minority women in Oklahoma, (28% of whom were Black, and 33% American Indian). At these events, open to potential parents and grandparents, professionals and "health information mavens/"Big Mamas" provided shower gifts to participants, and offered child care, while at the same time discussing prenatal and infant health development and safety and challenging popular myths about these factors. As with the previous

intervention, survey results indicated that participants increased their knowledge about safe parenting practices and infant health, but did not measure whether they put these ideas into practice.⁶¹

Two other interventions created social support groups for African American pregnant women. One of these, the Ohio Collaborative to Prevent Infant Mortality (OCPIM), involved a two-hour weekly program hosted in a local church recommended by a neighborhood association in a neighborhood where 75% of residents were low income and African American. At the weekly Moms2B program, a healthy meal was served, and the trained group facilitators led discussion of prenatal nutrition, pregnancy and parenting topics – part of a rotating six-month curriculum- while meeting one-on-one with participants to go over the social factors influencing their health and connect them to needed services. The staff, who were trained in motivational interviewing and in a support program model called “bridges out of poverty” maintained contact with participants between meetings through texts and phone calls. An evaluation compared the birth outcomes among the 195 participants in the program to the overall outcomes in the neighborhood where the program was held. While the differences were not statistically significant, infant mortality rate among participants was 0, while the overall infant mortality rate in the neighborhood dropped substantially, from 14.2/1000 live births to 2.9. Participants also reported high levels of satisfaction with the program.⁶²

A second intervention involved implementing the Birthing Project USA in Wisconsin. The Birthing Project USA, created in 1988 by Katheryn Hall-Trujillo in Sacramento, California and operating in up to 100 sites around the world, engages volunteer “Sister friends” – older African American women who provide one-on-one support to younger pregnant women in their community to reduce infant mortality.⁶³ The evaluation did not measure the effect of

participation on birth outcomes, but rather consisted of interviews with participants, who discussed their lack of social support especially in labor and delivery, due to the high level of incarceration among their partners and lack of community cohesiveness, and the need to build community to create more support for pregnant women. These two social support – community education programs seem to offer promising models, but more evaluation is needed to assess their effectiveness.

In addition to these programs focused on pregnant women, a single community-based program sought to address social barriers that may prevent African American pregnant women from obtaining the care and support they need. This intervention, the Genesee County Racial and Ethnic Approaches to Community Health (REACH) program, has brought together since 1999, local community members, the health department, and partners at an academic medical center and a local health care system, to identify and address causes of health disparities in infant mortality among women in the Flint, Michigan area.⁶⁴ The program employs Maternal and Infant Health Advocacy Services (MIHAS) advocates, local African American women, who are trained to provide case management and home visits to help pregnant mothers in navigating the “systems” of health care and social services. The program also seeks to go beyond the home visiting model to address structural and social determinants of health. One intervention the REACH program developed, based on community meetings and suggestions, is the “windshield tours” event. In these tours, health care providers and other community members took a driving tour of the neighborhood where the women participating in the program lived. The tour focused on neighborhood’s challenges (including lack of regular transportation and lack of grocery stores), assets, and issues that affected the women’s health. A long-term follow-up survey (n=25) indicated that participants in the tour significantly improved in their familiarity with the

neighborhood and issues (other than personal factors) that affected residents' health. Of these respondents, 28% reported "changes in their interactions with patients or neighborhood residents." Following the tour, MIHAS advocates reported that clinicians showed greater leniency on the women's lateness to medical appointments as well as developments such as the corner stores providing healthy options, the removal of tobacco ads from the neighborhood, the adding of more convenient bus stops, and greater level of connection between community members and physicians, as evidenced at community "ask the doctor" events. While evaluation of this program, like the other community-based interventions, did not link it to any changes in infant mortality rates, the results do indicate that it was effective in addressing the underlying social factors underlying infant mortality disparities, such as distrust and misunderstanding between patients and health care providers, and structural barriers to obtaining health care and maintaining a healthy prenatal environment.

A final article described a community-based intervention that sought to identify locally-related causes of specific leading causes of infant mortality in an urban community. This article described a Fetal and Infant Mortality Review (FIMR). While many causes of infant mortality are likely to be similar from one community to another, such a review may highlight specific local factors that are contributing to infant mortality and miscarriage, and which can be targeted through community-based programs. The FIMR protocol, which is designed to be community-based and systematic, was developed by the American College of Obstetricians and Gynecologists in partnership with the MCHB during the 1990s. These bodies have jointly developed a manual for conducting a FIMR. The process of a FIMR involves data collection, including interviews with families that have experienced the fetal or infant death, review of cases, and referral of information to a case review team, an advisory board, and finally a

community action team, which makes changes in the systems that effect mothers and infants.

One article in our review described and evaluated a FIMR in a Wisconsin city.⁶⁵ In this program, researchers collected data on all women who miscarried at 14 weeks or later, and on all infant deaths within a five zip code area in a two-year period. This process involved patching together data from a variety of sources, including hospitals, local health departments, medical examiners offices, and local newspapers. Family members were contacted with a letter of sympathy and an explanation of the FIMR. Those who were interviewed were offered referrals to psychological, social, and health care services at a local participating hospital. Of the 82 cases reviewed, 32 involved African American parents and infants. Most of these mothers were between ages 20-30, contradicting community perceptions that they were teenage mothers. Additionally, many late-term miscarriages resulted from infections or premature rupture of membranes (PROM), but interviews revealed that the women who experienced the miscarriages had not been told how to lower the risk of these occurrences in subsequent pregnancies. The FIMR involved providing women with information and referring them to healthcare facilities. As a result of the FIMR, referrals between different healthcare facilities were increased, and health education was coordinated to a greater degree. This evaluated review shows how this resource-intensive process can lead to identification of those at highest risk of further poor birth outcomes, as well as key opportunities for improved health education and services, and lead to better coordination of the health care and public health systems.

D.) MHealth and other Telephone-based Interventions.

A final type of intervention examined in this review is the use of MHealth (mobile health) technology, including smartphone apps, text messaging, or simply phone calls, for health education, social support, and care coordination. Two of these interventions showed promising

results in improving birth outcomes among African American women. The first combined MHealth and nursing quality improvement (NQI) efforts to improve safe sleep and breastfeeding practices among new mothers.⁵⁴ The NQI component involved nurse-champions who trained other nurses and served as role models in effectively delivering messages to new mothers about safe sleep. The MHealth components involved health messages and videos delivered by email or text to new mothers, which contained educational components about addressing barriers to safe sleep as well as testimonials from parents who had faced these challenges. New mothers received these messages every day for the first 11 days, then every 3-4 days for the following 60 days. Women at 16 hospitals were randomized to an intervention group and a control group that received information about breastfeeding from the nurses in the hospital and the text messages/videos. The NQI component alone did not show significant results in improving safe sleep practices, but the mHealth text and video component did. While about 30% of the participants in the study were African American, the study showed effectiveness in addressing a known postnatal antecedent of infant mortality in African American (and other) infants.

A second intervention involved less sophisticated messaging, but demonstrated the value of using phones for continued outreach to women at high risk for preterm birth, a key predictor of infant mortality. This program involved “telephonic risk assessment and case management” among pregnant Medicaid recipients, over 57% of whom were African American, in eight counties of the South Carolina Lowcountry.⁶⁶ This coastal region includes the metropolitan areas of Charleston and Beaufort, as well as numerous rural areas.⁶⁷ The program included four components: 1) identifying pregnant Medicaid recipients as early in pregnancy as possible; 2) risk assessment and education of participants on behaviors for a healthy pregnancy, via telephone; 3) making perinatal nurses available 24 hours a day 7 days a week, for consultation by

telephone; and 4) “patient centered” case management by telephone for women who had identified risk factors for PTB. An evaluation of the program found that the participants had significantly reduced rates of PTB and their infants spent significantly fewer days in the Neonatal Intensive Care Unit (NICU), compared to the corresponding population.⁶⁶ The evaluation did not break down the results by race, and did not measure which aspect(s) of the intervention were most effective. However, the study authors noted that the findings were consistent with prior research demonstrating that daily or frequent contact between a pregnant woman and a perinatal nurse is associated with reductions in PTB,^{68–70} and that since 1993, ACOG as well as the U.S. Preventative Services Task Force have endorsed daily contact with a patient initiated by a provider as an effective means to prevent preterm birth.^{71,72}

Overall, these two evaluations of telephone-based interventions suggest that such approaches are effective. Moreover, unlike in-person clinical or psychosocial interventions, these approaches circumvent structural barriers to contact between providers and pregnant women, including transportation, work and family conflicts, and community distrust of brick-and-mortar medical and social institutions. They also may be cost-effective, although neither article provided an analysis of the underlying program’s cost effectiveness.

E.) Conclusions and Recommendations

This review of literature demonstrates substantial scientific evidence exists for the efficacy of programmatic interventions in reducing antecedents and risks associated with elevated infant mortality in African Americans, even if few studies have linked interventions conclusively and directly to drops in infant mortality rates. The Healthy Start model involves programs with the longest history of successful implementation but shows little evidence of actually reducing disparities in infant mortality. However, the program is well-established, with

three decades of experience in implementing programs, and may provide an organizational base or valuable partner for additional programming. Similarly, this review shows that WIC, with its successful track record of reaching at-risk women, comprises a reliable resource for improving health and nutrition among African American pregnant and postpartum women and their children. Among other approaches, home visiting and education programs that involve trained community health workers (CHWs) and Centering Pregnancy, a form of group prenatal care, show promise in reducing antecedents and associated risks of infant mortality among African Americans. The exclusion of high-risk pregnant women from the Centering Pregnancy model, however, limits its wider applicability to those at highest risk of poor birth outcomes. Behavioral interventions, similarly, show demonstrated efficacy among African American mothers in reducing behavioral factors associated with elevated infant mortality, including smoking, exposure to second-hand smoke, IPV, and depression, but have built-in limitations in requiring one-on-one contact between professional or highly trained behavioral health experts and pregnant women. Community-based grassroots efforts, from community baby showers to volunteer-run educational programs, show some efficacy in increasing pregnant women's knowledge of healthy behaviors such as smoking cessation, breastfeeding, and safe sleep, but no demonstrated effectiveness in changing birth outcomes. Lastly, MHealth interventions appear to be highly feasible and scalable interventions in an era of near-universal mobile phone use, but the evidence of their effectiveness remains limited. This review indicates the need for more randomized controlled trials of various approaches to establish efficacy and cost- for programs to improve birth outcomes among African American infants. However, many promising approaches have already been shown in limited research to reduce the antecedents and behaviors associated with elevated African American infant mortality rates.

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IV. Interventions to Reduce Infant Mortality among Infants in U.S. Rural Communities

Our search strategies resulted in a final set of 14 recent articles on programmatic interventions that related to improving infant mortality or reducing birth outcomes among infants in the rural United States. To analyze the efficacy, efficiency, scalability and feasibility of the interventions described and evaluated in these articles, we categorized them by type of intervention. After in-depth review, we found that the articles could be most logically separated into the following categories: analyses of a) programs that involved enhanced prenatal and postnatal (perinatal) care, including a1) Healthy Start and other home visiting or coordination of care programs, a2) Centering Pregnancy/group prenatal care programs that targeted pregnant rural women; b) behavioral interventions – those seeking to change rural women’s behaviors to reduce their known risk factors for poor birth outcomes or infant mortality; c) community-based/grassroots interventions to increase social support for rural women during pregnancy and/or improve their knowledge of how to have a healthy pregnancy and reduce the risk of infant mortality; and d) mHealth (mobile health) or other telephone-based interventions to address risks for rural infant mortality. A detailed description and discussion of these programs follows.

A. Perinatal care interventions

a1) Healthy Start and other Home Visiting Programs

Perinatal home visiting programs have been in use for over 100 years as a means to reduce infant mortality in vulnerable groups.²⁴ While in many nations, prenatal home visiting programs have long been universal, the U.S. in recent decades has limited home visiting

programs, including Healthy Start and state- or locally- funded interventions, to the women perceived to be of greatest need.¹¹ Opponents expanding home visiting have cited insufficient evidence for the efficacy of these programs in improving outcomes.¹¹ Moreover, until recently few rigorous evaluations have been conducted of home visiting programs, fostering a circular logic that has limited further expansion or improvement of these programs.²⁵ Such programs have also varied widely in scope, training of staff, content, and implementation.^{25,12}

Our review found only three articles published since 2008 that rigorously evaluated home visiting and coordination of care in rural communities. One of these articles included a single Healthy Start program in a rural community (Lac du Flambeau, Wisconsin) in a nationwide evaluation. In this evaluation, 821 women who participated in Healthy Start at eight sites throughout the U.S. were surveyed. This article did not include a separate analysis of Healthy Start results in the rural community, so it is hard to know whether the program was effective in specifically reducing correlates of rural infant mortality. Overall, LBW rates in the surveyed Healthy Start participants were comparable to those of low-income women in a similar population-based sample. The participants self-reported higher rates of breastfeeding (75%) and safe sleep, or putting an infant to sleep on his or her back (70%) than comparable low-income women. Since both of these behaviors are associated with lower rates of infant mortality, this study provides some indirect limited evidence for the efficacy of these programs in reducing key antecedents of rural infant mortality.³³

A second article reviewed Vanderbilt University Medical Center's Maternal Infant Health Outreach Worker (MIHOW) program, a home visiting program that has aimed to reduce LBW and SIDS in rural populations. The program, which began in 1982, targets low-income, rural women in Tennessee, Kentucky, West Virginia, Mississippi, and Louisiana. Its original goals

were to “improve maternal health and child development, combat isolation and increase access to health care.”⁷³ The program employs peer mentors recruited from the community, who come from the same racial, cultural, and language group as the target population and are skilled in problem-solving and communication, as well as familiar with resources available to the women.⁷⁴ Each family receives a monthly home visit from early in pregnancy until the child’s third birthday.⁷³ While no rigorous evaluation of the entire program has been conducted, a smaller randomized controlled trial was recently conducted in which 178 Hispanic women in Tennessee were randomly assigned to MIHOW or to a Minimal Education Intervention where they received educational materials about maternal and infant health and development. Those assigned to MIHOW were significantly more likely to breastfeed exclusively and feel confident about breastfeeding (self-efficacy), to practice safe sleep with their infant, to engage in stimulating interaction with the infant in the home, and were significantly less likely to show symptoms of depression.⁷⁴ These results of a single, small scale study cannot be generalized to the entire population receiving MIHOW, since the majority of these women are not Hispanic and many live in more rural areas. However, other evaluations have demonstrated the efficacy of home visiting programs involving CHWs in improving behaviors and reducing antecedents of infant mortality, especially when outreach to the pregnant woman and family occurs earlier in the pregnancy.^{25,37} Together, these results suggest that interventions utilizing CHWs in rural settings are promising approaches to reducing infant mortality.

A third article in this group examined the Maternity Care Coordination (MCC) program in rural and urban North Carolina. This program incorporates elements of home visiting in that it seeks to help pregnant women receiving Medicaid navigate the complexities of the health care system, using trained nurses, social workers and trained “paraprofessionals.” These workers

provide health education; facilitate access and utilization of prenatal care; refer clients to community resources such as housing and transportation; refer clients to community agencies for information on pregnancy and newborn care; and refer to counseling services to address underlying issues that cause pregnant women stress or worry. When researchers compared birth outcomes in 2,255 mothers who received at least one MCC service to those outcomes in 4,869 women who were eligible but did not receive services, they found that the PTB was significantly lower in MCC mothers, although participation in the program did not significantly influence birthweight. Also, the study did not differentiate the results between urban vs. rural participants.

None of these three articles evaluated the cost effectiveness of the home visiting and care coordination programs. However, analysis of one home visiting program in an urban area of Ohio estimated that the cost of providing community care coordination via CHW home visiting to each pregnant client was \$751 in 2001-2004, and that the program prevented one LBW birth per 11.5 participants. Based on the Institute of Medicine's estimate for the additional medical costs of a LBW baby in the first year of life, the researchers estimated that they saved \$3.36 for each dollar invested in the program for the first year, and \$5.59 over the longer term.

Overall, these articles on Healthy Start, home visiting programs, and care coordination provide very limited information on the specific challenges to implementing these programs in rural areas, or their efficacy with rural populations. However, they do demonstrate that programs utilizing CHWs, nurses, or social workers to reach out to pregnant women at greatest risk of poor birth outcomes can be effective when they tailor the intervention to the pregnant woman's needs and offer education as well as coordination of care and assistance in navigating the fragmented health care and social service systems.

a2) Group Prenatal Care/Centering Pregnancy

Centering Pregnancy, a form of group prenatal care with a trademarked and accredited curriculum, has been adopted in over 585 clinical practice sites within the U.S. since first being introduced in the 1990s. It is currently offered at nine leading Maryland healthcare institutions according to Centering Healthcare, the organization that accredits this form of healthcare.⁷⁵ In a 2007 Randomized Clinical Trial, in which 1,047 pregnant women were randomly assigned to either standard individual prenatal care or group care following the Centering Pregnancy model, the group prenatal care was associated with a 33% drop in the rate of PTB.⁴³ A more recent (2012) retrospective cohort study conducted on a low-income population of women in South Carolina found that Centering Pregnancy significantly reduced PTB in the population, and eliminated the Black-white disparity in PTB.⁴⁴ Recent analyses also show that Centering Pregnancy is more cost effective than individual traditional prenatal care, although cost savings may accrue downstream, to the healthcare system overall, while initial investments are required at the level of the specific clinical practice, in scheduling and organizing groups.⁴⁷

The curriculum in Centering Pregnancy involves bringing women with low-risk pregnancies at the same gestational age together in groups, where 10 prenatal visits are conducted by a certified nurse midwife or physician in the second and third trimesters of pregnancy.⁷⁵ Each visit is between 90 minutes and two hours, and involves a one-on-one visit with the healthcare provider; women working together for self-assessment of blood pressure, weight, and other health data; and a provider-facilitated group discussion of “nutrition, common discomforts, stress management, labor and delivery, breastfeeding, and infant care” along with other topics important to the group.

One article in our review investigated outcomes from a Centering Pregnancy program in the mostly rural counties of Southwest Georgia. It found that the program participants had reduced rates of PTB compared to the overall population.⁴⁵ Other studies have found similar results, although a meta-analysis of Centering Pregnancy programs overall did not show a significant effect on rates of PTB.⁷⁶ The limits of this approach include that it is only offered at certain locations, and that not all “group prenatal care” models adhere to the guidelines established by the Centering Healthcare Institute. Also, the model is only available to women with low-risk pregnancy, and specifically excludes women with obesity, hypertension (high blood pressure), heart disease, or kidney disease.

B) Behavioral Interventions

Psychosocial interventions that help women address behaviors that put them at high risk for poor birth outcomes, such as prenatal smoking and substance use, have shown some efficacy in reducing these behavioral risk factors for infant mortality in urban populations.⁵⁷ In our review for rural populations, we found one article on a behavioral intervention that specifically targeted rural women. In this intervention, targeting pregnant smokers in Central Appalachia, participants were recruited from five medical practices that served the local low-income community. Smoking in rural areas remains higher than in urban areas, and in the area targeted by the intervention, 28.7% of the population smoked.⁷⁷ Participants were administered motivational interviews that focused on the 5 A’s (Ask, Advise, Assess, Assist, and Arrange), to address their smoking during pregnancy.⁷⁸ They were compared to an historical control group of women who received ordinary prenatal care. Twice as many women in the intervention group quit smoking during the second trimester than in the control group, and those who did not quit reduced their

smoking to a less-than-daily pattern. Overall, the intervention group experienced lower rates of fetal death and babies of longer gestation and higher birthweight than the control group. This intervention was expensive to implement, due to the need for trained motivational interviewers to meet one-on-one with pregnant women. However, a cost effectiveness analysis indicated that by leading pregnant women to quit smoking, this program could save \$7.5 million over five years due to lowered hospital costs for PTB and LBW babies and mothers.⁷⁸

C) Community-based/Grassroots Interventions

Another type of intervention has sought to engage members of the wider community in improving birth outcomes among groups at high risk. This type of intervention overcomes some of the perceived disadvantages of top-down, one-way educational models delivered by professionals, in that it promises an approach that is sensitive to cultural and community needs. These community-based interventions focus on involving members of communities and pregnant women in grassroots support and education about how to reduce the risks for infant mortality and create a healthy environment for the birthing and rearing of children. The first such intervention evaluated in our articles, “*Becoming a Mom/Comenzando bien*” was developed by the March of Dimes to provide community-based education for high-risk pregnant women. This curriculum, developed by the March of Dimes Kansas chapter and aimed at pregnant women in rural areas “where patients frequently have higher non-compliance rates, lower health literacy, and other factors associated with poor health outcomes,” brought together local obstetricians and nurse practitioners, the county health department, and a federally qualified health center (FQHC).⁷⁹ The prenatal care providers wrote “information prescriptions” for the women in their practice to attend the program, which included six sessions on health during pregnancy including stress

management, nutrition, substance use and smoking, labor and birth, infant care, postpartum care, and available community support services. It also emphasized breastfeeding, safe sleep, and smoking cessation. Participants were provided with incentive items, including diapers after one class attended, and a safe sleep crib after all six classes.⁷⁹ Participants were surveyed before and after the program, and results indicated that they significantly increased their knowledge of safe sleep practices from 84% to 99%, and used tobacco at a significantly lower rate than the average rate in the region (8% vs. 20%). They also increased their knowledge of preterm labor and postpartum symptoms.⁷⁹ This program was later implemented in a larger population, encompassing seven rural counties of southern Texas. In this version, half of the women participating were Spanish speakers, so Spanish language sessions were offered in half the locations.⁸⁰ The program leaders offered a wide array of incentives for attending each program session, including diapers, baby wipes, blankets, children's toys, and brushes for baby bottles. The pretest-posttest evaluation of the Texas program indicated that participants improved their knowledge of safe sleep, postpartum health, preterm labor, and that more intended to breastfeed than when they began the program. Also PTB rates were lower among participants, but this difference was not statistically significant.⁸⁰ Overall, these positive results in two very different rural contexts indicate that the March of Dimes *Becoming a Mom/Comenzando Bien* program could be very useful and successful in addressing rural maternal and infant health disparities.

A different form of community-based prenatal education implemented in rural areas is the community baby shower. Two articles evaluated different versions of this intervention. In the first, the Kansas (State) Department of Health implemented an eight-county program, in partnership with local community partners including churches, local health departments, and local hospitals, where trained Safe Sleep instructors hosted showers for local pregnant or

postpartum women.⁸¹ The instructors presented on safe sleep practices (in the crib, on the back), the benefits of breastfeeding, and smoking cessation. Women who participated in the program received a portable crib and/or a wearable blanket for their baby (depending on the funding level for the shower). Participation in the 18 showers held across the state varied, from two to 130 participants. A pretest-posttest evaluation of 845 participants indicated that women reported statistically significant improvements in knowledge and intentions to follow the risk reduction strategies presented at the shower, including safe sleep, likelihood of breastfeeding, smoking cessation – including knowledge of local tobacco cessation services, avoiding second-hand smoke, and increased confidence in their ability to breastfeed for more than six months.⁸¹ In a similar intervention, “A Healthy Baby Begins with You,” African American health professionals held community baby showers for minority women in rural and urban Oklahoma.⁶¹ These events, however, were open not just to pregnant and postpartum women, but also to potential parents, foster parents, and grandparents. At the shower, professionals and “health information mavens/Big Mamas” from the community provided shower gifts to participants, and offered child care, while at the same time discussing prenatal and infant health development and safety, and challenging popular myths about these factors. As with the previous intervention, survey results indicated that participants increased their knowledge about safe parenting practices and infant health, but it was not measured whether they put these ideas into practice.⁶¹

A third type of community-based intervention involved a partnership between African American sororities and the Arkansas (State) Department of Public Health.⁶⁰ In this intervention Sisters United, the sorority members were trained as volunteers, and then provided mini-trainings for African American women throughout the state on how to reduce their risks for infant mortality through practices including taking folic acid prenatally to reduce birth defects, getting

flu shots, engaging in infant safe sleep practices, and breastfeeding. Similarly to the prior educational interventions, program surveys showed that the trainings did increase participants' knowledge of these factors, but did not measure whether they put these suggestions into practice.⁶⁰

Overall, the Becoming a Mom/Comenzado Bien approach seems like the most promising of the rural community interventions – as it involves both provision of needed items for safe sleep and referrals to community resources, along with education. Community baby showers and other community-based educational events also show promise in improving rural pregnant women's knowledge of healthy prenatal and postpartum behaviors.

D) MHealth and Telemedicine Interventions

A final type of intervention examined in this review is the use of telemedicine or mHealth (mobile health) technology, including smartphone apps, text messaging, or simply phone calls, for health education, social support, and care coordination. Four of these interventions are included in our review, and showed promising, if inconsistent results in improving birth outcomes among rural women.

The first of these programs, STORC (Solutions to Obstetrics in Rural Counties), sought to reach high-risk pregnant women in rural Tennessee by allowing them to video chat with a maternal-fetal medicine specialist at a midlevel health center rather than traveling long distances (an average of 70 miles) to see the specialist providers.⁸² An analysis of outcomes in 312 participant surveys found that the women had lower rates of PTB than the overall population and that the majority of babies weighed over 5 lbs. at birth (LBW is less than 5.5 lbs.). The report on this program did not measure whether the improvement in birth outcomes was statistically

significant.⁸²

A second intervention combined mHealth and nursing quality improvement (NQI) efforts to improve safe sleep and breastfeeding practices among new mothers at 16 hospitals around the U.S.⁵⁴ The NQI component involved nurse-champions who trained other nurses and served as role models in effectively delivering messages to new mothers about safe sleep. The mHealth components involved health messages and videos delivered by email or text to new mothers, which contained educational components about addressing barriers to safe sleep as well as testimonials from parents who had faced these challenges. New mothers received these messages every day for the first 11 days, then every 3-4 days for the following 60 days. Women participating were randomly assigned to either an intervention group, or to a control group that received information about breastfeeding from the nurses in the hospital and the text messages/videos. The NQI component alone did not show significant results in improving safe sleep practices, but the mHealth text and video component did.⁸³

A third intervention, “GoMo Healthy,” used an mHealth approach to reach high-risk pregnant women in rural Arkansas.⁸⁴ Academic researchers developed this intervention in consultation with a 30-member rural advisory board, which included local rural health providers, directors of pregnancy testing sites, executives at local hospitals, the director of the regional health department, a former state senator, state department of health staff, two Hispanic bilingual community health workers (CHW), directors of regional social service agencies, and two new mothers. The intervention included a smartphone “prenatal technology platform” which delivered prenatal health information, instructional videos, and wellness tips to pregnant women via text message and websites; along with weekly contact from a CHW.⁸⁴ A pilot study of the program’s feasibility, where women were assigned, non-randomly, to the intervention or to a

control group that received printed prenatal education materials and ordinary prenatal care, indicated that the program was feasible and cost effective. The program experienced challenges in enrolling participants from the most vulnerable groups- undocumented women and pregnant teen girls, and this initial study, which included only 98 participants, was too small to statistically measure any improvements in birth outcomes. However, participants did report lower rates of LBW and PTB than the controls, and data did show some indication of cost-effectiveness.⁸⁴

A final intervention involved a less sophisticated approach, but demonstrated the value of using phones for continued outreach to women at high risk for preterm birth, a key predictor of infant mortality. This program involved “telephonic risk assessment and case management” among pregnant Medicaid recipients in eight counties of the South Carolina Lowcountry.⁶⁶ This coastal region includes the metropolitan areas of Charleston and Beaufort, as well as numerous rural areas.⁶⁷ The program included four components: 1) identifying pregnant Medicaid recipients as early in pregnancy as possible; 2) conducting a risk assessment and providing education of participants on behaviors for a healthy pregnancy, via telephone; 3) making perinatal nurses available 24 hours a day 7 days a week, for consultation by telephone; and 4) offering “patient centered” case management by telephone for women who had identified risk factors for PTB. An evaluation of the program found that the participants had significantly reduced rates of PTB and their infants spent significantly fewer days in the NICU, compared to the corresponding population.⁶⁶ The evaluation did not measure which aspect(s) of the intervention were most effective. However, the study authors did note that the findings were consistent with prior research demonstrating that daily or frequent contact between a pregnant woman and a perinatal nurse is associated with reductions in PTB,⁶⁸⁻⁷⁰ and that since 1993,

ACOG as well as the U.S. Preventative Services Task Force have endorsed daily contact with a patient initiated by a provider as an effective means to prevent preterm birth.^{71,72}

Overall, these evaluations of telemedicine and telephone-based interventions suggest that such approaches are promising, and in the case of smartphone interventions, cost-effective. Moreover, unlike in-person clinical or psychosocial interventions, these approaches circumvent structural barriers to contact between providers and pregnant women, including transportation, work and family conflicts, and community distrust of brick-and-mortar medical and social institutions.

e) Conclusions and Recommendations

This review of literature indicates that a limited number of programmatic interventions have been evaluated to reduce infant mortality and its associated antecedents and risks among rural community infants in the U.S. The Healthy Start model involves programs with the longest history of successful implementation, but there is little available evidence for its efficacy in rural areas. However, the program is well established, with three decades of experience in implementing future programs, and may provide an organizational base or valuable partner for implementing additional programs in some areas. Other home visiting and education programs that involve trained community health workers (CHWs), show some evidence of efficacy. Centering Pregnancy, a form of group prenatal care, has demonstrated efficacy in improving birth outcomes, but its limitations include the need to travel to a site to engage in group care, and the exclusion of high-risk pregnant women. Behavioral interventions, similarly, show demonstrated efficacy in reducing behavioral factors associated with elevated infant mortality, including smoking, exposure to second-hand smoke, IPV, and depression, but have built-in

limitations in requiring one-on-one contact between professional or trained behavioral health experts and pregnant women. One of the most promising interventions in this review is a community-based education program specifically designed for improving birth outcomes and maternal health in rural areas, the *Becoming a Mom/Comenzando Bien* prenatal education program developed by the March of Dimes and already successfully tested in rural Kansas and rural Texas. Community baby showers also offer an innovative approach to improving knowledge of safe sleep and maternal health, although there is little evidence for their efficacy in reducing poor birth outcomes. Lastly, mHealth interventions appear to be highly feasible and scalable interventions in an era of near-universal mobile phone use – and of particular usefulness in rural areas where access to in-person encounters with CHWs and health professionals is limited - but their base of evidence for effectiveness remains small. This review indicates the need for more randomized controlled trials of various approaches to establish effectiveness levels for programs addressing rural infant mortality and its risk factors and antecedents. Overall, this review provides a window into several promising approaches with some evidence of effectiveness in reducing the antecedents and behaviors associated with elevated infant mortality and associated poor birth outcomes in rural communities.

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Attachment 1: Literature review on interventions to reduce infant mortality among African American and rural Americans

Multiple searches were completed in Ovid – Pub Med and Ovid – Embase. Searches were refined and expanded for breadth of capture.

Ovid – PubMed 02.18.19

	Searches	Results
1	Population, rural[MeSH] or populations, rural[MeSH] or communities, rural[MeSH] or community, rural[MeSH] or rural communities[MeSH] or African americans [MeSH] or blacks[MeSH]	134454
2	(program evaluation[MeSH Terms]) OR (program evaluations[MeSH Terms]) OR (intervention studies[MeSH Terms]) OR (prevention[MeSH Terms]) OR (health promotion[MeSH Terms]) OR (health promotions[MeSH Terms])	134856
3	(infant mortality[MeSH Terms]) or (infant death[MeSH Terms]) or (mortality, infant[MeSH Terms]) or (birth, preterm[MeSH Terms) or (preterm birth[MeSH Terms])	46928
4	((#last-line-number AND (north america[mesh:noexp] OR united states[mesh])) OR (#last-line-number NOT (africa[mesh] OR asia[mesh] OR australia[mesh] OR canada[mesh] OR europe[mesh] OR south america[mesh])))	1297973
5	("2008/01/01"[Date - Publication] : "2019/12/31"[Date - Publication])	11012002
6	1 and 2 and 3 and 4 and 5	13

	Searches	Results
1	((infant mortality[Title/Abstract]) OR preterm birth[Title/Abstract] or birth outcomes[Title/Abstract])	28902
2	((intervention[Title/Abstract] OR program evaluation[Title/Abstract] or community-based[Title/Abstract]))	875440
3	((African American[Title/Abstract]) or Black[Title/Abstract] or rural[Title/Abstract]))	279554
4	((#last-line-number AND (north america[mesh:noexp] OR united states[mesh])) OR (#last-line-number NOT (africa[mesh] OR asia[mesh] OR australia[mesh] OR canada[mesh] OR europe[mesh] OR south america[mesh])))	1297973
5	("2008/01/01"[Date - Publication] : "2019/12/31"[Date - Publication])	11012002
6	1 and 2 and 3 and 4 and 5	86

Ovid – PubMed 02.19.19

	Searches	Results
1	((infant mortality[Title/Abstract]) OR preterm birth[Title/Abstract] or birth outcomes[Title/Abstract])	28931
2	((intervention[Title/Abstract] OR program evaluation[Title/Abstract] or community-based[Title/Abstract]) OR program[Title/Abstract])	1463040
3	((African American* [Title/Abstract]) or Black* [Title/Abstract] or rural[Title/Abstract])	299111
4	((#last-line-number AND (north america[mesh:noexp] OR united states[mesh])) OR (#last-line-number NOT (africa[mesh] OR asia[mesh] OR australia[mesh] OR canada[mesh] OR europe[mesh] OR south america[mesh])))	1298053
5	("2008/01/01"[Date - Publication] : "2019/12/31"[Date - Publication])	11024488
6	1 and 2 and 3 and 4 and 5	130

Ovid – Embase 02.18.19

	Searches	Results
1	rural population/ or rural.mp.	171528
2	African American/ or black*.mp.	332310
3	1 or 2	498454
4	Infant mortality/ or infant death.mp.	30997
5	Program evaluation/ or evaluation/	178289
6	Intervention study/	39479
7	Community-based.mp.	68469
8	Health promotion/	90647
9	5 or 6 or 7 or 8	366694
10	3 and 4 and 9	198

Date filters (2008-2019) were applied to the search. **103** articles were yielded for initial title screening. 61 articles were not US-focused and were thus excluded, yielding **42** articles for further review.

Ovid – Embase 02.19.19

	Searches	Results
1	rural population/ or rural.mp.	171528
2	African American/ or black* .mp.	332310
3	1 or 2	498454
4	Infant mortality/ or infant death.mp.	30997

5	(preterm birth or premature birth).mp.	26371
6	4 or 5	56539
7	Program evaluation/ or evaluation/ or program.mp.	1016478
8	Intervention study/	39479
9	Community-based.mp.	68469
10	Health promotion/	90647
11	7 or 8 or 9 or 10	1167760
12	3 and 6 and 11	520

Date filters (2008-2019) were applied to the search. 296 articles were yielded for initial title screening. 157 articles were not US-focused and were thus excluded, yielding 139 articles for further review.

These 5 searches yielded 410 articles, which were imported into Rayyan, a free web application designed for systematic reviews. With duplicates removed, 257 articles were available for inclusion/exclusion. Reasons for exclusion were:

- Wrong study design or publication type (n=179)
- Wrong outcome (n=66)
- Wrong population (n=24)

Blind review of abstracts was completed by two independent reviewers, and discrepancies were resolved. Upon further review, 7 of the 52 remaining articles were duplicates, and their removal left 45 unique articles for review.

Attachment 2: List of Articles Included in Review

	Article Title	Program/Intervention Name	Intervention Type	African American	Rural American	Authors	Journal	Year
1	An Intervention to Reduce Environmental Tobacco Smoke Exposure Improves Pregnancy Outcomes		Behavioral intervention	Yes		El-Mohandes, A. A. E.; Kiely, M.; Blake, S. M.; Gantz, M. G.; El-Khorazaty, M. N.	Pediatrics	2010
2	Impact of pre-conception health care: evaluation of a social determinants focused intervention	The Magnolia Project (Program within the Healthy Start Program)	Behavioral intervention	Yes		Livingood W.C.; Brady C.; Pierce K.; Atrash H.; Hou T.; Bryant 3rd. T.	Maternal and child health journal	2010
3	Very preterm birth is reduced in women receiving an integrated behavioral intervention: a randomized controlled trial.		Behavioral intervention	Yes		El-Mohandes, Ayman A. E.; Kiely, Michele; Gantz, Marie G.; El-Khorazaty, M. Nabil	Maternal and child health journal	2011
4	An integrated randomized intervention to reduce behavioral and psychosocial risks: pregnancy and neonatal outcomes.		Behavioral intervention	Yes		Subramanian, Siva; Katz, Kathy S.; Rodan, Margaret; Gantz, Marie G.; El-Khorazaty, Nabil M.; Johnson, Allan; Joseph, Jill	Maternal and child health journal	2012
5	Effectiveness of a Pregnancy Smoking Intervention: The Tennessee Intervention for Pregnant Smokers Program.	Tennessee Intervention for Pregnant Smokers program (TIPS)	Behavioral intervention	No	Yes	Bailey, Beth A.	Health education & behavior: the official pub of the Society for Public Health Education	2015

	Article Title	Program/Intervention Name	Intervention Type	African American	Rural American	Authors	Journal	Year
6	Evaluation of Bedtime Basics for Babies: A National Crib Distribution Program to Reduce the Risk of Sleep-Related Sudden Infant Deaths	Bedtime Basics for Babies	Behavioral intervention	Yes	No	Hauck, Fern R.; Tanabe, Kawai O.; McMurry, Timothy; Moon, Rachel Y.	Journal of Community Health	2015
7	Health Messaging and African-American Infant Sleep Location: A Randomized Controlled Trial		Behavioral intervention	Yes		Moon R.Y.; Mathews A.; Joyner B.L.; Oden R.P.; He J.; McCarter R.	Journal of community health	2017
8	The South Carolina centering pregnancy expansion project: Improving racial disparities in preterm birth	CenteringPregnancy	Centering Pregnancy	Yes	No	Crockett A.H.; Covington-Kolb S.; Zang L.; Chen L.	American Journal of Obstetrics and Gynecology	2017
9	Implementing Group Prenatal Care in Southwest Georgia Through Public-Private Partnerships	CenteringPregnancy	Centering Pregnancy	Yes	Yes	Grant J.H.; Handwerk K.; Baker K.; Milling V.; Barlow S.; Vladutiu C.J.	Maternal and child health journal	2018
10	Genesee County REACH Windshield Tours: enhancing health professionals understanding of community conditions that influence infant mortality.	Genesee County Racial and Ethnic Approaches to Community Health (REACH)	Community-based	Yes		Kruger, Daniel J.; French-Turner, Tonya; Brownlee, Shannon	The journal of primary prevention	2013
11	Reducing infant mortality in Arkansas: a grassroots initiative utilizing African-American sororities	Sisters United	Community-based	Yes	Yes	Smith M.R.; Sharma R.; Grimes D.	The Journal of the Arkansas Medical Society	2014

	Article Title	Program/Intervention Name	Intervention Type	African American	Rural American	Authors	Journal	Year
12	Becoming a Mom: Improving Birth Outcomes through a Community Collaborative Prenatal Education Model	"Becoming a Mom"	Community-based		Yes	Woods, Nikki Keene	Journal of Family Medicine and Disease Prevention	2015
13	Improving Maternal and Infant Child Health Outcomes with Community-Based Pregnancy Support Groups: Outcomes from Moms2B Ohio.	Moms2B	Community-based	Yes		Gabbe, Patricia Temple; Reno, Rebecca; Clutter, Carmen; Schottke, T. F.; Price, Tanikka; Calhoun, Katherine; Sager, Jamie; Lynch, Courtney D.	Maternal and child health journal	2017
14	Implementing Community Baby Showers to Address Infant Mortality in Oklahoma.	"A Healthy Baby Begins with You"	Community-based	Yes	Yes	Thornberry, Timothy; Han, Jennifer; Thomas, Linda	The Journal of the Oklahoma State Medical Association	2017
15	Enhancing Healthier Birth Outcomes by Creating Supportive Spaces for Pregnant African American Women Living in Milwaukee.	Milwaukee Birthing Project	Community-based	Yes		Mkandawire-Valhmu, Lucy; Lathen, Lorraine; Baisch, Mary Jo; Cotton, Quinton; Dressel, Anne; Antilla, Jeri; Olukotun, Oluwatoyin; Washington, Rosetta; Jordan, Lyanne; Hess, Alexa	Maternal and child health journal	2018
16	Outcomes of Community-Based Prenatal Education Programs for Pregnant Women in Rural Texas.	"Becoming a Mom"	Community-based		Yes	Ramsey, Joseph; Mayes, Brandii	Family & community health	2018

	Article Title	Program/Intervention Name	Intervention Type	African American	Rural American	Authors	Journal	Year
17	Implementation of a Statewide Program to Promote Safe Sleep, Breastfeeding and Tobacco Cessation to High Risk Pregnant Women	Safe Sleep Community Baby Showers	Community-based		Yes	Ahlers-Schmidt C.R.; Schunn C.; Engel M.; Dowling J.; Neufeld K.; Kuhlmann S.	Journal of community health	2019
18	The impact of nurse case management home visitation on birth outcomes in African-American women	Black Babies Start More Infants Living Equally Healthy (SMILE)	Home visiting	Yes		Wells N.; Sbrocco T.; Hsiao C.-W.; Hill L.D.; Vaughn N.A.; Lockley B.	Journal of the National Medical Association	2008
19	Reducing Low Birth Weight Through Home Visitation: A Randomized Controlled Trial:	Healthy Families New York (HFNY)	Home visiting	Yes		Lee, Eunju; Mitchell-Herzfeld, Susan D.; Lowenfels, Ann A.; Greene, Rose; Dorabawila, Vajeera; DuMont, Kimberly A.	Obstetrical & Gynecol Survey	2009
20	Healthy Start Program and Feto-Infant Morbidity Outcomes: Evaluation of Program Effectiveness	Central Hillsborough Healthy Start Project (CHHS)	Home visiting	Yes		Salihu, Hamisu M.; Mbah, Alfred K.; Jeffers, Delores; Alio, Amina P.; Berry, Lo	Maternal and Child Health Journal	2009
21	Characteristics, access, utilization, satisfaction, and outcomes of healthy start participants in eight sites	National evaluation of the Healthy Start Program	Home visiting	Yes	Yes	Rosenbach M.; O'Neil S.; Cook B.; Trebino L.; Walker D.K.	Maternal and child health journal	2010
22	Effectiveness of a federal healthy start program in reducing the impact of particulate air pollutants on feto-infant morbidity outcomes.	Central Hillsborough Healthy Start Project (CHHS)	Home visiting	Yes		Salihu, Hamisu M.; August, Euna M.; Mbah, Alfred K.; Alio, Amina P.; de Cuba, Raymond 2nd; Jaward, Foday M.; Berry, Estrellita Lo	Maternal and child health journal	2012

	Article Title	Program/Intervention Name	Intervention Type	African American	Rural American	Authors	Journal	Year
23	The Maternal Infant Health Outreach Worker program in low-income families.	Vanderbilt University Medical Center's Maternal Infant Health Outreach Worker program (MIHOW)	Home visiting		Yes	Elkins, Tonya; Aguinaga, Maria Del Pilar; Clinton-Selin, Caitlin; Clinton, Barbara; Gotterer, Gerald	Journal of health care for the poor and underserved	2013
24	Improved birth weight for Black infants: outcomes of a Healthy Start program.	Healthy Babies Healthy Start (HBHS)	Home visiting	Yes		Kothari, Catherine L.; Zielinski, Ruth; James, Arthur; Charoth, Remitha M.; Sweezy, Luz del Carmen	American journal of public health	2014
25	Effect of Home Visiting by Nurses on Maternal and Child Mortality: Results of a 2-Decade Follow-up of a Randomized Clinical Trial	Nurse-Family Partnership (NFP)	Home visiting	Yes	No	Olds, David L.; Kitzman, Harriet; Knudtson, Michael D.; Anson, Elizabeth; Smith, Joyce A.; Cole, Robert	JAMA Pediatrics	2014
26	A statewide medicaid enhanced prenatal care program impact on birth outcomes	Maternal Infant Health Program (MIHP)	Home visiting	Yes	No	Roman L.; Raffo J.E.; Zhu Q.; Meghea C.I.	JAMA Pediatrics	2014
27	Effects of maternity care coordination on pregnancy outcomes: propensity-weighted analyses	Maternity Care Coordination (MCC)	Home visiting	Yes	Yes	Hillemeier M.M.; Domino M.E.; Wells R.; Goyal R.K.; Kum H.-C.; Cilenti D.; Timothy Whitmire J.; Basu A.	Maternal and child health journal	2015
28	Statewide medicaid enhanced prenatal care programs and infant mortality	Maternal Infant Health Program (MIHP)	Home visiting	Yes	No	Meghea C.I.; You Z.; Raffo J.; Leach R.E.; Roman L.A.	Pediatrics	2015
29	Pathways community care coordination in low birth weight prevention	CHAP - Community Health Access Project	Home visiting	Yes	No	Redding, Sarah; Conrey, Elizabeth; Porter, Kyle; Paulson, John; Hughes, Karen; Redding, Mark	Maternal and Child Health Journal	2015
30	The impact of dose of the St. Louis Healthy Start program and prenatal care adequacy on birth outcomes	Healthy Start	Home visiting	Yes	No	Rotter, Beth; Elliott, Micheal; Recktenwald, Angela; Scharff, Darcy	Journal of Nursing Education and Practice	2015

	Article Title	Program/Intervention Name	Intervention Type	African American	Rural American	Authors	Journal	Year
31	Is Timing of Enrollment Associated with Birth Outcomes? Findings from a Healthy Start Program in Kansas.	Sedgwick County Healthy Babies Healthy Start (HBHS)	Home visiting	Yes	No	Brown, Kyrah K.; Johnson, Candace; Spainhower, Michele; Phillips, Nicole Fox; Maryman, J'Vonnah	Maternal and child health journal	2017
32	Preterm birth among African American women in a federal healthy start program: Informing pay for success	Healthy Start	Home visiting	Yes		Roman L.A.; Luo Z.; Meghea C.; VanderMeulen P.; Fawcett K.; Leach R.	Obstetrics and Gynecology	2018
33	Effectiveness of an infant mortality prevention home-visiting program on high-risk births in Ohio	Ohio Infant Mortality Reduction Initiative (OIMRI)	Home visiting	Yes		Swoboda C.M.; Benedict J.A.; Hade E.; McAlearney A.S.; Huerta T.R.	Public health nursing	2018
34	Using Fetal and Infant Mortality Reviews to improve birth outcomes in an urban community.	Fetal and Infant Mortality Review (FIMR)	Infant mortality review	Yes		Johnson, Teresa S.; Malnory, Margaret E.; Nowak, Emily W.; Kelber, Sheryl	Journal of obstetric, gynecologic, and neonatal nursing	2011
35	South Carolina Partners for Preterm Birth Prevention: a regional perinatal initiative for the reduction of premature birth in a Medicaid population	MaternaLink, South Carolina Partners for Preterm Birth Prevention	Telemedicine/mHealth	Yes	Yes	Newman, Roger B.; Sullivan, Scott A.; Menard, M. Kathryn; Rittenberg, Charles S.; Rowland, Amelia K.; Korte, Jeffrey E.; Kirby, Heather	American Journal of Obstetrics and Gynecology	2008
36	STORC helps deliver healthy babies: the telemedicine program that serves rural women with high-risk pregnancies	Solutions to Obstetrics in Rural Counties (STORC) project	Telemedicine/mHealth		Yes	Wood D.	Telemedicine journal and e-health	2011

	Article Title	Program/Intervention Name	Intervention Type	African American	Rural American	Authors	Journal	Year
37	The Effect of Nursing Quality Improvement and Mobile Health Interventions on Infant Sleep Practices: A Randomized Clinical Trial		Telemedicine/mHealth	Yes	Yes	Moon R.Y.; Hauck F.R.; Colson E.R.; Kellams A.L.; Geller N.L.; Heeren T.; Kerr S.M.; Drake E.E.; Tanabe K.; McClain M.; Corwin M.J.	JAMA	2017
38	The feasibility and promise of mobile technology with community health worker reinforcement to reduce rural preterm birth	"GoMo Health"	Telemedicine/mHealth		Yes	Cramer M.E.; Mollard E.K.; Ford A.L.; Kupzyk K.A.; Wilson F.A.	Public health nursing	2018
39	The impact of prenatal WIC participation on infant mortality and racial disparities	WIC	WIC	Yes		Khanani I.; Elam J.; Hearn R.; Jones C.; Maseru N.	American journal of public health	2010
40	Infant Mortality and Race in Kansas: Associations With Women, Infants, and Children Services.	WIC	WIC	Yes	No	Keene Woods, Nikki; Reyes, Jared; Chesser, Amy	Journal of primary care & community health	2016
41	The Impact of WIC on Birth Outcomes: New Evidence from South Carolina.	WIC	WIC	Yes	No	Sonchak, Lyudmyla	Maternal and child health journal	2016

**Exploring the Roles of Community Health Workers and Patient Navigators to
Improve Birth Outcomes: A Literature Review**

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The following review of literature has been completed for the Maryland Health Care Commission, pursuant to legislation (2018 Md. Laws, Chap. 83), requiring the Commission to conduct a study of infant mortality rates for African American infants and infants in rural area, which includes “thorough literature reviews on innovative and effective programs to reduce infant mortality with a specific focus on programs targeting rural and African American infants, and **the use of pregnancy navigators and community health workers.**”

Patient navigators serve a critical role in improving health outcomes in a variety of settings, including primary care, specialty care for chronic conditions, and community outreach. Beyond health outcomes, working with navigators may improve overall health by promoting self-efficacy and health literacy, which enables patients to become more independent in decisions related to their health and utilization of the health care system.¹ Furthermore, patient navigation has been shown to reduce health disparities related to income and race/ethnicity.²

The patient navigation workforce is comprised of both professional and lay workers, to include nurses, social workers, and community health workers. In the literature, in addition to being called patient navigators, individuals filling this role may also be referred to as Community Health Workers/Liaisons/Advisors, Case Managers, Promotoras, Guided Care Nurses, or Health Advocates. Regardless of the title or who is filling the role of navigator, the goals of patient navigation include working with patients to identify gaps and barriers to accessing health care, connecting patients to appropriate services, ensuring timely utilization of care, and providing health education and social support.^{3,4} This profession is distinct from others that link patients to care because service connection is typically linked to specific, measurable outcomes, such as ensuring patients attend appointments. For example, patient navigators in Maternal and Child

Health might ensure that women who have recently given birth attend a postpartum OB/GYN appointment.⁵

A recent review highlighted the ways in which patient navigation may be applied to women's health to reduce disparities and improve birth outcomes,¹ but few published studies provide examples of patient navigation in pregnancy. In the Community Health Access Program (CHAP), which targeted African American women in Urban Ohio who were at high risk for poor birth outcomes, community health workers (CHWs) connected women to social and health services.⁶ After connecting clients to services, CHWs tracked each identified issue to measurable completion, ensuring clients received the appropriate social services, or attended medical appointments. Women enrolled in CHAP had lower odds of having a low birth weight infant than comparable women who were not enrolled in the program.⁶

In a patient navigation program that addresses health during the postpartum period, "Navigating New Motherhood" recruited racial/ethnic minority women attending an urban clinic.⁵ These women received services related to scheduling post-partum appointments, mental health needs, and connection to social services like transportation and nutritional resources. In comparison to those not enrolled, women enrolled in the program were more likely to remain in post-partum care, receive depression screenings, and utilize contraception.⁵ Contraceptive use may prevent short interpregnancy intervals, which are associated with higher risk for maternal and infant mortality.^{7,8}

To date, there are no other peer-reviewed studies on the efficacy of patient navigation programs in pregnancy, but the effectiveness of patient navigation has been well-established for other health outcomes, and many of the same principles may apply. Patient navigator programs are critically important in fulfilling the health care needs of individuals with chronic health

conditions in areas of high poverty or limited access to health services.⁹ Many navigator programs have been established to specifically address the needs of medically underserved communities as well as consequent racial and ethnic health disparities.¹⁰ In terms of cancer-related care in Federally Qualified Health Centers, patient navigation and community health worker programs have been linked to increased referral and completion of cancer screening, reduced time to diagnosis, and completion of diagnostic resolution.¹⁰ In a review of these types of programs, navigators or CHWs identified and addressed barriers to care, scheduled appointments and facilitated referrals, ensured attendance to appointments, provided health education, arranged or provided social services like transportation, and encouraged/supported patients.¹⁰

Programs have also been developed to address the needs of patients with chronic conditions, like HIV/AIDS, diabetes, cardiovascular disease, and chronic kidney disease, who all experience similar barriers to managing their disease and accessing services.¹¹ Evaluations of these programs have provided mixed results, but generally, patient navigation improved processes of care, like disease screenings and adherence to follow-up procedures.¹¹ Most often in these interventions, lay workers were trained to be patient navigators, with primary roles being care facilitation, addressing patient attitudes and beliefs, support with health literacy issues, and tangible support, such as connecting patients to childcare providers, transportation services, and public services to help with financial needs.¹¹

Finally, patient navigation programs have been integrated in some primary care settings to address the unmet social needs of patients.¹² While this model is not commonly used, addressing the social determinants of health has been widely accepted as a critical component to achieving health equity.¹³ Patient navigators in this type of primary care setting assist patients

with accessing and adhering to care, system navigation, insurance issues, transitions between providers or care settings, mental illness, substance use, and specific issues related to the social determinants of health, like housing concerns, food insecurity, legal issues, employment and financial concerns, and lack of social support.¹² Each of these types of programs measures outcomes differently, and few have been formally evaluated, making it challenging to make definitive statements with regard to efficacy. However, a scoping review of these types of programs highlights the importance of tailoring navigation programs to specific patient populations.¹²

Given the success of patient navigation programs, it is likely that this model has been adapted to improve outcomes in communities with traditionally poor birth outcomes, like African American or rural communities. However, the published literature has not caught up with this transition. In evidence of this point, the search for relevant literature surrounding patient navigation, CHWs, and birth outcomes among African Americans produced a conference abstract for a presentation given at this year's Annual Meeting of the American College of Obstetricians and Gynecologists.¹⁴ The abstract details results of an evaluation of "Safe Start," a program targeting low-income women with chronic conditions, most of whom were African American and substance users. After receipt of intensive patient navigation and systematic case review with health care providers and insurers, program participants were more likely to have adequate prenatal care, attend postpartum appointments, and utilize postpartum contraception, while being less likely to require inpatient care or utilize emergency departments during pregnancy.¹⁴

Despite the lack of published evaluation results for patient navigation in pregnancy, a relatively small group of studies has been published discussing the efficacy of home visiting

programs for these communities. While home visiting programs are distinct from patient navigation programs in that they typically measure success in terms of birth outcomes, as opposed to service utilization outcomes, CHWs perform functions that are similar to patient navigators. As mentioned previously, CHAP is a program directed toward improving birth outcomes among urban African American women.⁶ CHWs in the program developed health and social “pathways” of care through an intensive home visiting program, which measures success in terms of both birth outcomes and measurable objectives, including connection to a medical home, maintenance of prenatal care, and utilization of referred social services. Furthermore, CHWs were salaried employees, but received bonus payments upon pathway completion.⁶

The U.S. Department of Health and Human Services maintains a database of evidence-based home-visiting models, highlighting those that meet their criteria for an effective intervention.¹⁵ Using sources identified on this website, and after an extensive search of PubMed and EMBASE, six published evaluations were identified for programs utilizing CHWs to address birth outcomes among African American women. There were no evaluations published that utilized CHWs to exclusively address birth outcomes in rural areas in the U.S., though one state-wide program included women in rural areas.¹⁶ There are also other programs that have been utilized but not evaluated within rural counties, including Parents as Teachers, Oklahoma’s Community-Based Family Resource and Support (CBFRS) Program, and Health Access Nurturing Development Services (HANDS) Program.¹⁵

Of the evaluations identified for African Americans, two evaluated Healthy Start programs,^{17,18} one evaluated a Resources, Education, and Care in the Home (REACH)-futures program,¹⁹ one evaluated a county-level program,²⁰ one included information on a state-based initiative to reduce infant mortality,¹⁶ and the final evaluated the previously-discussed CHAP

intervention.⁶ Across all interventions, CHWs were individuals who were hired from within the community and trained to conduct home visits and connect clients with services. In Kalamazoo, Michigan, the Black to White infant mortality ratio is higher than the national average, prompting the implementation of a Healthy Start Program.¹⁷ Program participants were recruited through obstetric clinics and had monthly, in-person visits with community case managers, who developed individualized care plans in conjunction with the client's health care provider. Case managers referred clients to community resources, provided education on maternal and infant health, and ensured clients had continuous access to prenatal care.¹⁷ Despite being more likely to smoke than non-users of the Healthy Start program, African American participants delivered higher birth weight infants than nonparticipants. There was no difference in birth weight for white participants vs. nonparticipants.¹⁷

In another study, researchers evaluated the “dose” of a Healthy Start program in St. Louis, MO.¹⁸ In this program, nurses provided in-home prenatal care, while CHWs provided education and service referrals to participants, who were all African American. In this evaluation, participants with more prenatal case management visits were less likely to deliver a preterm infant, though this association varied across levels of prenatal care (adequate vs. inadequate), and receiving in-home case management increased the odds of having adequate prenatal care.¹⁸

The Resources, Education and Care and the Home program (REACH-futures) in inner city Chicago was an adaptation of the original national REACH program that utilized nurses for home visiting.¹⁹ In REACH-futures, CHWs perform the same function as nurses, working as part of a nurse-led team, where nurses accompanied CHWs on some home visits (one prenatal, and three post-partum). CHWs visited clients monthly to provide social support, identify problems,

provide education and problem-solving, assist with goal-setting for parenthood and preventing future pregnancies, and connecting clients with community resources.¹⁹ The results of this evaluation indicated that using CHWs was as effective at improving birth outcomes as using nurse-only teams, which had reduced infant mortality in the regions targeted by the program.¹⁹

In Genessee County, Michigan, the Racial and Ethnic Approaches to Community Health (REACH) Project is a multi-component initiative to reduce infant mortality among African American women.²⁰ Community Health Advocates connect women to resources to help them address their health care, housing, and nutritional needs, working with clients through pregnancy and up to two years old. In addition to case management, CHWs host monthly support groups and annual baby showers.²⁰ While the rate of infant mortality in Genessee County has been at a historic low since the implementation of the program, it is likely the decline has occurred as a result of multiple components of the program, and cannot be directly attributed to the contributions of CHWs.²¹

Finally, the Ohio Infant Mortality Reduction Initiative utilizes CHWs to conduct home visits for African American women with the purpose of reducing infant mortality among African Americans in the state, some of whom live in rural areas.¹⁶ CHWs visit clients on a weekly or monthly basis, depending on their need, and provide education, social support, and referrals to community services and health care. In addition, they evaluate risk factors and address immediate needs of the client, such as housing insecurity, transportation barriers, mental health, and substance abuse issues.¹⁶ While birth outcomes have not yet been evaluated, findings indicate that this CHW-led program has influenced access to prenatal care by removing barriers, improved health care utilization, and increased maternal empowerment and self-efficacy, which may influence health behaviors.¹⁶ The findings of this study also indicate that transportation

barriers are more prevalent for clients living in rural areas, and provision of gas cards and bus passes greatly influenced attendance at prenatal care appointments.¹⁶

Altogether, the literature on patient navigation and home visiting by CHWs indicates that “pregnancy navigators,” or CHWs who perform patient navigation activities among pregnant women, could be a critical component to improving and promoting health equity in birth outcomes, which strongly influence infant mortality. Of the few programs with published evaluations, the services provided by CHWs, either as members or leaders of teams, have been associated with improved birth outcomes among African Americans, which will likely translate to improvements in infant mortality over time. This effectiveness has already been shown in CHAP and Safe Start, which are likely the first of many patient navigation programs that will emerge over the next several years to address disparities in birth outcomes.

In a recent review, McKenney et al. describe several ways in which patient navigators could be integrated into women’s health care to address inequities.¹ They first outline a model by which patient navigators enhance access to care, promote self-efficacy, and sustain engagement with care, assuming that self-efficacy and sustained engagement will be reinforced within the patient over time to allow for self-sustained engagement with care in the future. In practice, this means patient navigators should help schedule prenatal appointments, assist with barriers to attending appointments, connect patients to community resources (housing, food, transportation), offer social support throughout the prenatal period, help patients identify primary and pediatric care providers to be prepared for the postpartum period, and assist with the transition from obstetric to primary care.¹ While these activities are meant to serve as suggestions for how patient navigation could be integrated into obstetric care, there are similarities between these suggested services and those already provided by CHWs working in home visiting, as described in the preceding

paragraphs. Thus, current programs utilizing CHWs may only need to be altered to include the measurement of specific outcome objectives to transition them into “pregnancy navigator” programs. McKenney et al recommend several outcome measures to assess the effectiveness of navigation, including patient satisfaction, patient anxiety, time to diagnosis of pregnancy-related morbidities (e.g., gestational hypertension or diabetes), time to initiation of screening or therapy, and specific birth outcomes.¹ Taking a cue from the patient navigator literature for cancer and chronic disease, in addition to disease-specific metrics like preterm birth, low birth weight, or infant mortality, “pregnancy navigator” programs could include measurable objectives such as accessing referred social services, use of transportation incentives (i.e., bus passes or gas cards), attendance to prenatal care and other referred services, obtaining recommended prenatal screenings, or level of perceived social support. Thus, CHWs could easily transition to patient navigator roles to reduce disparities in birth outcomes.

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Additional Interventions: An Addendum to What Works to Save Babies' Lives? Reviews of Interventions to Reduce Mortality among African American and Rural Community Infants

In response to feedback from Maryland Healthcare Commission Working Group members, literature on three additional groups of interventions and one policy were investigated as an addendum to the review, "What Works to Save Babies' Lives? Reviews of Interventions to Reduce Mortality among African American and Rural Community Infants." These include peer-reviewed literature published in the last ten years on: a) interventions that involve administration of 17 hydroxyl-progesterone treatments or vaginal progesterone to pregnant women to prevent preterm birth; b) programs that combined several different interventions over a longer period; c) the effectiveness of Nurse-Family Partnership and telemedicine interventions in preventing or reducing rural infant mortality; and d) the impact of paid family leave on infant mortality.

These three types of interventions, none of which was included in the original review, were mentioned in comments or questions at an April 5, 2019 working group meeting. Later, work group members raised the question of paid family leave as a policy measure to reduce infant mortality. Because peer reviewed literature was available to respond to these comments, the additional investigation was conducted.

The literature for this addendum was obtained through the following methods: a) an additional review of the larger pool of articles (n=45) from which our final sample was taken to identify articles on the above topics that had been eliminated through our rules for exclusion; 2) an email from a commission working group member with articles attached; 3) PubMed search using key search terms for categories a., c., and d. No PubMed search was conducted for category b. because this category (combined interventions) did not lend itself to easy identification with search terms. This search was intended to identify any recent literature not obtained through our previous searches, but was not exhaustive. Additional articles were identified through review of references in the articles obtained through the above three methods, or through consultation of websites for programs referenced in the peer-reviewed articles.

Progestogen Treatments

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In the April 5 working group meeting, several participants who were clinicians discussed the clinical use of progestogens as an intervention to prevent preterm birth in women with previous spontaneous preterm birth and/or a short cervix. They suggested that these interventions could be integrated with existing community-based programs, which might help with recruitment of eligible women and adherence to treatment.

Progestogen treatments are administered in two forms: weekly intramuscular injection of the substance 17-[alpha]-hydroxyprogesterone caproate (17P) from the 16th through the 20th or 24th week, daily vaginal progesterone suppositories, or daily treatment with a vaginal progesterone gel.¹ The precise mechanism through which progestogens prevent preterm birth is not known, although there are indications that they inhibit synthesis of the prostaglandins (hormones that play a critical role in inflammation, which is a biological driver of preterm labor)²; as well as block estrogen receptors, and break down receptors for oxytocin, the hormone that stimulates uterine contractions.¹ Overall, research has indicated that “Progesterone is a key hormone involved in pregnancy maintenance,”³ (p. 462) and progestogens increase progesterone levels. Over the past fifteen years, scientific evidence mounted for the efficacy of clinically administered progestogens in preventing PTB among high-risk women. A 2017 review of the literature on this topic found that, in 7 out of 10 randomized-placebo controlled trials (the gold standard of scientific research), administering progestogens to women with a history of PTB significantly reduced rates of one or more antecedents to infant mortality: PTB, LBW, NICU admission, and/or significantly increased mean gestational age at delivery (GAD). Two of these (both with positive results) involved administration of 17P. Only one of three RCTs in which progestogens were administered to women with a short cervix, however, found significant differences in neonatal outcomes. Similarly, only two out of 11 RCTs in which progestogens were administered to women with twin pregnancies found any positive difference in neonatal outcomes. Six out of 12 RCTs in which progestogens were administered to women who had already had preterm labor or premature rupture of membranes found a positive difference in neonatal outcomes.¹ Overall, this review suggests that the evidence is strongest for the use of progestogens in women with a history of prior preterm birth.

This positive but mixed record of research on progestogens' effectiveness in improving birth outcomes was recently clarified somewhat by a systematic review and meta-analysis (a study in which data from many previous studies is pooled and collectively analyzed to come up with overall findings). The reviewers identified 40 RCTs that examined the effects of progestogens (24 studies), cerclage – sewing the cervix shut (11 studies) or an inert pessary (4 studies) and cerclage vs. progestogens (1 study) on neonatal outcomes. Their analysis found that vaginal progesterone (PV progesterone) significantly reduced VPTB (<34 weeks) in high-risk women overall, in women with a previous preterm birth, and in women with a short cervix. It also reduced PTB overall and neonatal death in high risk women. 17P was only shown to reduce PTB and neonatal death in women with a previous preterm birth. The authors concluded that PV progesterone has shown consistent effects in reducing PTV and improving birth outcomes, while more study is needed on 17P.⁴

As evidence accumulated for the effectiveness of progestogens in preventing PTB, the Society for Maternal-Fetal Medicine (SMFM) and the American College of Obstetricians and Gynecologists (ACOG) recommended in 2012 that progestogens be administered for women with a cervix of less than 20mm, and/or prior spontaneous PTB.⁵ Following these recommendations, several states initiated programs to ensure that clinicians administer progestogens in populations at highest risk for PTB and infant mortality.

In this new look at the literature, we identified three peer-reviewed publications that described these interventions/programs. The first program, the Ohio Progestogen Project, was conducted in 2014 and 2015 by the Ohio Perinatal Quality collaborative - a voluntary statewide network that brings together “stakeholders” including the state department of health, the state Medicaid department, the March of Dimes, local colleges of medicine, the state hospital association and other organizations seeking to improve birth outcomes.⁶ The project involved 23 prenatal clinics at 20 of the largest maternity hospitals in the state (which accounted for half of the state's births) together with the state Medicaid organization and Medicaid insurers. This systematic effort aimed to identify women with prior preterm birth or short cervix as candidates for prophylactic treatment with a progestogen, then to remove barriers to their receiving this treatment – either PV progesterone or 17P. At each of the 23 clinics, project leaders recruited and regularly met

with a team consisting of a nurse, a physician, and a data entry person. Together they identified ways to ensure that women had early access to prenatal care and were identified early in pregnancy as high risk (so they could initiate the progestogen treatment at the recommended time). The teams had to “align and communicate” with emergency departments, CHWs, WIC personnel, and facilitate rapid access to obstetric appointments for eligible women. They also coordinated with the state Medicaid program and insurers to reduce administrative barriers to getting prescriptions for the progestogens, and created a written administrative protocol. To facilitate early identification of women with a short cervix, they adopted a uniform protocol for ultrasound cervical length screening with at least one trained and credentialed ultrasonographer at each clinic. The project identified 2,562 eligible women during the 23 months of the study. Progestogens were prescribed to 62% of women before the end of the 20th week of pregnancy, and 72% before the end of the 24th week. VPTB (<32 weeks) declined 6.6% in the state during the time of the project – a reduction that project leaders attributed to its impact, using a statistical evaluation of PTB during the project and considering other possible contributors.

While treatment refusal and later entry to care played substantial roles in limiting women’s uptake of progestogen, project leaders found that the leading cause for delay or interruption of progestogen treatment in their population was “inefficient communication at the system level among health care providers, insurers, county eligibility staff, pharmacies, hospitals, and pregnant women” (p. 345). Women “were inadvertently disenrolled from Medicaid because the Medicaid eligibility system had not been notified of their current pregnancy status.”⁵ They additionally faced barriers caused by outdated or multiple treatment protocols used by hospitals, pharmacies, or insurers. To address this administrative barrier, the project leaders found it useful for teams at each clinic to designate a “progestogen navigator” who monitored eligible women and tracked them on a “progesterone log”. Additionally, after the program ended in February 2016, the state’s Medicaid managed care plans agreed to remove a requirement that progestogen formulations have prior authorization.⁷

In another study of 17P uptake, researchers reviewed patient data and interviewed personnel at centers around the U.S. funded by the federal Strong Start program, which is designed to reduce PTB and LBW among Medicaid and CHIP recipients. They found that only 14.95% of women

with prior preterm births received 17P, and that this was largely due to administrative barriers such as the difficulties with pre-authorization. “The barrier is just getting the medication,” one provider at a maternity center told the interviewers. “I meet [a patient] and...determine the need for [17P] and we fill out the form through the nurse. Sometimes it takes 2–3 or maybe even 4 weeks to get the medicine.” This delay makes it less likely for those patients who do not initiate care early to get it.⁸ As of 2017, Louisiana was the only state that did not require prior authorization for the brand name version of the drug, Makena.⁹

Another well-documented barrier to receiving 17P has been cost. Makena was approved by the FDA in 2011 under the Orphan Drug Act, which grants drug manufacturers exclusive rights to sell the branded version for seven years, and the manufacturer began charging \$1,500 per dose – or up to \$28,800 per patient.^{9 10} As of 2016, most states’ Medicaid Managed Care plans (including Maryland’s) covered this expensive prescription.⁹ However, even if Medicaid reimburses the cost, providers pay up front for the 17P – something they are not always willing to do. “If a patient does not show up for the 17P injection appointment, the provider’s office cannot claim reimbursement and must eat the cost of that dose,” providers told the Strong Start study interviewers (p. 1611).⁸ This situation may have changed since Makena’s 7-year exclusive right to sell the drug expired last year, and much cheaper generic versions have been available since mid-2018.¹¹ However, given previously mentioned findings that insurers, clinics, pharmacies, and providers may be using outdated protocols or lack current information on this drug, it is not clear that this change in availability has translated into practice.

Even if the cost barrier and concomitant prior authorization requirement have been removed, additional administrative barriers to access for progestogens may remain. A program launched in 2013 by the Louisiana Department of Health provides additional ideas for how to address access barriers. The state has one of the highest infant mortality rates in the country, as well as large racial disparities in infant mortality. The Department of Health nevertheless found in 2013 that fewer than 7% of pregnant women in the state who were eligible for progestogens received this treatment. The Department then launched a campaign that included the creation of a registry of eligible women, using vital records. Managed care companies were required to use these lists in reaching out to the woman, and were mandated to cover this treatment. The Department

streamlined ordering with a simple one-page order, and launched a physician education program about the benefits and uses of 17P. The state Medicaid program also stated it would impose a \$250,000 penalty to any plan that did not participate in covering Makena or compounded 17P. The Medicaid program also reimbursed home health agencies for 17P. The percentage of eligible women who received Makena increased to 23.7% in 2016, although the State Health Department continues to advocate for wider use of the drug.¹⁰

The possibility of integrating 17P or PV progesterone administration with another intervention, such as nurse home visiting, has recently been addressed in the literature. In one study, clients of an outpatient clinic for women with high risk pregnancies were enrolled in a 17P administration program, which included a home visit by a perinatal nurse. The nurse educated the patient about pregnancy, signs and symptoms of preterm labor, and 17P, and followed up with weekly visits to administer the 17P. Among those who then were hospitalized with preterm labor but did not deliver, the program followed up with either continued weekly visits, or increased to a daily protocol. The daily group members, who were matched by gestational age and Medicaid status to members of the weekly visit group, also received an electronic device and monitored their uterine activity for an hour two times a day and as needed, to assess signs and symptoms of preterm labor. The data from these electronic devices were transmitted to a regional perinatal call center, where nurses evaluated them. Nurses and physicians followed up in response to these data. The study results found that those who participated in the daily monitoring program had significantly lower rates of VPTB (<32 weeks) as well as significantly lower rates of PTB at <35 weeks than the weekly group. This study shows the value of using 17P or PV progesterone in conjunction with other programs, such as intensive nurse surveillance and home visiting.¹²

Compound-Combination Interventions

The wide variety in types of interventions to prevent infant mortality in African American and rural populations points to the fact that no one intervention may be the secret to addressing disparities in neonatal outcomes. As such, some large programs have incorporated numerous interventions over long periods of time. While the prior literature review included several interventions that were part of larger projects, it did not focus on the larger umbrella programs.

Here, two of these programs, which encompassed interventions within our earlier review, are discussed.

The National Institutes of Health-DC Initiative to Reduce Infant Mortality in Minority Populations consisted of an 18-year (1992-2010) federally funded collaborative project between the National Institute for Child Health and Development (NICHD), a center for coordinating data, and a number of intervention sites in the District of Columbia. The program combined research studies with evaluated interventions to provide a larger picture of the factors underlying the elevated infant mortality rate in the District, especially among African Americans, and inform successful interventions to reduce it. The program involved three phases – a design which enabled the revision of evaluated programs and research in response to the findings of each phase, and the incorporation of practical lessons learned.¹³

The first phase, (1992-1998), included two evaluated programs – a randomized trial of an educational program for new mothers without adequate prenatal care and a program to prevent adolescent pregnancy. Mothers who participated in the educational program were significantly more likely to complete scheduled immunizations for their infants within 9 months than those who were not assigned to this trial. It also included six studies, which examined NICU characteristics within the District, immunization rates of D.C. children, childhood injuries, the “barriers, motivators and facilitators” of prenatal care utilization, and alcohol consumption during pregnancy (p. S5). The study of prenatal care utilization barriers revealed that adolescent (<20 years) women and women over 29, as well as those without financial means or motivation to pay for care, were less likely to initiate prenatal care than others.¹³

The second phase, (1998-2004) involved revision of the adolescent pregnancy prevention program and alcohol consumption study, as well as an RCT of a psychosocial intervention for pregnant women who smoked or were exposed to second-hand smoke, or experienced depression or intimate partner violence. This last study was included in our review of the literature and has been discussed as a successful intervention.¹⁴

The final phase (2004-2010) included an RCT aimed at increasing the inter-pregnancy interval in teen mothers; an intervention using cognitive behavioral therapy plus the transdermal nicotine patch for smoking cessation among pregnant women; and a screening and secondary prevention program for elevated blood levels and secondhand smoke exposure among low-income pregnant women.¹³

By combining this diverse array of studies and interventions under a single network, the overall program leaders and coordinators could better learn from findings and implement procedures to better reach target populations across the interventions. They reported learning four main lessons, which are likely applicable to any programmatic intervention or group of interventions seeking to reach populations at elevated risk for infant mortality and maternal morbidity and mortality. First, they found that they had to organize the interventions and research activities at times and places that were convenient to participants, and hire study personnel who could relate to participants and who treated them with dignity and respect. At the same time, some participants found home visits to be intrusive, especially when they were sharing their living space and had little control over their environment. This difficulty arose within an intervention aimed at reducing participants' exposure to secondhand smoke/ETS. Second, the program leaders found that it was effective to use technology (such as recording devices) to collect information on stigmatized risk behaviors and sensitive information. Third, they found that integrating counseling and education worked to improve pregnancy outcomes; and last, they found that it was important to involve participants' family members in activities whenever appropriate – especially for adolescent pregnancy prevention.¹³

A third multi-stage program that incorporated numerous interventions was the REACH program, implemented in Genesee County (Flint), Michigan. The overall REACH (Racial and Ethnic Approaches to Community Health), program was initiated in 1999 by the U.S. Centers for Disease Control and Prevention. A group consisting of researchers from the University of Michigan School of Public Health, the local health care system, the county health department, and community-based organizations obtained federal funding for a REACH program to apply community-based participatory research (CBPR) principles to reducing the elevated African American infant mortality rate in the county (which was 2.5 of the white rate), and began

implementing it in 2000.^{15 16} The underlying CBPR principles comprise an equitable approach that places an equal value on community-generated knowledge” or “trench” experience, along with academic knowledge, or “bench” science, as well as a commitment to addressing the social and structural determinants of health disparities.¹⁵ These determinants consist of the larger, non-health factors, from lack of access to transportation or health care to racism in institutions and policies, poverty, and inequality.

The Genesee County REACH program involves a number of interventions informed by this community-engaged approach. The program employed a “three-theme approach”: mobilize the community, reduce racism (a determinant of infant mortality disparities) and enhance the health care system for mothers and infants.¹⁶ Two of these interventions have been previously discussed as they were included in the literature review: MIHAS, a program that employs local African American women as home visitors and community health advocates to help pregnant women navigate the health care and social services system; and “windshield tours”, driving tours of the neighborhood where the women participating in the home visiting program live. The latter sought to educate health care providers, administrators, and policy makers to the transportation, food shopping, quality of life, and other neighborhood-based challenges the women faced.^{15 16}

Another specific intervention consisted of 2.5 day “Undoing Racism” educational workshops, led by trained facilitators who discussed how the history of enslavement and anti-Black racial discrimination in the U.S. has engendered ongoing social inequities; how institutional gatekeeping (the filtering and control over how messages are communicated and delivered by insiders at an institution) can perpetuate racism; and how white persons can work to undo social ideas of racial superiority that they have internalized, while African Americans can undo internalized inferiority. This intervention ran into problems with the facilitators, who did not at first emphasize maternal and infant health, and who embraced a confrontational approach inspired by 1970s radical politics. A number of participants reacted negatively to this approach, and the intervention evaluation recommended that the program “focus on inclusiveness rather than separation” as well as recognize that in an increasingly diverse society, racism involves more than just white oppression of African Americans.¹⁷

Finally, the REACH program developed PRAT (Pregnancy Risk Assessment Tool), which it incorporated into electronic medical records across numerous local institutions involved in the program. PRAT was designed to standardize perinatal assessment of high-risk women, to incorporate evidence-based prenatal care guidelines, and to incorporate assessment, referral, and follow-up for both the medical and social determinants of health. For example, housing instability - a social determinant of health - could be considered an indicator that a pregnant woman is high risk and in need of referral to housing assistance, just as a history of preterm birth or a serious health condition like diabetes would indicate specific referral for these issues. PRAT also incorporated assessment of mental and emotional well-being as well as components to reinforce safe sleep practices.¹⁶

REACH program documents emphasize that it has maintained a consistent focus on community engagement, which entails more than “just conducting outreach or services within communities.” This involvement of the community at every level of the process, from program planning to design, implementation, dissemination of results, and evaluation, “has successfully engaged ‘non-traditional’ partners such as African American men as leaders for education, advocacy, and community support” in its efforts to reduce infant mortality, program documents assert.¹⁶

Program evaluations for this long-term project have focused more on measuring (and documenting the success in) short-term outcomes such as increased knowledge or awareness of racism and specific challenges faced by high risk, low income pregnant women in the community than longer-term outcomes like birth outcomes. However, the program’s ambitious goal of addressing the social and structural determinants of health is difficult to effectively measure. Such a focus makes the REACH program unusual, if not unique, in the field of interventions to address disparities in infant mortality.

Additional Rural Interventions

During the April 5 meeting, a participant called the group’s attention to the Nurse Family Partnership (NFP), a programmatic intervention to address infant mortality in rural areas, and other literature, which were not included in our review. The participant sent us seven articles, and also suggested that we include the NFP in our review addendum. Below, we discuss these articles and interventions.

Four of the articles we received were policy statements or commentaries, which focused on the main causes of rural health disparities for pregnant women: lack of access to specialist care as well as quality care, and recent closures of low-volume hospitals in economically depressed, rural areas, as central challenges to rural perinatal health.^{18 19} One of these articles mentioned as a key policy priority the Improving Access to Maternity Care Act, which has since been passed and signed into law.^{18 20} This 2018 law requires the Health Resources and Services Administration (HRSA) to collect data to identify maternity workforce shortage areas within the U.S., which will then allow the National Health Services Corps to send physicians to these areas.²⁰ Corps physicians commit to serve full-time or half-time for two years within a Health Professional Shortage area in return for partial forgiveness of their qualifying educational loans.²¹ Overall, these articles outline that the key driver of addressing maternal health inequities in rural areas will involve improving access to timely, quality care.

The three remaining articles described ANGELS - the Antenatal and Neonatal Guidelines, Education, and Learning System – a perinatal telemedicine intervention initiated in 2003 to reach Arkansas' numerous underserved areas. The program has equipped 20 rural sites with remote video and ultrasound linkup to a University of Arkansas maternal-fetal medicine specialist.²² (All of the state's maternal-fetal medicine specialists were located in Little Rock, the capital). Up to 2014, the program provided over 21,000 high-risk obstetric telemedicine consultations and facilitated over 5,000 transports of women to tertiary (high-level) facilities. ANGELS also works with the state's physicians to adopt protocols based on national evidence-based standards, in order to meet the needs of rural women, and has established a 24-hour call center staffed by nurses. These nurses provide guidance to providers and patients, while facilitating transport to tertiary facilities in cases where the infant is LBW. The program has since expanded to cover other aspects of health care through telemedicine.²² The articles did not report any measures evaluating the program's efficacy in lowering rates of infant mortality, but one did note that the state's 60-day neonatal mortality rate dropped significantly following the implementation of the ANGELS program,²³ and another reported that the proportion of ELBW infants (<1000g) delivered at the University of Arkansas Medical center increased 15% in the first year the program was implemented. A third article, analyzing the impact of the ANGELS on NICU

delivery through 2006, found that the program did not increase overall NICU use but did result in more deliveries occurring in an academic medical center.²⁴ Smaller increases were observed for LBW infants overall.²³ While this program was not included in our original review (likely due to the fact that the first article covering it was published in 2007, before our ten-year cutoff), the literature evaluating it adds to the evidence for telemedicine interventions as one means to address lack of access to care in high-risk rural pregnant women.

Finally, we examined the nurse family partnership and evidence for its efficacy in improving birth outcomes. The Nurse Family Partnership (NFP), run by a non-profit organization of the same name, has for over 40 years provided free nursing home visits to first-time mothers in underserved areas, from the prenatal period through the first two years of their child's life. The program claims to have served at least 280,000 families, and as of June 2018, reported employing 1,936 nurses to serve over 34,000 families in 594 counties within 43 states, 5 Indian Tribal areas, and the U.S. Virgin Islands – including 85 families in Maryland.²⁵

To investigate literature on the NFP's efficacy in improving birth outcomes among African American and rural infants, we employed two methods. First, we conducted a cursory search of PubMed. We searched for articles in English, with "nurse family partnership" in the title, published since 2009 – a strategy that yielded 28 articles. [Our search string was (("nurse family partnership"[Title]) AND ("2009/01/01"[Date - Publication]: "3000"[Date - Publication])) AND English[Language]]. Three of these articles related to program description and outcome measures. Other articles covered programs implemented in other countries, or examined process measures (i.e. how well the program was being implemented and barriers to effective implementation). Secondly, we read materials on the NFP website to identify other peer-reviewed research on the NFP and its impact on rural and African American populations.

Of these studies, an 18-year follow-up of a randomized clinical trial conducted in Memphis, Tennessee provided the strongest results of the NFP's long-term effect. In the sample of 1,138 women, 92.1% were African American, 98.1% were unmarried, 85.1% had a household income below the federal poverty threshold, and 64.1% were under 18 at initiation. The women were randomized to receive 1) transportation only, 2) transportation + screening/referral, 3)

transportation + screening/referral + nurse home visiting only during pregnancy, or 4) transportation + screening/referral + nurse home visiting from the prenatal period through their child's 2nd birthday. When the results from those in the first two groups and the last two groups were combined, a significant contrast appeared in maternal survival rates. In a comparison between those in treatment 2 to treatment 4, those in the latter group had a significantly lower preventable cause child mortality rate (0.0% vs. 1.6%).²⁶ This study suggests that the NFP had significant effects in addressing infant as well as child mortality in a high-risk African American urban population.

Other studies have been conducted on a national sample of NFP clients, in both rural and urban areas, since the program began “scaling up” in 1996. Several recent studies suggest that the NFP may improve some other factors positively correlated with infant survival, including breastfeeding, immunization, and birthweight. A 2017 study found that NFP clients were significantly more likely to have ever breastfed than a national reference group, even after adjustments were made for demographic differences between the two samples, but significantly less likely to have maintained breastfeeding by six months. The study also found that the NFP participants were significantly more likely to be current on immunizations at 6 months, but that these differences evened out by 12 months.²⁷ A second 2017 study comparing NFP clients (n=27,195) to a matched reference group, meanwhile, found that the clients had significantly lower rates of PTB (8.7%) than the matched controls (12.3%).²⁸ These studies, along with earlier studies of NFP local sites, suggest that the program has developed an effective approach to improving neonatal outcomes. While no recent studies specifically address its efficacy in rural populations, these national studies cover numerous rural sites, so it can be presumed that the NFP is likely to be effective in rural settings.

Family Leave Policies

We located several review articles and additional studies investigating how family leave policies in high-income countries affect birth outcomes. Two recent comprehensive reviews of health impacts of parental leave highlight strong evidence in support of *paid* parental leave as a promising strategy to reduce infant mortality.^{29,30} Within the United States, *unpaid* job-protected leave is available to many workers under the Family and Medical Leave Act (FMLA); however,

due to restrictions on eligibility, this unpaid leave is available only to 60% of private sector workers.³¹ One reviewed study of FMLA implementation showed that less-educated and single mothers are least likely to take unpaid leave.³² Further, voluntary paid parental leave is available to only a small percentage of workers, primarily professionals in high-paying, full-time jobs.³³ Seven states have passed paid family leave policies, with different eligibility criteria and levels of payment.³¹

Studies that examine the effect of family leave across different high-income countries demonstrate decreases in infant mortality following implementation or extension of paid family leave. One older study of family leave policies in 16 European countries estimated that a 10-week extension of paid leave predicted a 2.5-3.4% reduction in infant mortality rates, with the largest improvements in the post-neonatal phase.³⁴ Another study that included the United States and Japan in addition to the 16 European countries found a similar reduction in infant mortality, and noted a significant reduction across all infant mortality categories.³⁵ Both studies found the significant reduction in infant mortality was only associated with job-protected, *paid* leave. More germane to our review, a recent study of U.S. states that have some level of paid maternity leave through temporary disability insurance showed reductions in low birth weight births and infant mortality.³⁶ This study also found that even short periods of leave taken prenatally can reduce low birthweight deliveries. Other studies have also found that short paid leave taken prior to birth to be associated with reductions in preterm birth and birth complications.^{36,37} The effects of paid leave are most notable among disadvantaged groups, including low-income, unmarried, and Black mothers.^{29,32,36} Multiple factors have been identified as potentially accounting for the impact of paid leave on infant mortality, including higher rates of breastfeeding, more consistent medical care, increased economic resources, and lower maternal stress both during and after birth.^{31,38}

Conclusions

Overall, this addendum to our review provides new evidence and offers additional support for interventions already mentioned and for paid family leave policies as effective in improving birth outcomes in African American and rural women. The literature discussed here strongly suggests that progestogen administration during pregnancy in women with previous PTB or a short cervix can significantly reduce PTB – and likely improve neonatal survival. Further evaluation of this literature by clinical experts can provide additional guidance on the mode of delivery (17P vs.

PV progesterone) and means for recruiting more women to receive this clinical intervention. Such recruitment can be included in existing community-based or home visiting programs as well. The literature introduced here adds more evidence for the efficacy of telemedicine and home visiting programs in addressing infant mortality within high-risk rural areas, and of home visiting for African American women at high risk of poor birth outcomes. Last, the discussion of compound interventions offers useful examples of how communities and states can develop umbrella programs that tackle the problem of infant mortality in high-risk communities from multiple angles, as no one type of intervention is likely not going to be enough to solve the problem.

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