

2017

Assessing Effective Interventions in Pregnant and Postpartum American Indian and Alaska Native Women

Hope Thompson
Walden University

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Walden University

College of Health Sciences

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Hope Lauren Thompson

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2017

Abstract

Assessing Effective Interventions in Pregnant and Postpartum American Indian and

Alaska Native Women

by

Hope Lauren Thompson

MPH, Walden University, 2011

BS, Clayton State University, 2007

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Public Health - Epidemiology

Walden University

January 2018

Abstract

Through the creation of the Indian Health Service in 1955, the health status of American Indian and Alaska Native (AI/AN) has improved; however, AI/AN women of reproductive age still have some of the poorest health outcomes of all populations. This study aimed to examine effective interventions that seek to improve the health of AI/AN women during pregnancy, and immediately postpartum (up to 12 months post delivery). This study addressed the research question: What effect does parental competence have on early parenting and/or infant/toddler outcomes? The life course conceptual framework was used to demonstrate how life experiences impact current health. The methodology followed the preferred reporting items for systematic reviews and meta-analyses statement. A literature review from 1993-2015 using derivatives for race and pregnancy was conducted. Inclusion and eligibility were determined using a priori criteria and application of the population, intervention, comparator, outcome, and study design(s) approach. Study quality was assessed using the Cochrane risk of bias tool and an expert review panel. A meta-analysis was conducted to determine the impact of parental competence through parenting knowledge and self-efficacy. The findings of this study suggest that evidence based interventions focused on: reducing multiple risky maternal health behaviors, through education and treatment options (creating positive social change at the individual, family, and societal levels); increasing access to prenatal care early in pregnancy, through community based participatory research (creating change at the societal level); and supporting parental competence, through training (creating change at the organizational level), will promote positive birth outcomes in AI/AN women.

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Dedication

I dedicate this dissertation to the loving memory of my mama, Wanda E. Thompson. Look, Mama! I made it! Thank you for always being my biggest fan. I am so grateful for the wonderful life you gave me and the precious moments we shared. Every day I strive to live a life that makes you proud.

I also dedicate this dissertation to my grandma, Clara E. Johnson. Although, I know you don't fully understand the significance of this accomplishment, I thank you for always providing a helping hand, never saying no, and showing me that I am loved.

I love you both, always and forever!

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Chapter 1: Introduction to Study

Through the creation of the Indian Health Service (IHS) in 1955, the health status of American Indians and Alaskan Natives (AI/AN) has improved; however, while rates of infant mortality and preterm birth have decreased, they still remain significantly high when compared to other populations. AI/AN women are second only to non-Hispanic Black women in terms of greatest risk of poor birth outcomes (MacDorman, 2011). In 1980, infant mortality rates (IMRs) for AI/AN were 76% higher than White infants (Wong et al., 2014). But even as recently as 2009, the IMRs for AI/AN infants was 8.47 per 1,000 live births compared to only 5.33 of non-Hispanic Whites (Wong et al., 2014). In addition, AI/AN IMRs are different in that they are similar to rates of developing countries and are even higher than those of other minority populations (Johansson, Williams, & El-Mohandes, 2013). Inequalities in socioeconomic factors contribute to infant mortality and preterm birth in AI/AN. These include: lower rates of health insurance, higher poverty rates, and lower educational achievement (Johansson et al., 2013). In this chapter I will: (a) provide some background the importance of evaluative interventions for pregnant and postpartum AI/AN women; (b) provide the purpose of the study, as well as list the research question; (c) briefly discuss the conceptual framework for the study; (d) summarize the nature of the study; (e) provide a list of definitions that are pertinent to study; (f) give a list of assumptions; (g) discuss scope and delimitations; (h) discuss limitations of the study; and (i) provide the study significance.

Background

The biggest risk factor for poor birth outcomes is a lack of access to care (Partridge, Balayla, Holcroft, & Abenheim, 2012). This has been exacerbated as AI/AN populations have relocated from rural reservations to urban areas, that are often outside the service areas of IHS (Rutman, Loughran, Tanner, & Randall, 2016). Singh and Siahpush (2014) have shown higher rates of neonatal and postneonatal mortality occur among AI/AN infants compared to White infants living in the same area (Singh & Siahpush, 2014). More concerning, within the AI/AN population IMR and low birth weight (LBW) are higher among urban residing AI/ANs (Rutman et al., 2016).

Nevertheless, there have been improvements in maternal behavior. As recent as 2000-2010, the prevalence of women smoking during pregnancy decreased from 13.3% to 12.3% and smoking after delivery decreased from 18.6% to 17.2% (Tong et al., 2013). Through personalized counseling sessions with educational information regarding alcohol risk to mother and baby alcohol consumption rates have decreased, as women better understand the benefits of not drinking and feel supported in quitting (Ingersoll, Ceperich, Hetteema, Farrell-Carnahan, & Penberthy, 2013). Prenatal care has become fairly standard in pregnancy with other 90% of mothers receiving some care (Reichman, Corman, Noonan, & Schwartz-Soicher, 2010).

Due to limited published research on AI/AN women and children's health, identification of effective interventions addressing the complex risk factors associated with poor birth outcomes is a challenge for public health professionals. In order to ensure the program is likely to be culturally appropriate and readily accepted by the community,

health interventions for AI/ANs have to be designed and delivered in ways that are consistent with the norms and values of AI/AN cultures. Culture competency for AI/AN populations is generally recognized as focusing on collectivism. AI/AN collectivism in this sense is defined as: modesty and less driven by individual success; considering the elders of the community; having face-to-face meetings (a more culturally accepted form of communication, so that nonverbal communication may be taken into account); spirituality of all life (animals and plants are sacred and respected) and AI/AN are likely to incorporate prayer and traditional medicine into everyday life; historical trauma—including loss of land, language, tradition, and respect; and finally distrust of outsiders due to a previous history of being taken advantage of by the government and non-Natives (Noe, Kaufman, Kaufmann, Brooks, & Stone, 2014; Unger, Soto, & Thomas, 2008). This study is needed to show how essential interventions impact the maternal health of AI/ANs during the pregnancy and postpartum period.

Problem Statement

To date, there is not a published systematic review of effective public health interventions among AI/ANs during pregnancy and postpartum. Pregnancy is a crucial period to study because maternal health is an important predictor of birth outcomes. Likewise the postpartum period is a vital consideration because the way in which a mother cares for her baby can help reduce IMR. This lack of reviews shows how understudied evidence based interventions in the AI/AN population is in published literature, but what is even more problematic are the disparate health outcomes of AI/AN populations (Hwang, Shrestha, Yazzie, & Jackson, 2013). The greatest indicator of a

nation's health is infant mortality and although infant mortality rates in AI/ANs have significantly declined over the past 60 years, major disparities still exist between AI/AN, Whites, and other ethnic groups. In 2007, infant mortality rates were almost twice that of Whites, and in 2009, the rate for AI/AN mothers was 8.47 per 1,000 live births (Johansson et al., 2013; Wong et al., 2014). Additionally, AI/AN children 19 years and under had higher death rates than all U.S. children of all races. Furthermore, AI/AN populations are often subject to racial misclassifications, meaning that these death rates are very likely to be underreported (Wong et al., 2014).

This gap in research supports the need to systematically review interventions focused on maternal health during pregnancy and immediately postpartum. Researchers have indicated that successful interventions may necessitate modifying methods to adequately meet the needs of certain populations and cultures (Montag, Clapp, Calac, Gorman, & Chambers, 2012). Therefore, it is imperative that interventions are grounded in effective evidence based science.

Conceptual Framework

Life course is a conceptual framework that uses a temporal and social perspective to examine how an individual's or a generation's life experiences impact current health. Instead of looking at differences in health patterns one disease at a time, life course looks at social, economic, and environmental factors as the root cause of inequalities in health (Fine & Kotelchuck, 2010). The life course framework states that disparities in birth outcomes are the result of both differential exposures and experiences during pregnancy and over the life span (Lu & Halfon, 2003). In other words, early and midadulthood

experiences, both biological and behavioral, may add additional risk and exacerbate long-term risks to health. By utilizing the life course framework, an understanding of how various exposures affects two lives (mother and baby) simultaneously, is achieved. In addition, ways to achieve positive maternal and infant health outcomes are also supported. The final study results are generalizable to maternal and child health professionals who implement interventions during pregnancy and immediately postpartum in AI/AN women. More detailed information on this framework can be found in the literature review.

Purpose of the Study

The purpose of this current study is to examine effective interventions targeting maternal risk behaviors among AI/AN women during pregnancy, and immediately postpartum, defined as up to 12 months postdelivery. The result will be a complete systematic review and meta-analysis of all published literature from 1993-2015 on interventions in AI/AN women during pregnancy and the postpartum period. The independent variables for the study are: AI/AN women, age, and residency in one of four rural reservation communities. The dependent variable for the study is parental competency, with evaluation through increases in parenting knowledge and self-efficacy.

Research Question

This study will address the following research question: What effect does parental competence have on early parenting and/or infant/toddler outcomes? Using a fixed-effect model approach, this will test the null hypothesis that there is zero effect on parental

competence in every study, meaning that they do not work or do not improve parenting knowledge.

Nature of the Study

The nature of this study will be quantitative, a longitudinal retrospective systematic review. The data used to achieve the study objective come from a meta-analysis (generated from a systematic review), which looks at parenting knowledge and psychosocial and behavioral risks (i.e., drug and alcohol use), in order to determine the impact of interventions on pregnancy and postpartum outcomes (i.e. parenting and/or infant/toddler outcomes). Systematic reviews serve as an important piece of evidence based research and practice because they synthesize existing knowledge and data on an individual topic in order to make sound clinical choices (Haase, 2011). Their rigorous methods help to provide more reliable findings from which conclusions can be made (Haase, 2011). The preferred reporting items for systematic reviews and meta-analyses statement (PRISMA) is the most widely recognized and accepted standard for conducting a systematic review and reporting meta-analysis. It consists of a 27-item checklist and a four-phase flow diagram, with the goal of helping authors improve the reporting of systematic reviews and meta-analyses. It is particularly useful for evaluation of interventions (Moher, Liberati, Tetzlaff, Altman, & The PRISMA Group, 2010). A methodology adapted from the PRISMA statement will be used to report the findings of this systematic review.

A meta-analysis will be generated from the systematic review in order to determine the impact of evidence based interventions on pregnancy and postpartum

outcomes, by looking at parenting knowledge and psychosocial and behavioral risks (i.e., drug and alcohol use). Meta-analysis is used to estimate the mean and variance of underlying population effects from a collection of empirical studies addressing the same research question (Field & Gillett, 2010). The purpose of meta-analysis is to assess the average treatment effect, a confidence interval for the average treatment effect, and the distribution of treatment effects in the defined population; it increases the statistical power and the accuracy of the estimates of effect (Higgins & Green, 2011). In addition, from the meta-analysis it may be possible to determine which variables cause differences in effect sizes (Field & Gillett, 2010). If new studies are needed the meta-analysis can aid in the design of the study. It may show that an outcome index is more effective than others; therefore, it should be included in any future studies (Borenstein, Hedges, Higgins, & Rothstein, 2009). Meta-analysis provides a way to evaluate studies as a whole.

Definitions

Glossary of Terms

Descriptive studies: Observational studies that provide information on patterns of disease occurrence, but they can only examine association, they do not make assumptions about causality (Gordis, 2014).

Effective: Defined as a targeted intervention associated with an outcome that impacts a health behavior

Evaluation: To assess the degree to which an intervention is achieving its goals and targets, evaluation must take place. This regular review allows health professionals to

modify and enhance health actions taking place in the field. Evaluations should include recommendations for improving quality and efficiency (Patel, Burnett, & Curtis, 2003). Furthermore, evaluations should assess whether the intervention is serving a useful public health function and is meeting its overall objective (Patel et al., 2003).

Intervention: A method/program that attempts to change an unsafe health behavior that will hopefully produce a positive health outcome for mother and/or baby. It seeks to: (a) prevent the development of disease and its complications, and (b) interrupt and reduce transmission of disease (Patel et al., 2003). Effective interventions encourage the avoidance of behaviors likely to result in disease and transmission and ensure best treatments for disease (Patel et al., 2003).

Postpartum: Defined as up to 12 months postdelivery.

Screening: In terms of disease control, it can be defined as the examination of asymptomatic people in order to classify them as likely or unlikely to have the disease (Rothman, Greenland, & Lash, 2012). The goal of screening is to reduce morbidity or mortality from the disease among the people screened (it is a form of secondary prevention in public health); it is achieved by early treatment of the cases discovered (Rothman et al., 2012). A screening tool is a measure that can be used to identify, classify, and document people who are at risk for atypical development of a disease from those who are not (e.g., a mammogram to detect for breast cancer) (Rothman et al., 2012).

Validation: The World Health Organization (WHO) defines it as “the documented act of proving that any procedure, process, equipment, material, activity or system

actually leads to the expected results” (2007 p. 65). These studies are an essential part of good practice and provide validity evidence to support the effectiveness of a selection tool in the form of a statistical link between the test and the criterion (Industrial/Organizational Solutions, 2010).

Assumptions

It is assumed that all of the studies included in the meta-analysis are reported with enough details to facilitate sufficient information about the effects. It is assumed that the study samples are independent. It is assumed that the findings are exchangeable—in other words that similarities between the different studies are quantifiable. It is also assumed that the outcomes from the continuous data used in the meta-analysis have a normal distribution in each intervention arm in each study.

Scope and Delimitations

While AI/AN represent a small segment of the U.S. population, they bear a disproportionate burden of health disparities in comparison to other groups. AI/AN women of reproductive age and infants experience higher rates of adverse health outcomes, including diabetes and infant mortality (Ali, Jarrar, Sadig, & Yeatts, 2013; Alexander et al., 2008). In recognition of the important of maternal and child health, a critical review of the literature was conducted to identify interventions that improved the health of AI/AN women during pregnancy and postpartum. The life course framework was utilized since it shows how the health behaviors and health status of the mother affects fetal growth as well as the trajectory of the infant. This study is generalizable to AI/AN women during pregnancy and immediately postpartum. Specifically, it can be

generalized to self-identified AI/AN women, between the ages of 12-19 years old, living in rural, isolated reservations ranging in size from 15,000 to 25,000.

Limitations

As with any study, there are limitations. The first to consider is bias. Publication introduces various biases, as the published literature could be a misrepresentation of the population in the study. One threat to validity is publication bias, where studies that have more positive, statistically significant results are more likely to be published than those with less favorable or nonsignificant results (Ahmed, Sutton, & Riley, 2012). However, to compensate for this, in the literature search, peer-reviewed theses and dissertations, both published and nonpublished, were a part of the type of articles searched. Another bias is language bias, where non-English articles that report significant findings are more likely to be rewritten in English or only including studies that are in English; hence, the results may be different for articles written in languages other than English (Egger et al., 1997; Rothstein, Sutton, & Borenstein, 2006). This could not be helped, as the primary abstractor only speaks English and an interpreter could not be utilized.

In this study, those articles where the results of AI/ANs were grouped together with other ethnicities, or where AI/ANs were not identified separately and there was no discussion or data to support were excluded during the screening phase. This could present a potential data availability bias. Data availability bias is where individual participant data, particularly the study results, is unavailable for some studies (Ahmed et al., 2012). Lastly, limitations may have been found within the data source. Limitations of

secondary data include: missing data and out-of-range data. However, as part of the assumptions, it is assumed that sufficient data is reported in the studies.

Significance

The results of this study will provide an overview of all published literature from 1993-2015 on successful interventions in AI/AN women, highlight approaches used in these interventions, and identify gaps in AI/AN maternal research. As with meta-analysis, I will combine knowledge about previous studies in order to improve the evaluation of whether statistical differences exist between comparison groups. I also recommend public health strategies for improving interventions targeting pregnant and postpartum AI/AN women to ultimately reduce IMR. In addition to aiding public health professionals in developing successful interventions, ideally, this research will contribute to the published literature focused on pregnant/postpartum AI/AN women, particularly those at high risk of poor outcomes. Furthermore, it will raise awareness of factors and complications that lead to adverse birth outcomes. It may also serve as a guide to improve relationships between public health professionals and tribal nations. This chapter serves as an introduction to the importance of examining interventions that improve the health of pregnant and postpartum AI/AN women.

In the next chapter I will demonstrate the negative impact historical trauma and its generational effect has had on AI/AN women. The chapter seeks to establish historical trauma as one of the root causes of many risky maternal behaviors as a means of coping. Unfortunately, these coping mechanisms often lead to difficult pregnancies and adverse birth outcomes. The literature review chapter serves as justification for why an

examination of interventions during the pregnancy and postpartum period in AI/AN women should be conducted.

Chapter 2: Literature Review

Introduction

AI/AN women of reproductive age have the poorest health outcomes of all ethnic populations (Flores & Research, 2010; Johansson, Muller, Samos, & Goldberg, 2013; Mahoney & Michalek, 1998). White women of reproductive age represent the middle-class, well-educated population and are usually the standard or reference group for health status, as this population is significantly healthier than other populations (Braveman, 2006). AI/AN have significantly poorer health outcomes than White women of reproductive age, on average nearly three times worse (Baldwin et al., 2002). Even in terms of self-reporting, over one-quarter (31.5%) of AI/AN women define their health status as fair or poor, in comparison to 13.6% of White women (Zahnd & Wyn, 2014).

AI/AN populations have been persecuted and taken advantage of for hundreds of years by the government and non-Natives. This historical trauma is so severe, most AI/ANs refer to it as the *soul wound*, a spiritual trauma that was visited upon them (Szlemko, Wood, & Thurman, 2006). This trauma goes above and beyond physical trauma, AI/AN have experienced forced removal from their ancestral homelands, a loss of culture, involuntary socialization, and even genocide. These losses have also been linked to other risky maternal behaviors, such as alcohol and nonceremonial smoking/tobacco abuse, as potential coping mechanisms (Goodkind et al., 2010). Risky behaviors during pregnancy can lead to high IMRs, which for AI/AN women, is a product of a chronic, historical trauma across generations (Unger et al., 2008). These issues are not just experiences of the past, they continue to affect today's AI/AN women

of reproductive age, specifically, their interactions with healthcare providers and receipt of care.

The purpose of this current study is to examine effective interventions targeting maternal risk behaviors among AI/AN women during pregnancy, and immediately postpartum, defined as up to 12 months post-delivery. A systematic review and meta-analysis of the published literature from 1993-2015 will be completed to identify essential interventions to improve the health of AI/AN women during pregnancy and immediately postpartum. Identifying effective interventions enables maternal and child health (MCH) professionals to create effective, targeted strategies and policies impacting women of reproductive age and contributing to the foundation of scientific knowledge (Sequist, Cullen, & Acton, 2011).

In this chapter I: (a) review the literature on causes and contributors for higher IMRs in AI/AN women; (b) describe the selected framework utilized in the study; and (c) explains how the various factors impact IMRs. In this chapter I describe generational historical traumas experienced by AI/AN women and discuss how these have led to risky behaviors, a lack of trust, and reluctance to seek prenatal care in AI/AN women of reproductive age. I will further discuss how the traumas are not just physical, but related to land loss and relocation; being denied the right to raise their children with culture and tradition; religious persecution; and even stereotypical self-imagery.

Risky maternal behaviors such as inadequate prenatal care, which is often due to a lack of access to care, is the one of the main contributors to high IMRs (Alexander & Kotelchuck, 2001; Beck et al., 2002). In this literature review I demonstrate the various

reasons why AI/AN women often do not have sufficient prenatal care as well as have continuing issues of access to care and conflict with the health care field. The literature review indicates AI/AN women of reproductive age are more likely to have higher numbers of socioeconomic barriers to health (i.e. poor educational attainment, poverty, and stress) prior to pregnancy as well as chronic conditions (i.e. diabetes, obesity, and high blood pressure) and the impact these have on their birth outcomes. The review will also discuss how underfunded systems of care are for AI/AN women of reproductive age and how lack of infrastructure limits access to quality care. Additionally, I will illustrate why AI/AN women have a distrust in the health care field and how this further exacerbates risky health behaviors as a mechanism of coping with the trauma.

The life course framework explains the connection between early life events, generational experiences, and future health and disease. This framework is also used to describe the role of developmental influences of risk and protective factors, as well as various comorbidities' effect on a woman's health trajectory. Furthermore, it also provides evidence of the need to implement effective interventions in early pregnancy, particularly during the first trimester, for AI/AN women.

Causes of and Contributors to Infant Mortality Rates

Historical Trauma

AI/AN populations experience historical trauma, which plays a significant role in how they access health care. Historical trauma is defined as “complex and collective trauma experienced over time and across generations by a group of people who share an identity, affiliation, or circumstance” (Mohatt, Thompson, Thai, & Tebes, 2014, p. 131).

It is most important to emphasize that this trauma is generational. It can affect an individual even if he/she has not personally experienced it, but rather it is the shared memories, continuous effects on the group's language, cultural traditions, and ethnic identification that reflect the impact (Walters & Simoni, 2002). Furthermore, it is used as a possible causative factor for chronic angst within communities (Ehlers, Gizer, Gilder, Ellingson, & Yehuda, 2013). In other words, shared memories of the trauma are internalized and passed along to each new generation, lending to a negative impact on the health of AI/ANs (Walters & Simoni, 2002).

Some well-known traumas include: the Trail of Tears, the Allotment Act of 1887 (also known as the Dawes Act of 1887), and the removal of Native children from their homes to boarding schools. The Trail of Tears refers to the journey of the Cherokees from North Carolina to Oklahoma. Somewhere between 8,000 and 17,000 Cherokees died due to a lack of medical care, disease, scarce food, and harsh weather exposure (Szlemko et al., 2006). Likewise, Creek and Seminole nations lost nearly half of their populations due to relocations (Szlemko et al., 2006). Many other Eastern tribes did not endure such relocations because their population had already been mostly destroyed (Szlemko et al., 2006).

The Allotment Act of 1887 removed the traditional system of shared land holdings and gave land to select Native American individuals and families (Snipp, 2014). This not only disrupted their traditional practices and ways of life, but it also meant that if Native Americans wanted to keep their land they had to accept American citizenship (Snipp, 2014). As another way to force Native Americans into European American

culture, mandatory boarding schools were established for Native American youth by the United States government. Children were taken from their families, prohibited from speaking their native tongue, practicing their religion, or wearing customary clothing (Denison, Varcoe, & Browne, 2013). This meant that traditional values and cultural knowledge were now forbidden, preventing traditional upbringing and teaching to children by their parents (Denison et al., 2013).

December 26, 1862 and President Abraham Lincoln also play a role in the persecution of Native Americans. In a mere six weeks between August and September of 1862, nearly 1,000 people, including white settlers, soldiers, and Sioux Indians were killed during Minnesota's Great Sioux Uprising (Finkelman, 2013). The Sioux (also known as The Dakota) were fighting because they were facing starvation due to a delay in annuity payments (Finkelman, 2013). Ultimately, they were also fighting because they were desperate; the white settlers and government policies had threatened their existence by forcing the Sioux to give up their life and conform to the culture and laws of White people (Finkelman, 2013).

Treaties of 1851 and 1858 caused the Sioux to surrender most of southern Minnesota to the government in exchange for annual annuity payments for 50 years (Finkelman, 2013). The Sioux were in the middle of converting to a farming culture and did not have enough land to survive by hunting and fishing alone, so they depended on the annuity payments for survival (Wert, 2006). However, Indian traders and agents were often corrupt and cheated the Sioux out of most of their money (Wert, 2006). By the summer of 1862, payments were late and it was rumored that due to the financial burden

of the Civil War, there would be no payment (Wert, 2006). When Indian traders refused to allow the Sioux to purchase food on credit, the Sioux retaliated in violence, killing hundreds of white settlers and soldiers (Wert, 2006). September 23rd ended the uprising when the Sioux were defeated at the Battle of Wood Lake, led by General John Pope (Finkelman, 2013).

Though the battle was complete, the war was still not over. Pope, who felt it was his purpose to “exterminate the Sioux” (Martinez, 2013, p. 23), along with General Henry Hastings Sibley, were calling for accountability and wanted the Sioux punished for their crimes (Martinez, 2013). Hundreds of Sioux were arrested and 393 were tried for murder (Soodalter, 2009). After quick, erroneous trials, where the Sioux lacked defense counsel and were not permitted to testify on their own behalf or explain their circumstances, 323 Sioux were convicted and 303 were sentenced to death by hanging (Finkelman, 2013; Soodalter, 2009). However, no execution could occur without President Lincoln’s consent, so he ordered that every case be tried on its own merit (Soodalter, 2009). During the process, Pope, Sibley, and Governor Ramsey tried to pressure Lincoln into approving all the executions (Finkelman, 2013). Conversely, Bishop Henry Whipple, head of the Episcopal Church in Minnesota met with Lincoln in support of the Sioux, citing corruption within the Indian Agency system (Finkelman, 2013). After careful examination, 38 Sioux were proven to have participated in the uprising and were hanged, becoming the largest mass execution in American history and referenced by tribes today as “The 38” (Martinez, 2013, p. 32).

Religious Persecution

Grim and Finke (2007) defined religious persecution as “physical abuse or physical displacement due to one’s religious practices, profession, or affiliation” (Grim & Finke, 2007, p. 3). It is important to note that persecution is more than being denied rights, but also being harmed or made to relocate due to religious association (Grim & Finke, 2007). The worst times for AI/ANs were post-Civil War through the midtwentieth century. As a part of the Grant Peace Policy, the Board of Indian Commissioners was formed in 1869 (Grim & Finke, 2011). Their job was to teach AI/ANs about industry, civilization, and Christian principles (Grim & Finke, 2011). As previously discussed, during 1872, Native children were removed from their homes and sent to Christian missionary schools (Grim & Finke, 2011). In 1889, under the Rules of Indian Courts, prompted by Commissioner Thomas J. Morgan, AI/AN were to “conform to the white man’s ways, peaceably if they will, forcibly if they must...” (Irwin, 2000, p. 93).

Perhaps, the most famous and tragic demonstration of religious persecution is the massacre at Wounded Knee in 1890. Here, the Sioux believed that they had been defeated and restricted to reservations because the gods were angry with them for abandoning their traditional customs (Richardson, 2011). They further believed that if they would practice the Ghost Dance and reject the ways of the White man, the gods would create a better world for them (Richardson, 2011). On December 15, 1890, reservation police mistook the Sioux chief, Sitting Bull, for a Ghost Dancer and killed him, increasing tensions in the area (History.com Staff, 2009). On December 29, 1890, U.S. armies surrounded a group of Ghost Dancers and ordered them to give up their weapons (History.com Staff, 2009).

A fight broke out between a soldier and a Sioux, leading to an unknown fired shot (Maria Yellow Horse Brave Heart & DeBruyn, 1998). A massacre ensued, killing at least 150 Sioux, while only 25 soldiers died (Maria Yellow Horse Brave Heart & DeBruyn, 1998).

Suppression continued in 1892 and 1904, where the practice of tribal religions were completely banned (Wunder, 1996). Practicing AI/AN could be imprisoned or have rations withheld from them (Wunder, 1996). This ban was continued until 1934. In August 1978, the American Indian Religious Freedom Act (AIRFA) was passed to protect the constitutional First Amendment rights of AI/AN (Irwin, 2000). This was a weak attempt to right past wrongs that had often resulted in limited religious expression. In the case of *Lyng v. Northwest Indian Cemetery Protective Association*, the Supreme Court permitted the Forest Service to destroy ancient AI/AN sacred sites that were on federal land, citing that the First Amendment only protected against laws that made people violate their religion or penalized them for practicing their beliefs (Wunder, 1996). Subsequently, tribal sacred sites are no longer under government protection and are thus at risk of being desecrated (Wunder, 1996). But, even today, it can be a challenge for AI/ANs to practice their religions freely.

Breaking Treaties

As early as the Pre-Constitution Era (1533-1789), colonies negotiated land treaties with Indian tribes (Unger et al., 2008). These agreements were supposed to give tribes a status equal to that of the colonial governments. During the Formative Years (1789-1871) treaties were made that recognized Indian nations as distinct political entities in negotiations (Jensen, 2012). However, during the Era of Allotment and

Assimilation (1871-1928) AI/ANs were forced to adapt to White society (Jensen, 2012). The Bureau of Indian Affairs controlled federal economic assistance and social service programs for AI/ANs and would not allow AI/ANs to supervise the programs (Jensen, 2012).

The previously discussed Dawes Act of 1887, did not always give land to AI/ANs and during the Reorganization Era (1928-1945), it was ended in favor of funding for tribal land procurement (Unger et al., 2008). Unfair policies during this time also forced AI/ANs to decrease their livestock. During the subsequent Termination Era (1945-1961), the tribal self-government movement was overturned (Rosier, 2015). More than 50 AI/AN nations lost their recognition and tribal governments were ended (Rosier, 2015). The termination era's purpose was to encourage AI/AN to become a part of the larger U.S. society, rather than isolating them on reservations (Gilio-Whitaker, 2013). Unfortunately, all this did was create a new class of poor urban AI/ANs who did not have enough resources to survive in a competing, materialistic White world (Gilio-Whitaker, 2013). The latest era, the Self-Determination Era (1961-present) has created some reform, providing funding for tribal controlled programs, but the traumatic effects of previous broken treaties and discrimination still remain (Jensen, 2012).

Finding Gold and Relocating

A further example of AI/AN being forced off their land was the finding of gold and the start of The California Gold Rush, as thousands of Forty-niners invaded central Sierra Nevada (Spence, 1999). The miners and their camps destroyed ecosystems, brought disease, created conflict, and caused displacement of the natives (Spence, 1999).

In a single year everything about California changed. In 1848 only 400 settlers occupied the land, in 1849 90,000 miners had moved in (Smith, 2011). Initially, the California AI/ANs were cheap laborers and miners, although few were paid (Smith, 2011). Instead, most were only given food, clothes, and shelter. However, as gold diminished and settlers increased, exaggerated stories of violence between the settlers and native people grew (Smith, 2011). This led to fear, racism, and resentment of AI/ANs.

Americans saw the AI/AN miners and workers as competition and barriers to civilization, thus leading to attacks on AI/AN communities (Smith, 2011). Californian AI/ANs saw their population reduced from between 100,000 and 150,000 in 1848 to roughly 30,000 in the 1860s (Trafzer & Lorimer, 2013). By the end of the 1860s, the population was between 20,000 and 40,000 (Trafzer & Lorimer, 2013). The discovery of gold, along with the passage of the 1862 Homestead Act, and the building of the first transcontinental railroad in 1869, led to an expansion of White settlement into AI/AN territory (Ross, 2014). Between the 1830s and the 1880s, AI/ANs lost more than 450,000,000 acres of land and by the 1890s most AI/ANs had surrendered to reservation life (Ross, 2014).

Stereotypical Depictions of American Indian and Alaska Native Populations

AI/AN populations also experience varied distortions of their cultural identity. Images in textbooks often show them naked and if not explicitly stated, imply that they are un- or undereducated. These images are also present in movies, TV shows, comic books, and cartoons. Mihesuah described how the men are shown as uncivilized and primal, while the women are alcoholics who remain on the reservations (Mihesuah,

2009). Other images, perhaps not as negative, but just as clichéd, include tall, brown-skinned men with braided hair, clothed in buckskin and Pocahontas-looking women (Mihesuah, 2009). These descriptions of AI/ANs clearly do not reflect actual real natives. On the other hand, few photographers respect AI/ANs privacy. AI/ANs do not like to be photographed, without their permission, and prohibit pictures or videos from being taken during sacred ceremonies (Mihesuah, 2009).

While inappropriate or misleading images of AI/ANs are perpetuated, the history of AI/AN is also being misrepresented. In history class students learn about Christopher Columbus and how he “discovered” America, failing to acknowledge that this cultural encounter resulted in enslavement, violence, and religious persecution (Bickford & Hunt, 2014). Columbus has also been given a federal holiday, while AI/ANs have none. Martin noted how some institutions teach of the loss of AI/AN religion and traditions by saying that it was inevitable, that democracy, Christianity, and European culture would dominate the West (Martin, 2014). Others prefer to omit AI/AN history and impact completely (Martin, 2014). Movies are especially inaccurate, opting for more glamorized accounts such as Disney’s Pocahontas, or dramatized features such as *The Last of the Mohicans*. The real Pocahontas was a young girl, who died at 22 and was not provocatively dressed, nor did she love and marry John Smith (Mondloch, 2002). *The Mohicans* is spelled Mohegans and they are very much still around, residing in Connecticut (Johnson, 2015). These stereotypes perpetuate continued trauma for AI/AN populations.

Characterizing the Trauma

It has been hard to characterize and correct these on-going traumas, as they do not meet current definitions of posttraumatic stress disorder (PTSD) (Hartmann & Gone, 2014). PTSD is often associated with veterans who have returned from war, but it can affect any individual. It is usually regarded as a traumatic event that has chemically altered the brain and is recognized by intrusive thoughts, sleep disorders, and anxiety, even when no danger is present (Friedman, 2015; Ursano, Benedek, & Engel, 2012). Treatments for PTSD include counseling and medication. However, the historical traumas faced by AI/ANs impacts an entire community/group of people and require community renewal and transformation rather than individual counseling (Hartmann & Gone, 2014). These consistent examples of undue government influence on AI/AN populations and perceived persecution creates long-term stress for AI/ANs and demonstrates the foundation for this lack of trust. Lack of trust provides context for why AI/ANs adopt risky health behaviors, as emotional dysregulation can lead to or encourage health-compromising behaviors (Weiss, Tull, Sullivan, Dixon-Gordon, & Gratz, 2015). Unfortunately, the psychosocial stress of historical trauma and persecution, compounded by pregnancy-related stress, carry the greatest risk of adverse birth outcomes (Raglan, Lannon, Jones, & Schulkin, 2015; Shaw et al., 2014).

Socioeconomic Barriers

Many barriers exist that impact pregnant AI/AN women, including the following social determinants of health (SDoH): educational achievement, access to resources and services, and poverty. These factors, coupled with other risk factors, make a healthy

pregnancy and delivery challenging. It is well understood that mothers with low socioeconomic status (SES) are more likely to have poor birth outcomes than mothers with high SES. However, Nepomnyaschy discovered that no relationship exists between any indicator of SES, low birth weight (LBW), or small gestational age (SGA) for AI/AN (Nepomnyaschy, 2009). In other words, regardless of SES, AI/AN mothers do not have better birth outcomes. The study also showed that AI/AN mothers were more likely to be teen mothers, least likely to be married, and least likely to have grown up with both parents (Nepomnyaschy, 2009). In support of this, Alexander et al. found that AI/AN mothers were 59% more likely to be unmarried, 71% more likely to be living in urban areas, and less than 18 years old (Alexander et al., 2008). AI/AN mothers also had higher rates of LBW, preterm babies and infant mortality (Alexander et al., 2008). In both studies, even after adjustments for income and prenatal care, AI/ANs still had higher risks of adverse birth outcomes (Alexander et al., 2008; Nepomnyaschy, 2009). This suggests that not only are resource barriers a hindrance to health disparities, but also barriers that keep these populations from accessing the resources. Figure 1 shows various SDoH, post-colonial oppression, and historical trauma have impacted the current health of AI/ANs.

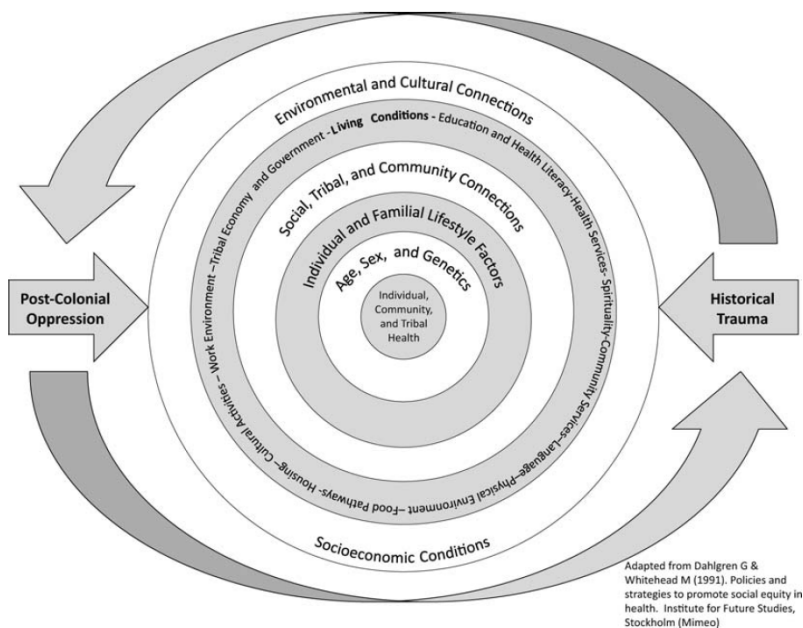


Figure 1. Impacts on the Current Health of AI/ANs

Reprinted with permission from (Mitchell, 2012)

Underfunded Systems of Care for AI/AN

While prenatal care is important for healthy pregnancies, accessibility and the quality of that care should also be considered. Access to care is of particular concern because it is a known risk factor for preterm birth (Raglan et al., 2015). Furthermore, access to prenatal care is critical considering the high numbers of co-morbidities that influence pregnancy in AI/AN women (which will be discussed in greater detail later in this chapter) (Raglan et al., 2015). Barriers to care may include: lack of adequate insurance coverage, perceived racial discrimination, mistrust of providers, and geographical location (Raglan et al., 2015). There is evidence that quality of care may play a greater role than the amount of care. Massey and colleagues' evaluation of CenteringPregnancy, which has a relationship-centered approach and provides more time

with providers, found improvements in maternal psychosocial function, gestational age, breastfeeding initiation, and approval of care (Massey, Rising, & Ickovics, 2006). Similar findings were also reported by Ricketts et al. who found enhanced prenatal care in high-risk women was useful in resolving risk factors (Ricketts, Murray, & Schwalberg, 2005).

In an effort to respond to some of the historical trauma, broken governmental treaties, and access to quality care, IHS was formed. IHS is responsible for providing health care services to the AI/AN population; however, those federal programs are gravely underfunded. Unfortunately, this means that not all AI/ANs are receiving care. Sixty percent less per capita funding is spent on AI/AN health care verses the average American (Goodkind et al., 2010). More disturbing, the government spends less money on AI/ANs when compared to other individuals who are imprisoned, receive Medicaid benefits, are veterans, or are military workers (Goodkind et al., 2010). In 2003, the per-capita funding of IHS was \$1,805 for AI/AN, \$3,489 for the Bureau of Prisons, \$3,501 for Medicaid, and \$5,019 for veterans (Warne, 2006). Oddly enough, according to treaties with the government, AI/AN is the only population in the United States that, as an enrolled member of a federally recognized tribe, is born with a legal right to health care services (Warne, 2006).

Compared to other groups, in its provision of care, the US government is insufficient when it comes to AI/AN populations. IHS provides primary care services free of charge and restricted free specialty services through contracts with private providers (Cunningham, 1993). Eligibility for IHS is dependent on affiliation with a federally recognized tribe and residence in or near an AI/AN community, where the IHS services

would be located (Cunningham, 1993). Unfortunately, services offered vary across tribes, IHS sites may be inaccessible due to geographic location, and funding is often limited.

While IHS services roughly 1.5 million individuals, this does not cover the 4.1 million individuals who report themselves as being AI/AN to the Census Bureau (Zuckerman, Haley, Roubideaux, & Lillie-Blanton, 2004). Part of the conundrum with this is that some of these self-identified AI/ANs are not members or descendants of recognized tribes, thereby rendering them ineligible for IHS (Zuckerman et al., 2004). Furthermore, most AI/ANs (55%-70%) live in urban areas, which are not near their home reservations, again making them ineligible for IHS care (Brown, Ojeda, Wyn, & Levan, 2000). Placements in urban areas are often the outcome of legalized segregation and discrimination, including mortgage lending and housing policies, by the federal government, which make it difficult for AI/AN to move up in SES (Smedley, Stith, & Nelson, 2003). Since they are unable to access IHS, they are forced to rely on other resources for health coverage or become uninsured (Zuckerman et al., 2004). Additionally, reimbursements received by IHS from Medicare, Medicaid, and private insurance companies allow IHS to supplement funds from the government for the delivery of health services (Cunningham, 1993). With such constraints, it is not surprising that IHS is often inadequate and alternative options for care are necessary.

Regrettably, other options for care can be difficult as these non-registered, urban AI/AN individuals are usually poor, have chronic conditions, and live in remote areas where there are little to no private providers (Cunningham, 1993). Zuckerman et al., showed that AI/ANs had only 49% health coverage through their employee (23% of low

income AI/ANs), compared to 83% of Whites (56% of low income Whites) (Zuckerman et al., 2004). They also found that 16% of AI/AN had only IHS coverage (23% of low income AI/ANs), while 19% were completely uninsured (25% of low income AI/ANs) (Zuckerman et al., 2004). This accounts for a 35% uninsured rate, nearly three times the 12% rate for Whites. Of that 35%, only about half of them even had access to IHS care (Zuckerman et al., 2004). Another issue with finding alternative care is that while AI/AN's SES may qualify them for welfare benefits (i.e. TANF), when they identify themselves as AI/AN, they are often rejected, since welfare offices may assume they are receiving sufficient services from IHS (Brown et al., 2000). While IHS is an important resource for connecting AI/ANs with health care, it is not comprehensive enough to meet all their needs.

Distrust in the Health Care Field

One reason for mistrust of Western medicine relates to the historic overt and subtle pressure to sterilize AI/AN women in the 1970s. More than 3,000 AI/AN women between the ages of 15-44 years were coerced into sterilization in a mere three years, 1973-1976, by IHS in the areas of Albuquerque, Aberdeen, Oklahoma City, and Phoenix (Cackler, Shapiro, & Lahiff, 2015; Pacheco et al., 2013). On one Navaho reservation from 1972-1978, sterilization procedure rates increased from 15.1% to 30.7% (Rutecki, 2010). The justification for these procedures was that scientists and doctors had deemed certain women unworthy of reproduction (Shreffler, McQuillan, Greil, & Johnson, 2015). Medical staff and government workers felt the individual woman or our society would be better off limiting AI/AN offspring, as they were typically impoverished, engaged in

risky behaviors, and had poor living conditions (Cackler et al., 2015). Contrarily, White women typically had more money and were better educated; therefore, AI/AN women were sterilized to help lower the number of low-income, minority families (Lawrence, 2000). An investigation by the General Accounting Office (GAO) revealed a lack of consent documentation and AI/AN women reported that they either did not give consent or were forced to consent (Pacheco et al., 2013). Mothers stated that they were told they would lose custody of their children, access to IHS health care, and/or access to the Bureau of Indian Affairs benefits if they were not sterilized (Pacheco et al., 2013).

It is also noteworthy to mention that these unethical procedures occurred after the exposure of the Tuskegee Syphilis Study, which set precedence for informed consent, and that AI/AN have yet to receive a formal apology (Hodge, 2013). The Tuskegee Syphilis Study was a federally funded study that began in 1932 in Macon County, Alabama (Daughtery-Brownrigg, 2012). This study was designed to address the epidemic of syphilis, a disease, if left untreated, leads to neurosyphilis, an infection of the central nervous system, which can cause death (Daughtery-Brownrigg, 2012). The participants of the study were poor Black sharecroppers. Although, they were part of a study that only tested for complications of syphilis and not treatment of syphilis, they were never informed of this (Daughtery-Brownrigg, 2012). Instead, they were told they were being treated for “bad blood” (McKenzie, 2014, p. 16), which meant anything from anemia to syphilis (McKenzie, 2014). At the study’s inception there was no official standard of care (only arsenic and mercury injections), no protocol for the experiment, and there was no cure (Daughtery-Brownrigg, 2012). When it was finally discovered that penicillin could

cure syphilis, the men were not informed, not cured, and oftentimes prevented from receiving penicillin from outside facilities (McKenzie, 2014). Instead, the men were lied to and told that they would receive a cure if and when one became available.

Additionally, the sharecroppers were never given a chance to terminate their involvement in the experiment (McKenzie, 2014). Due to racial tensions and concerns over the ethics of the experiment, an investigation was conducted, and ultimately the study was discontinued, in 1972 (Daughtery-Brownrigg, 2012).

Thankfully, the Tuskegee Syphilis Study led to the priority of protection for human rights and their involvement in research studies. The Declaration of Helsinki, The Belmont Report, informed consent, and Institutional Review Boards (IRBs) are some of the best examples. The Declaration of Helsinki was developed by The World Medical Association (WMA) in 1964 and is mostly for physicians, as it is a statement of ethical principles for medical research involving human subjects (The World Health Organization, 2001). However, the Declaration of Helsinki also encourages individuals involved in medical research using human subjects to embrace the same principles (The World Health Organization, 2001). The Belmont Report was created by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in 1979. It is a statement of basic ethical guidelines to aid in resolving any ethical concerns around the conduct of research with human subjects (Department of Health Education, 2014). Both the Declaration of Helsinki and the Belmont Report consider informed consent one of their basic principles. Informed consent allows an individual to agree to a study or treatment with the full understanding of how it affects

his/her health and life, including the dangers and disadvantages (Drazen, Solomon, & Greene, 2013). It also involves a signed consent form that gives permission for the study to be conducted, along with procedure outlines (Drazen et al., 2013). In 1981 the Department of Health and Human Services (DHHS) established a set of rules based on the Belmont Report and in 1991 the core set of those rules (the Common Rule) was adopted by most of the federal departments and agencies that sponsor human-subjects research (Rice, 2008). One of the main pieces of the Common Rule, in addition to informed consent, requires that IRBs be conducted. IRBs ensure that studies are being conducted with respect to human rights (Abbott & Grady, 2011). They are specifically designed to protect human research subjects and can approve, require changes for approval, or disapprove research (Abbott & Grady, 2011).

Unfortunately, the generational effects of the trauma of sterilization are still being felt today, as AI/AN women are less likely to receive prenatal care, particularly during the first trimester (Alexander et al., 2008). Many AI/AN women simply do not trust health care physicians or their facilities and only attend for routine treatment, if at all (Lawrence, 2000). Other lasting effects of the trauma of sterilization include: a loss of respect from other tribal communities, a loss of political power, and substance abuse. A high number of sterilizations within a tribe are often viewed as the inability of a tribe to protect its women, which results in a lack of reverence from other tribes (Lawrence, 2000). When large percentages of AI/AN women lost their ability to reproduce it also limited the community population. Being able to procreate is important to AI/AN women, as it is a way to increase tribal survival and restore culture, which is a reason they often

reject birth control (Lawrence, 2000). A lack of reproduction in women also meant that the tribe was restricted by its number of elected tribal officials, since population numbers denote tribal representatives (Lawrence, 2000). Finally, as a coping mechanism (which will be discussed in greater detail in a later section of this chapter), to handle the guilt and shame of the sterilizations, many AI/AN women turned to alcohol and drug abuse.

Shreffler et al. further recognized that surgical sterilization rates vary sizably by race, with it being more common among AI/AN women of reproductive age at 42% (Shreffler et al., 2015). It is also more common in ethnic populations where there are higher occurrences of lower income and lower educational levels (Shreffler et al., 2015). AI/AN women are twice as likely as White women to have been sterilized (Lawrence, 2000). Sadly, most of these were *forced sterilizations*, surgeries performed without the consent of the mother, as evidenced by the fact that 60% of AI/AN women stated they still wanted to have children after the procedure (Shreffler et al., 2015). In addition, 65% were under the age of 30 (Shreffler et al., 2015). As a result of sterilization, half of the AI/AN women reported subsequent reproductive/health issues (Shreffler et al., 2015).

Another reason medical interventions are often not accepted by AI/AN populations is due to their strong desire for culturally specific care, that focuses on family systems and natural and spiritual healing (Raglan et al., 2015). AI/AN populations have certain generational traditions around medicine and healing which should be considered and, if possible, incorporated into their care. AI/AN culture emphasizes a connection between medicine and religion and thus traditional healers are often used as link between a person's spirituality and their physical health (Johnston, 2004). Many AI/AN believe

that inherited diseases are the result of immoral behavior or even evil spirits; therefore, a traditional healer can help correct these wrongs and restore health (Johnston, 2004). The treatment of Western medicine may be rejected because it is often viewed as an obstruction to the lesson or message the AI/AN patient needs to learn (Broome & Broome, 2007). Health care providers must learn to incorporate both traditional and Western medicine into AI/AN care in order to provide a more holistic approach to treatment (Broome & Broome, 2007). This means culturally competent care, along with traditional healing practices must be maintained. Cultural competency, is defined as understanding and considering culture, economic position, education status, and health literacy level in order to communicate at a point that the patient recognizes (Noe, et al., 2014). The provider must also attempt to involve the family and tribal community, seeing them as part of the healing process as well. Demonstrating a respect and understanding of these concepts will allow providers to build trust with AI/AN and become an active proponent in AI/AN health care.

Noe et al. acknowledged that while a large percentage of AI/AN are serviced where they live, very few (15%) have access to service centers that provide traditional healing services (Noe et al., 2014). They go on to show that only 30% of AI/ANs feel that their facilities provide programs to support their needs (Noe et al., 2014). However, when asked how important it is that a facility meet their needs, on a scale of 1-5, with 5 being the most important, the average score was 4.45 (Noe et al., 2014). This cultural insensitivity further validates the need to create and implement native-specific provisions of care.

Early prenatal care is critical as it can identify factors that may put mother and baby at risk and when these factors are identified, it allows time for interventions to improve birth outcomes (Shi, Stevens, Wulu, Politzer, & Xu, 2004). Not receiving prenatal care, especially during the first trimester, can lead to pregnancy complications, preterm birth, LBW, and infant mortality (Denny, Floyd, Green, & Hayes, 2012; Dillard & Orlun-Volkheimer, 2014; Raglan et al., 2015). Delayed prenatal care can be a result of lack of access to care, but for AI/AN mothers it is also a result of mistrust of non-native people, particularly the government, and in distrust of Western doctrine (Raglan et al., 2015).

Pre-existing Conditions and Co-Morbid Pregnancy Related Conditions

Pregnancy related chronic conditions, such as gestational diabetes, can be dangerous for mother and baby, leading to difficult deliveries and stillbirth, as well as increased risk for type 2 diabetes and cardiovascular disease later in life (Ali et al., 2013). These kinds of chronic conditions are often more pronounced in minority populations, particularly AI/AN (Amparo, Farr, & Dietz, 2011). However, in AI/AN populations, co-morbidities are usually coupled with pre-existing conditions that can make pregnancy even more problematic. For example, AI/ANs of reproductive age are more likely to be obese, smoke, drink, and/or have mental stresses (Amparo et al., 2011). In support of this, Amparo and colleagues examined chronic diseases in AI/AN women and found that 41% of them have three or more chronic diseases or risky health behaviors, more than any other racial/ethnic minority group studied (Amparo et al., 2011). Similar findings were reported by Denny et al. who found that AI/AN women had the highest prevalence of

drinking, smoking, diabetes, and recurrent mental distress (Denny et al., 2012).

Furthermore, AI/AN reported the highest prevalence (34.4%) of multiple risky maternal behaviors (two or more) (Denny et al., 2012).

Realizing the connection between these comorbidities and historical trauma is vital for understanding the impact that they have on the current health status of AI/AN. Diet is one example, which if uncontrolled, can lead to obesity and even diabetes. Before AI/AN native lands were taken and colonized, food and drink was obtained through the resources on their land (Mitchell, 2012). These foods and drinks not only provided nutrition, but also cultural and social benefits to the family and community. However, as AI/AN were stripped of their lands and forced to move, there was a loss of traditional food practices as well as an increase in food insecurity (Mitchell, 2012). Consequently, this led to the establishment of government-sponsored food programs. These programs helped to resolve food scarcity issues, but they also introduced foods that contained more fat and calories and less fiber, than traditional AI/AN foods (Mitchell, 2012).

Another example is mental stress, which for such traumatic events experienced by AI/AN, can lead to PTSD. PTSD can also lead to elevated rates of substance abuse in AI/ANs (Gray & Nye, 2001). In fact, depression and substance abuse are the two most frequent comorbid diagnoses with PTSD (Willmon-Haque & BigFoot, 2008). Gutierrez et al. showed that for adults in treatment for substance abuse at a southwest AI/AN tribe, 84% of the women and 56.5% of the men reported a history of trauma (Gutierrez, Russo, & Urbanski, 1994). By comparison, Robin et al. showed that for a group of southwestern AI/ANs, not chosen for trauma history, 21.9% of them exhibited signs of PTSD, which is

analogous to survivors of mass shootings and combat (Robin, Chester, Rasmussen, Jaranson, & Goldman, 2006). These studies demonstrate that the high levels of mental stress, including PTSD, in AI/ANs are most related to traumatic exposure.

The current poor health status of AI/AN can also be linked to their risky behaviors, including: diet, misuse of drugs and alcohol, and sexual activity. In terms of diet, it has already been discussed that AI/ANs consume foods high in fat and calories. When compared with Whites, AI/ANs have a higher prevalence of obesity, with men being 33.9% to 23.3% and women being 35.5% to 21.0% (Cobb, Espey, & King, 2014). In both diabetes and high blood pressure, chronic diseases often the outcome of obesity, AI/ANs had higher occurrences, with diabetes being twice as more likely (Cobb et al., 2014). It should be noted that while AI/AN tend to consume less overall rates of alcohol, they have the highest rates of heavy drinking, binge drinking five or more times a month (Tann, Yabiku, Okamoto, & Yanow, 2007). This is reflective in research showing higher rates of binge drinking in AI/AN and the likelihood of drunk driving (Cobb et al., 2014). When compared to Whites, AI/ANs are more likely to be current smokers and like less likely to have never smoked (Cobb et al., 2014). These studies emphasize the importance of understanding how lifestyle changes can improve health conditions for AI/AN, in order to implement targeted interventions, reverse chronic disease, and prevent poor pregnancy outcomes in AI/AN women.

Health Behaviors as a Coping Mechanism

As it has been demonstrated in this literature review, AI/AN populations have been exposed to repeated historical trauma and continue to experience these effects.

Whitbeck et al. have shown that anger, anxiety, and depression are linked to emotional distress (Whitbeck, Adams, Hoyt, & Chen, 2004). Furthermore, these issues have been linked to current deleterious health issues such as cardiovascular disease and diabetes (Whitbeck et al., 2004). AI/ANs of reproductive age face a variety of normal stressors, including peer pressure, violence, and premature sexual activity, but they also face additional concerns around poverty, high school dropout, and suicide (Baldwin, Brown, Wayment, Nez, & Brelsford, 2011). The aforementioned traumas of racism, poverty, and death experienced by AI/AN has led to aggregated trans-generational stressors, which culturally and emotionally break down AI/ANs (Gray & Nye, 2001). This puts AI/ANs at an increased risk for chronic distress as a result of cultural trauma and violence (Baldwin et al., 2011). Consequently, this often leads to high rates of substance abuse, alcohol use, and risky sexual behaviors as a coping mechanism (Weiss et al., 2015). Frank & Lester offered support by showing that AI/ANs of reproductive age engage in risky behaviors more often overall than Whites and Blacks of reproductive age (Frank & Lester, 2002). Additional research supports the notion that trauma affects sexual decision-making, with a 20% likelihood of AI/AN women who were exposed to trauma engaging in casual sex with multiple partners (Willmon-Haque & BigFoot, 2008). This is compared to a 9% likelihood of women who experienced no trauma.

This research offers support as to why AI/AN mothers frequently engage in risky health behaviors. Evidence has illustrated in this literature review that AI/AN mothers do not get adequate prenatal care and/or that they use alcohol and smoke during pregnancy (Alexander et al., 2008; Baldwin et al., 2002; Johansson et al., 2013). But, why?

Researchers may inadvertently blame AI/AN mothers for their difficult pregnancies and poor birth outcomes. However, these risky health behaviors are AI/ANs way of coping with the stress they have endured as a result of trauma, alienation of culture, a lack of health equity, distrust in the healthcare field, poverty, and genocide. *Coping* is defined as “constantly changing cognitive and behavioral efforts to manage specific external and/or internal demands that are appraised as taxing” (Lazarus & Folkman, 1984, p. 8).

Unfortunately, not all coping mechanisms are positive or healthy. But, it is not uncommon, many ethnic populations often engage in risky health behaviors as a way to “escape” problems (Martin, Tuch, & Roman, 2003, p. 10). Avoiding blaming the victim and creating interventions that demonstrate cultural competency, address stressful life events, and offer social support are critical strategies to keep in mind when designing interventions for AI/AN women of reproductive age.

Conceptual Framework

The initial work by Lu and Halfon (2003) set a foundational tone for life course; here, racial-ethnic disparities in birth outcomes are assessed from a longitudinal and integrative view that says a woman’s health and development are a product of her lifetime. Prior to this work, one of the most widely accepted explanations for racial disparities was SES, as related to income, occupation, and educational achievement. However, after controlling for differences in SES, disparities still persist, which shows that SES cannot fully justify racial disparities in birth outcomes (Lu & Halfon, 2003). Ultimately, the strength of a woman’s reproductive health is influenced by her trajectory

as expressed by early life experiences and modified by aggregate allostatic load over her lifetime (Lu & Halfon, 2003).

The life course framework combines an emphasis on health equity and SDoH, along with understanding how environmental factors relate (Fine & Kotelchuck, 2010). It provides a multidimensional understanding of how health changes over a person's lifetime and across generations (Fine & Kotelchuck, 2010). There is much evidence to support the idea that while genes are the foundation of an individual and help to determine health and disease, environmental influences, beginning in utero and continuing across the life span, play an important, perhaps even greater, role (Bernstein & Merkatz, 2010). Rather than concentrating on differences in health patterns one disease at a time, the life course framework seeks comprehensive social, economic, and environmental factors as a primary cause of persistent inequalities in health for a wide range of disease across population groups (Fine & Kotelchuck, 2010). Figure 2 illustrates how biological, social, and psychological factors impact reproductive and gynecological health.

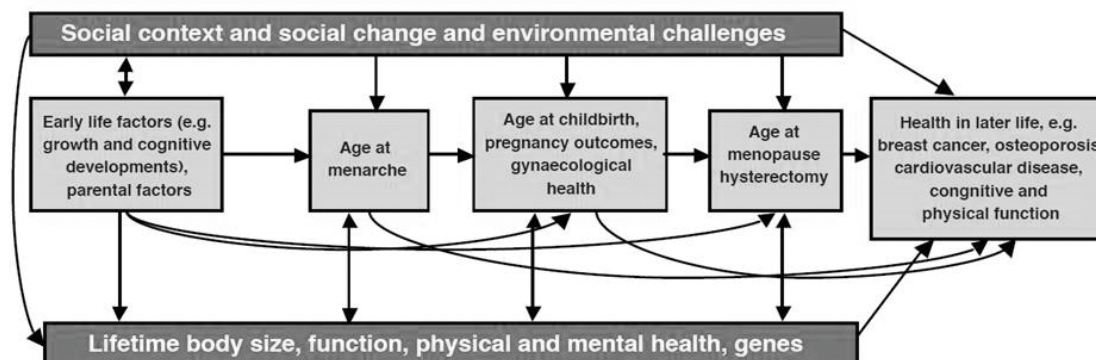


Figure 2. Factors That Impact Reproductive and Gynecological Health

Reprinted with permission from (Stephenson et al., 2011)

The life course framework posits that exposures in early life (as early as fetal development) can impact health through adulthood; in other words, health development begins in early conception and lasts throughout an individual's lifetime (Halfon, Larson, Lu, Tullis, & Russ, 2014). A myriad of inequalities, including racial and ethnic disparities, are influenced by life course development. Life course presents an understanding for how different exposures affect two lives at once. Using the life course framework to assess how maternal health during, and following pregnancy influences the future health of mother and the trajectory of the infant is key to achieving positive maternal and infant health outcomes (Pies & Kotelchuck, 2014). For this study, the key life course components that are the focus are: 1) the representation of health development as functional trajectories; 2) the role and developmental influences of risk and protective factors; and 3) multiple determinants of health outcomes.

The Representation of Health Development as Functional Trajectories

A trajectory illustrates changes in health over time. They are best represented by the end results of multiple risk and protective factors, functioning through latent, cumulative, and pathway mechanisms as well as various SDoH (Fine & Kotelchuck, 2010; Russ, Larson, Tullis, & Halfon, 2014). Thus, it is important to better understand the influence that different exposures and experiences have on future health. For example, a single stressor may have a small impact on a person's positive trajectory; however, the cumulative impact of several stressors could have a significant impact on health and development (Fine & Kotelchuck, 2010). Life course is reflective of a continuum of experiences, exposures, and interactions. Life course is not only an understanding of

ways to prevent disease, but it also, provides a positive state of wellbeing (Russ et al., 2014). Therefore, interventions that help to achieve positive health outcomes early in life might influence later health status. This consideration will also allow for the development of interventions that provide protective factors against negative effects. Figure 3 shows how social advantages and disadvantages over lifetimes and generations can affect health.

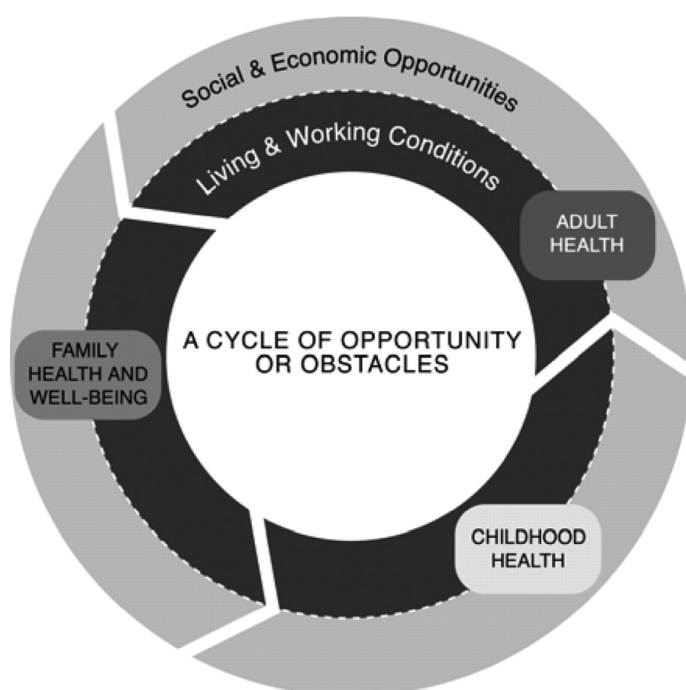


Figure 3. Advantages and Disadvantages vs. Health

Reprinted with permission from (Braveman & Barclay, 2009)

The Role and Developmental Influence of Risk and Protective Factors

Most studies on disease focus on a single or small group of risk factors; however, various risk and protective factors operate continuously throughout the life course shifting in both positive and negative directions. Life course suggests that multiple risk and protective factors lessen or exacerbate the impact of earlier risks (Russ et al., 2014).

For example, poor AI/AN mothers are more likely to live in urban, unsafe

neighborhoods, eat less healthy food options, and get less exercise. These are risk factors that make it harder for AI/AN mothers to reach their full potential. Contrarily, protective factors make enhance health and support healthy development. An example would be access and receipt of quality medical care, but also financial security or a having nurturing family.

Some effects are latent, meaning an experience at one point in the life course can impact an outcome years or decades later, regardless of what happens in between (Russ et al., 2014). Other factors are cumulative, meaning that multiple experiences work together to impact an outcomes (Russ et al., 2014). Even still there are pathway experiences, where an experience at point in the life course can increase the likelihood of other experiences that will impact outcomes (Russ et al., 2014). For instance, a poor education early in life increases the likelihood of not obtaining a high-level job in mid-life, which may result in financial difficulties or poverty in later-life. Figure 4 depicts how risk factors and protective factors affect a woman's reproductive health and development as well as add to inequalities in birth outcomes.

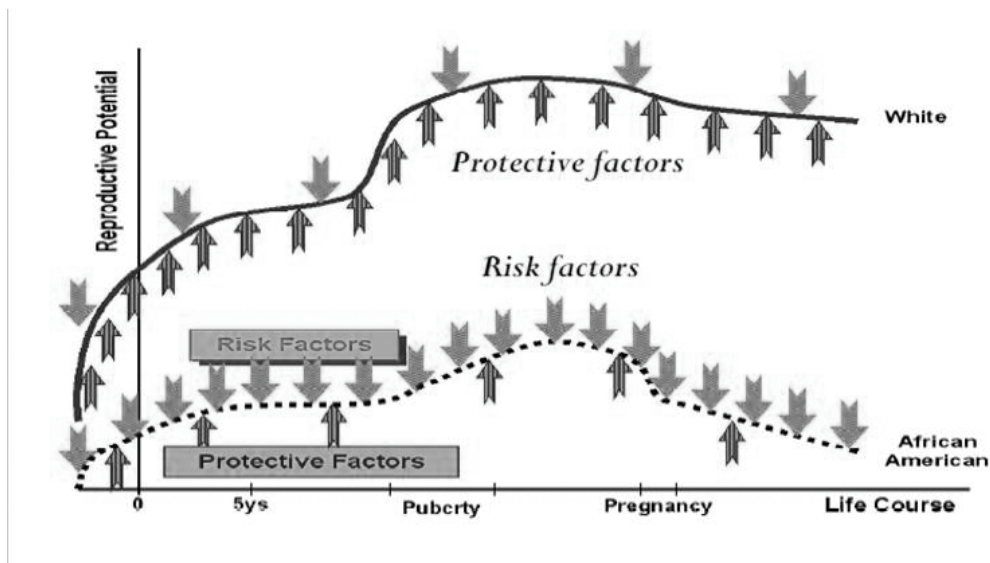


Figure 4. Risk Factors and Protective Factors vs. Health and Development

Reprinted with permission from (Contra Costa Health Services' Family Maternal and Child Health Programs, 2011)

It has been thoroughly demonstrated in this literature review that the historical trauma experienced by AI/ANs is transgenerational, meaning current generations are still suffering the effects. This is also related to risk and protective factors. Research shows that LBW mothers are more likely than non-LBW mothers to give birth to LBW babies (Coutinho, David, & Collins, 1997). Yao et al. supported this with their finding that regular prenatal stress across multiple generations increases hypothalamic-pituitary-adrenal (HPA) responses, which increases negative birth outcomes (Yao et al., 2014). This suggests that the mother's experiences and exposures have an effect on her reproductive health and therefore her baby's health. In other words, the generational

effect of trauma and other adverse SDoH (i.e., poverty) are likely to be mirrored by the AI/AN mother's poor health status and poor birth outcomes such as preterm birth or LBW. These are clear indications that interventions focusing on single causes of poor birth outcomes are ill equipped to deal with the multiple cause multiple outcome models that are unique to AI/AN women.

Multiple Determinants of Health Outcomes

As previously discussed, AI/AN women often have comorbidities that complicate pregnancy and threaten the health of baby. Examining society, it is easy to see that from the most privileged to the least privileged groups, health and developmental outcomes deteriorate. Life course acknowledges the effect that social circumstances have on health outcomes (Russ et al., 2014). Socioeconomic and racial inequalities negatively affect the middle and low income class groups. This not only refers to SES, but also, hierarchies such as neighborhood, family, and workplace. Our country spends more money on health care than any other country, yet our healthiness rank is lower than other affluent countries and even a few developing countries (Braveman & Barclay, 2009). This may be because we fail to consider the factors that keep people from making or help people to make healthy decisions. While people still have a responsibility for their health, life course recognizes that removing such socioeconomic barriers can help improve health status (Braveman & Barclay, 2009). Figure 5 shows how some social groups are more likely to experience poor health based on living conditions across lifetimes and generations.

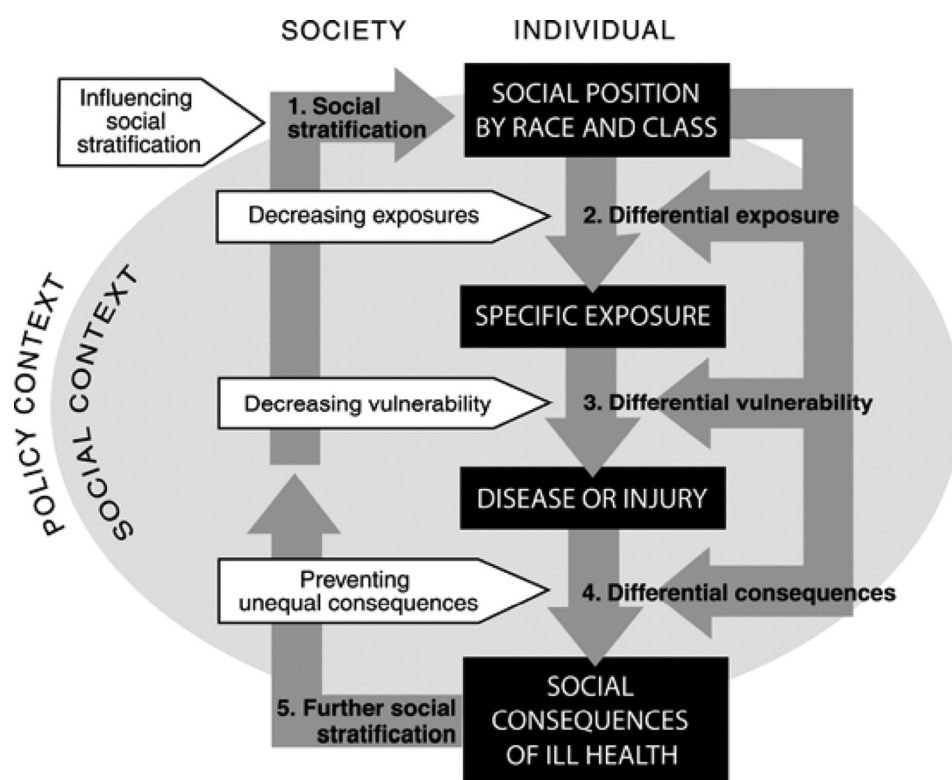


Figure 5. Social Groups and Living Conditions

Reprinted with permission from (Braveman & Barclay, 2009)

Recent evidence suggests that interventions aimed at supporting early child development, like those for mothers in early pregnancy, are necessary to reduce health and social inequalities (Russ et al., 2014). Since disadvantages (or advantages) start at birth and continue throughout life, mothers should begin pregnancy in a healthy environment, taking actions to decrease health disparities (Morrison, Pikhart, Ruiz, & Goldblatt, 2014). This needs to be a continuum of care, lasting throughout pregnancy and into the first years of the child's life (i.e., breastfeeding) (Marmot, Friel, Bell, Houweling, & Taylor, 2008). Interventions that address nutrition, good health behaviors, and provide social support to mothers are likely to have high emotional, physical, and cognitive gains

in infants (Morrison et al., 2014). These early interventions are more favorable over programs that target young adults from disadvantaged environments, as early interventions help to reduce the transgenerational effect of health disparities. Furthermore, research shows that while preschool education programs have positive effects on the social trajectories of underprivileged children, their life chances are still considerably worse than those advantaged children without targeted support (Morrison et al., 2014).

Application of Life Course

The mother's preconception health impacts the in utero environment for the pregnancy, which directly affects the baby's long term health, predisposing the child to chronic diseases (Bernstein & Merkatz, 2010). Similarly, the health status of a woman going into pregnancy will determine her health status during and after pregnancy (Bernstein & Merkatz, 2010). For example, an obese woman has an increased risk of developing gestational diabetes. Not only is a mother's health status during pregnancy influenced by its outcome, but it is also indicative of a mother's long-term health status (Bernstein & Merkatz, 2010).

The life course is an important framework for reproductive health because it recognizes the importance of early childhood health and development on subsequent outcome in adolescence and adulthood (Christiansen, Gibbs, & Chandra-Mouli, 2012). Furthermore, it not only considers adult health and illness during previous stages in life, but also the economic and social factors across the life course that influence health (Braveman, 2014). In order to prevent pregnant related mortality and morbidity,

especially in AI/AN families, interventions should be provided early in pregnancy, particularly during the first trimester or, if possible, prior to pregnancy (Christiansen et al., 2012).

Interventions help further the field of maternal and child research by indicating what works and what does not in disease prevention and health promotion. When designing interventions for AI/AN women of reproductive age it is important to address SES. AI/ANs who are unemployed, have disabilities, lack higher levels of education, and/or live in poverty face higher rates of poor health status and are more likely to give birth to disadvantaged babies (Coutinho et al., 1997). Interventions also need to be culturally appropriate, as was discussed in the Distrust in the Health Field section, so that AI/AN will be more open to Western methods of health care. Another vital consideration is for common co-morbidities that AI/AN women have that can complicate pregnancy, as was demonstrated in the Pre-existing Conditions or Co-Morbid Pregnancy-Related Conditions section. Finally, it might be necessary to use different approaches for those AI/AN women on reservations (who are registered with tribes) compared to urban AI/AN women who do not live on the reservation (and whom are likely to be non-registered), as access to care and needs may be different (Rutman, Park, Castor, Taualii, & Forquera, 2008).

The life course framework allows questions about time to be addressed: what is the best window for intervention on a particular outcome and is there a relationship between early and later interventions for a specific outcome (Lu, 2014). Two of the main points of the life course theory is to intervene when it counts the most and to do what

matters the most (Lu, 2014). When interventions are the most impactful, attention is given to early and preemptive care, for example improving women's health during the first trimester of pregnancy to prevent poor birth outcomes (Lu, 2014). When interventions matter the most, attention is given to outside socioeconomic factors, such as poverty, racism, and education that also affect health disparities (Lu, 2014). Considering the life course framework has major implications for interventions that target AI/AN women during the early stages of pregnancy and immediately postpartum.

Health Outcomes

Infant Mortality Rates

Pregnancy outcomes including LBW, preterm birth, and perinatal and neonatal mortality, which are often the result of risky maternal health behaviors, are public health concerns for women and children. Shah and associates demonstrated that these influences are often more prominent in minority populations, particularly the AI/AN community (Shah, Zao, Al-Wassia, & Shah, 2011). While overall IMRs have been decreasing, rates continue to remain high in AI/AN populations and disparities between AI/AN and Whites. AI/ANs are currently the ethnic group with the highest prevalence of several chronic health conditions and health-risk behaviors (Unger et al., 2008). Johansson and colleagues showed that from 1995-1999 and 2000-2004, AI/AN experienced significant rates of infant mortality (Johansson et al., 2013). Conversely, during this same time period, Whites experienced significant reductions in IMRs (Johansson et al., 2013). Wong et al. reported similar findings with IMRs being 914.3 for AI/AN and IMRs being 567.3 for Whites in the US from 1999-2009 (Wong et al., 2014). These high IMRs are

also linked to prenatal care. Grossman and colleagues defined inadequate prenatal care as those who started care in the third trimester (Grossman et al., 2002). Here, they found that more than 14% of AI/AN women met this criteria and that of those births, 5.7% of them were LBW babies and the IMR was 11.0 per 1,000 live births (Grossman et al., 2002). These statistics clearly demonstrate the disparity between Whites and AI/AN, which in the Grossman study, were all living in the same area. This means SDoH, like access to prenatal care, poverty, varying levels of education, and pregnancy comorbidities are likely responsible for the difference.

However, disparities between Whites and AI/ANs are not the only problems. Disparities between AI/ANs and other ethnic groups exist as well. Baldwin et al. demonstrated this in their study of singleton AI/AN births, in which the rate of inadequate patterns of prenatal care was 14.4% in urban AI/AN compared to African Americans, with 16.4% (Baldwin et al., 2002). IMRs were 5.4 per 1000 in urban AI/AN and 5.8 per 1000 in African Americans (Baldwin et al., 2002). Alexander et al. also corroborated such findings when comparing pregnancy outcomes of AI/ANs to Hispanics, finding the highest percentage of births that are very low birth weight, very preterm, and post-term belonging to AI/AN. In addition, IMRs for each category of birth weight and gestational age for AI/AN exceeded all other groups (Alexander et al., 2008).

Equitable access to prenatal care is vital for all women. Interventions to improve prenatal care must be designed so that they address the challenges specific to geographic areas as well as to the local AI/AN population (Baldwin et al., 2002). Since medical risk factors such as diabetes, renal disease, and obesity serve as comorbidities and are higher

in AI/ANs than other ethnic groups, interventions must be focused on AI/AN women that are at high risk for poor birth outcomes, due to multiple maternal risk factors (Raglan et al., 2015). AI/AN women are also more likely than other ethnic populations to experience a greater number of major stressors (i.e., domestic violence, psychological disorders, and substance abuse) prior to pregnancy and delivery (Goodkind, LaNoue, Lee, Freeland, & Freund, 2012). Thus, interventions that attempt to improve the well-being of AI/AN mothers may positively affect birth outcomes (Goodkind et al., 2012).

Prenatal care has become fairly standard in pregnancy, with over 90% of mothers receiving some care (Reichman, Corman, Noonan, & Schwartz-Soicher, 2010). However, timing and frequency of prenatal care should also be considered, as care in the first trimester and continuing throughout pregnancy, is associated with decreased risk of infant mortality, prematurity, and stillbirth (Partridge, Balayla, Holcroft, & Abenhaim, 2012). Interventions that promote prenatal care have also been shown to be successful at reducing drinking and smoking rates during pregnancy, since these behaviors are emphasized in prenatal care protocols (Reichman et al., 2010). Drinking during pregnancy can lead to various birth defects, developmental issues, (i.e., fetal alcohol syndrome), and even infant death (Krulwich, 2005). Personalized counseling sessions with educational information regarding alcohol risk to mother and baby have been shown to reduce consumption rates, as women better understand the benefits of not drinking and feel supported in quitting (Ingersoll, Ceperich, Hetteema, Farrell-Carnahan, & Penberthy, 2013). Smoking rates during pregnancy are highest in minority populations and have been linked to preterm birth and LBW, risk factors for infant death (Lawrence, Graber,

Mills, Meissner, & Warnecke, 2003; Wagijo, Sheikh, Duijts, & Been, 2017). However, interventions that focus on cultural strengths (i.e., family and community), spirituality, and stress-coping have been effective at reducing usage and/or helping pregnant women quit (Hanson & Jensen, 2015). This is due in part to the strength provided by family support and religious activity during difficult times (Hanson & Jensen, 2015). These types of interventions can also help reduce mental illness in pregnancy, as women with excess stress are more likely to drink or smoke during pregnancy (Watt et al., 2014). As has been thoroughly discussed, stress for AI/AN women is often a result of historical trauma or traumatic life events and socioeconomical disadvantage. These traumas are associated with poorer adulthood health, tobacco use and lung cancer (Hiratsuka, et al., 2017). However, interventions that utilize a community-based approach; are culturally aware; attempt to normalize the existence of traumatic events; strengthen patient resiliency; and create courteous patient-provider relationships are most effective in reducing stress in AI/AN women (Hiratsuka, et al., 2017).

Parental Competence

AI/AN women of reproductive age face many challenges when it comes to pregnancy. Almost half of AI/AN women become mothers in their teenage years and then go on to bear more than twice the amount of children as other women in the general population (Barlow et al., 2013). This coupled with that fact that AI/AN face higher rates of substance abuse and limited resources for and access to mental health services, puts AI/AN mothers at risk for adverse maternal outcomes and poor child rearing (Barlow et al., 2013). This also puts the children at higher risk for behavioral health problems.

Bearing this in mind, the concept of parental competence must be discussed, which has been defined in two parts, one by parental satisfaction, “the quality of affect associated with parenting” and two by efficacy, “the degree to which a parent feels competent and confident in handling child problems” (Johnston & Mash, 1989, p. 251). This is an important concept for this study because the role of parenthood is often stressful and this stress has been associated with parenting outcomes, child and maternal outcomes, the parent-child relationship, and family functioning. Ensuring that AI/AN mothers have parental competence helps to ensure that their babies will thrive.

Maternal mental health has important implications on parenting quality and child outcomes. There is strong evidence that shows that mothers who have poor parental competence, often exhibit a lack of sensitivity and controlling behavior patterns during interactions with their infant (Borghini et al., 2014; Feldman & Eidelman, 2006; Treyvaud et al, 2011). As mentioned, the stress and depression that may come with being a parent can prohibit the mother from being able to interpret the infants’ distress cues (Muzik et al., 2015). For the infant this leads to more behavioral problems, worse personal-social development, and other cognitive developmental issues (i.e. poor communication skills) (Borghini et al., 2014). Combined with the fact that mothers who are mentally ill are also likely to have other risk factors (i.e. poverty, inadequate resources or access to resources, limited social support, etc.), maternal psychology can weaken healthy child development (Muzik et al., 2015). It is important that interventions be friendly and strengths-based, multi-modal, offer some type of treatment for depression, trauma, and anxiety, while also focusing on parenting skills. Interventions

involving home-visiting programs or those using family system theories seem to be the most helpful, as they improve understanding of specific competences, promote parents' sensitivity and responsiveness toward the infant, provide counseling and education for the parents, and are long-term programs (Borghini et al., 2014; McDonough, 2005; Muzik et al., 2015).

In summary, interventions that focus on reducing multiple risky maternal health behaviors; work to increase access to prenatal care early in pregnancy; and support parental competence will promote positive birth outcomes in AI/AN women. Since I have demonstrated in this chapter why a systematic review of interventions is needed, in the next chapter I will discuss the best method for conducting this process.

Chapter 3: Research Method

Introduction

The purpose of this current study was to examine effective interventions targeting maternal risk behaviors among AI/AN women during pregnancy, and immediately postpartum, defined as up to 12 months post delivery. In this chapter I describe the systematic review methodology including the process for each phase of the study: (a) developing search strategies, (b) identifying and then screening a priori criteria, (c) establishing eligibility criteria, (d) assessing risk of bias and study quality, and (e) completing a meta-analysis.

The Walden University institutional review board (IRB) approved this study (IRB #08-22-17-0163660).

Systematic Review Methodology: Study Design

This study is a longitudinal retrospective systematic review, which utilizes a quantitative methodology. A *systematic review* is defined as “to collate all empirical evidence that fits pre-specified eligibility criteria to answer a specific research question. It uses explicit, systematic methods that are selected with a view to minimizing bias, thus providing more reliable findings from which conclusions can be drawn and decisions made.” (Higgins & Green, 2011, p. 147). Systematic reviews are a way of synthesizing existing knowledge and disseminating it in a manageable format that is then used to inform health care decisions (Haase, 2011). Systematic reviews also help plan future research agendas, and support the connection between best research evidence and ideal health care (Cook, Mulrow, & Haynes, 1997).

For this study, the lead researcher and primary investigator is myself. A secondary investigator, a colleague, was chosen to validate the results of the primary investigator's screening of a priori criteria. Two scientific advisors, both senior colleagues, provided guidance on methodology and helped to validate and verify the primary abstractor's process of each phase of the study. A group of 10 expert panelists, including the secondary investigator and senior scientific advisors was established to complete a risk of bias assessment. These panelists each reviewed a small group of the articles in addition to the primary investigator, who reviewed all articles. The panelist was chosen to help determine consensus of risk of bias judgment scores. The lead researcher, secondary investigator, and scientific advisors reviewed the risk of bias assessments from the expert panelists, and the lead researcher synthesized the results. The lead researcher will conduct a meta-analysis to determine the overall effect of interventions on the health of pregnant and postpartum AI/AN women.

Instrumentation/Measures

The methodology utilized in the study follows the PRISMA, excluding non applicable randomized control trial (RCT) requirements (i.e., providing a registered review protocol otherwise known as Protocol and registration section and an explanation on the source of funding for the systematic review otherwise known as Funding section). The original PRISMA Statement can be found in Appendix A.

Historically, since 1999, the systematic review reporting standard has been Cochrane Reviews, the highest standard in evidence based health care (The Cochrane Collaboration, 2015). However, Cochrane Reviews are primarily for RCTs/clinical trials.

Furthermore, the Cochrane Collaboration's finalized reporting standards for reviews, which provides authors with a list of criteria that are either required or highly recommended, includes the PRISMA Statement, which Cochrane has endorsed since 2009, when the PRISMA Statement was created (Higgins & Green, 2011).

What is now the PRISMA Statement began in 1987, when several authors examined more than 130 published articles for their quality of reporting and found that none met all mandatory scientific criteria (Moher et al., 2010). This led to the development of the quality of reporting of meta-analyses (QUOROM) in 1996. The QUOROM was a set of guidelines designed to focus on the reporting of meta-analyses of RCTs. In 2005, the QUOROM checklist and flow-diagram were revised and expanded. By 2009, the revision of these guidelines was renamed PRISMA to incorporate both systematic reviews and meta-analysis (Moher et al., 2010). In all journals, especially those that have endorsed QUOROM, the PRISMA Statement replaced QUOROM.

The PRISMA Statement is a 27-item checklist and four-phase flow diagram (discussed later in this chapter) that encompasses both systematic reviews and meta-analyses by helping authors improve the reporting of both. PRISMA can also be used as a basis for reporting systematic reviews of evaluations of interventions (Moher et al., 2010). The PRISMA Statement is used as a starting point for developing clinical practice guidelines and justification for further research. PRISMA can also be used to accurately and reliably summarize evidence relating to efficacy and safety of health care interventions (Moher et al., 2010). Finally, the PRISMA Statement is a way to ensure transparency and completeness in the reporting of systematic reviews. The checklist

includes items that are necessary for assessing interventions, and depending on the questions that are addressed, the items in the checklist may need to be modified (Liberati et al., 2009).

The required criteria for the PRISMA Statement includes seven main topics: *title*, *abstract*, *introduction*, *methods*, *results*, *discussion*, and *funding* (Moher et al., 2010). In order to properly follow the PRISMA Statement, each of these topics must be included or discussed in the systematic review. PRISMA defines each topic. As defined by PRISMA, the Title identifies the research as a systematic review and/or meta-analysis. The abstract provides a brief summary of the study. Within the Introduction, a rationale for the study in the context of what is known is provided, including objectives. The methods section details a review protocol, electronic search strategies; methodology for data extraction and validation, risk of bias assessment procedures, and meta-analysis (if appropriate). Results includes a flow diagram of the number of studies screened, those assessed for eligibility, and those included/excluded. In addition, data on risk of bias is described, as well as a presentation of meta-analysis outcomes. The discussion section summarizes the findings for each main outcome, describes the limitations of the study, and interprets the results with implications for future research. Finally, a list of sources of funding and the role of funders is provided in the funding section. A chart that depicts the adapted criteria used for this study is located in Table 1.

Table 1

PRISMA Statement vs Adapted Criteria

Selection/Topic	Item #	PRISMA	Primary Abstractor
Title			
Title	1	✓	✓
Abstract			
Abstract	2	✓	✓
Introduction			
Rationale	3	✓	✓
Objectives	4	✓	✓
Methods			
Protocol and registration ¹	5	✓	
Eligibility criteria	6	✓	✓
Information sources	7	✓	✓
Search	8	✓	✓
Study selection	9	✓	✓
Data collection process	10	✓	✓
Data items	11	✓	✓
Risk of bias in individual Studies	12	✓	✓
Summary measures	13	✓	✓
Synthesis of results	14	✓	✓
Risk of bias across studies	15	✓	✓
Additional analyses	16	✓	✓
Results			
Study selection	17	✓	✓
Study characteristics	18	✓	✓
Risk of bias within studies	19	✓	✓
Results of individual studies	20	✓	✓
Synthesis of results	21	✓	✓
Risk of bias across studies	22	✓	✓
Additional analysis	23	✓	✓
Discussion			
Summary of evidence	24	✓	✓
Limitations	25	✓	✓
Conclusions	26	✓	✓
Funding			
Funding	27	✓	

Note. This study is not a review of RCTs, so no protocol was registered regarding funding. Additionally, no funding was provided for this dissertation.

Data Collection Process

A literature review was conducted using a key word search. Multiple terms were searched including derivatives for race and pregnancy. Some examples of general terms searched were: Native American, Alaska Native, pregnant women, prenatal diagnosis, obstetrical, breastfeed, postpartum, and gestation. See Appendix B for a full listing of search terms. The time frame for the search was 1993-December 2015. Ten databases were searched: PubMed, Cochrane, Campbell Library, Embase, CINAHL, CAB Abstracts, Global Health, Agricola, World Cat, and Social Services Abstracts. See Table 2 for definitions of the databases.

Table 2

Database Search Names and Definitions

Database Name	Definition
PubMed	A service of the US National Library of Medicine that provides free access to MEDLINE, which contains articles on topics of medical, nursing, dental, and veterinary health care
Cochrane	Is a collection of high-quality, independent evidence used to inform healthcare decision-making. It hosts the Cochrane Database of Systematic Reviews (CDSR) which includes Cochrane reviews, protocols, and editorials.
Campbell Library	It hosts the Campbell Systematic Reviews, which is a peer-reviewed online monograph series of systematic reviews that summarizes the international research evidence on the effects of interventions in crime and justice, education, international development, and social welfare.
Embase	Excerpta Medica dataBASE; a biomedical and pharmacological databases of published literature, designed to support those in complying with the regulatory requirements of a licensed drug
CINAHL	Cumulative Index of Nursing and Allied Health Literature; the largest and most in-depth nursing research database
CAB Abstracts	The most thorough and extensive source of reference in the applied life sciences
Global Health	Covers all aspects of public health, both international and community levels, as well as other biomedical and life science fields
Agricola	AGRICultural OnLine Access; maintained by the US Dept of Agriculture and covers topics such as food and human nutrition; earth and environmental sciences; and agricultural engineering and technology
World Cat	A union catalog that itemizes the collections of 72,000 libraries in 170 countries and territories that participate in the Online Computer Library Center (OCLC) global cooperative
Social Services Abstracts	Covers current research focused on social work, human services, social welfare, social policy, and community development

Articles were selected if any of the search terms were included within the title, abstract, and/or body of the article. Various types of articles were searched including the following: peer-reviewed publications, theses, dissertations (both published and unpublished), and abstracts. From this search 2,664 articles were identified. Abstracted information was archived using EndNote 7.1.

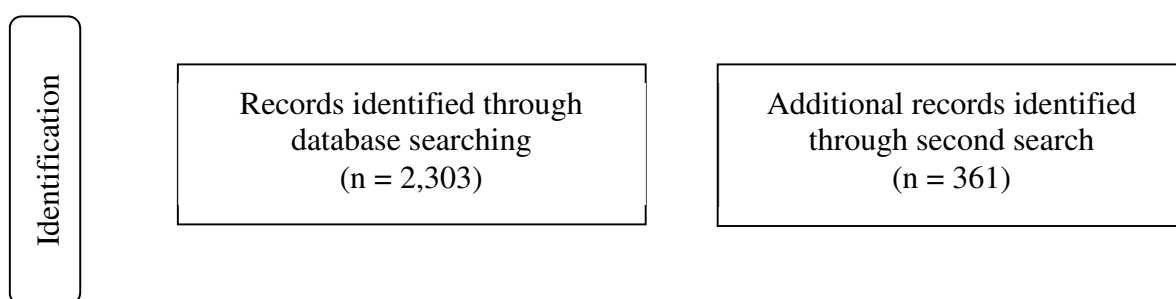


Figure 6. *PRISMA Flow Diagram of Identified Articles.*

All articles were considered for inclusion based on the a priori criteria developed using the PRISMA guidance (Table 3).

In order for an article to be included it had to meet certain criteria. Location was important because only articles in the United States were considered, all other countries were excluded. The focus was placed on the United States as most of the statistics reported and the primary investigator's understanding of AI/AN populations related to only the US. This also meant that if an article was not available in English, it was excluded. Next, full-length articles were essential because a complete, full-text article was necessary to complete screening (i.e., read the article to determine if other inclusion categories were met). Any incomplete articles were excluded, specifically abstracts from poster presentations, or incomplete theses, and dissertations. The time frame was set from

1993-2015, and due to availability issues, no articles prior to this date were considered. The target population for the study focused on AI/AN women of reproductive age, pregnant, and up to 12 months postpartum. If these women were not the topic of the article (i.e., an article about zoology, genetics, or archeology) or the article had no data analysis, did not separately identify AI/AN women's results as opposed to including their results in an "other" category grouped with other ethnicities, the article was excluded. Study design was a necessary category, as no articles that were purely descriptive or qualitative in nature were included. This included many examples such as narratives, screenings, intervention methods (i.e., published guidance), and studies that calculated risk. For a complete list of excluded study designs, refer to Table 3. Lastly, validation articles were included since they most often focused on the effectiveness of a tool that could be used in an intervention. Articles were then catalogued in an Excel spreadsheet, based on the inclusion and exclusion criteria in the a priori criteria (Table 3).

Table 3

A Priori Criteria

A Priori Criteria	
Inclusion	Exclusion
1. Location (target population of the article is in the United States)	1. Articles that are located outside of the US
2. Full-length articles (access to the entire article is provided)	2. Only the abstract is provided - the abstract was the only thing published and there is no full article to consider; - if the Library says they are unable to find the article
3. Time Period (the article is published within the years of 1993-2015)	3. Articles published before 1993
4. Target population – AI/AN women of reproductive age, pregnant, or postpartum, up to 12 months post-delivery (focus of intervention/evaluation must include maternal as defined by pregnant/postpartum AI/AN women) ¹	4. Articles where the women in the study are - not pregnant/postpartum; - not AI/AN; - where the results of AI/AN are grouped together with other ethnicities, specifically, if AI/AN is not identified separately and there is no discussion or data to support - unrelated topics (i.e. genetics, zoology, archeology, etc.)
5. Language (articles in English)	5. Articles in any other language other than English, the entire article must be in English
6. Quantitative intervention/evaluation studies (study design)	6. Purely design articles – specifically, articles that are descriptive or only qualitative in nature: - case studies/screenings - interviews/commentaries/editorials/letters/narratives; - make suggestions/recommendations for interventions/evaluations, but conduct no work (published guidance/literature reviews); - methodological papers that refer to a method/strategy that could be used in an intervention/evaluation, but no results are included; - historical articles/reviews; - prevalence/cross-sectional studies (descriptive analyses)/population based studies; - nonintervention epidemiologic studies, limited to correlation and calculating risk (complex analyses using regression models, etc.)
7. Validation articles	

¹ Any intervention conducted on the mother, during pregnancy, regardless of the intended outcome, is included (i.e. if the intervention is done on the mother, while she is pregnant, the article is included, even if the intended outcome is on infant focused).

A Priori Criteria

Screening was completed by the lead researcher, then validated by the secondary abstractor. Each article was reviewed and categorized in the Excel spreadsheet as either: accepted, rejected, or potentially acceptable but pending review (potentials). Accepted articles were those that met all a priori criteria. Rejected articles were those that met at least one of the exclusion criteria. Potential articles were those where: (a) categorization differed by abstractor, or (b) one or more a priori criteria were unclear. For example, the study had multiple target populations (i.e., the intervention was conducted during pregnancy on the mother, but with an intended outcome on the infant). These inconsistencies were resolved during in person meetings among scientific advisors and data abstractors to ensure consistent assessment. If the possible article was a clear intervention, with a study design, independently identifying AI/AN pregnant or postpartum women as participants, and had data to support results, the article was accepted for the screening phase. At this step, the quality of the article did not matter. Since quality was of little concern, at this point, validation articles were also included in the screening phase. These provide important information on the use of a tool that could be used in an intervention. However, during the eligibility part of the review, it was agreed that this area would need to be revisited, as validation articles are not actual interventions and ideally, it would be best to include articles where those validated tools were used in an intervention.

Next, to finalize the screening process the primary and secondary abstractor worked together to verify the reasons for exclusion. Both abstractors ranked each

exclusion reason, from most important to least important reason (Table 4). The first step was to remove duplicates. When conducting a systematic review it is vital to minimize bias, by conducting a thorough, objective, and reproducible multi database search (Kwon, Lemieux, McTavish, & Wathen, 2015). Unfortunately, this can result in the retrieval of numerous duplicate citations, abstracts and full text articles that report the same information. Removing these duplicates ensures a valid and reliable group of studies for inclusion in the review. Next, since a specific time period (1993-2015) had been chosen, all articles had to be published within that time frame. Once an article was identified within the correct time frame, it had to be available in the English language. In addition, the article had to be available in full text. Then, the article had to be related to the topic of AI/AN women, anything unrelated (genetics, archeology, zoology, etc.) was excluded. Next, the article was limited in geographical location to the United States only. While, it had been established that AI/AN women were the topic, the articles had to then include the target population of pregnant and/or postpartum women, up to 12 months post delivery. The final exclusion category was study design, which excluded articles that were qualitative or descriptive in nature. See Table 4 for the total numbers in each exclusion category (these categories are also fully defined in the a priori criteria in Table 3). For further verification, the primary abstractor sorted the spreadsheet by each exclusion type and reason. When exclusion reasons did not match, the abstractors came to consensus on a final reason for rejection.

Table 4

Exclusion Reasons and Numbers

Exclusion Reason Category	Total Numbers
Duplicates	N = 298
Time Frame	N = 64
Language	N = 74
Full-length	N = 47
Unrelated Topic	N = 279
Location	N = 608
Target Population	N = 617
Study Design	N = 633
TOTAL	N = 2,620

Eligibility

The next part of the review was application of the population, intervention, comparator, outcome, and study design(s) (PICOS) approach. PICOS is a structured approach for framing questions that impacts several PRISMA items such as objectives, eligibility criteria, data items, and study characteristics (Liberati et al., 2009). For this research, PICOS was defined in the following manner (see Table 5). If one or more parts of the criteria were missing, those articles were excluded.

A key feature of a systematic reviews is a description of eligibility criteria for including and excluding studies; this ensures accuracy and transparency (Beller et al., 2013). Study eligibility characteristics are likely to center on the Cochrane Collaboration endorsed PICOS: the types of participants in the study; the intervention of interest along with a comparison group; the main outcome being assessed; and the specific study designs (Higgins & Green, 2011). The population usually includes information on age, race, sex, and health status (for this study was pregnant or postpartum status). The

intervention identifies the plan for the population. The comparator is the main alternative that is being considered; however, in some cases an intervention may be examined without an alternative. The outcome focuses on accomplishments, improvements or measurable effects. The appropriate study design should be specific to the research question(s) or goals of the study. This type of analytical framework helps to visually map connections between the population of interest, exposures, modifying factors, and outcomes of interest (Russell et al., 2009). Furthermore, the PICOS approach provides a foundation for examining and interpreting relevant studies. In other words, PICOS helps to link the intervention to improved health outcomes.

Table 5

Population, Intervention, Comparator, Outcome, and Study Design(s) (PICOS) Approach

PICOS	
Population	The participant population must be defined as pregnant and postpartum women, up to 12 months following delivery.
Intervention	The intervention must be clearly reported in the article as a frequency, behavior, initiation, or sustained change of a health behavior. Other interventions (exposures) might include diagnostic, preventative, or therapeutic treatments, arrangements of specific processes of care, lifestyle changes, psychosocial or educational interventions or risk factors.
Comparator	Each intervention must describe the comparator, or the control or comparison group. The comparator could be a standard of behavior, population, or care.
Outcome	The outcomes of the intervention are likely to be behavior or health outcomes and must be clearly defined in order to interpret validity and generalizability
Study Design(s)	The study design must be clearly reported in the article.

Adapted from (Liberati et al., 2009)

First, 298 duplicates were removed. Then 2,322 articles were excluded for failure to meet the a priori criteria (refer to Table 4 for these exclusion reasons). This resulted in 44 articles being selected for the eligibility phase. See Figure 2 for the flow diagram of articles from identifying and screening a priori criteria through establishing eligibility criteria.

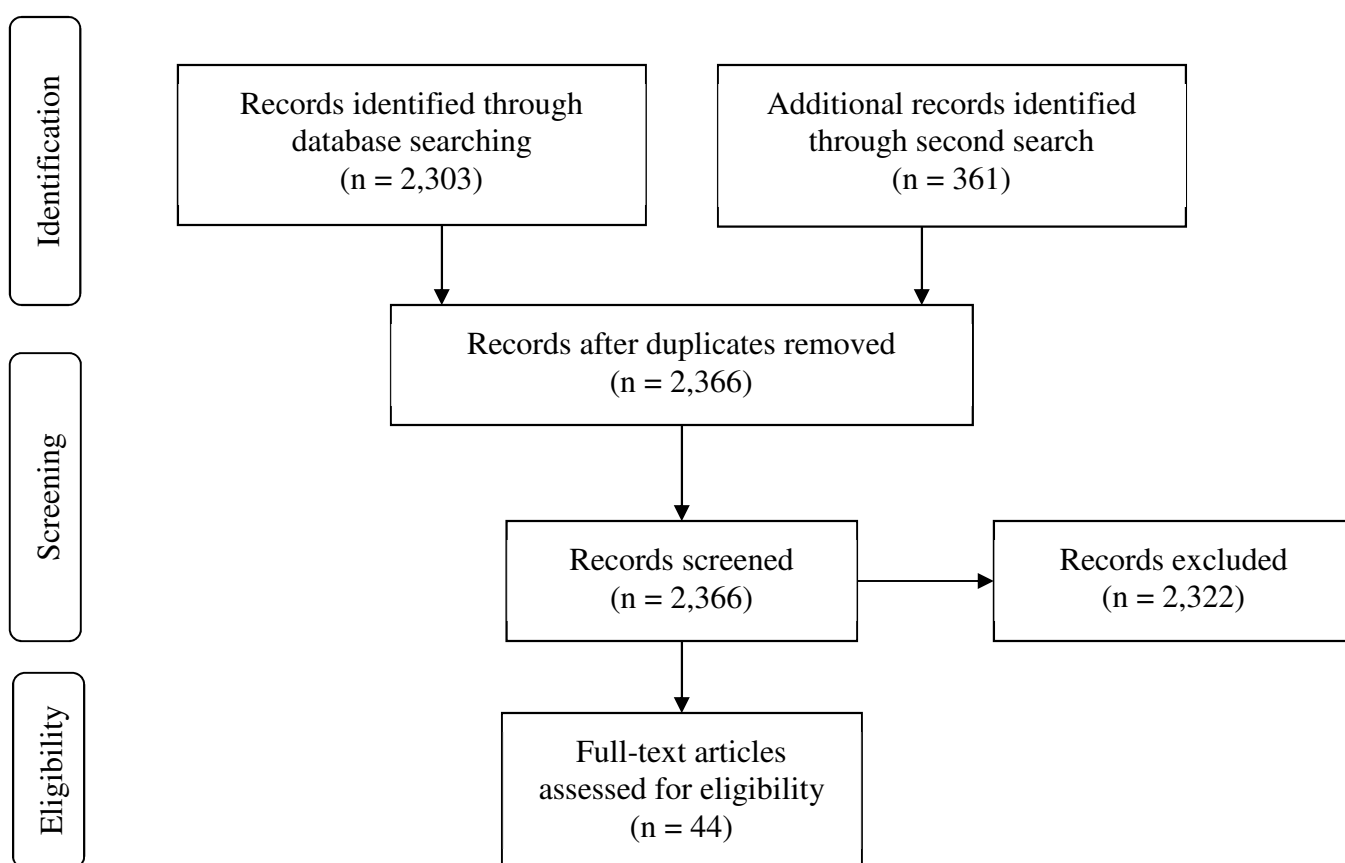
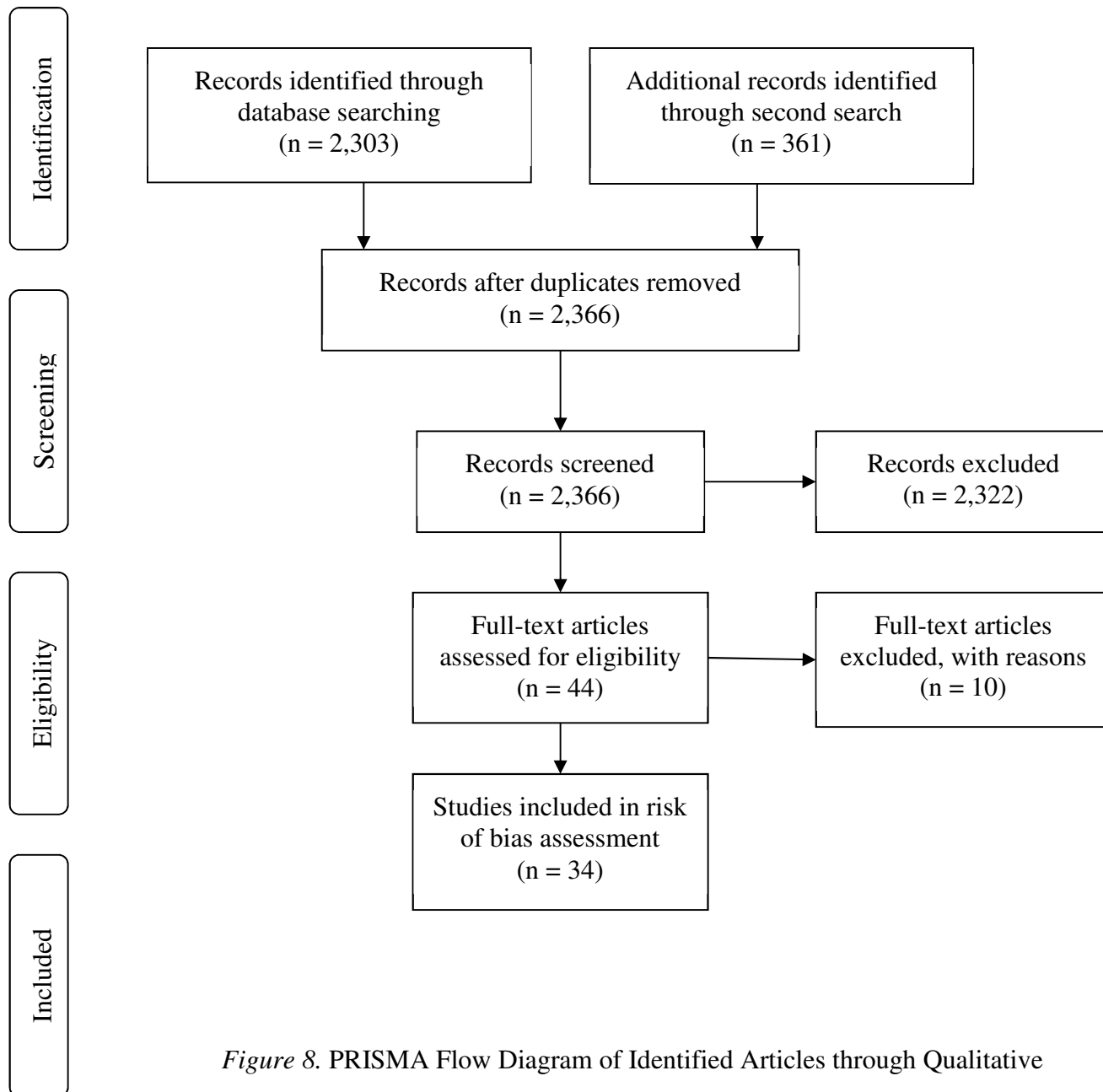


Figure 7. PRISMA Flow Diagram of Identified Articles through Establishing Eligibility Criteria

A spreadsheet of the 44 accepted articles was presented to the advisory group (secondary abstractor and scientific advisors) for review and consensus. The group excluded articles based on the primary abstractor's suggestions of unclear PICOS criteria.

Based on the application of PICOS and group consensus, 10 articles were excluded. Of the 10 that were excluded, eight were excluded because they were validation or reliability/agreement only articles presenting no intervention data or analyses. It was agreed by the group that, these are not interventions (i.e., they do not describe an intervention in which the validation tool is actually used, and do not meet the eligibility criteria). Two of the articles were excluded because their PICOS categories were incomplete (having no discussion of comparison group or study design). In total 34 articles were included for assessing risk of bias and study quality. See Figure 3 for depiction of included and excluded articles up to this point.



Synthesis

Assessing Risk of Bias and Study Quality

When conducting systematic reviews it is also important to focus on assessing and reporting risk of bias, more so than study quality (Liberati et al., 2009). While *quality* is not always clearly defined, it usually relates to the degree to which the study's design, conduct, analysis, and presentation answer the research question(s) (Higgins et al., 2011). PICOS and risk of bias are both assessments of quality. The Cochrane risk of bias was selected as the tool for quality assessment. Prior to 2005, there was no consistency between approaches for assessing quality of studies, most methods were not evidence based or used methods based on numerical scores, which have proven to be insufficient (Savovic et al., 2014). To address this, the Cochrane risk of bias tool was created. After evaluation of the tool in March of 2010, it has been widely accepted and is considered an improvement over other previously recommended methods in systematic reviews (Savovic et al., 2014). The PRISMA Statement recommends assessing risk of bias using the Cochrane risk of bias tool (see Appendix C for a copy of the tool), as it is a component methodology and is based on domains that represent good empirical evidence (Liberati et al., 2009). The tool covers six domains of bias: selection (random sequence generation and allocation concealment), performance (blinding of participants and personnel), detection (blinding of outcome assessment), attrition (incomplete outcome data), reporting (selective reporting), and other (other sources of bias). Table 6 provides a description of each domain.

Table 6

Risk of Bias Domains and Descriptions

Domain	Description
Random sequence generation	Describe the method used to generate the allocation sequence in adequate detail in order to determine if an assessment of whether it would produce comparable groups
Allocation concealment	Describe the method used to conceal the allocation sequence in adequate detail in order to determine if the intervention allocations could have been foreseen in advance of, or during, enrollment
Blinding of participants and personnel	Describe all measures used to blind participants and personnel from knowledge of which intervention a participant received, including if blinding was effective
Incomplete outcome data	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. Discuss whether attrition and exclusions were reported; the numbers in each intervention group; reasons for attrition/exclusions; and any re-inclusions in analyses performed by review authors.
Selective outcome reporting	Describe how the possibility of selective outcome reporting was examined by the review authors and the results
Other sources of bias	Describe any concerns about bias not addressed in the other domains

Adapted from: <http://ohg.cochrane.org/sites/ohg.cochrane.org/files/uploads/Risk%20of%20bias%20assessment%20tool.pdf>

Bias was assessed for each domain as a judgment score (high, low, or unclear) (see Appendix D for criteria for judging risk of bias). High judgments indicated that the bias was of significant magnitude and likely to have a notable effect on the results or conclusions of the study (Higgins et al., 2011). Low judgments indicated that there were no detections of bias or that bias was unlikely (Higgins et al., 2011). Unclear judgments indicated: (a) that there was inadequate detail reported about the results of the study or (b) although the results of the study were known, the associated risk of bias was unknown. (Higgins et al., 2011). In addition to judgment scores for the domain-level risk of bias, narrative explanations provided support for how the judgment score was reached.

In this study, risk of bias in each domain was assessed in all 34 articles by the primary abstractor and then validated by an expert review panel consisting of 10 reviewers, including the secondary abstractor and scientific advisors (for a list of expert panelists, see Appendix E). Seven expert reviewers in the panel, independently, assessed four articles for risk of bias. The secondary abstractor independently assessed three articles for risk of bias, while the scientific advisors, independently assessed two articles for risk of bias. Each expert reviewer also provided detailed support for each assessment, ensuring transparency. In addition, each expert reviewer was instructed to mark categories that did not apply to the study as “not applicable” and provide an explanation in the reviewer comment box. For example, if they reviewed an observational study, which would have no need for allocation concealment, due to the study design, it should be marked as “not applicable”. Then both data abstractors and scientific advisors met to discuss assessments and resolve any inconsistencies through consensus, ensuring uniformity in the categorization and scores process.

Next, the primary abstractor summarized the risk of bias for each domain within the study in a risk of bias table (this is found in the Results chapter). The primary abstractor then assigned an overall risk of bias judgment for each article – this was used to identify the low risk articles for inclusion in the meta-analysis. The first step was to decide which domains were the most important in the context of the article. It was decided by the advisory group that since this was not a review of RCTs, random sequence generation, allocation concealment, and blinding of participants and personnel, and incomplete outcome data were not the most significant domains for assessment. These

domains would likely be high (since there was unlikely to be randomization) or not applicable, due to study design. However, blinding of outcome assessment, selective outcome reporting, and other sources of bias were crucial domains for this systematic review, since they all impacted the outcomes. Furthermore, other sources of bias was necessary because this included biases that were not found within another category of bias, but indicated a major flaw within the study. Once key domains were determined for each article, overall risk of bias was interpreted for each article, based on the Cochrane Collaboration's Risk of Bias Tool. For example, an article was considered low risk of bias if, within the article, all key domains were judged and scored as "low risk". Table 7 contains explicit detail on summary assessments of risk of bias.

Table 7

Summary Assessment of Risk of Bias

Risk of Bias	Interpretation	Within an Article	Overall Risk of Bias
Low risk of bias	If present, the bias is unlikely to change the results remarkably	Low risk of bias for all key domains	Most information is from an article at low risk of bias
Unclear risk of bias	Risk of bias that raises some doubts about the results	Low or unclear risk of bias for all key domains	Most information is from an article at low or unclear risk of bias
High risk of bias	Bias may change the results remarkably	High risk of bias for one or more key domains	The amount of information from article at high risk of bias if ample enough to affect the interpretation of the results

Adapted from: (Higgins et al., 2011)

Analytic Design

There are multiple methods for analyzing data collected in systematic reviews. The primary method is meta-analysis. *Meta-analysis* refers to the use of statistical techniques in a systematic review to integrate and summarize the results of included studies that have already had analyses run and conclusions drawn (Liberati et al., 2009). Meta-analyses are also used to assess the consistency of evidence across studies and examine differences across studies (Higgins & Green, 2011). Karl Pearson, a British statistician was the first known person to attempt meta-analysis, by combining observations from different clinical studies (O'Rourke, 2007). He was tasked with analyzing data comparing infection and mortality among soldiers who had volunteered for vaccination against typhoid fever and those who had not across the British Empire. The majority of his studies showed significance in the association of vaccination with infection and death from typhoid, but there were irregularities with the associations (O'Rourke, 2007). He hypothesized that perhaps the soldiers who had volunteered for immunization were already had a lower risk of developing typhoid. He also noted that to resolve these irregularities, further analysis through experimental inquiry should be conducted.

After Pearson, in the 1920s and 1930s, Ronald Fisher began conducting studies in agricultural research where he urged scientists to summarize their research in a way that would allow for comparisons and combinations of estimates to be easily made (O'Rourke, 2007). A colleague of Fisher, William Cochran, expanded Fisher's work and created the random effects framework (O'Rourke, 2007). Along with another colleague, Frank Yates,

Cochran began applying these methods to agricultural data. Halfway through the 20th century, there were more than enough research reports looking for ways to develop and apply methods to synthesize results generated from separate, but similar studies.

However, it was not until 1976 when the phrase “meta-analysis” was coined by Gene Glass (O'Rourke, 2007). Soon thereafter, meta-analysis methods began appearing in published literature.

See Figure 9 for the complete four-phase flow diagram, which depicts the number of identified records, excluded articles, and included studies through each phase of the systematic review.

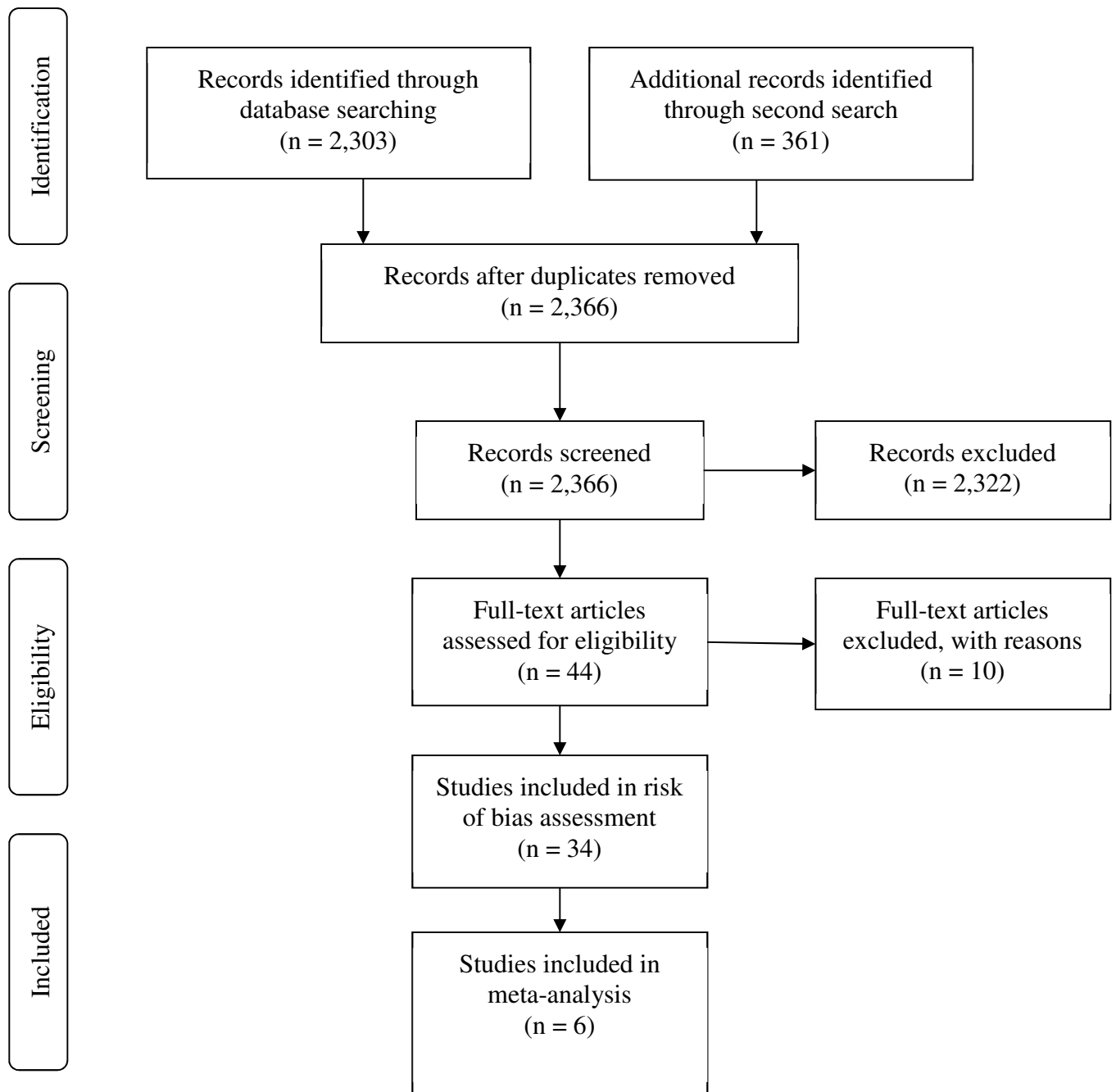


Figure 9. Complete PRISMA Flow Diagram

Research Question

This study addresses the following research question: What effect does parental competence have on early parenting and/or infant/toddler outcomes?

Using a fixed-effect model approach, this tests the null hypothesis that there is zero effect on parental competence in every study, meaning that they do not work or do not improve parenting knowledge.

Validity

There are three main types of threats to validity in a study: (a) internal threats, (b) external threats, and (c) construct threats. *Internal threats* are those that impede reliable inferences about the effect of the intervention (Henderson, Kimmelman, Fergusson, & Grimshaw, 2013). This may occur as bias in outcome assessments. As previously mentioned, only the articles having overall low levels of bias would be included in the meta-analysis. This included six articles. Cochrane recommends excluding high and unclear risk of bias articles because those errors will only be magnified by the meta-analysis, thus creating an incorrect result that would be interpreted as having credibility when it does not.

External threats are those unseen factors that obstruct the ability to determine generalizable cause-and-effect relationships (Henderson et al., 2013). A prime example of this is heterogeneity, which can be thought of as a comparison of apples to oranges and is often open for interpretation. However, since the studies for comparison in this meta-analysis each focus on a specific geographic area and a single population, it is assumed

that the studies are homogenous. A test of heterogeneity (discussed later in the chapter) will help to confirm this.

Lastly, *construct threats* relate to the degree to which inferences are justified from the sampling particulars of the intervention (Henderson et al., 2013). They arise from mischaracterizations in the relationship between the intervention and the outcome it represents. These can best be minimized by identifying, addressing, and confirming theoretical assumptions. In this study, these are reduced by following the PRISMA Statement guidance on how to properly conduct systematic reviews – this prevents error in execution of experimental operations.

Completing a Meta-Analysis

Effect Size

The first step to completing a meta-analysis is to find the effect size (ES) within each article or calculate it for each study to be included. An *effect size* is the main finding from a quantitative study and it tells the degree of the observed effect seen between groups in the study (Sullivan & Feinn, 2012). Since these calculated numbers can be quantitatively compared, the results from different studies are used in meta-analysis. To calculate the effect size a weighted mean must be established. In order to assign the weighted means, the combined effect needs to be determined. There are two models used in meta-analysis: fixed effect or random effect. Fixed effect assumes that data is coming from a single population and that nearly identical methods, patients, and measurements are used, producing nearly identical results (Borenstein et al., 2009). Any differences are from random errors within studies. In fixed effect, larger studies are thought to yield

more precise estimates than smaller studies. Random effect assumes that there are differences in study sample and design that lead to different results (Borenstein et al., 2009). Therefore, these studies are thought to be a random sample of the distribution of effects. Here, the weights are more balanced, with larger studies not leading the analysis and smaller studies not being underestimated (Valentine, Pigott, & Rothstein, 2010).

The decision to use one model over the other should be based on the type of inferences that the meta-analysis seeks to make. Of the six low risk articles, only two are similar enough to be compared. The topics of both interventions are related to changing behavior through home visiting efforts. A fixed effect is recommended for this study because both interventions take place in the same geographic area on a single population. Furthermore, the goal is to estimate a common effect size for the identified population (AI/AN women during pregnancy and postpartum), meaning that the results of the meta-analysis will allow inferences to be made about other studies similar to the studies included in this meta-analysis. Here, it is also important to note sources of error. With fixed effect models, error only occurs within studies. Thus, when there is a large enough sample size – whether in one study or across multiple studies, the error will tend towards zero.

In this meta-analysis the outcome focus is on the impact of parental competence. In the included studies this was measured through a 30-item maternal self-report survey, created to measure knowledge gains. In each study the authors calculated effect size estimates for the differences between the intervention and control groups in means using repeated measures analyses of covariance (ANCOVAs). More precisely, they were

calculated as the estimated group mean difference divided by the square root of the residual covariance estimate.

Since continuous data will be examined in the meta-analysis, the chosen summary statistic must be appropriate. In a fixed effects model, there are several methods choices for conducting the meta-analysis: inverse-variance, Peto method, or Mantel-Haenszel (M-H) method. The Peto method is only for combining odds ratios (ORs) and Cochrane does not recommend it as the standard approach to meta-analysis. The problem with Peto's method is that it only works well when there are similar numbers in both the intervention and control groups and when the effects are small (the ORs are close to one) (Higgins & Green, 2011). In studies where this is not the case, Peto's method, has been proven to deliver biased answers. The M-H method also uses pooled ORs, so it must be used for analyzing dichotomous variables and is usually the preferred method when doing so. However, since the data for this meta-analysis is continuous, the inverse variance method will be used. Both of the included studies report on parenting knowledge using the same scale, which means the mean difference can be used. This means that the standard deviations must be used together with the sample sizes to compute the weight given to each study.

There are many methods for calculating the standardized mean difference, according to Lipsey and Wilson (2007), the best formulas to use are either: (a) direct calculations based on means and standard deviations, (b) t test, (c) exact probability for a t test, or (d) estimates based on the correlation coefficient. For this study, the t test method will be utilized. The t test uses statistical methods to analyze the means of two

populations. It helps to identify whether a significance difference exists between those means. Since both articles provide p values, these can be converted into t values and applied to the following equation:

$$ES = t \sqrt{\frac{n_1+n_2}{n_1n_2}}$$

Once this has been calculated, the standard error (SE) will need to be

$$SE = \sqrt{\left[\frac{n_1+n_2}{n_1n_2}\right] + \left[\frac{ES_{sm}}{2(n_1+n_2)}\right]}$$

The SE is a measure of

ES precision; the smaller it is, the more precise the ES. The SE will later be used to create confidence intervals (CIs). Next, the weight for the standardized mean difference is determined. This equation is $W = \frac{(n \times ES) + (n \times ES) \dots}{n^2}$. The correlation coefficient is the next calculation to be done; that equation is $ES = r$. This tells the strength of the linear relationship between two variables. Finally, the 95% (CIs) can be computed, using the following equations: Lower Limit = $ES - 1.96(SE)$; Upper = $ES + 1.96(SE)$. The CI provides the range of values that is likely to contain the approximate mean of the population.

Homogeneity Analysis

The homogeneity analysis is the last piece of the meta-analysis puzzle and it is conducted to test the assumption that all of the ES are estimating the same population mean. To assess homogeneity, a Chi square statistic, or Q test is performed. This is done by squaring the ES and multiplying it by W. Once this is summed for all studies, the sums of W and W*ES from the previous calculations can be used to determine Q using the equation: $Q = \sum(W \times ES^2) - [\sum(W \times ES)]^2 / \sum W$. When calculating a Chi square statistic, degrees of freedom (df), must be accounted for. This equation is: $df = \#ES - 1$.

Then the critical value for a Chi square with that df and p value will need to be looked up and compared to the calculated Q. It is important to note here, that if there are only a few studies, the p-value should be set at $p = 0.10$.

Summary

At this point, it is time to interpret the data. For the sake of this meta-analysis, all calculations were conducted using Excel. All calculations and their sums for each study were combined into a summary table in order to create a *forest plot* (shown with included calculations in the Results chapter). A forest plot is the visual representation of results from the meta-analysis. In conclusion, meta-analysis presents a disciplined way for summarizing research findings and it is capable of finding relationships across studies that may be obscured in other approaches. In the next chapter I will provide the results of the meta-analysis, as well as the interpretation and its application to the current study.

Chapter 4: Results

Introduction

The purpose of this current study was to examine effective interventions targeting maternal risk behaviors among AI/AN women during pregnancy, and immediately postpartum, defined as up to 12 months post delivery. This study addresses the following research question: What effect does parental competence have on early parenting and/or infant/toddler outcomes? Using a fixed-effect model approach, I tested the null hypothesis that there is zero effect on parental competence in every study, meaning that they do not work or do not improve parenting knowledge.

The following chapter is divided into sections of: (a) data results from the assessment of risk of bias, (b) a meta-analysis, (c) forest plots, and (d) an answer to the research question. The meta-analysis includes: effect size (ES) calculations, using fixed effects, specifically the inverse-variance method; standardized mean difference calculations, using the t test method; confidence intervals calculations; homogeneity analysis; and I^2 calculations.

Data Collection

The time frame for the literature review search was 1993-December 2015. Multiple key word terms were searched including derivatives for race and pregnancy. Some examples of general terms searched were: Native American, Alaska Native, pregnant women, prenatal diagnosis, obstetrical, breastfeed, postpartum, and gestation. Appendix B includes the full listing of search terms. Table 2 includes the list of 10

databases searched and their definitions. The data collection plan described in the Methodology chapter is the same as the data collection process utilized.

Since this is a systematic review, baseline descriptives and demographics characteristics were not collected. However, for the two articles that were chosen for meta-analysis, the participants were all less than or equal to 32 weeks pregnant, 12-19 years of age at conception, AI/AN (self-identified), and living in one of the four participating reservation communities (Barlow et al., 2013; Barlow et al., 2015). For the Barlow, 2013 article, at baseline the participants were mostly first time mothers, unmarried, roughly 18 years old (Barlow et al., 2013). More than half of them have lived in two or more homes in the past year. The lifetime and during pregnancy substance use were higher than those for other AI/AN adolescents and for U.S. adolescents of all races during the same study period (Barlow et al., 2013). The study groups were similar at baseline, except for a slightly (but non-significant) higher mean Center for Epidemiologic Studies Depression Scale (CES-D) total score, rate of lifetime cigarette use, and rate of alcohol use during pregnancy (Barlow et al., 2013). For the Barlow, 2015 article, baseline values were represented by assessments conducted between 28 and 32 weeks gestation. The baseline value for the CES-D was calculated through the average scores from the first two time points in order to create a more accurate estimate of depressive symptoms during pregnancy (Barlow et al., 2015).

The communities in these studies were rural and isolated, consisting of 15,000 to 25,000 AI/ANs. The studies were designed for the poorest, most at risk communities in the country (Barlow et al., 2013). All four sites had significant behavioral health and

sociodemographic disparities, comparable to or surpassing those of other at-risk communities in the US (Barlow et al., 2013). However, the generalizability from these studies to very different types of tribal populations in the United States is unclear. But, since participants of the studies were from four diverse Native communities, the generalizability of the studies is likely to be greater than studies implemented on a single reservation (Barlow et al., 2015).

Covariates for the 2013 article were: total score on the CES-D, whether the mom had ever smoked cigarettes, and if the mom used alcohol during pregnancy (Barlow et al., 2013). These were used to control for nonequivalence (Barlow et al., 2013). In the 2015 article, covariates included: outcome measure values that were collected at baseline, mom's age, the sex and age of the baby at the time of assessment (Barlow et al., 2015). These were included to adjust for differences between nominal and actual assessment points, to control for nonequivalence, and to increase the statistical power for hypothesis tests by reducing errors in the model (Barlow et al., 2015).

Assessment of Risk of Bias Results

Thirty-four studies were assessed for their level of bias: high, low, or unclear. Of those 34 articles, 19 were judged as having an overall high risk of bias. A high risk meant that the amount of bias in these articles was high enough to affect the interpretation of the results and therefore would not be considered an evidence based practice. Nine of the 34 articles were judged as having an overall unclear risk of bias. An unclear risk meant that most of the information from these articles was too vague or inconclusive to determine the level of bias within the article. Judgements for all domains for each included article

can be found in Figure 10. For these reasons, 28 articles were not considered for further assessment.

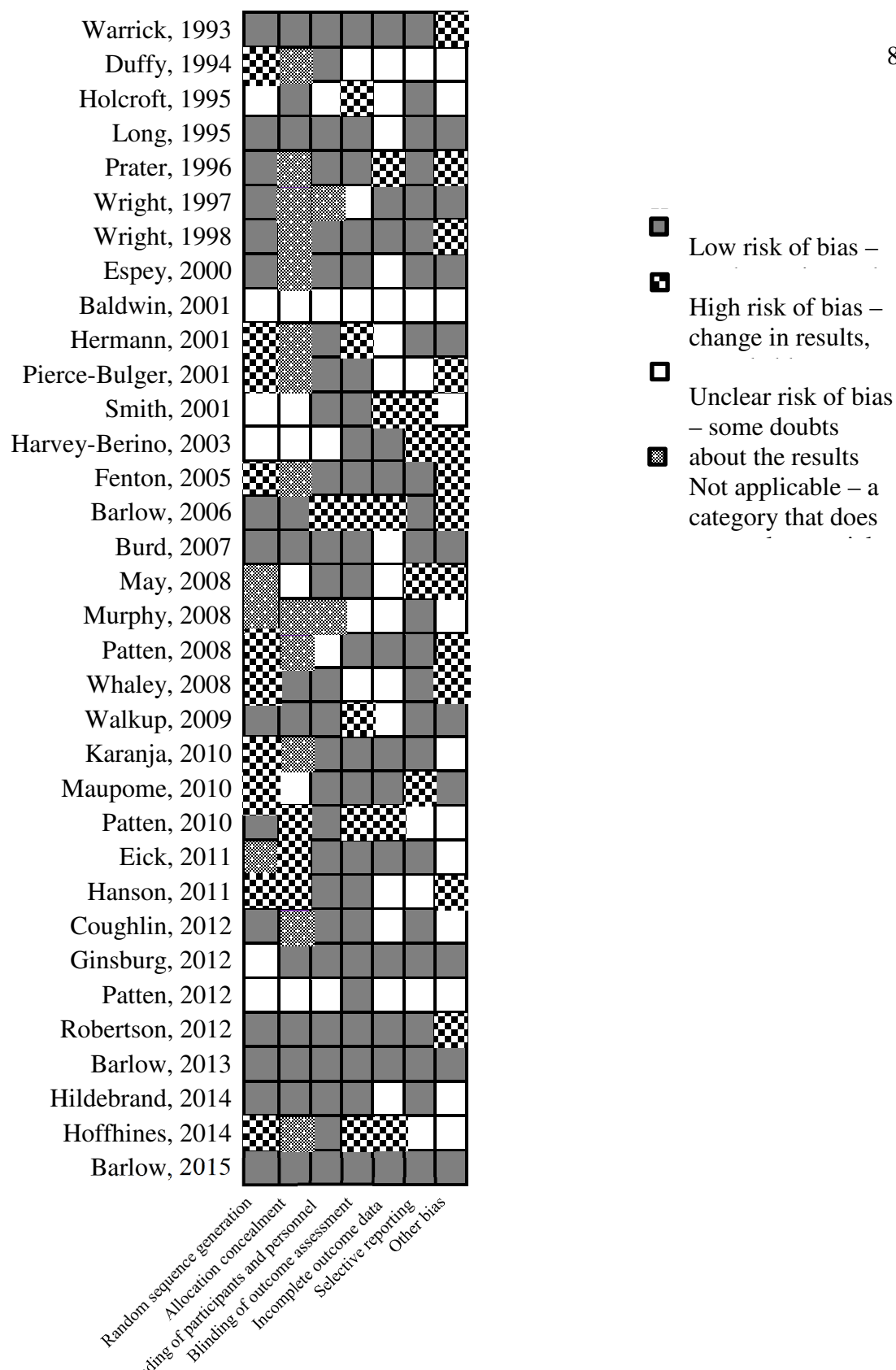


Figure 10. Risk of Bias Judgement Assessments by Author, Year, and Risk of Bias Category

All review judgments about each risk of bias item are presented as percentages across all included studies in Figure 11. This figure also shows impact by the three key domains, identifying low risk articles (explained in Table 6 and the Methodology chapter). Since this study was not a review of RCTs, the domains of random sequence generation, allocation concealment, and blinding of participants and personnel would not apply to the studies and therefore would not reflect potential bias. In addition, since there was so much variability in the study designs (i.e., case reports), incomplete outcome data would also not apply to most of the studies. Thus, the four domains: random sequence generation, allocation concealment, blinding of participants and personnel, and incomplete outcome data were not considered key domains. Cochrane points out that when assessing risk of bias it is important to choose domains that will emphasize the risk of bias in the results (Higgins & Green, 2011). Therefore, the blinding of outcome assessment and selective reporting were considered key because they both dealt with outcomes of the study and the impact that specific bias would have on the study results. The other bias domain was also considered key because the biases found here were not seen in other domains; yet, still highlighted significant flaws within the study. Table 8 presents the 34 risk of bias assessment included articles along with a summary of the study design, intervention, outcomes, and risk of bias – including the judgment scores and the specific biases that led to that score. Table 9 presents the six low risk of bias articles along with a summary of the study design, intervention, and outcomes.

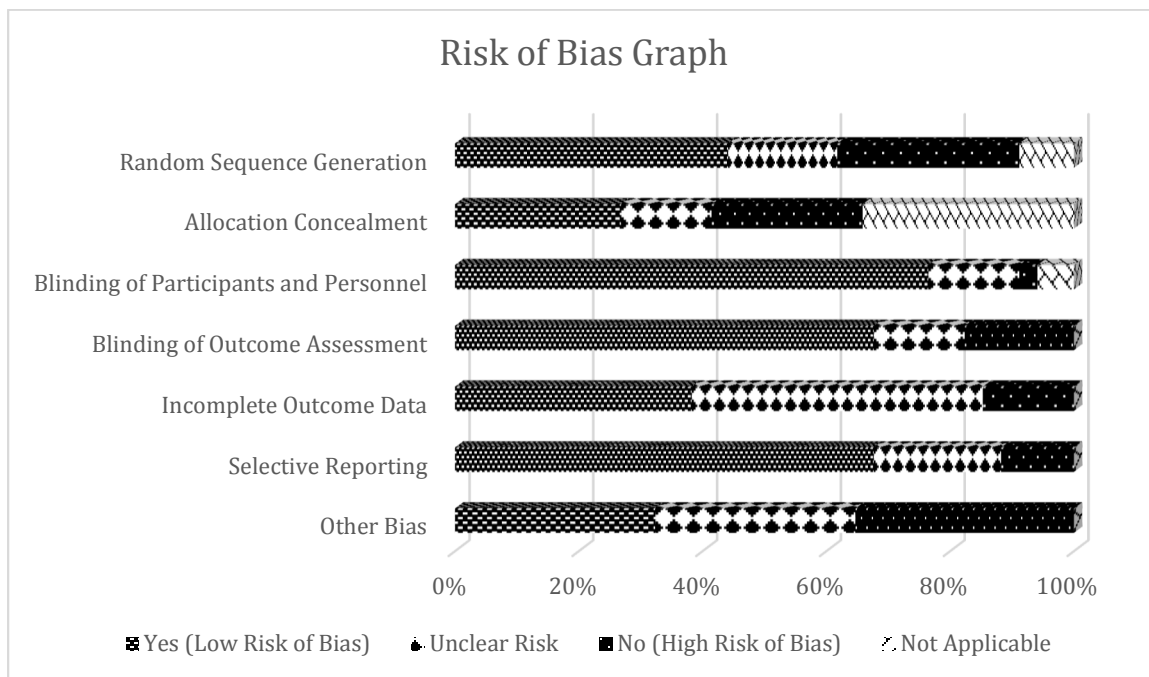


Figure 11. *Risk of Bias Graph*

This figure shows the impact by the three key domains, identifying low risk articles.

Table 8

Summary of Risk of Bias Assessment Included Articles

Author and Year	Participants	Intervention	Study Design	Outcomes	Judgement Score	Bias
Warrick, 1993	789 pregnant students; 8% were Native American	The TeenAge Pregnant and Parenting (TAPP) Demonstration that provided well-baby and maternal health care, given by a nurse practitioner, for students and their infants; a parenting-skills curriculum; day care for children up to 18 months of age; counseling; and care management	A multisite, longitudinal research design	With the exception of those who enrolled in a program in their 3rd trimester, pregnant and parenting students were consistently more likely to continue in school when they attended a comprehensive, school-based, community-linked program. Model 1 was the most successful ($p=0.001$) at keeping participants in high school.	High	Other sources of bias
Duffy, 1994	Native American women attending a prenatal clinic	A community baby shower with a health education focus to educate Native American women attending the prenatal clinic	Community-based participatory research with oral pre/posttest given	Pretest questions ranged from 0-70, while all of the post-test questions were answered 100% correctly by the Native Americans.	Unclear	Blinding of outcome assessment; selective outcome reporting; other sources of bias
Holcroft, 1995	Pregnant women who presented for prenatal care at a particular small town public hospital which serves Native Americans	Structured education and support from a breastfeeding educator to initiate breastfeeding and the duration of breastfeeding	Experimental with a posttest-only design; in this design women were recruited from a convenience sample	100% of the experimental group and 68% of the control group was found for initiation of breastfeeding ($p=0.004$). The experimental group also had a significance difference for the number of days of duration, (average mean 75.2 vs. the control group with 37.6; $t=2.68$; $p=0.01$).	High	Blinding of outcome assessment
Long, 1995	All participants enrolled in the Native American (pregnant and postpartum women) WIC program	A breastfeeding promotion program	A quasi-experimental design was used which incorporated historical	Peer counseling support increased initiation of breastfeeding (84% vs 70%; $p=0.05$) and duration of breastfeeding for	Low	N/A

table continues

Author and Year	Participants	Intervention	Study Design	Outcomes	Judgement Score	Bias
Prater, 1996	Urban Native American mothers who received service from the Perinatal Intervention Program between January 1, 1989 to December 31, 1993 and who delivered babies during the same time period (pregnant and postpartum women)	A 3 year Perinatal Program that aims to reduce infant mortality among the Native American population in Milwaukee through 3 primary interventions	Prospective cohort study	at least the first 3 months postpartum (49% vs 36%; p=0.08) Prenatal care was found to be a successful predictor of healthy babies (i.e. the more visits a mother made to the OB specialist, the healthier her baby). The more contacts with Perinatal Staff during pregnancy, the healthier the baby.	High	Other sources of bias
Wright, 1997	Navajo postpartum mothers	It consisted of 3 components: an intervention in the health care system, a community intervention, and an individual intervention – all focused on breastfeeding	A pre and posttest design of feeding practices	There was substantial improvement in breastfeeding rates after the intervention (from 64.2% to 77.8%). Both breastfeeding initiation (from 71.1% to 81.1%) and duration had increased and a smaller percentage of infants were given formula in the hospital (from 84.6% to 45.4%). Most important, the mean age at which formula was introduced increased from 12 days prior to the intervention to 48 days afterward (p<0.0001).	Unclear	Blinding of outcome assessment
Wright, 1998	Navajo postpartum mothers	A breastfeeding promotion program that evaluates changes in infant illness at the population level. The objective was to enable Navajo mothers to postpone the introduction of formula for at least 1 month.	Population-based cohort study	The proportion of women breastfeeding exclusively for any period of time increased from 16.4% to 54.6% after intervention. The proportion of infants fed formula from birth declined by almost one half from 83.6% to 45.4%.	High	Other sources of bias
Espey, 2000	A cohort of 172 Navajo women, including those postpartum 5-8 weeks, who had used Depo-Provera (DMPA) continuously for 1 or 2 years	This study aimed to clarify whether DMPA is associated with weight gain in Navajo women and to quantify the magnitude of weight gain	Retrospective chart review	Using DMPA is associated with significant weight gain in Navajo women (study subjects gained a mean of 6 lbs over 1 year and 11 lbs over 2 years relative to the comparison group; p<0.001); the weight gain is greater than that reported in previous uncontrolled studies in non-Navajo populations.	Low	N/A

table continues

Author and Year	Participants	Intervention	Study Design	Outcomes	Judgement Score	Bias
Baldwin, 2001	Rural MCH Program – directs care of pregnant women who reside w/in the Anchorage Service Unit, but live in remote villages and provides primary women's health care to women in village clinics w/in the service unit.	An 8 session nutrition education program for pregnant adolescents delivered by paraprofessionals in public schools	A descriptive study design - Program description and prospective annual survey of medical records	In 1985, 31% of women entered prenatal care in their 1st trimester, 58% in 2nd trimester, and 11% in their 3rd trimester. In 1999, statistics were 91%, 9%, and 9%, respectively. Breastfeeding as a method of nutrition has improved w/in this population over the years, w/ a beginning low of 60% to a high of 75%.	Unclear	Blinding of outcome assessment; selective outcome reporting; other sources of bias
Hermann, 2001	Rural pregnant adolescents participating in the Chickasaw Nation and Choctaw Nation WIC programs	An 8 session nutrition education program for pregnant adolescents delivered by paraprofessionals in public schools	A pre and posttest design	Nutrition education by paraprofessionals was effective in improving adolescents' dietary intake, maternal weight gain, and infant birth weight.	High	Blinding of outcome assessment
Pierce-Bulger, 2001	High social risk Anchorage Native mother/infant population (postpartum women)	A post neonatal infant mortality program to promote safe home environments for high social risk infants	Retrospective chart review	Ongoing evaluation processes have demonstrated a 50% reduction in infant mortality and very successful approaches to care for high social risk women and their families	High	Other sources of bias
Smith, 2001	The multicultural WIC mothers were 51% Alaskan Aleut, 27% white Non-Hispanic, 15% Asian, and 6% Hispanic. Other ethnic groups represented were Filipino, Eskimo, and Native American (postpartum women).	Community-based educational project where fifteen 30-minute programs were produced featuring a central nutrition theme	Pre- and posttest design	There was a significant change in knowledge in 9 of the 10 questions ($p < 0.05$). WIC participant enrolment increased from 321 to 405 participants (16%) during the 6-month broadcast period. WIC participant enrollment increased from 321 to 405 participants (16%) during the 6-month broadcast period.	High	Selective outcome reporting
Harvey-Berino, 2003	The St. Regis Mohawk community of Akwesasne, mother-child pairs (postpartum women).	An obesity prevention intervention with the parents of preschool Native American children	Random assignment experimental design	Weight-for-height z (WHZ) scores decreased in the PS condition and increased among the OPPS group ($p = 0.06$ - approached significance). Children in the OPPS condition also significantly decreased energy intake ($p < 0.05$).	High	Selective outcome reporting; other sources of bias
Fenton, 2005	Southwestern pregnant AI women	An evidence-based practice protocol for active management of the 3rd stage of labor to reduce maternal	Retrospective cohort design, using chart reviews	Active management was associated with reduced maternal blood loss on several measures when compared to routine management, including incidence of a 3	High	Other sources of bias

table continues

Author and Year	Participants	Intervention	Study Design	Outcomes	Judgement Score	Bias
		blood loss without increased risk of retained placenta		g/dl or greater postpartum hemoglobin decline (p<0.001), mean postpartum hemoglobin decline (p=0.001), and mean estimated blood loss (no statistical significance). Women who received active management had 87% reduced odds of a 3 g/dl or greater postpartum hemoglobin decline after adjusting for preeclampsia, manual placental extraction, laceration repair, and maternal age (OR: 0.13).		
Barlow, 2006	All pregnant AI adolescents (Apache and Navajo communities) aged 12-19 years at conception and at 28 weeks' or earlier gestation	A paraprofessional-delivered home-visiting intervention to promote child care knowledge, skills, and involvement among pregnant AI adolescents	Randomized controlled trial	Mothers in the intervention group had significantly higher parent knowledge scores at 2 months (adjusted mean difference +14.9; 95% CI +7.5 to +22.4) and 6 months postpartum (AMD +15.3; 95% CI +5.9 to 24.7). Intervention group mothers scored significantly higher on maternal involvement scales at 2 months postpartum (AMD +1.5; 95% CI -0.02 to +3.02) and scores approached significance at 6 months postpartum (AMD +1.1; 95% CI -0.06 to +2.2). Mothers in the intervention experienced a larger drop in depressive symptoms at both 2 (AMD -3.1; 95% CI -8.8 to +2.5) and 6 months (AMD -6.1; 95% CI -13.0 to +0.85) postpartum.	High	Blinding of outcome assessment; other sources of bias
Burd, 2007	Native American women (pregnant and young mothers)	A Sudden infant death syndrome (SIDS) risk reduction methodology delivered by hospital nurses or the home visiting staff	Pre and posttests	The pre-tests found substantial knowledge deficits about SIDS risk factors in both groups. The pre and posttest changes for the 9 risk factors ranged from 5% to 74%	Low	N/A
May, 2008	Pregnant Navajo women in Tuba City, AZ	A community-wide prevention of fetal alcohol syndrome (FAS) with case management	Prospective cohort study	All clients in CM reported at baseline to have been drunk over the past 6 months an average of 15 times; that number dropped significantly at 6 month follow-	High	Selective outcome reporting;

table continues

Author and Year	Participants	Intervention	Study Design	Outcomes	Judgement Score	Bias
		derived from strategies of motivational interviewing		up to 4.3 times and increased only modestly to 7.2 at 12 month follow-up. For CM pregnancies, 75.6% resulted in normal deliveries, 13.4% were preterm (most with no complications), 9.2% resulted in miscarriage/stillbirth, and 1.6% had abortions to protect maternal health.		other sources of bias
Murphy, 2008	Native new mothers (postpartum women) living in the southwestern US	An innovative program that targets promotion of breastfeeding among Native women as a type 2 diabetes prevention intervention	Prospective cohort study	Comparing the initial 12 month period with the most recent complete 12 month period, the combined full/nearly full and partial breastfeeding rates at 8 weeks increased from the 1st year average of 50.3% of all births to 65.5% (p<0.00001). When the same years were compared, the percentage of those initiating partial or full/nearly full breastfeeding and continuing to at least 8 weeks showed an increase of 25.15% (p=0.0002).	Unclear	Blinding of outcome assessment
Patten, 2008	Alaskan Native pregnant women	The state-of-the-art intervention for pregnant women consists of a brief (5-minute) cessation counseling session delivered by a trained provider and the provision of pregnancy specific, self-help materials	A retrospective review of a clinical database and medical records	There was a significant difference (p<0.001) in the proportion of women reporting they used tobacco during a previous pregnancy by type of tobacco used at the time of the intervention (100% among women who used Iqmik only or multiple tobacco products, 71% among those who smoked cigarettes only and 50% among those who used commercial smokeless tobacco only)	High	Other sources of bias
Whaley, 2008	Expectant Native American mothers in Southwest Oklahoma	An intervention to explore the strategies to prevent obesity in early childhood through the promotion of breastfeeding; avoiding overfeeding in infants and toddlers; and education	A cohort study of pregnant Oklahoma Native American mothers	Breastfeeding initiation rates increased from 59% to 89.5% in the study. The prenatal breastfeeding and early infant nutrition education was successful in breastfeeding initiation and duration up to 4 months. However, extended breastfeeding duration up to 1 year was	High	Other sources of bias

table continues

Author and Year	Participants	Intervention	Study Design	Outcomes	Judgement Score	Bias
				not significantly different b/w the intervention and control groups. Significant differences were found in saturated fat intake (p=0.033), monounsaturated fat intake (p=0.001), and food folate intake (p=0.002) for the control group.		
Walkup, 2009	Young, reservation-based American Indian mothers (pregnant to 12 months postpartum)	Home-visiting interventions that began during pregnancy and continued to 6 months postpartum to determine parenting knowledge, involvement, and maternal and infant outcomes.	Randomized control study	At 6 and 12 months postpartum, treatment mothers compared with control mothers had greater parenting knowledge gains, 13.5 (p < .0001) and 13.9 (p < .0001) points higher, respectively (100-point scale). No significant differences between study groups were seen for maternal involvement at any time point.	High	Blinding of outcome assessment
Karanja, 2010	Expectant American Indian mothers from three AI tribes who are members of the Northwest Portland Area Indian Health Board (NPAIHB)	Community-tailored interventions as well as family interventions that were delivered through home visits to promote breastfeeding and reduce the consumption of sugar-sweetened beverages	Pretest, posttest design, including a separate sample pretest–posttest design, also known as simulated before and after design	Breastfeeding initiation and 6-month duration increased 14 and 15%, respectively, in all tribes compared to national rates for American Indians. Parents expressed confidence in their ability to curtail family consumption of sugar-sweetened beverages.	Unclear	Other sources of bias
Maupome, 2010	Expectant American Indian mothers and their toddlers from birth	An overweight/obesity prevention and early childhood caries prevention project, using the ecology of the child to deliver the intervention, by targeting the parent, family network, and community at large	A control longitudinal cohort study	The comparison community D showed an increase of 34% (0.44 to 0.59) in d1t and 54% in d2t. In contrast, in all but one case the intervention communities showed decreases in both caries components (community A, -24% for d1t, -43% for d2t; community B, +132%, -100%; and community C, -36%, -36%, respectively)	High	Selective outcome reporting
Patten, 2010	Alaska Native pregnant women residing in the Yukon-Kuskokwim (Y-K) Delta region of Western Alaska	The Yukon-Kuskokwim Delta Regional Hospital (YKDRH) clinical cessation program provides nicotine dependence treatment and counseling services to all patients of the hospital through referrals from the medical staff	A randomized two-group design to assess the feasibility and acceptability of a targeted cessation intervention for Alaska Native pregnant women	The participation rate was very low with only 12% of eligible women (35/293) enrolled – suggesting that the program was not feasible or acceptable. Among enrolled participants, the study retention rates were high in both the intervention (71%) and control (94%) groups. The biochemically confirmed abstinence rates at follow-up were 0% and 6% for the	High	Blinding of outcome assessment

table continues

Author and Year	Participants	Intervention	Study Design	Outcomes	Judgement Score	Bias
Erick, 2011	A total of 1169 mother-infant pairs with mothers who delivered an infant during 1 of 3 influenza seasons on Navajo and White Mountain Apache Indian reservations (postpartum women)	The use of influenza vaccinations as a means of protecting infants from infection or reduction of severity of illness	Nonrandomized, prospective, observational cohort study	Maternal influenza vaccination was associated with a 41% (relative risk, 0.59; 95% CI: 0.37-0.93) reduced risk of laboratory-confirmed influenza virus infection and a 39% (relative risk 0.61; 95% CI 0.45-0.84) reduced risk of influenza-like illness (ILI) hospitalization among the infants born to these mothers	Unclear	Other sources of bias
Hanson, 2011	American Indian women of childbearing age (pregnant women) in Northern Plains' communities	The purpose of the project was to develop a culturally and linguistically appropriate media campaign focused on fetal alcohol spectrum disorders (FASD) prevention and awareness for American Indian populations in the Northern Plains	Used a convenience sample, with no survey methodology	The media campaign was seen as culturally appropriate (85.7% strongly agree/agree). The vast majority of those women sampled felt that the media campaign increased their knowledge about FASD (91.6% strongly agree/agree) and the effects of prenatal alcohol exposure (93.3% strongly agree/agree). Most women said that the campaign decreased their drinking behavior (71.8%). All information was self-reported.	High	Other sources of bias
Coughlin, 2012	American Indian pregnant women in Michigan	All HS clients receive a one-on-one visit with a HS nurse to assess medical, social and basic needs, followed by individually-tailored education based on identified risks, referrals to needed services (e.g. Medicaid, WIC, prenatal care), and monthly home visits during pregnancy	Retrospective cohort study design was used to analyze all American Indian births recorded in Michigan	At the $p < 0.001$ level, there were no differences between HS participants and non-participants in infant birth weight, small for gestational age (SGA), gestational age, adequacy of prenatal care, parity, sex, tobacco use during pregnancy, maternal age, or maternal education	Unclear	Other sources of bias
Ginsburg, 2012	Expectant reservation-based pregnant White Mountain Apaches	The goal of the intervention, entitled Living in Harmony (LIH), was to reduce depressive symptoms during pregnancy and prevent the	Randomized controlled trial	There were significant improvements on the Center for Epidemiology Studies-Depression scale (CES-D), Edinburgh Postpartum Depression Scale (EPDS), and Global Assessment Scale for	Low	N/A

table continues

Author and Year	Participants	Intervention	Study Design	Outcomes	Judgement Score	Bias
		onset of major depressive disorder postpartum		Children (CGAS) from baseline to post-intervention and follow-ups for both LIH and Educational-Support (ES) participants. However, controlling for the baseline differences, the analysis of covariance (ANCOVAs) showed no significant differences between LIH and ES on each outcome measure at each post intervention assessment point. No significant differences were found between the two groups on any baseline variable.		
Patten, 2012	Pregnant Alaska Native women	A targeted tobacco cessation intervention for Y-K Delta pregnant women	The intervention was evaluated in a pilot randomized trial	Participants rated the intervention as highly acceptable, and good with 83% completing the follow-up in late pregnancy. However the biochemically verified abstinence rates were not optimal (0% for the intervention, 6% among the controls).	Unclear	Selective outcome reporting; other sources of bias
Robertson, 2012	American Indian mother-child pairs (postpartum women)	A 10% chlorhexidine (CHX) dental varnish applied to the mothers' dentition in preventing caries in American Indian children. Mother-child pairs were enrolled when the child was 4.5-6.0 months	A placebo-controlled (1:1), double-blind, parallel group randomized clinical trial	The proportion of children caries-free at their final exam was 51.1% and 50.8% for the active and placebo groups ($P > 0.99$). The mean number of new carious surfaces (NNCS) for the active and placebo groups was 3.82 (standard deviation [SD] = 8.18) and 3.80 (SD = 6.08), respectively ($P = 0.54$). In this population CHX varnish did not reduce the mean NNCS or proportion of children with caries, but did reduce the proportion with severe caries.	High	Other sources of bias
Barlow, 2013	Pregnant American Indian teens from four southwestern tribal reservation communities	Family Spirit, a Native paraprofessional-delivered, home-visiting pregnancy and early childhood intervention,	The trial is a multisite, randomized, parallel-group trial of the Family Spirit intervention plus optimized standard care compared	At 12 months postpartum, mothers in the intervention group had significantly greater parenting knowledge (effect size estimate: 0.33), parenting self-efficacy (effect size estimate: -0.23), and home	Low	N/A

table continues

Author and Year	Participants	Intervention	Study Design	Outcomes	Judgement Score	Bias
		consisting of 43 highly structured lessons	with optimized standard care alone from pregnancy until 3 years postpartum in four tribal communities across three reservations in Arizona	safety attitudes (effect size estimate: 0.19) and fewer externalizing behaviors (adjusted mean difference= -0.09; 95% CI= -0.16 to -0.01, p=0.03; effect size: -0.19), and their children had fewer externalizing problems		
Hildebrand, 2014	Parents and caregivers of children birth to 3 years at four WIC clinics (postpartum women)	Behavior change intervention based on Social Cognitive Theory using Cialdini's Principles of Influence	Two-part, quasi-experimental design	The model had a small effect ($\Phi=0.10$) in distinguishing breastfeeding initiation; women in the influence model were 1.5 times more likely (95%CI, 1.19–1.86; $P<.05$) to initiate breastfeeding compared with women in the traditional model, controlling for parity, mother's age, and race. AI/AN women were less likely to breastfeed compared with women in the white group (OR 0.7; CI 0.5-0.8; $P<0.01$).	Unclear	Other sources of bias
Hoffhines, 2014	Pregnant mothers and their children up to 24 months	A certified lactation specialist conducted a class for the pregnant mothers covering the benefits of breastfeeding, common breastfeeding myths and problem-solving, latching techniques, breastfeeding positions, use of breast pumps (provided free of charge) and healthy feeding practices for toddlers	A survey of prevailing nutritional practice was the basis for design of the program	The breastfeeding initiation rate was successfully increased to 89% in the intervention group compared to the prevailing rate of 59%. However, it was sustained in only 35% at 6 months and at 12% at 12 months (the goal for initiation was exceeded but not for continuation at 6 & 12 months).	High	Blinding of outcome assessment
Barlow, 2015	Expectant American Indian teens from four southwestern reservation communities	Family Spirit: the first home-visiting intervention to be designed to address behavioral health disparities of the poorest and most underserved population in the United States, American Indians (particularly adolescents)	A multisite, randomized (1:1), parallel-group trial	From pregnancy to 36 months postpartum, mothers in the intervention group had significantly greater parenting knowledge (effect size=0.42) and parental locus of control (effect size=0.17), fewer depressive symptoms (effect size=0.16) and externalizing problems (effect size=0.14), and lower past month use of marijuana (odds	Low	N/A

table continues

Author and Year	Participants	Intervention	Study Design	Outcomes	Risk of Bias	
					Judgement Score	Bias
				ratio=0.65) and illegal drugs (odds ratio=0.67). Children in the intervention group had fewer externalizing (effect size=0.23), internalizing (effect size=0.23), and dysregulation (effect size=0.27) problems.		

table continues

Six articles were judged as having an overall low risk of bias based on the key domains of: blinding of outcome assessment, selective outcome reporting, and other sources of bias, as described in the Methodology chapter, and were selected for quantitative analysis. However, only two articles were similar enough in effect size to (outcome measure) be included in the meta-analysis.

Table 9

Summary of Low Risk of Bias Articles

Author and Year	Participants	Intervention	Study Design	Outcomes
Long, 1995	All participants enrolled in the Native American (pregnant and postpartum women) WIC program between January 1991 and January 1992	A breastfeeding promotion program	A quasi-experimental design was used which incorporated historical controls, using a retrospective chart review	Peer counseling support increased initiation of breastfeeding (84% vs 70%; $p=0.05$) and duration of breastfeeding for at least the first 3 months postpartum (49% vs 36%; $p=0.08$)
Espey, 2000	A cohort of 172 Navajo women, including those postpartum 5-8 weeks, who had used Depo-Provera (DMPA) continuously for 1 or 2 years	This study aimed to clarify whether DMPA is associated with weight gain in Navajo women and to quantify the magnitude of weight gain	Retrospective chart review	Using DMPA is associated with significant weight gain in Navajo women (study subjects gained a mean of 6 lbs over 1 year and 11 lbs over 2 years relative to the comparison group; $p<0.001$); the weight gain is greater than that reported in previous uncontrolled studies in non-Navajo populations
Burd, 2007	Native American women (pregnant and young mothers)	A SIDS risk reduction methodology delivered by hospital nurses or the home visiting staff	Pre and posttests	The pre-tests found substantial knowledge deficits about SIDS risk factors in both groups. The pre and posttest changes for the 9 risk factors ranged from 5% to 74%
Ginsburg, 2012	Expectant reservation-based pregnant White Mountain Apaches	The goal of the intervention, entitled Living in Harmony (LIH), was to reduce depressive symptoms during pregnancy and prevent the onset of major depressive disorder postpartum	Randomized controlled trial	There were significant improvements on the Center for Epidemiology Studies-Depression scale (CES-D), Edinburgh Postpartum Depression Scale (EPDS), and Global Assessment Scale for Children (CGAS) from baseline to post-intervention and follow-ups for both LIH and Educational –Support (ES) participants. However, controlling for the baseline differences, the analysis of covariance (ANCOVAs) showed no significant differences between LIH and ES on each outcome measure at each post intervention assessment point. No significant differences were found between the two groups on any baseline variable.
Barlow, 2013	Pregnant American Indian teens from four southwestern tribal reservation communities	Family Spirit, a Native paraprofessional-delivered, home-visiting pregnancy and early childhood intervention consisting of 43 highly structured lessons	The trial is a multisite, randomized, parallel-group trial	At 12 months postpartum, mothers in the intervention group had significantly greater parenting knowledge (effect size estimate: 0.33), parenting self-efficacy (effect size estimate: -0.23), and home safety attitudes (effect size estimate: 0.19) and fewer externalizing behaviors (adjusted mean difference= -0.09; 95% CI= -0.16 to -0.01, $p=0.03$; effect size: -0.19), and their children had fewer externalizing problems. In a subsample of mothers with any lifetime substance use at baseline ($N=285$; 88.5%), children in the intervention group had fewer
Barlow, 2015	Expectant American Indian teens from four southwestern reservation communities	Family Spirit: the first home-visiting intervention to be designed to address behavioral health disparities of the poorest and most underserved population in the United States, American Indians (particularly adolescents)	A multisite, randomized (1:1), parallel-group trial	From pregnancy to 36 months postpartum, mothers in the intervention group had significantly greater parenting knowledge (effect size=0.42) & parental locus of control (effect size=0.17), fewer depressive symptoms (effect size=0.16), externalizing problems (effect size=0.14), & lower past month use of marijuana (odds ratio=0.65) and illegal drugs (odds ratio=0.67).

Meta-Analysis

Meta-analysis is a statistical approach that allows a researcher to combine the results of several studies and then expand the base of studies in some meaningful way (DiMaggio, 2013). Because the methodology is systematic it makes the review and interpretation less subjective and more impartial (Lipsey & Wilson, 2001). Meta-analysis can be conducted when the effect sizes (ES) or the effect of the treatment is consistent in each study. For this study, two articles met that criteria; both were looking at parent and child emotional outcomes. The one specific outcome that both examined was parental competence, through knowledge gains.

As previously stated, determining the ES for each article is the first step in conducting the meta-analysis. Fortunately, with the two articles in this meta-analysis, the ES were already calculated. For the Barlow, 2013 article, standardized pairwise differences were defined as the average between treatment group differences in outcome scaled by the standard deviation of the outcome (Barlow et al., 2013). Standard differences denote treatment ES estimates on the standard deviation scale of the outcome (Barlow et al., 2013). In accordance with Cohen, 1988, values of 0.2, 0.5, or 0.8 are normally regarded as small, medium, and large, respectively (Cohen, 1988). In the Barlow, 2015 article ES were calculated for continuous outcomes and they were calculated as the estimated group mean difference divided by the square root of the residual covariance estimate (Barlow et al., 2015).

In the Barlow, 2013 article, at 12 months postpartum, mothers in the intervention group had both higher parenting knowledge and improved parenting self-efficacy, with

effect size estimates for the differences being 0.33 and -0.23, respectively (Barlow et al., 2013). In the Barlow, 2015 article across the study period, the mothers in the intervention group had more parenting knowledge and parental locus of control (or a parent's perceived power and ability in child-rearing situations, which is also parenting self-efficacy) with the effect sizes being 0.42 and 0.17, respectively (Barlow et al., 2015). As mentioned in the Methodology chapter, a fixed effect is recommended for this study since both interventions occur in the same geographic area with a single population. To investigate between-group differences in scalar outcomes, separate analysis of were fitted for each outcome. Each model included site (which was treated as a fixed effect); mother's total score on the Center for Epidemiologic Studies Depression Scale (CES-D); information on alcohol use during pregnancy; and information on lifetime cigarette smoking (Barlow et al., 2013).

Next, the inverse-variance method, used when there is continuous data, needs to be utilized to actually perform the meta-analysis. In these two studies, the standard deviations (or effect sizes) can be used together with the sample sizes to determine the weight given to each study, since they both reported on parenting knowledge using the same scale. The t-test is used to calculate the standardized mean difference. Then the standard error (SE) is computed, for ES precision. Using these calculations, weight for the standardized mean difference is configured, followed by correlation coefficient – determining the linear relationship's strength. Finally, using SE, the 95% confidence intervals (CIs) are calculated. This value can be easily checked since both articles already computed CIs. Lastly, the homogeneity analysis can be conducted. This is done to test the

assumption that all of the ES are estimating the same population mean. The test used in this analysis is a Chi square statistic (Q test), which is then summed for all studies. Using the sums of W and $W*ES$ from the previous set of calculations, Q is determined. Degrees of freedom (df) have to be considered when computing a Chi square statistic, as well as the critical and p -values. Since there are only two studies, the p value will be set at $p = 0.10$, as noted in the Methodology chapter. See Table 10 below that shows all of these equations and their values. The values that were already calculated in both of the Barlow articles were: ES; correlation coefficient (r), which is equal to ES; and 95% CIs. The other calculations were done using Excel 2016. See Table 11, Figure 12 and Table 12, Figure 13 for the forest plot of the results—one forest plot for parenting knowledge and another for self-efficacy, both components of parental competence.

Table 10

Meta-Analysis Calculations

Name of Equation	Formula of Equation	Value of Equation
Standardized mean difference	$ES = t \sqrt{\frac{n_1 + n_2}{n_1 n_2}}$	Barlow, 2013: 0.33 → parenting knowledge; -0.23 → improved parenting self-efficacy Barlow, 2015: 0.42 → parenting knowledge; 0.17 → self-efficacy
Standard Error (SE)	$SE = \sqrt{\left[\frac{n_1 + n_2}{n_1 n_2} \right] + \left[\frac{ES_{sm}}{2(n_1 + n_2)} \right]}$	Parenting knowledge: 0.045 Self-efficacy: 0.2
Weight (W)	$W = \frac{(n \times ES) + (n \times ES) \dots}{n^2}$	Parenting knowledge: 0.375 Self-efficacy: -0.03
Correlation Coefficient (r)	$ES = r$	Barlow, 2013: 0.33; -0.23 Barlow, 2015: 0.42; 0.17
95% Confidence Interval (CIs)	Lower Limit = $ES - 1.96(SE)$ Upper = $ES + 1.96(SE)$	Barlow, 2013: 0.65, 2.04 → parenting knowledge; -2.62, -0.39 → self-efficacy Barlow, 2015: 0.70, 1.86 → parenting knowledge; -3.00, -0.39 → self-efficacy
Chi square statistic	$ES^2 \times W$	Barlow, 2013: 0.0408375 → parenting knowledge; -0.001587 → self-efficacy Barlow, 2015: 0.1069875 → parenting knowledge; -0.000867 → self-efficacy

table continues

Name of Equation	Formula of Equation	Value of Equation
Q test	$\sum (W \times ES^2) - [\sum (W \times ES)]^2 / \sum W$	Parenting knowledge: 0.00151875 Self-efficacy: -0.0024
Degrees of freedom (df)	df = #ES-1	Barlow, 2013 and Barlow, 2015: 1
I ²	$I^2 = 100\% \times \frac{Q - df}{Q}$	Parenting knowledge: -6.57436214 Self-efficacy: 4.176666667

Table 11

Descriptive Information for Parenting Knowledge Forest Plot

Parenting Knowledge			
Study	Description	X	Y
Barlow, 2013	ES	0.33	3
	CI Lower	0.65	3
	CI Upper	2.04	3
Barlow, 2015	ES	0.42	2
	CI Lower	0.70	2
	CI Upper	1.86	2
Overall Effect	ES	0.38	1
	CI Lower	0.68	1
	CI Upper	1.95	1

Table 11 shows the ES and 95% CIs for each of the articles for parenting knowledge of the meta-analysis, including the average overall effect of ES and 95% CIs. These numbers are plotted on the X-axis. The Y numbers refer to the total number of plotted information.

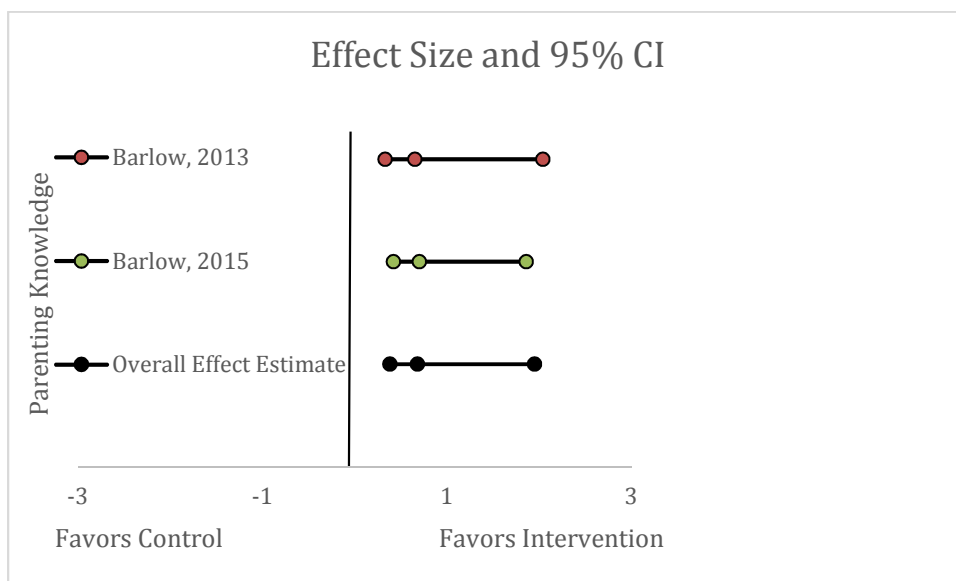


Figure 12. Forest Plot for Parenting Knowledge

This forest plot shows that parenting knowledge is favored by the intervention, since the lines are on the right side of the chart and does not cross or touch the middle line (line of no effect).

Table 12

Descriptive Information for Self-efficacy

Self-efficacy			
Study	Description	X	Y
Barlow, 2013	ES	-0.23	3
	CI Lower	-2.62	3
	CI Upper	-0.39	3
Barlow, 2015	ES	0.17	2
	CI Lower	-3.00	2
	CI Upper	-0.39	2
Overall Effect	ES	-0.03	1
	CI Lower	-2.81	1
	CI Upper	-0.39	1

Table 12 shows the ES and 95% CIs for each of the articles for self-efficacy of the meta-analysis, including the average overall effect of ES and 95% CIs. These numbers are plotted on the X-axis. The Y numbers refer to the total number of plotted information.

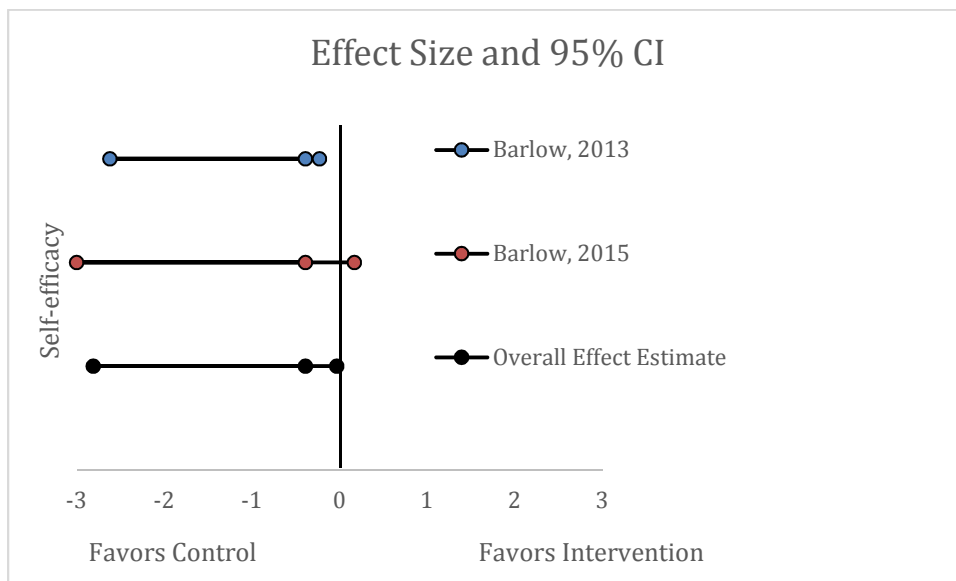


Figure 13. *Forest Plot for Self-efficacy*

This forest plot shows that self-efficacy is favored by the control, since the lines are on the left side of the chart and most of them cross or touch the middle line (line of no effect).

Summary

The last part of meta-analysis, the homogeneity analysis tests the assumption that all the effect sizes are estimating the same population mean. Rejecting homogeneity means that the distribution of the effect sizes is assumed to be heterogeneous. In this study, there are two Q values, one for parenting knowledge and one for self-efficacy. The first Q value is 0.00151875 for parenting knowledge and the second value is -0.0024 for self-efficacy. When compared to the critical values using a df of one, since there are two ES sizes for each article, both calculated Q values are smaller than the critical value of 2.71. This means the null hypothesis of homogeneity is rejected and there appears to be

heterogeneity. In other words, that the variability across effect sizes does not exceed what would be expected based on sampling error. But, the question is how much heterogeneity is present? A separate calculation for I^2 can help determine this.

The I^2 statistic tells the amount of variation across studies that is the result of heterogeneity as opposed to chance (Higgins & Thompson, 2002). It is a clear expression of the discrepancy of studies' results. As a general rule of thumb, 0.25 or less is considered low heterogeneity, 0.50 is considered moderate heterogeneity, and 0.75 and higher is considered high heterogeneity. In this study, the I^2 value for parenting knowledge is -6.57436214. This means that there is very low heterogeneity and that variations within the studies, pertaining to parenting knowledge are most likely due to chance (Lipsey & Wilson, 2001). Conversely, the I^2 value for self-efficacy is 4.176666667. This means that there is very high heterogeneity and that variations within the studies, pertaining to self-efficacy are most likely due to random differences across the studies or sources that are unidentified or measured (Lipsey & Wilson, 2001).

In this study, the null hypothesis states that there is no effect on parental competence in each study (e.g., that the interventions do not improve parenting knowledge). Based on the forest plots, the null hypothesis is rejected for parenting knowledge and accepted for self-efficacy. Looking at the parenting knowledge forest plot, the 95% CI lines from both studies are on the side of the chart that favors the intervention (or the positive side). Likewise, it can be seen that the 95% CI lines for both studies do not cross the line of no effect (or the vertical line at 0), meaning this information is statistically significant. Additionally, considering the overall effect

estimate 95% CI line, this also does not cross the line of no effect, indicating statistical significance. Conversely, upon examining the forest plot for self-efficacy, the 95% CI lines from both studies are on the side of the chart that favors the control (or negative side). Furthermore, one of the 95% CI lines from the studies crosses the line of no effect, while the other 95% CI line comes very close to the line of no effect. The overall effect estimate 95% CI also touches the line of no effect. This all indicates that there is not statistical significance related to self-efficacy.

In summary, this chapter presents the findings of the meta-analysis as well as how these findings answer the research question. In the final chapter I will interpret these findings and make recommendations for future research. Additionally, in the chapter I will provide implications for positive social change.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

The purpose of this current study was to examine effective interventions targeting maternal risk behaviors among AI/AN women during pregnancy, and immediately postpartum, defined as up to 12 months post-delivery. The nature of this study is quantitative, a longitudinal retrospective systematic review. This is the first published systematic review of evidence based public health interventions among AI/AN pregnant and postpartum women. This is indicative of how understudied evidence based interventions in the AI/AN population is in the scientific published literature. The following chapter is divided into sections of: (a) summary of key findings, (b), application of the key findings in the context of the proposed theoretical framework, (c) strengths of the study, (d) limitations of the study, (e) the public health implications of the study, and (f) conclusion.

Key Findings

The null hypothesis of homogeneity was rejected, indicating some heterogeneity. The I^2 statistic (-6.57436214) for parental knowledge showed that the amount of homogeneity was very low, meaning that any variations within the studies were most likely due to chance. On the other hand, the I^2 statistic (4.176666667) for self-efficacy showed that the amount of homogeneity was very high, demonstrating that variations within the studies were likely a result of random differences across the studies or sources that were unidentified or measured. The null hypothesis for the study, that there is no effect on parental competence in each study, (i.e., the interventions do not improve

parental competency) was rejected for parenting knowledge and accepted for self-efficacy.

Interpretation of the Findings

The small number of studies included in this systematic review and meta-analysis are concerning, especially considering the number and scope of articles identified in the search. Furthermore, the fact that the interventions in the meta-analysis only halfway improved parental competency (only parenting knowledge was improved and not self-efficacy) is problematic. These gaps in research supports the need to systematically implement interventions focused on AI/AN populations, specifically on maternal health early in pregnancy and immediately postpartum.

Parental competence is typically measured through The Parenting Sense of Competence (PSOC) scale on two levels: satisfaction and efficacy (Wells, 2013). Satisfaction is measured through a parent's worry, enthusiasm, and frustration (Wells, 2013). Efficacy is measured through a parent's proficiency, capability levels, and analytical abilities (Wells, 2013). High levels of parental competence can lead to increases in the quality of parent child interactions, parental warmth and responsiveness, and parental involvement (Children of Parents with a Mental Illness, 2016). In the child, these parental characteristics may act as buffers against behavior problems, depression, and anxiety, while simultaneously encouraging higher self-esteem, social contact, and better school performance (Children of Parents with a Mental Illness, 2016). Research shows that parental competence can be improved through intervention programs that focus on providing education on parenting skills and exhibiting proper parenting

behaviors; helping parents understand child development and age appropriate faculties; and teaching parents discipline strategies to improve communication with their children (Glimore & Cuskelly, 2008).

Likewise, it is imperative that interventions are grounded in evidence based practice. Interventions are usually considered evidence based if they are effective at achieving positive outcomes through rigorous evaluations (Wandersman, Alia, Cook, Hsu, & Ramaswamy, 2016). This lack of evidence based interventions are surprising, but not unexpected considering the amount of historical trauma AI/AN women of reproductive age have endured; the limited access to care that many AI/AN women face; and the lack of trust in the health care field that this population has.

Historical Trauma

Historical trauma is generational – the exposure of an earlier generation’s trauma that continues to affect subsequent generations (Myhra, 2011). Unfortunately, AI/AN populations are still experiencing trauma (e.g., Dakota Access Pipeline [DAPL]). For example, the DAPL crosses several private reservations and the Missouri River, threatening AI/AN drinking water, along with cultural and environmental resources (Rodgers & Burleson, 2017). Shared stories from trusted family members, with historically negative consequences cause internalized trauma to AI/AN children, which is carried into adulthood. This historical trauma is linked to emotional stress, including anxiety, self-destructive behavior, and depression and substance use disorders, like alcohol abuse and nonceremonial tobacco use in AI/AN adults (Myhra, 2011). Perhaps, the most unfortunate result is the extent to which individuals in AI/AN communities

suffer from historical trauma; the exact number of people affected by it is unknown. Left untreated, these behaviors (i.e. depression, substance abuse, etc.) continue during reproductive age making pregnancy challenging, increasing the need for more evidence based interventions addressing maternal outcomes among pregnant and postpartum AI/AN women.

Risky behaviors (i.e., cigarette smoking, alcohol abuse, and promiscuity) are significantly associated with trauma exposure (Layne et al., 2014; Simonich et al., 2015). In 2014, the highest prevalence of cigarette smoking was among AI/AN populations (Gould et al., 2017). Tobacco use during pregnancy is one of the most important reversible risk factors for adverse birth outcomes. A baby exposed to tobacco smoke is more likely to be born preterm, low birth weight, or even stillborn (Gould et al., 2017). Yet, despite the need for more strategies to reduce smoking during pregnancy, limited interventions have focused on AI/AN populations. In this study, of the 34 included articles, only three of the interventions focused on tobacco cessation, and all contained significant biases.

AI/AN have reported alcoholism as a result of feelings of disconnect to the community and discrimination. “I just think that my alcoholism can be linked to the notion that this society that we live in here is not my society; it’s not my culture.” (Myhra, 2011, p. 23). “...White people saying that Natives are nothing but alcoholics, drunks; they’ll never amount to nothing... ...I really truly believe that’s a lot of the reason why our people stay drunk is because of things that we have to listen to and go through.” (Myhra, 2011, p. 24). Traditional FAS interventions are designed for pregnant women,

but recent research shows that prevention of FAS must start prior to conception – either by reducing alcohol consumption in women at risk, or preventing pregnancy in women who consume high levels of alcohol (Hanson & Jensen, 2015). In this study, of the 34 included articles, only two of the interventions focused on reducing alcohol consumption, and all contained significant biases.

Risky sexual behaviors can lead to unintended and unwanted pregnancies. Research shows that young women who experience trauma are 20% more likely to engage in casual sex with multiple partners than women who have not experienced trauma (Willmon-Haque & BigFoot, 2008). As previously implied, AI/AN women may already be drinking alcohol and smoking. This is in addition to being sexually active. Hanson et al., 2015 concluded that 65% of AI/AN women who are drinking, smoking, and having sex, but not wanting to become pregnant, are also not using any contraceptive method (Hanson & Jensen, 2015). AI/AN women often experience shame and judgement around their behavioral choices, which can impede interventional help (Hanson & Jensen, 2015). Furthermore, culturally preferred methods for coping highlight self-reliance and other characteristics that are divergent from help seeking behavior (Snowden & Yamada, 2005). Instead of blaming the AI/AN mother for the potential risk to the baby, public health professionals should be implementing more interventions that seek to support the mother by reducing stress; providing safe coping mechanisms; and educating parents about prenatal care, early in pregnancy to improve maternal health. These types of interventions could also promote parental competency.

Limited Access to Care

Many racial minorities bear a disparate burden of morbidity and mortality due to a number of health conditions. These disparities are further exacerbated by limited access to health services. One in five (20%) of the AI/AN population is uninsured (Brown, Ojeda, Wyn, & Levan, 2000). As mentioned in the Literature Review, IHS has provided health services for the AI/AN population since 1955. But, unfortunately, only 20% AI/AN report having IHS coverage (Brown et al., 2000). Seventy-three percent (73%) of whites have jobs that offer insurance, but only 51% of AI/ANs are similarly employed (Brown et al., 2000). AI/AN children are two to three times as likely as white children to receive care inconsistently at the same location/office (Brown et al., 2000). But, how are these numbers related to accessing care?

Many of the health disparities that exist between AI/ANs and the rest of the population are explained by the differences in the way they access and utilize health care (Rutman, Phillips, & Sparck, 2016). Some common barriers to accessing health care include: less insurance coverage; geographic distance to care; inconsistent preventive care; previous negative experiences; and fear of the health care field (Gonzales, Lambert, Fu, Jacob, & Harding, 2014; Towne, Smith, & Ory, 2014; Sawchuck et al., 2016; Rutman et al., 2016). Insurance coverage is a major problem for AI/AN. As previously mentioned, few have coverage even under IHS or through employers. IHS services are provided at no cost; however, most of these facilities are located in rural areas, near reservations, and require the individual to be registered with the tribe (Boccuti, Swoope, & Artiga, 2014). But, at increasing rates, less AI/AN reside in rural areas, with roughly

71% living in urban areas as of 2010 (Rutman et al., 2016). Relocation rates stem from better opportunities for education, employment, and housing. In addition to the location of IHS clinics and facilities in mostly rural areas, when service demands surpass available funds (which is often the case), IHS services are then prioritized and rationed, thereby further limiting access (Boccuti et al., 2014). In terms of insurance coverage through employment, AI/AN have fewer jobs that offer coverage, and even with available coverage, some AI/AN are still unable to pay insurance premiums. Without adequate insurance coverage, many AI/AN are simply unable to afford the cost of seeing a medical provider.

As stated, the location of services can be problematic. Rural health providers are often as far as three times the distance of urban providers, often the distance to a provider exceeds what is feasible for AI/AN (Towne et al., 2016). This is further complicated if AI/AN clients do not have transportation to the medical office. If an individual does not have access to a car, having friends or family take her to an appointment or riding public transportation are the only options. Unfortunately, this also affects quality of care. Some individuals select closer locations (urban areas), even if the care is perceived to be inferior (Shah et al., 2014). The number of providers in different areas impacts access, with average numbers of providers significantly decreasing in urban areas (Towne Jr et al., 2014). Therefore, in areas where there are high proportions of AI/AN residents (i.e., most urban areas), the largest disparities in availability, distance, and utilization of providers exists (Towne Jr et al., 2014).

Seeking preventive care is associated with lower rates of chronic disease and hospitalizations (Bodenheimer, Chen, & Bennett, 2009; Rutman et al., 2016). However, more AI/AN report not having seen or spoken with a health professional in the past year or longer (Rutman et al., 2016). As previously stated, not regularly seeing a medical provider is most associated with cost. Other cost-related barriers include: lack of information about low or no cost health services; difficulty getting childcare while attending a doctor's appointment; and inability to take time off work to attend an appointment (Rutman et al., 2016).

However, simply having access to care does not equal better health, because it does not ensure quality. Research shows that prenatal care provided to AI/AN women is poorer than care delivered to non AI/AN women (Gould, Patten, Glover, Kira, & Jayasinghe, 2017). As with access to care, these barriers include: lack of cultural understanding; stigma around risky health behaviors; geographic location of care (i.e., lack of transportation); past negative experiences and discrimination; and fear of the health care system (Gould et al., 2017; Varcoe, Brown, Calam, Harvey, & Tallio, 2013).

In addition to quality care, the timing of prenatal care should also be considered, as care during the first trimester and continuing throughout pregnancy, is associated with decreased risk of adverse birth effects (Partridge, Balayla, Holcroft, & Abenheim, 2012). There are many barriers to adequate prenatal care. Parity could be an explanation, as women who have had previous negative experiences with pregnancy, delivery, or in the interactions with healthcare providers may not want to return for later pregnancies. Money is another justification. If a woman is unemployed she may lack resources to

access prenatal care. “I think it all depends on the resources that you have, in order to get here or to pay for it. I think that’s a major problem for some...” (Hawley et al., 2014, p. 2289). Furthermore, some women feel that doctors care more about making money, than providing care (Redding, 2015). This may all be influenced by the level of AI/AN trust of the healthcare field.

Lack of Trust in the Health Care Field

A patient’s trust is directly related to receptiveness of medical advice and compliance with treatment recommendations (Simonds, Goins, Krantz, & Marie, 2013). Unfortunately, racial minorities, such as AI/ANs, report lower trust in healthcare providers and healthcare systems, which is a likely contributor to health disparities (Simonds et al., 2013). In a recent study about cultural identity and patient trust, patients identifying as AI/ANs reported considerably less trust in the health care field than those who identified as another race (Simonds et al., 2013). Some AI/ANs feel that medical providers are not as educated as they should be. “I don’t think they know what they are doing up there. I don’t trust any of them.” (Simonds et al., 2013, p. 10). This perception may result from the IHS facilities that provide training opportunities for clinicians; these facilities, are seen as teaching hospitals (Brown & Birnbaum, 2005; Simonds et al., 2013). Other barriers to trust are embarrassment, high turnover rates in physicians, and lack of social courtesy. “Some people are embarrassed to go because they know that they did wrong.” (Simonds et al., 2013, p. 9). Additionally, there is less continuity of care with the constant changing of staff. “Different new providers coming in, the one you’re getting used to, next week it’s gone.” (Simonds et al., 2013, p. 10). It is difficult to

establish a relationship with a provider when they are changing...” (Simonds et al., 2013, p. 10). “Some of the employees are so rude that you just don’t want to deal with them.” (Simonds et al., 2013, p. 10). With the many perceived trust issues identified by AI/AN, it is paramount that interventions address these concerns through culturally appropriate programs, while providing quality care and improving community access to services.

Application of Life Course Framework

The life course framework for maternal and child health (MCH) focuses on the combination of three major themes: 1) early and preventive interventions; 2) multi-level cross sector interventions; and 3) multidimensional systems integration (Lu, 2014). The first theme relates to timing; knowing when to intervene to have the most impact. For this study, interventions early in pregnancy could prevent maternal complications, poor birth outcomes, and poor maternal health postpartum. The second theme relates to doing what matters the most. In this study, focusing on the pregnant woman to ensure her good health, provides a safer environment for delivery of a healthy baby. Another way to look at this theme is to establish a whole person, holistic approach that addresses social determinants of health (i.e., root causes) like racism, poverty, educational attainment, and employment opportunities. The last theme encompasses vertical, horizontal, and longitudinal dimensions of systems integration. Vertical integration refers to perinatal regionalization, or the categorization of hospitals in an area based on the breadth of perinatal services provided (Lasswell, Barfield, Rochat, & Blackmon, 2010). Horizontal integration refers to service coordination, including community and economic development. Longitudinal integration refers to a continuum of care across the life

course. All of these taken together indicate that MCH interventions should focus on a holistic approach, focusing on all three themes in order to produce lasting large scale change.

The life course framework presents a concept of how different exposures affect two lives simultaneously. Using the life course framework to assess how maternal health during, and following pregnancy influences the future health of the mother and the trajectory of the infant is key to achieving positive maternal and infant health outcomes (Pies & Kotelchuck, 2014). Research shows that infant mortality rates are directly proportionate to the health of the mother, only decreasing when the vitality of women of reproductive age improved (Russ, Larson, Tullis, & Halfon, 2014). Furthermore, health is determined by the timing and order of biological, cultural, and historic events, as discussed in the Literature Review chapter. For future research, the findings of this study suggest that successful, evidence based interventions should be piloted and replicated with results widely disseminated, taking into consideration vulnerable populations with unique circumstances and risk factors.

Without a doubt, evidence shows that adverse early life exposures increase disease risk, through both poor or small brain development and increases in harmful behaviors, as coping mechanisms (Bloom, 2012; Boekelheide et al., 2012; Graaf, Steegers, & Bonsel, 2013). Factors such as maternal stress during pregnancy, inadequate access to nutrition in utero, and childhood poverty are all precursors for an increased risk of later disease (Bullock, 2015). Interventions that prevent or reduce adversities early in pregnancy are critical (Bullock, 2015; Halfon, Larson et al., 2014; Bullock, 2015). The

further into the 'lifespan' (in this case, pregnancy) that intervention occurs, the lower the potential impact of that may be achieved. A clear example of this is in utero malnourishment leads to fetal changes that may alter the developing body's structure, function, and metabolism, thus predisposing the fetus to increased risk of disease development in adulthood (Gluckman, Hanson, Phil, Cooper, & Thornbug, 2008). Unfortunately, exposure predisposes the baby to development of adult onset diseases, including metabolic syndrome, insulin resistance, and obesity (Gluckman & Hanson, 2004).

So how can life course help? How does understanding the life course framework help MCH programs in the future? Research should move beyond understanding the problem to intervention research, with a particular focus on life course. Dr. Lu, Administrator, Maternal and Child Health Bureau/Human Resources and Services Administration (MCHB/HRSA), described it perfectly: "...our field cannot get stuck in the discovery phase. What we need are well designed intervention studies to demonstrate what works and what does not in disease prevention, and health promotion and optimization across the life course." (Lu, 2014, p. 341). Although, there is much research to show the negative effects of alcohol, substance abuse, and nonceremonial tobacco use, there are not enough evidence based interventions, focused on these topics, free of substantial biases, and designed specifically for AI/AN women during pregnancy and postpartum (Behnke, Smith, Committee on Substance Abuse, & Committee on Fetus and Newborn, 2013; Varner et al., 2014; Wendell, 2013). Timing is important. Interventions need to identify the best time frame for intervention, based on the desired outcome. For

example, in this study it should now be clear that interventions for AI/AN women of reproductive age need to center around healthy pregnancies in order to achieve healthy birth outcomes. Early interventions not only improve life chances for success, they also produce better economic returns, as there is potential for less healthcare to treat chronic conditions later in life (Wachs, Georgieff, Cusick, & McEwen, 2014).

Study Strengths

This study's biggest strength is the use of the PRISMA Statement to conduct the systematic review. In 2009 the PRISMA Statement was established to set exemplary guidelines for the reporting of systematic reviews and meta-analyses. Prior to that time, Cochrane reviews were the standard for systematic reviews (Dixon-Woods et al., 2006). However, since the Cochrane Collaboration's endorsement of the PRISMA Statement, research shows that there has been an increase in the quality of both the methodological process for and the reporting of systematic reviews using this method (Panic, Leoncini, Belvis, Ricciardi, & Boccia, 2013). Furthermore, it is suggested that more medical journals include PRISMA in the instructions for their authors (Panic et al., 2013). Although systematic reviews are published often, at an estimated 11 new reviews published daily (Moher et al., 2015; Littell, Corcoran, Pillai, 2008), systematic reviews have become the standard for evidence based practices due to their explicitly detailed methodology for searching for and synthesizing findings (Moher et al., 2015). This rigor and transparency give systematic reviews the greatest advantage over other methods of review.

Study Limitations

Two biases that could affect this study are selection bias and publication bias. *Selection bias*, which occurs when the selection of subjects in a study leads to a different outcome than what would have been obtained had the entire population been enrolled in the study (McDonagh, Peterson, Raina, Chang, & Shekelle, 2013). This could have occurred through individual errors in reading and reviewing studies by the primary investigator. However, criteria was set a priori and the PRISMA Statement was used as a protocol for methodology in order to reduce selection bias. Furthermore, a secondary investigator validated the primary investigator's choices in article selection, and two scientific advisors helped to resolve any inconsistencies. Although the primary investigator could not control for publication bias, it is assumed that articles without such bias are available. Publication introduces various biases, as the published literature could be a misrepresentation of the population in the study, meaning that smaller, more vulnerable populations might be harder to find in literature, as they may report smaller effects for the same questions as larger populations and are less likely to be published (Schmidt & Hunter, 2015). *Publication bias* is where studies with more positive, statistically significant results are published compared with those with less favorable or non-significant results (Ahmed, Sutton, & Riley, 2012). This was minimized by the inclusion of both published and unpublished theses and dissertations being included in the types of articles searched. A final weakness of this study also included the relatively small number of articles included in the meta-analysis. However, this is not unusual, as a

survey of leading journals found that many included fewer than 10 articles (Gerber et al., 2007).

Recommendations for Future Research

From the volume of articles identified (N = 2,664), it is clear that a large number of interventions are being conducted. This is especially encouraging since AI/AN face much higher rates of mortality, morbidity, and risk factors for poor health than other populations (Cobb, Espey, & King, 2014). However, most of these interventions contain significant biases. Additionally, when trying to improve parental competency, through parenting knowledge and self-efficacy, only parenting knowledge was enhanced. As has been demonstrated earlier in this chapter, parenting knowledge and self-efficacy work together to make up parental competency. Interventions must focus on both aspects in order to fully improve parental competence. As discussed in this chapter, the majority of the included studies do not have a specific focus on maternal health or outcomes, but focus on infant health and wellbeing. Therefore, future investigators should be more rigorous in the quality of research conducted and focus on low bias methods and designs. To summarize, more evidence based interventions, free of significant biases and inclusive of maternal outcomes, should be published to identify effective strategies for improving maternal health and parental competence among pregnant and postpartum AI/AN women.

Public Health Implications

This study identified several challenges of current interventions in pregnant and postpartum AI/AN women. Nearly 3,000 articles over the past 22 years were identified

which focused on ways to improve the quality of life for AI/AN women of reproductive age who are pregnant or postpartum. However, of studies that met the a priori criteria and PICOS approach, only 34 were eligible for inclusion in the risk of bias assessment. Consequently, after an assessment of risk of bias, only six of 34 were considered to be of low bias. Furthermore, of those same studies, only two of the studies' effect measures were similar enough to conduct a meta-analysis. This creates a huge gap in credible interventions targeting this high risk population.

Of the 34 qualitative synthesis eligible articles, 14 of them (more than 41%) involved interventions related to breastfeeding, focused on increasing initiation rates or duration lengths. While there are many proven benefits of breastfeeding, including reductions in: infant mortality, childhood obesity, and diabetes, the main benefactor is the baby (Stevens, Hanson, Prasek, & Elliott, 2008).

But, what about interventions that support the health and well-being of the mother?

With all of the known issues (i.e. mental health, substance abuse, alcohol abuse, etc.) that AI/AN women of reproductive age face, it would seem appropriate and necessary for there to be more interventions focusing on the health of the woman or interventions targeting women much earlier in pregnancy. This study indicates that most interventions are designed with a focus on the infant or occur late in pregnancy, when potential harm has already occurred, while there could be more focus on the women's needs during pregnancy, as this is the best way to ensure a healthy delivery and baby.

This finding identifies a gap in AI/AN maternal research through community based interventions that can target AI/AN women before pregnancy or during early pregnancy.

Interventions could focus on initiation of early prenatal care through the use of *community-based participatory research* (CBPR). CBPR is a method for engaging specific groups of people in the process of review and social change (Roberts, 2013). The foundation of CBPR is respect for the pride and sovereignty of people who make up a community by living in a certain geographic location or sharing racial, ethnic, or cultural identity (Roberts, 2013). The goal of CBPR is to achieve goodness as determined by these communities, such that is categorized by understanding from the specific population's perspective, mutuality, and objectivity (Roberts, 2013). This CBPR should engage the community in the design of the intervention through advisory committees that help to target specific groups and adapt programs to the community (McLeroy, Burdine, & Sumaya, 2003). This could create positive social change at the individual, family, and societal level.

As mentioned, access to care is also a problem for AI/AN women, so interventions targeting access are warranted. While IHS services are available free of charge and some specialty services are also available through contracts with private providers, available services vary across tribes and not all service areas have IHS hospitals or clinics. Since services are also limited by inadequate funding, some routine preventative care services might not be available for pregnant and postpartum AI/AN women, all year (Towne Jr et al., 2014). Another issue with access to care is location. Most AI/AN populations reside in urban areas usually far from reservations, limiting

access to IHS facilities and services. For those AI/AN women that do have access to care, most report lower use of services, and issues with providers including: a lack of confidence in current access to care; dissatisfaction with the quality of care, and poor communication with the providers (Zuckerman, Haley, Roubideaux, & Lillie-Blanton, 2004). These are problems with the system of care itself and future interventions should focus on implementing strategies in areas where there are larger populations of AI/AN, as these are where the majority of disparities in availability, utilization, and location of providers are occurring. This could create positive change at the organizational and societal levels.

Future interventions should also focus on reaching women occur early in pregnancy (particularly during the first trimester). Of the maternal risk factors mentioned in this dissertation that affect poor birth outcomes (e.g., rates of nonceremonial tobacco and alcohol use and mental illness), most are modifiable behavioral risk factors that, if changed, could lead to healthier pregnancies with better birth outcomes. Considering what is known about life course, as a result of historical trauma and other socioeconomic factors, AI/AN women tend to have higher levels of stress and mental distress, which can lower uterine blood flow and fetal oxygenation during pregnancy (Mehl-Madrona, 2000). Therefore, it is important that, early in pregnancy, AI/AN women are involved in interventions that teach stress coping techniques as well as how to work through past traumas (e.g., abuse and neglect), which will further help to promote parental competency. Historically, AI/AN have had little participation in the design of interventions/programs for their benefit. This means that the interventions should be

culturally sensitive so that AI/AN women can easily relate and participate. Additionally, it would be most helpful if they were delivered by a person of similar ethnicity, as they are more likely to respond to treatment (Cobb et al., 2014). This could create positive social change at the societal level.

As has been initially demonstrated in the Literature Review and here again in this chapter, substance and alcohol misuse is usually in response to historical and cultural trauma as well as violence as a means of coping. In the case of alcohol abuse, drinking during pregnancy is greatly influenced by social norms. Therefore, another part of the intervention should relate to education. When designing programs aimed at reducing or stopping drinking during pregnancy, understanding the misconceptions around alcohol use in pregnancy are crucial. These programs must emphasize the health risks of drinking (for mother and baby), specifically in the AI/AN community, as more targeted information is more likely to affect behavior. Ideally, interventions should also provide treatment and support options. In the case of nonceremonial tobacco use (cigarette smoking), personal counseling, nicotine replacement therapies, and social support/encouragement have all been shown to provide increased risk-reducing behavior and for the most benefit, should be incorporated in cessation programs during early pregnancy (Lumley, et al., 2009). In the case of parental competence, parent training programs that successfully blend training contents with parental perceptions and expectations yield higher effectiveness of a sense of competence and the perceptions of child problem behavior in parents (Graf, Grumm, Hein, & Fingerle, 2014). In children, successful training seems to yield decreases in children's dysfunctional behavior

problems (Graf, Grumm, Hein, & Fingerle, 2014). These educational gains could create positive social change at the individual, family, and societal levels.

Conclusion

While improvements have been made in MCH, there are still disparities – some growing, particularly in the AI/AN community compared with non-Hispanic Whites (Wong et al., 2014). For example, when Espey et al. (2014) examined all causes of mortality in AI/AN women, the age group 25 to 44 years (reproductive age) exhibited the highest numbers of death (Espey et al., 2014). Furthermore, cancer and heart disease were found to be the leading cause of death in AI/AN females (Espey et al., 2014). The third through sixth leading cause of death was unintentional injuries, diabetes, stroke, and chronic liver disease (Espey et al., 2014). A notable rate disparity was seen in non-Hispanic Whites, as these causes were ranked, sixth, eighth, third, and twelfth, respectively (Espey et al., 2014).

This study highlights the association of several of those MCH disparities, including historical trauma, limited access to care, and poor maternal health. The study also offers some solutions for further research and how improvements could be made. It is important to understand the changes in disparities in both risk factors and outcomes over time in order to produce culturally appropriate interventions for AI/AN women of reproductive age who are pregnant or postpartum. Understanding and, more specifically, addressing the needs of AI/AN mothers, as well as regional disparities, enables MCH professionals to create effective, targeted evidence based strategies and policies for the

future while contributing to the foundation of scientific knowledge (Sequist, Cullen, & Acton, 2011).

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Appendix A: Original PRISMA Statement

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	

Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	

Appendix B: List of Search Terms and Databases

Search Strategies

Medline via PubMed

Searched 2013/11/13

Search Statement	Search String	Results	Update 03/03/15
1.	"Indians, North American"[Mesh] OR "Inuits"[Mesh] OR "United States Indian Health Service"[Mesh]	13,636	14,373
2.	(Alaska native*[tiab] OR American Indian*[tiab] OR Amerindian*[tiab] OR Eskimo*[tiab] OR Inuit*[tiab] OR Native American*[tiab] OR ("North American"[tiab] AND Indian*[tiab]))	11,724	12,627
3.	1 OR 2	18,959	20,158
4.	"Abortion Applicants"[Mesh] OR "Abortion, Criminal"[Mesh] OR "Abortion, Induced"[Mesh] OR "Abortion, Legal"[Mesh] OR "Abortion, Spontaneous"[Mesh] OR "Abortion, Therapeutic"[Mesh] OR "Analgesia, Obstetrical"[Mesh] OR "Bottle Feeding"[Mesh] OR "Breast Feeding"[Mesh] OR "Delivery Rooms"[Mesh] OR "Delivery, Obstetric"[Mesh] OR "Fetal Monitoring"[Mesh]	1,052,587	1,102,843

	<p>OR "Fetal Therapies"[Mesh] OR "Infant Nutritional Physiological Phenomena"[Mesh] OR "Labor, Obstetric"[Mesh] OR "Labor Pain"[Mesh] OR "Maternal Behavior"[Mesh] OR "Maternal-Child Health Centers"[Mesh] OR "Maternal-Child Nursing"[Mesh] OR "Maternal Health Services"[Mesh] OR "Midwifery"[Mesh] OR "Mother-Child Relations"[Mesh] OR "Mothers"[Mesh] OR "Nurse Midwives"[Mesh] OR "Obstetrics"[Mesh] OR "Peripartum Period"[Mesh] OR "Posthumous Conception"[Mesh] OR "Postpartum Period"[Mesh] OR "Pregnancy Complications"[Mesh] OR "Pregnant Women"[Mesh] OR "Prenatal Care"[Mesh] OR "Prenatal Diagnosis"[Mesh] OR "Reproduction"[Mesh] OR "Reproductive Rights"[Mesh] OR "Reproductive Techniques"[Mesh]</p>		
5.	<p>Antenat*[tiab] OR Breast Fe*[tiab] OR Breastfe*[tiab] OR Gestat*[tiab] OR Intrapartum[tiab] OR</p>	674,371	721,421

	Matern*[tiab] OR Mother*[tiab] OR Obstetric*[tiab] OR Midwife*[tiab] OR Postpartum[tiab] OR Pregnanc*[tiab] OR Pregnant*[tiab]		
6.	4 OR 5	1,244,773	1,316,318
7.	3 AND 6	1,682	1786
8.	Limit to 1992-2015/12/31	1,224	80 (limit 11/13-12/15)

Embase (1988-present) via Ovid

Searched 2013/11/13

Search Statement	Search String	Results	Update 03/03/15
1.	american indian/ or eskimo/	11,277	12009
2.	(Alaska\$ adj native\$) or (American adj Indian\$) or Amerindian\$ or Eskimo\$ or Inuit\$ or (Native\$ adj America\$)	16,133	17154
3.	1 or 2	16,133	17154
4.	exp Delivery Room/ or exp Infant Nutrition/ or exp Infertility Therapy or exp Maternal Behavior/ or exp Midwife/ or exp Mother/ or exp Obstetric Procedure/ or exp Obstetrics/ or exp "Parameters Concerning the Fetus, Newborn and Pregnancy"/ or exp Perinatal Period/ or exp Pregnancy Disorder/ or exp	1,002,754	1063017

	Reproduction/ or Reproductive Rights/		
5.	Antenat\$ or (Breast adj Fe\$) OR Breastfe\$ OR Gestat\$ OR Intrapartum OR Matern\$ OR Mother\$ OR Obstetric\$ OR Midwife\$ OR Postpartum OR Pregnanc\$ OR Pregnant\$	783,008	832324
6.	4 or 5	1,152,893	1227416
7.	6 and 3	1,577	1706
8.	Limit to 1992-2015	1,492	163(limit 11/13- 12/15)

CINAHL via EBSCOHost

Searched 2013/11/13

Search Statement	Search String	Results	Update 03/03/15
1.	(MH "Eskimos") OR (MH "Native Americans")	5,567	5,976
2.	(Alaska* N1 native*) OR (American W1 Indian*) OR Amerindian* OR eskimo* OR inuit* OR (Native* N1 America*)	6,360	6,887
3.	1 or 2	6,360	6,887
4.	(MH "Abortion, Criminal") OR (MH "Analgesia, Obstetrical") OR (MH "Delivery Rooms+") OR (MH "Diagnosis, Obstetric") OR (MH "Fetal Development+") OR (MH "Fetal Monitoring+") OR (MH "Infant Feeding+") OR (MH "Infant Nutritional Physiology+") OR (MH	163,331	176,480

	"Maternal Behavior") OR (MH "Maternal Health Services+") OR (MH "Maternal-Child Care+") OR (MH "Maternal-Child Nursing") OR (MH "Midwifery+") OR (MH "Midwives+") OR (MH "Mother-Infant Relations") OR (MH "Mothers+") OR (MH "Obstetrics") OR (MH "Obstetric Nursing") OR (MH "Perinatal Nursing") OR (MH "Pregnancy Complications+") OR (MH "Prenatal Diagnosis+") OR (MH "Reproduction Techniques+") OR (MH "Reproduction+") OR (MH "Surgery, Obstetrical+")		
5.	Antenat* OR (Breast W1 Fe*) OR Breastfe* OR Gestat* OR Intrapartum OR Matern* OR Mother* OR Obstetric* OR Midwife* OR Postpartum OR Pregnanc* OR Pregnant*	159,536	173,578
6.	4 or 5	192,164	208,485
7.	3 and 6	664	726
8.	Limit to 1992-2015	634	45 (limit 11/13-12/15)

CAB Abstracts via Ovid (1973-present)

Searched 2013/11/13

Search Statement	Search String	Results	Update 03/03/15
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1.	Alaska Natives/ or exp American Indians/ or Inuit/	1,054	1,132
2.	(Alaska\$ adj Native\$) or (American adj Indian\$) or Amerindian\$ or Eskimo\$ or Inuit\$ or (Native\$ adj American\$)	2,918	3,138
3.	1 or 2	2,929	3,150
4.	exp Abortion/ or Childbirth/ or Fetal Development/ or Induced Abortion/ or exp Infant Feeding/ or Infant Nutrition/ or exp Maternal Behaviour/ or exp Maternity Services/ or Midwives/ or exp Mothers/ or Obstetrics/ or Postpartum Period/ or exp Pregnancy Complications/ or Prenatal Care/ or exp Prenatal Diagnosis/ or exp Prenatal Period/ or exp Sexual Reproduction/ or Traditional Birth Attendants/ or exp Weaning/	190,682	205,589
5.	Antenat\$ or (Breast adj Fe\$) OR Breastfe\$ OR Gestat\$ OR Intrapartum OR Matern\$ OR Mother\$ OR Obstetric\$ OR Midwife\$ OR Postpartum OR Pregnanc\$ OR Pregnant\$	187,687	201,227

6.	VV060.cc. (VV060 is Human Reproduction and Development)	31,623	36,771
7.	4 OR 5 or 6	291,020	312,001
8.	3 AND 6	206	226
9.	Limit to 1992-2015	166	19(limit 11/13-12/15)

Global Health via Ovid (1910-present)

Searched 2013/11/13

Search Statement	Search String	Results	Update 03/03/15
1.	Alaska Natives/ or exp American Indians/ or Inuit/	2,670	2922
2.	(Alaska\$ adj Native\$) or (American adj Indian\$) or Amerindian\$ or Eskimo\$ or Inuit\$ or (Native\$ adj American\$)	4,531	4,946
3.	1 or 2	4,562	4,979
4.	exp Abortion/ or Childbirth/ or Fetal Development/ or Induced Abortion/ or exp Infant Feeding/ or Infant Nutrition/ or exp Maternal Behaviour/ or exp Maternity Services/ or Midwives/ or exp Mothers/ or Obstetrics/ or Postpartum Period/ or exp Pregnancy Complications/ or Prenatal Care/ or exp Prenatal Diagnosis/ or exp Prenatal Period/ or exp Sexual Reproduction/ or	121,673	134,367

	Traditional Birth Attendants/ or exp Weaning/		
5.	Antenat\$ or (Breast adj Fe\$) OR Breastfe\$ OR Gestat\$ OR Intrapartum OR Matern\$ OR Mother\$ OR Obstetric\$ OR Midwife\$ OR Postpartum OR Pregnanc\$ OR Pregnant\$	147,718	162,155
6.	VV060.cc. (VV060 is Human Reproduction and Development)	76,893	86,186
7.	4 OR 5 or 6	201,533	220,178
8.	3 AND 6	498	541
9.	Limit to 1993-present	346	39(limit 11/13-12/14)

Cochrane

Searched 2013/11/13

Search Statement	Search String	Results	Update 03/03/15
1.	[mh "Indians, North American"]	165	186
2.	[mh Inuits]	26	30
3.	[mh 'United States Indian Health Service']	4	5
4.	(Alaska* near/1 Native*) or (American next Indian*) or Amerindian* or Eskimo* or Inuit* or (Native* near/1 America*):ti,ab,kw (Word variations have been searched)	261	444
5.	#1 or #2 or #3 or #4	324	508
6.	[mh "Abortion Applicants"]	1	1

7.	[mh "Abortion, Criminal"]	1	1
8.	[mh "Abortion, Induced"]	899	845
9.	[mh "Abortion, Legal"]	24	26
10.	[mh "Abortion, Spontaneous"]	624	349
11.	[mh "Abortion, Therapeutic"]	72	65
12.	[mh "Analgesia, Obstetrical"]	796	849
13.	[mh "Bottle Feeding"]	168	180
14.	[mh "Breast Feeding"]	1183	1136
15.	[mh Delivery Rooms"]	52	61
16.	[mh "Delivery, Obstetric"]	3881	4227
17.	[mh "Fetal Monitoring"]	343	360
18.	[mh "Infant Nutritional Physiological Phenomena"]	1727	1907
19.	[mh "Labor, Obstetric"]	1882	2005
20.	[mh "Labor Pain"]	105	136
21.	[mh "Maternal Behavior"]	199	219
22.	[mh "Maternal-Child Health Centers"]	40	44
23.	[mh "Maternal-Child Nursing"]	182	194
24.	[mh "Maternal Health Services"]	1430	1621
25.	[mh Midwifery]	225	257
26.	[mh "Mother-Child Relations"]	497	575
27.	[mh Mothers]	848	1000
28.	[mh "Nurse Midwives"]	93	99
29.	[mh "Peripartum Period"]	5	5
30.	[mh "Posthumous Conception"]	0	0
31.	[mh "Postpartum Period"]	977	1084
32.	[mh "Pregnancy Complications"]	7162	7906

33.	[mh "Pregnant Women"]	77	98
34.	[mh "Prenatal Care"]	983	1073
35.	[mh "Prenatal Diagnosis"]	862	954
36.	[mh Reproduction]	7645	8267
37.	[mh "Reproductive Rights"]	0	0
38.	[mh "Reproductive Techniques"]	3,143	3452
39.	#6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23 or #24 or #25 or #26 or #27 or #28 or #29 or #30 or #31 or #32 or #33 or #34 or #35 or #36 or #37 or #38	20,603	22,553
40.	Antenat* or (Breast next Fe*) or Breastfe* or Gestat* or Intrapartum or Matern* or Mother* or Obstetric* or Midwife* or Postpartum or Pregnanc* or Pregnant*	46,105	54,863
41.	#39 or #40	48,090	57,061
42.	#41 and #5	34	9(limit 11/13- 12/14)

SIGLE-Open Grey

Searched 2013/11/13

Search Statement	Search Strategy	Results	Update 03/03/15
1.	((Alaska* NEAR/1 native*) OR (American NEAR/1 Indian*) OR Amerindian* OR Eskimo* OR Inuit* OR (Native* NEAR/1	0	0

	America*)) AND (Antenat* OR (Breast NEAR/1 Be*) OR Breastfe* OR Gestat* OR Intrapartum OR Matern* OR Mother* OR Obstetric* OR Midwife* OR Postpartum OR Pregnanc* OR Pregnant* OR Prenat*)		
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Campbell Library

Searched 2013/11/13

Search Statement	Search String	Results	Update 03/03/15
1.	"Alaska Native" OR "Alaska Natives" OR "American Indian" OR "American Indians" OR Amerindian* OR Eskimo* OR Inuit* OR "Native American" OR "Native Americans"	28	30
2.	Antenat* OR "Breast Fed" OR "Breast Feed" OR "Breast Feeding" OR Breastfe* OR Gestat* OR Intrapartum* OR Matern* OR Mother* OR Obstetric* OR Midwife* OR Postpartum OR Pregnanc* OR Pregnant*	85	104
3.	1 AND 2	18	1 (limit 11/13- 12/14)

Agricola

Searched 2013/11/13

Search Statement	Search String	Results	Update 03/03/15
1.	("Alaska Native" OR "Alaska Natives" OR "American Indian" OR "American Indians" OR "Native American" OR "Native Americans" OR Amerindian? OR Eskimo? OR Inuit?) AND (Antenat? OR "Breast Bed" OR "Breast Feed" OR "Breast Feeding" OR Breastfe? OR Gestat? OR Intrapartum? OR Matern? OR Mother? OR Obstetric? OR Midwife? OR Postpartum OR Pregnanc? OR Pregnant?) Published after 1992	33	0 (limit 11/13-12/14)

Social Services Abstracts

Searched 2013/11/13

Search Statement	Search String	Results	Update 03/03/15
1.	SU.EXACT.EXPLODE("American Indians") OR SU.EXACT("Eskimos")	752	806
2.	(Alaska* NEAR/1 native*) OR (American PRE/1 Indian*) OR Amerindian* OR Eskimo* OR Inuit* OR (Native* NEAR/1 America*)	1,178	1284
3.	1 or 2	1,178	1284
4.	SU.EXACT("Abortion") OR SU.EXACT("Adolescent	6,140	6643

	Mothers") OR SU.EXACT("Adolescent Pregnancy") OR SU.EXACT("Amniocentesis") OR SU.EXACT("Artificial Insemination") OR SU.EXACT("Birth") OR SU.EXACT("Breast Feeding") OR SU.EXACT("Maternal/Maternity") OR SU.EXACT("Midwifery") OR SU.EXACT("Miscarriage") OR SU.EXACT("Mothers") OR SU.EXACT("Pregnancy") OR SU.EXACT("Prenatal Care") OR SU.EXACT("Prenatal Testing") OR SU.EXACT("Reproductive Technologies") OR SU.EXACT("Sexual Reproduction") OR SU.EXACT("Single Mothers") OR SU.EXACT("Unwanted Pregnancy") OR SU.EXACT("Working Mothers")		
5.	Antenat* OR (Breast PRE/1 Fe*) OR Breastfe* OR Gestat* OR Intrapartum OR Matern* OR Mother* OR Obstetric* OR Midwife* OR Postpartum OR Pregnanc* OR Pregnant* OR Prenat*	11,025	11,803
6.	4 OR 5	11,452	12,266
7.	3 AND 6	66	71
8.	Limit to 1992-2015	61	3(limit 11/13- 12/14)

WorldCat

Searched 2013/11/14

	Search String	Results	Update 03/03/15
Advanced search	ti:("Alaska Native" OR "Alaska Natives" OR "American Indian" OR "American Indians"	52 (limited to dissertations)	2 (limit dissertations: limit 11/13-12/14)

	<p>OR Amerindian* OR Eskimo* OR Inuit* OR "Native American" OR "Native Americans") AND (Antenat* OR "Breast Fed" OR "Breast Feed" OR "Breast Feeding" OR Breastfe* OR Gestat* OR Intrapartum* OR Matern* OR Mother* OR Obstetric* OR Midwife* OR Postpartum OR Pregnanc* OR Pregnant*)</p> <p>Limit to 1992-2015</p>		
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Appendix C: Cochrane Risk of Bias Tool

Domain	Support for judgement	Review authors' judgement
<i>Selection bias.</i>		
Random sequence generation.	Describe the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups.	Selection bias (biased allocation to interventions) due to inadequate generation of a randomized sequence.
Allocation concealment.	Describe the method used to conceal the allocation sequence in sufficient detail to determine whether intervention allocations could have been foreseen in advance of, or during, enrolment.	Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.
<i>Performance bias.</i>		
Blinding of participants and personnel <i>Assessments should be made for each main outcome (or class of outcomes).</i>	Describe all measures used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.
<i>Detection bias.</i>		
Blinding of outcome assessment <i>Assessments should be made for each main outcome (or class of outcomes).</i>	Describe all measures used, if any, to blind outcome assessors from knowledge of which intervention a participant received. Provide any information relating to whether the intended blinding was effective.	Detection bias due to knowledge of the allocated interventions by outcome assessors.
<i>Attrition bias.</i>		
Incomplete outcome data <i>Assessments should be made for each main outcome</i>	Describe the completeness of outcome data for each main outcome, including attrition and exclusions from the analysis. State whether attrition and exclusions were	Attrition bias due to amount, nature or handling of

<i>(or class of outcomes).</i>	reported, the numbers in each intervention group (compared with total randomized participants), reasons for attrition/exclusions where reported, and any re-inclusions in analyses performed by the review authors.	incomplete outcome data.
<i>Reporting bias.</i>		
Selective reporting.	State how the possibility of selective outcome reporting was examined by the review authors, and what was found.	Reporting bias due to selective outcome reporting.
<i>Other bias.</i>		
Other sources of bias.	State any important concerns about bias not addressed in the other domains in the tool. If particular questions/entries were pre-specified in the review's protocol, responses should be provided for each question/entry.	Bias due to problems not covered elsewhere in the table.

Appendix D: Criteria for Judging Risk of Bias from the Cochrane Risk of Bias Tool

RANDOM SEQUENCE GENERATION	
Selection bias (biased allocation to interventions) due to inadequate generation of a randomised sequence.	
Criteria for a judgement of 'Low risk' of bias.	<p>The investigators describe a random component in the sequence generation process such as:</p> <ul style="list-style-type: none"> • Referring to a random number table; • Using a computer random number generator; • Coin tossing; • Shuffling cards or envelopes; • Throwing dice; • Drawing of lots; • Minimization*. <p>*Minimization may be implemented without a random element, and this is considered to be equivalent to being random.</p>
Criteria for the judgement of 'High risk' of bias.	<p>The investigators describe a non-random component in the sequence generation process. Usually, the description would involve some systematic, non-random approach, for example:</p> <ul style="list-style-type: none"> • Sequence generated by odd or even date of birth; • Sequence generated by some rule based on date (or day) of admission; • Sequence generated by some rule based on hospital or clinic record number. <p>Other non-random approaches happen much less frequently than the systematic approaches mentioned above and tend to be obvious. They usually involve judgement or some method of non-random categorization of participants, for example:</p> <ul style="list-style-type: none"> • Allocation by judgement of the clinician; • Allocation by preference of the participant; • Allocation based on the results of a laboratory test or a series of tests; • Allocation by availability of the intervention.

Criteria for the judgement of 'Unclear risk' of bias.	Insufficient information about the sequence generation process to permit judgement of 'Low risk' or 'High risk'.
<p>ALLOCATION CONCEALMENT</p> <p>Selection bias (biased allocation to interventions) due to inadequate concealment of allocations prior to assignment.</p>	
Criteria for a judgement of 'Low risk' of bias.	<p>Participants and investigators enrolling participants could not foresee assignment because one of the following, or an equivalent method, was used to conceal allocation:</p> <ul style="list-style-type: none"> • Central allocation (including telephone, web-based and pharmacy-controlled randomization); • Sequentially numbered drug containers of identical appearance; • Sequentially numbered, opaque, sealed envelopes.
Criteria for the judgement of 'High risk' of bias.	<p>Participants or investigators enrolling participants could possibly foresee assignments and thus introduce selection bias, such as allocation based on:</p> <ul style="list-style-type: none"> • Using an open random allocation schedule (e.g. a list of random numbers); • Assignment envelopes were used without appropriate safeguards (e.g. if envelopes were unsealed or nonopaque or not sequentially numbered); • Alternation or rotation; • Date of birth; • Case record number; • Any other explicitly unconcealed procedure.
Criteria for the judgement of 'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'. This is usually the case if the method of concealment is not described or not described in sufficient detail to allow a definite judgement – for example if the use of assignment envelopes is described, but it remains unclear whether envelopes were sequentially numbered, opaque and sealed.
<p>BLINDING OF PARTICIPANTS AND PERSONNEL</p> <p>Performance bias due to knowledge of the allocated interventions by participants and personnel during the study.</p>	

Criteria for a judgement of 'Low risk' of bias.	Any one of the following: <ul style="list-style-type: none"> No blinding or incomplete blinding, but the review authors judge that the outcome is not likely to be influenced by lack of blinding; Blinding of participants and key study personnel ensured, and unlikely that the blinding could have been broken.
Criteria for the judgement of 'High risk' of bias.	Any one of the following: <ul style="list-style-type: none"> No blinding or incomplete blinding, and the outcome is likely to be influenced by lack of blinding; Blinding of key study participants and personnel attempted, but likely that the blinding could have been broken, and the outcome is likely to be influenced by lack of blinding.
Criteria for the judgement of 'Unclear risk' of bias.	Any one of the following: <ul style="list-style-type: none"> Insufficient information to permit judgement of 'Low risk' or 'High risk'; The study did not address this outcome.
BLINDING OF OUTCOME ASSESSMENT Detection bias due to knowledge of the allocated interventions by outcome assessors.	
Criteria for a judgement of 'Low risk' of bias.	Any one of the following: <ul style="list-style-type: none"> No blinding of outcome assessment, but the review authors judge that the outcome measurement is not likely to be influenced by lack of blinding; Blinding of outcome assessment ensured, and unlikely that the blinding could have been broken.
Criteria for the judgement of 'High risk' of bias.	Any one of the following: <ul style="list-style-type: none"> No blinding of outcome assessment, and the outcome measurement is likely to be influenced by lack of blinding; Blinding of outcome assessment, but likely that the blinding could have been broken, and the outcome measurement is likely to be influenced by lack of blinding.
Criteria for the judgement of 'Unclear risk' of bias.	Any one of the following: <ul style="list-style-type: none"> Insufficient information to permit judgement of 'Low risk' or 'High risk'; The study did not address this outcome.

INCOMPLETE OUTCOME DATA	
Attrition bias due to amount, nature or handling of incomplete outcome data.	
Criteria for a judgement of 'Low risk' of bias.	<p>Any one of the following:</p> <ul style="list-style-type: none"> • No missing outcome data; • Reasons for missing outcome data unlikely to be related to true outcome (for survival data, censoring unlikely to be introducing bias); • Missing outcome data balanced in numbers across intervention groups, with similar reasons for missing data across groups; • For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk not enough to have a clinically relevant impact on the intervention effect estimate; • For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes not enough to have a clinically relevant impact on observed effect size; • Missing data have been imputed using appropriate methods.
Criteria for the judgement of 'High risk' of bias.	<p>Any one of the following:</p> <ul style="list-style-type: none"> • Reason for missing outcome data likely to be related to true outcome, with either imbalance in numbers or reasons for missing data across intervention groups; • For dichotomous outcome data, the proportion of missing outcomes compared with observed event risk enough to induce clinically relevant bias in intervention effect estimate; • For continuous outcome data, plausible effect size (difference in means or standardized difference in means) among missing outcomes enough to induce clinically relevant bias in observed effect size; • 'As-treated' analysis done with substantial departure of the intervention received from that assigned at randomization; • Potentially inappropriate application of simple imputation.
Criteria for the judgement of 'Unclear risk' of bias.	<p>Any one of the following:</p> <ul style="list-style-type: none"> • Insufficient reporting of attrition/exclusions to permit judgement of 'Low risk' or 'High risk' (e.g. number randomized not stated, no reasons for missing data provided);

	<ul style="list-style-type: none"> The study did not address this outcome.
<p>SELECTIVE REPORTING</p> <p>Reporting bias due to selective outcome reporting.</p>	
Criteria for a judgement of 'Low risk' of bias.	<p>Any of the following:</p> <ul style="list-style-type: none"> The study protocol is available and all of the study's pre-specified (primary and secondary) outcomes that are of interest in the review have been reported in the pre-specified way; The study protocol is not available but it is clear that the published reports include all expected outcomes, including those that were pre-specified (convincing text of this nature may be uncommon).
Criteria for the judgement of 'High risk' of bias.	<p>Any one of the following:</p> <ul style="list-style-type: none"> Not all of the study's pre-specified primary outcomes have been reported; One or more primary outcomes is reported using measurements, analysis methods or subsets of the data (e.g. subscales) that were not pre-specified; One or more reported primary outcomes were not pre-specified (unless clear justification for their reporting is provided, such as an unexpected adverse effect); One or more outcomes of interest in the review are reported incompletely so that they cannot be entered in a meta-analysis; The study report fails to include results for a key outcome that would be expected to have been reported for such a study.
Criteria for the judgement of 'Unclear risk' of bias.	Insufficient information to permit judgement of 'Low risk' or 'High risk'. It is likely that the majority of studies will fall into this category.
<p>OTHER BIAS</p> <p>Bias due to problems not covered elsewhere in the table.</p>	
Criteria for a judgement of 'Low risk' of bias.	The study appears to be free of other sources of bias.

Criteria for the judgement of 'High risk' of bias.	There is at least one important risk of bias. For example, the study: <ul style="list-style-type: none">• Had a potential source of bias related to the specific study design used; or• Has been claimed to have been fraudulent; or• Had some other problem.
Criteria for the judgement of 'Unclear risk' of bias.	There may be a risk of bias, but there is either: <ul style="list-style-type: none">• Insufficient information to assess whether an important risk of bias exists; or• Insufficient rationale or evidence that an identified problem will introduce bias.

Appendix E: List of Expert Panelists

	Name of Expert Panelists
1	Carla DeSisto
2	Debra Kane
3	Denise D'Angelo
4	Alyssa Yang
5	Ashley Hirai
6	Ashley Busacker
7	Danielle Barradas
8	Danielle Arellano
9	David Goodman
10	Charlan Kroelinger