

SHEA, TAMRA L., PhD. Health Literacy, Understanding, and Decisional Satisfaction in Women's Decision-Making for Prenatal Aneuploidy Screening. (2018)
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Prenatal aneuploidy screening assesses the likelihood that a fetus will have a chromosomal anomaly. If a screen reveals a high probability, the pregnant woman will be offered diagnostic testing and the possibility of pregnancy termination if a serious anomaly is confirmed. Evidence indicates that incomplete understanding of prenatal aneuploidy screens, unclear risk perception, and the rapid integration of prenatal aneuploidy screening early in the first trimester of pregnancy may compromise the educational and decisional processes needed for women to make informed choices about prenatal aneuploidy screening. As prenatal aneuploidy screening occurs in a complex social, ethical, and political reality, a women's health literacy likely influences her understanding of and decisions made for prenatal aneuploidy screening.

Therefore, the purpose of this study was to explore women's informed decision-making for prenatal aneuploidy screening by investigating the relationships between women's understanding of prenatal aneuploidy screening, their health literacy, and their subsequent satisfaction with decisions made for prenatal aneuploidy screening. The study was guided by Faden and Beauchamp's (1986) model of informed consent, Nutbeam's (2000) concept of health literacy, and Holmes-Rovner and colleague's (1996) concept of satisfaction with a decision. The five domains of health literacy examined in this study include *Feeling understood and supported by health care providers*, *Appraisal of health information*, *Ability to actively engage with health care providers*, *Ability to*

find good health information, and Understand health information enough to know what to do (Osborne, Batterham, Elsworth, Hawkins, & Buchbinder, 2013).

A convenience sample of 95 adult women living in western North Carolina who were ≥ 18 weeks pregnant was recruited to participate in this descriptive, correlational study using cross-sectional methodology. Potential participants were invited to complete an online survey which was distributed via electronic mail to recipients of an electronic pregnancy and parenting newsletter. The survey was used to collect data on women's understanding of prenatal aneuploidy screening, their health literacy, and their satisfaction with decisions made for prenatal aneuploidy screening. Data analyses included descriptive statistics, bivariate correlational analysis, and multiple linear regression.

The majority of participants were Caucasian/White non-Hispanic and college-educated. Results indicate that 42.1% of participants did not report satisfaction with decisions made for prenatal aneuploidy screening. Higher levels of *Ability to actively engage with health care providers* was significantly associated with increased understanding of prenatal aneuploidy screening. *Feeling understood and supported by health care providers, Appraisal of health information, Ability to find good health information, and Understand health information enough to know what to do* were not significantly associated with understanding of prenatal aneuploidy screening. *Feeling understood and supported by health care providers* and *Ability to find good health information* were significantly associated with increased satisfaction with decisions made for prenatal aneuploidy screening. *Appraisal of health information, Ability to actively*

engage with health care providers, Understand health information enough to know what to do, and understanding of prenatal aneuploidy screening were not significantly associated with satisfaction with decisions made for prenatal aneuploidy screening. This new knowledge has important implications for nursing practice, education, and policy. This study's findings can be used to guide the development of interventions to promote women's informed decision-making for prenatal aneuploidy screening.

HEALTH LITERACY, UNDERSTANDING, AND DECISIONAL SATISFACTION
IN WOMEN'S DECISION-MAKING FOR PRENATAL
ANEUPLOIDY SCREENING

by

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This dissertation is dedicated to my children: Patrick Thomas, Colin James, Daniel Gordon, and Clara Eloise, without whom I may have completed this dissertation earlier, but without whom I never would have been inspired to do this work. Thank you for your patience and belief in me. I am hopeful that I have contributed to your understanding of what I mean when I say that I believe God wants each of us to develop our gifts to the best of our abilities.

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CHAPTER I

INTRODUCTION

Prenatal aneuploidy screening is offered with the goal of providing women with the opportunity to make informed choices about their pregnancy. Prenatal aneuploidy screening aims to detect chromosomal aneuploidy, the presence of an extra chromosome (Griffiths, Wessler, Carroll, & Doebley, 2015). Chromosomal aneuploidies that are compatible with life, but cause considerable morbidity, affect 0.67% of live births (American Congress of Obstetrics and Gynecology [ACOG], 2016a). The most common type of viable human aneuploidy is trisomy 21 or Down syndrome, occurring at a frequency of about 0.15% of all live births (Griffiths et al., 2015). Down syndrome is the most common genetic cause of intellectual disability worldwide (Centers for Disease Control and Prevention [CDC], 2015). As detection of fetal aneuploidy previously required invasive procedures associated with iatrogenic fetal loss, advanced maternal age was formerly the criterion for offering clinical detection of fetal aneuploidy. However, over the past two decades, identification of maternal biochemical markers that denote the risk of carrying an affected fetus through non-invasive serum screens has resulted in the incorporation of prenatal aneuploidy screening in routine prenatal care for all women regardless of age (Latendresse & Deneris, 2015). The decision to use prenatal aneuploidy screening therefore impacts each of the estimated 6,369,000 pregnancies that occur in the U.S. annually (Curtin, Abma, Ventura, & Henshaw, 2013). This decision

marks the beginning of a series of profoundly important decisions, including subsequent decisions on invasive diagnostic testing and whether to continue or terminate a pregnancy. Women are routinely asked to consent to prenatal aneuploidy screening early in pregnancy, despite evidence that many women do not understand the decision they are being asked to make or its implications for pregnancy (Farrell, Nutter, & Agatista, 2011; Chiang, Chao, & Yuh, 2006; Van den Berg, Timmermans, Ten Kate, Van Vugt, & Van der Wal, 2005). As a result, there is a crucial need for substantive knowledge to guide interventions that can improve women's understanding of prenatal aneuploidy screening and facilitate women's informed decision-making for prenatal aneuploidy screening.

Background

The increasing availability of medical technology has offered answers to certain questions of health and illness that can be perceived as providing patients with increased control over their health care. However, patients often find it difficult to refuse tests or treatments that are suggested to them, due to their trust in authoritative knowledge and the expertise of their health care providers, as well as the inherent difficulty of making decisions for which the perceived risks and benefits are uncertain (Aune & Möller, 2012; Chiang et al., 2006; Tymstra, 1991). Additionally, a culture of risk has been created in health care in which patients are evaluated not only by their present health condition, but by their potential for future disease (Lupton, 2009). This is particularly evident in the area of prenatal care. During the 20th century, a change occurred in the perception of pregnancy as an uncomplicated, normal event to one that is potentially pathological, requiring continued surveillance (Barker, 1998). Routine medical care throughout the

nine months of pregnancy, provided by a physician or midwife, is now standard in contemporary Western society. Beginning at the 8-9th week of pregnancy, the objectives of prenatal care are assessment of the maternal response to pregnancy and monitoring of fetal growth and development. Prenatal care includes maternal physical exams as well as prenatal screens and tests to detect fetal abnormalities.

The American Congress of Obstetrics and Gynecology (ACOG) currently recommends that screening for fetal aneuploidy be offered to all women presenting for prenatal care before 20 weeks' gestation (ACOG, 2016b). By definition, screening is considered secondary prevention among healthy persons with the goal of distinguishing those individuals who may have a condition from those individuals who likely do not (Latendresse & Deneris, 2015). Since first emerging in the 1990s, modalities of prenatal screening for fetal aneuploidy have continually evolved with technological innovations. The general types of prenatal aneuploidy screening currently offered include (a) maternal serum screening, which measures levels of specific biochemicals in the woman's blood between 12-18 weeks of gestation, (b) nuchal translucency, an ultrasound technique wherein the fluid volume at the back of the fetal neck is measured between 10-14 weeks' gestation, and (c) non-invasive prenatal testing (NIPT), which uses fragmented fetal DNA circulating in maternal blood, beginning at 10 weeks of gestation (Latendresse & Deneris, 2015).

Prenatal Aneuploidy Screening in Clinical Practice

The distinction between a screen and a test. The purpose of a screen is to detect indicators of disease, while the purpose of a test is to establish the presence or

absence of a condition (Vogt, 2005). A measure's sensitivity is its ability to correctly classify an individual as having indicators of a disease, thereby avoiding false positives (Vogt, 2005). A measure's specificity is its ability to correctly classify an individual as not having a disease, thereby avoiding false negatives. The sensitivity and specificity of the measure determines whether it functions in clinical practice as a screen or test. While a screen has higher sensitivity at the expense of specificity in order to not miss potential cases of disease, a test has higher specificity than selectivity, with emphasis on precision in identifying the absence of disease (Vogt, 2005).

The information provided with prenatal aneuploidy screening. Typically, women are given a pamphlet on the screening options for fetal aneuploidy at their first prenatal appointment and non-directive counsel from their care providers (K. Patten, personal communication, April 20, 2016). The information presented in the pamphlets is largely biomedical and focused on procedural details and facts about the timing of the screening options, with omission of information about the potential emotional and moral implications associated with positive screens (Bryant et al., 2001; Lawson, Carlson, & Shynkaruk, 2012; Michie, Michie, di Lorenzo, Lane, Armstrong, & Sanderson, 2004). Lawson et al. (2012) found that in the minimal information given about the conditions screened, an unbalanced and negative characterization of Down syndrome is presented with emphasis on its epidemiological origin and resultant intellectual disability. In an evaluation of patient educational materials for prenatal aneuploidy screening, Kloza et al. (2015) found that these informational pamphlets are typically written at 10-12th grade reading level. The average American reads at an 8th grade reading level (U. S.

Department of Education, National Center for Educational Statistics, 2013). While the woman's health care provider may engage in non-directive counsel with the patient to review the screening options, evidence suggests that physicians spend less than five minutes discussing prenatal screening in general with their patients (Cavanaugh, Matthews, & Crane, 2007; Park & Matthews, 2009). A commonly reported finding in the literature on prenatal aneuploidy screening is that health care providers' discussions about screening are narrowly focused on the technical and procedural differences between the screening options rather than why screening is done or the ethical issues surrounding screening, such as the potential for subsequent decision-making about pregnancy termination (Farrell, Agatista, & Nutter, 2014; Park & Matthews, 2009; Pilnick, 2008; Williams, Sandall, Lewando-Hundt, Heyman, Spencer, & Grellier, 2002).

Prenatal aneuploidy screening is based on risk assessment. After consenting to prenatal aneuploidy screening, a sample of maternal blood is drawn. With maternal serum screening, biochemical markers circulating in maternal blood are compared against median levels normed on women of corresponding gestational and maternal age to demarcate if a woman is at high risk of carrying a fetus with a chromosomal aneuploidy (Latendresse & Deneris, 2015). Non-invasive prenatal testing (NIPT) uses fragmented fetal DNA circulating in maternal blood to assess risk of fetal aneuploidy. Although NIPT is marketed and labeled as a test, it functions in practice as a screen (ACOG, 2012, 2016a). This confusing terminology may obfuscate the available options when women are making decisions about prenatal aneuploidy screening. If positive results occur from any type of prenatal aneuploidy screening, indicating that a woman is at high risk of

carrying a fetus with a chromosomal aneuploidy, current practice guidelines are to offer confirmatory diagnosis through invasive testing (ACOG, 2012, 2016a). Chorionic villus sampling or amniocentesis are the invasive procedures used to obtain a definitive diagnosis, which entail an increased risk for fetal injury or demise. At present, there is no treatment for the fetal condition if diagnosis of fetal aneuploidy is confirmed; elective termination of the pregnancy or continuation of the pregnancy are the only options (Fuchs & Peipert, 2005).

Key influences on decisions for prenatal aneuploidy screening. Women's decisions for prenatal aneuploidy screening are primarily driven by beliefs and attitudes about health and disability, pregnancy termination, the value of information, and modern medicine's role in pregnancy (García, Timmermans, & van Leeuwen, 2009; Hawthorne & Ahern, 2009; Kuppermann et al., 2006; Van den Berg et al., 2005). Decisions for prenatal aneuploidy screening are also influenced by numerous maternal characteristics including age, education, culture, race and ethnicity, and individual reproductive and life histories (Etchegary et al., 2008; Kuppermann et al., 2004). Lower rates of prenatal aneuploidy screening among minority women and lower income women in the U.S. have been found to be mediated by religious beliefs and fatalism (Kuppermann et al., 2006). Higher rates of prenatal aneuploidy screening among women with higher education have been found to be mediated by reduced fatalism and increased perceived procedure-related risk of fetal demise (Kuppermann et al., 2006). Women with higher educational attainment and economic privilege are more likely to decide to consent to prenatal aneuploidy screening (Kupperman et al., 2006). Additionally, women who are likely to

terminate an affected pregnancy are more likely to accept the screen, while women who feel that modern medicine interferes too much in pregnancy are more likely to decline prenatal aneuploidy screening (Kupperman et al., 2006; Van den Berg et al., 2005).

Emergent technology for prenatal aneuploidy screening results in women making decisions for prenatal aneuploidy screening very early in pregnancy. The current standard of care for prenatal aneuploidy screening for women in the United States involves maternal serum screening of biochemical markers between 12-18 weeks of pregnancy, which corresponds to late in the first trimester or early in the second trimester of pregnancy (ACOG, 2016b). This practice had allowed for at least two points of contact between an expectant woman and her prenatal care provider prior to making decisions for prenatal aneuploidy screening. However, the techniques used with NIPT that emerged commercially in 2011 have rapidly changed the patterns of practice for prenatal aneuploidy screening by allowing for assessment of fetal anomaly as early as the 10th week of pregnancy.

As the technology used with cell-free fetal DNA is still evolving, the laboratory techniques used with NIPT vary according to the companies that offer this screening test, as do the specificity and selectivity for the tests (Norton, Rose, & Benn, 2013). As a result, quality control and validity claims associated with NIPT have been called into question (Norton et al., 2013). Companies that market NIPT highlight their high positive predictive ability for aneuploidy and emphasize the ability of NIPT to provide results for aneuploidy detection, paternity, and fetal sex as early as the 10th week of pregnancy (Allyse et al., 2015). Citing concerns about the validity of NIPT across the prenatal

population, ACOG currently does not recommend NIPT unless a woman is at high risk of having a fetus with aneuploidy, such as women over the age of 35 years, women with a history of a previous pregnancy affected by fetal aneuploidy, and women with ultrasonographic findings indicating risk for fetal aneuploidy (ACOG, 2012, Allyse et al., 2015). Nonetheless, physicians are routinely offering NIPT and women are increasingly using NIPT (Allyse et al., 2015). Further, a recent survey indicates that many prenatal care professionals believe that NIPT will soon replace conventional maternal serum screening for prenatal aneuploidy screening (Haymon, Simi, Moyer, Aufox, & Ouyang, 2014). As screening with NIPT occurs as early as 10 weeks of pregnancy, women increasingly are making decisions whether or not to use prenatal aneuploidy screening as early as their first prenatal care appointment, shortly after many women have first learned that they are pregnant (Farrell et al., 2011). Therefore, women are being faced with this decision at the same time that they are adjusting to the new reality of being an expectant mother and with little time to learn about the screens and how they may impact the pregnancy. Further, as the screening occurs so early in pregnancy, women have little time to consider the ethical import of the screen as it relates to their personal beliefs, values, and life circumstances.

Informed Decision-making in Women's Health Care

When seeking to understand the factors influencing women's informed decision-making for prenatal aneuploidy screening, one can look to the broader body of research on women's health care decision-making in the clinical setting. In this section, an explanation of the rational model of decision-making in women's health care is

presented, followed by a discussion of women's informed decision-making across the lifespan, with regards to cancer screening, and in the context of pregnancy-related screens and tests. Within these topical areas, the similarities and differences between decision-making for prenatal aneuploidy and other types of decisions in women's health care are considered. A delineation of how prenatal aneuploidy is a uniquely complex decision within women's health care concludes this section.

The rational model of decision-making in the context of women's health care.

Pierce and Hicks (2001) assert that women's health care decisions can generally be examined from the foundation of a rational model of decision-making. They contend that health care decision-making centers on decisional dilemmas, which include not only the alternatives of a decision but the possible outcomes and probabilities attached to the alternative outcomes. Pierce and Hicks (2001) claim that decisions have four general options which comprise the alternatives from which to choose. Three options are 1) the personal appraisal of each outcome; 2) the probabilities of the outcomes of each alternative, which can be derived from objective or subjective data; and 3) the consequence or outcome, which may present one option as more attractive than another. The fourth option is described as a *decisional hazard* in clinical practice, which occurs when one alternative is presented as more attractive than another, thereby deterring adequate appraisal of other alternatives. Pierce and Hicks (2001) delineate objectives to guide research on patient decision-making in clinical practice. The objectives include (a) helping patients become more efficient, given their limited physical and cognitive resources; (b) mitigating the psychological stress of making the decision; (c) helping

patients avoid decision hazards; and (d) supporting patients to make decisions that accurately reflect their beliefs, values, and preferences.

Themes of women's informed health care decision-making across the lifespan. Brown, Carroll, Boon, and Marmoreo (2002) reviewed three separate qualitative studies about women's decision-making about healthcare issues to note common themes. The women's health issues spanned the life cycle and encompassed prenatal genetic screening, hormone replacement therapy, and use of complementary/alternative medicine in treatment for breast cancer. Emergent themes included *information seeking* about the health issue and *information sources*, with the use of both trusted health care providers and friends and family members as reliable sources of information. The third prevalent theme identified was *information sharing* within the context of the professional relationship. Brown et al. (2002) write that women who did not perceive an open informational sharing process with their health care providers were left "waiting, wondering, and unnecessarily anxious" (p.228). The fourth theme was *accepting the consequences* in terms of their individual beliefs and values. Brown and colleagues summarize their analyses by stating that the evidence overwhelmingly indicates that women consistently demonstrate a desire to have an active role in the decision-making process when confronted with a serious health care decision that can have positive or negative consequences for their individual future health and the well-being of their family. Further, Wildschut, Peters, and Weiner (2006) conducted an integrative review of the essential elements of screening across three domains in women's health where early detection can improve the quality and duration of life:

screening for Down syndrome and other chromosomal anomalies, osteoporosis, and breast cancer. Their findings indicate that it is imperative for women to receive clear and comprehensive information about the screening, including details of the screening options, the physical, economic, and psychological costs associated with the screens, and the implications for treatment and diagnosis. This finding is supported by Price and Bently's (2013) investigation of pharmacological decision-making among pregnant and post-partum women and their health care providers. Price and Bently found that when making decisions, women prioritized accurate, unbiased, and complete information and authentic information-sharing, problem-solving, and active communication with their health care providers.

Informed decision-making for cancer screening. Examinations of informed decision-making for cancer screening typically identify knowledge and perceived threat as key constructs (Mullen et al., 2006). Perceived threat is usually understood as a component of the Health Belief Model and the larger category of value expectancy models, which assumes a rational model of decision-making (Huston, Bagozzi, & Kirking, 2010; Simons-Morton, McLeroy, & Wendel, 2012). Evidence indicates that informed decision-making for cancer screening is highly influenced by perceived threat of cancer in terms of the perceived risk and gravity of cancer. Examinations of informed decision-making for mammography screening and cervical cancer screening indicate that women with a family history of cancer or high perceived risk of cancer are more likely to undergo cancer screening (Hoffman et al., 2010; Pace & Keating, 2014). However, as with the estimates of probability of having a child with a chromosomal abnormality,

quantified estimates of probability of having cancer and the risks associated with cancer screening are difficult for women to comprehend, leading to uninformed decisions (Hoffman et al., 2010). For example, Fallowfield et al. (2010) found that women tend to underestimate the risk of developing ovarian cancer while overestimating the potential benefits of ovarian cancer screening. In contrast, women tend to overestimate their risk of breast cancer mortality while also overestimating the potential benefit of screening with mammography to reduce that risk (Pace & Keating, 2014). Pace and Keating (2014) present a systematic review of informed decision-making for breast cancer screening with mammography that reflects the complexities of informed decision-making for medical screening more broadly. Their review highlights the importance of nuanced communication with patients to delineate the potential benefits of mammography while also explaining that the benefit of mammography is less than once believed and that the potential associated risks are greater than anticipated. Similar to prenatal aneuploidy screening, these potential risks include both a cascade of subsequent decision-making related to further medical testing and intervention (with biopsies, mastectomies, and radiation) as well as false positives and over-diagnosis (with the detection of non-life-threatening lesions) (Pace & Keating, 2014). Additionally, patient education concerning decisions for prenatal aneuploidy screening is similar to patient education concerning decisions for breast cancer and ovarian cancer screening in that health care providers have demonstrated difficulty in articulating the nuance and uncertain risks associated with morbidity and screening and they are more likely to discuss the benefits of screening

rather than the potential risks, while neglecting to elicit woman's preferences (Hoffman et al., 2010).

Informed decision-making for pregnancy-related screens and tests. Decisions for prenatal aneuploidy screening are closely akin to decisions concerning fetal ultrasonography, amniocentesis, and chorionic villus sampling. When a screen, such as the 20-week fetal ultrasound or prenatal aneuploidy serum screen, is abnormal, the expectant woman discusses the finding with her health care provider and is advised about diagnostic testing options, which include amniocentesis and chorionic villus sampling (Latendresse & Deneris, 2015). These invasive diagnostic procedures typically occur between the 10th -16th week of pregnancy, with the results in the form of a genetic karyotype available approximately four weeks later, in the middle of pregnancy (Allyse et al., 2015). These invasive diagnostic tests carry a small but significant risk of iatrogenic fetal demise and infection (Latendresse & Deneris, 2015). This narrow timeline adds to the difficulty of the decision to undertake prenatal diagnostic tests along with the anxiety following designation of high risk for fetal abnormality following a screen (Green, Hewison, Bekker, Bryant, & Cuckle, 2004; Heyman et al., 2006).

Anxiety surrounding prenatal decision-making. Decisions for diagnostic testing have been shown to be emotionally laden and associated with increased maternal stress (Green, et al., 2004; Pivetti, Montali, & Simonetti, 2012). In particular, the decision-making process is characterized by anxiety concerning fetal health and development, the fear of an abnormal result, and the possibility of pregnancy termination (Sarkar, Bergman, Fisk, & Glover, 2006). Moreover, anxiety surrounding the decision-making

for invasive prenatal diagnosis is heightened among women with favorable attitudes toward termination and lower among women who voice refusal to consider termination (Tercyak, Johnson, Roberts, & Cruz, 2001). This suggests that as the potential need for moral discernment and decision-making concerning pregnancy continuation or termination becomes imminent, women experience greater anxiety with prenatal decision-making.

The tentative pregnancy. Katz Rothman (1986) writes that during the four-week interval between the amniocentesis and the results, women experience a “tentative pregnancy,” in that while the pregnancy is medically acknowledged, the baby is not yet accepted until confirmation of fetal health via amniocentesis. Further, Katz Rothman asserts that the availability of amniocentesis and chorionic villus sampling has changed how women experience pregnancy in that women may have a disembodied and psychologically disengaged sense of pregnancy with possible delayed attachment to the unborn baby until fetal health is affirmed through medical technology. Hunt, de Voogd, and Catadneda’s (2005) qualitative examination of women’s experiences with communication in prenatal genetic decision-making suggests that the experience of a tentative pregnancy may extend to the experience of prenatal screening for aneuploidy. Once a pregnancy is designated “at-risk,” it acquires an ambiguous state, transforming a time of hopeful anticipation into a time of fear and doubt (Hunt et al., 2005).

Decisions made for prenatal aneuploidy screening are uniquely complex due to the moral implications of genetic screening, the relational state of pregnancy, and the temporal sensitivity of the decision. Comparisons of women’s health care decisions

broadly with decisions for prenatal screening and testing illuminate the impact of genetic knowledge and technological advancement on the complexity of health care decision-making. As the array of genetic screening options increases, the nuances and implications of the decisions become more obscured. Katz Rothman (2015) asserts that the big questions brought about by genetics often make people uncomfortable. For pregnant women, these questions entail choices about the kind of baby she wants to have and the types of disability that she views as acceptable. Further, these bigger ethical questions are typically couched in the smaller questions concerning which screens and predictive tests are desired for ourselves and our unborn children (Katz Rothman, 2015).

The relational aspect of pregnancy impacts decisions for prenatal aneuploidy screening. The decision for prenatal aneuploidy screening is also different from many other health care decisions in that it does not conform to the rational decision-making model which views choice as an objective activity that occurs in isolation based on individual interests (Sherwin, 2000). The decision for prenatal aneuploidy screening emerges within the relational dimensions between the expectant mother, her partner, her unborn baby, and her family members. The embodied state of pregnancy results in a unique relational state physically, emotionally, and psychologically between the expectant mother and to her pregnancy/unborn child. Evidence indicates that the extent to which a woman assigns personhood to her fetus impacts her sense of what is lost when perinatal loss occurs (Côté-Arsenault & Dombeck, 2001). Thus, the value of the fetus can be viewed as relational to the woman carrying the fetus (Sherwin, 2000). It follows that a woman's conceptualization of the pregnancy as a fetal person increases the ethical

stakes of her decision for prenatal aneuploidy screening. Further, Brauer (2016) suggests that because the fetus is within the pregnant female body, a woman's consent or declination of prenatal aneuploidy screening creates the presumption that the expectant mother takes responsibility for her unborn baby's health. Indeed, evidence suggests that the relational state of being pregnant may cause women to construct their decisions to accept or decline prenatal aneuploidy screening as expressions of their moral agency and sense of responsibility to the pregnancy/fetal person as well as to living family members (García, Timmermans, & van Leeuwen, 2012; Williams et al., 2005).

The decision for prenatal aneuploidy screening differs from most women's health care decisions in its temporal urgency. The decision for prenatal aneuploidy screening must be made in the early stages of pregnancy, within a few weeks that a woman learns she is pregnant. This temporal urgency is in stark contrast to the other screening decisions women make, such as for cervical cancer or mammography. Further, in order for the options of invasive diagnosis and termination to be available, the woman must make her decision for prenatal aneuploidy screening by 12-14 weeks of pregnancy (Farrell et al., 2011). Thus, the decision for prenatal aneuploidy screening does not conform to the rational model of decision-making because the rational model denies the temporal and political context of decision-making (Sherwin, 2000). Sherwin (2000) cautions that by the time a particular decision must be made, treatment options have been limited by a layer of political and policy decisions that occur in the institutions of health care and government. The set of options made available to women reflect a series of earlier decisions concerning the prioritization of the rights of the fetus and the rights of

the pregnant female (Sherwin, 2000). Hence, the temporal sensitivity of decisions made for prenatal aneuploidy screening is shaped by political decisions that establish the screening and treatment options made available vis-à-vis commercial access to the screens and legal access to termination (elective abortion). In summary, consideration of prenatal aneuploidy screening in the context of women's health care decision-making more broadly illustrates the unique complexity, urgency, and ethical dimensions of decision-making for prenatal aneuploidy screening, which underline the importance of gaining new knowledge to guide interventions to support women's informed decision-making for prenatal aneuploidy screening.

Rationale for the Study

Prenatal aneuploidy screening is offered on the basis of informed decision-making, yet the current practice of prenatal aneuploidy screening fails to ensure that women are making informed decisions. Prenatal aneuploidy screening has been integrated into prenatal care and marketed with the goals of providing women with information on the health status of their fetus and the opportunity to make informed decisions about their pregnancies. Empirical evidence suggests that many women have inadequate understanding of the purpose and scope of prenatal aneuploidy screening (Constantine, Allyse, Wall, Vries, & Rockwood, 2014; Farrell et al., 2011; Jaques, Sheffield, & Halliday, 2005; Schoonen, Wildschut, Essink-Bot, Peters, Steegers, & de Koning, 2012; Skirton & Barr, 2010; Van den Berg et al., 2005). Both qualitative and quantitative findings indicate that many women lack sufficient knowledge and understanding about the purpose and scope of prenatal aneuploidy screens and the

conditions they aim to detect (Cho, Plunkett, Wolf, Simon, & Grobman, 2007; Farrell et al., 2011; Farrell, Hawkins, Barragan, Hudgins, & Taylor, 2015; Skirton & Barr, 2010). Women often are not aware of the possibility of subsequent invasive testing and decision-making concerning pregnancy management following a positive screen (Farrell et al., 2011; Griffiths & Kuppermann, 2008; Seror & Ville, 2009; Skirton & Barr, 2010). In addition, women demonstrate inadequate knowledge of what their testing and health care options would be in the case of abnormal screen results (Farrell et al., 2011). The result of inadequate understanding of prenatal aneuploidy screening is that many women are falsely reassured by a low-risk (negative) result or unprepared to make life-altering decisions and manage the anguish that results from a high-risk (positive) result. Additionally, the rapid integration of prenatal aneuploidy screening into early prenatal care may impoverish the process of informed decision-making. The routinization of screening combined with the earlier window for first trimester screening reduces the time and attention given to the educational and decisional processes needed to make an informed choice (Farrell et al., 2011). Accordingly, the routinization of screening can have the effect of limiting rather than expanding individual choice because the more routine a test becomes, the less scrutiny and consideration of its ethical dimensions it receives from prospective parents and providers (Suter, 2002). That women often perceive the offer of the screen as assent to care rather than choice underscores the impact of the routinization of screening (Chiang et al., 2006; Jaques et al., 2005; Pilnik, 2008). When women do recognize the offer of prenatal aneuploidy screening as a choice, many are often left alone to think about the gravity of their decision and its moral

implications rather than in meaningful consultation with health care providers (Williams et al., 2005). Women report a need for increased dialogue with health care providers concerning the implications of prenatal aneuploidy screening as related to their personal needs, preferences, and their perceptions of disability (Ahmed, Bryant, Tizro, & Shickle, 2014; Farrell et al., 2011; Park & Matthews, 2009).

Decisions for prenatal aneuploidy screening profoundly impact the course of pregnancy. As women typically enter pregnancy with feelings of hope, the possibility that they may have a baby with an anomaly is quickly discounted (Tercyak et al., 2001). Many women do not understand that positive prenatal aneuploidy screening results will require subsequent decisions concerning diagnostic testing and termination of pregnancy (Farrell et al., 2011). Additionally, many women are not fully aware of the strengths and limitations of the screening options offered or the conditions for which they screen (Jaques et al., 2005; Van den Berg et al., 2005; Skirton & Barr, 2010). False positives and negatives occur with each type of prenatal screening. False positive results for maternal serum screening (the Quad screen) occur at a rate of approximately 5% for trisomy 21 (Down's syndrome) (Driscoll & Gross, 2009; Durkovic, Andoelic, Mandic, & Lazar, 2011). For NIPT, the reported rate of false positives for trisomies 21 and 18 varies, ranging from <1% (Nicolaidis, Syngelaki, Ashoor, Birdir, & Touzet, 2012) to 10.7% (Dar et al., 2014); the false positive rate may exceed the false negative rate for rarer trisomies (Reiss & Cherry, 2013). While the impact of false positive results is deep and produces sustained maternal anxiety and guilt, the sense of loss and mental anguish associated with a false negative result is overwhelming, destabilizing, and life-altering

(Chiang, Chao, & Yuh, 2007; Heyman et al., 2006; Sandelowski & Barros, 2005).

Moreover, when women fail to understand that the screen is not diagnostic, they risk making the grave decision to terminate the pregnancy without adequate understanding of how to interpret the results of the screen (Mennuti, Cherry, Morissette, & Dugoff, 2013).

New knowledge on informed decision-making and health literacy is needed to guide professional support for women in making informed decisions for prenatal aneuploidy screening. Evaluations of prenatal aneuploidy screening programs are limited and typically involve estimations of the uptake or acceptance of prenatal aneuploidy screening (Allyse et al., 2015; Dondorp et al., 2015). This seems to imply that high uptake of prenatal aneuploidy screening is the goal of offering prenatal aneuploidy screening. However, according to ACOG, the purported goal in offering women prenatal aneuploidy screening is to enable them to make an autonomous, informed decision about whether or not they want to participate in a risk assessment of carrying a fetus with aneuploidy (ACOG, 2016a). Thus, it is essential to examine whether women believe that they are making informed decisions that reflect their beliefs and values. Further, as current clinical practice fails to ensure women's informed choice for prenatal aneuploidy screening, there is an urgent need for knowledge generation to elucidate influences on women's understanding of prenatal aneuploidy screening. Higher health literacy is associated with better health knowledge, health behaviors, clinical outcomes, and engagement in healthcare decisions among non-pregnant adults (Goggins, Wallston, Nwosu, Schildcrout, Castel, & Kripalani, 2014; Kutner, Greenberg, Jin, Paulsen, & White, 2006). While there is minimal research on health literacy among prenatal

populations, it is known that women have inadequate understanding of prenatal aneuploidy screening. It is likely that health literacy influences women's understanding of and decisions made for prenatal aneuploidy screening (Lori, Dahlem, Ackah, & Adanu, 2014). Therefore, this study aims to explore women's informed decision-making for prenatal aneuploidy screening by investigating the relationships between women's understanding of prenatal aneuploidy screening, health literacy, and women's satisfaction with decisions made for prenatal aneuploidy screening.

Conceptual Framework

Conceptual models serve as the lens for research and offer a network of concepts within the phenomenon (Fawcett, 2005). This empirical analysis of women's informed decision-making for prenatal aneuploidy screening is informed by Faden and Beauchamp's model of informed consent, Nutbeam's concept of health literacy, and Holmes-Rovner's concept of satisfaction with a decision. These concepts were selected to identify women's needs when making informed decisions for prenatal aneuploidy screening and to illuminate potential decisional risks resulting from insufficient understanding of prenatal aneuploidy screening and reduced health literacy.

Faden and Beauchamp's Model of Informed Consent

Autonomy is recognized as an individual's capacity for self-determination. It entails the capacity to decide for oneself and follow a course of action in one's life (Buss, 2016). Autonomy is deeply valued in Western society due to the historical and political influences of John Locke's libertarian views of self-governance and natural rights (Zwolinski, n.d.). In health care, autonomy is protected by the theory and process of

informed consent or informed decision-making. The bioethicists Faden and Beauchamp (1986) developed a patient-centered model of informed consent derived from moral theory. Faden and Beauchamp outline three elements of informed consent: substantial understanding of the act and its consequences, freedom from control, and intentional authorization to proceed with the treatment in question. Faden and Beauchamp's model of informed consent holds that "Personal autonomy encompasses, at a minimum, self-rule that is free from both controlling interferences by others and from certain limitations such as an inadequate understanding that prevents meaningful choice" (p.99-100). According to Faden and Beauchamp's model, an informed decision occurs when one has the capacity to freely evaluate one's options and motives on the basis of his/her beliefs and desires and then acts in coherence with those evaluations.

Faden and Beauchamp's (1986) delineation of an informed decision, as occurring through (a) substantial understanding, (b) non-control or freedom from controlling influences, and (c) intentional authorization, is focused on the needs of the patient, rather than the legal requirements of the provider, and is specific enough to guide empirical inquiry. Substantial understanding includes cognitive awareness of the proposed treatment, the alternatives, and the possible consequences of that act as well as cognizance that one is granting authorization. Freedom from controlling influence is understood as freedom from coercion, persuasion, manipulation, and mental impairment. Intentional authorization involves a behavior that is willed in accordance with a plan wherein the actor has identified what will be done and how it will be done (Faden & Beauchamp, 1986).

Faden and Beauchamp (1986) contend that substantial understanding is generally the condition most in jeopardy with informed decision-making. Faden and Beauchamp (1986) claim that this increased jeopardy is due to the relationship between the condition of substantial understanding and the conditions of intentional authorization and non-control. If a patient truly understands what she is doing, then she will not have a problem with acting intentionally. Additionally, if a patient truly understands that the decision is for her to make autonomously, then she will not have a problem with non-control. Conversely, if either intentional authorization or non-control is not satisfied, it is also likely that substantial understanding has not occurred. Further, Faden and Beauchamp contend that if there are no problems with the condition of non-control, the establishment of substantial understanding is generally sufficient to secure informed consent. Thus, if the substantial understanding condition of informed consent has been satisfied for a medical treatment, then it is likely that an informed decision has occurred (Faden & Beauchamp, 1986).

Empirical application of Faden and Beauchamp's model of informed consent. Faden and Beauchamp's model of informed consent is widely regarded as the foundational model of informed consent in health care. Faden and Beauchamp's model has served as the framework for numerous empirical inquiries. It has recently guided examination of the need for informed consent in comparative effectiveness research studies, the process of obtaining informed consent for whole genome sequencing, and the quality of informed consent obtained by doctors and nurses in an acute care setting (Bernhardt et al., 2015; Chima, 2013; Hamel, Faden, Beauchamp, & Kass, 2014).

Application of Faden and Beauchamp's model of informed consent to decisions for prenatal aneuploidy screening. Prenatal aneuploidy screening is offered on the principles of self-determination and respect for autonomous decisions in reproductive health. In assessing women's decision-making for prenatal aneuploidy screening, Faden and Beauchamp's (1986) model of informed consent demonstrates the need to investigate the potential limitations on informed decision-making that occur through inadequate understanding of prenatal aneuploidy screening. These limitations may be due to insufficient understanding of (a) the screening options, including the option of no screening at all; (b) the possibility of subsequent decision-making following a positive screen result; and (c) the likelihood of having a positive screen result (Gert, 2000). Faden and Beauchamp's model of informed consent demonstrates the need to investigate individual-level factors that may limit women's understanding of prenatal aneuploidy screening. Therefore, Faden and Beauchamp's conception of *substantial understanding* will be operationalized and function as a key variable in this study.

Nutbeam's Concept of Health Literacy

First appearing in health-related literature in the 1990s, health literacy was originally conceptualized as a set of reading comprehension and numeracy skills required to understand health-related information (Mancuso, 2009). Nutbeam (2000) has suggested that a narrow definition of health literacy, limited to description of the relationship between patient literacy levels and understanding of health-related information, misses the deeper meaning of health literacy. Nutbeam (2000) contends that a broader and more complex understanding of health literacy is needed to understand and

identify what it is that health literacy enables people to do. Health literacy has evolved to entail the communication skills, information-seeking behaviors, and problem-solving abilities required to function within the health care system (Jordan, Osborne, & Buchbinder, 2011). The United States Health Resources and Services Administration's Agency for Health Care Research and Quality (AHRQ) define health literacy as "the degree to which individuals have the capacity to obtain, process, and understand basic health information needed to make appropriate health decisions." (U.S. Department of Health and Human Services, 2016). The National Academies of Science, Engineering, and Medicine (2015) describe health literacy as the place where an individual's skills and abilities intersect with the complexities and demands of health systems.

In this study, health literacy is used as a composite term to describe a range of skills and communication behaviors that promote individual health outcomes and facilitate health care decision-making. Therefore, this study is guided by the World Health Organization's conception of health literacy, which defines health literacy as "the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand, and use information in ways which promote and maintain good health," (Nutbeam, 1998, p. 10). According to Nutbeam (2000; 2015), health literacy encompasses the following: (a) functional health literacy, which includes sufficient skills in reading, writing, and numeracy, (b) interactive health literacy, which includes the cognitive and social skills used to participate in and extract meaning from communication and apply it to new situations, and (c) critical health literacy, which involves the more advanced cognitive skills that allow individuals to critically apply

information to achieve greater control over decisions and life events. This conception of health literacy indicates that health literacy may have serious implications on patient autonomy and self-efficacy in that one's access to health information and the ability to use it effectively is critical to empowerment (Nutbeam, 2000; 2015). Moreover, this taxonomy of health literacy suggests that the different categories of health literacy progressively promote greater autonomy in health care decision-making.

Empirical application of Nutbeam's concept of health literacy. Numerous measures of health literacy have been developed and validated in empirical literature (Sorensen et al., 2013). The majority of these measures are unidimensional and only assess one aspect of health literacy, typically health-related reading and numeracy ability (Jordan et al., 2011; Sorensen et al., 2013). Additionally, these traditional measures of health literacy were designed to function as short screening tools of functional health literacy for clinicians to use in daily practice. In the last five years, a more sophisticated, multidimensional measure of health literacy has been developed that aims to assess functional, interactive, and critical health literacy as described by Nutbeam (1998; 2015) (Osborne, Batterham, Elsworth, Hawkins, & Buchbinder., 2013). This measure aims to assess an individual's capacity to gain access to information from a variety of sources, to discriminate between sources of information, to understand and personalize health information, and to demonstrate self-efficacy to apply salient health information when making personal health care decisions (Osborne et al., 2013). In this study, health literacy will be an independent variable measured by five subscales of the Health Literacy Questionnaire. The Health Literacy Questionnaire has been used to apply

Nutbeam's (1998; 2015) conceptual understanding of health literacy in numerous empirical inquiries. The Health Literacy Questionnaire has been used to examine the relationship between health literacy and (a) socioeconomic characteristics and comorbidity among patients with chronic disease, (b) sociodemographic characteristics and use of hospital health services, (c) the needs of women living with breast cancer, and (d) educational attainment and health behavior (Friis, Lasgaard, Osborne, & Maindal, 2016; Friis, Lasgaard, Rowlands, Osborne, & Maindal, 2016; Jessup, Osborne, Beauchamp, Bourne, & Buchbinder, 2017; Huang, Lin, Lu, Tam, Chen, Hou, & Hsieh, 2017). The Health Literacy Questionnaire was designed using a validity-driven approach, which included in-depth grounded consultations, cognitive interviews with a diverse patient population, and extensive psychometric analyses, including confirmatory factor analyses (Osborne et al., 2013).

Application of Nutbeam's concept of health literacy to decisions for prenatal aneuploidy screening. The experience of pregnancy places a woman in the situation where she must make difficult decisions with unclear outcomes that will profoundly affect her own future, as well as the future of her unborn baby and her family. Pregnancy is a state of transition and liminality for women in that "a woman is no longer who she was, and not yet who she will be," (Côté-Arsenault, Brody, & Dombeck, 2009, p.73). Accordingly, pregnancy requires women to make important health decisions while in an unfamiliar, evolving context and with uncertain consequences. The decision to consent to or decline prenatal aneuploidy screening is complex, as it requires women to make a decision based on risk assessment and evaluation of values in a short amount of time.

Additionally, pregnancy places a woman in the role of patient in a health care system that is traditionally paternalistic, wherein the physician's offer of the prenatal aneuploidy screen can be perceived as implicit endorsement of the screen. Thus, the health care provider's structure or "choice architecture" for the offer of prenatal aneuploidy screening can unconsciously incline the patient's decision in a particular manner that compromises autonomy (Thaler & Sunstein, 2008, p. 6). Further, as alternatives become increasingly unfamiliar and complex, the structure and presentation of the choice is more likely to influence the outcome (Thaler & Sunstein, 2008). As a result, expectant women likely need strong health literacy to fully understand the options for prenatal aneuploidy screening, to assess the associated risks, and to make decisions that are congruent with their personal beliefs and values. Faden and Beauchamp's (1986) explication of informed consent as requiring adequate understanding of the choices involved in order to make a meaningful decision underscores the need to evaluate the influence of health literacy on autonomous, informed decisions for prenatal aneuploidy screening. Thus, a woman's health literacy, which encompasses her ability to access, process, and understand health-related information, may be a key influence on her understanding of prenatal aneuploidy screening which affects her ability to make an informed decision for prenatal aneuploidy screening. Therefore, Nutbeam's concept of *health literacy* will be operationalized through five subscales of the Health Literacy Questionnaire (Osborne et al., 2013), which will function as independent variables in this study.

Satisfaction with a Decision

The decisions that patients make in health care are frequently complex and value-laden. As competing alternative options often require a risk-benefit analysis, complete determination of the “right” choice is not readily apparent at the time of the decision. Holmes-Rovner et al. (1996) suggest that in evaluation of health care decisions for which there is no objective right or wrong choice, it is necessary to focus on the quality of the decision-making process. Holmes-Rovner et al. conceptualized satisfaction with a decision as the outcome of a deliberative process of decision-making. In this deliberative process, the choice is based on intentional evaluation of available evidence, the options and risks involved, and consideration of the patient’s values. The manifestation of this deliberative process of decision-making is satisfaction with the decision. According to Holmes-Rovner et al., a person experiences satisfaction with a decision when the decision is adequately informed, based on the decision-maker’s values, and behaviorally implemented.

Empirical application of Holmes-Rovner’s concept of satisfaction with a decision. The Satisfaction with Decision Scale was developed to examine global satisfaction in decision-making (Holmes-Rovner et al., 1996). The Satisfaction with Decision Scale captures three aspects of an effective decision that results in satisfaction. These attributes inquire if the decision was informed, consistent with the person’s values, and behaviorally enacted. The Satisfaction with Decision Scale was developed as a standardized measure of an outcome of decision-making to inform the design of patient-centered decision-support interventions for specific decision-making contexts (Holmes-

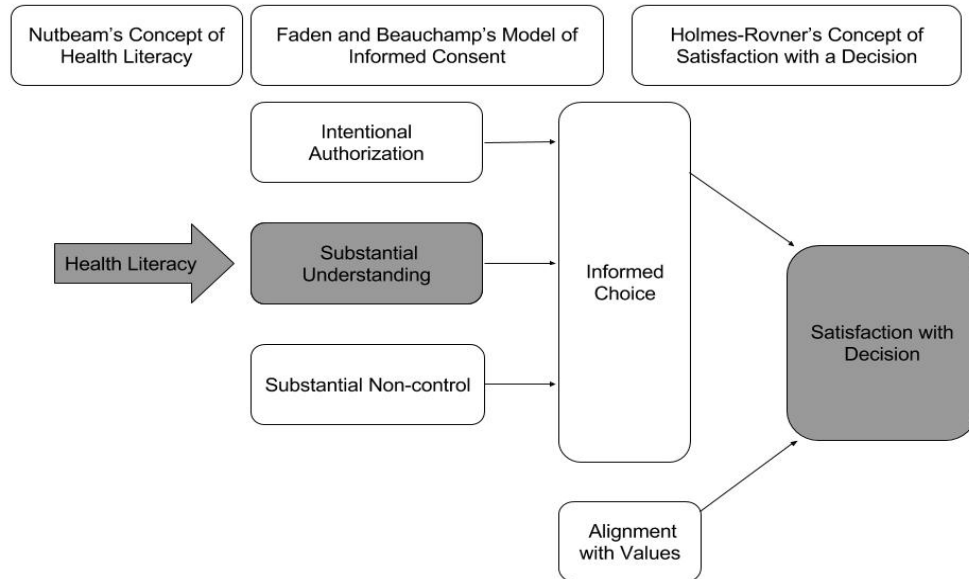
Rovner et al., 1996). A dependent variable in this study will be *satisfaction with a decision* as measured by the Satisfaction with Decision Scale (Holmes-Rovner et al., 1996). The Satisfaction with Decision Scale has been used to examine satisfaction with decisions made for treatment among primary care patients who were diagnosed with depression, type of surgery for women diagnosed with breast cancer, participation in cancer clinical trials, and cancer treatment in relation to support from health care providers and significant others (Lantz et al., 2005; Palmer-Wackerly, Kriger, & Rhodes, 2017; Stryker, Wray, Emmons, Winer, & Demetri, 2006; Willis & Holmes-Rovner, 2003). The Satisfaction with Decision Scale has also been used to evaluate decision aids to support informed choice for genetic testing for breast cancer and for treatment decisions for patients newly diagnosed with prostate cancer (Chabrera et al., 2015; Green, Peterson, et al., 2004). In this study, *satisfaction with decisions* made for prenatal aneuploidy screening will be operationalized using the Satisfaction with Decision Scale, which will function as a dependent variable.

Application of satisfaction with a decision to informed decision-making for prenatal aneuploidy screening and health literacy. Integration of Faden and Beauchamp's (1986) model of informed consent with Holmes-Rovner's concept of satisfaction with a decision and Nutbeam's (1998) concept of health literacy results in the following assumptions that constitute the conceptual framework for this study: (a) A decision that is authorized, free from controlling interferences, and based on substantial understanding is an informed decision; (b) An individual's health literacy likely contributes to the substantial understanding that is necessary for informed decision-

making; (c) An informed decision that is based on the decision-maker's values and is behaviorally implemented results in satisfaction with the decision; (d) An individual's health literacy likely contributes to satisfaction with a decision. Based on this conceptual framework, this study posits that women's understanding of prenatal aneuploidy screening will be influenced by health literacy. Additionally, this study posits that women's satisfaction with decisions made for prenatal aneuploidy screening will be influenced by health literacy and substantial understanding of prenatal aneuploidy screening. Operationalization of the concepts of *substantial understanding*, *satisfaction with a decision*, and *health literacy* will allow for measurement of these concepts and empirical examination of the relationships between these constructs that likely influence women's informed decision-making for prenatal aneuploidy screening. The conceptual framework for this study is depicted in Figure 1.1 below.

Figure 1.1

Conceptual Framework to Guide Study



Schematic drawing of the conceptual framework to guide the proposed study, wherein health literacy as described by Nutbeam (2000; 2016) influences substantial understanding as described by Faden and Beauchamp (1986), and substantial understanding influences satisfaction with a decision as described by Holmes-Rovner et al. (1996). The areas shaded in gray indicate the relationships to be examined in the proposed study.

Purpose

The purpose of this study is to explore the relationships between women's understanding of prenatal aneuploidy screening, health literacy, and satisfaction with decisions made for prenatal aneuploidy screening. The goals of the study are to advance nursing science and the practice of nursing with prenatal populations by providing a better understanding of women's needs when making informed decisions for prenatal aneuploidy screening. To do this, it is important to (a) examine how health literacy influences women's understanding of prenatal aneuploidy screening and (b) examine how health literacy and understanding of prenatal aneuploidy screening influence women's satisfaction with their decisions for prenatal aneuploidy screening. The findings of this study will be used to inform education for prenatal care providers and interventions for clients to facilitate prenatal care that upholds the ethical principles of self-determination and informed choice.

Assumptions

The following are assumptions related to the study:

1. Women are actually routinely offered prenatal aneuploidy screening.
2. The sample of pregnant women who answer survey questions are able to answer questions about their understanding of prenatal aneuploidy screening, health literacy, and their decision-making for prenatal aneuploidy screening.
3. Participants will respond honestly to the survey questions.
4. The selected instruments measure variables appropriately and adequately through documented evidence of validity and reliability.

5. Participants' perceptions about their health literacy, understanding of prenatal aneuploidy screening, and satisfaction with decisions made for prenatal aneuploidy screening, as obtained from the selected instruments, will provide meaningful information from which to draw conclusions about their decision-making for prenatal aneuploidy screening.

Chapter Summary

Evidence indicates that the routinization and rapid integration of prenatal aneuploidy screening in prenatal care has impoverished women's informed decision-making for prenatal aneuploidy screening. Women are routinely asked to consent to prenatal screening for fetal aneuploidy early in pregnancy despite evidence that many women do not understand to what they are consenting (Farrell et al., 2015; Farrell et al., 2011). Prenatal screening relies on assessment of risk rather than direct diagnosis. The decision to use prenatal screening is uniquely complex due to the bioethical questions posed by genetics, the relational state of pregnancy, and the temporal sensitivity of decision. The decision for prenatal aneuploidy screening marks the beginning of a series of profoundly important decisions, including subsequent decisions on invasive diagnostic testing and whether to continue or terminate a pregnancy. Due to inadequate understanding of the purpose and scope of prenatal screening and the difficulty of interpreting estimates of risk, many women are falsely reassured by a low-risk result and unprepared to make life-altering decisions and manage the despair that results from a high-risk result (Aune & Möller, 2012; Chiang et al., 2007). As a result, many women are inadequately prepared to make the decision for prenatal aneuploidy screening, a

decision that will affect the course of their pregnancy and may impact the trajectory of their lives. There is critical need for knowledge generation to illuminate influences on women's understanding of prenatal aneuploidy screening in order to guide professional support for women in making informed decisions for prenatal aneuploidy screening

A conceptual framework that integrates Faden and Beauchamp's (1986) model of informed consent with Holmes-Rovner's concept of satisfaction with a decision and Nutbeam's (1998) concept of health literacy provides the foundation for investigating the links between health literacy, women's understanding of prenatal aneuploidy screening, and their satisfaction with decisions made for prenatal aneuploidy screening. Applying this framework will allow investigation of (a) how health literacy influences women's understanding of prenatal aneuploidy screening and (b) how health literacy and understanding of prenatal aneuploidy screening influence women's satisfaction with their decisions for prenatal aneuploidy screening. The findings of this investigation will be used to guide interventions to promote women's informed decision-making for prenatal aneuploidy screening. In Chapter Two, an integrative review to evaluate and synthesize the available literature on women's experiences with prenatal genetic screening is presented to provide context for this proposed study.

CHAPTER II

REVIEW OF THE LITERATURE

Shea, T. L. (2016). Prenatal paradox: an integrative review of women's experiences with prenatal screening for fetal aneuploidy and neural tube defects. *Contemporary Nurse*, 1–27. doi: 10.1080/10376178.2016.1269609

Abstract

Background

Prenatal screening for fetal aneuploidy and neural tube defects has been incorporated in prenatal care through much of the industrialized world. As prenatal screening evolves technologically and becomes increasingly utilized worldwide, a summary and evaluation of the available evidence on women's experiences with prenatal screening is warranted.

Aims

To conduct an integrative review to evaluate and synthesize available literature to enhance understanding of women's experiences with prenatal screening for fetal aneuploidy and neural tube defects.

Design

Systematic literature searches from January 2005 through January 2016, using the CINAHL, PubMed, and PsychInfo electronic databases and ancestry searches of included

studies to identify previously published, peer-reviewed quantitative and qualitative studies.

Review Methods

The integrative review method as proposed by Whitemore and Knafl (2005) was selected to provide a rigorous course for the integration of qualitative and quantitative research findings.

Results

Thirty-nine studies were included in the review. The literature reveals that prenatal screening occurs in a complex social, ethical, and political reality in which experiential knowledge and biomedical authority are key influences. A theme of paradox emerged in the literature due to the incongruity between reported risk and perceived risk, the tension between informational utility and moral decisions concerning pregnancy management, and the pervasive influence of authoritative knowledge combined with women's reliance on experiential knowledge in their decisions for prenatal screening.

Conclusion

There is a need for future inquiry to critically examine the interrelationships of individual, biomedical, ethical, and sociopolitical factors surrounding prenatal screening.

Keywords: antenatal screening, prenatal screening, fetal aneuploidy, Down syndrome, neural tube defects, maternal serum screening, nuchal translucency, non-invasive prenatal testing

Background

Women are increasingly being asked to consent to prenatal screening for fetal aneuploidy and neural tube defects early in pregnancy, often at their first or second prenatal care appointments (Cleary-Goldman, Morgan, Malone, Robinson, D'Alton, & Schulkin, 2006). Fetal aneuploidy occurs when there are an abnormal number of chromosomes (Griffiths et al., 2015). Having an extra copy of a chromosome changes embryonic, and postnatal development, and physiology of the brain and major organs systems (Torres & Busciglio, 2014). The most common type of viable human aneuploidy is trisomy 21 or Down syndrome, occurring at a frequency of about 0.15 to 0.25% of all live births (International Clearinghouse for Birth Defects Surveillance and Research, 2014). Down syndrome is the most common genetic cause of intellectual disability worldwide and the leading cause of specific anomalies including congenital heart defects (Torres & Busciglio, 2014). Neural tube defects affect more than 300,000 live births each year worldwide and occur due to incomplete closure of the neural tube in the cranial region (anencephaly) or along the spine (spina bifida) (Cordero et al., 2010; Flores, Vellozzi, Valencia, & Sniezek, 2014). Infants born with anencephaly typically expire spontaneously within a few days of birth, while infants born with spina bifida have extensive physical impairment with varying degrees of paralysis (Cordero et al., 2010). The costs associated with chromosomal aneuploidy and neural tube defects include the financial and psychological burdens incurred due to long term management of physical and intellectual disabilities and the effects of caregiver burden on economic stability and psychological well-being (Tétreault et al., 2014).

Advanced maternal age or family history was formerly the criteria for prenatal screening for fetal aneuploidy, particularly Down syndrome (American Congress of Obstetrics and Gynecology [ACOG] 2016a; Latendresse & Deneris, 2015). However, the identification of maternal serum markers that denote the risk of carrying an affected fetus has resulted in prenatal screening being incorporated into routine prenatal care for women regardless of age (ACOG, 2016a). Uptake rates for prenatal screening exhibit geographic variation, with reported rates of 92% in Western Australia, 90% in Denmark, 83% in the United Kingdom, and 50% in China (Ekelund et al., 2011; Huang, Chen, & Pong, 2015; Hui, Muggli, & Halliday, 2016; Maxwell et al., 2011). Modalities of prenatal screening for fetal aneuploidy and neural tube defects include (a) maternal serum screening to measure levels of specific biochemicals in the woman's blood, (b) nuchal translucency, an ultrasound technique wherein the fluid collection at the back of the fetal neck is measured, and c) non-invasive prenatal testing (NIPT), which uses fragmented fetal DNA circulating in maternal blood (Latendresse & Deneris, 2015). Table 2.1 provides a description of these various modes of screening.

Table 2.1

Description of Prenatal Screens¹

Screen	Description	Recommended Gestational Age	Condition Screened	
			Aneuploidy	ONTD
Maternal Serum Screen	Measurement of biochemical markers: PAPP-A and hCG	10-14 weeks	X	
	AFP, hCG, uE3, and inhibin A (Quad screen)	15-18 weeks	X	X
Non-invasive Prenatal Testing (NIPT)	Maternal serum collected to sample cell-free fetal DNA	10+ weeks	X	
Nuchal Translucency	Ultrasonographic measurement of thickness of fetal nuchal fold; Commonly used in combination with maternal serum screening	10-14 weeks	X	

Note: 1. Abbreviations: AFP, alpha fetoprotein; hCG, human chorionic gonadotropin; ONTD, open neural tube defect; PAPP-A, pregnancy associated plasma protein A; uE3, unconjugated estriol (Latendresse & Deneris 2015).

2. Variance occurs with the screens offered and the timing based on regional differences in authorities' recommendations.

False positives and negatives occur with each type of prenatal screen, with false positives for the commonly used Quad screen occurring at a rate of approximately 7% for trisomy 21 (Durković, Anđelić, Mandić, & Lazar, 2011). While NIPT purportedly yields improved selectivity and specificity, it is not widely recommended due to limited validity and quality control (Norton, Rose, & Benn, 2013). Additionally, diagnostic confirmation through invasive testing following NIPT is still required (ACOG, 2012). As each type of prenatal screen relies on a risk assessment rather than direct diagnosis, a positive screen indicating high risk for fetal anomaly entails subsequent decision-making by prospective parents about diagnostic testing and the possibility of termination.

For the majority of women, prenatal screening for fetal aneuploidy and neural tube defects is typically performed as maternal serum screening alone or in combination with nuchal translucency (Boyd et al. n.d.). Women with positive screening results are designated as higher risk for carrying a fetus with aneuploidy or neural tube defects. High risk women are then presented with the option of invasive testing via amniocentesis or chorionic villus sampling to obtain definitive diagnosis, which entails risk for fetal injury or demise (ACOG, 2016b).

Prenatal screening is offered in the context of perinatal health care. Perinatal well-being is understood as the cognitive and affective self-evaluation of a woman's life surrounding the period before and after childbirth (Allan, Carrick-Sen & Martin, 2013). Perinatal well-being encompasses physical, psychological, social, spiritual, economical, and environmental elements surrounding pregnancy (Allan et al., 2013). This ecological conception of perinatal well-being requires that the evaluation of prenatal screening

methods and implementation include women's estimations of (a) the effects of screening on self, fetus, and family, (b) the influence of prenatal screening on maternal fetal attachment and maternal identity, which have lasting impact on maternal and neonatal outcomes, and (c) the experience of decision-making in consenting to or declining prenatal screening (Allan et al., 2013, Yarcheski, Mahon, Yarcheski, Hanks, & Cannella, 2009). These issues potentially have an impact on women's thinking regarding screening during pregnancy. In nursing practice, this author has noted the complexity of feelings that women express concerning whether or not to undergo prenatal screening for fetal anomalies. As prenatal screening evolves technologically and becomes increasingly utilized worldwide, a summary and evaluation of the available evidence on women's experiences with prenatal screening is warranted.

The Review

The aims of this integrative review are (a) to determine the state of the science of women's experiences with prenatal screening, (b) to synthesize the findings into a cohesive whole, and (c) to identify areas for future research.

Design

An integrative review is a method of review that is appropriate for the purpose of providing a comprehensive portrayal of a complex health care issue (Whittemore & Knafl, 2005). A distinction of the integrative review method is that it allows for the inclusion and synthesis of findings from both experimental and non-experimental research (Whittemore & Knafl, 2005). A design specialized to the integrative review as proposed by Whittemore and Knafl (2005) was deliberately selected to provide a rigorous

course for the collection, evaluation, analysis, and integration of separate qualitative and quantitative research findings into a meaningful whole.

Search Methods

A comprehensive search of the literature was performed using the electronic databases CINAHL, PsychInfo, and PubMed. The key terms were prenatal/antenatal screening, and maternal serum screening. Key terms were combined using the Boolean operator AND with the following terms: informed consent, decision-making, and experience. Inclusion criteria were original research, peer-reviewed, and published in the English language inclusive of January 2005 through January 2016. Exclusion criteria included: reviews, discussion papers, studies focused on diagnostic testing, and studies focused on the experiences of health care providers.

Search Outcome

In total, 209 potentially relevant studies were initially identified. Review of the reference citations of relevant papers yielded three additional reports. A diagram of information flow is depicted in Figure 2.1. Titles, abstracts, and full-text articles were examined to screen for relevant studies. Forty studies met inclusion criteria. Table 2.2 provides information on each study's purpose, sample, methodology, and findings.

Figure 2.1

PRISMA Flow Diagram

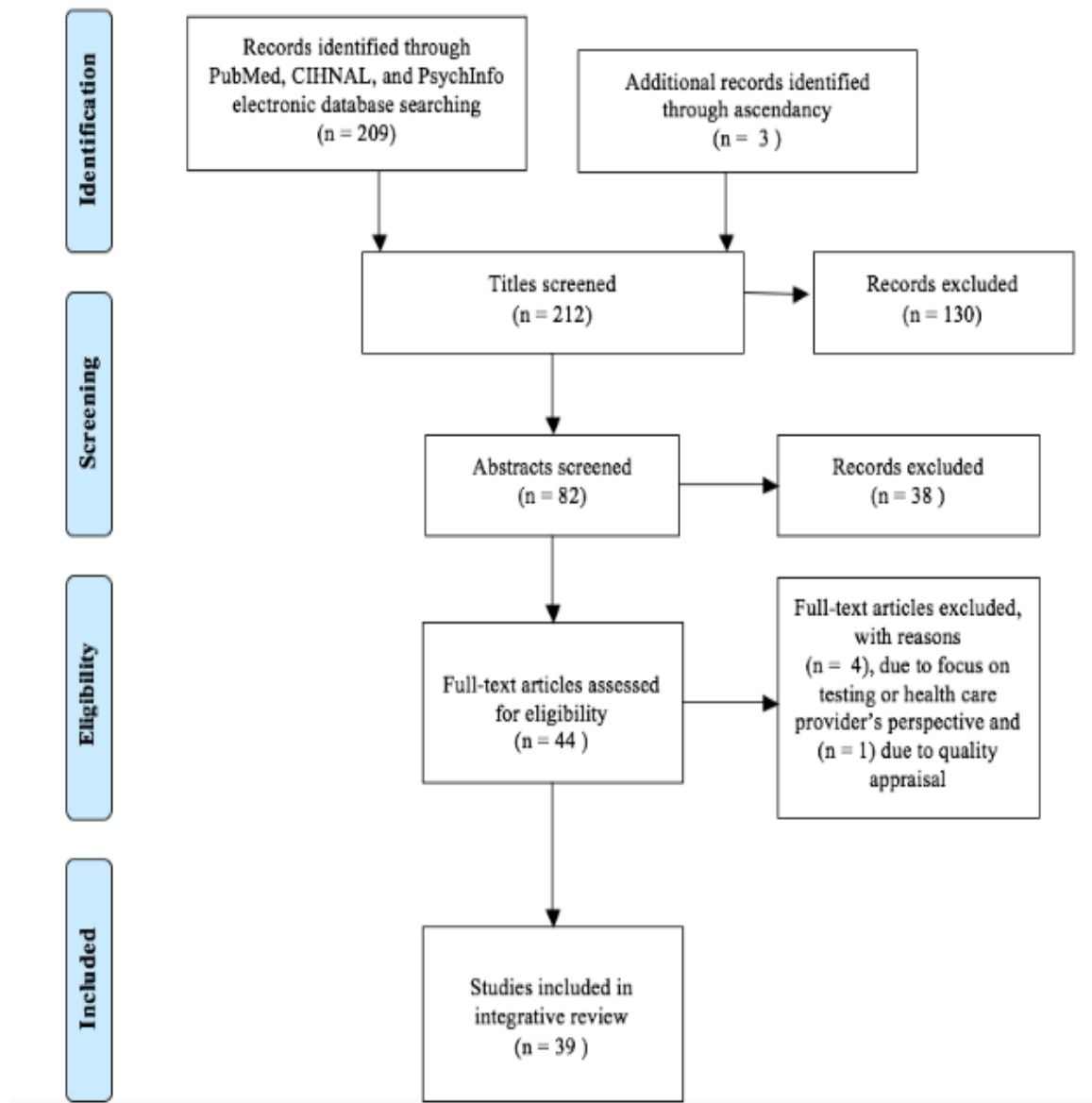


Table 2.2

Characteristics of Reviewed Studies in Chronological Order by Publication Date

Authors (Year) & Country	Purpose	Study Design & Measures	Sample	Main findings
Jaques et al. (2005) Australia	To determine whether women having 1 st trimester screening had made an informed choice	Cross-sectional descriptive survey; Multidimensional Measure of Informed Choice (MMIC) (Marteau et al. 2001)	n = 163 pregnant women undergoing nuchal translucency screening	Although two-thirds of women made informed choice, 46% understood the screen to be a routine part of prenatal care.
Lobel et al. (2005) United States	To identify factors associated with emotional distress among women having maternal serum alpha fetoprotein screening	Longitudinal comparative; Spielberger State-Trait Personality Inventory (Spielberger 1995) Life Orientation Test (Scheier & Carver 1985)	n = 87 pregnant women who had obtained negative screen result, n = 12 who declined screening	Satisfaction with information received was the strongest predictor of lower distress prior to the screen, while dispositional optimism and other medical concerns were predictors of distress after the screen. Women who screened exhibited more distress than those who declined.
Van den Berg et al. (2005) Netherlands	To assess informed choices and the psychological effects of informed choice about prenatal screening	Cross-sectional comparative descriptive; Decisional Conflict Scale (O'Connor	n = 1159 pregnant	Informed choice was associated with less decisional conflict and more satisfaction with decision, but not anxiety. One-third of women did not

make informed choice.

Williams et al. (2005) United Kingdom	To describe the experiences of 1st trimester nuchal translucency and maternal serum screening	In-depth interviews with open-ended questions	n= 14 pregnant, after the results of nuchal translucency screening were known	The majority of women were active agents in the decision-making and thought carefully about their moral values prior to prenatal screening. Women voiced feeling responsible for the quality of their unborn child's life.
Chiang et al. (2006) Taiwan, Republic of China	To describe decision-making for maternal serum screening from the perspective of pregnant women	Grounded theory	n = 26 pregnant women who were informed of positive results	Although screening was presented as a choice, women perceived it as routine. Women chose to screen to avoid having a child with Down syndrome, and because they trusted technology.
Lalor & Begley (2006) United Kingdom	To explore women's experiences of receiving news of fetal anomaly with routine ultrasound examination	Grounded theory	n = 38 pregnant women who had received news of adverse finding	The detection of fetal anomaly was shocking for women, yet they appreciated having foreknowledge of the condition. The expectation of fetal health intensified the adverse feelings.

Lawson & Turriff-Jonasson (2006) Canada	To examine how maternal serum screening influences prenatal attachment	Longitudinal comparative; Prenatal Inventory (Muller 1993).	n=101 pregnant women, identified as high risk for fetal anomaly	Lower attachment was associated with uptake of maternal serum screening, which may lead to feelings of ambiguity and confusion toward the fetus.
Georgsson Öhman et al. (2006) Sweden	To explore women's responses to nuchal translucency results indicating high-risk for Down syndrome	In-depth semi-structured interviews occurring at 3 separate times during pregnancy	n = 24 pregnant women designated as high-risk following scan	A false-positive screen for Down syndrome may result in profound anxiety with potential rejection of the fetus.
Heyman et al. (2006) United Kingdom	To explore women's perspective of being designated higher risk for chromosomal anomalies following prenatal screening	Descriptive, semi-structured interviews	pregnant women, n = 7 high risk, n = 14 low risk, n = 5 who declined screening, n = 1 with miscarriage	Women declined to screen due to opposition to pregnancy termination, positive view of Down syndrome, or to reduce anxiety. Some women designated high risk following the screen reported difficulty reconciling that no fetal health problem ever existed, even after confirmation of fetal health.

Rowe et al. (2006) Australia	To establish if decisions for prenatal screening are well informed and if informed decision-making is associated with better mood during pregnancy	Longitudinal prospective cohort study; Multidimensional Model of Informed Choice (MMIC) (Marteau, 2001); The Hospital Anxiety Scale (HADS)	n = 77 pregnant women	37% of decisions were informed; Women who participated in the screen were more likely to make an informed choice. Short term anxiety levels in those who were well-informed were not significantly different from those who were poorly informed.
Chiang et al. (2007) Taiwan, Republic of	To explore how receiving abnormal results from prenatal serum screening affects the maternal self	Grounded theory	n = 27 pregnant women who had been informed of abnormal results of maternal serum screening	Three forms of maternal self were identified: self-stigmatizing, self-knowledgeable, and self-conflicted.
Kleinveld et al. (2007) Netherlands	To determine if the offer and performance of prenatal screening influences a woman's sense of attachment to her fetus	Longitudinal Randomized control trial with women randomized into nuchal translucency, serum screening, or no screen; Pregnancy Involvement List (Kleinveld et al. 2007); Prenatal Attachment	n = 1031 pregnant women	The offer of prenatal screening temporarily increased maternal-fetal attachment.

Inventory (Muller 1993).

Etchegary et al. (2008) Canada	To explore how women make prenatal screening and testing decisions, particular the impact of experiential knowledge	Descriptive, semi-structured interviews	n = 22 mothers had the screen, n = 16 mothers declined the screen	Experiential embodied and empathetic knowledge influence women's understanding and risk perception.
Li et al. (2008) United	To understand factors that influence a woman's decision to participate in expanded alpha-fetoprotein	Cross-sectional, population-based case-control study	n = 199 women who declined the screen, n = 229 controls who accepted the screen, 70% were college educated	Factors significantly associated with screen decline: skepticism of its usefulness, influence of family, low educational level, willingness to keep affected fetus, not finding providers as useful sources of information, and misunderstanding the purpose of screening.
Pilnick (2008) United	To investigate information-giving by midwives and decision-making for nuchal translucency screening	Descriptive, discourse analysis	n = 14 pregnant women who were offered nuchal translucency screening	While women understood that a decision was needed, many did not perceive it as choice but as assent to routine and standard care.

Van den Berg et al. (2008) Netherlands	To understand prenatal screening decision-making	Path analysis; Pregnancy Related Anxieties Questionnaire	n = 1666 women; majority were middle to high educational level	Attitude toward pregnancy termination, perceived test efficacy, and subjective norm of the desirability of having prenatal screening determined a woman's attitude toward having the screen.
García et al. (2009) Netherlands	To explore the effect of the offer of screening on decision-making and the factors women consider in the decision	Semi-structured interviews embedded within a randomized controlled trial, with data analyzed with qualitative coding software	n = 59 women who were deciding whether to participate in screening	Women approached the moral dilemma of screening by considering their family members who will be affected by the possibility of having a disabled child, rather than abstract ethical principles.
Georgsson Öhman et al. (2009) Sweden	To explore how women reacted to high risk status and to evaluate whether actual risk and perceived risk are associated with worry or depressive symptoms	Longitudinal descriptive; Swedish Cambridge Worry Scale (Georgsson Öhman 2004); Edinburgh Postnatal Depression Scale (Cox et al. 1987)	n = 796 had slucency	Women's perceived risk may be vastly incongruent with screening-determined risk, with over half of the women who interpreted their risk as high actually having low risk. High risk was not associated with worry or depression

Hawthorne & Ahern (2009) Australia	To describe the experiences of women who are contemplating nuchal translucency screening for Down syndrome	Phenomenological	n = 20 pregnant women at 11-12 weeks gestation, before undergoing screening	Women expressed that nuchal translucency is valuable due to providing reassurance that one is not having a child with disability. Although women expressed anxiety concerning screening, they identified it as part of the role of good parenting.
Park & Matthews (2009) Canada	To investigate what women learn about prenatal screening and determine the role their physician plays in the decision	Descriptive, semi-structured telephone interviews	n = 11 women pregnant	Women were most influenced by family and friends in decisions to uptake screening. Women need more time to learn about screening options.
Rowe et al. (2009) Australia	To compare the growth of maternal fetal attachment in groups of women whose decisions about prenatal screening were informed versus not informed	Longitudinal Dimensional Model of FIC) (Marteau et al. anxiety and .DS); The Antenatal aire (AAQ)	n = 68 pregnant weeks, most with post-secondary training or college degree	Informed decision-making of maternal serum screening was significantly associated with lower maternal-fetal attachment prior to screening, but this difference resolved after screening results were known.

Seror & Ville (2009) France	To investigate women's attitudes and decisions regarding for Down	Cross-sectional	n = 341 women in a maternity unit who had recently given birth	Approximately one-half of the women screened did not know that results of the screen might require future decisions on pregnancy termination. One-third did not anticipate that screening might lead to decisions on invasive testing.
Czerwinski et al. (2010) United	To investigate the anxiety level of women based on how results of prenatal screens are disclosed, and to assess the accuracy of patient's perception of risk.	Descriptive comparative; Six-item short form Spielberger State-Trait Anxiety Inventory (Martreau & Bekker 1992)	n = 170 pregnant women referred to genetic counseling for advanced maternal age, abnormal screen, or other indication	Women born outside the United States were less likely to be aware of the screen prior to result disclosure. Most women did not respond to a question asking their numerical risk was.
Fransen et al. (2010) Netherlands	To assess ethnic differences in informed and background characteristics in decision-making on prenatal screening	Cross-sectional comparative	n = 65 Dutch, n = 54 Turkish and n = 19 Surinamese pregnant women	Significant differences existed in informed decision-making on prenatal syndrome: 71% of Dutch, 5% of Turkish and 26% of Surinamese made informed decisions.

Seror & Ville (2010) France	To explore women's attitudes toward decisions with prenatal screening and to assess if their attitudes correspond with their decisions	Cross-sectional	n = 341 stpartum	Decisions on screening were made based on attitudes toward termination, estimation of risk associated with invasive diagnostic testing, and the informational value of screens.
Skirton & Barr (2010) United Kingdom	To investigate knowledge about prenatal screening and explore the influences on decisions	Cross-sectional	n = 100 women, n = 11 partners, n = 78 midwives	Women reported health care but lack of was a barrier.
Dahl et al. (2011) Denmark	To evaluate the relationship between women's knowledge of prenatal screening and the psychological management of screen decisions	Cross-sectional descriptive; Decisional Conflict (O'Connor 1995); WHO Well-being Index (WHO, 1998); Cambridge Worry Scale (Green et al., 2003)	n = 4111 were offered	Higher knowledge was associated with reduced decisional conflict, but knowledge was not associated with worries in pregnancy.
Farrell et al. (2011) United States	To assess knowledge and decision-making among women who present for first trimester screening	Cross-section associational with survey	n = 139	Women had inadequate knowledge of the clinical features of Down syndrome and the possibility that screen results may require future complex decision-making.

Aune & Möller (2012) Sweden and Norway	To understand how women experience early ultrasound screening	Grounded theory	n = 10 pregnant women	A theme of "I want a choice but I don't want to decide" emerged. Women made choices independently, with a strong sense of personal responsibility
Carroll et al. (2012) United Kingdom	To inquiry how couples regard information and make decisions about prenatal screening	Qualitative structured	n = 16 + weeks gestation, n = 13 male spouses	Couples voiced a preference for joint yet private decision-making with the midwife's primary role being to provide information.
García et al. (2012) Netherlands	To determine if the offer of prenatal screening leads women to believe that they are morally compelled to screen	Cross-sectional descriptive with open-ended questionnaire, embedded in a randomized controlled trial	n = 111 pregnant women	Women did not feel morally compelled to consent to screening, but rather expressed that decisions to screen were based on perceived moral duties to existing family members.
Schoonen et al. (2012) Netherlands	To evaluate the provision of information for PGS using informed consent as a quality indicator	Cross-sectional design; A modified Multidimensional Model of Informed Choice (MMIC)	n = 510 pregnant women	75.5 % of women made an informed choice. Screened women were more likely to make an informed choice (94.3%) compared with those who did not participate in screening (64.9%)

Wätterbjörk et al. (2013) Sweden	To explore how couples make decision about prenatal screening	Exploratory using interpretive description	n = 15 pregnant women, n = 16 couples, n = 6 with partners	For some couples decision-making was straightforward. For others, decision-making was complex and confusing. Discourse with family and friends aided decisions.
Ahmed et al. (2014) United	To understand what women believe the dialogue between them and health professionals should be about to facilitate informed choices	Descriptive with semi-structure interviews and Framework analysis	n = 98 pregnant women of 5 ethnicities: African, British, White, Caribbean, Pakistani and Chinese	Women value the advice of health professionals in the context of decision-making for screening. Advice meant different things to different individuals, ranging from information to direction.
Constantine et al. (2014) United States	To evaluate Informed consent and compare screen acceptors to those who refused the screen	Cross-section associational	n = 226 pregnant women	56.2% of women did not make an informed decision. The decision to screen was less of an informed and deliberative action than the decision not to screen.
Dixon & Burton (2014) Canada	To evaluate how well midwives implement informed choice for prenatal screening in Ontario	Informed choice was measured using a modified Multidimensional Model of Informed Choice (MMIC) (Marteau et al. 2001)	n = 171 midwifery clients	93.0% of participants made an informed choice. Women who chose to utilize prenatal screening had lower knowledge scales than those who declined.

Van Schendel et al. (2014) Netherlands	To explore the attitudes of pregnant women and their partners related to non-invasive prenatal testing	Focus groups (face-to-face and online) and semi-structured interviews	Five focus groups of women n = 28	Participants expressed concern that earlier testing could lead to diminished time to make an informed decision and that widespread testing could increase social stigma of Down syndrome.
Vanstone et al. (2015) Canada	To identify women's values about decision-making through examining how women experience publicly funded non-invasive prenatal testing	Constructivist	n = 38 women designated at high risk for fetal aneuploidy	The values by which women base their decisions are modulated by the timing of screening, accuracy, and perceived risk. Many participants interpreted risk in a way that does not reflect clinical risk.
Martin et al. (2016) Netherlands	To examine if communication by clients during counseling for anomaly screening is related to midwives' psychosocial questions & communication	Cross-sectional associational; Roter Interaction Analysis System	184 videotaped prenatal counseling session with 20 midwives	The amount of client's psychosocial communication to the midwives' psychosocial and affective communication and the duration of counseling.

Quality Appraisal

Due to the diversity of primary sources, the need to systematically critique the rigor of the studies was recognized. Reports were scored according to a critique tool based on Bowling's (2009) checklist for quantitative research and Whitemore, Chase, and Mandle's (2001) guidelines for qualitative research. Of the 40 studies that met inclusion criteria, 39 were deemed high or adequate quality. One report failed to provide sufficient description of methods and analysis and was therefore removed prior to data analysis.

Data Abstraction and Synthesis

During the first stage of data abstraction, each article was read to obtain an overview. A data extraction matrix was used to capture and abstract qualitative and quantitative data. Relevant data were entered into a matrix to facilitate synthesis according to author(s), year, design, measures, sample characteristics, and findings. Whitemore and Knafl (2005) suggest using a qualitative analytic strategy to enhance rigor when synthesizing data from diverse methodologies. Thus, qualitative content analysis (Sandelowski, 2000) was chosen as the analytical method. First, open coding was used to organize key content in literature. Axial coding was then used to connect content and identify latent themes. Data abstraction, synthesis, and analysis was performed by the author.

Description of the Studies

In this integrative review, 39 original research reports on women's decision-making and experiences with prenatal screening were identified, reviewed, critiqued, and

synthesized. Of the articles reviewed, 21 used quantitative methods, 17 used qualitative methods, and one used mixed methods. The literature was represented internationally with numerous countries of publication, including Australia (4), Canada (5), Denmark (1), France (2), the Netherlands (9), Norway and Sweden (1), Sweden (3), United Kingdom (7), United States (5), and Taiwan (2). Although there was broad international representation, 23 of the 39 studies reviewed were conducted in northern Europe. The majority of the samples were comprised of pregnant women between 11-24 weeks pregnant, corresponding to the timing of prenatal screening. Four studies included male partners in addition to the female participants (Skirton & Barr, 2010; Carroll, Owen-Smith, Shaw, & Montgomery, 2012; Wätterbjörk, Blomberg, Nilsson, & Sahlberg-Blom, 2013; Van Schendel et al., 2014). Samples were predominantly middle to upper socioeconomic class, Caucasian, and possessing some university education. The predominantly operationalized constructs include: anxiety, maternal-fetal attachment, attitude toward screening, attitude toward termination of pregnancy, decisional conflict, informed consent, intention to screen, and knowledge of the screen. While ten studies measured knowledge of the screen, the type and number of items assessing knowledge varied considerably, thereby limiting comparison of knowledge of the screen across studies.

Results

To illuminate the multifarious aspects of a woman's experience with prenatal screening, the thematic findings from this review are categorized as (a) experiential knowledge, which encompasses embodied, subjective experiences and empathetic

knowledge obtained from people with whom one closely identifies; and (b) authoritative knowledge, which includes biomedical, technological, and expert professional knowledge that is perceived as legitimate and consequential for how health and illness are defined (Abel & Browner, 1998; Jordan, 2014).

Experiential Knowledge

Emotional distress. Lobel, Dias, and Meyer (2005) found that women who opted for maternal serum screening were modestly, but significantly more emotionally distressed throughout pregnancy than those who declined, even after receiving normal results. Women describe the receipt of a positive screen (indicating high risk for fetal abnormality) and the aftermath of time-sensitive decisions concerning confirmatory diagnosis and the possibility of termination as emotionally devastating and traumatic life experiences (Chiang et al., 2007; Etchegary et al., 2008; Heyman et al., 2006).

Additional emotional distress arises from doubt about which fetal conditions would make termination acceptable (García, Timmermans, & van Leeuwen, 2009). While a positive prenatal screen can result in profound anxiety, a heightened sense of risk and fear, and possible rejection of the fetus (Georgsson Öhman, Saltvedt, Waldenström, Grunewald, & Olin-Lauritzen, 2006; Hawthorne & Ahern, 2009; Heyman et al., 2006), it has not been found to be associated with depression (Georgsson Öhman, Grunewald, & Waldenström, 2009). Being labeled screen-positive can result in self-stigmatization, shame, guilt, and self-conflict both during pregnancy and even following the birth of a healthy, non-affected infant (Chiang et al., 2007; Heyman et al. 2006). Thus, while a negative screen (indicating low risk for fetal abnormality) may provide a sense of reassurance of fetal

health, a positive screen may result in emotional anguish, sustained anxiety, and altered adaptation to the parenting role.

Liminality. “Liminal space is a place of ambiguity and anxiety, of no-longer and not-yet,” (Carson, 2002, p.180). An emergent theme of the literature is the pronounced liminality of pregnancy in the context of prenatal screening, in that there is a cautious, hesitant approach to pregnancy, with an oscillation between committing to and holding back from the fetus emotionally (Georgsson Öhman et al., 2006; Hawthorne & Ahern, 2009; Rowe, Fisher, & Quinlivan, 2009). Kleinveld, Timmermans, Van den Berg, Van Eijk, and Ten Kate (2007) found that the offer of prenatal screening temporarily increased maternal fetal attachment, although this difference abated as pregnancy progressed. This finding sharply contrasts with research by Lawson and Turriff-Jonasson (2006) who determined that women who underwent prenatal screening experienced lower maternal fetal attachment than women who declined screening. Further, Rowe et al. (2009) found that women who made informed choices on prenatal screening demonstrated significantly lower attachment compared with women who did not make informed choices. Additionally, Hawthorne and Ahern (2009) learned that women who declined prenatal screening demonstrated a greater sense of connection with and responsibility to protect their pregnancies than women who participated in screening. These studies suggest that the offer of prenatal screening may increase feelings of attachment toward the pregnancy for some women, while other women postpone feelings of attachment until receipt of reassuring screening results. The discordant findings on maternal fetal attachment as related to prenatal screening should be evaluated in

consideration that these studies used widely divergent designs, samples, and instrumentation.

Uncharted territory. Prenatal screening is a situation in which risk cannot be defined objectively; rather, potential risk is depicted via a calculated odds ratio. The resultant interpretation of the probability of parenting a child with disabilities and the associated decision-making are identified as alien and destabilizing for women (Aune & Möller 2012; Hawthorne & Ahern 2009; Vanstone, Yacoub, Giacomini, Hulan, & McDonald, 2015). Women struggle with how to evaluate the results of screening (Czerwinski et al., 2010; Georgsson Öhman et al., 2009; Hawthorne & Ahern, 2009; Farrell et al., 2011). The language of chance and probability used to explain results of prenatal screening exacerbates feelings of confusion and anxiety, with the odds ratio so foreign and difficult for women to understand that it either is often grossly misinterpreted, unmemorable, or rendered meaningless (Czerwinski et al., 2010; Georgsson Öhman et al., 2009; Hawthorne & Ahern, 2009; Seror & Ville, 2009).

The prospect of facing ethical decisions concerning pregnancy management is unfamiliar and unanticipated for many women (Rowe, Fisher, & Quinlivan., 2006; Farrell et al., 2011). Seror and Ville (2009) learned that one-third of women considering prenatal screening were unaware that they may need to subsequently consider invasive diagnostic testing or pregnancy termination. Farrell et al. (2011) found that only about one-third of women considered the cascade of post-test decisions as an important factor to consider in their decision to screen. While women want the choice to screen, they

typically expect fetal health and are unready to make critical decisions following a positive screen result (Aune & Möller, 2012; Lalor & Begley, 2006).

Moral tension. A predominant theme in the literature is tension concerning the utility and morality of prenatal screening. Tension exists between the value of the foreknowledge provided by the screen and the uncertainty about how to act upon receipt of information concerning fetal anomaly (Aune & Möller, 2012; Hawthorne & Ahern, 2009; Seror & Ville, 2010; Van Schendel et al., 2014). Women make decisions about screening according to five main criteria: attitudes toward pregnancy termination, perceived risk of having a child with a disability, perception of risks associated with diagnostic testing, perceived benefit of obtaining information, and subjective norm of screening desirability (Li, Karlberg, Wi, & Norem, 2008; Van den Berg et al., 2008; Seror & Ville 2010). Although women desire the relief that accompanies a reassuring screen, they are conflicted in discerning how to proceed with non-reassuring results (Aune & Möller, 2012; García, Timmermans, & van Leeuwen, 2012; Vanstone et al., 2015). Tension is also expressed between the value of the screen in providing information, and the fear that prenatal screening may lead to limitless screens toward the creation of the idealized child, with selection for gender or cosmetic traits (Van Schendel et al., 2014).

Women experience conflict between moral duties arising from commitments to both the pregnancy and to existing family members. Torn between the fetus' life and the happiness of existing children and spouses, women voice concern that the hardship of caring for a disabled child will devastate family harmony (García et al., 2012; Hawthorne

& Ahern, 2009). Rather than analyzing the moral dimensions of prenatal screening according to abstract principles, women consider the concrete realities of family members whose lives will be affected by the decision (Aune & Möller, 2012; García et al., 2009; Hawthorne & Ahern, 2009; Wätterbjörk et al., 2013).

Exposure to disability. There is the suggestion that the stigma of parenting a disabled child and lack of experience with people with disabilities may color decisions related to prenatal screening (Chiang et al., 2006; García et al., 2012; Hawthorne & Ahern, 2009; Skirton & Barr, 2010). While women are typically aware that the screen is used to detect risk of having a child with Down syndrome, women possess inadequate knowledge of the clinical features of Down syndrome prior to making decisions about the screen (Farrell et al., 2011). Skirton and Barr (2010) found that while 35% of couples considering prenatal screening wanted to know more about people with Down syndrome, 19% of respondents believed that information about Down syndrome was irrelevant to their decisions. Alternatively, Chiang et al. (2007) found that many women designated high risk for carrying a fetus with Down syndrome experienced self-transcendence, with increased empathy for people whose lives are affected by Down syndrome.

Friends and family. Attitudes and decisions concerning prenatal screening may be more influenced by friends and family than health care professionals (Hawthorne & Ahern 2009; Li, Karlberg, Wi, & Norem, 2008; Park & Matthews, 2009). In a population-based case-control study, Li et al. (2008) found that women who decline screening were more likely to actively seek information on the screen from their friends and to involve their partners in the decision. Qualitative evidence indicates that women

assume a deep and personal responsibility toward decision-making and draw upon the experiences of friends and family to inform their decisions (Aune & Möller 2012; Etchegary et al., 2008; Williams et al., 2005).

Authoritative Knowledge

Inadequate understanding. Both qualitative and quantitative findings indicate that many women lack sufficient knowledge and understanding about the scope and limits of prenatal screening, Down syndrome, and subsequent testing prior to making a decision (Constantine et al., 2014; Farrell et al., 2011; Jaques et al., 2005; Schoonen et al., 2012; Skirton & Barr, 2010; Van den Berg et al., 2005). Substantial reports concern the extent to which informed choice occurs with prenatal screening (Chiang et al. 2006; Constantine et al., 2014; Dixon & Burton, 2014; Fransen, Essik-Bot, Vogel, Mackenbach, Steegers, & Wildschut, 2010; Jaques et al., 2005; Rowe et al., 2006; Rowe et al., 2009; Schoonen et al., 2012; Skirton & Barr, 2010; Van den Berg et al., 2005). The literature identifies two core characteristics of informed choice: first, that the choice occurs based on relevant and accurate information, and second, that the choice is aligned with the decision-maker's values. To evaluate knowledge of prenatal screening and informed choice, the studies reviewed most often used researcher-generated survey questions (Constantine et al., 2014; Dahl, Hvidman, Jørgensen, & Kesmodel, 2011; Farrell et al., 2011; Skirton & Barr, 2010; Van den Berg et al., 2005; Van den Berg et al., 2005), the Multidimensional Measure of Informed Choice (MMIC; Marteau, Dormandy, & Michie, 2001) (Jacques et al., 2005; Rowe et al., 2006; Rowe et al., 2009), or a modified version of the MMIC (Dixon & Burton, 2014; Fransen et al., 2010; Schoonen et al., 2012). The

MMIC is a measure derived from a definition of informed choice as “one that is based on relevant knowledge, consistent with the decision-maker’s values, and is behaviorally implemented,” (Marteau et al., 2001, p. 100). The MMIC utilizes knowledge in combination with value-consistency, which occurs when an individual has a positive attitude and accepts screening or a negative attitude and declines to screen; all other combinations of attitude and screen utilization are classified as uninformed choices (Marteau et al., 2001).

The prevalence of women who make uninformed choices varies geographically as follows: 33.3% in Australia (Jaques et al., 2005), 7% in Canada (Dixon & Burton, 2014), 25 - 33.3% in the Netherlands (Schoonen et al., 2012; Van den Berg et al., 2005), and 56.2% in the United States (Constantine et al., 2014). In studies using the MMIC, 12% to 73.5% of women made uninformed choices due to value inconsistency only, 37.3% to 49% made uninformed choices due to inadequate knowledge only, and 14.5% to 39% made uninformed choices due to both value inconsistency and inadequate knowledge (Fransen et al., 2010; Rowe et al., 2006). These findings indicate that even when women are given adequate information, a substantial minority do not possess sufficient understanding or clarity of values to make informed decisions.

Antecedent correlates of informed choice include higher educational level (Schoonen et al., 2012; Van den Berg et al., 2005), higher knowledge scores (Jaques et al., 2005), awareness that the screen is optional (Jaques et al., 2005), and being a member of the racial/ethnic majority (Fransen et al., 2010). Evidence on the relationship between the utilization of the screen and informed choice is contradictory. Rowe et al. (2006) and

Schoonen et al. (2012) found a positive correlation between utilization of the screen and informed choice, while Jaques et al. (2005) and Constantine et al. (2014) found that informed choice was less likely to occur among women who utilized the screen compared with women who declined the screen. The only statistically significant predictors of informed choice that are reported in the reviewed literature are educational level (Jaques et al., 2005; Schoonen et al., 2012), race/ethnicity (Constantine et al., 2014; Fransen et al., 2010), and income (Constantine et al., 2014), with lower educational attainment, lower income level, and status as a racial or ethnic minority associated with making an uninformed decision. Outcomes associated with informed choice for prenatal screening include reduced decisional conflict and greater satisfaction with the decision (Van den Berg et al., 2005). Outcomes associated with higher knowledge of prenatal screening alone include reduced decisional conflict and greater personal well-being (Dahl et al., 2011).

Professional advice. Women and their partners consider the decision to consent or decline screening a private, personal choice (Carroll et al., 2012; Williams et al., 2005), yet they still value professional advice when making decisions (Ahmed, Bryant, Tizro, & Shickle, 2014; Carroll et al., 2012). However, advice means different things to different women, particularly among diverse racial groups and ethnic cultures. For example, in assessing decision-making for prenatal screening among an all-White British sample, Carroll et al. (2012) found that couples did not consult with their health care providers and predominantly viewed the health care provider's role as purveyor of information. In contrast, in a racially diverse sample that included African, British

White, Caribbean, Chinese, and Pakistani women, Ahmed et al. (2014) found that some participants believed that the health professional's role entailed giving a recommendation or directive counsel on whether or not to screen. Despite these variations, many women express the need for increased discourse with care providers prior to making decisions about screening. Women report a lack of clarity about the risks and benefits of screening, the implications of screening, and what options are available following a positive screen (Ahmed et al., 2014; Park & Matthews, 2009). Notably, the duration of counseling and the health care provider's communication are positively associated with increased client psychosocial communication concerning the screen, indicating that the health care provider may need to take the lead in these conversations (Martin et al., 2016).

Routinization

A concern raised by several authors is that the integration of prenatal screening in routine prenatal care creates a technological imperative with women perceiving prenatal screening as compliance with protocol rather than an option (Chiang et al., 2006; Constantine et al., 2014; Jaques et al., 2005; Park & Matthews, 2009; Pilnick, 2008; Skirton & Barr, 2010; Van Schendel et al., 2014). Pilnick (2008) and Constantine et al. (2014) explicate that the offer of prenatal screening may be perceived as assent to a decision that is already endorsed by health experts rather than a choice requiring deliberation. However, García et al. (2012) found that the offer of prenatal screening did not lead women to believe that they are morally compelled to consent to the screen; the participants recognized that mothers have a responsibility to seek the best health for their child but opined that this responsibility does not include prenatal screening. Nonetheless,

women express that the earlier timing and widespread use of screening may lead to uncritical uptake and reduced discernment and dialogue concerning screening decisions (Hawthorne & Ahern 2009; Pilnick, 2008; Van Schendel et al., 2014).

Paradox

The final phase of data analysis in an integrative review involves coalescing specific findings to create a succinct summary (Whittemore & Knafl, 2005). In this review, a global theme of *paradox* was identified in the extant literature on women's experiences with prenatal screening for fetal aneuploidy and neural tube defects. A paradox is a proposition that is contradictory in nature (Oxford University Press, 2016). The proposition of prenatal screening presents three inherently contradictory situations for women. First, while women recognize the informational utility of prenatal screening, they are conflicted about making increasingly difficult choices. Second, while the option to screen is intended to empower women through the provision of information, women do not demonstrate sufficient understanding of the risk and benefits of screening, the conditions screened, the implications of screening, and their risk of having an infant affected by an anomaly. Third, although biomedical authority has a powerful and pervasive influence in prenatal care, paradoxically, women widely report a need for increased information, communication, and guidance from health care professionals.

Discussion

Incongruence occurs between the implementation of prenatal screening, the ethical imperative of informed choice, and women's experiences with prenatal screening. The goal of prenatal screening is to enable women to make informed choices about

whether they want to learn if they are at increased risk of having a child with an anomaly (ACOG, 2016a; Ames, Metcalfe, Archibald, Duncan, & Emery, 2015). Through informed choice, women should be empowered to voluntarily decide what is right for them. However, the offer of prenatal screening presents a paradox with inherently contradictory situations that combine to disempower rather than empower women. The discussion will focus on two central points of this paradox: (1) the conflict between the utility and morality of prenatal screening in the context of technologically-laden modern obstetric care and social bias against disability and (2) decision-making with insufficient knowledge, inadequate understanding, and incomplete professional guidance and discourse.

Although women recognize the informational utility of prenatal screening and widely voice the desire to have a choice, they express considerable uncertainty about whether to accept or decline the screens (Aune & Möller, 2012; Carroll et al., 2012; Chiang et al., 2007; García et al., 2009; Vanstone et al., 2015). Women often value the reassurance provided by a negative screen result, but have moral confliction about the nexus of prenatal screening to decisions about pregnancy termination and what fetal conditions might warrant termination. Further, concern has been raised regarding health professional bias that problematizes all fetal anomalies, focusing on the associated medical complications, while failing to imagine that people with disabilities can lead lives as rich and fulfilling as their own (Bauer, 2011; Parens & Asch, 2003). Juxtaposing these concerns with the findings of this review reveals that the process of receiving modern prenatal care in the context of a society and health care community that

uncritically integrates genetic technology and stigmatizes disability may have an internal momentum that drives toward prenatal screening as an imperative. Yet the findings here indicate that the experience and emotional impact of uncritically accepting prenatal screening may be profound and lasting. Nonetheless, the routinization of screening, the powerful influence of biomedical authority, and social norms of parenting and disability combine to create an environment in which it becomes difficult for women to opt out of prenatal screening, thereby impeding freedom of choice (Chiang et al., 2006; Constantine et al., 2014; Jaques et al., 2005; Pilnick, 2008; Van Schendel et al., 2014; Williams et al., 2005). As Hubbard explains, “as choices become available they all too rapidly become compulsions to ‘choose’ the socially endorsed alternative,” (Hubbard, Henifin, & Fried, 1982, p.210).

Current practice fails to secure women’s understanding of prenatal screening. Despite the receipt of information about prenatal screening, women have inadequate knowledge of the screens, the implications of screening, and the conditions detected (Farrell et al., 2011; Fransen et al., 2010; Georgsson Öhman et al., 2009; Seror & Ville, 2009; Park & Matthews, 2009). While many health professionals work toward the ideal of informed consent, women widely express that prenatal care providers do not communicate enough information about the risks and benefits of screening and the conditions they aim to detect. It is not surprising then that uninformed choice due to inadequate knowledge and value inconsistency is reported at average rates of 33% of cases where prenatal screens are offered worldwide (Constantine et al., 2014; Jaques et al., 2005; Rowe et al., 2006; Schoonen et al., 2012; Van den Berg et al., 2005).

Inadequate information about what life is like for those with disabilities results in women making their decisions about screening based on misinformation about the conditions screened. Additionally, there is discordance between a woman's clinical risk and her interpretation of that risk, with the majority of women misinterpreting their probability of having a child with a disability (Czerwinski et al., 2010; Hawthorne & Ahern, 2009; Vanstone et al., 2015). This skewed risk perception, in combination with the social stigma of disability and the milieu of risk awareness and geneticism prevalent in modern health care, contribute to a disempowering sense of fear and anxiety about having a less than ideal baby (Chiang et al., 2006; Chiang et al., 2007; Georgsson Öhman et al., 2009; Hawthorne & Ahern, 2009; Van Schendel et al., 2014).

The moral complexity of the decision whether or not to use prenatal screening requires that sources of knowledge elucidate choices that align with women's values. Therefore, it is vital that women understand the risks and benefits of screening and what treatment options are available if the screen indicates abnormality. However, the findings of this review indicate that the advice and information provided by health professionals is often superficial, incomplete, or too ambiguous to be useful (Ahmed et al., 2014; Farrell et al., 2011; Park & Matthews, 2009; Skirton & Barr, 2010). Women widely report a need for increased discourse with their health care providers to clarify their understanding of prenatal screening and facilitate decision-making. Thus, while the option to screen for fetal anomalies is intended to empower women through the provision of information and the opportunity to make an autonomous choice, current screening practices may

disempower women because they fail to adequately educate women, support their understanding, and insure informed choice.

Implications

Decisions about prenatal screening are value-laden, time-sensitive, and require risk assessment, discernment of preferences, and moral judgment. The findings of this review overwhelmingly demonstrate a need for interventions to support women's informed decision-making for prenatal screening. Evidence indicates that video tutorials, focused discussion with health professionals, and written and electronic decisional aides can support women's understanding of prenatal screening and facilitate decision-making that reflects women's preferences and values (Ahmed et al., 2014; Carroll et al., 2012; Kuppermann et al., 2009). These tools should be widely integrated in the first trimester at the initial prenatal care appointments to give women the opportunity to gain understanding of prenatal screening options, the conditions the screens detect, and the implications of screening. Sectors of the population of pregnant women, including racial/ethnic minorities and those with lower education, who are especially vulnerable to making decisions about prenatal screening that are inadequately informed may require targeted intervention to improve their understanding about prenatal screening (Fransen et al., 2010; Schoonen et al., 2012). The findings of this review indicate that many women do not understand that a low risk screen result does not guarantee a healthy child and a high risk result does not mean the fetus has an anomaly (Farrell et al., 2011; Pilnick, 2008). It is critical that all women who receive prenatal screening understand the distinction between a screen and a diagnostic test prior to any irreversible pregnancy

management decisions such as termination. Moreover, the routinization of prenatal screening underscores the importance of women understanding that the decision to use or decline a prenatal screen is their individual choice. Therefore, prenatal care providers can support women's understanding of prenatal screening by intentionally communicating the distinction between a screen and a test, and the volitional nature of prenatal screening.

Salient questions about women's experiences with prenatal screening are raised by the findings of this review and warrant future research: (1) Low educational level and minority race/ethnicity are associated with reduced rates of informed decision-making for prenatal screening. What other patient-level variables might explain insufficient knowledge and inadequate informed choice? (2) Evidence of the relationships between informed decision-making, screening uptake, and maternal fetal attachment is equivocal. How might informed consent and screening uptake impact maternal role identity both in the antepartum and postpartum periods? (3) While qualitative evidence emphasizes the situational and cultural context of women's experiences with prenatal screening, the evidence is largely limited to the perspectives of middle and upper class women in Northern Europe and Australia. What are the experiences of prenatal screening for ethnic minorities, economically disadvantaged women, and women outside of these geographic areas? Future research aimed at answering these questions will aid in supporting informed decision-making for prenatal screening for women across the world.

Finally, the value of prenatal screening is traditionally based on the principle of autonomy and the rational choice model of decision-making, with the premise that

women who have enough information can freely decide whether or not to undergo screening (Lalor & Begley 2006; Ames et al., 2015). Given the findings of this review, the rational choice model presents two problematic assumptions: the assumption of an independent decision-maker who makes decisions apart from social, cultural, and political influences and the assumption that objectivity results when ostensibly neutral information is produced and disseminated. In contrast, the findings here indicate that decisions about prenatal screening are embedded in a relational morality, which is contextually bound by the woman's experiences, environment, risk perception, and moral obligations to existing family members. A woman's risk perception is often incongruent with the screening-determined risk, and the milieu of risk awareness may constrain rather than enable free choice. Further, the moral tensions surrounding prenatal screening become increasingly complex and ethically contentious with the prospect of subsequent decisions. Therefore, additional inquiry and ethical debate is needed to illuminate how underlying presuppositions and ideological norms influence informed decision-making for prenatal screening.

Limitations

This integrative review is subject to several limitations. When synthesizing the findings of quantitative and qualitative studies and diverse methodologies, inaccuracy and bias may result. To mitigate this limitation, the guidelines established for integrative review by Whittemore and Knafl (2005) were followed. It is possible that some relevant studies were not included due to the limitations of review methods which rely on database searches with inconsistent key terms and indexing problems. Generalizability,

while supported by the international representation of the reviewed studies, is restricted due to variation in international policies and guidelines on prenatal screening, health care systems, and cultural beliefs and values. Further, this review grouped nuchal translucency, maternal serum screening, and NIPT under the inclusive umbrella of prenatal screening, which may obfuscate findings. However, the findings of this review suggest that the relevant variables and themes concerning women's decision-making and experiences with prenatal screening may not be test-specific, but rather inherent to the phenomenon of prenatal screening for fetal anomaly.

Conclusion

This review provides strong evidence that prenatal screening occurs in a complex social, ethical, and political reality in which women's experiential knowledge as well as biomedical authority act as key influences. A theme of paradox was identified that encompasses the moral ambiguity, insufficient knowledge, incomplete understanding, and unclear risk perception that surround decision-making for prenatal screening. This review highlights the need for future inquiry to identify individual-level factors that influence informed decision-making, to elucidate the prenatal screening-experiences of women globally and among racial and ethnic minorities, and to guide interventions that support informed decision-making for prenatal screening. Further, this review heralds a need for further ethical analysis on how prenatal screening is integrated and evaluated in prenatal care.

CHAPTER III

METHODS

Specific Aims and Research Questions

The overall goal of this study was to explore the relationships between women's understanding of prenatal aneuploidy screening, health literacy, and satisfaction with decisions made for prenatal aneuploidy screening.

Specific Aim 1: To assess women's satisfaction with decisions made for prenatal aneuploidy screening.

Research Question 1: Are women satisfied with the decisions they make for prenatal aneuploidy screening?

Specific Aim 2: To assess the influence of health literacy on women's understanding of prenatal aneuploidy screening.

Research Question 2: What is the relationship of health literacy to women's understanding of prenatal aneuploidy screening?

Specific Aim 3: To assess the influences of health literacy and understanding of prenatal aneuploidy screening on women's satisfaction with decisions made for prenatal aneuploidy screening.

Research Question 3: What is the relationship of health literacy and understanding of prenatal aneuploidy screening to women's satisfaction with decisions made for prenatal aneuploidy screening?

Conceptual Definition of Terms

Decision-making: A process of cognitive reflection and evaluation of alternative options that leads to an outcome or behavior.

Educational level: The highest formal education attained by the participant.

Health literacy: An individual's ability to seek, understand, and utilize health information within the broad social and environmental context of health services.

Informed decision: An autonomous, deliberate decision based on substantial understanding of available evidence of alternative options and risks of a proposed treatment and its implications.

Prenatal aneuploidy screening: The offer of a laboratory analysis to provide a risk assessment of carrying a fetus with chromosomal aneuploidy. This includes maternal serum screens (with or without nuchal translucency) or non-invasive prenatal testing.

Race/ethnicity: Self-identified ancestral origin according to socially constructed categories.

Satisfaction with a decision: The result of a choice that is adequately informed, based on the decision-maker's values, and behaviorally implemented.

Satisfaction with a decision made for prenatal aneuploidy screening: The result of a choice for prenatal aneuploidy screening that is adequately informed, based on the decision-maker's values, and behaviorally implemented.

Understanding of prenatal aneuploidy screening: Cognitive awareness that occurs when an individual has sufficient knowledge of prenatal aneuploidy screening and the

possible consequences of that act, including subsequent decision-making and ancillary diagnostic tests.

Uptake of prenatal aneuploidy screening: The behavioral implementation of the decision to consent to prenatal aneuploidy screening (uptake) or decline (no uptake).

Operational Definition of Terms

Educational level: The response to the question asking the participant to select their highest educational attainment: some high school, high school diploma or equivalent, college degree (associate or bachelor's), or graduate degree.

Gravidity: The response to the obstetrical history question asking the participant how many times she has been pregnant.

Health literacy: The scores of five domain scales of the Health Literacy Questionnaire (HLQ) (Osborne et al., 2013). The five domains are: 1) Feeling understood and supported by healthcare providers; 2) Appraisal of health information; 3) Ability to actively engage with healthcare providers; 4) Ability to find good health information; 5) Understand health information enough to know what to do.

Parity: The response to the obstetrical history question asking the participant how many children she has carried to at least 20 weeks of pregnancy.

Race/ethnicity: The response to the demographic question asking the participant which of the following categories best describes herself: a) Caucasian/White, b) African American/ Black, c) Hispanic/Latino, d) American Indian/Alaska Native, e) Asian, f) Hawaiian Native/Pacific Islander, g) other.

Satisfaction with decisions made for prenatal aneuploidy screening: The scores of the Satisfaction with Decision Scale (SWDS) (Holmes-Rovner et al., 1996).

Understanding of prenatal aneuploidy screening: The scores of the Maternal Serum Screening Knowledge Questionnaire (MSSKQ) (Goel, Glazier, Holzapfel, Pugh, & Summers, 1996).

Uptake of prenatal aneuploidy screening: The affirmative or negative response to the question: “Did you have a screening test to see if your baby might have a chromosome problem?”

Design

This study employed a correlational design to explore adult women’s decision-making for prenatal aneuploidy screening using cross-sectional methodology. The cross-sectional design allows for examination of relationships among a target population at one point in time (Polit & Beck, 2016). Correlational research provides a systematic investigation of relationships between variables, without necessarily determining cause and effect. A questionnaire was used to assess the relationships between women’s satisfaction with decisions made for prenatal aneuploidy screening, health literacy, and women’s understanding of prenatal aneuploidy screening. Decisions made for prenatal aneuploidy screening are complex and have a profound impact on prenatal care and pregnancy outcomes. Therefore, it is necessary (a) to examine how health literacy influences women’s understanding of prenatal aneuploidy screening and (b) to examine how health literacy and understanding of prenatal aneuploidy screening influence women’s satisfaction with their decisions made for prenatal aneuploidy screening. The

results of this study will aid in the development of education for prenatal care providers and interventions for clients to facilitate women's informed choice in decisions for prenatal aneuploidy screening.

Electronic survey methodology utilizing the online data collection software Qualtrics (Provo, Utah) was used in this study to allow a large number of expectant women living in western North Carolina to participate in the research. The online survey was distributed to eligible participants to recipients of an electronic pregnancy newsletter with an anonymous link. The electronic survey protected participants' anonymity while providing convenience, as participants could complete the survey at any computer, tablet, or smart phone with internet access.

Sample

The target population was adult pregnant women who are 18 or more weeks pregnant, 18 years of age or older, and attending prenatal care visits in western North Carolina. Participants were recruited using convenience sampling of the population of women receiving an electronic parenting newsletter through Mission Hospital, a regional obstetrical tertiary care center in western North Carolina. The electronic newsletter, *The Parent Review*, is received by approximately 1,500 recipients each month. *The Parent Review* is a free weekly pregnancy and parenting e-mail tailored to the recipient's week of pregnancy and to the age of the newborn through age three years. It includes information, news, and resources for expectant and new parents.

Setting

The Parent Review is received by current parents and expectant families living in the service area of Mission Hospital, where over 3,500 babies are delivered annually (WNC Healthy Impact, 2016). Mission Hospital is a not-for-profit, independent community health system that provides maternity services for women representing 19 counties in western North Carolina (Mason, 2014). Mission's service population primarily includes residents of the following counties in North Carolina: Buncombe, Haywood, Henderson, Madison, McDowell, Transylvania, and Yancey. The percentage of residents of these counties who are over age 25 years and have a high school diploma or higher degree ranges from 80.7-89.0%, and those with a bachelor's degree or higher ranges from 19.3-29.7% (U.S. Census Bureau, 2014). It was anticipated that a sufficient sample of pregnant women representing diverse educational levels could be recruited within three months. Data were collected using a convenience sample.

Sampling Plan

Inclusion and exclusion criteria. Inclusion criteria for the study were: women \geq 18 years old, \geq 18 weeks pregnant, and who consent to enroll in the study. The exclusion criteria included the following: maternal age $<$ 18 years old, $<$ 18 weeks pregnant, and non-English speaking women. Women who do not speak English were excluded because the instruments selected for this study had not been translated or validated with non-English speaking populations. Women under 18 years old were excluded because cognitive reasoning abilities are still developing in women under 18 years of age, which affect their perceptions of pregnancy and likely impact their understanding and decision-

making for prenatal aneuploidy screening (Wong, Hockenberry, & Wilson, 2011).

Women who are less than 18 weeks pregnant were excluded because prenatal aneuploidy screening typically occurs up to 18 weeks of pregnancy, and the aims of this study include assessment of satisfaction with the decision made for prenatal aneuploidy screening, which requires data to be collected after the participant has made the decision.

Sample size. A power analysis was done to determine the needed sample size using G*Power 3.1 (Düsseldorf, Germany). For a multiple linear regression of nine independent variables (educational level, five domain scores of the HLQ, one indicator variable representing majority/minority race/ethnicity, uptake of prenatal aneuploidy screening, and MSSKQ scores) on satisfaction with decisions made for prenatal aneuploidy screening (SWDS scores), a sample size of 92 is required to detect a medium effect size (Cohen's $f^2 = .15$) at a two-sided .05 significance level with 80% power. Therefore, the target sample size for this study is at least 92. An invitation to participate in the study was sent to recipients of Mission Health System's electronic pregnancy and parenting newsletter via electronic mail.

Protection of Human Subjects

Approval to conduct this study was sought and exempt status obtained from the Institutional Review Board for Mission Memorial Health System in Asheville, North Carolina and from the Institutional Review Board at The University of North Carolina at Greensboro (Appendix A. Mission Institutional Review Board Exempt Status Letter; Appendix B. The University of North Carolina Greensboro Exempt Status Letter). Participants were invited to participate in the study through an electronic parenting

newsletter distributed through Mission Health System (Appendix C. Recruitment E-mail). Potential participants were informed that their participation in the study is strictly voluntary. Consent forms were distributed at the beginning of the electronic survey. Potential participants could click a button to consent or not, where if they did not consent, the survey would automatically end. Signed consent forms were not required.

Personally identifiable health information was not collected. The Qualtrics survey was configured so that ISP addresses were not collected. There was little likelihood of any physical risk as a result of participating in this study. There was the potential for, yet unlikely risk of, emotional response for thinking about decisions related to the pregnancy. Participants were advised within the consent form that they are under no obligation to complete the survey and may stop the survey at any time. There were no anticipated direct benefits for the participants. Potential indirect benefits may accrue to women who participated in the study in that participation may increase understanding and self-awareness of one's understanding of screening tests, one's process of decision-making, and personal communication and informational needs related to health literacy. This increased awareness of self and identification of needs may lead to empowerment to seek and gain support in current and future health care decisions. The information gained in the course of this research will inform interventions and education for care providers to facilitate prenatal care that upholds the ethical principles of self-determination and informed choice for prenatal screening for fetal aneuploidy. Thus, the minimal and low potential risks to participants were deemed reasonable in relation to the potential benefits to participants and others.

Confidentiality and anonymity were maintained. Informed consent, the purpose of the study, and the study process was explained to participants on the face page of the electronic survey (Appendix D. Consent Form). The surveys and consent forms were electronically distributed and administered through the online data collection software Qualtrics via an anonymous survey link. The survey link was attached to the invitation to participate in the study which was emailed to recipients through Mission Health System. To minimize the possibility that non-pregnant women would happen upon the survey via an internet search engine, the survey was designed using Qualtrics survey protection settings to prevent indexing of the survey by internet search engines. To prevent a person from responding to the survey multiple times, Qualtrics survey protections were configured with the Prevent Ballot Box Stuffing option (Qualtrics Survey Software, n.d.). The collected data were stored by Qualtrics on secure servers equipped with firewalls until accessed by the researcher with correct login and password protection. Data were exported to the Statistical Package for the Social Sciences version 24 (SPSS v24) (IBM Corp., Armonk, NY), and the SPSS data file was password protected. Data files were also stored on a password protected Box account through the University of North Carolina Greensboro.

To encourage participation, potential participants were informed that upon completion of the survey, they would be eligible to enter a lottery to win one of two \$50 gift cards to Target or Walmart. Upon completion of the study survey, participants were redirected to a separate web link to enter their email address to enter the lottery for the gift cards. Participants were informed that entering their email address is optional and

they could click on a decline button if they did not want to enter the lottery. To maintain the anonymity of survey responses, the lottery drawing for the gift cards was separate from the main study survey, so responses could not be linked to participants' email addresses.

Measurement

A researcher-designed tool was used to collect demographic data with race/ethnicity and obstetric history. The demographic tool has a Flesch-Kincaid reading level of 4.9. Participants were asked to indicate their numbers of living children and previous pregnancies, the number of pregnancies they carried to at least 20 weeks of gestation, if they have any history of having a pregnancy in which their baby had a chromosomal disorder, and if they are aware of any ultrasonographic findings indicating a chromosome problem with their current pregnancy. To assess uptake of prenatal aneuploidy screening, participants were asked, "Did you have a screening test to see if this baby might have a chromosome problem?" To assess education, participants were asked to indicate their highest educational attainment: less than high school diploma, high school diploma or equivalent, some college, college degree, or graduate degree. Additional constructs were assessed using three instruments to measure the identified concepts: (a) the Health Literacy Questionnaire (HLQ) (2013), (b) the Maternal Serum Screening Knowledge Questionnaire (MSSKQ) (1996), and (c) the Satisfaction with Decision Scale (SWDS) (1996). The three instruments are outlined in Table 3.1 below.

Table 3.1

Key Variables and Measures

Variables	Instrument/Measure	Scoring	Reliability
Health literacy	Health Literacy Questionnaire domains (Osborne et al., 2013)	Domain scores are summed and divided by number of items	Estimates of reliability
	<i>4-point Likert scale, 4 items each</i>	<i>Score range</i>	—
	Feeling understood and supported by healthcare providers	1 – 4	$\rho^1 = 0.88$
	Appraisal of health information	1 – 4	$\rho = 0.77$
	<i>5-point Likert scale, 5 items each</i>	<i>Score range</i>	—
	Ability to actively engage with healthcare providers	1 – 5	$\rho = 0.90$
	Ability to find good health information	1 – 5	$\rho = 0.89$
	Understand health information enough to know what to do	1 – 5	$\rho = 0.88$
Satisfaction with decisions made for prenatal aneuploidy screening	The Satisfaction with Decision Scale. A 6-item measure to assess degree of satisfaction with the process of decision-making (Holmes-Rovner et al., 1996)	Responses are on a 5-point Likert scale. Scores are summed for a range of 5 – 30.	$\alpha = 0.86$
Understanding of prenatal aneuploidy screening	The Maternal Serum Screening Knowledge Questionnaire. A 14-item instrument, 12 of which are applicable to prenatal aneuploidy screening (Goel et al., 1996).	Responses occur on a 5-point scale (range -2 to 2). Scores are summed and divided by the number of items, for a range of -2 to 2.	$\alpha = 0.74$

Note. 1. ρ = Index of composite reliability (Raykov's rho)

The Health Literacy Questionnaire

Health literacy was measured using the Health Literacy Questionnaire (HLQ) (Osborne et al., 2013; Osborne et al., 2014). The HLQ is a 44-item multi-dimensional assessment of health literacy that was developed using a validity-driven approach (Buchbinder et al., 2011). The development process for the HLQ included in-depth grounded consultations with a broad range of adult populations, patients, clinicians, and policy makers in combination with concept mapping, cognitive interviews, and extensive psychometric analyses (Osborne et al., 2013). The HLQ measures nine domains of health literacy and is designed to be used for program evaluation, needs assessment, and intervention development. Each domain of health literacy is captured by a scale in the HLQ. Five of the domains reflect core behavioral competencies necessary for health care decision-making and will be measured in this study. These domains are: 1) Understand health information enough to know what to do; 2) Ability to find good health information; 3) Feeling understood and supported by healthcare providers; 4) Ability to actively engage with healthcare providers; and 5) Appraisal of health information. For this study, health literacy is operationalized using the scale scores for these five domains of health literacy. These domains correspond to Nutbeam's three levels of health literacy as depicted in Table 3.2 below.

Table 3.2

Connection Between Nutbeam’s Schema¹ and Health Literacy Questionnaire Domains²

Nutbeam’s Schema for Health Literacy	Health Literacy Questionnaire Domain
Basic/functional health literacy: sufficient basic numeracy and literacy skills to be able to function effectively in everyday situations	Ability to find good health information
	Understand health information enough to know what to do
Communicative/interactive health literacy: more advanced cognitive and literacy skills needed to actively participate in and derive meaning from various types of communication, and to apply new information to dynamic situations	Feeling understood and supported by healthcare providers
	Ability to actively engage with healthcare providers
	Ability to find good health information
Critical health literacy: more advanced cognitive skills, which together with social skills, can be applied to critically analyze information, and to use this information to exert greater control over life events and situations	Appraisal of health information

Note. 1. Schema adapted from Nutbeam (2000).

2. Connection between Nutbeam’s schema and Health Literacy Questionnaire domains adapted from Osborne et al. (2013).

The HLQ scales each are comprised of four to five items that are scored as a graded Likert response. The response set and scoring (in parentheses) for the scales *Feeling understood and supported by healthcare providers* and *Appraisal of health information* are: strongly disagree (1), disagree (2), agree (3), and strongly agree (4) (Health Literacy Questionnaire Scoring Algorithm Instructions, 2016). The response set and scoring (in parentheses) for the scales *Ability to actively engage with healthcare providers*, *Ability to find good health information*, and *Understand health information well enough to know what to do* are: cannot do or always difficult (1), usually difficult

(2), sometimes difficult (3), usually easy (4), and always easy (5). Initial psychometric testing of the HLQ was performed with samples comprised of adult patients attending a private rheumatology clinic, adults receiving home care through a metropolitan community care organization, and adult patients who were treated at the emergency department of a regional teaching hospital (Osborne et al., 2013). Evidence of construct validity for the HLQ was supported empirically with confirmatory factor analysis (CFA) (Osborne et al., 2013). For each of the subscales, CFA using a one-factor model demonstrated satisfactory fit, with each scale meeting the following criteria: Comparative Fit Index (CFI) > 0.95, Tucker-Lewis Index (TLI) > 0.95, and Weighted Root Mean Square Residual (WRMR) < 1.0. Evidence of reliability for the HLQ scales was supported with additional CFA and calculation of Raykov's *rho* (see Table 1) using a replication sample, which included patients with both chronic and acute illness.

While potential cultural differences may exist between Australian and American populations, the rigorous development of the HLQ and extensive psychometric testing across diverse adult populations provide evidence to support the use of the HLQ among English-speaking adult pregnant women in the United States (U.S.). To date, there are no published records indicating that the HLQ has been tested in the U.S., nor among populations of women receiving prenatal care. Thus, the HLQ has not been established as a reliable and valid instrument in the target population for this proposed study. However, its use among pregnant women from diverse socioeconomic, educational, and cultural backgrounds is supported in that the samples used for development and testing of the HLQ included adults, the majority being female, across a wide range of ages and

representing broad socioeconomic and health continuums in Western societies (Osborne et al., 2013). The HLQ has a Flesch-Kincaid reading level of 7.6.

The Maternal Serum Screening Knowledge Questionnaire

Understanding of prenatal aneuploidy screening was assessed using the Maternal Serum Screening Knowledge Questionnaire (MSSKQ) (Goel et al., 1996). The MSSKQ is a 14-item instrument designed to assess women's knowledge of maternal serum screening for chromosomal aneuploidy and neural tube defects. The following four domains of knowledge are assessed in the MSSKQ: a) screening test characteristics, b) the timing and indications for the screen, c) the role of ancillary tests and risks associated with those tests, and d) the conditions screened and the risk factors for those conditions. As two of the items pertain to neural tube defects and not chromosomal aneuploidy, the instrument was modified to include the remaining 12 items that are relevant to prenatal aneuploidy screening. Each item response occurs on a 5-point Likert scale. Items are recoded with a value of 2 assigned if the correct response is given with a "strongly agree" or "disagree," and a value of 1 for a correct response with an "agree" or "disagree" statement. Incorrect responses are assigned a value of - 2 and - 1, respectively. A value of 0 is assigned for a "not sure" response (Goel et al., 1996). Sum scores are divided by the number of items, for a range of -2 to 2, with higher scores indicating greater understanding. Construct validity of the MSSKQ is supported by correlations between higher MSSKQ scores among respondents with higher education and those who report having discussed prenatal screening with their health care providers. Further, the MSSKQ has evidence supporting reliability with a coefficient alpha of 0.74 and test-

retest reliability of 0.76 (Goel et al., 1996). The MSSKQ has a Flesch-Kincaid reading level of 7.8.

The Satisfaction with Decision Scale

Satisfaction with decisions made for prenatal aneuploidy screening was be assessed using the Satisfaction with Decision Scale (SWDS) (Holmes-Rovner et al., 1996). This six-item scale was developed by a nurse researcher to measure global satisfaction with an identified decision and the attributes of an effective decision (Holmes-Rovner et al., 1996). The scale is designed to be tailored to the specific health care decision of interest. The instrument employs a 5-point Likert scale to measure a respondent's level of agreement with the following items: a) I am satisfied that I was adequately informed about the issues important to my decision about using a screening test to detect a chromosome problem with my baby; b) the decision I made was the best decision possible personally for me; c) I am satisfied that the decision was consistent with my personal values; d) I expect to carry out (or continue to carry out) the decision that I made; e) I had as much input as I needed in the decision about using a screening test to detect a chromosome problem with my baby; and f) I am satisfied with my decision about using a screening test to detect a chromosome problem with my baby (Wills & Holmes-Rovner, 2003). Responses are scored as follows: Strongly disagree (1), Disagree (2), Neither agree nor disagree (3), Agree (4), and Strongly agree (5). Responses to the items are added together, for a range of 6-30. The resulting score reflects a respondent's degree of satisfaction with the decision made for prenatal aneuploidy screening, with higher scores indicating greater satisfaction with the decision.

The Satisfaction with Decision Scale has evidence supporting reliability with a coefficient alpha reported at 0.86 (n = 252) (Holmes-Rovner et al., 1996). Additionally, Holmes-Rovner and colleagues found evidence of discriminant validity for the measure based on its relationship to the Decisional Conflict Scale ($r = -0.66$), and evidence of concurrent validity based on the measure's relationship to the Confidence in Decision Scale ($r = 0.64$) (Holmes-Rovner et al., 1996). The SWDS has a Flesch-Kincaid reading level of 8.6.

Following consent, the HLQ, MSSKQ, and SWDS were presented first, followed by the tool for collecting demographic and obstetric data. Directions for completing the questionnaire were included at the top of the first page of the questions. Specific directions for completing each instrument were delineated at the top of the screen at the beginning of the series of questions for each instrument. A copy of the survey (excluding the HLQ due to the license agreement) is available as an appendix (Appendix E. Study Survey). Permission to use the HLQ was obtained (Appendix F. HLQ License), and the other measures are available for use in academia without permission. The variables of interest in this study and their parameterization are summarized in Table 3.3.

Table 3.3

Variable Categorization

Variable Label	Description	Type
<i>Key Variables</i>		
Health care provider support	Health literacy domain score: Feeling understood and supported by healthcare providers (1-4)	Scale, ordinal
Critical appraisal	Health literacy domain score: Appraisal of health information (1-4)	Scale, ordinal
Active engagement	Health literacy domain score: Ability to actively engage with healthcare providers (range 1-5)	Scale, ordinal
Find health information	Health literacy domain score: Ability to find good health information (1-5)	Scale, ordinal
Understand health information	Health literacy domain score: Understand health information well enough to know what to do (1-5)	Scale, ordinal
MSSKQ	Maternal Serum Screening Knowledge Questionnaire score (-2 to 2)	Scale, ordinal
SWDS	Satisfaction with Decision Scale score (6-30)	Scale, ordinal
<i>Covariates</i>		
Educational level	0 = Less than high school diploma 1 = High school diploma or equivalent 2 = Some college 3 = Associate of Bachelor's degree 4 = Graduate degree	Categorical, ordinal
Parity	Number of live births 0 = 0 births 1 ≥ 1 live birth	Categorical, ordinal
Race/Ethnicity	0 = Other 1 = White, non-Hispanic	Categorical, nominal
Uptake	Uptake of prenatal aneuploidy screening 0 = No, 1 = Yes	Dichotomous, nominal

Data Collection

The survey was presented electronically via Qualtrics. Following a brief description of the study, an invitation to participate in the study and the link to the survey was sent via electronic mail to the recipients of the electronic parenting newsletter. Consent to participate was obtained on the face page of the electronic survey. The survey was presented with the measures as previously described in this chapter. Completed data was saved in the survey program. To eliminate data entry error, the data was electronically exported directly into SPSS. To ensure confidentiality, no respondent identifiers or personally identifiable health information was collected.

Strategies were implemented to ease navigation through the survey. A neutral white color was used with black text to enhance readability (Ritter & Sue, 2007). Questions were bolded and responses were not in bold (Fanning, 2005). Items required a response to proceed to the next question to avoid incomplete data. A tracking bar was displayed on the screen to indicate the participant's progress in completion of the survey.

Data Analysis

Analyses were performed using the Statistical Package for the Social Sciences version 24 (SPSS v24) (IBM Corp., Armonk, NY). To eliminate data entry error, the data were electronically exported directly into SPSS v24. Data were screened for missing values. A two-sided p -value $\leq .05$ was considered statistically significant. Continuous variables were assessed for outliers and normality in univariate analysis using box-plots, normal P-P plots, and Kolmogorov-Smirnov tests. Scatter plots were used to assess the linearity of the relationships between continuous variables. Spearman's *rho*

and point-biserial coefficients were used for bivariate correlational analysis. Regression assumptions were assessed with analysis of studentized deleted residuals.

Multicollinearity was examined using variance inflation factors (VIFs). Additional analyses occurred in accordance with each specific aim:

Specific Aim 1: To assess women's satisfaction with decisions made for prenatal aneuploidy screening.

Analysis for Aim 1. Descriptive statistics were used to describe the frequency at which women are satisfied with decisions made for prenatal aneuploidy screening. The proportion of women who are satisfied with decisions made for prenatal aneuploidy screening was estimated along with a 95% confidence interval (CI).

Specific Aim 2: To assess the influence of health literacy on women's understanding of prenatal aneuploidy screening.

Analysis for Aim 2. Multivariable linear regression was used. The five domain scores of health literacy (HLQ domain scores), the independent variables, were regressed on women's understanding of prenatal aneuploidy screening (MSSKQ scores), the dependent variable, adjusting for uptake of prenatal aneuploidy screening, educational level, and race/ethnicity.

Specific Aim 3: To assess the influences of health literacy and understanding of prenatal aneuploidy screening on women's satisfaction with decisions made for prenatal aneuploidy screening.

Analysis for Aim 3: Multivariable linear regression was used. The five domain scores of health literacy (HLQ domain scores) and understanding of prenatal aneuploidy screening

(MSSKQ scores), the independent variables, were regressed on women's satisfaction with decisions made for prenatal aneuploidy screening (SWDS scores), the dependent variable, adjusting for uptake of prenatal aneuploidy screening and parity.

Chapter Summary

A descriptive, correlational study was conducted to explore women's informed decision-making for prenatal aneuploidy screening using cross-sectional methodology. A convenience sample of 95 adult English-speaking women ≥ 18 weeks pregnant was recruited to participate in the study through an electronic parenting newsletter. The study was guided by Faden and Beauchamp's (1986) model of informed consent, Nutbeam's (2000) concept of health literacy, and Holmes-Rovner and colleague's (1996) concept of satisfaction with a decision. Potential participants were invited to complete an online survey which included a tool to collect demographic information and obstetric history and three instruments to measure health literacy, understanding of prenatal aneuploidy screening, and satisfaction with decisions made for prenatal aneuploidy screening. The plan for data analyses included descriptive statistics and multiple linear regression to assess the relationships between health literacy, understanding of prenatal aneuploidy screening, and satisfaction with decisions made for prenatal aneuploidy screening.

CHAPTER IV

RESULTS

The findings of this study are reported in this chapter. The response to the survey is presented followed by a description of the participants. The instrument scores are presented followed by results of univariate and bivariate analyses. Results of the analyses for each research question are provided followed by a chapter summary. A two-sided p -value ≤ 0.05 was considered to be statistically significant. All analyses were performed using SPSS v24 (IBM Corp., Armonk, NY).

Response to the Survey

A survey was developed in Qualtrics to collect data on women's understanding of prenatal aneuploidy screening, women's satisfaction with decisions made for prenatal aneuploidy screening, and the five domains of health literacy. The survey was distributed via an electronic pregnancy and parenting newsletter through Mission Health Services. An email was sent to recipients of the newsletter with an invitation to participate in the study and a link to the survey. The survey was open for four weeks, with an electronic mail reminder distributed every ten days until the close of the survey. The Qualtrics survey was opened by 31.7% (507) of the estimated 1600 recipients of the pregnancy and parenting newsletter. Of those who opened the survey, 18.7% (95) submitted a completed survey. This yielded an estimated return rate of approximately 6.0% of the possible newsletter recipients.

Analysis

Descriptive Statistics of the Participants

The results of the demographic data collected in the survey are depicted in Table 4.1. The women respondents had a mean age of 31.19 years (SD=4.88). The mean gestational age of participants' pregnancies was 28.07 weeks (SD=6.44). The participants reported their race/ethnicity as follows: 3.2% Asian, 13.7% Black/African American, 78.9% Caucasian/White non-Hispanic, and 4.2% Hispanic. The educational level of participants was reported as 20.0% high school diploma or GED, 21.1% some college, 33.7% college degree (Associate's or Bachelor's), and 25.3% graduate degree. Nearly one-quarter (24.2%) of participants were pregnant for the first time. The majority (43.2%) of participants had not completed a pregnancy beyond 20 weeks, 45.3% of participants were carrying a pregnancy beyond 20 weeks for the first time, and 11.5% of participants had completed one or more pregnancies beyond 20 weeks. Nearly one-third (32.6%) of women reported never giving birth to a live infant.

Most women reported that they were offered a prenatal aneuploidy screen, while 4.2% reported that they were not offered the screen and 7.4% were not sure if they were offered the screen. Over one-half (55.3%) of women reported that they had the prenatal aneuploidy screen, while 38.9% reported not having the screen and 5.3% were not sure if they had the screen. The information received about the prenatal aneuploidy screen was reported as follows: 24.2% oral explanation only, 24.2% oral explanation with discussion, 13.7% written (pamphlet) only, 14.7% written (pamphlet) and oral explanation, 17.9% written (pamphlet) with discussion, and 5.3% not sure.

Most women (91.6%) reported that they were not told that their current pregnancy may be affected by a chromosome problem. A few women (3.2%) reported that they were told that their pregnancy may be affected by a chromosome problem, and a few participants (5.3%) were not sure if they were told that their pregnancy may be affected by a chromosome problem. Nearly one-quarter (26.3%) of respondents reported no experience with individuals with disabilities, with 45.3% reporting some experience, 17.9% reporting above average experience, and 10.5% reporting frequent experience with individuals with disabilities.

Table 4.1

Sample Description (N = 95)

Variable	Mean \pm SD ¹ (min, max)
Age	31.19 \pm 4.88 (20, 41)
Gestational age in weeks	28.07 \pm 6.44 (18, 41)
	Frequency (%)
Race/ Ethnicity	
Asian	3 (3.2)
Black/African American	13 (13.7)
Caucasian/White non-Hispanic	75 (78.9)
Hispanic	4 (4.2)
Other	0
Educational level	
Some high school	0
High school diploma or GED	19 (20.0)
Some college	20 (21.0)
College degree (Associate's or Bachelor's)	32 (33.7)
Graduate degree	24 (25.3)
Gravida (# of pregnancies)	
1	23 (24.2)
2	45 (47.4)
3	19 (20.0)
4	6 (6.3)
5	1 (1.1)
6	1 (1.1)
Parity (# of completed pregnancies > 20 weeks)	
0	41 (43.2)
1	43 (45.3)
2	8 (8.4)
3	3 (3.1)

Note.

1. SD: Standard deviation

Variable	Frequency (%)
Number of live-born children	
0	31 (32.6)
1	46 (48.4)
2	15 (15.8)
3	2 (2.1)
4	1 (1.1)
Was offered screen for chromosome problems	
Yes	84 (88.4)
No	4 (4.2)
Not sure	7 (7.4)
Had screen for chromosome problem	
Yes	53 (55.8)
No	37 (38.9)
Not sure	5 (5.3)
Type of information presented	
Oral explanation only	23 (24.2)
Oral explanation with discussion	23 (24.2)
Written (pamphlet) only	13 (13.7)
Written and oral explanation	14 (14.7)
Written (pamphlet) with discussion	17 (17.9)
Not sure	5 (5.3)
Was told this pregnancy may have chromosome problem	
Yes	3 (3.2)
No	87 (91.6)
Not Sure	5 (5.3)
Experience with individuals with disabilities	
None at all	25 (26.3)
Some	43 (45.3)
Above average	17 (17.9)
Frequent	10 (10.5)

Note.

1. SD: Standard deviation

Descriptive Statistics of the Instruments

The scales used in this study include the Maternal Serum Screening Knowledge Questionnaire (MSSKQ) (Goel et al., 1996), the Satisfaction with Decision Scale (SWDS) (Homes-Rovner et al., 1996), and the following five subscales of the Health Literacy Questionnaire (HLQ) (Osborne et al., 2013) : *Feeling understood and supported by healthcare providers, Appraisal of health information, Ability to actively engage with health care providers, Ability to find good health information, and Understand health information enough to know what to do.* The seven scales used in this study were completed by each of the 95 participants. Table 4.2 illustrates the results of the descriptive statistics for these scales.

Table 4.2

Description of Instrument Scores (N = 95)

Scale	Number of Items	Possible Score	Mean \pm SD	Range of Scores	Estimate of Reliability ¹
Maternal Serum Screening Knowledge Questionnaire²	12	-2 - 2	0.63 \pm 0.29	0 – 1.58	$\alpha = 0.69$ $\lambda_2 = 0.70$
Satisfaction with Decision Scale³	6	6 - 30	24.00 \pm 4.60	12.00 – 30.0	$\alpha = 0.91$
Feeling understood and supported by healthcare providers⁴	4	1.00 – 4.00	3.04 \pm 0.58	1.00 – 4.00	$\alpha = 0.87$
Appraisal of health information⁴	4	1.00 – 4.00	2.91 \pm 0.54	1.20 – 4.00	$\alpha = 0.82$
Ability to actively engage with healthcare providers⁴	5	1.00 – 5.00	3.73 \pm 0.58	2.20 – 5.00	$\alpha = 0.90$
Ability to find good health information⁴	5	1.00 – 5.00	3.92 \pm 0.50	2.40 – 5.00	$\alpha = 0.83$
Understand health information enough to know what to do⁴	5	1.00 – 5.00	3.73 \pm 0.58	2.60 – 5.00	$\alpha = 0.80$

Note. 1. α = Cronbach's alpha; λ_2 = Guttman's lambda₂

2. Maternal Serum Screening Knowledge Questionnaire (Goel et al., 1996)

3. Satisfaction with Decision Scale (Holmes-Rovner et al., 1996)

4. Subscale of the Health Literacy Questionnaire (Osborne et al., 2013)

The MSSKQ is a 14-item instrument, of which 12 items apply to prenatal aneuploidy screening and were included in the survey (Goel et al., 1996). For each item of the MSSKQ, a statement is given, which is true or false, and participants are asked to rate how much they agree or disagree with each statement. In general, the majority of participants responded correctly to 8 of the 12 MSSKQ statements. However, the majority of participants did not respond correctly to the following four statements: (a) *If the prenatal screen is abnormal, something is usually wrong with the baby.* (False) (b) *Having prenatal screening is routine for all women.* (False); (c) *Amniocentesis can cause miscarriage in 1 in 200 women.* (True); and (d) *Amniocentesis is a test of the mother's blood that can detect Down syndrome.* (False). The frequency and percentages of the responses to each of the items of the MSSKQ are depicted in Table 4.3.

Table 4.3

Descriptive Statistics for the Maternal Serum Screening Knowledge Questionnaire (N = 95)

Statement (True/False)¹	Frequency (%)	
<i>If the results of the prenatal screen are abnormal, further tests are needed to tell if something is wrong.</i> (True)	Correct	65 (64.2)
	Incorrect	16 (17.9)
	Not sure	18 (18.9)
<i>Women who have a normal prenatal screen can be sure that they will have a healthy baby.</i> (False)	Correct	63 (66.3)
	Incorrect	4 (4.2)
	Not sure	28 (29.5)
<i>The prenatal screen only detects Down syndrome.</i> (False)	Correct	79 (83.2)
	Incorrect	4 (4.5)
	Not sure	12 (12.6)

Statement (True/False) ¹		Frequency (%)
<i>If the prenatal screen is abnormal, something is usually wrong with the baby. (False)</i>	Correct	35 (36.8)
	Incorrect	31 (32.6)
	Not sure	29 (30.5)
<i>Prenatal screening is not accurate when done at the wrong time of pregnancy. (True)</i>	Correct	55 (59.0)
	Incorrect	6 (6.3)
	Not sure	33 (34.7)
<i>Having prenatal screening is routine for all women. (False)</i>	Correct	40 (42.1)
	Incorrect	34 (35.8)
	Not sure	21 (22.1)
<i>Amniocentesis can cause miscarriage in 1 in 200 women. (True)</i>	Correct	46 (48.4)
	Incorrect	8 (8.4)
	Not sure	41 (43.2)
<i>Ultrasound can be used to find every kind of birth defect. (False)</i>	Correct	83 (87.3)
	Incorrect	2 (2.1)
	Not sure	10 (12.6)
<i>Amniocentesis is a test of the mother's blood that can detect Down syndrome. (False)</i>	Correct	40 (42.1)
	Incorrect	14 (14.7)
	Not sure	41 (43.2)
<i>The chance of having a baby with Down syndrome is higher when the mother is older. (True)</i>	Correct	92 (96.8)
	Incorrect	0
	Not sure	3 (3.2)
<i>All children born with Down syndrome have physical and mental disabilities that require lifelong care in an institution. (False)</i>	Correct	80 (84.2)
	Incorrect	6 (6.3)
	Not sure	9 (9.5)
<i>If amniocentesis shows Down syndrome, the only options are to have a baby with Down syndrome or to terminate the pregnancy. (True)</i>	Correct	59 (62.1)
	Incorrect	9 (9.5)
	Not sure	27 (28.4)

Note. 1. Correct is response of *Agree* or *Strongly agree* for positively scored items and *Disagree* or *Strongly disagree* for negative scored items; Incorrect is response of *Disagree* or *Strongly disagree* for positively scored items and *Agree* or *Strongly agree* for negatively scored items; Not sure is response of *Neither agree nor disagree*

The SWDS is a 6-item measure to assess degree of satisfaction with the process of informed health care decision-making (Holmes-Rovner et al., 1996). Scores range from 6-30 with higher scores indicating greater satisfaction. A score ≥ 24.0 on the SWDS has been used to demarcate satisfaction with the decision (Hitz, Ribí, Li, Klingbiel, Cerny, & Koeberle, 2013). The mean score of the SWDS was 24.00 ± 4.60 . The mean and range of scores for the items of the SWDS are depicted in Table 4.4.

Table 4.4

Descriptive Statistics for Items of the Satisfaction with Decision Scale¹ (N = 95)

Item	Possible Score	Mean \pm SD	Range of Scores
<i>I was adequately informed about the different options available for prenatal screening for chromosome problems for my baby.</i>	1 – 5	3.82 \pm 0.99	1 - 5
<i>The decision I made was the best decision for me personally.</i>	1 – 5	4.20 \pm 0.74	3 - 5
<i>The decision I made was consistent with my values.</i>	1 – 5	3.71 \pm 1.09	1 - 5
<i>I expect to carry out the decision.</i>	1 – 5	4.19 \pm 0.72	3 - 5
<i>I had as much input as I wanted in the choice to use prenatal screening for chromosome problems for my baby.</i>	1 – 5	3.99 \pm 1.00	1 - 5
<i>I am satisfied with the decision I made about prenatal screening for chromosome problems with my baby.</i>	1 - 5	4.08 \pm 0.50	2 – 5

Note. 1. Satisfaction with Decision Scale (Holmes-Rovner et al., 1996)

The HLQ is a multi-dimensional assessment of health literacy with nine subscales (Osborne et al., 2013). Five of the subscales measure core behavioral competencies necessary for health care decision-making and were included in the survey. In general, participants reported moderate to high health literacy across the five domains.

Reliability of the scales. Cronbach's alpha coefficients were estimated for each of the scales. Table 4.2 includes the estimated reliability for each scale. Reliability coefficients above .80 are highly desirable, while reliability coefficients of .70 to .75 may be adequate (Polit, 2010). The SWDS and the five subscales of the HLQ each demonstrated desirable reliability. For the MSSKQ, the estimate of reliability using Cronbach's alpha was 0.69, which is less than desirable. However, Cronbach concluded that the alpha formula is not appropriate for scales for which questions are designed to target different areas or processes because alpha assumes essential tau-equivalence (Cronbach & Shavelson, 2004). Thus, alpha assumes that the scale is unidimensional and that the covariances between items are essentially equal (DeVellis, 2017; Tavakol & Dennick, 2011). As factorial validity has not been demonstrated for the MSSKQ, it is reasonable to consider an alternative to Cronbach's alpha for an estimate of reliability for the MSSKQ. Guttman's λ_2 is recognized as a more appropriate estimate of reliability than Cronbach's alpha, in most cases, because it does not have the assumptions of tau-equivalence (Revelle & Zinbarg, 2009; Sijtsma, 2009). Therefore, Guttman's λ_2 for the MSSKQ was calculated ($\lambda_2 = .70$). The value of .70 is acceptable and approaches the estimates of reliability of the MSSKQ reported in the literature (Glazier et al., 1997; Goel et al., 1996). In sum, the estimates of reliability calculated for the five

scales used in this study indicate that the items performed relatively consistent with how they performed in previous studies (Glazier et al., 1997; Goel et al., 1996; Holmes-Rovner et al., 1996; Osborne et al., 2013).

Univariate Analyses

Key variables were assessed for normality and the presence of outliers using boxplots and histograms. No extreme outliers were identified across the key variables. Histograms, P-P plots, and 1-sample Kolmogorov-Smirnov tests were used to assess normality and indicated that the key variables were normally distributed.

Bivariate Analyses

Bivariate analyses included the key variables of educational level, parity, race/ethnicity, screen uptake, MSSKQ scores, SWD scale scores, and the following domains of health literacy measured by the HLQ: *Feeling understood and supported by healthcare providers, Appraisal of health information, Ability to actively engage with health care providers, Ability to find good health information, and Understand health information enough to know what to do*. An indicator variable was created for Caucasian/White non-Hispanic race/ethnicity with the reference category being other race/ethnicity (i.e., women who did not identify as Caucasian/White non-Hispanic). Scatterplots with LOESS and linear fit lines were used to explore bivariate relationships and indicated linear relationships between the key variables. Bivariate analyses were conducted between key variables using Spearman's *rho* and point biserial correlation coefficients. These results are displayed in Table 4.5. The results suggest that 30 out of 54 correlations were statistically significant. The variable of parity did not have statistically

significant correlations. Screen uptake was significantly and negatively correlated with the health literacy domain of *Ability to find good health information*, $\rho(93) = -.225, p < .05$), suggesting that positive screen uptake is weakly correlated with decreasing *Ability to find good health information*. Each of the remaining statistically significant correlations were positive in their direction. The significant positive correlation coefficients for educational level suggest that increasing educational attainment has a moderately positive relationship with the key variables of Caucasian/White non-Hispanic race/ethnicity, $r_{pb}(93) = .360, p < .01$; MSSKQ scores, $\rho(93) = .461, p < .01$; SWDS scores, $\rho(93) = .441, p < .01$; *Feeling understood and supported by healthcare providers*, $\rho(93) = .417, p < 0.01$; *Appraisal of health information*, $\rho(93) = .400, p < .01$; *Ability to actively engage with health care provider*, $\rho(93) = .477, p < .01$; *Ability to find good health information*, $\rho(93) = .512, p < .01$; and *Understand health information enough to know what to do*, $\rho(93) = .597, p < .01$ (Polit, 2010). The significant positive correlation coefficients for Caucasian/White non-Hispanic race/ethnicity suggest that Caucasian/White non-Hispanic race/ethnicity has a moderately positive relationship with MSSKQ scores, $r_{pb}(93) = .384, p < .01$; SWDS scores, $r_{pb}(93) = .397, p < .01$; *Feeling understood and supported by healthcare providers*, $r_{pb}(93) = .274, p < 0.01$; *Appraisal of health information*, $r_{pb}(93) = .397, p < .01$; *Ability to actively engage with health care provider*, $r_{pb}(93) = .459, p < .01$; *Ability to find good health information*, $r_{pb}(93) = .418, p < .01$, and *Understand health information enough to know what to do*, $r_{pb}(93) = .451, p < .01$. In general, the significant and positive correlation coefficients between the MSSKQ scores, the SWDS scores, and the five

subscales of the HLQ (*Feeling understood and supported by healthcare providers, Appraisal of health information, Ability to actively engage with health care provider, Ability to find good health information, and Understand health information enough to know what to do*) suggest moderate to strong positive relationships between the instrument scale scores (Polit, 2010). This means that as scores on one of the instruments increased, scores on each of the other instruments also increased.

Table 4.5

Intercorrelations Between Key Study Variables (N = 95)

Variable	1	2	3	4	5	6	7	8	9	10
1 Education level	-									
2 Parity ≥ 1, 0 (RC) ¹	.093	-								
3 Race/ethnicity Caucasian, Other (RC) ¹	.360**	.092	-							
4 Screen uptake No uptake (RC) ¹	-.209*	.017	-.200	-						
5 MSSKQ²	.461**	-.032	.384**	-.018	-					
6 SWDS³	.441**	.182	.397**	-.091	.390**	-				
7 Feeling understood and supported⁴	.417**	.179	.274**	-.072	.299**	.618**	-			
8 Appraisal of health information⁴	.400**	.058	.397**	-.178	.361**	.482**	.627**	-		
9 Ability to actively engage with providers⁴	.477**	.103	.459**	-.028	.523**	.370**	.367**	.465**	-	
10 Ability to find good health information⁴	.512**	.141	.418**	-.225*	.472**	.674**	.605**	.677**	.511**	-
11 Understand health information⁴	.597**	.178	.451**	-.159	.425**	.543**	.494**	.506**	.662**	.801**

Note. * $p < .05$; ** $p < .01$

1. RC = Reference category

2. Maternal Serum Screening Knowledge Questionnaire (MSSKQ) (Goel et al., 1996)

3. Satisfaction with Decision Scale (SWDS) (Holmes-Rovner et al., 1996)

4. Subscale of the Health Literacy Questionnaire (HLQ) (Osborne et al., 2013)

Research Question 1

Specific Aim 1: To assess women's satisfaction with decisions made for prenatal aneuploidy screening.

Research question 1: Are women satisfied with the decisions they make for prenatal aneuploidy screening?

Descriptive statistics were used to estimate the proportion of women who are satisfied with decisions made for prenatal aneuploidy screening along with the 95% confidence interval (CI). The established cut-off score of 24 for the SWDS was used to indicate satisfaction with decisions made for prenatal aneuploidy screening ((Hitz et al., 2013; Holmes-Rovner, 1996). Descriptive statistics indicate that 55 of the 95 participants scored ≥ 24.0 on the SWDS. The proportion of participants with scores ≥ 24.0 , along with a 95% confidence interval using the Wilson limits was computed (Brown, Cai, & DasGupta, 2001). Table 4.6 illustrates the results of the proportion estimation of women who reported satisfaction with decisions made for prenatal aneuploidy screening as measured by the SWDS. Results show that 57.9% [47.8%, 67.3%] of the sample reported satisfaction with decisions made for prenatal aneuploidy screening. Thus, if this study were repeated over and over again, each time with 95 participants, then the true population percent who are satisfied with decisions made for prenatal aneuploidy screening would be enclosed by the interval (47.8%, 67.3%) approximately 95% of the time. Additionally, descriptive statistics indicate that 40 of the 95 participants scored < 24.0 on the SWDS. The proportion of participants with scores < 24.0 , along with a 95% confidence interval using the Wilson limits was computed. The results show that

42.1% [32.7%, 52.2%] of participants did not report satisfaction with decisions made for prenatal aneuploidy screening. Thus, if this study were repeated over and over again, each time with 95 participants, then the true population percent who do not report satisfaction with decisions made for prenatal aneuploidy screening would be enclosed by the interval (32.7%, 52.2%) approximately 95% of the time.

Table 4.6

Satisfaction with Decisions Made for Prenatal Aneuploidy Screening¹ (N = 95)

Satisfaction with Decision Scale Interpretation	Frequency	Percentage [95% CI]
Satisfied with decision	55	57.9% [47.8%, 67.3%]
Not satisfied with decision	40	42.1% [32.7%, 52.2%]

Note. 1. As measured by the Satisfaction With Decision Scale (Holmes-Rovner et al., 1996).

Research Question 2

Specific Aim 2: To assess the influences of health literacy on women's understanding of prenatal aneuploidy screening.

Research question 2: What is the relationship of health literacy to women's understanding of prenatal aneuploidy screening? Specifically, do the five domain scores of health literacy (HLQ domain scores) influence women's understanding of prenatal aneuploidy screening (MSSKQ scores), adjusting for educational level, and race/ethnicity, and uptake of the prenatal aneuploidy screen?

The five domain scores of health literacy (*Feeling understood and supported by healthcare providers, Appraisal of health information, Ability to actively engage with health care providers, Ability to find good health information, and Understand health information enough to know what to do*), the independent variables, were regressed on MSSKQ scores (the dependent variable), adjusting for educational level, race/ethnicity, and uptake of the prenatal aneuploidy screen. Regression assumptions were evaluated with analysis of studentized deleted residuals. The P-P plot and 1-sample Kolmogorov-Smirnoff test indicated normal distribution of the residuals. The scatterplot of studentized deleted residuals versus predicted Y indicated no violations of the regression assumptions of linearity, normality, or homoscedasticity. The Durbin-Watson statistic for autocorrelation of residuals in linear regression was acceptable, indicating no violation of the assumption of independence (1.79; Norušis, 2007). Collinearity statistics were checked with Variance Inflation Factors (VIFs) with values greater than 7

considered problematic; VIFs were acceptable (max VIF = 3.89; Tabachnick & Fidell, 2013).

Multiple linear regression of MSSKQ scores occurred with two-stage hierarchical modeling. In the first linear model, educational level, race/ethnicity, and uptake of the prenatal aneuploidy screen were regressed on MSSKQ scores. Variables in the second linear model were added to (a) identify if the HLQ domain scores significantly influenced MSSKQ scores and (b) detect if a significant R^2 change occurred between Model 1 and Model 2. In the second linear model, *Feeling understood and supported by healthcare providers*, *Appraisal of health information*, *Ability to actively engage with health care providers*, *Ability to find good health information*, and *Understand health information enough to know what to do* were added to the regression model. Complete results for the multiple linear regression for Aim 2 are presented in Table 4.7.

In Model 1 of the multiple linear regression for Specific Aim 2, educational level, race/ethnicity, and uptake of the prenatal aneuploidy screen were found to explain a significant amount of the variance in mean MSSKQ scores ($R^2 = .251$, adjusted $R^2 = .227$, $F(3, 91) = 10.18$, $p < .001$). Statistical significance was found for educational level and race/ethnicity in relation to MSSKQ scores as the dependent variable. For each additional educational level (some college, college degree, or graduate degree) beyond high school, the predicted mean MSSKQ score increased by 0.356 points, adjusting for uptake of the prenatal aneuploidy screen and race/ethnicity ($b = 0.356$; 95% $CI [0.580, 1.996]$, $p < .001$). The predicted mean MSSKQ score increased by 0.269 point for Caucasian/White non-Hispanic women compared to women who are not

Caucasian/White non-Hispanic, adjusting for uptake of the screen and educational level ($b = 0.269$; 95% CI [0.699, 4.383], $p = .007$). Thus, educational level and race/ethnicity significantly predicted the mean MSSKQ scores in Model 1 for Specific Aim 2.

In Model 2 of the multiple linear regression for Specific Aim 2, educational level, race/ethnicity, uptake of the prenatal aneuploidy screen, and the five subscales of the HLQ (*Feeling understood and supported by healthcare providers, Appraisal of health information, Ability to actively engage with health care providers, Ability to find good health information, and Understand health information enough to know what to do*), were found to explain a significant amount of the variance in mean MSSKQ scores ($R^2 = .386$, adjusted $R^2 = .329$, $F(5, 86) = 6.753$, $p < .001$). Uptake of the prenatal aneuploidy screen, educational level, race/ethnicity, and the five subscales scores of the HLQ account for 32.9% of the variation in MSSKQ scores. The R^2 change indicates that the addition of the five HLQ subscales to the model significantly explained an additional 13.5% of the variation in mean MSSKQ scores compared with Model 1 ($R^2_{\text{change}} = .135$, $F_{\text{change}} = 3.767$, $p = .004$). Statistical significance was found for educational level and *Ability to actively engage with health care providers* in relation to MSSKQ scores as the dependent variable. For each additional educational level (some college, college degree, or graduate degree) beyond high school, the predicted mean MSSKQ score increased by 0.225 points, adjusting for race/ethnicity, uptake of the prenatal aneuploidy screen, *Feeling understood and supported by healthcare providers, Appraisal of health information, Ability to actively engage with health care providers, Ability to find good health information, and Understand health information enough to know what to do* ($b = .225$; 95% CI [0.047,

1.585], $p = .038$). For each additional point increase in the *Ability to actively engage with health care providers* scale score of the HLQ, the predicted mean MSSKQ score increased by 0.317 points, adjusting for educational level, race/ethnicity, uptake of the prenatal aneuploidy screen, *Feeling understood and supported by healthcare providers*, *Appraisal of health information*, *Ability to find good health information*, and *Understand health information enough to know what to do* ($b = .317$; 95% CI [0.532, 2.635], $p = .004$).

Table 4.7

Summary of Hierarchical Multiple Linear Regression of Maternal Serum Screening Knowledge Questionnaire¹ Scores (N =95)

Variable	Model 1			Model 2		
	β	95% CI	p	β	95% CI	p
Uptake of screen	.103	[0.644, 2.249]	.273	.075	[-0.808, 1.974]	.407
Educational level	.356	[0.580, 1.996]	<.001	.225	[0.047, 1.585]	.038
Race/ Ethnicity	.269	[0.699, 4.383]	.007	.113	[-0.862, 2.991]	.275
Feeling understood and supported by health care providers ²				.037	[-1.338, 1.825]	.760
Critical appraisal of health information ²				.016	[-1.635, 1.863]	.897
Ability to actively engage providers ²				.317	[0.532, 2.635]	.004
Ability to find good health information ²				.278	[-0.421, 4.762]	.100
Understand health information enough to know what to do ²				.159	[-0.614, 3.197]	.321
R^2		.251			.386	
adjusted R^2		.227			.329	
p for change in R^2		< .001			< .001	

Note.

1. Maternal Serum Screening Knowledge Questionnaire (Goel et al., 1996).
2. Subscale of the Health Literacy Questionnaire (Osborne et al., 2013).

Research Question 3

Specific Aim 3: To assess the influences of health literacy and understanding of prenatal aneuploidy screening on women's satisfaction with decisions made for prenatal aneuploidy screening.

Research question 3: What is the relationship of health literacy and understanding of prenatal aneuploidy screening to women's satisfaction with decisions made for prenatal aneuploidy screening? Specifically, do the five domain scores of health literacy (HLQ domain scores) and understanding of prenatal aneuploidy screening (MSSKQ scores) influence women's satisfaction with decisions made for prenatal aneuploidy screening (SWDS scores), adjusting for uptake of prenatal aneuploidy screening and parity?

The five domain scores of health literacy (*Feeling understood and supported by healthcare providers, Appraisal of health information, Ability to actively engage with health care providers, Ability to find good health information, and Understand health information enough to know what to do*) and MSSKQ scores, the independent variables, were regressed on SWDS scores (the dependent variable), adjusting for uptake of the prenatal aneuploidy screen and parity. Regression assumptions were evaluated with analyses of studentized deleted residuals. Normal distribution of the residuals was indicated by the P-P plot and 1-sample Kolmogorov-Smirnoff test. A scatterplot of studentized deleted residuals versus predicted Y indicated no violations of linearity, normality, or homoscedasticity. Evaluation of the Durbin-Watson statistic indicated no

violation of the regression assumption of independence (2.05; Norušis, 2007).

Collinearity statistics were acceptable (max VIF = 4.00; Tabachnick & Fidell, 2013).

Multiple linear regression of SWDS scores occurred with two-stage hierarchical modeling. In Model 1 of Specific Aim 3, parity and uptake of the prenatal aneuploidy screen were regressed on SWDS scores. Variables in Model 2 were added to the model to (a) identify if the HLQ domain scores significantly influenced SWDS scores and (b) assess if a significant R^2 change occurred between Model 1 and Model 2. Thus the five domains of health literacy and MSSKQ scores were added to the regression model in the second linear model. Complete results for the multiple linear regression for Specific Aim 3 are presented in Table 4.8.

In Model 1 of the multiple linear regression for Specific Aim 3, parity and uptake of the prenatal aneuploidy screen did not explain a significant amount of the variance in mean SWDS scores ($R^2 = .055$, adjusted $R^2 = .035$, $F(2, 92) = 2.697$, $p = .073$). For Model 1, statistical significance was found for parity in relation to SWDS scores as the dependent variable. The predicted mean SWDS score increased by 0.223 point for women who have completed at least one pregnancy with a fetus who reached at least week 20 of gestation compared to nulliparous women, adjusting for uptake of the prenatal aneuploidy screen ($b = 0.223$; 95% CI [0.023, 0.459], $p = .030$).

In Model 2 of the multiple linear regression for Specific Aim 3, parity, uptake of the prenatal aneuploidy screen, *Feeling understood and supported by healthcare providers, Appraisal of health information, Ability to actively engage with health care providers, Ability to find good health information, Understand health information enough*

to know what to do, and MSSKQ scores were found to explain a significant amount of the variance in mean MSSKQ scores ($R^2 = .464$, adjusted $R^2 = .414$, $F(6, 86) = 8.75$, $p = .004$). This means that parity, uptake of the prenatal aneuploidy screen, the five subscale scores of the HLQ, and MSSKQ scores account for 41.4% of the variation in mean SWDS scores. The R^2 change indicates that the addition of the five HLQ subscale scores and the MSSKQ scores to the model significantly explained an additional 40.8% of the variation in mean SWDS scores compared with Model 1 ($R^2_{\text{change}} = .408$, $F(6, 86)_{\text{change}} = 10.912$, $p < .001$). Statistical significance was found for *Feeling understood and supported by health care providers* and *Ability to find good health information* in relation to SWDS scores as the dependent variable. For each additional point increase in the *Feeling understood and supported by health care provider scale*, the predicted mean SWDS score increased by 0.329 points, adjusting for parity, uptake of the prenatal aneuploidy screen, *Appraisal of health information*, *Ability to actively engage with health care providers*, *Ability to find good health information*, *Understand health information enough to know what to do*, and MSSKQ scores ($b = .329$; 95% CI [0.142, 0.725], $p = .004$). For each additional point increase in the *Ability to find good health information scale*, the predicted mean SWDS score increased by 0.402 points, adjusting for parity, uptake of the prenatal aneuploidy screen, *Feeling understood and supported by health care providers*, *Appraisal of health information*, *Ability to actively engage with health care providers*, *Understand health information enough to know what to do*, and MSSKQ scores ($b = .402$; 95% CI [0.137, 1.109], $p = .013$).

Table 4.8

Summary of Hierarchical Multiple Linear Regression for Satisfaction With Decision Scale¹ Scores (N =95)

Variable	Model 1			Model 2		
	β	95% CI	<i>p</i>	β	95% CI	<i>p</i>
Parity	.223	[0.023, 0.459]	.030	.041	[-0.136, 0.226]	.623
Uptake of screen	-.082	[-0.435, 0.184]	.422	.023	[-0.216, 0.286]	.783
Feeling understood and supported ²				.329	[0.142, 0.725]	.004
Critical appraisal of health information ²				-.075	[-0.426, 0.214]	.513
Ability to actively engage with healthcare providers ²				-.029	[-0.228, 0.171]	.778
Ability to find good health information ²				.402	[0.137, 1.109]	.013
Understand health information enough to know what to do ²				.050	[-0.348, 0.497]	.727
MSSKQ ³ scores				.106	[-0.017, 0.060]	.281
R^2		.055			.464	
adjusted R^2		.035			.414	
<i>p</i> for change in R^2		.073			.004	

Note.

1. Satisfaction with Decision Scale (Holmes-Rovner et al., 1996).
2. Subscale of the Health Literacy Questionnaire (Osborne et al., 2013).
3. MSSKQ = Maternal Serum Screening Knowledge Questionnaire (Goel et al., 1996).

Analysis of influence. Cook's distance, leverage points, and DFBeta statistics were evaluated. Cook's distance measures the simultaneous change in all regression coefficients, with values > 1 being problematic (Montgomery, Peck, & Vining, 2012). Evaluation of Cook's distance values for the regression models revealed no cases with substantial influence on all regression coefficients (maximum Cook's distance = 0.29). High leverage indicates unusual combinations of the independent variables. Leverage values were considered influential if participants exceeded 0.168 (2 x average centered leverage) for the regression models for both Specific Aim 2 and Specific Aim 3 (Montgomery et al., 2012). There were four cases with leverage > 0.168 . DFBeta statistics measure the change that each case has on the regression coefficient. A cutoff of 0.205 was used for DFBetas ($2/\sqrt{95}$) (Montgomery et al., 2012). Evaluation of DFBetas indicates that no cases were unusually influential in estimating the regression coefficients. In sum, the analysis of influence indicates no substantial influence on the multiple linear regressions performed.

Chapter Summary

Ninety-five adult women aged 18 years and older, who were 18 or more weeks pregnant were recruited to take a Qualtrics survey using convenience sampling of recipients of an electronic pregnancy and parenting newsletter distributed in western North Carolina. The survey was used to collect data on participants' demographic and obstetrical information and included five scales: the MSSKQ (Goel et al., 1996), the SWDS (Holmes-Rovner et al., 1996), and five subscales of the HLQ (Osborne et al., 2013). The average age of participants was 31 years. The sample predominantly

identified as Caucasian/White non-Hispanic and the majority of participants were college-educated. Approximately 1 in 4 participants (24%) were experiencing pregnancy for the first time. Over one-half (55.3%) of participants reported having the prenatal aneuploidy screen, while the remaining women reported that they did not have the screen (38.9%) or were unsure if they had the screen (5.3%). Eight of the 12 items of the MSSKQ, which measures knowledge of prenatal aneuploidy screening, were answered correctly by the majority of participants, while four of the items of the MSSKQ were answered incorrectly by the majority of participants.

Analysis for Specific Aim 1 indicates that 57.9% [47.8%, 67.3%] of the sample reported satisfaction with decisions made for prenatal aneuploidy screening as measured by the SWDS (Holmes-Rovner et al., 1996). Multiple linear regression models were utilized for the analyses for Specific Aim 2 and Specific Aim 3. Analyses for Specific Aim 2 indicate that educational level, race/ethnicity, uptake of the prenatal aneuploidy screen, and the five subscale scores of the HLQ (*Feeling understood and supported by healthcare providers, Appraisal of health information, Ability to actively engage with health care providers, Ability to find good health information, and Understand health information enough to know what to do*; Osborne et al., 2013), explain a significant amount (32.9%) of the variance in mean MSSKQ (Goel et al., 1996). Each educational degree (Associate's, Bachelor's, and graduate) attained beyond high school and increasing *Ability to actively engage with health care providers* as measured by the HLQ (Osborne et al., 2013) are significantly associated with increased understanding of prenatal aneuploidy screening as measured by MSSKQ scores. Analyses for Specific

Aim 3 indicate that parity, uptake of the prenatal aneuploidy screen, the five subscale scores of the HLQ (*Feeling understood and supported by healthcare providers, Appraisal of health information, Ability to actively engage with health care providers, Ability to find good health information, and Understand health information enough to know what to do*; Osborne et al., 2013), and MSSKQ scores explain a significant amount (41.4%) of the variation in mean SWDS scores (Holmes-Rovner et al., 1996). The health literacy domains of *Feeling understood and supported by health care providers* and *Ability to find good health information* as measured by the HLQ (Osborne et al., 2013) are significantly associated with greater satisfaction with decisions made for prenatal aneuploidy screening as measured by the SWDS.

CHAPTER V

DISCUSSION

Introduction

The aims of this study were to examine the relationships between women's understanding of prenatal aneuploidy screening, health literacy, and satisfaction with decisions made for prenatal aneuploidy screening. The five domains of health literacy examined in this study are labeled *Feeling understood and supported by health care providers*, *Appraisal of health information*, *Ability to actively engage with health care providers*, *Ability to find good health information*, and *Understand health information enough to know what to do* (Osborne et al., 2014). A survey to collect data on women's understanding of prenatal aneuploidy screening, the five domains of health literacy, and satisfaction with decisions made for prenatal aneuploidy screening was completed by 95 pregnant women living in western North Carolina. The survey was distributed via electronic mail to recipients of an electronic pregnancy and parenting newsletter. In this chapter, an overview of the study findings is presented followed by explanation and interpretation of the findings in relation to prior research. Conceptual considerations and implications for practice, education, and policy are discussed. Limitations of findings are considered, and recommendations for future research are delineated.

Overview of Major Findings

Satisfaction with decisions made for prenatal aneuploidy screening was reported by 57.9% of the sample. Increasing *Ability to actively engage with health care providers* was significantly associated with increased understanding of prenatal aneuploidy screening. *Feeling understood and supported by health care providers*, *Appraisal of health information*, *Ability to find good health information*, and *Understand health information enough to know what to do* were not significantly associated with understanding of prenatal aneuploidy screening. *Feeling understood and supported by health care providers* and *Ability to find good health information* were significantly associated with increased satisfaction with decisions made for prenatal aneuploidy screening. *Appraisal of health information*, *Ability to actively engage with health care providers*, *Understand health information enough to know what to do*, and understanding of prenatal aneuploidy screening were not significantly associated with satisfaction with decisions made for prenatal aneuploidy screening.

Discussion

Sample Comparison with Population and Prior Research

The mean age of participants was 31.2 years. The sample had a higher number of multigravidas (75.8%) compared to primigravidas (24.2%). Nationally, the mean age of mothers giving birth for the first time is 26.3 years (Martin, Hamilton, & Osterman, 2017). In 2016, the birth rate among women aged 30 to 34 years surpassed the birth rate of women aged 25 to 29 years, the demographic with the highest birth rate for over three decades (Martin et al., 2017). The mean age of the sample therefore aligns with the

national trend of women in their thirties having a higher fertility rate than younger women.

Race/ethnicity. The survey was distributed to recipients of a pregnancy and parenting electronic newsletter through Mission Health in western North Carolina. Mission Health primarily serves residents of the following counties in North Carolina: Buncombe, Haywood, Henderson, Madison, McDowell, Transylvania, and Yancey. Among infants born in these counties, approximately 55% are born to Caucasian/White mothers, 27% are born to Black/African American mothers, 15% are born to Hispanic mothers, and the remaining 3% are born to other racial/ethnic minorities (North Carolina State Center for Health Statistics, 2014). This population is fairly representative of national trends for which approximately 53% of births occur to Caucasian/White mothers, 15% to Black/African American mothers, 22% to Hispanic mothers, and 10% to other racial/ethnic groups (Monte & Ellis, 2014).

For the participants in this study, 78.9% identified as Caucasian/White non-Hispanic, 13.7% identified as Black/African American, 4.2% identified as Hispanic, and 3.2% identified as Asian. The findings indicate that the sample in this study has a greater proportion of Caucasian/White women and a smaller proportion of Black/African American and Hispanic women compared to the population of women giving birth in western North Carolina. In comparison with prior research concerning prenatal screening among women in North America, this sample had a larger number of Black/African American and Hispanic women than the samples in Constantine et al. (2014) and Dixon and Burton (2014). The sample in this study had similar racial and ethnic representation

to Farrell et al.'s (2011) study for which the sample was 74.4% White, 14.0% Black/African American, and 2.1% Hispanic. The over-representation of Caucasian/White women in this study may be explained by the relatively lower rates of internet use among racial/ethnic minorities in the U.S. Seventy-eight percent of Black/African Americans and 81% of Hispanics use the internet, compared to 85% of the Caucasian/White population in the U.S. (Perrin & Duggan, 2015).

Educational level. Most participants had either a college (33.7%) or graduate (25.3%) degree, with the remainder having completed some years of college (21.1%) or high school (20.0%). The approximate proportion of adults in the area served by Mission Health who hold a high school diploma or higher degree ranges from 80.7-89.7%, and those with a bachelor's degree or higher ranges from 21.7-35.9% (U.S. Census Bureau, 2016). As the sample did not include individuals without a high school diploma or equivalent, the sample does not represent that sector of the population.

Offer and uptake of the prenatal aneuploidy screen. The majority (88.4%) of participants reported that they were offered the prenatal aneuploidy screen. However, 7.4% of participants were not sure if they were offered the screen, and 4.2% of participants reported that they were not offered the prenatal aneuploidy screen. While the majority (91.6%) of the sample responded that they were not told by a health care provider that their baby might be affected by a chromosome problem, 5 women (5.3%) were not sure whether or not they were told that their baby might have a chromosome problem. These findings suggest that aneuploidy screening and diagnostic testing are not being discussed and offered to all women early in pregnancy as recommended by the

American Congress of Obstetricians and Gynecologists (ACOG; 2016b) or that some women do have inadequate understanding of discussions about the prenatal aneuploidy screen and its results.

The majority (55.8%) of women in the sample underwent prenatal aneuploidy screening. Over one-third (38.9%) of the sample declined the prenatal aneuploidy screen and 5.3% did not know whether or not they had the screen. More women in this study underwent prenatal aneuploidy screening compared with Dixon and Burton's (2014) study regarding informed choice for prenatal screening in Ontario, Canada, for which 48.5% of the sample chose to have a prenatal screen. Additionally, a greater number of women in this study underwent prenatal aneuploidy screening compared with the proportion (27.4%) of women who underwent screening in Constantine et al.'s (2014) study examining informed choice for prenatal screening in the Midwest United States (U.S.). The increased proportion of women who had the prenatal aneuploidy screen in this sample compared with the aforementioned studies may be explained by increasing numbers of women accepting the prenatal aneuploidy screen following ACOG's recommendation in December 2012 that all women be offered prenatal aneuploidy screening (ACOG, 2016b). International reports indicate that when health policy shifts to the offer of prenatal aneuploidy screening for all women, screening becomes more widely adopted by women (Zeng, Zannoni, Löwy, & Camporesi, 2016).

Understanding of Prenatal Aneuploidy Screening

Understanding of prenatal aneuploidy screening was measured by the MSSKQ scale. The range of possible scale scores for the MSSKQ is -2 to 2 (Goel et al., 1996).

Previous cut-offs for the MSSKQ are as follows: Scores ≤ 0 indicate guessing or lack of information; scores > 0 and < 0.5 indicate a low level of knowledge; scores 0.5 through 1.0 indicate moderate level of knowledge; and scores > 1.0 indicate a high level of knowledge (Goel et al., 1996; Glazier et al., 1997). For this sample, the mean scale score of the MSSKQ was 0.63 (SD=0.29). Using the established cut-offs, results of the survey show that on average participants demonstrated moderate knowledge of prenatal aneuploidy screening. In this study, the MSSKQ was adapted to include only the 12 items that pertained to aneuploidy screening and not to include the two items specific to neural tube defects. Consequently, comparison of this study's MSSKQ scores with previous reports of MSSKQ scores should be done with caution. The mean MSSKQ scale score for this sample was higher than the mean MSSKQ scale score (0.62) reported with its initial use by Goel et al. (1996) among higher income and highly educated pregnant women, but lower in comparison to the mean MSSKQ scale score (0.78) among the same sample at re-test. The mean MSSKQ scale score for the sample in this study was lower compared to the mean MSSKQ scale score (0.89) for the treatment group and higher than the mean MSSKQ scale score for the control group (0.52) in Glazier et al.'s (1997) study investigating the efficacy of a revised educational pamphlet. A majority of participants in this study did not demonstrate adequate understanding for one-third (4 of 12) of the items measuring understanding of prenatal aneuploidy screening, as discussed below.

Inadequate understanding of the information that the screen provides.

Among participants, 32.6% responded incorrectly to *If the prenatal screen is abnormal,*

something is usually wrong with the baby (False), and 30.5% neither agreed nor disagreed with this statement, for a mean score of 0.08 (SD=0.91). Additionally, the mean score for *If the prenatal screen is abnormal, something is usually wrong with the baby* is lower in comparison to the mean score (0.53) reported for this item by Goel et al. (1996). This finding suggests that many participants may not understand that the prenatal aneuploidy screen functions as a screen to demarcate higher risk, but not certitude, of having a baby with a chromosomal anomaly. The finding may also indicate that many women do not clearly understand the distinction between a screen and a diagnostic test. The findings here support Seror and Ville's (2009) finding that approximately 50% of women who are offered screening are not aware of the implications of screening or do not adequately understand the intent of screening.

Inadequate understanding that the screen is optional. Among participants, 35.8% responded incorrectly to *Having prenatal screening is routine for all women* (False), while 22.1% of participants neither agreed nor disagreed with this statement, for a mean score of 0.14 (SD=1.06). The mean score for *Having prenatal screening is routine for all women* among this sample is lower in comparison to the mean score (0.55) reported for this item by Goel et al. (1996). The finding suggests that many women may perceive prenatal aneuploidy screening as a routine aspect of standard prenatal care and may not understand that the offer of the screen includes a choice to be made rather than compliance with standard care. This finding supports Jaques et al. (2005) and Chiang et al. (2006) research that found that many women perceive the offer of prenatal aneuploidy screening as assent to routine care rather than as a choice. An alternative explanation is

that contemporary interpretation of this item may be influenced by prenatal aneuploidy screening being more frequently offered and accepted than it was 10 or 20 years ago, with the screen viewed as commonly occurring among women rather than as a standard part of prenatal care.

Inadequate understanding that invasive diagnostic testing would be offered in the event of a positive screen. Among the participants, 8.4% responded incorrectly to *Amniocentesis can cause miscarriage in 1 in 200 women* (True), and 43.2% neither agreed or disagreed with this statement, for a mean score of 0.40 (SD=0.642). The mean score for *Amniocentesis can cause miscarriage in 1 in 200 women* among the participants in this study is lower in comparison to the mean score (0.75) reported for this item by Goel et al. (1996). Additionally, 14.7% of participants responded incorrectly to *Amniocentesis is a test of the mother's blood that can detect Down syndrome* (False), and 43.2% of participants neither agreed nor disagreed with this statement, for a mean score of -0.18 (SD=1.21). The mean score for *Amniocentesis is a test of the mother's blood that can detect Down syndrome* among this study's participants is lower in comparison to the mean score (-0.04) reported for this item by Goel et al. (1996).

The findings for these latter two items indicate that many women do not have adequate knowledge of the diagnostic tests (including amniocentesis) that are used to confirm the findings of a positive screen nor adequate knowledge of the risks associated with the diagnostic tests. The findings for the two items concerning amniocentesis may also point to decreased familiarity with amniocentesis secondary to lower rates of amniocentesis among women today compared to the late 1990s, when the MSSKQ was

developed (Turner, Rad, Afshar, Aghajanian, Williams, & Esakoff, 2014). The results support Rowe et al.'s (2006) finding that nearly one-third of the women offered prenatal screening were unsure of what the options would be and what type of tests would be offered following a positive screen result. The results also support Farrell et al.'s (2011) conclusion that many women do not consider the risks associated with diagnostic testing and the potential cascade of post-test decisions when considering prenatal aneuploidy screening.

Prenatal aneuploidy screening is the first step in a potential series of decisions about diagnostic testing and possible pregnancy termination in the event of confirmation of fetal chromosomal anomaly. Gert (2002) has suggested that when informing patients, health care providers should share information that would not be a surprise to themselves, but which they believe would be a surprise to the patient. Whereas it would not be surprising to the health care provider that the next steps following a positive prenatal aneuploidy screen would be the offer of invasive diagnostic testing, this study's findings, in combination with the aforementioned prior studies (Farrell et al., 2011; Rowe et al., 2006), suggest that the offer of amniocentesis and its associated risks would be surprising for many women. Thus, the findings point to a need for more explicit discussions about what the next steps would be following a positive prenatal aneuploidy screen, specifically the option of invasive diagnostic testing and the subsequent possibility of making a decision about pregnancy termination.

The findings suggest inadequate understanding of prenatal aneuploidy screening. This study was informed by Faden and Beauchamp's (1986) model of

informed choice. Faden and Beauchamp identify three essential conditions of informed consent: (a) intentional authorization, (b) substantial understanding of the act and its consequences, and (c) freedom from coercive control. Substantial understanding includes (a) cognitive awareness of the proposed treatment, the alternatives, and the possible consequences of that act, and (b) cognizance that one is granting authorization (Faden & Beauchamp, 1986). This study's findings on women's understanding of prenatal aneuploidy screening call into question whether women understand that the prenatal aneuploidy screen (a) provides information about the risk of having a baby with a chromosome abnormality rather than certitude of fetal anomaly, (b) is an option that they can choose to accept or decline, and (c) will require additional decision-making concerning invasive diagnostic testing and its associated risks in the event of a positive screen.

Health Literacy

Feeling understood and supported by health care providers, Appraisal of health information, Ability to actively engage with health care providers, Ability to find good health information, and Understand health information enough to know what to do were measured by subscales of the Health Literacy Questionnaire (HLQ) (Osborne et al., 2014). Higher HLQ subscale scores represent greater health literacy. This author was not able to locate any reports of prior use of the HLQ among pregnant women nor adult women living in the U.S. Beauchamp et al. (2015) used the HLQ to assess health literacy among adults living in Australia, with the majority being female and living with at least one health condition. Compared with the HLQ subscale scores for Beauchamp et al.'s

sample, this study's sample yielded lower mean scores for *Feeling understood and supported by health care providers* (3.04), *Ability to actively engage with health care providers* (3.73), and *Understand health information enough to know what to do* (3.73). Beauchamp et al. report mean scores of 3.21 for *Feeling understood and supported by health care providers*, 3.97 for *Ability to actively engage with health care providers*, and 3.85 for *Understand health information enough to know what to do*. The comparison also shows that the sample in this study had higher mean scores for *Appraisal of health information* (2.91) and *Ability to find good health information* (3.92) compared with the sample in Beauchamp et al. (2015). Beauchamp et al. report mean scores of 2.78 for *Appraisal of health information* and 2.92 for *Ability to find good health information*. Results indicate that on average participants reported moderate to high levels of health literacy across the five domains of health literacy measured by the HLQ and that the subscale scores for the five domains of health literacy are comparable with prior use of the HLQ among adult women.

Satisfaction with Decisions Made for Prenatal Aneuploidy Screening

Satisfaction with decisions made for prenatal aneuploidy screening was measured by the Satisfaction with Decisions Scale (SWDS; Holmes-Rovner et al., 1996). The range of possible scores for the SWDS is 6 to 30 with higher scores indicating greater satisfaction and scores ≥ 24.0 , signifying satisfaction with a given decision (Holmes-Rovner et al., 1996; Palmer-Wackerly et al., 2017; Wills & Holmes-Rovner, 2003). The mean score of the SWDS was 24.00 (SD=4.60). Results show that 57.9% (95% CI=47.8%, 67.3%) of the sample reported satisfaction with decisions made for prenatal

aneuploidy screening and that 42.1% (95% CI=32.7%, 52.2%) of participants did not report satisfaction with decisions made for prenatal aneuploidy screening. To this author's knowledge, no prior studies have measured women's satisfaction with decisions made for prenatal aneuploidy screening.

Women's satisfaction with decisions made for prenatal aneuploidy screening was compared to published reports of women's satisfaction with other health care decisions. A lower percentage of women in this study demonstrated satisfaction with decisions made for prenatal aneuploidy screening compared to the percentage of women (80.6%) who demonstrated satisfaction with decisions made for breast cancer treatment (Lantz et al., 2005). Additionally, a lower percentage of women in this study demonstrated satisfaction with decisions made for prenatal aneuploidy screening compared to the percentage of women (74.0%) who demonstrated satisfaction with decisions made for type of delivery (Cesarean or vaginal) (Wittmann-Price et al., 2011). Hence, the women in this study demonstrated lower satisfaction with decisions made for prenatal aneuploidy screening when compared to reports of satisfaction for other women's health care decisions.

The Relationship of Health Literacy to Understanding of Prenatal Aneuploidy Screening

To examine the relationship of health literacy to understanding of prenatal aneuploidy screening, the five domains of health literacy (*Feeling understood and supported by health care providers, Appraisal of health information, Ability to actively engage with health care providers, Ability to find good health information, and*

Understand health information enough to know what to do) were regressed on MSSKQ scores, while controlling for uptake of the prenatal aneuploidy screen, educational level, and race/ethnicity. Increasing *Ability to actively engage with health care providers* was significantly associated with increased understanding of prenatal aneuploidy screening. *Feeling understood and supported by health care providers*, *Critical appraisal of health information*, *Ability to find good health information*, and *Understand health information enough to know what to do* were not associated with understanding of prenatal aneuploidy screening. The significant R^2 change between the first and second regression models indicates that 32.9% of the variation in understanding of prenatal aneuploidy screening can be explained by uptake of prenatal aneuploidy screening, educational level, race/ethnicity, and the the five domains of health literacy. Thus, while each of the five domains of health literacy did not individually predict understanding of prenatal aneuploidy screening, the addition of the five domains of health literacy helps to explain the variation in understanding prenatal aneuploidy screening.

Educational level was included in the regression of MSSKQ scores as a control. The finding that educational level is significantly associated with increasing understanding of prenatal aneuploidy screening is to be expected and consistent with previous studies. Both Schoonen et al. (2012) and Van den Berg et al. (2005) found a better knowledge of screening among women with higher educational attainment.

The author is not aware of any previous study specifically examining the relationship between the health literacy domain of *Ability to actively engage with health care providers* and understanding of prenatal aneuploidy screening. However, the

significant relationship supports prior research. Martin et al. (2016) found a significant association between women's psychosocial communication and health care providers' psychosocial questions, affective communication, and the duration of counseling for prenatal fetal anomaly screening. Martin et al. (2016) suggested that the positive association may be explained by individual characteristics of women, including a "better ability to engage in psychosocial interactions," (Martin et al., 2016, p.89). The findings of this study, in conjunction with Martin et al.'s (2016) findings, suggest that understanding of prenatal aneuploidy screening is enhanced by a woman's interaction and communication with her health care providers. When women are actively engaged with their providers in discussions about prenatal aneuploidy screening, they are more likely to make an informed decision.

It was unexpected that *Understand health information enough to know what to do* did not individually predict understanding of prenatal aneuploidy screening because the complexity of the information about prenatal aneuploidy screening and women's difficulty in understanding the information is well-documented in the literature (Farrell et al., 2011; Fransen et al., 2010; Georgsson Öhman et al., 2009; Park & Matthews, 2009; Seror & Ville, 2009). A possible explanation for this lack of a significant relationship between *Understand health information enough to know what to do* and understanding of prenatal aneuploidy screening is that the range of scores measuring *Understand health information enough to know what to do* was relatively narrow (2.60 – 5.00 out of a possible score of 5) compared with the range of scores for the other four domains of health literacy. This narrow range of scores for *Understand health information enough to*

know what to do may be due in part to the majority of the sample having a college degree or graduate degree. More highly educated individuals have demonstrated increased cognitive ability to understand health information as well as greater confidence in their ability to understand health information (Bo, Friis, Osborne, & Maindal, 2014; Cutler & Lleras-Muney, 2010). Further, the items on the survey that assessed *Understand health information enough to know what to do* are part of the HLQ, for which participants are asked to respond to statements about health care and health information in general rather than specific to the topic of prenatal aneuploidy screening. It is possible that some women who may have difficulty understanding the specific information about prenatal aneuploidy screening well enough to know what to do did not report difficulty in *Understand health information enough to know what to do* when considering general health information.

The Relationship of Health Literacy and Understanding of Prenatal Aneuploidy Screening to Satisfaction with Decisions Made for Prenatal Aneuploidy Screening

To examine the relationship of health literacy and understanding of prenatal aneuploidy screening to satisfaction with decisions made for prenatal aneuploidy screening, the five domains of health literacy (*Feeling understood and supported by health care providers, Appraisal of health information, Ability to actively engage with health care providers, Ability to find good health information, and Understand health information enough to know what to do*) and MSSKQ scores were regressed on SWDS scores. While controlling for parity and uptake of the prenatal aneuploidy screen, results indicate that increasing *Feeling understood and supported by health care providers* and

increasing *Ability to find good health information* are significantly associated with increasing satisfaction with decisions made for prenatal aneuploidy screening. *Appraisal of health information, Ability to actively engage with health care providers, Understand health information enough to know what to do*, and understanding of prenatal aneuploidy screening were not significantly associated with satisfaction with decisions made for prenatal aneuploidy screening. The R^2 change between the first and second regression models was significant, indicating that 41.4% of the variation in satisfaction with decisions made for prenatal aneuploidy screening can be explained by parity, uptake of prenatal aneuploidy screening, the five domains of health literacy, and understanding of prenatal aneuploidy screening. Thus, while three of the five domains of health literacy and understanding of prenatal aneuploidy screening did not individually predict satisfaction with decisions made for prenatal aneuploidy screening, the addition of the five domains of health literacy and understanding of prenatal aneuploidy screening helps to explain the variation in satisfaction with decisions made for prenatal aneuploidy screening.

No previous studies were identified that examined the influence of the five health literacy domains and understanding of prenatal aneuploidy screening on satisfaction with decisions made for prenatal aneuploidy screening. The significant relationships between *Feeling understood and supported by health care providers* and *Ability to find good health information* and satisfaction with decisions made for prenatal aneuploidy screening support prior research on women's experiences with prenatal aneuploidy screening. Van den Berg et al. (2005) found that informed decision-making was a

significant predictor of satisfaction with decisions made for prenatal screening.

Additionally, Ahmed et al. (2014) learned that most women want health professionals to help them work through information about prenatal aneuploidy screening to help them discern which choice is best for them. The results of this study in conjunction with Van den Berg et al.'s (2005) and Ahmed et al.'s (2014) research indicate that a woman's satisfaction with decisions made for prenatal aneuploidy screening increases when she has access to high-quality information and feels supported by health care professionals to understand the information and arrive at a decision that aligns with her values.

It is surprising that understanding of prenatal aneuploidy screening did not individually predict women's satisfaction with decisions made for prenatal aneuploidy screening. According to Holmes-Rovner et al. (1996), satisfaction with a decision occurs with intentional evaluation of available information on the options and risks involved with a course of action and alignment of values. Thus, adequate understanding of the screen is conceptually a necessary feature of satisfaction with a decision for prenatal aneuploidy screening. Additionally, informed decision-making is associated with greater satisfaction with decisions about prenatal aneuploidy screening (Van den Berg et al., 2005). One explanation for why understanding of prenatal aneuploidy screening did not individually predict satisfaction with decisions made for prenatal aneuploidy screening is that the participants' perception of being adequately informed about prenatal aneuploidy screening, which is measured by the SWDS, may be greater than their objective understanding of prenatal aneuploidy screening, which is measured by the MSSKQ. Extant research indicates that women frequently have inadequate understanding of

prenatal aneuploidy screening, the implications of screening, and the conditions detected, despite having received information (Farrell et al., 2011; Fransen et al., 2010; Georgsson Öhman et al., 2009; Park & Matthews, 2009; Seror & Ville, 2009). It is possible that some women in this study may have indicated that they felt adequately informed about the screen (on the SWDS) while demonstrating inadequate understanding of prenatal aneuploidy screening (as measured by the MSSKQ). Additionally, some people may be less likely to question their satisfaction with a decision once the decision is made and cannot be changed. An alternative explanation is that the MSSKQ may not measure what women believe is relevant and important to know about prenatal aneuploidy screening. In this scenario, some women may have demonstrated inadequate understanding of prenatal aneuploidy screening while reporting high satisfaction with their decisions because they believe that they were adequately informed on the issues surrounding prenatal aneuploidy screening that they identify as salient.

Conceptual Considerations

The significance of the associations between the health literacy domains of *Ability to actively engage with health care providers* and understanding of prenatal aneuploidy screening and *Feeling understood and supported by health care providers* and *Ability to find good health information* and satisfaction with decisions made for prenatal aneuploidy screening may be explained by Nutbeam's (2000) explication of the three levels of health literacy. Nutbeam conceived of three subtypes of health literacy: basic functional health literacy, communicative/interactive health literacy, and critical health literacy. *Feeling understood and supported by health care providers*, *Ability to actively*

engage with health care providers and *Ability to find good health information*, are the three domains of health literacy that comprise communicative/interactive health literacy (Nutbeam, 2000; Osborne et al., 2013). Communicative/interactive health literacy includes the advanced cognitive and literacy skills required to actively participate in and derive meaning from various forms of communication and to apply new information to dynamic situations (Nutbeam, 2000). Therefore, *Feeling understood and supported by health care providers*, *Ability to actively engage with health care providers*, and *Ability to find good health information* impact the information-gathering and problem-solving processes necessary for effective health care decision-making (Jordan, Buchbinder, & Osborne, 2010; Nutbeam, 2000). The overall findings of this study indicate that communicative/interactive health literacy, as conceived by Nutbeam, significantly influences understanding of prenatal aneuploidy screening and satisfaction with decisions made for prenatal aneuploidy screening.

Conclusions

The following conclusions are drawn from the findings of this study:

1. Women did not have sufficient understanding that the prenatal aneuploidy screen (a) provides information about the risk of having a baby with a chromosome abnormality rather than certitude of fetal anomaly, (b) is an option that they can choose to accept or decline, and (c) will require additional decision-making, in the event of a positive screen, concerning invasive diagnostic testing, its associated risks, and possible termination.

2. *Ability to actively engage with health care providers* significantly influenced understanding of prenatal aneuploidy screening.

3. *Feeling understood and supported by health care providers* and *Ability to find good health information* significantly influenced satisfaction with decisions made for prenatal aneuploidy screening.

4. Nearly 1 out of every 2 women failed to demonstrate satisfaction with their decision made for prenatal aneuploidy screening. This means that that nearly half of the decisions made for prenatal aneuploidy screening were inadequately informed and/or incongruent with the patient's values.

Implications for Practice, Education, and Policy

The responsible translation of reproductive and genetic technologies into prenatal care requires that health care professionals ensure women's informed decision-making in clinical practice (Badzek, Henaghan, Turner, & Monsen, 2013). As members of the prenatal care team, professional registered nurses have a professional and ethical responsibility to facilitate women's informed decision-making for prenatal aneuploidy screening. Professional registered nurses have an ethical duty to ensure that women understand what it is that they are accepting or declining with decisions for prenatal aneuploidy screening. This study's findings suggest that women have inadequate understanding that the prenatal aneuploidy screen (a) provides information about the risk of having a baby with a chromosome abnormality rather than certitude of fetal anomaly, (b) is an option that they can choose to accept or decline, and (c) will require additional decision-making concerning invasive diagnostic testing in the event of a positive screen.

This study indicates that a woman's communicative/interactive health literacy plays a critical role in the problem-solving and evaluation of health information required for women to attain substantial understanding of prenatal aneuploidy screening and to make decisions about prenatal aneuploidy screening that are aligned with their values. The findings highlight the need for patient-centered strategies that promote open and intentional communication about prenatal aneuploidy screening (Moore, Titler, Kane Low, Dalton, & Sampsel, 2015). In this study, nearly half of women made decisions regarding prenatal aneuploidy screening that were based on inadequate understanding and/or that were incongruent with their values. It is imperative that health care professionals ensure that women have substantial understanding of prenatal aneuploidy screening so that women can make decisions for screening that are informed and consistent with their values. Interventions are needed to (a) ensure access to comprehensive information about prenatal aneuploidy screening with assessment of women's understanding, (b) facilitate women's active engagement through the creation of a prenatal care environment that conveys understanding and nonjudgmental guidance throughout the decision-making process, and (c) address the educational needs of health professionals who provide prenatal care.

Ensuring access to comprehensive information and assessing women's understanding of prenatal aneuploidy screening. Prenatal care professionals, including professional registered nurses, have an ethical responsibility to know that women understand what it is that they are accepting or declining with the offer of prenatal aneuploidy screening (Consensus Panel on Genetic/Genomic Nursing

Competencies, 2009). Interventions are needed to ensure that women are provided with accurate, unbiased, and comprehensive information about prenatal aneuploidy screening. This information should include the implications of screening and the conditions screened. To avoid women being surprised in the trajectory of prenatal care, the information should include the possibility of subsequent decision-making about diagnostic testing and pregnancy termination. Further, this information needs to be in plain language that is accessible to women with lower literacy and numeracy skills and available to women in their preferred language.

It is not enough to provide women with information. It is imperative that health care professionals assist women to attain a basic understanding of prenatal aneuploidy screening before making their decisions. Nurses have expertise in using a variety of creative methods to teach patients about complex health topics. Professional registered nurses can partner with genetic counselors and prenatal care providers, including advanced practice nurses, to develop a variety of instructional tools to help women understand prenatal aneuploidy screening. Further, as members of the prenatal care team, it is incumbent upon professional registered nurses to assess women's understanding of prenatal aneuploidy screening. Registered nurses need to work within their practice settings to establish a process by which women's understanding of prenatal aneuploidy screening is assessed and resources are provided when misunderstanding occurs.

Facilitating women's active engagement and creating a supportive, nonjudgmental prenatal care environment. Informed consent is an interaction between health care professionals and patients that requires clear and specific

communication regarding the issues at stake (Badzek et al., 2013). How information is provided and the manner in which it is explained may have more influence on a woman's health decision than the amount of information that is presented (Moore et al., 2015). In practice, health literacy is a function of the relationship between individual communication capacities and the health care system (Baker, 2006). Therefore, interventions are needed to create a process in which women can have meaningful discussions about prenatal aneuploidy screening with prenatal care providers. Registered nurses have a social and professional responsibility to be informed and educate other health professionals on the positive associations between supportive communication and women's understanding of prenatal aneuploidy screening and satisfaction with their decisions for screening. Interventions are needed to support women in articulating their concerns and asking pertinent questions about prenatal screening. In their advocacy role, professional registered nurses can be present in discussions about prenatal aneuploidy screening to verify that women understand that they have a genuine choice of whether or not to use the screen and to assess for possible misinterpretation of information (Skirton, Lewis, Kent, & Coviello, 2010). A nonjudgmental prenatal care environment should include the support women are provided whether they choose to accept or decline the screen. Further, as environmental factors (e.g., workload, short appointment times) affect how providers engage patients in clinical decision-making and with prenatal aneuploidy screens increasingly being offered to women in the first trimester, interventions are needed to allow for adequate time for discussion about prenatal aneuploidy screening during the initial prenatal care appointment (Allyse et al., 2015; Moore et al., 2015).

Addressing the educational needs of prenatal care providers. Previous research suggests that educational gaps exist among health care providers on prenatal aneuploidy screening, including the professional guidelines and policies for prenatal aneuploidy screening, limitations of screening, and resources available for parenting a child with disabilities (Farrell et al., 2011; Haymon et al., 2014). As a result, health care professionals may be inadequately prepared to have the type of meaningful discussions about prenatal aneuploidy screening that assist women in making informed decisions. Educational interventions are needed to train health care providers on managing discussions about prenatal aneuploidy screening to assist women in understanding the information about prenatal aneuploidy screening and to guide women in making decisions that are well-informed and consistent with the woman's values.

Limitations of the Study

Threats to internal validity. Internal validity involves the rigor and degree of control in a study (Gliner, Morgan, & Leech, 2009). Research conducted with human subjects, especially research using nonexperimental methods, often has methodological, design, and data limitations that can reduce the extent to which inferences can be made (Gliner et al., 2009). By design, this correlational study focused on the relationships between women's understanding of prenatal aneuploidy screening and satisfaction with decisions made for prenatal aneuploidy screening and aspects of health literacy that are potentially amenable to interventions. This study is likely limited by unmeasured personal, social, and contextual factors that may influence women's understanding of prenatal aneuploidy screening and satisfaction with decisions made for prenatal

aneuploidy screening. The mode of the exchange of information (written, oral, discussion, video, etc.) between women and their prenatal care providers and the duration of time spent presenting and discussing the screen may influence women's understanding of prenatal aneuploidy screening and satisfaction with decisions made for prenatal aneuploidy screening. This study is also limited by the type of data collected. Although it was assumed that participants answered the survey questions honestly and accurately, the results cannot be verified. This study may also be limited by the content of the MSSKQ. While the MSSKQ has been validated in prior research with women undergoing prenatal aneuploidy screening, the types of screens offered and the timing of the screens are different today than when the MSSKQ was developed (Goel et al., 1996; Glazier et al., 1997). These differences may affect how women understand the underlying constructs that are assessed with the MSSKQ.

Threats to external validity. External validity refers to the extent to which findings can be generalized beyond the study (Gliner et al., 2009). The present study is limited by convenience sampling of women who receive the electronic pregnancy and parenting newsletter distributed through Mission Health System in western North Carolina. The primary limitation of convenience sampling is that the accessible population might not be representative of the theoretical population, thereby limiting external validity (Gliner et al., 2009). While this study included a higher proportion of racial/ethnic minorities compared to other studies investigating informed decision-making for prenatal screening (Constantine et al. 2014; Dixon & Burton, 2014), this study had a smaller proportion of Black/African American and Hispanic women

compared to the population of women giving birth in western North Carolina. Additionally, the sample was predominantly college-educated. Therefore, this study's findings should be interpreted with caution for women who are racial/ethnic minorities and women who are not college-educated. Lastly, as convenience sampling was used, the confidence intervals presented in this study should be interpreted with caution.

Recommendations for Future Research

Future research needs to investigate mechanisms to promote open communication concerning prenatal aneuploidy screening between women and prenatal care providers. Research is essential to identify communication strategies that help women to actively engage with their prenatal care providers and feel understood when articulating concerns and making decisions about prenatal aneuploidy screening. Additionally, it is necessary to investigate the influence of health literacy on women's understanding of prenatal aneuploidy screening among vulnerable populations, including racial and ethnic minorities and women with no college education. Moreover, it is imperative to explore women's informed decision-making for prenatal aneuploidy screening in the context of the legal framework for abortion in the U.S., where gestational limits on pregnancy termination currently vary by state.

Future research should address questions regarding how prenatal care providers can facilitate women's informed decision-making for prenatal aneuploidy screening. It is important to determine the knowledge base of prenatal care providers on the topic of prenatal aneuploidy screening and to identify their educational needs concerning prenatal aneuploidy screening. Quality assurance studies are needed to investigate the provision

of comprehensive and unbiased information about prenatal aneuploidy screening. Further, there is a need for studies to develop and test interventions for prenatal care providers to improve their capacity to discuss prenatal aneuploidy screening with patients and provide guidance in decision-making without influencing the final choice for such screening.

Lastly, as the types of screens offered for prenatal aneuploidy screening have evolved with advancements in genetics and technology over the past 10 to 20 years, psychometric evaluation of the MSSKQ (Goel et al., 1996) is warranted. Psychometric evaluation should include examination of the content validity of the MSSKQ with subject matter experts in the context of first-trimester screening options. Moreover, assessment of construct validity via factorial validity is necessary to determine if the underlying putative structure of the MSSKQ adequately measures women's knowledge of prenatal aneuploidy screening.

Chapter Summary

As prenatal aneuploidy screening is increasingly offered to all pregnant women, health care providers have the responsibility to support women in making an informed and autonomous decision that is aligned with the patient's values. This study demonstrates a clear need for improving women's understanding of prenatal aneuploidy screening to enable women to make decisions that are congruent with their personal beliefs and values. While a majority (57.9%) of the sample demonstrated satisfaction with decisions made for prenatal aneuploidy screening, a substantial proportion (42.1%) did not report satisfaction with decisions made for prenatal aneuploidy screening. This

study shows that women's informed decision-making for prenatal aneuploidy screening is a process that is supported by the communicative/interactive health literacy domains of *Feeling understood and supported by health care providers*, *Ability to actively engage with health care providers*, and *Ability to find good health information*. Understanding of prenatal aneuploidy screening was predicted by *Ability to actively engage with health care providers*. Satisfaction with decisions made for prenatal aneuploidy screening was predicted by *Feeling understood and supported by health care providers* and *Ability to find good health information*. As genetic and reproductive technologies continue to develop, options for prenatal screening will become more diverse, and decisions about prenatal screening will likely become increasingly complex and morally contentious. The results of this and other studies highlight the importance of deliberate exchange of information and discussion between women and their prenatal care providers in decisions about prenatal screening (Farrell et al., 2011; Farrell et al., 2014; Martin et al., 2016; Park & Matthews, 2009). To facilitate informed decision-making for prenatal aneuploidy screening, it is important to create a health care environment in which clear and comprehensive information about prenatal aneuploidy screening and its implications is provided, understanding of prenatal aneuploidy screening is assessed, active and direct communication about prenatal screening occurs, and women feel supported and understood by their prenatal care providers in the decision-making process.

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APPENDIX A

MISSION INSTITUTIONAL REVIEW BOARD EXEMPT STATUS LETTER

Institutional Review Board

509 Biltmore Avenue, Asheville, North Carolina
28801 phone (828) 213-1105 fax (828) 213-7056
www.missionhospitals.org

Date: July 28, 2017

To: Tamra Shea, MSN
From: Mission Health Institutional Review Board

Study Title: [1070492-1] Health Literacy, Understanding, and Decisional Satisfaction in Women's Informed Decision-Making for Prenatal Aneuploidy Screening

IRB Reference #: 17-07-1716, NF
Submission Type: New Project

Action: Determination of Exempt Status
Decision Date: July 28, 2017

On July 28, 2017, the Mission Health Institutional Review Board reviewed your proposed study, "**[1070492-1] Health Literacy, Understanding, and Decisional Satisfaction in Women's Informed Decision-Making for Prenatal Aneuploidy Screening**" via Exempt Review and determined that this project is EXEMPT from IRB review 21 CFR 56.104; 45 CFR 46.101(b), category 2.

We will file a copy of this correspondence in our office.

You must notify the IRB of any changes in this project that may alter the IRB's determination. As with any changes to the research itself, financial relationships or interests that develop with a sponsor later or over time must be brought to the attention of the Mission Health Cancer Institutional Review Board and to Mission Health's Corporate Compliance Officer for further consideration.

If you have any questions, please contact Elizabeth Hamilton at (828) 213-1105 or elizabeth.hamilton@msj.org. Please include your study title and reference number in all correspondence with this office.

This letter has been electronically signed in accordance with all applicable federal regulations and a copy of this letter is retained within the electronic study folder and Mission Health System records.

cc: file; Research Institute

APPENDIX B

UNCG INSTITUTIONAL REVIEW BOARD EXEMPT STATUS LETTER



THE UNIVERSITY of NORTH CAROLINA
GREENSBORO

OFFICE OF RESEARCH INTEGRITY

2718 Beverly Cooper Moore
and Irene Mitchell Moore
Humanities and Research
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Greensboro, NC 27402-6170
336.256.0253
Web site:
www.uncg.ed
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Federalwide
Assurance
(FWA) #216

To: Tamra Shea, School of Nursing

From: UNCG IRB

Date: 6/15/2017

RE: Notice of IRB Exemption

Exemption Category: 2.Survey, interview, public observation

Study #: 17-0224

Study Title: Health Literacy, Understanding, and Decisional Satisfaction in Women's Informed Decision-Making for Prenatal Screening

This submission has been reviewed by the IRB and was determined to be exempt from further review according to the regulatory category cited above under 45 CFR 46.101(b).

Study Description:

Women are routinely asked to consent to prenatal aneuploidy screening to detect fetal chromosomal problems in early pregnancy despite evidence that many women do not understand what they are consenting to. The objective of this proposed study is to investigate the relationships between women's understanding of prenatal aneuploidy screening, health literacy, and satisfaction with decisions made for prenatal aneuploidy screening.

Specific Aim 1: To assess women's satisfaction with decisions made for prenatal aneuploidy screening.

Research Question 1: How satisfied are women with the decisions they make for prenatal aneuploidy screening?

Specific Aim 2: To assess the influence of health literacy on women's understanding of prenatal aneuploidy screening.

Research Question 2: What is the relationship of health literacy to women's understanding of

prenatal aneuploidy screening?

Specific Aim 3: To assess the influences of health literacy and understanding of prenatal aneuploidy screening on women's satisfaction with decisions made for prenatal aneuploidy screening.

Research Question 3: What is the relationship of health literacy and understanding of prenatal aneuploidy screening to women's satisfaction with decisions made for prenatal aneuploidy screening?

Investigator's Responsibilities

Please be aware that any changes to your protocol must be reviewed by the IRB prior to being implemented. Please utilize the most recent and approved version of your consent form/information sheet when enrolling participants. The IRB will maintain records for this study for three years from the date of the original determination of exempt status.

Signed letters, along with stamped copies of consent forms and other recruitment materials will be scanned to you in a separate email. **Stamped consent forms must be used unless the IRB has given you approval to waive this requirement.** Please notify the ORI office immediately if you have an issue with the stamped consents forms.

Please be aware that valid human subjects training and signed statements of confidentiality for all members of research team need to be kept on file with the lead investigator. Please note that you will also need to remain in compliance with the university "Access To and Retention of Research Data" Policy which can be found at http://policy.uncg.edu/university-policies/research_data/.

CC:

Denise Cote Arsenault, School of Nursing

APPENDIX C

RECRUITMENT EMAIL

Please consider completing a survey for pregnant women on how they understand and view information on prenatal care and screening. The information you provide will help to improve health care for expectant mothers, and the survey takes less than 15 minutes to complete.

Upon completion of the survey, you will be eligible to *win one of two \$50.00 gift cards to Target or WalMart!*

To participate, simply click on the link: "Let Us Know What You Think"

Thank you so much for assisting in improving care for women and children.

Tamra L. Shea, MSN, RN
and
Denise Côté-Arsenault, PhD, RN, FNAP, FAAN
The University of North Carolina Greensboro

Mary Ellen Wright, PhD, APRN, CPNP
Nurse Researcher Women's and Children's Health
Mission Health

APPENDIX D

CONSENT FORM

**UNIVERSITY OF NORTH CAROLINA GREENSBORO
and
MISSION HEALTH SERVICES**

CONSENT TO ACT AS A HUMAN PARTICIPANT

Project Title: Health Literacy, Understanding, and Decisional Satisfaction in Women's Decision-Making for Prenatal Aneuploidy Screening

Principal Investigator and Faculty Advisor: Tamra L. Shea and Dr. Denise Côté-Arsenault

What are some general things you should know about research studies?

You are being asked to take part in a research study. Your participation in the study is voluntary. You may choose not to join, or you may withdraw your consent to be in the study, for any reason, without penalty. Research studies are designed to obtain new knowledge. This new information may help people in the future. There may not be any direct benefit to you for being in the research study. There also may be risks to being in research studies. If you choose not to be in the study or leave the study before it is done, it will not affect your relationship with the researcher, the University of North Carolina at Greensboro, or your treatment at Mission Health Services.

Details about this study are discussed in this consent form. It is important that you understand this information so that you can make an informed choice about being in this research study.

You may print this page on your web browser to obtain a copy of this consent form. If you have any questions about this study at any time, you should ask the researchers named in this consent form. Their contact information is below.

Voluntary participation: Your participation in the study is completely voluntary. The treatment and services you receive at this clinic or practice will not be affected by your participation in this study. Participation in the research project will in no way affect your current or future receipt of services from this clinic site or practice.

What is the study about?

This is a research project. Your participation is voluntary. The purpose of the study is to advance understanding of the women's decision-making for prenatal screening.

Why are you asking me?

Any woman who is \geq 18 weeks pregnant, who is receiving prenatal care, who is \geq 18 years old, and who is English-speaking, is invited to participate in this study.

What will you ask me to do if I agree to be in the study?

You are asked to complete an online survey about your experiences with decision-making for prenatal screening and your understanding of health information. The survey will also include questions about your obstetric history and general questions about you, such as your age and race/ethnicity. You may stop taking the survey at any time. It is anticipated that the survey will take approximately 20 minutes to complete. There is little likelihood of any physical risk as a result of participation in this research project.

Participants are not asked to perform any tasks as a part of the survey that could result in physical harm. There is no physical assessment or invasive procedures in this study.

There is no direct involvement with the fetus.

If you have questions about this study, please contact Tamra Shea, RN at (828) 545-9809.

Is there any audio/video recording?

There is no audio or video recording in this study.

What are the risks to me?

The Institutional Review Boards at the University of North Carolina at Greensboro and at Mission Health System has determined that participation in this study poses minimal risk to participants. You will be asked to provide information about your experience of decision-making, understanding of health information, obstetric history, and demographic data. These questions have a small likelihood of low embarrassment or upset feelings by questions that ask you to think about your access to and understanding of health information, communicating with health professionals, decision-making processes, and obstetric history. As pregnant women are at risk of being fatigued, a potential risk would be contribution to fatigue. The likelihood of physical fatigue is minimal and the 20 minutes to complete the survey are no more than regular waiting times in most clinics.

If you have questions, want more information, or have suggestions, please contact: Tamra Shea, RN, MSN (principal investigator); (828) 545-9809; tlshea@uncg.edu.)AND Denise Côté-Arsenault, PhD (faculty sponsor,); (336) 334-5182; d_cotear@uncg.edu).

If you have any concerns about your rights, how you are being treated, concerns or complaints about this project or benefits or risks associated with being in this study please contact the Office of Research Integrity at UNCG toll-free at (855)-251-2351.

Are there any benefits to society as a result of me taking part in this research?

The study may help us understand prenatal screening from the woman's perspective. Findings will inform interventions and education for care providers to improve prenatal care.

Are there any benefits to *me* for taking part in this research study?

There are no direct benefits to you for participating in this research study.

Will I get paid for being in the study? Will it cost me anything? There is no cost to participate in the study. As an incentive, upon completion of the survey you will be eligible to enter a lottery for one of two \$50 gift cards. Should you choose to withdraw from the study prior to completing the survey, the incentive will not be offered. Entry into the lottery for the gift cards will occur through a linked survey.

How will you keep my information confidential?

All information obtained in this study is strictly confidential and anonymous unless disclosure is required by law. The information that you give in the study will be handled confidentially. Your data will be de-identified which means that your name will not be linked to the data. As this is an online survey, absolute confidentiality of data provided through the Internet cannot be guaranteed due to the limited protections of Internet access. Please be sure to close your browser when finished so no one will be able to see what you have been doing. The de-identified data will be stored in a database stored on a secured server. The de-identified data will be kept for ten years or the completion of all analyses, whichever occurs first.

What if I want to leave the study?

You have the right to refuse to participate or to withdraw at any time, without penalty. If you do withdraw, it will not affect you in any way. If you choose to withdraw, you may request that any of your data which has been collected be destroyed unless it is in a de-identifiable state. The investigators also have the right to stop your participation at any time. This could be because the entire study has been stopped. If you want to withdraw from the study, you may stop answering the survey questions at any time.

What about new information/changes in the study?

If significant new information relating to the study becomes available which may relate to your willingness to continue to participate, this information will be provided to you.

Voluntary Consent by Participant:

By completing this survey, you are agreeing that you read, or it has been read to you, and you fully understand the contents of this document and are openly willing consent to take part in this study. All of your questions concerning this study have been answered. By completing this survey, you are agreeing that you are 18 years of age or older and are agreeing to participate in this study described to you by Tamra Shea.

APPENDIX E

STUDY SURVEY

Maternal Serum Screening Knowledge Questionnaire (MSSKQ)

This part of the survey asks about how you understand and view information on prenatal screening.

DIRECTIONS: The following questions contain a number of statements with which some people agree and others disagree. Please rate how much you personally agree or disagree with these statements by checking on the box next to the response.

1. If the results of the prenatal screen are abnormal, further tests are needed to tell if something is wrong.				
<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neither agree nor disagree	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
2. Women who have a normal prenatal screening can be sure that they will have a healthy baby.				
<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neither agree nor disagree	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
3. The prenatal screen only detects Down syndrome.				
<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neither agree nor disagree	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
4. If the prenatal screen is abnormal, something is usually wrong with the baby.				
<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neither agree nor disagree	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
5. Prenatal screening is not accurate when done at the wrong time of pregnancy.				
<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neither agree nor disagree	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree

6. Having prenatal screening is routine for all women.				
<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neither agree nor disagree	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
7. Amniocentesis can cause miscarriage in 1 in 200 women.				
<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neither agree nor disagree	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
8. Ultrasound can be used to find every kind of birth defect.				
<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neither agree nor disagree	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
9. Amniocentesis is a test of the mother's blood that can detect Down syndrome.				
<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neither agree nor disagree	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
10. The chance of having a baby with Down syndrome is higher the older the mother.				
<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neither agree nor disagree	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
11. All children born with Down syndrome have severe physical and mental disabilities that require lifelong care in an institution.				
<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neither agree nor disagree	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
12. If amniocentesis shows Down syndrome, the only options are to have a baby with Down syndrome or to terminate the pregnancy.				
<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neither agree nor disagree	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree

Satisfaction with Decision Scale

In this part of the survey, we want to learn about your decision-making for prenatal screening for chromosome problems with your baby.

DIRECTIONS: Please answer the following questions about your decisions about prenatal aneuploidy screening to learn if your baby might have a chromosome problem. Please indicate to what extent each statement is true for you AT THIS TIME. (Select one number for each statement.)

1. I was adequately informed about the different options available for prenatal screening for chromosome problems with my baby.

<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neither agree nor disagree	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
--	-----------------------------------	---	--------------------------------	---

2. The decision I made was the best decision for me personally.

<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neither agree nor disagree	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
--	-----------------------------------	---	--------------------------------	---

3. I decision that I made was consistent with my values.

<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neither agree nor disagree	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
--	-----------------------------------	---	--------------------------------	---

4. The expect to continue to carry out the decision that I made about prenatal screening for chromosome problems with my baby.

<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neither agree nor disagree	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
--	-----------------------------------	---	--------------------------------	---

5. I had as much input as I wanted in the choice to use prenatal screening for chromosome problems with my baby.

<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neither agree nor disagree	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
--	-----------------------------------	---	--------------------------------	---

6. The am satisfied with the decision I made for prenatal screening for chromosome problems with my baby.

<input type="checkbox"/> Strongly disagree	<input type="checkbox"/> Disagree	<input type="checkbox"/> Neither agree nor disagree	<input type="checkbox"/> Agree	<input type="checkbox"/> Strongly agree
--	-----------------------------------	---	--------------------------------	---

Questions to Collect Demographic and Obstetric Data

This part of the survey is to learn background information about you and your obstetric history.

DIRECTIONS: Please fill in the blank or circle the number of your answer.

1. Please state your age in years. _____years

2. What is the highest grade you have completed?
 - a. Less than High School Diploma
 - b. High School Diploma or GE
 - c. Some college
 - d. Associate or Bachelor's degree
 - e. Graduate degree

3. Which of these groups best represents your race or national ethnicity?
 - a. American Indian/ Alaska Native
 - b. Asian
 - c. African American
 - d. Caucasian/ White (not Hispanic)
 - e. Hispanic/ Latino
 - f. Hawaiian Native/ Pacific Islander
 - e. Other _____ (fill in)

DIRECTIONS: Please fill in the blanks or select your answer.
Please give details for "If Yes" answer below.

4. Are you currently pregnant? Yes No Not Sure

If Yes, continue to question 5. If no: Skip to question 10.

5. How many weeks pregnant are you? _____

6. Have you been told by your health care provider that an ultrasound done for this pregnancy shows that your unborn child might have a chromosome problem?
Yes No Not Sure

7. For this pregnancy, were you offered a screen to see if your baby might have a chromosome problem?

Yes No Not Sure

If Yes, continue to question 8. If no: Skip to question 9.

8. How was the information about the screen given to you?

Verbal/Oral Written (pamphlet) Discussion Not Sure

9. For this pregnancy, have you had a screen to see if your baby has a chromosome problem?

Yes No Not Sure

10. How many times have you been pregnant?

(including your current pregnancy, if you are pregnant)? _____

11. How many pregnancies have you completed through 20 weeks? _____

12. How many children have you given birth to? _____

13. How would you describe your experience or contact with individuals with disabilities?

Little or none at all Some Above average Frequent

APPENDIX F

HLQ LICENSE AGREEMENT

HLQ Licence Agreement Parties

Deakin University

ABN 56 721 584 203

a body politic and corporate established pursuant to the *Deakin University Act 2009* (Vic) of Locked Bag 20000, 1

Gheringhap Street, Geelong, Victoria, 3220

(Deakin)

The party identified in item 1 of the Schedule

(Licensee)

Background

Deakin and Monash University own the Health Literacy Questionnaire (**HLQ**).

Deakin administers licences to the HLQ on behalf of the owners.

The Licensee seeks to obtain a licence to use HLQ for the Approved Purposes and Deakin has agreed to provide a licence in respect of HLQ (**Licence**) to the Licensee on the terms and conditions of this Agreement.

Agreement

Definitions and Interpretation

Definitions

In this Agreement:

Approved Purposes means the purposes described in **Item 3** of the **Schedule**.

Commencement Date means 14 days following the date on which the last of the parties signs this Agreement.

HLQ means the health literacy questionnaire developed by Richard Osborne, Rachele Buchbinder, Gerald Elsworth and Roy Batterham and more fully described at "The grounded . psychometric development and initial validation of the Health Literacy Questionnaire (HLQ)" *BMC Public Health* 2013, 13:658.

Intellectual Property in respect of HLQ means any and all statutory and other proprietary rights in respect of HLQ recognised at common law, or laws relating to trademarks, patents, circuit layout, copyrights, designs, confidential information, know how and all other rights with respect to Intellectual Property as defined in article 2 of the July 1967 Convention establishing the World Intellectual Property Organisation.

Licence Fee means the fee payable by the Licensee to Deakin during the Term in consideration for the grant of licence to use HLQ. The Licence Fee is set out in **Item 2** of the **Schedule**.

Term means the period identified in **Item 4** of the **Schedule**, which commences on the Commencement Date.

Territory means the territory in which the Licensee is licensed to administer and supply HLQ as identified in **Item 5** of the **Schedule**.

Interpretation

In this Agreement, unless the context requires otherwise, a reference to:

a clause or schedule, is a reference to a clause of or schedule to this Agreement;

'this Agreement' includes any schedules and attachments to this Agreement;

a document or agreement, including this Agreement, includes a reference to that document or agreement as novated, altered or replaced from time to time;

a person, includes a partnership, joint venture, unincorporated association, corporation and a government or statutory body or authority;

'dollars' or '\$' is a reference to Australian dollars;

a business day means a day other than a Saturday or Sunday on which banks are open for business in Melbourne, Victoria and if the day on which a thing is to be done under this Agreement is not a business day, it must be done on the next business day;

any law or legislation includes any statutory modification or amendment of that law or legislation and any subordinate legislation or regulations made under that law or legislation;

writing includes typewriting, printing, photocopying and any other method of representing words, figures or symbols in a permanent visible form;

the word 'include' or 'including' is to be interpreted without limitation;

o) the singular includes the plural and the plural includes the singular; and

(k) a gender includes all genders.

1.3 If a word or phrase is given a defined meaning, other grammatical forms of that word or phrase have a corresponding meaning.

Headings are for reference only and do not affect the meaning of this Agreement.

This Agreement may not be interpreted adversely to a party only because that party was responsible for preparing it.

Licence

Deakin grants to the Licensee a non-exclusive, non-transferable, revocable licence (excluding any right of sub-licence) to use, reproduce and communicate HLQ for the Approved Purposes in the Territory and for the Term, subject to the terms and conditions of this Agreement.

If provided in **Item 6 of Schedule 1**, Deakin grants to the Licensee the right to use the HLQ to prepare and produce a cultural adaptation and/or translation of the HLQ into the language identified in **Item 6 of Schedule 1 (Translation)** subject to the following conditions:

Licensee must undertake the cultural adaptation and/or translation of the HLQ only in accordance with the Translation and Cultural adaptation procedure attached as **Annexure A**;

Licensee must provide a copy of the forward and backward translations to Deakin for approval at least 60 days before Licensee proposes to administer the HLQ (**Administration Date**) to allow sufficient time for review of documents by Deakin, preparation of the provisional final translation of the HLQ, local validation, and finalisation as described in **Annexure A**;

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Deakin will own all Intellectual Property rights in the Translation and the Licensee assigns such rights to Deakin upon their creation.

If, with Deakin's prior consent, the Licensee engages a third party to prepare the Translation, such third party must assign to Deakin in writing all Intellectual Property rights in the Translation. Deakin is entitled to approve the contents of the agreement between the Licensee and third party translator as a condition of providing its consent pursuant to this **clause 2.2(d)**.

The Licensee acknowledges that it may not disclose, use, reproduce, communicate or exploit or permit such disclosure, use, reproduction or communication of HLQ for any purpose other than the Approved Purposes, or in any jurisdiction other than the Territory, unless otherwise agreed in writing with Deakin.

Licence Fee

In consideration for the grant of the Licence for the Term, the Licensee will pay to Deakin the Licence Fee at the times and in the manner set out in **Item 2** of the **Schedule**.

If the Licence Fee is specified in **Item 2** of the **Schedule** as payable annually then, subject to **clause 3.3**, it must be paid annually in advance in each year of the Term. The first payment must be paid on or before the Commencement Date, and thereafter must be paid on or before each anniversary date of the Commencement Date during the Term.

By agreement with Deakin, the Licensee may pay the Licence Fee payable for each year of the Term in a single payment which must be made on or before the Commencement Date.

Deakin reserves the right to revise the Licence Fee for

any use of HLQ in excess of the number of implementations specified in the Approved Purpose; or

any subsequent extension of this Licence Agreement.

Obligations of Licensee

The Licensee must:

ensure that HLQ is used only for the Approved Purposes;

reproduce and communicate HLQ only for the Approved Purposes:

unless permission is granted in **Item 6** of **Schedule 1**, not modify or translate HLQ, without the express written approval of Deakin;

The Licensee will itself administer HLQ. The Licensee acknowledges and agrees that it must implement HLQ in a manner that ensures the monitoring, calculation and reporting by the Licensee of usage of HLQ, and that may (at the sole discretion of Deakin) be readily audited by Deakin.

other than as provided by **clause 2.2**, the Licensee must not, and must not allow or cause any other person to:

print, copy, reproduce or communicate HLQ by any means or in any form;

give, lease, assign, license, sub-license, transfer, distribute, disclose, disseminate or publish HLQ in any form to any other person or attempt to do any of these acts without the written authority of Deakin;

reverse engineer or decompile HLQ; or

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alter, change, remove or obscure any notices or other indications (including copyright notices) as to ownership of HLQ.

The Licensee must provide to Deakin

a de-identified copy of the data in a locked Excel or other standard database agreed with Deakin; and additional non-identifying information about the person to whom the HLQ was administered as determined in consultation with Deakin.

Intellectual Property

The Licensee agrees that all Intellectual Property in HLQ, and any content and/or documentation that accompany and/or are made available through HLQ, and in any modifications, new versions or enhancements to HLQ (whether authorised or unauthorised) belongs to Deakin, and that the only rights the Licensee has in HLQ are those granted to it under this Agreement.

The Licensee agrees that if any modifications (whether authorised or unauthorised) are made to HLQ by or on behalf of the Licensee or as a consequence of the Licensee's use of HLQ, including cultural adaptations and/or translations as set out in **clause 2.2**, all Intellectual Property in such modifications must be assigned to Deakin, and the Licensee will do all things reasonably necessary (including the execution of documentation) to effect such assignment upon request by Deakin.

Warranties and Limitation of Liability

The Licensee agrees that, to the extent permitted by Australian law, all warranties (including implied warranties), other than express warranties given in this Agreement, in respect of the subject matter of this Agreement are excluded and of no effect. Where the exclusion of a given implied warranty would be void or unenforceable, the Licensee agrees that Deakin's liability for a breach of such warranty will be limited, at Deakin's discretion to the re-supply of HLQ or the payment of the cost of the re-supply of HLQ.

For the avoidance of doubt, the Licensee agrees that it uses HLQ entirely at its own risk, and Deakin does not warrant that HLQ is suitable for any particular purpose, that HLQ will function or perform in a particular manner, or that the Licensee will derive any particular result or outcome from its use of HLQ.

The Licensee agrees that Deakin's aggregate liability for all causes of action against Deakin, whether contractual, tortious or otherwise, will not exceed the aggregate of Licence Fees paid by the Licensee as at the date on which the first such cause of action arose. Deakin will not be liable to the Licensee for any indirect or consequential losses, damages, costs and/or expenses incurred or sustained by the Licensee under, or as a result of exercising rights in, this Agreement (including as a result of any negligence by Deakin), and in particular will not be liable for any loss of revenue or profits, loss of data, loss of goodwill or failure to realise an anticipated saving or benefit.

The Licensee agrees to indemnify Deakin from and against liability and all loss and damage of any kind whatsoever caused directly or indirectly by any claim or action against Deakin arising directly or indirectly out of the Licensee's use of HLQ or any breach by the Licensee of the terms and conditions of this Agreement.

Termination

Deakin may terminate this Agreement immediately by giving written notice of termination to the Licensee if the Licensee:

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breaches its obligations in respect of this Agreement and fails to remedy such breach within 14 days of receiving a notice from Deakin specifying the breach, and requesting its rectification; or

fails to pay Licence Fees payable under this Agreement within 30 days of invoice by Deakin,

The Licensee may terminate this Agreement on 30 days' notice to Deakin. Termination by the Licensee under this **clause 7.2** will not attract any obligation for Deakin to reimburse the Licensee any Licence Fees paid by the Licensee to the date of termination.

Upon termination of this Agreement, all licences granted under this Agreement terminate, and the Licensee must immediately cease all use of HLQ.

Termination, completion or expiry of this Agreement for any reason shall not extinguish or otherwise affect:

any rights of either party against the other which:

accrued prior to the time of the termination; or

otherwise relate to or may arise at any future time from any breach or non-observance of obligations under this Agreement which arose prior to the time of the termination, completion or expiry; or

the provisions of this Agreement, which by their nature survive termination (including **clauses 4, 5, 6, 7.3 and 8**).

Confidentiality

The Licensee undertakes to keep secret and protect the confidential nature of all information and documentation provided to it, learnt by it or to which it has or has had access, arising out of or in connection with any aspect of the negotiation or performance of this Agreement including, without limitation, the terms of this Licence Agreement, the Licence Fee, and any source code and object code for HLQ ("Confidential Information"). To this end the Licensee must not use, disclose or in any way communicate to any other person the details of any Confidential Information without the prior written consent of Deakin.

GST

Unless otherwise expressly stated, all consideration to be provided under this Agreement is exclusive of GST.

If GST is imposed on any supply made under this Agreement, unless the consideration for that supply is specifically described in this Agreement as 'GST inclusive', the recipient of the taxable supply must pay to the supplier an additional amount equal to the GST payable on the taxable supply. Subject to the recipient receiving a tax invoice in respect of the supply, payment of the GST must be made at the same time as payment for the taxable supply.

If this Agreement requires a party to pay for, reimburse or contribute to any expense, loss or outgoing of another party, and that other party can obtain an input tax credit on an acquisition associated with the expense, loss or outgoing, the amount required to be paid, reimbursed or contributed by the first party will be the amount of the expense, loss or outgoing reduced by the amount of that input tax credit. The reduction is to be made before any increase for GST under **clause 9.2**.

Terms used in this **clause 9** have the meaning given to them in the *A New tax System (Goods and Services Tax) Act 1999* (Cth).

D

Notices

A notice, demand, consent or other communication (**Notice**) given to a party under this Agreement is only effective if it is in writing delivered or sent by prepaid post to that party at its address set out in this Agreement. Subject to **clause 10.3** a Notice given for any purpose under this Agreement is taken to be received:

if hand delivered, on delivery;

if sent by prepaid post, three (or in the case of a Notice sent to another country, nine) business days after the date of posting;

If any Notice is given on a day that is not a business day or after 5.00pm on a business day in the place of business of the receiving party, it is to be treated as having been given at the beginning of the next business day.

If a party gives the other party three business days' notice of a change of its address a Notice is only effective if it is given to that party at the latest address.

Dispute Resolution

Where there is a dispute concerning this Agreement, a party alleging the dispute must serve on the other party a notice setting out the details of the dispute.

On receipt of a notice under **clause 11.1** senior officers representing each of the parties must meet within five business days and, acting reasonably and in good faith, do their best to resolve the dispute through negotiation.

Neither party may commence any court proceedings (except for applications for urgent injunctive relief) for a period of 20 days after the meeting referred to in **clause 11.2**.

Miscellaneous

Entire Agreement

This Agreement constitutes the entire agreement between the parties as to its subject matter. It supersedes all prior understandings or agreements between the parties and any prior condition, warranty, indemnity or representation imposed, given or made by a party in connection with that subject matter.

Variation

This Agreement may only be altered or varied in writing signed by each of the parties.

Waiver

A waiver of any right under this Agreement must be in writing signed by the party granting it. A waiver is only effective in relation to the particular obligation or breach for which it is given. It is not to be taken as an implied waiver of any other obligation or breach or an implied waiver of that obligation on any other occasion.

The fact that a party fails to do, or delays in doing, something the party is entitled to do under this Agreement does not amount to a waiver.

Assignments and Transfers

A party must not assign or transfer any of its rights or obligations under this Agreement without the prior written consent of the other party.

Part or all of any clause of this Agreement that is illegal or unenforceable in any jurisdiction will be severed in the relevant jurisdiction and the remaining provisions of this Agreement will continue in force. The legality or enforceability of the provision in any other jurisdiction will not be affected.

Costs

Except as otherwise set out in this Agreement, each party must pay its own costs and expenses in relation to preparing, negotiating, executing and completing this Agreement and any document related to this Agreement.

Execution of Separate Documents

This Agreement is properly executed when;
each party executes this document; or

if the parties execute separate but identical documents, when those separately executed documents are exchanged between the parties, including by mail, facsimile transmission or electronically.

Governing Law

This Agreement is governed by the laws of the State of Victoria.

Execution and Date

Executed as an agreement.

Date:

Signed for and on behalf of Deakin University
by its duly authorised officer in the presence of:

[Handwritten signature: Randall]

Signature of witness

[Handwritten signature: Melanie Randall]

Name of witness (please print)

[Handwritten signature: Dr Greg Pullen]

Signature of authorised officer

Dr Greg Pullen
Senior Commercial Manager
Deakin Research Commercial

Name of authorised officer (please print)

Office held

Date: 6/10/2015

Signed for and on behalf of The party
identified in Item 1 of the Schedule by its
duly authorised officer in the presence of:

[Handwritten signature: Kelly Hedgcock]

Signature of witness

[Handwritten signature: Kelly Hedgcock]

Name of witness (please print)

[Handwritten signature: Heidi Kronchuk]

Signature of authorised officer

Heidi Kronchuk
Name of authorised officer (please print)

Associate Dean for Academic Programs
Office held

Date: 6/24/2016

Schedule 1

Licence Number: L1624IF

Item 1 – The Licensee (Parties)

Name: The University of North Carolina at Greensboro

Address: UNCG School of Nursing, PO Box 26170,
Greensboro, NC 27402-6170 USA

Authorised Officer: Dr. Heidi Krowchuk

Tel: (336) 334-4899

Email: heidi_krowchuk@uncg.edu

Item 2 – Licence Fee Waived (for the duration of the term)

Item 3 – Approved Purpose

Purpose: Use of the English HLQ for the project
“Influences on Women’s Decision-Making
Concerning Prenatal Screening”

Number of Authorised
Implementations: 112

Item 4 – Term of Licence

Start Date: 24th June 2016

End Date: 31st December 2017

Item 5 – Territory USA

Item 6 – Cultural Adaptation and/or Translation Rights

*The Licensee does not have a right to prepare or
obtain a cultural adaptation of the HLQ*

*The Licensee does not have a right to obtain a
translation of the HLQ*