

ULTRASOUND RESEARCH TO PRACTICE IN THE PRENATAL DETECTION OF  
CONGENITAL HEART DEFECTS

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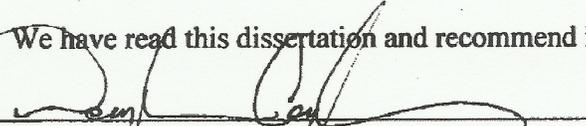
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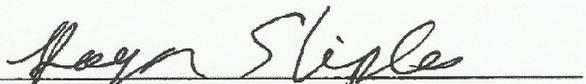
I am submitting herewith a dissertation written by Janai Buentello entitled "Ultrasound Research to Practice in the Prenatal Detection of Congenital Heart Defects." I have examined this dissertation for form and content and recommend that it be accepted in partial fulfillment of the requirements for the degree of Doctor of Philosophy with a major in Health Studies.

  
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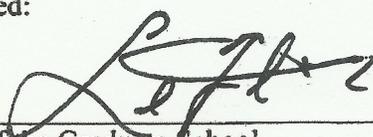
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## DEDICATION

I dedicate this body of work to the following women

who were pioneers in their own right:

To Florence Elizabeth Richardson,

Letha Gibson Thompson,

Helen McKiddy,

and to Evangelina “Nina” Buentello.

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## ABSTRACT

JANAI BUENTELLO

### ULTRASOUND RESEARCH TO PRACTICE IN THE PRENATAL DETECTION OF CONGENITAL HEART DEFECTS

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The American Institute of Ultrasound in Medicine (2013b) recommended the addition of an interrogation process called OFTV to improve prenatal detection rates of critical CHD that represented a significant departure in ultrasound imaging practice. The purpose of this research study was to assess mediating factors or barriers that influenced sonographer's practice of OFTV inclusion during routine obstetrical ultrasounds between 18-22 weeks gestation. Factors included attitude and perceived behavioral control (PBC) toward OFTV inclusion and credentialing status. The relationships between OFTV inclusion, credentialing status, educational attainment, and facility accreditation were also examined. Attitude and perceived behavioral control constructs from the theory of planned behavior served as a theoretical framework. A mixed method approach collected primary quantitative and qualitative datum. The dependent variable was OFTV inclusion. A convenience sample of 109 ARDMS credentialed sonographers in the United States responded to a one shot survey, the majority of who performed obstetrical ultrasounds for more than ten years. Findings revealed that attitude and PBC correlated with OFTV inclusion, with attitude and OFTV inclusion having the highest significant correlation

( $r = .592$ ), at  $p = .01$ . No significant correlation was found between PBC and overall scanning practice behaviors ( $r = .058$ ). At  $p = .01$ , there was a significant correlation between OFTV inclusion and ARDMS obstetrical credentialing ( $r = .279$ ). However, there were no significant correlations between OFTV inclusion and education ( $r = .0060$ ) or OFTV inclusion and facility accreditation ( $r = .009$ ). At  $p = .01$ , results also revealed significant correlations between OB credentialing status and overall scanning practices ( $r = .279$ ). Analyses for the null hypotheses confirmed ARDMS obstetrical credentialing status had the greatest impact on OFTV inclusion. Qualitative analyses revealed maternal obesity and poor fetal lie as the most common barriers to OFTV inclusion. However, the majority of barriers reported were environmental in nature to include time restrictions and scanning protocols. This study provided a baseline translation (adoption rate) of 62% with a rejection rate of 18%. A larger sample of obstetrical sonographers in the United States may provide a fuller understanding of the mediating factors or barriers that influence ultrasound research of OFTV inclusion to bedside practice.

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## CHAPTER I

### INTRODUCTION

Congenital heart defects (CHD) are the most common developmental birth defect affecting approximately one percent of births or approximately 40,000 babies born annually in the United States with CHD. The risk of CHD is six times more likely than Down's syndrome and is four times more likely than spina bifida (Carvalho, Mavrides, Shinebourne, Campbell, & Thilaganathan, 2002). CHD are structural defects in the interior walls of the heart, heart valves, or the arteries and veins that carry blood to and from the heart. Alteration in normal blood flow patterns may affect the heart's structure and function causing congestive heart failure and low birth weight (Knapp, Metterville, Kemper, Prosser, & Perrin, 2010; Mahle & Wernovsky, 2004). Babies with heart defects are often born before 37 weeks gestational age and present with neurological damage that is linked to developmental delays, disabilities, and mild cognitive impairment (Marino et al., 2012). Speech deficits, impaired social interactions, and major organ impairment are also possible, and in severe cases, congenital heart defects may result in neonatal death (Brosig, et al., 2013; Fixler, Nembhard, Salemi, Ethen, & Canfield, 2010).

There are two broad categories of CHD: *common* and *critical*. The words *common* and *critical* characterize CHD in terms of frequency and severity along with the human cost in terms of survival, quality of life, and financial lifetime burden. The March of Dimes (2013) lists *common* CHD as patent ductus arteriosus (PDA), septal defects (atrial

and ventricular), and coarctation of the aorta (COA). Ventricular septal defects are the most frequent type of common CHD in the United States (Botto, Correa, & Erickson, 2001). Specific CHD such as patent ductus arteriosus may resolve spontaneously or with medication. Some atrial septal defects (ASD) may resolve spontaneously. Coarctation of the aorta may be mild or may be lethal.

The most lethal of all congenital malformations are heart related (Hoffman & Kaplan, 2002; Reller, Riehle-Colarusso, Mahle, & Correa, 2008). The March of Dimes (2013) names seven critical congenital heart defects (CCHD): hypoplastic left heart syndrome (HLHS), pulmonary atresia (PA), tetralogy of Fallot (TOF), total anomalous pulmonary venous return (TAOV or TAPVR), transposition of the great arteries (TGA), tricuspid atresia (TA), and truncus arteriosus (Appendix A).

For every four CHDs, approximately one is a severe heart defect coined a *critical* congenital heart defect (CCHD) because of the significant morbidity and mortality that often requires emergent medical and surgical interventions, multiple surgeries, and possibly heart transplantation within the first year of life (Acherman et al., 2007; Sklansky, Berman, Puretz, & Chang, 2009). CCHDs represent 25% of newborn deaths within the first week (Kuehl, Loffredo, & Ferencz, 1999). More than half of CCHD are missed during standard prenatal obstetrical ultrasound in the United States despite near universal coverage of obstetrical ultrasound (Chew, Halliday, Riley, & Penny, 2007).

The economic cost of CHD has been analyzed in terms of expenses before and after birth. These factors translate into pre and postnatal screening, prenatal surgical costs, emergency transportation costs to tertiary centers, length of hospital stays, and

postnatal treatment efficacy in terms of immediate and lifetime costs. The human cost has been described in terms of difficult decisions causing heightened patient anxiety, timing of diagnosis (early to late gestation), false positive results that may result in unnecessary additional expensive screening, increased risk associated with caesarean section, and pregnancy termination secondary to prenatal diagnosis (Bromley, Shipp, Lyons, Navathe, Groszmann, & Benacerraf, 2014; Chasen & Kalish, 2013; Garne, Stoll, & Clementi, 2001; Oztarhan et al., 2010).

In 2004, it was estimated that there was approximately 1.4 million Americans living with CHD with annual hospital costs of more than one billion dollars (Russo & Elixhauser, 2007). Health care services approached \$100,000 for each privately insured newborn affected by a CHD in 2010 (Boulet, Groose, Riehle-Colarusso, & Correa-Villasenor, 2010). Jegatheeswaran et al. (2011) compared emergency transportation costs of \$542,000 to tertiary treatment centers when 147 CCHD were missed during prenatal ultrasounds in Northern California and North Western Nevada. Approximately seventy percent were missed before birth and were 16.5 times more likely to require emergency transport.

Fixler, Nembhard, Xu, Ethen, and Canfield (2012) compared proximity to a cardiac tertiary medical facility and parental acculturation in terms of race/ethnicity, language, and culture to the human cost in terms of life lost within the first year for infants born with a CCHD in Texas between the years of 1996-2003. Fixler et al. reported that distance to a tertiary medical facility and the parental birth country were irrelevant to survival rates; however, Fixler et al. did find that survival was significantly lower ( $P <$

0.05) for infants born with a specific CCHD, hypoplastic left heart syndrome, to families who lived in higher poverty counties bordering Mexico and delayed referrals attributed to fear of applying for federal assistance in non documented immigrant populations.

### **Maternal, Familial, and Fetal Risk Factors for Congenital Heart Defects**

Multifactorial etiology of CHD involving the mother, family, and or fetus has been linked to specific CHD (Donofrio et al., 2014). For instance, pre-gestational or first trimester diagnosed maternal diabetes mellitus has been associated with heterotaxy, truncus arteriosus, d-TGA, and single ventricle defects in the fetus. Poorly controlled diabetes mellitus during pregnancy and gestational diabetes that occur when placental hormones change the way the mother's insulin works increases the risk of third trimester ventricular hypertrophy (enlarged fetal heart chamber) (Donofrio et al., 2014; Lisowski et al., 2010). According to Gilboa et al. (2010) pre-pregnancy obesity with elevated body mass index of greater than or equal to 25.0 kg/m<sup>2</sup> was associated with two types of CHD: conotruncal defects and right ventricular outflow tract defects (RVOT). Conotruncal heart defects such as tetralogy of Fallot, total anomalous pulmonary venous return, and hypoplastic left heart syndrome have been linked to pre-pregnancy obesity. Pulmonary valve stenosis and septal defects (secundum atrial septal defects) are examples of RVOT defects associated with pre-pregnancy obesity (Gilboa et al).

Nearly fifty percent of women 15-49 in the United States are classified as overweight or obese (Racusin, Stevens, Campbell, & Aagaard-Tillery, 2012). According to the American College of Obstetricians and Gynecologists (ACOG, 2013) thirty percent of women in the United States are obese, more than fifty percent are overweight or obese,

and eight percent are extremely obese, placing them at greater risk for pregnancy complications. The National Institute of Medicine uses the following criteria to describe weight among women and men as: normal with a body mass index (BMI) of 18.5 -24.9 kg/m<sup>2</sup>, overweight as a 25-29.9 kg/m<sup>2</sup>, obese as 30 kg/m<sup>2</sup> or greater, with a sub-classification of Class I (BMI of 30-34.9), Class II (BMI of 35-39.9), and Class III (BMI of greater than 40) (National Institute of Health, 2014).

Obesity increases a woman's risk of having a fetus with a heart defect from two to 6.5 fold with specific CHD: atrial and ventricular septal defects, aortic coarctation, and outflow tract defects (Watkins, & Botto, 2001; Watkins, Rasmussen, Honein, Botto, & Moore, 2003). Waller et al. (2007) found that maternal obesity was associated with significantly increased risk for a fetus with a CHD along with other structural defects in a population based study of women enrolled in the National Birth Defects Prevention Study between the years of 1997 – 2002. Marengo, Farag, and Canfield (2013) found increased risk for CHD, specifically atrial and ventricular septa defects, pulmonary valve atresia, and patent ductus arteriosus with increasing body mass index (BMI) during pregnancy. Also, women with a BMI greater than 30.0 kg/m<sup>2</sup> were at substantially higher risk for a CCHD called tetralogy of Fallot.

Uncontrolled maternal phenylketonuria (PKU), maternal autoimmune antibodies (SSA) / SSB), in vitro fertilization (IVF) (IVF alone and IVF with ICSI) are maternal risk factors for CHD (Davies et al., 2012; Rimm, Katayama, & Katayama, 2011). Maternal exposure to known teratogens that may cause embryologic malformations include anticonvulsants (Matalon, Schechtman, Goldzweig, & Ornoy, 2002; Okuda & Nagao,

2006), Lithium, ACE inhibitors, retinoic acids, excessive doses of Vitamin A, and selective serotonin uptake inhibitors (Lattimore et al., 2005), Vitamin K antagonists (Coumadin), and first trimester exposure to non-steroidal anti-inflammatory drugs (Donofrio et al., 2014). Maternal infections such as rubella in the first trimester (Botto, Lynberg, & Erickson, 2001) may cause specific CHD along with parvovirus (Fifth's disease), cytomegalovirus (CMV) and Coxsackie virus (Simpson, 2009), which may increase the risk of fetal heart inflammation (myocarditis).

Familial risk factors for a CHD are related to partial absence of chromosome 22 called 22q11.2 deletion syndrome (aka: autosomal dominant Opitz G/BBB syndrome or CATCH22), Alagille's syndrome, trisomy 21 (Down's syndrome), Turner's and Noonan's syndrome (Donofrio et al., 2014; Jones, 1997). Chromosomal abnormalities make up about 15% of infants with CHD with the majority found in trisomies 13, 18, 21, and Turner's syndrome (Donofrio et al., 2014). Ventricular septal defects and atrial ventricular septal defects are frequently associated with chromosomal anomalies. Maternal and paternal structural heart defects may also increase the risk of a CHD in an offspring (Oyen et al., 2009).

In obstetrical ultrasound imaging, fetal risk factors for CHD are related to an abnormal appearing fetal heart and or non-cardiac related fetal abnormalities. Suspicion is raised when the standard 4-chambered view (4CV) and or the OFTV are abnormal, when the heartbeat is irregular, (arrhythmia / dysrhythmia), or the heart beats faster (tachycardia) or slower (bradycardia) than normal.

Fetal anomalies unrelated to the fetal heart are referred to as extracardiac anomalies that alert sonographers of the potential of a CHD (Yagel et al., 1997; Yagel, Arbel, Anteby, Raveh, & Achiron, 2002; Donofrio et al., 2014). Examples of extracardiac anomalies that place a fetus at higher CHD risk are an abnormal fetal neck swelling (edema) measured the first trimester nuchal translucency ultrasound, a single umbilical artery instead of two, an umbilical cord cyst, and monochorionic twins with twin-to-twin transfusion (Donofrio et al., 2014). According to Bahtiyar, Dulay, Weeks, Friedman, and Copel (2007) monochorionic / diamniotic twins have an approximately 9-fold increased risk for CHD and a 13-14 fold increased risk when complicated by twin-to-twin transfusion syndrome. Other extracardiac abnormalities seen during ultrasounds that may increase the fetal risk CHD risk include abnormal fetal body fluid collection called fetal hydrops, and a diaphragmatic hernia where a hole in the fetal diaphragm allows organs such as the stomach, liver, or intestines to seep into the chest cavity. Boyd, et. al., (2012) concluded that “the sonographer’s awareness of the signs and symptoms of intrauterine conditions and subtle changes exhibited by fetuses can facilitate early diagnosis, intervention, and treatment...reducing the morbidity and mortality” rates (p. 255).

### **Surveillance and Prevalence of Congenital Heart Defects**

Forty-one states have birth defects tracking programs that report data to the National Birth Defects Prevention Network (Centers for Disease Control and Prevention [CDC], 2012). The CDC funds 14 population based state programs located in Arizona, Colorado, Oklahoma, Louisiana, Florida, Puerto Rico, Minnesota, Michigan, Illinois, Kentucky, Ohio, New Hampshire, New Jersey, and Rhode Island who have established

interest, resources, and community engagement. Federally funded state-based tracking programs monitor over 40 different birth defects to include CHD in order to estimate prevalence data (National Center on Birth Defects and Developmental Disabilities, 2015).

The actual prevalence of CHD is difficult to determine because of the uncertain verification methods used to collect data throughout the United States. Pierpont et al. (2007) suggested that the prevalence of CHD was underreported because of exclusion criteria used and could reach 50 per 1000 per live births. Early diagnosis in the first trimester of a CCHD has also been shown to reduce CHD prevalence when pregnancy termination occurred (Chasin & Kalish, 2012; Oztarhan et al., 2010).

The National Birth Defects Prevention Network (NBDPN) with the CDC has reported prevalence data from population-based surveillance programs since 1997 (NBDPN, 2011). Active case ascertainment and passive case ascertainment with or without confirmation are systematic retrieval methods employed in various states. Active case ascertainment involves trained professionals sent to collect on-site data from medical records such as clinical notes, imaging reports, and autopsy records. In contrast, passive retrieval methods rely on hospital employees to supply information to state health authorities; however, active case ascertainment is costly to maintain. Data is used to study epidemiological cluster events, disease etiology and trends, prevention efforts and state allocation of finite resources for interventions. Statistics assist policy makers and health providers to care for affected infants and families.

## **Ultrasound Imaging of Congenital Heart Defects in Clinical Practice**

Over the last decade, physicians outside of the United States have reported significantly increased prenatal detection rates of CHD using obstetrical ultrasound (Carvalho et al., 2002). Two key factors improved detection rates: physician's attitude toward risk status and ultrasound imaging protocol. Carvalho and colleagues began using a new protocol screening *every* fetus for CHD during routine 18-22 week ultrasounds, regardless of family history or exposure to teratogens (2002).

The change in ultrasound screening protocol involved adding an interrogative process that views the ventricular outflow tracts to the standard, but limited four-chambered heart view (4CV) (Chaoui, 2003; Friedberg et al., 2009). Outflow tract views (OFTV) included those CCHD that were missed using only the 4CV (Simpson, 2009; Sklansky, Berman, Poretz, & Chang, 2009) (Appendix B). The International Society of Ultrasound in Obstetrics and Gynecology (2013) and the Australasian Society for Ultrasound in Medicine (2014) added OFTV to their standard scanning protocols. Based on evidentiary research, major medical organizations in the United States consensually agreed upon this practice standard change in 2013 via clinical practice guidelines for the performance of routine obstetrical ultrasound (ACR, 2014; American Institute of Ultrasound in Medicine [AIUM], 2013b; Kirk et al., 1997; Lee, 1998).

Medical organizations in the United States generating practice guidelines for routine obstetrical ultrasound are the AIUM, the American College of Radiology, the American College of Obstetricians and Gynecologists (ACOG), and the Society of Radiologists in Ultrasound (AIUM, 2013b). Clinical practice guidelines for a targeted

ultrasound of the fetal heart called fetal echocardiograms and were established by the AIUM in conjunction with the ACOG, the Society of Maternal Fetal Medicine (SMFM), and the American Society of Echocardiography (ASE) and endorsed by the ACR (AIUM 2013d). As of 2013, OFTV inclusion is now considered standard practice behavior for routine obstetrical ultrasounds between 18-22 weeks gestation as well as fetal echocardiography.

Practice guidelines maximize detection rates of disease, reduce clinical indecision, and promote equitable care (AIUM, 2013; Institute of Medicine [IOM], 2011). The AIUM practice guidelines are issued to physicians responsible for interpreting medical ultrasounds and supervising non-physicians who perform obstetrical sonography. Many, but not all non-physicians who practice sonography in the United States, are called diagnostic medical sonographers (sonographers). However, the AIUM practice guidelines directly influence sonographers' scope of practice, code of ethics, protocols, and scanning repertoires (Society of Diagnostic Medical Sonography [SDMS], 2000).

OFTV inclusion during routine obstetrical ultrasounds performed between 18-22 weeks gestation was a significant departure in bedside practice requiring education, extensive training, additional performance time, and adequate equipment (Carvalho et al., 2002; Sklansky, 2007, Scott et al., 2008). No empirical evidence was found in the literature review to suggest that uptake of this clinical recommendation was embraced by those whose attitudes and practice behaviors would by necessity require change. Translation of this research of OFTV inclusion to practice would require commitments from key stakeholders. Physicians who agreed with the evidence would prescribe OFTV

in scanning protocols. Sonographers would become skilled in the interrogation process and medical facilities were to provide adequate allocation of time and training to add OFTV in order to improve CHD detection rates.

The AIUM clinical practice guidelines acknowledge the operator dependency inherent in the immediate, real-time data analysis that occurs during an ultrasound. The pregnant mother, fetus, and ultrasound imaging equipment are also recognized by the AIUM as potential barriers (AIUM, 2013a). Sonographer's dispositional attitude toward translating this research to practice, their current clinical practice behaviors, perceived behavioral control, subjective norms operationalized as professional norms, perceived barriers, and intent to follow recommended guidelines have yet to be fully explored.

### **Statement of the Purpose**

The purpose of this research study was to assess mediating factors or barriers which influenced sonographer's practice of OFTV inclusion during routine obstetrical ultrasounds between 18-22 weeks gestation. Factors included attitude and perceived behavioral control toward OFTV inclusion and credential status. The relationships between inclusion of OFTV, credential status, education, and facility accreditation were also examined. The theory of planned behavior served as a theoretical framework.

### **Research Questions**

The following questions were addressed in this study:

1. How do sonographer's attitudes and perceived behavioral control toward the inclusion of ventricular OFTV in routine obstetrical ultrasounds between 18-22 weeks gestation relate to practice behaviors?

2. What relationship exists between sonographer's attitudes toward the inclusion of OFTV in routine obstetrical ultrasounds and sonographer's demographic characteristics of credentialing, educational attainment, and facility accreditation?

### **Hypotheses**

Two null hypotheses were tested at the .05 level of significance:

HO<sub>1</sub>: There will be no statistically significant difference toward the inclusion of OFTV in routine obstetrical ultrasounds between sonographers with ARDMS credentials in obstetrics and sonographers without ARDMS credentials in obstetrics.

HO<sub>2</sub>: There will be no statistically significant difference toward the inclusion of OFTV in routine obstetrical ultrasounds between sonographers who seek advanced ultrasound certification and sonographers who do not seek advanced ultrasound certification.

### **Delimitations**

Potential study participants were considered eligible if they were:

1. Sonographers who practiced medical ultrasound in the United States included on a rented list provided by the ARDMS.

### **Limitations**

The study was limited by the following:

1. Self-reporting with no observation of direct practice behavior.
2. Non-physician sonographers practicing in the United States.
3. Participant's recall bias (faulty memory) that might influence responses.

## **Assumptions**

This researcher assumed that all participants provided honest answers.

## **Definitions of Terms**

*AIUM*: American Institute of Ultrasound in Medicine is a multidisciplinary organization of physicians, sonographers, educators, scientists, ultrasound manufacturers, and engineers interested in ultrasound education and professionalization. The AIUM provides clinical practice guidelines and facility accreditation in order to maximize the efficacy of ultrasound practice by reducing uncertainty in clinical decisions and to promote equitable patient care (AIUM, 2013b; Kurtz, 2003).

*American College of Obstetricians and Gynecologists (ACOG)*: provides evidence based education, encourages integration of research to practice and scholarship, and values women's access to quality health care (ACOG, 2009).

*American College of Radiology (ACR)*: membership organization of radiologists, radiation oncologists, and medical physicists in the United States with purpose to advance radiologic science and provide practice guidelines (ACR, 2014).

*American Registry of Diagnostic Medical Sonography (ARDMS)*: provides credentialing in several ultrasound specialties of which obstetrical ultrasound and fetal echocardiography are included (ARDMS, 2014).

*American Society of Radiologic Technologists (ASRT)*: professional organization for radiologic science professionals; provides continuing education, peer-reviewed journals.

*Australasian Society for Ultrasound in Medicine: (ASUM)* Australian and New Zealand multi-disciplinary society advances clinical ultrasound practice by disseminating scientific information, setting standards of practice (ASUM, 2015).

*Diagnostic Medical Sonographer (sonographer):* individual qualified by professional credentialing, academic, and clinical experience with demonstrated competency to provide diagnostic information to a supervising physician.

*Diagnostic Medical Sonography:* field of medicine using sound waves to diagnosis disease with concentrations in general, cardiac, vascular ultrasound concentrations.

*Fetal Echocardiography:* a targeted ultrasound identifying and characterizing CHD going beyond interrogation of the 4CV and OFTV performed by advanced practice sonographers and perinatologists, obstetricians and radiologists with advanced training, and pediatric cardiologists (AIUM, 2013a).

*Four-chambered view: (4CV)* an interrogative process of the fetal heart performed during routine obstetrical ultrasound between 18-22 weeks gestation.

*International Society of Ultrasound in Obstetrics and Gynecology:* professional membership association and charity with 9,000 members and 126 countries promoting education and research in obstetrical/gynecological ultrasound (ISUOG, 2014).

*Maternal fetal medicine specialists (MFMS) / perinatologist:* obstetricians with additional years of education in the management of complicated pregnancies.

Obstetricians typically refer pregnant women when a CHD is suspected to MFMS who may provide services such as fetal echocardiography, amniocentesis, and genetic counseling in tertiary centers (Sciscione et al., 2014).

*Nuchal translucency screening:* Non-invasive, first trimester ultrasound with maternal serum biochemical markers to screen for fetal anomalies and chromosomal defects.

*Outflow tract views (OFTV):* aka: ventricular outflow tract views are an interrogative process of the great cardiac vessels using sound waves to detect CCHD.

*Protocol:* a procedure for carrying out a scientific experiment (Merriam's –Webster's online dictionary, 2014); a standardized procedure ensuring consistency and equity.

*RDCS:* registered diagnostic cardiac sonographer credentialed by the ARDMS.

*RDMS:* registered diagnostic medical sonographer credentialed by the ARDMS in any one or more specialties: abdomen, adult echocardiography, breast, fetal echocardiography, pediatric echocardiography, neurosonology, obstetrics & gynecology and vascular technology used to identify and characterize disease.

*RT (R):* registered radiologic technologist credentialed by the American Registry of Radiologic Technologists (ARRT).

*RT (S):* registered in general sonography by the American Registry of Radiologic Technologist (ARRT).

*Society of Diagnostic Medical Sonography (SDMS):* largest ultrasound organization established in 1970, with over 28,000 members who are primarily sonographers; publishes a scientific journal, formulates clinical practice standards, scope of practice, and ethics for sonographers (SDMS, 2014).

*Society of Radiologists in Ultrasound (SRU):* founded in 1993 to advance the specialty of ultrasound in the practice of radiology.

*Teratogen*: something that causes a malformation of an embryo (Merriam's –Webster's online dictionary, 2014); may be genetic, environmental, medication exposure.

*Toward the inclusion*: a positive attitude toward the OFTV inclusion was seen as occurring along a behavioral spectrum beginning in an initial adoption phase of occasionally attempting OFTV to always attempting OFTV where always attempting OFTV represents full adoption or complete translation of research to practice.

*Ultrasound (sonogram)*: ultrasound is the electromagnetic energy used to perform a sonographic examination (sonogram). Both the public and medical professionals commonly interchange these words.

### **Importance of the Study**

The change in attitude toward risk status and practice behavior by physicians outside of the United States performing routine obstetrical ultrasound prompted the AIUM to recommend protocol changes in performance of routine obstetrical ultrasound between 18 -22 weeks of gestation. Surveying sonographers about their attitude and perceived behavioral control may help to better understand the process of translating research to practice with the adoption of the AIUM clinical practice guidelines. This research study provided baseline data on factors that mediated adoption of new practice behaviors. By identifying potential modifiable factors, health educators may assist in the translation process by designing, implementing, and formally evaluating continuing education programs that support OFTV inclusion in routine obstetrical ultrasound.

## CHAPTER II

### REVIEW OF THE LITERATURE

The purpose of this research study was to assess the mediating factors or barriers that may influence sonographer's practice of OFTV inclusion during routine obstetrical ultrasounds between 18-22 weeks gestation. Factors included attitude and perceived behavioral control toward OFTV inclusion and credential status. The relationships between inclusion of OFTV, credential status, educational attainment, and facility accreditation were also examined. Constructs from the theory of planned behavior served as a theoretical framework. *EBSCOhost*, *PubMed*, and *CINHAL* databases were primarily used for this literature review through the *Texas Woman's University's* library. English-only articles limited the search. Examples of key search words began with: clinical practice guidelines, congenital heart defects, critical congenital heart defects, fetal echocardiography, prenatal surveillance, and the theory of planned behavior. Eleven focal areas were retrieved from this literature review: *diagnostic medical sonographers in the United States*, *ultrasound workforce in the United States*, *clinical practice guidelines*, *the 4CV and OFTV*, *efficacy of the 4cv and OFTV*, *supervising physicians and diagnostic medical sonographers*, *ultrasound scanning protocols*, *prenatal ultrasound surveillance of CHD*, *ultrasound-related barriers to imaging the fetal heart*, *adherence barriers to clinical practice guidelines*, and *the Theory of Planned Behavior*.

## **Diagnostic Medical Sonographers in the United States**

In the 1960s, ultrasound technology became an accepted diagnostic tool for radiology, obstetrics, and cardiology (Hall, 2003). Radiologists and radiologic technologists originally provided a makeshift workforce (Berman, 1983). The inherent synergism between sonographic machine and individual delivering immediate results (Evans, 2007, Filly, 1998) necessitated a practice change affecting the attitude and practice behaviors of the existing workforce that consisted of primarily radiologic technologists (American Society of Radiologic Technology [ASRT], 2013; U. S. Department of Labor, Bureau of Labor Statistics, [BLS] 2014).

The medical application of ultrasound technology required the development of a highly specialized workforce. With the purchase of ultrasound equipment, ultrasound machine manufacturers hired medical ad hoc application specialists for on-site, cursory, one-on-one technical training. Leading commercial vendors hosted national seminars where early adopters could share their medical discoveries using this non-invasive, non-ionizing energy source (Baker, 2007; Hagen-Ansert & Baker, 2007).

The American Society of Ultrasound Technical Specialists, was established in 1970 (Hagen-Ansert & Baker, 2007) which later changed its name in 1980 to the Society of Diagnostic Medical Sonography (SDMS) to reflect its membership diversity. The SDMS gathered practice communities together, provided educational venues and a platform for sonographers to present their research. The SDMS helped framed the sonographer's scope of practice, clinical practice standards, and code of ethics that promoted quality, equity, and individual accountability (Baker, 2007; Boodt, 2004;

Hagen-Ansert, 2006; SDMS, 2014). The SDMS hosts annual conferences, awards, continuing medical education, provides the *Journal of Diagnostic Medical Sonography*, and webinars on the fetal heart imaging (Baker & Whitney, 2012).

Over time a didactic curriculum was developed for hospital and college-based ultrasound programs with supervised hands-on clinical training (Anderhub, 1985, 1987; Lea, 1985). Medical university teaching hospitals served as primary education sites with the latest ultrasound equipment. Tertiary centers became research hubs where population-based studies were ideal for testing scanning protocols such as the 4CV and OFTV, and defining populations at risk (DeVore, 1992; Jeffrey & Laing, 1982). ARDMS credentialed sonographers became the backbone of ultrasound research establishing ultrasound's efficacy in obstetrics, perinatology, and radiology (Bendick, 2012; Clark et al., 2009; Trivedi et al., 2012).

Programmatic peer-reviewed assessment and recommendations for accreditation of ultrasound programs began in 1982 with the Joint Review Committee on Education in Diagnostic Medical Sonography (JRCDMS) (Baker, 2005; Kuntz, 2004). The Commission on Accreditation of Allied Health Education Programs (CAAHEP) was sought to assure the public that qualified graduates would provide equitable care, with knowledge of basic scanning protocols (Andrist, 2001; Boodt, 2004; CAAHEP, 2011; Hagen-Ansert, 2006; SDMS, 2000; SDMS, 2014). Currently, CAAHEP accredits over two hundred-ultrasound programs in the United States with learning concentrations in general, cardiac, and vascular ultrasound. Obstetrical and abdominal ultrasound is included in the general learning concentration (CAAHEP, 2014).

*CAAHEP Standards and Guidelines* for programmatic accreditation were endorsed by the American College of Cardiology, American College of Radiology, American College of Obstetricians and Gynecologists, American Institute of Ultrasound in Medicine, American Society of Echocardiography, American Society of Radiologic Technologists, Society of Diagnostic Medical Sonography, Society for Vascular Surgery, and Society for Vascular Ultrasound. Multiple medical disciplines necessitated a broad spectrum of foundational knowledge and clinical training for graduates (Hagen-Ansert & Baker, 2007). Currently, graduates are expected to identify congenital / genetic anomalies such as CHD using physician proscribed protocols (CAAHEP, 2011).

Sonographers in the United States and Canada described their work experience as investigative in nature, each choosing the degree of interrogation necessary to provide clinical information based on their level of suspicion (Bendick, 2012; Filly, 1998; Finberg, 2004; Persutte, 2002). Sonographer's concern for diagnostic quality (Bastian et al., 2009; Brahee et al., 2013; Persutte, Dubose, & West, 2002) and the ability to provide equitable care has been specified in the sonographer's code of ethics (Boodt, 2004).

Because of the critical nature of ultrasound results, practicing sonographers modeled for students an evidence-based framework for developing decision-making ultrasound skills (Baun, 2004; CAAHEP, 2011). The teaching linchpin was the application of the scientific methodology of observation, hypothesis, data collection, data analysis, and conclusion making (Bendick, 2012; Evans & Boyce, 2008; Newberry, 2009; Rapp, 1995). Students were taught to compare and contrast their ultrasound findings with patient charts, previous diagnostic imaging, and laboratory results (CAAHEP, 2011).

Educators knew that hands-on experience was key to teaching ultrasound students how to identify CHD. According to Tegnander and Eik-Nes (2006) clinical, hands-on experience had a significant impact on detection rates of CHD in a ten-year study of sonographer/midwives. Currently CAAHEP (2011) accredited programs require ultrasound programs to provide clinical exposure for a minimum of 500 completed obstetrical/gynecologic examinations and because of the exactness of skills required to identify their real time analysis of pathology; a “student / clinical staff ratio not greater than one-to-one (p. 4)”. In an ARDMS task force survey, sixty-six percent of obstetrical sonographers (n=639) reported participating in clinical teaching activities with sonography students (DuBose, Weinberg, Carlton, Diacon, & Balderston, 2006).

Few ultrasound textbooks were available when formal ultrasound programs were first established. Didactic educators depended on practicing sonographers to provide case studies, published medical books and journals, live human models and cadavers, and ultrasound simulators to brand indelible images of normal anatomy and pathology in the student’s mind (Miller & Dunn, 1997; Roll, Selhorst, & Evans; 2014). Phantoms were used to teach diagnostic ultrasound image quality, acoustical physics, and safe exposure levels (Boyce, 1993; Damewood, Jeanmonod, & Cadigan, 2011).

Unlike textbook images, real-time imaging was a dynamic process that produced a visual status report of the native fetal heart (Sklanksy, 2007). Interrogation required the sonographer to sift through layers of tissues planes using a probe placed on the maternal belly with gel to displace the air. The sonographer manipulated the probe using a combination of sliding, rocking, tilting, and rotating, while applying a downward

pressure in order to achieve a saturation point in discovery necessary to make real time judgments in terms of normal, abnormal, or indeterminate findings (AIUM, 1999).

Psychomotor skills specific to sonographers involve visuomotor and visuospatial skills.

According to Nicholls, Sweet, & Hyett (2014) visuomotor skills or eye-hand coordination required the sonographer to retrieve learned mental images of a normal 4CV or OFTV manipulating the probe until a match could be made. However, visuospatial skills required the sonographer to create 3-dimensional mental images in real time. According to Hedrick (2005) the diagnostic value was dependent on the sonographer's knowledge of cross-sectional anatomy, pathophysiology, blood flow dynamics (hemodynamics), and acoustic physics (Hedrick, 2005). Cognitive, visuomotor, and visuospatial skills have been practiced at clinical sites in a real life environment exposing students to varying levels of training in anatomy and pathology detection using clinical resources.

Many physicians suggested CHD detection is dependent on the sonographer's knowledge, training, and experience (Abu-Rustum, Ziade, & Abu-Rustum, 2011; Buskens et al., 1996; Simpson, 2009; Wong, Chan, Cincotta, Lee-Tannock, & Ward, 2003). Tertiary medical research centers where population-based studies occurred because of inherent pathology clusters provided clinical resources for training and exposure to fetal heart pathology. Sonographers who migrated into formal teaching institutions, practicing sonographers, and students benefited from an eddy effect where sharing of current information on disease trends and new research techniques such as OFTV inclusion were commonplace (CAAHEP, 2011, Letourneau et al., 2013; Rapp, 1995). Achiron, Glaser, Gelernter, Hegesh, & Yagel (1992) reported that sonographers

provided visual data in a population-based study of CHD (N=5,400) between 1988 and 1990 finding that CHD occurred more frequently in low risk populations that had no identifiable risk factors. Dashe, McIntire, & Twickler (2009a) concurred that seventy-eight percent of CHD were identified in a low risk population where a hand-full of sonographers performed 10,112 ultrasounds from 2003-2007.

### **Ultrasound Workforce in the United States**

According to the BLS (2012) approximately 57,700 diagnostic medical sonographers worked primarily in general medical and surgical hospitals. Others reported employment in physician's offices, medical and diagnostic laboratories, outpatient care centers, and colleges, universities and proprietary schools. California, Florida, Texas, New York, and Pennsylvania employed the majority of sonographers.

In 1975, the American Registry of Diagnostic Medical Sonography (ARDMS) began credentialing individuals who demonstrated minimum entry-level medical knowledge of ultrasound with the successful completion of two board examinations: acoustical physics with at least one specialty examination (Early, 1985; Lea, 1985). The ARDMS (2014) currently provides credentialing in ten ultrasound specialties: abdomen, breast, fetal echocardiography, neurosonology, obstetrics and gynecology, pediatric sonography, adult echocardiography, fetal echocardiography, pediatric echocardiography, and vascular technology. Multi-credentialing that required additional education and training has become common among sonographers.

As of November 2013, there were approximately 38,691 obstetrical sonographers and nine hundred eighty nine fetal echocardiographers credentialed in the United States

(Bethesda List Center [BLC], 2014). The Cardiovascular Credentialing International agency and the American Registry of Radiologic Technology (ARRT) has also credentialed ultrasound professionals. The ARRT census of January 2015 reported 869 radiologic technologists credentialed in general sonography (ARRT, 2015).

According to the U. S. Department of Health and Human Services' National Center for Health Statistics (2013) there were 24,535 radiologists / diagnostic radiologists and 34,083 obstetricians / gynecologists reported in the United States in 2010. According to Rayburn, Klagholz, Elwell, & Strunk (2012) there were 1,355 maternal fetal medicine specialists (MFMS) in the United States in 2010 with one MFMS for every 24 general obstetrician / gynecologist and one MFMS for every 3,150 births.

### **Clinical Practice Guidelines**

Clinical practice guidelines are recommendations to physicians used to maximize detection rates of disease, reduce clinical indecision, and promote equitable care (AIUM, 2013; IOM, 2011). According to Rosenfeld and Shiffman (2009) practice guidelines improve diagnostic accuracy by addressing practice variation when clinical indecision is reduced. Practice guidelines are updated periodically using expert consensus of best practices for patient management typically based on randomized clinical trials, unpublished data, and peer-reviewed journals. Professional organizations with extensive research staff typically dispense practice guidelines with item lists and an explanation (Graham, 2014). Grading systems may accompany practice guidelines using the adjectives *good, fair, insufficient, or conflicting evidence* for the recipient's use in deciding to accept or reject proposed practice changes (Agency for Healthcare Research

and Quality, 2011). Accreditation agencies may use practice guidelines as an evaluation tool or rubric to measure adherence (Rosenfeld & Shiffman, 2009). AIUM accreditation promotes guideline compliance by performing film analysis and sonographer credentialing (Abuhamad, Benacerraf, Woletz, & Burke, 2004). How accreditation status influences the AIUM recommendation to include OFTV is unknown.

The AIUM clinical practice guidelines issue recommendations to physicians responsible for interpreting medical ultrasounds. Clinical practice guidelines neither set legal precedents nor dictate procedural exclusivity. The AIUM, ACR and the Inter-societal Commission for the Accreditation of Echocardiography Laboratories (ICAEL) accredit ultrasound facilities as an outward sign of meeting or exceeding a level of excellence (Having, Barwick, & Collins, 2011). The AIUM, ACR, ACOG, and the SRU developed clinical practice guidelines to maximize the efficacy of medical ultrasound practice by reducing uncertainty in clinical decision-making. These collective organizations exemplify what Zerhouni (2006) meant by the need for a coordinated effort to reduce disease burden and “accelerate the application of new knowledge and techniques at the front line of clinical practice” (p. 172). Clinical practice guidelines are updated periodically to inform physicians about new evolving knowledge.

### **The 4CV and OFTV**

Jeffrey and Laing (1982) predicted the near-universal medical adoption of prenatal ultrasound screening for CHD using the 4CV view of the heart. As part of a standard examination of the fetal anatomy performed between 18-22 weeks gestation, the

AIUM clinical practice guidelines (AIUM 2003) suggested interrogation of the fetal chest to include the 4CV and if technically feasible, OFTV.

Obtaining a satisfactory 4CV requires the heart to be located in the left chest, with approximately equal-sized ventricles, approximately equal-sized atrias, an intact primum portion of the atrial septum, the foramen ovale that flaps into the left atrium, offset atrioventricular valves, and an intact interventricular septum (Lee, 1998).

In 2013, OFTV became a standard in routine obstetrical ultrasounds performed in the United States (AIUM, 2013b). The sonographer begins the OFTV interrogation at the familiar 4CV. The probe is angled cephalic (toward the fetal head) when the interventricular septum is tangential to the ultrasound beam. The left and right ventricular outflow tracts should originate in their perspective ventricles with the left ventricular outflow tract coursing toward the right fetal shoulder and the right ventricular outflow tract coursing from anterior to posterior crossing the aorta (Lee, 1998). The sonographer follows the mix-master effect of the heart's great vessels to ascertain whether the vessels are of approximate size and that the vessels cross each other at right angles from their origins as the vessels exit the ventricular chambers (Lee).

### **Efficacy of the 4CV and OFTV**

Retrospective film analysis, patient chart review, patient interviews, and or data culling from birth defect registries have dominated inquiry about scanning protocols such as the 4CV and OFTV in prenatal detection of CHD using ultrasound technology (Chew et al., 2007; Dashe et al., 2009a; Donofrio et al., 2014). Copel Pulu, Green, Hobbins, & Kleinman (1987) found the 4CV to have ninety percent sensitivity and almost hundred

percent (99.7%) specificity for CHD when performed after eighteen weeks gestation. Achiron et al. (1992) reported an increased sensitivity from 48% to 78% with a positive predictive value from 92% to 95% with extended interrogation using OFTV. Unfortunately, more than half of CCHD were reported missed despite near-universal ultrasound coverage (Acherman et al., 2007; Chew et al., 2007). Ogge, Gaglioti, Maccanti, Faggiano, & Todros (2009) evaluated the combination of 4CV and OFTV in large scale, population-based study finding a 65% sensitivity with a specificity of 99.7% and predictive value of 70.4%. Ogge et al. found the 4CV to have a sensitivity of 60.3% attributing the results to additional training of existing operators who had years of experience and improved equipment. Sklansky, Bermna, Pruetz, and Chang (2009) reported that OFTV were more sensitive than the 4CV in detection of ductal dependent CHD that potentially require emergent care. The 4CV excludes portions of the heart most closely related to CCHD that could benefit from early detection.

Therefore, in 2003, AIUM clinical practice guidelines began encouraging OFTV inclusion by stating, “if *technically feasible*, [italics added] an extended basic cardiac examination can also be attempted to evaluate both outflow tracts (AIUM, 2003, p. 1122).” In 2007, AIUM clinical practice guidelines stated, “*if technically feasible*, [italics added] views of the outflow tracts should be attempted as part of the cardiac screening examination (AIUM, 2010, p. 163)”. The 2013 AIUM practice guidelines accelerated compliance by dropping the words “if technically feasible”, “can be also attempted”, and “should be attempted” by including OFTV to the master list of recommendations for a routine obstetrical ultrasound (AIUM, 2013b).

In 2013, interrogation of the OFTV was added as a minimum standard of practice to complement the 4CV (AIUM, 2013b) to maximize detection of CCHD seen only with OFTV. This practice may potentially translate into increased screening sensitivity of CCHD lowering mortality rates by improving neonatal outcomes with early detection (Simpson, 2009; Sklansky et al., 2009).

### **Supervising Physicians and Diagnostic Medical Sonographers**

Physicians in the United States are legally responsible for interpreting medical ultrasounds and supervising non-physicians who perform them (AIUM, 2013b). Physicians serve as medical directors in accredited ultrasound programs (CAAHEP, 2011). Physician's input helped to frame the sonographer's *Scope of Practice* and they continue to advise on practice issues (SDMS, 2000).

Physicians employ two levels of clinical supervision: general and direct (SDMS, 2000). General supervision does not require the physician's presence in the ultrasound laboratory or office suite when an ultrasound is performed. Direct supervision requires the physician's physical presence. However, physicians working in AIUM accredited sites must have a mechanism to address emergency findings for the referring physician and patient who may leave the facility before the physician interprets the ultrasound, and ultrasounds must be interpreted by the end of the next business day (AIUM, 2010b).

The hierarchical relationship and the multidisciplinary nature of ultrasound supervision was characterized by Acherman et al. (2007) when describing the referral process of patients with a suspected CHD to a tertiary center from community hospitals, imaging centers, and physician's offices. Acherman et al. qualified the level of

supervision for fetal echocardiography performed in a tertiary center as “under the real-time supervision of a fetal cardiologist” (p. 1716).

Ultrasound supervision levels that include adherence to prescribed scanning protocols of the fetal heart are difficult to obtain without active case ascertainment involving chart review or actual image film analysis (Acherman et al.). Friedberg et al. (2009) added that the “medical practice performing the ultrasound” was a key factor in prenatal CHD detection. Acherman et al. proposed universal fetal echocardiography because of low detection rates of CHD in the United States. In contrast, Meyer-Wittkopf, Cooper, & Sholler (2001) posited that improved prenatal CHD detection could be achieved with a collaborative, engaging relationship between physician and sonographer.

According to the AIUM (2010b) sonographers “play a critical role in extracting the information essential to deriving a diagnosis” for the supervising physician’s interpretation. The official scope of sonography practice (SDMS, 2000) states that sonographers use “independent judgment and systematic problem solving methods to produce high quality diagnostic information” (pg. 1). The *Standards and Guidelines for the Accreditation of Educational Programs in Diagnostic Medical Sonography* expressed its understanding of sonographer’s responsibilities to “identify and appropriately document the abnormal sonographic and Doppler patterns of disease processes, pathology.... (CAAHEP, 2011, p. 10) The *AIUM Practice Guideline for Documentation of an Ultrasound Examination* (AIUM, 2014) recognized the need for the “diagnostic ultrasound health care team” to communicate effectively and document pertinent information in light of practice variations. According to DuBose et al. (2006) eighty-six

percent of sonographers communicate their real time analytical findings in verbal, written, and/or computerized reports detailing the level of compliance with physician prescribed scanning protocols describing the level of fetal heart interrogation, i.e., OFTV inclusion. According to Dashe et al (2009a) and Guthrie (2013) patients were routinely dismissed before the supervising physician reviewed the sonographer's real-time analysis. Ultrasound scholars who have studied substantial changes in sonographer's attitudes and diagnostic responsibilities challenge the current scope of practice (Ismail, 2012; Mitchell, 2002; Persutte, 1997).

### **Ultrasound Scanning Protocols**

A protocol is a procedure for carrying out a scientific experiment (Merriam's – Webster's online dictionary, 2011). It is analogous to landmarks on a roadmap where discoveries are made in contrast to a topographical check off list (Webster's Online Dictionary, 2011). Beginning in the 1980s, sonographers began collecting and comparing protocols in order to standardize their methodology and to establish ultrasound's efficacy (Bendick, 2012; Nicholls, Sweet, & Hyett, 2014; Bell & Nowers, 1986). Bell and Nowers did not specify the 4CV or the OFTV but concluded that sonographers develop their own scanning repertoires dependent on equipment availability, information requested, and the assessed needs of the patient. Graduates from CAAHEP accredited ultrasound programs “demonstrate the ability to perform sonographic examinations ... according to protocol guidelines established by national professional organizations.... (CAAHEP, 2011, p. 9).”

The 2003 *AIUM Practice Guideline for the Performance of an Antepartum Obstetric Ultrasound Examination* included the 4CV with admonition to attempt OFTV (AIUM, 2003) in a recommended scanning protocol.

The AIUM recommendation OFTV inclusion in the preferred scanning protocol for routine obstetrical ultrasound performed between 18 – 22 weeks gestation as a minimum standard. However, physicians autonomously determine “on a case by case basis ... the specifics of image acquisition (Glazer & Ruiz-Wibbelsmann, 2011, p. 21)”.

### **Prenatal Ultrasound Surveillance of Congenital Heart Defects**

The fetal heart is routinely surveyed using ultrasound throughout a pregnancy. Cadkin and McAlplin (1984) described the fetal heart between 41 and 43 days of gestation as a rhythmic, blinking, flashing echo using real-time ultrasound. First trimester ultrasound evaluates the presence of a gestational pregnancy sac (s). Within the gestational sac, an embryo can be visualized as early as five to six weeks gestation. The sonographer measures the length of the embryo at this early stage to determine fetal age. Fetal heart activity can be observed and quantified using ultrasound when an embryo is 2 mm or greater in length. The heart is the first organ to form embryologically and to function as a circulatory system (Sakabe et al., 2005). A normal fetal heart beats between 120 and 160 times per minute. Sonographers assess the fetal heart by listening to the rhythm using pulsed Doppler or visualizing its movement using motion tracing (M-mode). It is then that mothers may hear and see their baby’s heart beating rhythmically for the first time. Fetal hearts that beat slower than normal are called bradycardiac and

those that beat faster than normal are called tachycardiac. Abnormal heart rhythms alert the sonographer of the increased risk of a CHD (Donofrio et al., 2014).

In contrast to patient's expectations, the AIUM clinical practice guidelines discourage the use of pulsed Doppler before 10 weeks gestation to avoid unnecessary fetal exposure to electromagnetic non-ionizing radiation. Sonographers may apply the protective ALARA principle using as low as reasonably achievable exposure levels of non-ionizing radiation during the first trimester when examining the tiny, developing fetal heart (AIUM, 2013b; Hedrick, 2005). The AIUM recommends recording the fetal heart using a 2-dimensional video clip or M-mode (motion) imaging that records the tracing of the heart without the added energy absorption necessary for pulsed Doppler use (AIUM, 2013b; Sheiner & Abramowicz, 2005).

Between 11 and 14 weeks gestation, the nuchal translucency screening (NT scan) is offered as a non-invasive ultrasound examination. It is coupled with maternal serum biochemical tests to identify chromosomal disorders, some of which may be associated with CHD (AIUM, 2013b; Ghi, Huggon, Zosmer, & Nicolaides, 2001). The sonographer measures the accumulation of fluid underneath the skin line of the fetal neck searching for edema in the posterior neck region. Edema has been associated with cardiovascular (heart) and pulmonary (lung) defects, chromosomal anomalies, skeletal anomalies, and maternal infections (Nicolaides, 2004).

Second trimester ultrasounds are routinely performed to assess fetal number (single or multiple), position, heart activity, biometry, anatomy, placental height, and amniotic fluid volume (AIUM, 2013b). Sonographers assess biometrics for fetal growth

measuring the fetal head, belly, and femur length to estimate fetal weight. A meticulous search of fetal anomalies is performed during the anatomical survey. Interrogating the fetal heart using the 4CV has been a part of the standard scanning protocol recommended since the 1980s and since 2013 includes OFTV (AIUMb).

Third trimester ultrasounds may be performed to evaluate pregnancies for women with no prior prenatal care or with chronic maternal conditions such as diabetes or hypertension that may adversely affect the development of a healthy fetus that potentially damages the fetal heart. Subtle cardiac anomalies and anomalies that develop over time may go undetected before birth because fetal anatomical surveys are generally performed between 18-22 weeks gestation.

Fetal echocardiography is a targeted interrogation of the fetal heart separate and distinct from previous ultrasounds mentioned. Patients are referred to tertiary centers for a closer look at the fetus when a known CHD risk factor is present or a suspicious finding on a routine obstetrical ultrasound anytime during the pregnancy. The most common medical indication for referring a patient to a tertiary center for targeted interrogation of the fetal heart is suspicion of a CHD during a routine obstetrical ultrasound (Donofrio et al., 2014; Li, Wang, Yang, Yan, & Wu, 2008). Sonographers with advanced expertise in fetal heart interrogation perform echocardiograms. They report their findings to physicians trained in maternal fetal medicine or specially trained obstetricians, radiologists, and pediatric cardiologists. Separate practice guidelines were developed for fetal echocardiograms that extend fetal heart interrogation (AIUM 2013b).

Earlier prenatal detection provides time for informed decisions, management and counseling, prenatal surgical interventions, and collaborative team efforts at tertiary centers that may improve the outcome of affected newborns (AIUM, 2013a).

### **Ultrasound-Related Barriers to Imaging the Fetal Heart**

Webster's online dictionary (2011) defines a barrier as something that obstructs movement, access, or progress. AIUM's clinical practice guidelines reflect physicians' awareness of the technical limitations of current practice behaviors identifying potential sources pertaining to the mother, the fetus, and the medical environment itself (AIUM, 2007; AIUM, 2013; Copel et al., 1987; Schreckengost & Filly, 2005).

The most cited maternal barrier to overall fetal body access using ultrasound technology is obesity (American College of Obstetricians and Gynecologists, 2013; Espinoza et al., 2014; Kritzer, Magner, & Warshak, 2014). Maternal obesity impairs the acoustic ultrasound window necessary to adequately see the fetus. Two factors work in tandem to cause suboptimal visualization: increased distance from the ultrasound probe and undue sound wave absorption (Paladini, 2009).

Excessive layers of adipose tissue with increased maternal abdominal girth found in overweight and obese pregnant women increase the distance between the fetus and the probe that glides on the maternal abdominal surface. Increased depth caused by adipose tissue is inversely related to optimal imaging of the fetal heart. The second factor is the absorption of ultrasound energy by the excessive maternal adipose (fat) tissue resulting in loss of detail in the millimeter thick walls of the tiny heart (Paladini, 2009).

Aagaard-Tillery et al. (2010) reported that maternal obesity significantly deterred visualization of the fetus during the genetic ultrasound. Wolfe, Sokol, Martier, & Zador (1990) reported a 14.5% loss of visualization of fetal anatomy, specifically the fetal heart and spine, in obese women at a mean gestational age of 28.5 weeks with a BMI greater than the 90<sup>th</sup> percentile.

In a population-based study of 3, 096 pregnant women, Best, Tennant, Bell, and Rankin (2012) found that fetal heart anomalies were more difficult to detect (11.5%) as maternal BMI increased when compared to other organ systems (urinary, nervous, orofacial, and digestive systems). Dashe, McIntire, and Twickler (2009b) reported decreased visualization of fetal anomalies as BMI increased. In contrast, Foy, Wheller, Samuels, and Evans (2013) found no association between image quality and maternal BMI. However, their small sample size (n= 37) could have biased their observation.

Hendler et al. (2005) studied whether repeated ultrasounds would improve fetal heart visualization. Suboptimal visualization was defined as a failure to obtain a 4CV, OFTV, or both, during a routine obstetrical ultrasound (N= 372) performed between 18.0 – 21.0 weeks gestation and a repeat ultrasound between 18.9 – 23.9 weeks. Women were classified by maternal habitus using body mass index (BMI) as less than 30 kg/mg<sup>2</sup> (non-obese), 30.0 – 34.9 kg/mg<sup>2</sup> (obesity class I), 35.0 – 39.9 kg/mg<sup>2</sup> (obesity II,) and 40 kg/mg<sup>2</sup> or greater as morbidly obese.

Sixty-three percent were obese with a BMI > 30.0 kg/m2. Registered (credentialed) sonographers attempted to interrogate the fetal heart with the following criteria for the initial obstetrical ultrasound: the cardiac axis and position, 4CV, and

OFTV. Hendler et al. (2005) reported that suboptimal visualization increased with increasing BMI with persistent suboptimal fetal heart imaging in the obese population.

Khoury, Ehrenberg, and Mercer (2009) studied maternal BMI on ultrasound visualization of specific fetal anatomy. Two groups of pregnant women were compared: obese women described as having a BMI greater than  $30\text{kg/m}^2$  and non-obese women described as having a BMI of  $18.5 - 24.9\text{kg/m}^2$ . Overweight women with a BMI of  $25 - 29.9\text{kg/m}^2$  were excluded. Eight hundred fourteen pregnant women participated in the study with 148 normal weight women and 666 obese women. Specific fetal anatomy included the fetal heart (axis, four chambered view, OFTV, and aortic arch), abdominal wall (insertion of the umbilical cord into the fetal abdomen and a 3 vessel count), fetal face (nose, lips, and midline profile), the cervical, thoracic, and lumbar spine, and arms and legs. Comparing the women who were obese to women who were not obese, the fetal heart was most frequently cited as visually impaired (50.9% vs. 26.9%  $p < 0.0001$ ) followed by the fetal face (39.1 vs. 19.3%) ( $p < 0.0001$ ), and the abdominal wall ( $p < 0.0001$ ). Not unexpectedly, suboptimal imaging occurred in obese women more frequently than women with normal BMI (64.6% vs. 48.6%) during the targeted ultrasound performed in a tertiary medical facility by experienced, credentialed diagnostic medical sonographers and rescanned by a physician. However, Khoury et al. (2009) also found that fetal imaging improved with gestational age with the exception of the heart and midline face.

In a five-year retrospective study of routine initial obstetrical ultrasounds performed between 18-24 weeks gestation in a population based study of 10,112 women,

Dashe, McIntire, and Twickler (2009a) reported maternal obesity significantly limited adequate fetal visualization of specific body parts. Women were classified as underweight (less than  $18.5 \text{ kg/m}^2$ ,  $n= 2\%$ ), normal weight ( $18.5\text{-}24.9 \text{ kg/m}^2$ ,  $n= 38\%$ ), overweight ( $25.0\text{-}29.9 \text{ kg/m}^2$ ,  $n= 34\%$ ) and obese ( $>29.9 \text{ kg/m}^2$ ,  $n=26\%$ ). Adequate visualization of the 4CV, cerebral ventricles and posterior fossa, midline fetal face, abdominal wall, umbilical cord, stomach, kidneys, and spine were significantly compromised with increasing maternal BMI ( $P < 0.001$ ). There were 2,676 obese women in this study. Experienced ARDMS credentialed sonographers were unable to complete anatomical surveys requiring a repeat ultrasound evaluation of 50% of obese women's pregnancies because of poor visualization of fetal structures.

In a prospective study of 283 women with a BMI  $> 30 \text{ kg/m}^2$  ( $n=223$ ) and non-obese women with a BMI of  $20\text{-}24.9 \text{ kg/m}^2$  ( $n= 60$ ), Fuchs et al. (2013) determined that image quality in ultrasounds performed between 20-24 weeks was significantly lower in obese women. Image criteria included the 4CV, OFTV, head, abdomen, femur, face, diaphragm, kidneys and spine. Ultrasounds could not be completed in 29% of obese women compared to 18% in the non-obese group. The OFTV could not be visualized 13% of the time in the obese group compared to 5% in the non-obese group.

Potential access barriers, related to the fetus, involve the millimeter-sized walls of the heart, fetal heart movement, the evolution (delayed ultrasound debut) of specific heart defects, fetal body movement, position of the fetus (fetal lie) and oligohydramnios. Therefore, the fetal heart has been referred to as the sonographer's Achilles' heel because the heart is a tiny, geometrically complex moving target (Skansky, 2007).

To combat the hypnotic effect of fetal heart movement with added distraction from rushing cardiac blood flow patterns, fetal activity, and maternal respiratory movement, ultrasound equipment manufacturers provided a key tool called cine loop (Cohen & Moore, 2004). Cine loop allowed sonographers to scroll through a series of images temporarily stored immediately before freezing an ultrasound image (Garg et al., 2014; Mekjarasnapha et al., 2013). In a study reported by Vettraino, Huang, and Comstock (2002) sonographers used this key tool to capture an image of the heart in diastole, meticulously measuring the millimeter sized fetal heart valves noting placement of the mitral and tricuspid valves in 145 patients. Abnormal valve placement may alert sonographers that an atrioventricular defect is present or the presence of a rarer CHD called Ebstein's anomaly that carries a poor pregnancy outcome.

A profound access barrier to CHD is the delayed ultrasound debut or development over time of a CHD (DeVore, Medearis, Bear, Horenstein, & Platt, 1993; Foy et al., 2013; Trivedi et al., 2012). Subtle changes to heart structure in some CHD may not be appreciated when ultrasounds are prescribed too early or when the physician relies only on the 4CV to the exclusion of OFTV in scanning protocols (Trivedi et al., 2012; Wong et al., 2003). In the United States, physicians typically prescribe fetal anatomical ultrasound surveys between 18 -22 weeks gestation (AIUM, 2013) before some fetal heart malformation may be visible by ultrasound.

For example, transposition of the great arteries (TGA) is a CCHD present at 34 days post conception (Jones, 1997). However, TGA may need the 4CV and OFTV to appreciate the heart defect (Chaoui, 2003; Moon, 2003; Smrcek et al., 2006; Zhivora,

2008). Chronic maternal illnesses such as poorly controlled diabetes mellitus may cause enlargement of the fetal heart ventricle called ventricular hypertrophy over the course of the pregnancy and may be unappreciated by ultrasound until the third trimester (Donofrio et al., 2014). Another example of delayed ultrasound debut is the development of a hypoplastic left heart where a portion of the heart begins to appear smaller in a third trimester ultrasound as a result of hemodynamic changes (Foy et al., 2013).

Suboptimal fetal positioning within the maternal womb may present as an access barrier to the fetal heart. Jeffrey and Laing (1982) posited that a prone fetal presentation (lie) where the fetal spine is upright and closest to the maternal abdominal wall poses a significant barrier to heart interrogation. Poor fetal position poses a practice barrier for OFTV inclusion because the apex of the fetal heart is placed at an awkward angle. Sonographer painstakingly manipulate the probe, applying pressure through the probe, tilting, rocking, and sliding the probe to avoid the denser fetal ribs and spine that cause a sound wave fall-out effect (AIUM, 1999). The fallout effect or shadowing resembles a car headlight devoid of practical information. Prone fetal positioning significantly affects image quality and multiplies the sonographer's physical and cognitive strain in order to adequately assess the fetal heart (Dashe et al., 2009b; DeVore et al., 1993; Lee, 1998). Letourneau et al. (2013) recognized fetal lie as a barrier when he suggested that sonographers start with the heart by choosing to begin an ultrasound with a cursory glance for optimal fetal positioning to improve the odds of OFTV inclusion.

Oligohydramnios, or inadequate amniotic fluid, may present an obstructive barrier resulting in uterine compression that shrink-wraps the fetus (Jones, 1997; Kirk et al.,

1997; Lee, 1998; Trivedi et al., 2012). Amniotic sac leakage or rupture is the most common cause of oligohydramnios (Jones, 1997). With adequate amniotic fluid, the fetus is nestled in a warm, protective bath produced primarily by the fetus after the fourth month. Sonographers routinely measure the amniotic fluid volume that provides a natural medium in which to transmit sound waves (Reddy, Abuhamad, Levine, & Saade, 2014). In contrast, polyhydramnios, an excessive amount of amniotic fluid seen with some CHD, may present as an obstructive barrier because intrauterine pressure inside the amniotic sac causes the outer surface of the uterus to become too tense to apply adequate probe pressure to interrogate the fetal heart (Dashe, McIntire, Ramus, Santos-Ramos, & Twickler, 2002; Sandlin, Chauhan, & Magann, 2013).

External barriers using ultrasound technology have been addressed in ultrasound research. Leading researchers in CHD cite environmental practice barriers to prenatal detection of CHD consisting of: the type of medical facility and specific cardiac defect (Acherman et al., 2007; Bahtiyar et al., 2007; Friedberg et al., 2009; Kirk et al., 1997; Wong et al., 2003), sonographer's lack of education (Friedberg et al., 2009; Michelfelder & Cnota, 2009) sonographer's experience (Trivedi et al., 2012), sonographer's inadequate training (Tegnander & Eik-Nes, 2006), need for additional skills for physicians and sonographers in scanning obese patients (Khoury et al., 2009); inadequate scanning time (Abu-Rustum, Ziade, & Abu-Rustum, 2011; Chaouri, 2003), practice inertia (Chaoui, 2003), sonographer's work-related musculoskeletal injuries (WRMSI) (Phatak & Ramsey, 2010), and suboptimal equipment (AIUM, 2013b; Lee, 1998).

Friedberg et al. (2009) found the type of CHD and the “medical practice performing the ultrasound” were key factors in prenatal CHD detection suggesting “more extensive collaborative guidelines ...and increased education of obstetrical and radiology ultrasonographers ... (p. 31).” According to Michelfelder & Cnota (2009) a broader systemic “problem at the ‘front lines’ of obstetrical imaging suggested improved training of obstetrical residents and better education in normal fetal heart anatomy and pathology for ultrasound professionals [sonographers].

Trivedi et al. (2012) cited numerous factors impacting the rate of misdiagnosis of CHD among pediatric cardiologists and medical imaging specialists [physicians]. Trivedi et al. also cited the sonographer’s experience as the most important factor in misdiagnosis of CHD by physicians along with maternal body habitus, inadequate amniotic fluid, delayed debut of the CHD, extra-cardiac anomalies, and early timing of the ultrasound.

Inadequate training has been cited as a potential barrier to inclusion of OFTV (Friedberg et al., 2009; Tegnander & Eik-Nes, 2006). Letourneau et al. (2013) described a long learning curve with months of supervised, hands-on training before experienced obstetrical sonographers in Manitoba, Canada, (N=52) developed competent interrogative skills using OFTV. In contrast, Wong et al. (2003) placed the onus on the interpreting physician to provide adequate supervision and training in tertiary and non-tertiary medical facilities to improve detection rates.

Restrictive time allocation to perform a complete fetal heart assessment with OFTV has been cited as a practice barrier (Abu-Rustum, Ziade, & Abu-Rustum, 2011; Chaouri, 2003, Skansky, 2007). According to Persutte (2002) and Wong et al. (2003)

study length for an obstetrical ultrasound is directly influenced by the sonographer's index of suspicion (actual prevalence reported and perceived risk assessment).

Sonographers may choose to perform a quick assessment in situations where a lethal syndrome is present (Persutte) such as stillbirth. When numerous anomalies are present, sonographers may choose to avoid redundant, time-consuming fetal heart assessment, knowing eminent referral with a fetal echocardiography, parental genetic testing and counseling is likely to occur. According to Persutte, DuBose, and West (2002) performance times for an obstetrical ultrasound varies depending on sonographer's experience. While Letourneau et al. (2014) suggested a long learning curve for OFTV inclusion in routine practice, Schreckengost and Filly (2005) argued that OFTV inclusion required minimum additional time once the sonographer acquired competent skills.

An environmental factor that may represent an obstructive barrier to additional scanning time and effort required for OFTV inclusion is risk aversion to work-related musculoskeletal injuries (WRMSI) rampant among sonographers. According to Evans, Roll, and Baker (2009) 90% of sonographers in a large cross sectional sample (n= 2964) reported scanning in pain, believed to be related to WRMSI from sustained pressure applied to the probe, arm abduction, and cervical neck and trunk twisting. In 2010, Evans, Roll, Hutmire, & Baker narrowed their research to wrist-hand-finger discomfort finding 60% of sonographers and vascular technologists (N= 1722) experienced pain. Hill, Slade, & Russi (2009) reported similar findings of sonographers working in a tertiary center (N= 27) with 96% reporting musculoskeletal symptoms involving the shoulder (73%), low back (69%), and hand / wrist symptoms (54%). Dashe, McIntire,

and Twickler (2009b) suggested studying the effects of physical force that obstetrical sonographers exert when extracting optimal diagnostic fetal heart images. Vetter et al. (2013) studied the downward sustained pressure associated with varying probe designs finding that the smaller probe design required higher average maximum grip pressure in order to obtain diagnostic images.

Phatak and Ramsey (2010) reported “excessive operator strain” in 51.4% among sonographers attempting second trimester obstetrical ultrasounds of women with BMI > 30 kg/m<sup>2</sup> (n= 70) resulting in additional scanning time and repeat ultrasounds for almost 50% of obese patients with BMI > 40 kg/m<sup>2</sup> (n= 7). Phatak and Ramsey voiced their concern that the upcoming guidelines suggesting additional fetal imaging and extended fetal heart evaluation in light of their study of the impact of maternal obesity on the second trimester anomaly scan may tax medical resources. Failed initial attempts to adequately visualize the fetal heart requiring additional medical resources such as serial ultrasounds to obtain optimal images have been previously reported (Hendler et al., 2005; Wax, Pinette, Cartin, & Blackstone, 2007).

Hill et al. (2009) described sonographer’s work environment as a high demand / low control environment with the majority (89%) reporting requirements to work fast while avoiding mistakes (100%), and often facing conflicting work demands (69%). Taba et al. (2012) reported that inadequate medical resources such as restrictive time contributed to non-adherence of clinical practice guidelines among physicians. Inadequate resources of time with heavy patient workloads, compromised image quality, in relation to WRMSI among sonographers have been posited (Brown & Baker, 2004;

David, 2005; Jakes, 2001; Evans, Roll, Li, & Sammet, 2010; Persutte, DuBose, & West, 2002; Pocratsky, Ashby, & Beasely, 2014).

Cabana et al. (1999) reported that practice inertia influenced adherence to clinical practice guidelines among physicians in a variety of disciplines unrelated to ultrasound practice. In the 1980s, the 4CV was touted as the optimal tissue plane to rule out CHD (Jeffrey & Laing, 1982). However, Lee (1998) and Chaoui (2003) suggested that a complacent attitude toward the 4CV had resulted in a simple, heart-chamber count that may limit adequate interrogation of the fetal heart for CHD. DeVore (1992) first reported OFTV inclusion during second and third trimester fetal echocardiograms performed. Improved detection rates of CCHD have been reported using both interrogation techniques (Chew et al., 2007; Ogge, Gaglioti, Maccanti, Faggiano, & Todros, 2006; Sklansky et al., 2009). The persistent attitude toward the familiar 4CV as easier to perform compared to OFTV and the 4CV as an “end in itself” that would require a “paradigm shift” in order to incorporate OFTV in routine practice (Sklansky et al., 2009, p. 898) may suggest practice inertia as a progress barrier to OFTV inclusion. Practice inertia among sonographers as it relates to exclusion of OFTV has not been studied.

Ultrasound equipment is recognized as a potential barrier to ultrasound practice (AIUM, 2013b; Lee, 1998). Several options that improve image quality are available at the time of purchase such as transducers (probes) with varying frequencies, cine loop/clips, color flow mapping, spectral Doppler, harmonics, and 3 and 4 dimensional imaging. Some options such as color flow mapping and 3 and 4 dimensional imaging may dramatically improve image quality but require extensive training (Sklansky, 2007).

The AIUM (2013b) recommends selecting the most appropriate probe available that will balance resolution and penetration. A lower frequency probe may be selected to penetrate maternal adipose tissue in the second trimester compared to a transvaginal probe with a higher frequency but less penetration needed in the first trimester.

The cine loop option similar to the play back mechanism used in televised sports events is available for purchase and used by the sonographer at the bedside for a quick review of the last few seconds of imaging. The AIUM (2013b) recommends using a 2-dimensional video cine clip to document the fetal heart. This provides an opportunity for the physician to visualize the fetal heart *in utero* with both dynamic and static imaging data (Sklansky, 2007). According to Benacerraf, Shipp, and Bromley (2006)

With current 2D technology, the quality of the examination is largely based on the skill and experience of the person obtaining the images rather than on the physician interpreting the scans, unless the physician performs his or her own additional imaging (double scanning). If an image acquisition is omitted in a 2D US examination, the patient must return for a repeat US examination, as there is no permanent record of the entire survey (p. 994).

According to Poole et al. (2013) addition of cine clips increased the confidence level of radiologists and perinatologists to identify normal fetal heart anatomy. In the best possible scenario, two experts, the physician and the sonographer, work together to provide quality fetal heart imaging. Standardization of scanning practices may occur when the supervising physician prescribes cine loops and OFTV (Scott et al., 2014).

### **Adherence Barriers to Clinical Practice Guidelines**

Cabana et al. (1999) investigated potential barriers to guideline adherence among physicians from a variety of disciplines and countries influencing knowledge, attitude, and behavior categorized into seven domains published in 76 articles containing 120 surveys. The surveys addressed seven domains regarding clinical practice guideline adherence: lack of awareness (n=46) and lack of familiarity (n=31), lack of agreement with general and specific guidelines (n=33), lack of self-efficacy (n=19), outcome expectancy (n=8), change motivation / practice inertia (n=14), and external barriers related to specific guidelines adherence, patient's expectation/beliefs, and environmental factors (n=34).

The majority of surveys (n=70; 58%) addressed only one barrier. At least 10% of physicians reported lack of awareness of practice guidelines. However, lack of familiarity with practice guidelines was more common than lack of awareness. Lack of adherence to specific practice guidelines was more common than the concept of practice guidelines in general. Cabana et al. suggested that actual skills versus lack of preparation might bias responses to questions about self-efficacy. Lack of outcome expectancy may be influenced by lack of knowledge about the problem and belief that success is reasonable. More than 20% of surveys (n=14) probing about practice inertia as a barrier to practice change by following practice guidelines responded positively. Cabana et al. identified external barriers such as lack of resources in time restrictions, low reimbursement, and perceived increase in medico-legal issues. Overall, Cabana et al. suggested that future

research should study multiple barriers that may more fully add to the gap in knowledge about guideline adherence.

Cabana, Rand, Becher, and Rubin (2001) narrowed their research to a disease specific practice guidelines (asthma) from the 1997 National Heart, Lung, and Blood Institute among 829 primary care pediatricians. The majority of physicians (88%) were aware of practice guidelines. However, non-adherence to practice guidelines' particularities prompted Cabana, Rand, Becher, and Rubin to suggest interventions addressing specific barriers.

Nirenberg, Reame, Cato, and Larson (2010) found that normative beliefs and advanced certification influenced oncology nurses' use of guidelines. Behavioral control, positive subjective norms, and professionalism influenced use of practice guidelines among nurses while burnout negatively affected intention (Kogan & Tabak, 2012). Taba et al. (2012) reported that inadequate medical resources, specifically time restrictions, contributed to non-adherence of practice guidelines among physicians. Whether these barriers affect sonographer's practice change to include OFTV is unknown.

### **Theory of Planned Behavior**

Fishbein and Ajzen's (2010) theory of planned behavior, a reasoned action approach (Ajzen, 1986), attempts to explain and predict human behavior using four core constructs: attitude, subjective norm, perceived behavioral control, and intention. The TPB was chosen because of its application in health studies research where social scientists have observed human social interaction. Harbour (2009) studied primary care provider's behavior in counseling patients to engage in physical activity. Nirenberg

(2009) studied oncology nurses' use of practice guidelines. Cafiero (2012) studied intent to use health literacy strategies among nurse practitioners and Aggarwal (2013) studied healthcare leaders' intention to serve as organizational teachers in a specific healthcare system. The TPB was also chosen for its potential to provide a conceptual framework for behavioral change interventions and formal evaluations (United States Department of Health and Human Services, 2005).

The TPB posits that human behavior (action) can be best predicted by the intent to act. Fundamentally, an individual is more likely to perform a targeted behavior when that individual has a strong intention to perform a behavior – the stronger the intention, the more likely the behavior will be performed. Intention has been referred to as a proximal goal. Therefore, intention is the immediate antecedent of behavior measuring readiness to act (Ajzen, 2011, Fishbein & Ajzen, 2010). In the TPB framework, the antecedents to intention are dependent on the remaining three constructs: attitude toward the behavior, subjective norm, and perceived behavioral control where each is weighted in relationship to the specific behavior and context.

Attitude defined as the degree to which an individual favors or disfavors a behavior is based on an individual's subjective evaluation of the probability of an expected outcome (behavioral belief). Current social scientists appreciate the theoretical multidimensional aspects of attitude such as cognition, emotion, and motivation. While each of these plays a pivotal role in the understanding of attitude as a construct, a measureable scale along a bipolar continuum based on individual's subjective evaluation

provided scoring standardization. Attitude may be reliably measured “as dispositions to respond...toward a given” behavior (Fishbein & Ajzen, 2010, p. 96).

Subjective norms are internalized belief (social pressure) to act or not act, from a significant other or referent group’s belief about a targeted behavior. Normative beliefs are the perceived behavioral expectations of those most influential in creating the social pressure to perform in a particular fashion. It is characterized by the power to reward or coerce, to decree by right, expertise, or modeling (wanting to identify with the change agent) (Fishbein & Ajzen, 2010). While an individual may possess the will to act, behavior may be subject to outside pressures to conform. Physicians as a referent group who prescribe OFTV in scanning protocols may motivate sonographers to include OFTV. Conversely, physicians who do not agree with AIUM recommendations may avoid OFTV inclusion in scanning protocols. Sonographers who gain expertise in OFTV and act as change agents may motivate other sonographers to model their behavior to include OFTV. Therefore, Ajzen’s construct of subjective norms was operationalized as *professional* norms to characterize the domain specific motivation to comply within the contextualized hierarchy of medicine where physicians prescribe behavior and sonographers follow physician’s dictates or where referent expert sonographers’ behavior may motivate other sonographers to emulate behaviors.

The third antecedent to intention is perceived behavioral control defined as a person’s belief that she/he is capable of performing a behavior based on requisite knowledge and skills, and where there is an absence of environmental barriers that preclude performance (control beliefs). Perceived behavioral control is similar to existing

self-efficacy constructs. However, the TPB emphasizes the influence of external factors on behavioral control beliefs. For instance, a person may choose to perform a behavior and may be motivated or pressured by professional group norms to perform a behavior and possess the requisite skills to accomplish the behavior but lack adequate external resources such as time to perform a given behavior. Therefore, actual control may preempt perceived behavioral control. A person's volition or one's own free will may be restricted because of external factors beyond a person's control. Normative beliefs influence an individual's subjective norms. Control beliefs influence perceived behavioral control. Each of the three constructs is weighted individually and may vary widely between individuals and groups.

In this framework, rationality and deliberation are *not* assumed to precede behavior. Fishbein and Ajzen (2010) argue that behavior may appear irrational or not planned. Instead, spontaneity or some degree of deliberation drives behavior based on salient beliefs that quickly surface that is derived from stored factual or fictitious information. This information is subject to change, and thus behavior may change. According to Fishbein and Ajzen, behavior follows a reasonable plan in that it is based on the information at hand. Salient behavioral beliefs emerge and serve as resources for attitude defined as disposition toward a behavior.

Fishbein and Ajzen suggested tightly operationalizing the behavior describing a four-part formula: specific action, directed target of the action performed, context in which the action is performed, and time in which it is performed (Ajzen & Fishbein, 2010). In this study, the action-behavior would be *OFTV*, the directed target of the action

would be *OFTV interrogation acts*, the time would be *between 18-22 weeks gestation*, and the context would be *during a physician supervised obstetrical ultrasound*.

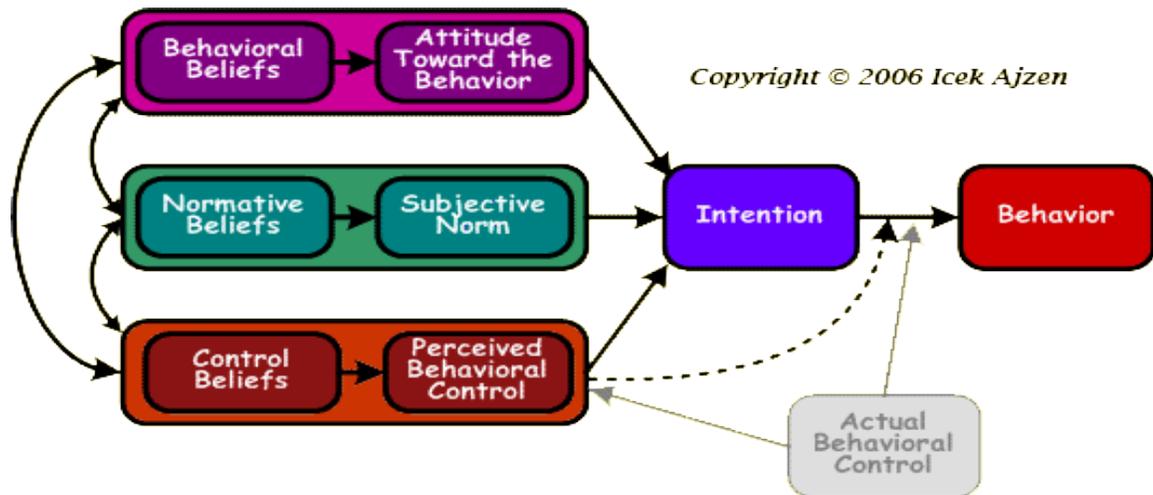


Fig. 1. Schematic: Theory of planned behavior

### Summary

This literature review examined how a public health threat of more than half of CCHD are still missed despite near universal obstetrical ultrasound screening in the United States (Chew et al., 2007). This researcher relied on a continuing scholastic conversation of medical ultrasound researchers published in ultrasound specific peer-reviewed journals from 1980s through 2014 to identify salient beliefs about the importance of and barriers to OFTV inclusion. Secondly, a close read of the AIUM practice guidelines for fetal heart interrogation resulted in evidence of consensus beliefs regarding the documentation, timing of ultrasound referrals, fetal safety, minimum criteria for fetal heart assessment, and legal status of recommendations.

Continuing education and training of sonographers about ultrasound surveillance of CHD was encouraged in the literature. Sonographers were characterized by their

efforts to professionalize ultrasound practice, formalize ultrasound education with peer reviewed accreditation and credentialing, develop community engagement, advance professional values of individual accountability and provision of equitable care.

Congenital heart defects were characterized by type, prevalence, financial cost, clinical impact, and population risk factors involving mother, family, and fetus.

Ultrasound supervision, scanning protocols, interrogation techniques, and barriers to OFTV inclusion were included in this literature review.

Advances in ultrasound technology were reviewed. AIUM practice guidelines suggested various ways of documenting fetal hearts using optional equipment. Suboptimal equipment and practice inertia resulting in poor visualization of the fetus and heart were noted.

Maternal, fetal, or environmental barriers were distinguished. The most common maternal barrier involved maternal obesity causing suboptimal imaging. Fetal positioning was most often cited as a barrier to fetal heart interrogation. Environment constraints were cited as time restrictions, heavy workloads, a long learning curve to learn OFTV, and musculoskeletal injuries among sonographers.

The TPB was chosen because of its application in health studies research where social scientists have observed human social interaction. Potential benefits for health educators to apply the TPB to design, implement, and evaluate behavioral change determinants may be well within the scope of health education as well as advocacy for change beyond individual behavioral modification.

## CHAPTER III

### METHODOLOGY

Two primary questions guided this research. The first question asked “how a sonographer’s attitude and perceived behavioral control toward the inclusion of ventricular OFTV in routine obstetrical ultrasounds between 18-22 weeks gestation related to practice behaviors”. The second research question asked “what relationship existed between sonographer’s attitude toward OFTV inclusion in routine obstetrical ultrasounds and sonographer’s demographic characteristics of credentialing, educational attainment, and facility accreditation”. Additional qualitative data were collected about perceived norms, perceived barriers to OFTV inclusion, and intent that provided rich data to more fully characterize the population and supply a resource for future investigation.

In the TPB framework, the antecedents to intention are dependent on the remaining three constructs: attitude, subjective norm, perceived behavioral control. Attitude, which was defined as the degree to which an individual favors or disfavors a behavior, is based on that individual’s subjective evaluation of the probability of an expected outcome (behavioral belief). Attitude may be reliably measured “as dispositions to respond...toward a given” behavior (Fishbein & Ajzen, 2010, p. 96). The phrase, *toward the inclusion of OFTV*, was used in this research to capture participants’ attitude toward behavior occurring along a broad behavioral spectrum starting from the initial phase of occasionally attempting OFTV to always attempting OFTV during routine obstetrical ultrasound. Always attempting OFTV in routine obstetrical ultrasound

between 18-22 weeks gestations would signify complete adoption and thus full translation of research to practice. Rogers (1995) posited that a period of trial and error occurred when early adopters of innovation tested its suitability in real world situations and that the level of complexity of the new innovation was a key variable. The AIUM (2007) included the phrase *when technically feasible* to acknowledge the level of complexity as well as a phasing-in period of time required for translation of this research into routine real-time clinical practice where barriers would be expected.

A mixed method approach captured primary quantitative and qualitative datum examining sonographer's attitude toward OFTV inclusion and perceived behavioral control was an initial step in understanding progress toward OFTV inclusion. The theory of planned behavior was chosen because of its durable history of helping to understand dispositional attitude and barriers in healthcare settings familiar to physicians, nurses, and healthcare leaders (Aggarwal, 2013; Cafiero, 2012; Harbour, 2009; Nirenberg, 2009). A survey instrument was mailed using the United States postal service.

### **Population and Sample**

According to the ARDMS (2014), there were approximately 38,691 obstetrical sonographers and 989 fetal echocardiographers credentialed in the United States in 2013. Inclusion criteria consisted of ARDMS credentialing in at least one ultrasound specialty in the United States over the age of 18. The BLC provided the ARDMS mailing list. The BLC had a minimum order of approximately 2, 334 records with 1,167 in each list. Essentially two electronic BLC lists were provided. Inclusion criteria for the BLC lists included one containing potential participants with credentialing in only obstetrics and

another list containing potential participants with at least one credential in abdominal ultrasound to exclude obstetrics. The BLC used a randomized process for each list based on internal coding which had assigned numbers each time a new record was added to the BLC's master file. Two electronic lists were transferred electronically to include only names and home addresses. A second culling was performed after receipt by removing potential participants unlikely to practice routine obstetrical ultrasound. Exclusion included known faculty of ultrasound programs and application specialists (n=19). Every other name was selected from each list until a minimum number of 500 potential participants were attained from each list.

Of the 1,000 potential participants, 50% were ARDMS credentialed in obstetrical ultrasound (n=500) and 50% were ARDMS credentialed in abdominal ultrasound and if applicable, ARDMS specialty (ies) *other than obstetrics* (n= 500). The decision to use a 50/50 split was an attempt to reflect the ultrasound workforce diversity where medical supervision and proximity may influence performance. The 50/50 split provided the opportunity to compare two groups currently practicing obstetrical ultrasound in the United States: those with ARDMS credentialing in obstetrics and sonographers not ARDMS credentialed in obstetrics.

Another exclusion narrowed the focus to *routine* obstetrical ultrasounds verses ultrasounds referred to tertiary centers for increased risk of CHD. This was an attempt to align this research effort with prior research that considered risk status a criterion. Friedberg et al. (2009) found that the “medical practice performing the US [ultrasound]” was a key factor in CHD detection rates (p. 30).

### **Protection of Human Participants**

Institutional review board approval for this research was obtained from *Texas Woman's University* in August 2014 (Appendix C). Agency (ARDMS) research approval with mailing list rental was given in September 2014 (Appendix D). The participation consent letter (Appendix E), survey instrument (Appendix F), and self-addressed stamped envelope were mailed using the United States postage service. The research did not include emails or telephone interviews of participants per the rental agreement. However, two brief contacts (telephone: verbal and text) prompted by two potential participants after receiving the survey were made to answer protocol questions. No further contact was made. Electronic survey data was password protected. All materials were kept in a locked cabinet in the researcher's office.

### **Data Collection Procedures**

After IRB and agency approval, a pilot study was designed to establish baseline validity and reliability. Face and content validity baseline measures were captured using feedback from two subject matter experts (SMEs). The survey instrument was pilot-tested using six participants from the target population to calculate baseline reliability measures.

#### **Validity Measures**

Face validity was assessed using two doctoral prepared SMEs familiar with the practical application of the theory of planned behavior. According to their feedback, based upon the theoretical framework and research purpose, the survey instrument appeared to possess adequate face validity to address the research questions. They agreed that adapting Ajzen's construct from subjective norms to *professional* norms reflected the

medical context in which sonographers operate under the direct supervision of physicians who prescribe behavior and sonographers expected to follow suit or where referent expert sonographers' behavior may motivate other sonographers to emulate their behaviors.

Exception was noted by the SME in regard to the intent section survey questions because two of the three questions measuring intent assessed different concepts. Specifically, only the first question asked about intent to follow clinical practice guidelines that endorsed OFTV inclusion in routine obstetrical ultrasounds. The two remaining questions in the intention section were not revised because the information sought was considered pertinent data that may be used for future research efforts.

Measuring survey item relevance agreement between the two SMEs assessed content validity. A content validity index (CVI) was calculated resulting in  $CVI = .75$  (Appendix G). Based upon SMEs feedback, there were revisions in wording and scales. According to Gajewski et al. (2012) a CVI of .80 is acceptable.

### **Reliability Measures**

A test-retest format was formulated for a pilot group. The survey was completed on two separate dates approximately one week apart. Six participants completed survey-1, but only 5 completed both. Correlation coefficients for the 5 participants were 0.989, 0.975, 0.970, 0.982 and 0.981. Thus the resultant overall correlation coefficient was  $r = 0.979$ , indicating the survey instrument had high test-re-test reliability.

Internal consistency was measured for the following sections; attitude (.742), perceived behavioral control (.832), professional norms (.914) and intention (.400). Pallant (2010) noted Cronbach alpha values greater than .7 were acceptable and greater

than .8 preferred for high internal consistency reliability among survey items. A low internal consistency for the intent section was expected because varying concepts were addressed in the intention section, specifically, intent to follow the clinical practice guideline of OFTV inclusion, intention to learn more about OFTV anomalies, and intention to sit for an advanced certification within the next year.

Table 1

*Reliability Statistics*

Reliability Statistics	Cronbach's Alpha		
	Cronbach's Alpha	Based on Standardized Items	N of Items
Attitude	.742	.786	4
PBC	.832	.837	3
Professional norm	.914	.948	4
Intention	.400	.400	3

Quantitative and qualitative primary data were collected in survey format.

Returned completed surveys constituted informed consent. All returned surveys were opened upon receipt, stapled to their corresponding envelope, and assigned a reference number. Ample response time was given from September 21, 2014 to November 31, 2014. No more surveys were returned after the closure date of November 31, 2014.

EXCEL software was used to organize, compile, and manage raw data. Data preparation consisted of assigning numbers to each survey (n=109). The Statistical Package for Social Scientists SPSS software version 22 was used for quantitative data analyses. An MSWord table was created to collect qualitative data.

## Instrumentation

A survey instrument, consent form, and self-addressed stamped envelope were mailed using the United States mail service. Explanation of the survey's purpose, contact information, voluntary status, ability to withdraw without penalty, and potential risks were explained. No direct benefits or rewards were promised or provided.

The survey instrument was adapted using Ajzen's (2002) standard template based on the theory of planned behavior with permission (Appendix H). The 28-item survey was organized into seven sections: demographics (n=8), scanning practices and protocols (n=4), attitudes toward incorporating OFTV in routine 18-22 week scans (n= 4), perceived behavioral control (n=3), professional norms (n=4), intentions (n=3), and barriers (n=2). The majority of survey questions (57%; n= 18) were related to the theoretical constructs consisting mostly of close-ended questions. Understanding intention is the immediate antecedent to behavior and is dependent on the remaining constructs of attitude, subject (professional) norms and perceived behavioral control, theoretical constructs were operationally defined as:

*Attitude*- the degree to which an individual favors or disfavors a behavior based on that individual's subjective evaluation of the probability of an expected outcome (behavioral belief)

*Subjective (professional) norm* – Ajzen's construct of subjective norms was operationalized as *professional* norms to characterize the domain specific motivation to comply within the contextualized hierarchy of medicine where physicians prescribe behavior and sonographers are motivated to

comply and or where referent expert sonographers' behavior may motivate others to emulate their behaviors.

*Perceived behavioral control* – belief in the self-efficacy of a behavior based on requisite knowledge and skills, and absence of actual environmental barriers that preclude performance; emphasizes the influence of external factors on behavioral control where actual control preempts perceived behavioral control.

*Intent (Intention)*: the immediate antecedent to behavior where a strong commitment coupled with motivation to act is based on a person's cost benefit analysis to participate in specific task; indicates a person's readiness to perform a specific task; based on the attitude toward the behavior, subjective (domain specific professional) norms, and perceived behavioral control in relationship to the behavior and context.

A Likert scale with a forced-response format and endpoint extremes (strongly agree to strongly disagree) measured all constructs from 1 (strongly agree) to 5 (strongly disagree) and resulted in a summative score. The summative score for attitude was defined as Total Attitude. Questions 13 through 16 measured attitude. The summative score for perceived behavioral control defined the Total PBC, questions 17 through 19 measured perceived behavioral control. The summative score for professional norms defined Total PN, questions 20 through 23 measured professional norms. The summative score for intention defined Total Intent. Questions 24 through 26 measured intention in

terms of intention to follow CPC (24), the plan to learn more about OFTV heart anomalies to improve detection rates, and intention to sit for a credentialing examination within the next year (26).

Two sections, Perceived Behavioral Control and Barriers, were closely related. Manipulating question placement and formatting produced quantitative as well as qualitative data that could be triangulated for richer data collection. While perceived behavioral *control* was previously measured using a Likert scale with a forced-response format and endpoint extremes (strongly agree to strongly disagree), perceived barriers to OFTV inclusion was asked in an open-ended question placed at the end of the survey to capture the participant's easily retrievable salient beliefs. This mixed method approach was an effort to reduce systematic bias if relevant salient beliefs were not identified or dismissed as irrelevant in the literature review (Fishbein and Ajzen, 2010).

An MSWord table was created to organize qualitative data consisting of all handwritten comments on the survey instrument. One open-ended question (27) occurred near the end of the survey. Five closed-ended questions (1, 2, 5, 7, and 8) provided an additional comment space (*other: please specify*) and white space was provided at the end of the survey for general comments. Transfers of exact sentences, and words or phrases, were collated. Exact words, phrases, or sentences were tallied separately and categorized into general themes when applicable. For example, maternal obesity, maternal body habitus, and the acronym MBH were placed in the same general category.

Three non-participant individuals, a PhD rhetorician, a registered nurse with forty years of experience in obstetrics and gynecology, and an ARDMS credential obstetrical

sonographer with a college degree in diagnostic medical sonography and thirty years of clinical experience in obstetrical ultrasound, were asked to review the de-identified qualitative data table with generated themes. A traditional qualitative practice of making sense of data “derived from community consensus regarding what is ‘real’, what is useful, and what has meaning” was reached with 100% consensus (Denzin & Lincoln, 2005, p. 197; Silverman & Marvasti, 2008).

Survey items were developed from the literature using Ajzen’s TPB as a guide. The literature review revealed a continued scholastic conversation published about CHD surveillance using ultrasound technology in ultrasound specific peer-reviewed journals from the 1980s through 2014, along with official documents and position statements from leading professional organizations such as the SDMS’ scope of practice and code of ethics for sonographers (SDMS, 2000). Salient beliefs about the importance of and barriers to OFTV inclusion within the context of CHD surveillance using ultrasound technology were retrieved. Secondly, a close read of the AIUM practice guidelines (AIUM, 2013) pertaining specifically to fetal heart throughout pregnancy resulted in five professional consensus beliefs: documentation methods, timing of routine ultrasound referrals, fetal safety, minimum protocol criteria, and legal status of practice guidelines.

Key survey limitations included lack of established validity and reliability measures. Other research limitations included survey completion and response rates. Previous research studying ultrasound practice in the United States reported higher response rates compared to this study. However, research designs, distribution modes, scope, and sample sizes differed (Ismail, 2012; Miller, 1998; Mitchell, 2002; Newberry,

2009). Persutte's (1997) study is closely related to this research in design, distribution mode, sample size, and similar interest in sonographer's attitudes, practice behaviors, albeit, not specifically heart interrogation. Although Persutte had an impressive 59% response rate compared to this research with a 13.6% response rate, both sample sizes were relatively equal. In regard to response rates, Hablesleben and Whitman (2013) suggested quality over quantity.

A larger representative sample size might increase the statistical power of the study by decreasing Type II error risks. Much has been written on improving response rates by combining distribution modes, collaboration with national societies with proprietary e-mail addressed, marketing / analysis software, and increased credibility, participation incentives, and pre and post advertisements. Nirenberg (2009) reported an 8.8% overall response rate to an online survey about factors associated with oncology nurses' use of clinical practice guidelines. Nirenberg dispersed her electronic survey in collaboration with a national nursing society using a concurrent web option offering an e-mail invitation with instructions to access the web-based survey, a lottery incentive, and an e-mail reminder one week later. In 2012, Medway and Fulton studied concurrent web-options with a mail out survey finding that concurrent offers may confuse respondents or cause implementation failures and lack of efficacy for incentives. In contrast, Busby and Yoshida (2015) found that offering a lottery incentive was cost effective in web-based research and for the time being, researchers would continue to promote higher response rates by advertising surveys in a variety of free forums and interest groups. Onsite

forums at national ultrasound meetings where surveys may be dispensed quickly using portable computers may increase participation response rates.

Other limitations to this study included the inability to measure actual scanning practice behaviors that could be compared to attitudinal items and the inability to study scanning practice behaviors in a cohort over time. Logistics precluded either of these options and yet, this study provided rich baseline data.

## **Data Analysis**

### **Statistical Analysis**

Raw data sets with multiple variables were input into Excel spreadsheets and analyzed using SPSS version 22 software. Qualitative data was tabulated and collated into general themes. Descriptive statistics included frequencies and percentages to characterize sonographer's education, credentialing, and years of practice, physician's discipline, supervision level, and referral pattern, facility accreditation status, and ultrasound equipment capabilities. Inferential statistics included correlation analysis and a Mann-Whitney U test for analysis of variance. Spearman rho correlation coefficient was used to examine associations between variables. The Mann-Whitney U test was used to compare two independent sampling groups: sonographers with ARDMS credentials in obstetrics and sonographers not ARDMS credentialed in obstetrics. Sonographer's OFTV inclusion in routine obstetrical ultrasounds between 18-22 weeks gestation in the United States was the main dependent variable.

## **Summary**

The purpose of this research study was to assess mediating factors or barriers that may influence sonographer's practice of OFTV inclusion during routine obstetrical ultrasounds between 18-22 weeks gestation. Factors included attitude and perceived behavioral control toward OFTV inclusion and credential status. The relationships between inclusion of OFTV, credential status, educational attainment, and facility accreditation were also examined. Constructs from the theory of planned behavior served as a theoretical framework. Primary data was collected using a one-shot survey mailed using the United States postal service. Survey items were adapted from a questionnaire template provided with permission from Ajzen using the theory of planned behavior as a theoretical framework. The anonymous survey required no identifiable data. No direct benefits or rewards were offered or provided. After obtaining TWU IRB and agency (ARDMS) approval, the survey was launched September 21 and closed November 31, 2014. Raw data sets with multiple variables were captured using MSWord tables, EXCEL spreadsheets and analyzed using SPSS software.

## CHAPTER IV

### RESULTS

This research study assessed mediating factors or barriers that may influence a sonographer's practice of OFTV inclusion during routine obstetrical ultrasounds between 18-22 weeks gestation. Factors included attitude and perceived behavioral control toward OFTV inclusion and credential status. The relationships between inclusion of OFTV, credential status, educational attainment, and facility accreditation were also examined. Constructs from the theory of planned behavior served as a theoretical framework.

#### **Research Questions**

The following questions were addressed in this study:

1. How do sonographer's attitude and perceived behavioral control toward the inclusion of ventricular OFTV in routine obstetrical ultrasounds between 18-22 weeks gestation relate to practice behaviors?
2. What relationship exists between sonographer's attitudes toward the inclusion of OFTV in routine obstetrical ultrasounds and sonographer's demographic characteristics of credentialing, educational attainment, and facility accreditation?

Two null hypotheses were tested at the .05 level of significance:

1.  $H_{O1}$ : There will be no statistically significant difference toward the inclusion of OFTV in routine obstetrical ultrasounds between sonographers with ARDMS

credentials in obstetrics and sonographers without ARDMS credentials in obstetrics.

2. HO<sub>2</sub>: There will be no statistically significant difference toward the inclusion of OFTV in routine obstetrical ultrasounds between sonographers who seek advanced ultrasound certification and sonographers who do not seek advanced ultrasound certification.

### **Demographics**

Out of 1,000 surveys mailed, a total of 136 were returned. Of the 136 surveys returned, a total number of 109 were valid, representing a 13.6% response rate. Ten surveys were returned unopened. The remaining 17 sonographers provided reasons with regret for their ineligibility. Employment outside of obstetrical ultrasound was the most common reason given for their ineligibility.

### **Raw Data**

Demographic questions assessed participant's educational attainment, credentialing status, and years of practice in obstetrical ultrasound. The majority of participants (92%) reported earning a college degree: 42% with an associate degree, 38% with a baccalaureate degree, and 5% with a master's degree. Eight percent reported an earned high school diploma or GED. Seven percent of participants described their highest level of education in terms of ultrasound-specific education: a certificate in radiologic technology and or diagnostic medical sonography program (n=4), a hospital-based Radiologic Technology program (n=2), three years of college (n=1), and a technical school (n= 1) (Table 2).

Table 2

*Demographic Variables*

<i>Q1: What is your highest level of education?</i>	n	%
High school or GED	9	8
Associate degree	46	42
Baccalaureate degree	41	38
Master's degree	5	5
Other	8	7
Total	109	100

Among the eligible sample (n=109) seventeen different types of imaging credentials were reported (Table 3). The majority (66%) was multi-credentialed and 75% were ARDMS credentialed in obstetrics. Forty percent of participants reported ARRT credentials in radiologic technology. Thirty-two percent of participants reported ARDMS credentials in abdominal ultrasound and 22% were ARDMS credentialed in vascular ultrasound. Of the 109 participants, 25% of those performing obstetrical ultrasound were not ARDMS credentialed in obstetrics.

Table 3

*Credentialing Variables*

<i>Q2: Type of Credential Earned</i>		n	% rounded	Single imaging credential	Two or more imaging credentials
1	RDCS (FE) Fetal echocardiography n=18; RDMS (FE) Fetal echocardiography n=2	20		5	15
2	RDMS (OB) Obstetrics / gynecology	82		27	52
3	RT (R) Radiologic technology	44	40	1	43
4	RDMS (AB) abdominal	35	32	3	32
5	RDMS (RVT) vascular technology	24	22	-	24
6	RDMS (Breast)	10	9	-	10
7	RT (M) mammography	4	4	-	4
8	RT (VS) vascular sonography	3	3	-	3
9	RT (S) general sonography	2	2	-	1
10	NT nuchal translucency	1	1	-	1
11	CCI (V) vascular	1	1	-	1
12	CCI (AE) adult echocardiography	1	1	-	1
13	RDCS (AE) adult echocardiography	3	3	-	3
14	RDCS (PE) pediatric echocardiography	1	1	-	1
15	RDMS (NEURO) neurosonography	3	3	-	3
16	RT (CT) computed axial tomography	1	1	-	1
17	RT (MR) magnetic resonance imaging	1	1	-	1
Multi-credentialing precludes totals					

Of the 109 participants, twenty were ARDMS credentialed as fetal echocardiographers. Of the twenty fetal echocardiographers, ten were ARDMS credentialed in obstetrics, eight were ARRT credentialed radiologic technologists, and six were credentialed in vascular technology (n=5 ARDMS; 1=ARRT) (Table 4).

Table 4

*Fetal Echocardiographers*

Credentialing Agency / Fetal Echocardiographers (N=20)	n	% rounded
ARDMS Fetal Echocardiography (RDMS and RDCS)	20	18
ARDMS obstetrics	10	50
ARRT Radiologic Technology	8	40
ARDMS Vascular Technology (5); ARRT Vascular Technology (1)	6	30
ARDMS Abdominal Ultrasound	3	15
Nuchal Translucency	1	1
ARDMS Neurosonology	1	1
ARDMS Breast	2	2
ARRT Computer Axial Tomography (CT)	1	1

The majority of participants (69%) reported performing obstetrical ultrasounds more than ten years. Seventeen percent reported performing obstetrical ultrasound from one to five years. Ten percent reported performing obstetrical ultrasound from six to ten years, and 4% reported performing obstetrical ultrasound for less than one year (Table 5).

Table 5

*Length of Experience*

<i>Q3: How long have you performed obstetrical ultrasounds?</i>		
Choice	n	% rounded
Less than one year	4	4
1-5 years	19	17
6-10 years	11	10
More than 10 years	75	69
Total	109	--

Questions related to work environment included supervising physician's medical discipline and supervising physician's level of engagement, along with the participant's

clinical decision-making process toward OFTV inclusion. Questions regarding accreditation status and ultrasound equipment were also assessed.

Radiologists supervised the majority of participants (54%) followed by obstetricians (20%) and maternal fetal medicine specialists (16%). Less than ten percent were supervised by a dual combination of physicians with different medical disciplines: radiologists, maternal fetal medicine specialists, obstetricians, and a sonologist (Table 6).

Table 6

*Supervising Physicians*

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*Q5. Who is your supervising physician responsible for obstetrical ultrasound interpretation?*

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Supervising physicians' medical discipline	n	%
Radiologist	59	54
Obstetrician	22	20
Maternal fetal medicine specialist	17	16
Maternal fetal medicine specialist and Radiologist	2	--
Maternal fetal medicine specialist and Sonologist	1	--
Maternal fetal medicine specialist and obstetrician	3	--
Radiologist and obstetrician	3	--
Family medicine	1	--
Other: non specified	1	
Total	109	

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Of the 109 participants, 70% of participants reported that they never observed their supervising physician scan, back scan, or spot check the fetus after the sonographer's real time analysis. Sixteen percent reported observing the supervising physician scan, back scan, or spot check the fetus one out of every four exams. Ten percent reported the supervising physician scanned every patient after the sonographer's real time analysis (Table 7). Fifty-one percent of sonographers reported never observing

referrals for a targeted examination of the fetal heart when OFTV could not be obtained during routine 18-22 weeks gestation. However, 27% reported that approximately one out of four patients were referred (Table 8).

Table 7  
*Sonographer's Observations*

*Q6: Approximately how often do you observe your supervising physician scan (back scan /re-scan; spot check) the fetus after you have completed your real-time analysis?*

Choices	n	Percent rounded
Never	76	70
Twenty five percent	17	16
Fifty percent	2	2
Seventy five percent	3	3
Always	11	10
Total	109	100

Table 8  
*Patient Referral Pattern*

*Q12: How often have you observed level II patient referrals when OFTV could not be obtained during routine 18-22 week scans? (Observation: discussion with physician or patient, reading ob results, making appointments....)*

	n	% rounded
Never	55	51
25%	29	27
50%	7	7
75%	3	3
Always	14	13
Total	108	

The survey item (4) that assessed whether higher maternal risk factors for CHD influenced their decision to attempt OFTV with specific examples such as maternal

obesity, diabetes, or an abnormal nuchal translucency, the majority (62%) reported affirmatively. Thirty-nine percent reported known risk factors for CHD would not influence their decision to include OFTV. Additionally, nine participants wrote supporting comments in the survey’s margins: “I do OFTV on every patient,” “I attempt OFTV on everyone”, “it’s required”, “all pts [patients] get OF [OFTV] scanned,” “OFTV attempted on any pt [patient in which] you can get a 4cv [4CV],” and “we attempt regardless of risk status” (Table 9).

Table 9

*Risk Assessment*

*Q4: Do higher maternal risk factors for a congenital heart defect influence your decision to attempt outflow tract views (OFTV)? (Examples of higher risk factors: maternal obesity, diabetes, abnormal NT scan....)*

Choice	n	% rounded
Yes	67	62
No	42	39
Total	109	100

The majority of participants (63%; n= 106) worked in medical facilities with ultrasound accreditation from three agencies: *American College of Radiology (ACR)*, *AIUM*, or *Inter-societal Accreditation Commission (IAC)*. The ACR accredited the majority of facilities (33%) with 28% accredited by the AIUM. However, 36% of participants reported working in a non-ultrasound accredited facility (Table 10).

Table 10

*Accreditation Status*

<i>Q7: What is the accreditation status of your imaging facility?</i>	n	Percent rounded
Non-accredited	39	37
ACR	36	34
AIUM	30	28
ICAVL (IAC)	1	1
Total	106	

Ninety-one percent of participants rated the fetal heart imaging capabilities of the ultrasound equipment used for obstetrics as excellent (49%) or good (42%). Two percent of participants rated their equipment as poor for imaging the fetal heart (Table 11).

Table 11

*Ultrasound Equipment*

<i>Q8: Please rate the fetal heart imaging capabilities of your ultrasound equipment as:</i>	n	% rounded
Choice		
Excellent	52	49
Good	45	43
Fair	7	7
Poor	2	2
Total	106	---

Survey items regarding scanning practice behaviors specifically related to documenting the fetal heart included 2-dimensional video clips (2DVC), spectral Doppler to hear the fetal heart, and OFTV inclusion attempts. Forty percent of participants reported *never* including a 2DVC of the fetal heart. Approximately one in three participants reported *always* recording the fetal heart with 2DVC (Table 12).

Forty-five percent of participants reported never using spectral Doppler during the first trimester ultrasound. Twenty-six percent reported always incorporating spectral Doppler to document the presence or absence of fetal heart activity in the first trimester (Table 13). The majority of participants (62%) reported *always* attempting to include OFTV. However, approximately one in three participants reported *never* attempting OFTV or occasionally attempting OFTV (Table 14).

Table 12

*Practice Behavior One: Two-Dimensional Video Clips*

*Q9: How often do you record the fetal heart using a 2-dimensional video clip? (Practice Behavior 1)*

Scale	n	% rounded
Never	43	40
25%	22	20
50%	7	7
75%	5	5
Always	31	29
Total	108	

Table 13

*Practice Behavior Two: Spectral Doppler*

*Q10: In the first trimester, how often do you use spectral Doppler for the presence / absence of fetal heart activity?*

Scale	n	% rounded
Never	45	42
25%	27	25
50%	5	5
75%	2	2
Always	28	26
Total	107	

Table 14

*Practice Behavior Three: OFTV Attempts*

<i>Q11: How often do you attempt outflow tract views (OFTV) during routine 18-22 week scans?</i>		
N= 108	n	% rounded
Never	19	18
25%	14	13
50%	5	5
75%	3	3
Always	67	62
Total	108	

In assessing participant's attitude toward OFTV inclusion during routine obstetrical ultrasound performed between 18-22 weeks gestation, 81% agreed or strongly agreed (37%; 44% respectively) that obtaining OFTV was technically feasible (Table 15). Seventy-six percent of participants either agreed or strongly agree (39%; 37% respectively) that obtaining OFTV would help them to identify critical heart defects that are otherwise undetectable using only the 4CV (Table 16). Sixty-nine percent of participants either agreed or strongly agreed (37%; 32% respectively) that OFTV would help them to provide approximately the same level of care for many of their patients (Table 17). Sixty-seven percent either agreed or strongly agreed (43%; 24% respectively) that interrogating the fetal heart using OFTV made their job more interesting (18).

Table 15

*Attitude One**Q13: Obtaining OFTV is technically feasible most of the time during routine 18-22 week scans.*

	n	% rounded
Strongly agree	47	44
Agree	40	37
Undecided	16	15
Disagree	2	2
Strongly disagree	2	2
Total	107	

Table 16

*Attitude Two**Q14: OFTV help me to identify critical heart defects that are otherwise undetectable using only the 4-chambered view.*

Choice N= 106	n	% rounded
Strongly agree	39	37
Agree	42	40
Undecided	21	20
Disagree	2	2
Strongly disagree	2	3
Total	106	

Table 17

*Attitude Three**Question 15: OFTV help me to provide approximately the same level of care for many of my patients.*

Choice N= 107	n	% rounded
Strongly agree	34	32
Agree	39	37
Undecided	26	25
Disagree	5	5
Total	106	

Table 18

*Attitude Four*

Question 16: Interrogating the fetal heart using OFTV during routine 18-22 week scans makes my job more interesting.		
Choice N=107	n	% rounded
Strongly agree	25	24
Agree	46	43
Undecided	20	19
Disagree	14	13
Strongly Disagree	2	2
Total	107	

In assessing participant's perceived behavioral control toward OFTV inclusion, 74% either agreed or strongly agreed (32%; 41%) that they felt comfortable with their scanning abilities (Table 19). The majority of participants disagreed or strongly disagreed (26%; 26% respectively) that it was their decision to include OFTV (Table 20). Sixty-four percent either agreed or strongly agreed (45% 19% respectively) they had enough time to complete obstetrical examinations without feeling rushed (Table 21).

Table 19

*Perceived Behavioral Control One*

Q17: I feel comfortable with my scanning abilities to obtain OFTV when needed.		
Choice	n	% rounded
Strongly agree	43	40
Agree	35	32
Undecided	6	6
Disagree	16	15
Strongly Disagree	8	8
	108	

Table 20

*Perceived Behavioral Control Two*

Q18: It is generally my decision whether to include or exclude OFTV during routine 18-22 weeks scans.

Choice (N= 107)	n	% rounded
Strongly agree	16	14
Agree	24	22
Undecided	11	10
Disagree	28	26
Strongly Agree	28	26
Total	107	

Table 21

*Perceived Behavioral Control Three*

Q19. Generally I have enough time to complete scans without feeling rushed throughout the day.

Choice	n	% rounded
Strongly agree	21	19
Agree	49	45
Undecided	5	5
Disagree	25	23
Strongly Disagree	8	7
Total	108	

In assessing participant's professional norms and OFTV inclusion during routine 18-22 week obstetrical ultrasounds, 58% either agreed or strongly agreed (29% 29% respectively) that professional colleagues whose opinions they valued obtained OFTV. However, approximately one in three participants either disagreed or strongly disagreed (22% 7% respectively) that their professional colleagues obtained OFTV (Table 22). When asked if their professional colleagues whose opinion they valued would approve of the participant obtaining OFTV, 80% of participants either agreed or strongly agreed (39% 41% respectively) (Table 23). Sixty-three percent either disagreed or strongly

disagreed (40%; 13% respectively) they felt pressured to follow practice guidelines that include OFTV in routine obstetrical ultrasound between 18-22 weeks gestation (Table 24). Seventy-seven percent either agreed or strongly agreed (33%44% respectively) they felt obligated to the patient to obtain OFTV (Table 25).

Table 22

*Professional Norms One*

Q20. Most of my professional colleagues whose opinions I value obtain OFTV during routine 18-22 weeks scans.

Choice N=108	n	% rounded
Strongly agree	31	29
Agree	31	29
Undecided	14	13
Disagree	24	22
Strongly Disagree	7	7
Total	107	

Table 23

*Professional Norms Two*

Q21: Most of my professional colleagues whose opinions I value would approve of me obtaining OFTV during routine 18-22 weeks scans.

Choice	n	% rounded
Strongly agree	44	41
Agree	42	39
Undecided	15	14
Disagree	5	5
Strongly Disagree	2	2
Total	108	

Table 24  
*Professional Norms Three*

Q22: I feel pressured to follow clinical practice guidelines that add OFTV during routine 18-22 weeks scans.		
Choice (N=106)	n	% rounded
Strongly agree	11	10
Agree	20	19
Undecided	20	19
Disagree	42	40
Strongly Disagree	13	12
Total	106	

Table 25  
*Professional Norms Four*

Q23: I feel obligated to the patient to obtain OFTV during routine 18-22 weeks scans.		
Choice	n	% rounded
Strongly agree	47	44
Agree	36	33
Undecided	10	9
Disagree	11	10
Strongly Disagree	4	4
Total	108	

The survey item that assessed intention to follow OFTV inclusion guidelines resulted in 84% either agreed or strongly agreed (33%; 51% respectively) (Table 26). Eighty-eight percent either agreed or strongly agreed (47; 41% respectively) planned to learn more about OFTV heart anomalies (27).

Table 26

*Intentions One*

Q24: I intend to follow clinical practice guidelines that now endorse OFTV during routine 18-22 weeks scans.		
Choice	n	% rounded
Strongly agree	54	51
Agree	35	33
Undecided	6	6
Disagree	8	8
Strongly Disagree	2	2
Total	105	

Table 27

*Intentions Two*

Q 25. I plan to learn more about OFTV heart anomalies so that I can improve my detection rate of heart defects.		
Choice (n=106)	n	% rounded
Strongly agree	43	41
Agree	50	47
Undecided	9	9
Disagree	2	2
Strongly disagree	2	2
Total	106	

Approximately one in four participants (n=29) indicated intention to take at least one out of nine advanced certification examinations with the next year. Fetal echocardiography was the most common (n= 12) certification examination selected, followed by obstetrics (n=6). Other advanced credentialing examinations included vascular (n=5), adult echocardiography (n= 5), and breast sonography (n=3) (Table 28).

Table 28  
*Intentions Three*

Q26. Which of the following examinations do you intend to take within the next year?

Credentialing agency	Type of Examination	n	% rounded
ARDMS *	Fetal echocardiography RDMS n=10; RDCS n=2	12	--
ARDMS	Obstetrics and gynecology	6	--
ARDMS	Cardiac Sonography (Adult)	5	--
ARDMS	Vascular Technology	5	--
ARDMS	Breast	3	--
ARDMS	Neurosonology	1	--
ARDMS	Pediatric Sonography	1	--
ARRT	General sonography	1	--

- RDMS FE and RDCS FE are the same examination differentiated by the ARDMS credentialing pathway.
- Numbers above represent only the type of examinations participants intend to take in the next year. A participant may intend to take more than one examination in a given year.

[Yes, I intend to take an examination(s) within the next year].	29	27%
Intending to take obstetrical credential within the next year (n= 10 without ob credential)	3	3%

The majority of participants (n= 103) noted three major types of barriers to inclusion of OFTV related to the mother, fetus, and environment. Of the three major types of barriers reported, 14 different perceived barriers were hand written in the space provided. Fifty-two percent of the participants chose maternal obesity, maternal body habitus, or patient size. This was the only maternal risk factor reported as a barrier to OFTV inclusion. The second most common barrier reported by 40% of the participants was fetal lie. Three other fetal-related barriers to OFTV inclusion were fetal heart anomalies, excessive fetal movement during the ultrasound, and oligohydramnios (excessive amniotic fluid). Nine barriers were environment-related based on the

frequency of responses: inadequate scanning time with heavy workloads, supervising physician did not require OFTV in the protocol, lack of knowledge, suboptimal equipment, lack of training, lack of experience, distractions during the ultrasound from family/friends, physician’s prescription of ultrasound too early for OFTV inclusion, and belief that the patient must be in a high risk category before OFTV inclusion (Table 29).

Fifty-two percent of participants never worried about the risk of repetitive strain injury, aggravating an existing work-related injury, or pain caused by OFTV inclusion. However, 48% had at least some level of worry about work-related injuries from additional interrogation of the fetal heart using OFTV (Table 30).

Table 29

*Qualitative Data*

Q27: What key barriers prevent you from interrogating the heart using OFTV during routine 18-22 week scan? (N=103)

	Barriers	Risk source	n	% rounded
1	Maternal obesity, maternal body habitus, patient size	Maternal	54	52 %
2	Fetal lie, prone presentation; fetal malposition	Fetal	41	40 %
3	Time per scan, time it takes, time constraints; Patient volume 18-22; Very heavy patient load 25+ scans / day; chaotic environment	Environmental	10	10%
4	Radiologist not interested in reading OFTV; physician not comfortable with reading OFTV; radiologists don’t want responsibility of reading OFTV; OFTV not included in hospital policy/protocol for routine prg [pregnancy] scans; exclusion from regular protocol; not in level II protocol, Institution and radiologist rules [exclude OFTV]; never been asked by Dr. or radiologist; only protocol [excluded from protocol]; OFTV not requested	Environmental	8	8

(Continued)

5	Lack of knowledge	Environmental	7	7
6	The equipment is over 15 years old; equipment quality [suboptimal]	Environmental	6	6
7	Lack of training	Environmental	5	5
8	Lack of experience	Environmental	5	5
9	Abnormal relationship of the heart [??]; fetal anomalies	Fetal	4	4
10	Excessive fetal movement (activity) (27);	Fetal	4	4
11	Distractions by entirely too many people in the room (children) for the “show”.	Environmental	3	3
12	Ob too early to perform OFTV [physician prescribed the ultrasound too early to obtain OFTV]; orders coming in at 17 wks; too immature	Environmental	3	3
13	Oligohydramnios	Fetal	2	2
14	Do not do high risk OBs, and never have.	Environmental	1	1

Table 30

*Work-related Musculoskeletal Injuries*

*Q 28: How often do you worry that including OFTV during routine 18-22 week scans increase your risk of repetitive strain injury, aggravate an existing work-related injury, or cause you pain?*

Choices (N=106)	n	% rounded
Never	55	52
25%	17	16
50%	21	20
75%	7	7
Always	6	6
Total	106	

Spearman rho correlation testing were performed to address the two research questions examining sonographer’s attitudes and perceived behavioral control toward the inclusion of OFTV, scanning practice behaviors, and the demographic characteristics of

credentialing status, educational attainment, and facility accreditation. Mann-Whitney U testing was performed to address the two null hypotheses.

Table 31

*T-Attitude, T-PBC, OFTV Inclusion, and Overall Practice Behavior*

Spearman's rho		T-Attitude	T-PBC	OFTV Inclusion	Overall Scanning Practice Behaviors
T-Attitude	Correlation Coefficient	1.000	.499**	.592**	.240*
	Sig. (2-tailed)	.	.000	.000	.012
	N	109	109	108	109
T-PBC	Correlation Coefficient	.499**	1.000	.398**	.058
	Sig. (2-tailed)	.000	.	.000	.551
	N	109	109	108	109
Include OFTV	Correlation Coefficient	.592**	.398**	1.000	.526**
	Sig. (2-tailed)	.000	.000	.	.000
	N	108	108	108	108
Overall Scanning Practice Behaviors	Correlation Coefficient	.240*	.058	.526**	1.000
	Sig. (2-tailed)	.012	.551	.000	.
	N	109	109	108	109

\*\* . Correlation is significant at the 0.01 level (2-tailed).

\* . Correlation is significant at the 0.05 level (2-tailed).

Table 32

*Ob Credential, Education, Facility Accreditation, OFTV Inclusion, Scanning Practice, and Total Attitude*

Spearman's rho		OB Cred	Education	Facility Accreditation	Inclusion OFTV	Scanning practice	T-Attitude
OB Cred	Correlation	1.000	-.058	.020	.282**	.279**	.234*
	Coefficient						
	Sig. (2-tailed)	.	.565	.840	.003	.003	.014
	N	109	101	106	108	109	109
Education	Correlation	-.058	1.000	.065	.060	-.038	.006
	Coefficient						
	Sig. (2-tailed)	.565	.	.525	.551	.706	.952
	N	101	101	99	101	101	101
Facility Accreditation	Correlation	.020	.065	1.000	.081	.003	.009
	Coefficient						
	Sig. (2-tailed)	.840	.525	.	.407	.977	.925
	N	106	99	106	106	106	106
Inclusion OFTV	Correlation	.282**	.060	.081	1.000	.526**	.592**
	Coefficient						
	Sig. (2-tailed)	.003	.551	.407	.	.000	.000
	N	108	101	106	108	108	108
Scanning practice	Correlation	.279**	-.038	.003	.526**	1.000	.240*
	Coefficient						
	Sig. (2-tailed)	.003	.706	.977	.000	.	.012
	N	109	101	106	108	109	109
T-Attitude	Correlation	.234*	.006	.009	.592**	.240*	1.000
	Coefficient						
	Sig. (2-tailed)	.014	.952	.925	.000	.012	.
	N	109	101	106	108	109	109

\*\* . Correlation is significant at the 0.01 level (2-tailed).

\* . Correlation is significant at the 0.05 level (2-tailed).

## Summary

Primary data collection was accomplished using an anonymous survey instrument that provided demographic, scanning practices, and data related to the theoretical construct under investigation. Descriptive statistics and inferential statistics examined the sample in terms of OFTV inclusion, credential status, education attainment, years of experience in obstetrical ultrasound, scanning practice behaviors, and work environment. Theoretical constructs of attitude, perceived behavioral control, subjective norms operationalized as professional norms, and intentions were also examined. ARDMS credentialing status was found to be an overarching variable mediating OFTV inclusion.

There was a statically significant difference between sonographers with an ARDMS credential in obstetrics and sonographers without ARDMS credentials in obstetrics in their OFTV inclusion during routine obstetrical ultrasound between 18-22 weeks gestation. Sonographers holding an ARDMS credential in obstetrics were more favorable toward OFTV inclusion leading to rejection the null hypothesis. However, there was no statistically significant difference found between sonographers who intend to sit for an advanced certification examination and those who do not intend to sit for an advanced certification examination, and their OFTV inclusion. Thus, the null hypothesis was retained.

Qualitative data revealed emerging themes that corresponded to prior research that identified maternal, fetal, and environmental factors that influence OFTV inclusion. Maternal obesity and poor fetal positioning (lie) were considered key barriers to OFTV inclusion. The majority of barriers noted were environmental. Two of the most frequently

reported environment barriers were time restrictions and current scanning protocols. The outcomes from this research can guide program development for the adoption of clinical practice guidelines for improved prenatal detection of CHD.

## CHAPTER V

### CONCLUSIONS AND RECOMMENDATIONS

The four-chambered view of the fetal heart has been the mainstay of ultrasound surveillance for CHD since the 1980s. In 2013, the AIUM recommended the addition of an interrogation process called outflow tract views to help identify critical congenital heart defects that are undetectable using the standard four-chambered view of the heart. This scanning protocol change was a significant departure in ultrasound imaging practice in the United States. This study examined the translation of evidence based ultrasound research of OFTV inclusion to practice during routine obstetrical ultrasounds between 18-22 weeks gestation in order to improve prenatal detection of CHD.

#### **Summary**

##### **Purpose of the Study**

The purpose of this research study was to assess mediating factors or barriers that may influence sonographer's practice of OFTV inclusion during routine obstetrical ultrasounds between 18-22 weeks gestation. Factors included attitude and perceived behavioral control toward OFTV inclusion and credential status. The relationships between inclusion of OFTV, credential status, educational attainment, and facility accreditation were also examined. Constructs from the theory of planned behavior served as the theoretical framework.

ARDMS credentialing in obstetrics was significantly related to OFTV inclusion, scanning practice, and total attitude toward OFTV inclusion. Positive significant

correlations were found between sonographer's attitude, perceived behavioral control, and inclusion of OFTV in routine obstetrical ultrasounds between 18-22 weeks gestation with attitude and OFTV inclusion having the highest significant correlation. There was no significant correlation found between perceived behavioral control and overall scanning practice behaviors. There were no significant correlations between attitude toward OFTV inclusion and education or attitude toward OFTV inclusion and facility accreditation.

### **Description of the Sample**

The sample consisted of 109 non-physician and ARDMS credentialed sonographers who performed routine obstetrical ultrasound in the United States. The majority of participants were ARDMS credentialed in obstetrics with ten or more years of experience with almost an even split between an earned associate or baccalaureate degree and were currently employed in accredited facilities supervised primarily by radiologists.

### **Data Collection Methods**

A mixed method approach collected primary quantitative and qualitative datum. Excel software was used to organize, compile, and manage data. SPSS software version 22 was used for data analyses. Qualitative data revealed various emerging themes to more fully characterize practice behaviors and phenomenon related to translation of OFTV inclusion to practice. Constructs from the theory of planned behavior included attitude toward OFTV inclusion, perceived behavioral control, subjective norms operationalized as professional norms, and intent.

## Conclusions

The first research question asked, “How are sonographer’s attitude and perceived behavioral control toward inclusion of OFTV during routine obstetrical ultrasounds between 18-22 weeks gestation related to practice behaviors?” Positive significant correlations were found between sonographer’s attitude, perceived behavioral control, and inclusion of OFTV in routine obstetrical ultrasounds between 18-22 weeks gestation with attitude and inclusion of OFTV having the highest significant correlation ( $r=.592$ ), at  $p=.01$  (Table 31). However, there was no significant correlation found between perceived behavioral control and overall scanning practice behaviors ( $r= .058$ ).

The second research question asked, “What relationships exist between sonographer’s attitude toward inclusion of OFTV and demographic characteristics of credentialing, educational attainment, and facility accreditation?” At  $p= .05$ , significant correlation was found with attitude toward including OFTV and ARDMS obstetrical credential ( $r= .234$ ). However, there were no significant correlations between attitude toward OFTV inclusion and education ( $r= .006$ ); and attitude toward OFTV inclusion and facility accreditation ( $r= .009$ ). The relationship between ARDMS obstetrical credential status, scanning practices and inclusion of OFTV was also examined. At  $p= .01$ , results revealed significant correlations between ARDMS obstetrical credential status and scanning practices ( $r= .279$ ); and between ARDMS obstetrical credential status and inclusion of OFTV ( $r= .282$ ) at  $p= .01$  (Table 32).

The null hypotheses were tested at the .05 level of significance.  $H_{O1}$ : There will be no statistically significant difference toward the inclusion of OFTV in routine

obstetrical ultrasounds between sonographers with ARDMS credentials in obstetrics and sonographers without ARDMS credentials in obstetrics. A Mann-Whitney U test demonstrated statistically significant difference in OFTV inclusion between sonographers with ARDMS credentials in obstetrics (m=58.80, n=82) and sonographers without ARDMS credentials in obstetrics (m= 40.92, n= 26), U= 713, z= -2.922, p= .003, with a medium effect size of  $r = .3$  (Table 33). According to Pallant (2010), the effect size can be calculated using  $r = z / \sqrt{N}$  (total number of cases), which is an indication of the strength of association between two variables. Cohen's (1992) criteria for independent groups assign  $r = .3$  as a medium effect size, indicating a medium effect of ARDMS credentials in obstetrics on the practice of OFTV inclusion. As a result, the first null hypothesis was rejected.

Table 33

*ARDMS OB Credential and OFTV Inclusion*

	Include OFTV
Mann-Whitney U	713.000
Wilcoxon W	1064.000
Z	-2.922
Asymp. Sig. (2-tailed)	.003
a. Grouping Variable: RDMS OB Credential	

H02: There will be no statistically significant difference toward the inclusion of OFTV in routine obstetrical ultrasounds between those who seek advanced ultrasound certification and those who do not seek advanced ultrasound certification. A Mann-Whitney U test demonstrated no statistically significant difference in OFTV inclusion

between sonographers who intend to sit for advanced certification (m=58.43, n= 28) and sonographers who do not intend to sit for an advanced certification (m= 51.73, n= 78), U= 954, z=-1.141, p= .254 (Table 34). These results failed to reject the second null hypothesis.

Table 34

*OFTV Inclusion and Seeking Advanced Certification*

	Include OFTV
Mann-Whitney U	954.000
Wilcoxon W	4035.000
Z	-1.141
Asymp. Sig. (2-tailed)	.254
a. Grouping Variable: Advanced Certification Intent	

Analyses for the null hypotheses confirmed OB credential status had the greatest impact on the practice of OFTV inclusion. Qualitative analyses revealed maternal obesity and poor fetal lie were the most common barriers to OFTV inclusion. However, the majority of barriers were environmental with the two most frequent being time restrictions and scanning protocols.

Table 35

*Research Hypotheses: Rejected or Failed to Reject the Null*

Research Hypothesis	Reject or Failed to Reject the Null
HO <sub>1</sub> : There will be no statistically significant difference toward the inclusion of OFTV in routine obstetrical ultrasounds between sonographers with ARDMS credentials in obstetrics and those not ARDMS credentialed in obstetrics.	Reject
HO <sub>2</sub> : There will be no statistically significant difference toward the inclusion of OFTV in routine obstetrical ultrasounds between those who seek advanced ultrasound certification and those who do not seek advanced ultrasound certification.	Failed to reject the null.

**Discussion and Implications**

Among the research sample, ARDMS credentialing in obstetrics was the key-mediating factor of OFTV inclusion. While the entire sample consisted of ARDMS credentialed sonographers in at least one specialty, the majority (66%) was multi-credentialed. However, only 75% of participants were ARDMS credentialed in obstetrics although the sample majority had performed obstetrical ultrasound for ten or more years. This may imply that discipline-specific credentialing in obstetrics is not an employment prerequisite. Obtaining multiple credentials may be a function of employment or simply an interest in a specific area of ultrasound in facilities where high demand for additional

knowledge and training other than obstetrics provides a learning environment with exposure to other disease pathology and the opportunity to become eligible to earn additional credentials. Twenty-nine participants indicated intent to sit for a credentialing examination within the next year. Twelve of the 29 participants indicated intent to sit for the fetal echocardiography examination and six intended to take the obstetrics examination within the next year. Obstetrics and fetal echocardiography examinations each require knowledge of OFTV inclusion as part of fetal heart interrogation. Certification by credentialing is a known industry standard in medicine and health education but the public may be unaware of the importance of credential status. How ARDMS credentials in obstetrics mediate OFTV inclusion is unclear.

The rate of adoption of OFTV among participants was an important piece of baseline data obtained in this convenience sample. Sixty-two percent of participants stated that they always attempted OFTV during routine obstetrical ultrasounds while collectively 31% never or only occasionally attempted OFTV (18%; 13% respectively). The sample majority agreed that OFTV inclusion would help them to identify critical congenital heart defects, to dispense equitable care, and to make their job more interesting. The attitudes of individual accountability and provision of equitable care closely matched attributes espoused in the sonographer's scope of practice and code of ethics. Fishbein and Ajzen's TPB suggested that salient beliefs that inform behavior might be amended when inaccurate information is revised.

Another important piece of baseline data was obtained in this study. Nine of the 14 *key* barriers reported by participants in an open-ended question were environmental in

nature, one of which was worry about musculoskeletal injuries as a result of the additional scanning required to include OFTV in routine practice. Participants practiced what Fishbein and Ajzen (2010) referred to as the subjective evaluation of the probability of an expected outcome (behavioral belief) when they answered the question by weighing the potential personal cost of OFTV inclusion to the potential benefit of detecting a congenital heart defect. In fact, forty-eight percent of participants reported at least some level of worry about the risk of repetitive strain injury, aggravation of an existing work-related injury, or pain associated with routine OFTV inclusion. Expected outcomes of ultrasound surveillance are generally posed as a positive outcome for the fetus such as improved detection of critical congenital heart defects that may improve the quality of life with medical intervention.

However, expected outcomes of ultrasound surveillance with routine OFTV inclusion among almost half of the study participants suggested a negative outcome for the sonographer. Musculoskeletal injuries among sonographers have been documented in terms of loss of wages and attrition when sonographers leave their careers as a result of work related injuries.

Letourneau et al. (2014) suggested a long learning curve was required to incorporate OFTV. Training may consist of self-directed reading and tedious repetition in order to develop cognitive real time diagnostic skills and interrogative scanning techniques exacerbated by barriers such as maternal obesity, poor fetal position, and lack of environmental support. Schreckengost and Filly (2005) argued that OFTV inclusion required minimum additional time once the sonographer acquired competent skills.

Health educators may be able to reframe relevant issues with positive campaigns that address the efficacy of OFTV, professional duty of care, streamlining of the OFTV inclusion criteria, and advocacy for change beyond individual behavioral modification.

Health educators may be interested in studying why almost half of the participants in this convenience sample worried about work related injuries and the additional scanning required for OFTV inclusion in routine practice. This would require an understanding of the associated salient beliefs of sonographers about their participation in surveillance of congenital heart defects, sonographer's attitudes toward maternal risk factors such as maternal obesity, the actual time to learn and perform OFTV, and whether these salient beliefs are based on fact. There is a paucity of empirical data about time allocation required to learn, obtain, and routinely incorporate OFTV as well as the level of industrial support to make this significant change in clinical practice possible. Health educators may be interested in learning how the provision of education and training may promote work site health among sonographers who perform OFTV in routine practice if in fact there is a decided association between work related injuries and OFTV inclusion. Freudenberg, Bradley and Serrano (2009) suggested advocating changes in industrial practices such as the production of unsafe products. Health educators could direct research related to population health for sonographers as a social class who provide real time analysis with documented medical imaging as a product to supervising physicians who direct their work (Hofrichter, 2003).

As this study demonstrated, OFTV inclusion was dependent on multiple factors. OFTV inclusion was suggested over a decade ago and a new perspective by health

educators may be beneficial because they are skilled experts in seven specific areas: individual and community assessment, program planning, program implementation, program process and outcome evaluation, program administration, resource identification, communication and health advocacy.

### **Study Limitations**

Primary study limitations included lack of baseline instrument validity, reliability, self-report, and response rate. Adequate content validity and test-retest reliability were achieved prior to survey implementation. High internal consistency was achieved for all constructs with the exception of intention. However, intention was a supporting construct and these survey items were retained in order to collect pertinent data.

The response rate was 13.6%. One hundred thirty six surveys were returned with 109 surveys meeting inclusion criteria in the self-addressed stamped envelopes. The most common reason given for non-participation was working outside of obstetrical ultrasound. The reason(s) for such a high non-response rate was unclear and a reminder postcard was not sent. Although the response rate was disappointing, the quality of results was encouraging considering this research study was an initial attempt to capture data for factors relating to OFTV inclusion. Collecting electronic data using portable lap top computers and offering a lottery incentive may increase response rates in future research efforts (Busby & Yoshida, 2015).

An exclusionary limitation occurred with sample method. This was a convenience sample of non-physician, ARDMS credentialed sonographers in the United States in which results cannot be generalized. A larger professional group of radiologic

technologists who may also perform routine obstetrical ultrasound but who are not ARDMS credentialed were excluded and may provide an impetus for future research.

### **Recommendations**

Prenatal ultrasound surveillance for CHD in the United States is multi-layered. It includes the patient foremost, with referring and supervising physicians, sonographers, educational and medical institutions, private and federal funders, and of course, the engineers and scientists who develop the ultrasound technology. Each plays a significant role in how fetal heart surveillance and research continues in the United States.

Acherman et al. (2007) posited that ineffective fetal heart interrogation reflected the complexity of prenatal screening efforts that continues today.

### **Suggested Future Research Interests**

Health educators could begin with a research agenda to randomly sample a larger population of sonographers who practice obstetrical ultrasound to confirm or deny the statistically significant difference found in this small convenience sample. Health educators may also be interested in learning how ARDMS credentialing in obstetrics mediates OFTV inclusion in order to inform the public about the importance of professional standards in ultrasound as well as health education.

Health educators may consider leading a multidisciplinary approach bringing together sonographers and physicians who support shared values of credentialing and qualification prized by each (Clark, 1994). Health educators are equipped to perform needs assessments, program development, and facilitation with process and outcome evaluations using data collection and analysis skills, and process and outcome evaluation

of targeted programs to increase public awareness of related issues. This multidisciplinary collaboration could be shared at national conferences in health education / health promotion and ultrasound conferences.

Health educators may consider future research on workplace safety / risk avoidance for those who may believe that OFTV inclusion in routine obstetrical practice may cause them bodily harm. Health educators could investigate physician's level of acceptance of OFTV inclusion in prescribed protocols that direct sonographer's scanning behaviors, sonographers OFTV inclusion criteria, and relevant environmental barriers to inclusion in order to search for modifiable factors to be used in program planning.

A health educator could borrow ideas from Latourneau's et al. (2014) example of agenda setting and community engagement in a Canadian province where local resources of time and expertise were used to encourage OFTV inclusion. A new program called *Start With The Heart On the Mother's Side* addresses three salient beliefs about perceived behavioral control and barriers found in this research: maternal obesity, poor fetal position, and worry of occupational injury by the addition of OFTV inclusion. Neither maternal obesity nor poor fetal position is sonographer dependent. However, behavior modification to avoid actual or perceived risks of injury is addressed in this new program. Letourneau et al. suggestion to start with the heart may increase the odds of OFTV inclusion by finding the fetus in an optimal position or before the fetus becomes more active. Placing the mother in a decubitus posture displaces the increased abdominal girth caused by maternal obesity and may reduce the additional downward pressure applied to the probe that is often required to penetrate the maternal abdomen when the mother is

supine. This strategy may offset sonographer's cognitive and physical fatigue by performing a complex fetal heart interrogation earlier in the obstetrical ultrasound. Secondly, the phrase, *on the mother's side*, is a double entendre. It refers to the above mentioned strategy of positioning the mother on her side and it appeals to the critical caring role sonographer's play in the detection of CHD.

OFTV inclusion has been suggested since 2003. The attitudes and barriers to OFTV inclusion of educators with clinical resources and curriculum in accredited ultrasound programs that teach obstetrical ultrasound have yet to be surveyed. This may produce more insight into how OFTV inclusion may be accomplished on a grander scale.

No correlation was found between OFTV inclusion and education. However, only one non-ultrasound specific question was asked about education. Sonographers typically meet continuing medical education requirements by attending national ultrasound meetings and reading articles in peer-review journals. However, transportation, attendance, and hotel accommodation where national meetings occur are exorbitant for many sonographers. Health educators possess key skills to collaborate with sonographers to design affordable programs and materials to teach OFTV inclusion. The following example was designed to influence attitude, to build capacity, to inform, and to accommodate actual or perceived barriers to OFTV inclusion:

- *Hands On the Heart*: After conducting a needs assessment and identifying local resources, a health educator may orchestrate a participatory training cooperative that matches experienced sonographers willing to share time and expertise with less experienced sonographers. Health educators could serve as a resource

facilitator for this program, and assist sonographer's in preparing lectures and education materials. This is an example of a short-term goal-directed intervention addressing lack of knowledge, training, and skills.

- Examining physician's attitudes toward AIUM 2013 clinical practice guideline adherence and prescription of scanning protocols to include OFTV may be an area of interest to health education researchers. *Leading with the Heart* is an idea for a program to encourage physicians to back-scan the fetal heart of the majority of obstetrical ultrasounds they interpret.

Organizational behaviorists may be interested in a cost – benefit analysis of OFTV inclusion in chaotic work environments with heavy patient loading. Ethicists may be interested in researching whether the decentralized health imaging services produces service disparities in prenatal ultrasound screening programs in the United States.

Translating research to practice in the detection of congenital heart defects requires a multi-disciplinary approach of many professional. Widening health educator's scientific knowledge base about the prevalence and ultrasound surveillance of congenital heart defects introduces health educators into an area that is little known outside of ultrasound communities (Garner, 2012).

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## APPENDIX A

### Definitions of Common and Critical Congenital Heart Defects

## Definitions of Common and Critical Congenital Heart Defects

Common fetal heart defects:

*Patent ductus arteriosus (PDA)*: improper closing of ductus arteriosus at birth causing breathing difficulties or heart failure that requires medication and or surgery; small PDA close without any intervention.

*Septal defects (atrial and ventricular)*: hole in septum (wall) causes blood to be shunted in the wrong cavity or to go in the wrong direction; atria receives blood from body, ventricles pump blood out to body; approximately 50% of ASDs resolved spontaneously; VSDs may require surgery.

*Coarctation of the aorta (COA)*: an abnormal narrowing of the aorta that carries blood away from the heart; requires balloon angioplasty or mesh tube; some babies require surgery.

Critical congenital heart defects (not all inclusive)-

*hypoplastic left heart syndrome (HLHS)*: incomplete formation of the left side of heart needing open heart surgery or heart transplantation, and medications

*pulmonary atresia (PA)*: incomplete formation of pulmonary artery causing inadequate blood flow from heart to the lungs; open heart surgery or transplantation, and or medications required

*Tetrology of Fallot (TOF)*: inadequate blood flow to lungs; heart surgery; lifelong medications

*Total anomalous pulmonary venous return (TAOV or TAPVR)*: veins that take blood from the lungs to the heart are not connected correctly and the blood

stays in a loop between the heart and lungs; requires immediate surgery to avoid an overworked heart that leads to heart failure;

*Transposition of the great arteries (TGA)*: incorrect placement of two vessels causing inadequate blood oxygenation; surgery and lifelong medications.

*Tricuspid atresia (TA)*: tricuspid valve is absent or underdeveloped causing inadequate blood flow into the lungs; requires surgery

*Truncus arteriosus*: missing a second artery that exists the heart causing a mixture of oxygenated blood with non-oxygenated blood resulting in high blood pressure in the arteries to the lungs (March of Dimes, 2013).

## APPENDIX B

Examples of Potential Detection of CCHD with 4CV verses OFTV

Examples of Potential Detection of CCHD with 4CV verses OFTV

Abnormal 4CV	Anomalies Requiring OFTV to Visualize CCHD
<p>Hypoplastic left heart syndrome (HLHS)</p> <p>Severe Aortic coarctation</p> <p>Critical Aortic Stenosis</p> <p>Tricuspid atresia (TA)</p> <p>Pulmonary atresia with intact ventricular septum</p> <p>Atrioventricular septal defect (ASD)</p> <p>Double inlet ventricles</p> <p>(Simpson, 2009)</p>	<p>Great artery transposition</p> <p>Tetralogy of Fallot +/- pulmonary atresia</p> <p>Common arterial trunk</p> <p>Milder forms of aortic coarctation</p>

APPENDIX C

Texas Woman's University Institutional Review Board Letter of Approval



Institutional Review Board  
Office of Research and Sponsored Programs  
P.O. Box 425619, Denton, TX 76204-5619  
940-898-3378  
email: IRB@twu.edu  
<http://www.twu.edu/irb.html>

DATE: June 30, 2014  
TO: Ms. Janai Buentello  
Department of Health Studies  
FROM: Institutional Review Board - Denton

Re: *Approval for Ultrasound Research to Practice in the Prenatal Detection of Congenital Heart Defects (Protocol #: 17699)*

The above referenced study has been reviewed and approved at a fully convened meeting of the Denton Institutional Review Board (IRB) on 6/6/2014. This approval is valid for one year and expires on 6/6/2015. The IRB will send an email notification 45 days prior to the expiration date with instructions to extend or close the study. It is your responsibility to request an extension for the study if it is not yet complete, to close the protocol file when the study is complete, and to make certain that the study is not conducted beyond the expiration date.

If applicable, agency approval letters must be submitted to the IRB upon receipt prior to any data collection at that agency. A copy of the approved consent form with the IRB approval stamp is enclosed. Please use the consent form with the most recent approval date stamp when obtaining consent from your participants. A copy of the signed consent forms must be submitted with the request to close the study file at the completion of the study.

Any modifications to this study must be submitted for review to the IRB using the Modification Request Form. Additionally, the IRB must be notified immediately of any adverse events or unanticipated problems. All forms are located on the IRB website. If you have any questions, please contact the TWU IRB.

cc. Dr. Gay James, Department of Health Studies  
Dr. Jody Terrell, Department of Health Studies  
Graduate School

APPENDIX D

American Registry of Diagnostic Medical Sonography Approval

American Registry of Diagnostic Medical Sonography Approval

From:	Barbara Higgins <bhiggins@bethesda-list.com>
To:	Janai Buentello <janaidb@aol.com>
Subject:	RE: quote
Date:	Thu, 4 Sep 2014 18:53:01 +0000

*ARDMS has approved the survey so I can get this order started once I receive the proper forms back from you*

Thank you,

Barbara Higgins | Bethesda List Center  
4300 Montgomery Avenue, Suite 204-B | Bethesda, MD 20814  
Main: 301.986.1455 | Fax: 301.907.4870 | Direct: 301.968.1720  
[www.bethesda-list.com](http://www.bethesda-list.com) | <http://www.facebook.com/BHigginsBethesdaListCenter>

APPENDIX E

Texas Woman's University Consent Form to Participate in Research

TEXAS WOMAN'S UNIVERSITY  
CONSENT TO PARTICIPATE IN RESEARCH

Title: Ultrasound Research to Practice in the Prenatal Detection of Congenital Heart Defects

Investigator: Janai Buentello, Student researcher.....janaidb@aol.com 940 3  
Advisor: Jody Terrell, PhD.....JTerrell@twu.edu 940 898 2844

Explanation and Purpose of the Research

You are being asked to participate in a research study for Janai Buentello's dissertation at Texas Woman's University, Denton, Texas. The purpose of this research study is to assess sonographer's attitudes and barriers toward the inclusion of ventricular outflow tracts (OFTV) in routine obstetrical ultrasounds between 18-22 weeks gestation in the United States. You have been asked to participate in this study as a credentialed sonographer listed by the ARDMS. This survey is not affiliated with or endorsed by the ARDMS®.

Description of Procedures

The survey will take approximately 10 minutes. Questions about your routine current practices, education and work experience will be asked. Similar questions will address slightly different issues. Comments are welcome. In order to be a participant in this study, you must be at least 18 years of age or older and be an Active ARDMS credentialed sonographer in the United States.

Potential Risks

Discomfort with the questions is a possible risk. You may stop answering questions at any time. The researcher has provided contact numbers if you need to talk to a professional about your discomfort.

Another risk in this study is loss of confidentiality. Confidentiality will be protected to the extent that is allowed by law. There is a potential risk of loss of confidentiality in all emails, downloading, and Internet transactions. All materials will be stored in a locked cabinet in the researcher's office and destroyed within 5 years after the study is concluded. Only the researcher and her advisor will have access. The results may be reported in academic writings but all identifiers, if any, will be excluded.

The researchers will try to prevent any problems that could occur because of this research. Let the researchers know at once if there is a problem and they will help you. However, TWU does not provide medical services or financial assistance for injuries that might happen because you are taking part in this research study.

Participation and Benefits

Your return of this completed survey constitutes your informed consent to act as a participant in this study. Your participation in this study is completely voluntary and you may withdraw from the study at any time. There are no direct, tangible benefits.

Questions Regarding the Study

If you have any questions about the research study or would like to know the results of this study, you should ask the researchers; their phone numbers are at the top of this form. If you have questions about your rights as a participant in this research or the way this study has been conducted, you may contact the Texas Woman's University Office of Research and Sponsored Programs at 940 898 3378 or via email at [IRB@twu.edu](mailto:IRB@twu.edu).

Approved by the  
Texas Woman's University  
Institutional Review Board  
Date: 6-6-14  
Revised: 6-22-14

Page 1 of 1

APPENDIX F

Data Collection Instrument: Research Survey

## Data Collection Instrument: Research Survey

### *Demographics*

1. What is your highest level of education?
  - a. High school diploma or GED
  - b. Associate degree
  - c. Baccalaureate degree
  - d. Masters degree
  - e. PhD / EdD
  - f. Other (please specify):

---
  
2. Which of the following healthcare-related credentials have you earned?
  - a. RDCS (FE)
  - b. RDMS (FE)
  - c. RDMS (OB)
  - d. RT (R)
  - e. RT (S)
  - f. Other (please specify org/credential):

---
  
3. How long have you performed obstetrical ultrasounds?
  - a. less than one year
  - b. 1 – 5 years
  - c. 6 – 10 years
  - d. more than 10 years
  - e. never
  
4. Do higher maternal risk factors for a congenital heart defect influence your decision to attempt outflow tract views (OFTV)? (*Examples of higher risk factors: maternal obesity, diabetes, abnormal NT scan....*)
  - a. yes
  - b. no

5. Who is your supervising physician responsible for obstetrical ultrasound interpretation?

- a. Radiologist
  - b. Obstetrician
  - c. Perinatologist
  - d. Other (please specify):
- 

6. Approximately how often do you observe your supervising physician scan (back scan / re-scan; spot check) the fetus after you have completed your real-time analysis?

- c. never
- d. 25%
- e. 50%
- f. 75%
- g. always

7. What is the accreditation status of your imaging facility?

- a. AIUM accredited
  - b. ACR accredited
  - c. Non- accredited
  - d. Other (please specify):
- 

8. Please rate the fetal heart imaging capabilities of your ultrasound equipment as:

- a. excellent
  - b. good
  - c. fair
  - d. poor
  - e. Comments:
- 

***Scanning Practices and Protocols***

9. How often do you record the fetal heart using a 2-dimensional video clip?

- a. never
- b. 25%
- c. 50%
- d. 75%
- e. always

10. In the first trimester, how often do you use spectral Doppler for the presence/absence of fetal heart activity?

- a. never
- b. 25%
- c. 50%
- d. 75%
- e. always

11. How often do you attempt outflow tract views (OFTV) during *routine* 18 – 22 week scans?

- a. never
- b. 25%
- c. 50%
- d. 75%
- e. always

12. How often have you observed level II patient referrals when OFTV could not be obtained during routine 18- 22 weeks scan? (*Observation: discussion with physician or patient, reading ob results, making appointments...*)

- a. never
- b. 25%
- c. 50%
- d. 75%
- e. always

***Attitudes Toward Incorporating OFTV in Routine 18-22 Week Scans***

13. Obtaining OFTV is technically feasible most of the time during *routine* 18 – 22 week scans.

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
<input type="checkbox"/>	□□	□□□	□□□□□□□□	□□□□□□□□	□□□□□

14. OFTV help me to identify critical heart defects that are otherwise undetectable using only the 4-chambered view.

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
<input type="checkbox"/>	□	□□□	□□□□□□□□	□□□□□□□□	□□□□□□□

15. OFTV help me to provide approximately the same level of care for many of my patients.

	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree
	□□□□□	□□□□	□□□□□□□□	□□□□□□□□	□□□□□□□

16. Interrogating the fetal heart using OFTV during *routine* 18 – 22 week scans makes my job more interesting.

Strongly Agree Agree Undecided Disagree Strongly Disagree  
□□□□ □□□ □□□□□□□ □□□□□□□ □□□□□□□

***Perceived Behavioral Control***

17. I feel comfortable with my scanning abilities to obtain OFTV when needed.

Strongly Agree Agree Undecided Disagree Strongly Disagree  
□□ □□ □□□□□□ □□□□□□□ □□□□□□□

18. It is generally my decision whether to include or exclude OFTV during *routine* 18 – 22 week scans.

Strongly Agree Agree Undecided Disagree Strongly Disagree  
□□□□ □□□ □□□□□□□ □□□□□□□ □□□□□□□

19. Generally I have enough time to complete scans without feeling rushed throughout the day.

Strongly Agree Agree Undecided Disagree Strongly Disagree  
□ □ □□ □□□□□□ □□□□□□□ □□□□□□□

***Professional Norms***

20. Most of my professional colleagues whose opinions I value obtain OFTV during routine 18 - 22 week scans.

Strongly Agree Agree Undecided Disagree Strongly Disagree  
□□ □□□ □□□□□□□ □□□□□□□ □□□□□□□

21. Most of my professional colleagues whose opinions I value would approve of *me* obtaining OFTV during routine 18 - 22 week scans.

Strongly Agree Agree Undecided Disagree Strongly Disagree  
□□ □□ □□□□□□□ □□□□□□□ □□□□□□□

22. I feel pressured to follow clinical practice guidelines that add OFTV during routine 18 - 22 week scans.

□ Strongly Agree Agree Undecided Disagree Strongly Disagree  
□ □ □□ □□□□□□ □□□□□□□ □□□□□□□

23. I feel obligated to the patient to obtain OFTV during routine 18-22 week scans when feasible.

Strongly Agree Agree Undecided Disagree Strongly Disagree  
□ □□ □□□□□□ □□□□□□□ □□□□□□□

***Intentions***

24. I intend to follow clinical practice guidelines that now endorse OFTV during routine 18-22 week scans.

Strongly Agree   Agree                      Undecided                      Disagree                      Strongly Disagree  
□□                      □□□                      □□□□□□□□                      □□□□□□□□                      □□□□□□□

25. I plan to learn more about OFTV heart anomalies so that I can improve my detection rate of heart defects.

Strongly Agree   Agree                      Undecided                      Disagree                      Strongly Disagree  
□□                      □□□                      □□□□□□□□                      □□□□□□□□                      □□□□□□□

26. Which of the following examinations do you intend to take within the next year?

- a. None
- b. ARDMS (FE)
- c. RDCS (FE)
- d. ARRT (S)
- e. Other (please specify org/credential): \_\_\_\_\_

***Barriers***

27. What key barriers prevent you from interrogating the heart using OFTV during routine 18-22 week scans?

28. How often do you worry that including OFTV during *routine 18-22 week scans* increase your risk of repetitive strain injury, aggravate an existing work-related injury, or cause you pain?

- a. never
- b. rarely
- c. sometimes
- d. often
- e. always

*Additional comments are welcome. A stamped envelope is enclosed for your convenience. Thank you for participating in this research.*

## APPENDIX G

Content Validity Index (CVI)-Survey 1 (Relevance scoring)

## Ultrasound Research to Practice in the Prenatal Detection of Congenital Heart Defects

Content Validity Index (CVI)-Survey 1 (Relevance scoring)

- 1 = Not sure at all
- 2 = Not very sure
- 3 = More or less sure
- 4 = Fairly sure
- 5 = Absolutely sure

Survey Item No.	S1-Rater-1	S1-Rater-2	CVI
Attitude			
Q13	4	3	
Q14	4	4	
Q15	4	5	
Q16	4	4	
Perceived behavioral control			
Q17	5	5	
Q18	5	5	
Q19	4	4	
Professional Norms			
Q20	5	5	
Q21	4	4	
Q22	5	5	
Q23	2	2	
Q24	2	2	
Intention			
Q25	5	5	
Q26	2	2	
Q27	2	2	
Total score (possible 75)	55	57	112/150
Overall CVI			<b>.75</b>

## APPENDIX H

Dr. Icek Azjen's Approval Email

**From:** Icek Ajzen <aizen@psych.umass.edu>  
**To:** 'Janai Buentello' <janaidb@aol.com>  
**Subject:** RE: Permission to use TPB in dissertation research  
**t:**  
**Date:** Mon, Jul 14, 2014 12:09 pm

Dear Janai Buentello,

The theory of planned behavior is in the public domain. No permission is needed to use the theory in research, to construct a TPB questionnaire, or to include an ORIGINAL drawing of the model in a thesis, dissertation, presentation, poster, article, or book. If you would like to reproduce a published drawing of the model, you need to get permission from the publisher who holds the copyright. You may use the drawing on my website (<http://people.umass.edu/aizen/tpb.diag.html>) for non-commercial purposes, including publication in a journal article, so long as you retain the copyright notice.

Best regards,

Icek Ajzen

Professor Emeritus

University of Massachusetts – Amherst

<http://www.people.umass.edu/aizen>

## APPENDIX I

### Qualitative Instrument: Similar Comments and Generated Themes

Barrier	Actual Comments	General Theme
1	Maternal obesity, maternal body habitus, patient size	Maternal obesity
2	Fetal lie, prone presentation; fetal malposition	Fetal lie
3	Time per scan, time it takes, time constraints; Patient volume 18-22; Very heavy patient load 25+ scans / day; chaotic environment	Time constraints when performing ultrasound
4	Radiologist not interested in reading OFTV; physician not comfortable with reading OFTV; radiologists don't want responsibility of reading OFTV; OFTV not included in hospital policy/protocol for routine prg [pregnancy] scans; exclusion from regular protocol; not in level II protocol, Institution and radiologist rules [exclude OFTV]; never been asked by Dr. or radiologist; only protocol [excluded from protocol]; OFTV not requested	Protocol
5	Lack of knowledge	Lack of knowledge
6	The equipment is over 15 years old; equipment quality [suboptimal]	Suboptimal equipment
7	Lack of training	Lack of training
8	Lack of experience	Lack of experience
9	Abnormal relationship of the heart [?]; fetal anomalies	Structural fetal heart anomalies
10	Excessive fetal movement (activity) (27);	Excessive fetal movement
11	Distractions by entirely too many people in the room (children) for the "show".	Distractions during ultrasound
12	Ob too early to perform OFTV [physician prescribed the ultrasound too early to obtain OFTV]; orders coming in at 17 wks; too immature	Ob too early to perform OFTV
13	Oligohydramnios	Inadequate acoustic window
14	Do not do high risk OBs, and never have.	High risk status