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**DIVISION OF FAMILY HEALTH SERVICES: BUREAU OF FAMILY AND COMMUNITY HEALTH**

***HEALTHY START REDESIGN PLANNING CONTRACT: COH8T***

**TASK 5: SUMMARY OF THE RESEARCH CONDUCTED ON THE CURRENT LITERATURE AND BEST**

**PRACTICES NATIONWIDE**

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## Introduction

The Florida Healthy Start program seeks to improve maternal and infant health outcomes including reducing infant and maternal morbidity and mortality. To do this, Florida's Healthy Start Coalitions currently provide the following services: universal risk screening; information and referral; comprehensive assessment; ongoing care coordination; psychosocial, nutritional and smoking cessation counseling; childbirth, breastfeeding and parenting support and education; and home visiting. The goal of the redesign project is to increase delivery of effective, evidence-based services in order to better improve maternal and infant health outcomes for Florida's residents.

The redesign process will utilize a Redesign Committee (Steering Committee) for oversight as well as over twenty diverse Subject Matter Experts, through committee structure, in a two-year process to:

- Review and evaluate the Florida Healthy Start program components to assess which are research-informed and evidence-based
- Develop a comprehensive plan for implementing the redesign to assure program quality and fidelity
- Identify key effective program elements, processes, and quality indicators that must be monitored during implementation and maintenance
- Propose the elements, process, and options for a coalition allocation methodology that promotes quality, fidelity, and productivity
- Develop a modular evaluation of the redesign of the program that can be implemented in phases.

This document summarizes existing research regarding risk and protective factors impacting birth outcomes of the Healthy Start program and identifies existing evidence-based practices. This document will be used as a resource and reference for the next two tasks: reviewing current Healthy Start program components to assess which are research-informed and evidence-based and to recommend new components or changes to components where applicable. For example, to what extent do the current program components address identified risk and protective factors? And, to what extent do the current program components utilize practices which are evidence-based? That is one reason why a high standard of evidence is specified: the redesign effort must rest on a solid and defensible foundation.

Although there is debate in the field of evaluation regarding what counts as credible evidence (Donaldson, Christie, and Mark, 2009) this document uses the following definition to determine evidence-based practices:

Determination as an evidence-based practice by a meta-analysis of randomized controlled trials (RCT) with an assessment of study quality using a rigorous process by organizations such as the Cochrane Collaborative or U.S. Preventive Services Task Force.

OR

A combination of a meta-analysis or systemic review of experimental studies in peer-reviewed journals AND recommendations from reputable sources (such as the Centers for Disease Control and Prevention) based on a body of evidence not limited to experimental studies.

When a practice is not identified as evidence-based, it does not mean that there is no evidence of effectiveness but that the practice does not meet the standard listed above. Although evidence of effectiveness reflects internal validity, it does not reflect external validity which is necessary to “make judgments about whether to implement the program at another location with the kinds of prospective clients present there” (Chen, Donaldson, and Mark, 2011, p. 11); method of establishing external validity (Chen, Donaldson, and Mark, 2011).

This summary includes both risk and protective factors that impact Healthy Start outcomes and intervention categories, within which evidence-based practices reside. For example, smoking during pregnancy is a risk factor for outcomes of interest; smoking cessation is an intervention category. Then, there are evidence-based practices to achieve smoking reduction or cessation within that category. Of the 13 risk and protective factors reviewed, there were evidence-based reviews of experimental studies available for six risk and protective factors and a combination of data for another two factors. Of the 15 intervention categories, there were evidence-based reviews of experimental studies available for 11 of the intervention categories.

There are, however, limitations to this approach.

- Evidence at the pre-defined level was not available for every factor and intervention category relevant to the Healthy Start system. Subject Matter Experts provided input regarding this issue (see Appendix C): the standard set will be used when available and the minimum for determination of evidence-based will be the federal standard. When evidence at the federal level is not available, other evidence may be used to drive program improvement but the component will not be considered evidence-based. These components will have a clear plan for evaluation to develop the evidence base.
- Critiques of existing risk and protective factors and practices are often not presented within evidence-based reviews. For example, while the life course approach has been adopted by federal and state agencies, an evidence-base is not yet available. The life

course perspective and limitations of prenatal care access are included based on their acceptance at the federal level.

This document also has limitations similar to other reviews. First, there were variations among the sources in terms of methods, categorizations of race or ethnicity, and other study characteristics. Second, contributions of each risk factor to poor birth outcomes cannot be isolated and estimated, even for a specific population. Third, there is the risk that a factor or intervention was missed; utilizing subject matter experts to provide input, however, should minimize that risk.

Finally, this document was developed for the Healthy Start redesign process and so is limited in its purpose and scope. This document is not intended for publication and so contains limited background on the Healthy Start program or the Healthy Start Redesign Process.

### ***What happens next?***

This draft document will next be distributed to the twenty-two Subject Matter Experts who will provide valuable input based on their combined experience and expertise in maternal and child health and the Florida Healthy Start system. Subject matter experts will be asked:

1. Are there risk and protective factors or interventions not included that should be? Are there risk factors or interventions included that are not part of the Healthy Start scope?
2. What are your cautions, if any, about the limitations of the risk factors and interventions?

Once the feedback from the subject matter experts has been incorporated into this document and it is adopted by the Redesign (Steering) Committee, then the next phase of the project will begin. The next task in the redesign process is to assess the extent to which existing Healthy Start components and services are research-informed and evidence-based. In the next task, Subject Matter experts will also suggest revisions and replacements to the existing program based on that analysis.

## ***How is this document organized?***

This document presents risk and protective factors and interventions within three broad sections: maternal health, infant health, and preconception and interconception health. There is, of course, overlap among those categories. For example, smoking cessation is a risk factor for both maternal and infant health and could be addressed as an intervention anytime during the mother's lifespan. Risk and protective factors are repeated in each section for ease of reference while interventions are addressed only in one section due to the length of those descriptions. At the end of each sub-section, there is a table summarizing the risk and protective factor or intervention, the conclusion, and the available levels of evidence.

Given the broad outcomes of the Healthy Start system, it is necessary to define the parameters of that system in order to identify evidence-based practices. In effect, the risk and protective factors analysis answers the question *given the identified birth outcomes, what risk factors should be addressed?* The intervention section identifies which practices have been proven effective for these risk and protective factors. For example, the document summarizes the research around the impact of breastfeeding on the outcomes of interest and what breastfeeding practices, if any, have been proven effective at this time. Healthy Start outcomes are as follows:

- Reduce infant mortality
- Reduce the number of low birthweight babies
- Improve health and developmental outcomes

Each sub-section first presents risk and protective factors for which current research suggests an impact on these outcomes of interest. The intent is to identify generally accepted risk factors impacting the identified birth outcomes so that the Subject Matter Experts can determine what practices to include in the redesign process. In order to identify these generally accepted risk factors, several sources were used:

- Evidence-based reviews limited to experimental studies with standards for assessing quality (level 1)
- Centers for Disease Control and Prevention or USPTF recommendations based on national data and/or systemic reviews (level 2)
- Meta-analysis/systemic reviews published in peer-reviewed journals (level 3)

The identified evidence levels for risk and protective factors and the identified evidence levels for interventions are similar although not identical as research on risk and protective factors is by necessity different than research on interventions where manipulation can occur: experimental studies are not possible with some risk and protective factors. It is not possible, for example, to randomize populations and manipulate a risk behavior. In addition, the nature of risk and protective factors which are behavioral, biological, and social are different than the

nature of structured interventions where a population is identified, services are provided, and outcomes assessed. Therefore, the two sections (risk and protective factors and interventions) are also formatted differently.

Each risk and protective factor is listed separately although one study may have discussed multiple risk factors and indeed, many risk factors are interrelated. When a study addressed multiple risk factors, it is described in detail in the first sub-section in which it appears and then is referenced in later sections by the levels noted above.

Finally, it is not the intent of this document to create a checklist of risk factors to address without considering the context in which Healthy Start operates. Current research has not identified the contribution of each factor to poor birth outcomes but these risk factors can inform interventions necessary to impact the desired outcomes. There is a growing school of thought – albeit without a strong evidence base at this time – that addressing research-based risk factors is insufficient to make additional progress on reducing infant mortality, low birth weight babies, and improving health and developmental outcomes. Please see the discussion below on the life course perspective; limitations to prenatal care access are discussed in sections on prenatal care.

There were similar levels of evidence used to assess relevant evidence-based practices:

- Evidence-based reviews of randomized controlled trials and an assessment of study quality such as Cochrane Reviews, US Preventive Services Task Force, or the Agency for Healthcare Research and Quality (level 1)
- Meta-analysis or systemic reviews of experimental studies in peer-reviewed journals (level 2)
- Centers for Disease Control and Prevention recommendations based on national data and/or systemic reviews (level 3)

As noted above, the identified evidence levels for risk and protective factors and the identified evidence levels for interventions are similar although not identical as research on risk and protective factors is by necessity different than research on interventions where manipulation can occur.

For each sub-section, the data is presented in this order. First, a summary of the levels of evidence is provided, then a description of the evidence, and finally, conclusions. Where evidence-based practices exist, they are presented in tabular form for easy reference in the next step of the redesign process; more detailed descriptions were developed as a resource for the next task in the Healthy Start Redesign process. The last sub-section of each section is a table summarizing the available evidence and conclusions for each intervention category. Following the last section (Preconception and Interconception Care), a table summarizing the risk factors each evidence-based practice impacts is provided.

## Life Course Perspective

As noted, the Life Course is a perspective or framework for examining risk factors, protective factors and assets that occur over life. It is thought of as an accumulation of experiences and exposures that have later impact on multiple outcomes. This section provides a very brief introduction to provide context for the data that follows; a complete summary is beyond the scope of this document.

Misra, Guyer, and Allston (2003) state that although prenatal care utilization has increased, perinatal indicators have not improved and propose a life span approach with a multiple determinants model to address this gap. The authors note that while public health has a history of addressing health issues from a broad perspective, current pregnancy health care practices are focused on an individual model of addressing known risk factors. They suggest this led to an overemphasis on early entry to prenatal care when the issue is much more complex and when influencers of pregnancy outcomes are not limited to the prenatal period. This multiple determinants model integrates social, psychological, behavioral, environmental, and biological factors that shape pregnancy throughout the life span.

Wadhwa et al. (2001) note that maternal stress and maternal urogenital tract infections “are significantly and independently associated with an increased risk of spontaneous preterm birth” (p. 17) and posit a biobehavioral model that identifies chronic maternal stress as a risk factor and its effect on both biological and behavioral mechanisms influencing preterm birth. The authors also note that “no current intervention or practice has produced an appreciable impact on the prevention or reduction of preterm birth in the U.S.” (p. 18). The authors also note that stress may not be an individual-level risk factor, but also part of the individuals’ social context. Hobel and Culhane (2003) note that stress conceptualized as a life event ignores endemic and chronic conditions associated with low-income, such as safety, finding suitable child care, and a chronic lack of resources. The authors also note that the literature offers a limited conceptualization of stress as it addresses an individual level, rather than a community level.

Lu, Kotelchuck, Hogan, Jones, Wright, and Halfon (2010) propose a twelve-point plan for addressing health disparities, noting that studies of maternal behaviors, prenatal care utilization, psychosocial stress, and infections “do not adequately account for the racial gap in birth outcomes” (p. 62). They propose a life-course approach which “conceptualizes birth outcomes as the end product of not only nine months of pregnancy but the entire life course of the mother before pregnancy” (p. 62). The twelve-point plan which includes items relevant to the Healthy Start system is as follows:

- provide interconception care to women with prior adverse pregnancy outcomes
- increase access to preconception care to African American women
- improve the quality of prenatal care
- expand healthcare access over the life course
- strengthen the father involvement in African American families

- enhance coordination and integration of family support systems
- create reproductive social capital in African American communities
- invest in community building and urban renewal
- close the education gap
- reduce poverty among African American families
- support working mothers and families
- undo racism

Several of the recommendations are not dissimilar from those made by the Centers for Disease Control (Johnson et al., 2006) regarding the importance of preconception and interconception care in addressing influencers of pregnancy that occur before the prenatal period.

# Section I: Maternal Risk Factors and Interventions

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## **Maternal Health Risk and Protective Factors**

### ***Adolescent pregnancy***

There were no evidence-based reviews (level 1) of the impact of adolescent pregnancy on the outcomes of interests. The link between adolescent pregnancy and poor birth outcomes, however, was documented in a review of national data, which is the highest level of available evidence (experimental studies are not possible with this and several of the other risk factors). Menacker, Martin, MacDorman, and Ventura (2004), in national vital statistics report reviewed the number and rate of U.S. births for 10-14 year olds for 1990-2002 by race, Hispanic origin, and by State. The authors found that teen mothers were least likely to receive timely prenatal care compared with mothers of older age groups. Compared with infants of mothers aged 20-39 years, infants of the youngest mothers experienced almost twice the rates of preterm delivery (21.3%) and low birthweight (12.6%). The infant mortality rate for adolescent mothers (15.4 per 1,000) was two to three times higher than that for infants of mothers aged 20-44 years. The 2007 linked data set (Mathews and MacDorman, 2011) confirmed that infant mortality was impacted by the age of the mother, with teenage mothers having a rate of 9.80 per 1,000; birth to the youngest mothers (under age 15) had the highest mortality rate, at 14.53 per 1,000. Therefore, adolescent pregnancy can be considered to impact the outcomes of interest.

### ***Alcohol, tobacco, and other drugs***

Evidence regarding the impact of alcohol, tobacco, and other drugs on birth outcomes was available from the U.S. Preventive Services Task Force (level 1) and meta-analysis/systemic reviews (level 2). The U.S. Preventive Services Task Force (2009) found that tobacco cessation at any point throughout pregnancy yields substantial health benefits for the expectant mother and baby (level 1). A Centers for Disease Control (Johnson et al., 2006) report identified conditions for which scientific evidence of impact on birth outcomes exists including alcohol, tobacco and other drug use (level 2). The 2006 Centers for Disease Control recommendations to improve preconception health and health care were developed by reviewing published research, a workgroup of 22 programs, evaluating best and emerging practices, and convening a workgroup of subject matter experts (level 2), although not all factors had a systematic review. Published research was not limited to experimental studies but was reviewed by the subject matter experts. Per the authors (Johnson et al., 2006), the recommendations reflect “the research, professional opinion, practice in medicine, public health and related fields, which are sufficient to guide changes in program, practice, and policy” (p. 3). The subject matter experts reviewed evidence on the effectiveness of interventions such as folic acid use; STDs; and cessation of alcohol, tobacco and other drugs. In 2006, the U.S. Surgeon General released a report on the impact of secondhand smoke (level 2). The report found that evidence was inadequate to infer a causal relationship on neonatal mortality and on child development and that evidence was suggestive but not sufficient to infer a causal relationship between maternal

exposure to secondhand smoke during pregnancy and preterm delivery. The report did find, however, that evidence was sufficient to infer a causal relationship between exposure to secondhand smoke and sudden infant death syndrome (U.S. Department of Health and Human Services, 2006a). Two additional meta-analyses (Hackshaw, Rodeck, & Boniface, 2011; Leonardi-Bee, Britton, & Venn, 2011) found evidence linking secondhand smoke exposure of pregnant women to be associated with stillbirth and birth defects though not with perinatal or neonatal death. Therefore, alcohol, tobacco, and other drugs can be considered to impact the outcomes of interest.

### ***Intimate partner violence***

There were no evidence-based reviews (level 1) of the impact of domestic violence on outcomes of interest. Jasinski (2004) conducted a literature review of research on U.S. populations. The review found evidence that intimate partner violence delayed prenatal care and resulted in low birth weight, premature labor, fetal trauma, and health issues for the mother. The author did not specify inclusion criteria. There is not enough evidence to document the impact of domestic violence on the outcomes of interest.

### ***Nutrition***

Evidence on the impact of nutritional supplements on outcomes of interest was available from evidence-based reviews (level 1). In a Cochrane Review, De-Regil et al. (2010) found five trials involving 6,105 women (1,949 with a history of a pregnancy affected by a neural tube disorder and 4,156 with no history of neural tube disorders). Overall, the results are consistent in showing a protective effect of daily folic acid supplementation alone or in combination with other vitamins and minerals in preventing neural tube disorders compared with no interventions/placebo or vitamins and minerals without folic acid (risk ratio 0.28, 95% confidence interval 0.15 to 0.52).

In another Cochrane Review (level 1), Mahomed, Bhutta, and Middleton (2007) included 17 randomized controlled trials involving over 9,000 women and their babies in their review of zinc supplemental effects. Zinc supplementation resulted in a small but significant reduction in preterm birth (relative risk 0.86, 95% confidence interval 0.76 to 0.98 in 13 randomized controlled trials of 6,854 women).

In a systemic review for the Agency for Healthcare Research and Quality not limited to randomized controlled studies, Viswanathan et al. (2008) found weak of moderate evidence regarding weight gain outside of Institute of Medicine recommendations for preterm birth, low birthweight, and infant mortality.

Findings from the evidence-based reviews (level 1) and two Centers for Disease Control Publications (D'Angelo & Colley, 2002; Johnson et al., 2006) (level 2 and level 2 respectively) suggest that folic acid impacts outcomes of interest.

### ***Prenatal care***

In a CDC study examining infant mortality nationwide, Mathews and MacDorman (2011) found that entry into prenatal care occurring after the first trimester was associated with fetal and infant deaths; this is, however, correlational and not experimental data. The CDC/ATSDR Preconception Care Work Group and the Select Panel on Preconception Care (Johnson et al., 2006) found that deficient prenatal care has been linked to increased risk for low infant birth weight, premature birth, neonatal mortality, infant mortality, and maternal mortality (level 2). A Cochrane Review (level 1), however, reviewed randomized trials of prenatal care of varying frequency for low-risk women. Ten trials involving over 60,000 women were included: seven trials evaluated the number of visits and three evaluated the type of care. The reviewers found that a reduction in the amount of visits for low-risk women was not associated with an increase in adverse maternal or perinatal outcomes. Finally, a meta-analysis/systemic review (Kirkham, Harris & Grzybowski, 2005) found that the clinical components of prenatal care visits are controversial and that evidence supporting the clinical practices is varied (level 3).

There is a school of thought that access to prenatal care, however, may not address all the factors contributing to poor birth outcomes. In several statewide quasi-experimental scale studies, the authors found that “Even when affordable care was available, many low-income women did not avail themselves of it. Although women knew the importance of prenatal care, there was a gap between attitudes and actually seeking appropriate care” (Gazmararian, Arrington, Bailey, Schwarz, and Koplan, 1999, p 177). Marin, Ramirez, Wise, Pena, Sanchez, and Torres (2009) found that although Medicaid managed care programs in Puerto Rico had generally positive effects on the frequency and adequacy of care when compared with traditional Medicaid, it did not eliminate the gap between the frequency and adequacy of care received by pregnant women enrolled in Medicaid when compared to utilization levels of pregnant women enrolled in a private insurance program. Borders and Blakely (2009) found that managed care programs do not ensure access to prenatal care and that both economic and noneconomic barriers need to be addressed.

Therefore, the available data are inconclusive.

### ***Sexually transmitted diseases (STD)***

There are no evidence-based reviews (level 1) of the impact on sexually transmitted diseases on the outcomes of interest. Workowski and Berman (2010) authored treatment guidelines for the Centers for Disease Control and Prevention. The guidelines were developed using expert opinion, a systemic review of studies with an assessment of study quality, and review by a

workgroup to process the results (level 2). The authors report that intrauterine or perinatally transmitted STDs have negative impacts on pregnant women and their fetuses and recommend that all pregnant women and their partners should be asked about sexual history, counseled, and offered treatment, if applicable. The Centers for Disease Control (Johnson et al., 2006) select panel on preconception, however, identified conditions for which scientific evidence of impact on birth outcomes exists, including sexually transmitted disease (level 2 for risk and protective factors). Therefore, sexually transmitted diseases can be considered to impact the outcomes of interest.

### ***Stress and perinatal depression***

There was an evidence-based review (level 1) and two systemic reviews (level 3) of perinatal depression. An Agency for Healthcare Research Quality evidence review (Gaynes et al., 2005) examined depression prevalence, screening accuracy, and the impact of interventions; depression can have negative consequences for the women and for their children. For prevalence and screening, inclusion criteria mandated diagnostic confirmation by a reference standard; there were 30 studies of prevalence and 10 of screening accuracy. The authors' combined estimates for depression were lower than other reviews due to excluding self-report and excluding minor depression. Final combined estimates were 14.5 percent of pregnant women and 14.5 percent of postpartum women having a new episode of major or minor depression. Study populations, however, were almost uniformly Caucasian.

Ammerman, Putnam, Bosse, Teeters, and Van Ginkel (2010) reviewed the prevalence of elevated levels of depressive symptoms in the home visiting population, which typically is lower socio-economic status and found prevalence levels of 25.9 to 28.5 percent, and as high as 61 percent; differences in screening and cut offs make comparisons difficult. These estimates were for depressive symptoms and not for diagnostic criteria of major depressive disorder. Risk factors for antenatal depression include low-income, lack of social support, stress or negative life events, and poor relationships (Ammerman, Putnam, Bosse, Teeters, and Van Ginkel, 2010; Dennis, Ross, and Grigoriadis, 2007).

Grote et al. (2010) conducted a meta-analysis of studies examining the impact of depressive symptoms during pregnancy and preterm birth, low birth weight, and intrauterine growth restriction. The authors identified 29 studies that met their inclusion criteria. The authors found that depression during pregnancy was associated with modest but statistically significant risks of preterm birth and low birthweight. Moderating factors included country location and U.S. socioeconomic status; the type of depression measurement moderated the strength of the finding. Categorical measures produced stronger effects.

### ***Unintended pregnancy***

There were no evidence-based reviews of unintended pregnancy (level 1). The Institute of Medicine (2011) released guidelines on clinical preventive services for women (level 2). To generate conclusions, the committee reviewed existing U.S. Preventive Services Task Force recommendations, Bright Futures recommendations (from the American Academy of Pediatrics) and the Advisory Committee on Immunization Practices; reviewed available evidence using categories similar to those identified in this report; and heard from experts, researchers, and stakeholders. The Institute of Medicine concluded that consequences of unintended pregnancy have been documented but research is limited for some outcomes. Given the available evidence, the Institute of Medicine recommends prevention of unintended pregnancies. Although approximately half of all pregnancies in the United States each year are unintended (Finer & Henshaw, 2006) there is not enough evidence at this time to document the impact of unintended pregnancy on the outcomes of interest.

### ***Other risk factors***

Although Healthy Start cannot impact some risk factors – such as the race or marital status of a pregnant woman - they are listed here to identify what types of clients are likely to be at most risk; this information will be used in later phases of the project. These include race, ethnicity, marital status, low education levels, and prior poor pregnancy outcomes. No levels of data are specified as conclusions are not being drawn. The Centers for Disease Control and Prevention report that the highest rates of fetal and infant mortality are associated with a group of variables (Mathews & MacDorman, 2010), including mothers who are unmarried and mothers with low educational levels. Three other statewide studies (Aubry, Wojtowycz, Bode, Parker, & Luke-Houseman, 2010; Fournier, 2009; and Ramakrishan, 2005) also assessed variables associated with fetal and infant deaths and identified previous poor pregnancy outcomes as a risk factor for future pregnancy outcomes.

### **RACE AND ETHNICITY**

There are continuing and persistence racial disparities in the outcomes of interest (U.S. DHHS, 2006). In a review for the federal Healthy Start program, the U.S. Department of Health and Human Services (2006) identified racial disparities in not only poor birth outcomes, but also in behavioral factors (both preventive and risk), as well as biological and social risk factors. Pies, Parthasarathy, and Posner (in press) note that despite high rates of entry to prenatal care, disparities in poor birth outcomes continue.

Despite recent improvements in the timing of prenatal care across each of the largest racial and ethnic groups, there continues to be a large disparity between races and ethnicities. In 2005, 76.3 percent of African American and 74.4 percent of Hispanic or Latino women in the United States received prenatal care during the first trimester, compared to 85.0 percent of white women (National Center for Health Statistics, 2009). The U.S. Department of Health and Human Services (2006) also identifies race and ethnicity as a risk factor in poor birth outcomes.

The U.S. Department of Health and Human Services (2006) notes the continuing disparity among races in infant mortality: in 2002, infants born to black women were twice as likely to die in the first year as infants overall and noted that the states with the highest rates of infant mortality are also those with the highest racial/ethnic disparities in infant mortality. The study identified disparities in preventive behaviors, risk behaviors, and biological and risk factors.

Sparks' (2009) research explored the degree to which socio-demographic characteristics, health care access, maternal health status and health behaviors influence birth-weight disparities among seven racial/ethnic groups. Binary logistic regression models were estimated using a nationally representative sample of singleton, normal for gestational age births from 2001 using the ECLS-B, which has an approximate sample size of 7,800 infants. The multiple variable models examine disparities in low birthweight for seven racial/ethnic groups, including non-Hispanic white, non-Hispanic black, U.S.-born Mexican-origin Hispanic, foreign-born Mexican-origin Hispanic, other Hispanic, Native American, and Asian mothers. Only non-Hispanic black mothers have a low birthweight disadvantage compared to non-Hispanic white mothers. Sparks reported that prenatal care adequacy and high maternal health risks are the only variables that influence low birthweight for all racial/ethnic groups. In particular, maternal WIC usage appeared to lower the odds that a mother will have a low birthweight infant.

### MARITAL STATUS

Lu and Lu (2007) argue that “the problem of infant mortality in the U.S. is in essence a problem of broken relationships at many levels—at home, in our neighborhoods and communities, and in our society at large.” According to the authors, infants born to single mothers are at greater risk for infant death than those born to married mothers (Mathews, Menacker & MacDorman, 2004). In 2002, infants of married mothers had a mortality rate of 5.4 per 1,000 live births. The mortality rate for infants of unmarried mothers was 9.9, more than 83 percent higher than the rate for infants of married mothers (Mathews, Menacker, & MacDorman, 2004). Findings were consistent with the 2007 linked data set, which documented that infants of unmarried mothers had an infant mortality rate of 9.17 per 1,000 which is 78 percent higher than married mothers (Mathews and MacDorman, 2011).

Across all racial-ethnic groups, marital status offers protection against infant mortality. There are important racial-ethnic differences in the proportion of infants born to unmarried mothers. In 2002, approximately one of every three infants in the U.S. was born to an unmarried mother. Nearly 70 percent of all black infants, nearly 60 percent of American Indian infants, and 44 percent of Hispanic infants, however, were born to unmarried mothers, compared to 23 percent of white infants and 15 percent of Asian and Pacific Islander infants. Black mothers were three times as likely as white mothers and more than four times as likely as Asian and Pacific Islander mothers to be unmarried (Mathews, Menacker, & MacDorman, 2004).

While the specific reasons for the higher rates of infant mortality among infants of unmarried mothers are not known, Lu and Lu (2007) argue that it can be attributed to these mothers' relative lack of social support and resources (Raatikainen, Heiskanen, & Heinonen ,2005).

Marital status appears to buffer the impact of stress on birth outcomes by increasing social support. Additionally, a broken relationship with the baby's father can be an important source of stress for the mother and an important risk factor for preterm birth and low birthweight. Marital status, however, does not always guarantee support and resources. The failure of marriage to improve outcomes for teenagers could be an indication that early marriage is less helpful for a pregnant teen than her own family's support.

Eighty-one percent of the black mothers in the study indicated that the father provided financial help during the pregnancy, and three-fourths reported that the father came to visit her and the infant in the hospital. Nearly all unmarried fathers interviewed reported that they wanted to stay involved in raising their children in the coming years (Carlson, McLanahan, & England, 2004). However, these unmarried families are seen as fragile because of the multiple risk factors associated with non-marital childbearing and relational disengagement. At one year after a non-marital birth, only six percent of these relationships resulted in marriage, and one-third had separated. The fragility and instability of these relationships can also be an important source of stress. Studies found that infants born to unmarried mothers in co-habiting relationships are at lower risk for infant death than those born to single mothers, but are still at higher risk than those born to married mothers (Luo, Wilkins, & Kramer, 2004).

## ***Summary of evidence on maternal health risk and protective factors***

Figure 1 provides a summary of the preceding pages. The first column lists the risk and protective factors relevant to maternal health while the second column lists the conclusion drawn based on the available evidence and the evidence standard set. The final column documents the levels of evidence available for that risk or protective factor using the definitions on page 4 and provided in the table note for ease of reference.

Figure 1: Summary of maternal risk and protective factors

Risk and protective factor	Conclusion based on the evidence standard set and evidence obtained at the time of this report	Available levels of evidence		
		1	2	3
<b>Adolescent pregnancy</b>	Adolescent pregnancy impacts the outcomes of interest.			
<b>Alcohol, tobacco, and other drugs</b>	Use of alcohol, tobacco, and other drugs impact the outcomes of interest.	X	X	
<b>Intimate partner violence</b>	There is not enough evidence to form a conclusion.			
<b>Nutrition</b>	Folic acid impacts the outcomes of interest.	X	X	
<b>Prenatal care: late/no entry and access</b>	The results are inconclusive.	X	X	X
<b>Sexually transmitted diseases</b>	Sexually transmitted diseases impact the outcomes of interest.		X	
<b>Stress and perinatal depression</b>	Stress and perinatal depression impact the outcomes of interest	X		X
<b>Unintended pregnancy</b>	There is not enough evidence to form a conclusion.		X	

Note: Evidence-based reviews limited to experimental studies with standards for assessing quality (level 1); Centers for Disease Control and Prevention or USPTF recommendations based on systemic reviews (level 2); Meta-analysis/systemic reviews published in peer-reviewed journals (level 3).

## Maternal Health Interventions

### *Alcohol and substance abuse*

Available evidence on the effectiveness of alcohol and substance abuse interventions was available from four evidence-based reviews (level 1), however, the evidence was inconclusive. Therefore, the Subject Matter Experts were asked to assist in compiling and assessing evidence (please see Appendix C).

#### EVIDENCE-BASED REVIEW

Two Cochrane Reviews have been conducted on interventions for alcohol and for illicit drug use. The first (Stade, Bailey, Dzenoletas, Sgro, Dowswell, and Bennett, 2009) reviewed randomized controlled trials of psychological and/or educational interventions for reducing alcohol consumption in pregnant and preconceptual women. Only four studies met the inclusion criteria; results were mixed. The authors conclude that these interventions may increase abstinence and reduce consumption but that further research is needed.

In the second review, Terplan and Lui (2007) reviewed psychosocial interventions for drug treatment. Nine trials were included, five using contingency management and four using motivational interviewing. The authors concluded that contingency management led to better retention of participants but could not conclude on the impact on obstetrical and neonatal outcomes.

In a third Cochrane Review, Doggett, Burrett, and Osborn (2005) reviewed home visiting programs for outcomes related to women with alcohol and drug programs. The review found evidence that home visits after birth increased the engagement of these women in drug treatment services but there were insufficient data to say if this improved the health of the baby or mother.

The U.S. Preventive Services Task Force (Whilock, Polen, Green, Orleans, and Klein, 2004) found good evidence that screening the general population in primary care settings can accurately identify patients whose levels or patterns of alcohol consumption do not meet criteria for alcohol dependence, but place them at risk. The authors found that the evidence on the effectiveness of counseling to reduce alcohol consumption during pregnancy is limited; however, studies in the general adult population show that behavioral counseling interventions are effective among women of childbearing age.

## META-ANALYSIS OR SYSTEMIC REVIEW

Milligan et al. (2010) conducted a meta-analysis to assess the impact of integrated vs. non-integrated substance abuse programs for women. Integrated programs are those that address physical, social, and mental health as well as children's need through prenatal services, parenting programs, child care, and other child-centered services. This review was not limited to pregnant women nor was it limited to randomized controlled studies. The studies included two randomized trials, nine quasi-experimental, and 10 cohort studies; study quality was assessed using the Jadad scale. Two quasi-experimental studies comparing integrated treatment to no treatment found reduced use of alcohol and other drugs using both self-report and urine toxicology. Nine of 16 studies comparing integrated to non-integrated programs found no significant differences in the two treatment methods. Milligan et al. report that integrated programs are effective in reducing maternal substance use but are not significantly more effective than non-integrated programs.

## INDIVIDUAL EXPERIMENTAL STUDIES

Two studies of a program in California (Taillac, Goler, Armstrong, Haley, & Osefj, 2007; Goler, Armstrong, Taillac, and Osego, 2008) using randomized controlled trials showed positive results. Early Start is an obstetric, clinical-based perinatal substance abuse intervention program, with the key feature being that the Early Start specialist is on site and part of the prenatal care team. Women who are identified as at-risk through screening are provided counseling and case management. All women, however, are educated about the risk of alcohol, tobacco, and other drugs through various channels and throughout their pregnancy. The first study was a retrospective study; the second was a randomized control study of 3,276 diverse subjects. Both studies documented positive results on abstinence and birth outcomes such as low birth weight and preterm delivery.

The Parent-Child Assistance Program, in a small randomized control study reported by the Office of Juvenile Justice (n.d.), documented higher abstinence and increased use of birth control. The Parent-Child Assistance Program is for women with children 0 to 3 and provides therapy, education, mentoring, and case management. It is an intensive three-year home visitation program. The program focuses on reducing alcohol and other drugs, but also works to reduce other risk behaviors and the health and well-being of mothers and their children.

Sweeney, Schwartz, Matlis & Vohr (2000) reported on a randomized control study of Project Link. Project Link serves pregnant and postpartum women with substance abuse problems, of whom 50 percent were white. Services included both outpatient and group therapy with one hour per week in individual therapy plus 1.5 hours per week in group therapy for three months to one year. Services were provided by a Masters level clinician with licensure. The study investigated whether an integrated program of prenatal care and substance abuse treatment would improve neonatal outcomes. The study included 87 women each in a control and experimental group. Infants born to women who enrolled prenatally were 400 gm heavier ( $p <$

0.001), and their gestational age was 2 weeks longer ( $p < 0.001$ ) than infants of mothers enrolled postpartum. In addition, they were approximately one-third as likely to be born with a low birth weight ( $p < 0.01$ ) and approximately one-half as likely to be admitted to the neonatal intensive care unit ( $p < 0.05$ ).

*Seeking Safety* is a psychotherapy intervention for those suffering from posttraumatic stress disorder and substance use; the program is not limited to women nor to pregnant women. The *Seeking Safety* website lists four randomized controlled trials conducted on the *Seeking Safety* program that demonstrated positive results on substance abuse and associated problems. The four **RCTs** are by Najavits, Gallop, and Weiss (2006); Hien et al. (2004); Zlotnick, Johnson, and Najavits (2009); and Hien et al. (2009). Najavits, Gallop and Weiss assessed the impact on adolescent girls; Hein et al. (2004) assessed the program impact on low-income urban women; Zlotnick, Johnson, and Najavits (2009) studies women in community treatment programs; and Hein et al. (2009) studied women in prison. Najavits, Gallop, and Weiss compared the program to treatment as usual for 33 outpatients through three months.

Winhusen et al. (2008) reported on a randomized controlled trial of 200 pregnant substance abusers entering outpatient substance abuse treatment. Women were assigned to either three individual sessions of Motivational Enhancement Therapy (MET-PS) or three sessions of the established program. Just over 80 percent completed the active phase. There was no difference between the treatment or control groups although there was some evidence that MET-PS might be more effective for minority groups. A follow up study conducted in 2010 (Kropp et al.) pooled results to determine the impact of treatment. Again, MET-PS was not more effective at modifiable healthy behaviors.

There have been three studies of brief interventions for alcohol use during pregnancy. O'Connor and Whaley (2007) reported on 255 WIC participants who reported using alcohol. The participants were randomized to assessment-only or brief intervention. The brief intervention consisted of 10 to 15 minute counseling sessions with a nutritionist who used a scripted manual. Women in the treatment group were five times more likely to report abstinence and newborns of those women had higher birth weights and less fetal mortality. Nilsen (2009) reported on four randomized controlled trials of brief interventions that demonstrated reductions in alcohol consumption, but the control groups did as well; statistically significant differences were difficult to detect. Tzilos, Sokol, and Ondersman (in press) reported on a small randomized controlled study ( $n=50$ ) of a computer-delivered intervention and also reported that both treatment and control groups reduced alcohol use with no statistically significant difference.

The Centers for Disease Control and Prevention developed and tested the CHOICES program, which consists of four counseling sessions and one contraception consultation and services visit (Centers for Disease Control, 2003). The sessions included an in-depth assessment, counseling about the consequences of alcohol use, and referral to community treatment services if needed. The counseling sessions are delivered by a mental health clinician; the contraception counseling session is delivered by a family planning clinician. Outcomes are both adoption of

effective contraception and reduction of alcohol use. Two randomized controlled studies (Floyd et al., 2007; Velasquez, Ingersoll, Sobell, Floyd, Sobell & Sternberg, 2010) documented that project CHOICES reduces the risk of an alcohol-exposed pregnancy.

Elsinga et al. (2008) reported on a randomized controlled trial (n=633) of preconception counseling and education. The authors report that the women in the treatment group were significantly more likely to use folic acid before pregnancy and to reduce alcohol use during the first three months of pregnancy.

## CONCLUSION

Four evidence-based reviews (level 1) found only effectiveness of retention or engagement, but found insufficient evidence of impact on abstinence. One meta-analytic review (level 2) and four individual studies documented evidence of effectiveness with pregnant women. Therefore, there are no evidence-based practices in substance abuse prevention using the standard identified for this review, but there is evidence using the standard the Subject Matter Expert committee members identified (at least two high-quality studies).

## ***Care coordination and case management***

Available evidence on the effectiveness of care coordination and case management was available from two types of sources: an evidence-based review (level 1) and a meta-analysis or systemic review in peer-reviewed journal (level 2), however, the evidence was inconclusive. Therefore, the Subject Matter Experts were asked to assist in compiling and assessing evidence (please see Appendix C). Per Subject Matter Expert input, care coordination and case management were assessed as a stand-alone practice and not within the context of programs offered primarily through home visits. This is because care coordination has a clear outcome related to providing knowledge, encouragement, linkages, and support and may occur in a variety of settings. Evidence-based programs described later in this document that utilize a home visiting strategy may or may not include care coordination as a specific activity.

### **EVIDENCE-BASED REVIEW**

In a Cochrane Review, Hodnett, Fredericks, and Weston (2010) assessed the effects of programs offering additional social support compared with routine care, for pregnant women believed to be at high risk for giving birth to babies preterm or would weigh less than 2500 gm, or both, at birth. Secondary objectives were to determine whether effectiveness of support was mediated by timing of onset (early versus later in pregnancy) or type of provider (healthcare professional or lay woman). The study included randomized trials of additional support during at-risk pregnancy by either a professional (social worker, midwife, or nurse) or specially trained lay person, compared to routine care. The authors defined additional support as some form of emotional support and information or advice or both, either in home visits or during clinic appointments, and could include tangible assistance such as transportation to clinic appointments. The authors found that programs which offer additional support during pregnancy are unlikely to prevent the pregnancy from resulting in a low birthweight or preterm baby; they may be helpful in reducing antenatal hospital admission and caesarean birth.

### **META-ANALYSIS/SYSTEMIC REVIEW**

Hollowell, Oakley, Kurinczuk, Brocklehurst, and Gray (2011) conducted a systematic review of antenatal care for high-risk groups, including teens, racial and ethnic minorities, homeless women, prisoners, victims of domestic violence, women with substance abuse problems, and women with mental illness. The authors note that prior reviews of antenatal care found some positive evidence of beneficial effects on maternal and infant health and wellbeing, but not specifically on infant mortality. The inclusion criteria were experimental or observational studies with a control or comparison group in peer reviewed journals with a focus on high-income countries; the authors identified 36 studies with 15 meeting the methodological criteria for internal validity. The authors concluded that there was insufficient evidence of adequate quality to assess the impact of support on infant mortality.

## OTHER STUDIES

As noted the Subject Matter Expert Committee members documented that two or more published high- or moderate-quality experimental or quasi-experimental impact studies was an acceptable standard when evidence at the original standard set was not available. There have been two quasi-experimental studies of Care Coordination models similar to Healthy Start but not two studies of the same program.

Ricketts, Murray, and Schwalengerg (2005) examined low-birthweight rates among participants in Colorado's Prenatal Plus program by prenatal risk factors (smoking, inadequate weight gain during pregnancy, and psychosocial problems) and the effect of successful resolution of these risks during pregnancy. Researchers collected data for 3,569 Medicaid-eligible women who received care coordination, nutritional counseling, or psychosocial counseling through the Prenatal Plus Program in 2002. Data were analyzed to determine the prevalence of specific risks, the proportion of women who resolved each specific risk, and the low birthweight rates for births to women who did and did not resolve risk. Low birthweight rates were analyzed with  $\chi$  tests of significance. Ricketts, Murray, Schwalenberg (2005) reported that women who quit smoking had a low birthweight rate of 8.5 percent, compared with a low birthweight rate of 13.7 percent among women who did not. Women with adequate weight gain had a low birthweight rate of 6.7 percent, compared with 17.2 percent among women with inadequate weight gain. Women who resolved all of their risks had a low-birthweight rate of 7.0 percent, compared with a rate of 13.2 percent among women who resolved no risks. Women who had at least 10 Prenatal Plus visits were more likely to resolve their risks than were women who had fewer visits.

Willems Van Dijk, Anderko, and Stetzer (2010) used a cross-sectional design to compare a birth outcomes of 10,715 Medicaid births (23.6 percent of total Medicaid births in Wisconsin) receiving prenatal care coordination (PNCC) to Medicaid births without PNCC. The authors controlled for nine covariates, including age, race, marital status, education, smoking, etc. Services were provided in clinic or community-based settings by professionals or paraprofessionals of state-certified PNCC agencies. PNCC was delivered consistently through the use of a manual documenting the use of a pregnancy risk assessment, mutually agreed-upon plan of care, and ongoing care, coordination and educational services delivered face to face (one on one or in group settings) or via phone. Twenty-two percent of women received PNCC in their home. Women who participated in PNCC demonstrated significantly better birth outcomes included fewer low birthweight infants and fewer preterm infants; outcomes were positively correlated with dosage.

## CONCLUSIONS

Findings from the evidence-based review (level 1) conducted by the Cochrane Collaborative found no evidence of effectiveness of additional support (defined as emotional support,

information, advice, or tangible assistance) on preterm births or low birth weight. A systemic review (level 2) found insufficient evidence of adequate quality to assess the impact on infant mortality. Therefore, there are no evidence-based practices in care coordination using the standard identified for this review. When a practice is not identified as evidence-based, it does not mean that there is no evidence of effectiveness but that the practice does not meet the standards used for this report and described on page 5.

## ***Continuous support and augmented prenatal care***

Available evidence on the effectiveness of continuous support was available from three evidence-based reviews (level 1), a meta-analytic/systemic review (level 2) and individual experimental studies (level 3)

### **EVIDENCE-BASED REVIEWS**

Hodnett, Gates, Hofmeyr, Sakala, and Weston (2011) reviewed studies including 21 trials, from 15 countries, involving more than 15,000 women in a wide range of settings and circumstances. The continuous support was provided either by hospital staff (such as nurses or nurse-midwives), women who were not hospital employees and had no personal relationship to the laboring woman (such as doulas), or by companions of the woman's choice from her social network (such as her husband, partner, mother, or friend). Women who received continuous labor support were more likely to give birth 'spontaneously', i.e. give birth with neither caesarean nor vacuum nor forceps. In addition, women were less likely to use pain medications, were more likely to be satisfied, and had slightly shorter labors. No adverse effects were identified. Continuous support from a person who is present solely to provide support, is not a member of the woman's social network, is experienced in providing labor support, and has at least a modest amount of training, appears to be most beneficial. Support from a chosen family member or friend appears to increase women's satisfaction with their childbearing experience.

Hodnett, Fredericks, and Weston (2010) examined programs providing emotional support, practical assistance, and advice offered in addition to usual care. The review of 17 randomized controlled trials, involving 12,264 women, found that women who received additional support during pregnancy were less likely to be admitted to the hospital for pregnancy complications and to have a caesarean birth. The additional support, however, did not reduce the likelihood of preterm birth or low birthweight.

Hatem, Sandall, Devane, Soltani, and Gates (2008) conducted a review of midwife-led care (providing care antepartum, intrapartum, and postpartum). This was compared with models of medical-led care and shared care, and identified 11 trials, involving 12,276 women. Midwife-led care was associated with several benefits for mothers and babies, and had no identified adverse effects. The main benefits were a reduction in the use of regional analgesia, with fewer episiotomies or instrumental births. Midwife-led care also increased the woman's chance of being cared for in labor by a midwife she had gotten to know, and the chance of feeling in control during labor, having a spontaneous vaginal birth and initiating breastfeeding. There was, however, no difference in caesarean birth rates. Women who were randomized to receive midwife-led care were less likely to lose their baby before 24 weeks' gestation, although there were no differences in the risk of losing the baby after 24 weeks, or overall. In addition, babies of women who were randomized to receive midwife-led care were more likely to have a shorter length of hospital stay. The review concluded that most women should be offered midwife-led

models of care, although caution should be exercised in applying this advice to women with substantial medical or obstetrical complications.

### META-ANALYSIS/SYSTEMIC REVIEWS

Dennis and Kingston (2008) conducted a meta-analysis of randomized trials of telephone support for women during pregnancy and the early postpartum period. Outcomes of interest included smoking cessation, preterm birth, low birthweight, breastfeeding, or postpartum depression. The service delivery mechanism was telephone support only; support was provided through peer counselors, midwives, or nurses, depending on the study. The authors identified 14 studies meeting the criteria for inclusion; studies were assessed using the recommendations of the Cochrane Review. Studies include telephone support provided alone or as an adjunct to other strategies. The authors found support for prevention of smoking relapse, risk reduction of low birthweight, increase in breastfeeding, and a decrease in postpartum depressive symptoms. Telephone support as a primary intervention was only beneficial in breastfeeding outcomes and decreasing postpartum depressive symptoms.

### INDIVIDUAL EXPERIMENTAL STUDIES

Hobel, et al. (1994) tested whether preterm birth prevention education plus increased clinic visits and selected prophylactic interventions reduce preterm birth. The study design randomized eight prenatal county clinics; high-risk patients in all clinics were identified with a risk scoring system derived from a similar population. High-risk patients (N = 1774) in experimental clinics were offered a program of education and more frequent visits and were randomized to receive various secondary intervention protocols in addition to the basic interventions of education and more frequent visits. Control clinic patients (N = 880) received standard county care. Preterm birth rates were 19 percent lower among the experimental high-risk patients (7.4% vs 9.1%), and differences were significant ( $p < 0.05$ ) when preterm risk was taken into account.

Massey, Schindler Rising, and Ickovics (2006) documented the components of CenteringPregnancy, a group prenatal care program. The program is provided in a clinic setting based on the premise that group care is efficient and enhances learning and supports; participants are referred through public hospitals. The program provides group prenatal care, assessment, education and skill-building, and support in 10 defined two-hour sessions. Services are provided by health care providers and trained healthcare practitioners. Two randomized controlled studies have been completed (Ickovics et al., 2007; Ickovics et al., 2011); the study of teens used matched groups. The 2007 study randomly assigned 1,047 pregnant women; women with medical conditions were excluded. The average age was 20, with 49 percent of participants between 14 and 19; eighty percent were African American. Women assigned to group care were significantly less likely to have preterm births and more likely to have adequate care and to breastfeed than those in individual care. The 2011 study assessed

additional outcomes on the same sample: high-stress women reported significantly decreased stress in the third trimester and lower depression one year postpartum. There are three additional randomized control trials documenting positive results.

Klerman, Ramey, Goldenrod, Marbury, Hou, and Sliver (2001) investigated augmented prenatal care for high-risk African American women. Augmented care included educationally oriented peer groups, additional appointments, extended time with clinicians, and other supports. Augmented care was provided in clinics; participants also received seven home visits using the Nurse Family Partnership model. Women were over 16, eligible for Medicaid, had scored 10 or higher on a risk assessment scale, and had no major medical complications. They were randomly assigned to augmented care (n = 318) or usual care (n = 301). More smokers in augmented care quit smoking. Pregnancy outcomes did not differ significantly between the groups; however, among patients in augmented care, rates of preterm births were lower.

## CONCLUSION

There have been three Cochrane Reviews of support that found evidence for positive outcomes of continuous support. Although one review found positive impacts on pre-term birth, another review did not. One review found positive impacts on breastfeeding. A meta-analysis found evidence of effectiveness for telephone support. There were also experimental studies available for augmented prenatal care. Therefore, support programs can be considered as evidence-based practices for maternal and infant health although inconclusive for preterm, low birthweight, and infant mortality.

### ***Facilitating access to prenatal care***

There were no evidence-based reviews (level 1) or meta-analysis/systemic reviews in peer-reviewed journals limited to randomized controlled studies (level 2) regarding facilitating access to prenatal care.

### **CONCLUSION**

There are no evidence-based reviews (level 1) or meta-analysis/systemic reviews (level 2). Although the Centers for Disease Control (Johnson, 2006) recommends health insurance coverage for women with low incomes to improve access to preventive, preconception, and interconception care (level 2), there are no evidence-based practices. When a practice is not identified as evidence-based, it does not mean that there is no evidence of effectiveness but that the practice does not meet the standards used for this report and described on page 5.

## ***Intimate partner violence***

Available evidence on the effectiveness of interventions addressing intimate partner violence was available from three sources: evidence-based reviews (level 1) and meta-analysis or systemic review in peer-reviewed journal (level 2).

### **EVIDENCE-BASED REVIEW**

In a review for the U.S Preventive Services, Nelson, Nygren, McInerney, and Klein (2004) found few trials examining the effectiveness of screening in either detection or the impact of screening on violence or health outcomes. The review was not limited to pregnant women.

### **META-ANALYSIS/SYSTEMIC REVIEW**

Sharps, Campbell, Baty, Walker, and Bair-Merritt (2008) reviewed home visitation studies to assess impact on perinatal intimate partner violence and found no programs designed to address partner violence, although programs that screened for partner violence found high rates.

The Canadian Task Force on Preventive Health Care (Wathen and MacMillan, 2003) found some evidence that advocacy and counseling was an effective strategy for the general population but did not limit the review to pregnant women.

Ramsay, Richardson, Carter, Davidson and Feder (2002) conducted a systemic review of screening for domestic violence, but did not limit the review to pregnant women. Although the authors found that women were open to the screenings and that screenings detected domestic violence, outcomes were limited to increased referrals to outside agencies.

### **INDIVIDUAL EXPERIMENTAL STUDIES**

There were few randomized controlled trials published with either negative or positive results. Kiely, Ayman, El-Mohandes, El-Khorazaty, and Gantz (2010) conducted a randomized controlled trial of individually-tailored counseling sessions and found less recurrent episodes of victimization among the treatment group, particularly those with minor intimate partner violence. The integrated cognitive behavioral intervention was designed to address multiple risk factors, including cigarette smoking, environment smoke, depression, and intimate partner violence. The intervention was delivered during routine prenatal visits at the clinic by masters level trained staff; it was designed for a minimum of four sessions but required eight for completion. In four additional articles about this intervention, the authors reported less risk behaviors in all four categories.

## CONCLUSION

There was limited evidence available for interventions targeting intimate partner violence among pregnant women. Therefore, there are no evidence-based practices in intimate partner violence using the standard identified for this review. When a practice is not identified as evidence-based, it does not mean that there is no evidence of effectiveness but that the practice does not meet the standards used for this report and described on page 5.

## ***Nutritional interventions***

Available evidence on the effectiveness of nutritional interventions was available from two sources: four evidence-based reviews (level 1) and a meta-analysis or systemic review in peer-reviewed journal (level 2).

### **EVIDENCE-BASED REVIEWS**

In a Cochrane Review, (Kramer & Kakuma, 2010) five trials involving 1,135 women receiving nutritional advice showed an increase in the mother's energy intake but no clear benefit for the developing baby. In a review of 13 trials involving 4,665 women receiving energy and protein balanced supplements, including to undernourished women, results showed fewer small babies and fewer stillbirths, but the impact on long-term health of the baby is uncertain. An examination of two trials involving 1,076 women receiving high-protein supplementation showed no benefit for babies or women. Three trials involving 966 women receiving isocaloric protein supplements (i.e. without energy supplementation) showed no benefit and potential harm to the baby. A comparative review of four trials involving 457 women undergoing energy/protein restriction in women with overweight or high-weight gain found no benefit and potential harm to the developing baby. The overall findings suggest that nutritional advice to women and balanced energy/protein supplements may be beneficial but high-protein supplements for pregnant women and energy/protein restriction for overweight pregnant women may both be harmful.

In another Cochrane Review, the evidence from four trials, involving 334 participants, does not suggest a protective effect of maternal dietary antigen avoidance during pregnancy on the incidence of atopic eczema during the first 18 months of life. However, the restricted diet during pregnancy was associated with a slightly but statistically significantly lower mean gestational weight gain (Kramer and Kakuma, 2009). One crossover trial involving 17 lactating mothers of infants with established atopic eczema found that maternal dietary antigen avoidance was associated with a non-significant reduction in eczema severity.

In the third Cochrane Review, Haider and Bhutta (2006) examined nine trials (15,378 women) comparing supplementation of two or less micronutrients or no supplementation or a placebo in which multiple-micronutrient supplementation resulted in a statistically significant decrease in the number of low birthweight babies (relative risk (RR) 0.83; 95% confidence interval (CI) 0.76 to 0.91), small-for-gestational-age babies (RR 0.92; 95% CI 0.86 to 0.99) and in maternal anemia (RR 0.61; CI 0.52 to 0.71). However, differences lost statistical significance when multiple-micronutrient supplementation was compared with iron folic acid supplementation alone.

The Task Force on Community Preventive Services (2004) recommends community-wide education campaigns to promote the use of folic acid supplements among women of childbearing age. These campaigns involve the dissemination of coordinated educational and

motivational messages and materials within the community. Educational content can be delivered through mass media messages and articles; community activities and promotions; and distribution of small media (posters, flyers, brochures, etc.).

### META-ANALYSIS OR SYSTEMIC REVIEWS

Chivu, Tulchinsky, Soares-Weiser, Braunstein, and Brezis (2008) conducted a systematic review of studies to assess folic acid awareness, knowledge, and consumption, but did not limit the review to experimental designs. The authors conducted a narrative review and found that the studies led to small increases in knowledge, awareness, and consumption. They further noted that studies did not use formal social marketing concepts and concluded that health education approaches to date have had suboptimal effects.

Campbell, Johnson, Messina, Guillame, and Goyder (2011) conducted a systemic review of interventions to reduce weight gain during pregnancy; the studies were not limited to randomized controlled trials. The authors found no statistically significant effect on weight gain despite what they classified as intense interventions.

### CONCLUSIONS

Findings from four evidence-based reviews suggest that folic acid supplements can be considered an evidence-based practice. Other findings suggest that nutritional advice to women and balanced energy/protein supplements may be beneficial but high-protein supplements for pregnant women and energy/protein restriction for overweight pregnant women may both be harmful. Therefore, folic acid supplements during the preconception period can be considered as an evidence-based practice.

### ***Outreach and screening***

Although outreach is often included as part of an intervention, there were no evidence-based reviews (level 1), meta-analysis or systemic reviews (level 2), or individual studies using a randomized control design (level 3) that assessed the effectiveness of specific outreach strategies found. There were also no evidence-based reviews (level 1) or meta-analysis/systemic reviews (level 2) related to screening found. Therefore, there is not enough evidence to draw a conclusion.

## ***Smoking cessation***

Available evidence on the effectiveness of smoking cessation was available from two evidence-based reviews (level 1).

### EVIDENCE-BASED REVIEW

In a Cochrane Review, Lumley, Chamberlain, Dowswell, Oliver, Oakley, and Watson (2009) reviewed 72 trials of predominantly individual strategies such as advice and counseling; stages of change; feedback of fetal health status; pharmacological agencies; and social support and encouragement, including rewards. The authors assessed the effects of smoking cessation interventions during pregnancy on smoking perinatal health outcomes; the review was limited to randomized controlled trials where smoking cessation during pregnancy was a primary aim of the intervention. The authors found that smoking cessation interventions reduced the proportion of women who continued to smoke in late pregnancy, and reduce low birthweight and preterm birth. The most effective interventions appeared to be providing incentives and that stage of change-based interventions had no advantage. Lumley et al. recommended that smoking cessation interventions be implemented in all maternity care settings. There is growing evidence of the interrelationship among depression, stress, and smoking while pregnant (Lumley et al., 2009): depressed women are up to four times more likely to smoke during pregnancy. Findings also suggest that there are significant prior or current psychological symptoms among women who smoke.

The U.S Preventive Services Task Force (2009) conducted a systematic review and recommended person to person psychosocial interventions that exceed minimal advice to quit, and that smoking cessation interventions occur preconception through post partum care. Person to person psychosocial interventions involved recommendations to stop smoking, self-help materials, and intensive telephone or in person counseling. The review found that augmented, pregnancy-tailored counseling is more effective than brief, generic counseling sessions alone. In addition, more or longer sessions improve quit rates, with a plateau of 90 minutes total counseling contact time. Counseling should include problem-solving guidance and social support; complementary practices included motivational interviewing, assessing readiness to change, offering more intensive counseling or referrals, and quit lines.

Priest et al. (2008) in a Cochrane Review of interventions to reduce environmental tobacco smoke and found 36 studies that met the inclusion criteria. Eleven of the 36 studies demonstrated a statistically significant effect; of those, four used intensive counseling sessions for parents. The authors found that the evidence for the effectiveness of parental education and counseling interventions for environmental tobacco smoke is inconclusive at this time.

Due to stigma associated with smoking during pregnancy, multiple choice questions – as opposed to a simple yes/no – can increase disclosure (U.S. Preventive Services Task Force, 2009). The U.S. Preventive Services Task Force (2009) did not make any recommendations

regarding tobacco use medication, although Lumley et al. (2009) report no significant advantage of nicotine replacement therapy and unclear data on safety. U.S. Preventive Services Task Force (2009) reports that relapse may be decreased by emphasizing the impact on the infant, although research is lacking in this area.

## CONCLUSIONS

Findings from two evidence-based reviews (level 1) found that smoking cessation interventions for pregnant women were effective. Evidence-based programs encompass attention to smoking behavior; support for smoking cessation and relapse prevention. Evidence-based support for smoking cessation include providing incentives (helped 24 percent of women to quit smoking during pregnancy); cognitive behavior therapy (CBT), educational and motivational interviewing strategies; and feedback of fetal health status or measurement of by-products. Stage of change interventions did not produce an advantage of cognitive behavioral therapy alone. Nicotine Replacement Therapy does not appear to have a significant advantage over other interventions and the effect on fetal development is unclear. Therefore, smoking cessation programs can be considered as evidence-based practices.

Figure 2 provides a summary of smoking cessation practices found in the evidence-based reviews (level 1) to be effective.

Figure 2: Summary of smoking cessation practices with evidence of effectiveness

<b>Practice and citation</b>	<b>Outcome domain</b>	<b>Target population</b>	<b>Major Activities</b>
<b>TFS Albrecht, 1998</b>	Smoking cessation	Teens	Eight modules with experiential learning, plus peer support (buddies). Intervention included social activities and immediate rewards.
<b>Significant Other Supporter Donatelle, 2000</b>	Smoking cessation	Adults	Rewards and social support. Activities included written information, self-help kit, monthly telephone calls, a social supporter, and incentives for both the participant and their social supporter.
<b>Mental health counselors Dornelas, 2006</b>	Smoking cessation	Low-income Hispanic women	CBT approach with one 90-minute psychotherapy session followed by bi-monthly calls during pregnancy and monthly after delivery.
<b>Contingent voucher Heil, 2008</b>	Smoking cessation, fetal weight	Diverse WIC participants; 54% first time mothers	Rewards-based program with routine advice plus daily monitoring for 5 days, twice/week for 7 weeks, once/week for 4 weeks, then every other week. Vouchers were dependent on biochemical validation.

<b>Practice and citation</b>	<b>Outcome domain</b>	<b>Target population</b>	<b>Major Activities</b>
<b>Peer counseling Malchodi, 2003</b>	Reduction in smoking	Adult, low-income uninsured Hispanic women	Peer counseling through lay community health outreach workers (telephone or home visit).
<b>Telephone counseling Rigotti, 2006</b>	Smoking cessation	Adult	Activities included a mailed pregnancy-tailored self-help book; prenatal care providers sent ACOG* guidelines and reminder. The project also included brief counseling and referral to quitline. Series of telephone calls with trained dedicated counselor up to 90 minutes during pregnancy and up to 15 postpartum.
<b>SCRIPT Windsor, 2000</b>	Smoking cessation	Adult	Patient education program consisting of a self-help plus quit kit, monetary incentives, and 3 motivational phone calls.

Source: Lumley, Chamberlain, Dowswell, Oliver, Oakley, and Watson (2009); U.S. Preventive Services Task Force, 2009

\*American College of Obstetrics and Gynecology

## ***Teen pregnancy prevention***

Available evidence on the effectiveness of teen pregnancy prevention was available from an evidence-based review (level 1). Although teen pregnancy prevention is not currently a core service of Healthy Start, there is some evidence that adolescent pregnancy is a risk factor for poor birth outcomes. Therefore, teen pregnancy prevention is included in the research review for consideration by the Subject Matter Experts in the redesign process.

### **EVIDENCE-BASED REVIEW**

The U.S. Department of Health and Human Services commissioned an evidence review of teen pregnancy prevention programs (U.S. DHHS, n.d.) that conducted a broad literature search resulting in 1,000 studies. The authors screened for programs that used an eligible research design, targeted teens, and targeted outcomes in four eligible domains. Mathematica Policy Research then assessed 190 studies by assigning points for study design (randomized controlled and quasi-experimental) and attrition; studies were assigned ratings of high, moderate, or low based on study design and attrition. To meet the criteria of evidence-based, the model had to have at least one high or moderate-quality study documenting statistically significant impacts in one or more of the outcome domains. Twenty-eight programs met the criteria, although only six were classified as high-quality with sustained impacts. The remaining 22 studies were classified as high-impact with short-term impact, moderate impact, etc.

### **CONCLUSION**

Findings from the evidence-based review (level 1) conducted by the Department of Health and Human Services document that six teen pregnancy programs are effective in achieving outcomes with specific programs achieving outcomes for specific populations. Of those, four were identified as impacting Healthy Start outcomes of interest; the remaining two impacted outcomes related to increasing knowledge about HIV and living with HIV. Therefore, the four programs listed below can be considered as evidence-based practices for the specific population for the specific outcome domain listed.

Figure 3: Summary of evidence-based Teen Pregnancy Prevention program models from evidence-based reviews (level 1)

<b>Model</b>	<b>Outcome domain(s) with documented favorable impact not limited to sub-groups</b>	<b>Target population</b>	<b>Major Activities</b>
<b>Assisting in Rehabilitating Kids (ARK)</b>	increase abstinence, increase safer sex, and reduce risky sex behaviors in substance-dependent youth	Available information describes the target population as substance-dependent adolescents (average age is 16 years) in residential treatment facilities.	The intervention consists of 12 sessions, each lasting 90 minutes, delivered to small groups of mixed-gender youth covering information, behavioral skills, and motivation.
<b>Children’s Aid Society – Carrera</b>	reducing teen pregnancy, sexual initiation and sexual behaviors, and drug use; and improving sexual and reproductive health knowledge, employment, health care utilization, and academic skills	The program targets high-risk youth, male and female. It is offered to youth from 11 years old up through high school age.	The <i>CAS–Carrera</i> program is a multiyear, comprehensive program based on a holistic youth development model. It consists of five activity components and two service components.
<b>Promoting Health Among Teens!</b>	to improve awareness and knowledge about HIV/STIs; increase understanding of how abstinence can prevent pregnancy, STDs, and HIV; strengthen behavioral beliefs that support condom use; and build refusal and negotiation skills for practicing abstinence as well as for effective use of condoms.	Available information describes the target population as African American male and female adolescents in grades 6 and 7 from low-income urban communities.	The intervention consists of up to 12 modules, delivered over two or three consecutive Saturdays for a period of 8 or 12 hours. Four of the modules are targeted specifically to encouraging abstinence, four are targeted to encouraging condom use, and four cover general content related to HIV/STI knowledge.

<b>Model</b>	<b>Outcome domain(s) with documented favorable impact not limited to sub-groups</b>	<b>Target population</b>	<b>Major Activities</b>
<b>Sisters Saving Sisters</b>	to reduce frequency of unprotected sexual intercourse (with and without drug and alcohol use), number of sexual partners, and incidence of sexually transmitted infections	Available information describes the target population as sexually active Latina and African American female patients, ages 12–19, recruited from family planning clinics.	Sisters Saving Sisters is a skills-based risk-reduction intervention administered in small groups of 2–10 female adolescents, by trained facilitators in one 250-minute session in a community-based clinic setting.

Source: U.S. Department of Health and Human Services, 2010

## Summary of evidence on maternal health interventions

Figure 4 provides a summary of the preceding pages. The first column lists the interventions relevant to maternal health while the second column lists the conclusion drawn based on the available evidence and the evidence standard set. When a practice is not identified as evidence-based, it does not mean that there is no evidence of effectiveness but that the practice does not meet the standards used for this report and described on page 5. The final column documents the levels of evidence available for that intervention using the definitions on page 5 and provided in the table note for ease of reference.

Figure 4: Summary of maternal health interventions

Intervention category	Conclusion based on the evidence standard set and evidence obtained at the time of this report	Available levels of evidence		
		1	2	3
<b>Alcohol and substance abuse</b>	There are no evidence-based practices in alcohol and substance abuse at the standard set but there are practices where at least two studies documented evidence of effectiveness.	X		
<b>Care coordination and case management</b>	Available evidence found no evidence-based practices in care coordination.	X	X	X
<b>Continuous support and augmented prenatal care</b>	There are evidence-based practices for continuous support and augmented prenatal care.	X		
<b>Facilitating access to prenatal care</b>	Insufficient evidence to draw a conclusion.			X
<b>Intimate partner violence</b>	Available evidence found no evidence-based practices for intimate partner violence.	X	X	
<b>Nutritional interventions</b>	There are evidence-based practices for nutritional interventions.	X	X	
<b>Outreach and screening</b>	No available evidence.			
<b>Smoking cessation</b>	There are evidence-based practices in smoking cessation.	X		
<b>Teen pregnancy prevention</b>	There are evidence-based practices in teen pregnancy prevention.	X		

Note: Evidence-based reviews of randomized controlled trials and an assessment of study quality such as Cochrane Reviews, US Preventive Services Task Force, or the Agency for Healthcare Research and Quality (level 1); Meta-analysis or systemic reviews of experimental studies in peer-reviewed journals (level 2); Centers for Disease Control and Prevention recommendations based on national data and/or systemic reviews (level 3).

# Section II: Infant Health

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## **Infant Health Risk and Protective Factors**

### ***Breastfeeding***

There was an evidence-based review (level 1) regarding the impact of breastfeeding on the outcomes of interest. Chung, Raman, Trikalinos, Lau and Ip (2008) in their evidence-based review for the US Preventative Services Task Force found (level 1) that there is high certainty that the net benefit of breastfeeding is moderate or there is moderate certainty that the net benefit is moderate to substantial. The study reviewed thirty-eight randomized, controlled trials (36 in developed countries) that met eligibility criteria. Hauck, Thompson, Tanabe, Moon, and Venneman (2011) conducted a meta-analysis of the impact on breastfeeding on SIDS; the authors found that breastfeeding is protective against SIDS and that the effect is stronger for exclusive breastfeeding. Based on the Cochrane review and supporting studies, breastfeeding can be considered to have an impact on the outcomes of interest.

### ***Sudden Infant Death Syndrome (SIDS)/Infant sleep position***

There were no evidence-based reviews (level 1) available regarding infant sleep position. There are existing recommendations (level 2) and meta-analysis/systemic reviews available (level 3). The Centers for Disease Control and Prevention (1996) identified the following as risk factors for Sudden Infant Death Syndrome: lack of breast-feeding, exposure to tobacco smoke in utero or during infancy, and infant sleeping prone. (Breastfeeding and tobacco exposure are discussed elsewhere in this document.) There are, however, other risk factors, including male sex, maternal characteristics, and late or no prenatal care. Gunn, Gunn, and Mitchel (2000) report – based on their meta-analysis and systemic review – that the prone sleeping position is causally associated with SIDS. The authors also analyzed 50 cohort and case studies and found a relationship between maternal smoking and SIDS as well. Hauck and Tanabe (2007) found observational studies supported avoiding prone sleeping and tobacco-smoke exposure. In 2006, the U.S. Surgeon General released a report on the impact of secondhand smoke. The report found that evidence was inadequate to infer a causal relationship on neonatal mortality and on child development and that evidence was suggestive but not sufficient to infer a causal relationship between maternal exposure to secondhand smoke during pregnancy and preterm delivery. The report did find, however, that evidence was sufficient to infer a causal relationship between exposure to secondhand smoke and sudden infant death syndrome (U.S. Department of Health and Human Services, 2006a). Given the available evidence, therefore, infant sleep position and exposure to secondhand smoke can be considered to impact outcomes of interest.

### ***Well-child care***

There was one evidence-based review (level 1) regarding the impact of prescribed well-child care visits on health and developmental outcomes. In a review for the U.S. Preventive Services

Task Force, Nelson, Nygren, Walker and Panoscha (2006) reviewed the evidence of effectiveness of screening and interventions for speech and language delay in primary care for children up to 5 years old. Outcome measures included speech and language measures as well as other functional and health outcomes. The review was limited to randomized controlled trials. The authors found that use of risk factors to guide selective screening is not supported, and that there was insufficient evidence to determine the effectiveness of screening. There is insufficient evidence to link well-child care to the outcomes of interest.

## ***Summary of evidence on infant risk and protective factors***

Figure 5 provides a summary of the preceding pages. The first column lists the risk and protective factors relevant to infant health while the second column lists the conclusion drawn based on the available evidence and the evidence standard set. The final column documents the levels of evidence available for that risk or protective factor using the definitions on page 4 and provide in the table note for ease of reference.

Figure 5: Summary of infant health risk and protective factors

Risk and protective factor	Conclusion based on the evidence standard set and evidence obtained at the time of this report	Available levels of evidence		
		1	2	3
<b>Adolescent pregnancy</b>	Adolescent pregnancy impacts the outcomes of interest.			
<b>Alcohol, tobacco, and other drugs</b>	Use of alcohol, tobacco, and other drugs impact the outcomes of interest.	X	X	
<b>Breastfeeding</b>	Breastfeeding impacts the outcomes of interest.	X		
<b>Infant sleep position</b>	Infant sleep position can be considered to impact outcomes of interest.		X	X
<b>Sexually transmitted diseases</b>	Sexually transmitted diseases impact the outcomes of interest.		X	
<b>Stress and perinatal depression</b>	Stress and perinatal depression impact the outcomes of interest	X		X
<b>Unintended pregnancy</b>	There is not enough evidence to form a conclusion.		X	
<b>Well-child care</b>	There is not enough evidence to form a conclusion.			

Note: Evidence-based reviews limited to experimental studies with standards for assessing quality (level 1); Centers for Disease Control and Prevention or USPTF recommendations based on systemic reviews (level 2); Meta-analysis/systemic reviews published in peer-reviewed journals (level 3).

## Infant Health Interventions

Please see the intervention summaries regarding Home Visiting, Smoking Cessation, and Maternal Depression as well in other sections of this report.

### ***Breastfeeding***

Available evidence on the effectiveness of breastfeeding was available from evidence-based reviews (level 1) and one meta-analytic/systemic review (level 2).

#### EVIDENCE-BASED REVIEWS

Dyson, McCormick, and Renfrew's (2008) conducted a Cochrane review of interventions designed to encourage women to breastfeed. The authors defined effectiveness in terms of changes in the number of women who start to breastfeed. Search strategies included the Cochrane Pregnancy and Childbirth Group's Trials Register, hand searches of the Journal of Human Lactation, Health Promotion International and Health Education Quarterly from inception to August 15, 2007, and scanned reference lists of all articles obtained. Selection criteria were randomized controlled trials, with or without blinding, of any breastfeeding promotion intervention in any population group except women and infants with a specific health problem. The authors included eleven trials in their review and they were all conducted in the United States. They concluded that health education and peer support interventions can result in some improvement in the number of women beginning to breastfeed. In particular, they found that the impact is even stronger from needs-based, informal repeat education sessions than more generic, formal antenatal sessions.

Britton, McCormick, Renfrew, Wade and King (2006) conducted another Cochrane review to assess the effectiveness of support for breastfeeding mothers. Like the review above, they looked at the Cochrane Pregnancy and Childbirth Group's Trials Register (January 2006) and they also searched MEDLINE (1966-November 2005), EMBASE (1974 to November 2005) and MIDRIS (1991 to September 2005). The selection criteria were randomized or quasi-randomized trials that compared extra support for breastfeeding mothers with usual maternity care. They included thirty four trials from fourteen countries in their review. The authors concluded that additional professional support was effective in prolonging any breastfeeding, but its effects on exclusive breastfeeding were less clear. With lay support, however, the authors found additional support to be effective in prolonging exclusive breastfeeding although effects on duration of any breastfeeding were uncertain.

Chung, Raman, Trikalinos, Lau, and Ip (2008), on behalf of the U.S. Preventive Services Task Force (USPSTF), conducted an evidence review of interventions in primary care to promote breastfeeding. The authors conducted electronic searches of MEDLINE, the Cochrane Central Register of Controlled Trials, and CINAHL from September 2001 to February 2008. The authors

selected randomized, controlled trials of primary care initiated interventions to promote breastfeeding, mainly in developed countries; thirty-eight trials met their criteria. They found that the evidence from these trials suggested that breastfeeding interventions are more effective than usual care in increasing short- and long-term breastfeeding rates. The authors also found that combined pre- and postnatal interventions and inclusion of lay support in a multi-component intervention may be beneficial.

A Cochrane review of proactive telephone support by health professionals was found to be beneficial for breastfeeding outcomes (Dennis & Kingston, 2008). The review identified 14 trials involving 8,037 women who received proactive telephone support from health professionals during pregnancy and the early postpartum period. Outcomes of interest were smoking, preterm birth, low birthweight, breastfeeding and postpartum depression. The authors caution, however, that there were a small number of trials included for each outcome category.

A Cochrane review by Fairbank, O'Meara, Renfrew, Woolridge, Snowden, and Lister-Sharp (2000) found that media campaigns, especially television commercials, can improve attitudes toward breastfeeding and can increase initiation rates.

#### META-ANALYSIS/SYSTEMIC REVIEW

The Centers for Disease Control (CDC) prepared a guide (Shealy, Li, Benton-Davis, and Grummer-Strawn, 2005) to breastfeeding interventions that reviewed not only evidence based practices but also promising practices. In addition to the interventions reviewed above, the CDC guide also recommended other interventions such as support for breastfeeding in the workplace and media and social marketing.

#### CONCLUSIONS

Findings from evidence-based reviews (level 1) found that breastfeeding interventions are effective. Evidence-based approaches included health education and peer support interventions; needs-based, informal repeat education sessions than more generic, formal antenatal sessions; and combined pre- and postnatal interventions and inclusion of lay support in a multi-component interventions. Therefore, breastfeeding interventions can be considered as evidence-based practices.

Figure 6 provides a summary of practices identified as effective in the evidence-based review (level 1).

Figure 6: Summary of breastfeeding (BF) practices with evidence of effectiveness

<b>Practice and citation</b>	<b>Outcome domain</b>	<b>Target population</b>	<b>Major Activities</b>
<b>Moms Into Learning about Milk (MILK) Bonuck, 2005</b>	Breastfeeding intensity at 13 and 52 weeks, self report, on a 7-level scale	Low-income, primarily Hispanic and/or black women	Professional one-on-one skills-based, prenatal and postnatal education and support offered routinely.
<b>Breastfeeding education and support Brent, 1996</b>	Increase the incidence and duration of breastfeeding	Low-income, inner-city, English speaking, nulliparous, pregnant women	Lactation consultant prenatal, postpartum education into 1 <sup>st</sup> year of child's life.
<b>Best Start Program Ryser, 2004</b>	Any breastfeeding at 1 week postpartum; Attitudes to breastfeeding; Social and professional support	54 English speaking pregnant women, 18 or older, Medicaid eligible, access to phone and stated feeding intention of 'bottle feed' or 'undecided'	Social marketing approach with counseling, viewing videotapes, reading written material.
<b>Pediatrician counseling Serwint, 1996</b>	Assess impact of prenatal pediatrician visits on breastfeeding decisions of low-income mothers	156 nulliparous women, > 18 years, low-income, urban	Pediatrician training, patient prenatal counseling on feeding options, advantages of breastfeeding, infant car safety, access to healthcare.
<b>Breastfeeding peer counseling Chapman, 2004</b>	Breastfeeding rates at birth and 1, 3, and 6 months postpartum	Pregnant women, low income, considering breastfeeding, have delivered a healthy singleton	Breastfeeding education and peer counseling.
<b>Breastfeeding promotion packs Howard, 2000</b>	Any breastfeeding at delivery; Mean duration of any BF (days); Cessation of breastfeeding during hospital stay; Risks for cessation of breastfeeding at 2 weeks	547 pregnant women (primarily white and privately insured)	At first prenatal visit participants received breastfeeding educational information.

<b>Practice and citation</b>	<b>Outcome domain</b>	<b>Target population</b>	<b>Major Activities</b>
<b>Volunteer breastfeeding counselors Gaffey, 2004</b>	Prevalence of any breast feeding at six weeks	720 women from general population considering breastfeeding	Peer support with counselors that visited the women once before birth and offered postnatal support by phone or by home visits, if requested.

Source: See *References* for study citations.

## ***Infant sleep practices***

No evidence-based reviews (level 1) or meta-analysis/systemic reviews from peer reviewed journals (level 2) of sleep interventions were found. Therefore, the Subject Matter Experts were asked to assist in compiling and assessing evidence (please see Appendix C).

### EVIDENCE-BASED REVIEWS

No reviews of sleep interventions were found in the Cochrane Review, U.S. Preventative Services Task Force, or peer-reviewed journals. Allen, Gray, Oakley, Kurinczuk, Broklehurst, and Hollowell (2009) found a lack of high-quality evidence for modifications of infant sleep position. The authors indicated that a systematic review of evidence relating to interventions to reduce SIDS was limited to interventions which targeted maternal smoking and infant exposure to second-hand smoke. They did not find any systematic reviews that evaluated interventions to modify infant sleeping position or adverse sleeping environments. (Maternal smoking is reviewed separately.) Breastfeeding interventions are also reviewed separately.

### INDIVIDUAL EXPERIMENTAL STUDIES

Although not related to sleep position, Barr et al. (2009) conducted a randomized controlled trial of educational materials regarding crying and shaken-baby syndrome to determine if educational materials changed knowledge and behavior. Just over 1,350 mothers each were assigned to the control and to the treatment group (n=2,700). Mothers were recruited at prenatal clinics, hospital maternity units, and pediatric offices. Educational materials included 11-page booklets, DVDs, and a diary; telephone instructions were provided regarding the diary which allowed infant states and caregiver activities. Mothers received a telephone reminder regarding diary completion. Outcome measures were determined through 60-day follow up phone calls. The treatment group demonstrated greater knowledge regarding infant knowledge and shaking knowledge but similar behavioral responses to the control group.

There have been several studies of hospital-based educational interventions relating to infant sleep position and shaken baby, but no experimental studies. Although conducted in Brazil, there was one randomized trial of an educational intervention in the maternity unit. Issler, Marostica, & Giugliani (2009) conducted a randomized trial with 228 mother-infant pairs. The intervention was an individual orientation session in the maternity unit, with written and oral materials about the importance of the supine position as a preventive measure for SIDS. The authors then assessed sleeping position at 3 months of age assessed during a home visit. Among mothers in the intervention group, 42.9 percent put their infants to sleep in a supine position at the 3-month visit, compared with 24 percent of mothers in the control group (p = 0.009). In a multivariate analysis, the intervention at the hospital was the only variable that influenced maternal practices with respect to infant sleep positioning (OR 2.22; 95% CI 1.17-4.19).

## CONCLUSIONS

Sudden Infant Death Syndrome-related interventions that shown to be effective were limited to those which targeted maternal smoking. Therefore, there are no additional evidence-based practices meeting the standard identified for this review. This does not mean that there is no evidence of effectiveness but that this practice does not meet the standards used for this report and described on page 5.

## ***Summary of evidence on infant health interventions***

Figure 7 provides a summary of the preceding pages. The first column lists the interventions relevant to infant health while the second column lists the conclusion drawn based on the available evidence and the evidence standard set. When a practice is not identified as evidence-based, it does not mean that there is no evidence of effectiveness but that the practice does not meet the standards used for this report and described on page 5. The final column documents the levels of evidence available for that intervention using the definitions on page 5 and provided in the table note for ease of reference.

Figure 7: Summary of infant health interventions

Intervention category	Conclusion based on the evidence standard set and evidence obtained at the time of this report	Available levels of evidence		
		1	2	3
<b>Breastfeeding</b>	There are evidence-based practices in breastfeeding.	X	X	
<b>Programs delivered through Home Visiting*</b>	There are evidence-based practices in home visiting.	X	X	
<b>Infant sleep practices</b>	No available evidence.			
<b>Maternal depression*</b>	There are evidence-based practices in maternal depression.	X	X	
<b>Outreach and screening</b>	No available evidence.			
<b>Smoking cessation*</b>	There are evidence-based practices in smoking cessation.	X		

Note: Evidence-based reviews of randomized controlled trials and an assessment of study quality such as Cochrane Reviews, US Preventive Services Task Force, or the Agency for Healthcare Research and Quality (level 1); Meta-analysis or systemic reviews of experimental studies in peer-reviewed journals (level 2); Centers for Disease Control and Prevention recommendations based on national data and/or systemic reviews (level 3).

\*Please see the sections on maternal and preconception/interconception health for a description of these interventions.

# Section III: Preconception and Interconception Health

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## **Pre and Interconception Risk and Protective Factors**

### ***Adolescent pregnancy***

There were no evidence-based reviews (level 1) of the impact of adolescent pregnancy on the outcomes of interests. The link between adolescent pregnancy and poor birth outcomes, however, was documented in a review of national data, which is the highest level of available evidence (experimental studies are not possible with this and several of the other risk factors). Menacker, Martin, MacDorman, and Ventura (2004), in national vital statistics report reviewed the number and rate of U.S. births for 10-14 year olds for 1990-2002 by race, Hispanic origin, and by State. The authors found that teen mothers were least likely to receive timely prenatal care compared with mothers of older age groups. Compared with infants of mothers aged 20-39 years, infants of the youngest mothers experienced almost twice the rates of preterm delivery (21.3%) and low birthweight (12.6%). The infant mortality rate for adolescent mothers (15.4 per 1,000) was two to three times higher than that for infants of mothers aged 20-44 years. The 2007 linked data set (Mathews and MacDorman, 2011) confirmed that infant mortality was impacted by the age of the mother, with teenage mothers having a rate of 9.80 per 1,000; birth to the youngest mothers (under age 15) had the highest mortality rate, at 14.53 per 1,000. Therefore, adolescent pregnancy can be considered to impact the outcomes of interest.

### ***Alcohol, tobacco, and other drugs***

Evidence regarding the impact of alcohol, tobacco, and other drugs on birth outcomes was available from the U.S. Preventive Services Task Force (level 1), and recommendations based on systemic reviews (level 2). The U.S. Preventive Services Task Force (2009) found that tobacco cessation at any point throughout pregnancy yields substantial health benefits for the expectant mother and baby (level 1). A Centers for Disease Control (Johnson et al., 2006) report identified conditions for which scientific evidence of impact on birth outcomes exists including alcohol, tobacco and other drug use (level 2). The 2006 Centers for Disease Control recommendations to improve preconception health and health care were developed by reviewing published research, a workgroup of 22 programs, evaluating best and emerging practices, and convening a workgroup of subject matter experts (level 2), although not all factors had a systematic review. Published research was not limited to experimental studies but was reviewed by the subject matter experts. Per the authors (Johnson et al., 2006), the recommendations reflect “the research, professional opinion, practice in medicine, public health and related fields, which are sufficient to guide changes in program, practice, and policy” (p. 3). The subject matter experts reviewed evidence on the effectiveness of interventions such as folic acid use; STDs; and cessation of alcohol, tobacco and other drugs. In 2006, the U.S. Surgeon General released a report on the impact of secondhand smoke. The report found that evidence was inadequate to infer a causal relationship on neonatal mortality and on child development and that evidence was suggestive but not sufficient to infer a causal relationship

between maternal exposure to secondhand smoke during pregnancy and preterm delivery. The report did find, however, that evidence was sufficient to infer a causal relationship between exposure to secondhand smoke and sudden infant death syndrome (U.S. Department of Health and Human Services, 2006). Two additional meta-analyses (Hackshaw, Rodeck, & Boniface, 2011; Leonardi-Bee, Britton, & Venn, 2011) found evidence linking secondhand smoke exposure of pregnant women to be associated with stillbirth and birth defects though not with perinatal or neonatal death. Therefore, alcohol, tobacco, and other drugs can be considered to impact the outcomes of interest.

### ***Intervals between pregnancy***

There were no evidence-based reviews (level 1) available regarding the impact of intervals between pregnancy and the outcomes of interest. The Centers for Disease Control and Prevention (Johnson, 2006) did not identify intervals as a condition for which evidence of impact on outcomes of interest exist. The Institute of Medicine (2011) released guidelines on clinical preventive services for women (level 2). To generate conclusions, the committee reviewed existing U.S. Preventive Services Task Force recommendations, Bright Futures recommendations (from the American Academy of Pediatrics) and the Advisory Committee on Immunization Practices; reviewed available evidence using categories similar to those identified in this report; and heard from experts, researchers, and stakeholders. The Institute of Medicine documented the impact of closely spaced intervals between pregnancies. Given the available evidence, the Institute of Medicine recommends prevention of unintended pregnancies, including those resulting in short intervals. Hogue, Menon, Dunlop, and Kramer (in press) updated Conde-Agudelo et al.'s review regarding the impact of short intervals between pregnancies. Although studies had methodological limitations and were not limited to randomized controlled trials, the authors concluded that increased risk for preterm birth associated with an inter-pregnancy interval of less than six months is at least 40 percent; this is consistent with prior reviews. There is not enough evidence at this time to document the impact of intervals between pregnancies on the outcomes of interest.

### ***Intimate partner violence***

There were no evidence-based reviews (level 1) of the impact of domestic violence on outcomes of interest. Jasinski (2004) conducted a literature review of research on U.S. populations. The review found evidence that intimate partner violence delayed prenatal care and resulted in low birth weight, premature labor, fetal trauma, and health issues for the mother. The author did not specify inclusion criteria. There is not enough evidence to document the impact of domestic violence on the outcomes of interest.

## ***Nutrition***

Evidence on the impact of nutritional supplements on outcomes of interest was available from evidence-based reviews (level 1). In a Cochrane Review, De-Regil et al. (2010) found five trials involving 6,105 women (1,949 with a history of a pregnancy affected by a neural tube disorder and 4,156 with no history of neural tube disorders). Overall, the results are consistent in showing a protective effect of daily folic acid supplementation alone or in combination with other vitamins and minerals in preventing neural tube disorders compared with no interventions/placebo or vitamins and minerals without folic acid (risk ratio 0.28, 95% confidence interval 0.15 to 0.52).

In another Cochrane Review, Mahomed, Bhutta, and Middleton (2007) included 17 randomized controlled trials involving over 9,000 women and their babies in their review of zinc supplemental effects (level 1). Zinc supplementation resulted in a small but significant reduction in preterm birth (relative risk 0.86, 95% confidence interval 0.76 to 0.98 in 13 randomized controlled trials of 6,854 women).

In a systemic review for the Agency for Healthcare Research and Quality not limited to randomized controlled studies, Viswanathan et al. (2008) found weak of moderate evidence regarding weight gain outside of Institute of Medicine recommendations for preterm birth, low birthweight, and infant mortality.

Findings from the evidence-based reviews (level 1) and two Centers for Disease Control Publications (D'Angelo & Colley, 2022; Johnson et al., 2006) (level 2 and level 2 respectively) suggest that folic acid impacts outcomes of interest.

## ***Preconception and interconception care***

There were no evidence-based reviews (level 1) on preconception or interconception care. In 2006, however, the Centers for Disease Control and Prevention developed recommendations to improve preconception health and preconception health care using a review of published research and expert opinion based on the impact of preconception care on pregnancy outcomes such as low birthweight, premature birth, and infant mortality (level 2).

Recommendations regarding preconception and interconception care therefore, are not based on a review of randomized controlled trials but do reflect available evidence, research, and expert opinion (Johnson, 2006). Those recommendations are (Johnson, 2006):

- Recommendation 1. Individual Responsibility Across the Lifespan. Each woman, man, and couple should be encouraged to have a reproductive life plan.
- Recommendation 2. Consumer Awareness. Increase public awareness of the importance of preconception health behaviors and preconception care services by using information

and tools appropriate across various ages; literacy, including health literacy; and cultural/linguistic contexts.

- Recommendation 3. Preventive Visits. As a part of primary care visits, provide risk assessment and educational and health promotion counseling to all women of childbearing age to reduce reproductive risks and improve pregnancy outcomes.
- Recommendation 4. Interventions for Identified Risks. Increase the proportion of women who receive interventions as follow-up to preconception risk screening, focusing on high priority interventions (i.e., those with evidence of effectiveness and greatest potential impact).
- Recommendation 5. Interconception Care. Use the interconception period to provide additional intensive interventions to women who have had a previous pregnancy that ended in an adverse outcome (i.e., infant death, fetal loss, birth defects, low birthweight, or preterm birth).
- Recommendation 6. Prepregnancy Checkup. Offer, as a component of maternity care, one prepregnancy visit for couples and persons planning pregnancy.
- Recommendation 7. Health Insurance Coverage for Women with Low Incomes. Increase public and private health insurance coverage for women with low incomes to improve access to preventive women's health and preconception and interconception care.
- Recommendation 8. Public Health Programs and Strategies. Integrate components of preconception health into existing local public health and related programs, including emphasis on interconception interventions for women with previous adverse outcomes.
- Recommendation 9. Research. Increase the evidence base and promote the use of the evidence to improve preconception health.
- Recommendation 10. Monitoring Improvements. Maximize public health surveillance and related research mechanisms to monitor preconception health.

There is not enough evidence at this time, however, to document the impact of preconception and interconception care on the outcomes of interest.

### ***Sexually transmitted diseases (STD)***

There are no evidence-based reviews (level 1) of the impact on sexually transmitted diseases on the outcomes of interest. Workowski and Berman (2010) authored guidelines for the Centers for Disease Control and Prevention. The guidelines were developed using expert opinion, a

systemic review of studies with an assessment of study quality, and review by a workgroup to process the results (level 2). The authors report that intrauterine or perinatally transmitted STDs have negative impacts on pregnant women and their fetuses and recommend that all pregnant women and their partners should be asked about STDs, counseled, and offered treatment, if applicable. The Centers for Disease Control (Johnson et al., 2006) select panel on preconception, however, identified conditions for which scientific evidence of impact on birth outcomes exists, including sexually transmitted disease (level 2). Therefore, sexually transmitted diseases can be considered to impact the outcomes of interest.

### ***Stress and perinatal depression***

There was an evidence-based review (level 1) and two systemic reviews (level 3) of perinatal depression. An Agency for Healthcare Research Quality evidence review (Gaynes et al., 2005) examined depression prevalence, screening accuracy, and the impact of interventions; depression can have negative consequences for the women and for their children. For prevalence and screening, inclusion criteria mandated diagnostic confirmation by a reference standard; there were 30 studies of prevalence and 10 of screening accuracy. The authors' combined estimates for depression were lower than other reviews due to excluding self-report and excluding minor depression. Final combined estimates were 14.5 percent of pregnant women and 14.5 percent of postpartum women having a new episode of major or minor depression. Study populations, however, were almost uniformly white.

Ammerman, Putnam, Bosse, Teeters, and Van Ginkel (2010) reviewed the prevalence of elevated levels of depressive symptoms in the home visiting population, which typically is lower socio-economic status and found prevalence levels of 25.9 to 28.5 percent, and as high as 61 percent; differences in screening and cut offs make comparisons difficult. These estimates were for depressive symptoms and not for diagnostic criteria of major depressive disorder. Risk factors for antenatal depression include low-income, lack of social support, stress or negative life events, and poor relationships (Ammerman, Putnam, Bosse, Teeters, and Van Ginkel, 2010; Dennis, Ross, and Grigoriadis, 2007).

Grote et al. (2010) conducted a meta-analysis of studies examining the impact of depressive symptoms during pregnancy and preterm birth, low birth weight, and intrauterine growth restriction. The authors identified 29 studies that met their inclusion criteria. The authors found that depression during pregnancy was associated with modest but statistically significant risks of preterm birth and low birthweight. Moderating factors included country location and U.S. socioeconomic status; the type of depression measurement moderated the strength of the finding. Categorical measures produced stronger effects.

### ***Unintended pregnancy***

There were no evidence-based reviews of unintended pregnancy (level 1). The Institute of Medicine (2011) released guidelines on clinical preventive services for women (level 2). To generate conclusions, the committee reviewed existing U.S. Preventive Services Task Force recommendations, Bright Futures recommendations (from the American Academy of Pediatrics) and the Advisory Committee on Immunization Practices; reviewed available evidence using categories similar to those identified in this report; and heard from experts, researchers, and stakeholders. The Institute of Medicine concluded that consequences of unintended pregnancy have been documented but research is limited for some outcomes. Given the available evidence, the Institute of Medicine recommends prevention of unintended pregnancies. Although approximately half of all pregnancies in the United States each year are unintended (Finer & Henshaw, 2006) there is not enough evidence at this time to document the impact of unintended pregnancy on the outcomes of interest.

## ***Summary of evidence on pre and interconception risk and protective factors***

Figure 8 provides a summary of the preceding pages. The first column lists the risk and protective factors relevant to preconception and interconception health while the second column lists the conclusion drawn based on the available evidence and the evidence standard set. The final column documents the levels of evidence available for that risk or protective factor using the definitions on page 4 and provided in the table note for ease of reference.

Figure 8: Summary of preconception and interconception risk and protective factors

Risk and protective factor	Conclusion based on the evidence standard set and evidence obtained at the time of this report	Available levels of evidence		
		1	2	3
<b>Adolescent pregnancy</b>	Adolescent pregnancy impacts the outcomes of interest.			
<b>Alcohol, tobacco, and other drugs</b>	Use of alcohol, tobacco, and other drugs impact the outcomes of interest.	X	X	
<b>Intervals between pregnancy</b>	There is not enough evidence to draw a conclusion.		X	
<b>Intimate partner violence</b>	There is not enough evidence to draw a conclusion.			
<b>Nutrition</b>	Folic acid impacts the outcomes of interest.	X	X	
<b>Preconception and interconception care</b>	There is not enough evidence to draw a conclusion.		X	
<b>Sexually transmitted diseases</b>	Sexually transmitted diseases impact the outcomes of interest.		X	
<b>Stress and perinatal depression</b>	Stress and perinatal depression impact the outcomes of interest	X		X
<b>Unintended pregnancy</b>	There is not enough evidence to draw a conclusion.		X	

Note: Evidence-based reviews limited to experimental studies with standards for assessing quality (level 1); Centers for Disease Control and Prevention or USPTF recommendations based on systemic reviews (level 2); Meta-analysis/systemic reviews published in peer-reviewed journals (level 3).

## Preconception and Interconception Health Interventions

### *Programs delivered through home visits*

Available evidence on the effectiveness of home visitation was available from three types of sources: evidence-based review (level 1) and meta-analysis or systemic review in peer-reviewed journal (level 2).

#### EVIDENCE-BASED REVIEWS

The U.S. Department of Health and Human Services commissioned an evidence review of home visiting services (Paulsell, Avellar, Martin, and Del Grosso, 2010) that conducted a broad literature search resulting in 8,200 citations. The authors then screened for programs where home visiting was the primary service delivery strategy, used an eligible research design, targeted pregnant women and children up to 5, targeted outcomes in eight eligible domains, and included a named home visiting model. The team then identified 250 programs for review by assigning points for study design (randomized controlled and quasi-experimental) and sample size. Eleven models were prioritized for review; studies were assigned ratings of high, moderate, or low based on study design and attrition. To meet the criteria of evidence-based, the model had to have at least one high or moderate-quality study documenting statistically significant impacts in two or more of the eight outcome domains or at least two high or moderate impact studies of non-overlapping samples that found one or more statistically significant impact in the same domain. Of the 11 prioritized models, seven received an evidence rating of high or moderate. Evidence ratings were dependent on research design, sample size, quality of outcome measures, duration of impact, replication of impacts, subgroup findings, unfavorable or ambiguous impacts, evaluator independence, and magnitude of impacts. All seven had favorable impacts; of those seven, four also had unfavorable or ambiguous impacts. Since the initial publication, an eighth program was identified as evidence-based using the process described.

The U.S Preventive Services Task Force (Bilukha et al., 2005) found that early childhood home visitation programs are effective in preventing child abuse and neglect; programs do this by addressing both parents and children. Programs seeks to positively impact parents' knowledge, skills, self-confidence, access to resources, and parenting ability and child development, skills, health, and well-being.

#### META-ANALYSIS/SYSTEMIC REVIEW

The Council on Community Pediatrics (2009) summarized the impact of home visiting studies including a review by U.S Preventative Services Task Force noted above, the British Task Force, and the Canadian Task Force on Preventive Care. The Council found that these reviews – along

with other studies - supported the impact of home visiting on parent skills and the home environment, child behavioral problems, cognitive development, maternal life course, unintentional injury, detection and management of depression, attachment, social supports, and breastfeeding. Findings on depression management are not consistent with other findings; those finding resulted from the British Task Force and cultural differences may be a mitigating factor. The Council noted that while home visiting benefits high-risk families, domestic violence in the home or family mental illness means that families are less likely to respond to home visiting support.

### INDIVIDUAL EXPERIMENTAL STUDIES

Although not considered in the assessment of the evidence base, additional individual experimental studies are provided on evidence-based practices as a resource for the next phase of the Redesign process.

Perhaps the best known home visiting model is the Nurse Family Partnership, due in part to the extensive research that has occurred. In five studies Kitzman et al., 1997; Kitzman et al. 2000; Olds et al., 2002; Olds et al., 2004; and Olds et al., 2007, Nurse Family Partnership has been shown to have the following impacts:

- Kitzman et al. (1997) in a randomized control trial of the program in Tennessee found less pregnancy-induced hypertension and in the following two years fewer health care encounters for children due to injuries or ingestion and fewer second pregnancies.
- Kitzman et al. (2000) conducted follow-up on a prior randomized control study of the Nurse Family Partnership and found that women had fewer subsequent pregnancies, fewer closely spaced pregnancies, longer intervals between the births of the first and the second child, and less use of AFDC and food stamps. These effects were similar with those seen during program operation.
- Olds et al. (2002) used a randomized control design to assess the effectiveness of home visiting by paraprofessionals versus nurses using the Nurse Family Partnership model. The authors found that paraprofessionals positively impacted parent-child responsive interaction and that nurses positively impacted smoking cessation, inter-pregnancy intervals, hours worked, parent-child responsive interaction, and healthy child development outcomes.
- Olds et al. (2004) at the age six follow-up of the Elmira program, found fewer subsequent pregnancies and births among the intervention population; longer intervals between births; and less use of welfare and food stamps. In addition, children served by the program had higher receptive vocabulary scores and fewer behavioral problems.

- Olds et al. (2007) at the age nine follow-up of the Elmira program, found participants had longer intervals between births than the control group; fewer cumulative subsequent births per year; decreased use of welfare and food stamps; and those children had better academic achievement.

Lee, Mitchell-Herzfeld, Lowenfels, Green, Dorabawila, and DuMont (2009) found evidence of effectiveness of the Healthy Families program in New York using a randomized control design. The program was found to reduce the risk of delivering low birth weight babies, with further risk reduction when the program began before 24 weeks. The program as delivered provided social support, health education, and access to service. Healthy Families focuses on improving mothers' social support, providing prenatal education, and linking the mother to services in the community. The authors found that Healthy Families clients were less likely to have a low birthweight baby, with earlier enrollment creating a larger reduction. The authors also found that clients increased association with a primary care provider. The authors did not present conclusions on access to services as there was no control, but mothers did access more services. The authors also did not conclude on reducing mother's stress or increasing social support due to lack of control data.

## CONCLUSION

Findings from the evidence-based review (level 1) conducted by the Department of Health and Human Services document that eight home visiting programs are effective in achieving outcomes with specific programs achieving outcomes for specific populations, as shown in Figure 9; another 10 programs did not receive evidence ratings of high or moderate. In a Cochrane Review (level 2), Doggett, Burrett, and Osborn (2005) reviewed home visiting programs for outcomes related to women with alcohol and drug programs, however, and the review found evidence that home visits after birth increased the engagement of these women in drug treatment services but there were insufficient data to say if this improved the health of the baby or mother. Therefore, the eight programs listed below can be considered as evidence-based practices.

Figure 9: Summary of evidence-based Home Visiting program models from evidence-based reviews (level 1)

<b>Model/Practice Researched</b>	<b>Outcome domain(s) with documented favorable impact not limited to sub-groups</b>	<b>Target population</b>	<b>Major Activities</b>
<b>Nurse Family Partnership*</b>	child health; maternal health; child development and school readiness; reductions in child maltreatment; positive parenting practices; family economic self-sufficiency.	First time, low income mothers. Appropriate for teens and minorities.	One on one home visits from pregnancy through 2 years.
<b>Parents as Teachers*</b>	child development and school readiness; positive parenting practices.	Low income mothers; appropriate for teens.	One on one home visits; groups meetings; developmental screening; resource network.
<b>HIPPY</b>	child development and school readiness; positive parenting practices.	Parents of children ages 3 - 5; racially and ethnically diverse.	Home visits and group meetings; referrals and information.
<b>Healthy Families USA*</b>	child health; child development and school readiness; positive parenting practices.	Parents facing challenges. Individual programs select characteristics.	Screenings, assessments, home visitation prior to birth till child enters kindergarten.
<b>Healthy Steps</b>	child health	Parents of children birth through three.	Home visits, well child visits, screening, info line, referrals, books, and educational materials.
<b>Family Check Up</b>	child development and school readiness; positive parenting practices.	Parents of children age 2 to 17.	Home visits; referrals, assessments, groups, school interventions.
<b>Early Head Start*</b>	child development and school readiness; positive parenting.	Low-income pregnant women and families birth to three.	Home visits, group activities, child care, screenings.

<b>Model/Practice Researched</b>	<b>Outcome domain(s) with documented favorable impact not limited to sub-groups</b>	<b>Target population</b>	<b>Major Activities</b>
<b>Public Health Nursing Early Intervention Program*</b>	child health; family economic self-sufficiency.	Latina and African American adolescents pregnant with their first child.	Home visits from mid-pregnancy through the child's first year of life and educational courses.

Source: U.S. Department of Health and Human Services, 2010

\*Also had at least one unfavorable or ambiguous impact

## ***Maternal depression***

Available evidence on the effectiveness of maternal depression was available from two sources: three evidence-based reviews (level 1) and three meta-analysis or systemic review in peer-reviewed journal (level 2).

### **EVIDENCE-BASED REVIEW**

An Agency for Healthcare Research Quality evidence review (Gaynes et al., 2005) examined prevalence, screening accuracy, and intervention impact. For prevalence and screening, inclusion criteria mandated diagnostic confirmation by a reference standard; there were 30 studies of prevalence and 10 of screening accuracy. For intervention impact, studies had to use a randomized control group or prospective cohort study; there were 15 studies meeting the criteria. In addition, the authors assessed study quality on reporting completeness, external and internal validity, and power of precision. Strength of evidence was rated on the number of studies, the aggregate sample sizes, the quality of individual studies, and the representativeness of the study populations. The authors found that psychosocial interventions during pregnancy did not demonstrate positive outcomes; six of nine post partum interventions did produce significant improvement for the experimental group. Study populations reflected a limited ethnic and racial mix (Gaynes et al., 2005).

Dennis, Rosee and Grigoriadis (2007) found only one trial meeting Cochrane Review standards that evaluated interpersonal psychotherapy for treating antenatal depression.

A Cochrane review of proactive telephone support by health professionals was found to be beneficial for decreasing postpartum depressive symptoms (Dennis & Kingston, 2008). The review identified 14 trials involving 8,037 women who received proactive telephone support from health professionals during pregnancy and the early postpartum period. Outcomes of interest were smoking, preterm birth, low birthweight, breastfeeding and postpartum depression. The authors caution, however, that there were a small number of trials included for each outcome category.

### **META-ANALYSIS/SYSTEMIC REVIEW**

Shaw, Levitt, Wong, and Kaczorowski (2006) conducted a systematic review on postpartum care; studies were randomized controlled trials that were assessed using the Jadad scale to assess quality. A total of 22 studies were included; fourteen scored three out of a possible five with one point typically missing for blinding. The authors concluded that there were promising results for low-income women and those at high risk; outcomes included improvements in parenting knowledge, confidence, or infant-child interactions. These results were from intervention with nurses, case conferencing, or pediatric visits. Less intensive peer support also improved mental health outcomes.

Leis, Medleson, Tandon, and Perry (2009) also conducted a review of randomized controlled trials assessing home-based psychological interventions to prevent and treat postpartum depression. The authors found that home-based approaches – including cognitive behavioral, psychodynamic, and non-directive counseling – had evidence of effectiveness on reducing levels of maternal depression. Roman et al. (2007; Roman et al., 2009) reported that adding a nurse-home visiting team as part of Medicaid enhanced prenatal/postnatal services resulted in fewer depressive symptoms among the intervention cohort. Effects were strongest for women with low psychosocial resources, high stress, or both.

In contrast, Ammerman, Putbam, Bosse, Teeters and Van Ginkel (2010) found that home visitation has little impact on maternal depression and notes that research suggests that home visiting programs identify maternal depression as a challenge. Ammerman et al. do identify promising practices, including programs using In-home Cognitive Behavioral Therapy (CBT) where CBT is evidence-based and can be modified for setting, population, and context.

## CONCLUSION

Findings from the evidence-based reviews (level 1) and systemic reviews (level 2) suggest that psychosocial interventions during pregnancy did not demonstrate positive outcomes although post-partum interventions did. Therefore, post partum interventions can be considered as evidence-based practices. These would include interventions with nurses, case conferencing, or pediatric visits; cognitive behavioral therapy; and peer support. Data on home-based approaches is mixed.

Figure 10: Summary of maternal depression practices with evidence of effectiveness from the evidence-based review (level 1)

<b>Practice and citation</b>	<b>Outcome domain</b>	<b>Target Population</b>	<b>Major Activities</b>
<b>Telephone peer support Dennis, 2003</b>	Lower EPDS scores	Postpartum women	Mother to mother telephone based peer support.
<b>Individual counseling Hiscock &amp; Wake, 2002</b>	Improvement in EPDS scores and reported sleep quality improvements at four months.	Postpartum women	Three private sessions covering sleep management and controlled crying.
<b>Group Zlotnik, Johnson, Miller, Pearlstein, &amp; Howard, 2001</b>	Lower depression scores (BDI); lower postpartum depression	Pregnant women, low SES	Four prenatal therapy/skills group sessions.
<b>Group Honey, Bennett, &amp; Morgan, 2002</b>	Reduction in depressive symptoms (EPDS)	Postpartum women	Psycho-educational group sessions.

Source: Gaynes et al. (2005); Hiscock & Wake, 2002; Honey, Bennett, & Morgan, 2002; Zlotnik, Johnson, Miller, Pearlstein, & Howard, 2001.

## ***Parent education***

Available evidence on the effectiveness of parent education was available from two evidence-based reviews (level 1); there were also two meta-analysis/systemic (level 2) reviews for fathering programs specifically.

### **EVIDENCE-BASED REVIEWS**

Bryanton and Beck (2010), in a Cochrane Review, assessed the effects of structured postnatal education delivered by an educator to an individual or group on infant general health and parent-infant relationships. The review included randomized controlled trials of any structured postnatal education provided by an educator to individual parents or groups of parents within the first two months postbirth related to the care of an infant or the parent-infant relationship. The authors found that “the benefits of educational programs to participants and their newborns remain unclear. Education on sleep enhancement appears to increase infant sleep and education about infant behavior potentially enhances mothers' knowledge; however more and larger, well-designed studies are needed to confirm this.”

Gagnon and Sandall (2007) examined the benefits of antenatal education for childbirth, and the best educational approaches to use. Antenatal education aims to help prospective parents prepare for childbirth and parenthood. Prospective parents often look to antenatal education to provide important information on issues such as decision making about and during labor, skills for labor, pain relief, infant and postnatal care, breastfeeding and parenting skills. There are many varied ways of providing this antenatal education and some may be more effective than others. The review found nine trials involving 2,284 women. Interventions varied greatly and no consistent outcomes were measured. The review of trials found a lack of high-quality evidence from trials and so the effects of antenatal education remain largely unknown. Further research is required to ensure that effective ways of helping health professionals support pregnant women and their partners in preparing for birth and parenting are investigated so that the resources used meet the needs of parents and their newborn infants.

### **META-ANALYSIS/SYSTEMIC REVIEWS**

Bronte-Tinkew, Burkhauser, and Metz (2008) conducted a review of fathering programs and classified eight programs as model programs. Bronte-Tinkew, Carrano, Allen, Bowie, Mbawa, and Matthews (2007) conducted a similar review of teen fatherhood programs; that review identified one model program. Model programs were evaluated using randomized control trials, at least one outcome was positively changed by 10 percent and was significantly significant at .05 level had sample sizes exceeding 30, retained at least 60 percent of the original sample, was evaluated externally, and evaluation results were publicly available.

## CONCLUSION

Most research on interventions for parent education, when found to be effective, overlap with home visitation. If examined separately from home visitation, the available Cochrane reviews found the results to be unclear. For fathering programs specifically, however, there is evidence from two systemic reviews (level 2) that fathering programs are effective. Bronte-Tinkew, Burkhauser, and Metz (2008) note the limitations of the studies and that programs were not replicated. Therefore, there are no evidence-based practices outside of the home visiting framework. When a practice is not identified as evidence-based, it does not mean that there is no evidence of effectiveness but that the practice does not meet the standards used for this report and described on page 5.

## ***Preconception/Interconception***

Evidence-based reviews of interventions targeting interconception were presented in the sections on home visiting. There is one evidence-based reviews (level 1) and one recommendation based on a systemic review (level 3) for additional interventions related to preconception or interconception care.

Lopez, Tolley, Grimes, and Chen-Mok (2011) conducted a Cochrane Review of theory-based interventions for contraception. The area of interest was those trials testing a theory-based program with outcomes of pregnancy, choice of birth control, and birth control use. The authors found 14 trials that met the inclusion criteria; social cognitive theory was the theoretical basis for five of the 14 trials, of which three showed positive results. The authors found insufficient research but suggested that practitioners could adapt the effective interventions.

The Institute of Medicine (2011) released guidelines on clinical preventive services for women (level 3). To generate conclusions, the committee reviewed existing U.S. Preventive Services Task Force recommendations, Bright Futures recommendations (from the American Academy of Pediatrics) and the Advisory Committee on Immunization Practices; reviewed available evidence using categories similar to those identified in this report; and heard from experts, researchers, and stakeholders. Two findings regarding effective interventions are relevant to preconception and interconception care. First, the Institute of Medicine identified that counseling for sexually transmitted infections is effective in reducing prevalence. Second, the Institute of Medicine identified that contraception and contraceptive counseling is effective in reducing unintended pregnancies.

## **CONCLUSION**

There was one evidence-based reviews (level 1) and one recommendation (level 3) . Although the Centers for Disease Control (Johnson, 2006) recommends preconception and interconception care, there are no evidence-based practices to adopt or adapt. Lu (2007) supports recommendations for preconception care; but grades the recommendations for clinical practice as a "C" rating, meaning that while the recommendation is considered best practice, no evidence base exists. This does not mean that there is no evidence of effectiveness but that the practice does not meet the standards used for this report and described on page 5.

## ***Summary of evidence on preconception and interconception interventions***

Figure 11 provides a summary of the preceding pages. The first column lists the interventions relevant to preconception and interconception health while the second column lists the conclusion drawn based on the available evidence and the evidence standard set. When a practice is not identified as evidence-based, it does not mean that there is no evidence of effectiveness but that the practice does not meet the standards used for this report and described on page 5. The final column documents the levels of evidence available for that intervention using the definitions on page 5 for ease of reference.

Figure 11: Summary of preconception and interconception health interventions

Intervention category	Conclusion based on the evidence standard set and evidence obtained at the time of this report	Available levels of evidence		
		1	2	3
<b>Alcohol and substance abuse*</b>	There are no evidence-based practices in alcohol and substance abuse but there are practices where at least two studies documented evidence of effectiveness.	X		
<b>Programs delivered through Home Visiting</b>	There are evidence-based practices in home visiting.	X	X	
<b>Intimate partner violence*</b>	Available evidence finds no evidence-based practices for intimate partner violence.	X	X	
<b>Maternal depression</b>	There are evidence-based practices in maternal depression.	X	X	
<b>Nutritional*</b>	There are evidence-based practices in nutrition.	X	X	
<b>Parent education</b>	Available evidence finds no evidence-based practices outside of home visiting for parent education.	X	X	
<b>Outreach and screening*</b>	No available evidence.			
<b>Preconception and interconception care</b>	Available evidence is insufficient to draw a conclusion outside of home visiting for interconception care.	X	X	X
<b>Smoking cessation*</b>	There are evidence-based practices in smoking cessation.	X		
<b>Teen pregnancy prevention*</b>	There are evidence-based practices in teen pregnancy prevention.	X		

Note: Evidence-based reviews of randomized controlled trials and an assessment of study quality such as Cochrane Reviews, US Preventive Services Task Force, or the Agency for Healthcare Research and Quality (level 1); Meta-analysis or systemic reviews of experimental studies in peer-reviewed journals (level 2); Centers for Disease Control and Prevention recommendations based on national data and/or systemic reviews (level 3).

\*Please see the sections on maternal and health for a description of these interventions.

## Risk and Protective Factors Addressed by Identified Evidence-based Practices

The table below combines the summary of risk factors with the summary of intervention categories to provide an “at a glance” reference of risk and protective factors identified as impacting the outcomes of interest and interventions for which evidence-based practices exist. Each risk factor is included in a row while each evidence-based practice category is in a column. When a practice is not identified as evidence-based, it does not mean that there is no evidence of effectiveness but that the practice does not meet the standards used for this report and described on page 5. Where an evidence-based practice is effective for that risk factor, the level of evidence – and any comments – are noted. For example, both home visiting and smoking cessation interventions have documented evidence in smoking cessation. For some risk factors, however, there are not evidence-based practices listed.

	Outcomes impacted	Programs using Home Visits	Maternal Depression	Smoking Cessation	Breast-feeding	Teen Pregnancy Prevention	Folic Acid	Support and Augmented Care	Alcohol and Substance Abuse
<b>Alcohol and other drugs</b>	Infant mortality								Individual experimental studies document impact of interventions
<b>Adolescent Pregnancy</b>	Infant mortality Preterm birth, low birthweight					Level 1 evidence documents impact of interventions			
<b>Breast-feeding</b>	Infant mortality				Level 1 evidence documents impact of interventions			Level 2 evidence documents impact of interventions	
<b>Folic acid</b>	Birth defects						Level 1 evidence documents impact of interventions		

	<b>Outcomes impacted</b>	<b>Programs using Home Visits</b>	<b>Maternal Depression</b>	<b>Smoking Cessation</b>	<b>Breast-feeding</b>	<b>Teen Pregnancy Prevention</b>	<b>Folic Acid</b>	<b>Support and Augmented Care</b>	<b>Alcohol and Substance Abuse</b>
<b>SIDS/ISP</b>	Infant mortality			Smoking is a risk factor for SIDS (level 2 evidence)	Breastfeeding is a protective factor for SIDS (level 2 evidence)				
<b>Stress and depression</b>	Preterm birth, low birth-weight		Level 1 evidence documents impact of post-partum interventions on risk factor				Level 2 evidence documents impact of interventions on risk factor		
<b>Tobacco</b>	Infant mortality	Some studies document impact of Home Visiting on smoking cessation		Level 1 evidence documents impact of interventions on risk factor			Level 2 evidence documents impact of interventions on risk factor		

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## Appendix A: Methodology

The Guide to Community Preventive Services (Task Force on Community Preventive Services, 2005; The Community Guide, n.d.) has developed 1) a process for a systematic review and 2) a process for using evidence-based resources for program design, implementation and evaluation. These integrated processes will serve as the resource for the Healthy Start redesign process; the processes are aligned with those proposed by the U.S. Department of Health and Human Services (2009) to identify and select evidence-based interventions and with the tasks referenced in the Request for Proposal for the redesign process.

The steps to collect and evaluate evidence and translate it into recommendations are: (1) develop the conceptual model to organize, group, and select interventions to be reviewed; (2) select interventions to be reviewed; (3) search for and retrieve evidence; (4) assess the quality of and summarize the body of evidence of effectiveness; (5) translate evidence of effectiveness into recommendations; (6) consider evidence other than effectiveness; and (7) identify and summarize research gaps. (Steps 5 through 7 will occur under the next phase of the Healthy Start Redesign process).

The first step in this process was to develop the conceptual framework to identify interventions and an analytic framework for each intervention type (Briss et al., 2000; Donaldson, 2007; U.S. Department of Health and Human Services, 2009). The conceptual framework identified interventions that impact the desired outcomes while the analytic framework mapped each intervention to its health and other effects. In order to develop the conceptual framework, we collected prior research on the outcomes of interest, reviewed program documents, and engaged relevant stakeholders. For example, the Centers for Disease Control/ATSDR Preconception Work Group and the Select Panel on Preconception Care (Johnson et al., 2006) developed recommendations to improve preconception health and care in an effort to improve pregnancy-related health outcomes as risk factors for adverse outcomes for women and infants occur during the preconception period. In order to do so, the Preconception Work Group reviewed published research, convened a work group, evaluated best and emerging practice models, and convened a panel to make the final recommendations. Their findings and recommendations are reflected in the conceptual framework. This document was also informed by the work of the Florida Association of Healthy Start Coalitions Evaluation Subcommittee; committee members shared the work they had completed in reviewing research on best practices and evidence-based models. Finally, the conceptual framework was also guided by the Healthy Start statute. The Healthy Start statute established prenatal and infant health care coalitions to provide coordinated community-based prenatal and infant health care, conduct community assessments to identify local need and develop a service delivery plan, solicit and select local service providers, and determine the allocation of resources to providers.

After the conceptual framework was developed, the team identified maternal and child health interventions to review. An intervention is characterized by what was done, how it was delivered, who was targeted, and where it was delivered. Interventions can be either single-

component or multi-component. To select interventions, the team identified the component, primary outcome measure, and target population and then conducted both a systematic search and utilized recommendations from stakeholders. There were several channels used for finding relevant evidence-based interventions:

- First, in order to build off prior efforts, the team searched for evidence-based reviews that included randomized controlled trials and an assessment of study quality such as Cochrane Reviews, US Preventive Services Task Force review, or Agency for Healthcare Research and Quality reviews. If reviews found little evidence of effectiveness for a particular intervention, that is noted.
- The team then looked for meta-analysis or systemic reviews in peer-reviewed journals or published by reputable sources such as the Centers for Disease Control; the evidence-standards used by each review are noted in the document but typically were limited to randomized controlled trials and included an assessment of study quality.
- Searches were then performed for individual studies of randomized controlled trials. Search procedures included a review of PubMed, Psychology and Behavioral Sciences Collection, Academic Search Elite, and citations of reviewed studies and publications. Once the team identified the individual studies of interventions, we summarized the evidence and assessed the strength of the body of evidence using a standardized abstraction form (Zaza et.al. 2000).

Results from the above sources were organized by levels of evidence within either risk or intervention categories and conclusions drawn based on the standard identified.

## **Appendix B: Subject Matter Experts**

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## Appendix C: Subject Matter Expert Committee Input on Evidence Standards

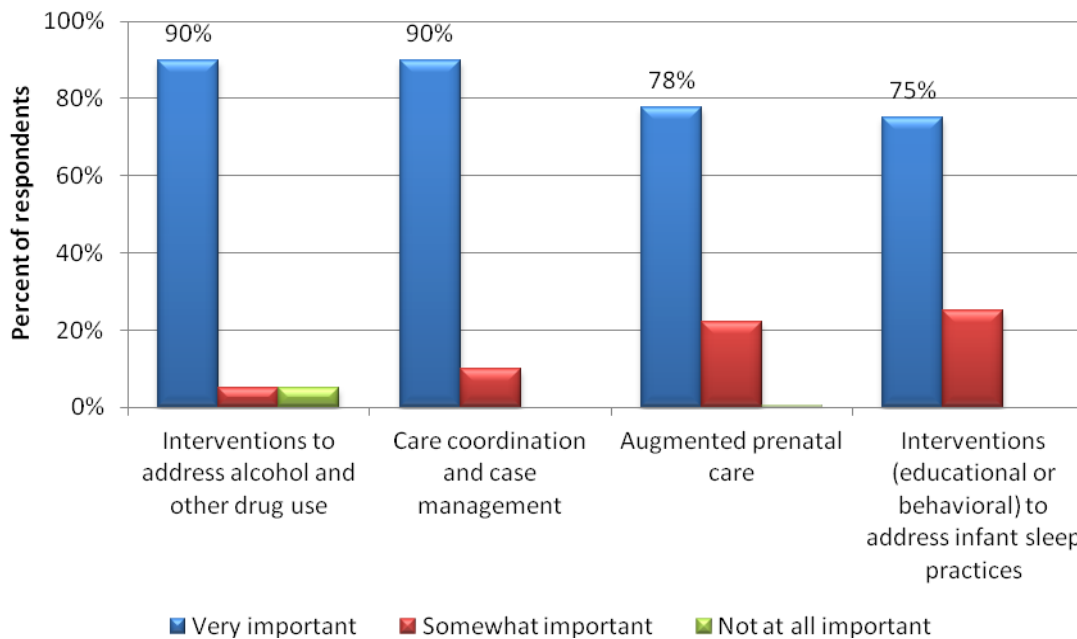
Of the 15 intervention categories, there were evidence-based reviews of experimental studies available for 11 of the intervention categories. For the four interventions noted below, it does not mean that there was no evidence of effectiveness but that there was either no evidence of the standard listed above or the evidence was inconclusive. Although individual studies can reflect internal validity, one study cannot establish external validity which is necessary to “make judgments about whether to implement the program at another location with the kinds of prospective clients present there” (Chen, Donaldson, and Mark, 2011, p. 11); meta-analysis is one method of establishing external validity (Chen, Donaldson, and Mark, 2011). The four for which evidence of the above standards was not available are:

- Interventions to address alcohol and other drug use
- Care coordination and case management
- Augmented prenatal care
- Interventions (educational or behavioral) to address infant sleep practices

The Subject Matter Experts were asked to assist in compiling and assessing evidence for the above four interventions. Twenty of the 25 members of the Subject Matter Expert Committee provided input about the relative importance of the four intervention categories, appropriate levels of evidence, and possible sources of evidence.

As shown in Figure C1, “interventions to address alcohol use” and “care coordination / case management” were identified as *very important* by 90 percent of respondents; 78 percent and 75 percent of respondents reported that “interventions to address infant sleep practices” and “augmented prenatal care” were *very important*, respectively. Therefore, all interventions will be included in the final Task 5 document. Open-ended comments follow the graphic.

Figure C1: How important is it to the redesign effort to identify evidence-based practices or promising practices for each of the following?



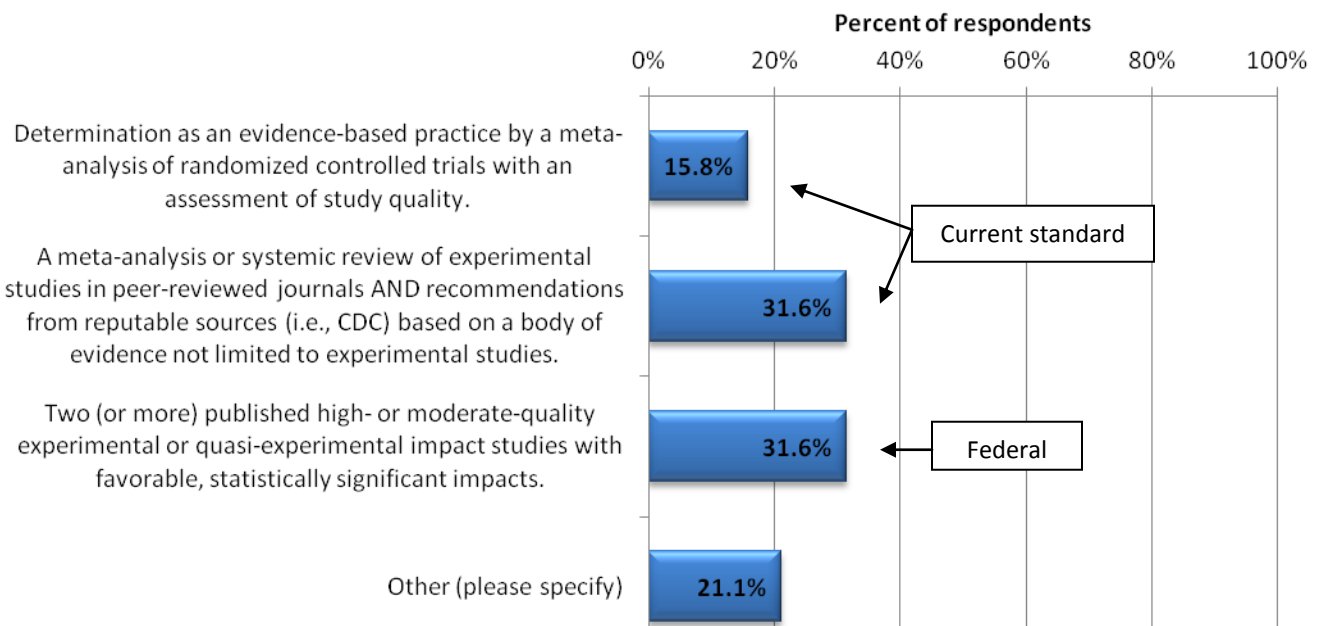
Open-ended comments regarding the first question related to the need to address all four interventions, questions on the scope of both augmented prenatal care and care coordination, and suggestions regarding evidence.

- At this point, we need to know our best choices
- difficult to rank -- all are very important
- Evidence based practice should guide us in any type of health education, care coordination and prenatal care. It is of utmost importance to keep staff, case managers and anyone that comes in contact with clients up to date with the current practice guidelines and care.
- I think that every activity/intervention needs to be reviewed, but my responses reflect the priority in which to review them
- I think we are better off defining specific components of this activity and looking at the evidence base of each of the components. This would/could include: home visiting (although I have the same problems defining what the heck this includes), assessment, education and support etc.
- I wonder about evidence-based interventions for trauma because many women who engage in high risk behaviors such as smoking, drinking, drug usage; women who have mental health issues; or women who have chronic health conditions are women who have experienced trauma. There are evidence-based interventions for improving coping skills and reducing harmful behaviors.
- I'm not sure what augmented prenatal care is. Please provide more information.

- In my experience I have found that there are not a great number of evidence based studies for case management in particular. I think it is important however that these types of interventions follow best practice standards such as those used by the Council on Accreditation (COA) which are based on research.
- Training options limited for staff interfacing with pregnant women. No curriculum, trainers manual, etc.
- We were unclear about your definition of "augmented" in relationship to prenatal care

Members of the Subject Matter Expert Committee were also asked to identify the lowest level of evidence that useful or acceptable for program development. As shown in Figure C2, 47.4 percent of respondents confirmed the standard set for the review while another 31.6 percent chose the standard often used in federal reviews, and 21.1 percent chose another option. Other comments follow the graph but suggest that the best available evidence should be used. Therefore, the standard set will be used when available and the minimum for determination of evidence-based will be the federal standard. When evidence at the federal level is not available, other evidence may be used to drive program improvement but the component will not be considered evidence-based. These components will have a clear plan for evaluation to develop the evidence base.

Figure C2: What is the lowest level of evidence that you think is useful/acceptable for program development?



Other comments included:

- Category 3 is the general minimum for evidence-based practice, but depending on what is possible, we may need to go with research-informed as a promising practice
- I do not believe there are enough studies in the literature that would satisfy the needs of the populations in FL. for case management. Again, interventions should meet basic best practice standards.
- I have mixed feelings on this one. I fear that if we only look at interventions that meet the above criteria, we will miss things that show some promise. I would suggest even looking at one published study with statistically significant impacts.
- Varies pending context

Finally, respondents provided open-ended comments as shown below (comments were provided in two areas and therefore individual respondents may be represented twice). Most pertained to possible resources for evidence while several related to the difficulty of finding evidence related to alcohol and other drugs as well as for case management. One comment provided here and others provided in question 1 (presented earlier) noted the appropriate context and bounding of interventions. Members volunteered for task forces; one of the task forces will discuss the issue of interventions provided within the context of home visiting.

Open-ended comments:

- Check out the Seeking Safety model. This is an intervention for substance using women who have past experiences of trauma.
- Great start!
- I don't know if I can do all 4 (task forces), but I am willing to work on a couple.
- I have reached out to others. If they provide the additional information, I will pass along accordingly.
- I will forward any research studies that I can find on the subjects identified.
- I would like to be able to discuss the standards of best practice found in the Council on Accreditation and/or those from the CDC.
- none at present
- The Health Resource and Services Administration (HRSA) recently did a meta analysis for case management that is available. I have found that most of the published work may be statistically significant but the power of the study is low or the outcomes selected for study are of somewhat less importance the overall goal (e.g., increased number of referrals)
- The Juvenile Welfare Board Children's Services Council of Pinellas researchers have assisted us in researching evidence based programs for alcohol and drug interventions without success.
- These interventions are provided within the context of a home visiting program so it is important to look at evidence-based home visiting programs - their home visitor education and training requirements, frequency and intensity of services, etc. I also think we need to look at effective interventions for changing behavior such as

motivational interviewing. In other words, we need to look at how the interventions are being delivered as well as the intervention itself.

- thought we already had a task force doing this
- WI study in JOGNN 2011 (sent via email); multi-site evaluations of Centering Pregnancy (will send citations); evaluations of HV models (NFP, EHS, etc) see state , federal MIECHV plan
- Would recommend that we are able to reach out to others that may be able to participate accordingly.

## **Appendix D: Summary of Subject Matter Expert Committee Feedback on Draft Document**

### **Introduction**

The goal of Task 5 is to summarize existing research regarding risk and protective factors impacting birth outcomes of the Healthy Start program and to identify existing evidence-based practices. Task 5 will be used as a resource and reference for the next two tasks: reviewing current Healthy Start program components to assess which are research-informed and evidence-based and to recommend new components or changes to components where applicable.

Subject Matter Experts have previously provided input into the evidence standards and specific components such as Care Coordination. This document summarizes their comments after reviewing the entire Research Review document to identify if any risk factors or intervention categories were missing but also to ensure that those included were germane to maternal and infant health. The document first presents their responses by question, and then how those responses were addressed in the final document.

### **Responses, by Question**

#### **Question 1: Are there any risk factors that are missing? If yes, do you have any suggestions on sources of research on these risk factors?**

- Since weight is a risk factor included on the prenatal screen, should this be included? Both underweight and overweight are risk factors for adverse birth outcomes.
- Homelessness affects a large portion of our clients served
- Developmental growth
- Homelessness (up 34% in FL)
- Infant mental health bonding
- I think you have captured all of them based on the current research. Although I would like to be able to propose more women's health topics/risks e.g., obesity.

**Question 2: Are there any risk factors included in the review that, while supported by research, are not within the scope of Healthy Start to address?**

As shown, at least 80 percent of respondents identified that the risk factors included in the review were within the scope of Healthy Start.

Figure D1: Percent of respondents identifying a risk or protective factor as within the scope

<b>Risk or Protective Factor</b>	<b>Percent of respondents identifying that the factor was within the scope of Healthy Start.</b>
Infant sleep position	100%
Breastfeeding	100%
Alcohol, tobacco, and other drugs	100%
Stress and depression	100%
Prenatal care	92%
Nutrition	92%
Preconception/interconception care	92%
Intervals between pregnancy	92%
Unplanned pregnancy	92%
Intimate partner violence	92%
Well-child care	85%
Adolescent pregnancy	85%
Sexually transmitted diseases	83%

**Question 3: Are there any intervention categories missing? If yes, do you have any suggestions on sources of evidence for these interventions?**

- Stress and perinatal depression are listed as maternal risk factors but no interventions are listed in this section. There are evidence-based interventions for depression that are not specific to pregnant women but should still be included. The goal is not to prevent postpartum depression but to provide intervention to those pregnant women with depression in order to prevent poor birth outcomes and developmental delays in infants. Some studies to consider are: 1. Efficacy of peer support intervention for depression: a meta-analysis by Pfeiffer, Heisler, Piette, Rogers and Valenstein, 2010 2. Psychoeducational treatment and prevention of depression: The "coping with depression" course thirty years later by Cuijpers, Munoz, Clarke, and Lewinsohn, 2009 3. Psychoeducation for depression, anxiety and psychological distress: a meta-analysis by Donker, Griffiths, Cuijpers and Christensen, 2009 4. Setting the stage for integration of motivational interviewing with cognitive behavioral therapy in the treatment of depression by Heather Flynn, 2011 5. Brief Psychotherapy for depression in primary

care: a systematic review of the evidence 6. Interpersonal psychotherapy for depression: a meta-analysis by Cuijpers, Geraedts, Van Oppen, Andersson, Markowitz and van Straten 7. Non drug strategies in the management of depression: a comprehensive review of systematic review and meta-analysis of randomised controlled trials by Dinghra and Parle, 2011 8. Review : Cognitive behavior therapy is a effective treatment for depression . . .by Haby, Donnelly, Corry and Vos, 2006 9. Cognitive therapy for depression by Rupke, Blecke and Renfrow, 2006 10. Clinical report: Incorporating recognition and management of perinatal and postpartum depression into pediatric practice by AAp Committee of psychosocial aspects of child and family health 10. Clinical practice guideline on the management of depression in adults from the Agency for Healthcare Quality and Research 2008 11. Systematic review of multifaceted interventions to improve depression care by Williams, Gerrity, Holsinger, Dobscha, Gayes and Dietrich, 2007

- I think it was touched on, but not named and that is "centering pregnancy"
- Developmental Screening
- Father involvement
- Birth Planning (support, doulas)
- I would suggest that HS does mandate pre-interconception care, though not funded. In that respect perhaps interventions related to women's health can be proposed.

**Question 4: Are there any intervention categories included in the review that, while supported by evidence, are not within the scope of Healthy Start?**

Although the interventions and components will be discussed in depth later in the redesign process, less than 80 percent of respondents identified depression, alcohol and substance abuse, teen pregnancy prevention, and intimate partner violence as being within the scope of Healthy Start. This question was difficult for some to answer and points to the need for more discussion. As one person noted, "Healthy Start must screen for substance abuse and even do an assessment but they typically then need protocols to refer clients out for treatment. So, does that make the risk factor for substances within the scope or not?"

Figure D2: Percent of respondents identifying an intervention as within the scope

Intervention Category	Percent of respondents identifying that the intervention category was within the scope of Healthy Start.
Home visiting	100%
Care coordination/case management	100%
Breastfeeding	100%
SIDS and infant sleep practices	100%
Facilitating access to care	100%
Screening	100%
Smoking cessation	91%
Parent education	91%
Nutrition	91%
Outreach	91%
Continuous support	82%
Depression	73%
Teen pregnancy prevention	73%
Alcohol and substance abuse	64%
Intimate partner violence	58%

**Question 5: What are your cautions, if any, regarding the limitations of the risk factors and interventions that were included in the review?**

- Inclusion of specialized wraparound services such as drug and alcohol counseling, breastfeeding counseling and support, nutrition, psychosocial counseling and support, parenting education are areas which require training programs, use of evidence based curriculum and continuing education for staff that is not always available at the local level.
- HS generally does not provide substance abuse treatment but they could provide something like the Seeking Safety model which focuses on improving coping skills.
- My cautions/concerns are as follows: that "undo racism" was part of a 12 part plan, that seemed strange - that Medicaid managed care in Puerto Rico was not effective, why? - obesity was not noted as a part of the nutrition and cause for infant mortality - (page 20-22) stated evidence was inconclusive for women that received PNCC yet it states the study group had better birth outcomes? - the augmented pgs were enhanced how and it what ways?-page 36 stated that teen pg prevention not a core service and needs to be! - pg 39 stated no available evidence that outreach and screening were not evidenced based,? -

- Males are only viewed in negative connotations. Why is it that we only consider men when violence or financial failings are involved and not the positive aspects of male involvement? Why is this the default position of these initiatives. It's rather insulting as a man and makes involvement problematic.
- Our area feels that preventing teen repeat pregnancies is within our scope, but preventing first time teen pregnancies is stretching our scope.
- The rise in cost of a paraprofessional model that may lend itself towards a more diverse professional team approach, in order to include a broader scope of intervention.
- We need to discuss the criteria for deciding what is acceptable with Healthy Start. We have not described and agreed upon parameters, and then ultimately selection criteria.
- While all can be considered within the scope of HS, we can't be all things to all pregnant women. So perhaps the scope should be narrowed a bit - although I don't know how - care coordination is a linking process to all needed services.
- Again, it was good to see the review mention that some components/interventions not defined as evidence based will be included for further evaluation.

**Question 6: Do you have any other comments?**

- It is difficult for HS to provide all the services included above while trying to serve all pregnant women who are eligible for services. It is difficult to say what is in the scope of Healthy Start before making a decision about who we should be serving.
- I am concerned about the outreach and screening not being evidence based but yet on page 54 it is recommended to increase public awareness? The other concern was about the high risk families not responding to home visiting and this is 100% right on the mark and is increasing in my area in great numbers. It was a very interesting read and love being a part of this process!
- Is there some way to group the risk factors and intervention to organize the scope?
- Stress was not identified nor provider education. Once again, we look at things without considering our short-comings as a public health system.
- We need to discuss the over view before getting into specifics.
- Is treatment of depression within the scope of HS - only in that we would refer a client to needed treatment - not necessarily that we would do the treatment ourselves - so it's a little hard to know how to answer the question.
- Well done review.

## Revisions Made

This section provides a summary of the changes made to the document in response to the feedback from the Subject Matter Expert Committee members. Revisions were made only when there was evidence available at the level identified by the Subject Matter Expert Committee and when more than one respondent identified the risk factor or intervention as missing. This section first addresses comments regarding risk factors and interventions and then general comments made.

### *Risk Factors and Interventions*

- Maternal weight: Research on this topic was reviewed. Only one study was of the evidence level recommended by the Subject Matter Expert Committee and the authors found weak or moderate evidence regarding weight gain. Therefore, no revisions were made to the Research Review document.
- Homelessness: Although there was some evidence of the impact on homelessness on poor birth outcomes, there was no evidence at the level set by the Subject Matter Expert Committee regarding the impact of homelessness on poor birth outcomes. Therefore, no revisions were made to the Research Review document.
- Stress: Research on this topic was reviewed and stress and depression were found to impact the outcomes of interest. Evidence from three evidence-based reviews and three meta-analysis or systemic reviews regarding interventions to address stress and depression were included in the research review. Those sources identified effective post-partum interventions.
- Developmental screening is addressed in some of the programs that use home visiting as a primary strategy (please see page 59) and in well-child care (please see page 41).
- Centering pregnancy is included, please see pages 24 – 26.
- Father involvement programs are included, please see pages 67 – 68.
- Birth support programs are included, please see pages 24 – 26.

### ***Other Comments and Concerns***

The most prevalent open-ended comments fell into one of two themes. Each theme is stated below along with how it will be addressed in the redesign process.

- The extent of **the scope of Healthy Start**: Interventions and components will be discussed in depth during the next phase of the redesign process. The Subject Matter Expert Committee- and other stakeholders – will discuss the target population, depth vs. breadth of services, the scope of Healthy Start, components and interventions, and appropriate client and population outcomes.
- **How evidence standards were applied** and how the resulting conclusions will be used: When an intervention category is not identified as evidence-based, it does not mean that there is no evidence of effectiveness but that the category did not meet the evidence standards set by the Subject Matter Expert Committee. During the next phase of the redesign process, the Subject Matter Expert Committee may use the best available evidence for program improvement but the component will not be considered evidence-based. These components will have a clear plan for evaluation to develop the evidence base.