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Women's Knowledge of Prenatal Ultrasound and Informed Choice

By

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ABSTRACT

The Alberta Medical Association has recently set forth guidelines recommending an 18-20 week prenatal ultrasound screen for all pregnant women. Little, however, is known about women's understanding of prenatal ultrasound testing and whether this knowledge is sufficient to facilitate an informed choice. A quasi-experimental study, of healthy low-risk pregnant women, was performed to address: a) the current means and methods by which pregnant women were provided with prenatal ultrasound information, b) the knowledge women had prior to testing, and c) the effectiveness of providing supplementary written information in terms of knowledge retained.

One hundred and thirteen women were recruited from a Calgary radiology department to complete a self-administered knowledge questionnaire prior to their 18-20 week ultrasound. Women's understanding, in terms of the purpose, benefits, limitations and implications of ultrasound testing was evaluated. Overall, women were not fully informed about the limitations and implications of testing to facilitate an informed choice. Over half of the participants (54.9%) received no information on ultrasound from their health care providers prior to testing, and for the most part, prenatal care providers were not considered to be very helpful sources of information. In spite of this, a considerable majority of women (69.0%) were not dissatisfied with the information they received. Only 54.0% of women were aware of the purpose of second trimester ultrasound testing in screening for birth defects. Over half of the women (52.2%) did not give consideration to the drawbacks to ultrasound testing. There existed some uncertainty about women's understanding of the diagnostic capabilities and limitations of ultrasound testing as well as the perceived risks of ultrasound exposure.

An additional 43 women participated in a two-part pilot study to measure the effect of supplementary written information on women's understanding of ultrasound. The use of a supplementary pamphlet was well received and appeared to improve women's understanding of ultrasound testing and their view of the informed choice process.

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DEDICATION

This thesis is dedicated to my family, Lisa (Bear), Ron and Zenon.

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CHAPTER 1

THE RESEARCH PROBLEM

1.1 Introduction

The objective of prenatal testing is to provide women with information concerning the development and wellbeing of their fetus. In Canada, prenatal testing is delivered in accordance with the guidelines established jointly by the Society of Obstetricians and Gynecologists, the Canadian College of Medical Geneticists and the Canadian Pediatric Society (SOGC, 1991).

There are two distinct types of prenatal testing: prenatal diagnosis and prenatal screening. Although diagnostic for fetal aneuploidy, invasive techniques such as amniocentesis and chorionic villus sampling place the pregnancy at risk for miscarriage. Prenatal diagnosis is, therefore, reserved for women at increased risk of delivering a child with a genetic abnormality. Prenatal screening tests, on the other hand, are noninvasive testing options available to all pregnant women. Of all the testing options currently available, ultrasound is the most commonly used and most powerful prenatal test for the detection of fetal abnormalities (Levi, Crouzet, Schaaps, Defoort, Coulon and Buelens, 1989; Chitty and Winter, 1991).

The provision of pretest information should be a compulsory adjunct to any prenatal testing. The Ethics and Public Policy Committee of the Canadian College of Medical Geneticists believe that prenatal diagnosis should involve allowing women to make informed choices (1991). Women have the right to make autonomous and informed decisions regarding prenatal interventions which may affect themselves or their fetuses. Intrinsic to informed choice is the knowledge and understanding of the intervention in terms of the purpose, benefits, risks and limitations as well as any possible consequences of testing, and alternative options available.

At present, the provision of pretest ultrasound information is not a prerequisite to testing. It is the belief of the investigator that women receive little to no information prior to their ultrasound screen, and lack sufficient knowledge to make an informed choice.

1.2 Conceptual Framework

For the purpose of setting up the structure of this study, the key elements of informed choice, and knowledge required to meet the requirements of informed choice are provided as the conceptual framework. The relationship between the elements of knowledge and informed choice are extensively established in the literature review, but will be overviewed in a summary form below.

Major congenital malformations are present in 2-5% of newborns and account for 20-30% of all perinatal deaths worldwide (Chitty, Hunt, Moore and Lobb, 1991; Kalter, 1991). Many of these anomalies occur in newborns of healthy low-risk women. Prior to ultrasound testing, many of these anomalies remained unsuspected until the time of delivery. With advances in ultrasound technology and the increase in prevalence of women having second trimester ultrasound testing, more fetal anomalies are prenatally detectable. Hence, ultrasound screening has added a new dimension to prenatal testing because, in most cases, fetal problems are detected in women who were unaware of their risks before pregnancy.

Unlike the discrete event of an informed consent, informed choice is considered a process of decision making which evolves through the evaluation of the information and personal values related to testing. Disclosure, comprehension and voluntary choice are the tenets of informed choice process (Chervenak, McCullough and Chervenak, 1989; Summers, 1994; Kuczewski, 1996; Etchells, Sharpe, Walsh, Williams and Singer, 1996). Disclosure includes a thorough discussion of the purpose, advantages, risks, limitations and implications of testing. Comprehension, as the name infers, refers to the woman's ability to

understand the relevant information and to appreciate the consequences of her decision. A voluntary choice can only be made if the woman received all information relevant to the decision to undergo or forgo the test, and if the woman feels free of coercion or persuasion (Truog, 1996).

The benefits of being able to screen for fetal anomalies may be fundamental to some women but entirely unacceptable to others. Hence, the decision about whether to undergo prenatal testing should be made by the pregnant woman on the basis of the informed choice process. This position is directed by the ethical principles of autonomy and beneficence. Respect for patient autonomy obligates the clinician to acknowledge the values and beliefs of the pregnant woman (Chervenak, McCullough and Cervenak, 1989, p. 858).” Beneficence, as described by Chervenak, McCullough and Cervenak (1989) obligates the clinician to seek the greater balance of benefits over harms in providing obstetric care. An effective informed choice process is believed to influence a woman’s sense of control and consequently, their well being. Additionally, it has been hypothesized that the process of full pre-test disclosure and comprehension may help women be more prepared psychologically, should a fetal anomaly be detected.

To achieve the aim of informed choice, it is essential that adequate information is provided. Both knowledge and interpersonal skills are key in the facilitation of the informed choice process. In general terms, women should be aware of the objectives, benefits and risks, available alternatives and the potential outcomes of each testing alternative. Guidelines define good clinical practice, but unfortunately, there are no published guidelines outlining the minimal information women require to make fully and informed choices on testing.

1.3 Hypothesis

It is hypothesized that pregnant women have limited knowledge of the purpose, benefits, limitations and potential consequences of prenatal ultrasound and do not recognize that an ultrasound investigation provided at 18-20 weeks gestation

is considered optional. Hence, women lack complete and necessary information to facilitate an informed choice.

1.4 Research Questions

Primary Question: Do women receive and retain sufficient information as to the purpose, benefits, limitations and potential consequences of prenatal ultrasound to enable them to make an informed choice about whether to proceed with this intervention? Additionally, do women view prenatal ultrasound as an optional test and understand that they are under no obligation to proceed with testing?

Secondary Questions: Does supplementary information provide women with a better understanding prior to their 18-20 week ultrasound scan? Does this additional information change women's views on informed choice?

1.5 Study Objective

This study will examine the current means and methods by which pregnant women are provided with prenatal ultrasound information, and the knowledge base women have prior to testing. 'Sufficient knowledge' will be measured in relation to what will be defined, as a minimal information base believed to facilitate an informed choice. Additionally, the effectiveness of providing supplementary written information in terms of knowledge retained will be assessed. This method of providing information is one of many options. It is a method that is inexpensive and can be made accessible to health care providers, should it prove to be a useful intervention.

CHAPTER 2

LITERATURE REVIEW

The literature review will open with a historical perspective of ultrasound. The emphasis will then be placed on familiarizing the reader with literature regarding the genetic indications, benefits, limitations and implications of second trimester prenatal ultrasound screening. Following this, the focus will shift to a review of the ethical obligations relating to women's informed choice of prenatal testing. Lastly, the two issues of prenatal ultrasound screening and informed choice will be brought together to outline the current concerns and rationale for this thesis project.

2.1 An historical perspective on prenatal screening

Prenatal screening is thought of as an innovative field stemming from the successes of modern medical technology. However, as early as the late 19th century, prenatal diagnosis was first considered. In 1897, Edward Davis Parker of Jefferson Medical College successfully radiographed a fetal skull inside the cadaver of a pregnant woman (Resta, 1997). The first prenatal diagnosis was reported in 1917, performed on a pregnant woman presenting with polyhydramnios and an intrauterine demise at 7 months gestation. James Thomas Case performed an abdominal X-ray and presented his findings of what would be described as anencephaly. The diagnosis was later confirmed on fetal pathology. These observations were published in *Surgery, Gynecology and Obstetrics* (1917).

Prenatal screening began with identification of maternal age as a risk factor for Down Syndrome. This was first described two decades before the discovery of

Trisomy 21 in Down Syndrome (Penrose, 1933). The origin of serum screening started with the discovery of raised serum alpha fetoprotein and its associated risk factor for anencephaly (Hino, Koki and Nimpu, 1972; Brock, Boten and Monaghan, 1973), and spina bifida (Brock, Bolton and Monaghan, 1973; Wald, Brock and Bonnar, 1974). In the early eighties, Cuckle, Wald and Lindenbaum (1984) reported an association with low serum alpha fetoprotein and Down Syndrome. From that date, several additional serum markers (unconjugated estriol, human chorionic gonadotropin, inhibin A) have been found to be useful serum screen tools for fetal aneuploidy (Wald, Densem, Smith and Klee, 1994).

Ultrasound was first introduced in the late 1950's, and for the next two decades it was limited in use to the assessment of the gestational age, fetal number and viability and to assist with the procedure of amniocentesis. With improved resonance and advanced technology, prenatal ultrasound has gained wide acceptance as a powerful multipurpose screening tool for fetal aneuploidy and congenital malformations.

2.2 Prenatal ultrasound as a routine population based screen

Screening by definition is the identification, within a low risk population, of a subgroup of patients whose risk is increased sufficiently to warrant a more specific test (Jaffe and Abramowicz, 1997). There are several perspectives regarding the use of routine second trimester ultrasound as a population based screen. From a neonatal and maternal outcome perspective, it has been argued that ultrasound screening has not had a positive impact. A large randomized control study (RADIUS) of 15,000 low-risk pregnant women measured the outcome parameters of adverse perinatal outcome (fetal or neonatal death or morbidity), rates of preterm birth, perinatal outcomes of post-dated pregnancies and multiple gestations (Ewigman et al, 1993; Bernascheck, Stuempfle and Detinger, 1994). Although the rates of detection of twin gestations and congenital malformations were increased with ultrasonography, perinatal outcome did not improve. A meta-analysis of four published studies encompassing 15,935

pregnancies supported some of the RADIUS study findings (Bucher and Schmidt, 1993). However, they noted a lower perinatal mortality in the population with detected fetal anomalies due to the increased rate of induced abortion. The conclusion from these studies was that routine ultrasound screening during pregnancy does not appear to improve perinatal outcomes, and may not have a beneficial effect on maternal management or outcome. The RADIUS study has been strongly criticized because of the possibility of selection bias and because of problems in terms of generalizability and appropriateness of outcome parameters measured (Berkowitz, 1993; Skupski, Chervnak and McCullough, 1994). In a recent report of support for second trimester ultrasound screening, Zimmer, Avraham, Sujoy, Goldstein and Bronshtein (1997) undertook a five-year retrospective study to examine the influence of prenatal ultrasound on the prevalence of congenital anomalies at birth. Fetal anomalies included major central nervous system defects such as hydrocephalus and spina bifida, cardiac, renal and gastrointestinal defects. The incidence of birth defects per year decreased from 1.94 per cent in 1989 to 1.34 per cent in 1993 ($p < 0.01$). The incidence of pregnancy terminations for the indication of fetal anomalies increased during these years from 0.35 per cent in 1989 to 0.83 per cent in 1993 ($p < 0.003$). From this, Zimmer and colleagues concluded that 1) there was a continuing significant improvement in the detection rate of fetal malformations, and 2) ultrasound detection of fetal malformations had an impact on the prevalence of birth defects in newborns. The latter finding has not been seen in Alberta. The Alberta Congenital Anomalies Surveillance Program (ACASS), which ascertains records from multiple sources of all births over 20 weeks gestation to one year of age in the province, has not reported a significant change in any of the common birth defects recorded between the years of 1980 to 1995. However, there has been a decreasing trend of anencephalic births and increasing trend of Down Syndrome rates (ACASS, 1998 In Press). A fetal registry has recently been implemented in Alberta, to assess the incidence of fetal anomalies that are currently missed by the ACASS registry.

Johnson (1998) presents an overview of the Canadian Standards of Clinical Practice in the performance of obstetric ultrasound examination. The emphasis, as expected, is on fetal management. There is inadequate information regarding the requirements of disclosure of prenatal ultrasound testing to pregnant women.

2.3 Purpose of second trimester ultrasound testing

High-resolution real-time ultrasound performed between 18-20 weeks has greatly improved the ability to diagnose congenital anomalies. Based on a number of retrospective and prospective studies of low-risk women, the sensitivity and specificity of ultrasound screening ranges from 14-85%, and from 93-99%, respectively (Chitty, Hunt, Moore and Lobb, 1991; Shirley, Bottomly and Roberston, 1992; Nicolaides, Snijders, Gosden, Berry and Campbell, 1992; Luck, 1992; D'Alton, Craigo and Bianchi, 1994). Fetuses with structural anomalies detected prenatally have a higher incidence of aneuploidy than do cases with similar abnormalities identified after birth. This is because pregnancies carrying a fetus with a chromosome aneuploidy are at a far greater risk of second or third trimester pregnancy loss or intrauterine demise than karyotypically normal pregnancies (D'Alton and Craigo, 1994). Many of the sonographically identified fetal abnormalities carry a greater risk for aneuploidy than the commonly accepted risk factors such as advanced maternal age. Offering cytogenetic evaluation to women with abnormal ultrasound findings has, therefore, become an increasingly common practice.

The frequency of chromosome abnormalities reported from prenatal sonographic identification of fetal anomalies is dependent on the type, number and severity of the structural defect(s), as well as the other risk factors such as maternal age and family history (Nyberg and Crane, 1993; D'Alton and Craigo, 1994; Twining, 1995). Table 2.1 provides the chromosome risks for a number of isolated fetal anomalies.

Table 2.1: Examples of fetal anatomic abnormalities and the associated risk for fetal aneuploidy

Fetal ultrasound finding	Chromosome risk (%)
Holoprosencephaly	25
Neural tube defect	10
Endocardial cushion defect	60
Ventricular septal defect	10-15
Diaphragmatic hernia	5-16
Cystic hygroma	60-70
Omphalocele	25-40

Source: Table courtesy of Jie Xu, Cytogenetics Fellow, University of Calgary. 1998

2. 4 Safety of Prenatal Ultrasound

Prenatal diagnostic ultrasound exposure is not believed to be harmful to the mother or her developing fetus. However, one must recall that the fundamental principle of human teratology is that “one cannot demonstrate absolute safety, one can only attempt to estimate the possible risks” (Brent, Jensch and Beckman 1991, p. 124)

Brent and colleagues (1991) provide a comprehensive and critical evaluation of 21 epidemiological studies evaluating the reproductive risks of ultrasound (Appendix A). Their evaluation is most comprehensive as it systematically considers all criteria for evaluating the cause-effect relationship between exposure and several outcome measures, including: fetal growth, congenital malformations, stillbirth, physiological effects, postnatal neurological and behavioral effects, postnatal cancer occurrence and chromosome abnormalities. Based on this intensive review, Brent concluded that “diagnostic ultrasound presents nonmeasurable risks to the developing embryo” (Brent, Jensch and Beckman 1991, p.140). As the technology of ultrasound is not stagnant, this conclusion is presented with a caveat, in that it would be “inaccurate to label the modality of ultrasound as totally safe regardless of exposure” (Brent, Jensch and Beckman 1991, p.140).

It has been hypothesized that ultrasound may have more subtle effects on the fetus that are not seen until early childhood. In a case control study of 72 cases and 70 matched controls aged 2 through 8 years, Campbell, Elford and Brant (1993) suggested an association between prenatal ultrasound exposure and delayed speech (Odds Ratio 2.8, 95% confidence limit 1.5 to 5.3; $p \leq 0.001$). However, in a letter to the editor, Dyke (1994) suggests significant flaws within the study. First, cases and controls were matched on gender, birth date and weight, sibling order, associated health problems, and gestational age. Other possible contributors, such as increased rates of family breakdown, day-care use, inadequate prenatal nutrition and prenatal exposure to possible noxious agents, were not considered. Second, it would be not be possible to repeat such a study as sufficient numbers of unexposed control subjects would be difficult to obtain due to the increase in prevalence of prenatal ultrasound exposure. In a large randomized Norwegian study of 1107 study and 1184 control subjects, Salvesen, Vatten, Bakketeig and Eik-Nes (1992) reported no evidence of delayed speech in children followed for a 7 year period.

Although it would appear that there is little scientific evidence to suggest a deleterious or adverse developmental effect of ultrasound on the developing fetus, continual long term prospective studies are required to examine the immediate or the delayed effects, particularly as the use of newer technology of enhanced resolution and imaging increases.

2.5 Limitations of prenatal ultrasound

Prenatal screening has advantages over prenatal diagnostic testing, as it is procedurally simple, relatively inexpensive and noninvasive. Although the technology and resonance of ultrasound is improving dramatically, it is not considered diagnostic for all fetal abnormalities. As is the nature of screening, ultrasound is limited in its ability to provide a definitive answer, one hundred percent of the time.

Pretorius and Nyberg (1994) classify the limitations of ultrasound into four categories as outlined in the table on the following page. Personal clinical examples are also provided for each category.

In addition to the described constraints of prenatal ultrasound, other limitations can occur. Consider the sequence of events with the following scenario.

A healthy young woman undergoes a 'routine' second trimester ultrasound. A fetal anomaly is detected. There is considerable uncertainty regarding the diagnosis and associated prognosis of the anomaly. The option of continuing or terminating the pregnancy is provided to this couple based on these limited facts.

In situations such as this, parents are left with many unanswered questions and are faced with difficult decision-making without sufficient information to facilitate this process.

In most cases prenatal testing can provide a diagnosis but little in the way of effective or successful treatment. Thus, prenatal diagnosis of a fetal anomaly provides women with a reproductive choice. Selective abortion is just one choice available to women. Alternatively, some women may wish to prepare psychologically for the birth of the child with a malformation or to place the child for adoption following delivery.

A second common clinical scenario would be one where a fetus is suspected of carrying a chromosome anomaly and invasive prenatal diagnosis is offered. Unlike other invasive and risky procedures, the associated risks of prenatal diagnosis must be taken in a different light, as it is not so much a risk to the woman as it is to her pregnancy. For example, one in 200 pregnancies are lost to miscarriage following amniocentesis, and a considerable proportion of these are most likely to be karyotypically normal (Canadian Guidelines for Prenatal Diagnosis of Genetic Disorders, 1993).

Table 2.2 : Limitations of prenatal ultrasound in the detection of fetal anomalies

Limitations of prenatal ultrasound*	Related examples **
Operator-dependence of ultrasound	<p>Operator experience and expertise</p> <p>Completeness of the fetal survey.</p> <p>Time spent surveying the fetal anatomy</p>
Technical limitations and artifacts	<p>The resonance capabilities of the technology</p> <p>Maternal obesity</p> <p>Excess or reduced amount of surrounding amniotic fluid</p> <p>Fetal number and fetal position.</p> <p>Imaging capacity of the ultrasound equipment.</p>
Limitations due to embryonic development and physiology/ other	<p>The significance of some anomalies detected at 18-20 weeks cannot be fully assessed until later in pregnancy.</p> <p>A number of malformations are undetectable prior to 24 weeks gestation.</p> <p>The prevalence of the congenital anomaly, in the referral population, has an effect on the detection rate.</p>
Limitations due to non-specificity of sonographic findings.	<p>Aneuploidy is one differential diagnosis associated with an identified anomaly. Other causes need to be explored, as appropriate management is dependent on the underlying etiology. The literature varies regarding management of minor isolated anomalies, therefore invasive testing is not uniformly offered for these isolated anomalies.</p>

*Source: Adapted from Pretorius and Nyberg (1994).

** Source: the Candidate's clinical experience

2.6 Consequences of testing

Most women undergo prenatal testing in their pregnancy for the purpose of reassurance (Green, 1994; Statham 1994). In the majority of cases they receive just that. However, when an ultrasound is abnormal or uncertain, the psychological ramifications can be significant for the woman, her family and the fetus (Marteau, Johnson and Shaw, 1989; Marteau, Cook and Kidd, 1992; Ormond, Pergament and Fine, 1996).

Adverse maternal psychological effects associated with the prenatal serum screening for Down syndrome have been reported by several researchers (Evans, Bottoms and Carlucci, 1988; Abramsky, 1994; Abuelo, Hopmann, Barsel-Bowers and Goldstein, 1991; Marteau, 1995). The latter authors noted that young women who screened positive for Down syndrome and who ultimately had a normal pregnancy outcome, experienced anxiety levels greater than women undergoing amniocentesis because of advanced maternal age. Marteau (1992) prospectively surveyed a cohort of pregnant women who screened positive for serum alpha-fetoprotein. Three weeks following their subsequent diagnostic testing, she found that these women were still more anxious and worried about their baby's health and held more negative attitudes towards their pregnancy as compared with women who had received a normal serum alpha fetoprotein screen result. Marteau argues that the raised anxiety associated with prenatal screening, in part, reflects the failure of the screening service to provide adequate pre-test information. Although not yet published in the literature, it is postulated that similar emotional anguish will be associated with abnormal or suspected abnormal ultrasound results.

With advances in prenatal screening has come a new dimension in the practice of prenatal medicine. The majority of malformations, whether detected prenatally or at birth, occur in pregnancies with no recognizable risk factors (Nicolaidis, Snijders, Gosden, Berry and Campbell, 1987). In view of this, the detection of a fetal malformation can be seen as a double-edged sword. Women previously unaware of their risks for fetal problems can find themselves in complex

circumstances following the report of an unexpected abnormal result. There is often a window of uncertainty regarding the clinical significance of a suspected sonographic finding. An undetermined diagnosis can leave pregnant women with a number of unanswered questions, particularly if they have not been provided with sufficient pretest information or at least been made aware of these potential consequences.

The Alberta Medical Association, under the direction of a multi-stakeholder steering committee, is in the process of publishing Clinical Practice Guidelines for Prenatal Ultrasound. The second trimester prenatal ultrasound guidelines meet most requirements of disclosure but do not address at any length two important issues: the psychological repercussions following an abnormal or questionably abnormal result, and the degree of uncertainty that may arise regarding the prognosis related to a complex or uncertain ultrasound finding.

Apart from reassurance, the next important motive for undergoing prenatal testing, as viewed by women in a post-partum survey, is that "it seems to be the obvious thing to do because it is offered" (Roelofsen, Klamerbeek, Tymstra, Beekhuis and Mantingh, 1993, p. 741).

Prenatal testing is viewed as an expected component of routine prenatal care. Alberta Health conducted a survey of women from selected prenatal classes and found that two-thirds of respondents considered ultrasound as routine (Alberta Medical Association, 1996). A survey of Manitoba family physicians and obstetricians, reported that 22% of the respondents ordered a maternal serum alpha fetoprotein test automatically for all patients as a part of routine prenatal blood work (Chodirker and Evans 1993). Marteau, Slack, Kidd, and Shaw (1992) noted in two tape recorded antenatal consultation studies between women and their prenatal care providers, that AFP screening and amniocentesis testing was presented to women "in such a way as to encourage them to undergo the test: practical details of when to attend were frequently given, but patient choice was not emphasized, and the limitations of the test were rarely mentioned" (Marteau, Slack, Kidd and Shaw, 1992; Marteau, Plenicar and Kidd, 1993, p. 137).

Social pressure exerted on women is also believed to be another underlying reason why women undergo prenatal testing. Spouses, family, friends, and physicians are considered to have a direct influence on a woman's decision (Clarke, 1990). Consequently, the question, 'why do women choose to have tests?' ignores an important issue: many women do not *choose* testing, as they are unaware or lose sight of their autonomous right of personal choice.

2.7 Informed choice

Deber (1994) outlines the distinction between the legal notion of "informed consent" and the ideal of the process of informed choice:

"Informed consent does not mean that the patient is an active partner in care, and, therefore, it cannot achieve the benefits of a model in which the patient is an informed partner who understands and sets treatment goals (p.425)."

This suggests a shift away from the paternalistic 'clinician decides' to 'clinician informs but does not decide' process of decision-making. The concept of informed choice includes the full access and understanding of relevant information, and the use of this information to evaluate all options available before making a decision about testing.

Etchells, Sharpe, Burgess and Singer (1996) describe disclosure as the "provision of relevant information by the clinician and its comprehension by the patient (p. 387)." A woman's decision about any prenatal test should be based on an informed choice, following the disclosure of required information by their primary care provider. To make prenatal testing decisions, women need to have a clear understanding of the test in terms of the 1) potential risks; 2) expected benefits; 3) alternative options to testing and, 4) consequences of accepting, declining or delaying testing. The latter must not only include medical, but also the social and psychological consequences of their decision. Additionally, the decision to consent or decline testing must be voluntary (Deber, 1994).

Disclosure is viewed as a process rather than a discrete event (Deber, 1994; Etchells, 1996). Clinicians have a key role in facilitating this process. To facilitate an informed choice, Deber (1994) suggests that patients would rather share in decision making rather than take complete and total responsibility in this process of decision making. Chervenak, McCullough and Chervenak, (1989) concur with Deber and propose a five stage strategy for prenatal informed consent for sonography (Table 2.3). This process brings together the clinical judgement and experience of the physician, and the autonomy-based informed choice and decision making role of the pregnant woman. This consent process adheres to ethical principles of beneficence and respect for patient autonomy.

Table 2.3: Informed consent process for prenatal ultrasound testing

Source: Chervenak, McCullough and Chervenak (1989)

Stage of informed choice process	Description
I: Pre-test information	"Shortly after the pregnancy is confirmed every pregnant woman should be provided with information about the actual and theoretical benefits of ultrasound and its potential harms."
II: Evaluative stage	"The pregnant woman should evaluate this information in terms of her own values and beliefs, and also consider the clinical data available in this process."
III: Pregnant woman's preference	"The woman articulates her preference regarding the use of ultrasound in the management of her pregnancy."
IV: Provider's view	"The provider's own recommendation, based on the literature and clinical to the pregnant woman is given to the woman."
V: Pregnant woman's decision	"The pregnant woman makes her own autonomous decision about prenatal ultrasound."

In reality, the disclosure of information to pregnant women has been seen to be neither consistent, nor necessarily accurate. Using a qualitative approach, Marteau (1992), tape-recorded consultations between 102 pregnant women and their obstetricians or midwives. Eighteen women received no screen information but elected to proceed with amniocentesis. Of the remaining 84 women, information about the test results (such as when and how they would be received and the meaning of any such results) was rarely given. Procedures following a positive result were mentioned on 28 occasions. Marteau noted that inaccurate information was provided to women about the conditions being screened for, and the meaning of a positive and negative result was rarely mentioned. On 10 occasions, the test was presented in a way that could have been misinterpreted as a general screening test to pick up all fetal abnormalities. Additionally, in over half the consultations, serum screening was presented as a test that was carried out routinely, and the women were not invited to make a decision.

In an earlier study, Marteau (1989) found that clinicians underestimated patients' need for information and their ability to understand such information. This may be due to an underlying assumption among many providers that women are already well informed about prenatal ultrasound through informal means such as the media, their own reading, a previous pregnancy experience and hearsay. In support of this premise, a survey was conducted in 1990 on a sample of post-partum women in France who had prenatal diagnosis and a normal outcome. Forty two percent of the women sampled claimed that media were their main source of information (Julian-Reynier, 1994).

Truog (1996) argues that physicians most often provide care to their patients under the auspices of a "presumed consent." He provides an example of a patient, having signed a general consent for treatment upon admission to the hospital, received a variety of interventions, all without additional informed consent. Truog explains that there is a widespread consensus that no reasonable person would refuse any required interventions. Similarly, presumed consent for prenatal ultrasound testing can be invoked when there is a widespread

consensus that this intervention would not be reasonably refused among women receiving prenatal care.

"Capacity," the second element of the informed choice process refers to the patient's ability to comprehend relevant information and to appreciate those consequences of her decision that might reasonably be foreseen (Etchells, Sharpe, Elliott and Singer, 1996).

How does one evaluate the woman's ability to understand pertinent information and appreciate its implications? Marteau, Johnston, Plenicar, Shaw and Slack (1988) evaluated maternal familiarity with, and knowledge of, the common prenatal diagnostic and screening tests. A self-administered questionnaire was given to women who had never been pregnant, to women who were two days post partum, and to women 16 weeks pregnant. Marteau and colleagues found that while knowledge of tests was greater post-partum than antenatally, a sizable minority (39%) of post-partum women could not correctly state whether they had undergone maternal serum screening for spina bifida. Similar findings were found by other researchers (Green, Statham and Snowdon, 1993; Goel, Glazier, Holzapfel, Pugh and Summers, 1996). Marteau suggested several explanations for this lack of knowledge; the women may have not been informed that they were tested, may have failed to understand, or may have failed to retain the information about the screen test.

In a survey of 353 pregnant women, Smith, Shaw and Marteau (1994) found that although women were knowledgeable about the practical aspects of serum testing, they were less informed about the likelihood and significance of possible false negative and false positive test results. In other words, many pregnant women do not clearly distinguish the difference between prenatal screening and prenatal diagnosis. In a review article of informed decisions on prenatal testing, Marteau (1995) hypothesized that with this unfamiliarity of the concept of false positive results, women can experience difficulty altering a belief formed by an initial result that something is wrong with their baby. Several researchers support the belief that patients considering participation in maternal serum

screening should be told what the test is for, the possibility of false negative and false positive results, as well as their associated implications (Edwards and Hall, 1992; Green, Statham and Snowdon, 1993; Goel, Glazier, Holzapfel, Pugh and Summers, 1996). Based on clinical experience, most women proceed with maternal serum screening and prenatal ultrasound testing without considering the consequences of the tests.

According to the Canadian statutory and common law, the necessary elements of disclosure must include information that is relevant to a "reasonable person" (Etchells, Sharpe, Walsh, Williams and Singer, 1996). The concept of "a reasonable person" raises interesting ethical and moral issues which are beyond the scope of this discussion. From a legal standpoint, "advice on informed consent makes it clear that under common law, patients have a right to receive sufficient information in a way that they can understand about the proposed treatments, the possible alternatives and any substantial risks so that they can make a balanced judgment in deciding whether to submit to medical intervention" (Williams and Waldron, 1992, p. 1443). Providing information leads to the obvious reduction in the potential for subsequent litigation, but also has been reported to improve medical outcomes and to result in a greater sense of personal control (Dawes, 1994, Press and Browner, 1995). In ethical terms, respect for the patient's autonomy and the promotion of the patient's well being are the moral basis of the informed consent requirement (Etchells, Sharpe, Walshe, Williams and Singer, 1996).

2.8 Ethical Dimensions of informed choice and prenatal testing

Central to informed choice are two ethical obligations which health providers have to their patients, namely, beneficence-based and autonomy-based obligations.

The principle of beneficence is the duty to benefit others. A central belief reflected in this principle is "the duty or obligation to assist others, to contribute

to their welfare, and in doing so, to always act in the best interest of the patient ” (Alberta Association of Registered Nurses, 1996, p.10). The obligation of ensuring that non-directive and relevant information is provided to pregnant women is the direct responsibility of the primary care provider. Women with access to information about the capacity of prenatal screening will be better equipped to make an informed choice and, quite likely, experience reduced anxiety if faced with a false positive result (Ormond, Pergament and Fine, 1996). Furthermore, women having more pre-test information may benefit from preparing themselves for a possible adverse fetal outcome (Weinman and Johnston, 1988).

The principle of autonomy is the “right to choose for oneself what one believes to be in one’s best interests (Etchells, Spapre, Elliott and Singer, 1996, p. 388). It is the concept of self-determination, of being in charge of one’s person. The acknowledgement of this ethical principle by health care providers reflects the commitment to respect clients’ choices in treatment and their need to make informed choices.

Under the directive of these ethical principles, and with the increasing potential of prenatal diagnostic technologies, health providers will need to take more responsibility in informing women about the implications of testing. From personal clinical experience, it would appear that women eligible for prenatal diagnosis (amniocentesis) are better informed about testing options than healthy low-risk pregnant women. The route to undergoing an amniocentesis in the Calgary region provides evidence of support. It is mandatory in the region, that pregnant women who are eligible and interested in amniocentesis attend a pre-test counselling session to discuss the purpose, benefits, risks, implications and alternative options to testing. This standard of practice stems from the respect for the patients’ access to quality information regarding prenatal tests that pose both risks and benefits to the pregnancy.

Pre-test counselling is also available for women interested in a non-invasive maternal serum prenatal screening for neural tube defects and Down syndrome.

However, this counselling is not mandatory, and it is estimated that less than half of the women undergoing testing receive pre-test counselling (unpublished data from the Department of Medical Genetics, Alberta Children's Hospital). Many women, therefore, are not informed of the possible implications to the screen and may find themselves, quite unexpectedly, confronted with a predicament regarding their increased risk assessment and eligibility for amniocentesis. Abramsky (1994) concurs with this observation concerning the practice of educating pregnant women about prenatal testing, and points out that "the more physically invasive the test is, the more risk it poses to the pregnancy and the more counselling the woman gets prior to the test". However, it is our belief that the level of invasive risk to the pregnancy should not be the sole indicator of the information needs of pregnant women.

Press and Browner (1995) pose an interesting question that takes the other extreme of the ethical principle of autonomy and individual rights: "Do patients have a right not to know equal to their right to know?" Truog (1996) presents an interesting and logical argument against Press and Browner's perspective in stating that "the right not to know and the right to know require the same standards of competence, voluntariness and disclosure" (Truog 1996, p. 88). Hence, providing routine care and testing without an explanation denies the patient a choice among alternatives, including the "right to refuse." The "right not to know," therefore, infringes on the principle of patient autonomy. Just as important, Ost (1984) claims that the patient's "right not to know" places a burden on the families and health care providers, by making them responsible for medical decisions.

There are opposing views to the belief that it is ethically unacceptable to withhold information that may affect how an individual reaches a decision about testing. Wald and Law (1992) assert that providing such detailed information is appropriate for amniocentesis but not when offering an initial screening test. They claim that more anxiety than necessary is the end result of providing such

detailed information. "The detail should vary according to the test procedure, the expectations of the people being screened and the individual person concerned(p. 892)." Kerrigan and colleagues (1993) oppose Wald and Law's position. In a comparative analysis of a group of surgical patients receiving detailed information and a second group receiving minimal information about surgical risks, Kerrigan et al. (1993) did not find a significant difference in anxiety, and concluded that the former group benefited with full information prior to consenting to surgery.

Women would be better equipped to make an informed choice if they are provided with unbiased and relevant information and given the time to consolidate this information. The difficulty is finding a balance between the provision of sufficient information and the minimization of the possible adverse emotional consequences of participation in screening.

2.9 Summary

The Society of Obstetricians and Gynecologists of Canada recognizes the clinical benefits of early identification of unexpected congenital anomalies in low-risk pregnancies and supports the use of 18-20 week ultrasound screening (SOGC Guidelines, 1993). Alberta Health is following suit and have currently established Clinical Practice Guidelines supporting the appropriateness of offering second trimester ultrasound screening to women as a part of their routine prenatal care.

The Canadian Task Force on the Periodic Health Examination (1996) emphasized the obligation clinicians have in providing information on Maternal Serum Screening. The same recommendation was not made for prenatal ultrasound. Alberta Health's Clinical Practice Guidelines for Prenatal Ultrasound recognizes the importance of pre-test education. Ensuring that women have a clear understanding of purpose, benefits, limitations and implications of prenatal ultrasound testing is an obligation of prenatal care providers.

What is not currently understood is the level of knowledge women have of testing, whether this knowledge is sufficient to provide an informed choice, and how supplementary information will effect women's understanding of prenatal ultrasound. These are the bases of the investigation reported in the following chapters.

CHAPTER 3

METHODS

3.1 Study Design

As discussed in Chapter 1, the objective of this study was to examine how and what information women receive on ultrasound testing, and whether this information was correct and useful to women in facilitating an informed choice on testing. Additionally, the effectiveness of providing supplementary written information in terms of knowledge retained and its perceived usefulness was also assessed.

These objectives were examined utilizing a quasi-experimental design using two groups of pregnant women. A knowledge questionnaire was provided to one sample of low-risk pregnant women attending the Elliott, Fong, Wallace and Associates Radiology Department (EFW) for their 18-20 week ultrasound scan. This group provided data in reference to: 1) information commonly received from prenatal care providers, 2) the usefulness of the information received, and 3) women's general understanding of prenatal ultrasound testing. A second sample of women were recruited through the Low Risk Maternity Clinic (LRMC) at the Foothills Hospital. These low risk pregnant women were initially surveyed at 14 weeks of pregnancy, then after receiving the information pamphlet specific to prenatal ultrasound, they were again surveyed at their 18-20 week ultrasound scan. This group provided information regarding the effect of women's understanding of prenatal ultrasound following the provision of supplementary written information.

The study design is depicted below. Randomization and random sampling did not take place in this study, thus, this study should be considered quasi-experimental. Although a true experimental design, such as a cohort, would have minimized threats to internal validity and provided more assurance of the

study's findings, it was simply not practical in this context. A true experimental design would have required a large sample size, and quite possibly, a multi-centre approach, whereby several clinicians from various prenatal care services would have agreed to participate. This would have been beyond the scope of a master's project.

Study Design:

	Gestational Age		
	14 –15 weeks	14-15 weeks	18-20 weeks
Group 1 (EFW)	—	—	O
Group 2 (LRMC)	O ₁	X	O ₂

O refers to measurement through survey and X refers to education intervention.

Group 1 refers to the women recruited at 18 weeks through the Elliott, Fong, Wallace and Associates Radiology Department. Group 2 refers to the women recruited at 14 weeks through the Low Risk Maternity Clinic.

A self-administered knowledge questionnaire and an information pamphlet were the instruments designed for use in this study. Both were constructed to provide and elicit information regarding the purpose, risks, benefits and limitations of prenatal ultrasound. Presented next, are the definitions of the two important variables: 'sufficient knowledge' and 'informed choice.' This is followed by a description of the two instruments in terms of their development, design, and validity testing.

3.2 Definitions of: 'Sufficient knowledge' and 'Informed choice'

Fundamental to the validity of a study questionnaire are clear definitions of what the instrument is intended to measure. The definitions of two key terms in the primary research question: 'sufficient knowledge' and 'informed choice' are first provided, followed by a description of the instrument's design and the tests undertaken to ensure validity and reliability.

There are no published guidelines outlining the minimum information requirements needed to facilitate an informed choice about prenatal ultrasound

testing. It is recognized that individuals should be aware of the purpose or objectives of testing and the advantages, limitations and alternative options available, prior to proceeding with testing. Hence, a blueprint outlining items related to each of these categories was compiled and reviewed by appropriate specialists for content validity. Items of the blueprint, and the elements within each item are described below.

6) Purpose of the ultrasound scan

Women should be aware of:

- i The use of ultrasound in evaluating fetal growth and development, assessing gestational age, fetal number and viability.
- ii The additional objective of an 18-20 week ultrasound in screening for fetal anomalies.

Justification:

In order to make an informed choice women need to be aware of the objective of an 18-20 week ultrasound in screening for birth defects.

2. Advantages of an 18-20 week prenatal ultrasound.

Women should be aware of:

- i. The capability of ultrasound in detecting serious birth defects.
- ii. An 18-20 week scan which reveals no anatomical fetal problem, does not exclude the risk for delivering a child with a fetal malformation, but can provide considerable reassurance.
- iii. There are no reported medical risks of ultrasound exposure to the mother or the developing fetus.

Justifications:

The diagnosis of a fetal anomaly provides women with management options, support, and a reproductive choice in their pregnancy, all of which support a woman's autonomous rights.

An ultrasound revealing an anatomically normal appearing fetus can provide considerable reassurance and be a positive experience for both the woman and her partner.

An ultrasound can provide women with considerable information about the pregnancy at no cost in terms of invasiveness or medical risk.

6) Limitations of prenatal ultrasound.

Women should be aware of:

- i. Ultrasound is not diagnostic for all malformations.
- ii. In some cases, there can be uncertainty in providing women with complete information in terms of the fetal diagnosis or prognosis.
- iii. Some anomalies are not apparent until late in gestation.

Justifications:

The difference between diagnostic and screening tests when making an informed choice about prenatal ultrasound should be understood.

An anomaly detected sonographically at 18 weeks may not necessarily provide enough information regarding the severity of the disorder. Therefore, women may be left with many unanswered questions and be required to make choices about the management of their pregnancy based on this limited information.

Further invasive testing may also be offered to women in view of the ultrasound findings, which would place the pregnancy at a risk for miscarriage.

An ultrasound performed prior to 18 weeks gestation is limited in its' ability as a screening tool for all fetal malformations. Some anomalies are not detectable until later in pregnancy and would go undetected at 18 weeks.

4. Consequences of ultrasound testing

Women should be aware of:

The potential psychological consequences of prenatal ultrasound screening, particularly if a fetal anomaly is suspected, or detected. In such circumstances, women may be faced with a difficult dilemma in terms of reaching a decision regarding the management options available to her in her pregnancy.

Justification:

Avoiding this discussion directly violates the ethical principles of beneficence and autonomy. The consequences of being poorly informed about tests include undergoing tests that, with more information, women may have not undergone.

Having more information might also be of benefit in preparing women for the possible adverse outcomes of testing.

5. The optional choice of prenatal ultrasound testing

Women should be aware of:

The choice they have about ultrasound testing. The right to refuse the test is equal to their right to accept testing. Options to testing include maternal serum screening or no testing.

Justification:

'Voluntariness' is an important element of the informed choice process. Full disclosure and comprehension of the relevant information is first required to make a decision.

Informed choice is the process undertaken by an individual patient, when making an autonomous decision about a particular medical intervention. Etchells, and colleagues (1996) describe three components in this process: disclosure, capacity and voluntariness:

"Disclosure" refers to the provision of relevant information by the clinician and its comprehension by the patient.

"Capacity" refers to the patients' ability to understand the relevant information and to appreciate those consequences of her decision that might reasonably be foreseen.

"Voluntariness" refers to the patient's right to come to a decision freely, without force, coercion or manipulation.

All three components of the informed choice process were examined in the knowledge questionnaire.

3.3 Study Instruments

Prenatal Ultrasound pamphlet

A prenatal ultrasound information pamphlet (Appendix I) was designed using information attained from 1) the researcher's clinical experience; 2) a review of available educational materials on maternal serum screening (Alberta Hereditary Diseases Program brochures on amniocentesis and maternal serum prenatal screening; Ontario Maternal Serum Screening Brochure, Ormond, 1993); 3) the literature cited in this review, and 4) expert clinical opinions. The information pamphlet was written to reflect the items outlined in blueprint of sufficient knowledge presented above. This material was considered to be the minimum

information necessary to facilitate an informed choice on prenatal ultrasound testing.

This pamphlet was carefully examined by specialists in the fields of family medicine, genetics, obstetrics, radiology and social work. Low risk pregnant women attending the Department of Medical Genetics at the Alberta Children's Hospital for antenatal genetic counselling also provided input regarding the content and readability of the pamphlet. Appropriate revisions were made in accordance with all of the suggestions provided.

Prenatal Ultrasound questionnaire

Since there was no existing questionnaire instrument specific to prenatal ultrasound, an instrument was devised to address the research questions and the minimum knowledge requirements necessary to facilitate an informed choice on testing. The questionnaire consists of both closed and open-ended questions. The subjects were required to simply check the appropriate response category in the closed-ended questions, and provide a short answer to the open-ended questions. Question items fall under one of the following categories: source and comprehensiveness of information previously received; conditions which are screened for by prenatal ultrasound and those for which screening is not done; practical details of the ultrasound procedure; the meaning of test results.

The questionnaire was developed and evaluated in several phases to determine whether the instrument was clearly worded, free from major biases, and elicited the type of information envisioned. Appropriate revisions were made at each phase.

To assess content validity, the questionnaire was reviewed by professionals with expertise in the field of prenatal diagnosis. Professionals included family physicians (2), geneticists (2), genetic counsellors (6), an obstetrician, and radiologists (2). This group assessed the representativeness of the questions in

relation to the objectives of the study. The questions were modified to ensure that the domains of sufficient knowledge and informed choice were covered.

To evaluate face validity, the revised questionnaire was given to professionals with expertise in questionnaire development and analysis. These professionals included a research analyst, a professor of psychometrics, a behavioral psychologist and a professor in health care research. Based on their feedback, minor grammatical revisions and changes pertaining to questionnaire format were made for the purpose of simplifying wording and encouraging participant interest.

The questionnaire was also discussed with six non-pregnant women who had experienced pregnancies and prenatal ultrasound testing. Three women had delivered children with congenital birth defects and three had normal pregnancy outcomes. These women shared their experiences with prenatal ultrasound and their impressions of the questionnaire items. Modifications were made based on their feedback. There was consensus among this group that the question item pertaining to the 'drawbacks' or implications of ultrasound testing, was a difficult one to explore. It was believed that a more direct question might in fact frighten most women, yet the question as set forth might not address what it is supposed to address. Upon further review with the above mentioned experts, it was decided to leave the question as it was, noting its limitations.

Criterion validity was not evaluated, as there was no similar scale to which comparisons could be made. Similarly, construct validity could not be accurately measured, as there have been conflicting reports regarding the determinants of women's knowledge of prenatal testing. In a study of subject's knowledge about serum screening for Down syndrome, Smith et al (1994) found that sociodemographic variables (age, number of children, socioeconomic class and ethnicity) were weak predictors of the variance of knowledge. On the other hand, Green, Statham and Snowdon (1993) suggested that age, parity and education, all of which are indicators of sociodemographic status, were strongly related to women's knowledge of testing.

Reliability was tested during the formal study. Five women from Group 2 were contacted by telephone within one week of completing the first questionnaire, and were asked to respond to three selected question items. There was no discrepancy noted in the responses of any of the women.

3.4 Questionnaire pre-test.

A Pre-test of knowledge questionnaire was performed in January, 1998. Fourteen pregnant women were recruited from the Department of Medical Genetics Amniocentesis Counselling sessions at the Alberta Children's Hospital, to complete and provide input into the questionnaire. The amniocentesis counselling sessions are offered by prenatal genetic counsellors to all pregnant women within Region 4 and are mandatory if a woman is considering prenatal diagnosis. Women attending the amniocentesis counselling session were 35 years of age and older and had a negative family history of genetic concern. Consenting volunteers who reviewed the questionnaire provided positive feedback in terms of the clarity of the question items.

A descriptive analysis of the pre-test sample is presented in Appendix J. The analysis of the pre-test data indicated that the question items and analysis procedure did provide the kinds of results that would be appropriate for addressing the research questions.

3.5 Subjects and Subject Selection

The clinics selected for this study were chosen because of their large obstetric practices and their openness and interest in this project.

Group 1 participants were women presenting for an 18-20 week ultrasound scan at the Elliott Fong and Wallace Radiology and Diagnostic Imaging facility (EFW) located in the Foothills Professional Building in Calgary. EFW is situated close to the Foothills Hospital and offers a large obstetric ultrasound service to Family Physicians, Obstetricians and Midwives in the Northwest Calgary. Participants

in Group 1 received no additional information on prenatal ultrasound, apart from what was routinely provided by their clinician. Although this group was not randomly selected, an assumption was made that the women were representative of the general population of healthy low-risk pregnant women being seen in the Calgary region; at least in the Northwest area of Calgary.

Participants in Group 2 were healthy pregnant women recruited from the Low Risk Maternity Clinic (LRMC) at the Foothills Provincial Hospital. This clinic is operated by four Family Physicians who restrict their practice to low risk obstetrics. Women are generally seen between 8 and 12 weeks of their pregnancy for their first prenatal visit, and are then followed in accordance with the clinical practice guidelines.

Participants from Group 2 were given the first knowledge questionnaire (the 'pre-intervention questionnaire') at 14-15 weeks in their pregnancy. Once completed, they were provided with supplementary prenatal ultrasound pamphlet, and at the time of their 18-20 week ultrasound, were asked to complete the second knowledge questionnaire ('post-intervention questionnaire').

3.6 Exclusion Criteria

All healthy pregnant women during the study period were eligible, but subject to the following exclusions:

1. Women with pregnancies greater than 20 weeks gestation.
2. Women who did not understand English and were, therefore, unable to provide an informed consent to participate.

3.7 Study Procedure

Group 1

Women attending EFW for an 18-20 week ultrasound were approached by the reception staff to participate in the study. The staff were instructed to inform the women that the study was strictly voluntary and detailed information about the study was provided in the package. If the woman agreed to be involved in the

study, based upon the receptionist's comments, a package was provided to them prior to their scan.

The provided package contained:

- 1 A cover letter describing the study and information concerning the maintenance of subject confidentiality and anonymity (Appendix B).
- 2 The knowledge questionnaire (Appendix C).
- 3 A tear-off sheet on the back of the questionnaire offering a summary of the study results for those women interested. This form would provided the names and addresses of those interested. This form was separated from the questionnaire to maintain anonymity (Appendix D).
- 4 A brief questionnaire (called a 'postcard') regarding basic sociodemographic variables was included in this package, for women who were not interested in completing the questionnaire but willing to complete this optional form (Appendix E).

Completing the questionnaire was interpreted as an indication of consent to participate. Once completed, the questionnaire was sealed and returned to the receptionist. Questionnaires were picked up on a regular basis by the researcher.

Group 2

Women attending the LRMC for their second prenatal visit (approximately 14-15 weeks gestation) were approached by the clinic nurse about participating in the study. Approaching women on their first prenatal visit was avoided for two reasons: 1) this was a busy clinic visit for the patient, nurse and physician, 2) it would be expected that a small proportion of women would miscarry between 12 weeks and 14-15 weeks gestation.

Women who chose to participate were provided with the study package.

This package included:

1. A cover letter describing the study and information concerning the maintenance of subject confidentiality and anonymity (Appendix B),
2. The pre-test knowledge questionnaire (Appendix F) .
3. A consent form asking whether the participant would be willing to complete a second questionnaire at the time of their 18-20 ultrasound, and if so, whether the participant would permit the researcher to contact them directly to obtain the date and location of the scan (Appendix G).

Once completed, the questionnaires were sealed and returned to the nurse receptionist. The participants were then provided with the ultrasound information pamphlet and encouraged by the nurse to review this information and to contact the researcher should they have any questions.

Participants in Group 2 who consented to follow-up were contacted by the researcher within one week. The telephone contact served 2 purposes: 1) to review any questions or concerns the participants had about the study, the ultrasound information pamphlet or ultrasound in general, and 2) to determine the date and location of their scheduled ultrasound.

The second 'post-intervention' questionnaire (Appendix H) was provided to the women by the receptionist at the ultrasound department just prior to their scheduled 18-20 week ultrasound appointment. The post-test questionnaire asked a few additional questions as compared with the pre-test questionnaire. Specifically, women were asked if their caregiver provided them with helpful information, if the test was presented as an option, and if they were aware how the results would be relayed to them. Once completed, it was sealed and returned to the receptionist. A tear-off sheet at the back of the questionnaire was included in the post-test questionnaire so that those interested in the results of the survey could complete the sheet and return it separately from the questionnaire.

3.8 Sample size and Power

Group 1

A consultation was made with a Biostatistician. Group 1 data collection of was completed over a period of 22 consecutive weeks, with a total of 113 completed questionnaires received. Based on a sample of approximately 100, with an estimated difference in proportion of 0.5, an alpha of 0.05 and power of 80%, one would predict that this sample would provide a standard error of 0.1 and a confidence interval of 0.5 ± 0.1 .

Group 2

It was assumed that the sample size of Group 2 would be considerably smaller due to the limited monthly referrals received through the Low Risk Maternity Clinic. Hence, it was decided to open recruitment for a period of 20 consecutive weeks and present the analysis descriptively as a pilot project.

3.9 Data management

As questionnaires were received, they were assigned an identification number. The data from the questionnaires were then entered directly into a work manual and, into a microcomputer database by the researcher. This double entry was done to ensure the accuracy of the data entry procedure. Once all questionnaire items were entered, the data were examined for unusual entries against the work manual and the original questionnaires. Corrections were made as necessary.

Sociodemographic information from women who did not complete the questionnaires were also entered in a similar fashion. This information was not available from women who outrightly declined participation, and from women who were not provided a questionnaire by the staff due to some oversight.

3.10 Data Analysis

The data was analyzed using the Statistical Software Package for the Social Sciences (SPSS). Study variables explored in the analysis are outlined in Table 3.1.

Table 3.1: Study variables

Variables used in analysis*	
Independent variable	Pamphlet information provided to Group 2
Dependent variables	Knowledge Perception of informed choice
Sociodemographic variables	Age Education Marital status Language spoken Employment status
Other variables	Parity Health education experience Primary care provider Sources of ultrasound information

*All variables, except age, are categorical and will be re-coded as di- or trichotomous variables.

The data were first analyzed to obtain a description of the respondents with respect to their sociodemographic information. Sociodemographic variables were described in terms of their frequencies and total percentages. Differences between Group 1 and 2 were assessed using one-way analysis of variance for continuous measures and contingency table analysis for categorical variables. If assumptions were met a chi square analysis was performed on the 2x2 tables. If

cells within the 2x2 table had an expected count less than 5, a Fisher's exact test was used.

Three phases of data analysis followed this sociodemographic descriptive phase. The objectives, corresponding questions, and method of analysis of the three phases is provided below.

Phase 1: Data Summary Phase

The emphasis in this phase relates to how women receive information on prenatal ultrasound and their views as to the usefulness of different sources. This phase answers, in part the primary research question: Do women receive information on prenatal ultrasound?

The objectives of this phase are outlined below.

Objective 1:

To determine the information women receive about ultrasound testing, based upon the answers to the following questions:

- Q1 How do women receive information?
- Q2 How do they view the usefulness of the information received?
- Q3 What information did they receive from their own care provider?
- Q4 How do women expect to be informed of their test results?

Objective 2:

To evaluate of women's information regarding the purpose, benefits, limitations and consequences of prenatal ultrasound, based upon answers to the following questions:

- Q1 Do women have a general understanding as to how ultrasound works?
- Q2 Are women aware of the indication for their ultrasound and main purpose of an 18-20 week prenatal ultrasound?
- Q3 Do women receive information as to the benefits of prenatal ultrasound?
- Q4 Do women receive information as to the limitations of prenatal ultrasound?
- Q5 What do women perceive as the potential consequences of ultrasound?

Objective 3:

To evaluate women's views of prenatal ultrasound and informed choice, based upon the answers to the following questions.

- Q1 Do women strongly agree that their prenatal care provider gave them information that helped them understand the benefits and limitations of testing?
- Q2 Were women informed that prenatal ultrasound is an optional test?
- Q3 Are there variables which can be identified that are associated with women's views of any measures described above?

Item by item frequency distributions of responses to each questionnaire items was the statistical approach used in this first phase of data analysis. Differences between groups were assessed using Chi square analysis.

Phase 2: Analytical phase

To assess women's understanding of prenatal ultrasound, an index of overall knowledge was constructed on the basis of the questionnaire items. Scores were obtained by summing the number of items answered correctly for a maximum score of nine. Similar test measures have been reported measuring women's understanding of other types of genetic testing (Faden, et al, 1985; Mareau, Johnston, Plenicar, Shw and Slack, 1988; Green, Shatham and Snowdon, 1993; Ormond Pergament and Fine, 1996; Decruyenaere, Evers-Kiebooms, Denayer and Van den Berghe 1992). A detailed description of the knowledge index is outlined in Appendix K.

Objective 1:

To evaluate the index scores and determinants of women's knowledge of prenatal ultrasound, based upon the answers to the following questions.

- Q1 Based on the index scores, what is the variability of knowledge women have on prenatal ultrasound testing?
- Q2 Are there determinants associated with higher or lower index scores?
- Q3 What is the relationship between informed choice and the knowledge index score?

The mean and median scores of Group 1 were calculated, and analysis of variance was used to evaluate the relationships between the sociodemographic and independent variables.

Phase 3 : Pilot phase

A descriptive analysis of the effect of pretest information on women's knowledge of prenatal ultrasound.

Objective 1

To measure the effectiveness of the information pamphlet on women's knowledge of prenatal ultrasound, based upon the answers to the following questions.

- Q1 Does supplementary information appear to improve women's knowledge in this sample?
- Q2 Do women's views on informed choice change with the supplement of written information?

This phase of analysis is presented as a pilot. The pre- and post-intervention mean and median scores are determined, as well as the difference in the number of correct responses to each index item are presented. A comparison is made between Group 1 and Group 2. In view of the small sample size, this comparison is descriptive in nature.

3.11 Ethics

Ethical approval was provided by the Conjoint Health Research Ethics Board, University of Calgary. The Management committees from Elliott, Fong, Wallace and Associates and the Low Risk Maternity Clinic, Foothills Hospital, reviewed the proposal and the instruments.

All women eligible to participate were informed in writing as to the purpose of the study and assured that their participation was voluntary. Group 2

participants were asked to provide their initials and birth dates on their second questionnaires but were assured of confidentiality of their provided information.

According to the 'Guidelines for Questionnaires', provided by the Conjoint Health Research Ethics Board, an informed consent was assumed upon return of the completed questionnaire.

It was anticipated that women would take an interest in the study and respond to the questionnaire, as most pregnant women are interested in optimal prenatal care. It is possible that the findings of this study would have a beneficial impact on women's prenatal care in the aspect of personal autonomy and informed choice.

CHAPTER 4

RESULTS

A brief summary of the response rate is presented first, followed by a description of the sample and the results of the analysis as described in the previous chapter.

4.1 Response rate

Group 1: Estimated 'Approach' and 'Response' Rates

As described in Chapter 2, eligible women were asked by the receptionists of Elliott, Fong, Wallace and Associates (EFW) to participate in the study. Because of the method of distributing the questionnaire, it was not possible to determine with certainty, the number of eligible women who were inadvertently missed by the staff. Thus, an accurate response rate could not be calculated.

Alternatively, an 'approach' and 'estimated response' rate will be given. According to the receptionists of EFW, none of the women who were approached about participating in the study, refused to accept the questionnaire package. Hence, an 'approach rate' will be defined as the number of women who were approached by the EFW staff to participate in the study. An 'estimated response rate' will be defined as the number of women who actually took part in the study following recruitment.

Approximately 45 obstetric ultrasound scans are performed at EFW per week. Of these, 50-70% are performed on women between 18-20 weeks gestation. Over the course of 22 weeks, 117 of the 495 to 742 potentially eligible participants women were approached for recruitment. Based on this, an estimated approach rate was 15.2-22.8%.

All but 3 of the 117 women known to have been provided with the study package completed the questionnaire. One questionnaire was rejected because of an early gestational age (10 weeks by dates and ultrasound). Hence, the estimated response rate for Group 1 is 97.4%.

Group 2: Estimated 'Approach' and 'Response' Rates

On average, two new referrals were seen by the Low Risk Maternity Clinic (LRMC) per day. The collection of data took place over a period of 20 weeks. Thus, it was expected that approximately 200 women would have been eligible to participate in the study. Forty-three women were provided with the first questionnaire. None of the women who were approached refused the questionnaire package. Based on this information, an approach rate of 21.5% was calculated. Although all 43 women completed the first questionnaire, only 26 completed the follow-up questionnaire. Therefore, the estimated response rates for Group 2 were 100.0% for the first questionnaire and 39.5% for the second. Women who took part in completing the first questionnaire but not the second, were classified as "Group 2 Q1 participants."

Two women who consented to complete the second questionnaire were lost to follow up. The dates of their ultrasounds were obtained, the questionnaires were provided but were not returned, and attempts to contact by telephone following their scheduled ultrasound dates were not successful. As these women did not decline participation in the second component of the study, they will not be included with the Group 2Q1 participants. Their pre-intervention data will be combined with the other Group 2 participants but when making comparisons with the pre-intervention with post-intervention subjects, they will be excluded.

4.2 Sociodemographic description of sample

The following section provides a description of Group 1 (n=113), Group 2 (n=26), and Group 2 Q1 participants (n=17) with respect to the sociodemographic variables including age, marital status, parity, education and employment status.

Group 1 characteristics

1. Age

The mean and median age of participants was 30.4 years (95%CI: 29.5 to 31.2years) and 31 years (25th percentile: 28 years; 75th percentile: 34 years) respectively. As the median approximates the mean age, a normal distribution of age can be assumed.

2. Marital status

One hundred and nine of the 113 women responding to the question of marital status were legally married or in common-law relationships. One woman was separated. This figure is far above the 1991 census data for the Calgary region provided by Statistics Canada (96.5% versus 54.2%; difference of 42.3%). This implies that pregnant women of Group 1 may not be reflective of the general population of women in the Calgary region.

3. Parity

There was a relatively equal distribution of parity among the subjects. The mean age of the nulliparous women was 29.3 years (95% CI: 23.06-30.53 years) compared to the mean age of 31.3 years (95% CI: 30.16-32.48 years) of the multiparous women. This difference in age was statistically significant (t test: $t=2.35$, 107 degrees of freedom $p=0.02$).

All of the multiparous women had had an ultrasound in their previous pregnancy(ies). Thirty-three women (16 of the nulliparous and 17 of the multiparous women) had already received an ultrasound prior to their 18-20 week scan. Thus, 73 of the 110 women (66.4%), had undergone an ultrasound scan in their current or prior pregnancy(ies).

4. Language and education

English was the first language of most participants (104 of the 109 women responding to this question). Five women spoke other languages, but judging by their written responses to the open-ended questions, had no difficulty with their comprehension of English.

Most women participating in this study were well educated. Ninety-two of the 108 women responding to the question on education, had some secondary education or had completed college or university. Sixteen women had not achieved additional education beyond high school. One quarter of the sample (30 of 108 respondents) reported having some training in the health care industry.

5. Employment status

Eighty-six of 110 women were either employed outside the home or were full-time students. The remaining women were at home full time with children (n=18) or were unemployed (n=6).

6. Choice of primary care provider

Sixty-four women (56.6%) chose their family physician as their prenatal care provider. Ten women (8.9%) elected to have their prenatal care provided by another family physician practicing obstetrics. Twenty-three women (20.3%) selected a physician working through the Low Risk Maternity Clinic, Foothills Hospital and 2 selected a physician through the Maternity Care Centre at the Peter Lougheed Hospital.

Only 11 women (9.8%) received their care through an obstetrician. This small number was not unexpected during this study period, as Alberta's obstetricians, in dispute with the Alberta Medical Association and provincial government, were not accepting new patients. Three women received their care through a midwife.

Table 4.1: Summary of sociodemographic characteristics of Group 1 (n=113)

	N	%
Maternal age:		
Mean: 30.4 years		
≤ 25 years	16	14.1
26 - 30 years	38	33.6
31 – 35 years	40	35.4
36 years	15	13.4
No response	4	3.5
Marital status:		
Married or common-law	109	96.5
No response	4	3.5
Educational achievement:		
Less than high school or completed high school	16	14.2
Some post-secondary or completed post-secondary	92	81.4
No response	5	4.4
Health care training:		
No response	30	26.5
	5	4.4
Parity:		
Nulliparous	50	44.2
Multiparous	60	53.1
No response	3	2.7
Employment status:		
Employed outside of home or student	86	76.1
Unemployed or at home with children	24	21.2
No response	3	2.7
Primary care provider:		
Own family physician	64	56.6
Physician from Low Risk Maternity Clinic	23	20.4
Physician from Maternity Care Centre, PLC	2	1.7
Family physician referred for prenatal care	10	8.9
Obstetrician	11	9.8
Midwife	3	2.6
No response	0	

A summary of the sociodemographic variables of Group 1 is outlined in Table 4.1. There were three women who completed the “postcard,” declining participation in the study. Two provided a reason for declining participation.

Their reasons were: "I am a family doctor-would likely bias results from the questions I looked at" and, "not enough information provided as to the ultimate purpose of the study or what will be done with the results." Two women, one of whom gave her reason for not choosing to participate, provided information pertaining to their demographics. Both were in their thirties, were married and were employed. One woman completed high school and the other was a family physician. One woman did not provide any demographic information.

Group 2 participants

The following outlines the sociodemographic characteristics of the 26 participants of Group 2. Information on the women who completed the first questionnaire but chose not to proceed with the second questionnaire is also provided.

1. Age

The mean and median age of participants was 30 years (95% CI: 28.6 to 32.1 years) and 31 years (25th percentile: 27 years; 75th percentile: 33 years) respectively. The difference between the mean and median age suggests an asymmetrical frequency distribution. It was assumed that this skewed distribution is due to the small sample size.

2. Marital status

All 26 participants were legally married or in common-law relationships.

3. Parity

There were 15 nulliparous and 11 multiparous women participating. All multiparous women had had an ultrasound in their previous pregnancy(ies). Two women had already received an ultrasound prior to their recruitment into the study. Both were multiparous with a history of vaginal bleeding.

4. Language and education

English was the second language of only two women. There was no evidence to suggest a difficulty with the English language from the open-ended responses to the respective question items. Most women participating in this study are well educated. Twenty-five participants (96.1%) had some secondary education or had completed college or university. Additionally, 6 women (23.1%) reported having some training in the health care industry.

Twenty-three women were either self-employed or working outside the home.

Group 2 Q1 participants

Group 2 Q1 participants were defined as women who completed the first questionnaire but declined participation in the follow-up questionnaire.

Seventeen of 43 women (39.5%) recruited from the Low Risk Maternity Clinic did not complete the second questionnaire. Nine women (52.9%) completed the provided consent form (Appendix G) stating that they were not interested in participating further in the study. Five women (29.4%) did not sign the form, which may have been an oversight or their intention. Three were excluded as they were of late gestational age or were unable to be contacted by phone regarding follow-up. Sociodemographic characteristics of the Group 2 Q1 participants is presented in Appendix L.

4.3 Comparative summary of sociodemographic characteristics of study participants

Comparisons were made between Group 2 and Group 2 Q1 women to determine if there were sociodemographic differences between the two groups (Appendix L). No significant differences were seen with age, parity, education, employment or health education to suggest a reason for the non-interest among the Group 2Q1 women.

Comparisons were also made between Group 1 (n=113) and Group 2 women (Group 2 and Group 2 Q1; n=43). Group 1 and Group 2 were similar with respect to the sociodemographic variables measured with the exception of employment status. Group 2 women were more likely to be either employed outside of the home or students than Group 1 women (90.6% versus 76.1%: $\chi^2 (1)=4.48, p=0.03$). As there was no difference in education achievement, in that over 80% of the participants had at least some post-secondary education, the issue of the difference in employment status was not considered clinically important.

It is evident based on the marital status, education, employment status and health education and experience of the women in this study, that this population is select and not representative of the general population. Comparisons made with Statistics Canada census data (1991) of the Calgary region confirm this. Given that EFW is situated close to the Foothill Medical Centre, the Alberta Children's Hospital, the University of Calgary, and is also in proximity to the downtown core, higher levels of education, employment and health experience were not unexpected.

4.4 Phase 1 Data Analysis

Objective 1: Pre-test information women receive on ultrasound

i. Sources and usefulness of information received.

The analysis begins with an exploration of women's sources of information on prenatal ultrasound and women's perceptions of the usefulness of those sources.

Only the data collected from Group 1 (n=113) were analyzed. Pre-intervention Group 2 and Group 2Q1 women were excluded from this exploration as they were surveyed earlier in their pregnancy and would have had less time to obtain information from available sources. Group 2 post-intervention women were also excluded as they were provided with written information at 14 weeks of pregnancy. This source alone, or the insight gained from the reviewing this

source, may have had an influence on their desire to learn more about ultrasound.

Women were provided with a list of possible referents and asked:

“From which of the following sources, if any, have you received information on prenatal ultrasound?”

They were then asked to assess the usefulness of the information received. Response options were presented on a 4 point Likert scale. Choices ranged from ‘very helpful’ to ‘not at all helpful’ (Table 3.2). Ninety-seven women (85.8%) utilized at least one health care provider as a source of information. Thirteen (11.5%) women did not receive any information from a health care provider, and 3 women (2.6%) choose not to respond. Of the 97 women using one or more health care sources, only 31 (31.9%) considered them to be ‘very helpful’ sources of information. The majority (54 of the 97 women: 55.7%) considered the health care sources as ‘somewhat helpful.’ Two women found their health care sources somewhat unhelpful and 2 (2.1%) women considered their source(s) to be not at all helpful. Eight (8.2%) did not provide a response in terms of usefulness of information received. The 13 respondents who did not use any of the health care sources listed, used friends (n=9) and books (n=4) as their only sources of information. Four of these 13 considered their sources very helpful.

Forty-one women (36.3%) used a family physician as their sole health care source. Of these, 15 women (36.6%) considered this referent as a very helpful source of information, and the remaining 26 women (63.4%) considered this source as only ‘somewhat helpful.’

Table 4.2: Sources and usefulness of sources of prenatal ultrasound information (n=113)

Usefulness of information received						
Source	# (%)	Very helpful N(%)	Somewhat helpful N(%)	Somewhat unhelpful N(%)	Not at all helpful N(%)	No response N(%)
One or more Health Care source	97 (85.8)	31(31.9)	54 (55.7)	2 (2.1)	2 (2.1)	8 (8.2)
No health care source	13 (11.5)					
No response	3 (2.7)					
Family doctor only	41 (36.3)	15(36.6)	26 (63.4)	0	0	0
Friends/ relatives (not exclusively)	50 (44.2)	18(36.0)	29 (58.0)	1 (2.0)	0	2 (4.0)
Media (news, internet, TV, magazines)	26 (23.0)	2 (7.8)	19 (73.0)	0	3 (11.4)	2 (7.8)
Books	53 (46.9)	25(47.2)	20 (37.7)	3 (5.7)	0	5 (9.4)

- Health care sources included: Family physicians, Obstetricians, Midwives, Nurses, Prenatal Classes and Genetic Counsellors.

Beyond health care providers, women commonly received information from friends, relatives (n= 50: 44.2%) and books (n= 53 46.9%). Books were viewed quite favorably. Twenty-five of the 53 women (47.2%) using books, found them to be very helpful. Media (television, internet, newspaper and radio) was the

least used referent (n=26). Only 2 women (7.8%) considered media to be a very helpful information source.

ii. Information recalled having received from their prenatal care provider

Next explored was the information women recalled having received from their care provider:

“At your early prenatal visits before this appointment, what information on ultrasound did your prenatal care provider give you?”

Sixteen women (14.1%) chose not to respond to this question item, and 62 of the 97 respondents (54.9%) claimed to have received no further information apart from the location and time of appointment. Written information was provided to 15 (13.3%) respondents. It is speculated that this number was positively influenced by the recent publication of the patient pamphlet by the Alberta Medical Association. Twenty women (17.7%), recalled having had a discussion with their prenatal care provider.

Four themes were extracted from the comments provided by women claiming to have had a discussion with their care provider. The four themes with examples from selected responses are provided below.

1. The purpose or objectives of ultrasound testing.

The most common discussion centered on the purpose of ultrasound testing. Examples provided were:

“What was being looked for.”

“What we might see (eg. body, shape etc.).”

All but one of the comments were vague in directly stating that an objective ultrasound was to screen for birth defects. The one exception was stated as follows:

“An ultrasound at 18 weeks was very good for determining fetal anomalies.”

2. The expected pregnancy management following the detection of a fetal anomaly.

The implications on the management of the pregnancy following the detection of an anomaly was suggested, in a somewhat nebulous fashion, by one woman with the following comment:

“[What] to do if something was wrong.”

3. The medical risks of ultrasound exposure to the developing fetus.

The misconceptions of medical risks associated with ultrasound exposure were raised by the following statement:

“[Possible] speech delays etc.”

4. A woman’s right to make a personal choice about testing.

The choice to proceed or forgo testing was addressed by two women. Their comments were as follows:

“[Ultrasound] was my choice, I did not have to get it done.”

“[Not] mandatory, our choice.”

Objective 2: Evaluation of the knowledge index items

The next objective of the first phase of data analysis explores women’s knowledge of ultrasound, related to the purpose, benefits, limitations, and consequences of testing. A general overview of women’s knowledge pertaining to the index items was explored using the 113 subjects from Group 1.

i. Women’s understanding of how ultrasound works.

First explored was the working knowledge women have of prenatal ultrasound. Table 4.3 provides a summary of the Group 1 responses to the question:

“Which answer best describes how ultrasound works?”

The correct answer is highlighted in bold. The vast majority, 97 of the 111 respondents (85.8%), provided the correct response. Of concern were the 14 women who responded incorrectly; 6 considered ultrasound as a form of an X-ray, 6 did not believe ultrasound used either sound waves or X-ray and 2 were

uncertain. Two women chose not to respond. This indicates that 15% of women were either not provided, or failed to retain information about the procedure of ultrasound testing.

Table 4.3 Women's understanding of how ultrasound works (Group 1, n=113)

Which answer best describes how ultrasound works?	N (%)
Uses sound waves to take a picture of the baby in the womb.	97 (85.8)
Uses X-rays to take a picture of the baby in the womb.	6 (4.4)
None of the above	6 (7.8)
I am not sure	2 (2.2)
No response	2 (1.1)

ii. Women's understanding of the purpose of ultrasound testing.

The purpose of ultrasound testing was investigated using two questions. Women were asked what they understood to be the reason for their scan, and to describe the main purpose of ultrasound. The intent of the two questions, was to determine the extent to which women were aware of the scan's function as a means of detecting fetal abnormalities.

Women were provided with 4 response options to the first question:

"What do you understand is the reason for your ultrasound today?"

Only sixty-one women (54.0%) considered screening for birth defects as an objective. Five women (4.4%) were uncertain of the reason for their scan, 23 (20.3%) believed the scan was to confirm their due date, and 9 chose not to respond (Table 4.4).

Women were then asked:

“What is the main use of ultrasound?”

Most respondents (107 of 113: 94.6%) selected the correct option: to check age, growth and development of the baby. Five women (4.4%) selected the incorrect response: “to test for blood disorders.” One woman chose not to respond.

Table 4.4: Views as to the indication of their 18-20 week ultrasound (n=113).

What do you understand is the reason for your ultrasound today ?	N (%)
To determine my due date (only)	14 (12.4)
To determine my due date and ‘other’ reasons	9 (8.0)
To find out if the baby has a birth defect (only)	28 (24.8)
To find out if the baby has a birth defect and ‘other’ reasons	10 (8.8)
To determine my due date and find out if the baby has a birth defect	23 (20.3)
*‘Other’ reasons only	15 (13.3)
Uncertain	5 (4.4)
No response	9 (8.0)

*‘Other’ response items included: to evaluate the presence of a multiple gestation (4), to assess that the baby is “developing (growing) normally” (12), an 18-20 week ultrasound is considered “routine” (11), and, to determine the cause for experienced obstetric problems, such as cramping and spotting (7).

iii. Women’s views of the personal benefit to testing.

The following open-ended question examined women’s understanding of the advantages of a second trimester ultrasound scan.

“How will having an ultrasound benefit you?”

Ninety-nine respondents provided 115 statements in response to this question (Table 4.5). The most common benefit cited was that of reassurance received following the test (n=64). Nine responses centered on the benefit of having an awareness of an abnormality and how this would provide them with a choice

regarding the management of their pregnancy, or the benefit of being better prepared for the problem at birth. Examples are outlined below:

"It will let me know if anything is wrong so I can prevent it as much as possible."

"If something is dreadfully wrong, the choice to treat or end the pregnancy."

"If any problems, allows time to adjust."

Table 4.5: Responses to an open-ended question regarding the benefits of ultrasound.

How will having an ultrasound benefit you? (total of 115 responses)	N (%)
Reassurance/peace of mind	64 (55.6)
Confirmation of due date	16 (13.9)
To make sure the baby is alright , healthy, growing and to look for birth defects	16 (13.9)
Other benefits:	9 (7.8)
To determine fetal gender	3
To look for twins	4
To rule out reasons for obstetric complications	2
Individual choices related to having an awareness of an anomaly.	9 (7.8)
Uncertain	1 (0.9)
No response	23

iv. Women's understanding as to the safety of ultrasound.

Women's understanding about the safety of ultrasound exposure were examined with the questions:

"Is there a medical risk to the mother (baby) from prenatal ultrasound?"

Although 91 women (80.5%) correctly stated that there was no medical risk to the mother, 15 women (13.3%) were uncertain, 5 (4.4%) stated that there was a

risk but provided no examples in support of their answer, and 2 (1.8%) chose not to respond.

There was considerably more uncertainty regarding women's understanding of the medical risks of diagnostic ultrasound exposure to the developing fetus. Seventy-seven respondents (68.1%) claimed that there was no medical risk to the baby from ultrasound testing. Thirteen women (11.5%) stated that there was a related risk. Examples provided were stated as follows:

"Inner ear damage if exposed too much"

"Link between ear disorders, frequent ear infections and ultrasound"

"Hearing damage with prolonged exposure"

"Birth defects"

"Slight risk from radiation"

The remaining 21 women (18.6%) were uncertain and two chose not to respond.

The paired responses to these two items are depicted in Table 4.6. Seventy-four of 110 women responding to both questions, claimed that there was neither a risk to the woman or to the fetus. Fourteen women were uncertain and 3 women claimed a risk to both the woman and fetus.

Table 4.6: Women's understanding of the medical risks of ultrasound exposure.

Medical risk to the mother	Medical risk to the baby			
	No	Yes	Uncertain	Total
No	74	10	6	90
Yes	1	3	1	5
Uncertain	1	0	14	15
Total	76	13	21	110

v. Women's understanding of the diagnostic abilities and limitations of ultrasound.

The last item addressing women's understanding of the advantages of prenatal ultrasound in relation to the informed choice process, was presented as follows:

“ Do you know of any problems an ultrasound can identify in the baby?”

A 'yes' answer would only be accepted if correct examples were provided. Three women chose not to respond to this question. Eighty women correctly identified at least one fetal anomaly, but the 30 (26.5%) remaining, did not know, or could not correctly provide an example of fetal problem detectable by ultrasound.

The limitations of prenatal testing were investigated using two questions.

First, women were asked:

“ Do you know of any problems an ultrasound can fail to identify in the baby?”

There was considerable less familiarity regarding this limitation of ultrasound, as 6 women (5.3%) chose not respond, and 42 (37.2%) women stated that they were unaware of fetal problems that could go undetected by ultrasound screening. The remaining 65 women (57.5%) provided correct examples to support their response.

The paired responses to these two related questions are outlined in Table 4.7. This table clearly outlines the difference in women's understanding of the diagnostic capabilities and limitations of ultrasound. Women were more familiar with the problems identifiable, and less familiar with the problems not recognizable by ultrasound (McNemar's Test $p=0.004$).

Table 4.7: Women's understanding of the diagnostic capabilities and limitations of ultrasound.

Do you know of any problems an ultrasound can identify in the baby?	Do you know of any problems an ultrasound can <u>fail</u> to identify in the baby?		
	No	Yes	Total
No	26	3	29
Yes	16	62	78
Total responses	42	65	107

McNemar's test for paired data: $p\text{-value} = \Pr(X \leq 3) + \Pr(X \geq 16)$ when X is distributed Binomial (19,0.5). $p=0.004$

The second and central limitation of prenatal ultrasound testing is the inability to provide 100% certainty in cases where no fetal anomaly is detected. To evaluate the awareness women have regarding this limitation, women were asked the following 'true' or 'false' question:

"A 'normal' ultrasound result guarantees that the baby will be born free of birth defects."

The vast majority of women ($n=103$: 91.1%) responded correctly. Of the 10 (8.8%) remaining, 2 chose not to respond, 2 women responded incorrectly, and 6 stated that they were uncertain.

vi. Consequences to ultrasound testing.

To examine women's views on the consequences to testing, women were asked:

"Can you think of any drawbacks to having an ultrasound?"

Twenty women (17.7%) did not respond to this open-ended question. Of the remaining 93 women, 59 (52.2%) responded "no," that they could not think of any drawbacks to testing. Twenty-two women considered the following as drawbacks to testing: full bladder ($n=7$); delayed deleterious effect of ultrasound

on the fetus (n=12), and the inadvertent disclosure of the fetal gender to the woman (n=3).

Five responses (4.4%) related to the diagnostic limitations of ultrasound screening. These responses were as follows:

"False sense of security – not 100% accurate or fail safe"

"Human error is always a possibility"

"Not 100%"

"False identification of abnormalities leading to unnecessary and invasive tests"

"False assurance or unnecessary interventions"

An additional 5 comments centered on the implications of an abnormal result:

"Finding out something is wrong"

"Finding out bad news"

"Finding out the baby is abnormal (good to know but a scary thought)"

"What to do about minor problems"

"If something is abnormal-decision early about what to do"

There were two comments distinct from any of the others:

"knowing is not always best"

"[darned] expensive to fund"

A summary and examples of comments provided are presented below.

Table 4.8: Women's views on the drawbacks to ultrasound testing (n=113)

Can you think of any drawbacks to having an ultrasound?	N (%)
No drawbacks known	59 (52.2)
Full bladder	7 (6.3)
Identification of fetal gender	3 (2.6)
Possible (long-term) risks to the baby	12 (10.6)
Diagnostic limitations of ultrasound (examples presented in the text)	5 (4.4)
Implications of an abnormal ultrasound (examples presented in the text)	5 (4.4)
Other (examples presented in text)	2 (1.8)
No response	20 (17.7)

4.5 Overall summary of women's knowledge of ultrasound

The following points summarize the results presented in the previous section.

The majority of women (97 of 111: 85.8%) were aware that the technology of ultrasound uses sound waves, not X-rays.

Sixty-one of 113 women (54.0%) stated that screening for birth defects was an objective of their ultrasound test.

One hundred and seven women (94.6%) stated that the main use of ultrasound was to check for age, growth and development of the baby.

Sixty-four of 115 responses (55.6%) to the open-ended question on the benefit of ultrasound, claimed that they would benefit from the reassurance provided through testing. Nine of 115 responses (7.8%) related to the implications of testing, should an anomaly be detected.

Seventy-four of 110 women (67.3%) stated that there was no medical risk to the mother or the fetus from diagnostic ultrasound exposure.

Fourteen women (12.8%) were uncertain of the risks to the mother or the fetus from exposure.

Twenty-six of 110 women (23.6%) could not correctly provide examples of problems ultrasound can detect or fail to detect at 18-20 weeks gestation. There was more uncertainty regarding the diagnostic limitations of testing.

Fifty-nine women (52.2%) could not identify a drawback to ultrasound testing. Five (4.4%) considered the diagnostic limitations of ultrasound as a drawback and 5 (4.4%) considered the detection of a fetal problem as a drawback.

Appendix L provides a summary of responses to the knowledge items provided by Group 1 participants. In addition, this appendix provides a comparative summary of the knowledge index items provided by the Group 2 pre-intervention participants and Group 2 Q1 participants. There were no statistical differences in responses to the knowledge items between the Group 2 and Group 2 Q1 participants.

Differences in correct responses to the knowledge items between Group 1 (n=113) and the Group 2 pre-intervention and Q1 subjects (n=43) were reviewed and are also presented in Appendix L. Group 2 subjects were recruited 3 to 4 weeks earlier in pregnancy than the women of Group 1. In view of the disparity in sample sizes and gestational ages of the two groups, as well as other possible confounding variables, differences in knowledge between the two groups were anticipated. There were statistically significant differences found in 5 of the 9 knowledge index items. Women of Group 1 were more likely to respond correctly to questions relating to: the problems identifiable and not identifiable by ultrasound, and the diagnostic limitations and benefits of testing. Interestingly, women of Group 2 were more likely to respond correctly to the safety of ultrasound to the woman (95.3% versus 81.4%). The practical significance of this finding is difficult to interpret.

4.6: Women's views of ultrasound and informed choice

This next section explores responses to questions relating directly to the issue of informed choice. A general overview of women's views on the disclosure process was explored using the 113 subjects from Group 1.

The key question pertaining to the disclosure process and informed choice, was asked as follows:

Please indicate how much you agree with the statement "My care provider gave me information on prenatal ultrasound that helped me understand its benefits and limitations."

Over half of the respondents (n=60: 53.1%) selected the 'somewhat agree' response option, while only 15.9% of respondents (n=18) were strongly convinced that their care giver provided them information that facilitated their understanding of the benefits and limitations of testing. Twenty-two women (19.5%) felt negatively towards the disclosure process by disagreeing with the statement and 13 (11.5%) chose not to respond.

Determinants that influenced women's beliefs on the disclosure process and how they consequentially responded to the question presented above were also examined. Factors such as education and prenatal care provider were not found to be associated with women's views of informed choice. Parity, however, was found to be strongly related to women's views of the disclosure process (Table 3.9). Fourteen of the 53 (26.4%) multiparous women strongly agreed to the statement of informed choice compared with only 3 of the 47 (6.4%) nulliparous women. All multiparous women had experience with prenatal ultrasound from their previous pregnancies, and 1 of the 3 nulliparous women had received an ultrasound prior to completing the questionnaire. Although not significant, there was a trend associated with maternal age and views on the disclosure process, in that older women were more satisfied with information received from their

caregiver than women of a younger maternal age. This is consistent with the finding of parity as a significant determinant, as the mean maternal age of multiparous women is greater than nulliparous women.

Table 4.9 Statistical associations between the categorical sociodemographic variables and responses to the informed choice question.

	Strongly Agree	Somewhat Agree	Somewhat Disagree	Strongly Disagree	Test of significance*
Mean age: (95%CI)	31.9 yr (29.9-33.9)	30.1 yr (28.9-31.2)	30.0 yr (26.9-33.0)	28.1 yr (24.2-31.9)	Not significant, (overlapping CI) but a trend noted
Parity:					Significant: FET, p=0.04
Nulliparous	3	31	7	6	
Multiparous	14	30	6	3	
Education:					Not significant FET, p=0.06
High school	5	7	1	1	
Secondary	12	52	12	8	
Health Education					Not significant FET, p=0.25
No	14	38	11	5	
Yes	3	21	2	4	
Prenatal care provider:					Not significant FET, p=0.16
Family physician	14	38	7	7	
Low risk maternity doctor	2	15	5	1	
Obstetrician	0	7	1	1	
Midwife	1	2	0	0	

*Fisher's exact test (FET) calculations were used to test for whether an association existed. Assumptions for FET was not met in the case of measuring an association between the prenatal care providers, therefore this category was collapsed into 2 categories: family physician and 'other provider'. Statistical significance was considered when $p < 0.05$

The caregiver's obligation of providing testing as an option to women was then explored with the question:

"Were you specifically told that prenatal ultrasound is an optional test?"

Although 25 women (22.1%) recalled having being offered testing as an option, over half of the respondents (n=62: 54.9%) stated that they were not informed and an additional 14 (12.4%) did not recall having been told that they had a choice about testing. Twelve women (10.6%) did not to respond.

Women's views of their autonomous right to make a decision about testing was considered with the next question:

How much do you agree with this statement "It is currently a woman's choice whether or not to have a prenatal ultrasound"

Forty-eight women (42.5%) felt strongly that it was a woman's choice whether or not to proceed with testing. There were remaining, 41 women (36.3%) who, with reservation, only 'somewhat agreed,' and 20 women (17.7%) disagreed entirely that it is a woman's choice.

4.7: Phase 2 of Data Analysis

The following section provides the overall knowledge index scores and an exploration into the determinants of that knowledge. Information is presented on the 88 participants of Group 1 (77.8%) who completed all index items. The mean and median scores were 6.5 (std. deviation: 1.69) and 7.0 (25th percentile: 5.25; 75th percentile: 8.0), respectively. The difference between the mean and median values suggests a skewed distribution (Kolmogorov-Smirnov= 2.113, $p < 0.0001$). Measures of association between index scores and sociodemographic characteristics are presented in Table 4. 10. No differences in knowledge scores were found between Groups 2 and 2Q1 in terms of the demographic variables of parity, employment, health education and primary prenatal care providers.

Although not statistically significant, there was a correlation, suggesting a trend between maternal age and scores, in that older women tended to score higher

than the younger women (Pearson correlation, $r=0.42$). A trend was also found for women's education achievement. Specifically, more educated women tended to have higher knowledge scores. A larger sample size would provide a clearer picture regarding the trends seen with maternal age and education.

Table 4. 10: Statistical measures of association between sociodemographic variables and knowledge index scores of Group 1 (n=113)

	Mean Scores	Test of significance
Age (n=87)		Pearson correlation: $R=0.42$, $p<0.0001$ Trend noted
Parity (n=87):		ANOVA:
Nulliparous	6.3	$F(1,85)=1.406$, $p=0.24$
multiparous	6.8	Not significant
Education achievement (n=86):		ANOVA:
High school	5.8	$F(1,84)=2.950$, $p=0.09$
Some or completed secondary education	6.7	Trend noted
Health education (n=86):		ANOVA:
No training	6.4	$(1,84)=0.991$, $p=0.32$
Training	6.8	Not significant
Employment (n=86):		ANOVA:
Employed or student	6.7	$F(1,84)=1.057$, $p=0.31$
Unemployed or at home with children	6.2	Not significant
Prenatal Care Provider (n=88):		*ANOVA:
Family doctor	6.5	$F(1,76)=0.840$, $p=0.36$
Low risk maternity doctor (FHH or PLC)	6.9	Not significant
Obstetrician	6.4	
Midwife	6.0	

*ANOVA between FP and LRMC was performed only due to the inadequacy of sample size of the Obstetricians and Midwives

The relationship between women's index scores and their views on the disclosure process (responses to the question: "My care provider gave me information of prenatal ultrasound that helped me understand its benefits and limitations) was examined. The mean knowledge scores between women who strongly agreed (mean = 6.5), somewhat agreed (mean = 6.8), and disagreed (mean = 6.1) concerning the helpfulness of their provider's disclosure process, were not significantly different (ANOVA: $F(2,82)=1.062$, $p=0.35$). This suggests that women who felt their prenatal care provider gave them helpful information to facilitate an informed choice, did not necessarily have a greater understanding of the purpose, benefits, limitations and consequences of testing.

4.8: Phase 3 Pilot phase

This final phase will present the results of the pilot study performed to address the secondary questions of this research project:

Does supplementary information provide women with an improved understanding regarding the knowledge index items tested?

Does this supplementary information change women's views on informed choice?

Analysis was based on 24 patients of the Low Risk Maternity Clinic (Group 2) who completed the pre- and post-intervention questionnaires.

The mean pre-and post-intervention scores were 5.58 (95%CI: 4.80-6.36) and 8.37 (95%CI: 7.69-9.05) respectively. The difference in mean scores was statistically significant ($t = -7.84$, $p < 0.001$).

A comparison of the number of correct responses to the index items between the 24 Group 2 subjects prior to, and after the intervention, is provided in Table 4. 11. In view of the small sample size, interpretation is limited to a descriptive analysis. However, it would appear that the education pamphlet resulted in a considerable increase in knowledge on all but one of the measured items.

Marked improvements were seen in: women's understanding of what fetal problems ultrasound can and cannot identify; the safety of ultrasound exposure to the developing fetus and, the benefits of ultrasound testing. There was no change in the knowledge item that questioned the medical risk of ultrasound exposure to the woman. The subject who incorrectly responded to this question before the intervention was not the same individual who responded incorrectly following the intervention.

Index scores increased or remained the same after education for all but 1 subject. This subject's response to the open-ended question regarding the drawbacks of ultrasound testing was correct in the pre-intervention stage: "Could instill a false sense of security about the perfect baby" and incorrect in the post-intervention stage "No, I cannot think of any drawbacks to ultrasound testing."

Table 4. 11: Comparison of the number of correct responses to knowledge index items between Group 2 pre-intervention and post-intervention subjects (n=24).

Correct responses	Pre-intervention N (%)	Post- intervention N (%)	Difference
Purpose:			
Main use of ultrasound	20 (83.3)	23 (95.8)	+3
General knowledge			
How ultrasound works	21 (87.5)	23 (95.8)	+2
Benefits			
Problems identifiable by ultrasound	7) (54.2)	19 (79.2)	+6
No medical risk to woman	23 (95.8)	23 (95.8)	0
No medical risk to fetus	14 (58.3)	20 (83.3)	+6
Personal benefits (reassurance/ affect on pregnancy management)	10 (41.7)	19 (79.2)	+9
Limitations			
Diagnostic limitations	19 (79.2)	22 (91.7)	+3
Limitations in identifying all fetal anomalies	9 (37.5)	18 (75.0)	+9
Consequences			
Drawbacks, implications of testing	4 (16.7)	8 (33.3)	+4

A comparison was made between the post-intervention index scores and scores from the Group 1 subjects (Table 4.12). The mean scores of Group 1 and Group 2 post-intervention subjects were 6.5 (SD: 1.69) and 8.37 (SD: 1.61) respectively. The difference in mean scores was found to be statistically significant ($t[135]=-4.59$, $p<0.001$). As the sociodemographic characteristics were found to be similar, the key difference thought to exist between the two groups was the use of the educational pamphlet.

Last examined was whether women's views of the disclosure process changed with the supplement of written information. The expectation was that the educational information provided to women prior to testing would improve their views on the disclosure process. A comparison in the views of the informed choice process between Group 2 pre-and post-intervention was not possible, as women were not asked this question in the pre-intervention stage. Thus, a comparison was made between Group 1 and Group 2 post-intervention subjects. In view of the small and discrepant sample sizes, a test of significance was not performed. It would appear that more subjects of Group 2 were more likely to strongly agree than women of Group 1 to the informed choice question. There were close to equal proportions of women in both groups who 'somewhat agreed' or 'disagreed.' All women of Group 2 responded to the question, whereas 13 (11.5%) of Group 1 chose not to respond (Table 4.12).

Table 4. 12: Differences in mean index scores and responses to the disclosure question item between Group 2 post-intervention (n=24) and Group 1(n=113)

Informed choice	Group 1 (n=113) N (%)	Group 2 Post-Inter- vention (n=24)N(%)
Strongly agree	18 (15.9)	6 (25.0)
somewhat agree	60 (53.1)	13 (54.2)
Disagreed	22 (19.5)	5 (20.8)
No response	13 (11.5)	0 (0.0)
Mean knowledge index score	6.5 (SD: 1.69)	8.37 (SD: 1.61)

CHAPTER 5

DISCUSSION

This chapter will provide an overall summary and interpretation of the study results presented in Chapter 3. Included in this discussion will be an overview of the response rate and sociodemographic characteristics of the study sample, followed by a summary of the three phases of the data analysis. A discussion of the strengths and limitations of the study, and recommendations for future research will be presented in the final section.

5.1 Response Rate

An accurate response rate could not be determined for the Group 1 subjects from the Elliot, Fong, Wallace and Associates Radiology Clinic, as there was no available record of the total number of women eligible during the 22 week study period.

It was estimated that 15.2 to 22.8% of women eligible to participate in this study were approached by the receptionists of EFW. Of those women approached, 97.4% agreed to participate in the study.

The estimated approach rate for the Group 2 subjects from the Low Risk Maternity Clinic, Foothills Hospital, was similar to that of Group 1 (21.5%). All women approached, completed the first questionnaire, but only 39.5% chose to continue with the second component of the study. No differences in the sociodemographic characteristics or the pre-test knowledge were found between the two subgroups of Group 2 subjects to suggest a reason for this paucity in follow-up. Women who had declined follow-up were not interviewed and, therefore, it could not be determined how these women came to their decision.

One could postulate several possible reasons for the disinterest in follow-up among the Group 2 LRMC women. Women may have perceived the

commitment of reviewing the information pamphlet, being contacted by phone, and complying with completing the second questionnaire, a considerable obligation. Or, conceivably, some women may have made the decision against prenatal ultrasound and therefore, saw no need in learning more about this testing option.

Alternatively, the receipt of the pamphlet may have influenced women's decision to participate in the second questionnaire. Some women, when faced with the questionnaire and information pamphlet, may have experienced anxiety or ambivalence towards the scope of the disclosure and decision-making process and hence chose against follow-up. From clinical experience, a few women, when encountered with new information about prenatal testing, come to realize the realm of questions and issues that they may have not considered or chosen to consider prior to their prenatal counselling session. Thus, gaining a greater awareness of prenatal ultrasound testing may not be a choice for all women.

5.2 Sociodemographic characteristics

Women participating in this study were, for the most part, married, highly educated and employed.

The mean age of Group 1 participants was similar to women of Group 2 and Group 2 Q1 (30.4 years, 30.3 years and 31.4 years respectively). The vast majority of women (97.4%) were either married or living as married. Approximately half (46.1%) of Group 1 and Group 2 women were nulliparous. All multiparous and 16 (22.2%) of the nulliparous women had prior experience with prenatal ultrasound testing.

There was a statistically significant difference in employment status between Groups 1 and 2, in that more women of Group 2 were either employed outside the home or were students as compared to women of Group 1 (90.6% vs. 76.1%). This study, however, did not analyze specifically, the nature of the employment. As both samples were highly educated (82% had attained some or completed their post-secondary education) and no statistically significant difference was

seen in academic achievements, this difference was not considered clinically significant. Nearly one quarter of the participants (23.7%) had some health care training and experience.

It is believed that this population was of a higher socioeconomic status given the close proximity of the target population to the Foothills Provincial Hospital, The Alberta Children's Hospital, The University of Calgary and the business sector of downtown Calgary. Given these particular sociodemographic characteristics, the generalizability of study's findings should be limited to a similar study population.

5.3 Summary of Analysis Phases

How women receive information about ultrasound testing and whether they view this information as helpful in reference to the issue of informed choice, raised some interesting findings.

Ninety-seven women of Group 1 (85.8%) used at least one health care provider as a source of information, but less than one-third (31.9%) found the information received, very helpful. The most commonly used health care provider, a family physician, was seen to be a very useful source of information by only 36.6% of the respondents, the remaining 63.4% of respondents considered this source as only 'somewhat helpful.'

It was somewhat disturbing to find that 11.5% of women claimed to have received no information from any health care source prior to their ultrasound scan. This study was limited in determining the underlying reason for this inadequacy of care. This finding may suggest that one in eleven health care providers evaded their responsibility in providing women with information, or a means of obtaining information through another health care service.

In terms of information received, more than half of the respondents (54.9%) stated that they received no additional information, apart from instructions on their appointment time and location. Twenty women (17.7%) claimed to have had a discussion with their care giver. Because of the vague comments which

these women provided, i.e. "what was being looked for," and "size of baby, due date determination" it was difficult to determine the extent of the discussion.

These two findings imply that a large proportion of health care providers do not discuss prenatal ultrasound with their patients prior to testing, and are for the most part, not considered to be very helpful sources of information.

Despite the low levels of perceived usefulness of information received from prenatal care providers, a greater number of women were *not* dissatisfied with the information received. Sixty-nine percent of the respondents (78 of 113) professed satisfaction with their care provider's disclosure process. One possible explanation for this incongruity relates to *how*, rather than *what* information was presented. Prenatal screening is considered by the majority of women and their care providers as a 'routine' standard of practice (Carroll, Reid, Woodward et al, 1997). If prenatal providers handle ultrasound testing in such a routine manner as they would with a simple blood test, women may fail to perceive the need for full disclosure.

No association was found between women's overall knowledge, as measured by the index scores, and their satisfaction with their provider's disclosure of information. Women's personal obstetric experience, however, was found to be a determinant of satisfaction. Multiparous women were more likely to feel that they received information to help them better understand the benefits and limitations of testing. Green, Statham and Snowdon (1993) have reported a similar finding. Parity, however, was not associated with higher index scores on knowledge. This implies that experience may play a role in helping women feel 'more comfortable' about prenatal ultrasound testing, but not necessarily more knowledgeable. Put differently, it is the women's experience, not the knowledge acquired from their information sources, that contributes to their views on the disclosure process.

Women were not dependent on health care professionals as their only source of information. Friends and relatives were commonly sought out as information sources (n=48: 42.5%). In this study, friends and relatives were considered very helpful among 16 of the 48 women (33.3%). Hearsay has been reported to be an

important source of women's knowledge of prenatal testing (Green, Statham and Snowdon, 1993; Salonen, Kurki and Lappalainen, 1996). Books were another common source of information, used by 48 women (42.5%). As books are readily available, convenient and for the most part, reader-friendly, it was not surprising to find that they were considered very useful by 47.9% of respondents.

Despite the relatively high rate of satisfaction with the disclosure process, there was a deficiency in the comprehension of information within all domains of knowledge, particularly in relation to the purpose, limitations and implications of testing.

The overall mean index score for women of Group 1 was 6.5 (SD 1.69). Although no statistically significant associations were noted between women's index scores and the sociodemographic variables measured, two trends were seen. Older and more educated women tended to have higher knowledge scores. A previously reported study concurred with this finding (Green, Statham and Snowdon, 1993), suggesting that a larger sample size may have provided more power to find a statistically significant difference. It was somewhat surprising to find that health care training or experience was not associated with increased knowledge.

Integral to the concept of informed choice is the presentation of testing as an option to women. This concept of choice applies equally to the right to accept as well as refuse an intervention. A disparity in this study was found between women's views of their autonomous right to make a choice on testing, and whether they were explicitly told that they had this choice. Sixty-nine percent of subjects believed that it was a woman's choice whether or not to proceed with ultrasound testing. In spite of this, only 22.1% recalled having been *given* a choice about testing. Hence, most participants were not informed of their autonomous right of choice. An assumption may exist among prenatal care providers that women are aware of their choice on testing. Alternatively, there may be a belief that a non-invasive procedure such as prenatal ultrasound does not obligate the caregiver to provide such detailed information.

It was somewhat disturbing to find the contrast between women's views of the use of second trimester ultrasound screening, and their perceptions as to the

indication for *their* ultrasound test. Although 94.7% of Group 1 respondents considered 'the evaluation of fetal growth and development' as the main use of ultrasound screening, only 54.0% considered screening for birth defects as the reason for *their* 18-week scheduled scan. One could postulate that women were aware of the purpose of screening for birth defects, but did not necessarily apply that understanding to their own pregnancy, suggesting that women might wish to avoid the possibility of detecting a fetal anomaly in their own pregnancy.

A second possible explanation for the disparity may be due to a response bias in the former question. It is feasible that the response options provided in the general question pertaining to the use of second trimester ultrasound screening biased women to select the correct answer. Women may have selected the response "to check growth and development of the baby" in the first question, as it was considered to be the more likely or 'socially acceptable' answer. In a study conducted in North Essex on a representative sample of 800 women, it was found that only 60% of women selected "to look for abnormalities" in a multiple choice question on prenatal screening (Newburn and Gready, 1996). Green, Stratham and Snowdon (1993) observed that 77% of their population surveyed selected "[looking] for abnormalities" as the primary purpose of ultrasound screening.

The primary benefit to ultrasound testing was reassurance. Over half of the Group 1 respondents (55.6%) expected to be reassured by their ultrasound result. This is indeed the case in the vast majority of second trimester ultrasounds performed. Naturally, women hope that their baby would be normal and do not want to consider the opposite alternative. Most women in this study did not articulate the foreseeable consequences of their decision to proceed with ultrasound testing. The small number of women who openly considered ultrasound as a means of screening for fetal anomalies did not uniformly agree that this new knowledge would be of personal benefit. In the two open-ended questions: "How will an ultrasound benefit you," and "Can you think of any drawbacks to having an ultrasound," a contrast of opinions on the detection of fetal anomalies was seen. Nine of the 113 subjects (7.8%) considered the

possibility of detecting a fetal abnormality as a benefit to ultrasound screening, as opposed to the 4.4% of women who considered this awareness as a drawback.

“Knowing is not always best” a comment provided by one woman, best describes this dichotomy. The prospect of a fetal abnormality may be too emotionally and psychologically threatening for women and their care providers to discuss this possibility at length prior to testing. In a literature review reported by Marteau (1995), 62% of women reported, after delivery, having concerns about a fetal abnormality during pregnancy, but only 17% of them reported this fear while pregnant. This reluctance would consequently interfere with the discussion of ultrasound screening for fetal abnormalities. Arguably, this lack of disclosure runs counter to the obligation of ensuring full disclosure and respecting patient autonomy in their decision-making. Yet, based on this study’s findings, not all women openly consider, or wish to consider, the implications of detecting a fetal anomaly in their pregnancy. The expectations women have on the disclosure process were not evaluated to provide any further discussion. A qualitative approach to this deficient area of knowledge would be the most suitable way to address this interesting dichotomy.

Ninety-one percent of women (103 of 113) correctly responded to the ‘true’ or ‘false’ question pertaining to the diagnostic limitations of second trimester ultrasound screening. Yet, when asked what fetal problems ultrasound may fail to detect in the second trimester, only 37.2% (42 of 113) provided correct examples. These findings imply that women may be aware that ultrasound is limited in its diagnostic capabilities of detecting all fetal anomalies, but are not fully aware of what those limitations are.

Based on the current literature, there is considerable scientific evidence that diagnostic ultrasound is a safe procedure for the woman and her developing fetus. In spite of this, there exists a number of misconceptions and uncertainties among pregnant women regarding the medical risks of ultrasound.

Thirteen women (11.5%) claimed that diagnostic ultrasound exposure placed the fetus at immediate or delayed medical risk. The source of this misconception is not known and was not investigated in this study. Fourteen of 110 women

(12.7%) expressed uncertainty about risks of ultrasound exposure to the woman or her fetus. The underlying reason for this uncertainty can be postulated.

Women may have received the information but failed to understand it, may not have been informed due to some reluctance on behalf of the care provider, or alternatively, may have received and assimilated information from too many referents resulting in confusion and unnecessary misunderstandings.

Nevertheless, this findings suggests a deficiency of knowledge as to the risks of ultrasound testing among low-risk pregnant women.

Women, for the most part, are not benefiting from the knowledge and experience available to them through the prenatal care provider. They are not being fully informed about the purpose, limitations and implications of the test procedure. Overall, it appears that women underwent prenatal ultrasound testing without having been encouraged to give it much thought.

Justifiably, prenatal practices have busy schedules and minimal resources available to devote the time required to effectively provide information to all their patients regarding the purpose, benefits, limitations and implications of prenatal testing. Time restraints have been even more compounded by the recent dispute between Obstetricians and the provincial governing body. Needless to say, this dispute would likely have resulted in considerable upheaval within many levels of prenatal service. As Obstetricians were not taking on new patients, additional strain was placed on other prenatal care providers. This shuffling of prenatal services would have direct implications, not only on how women were cared for during their pregnancy, but on how women perceived their level of care. What is central to the process of disclosure is the development of a comfortable and trusting rapport between the woman and her prenatal care provider. Inadequate time, inconsistent care providers, and limited resources required to develop and maintain this relationship would have potentially hindered this process.

Alternative approaches using different methods of achieving an informed choice on testing are required. These different methods would not remove the primary

care giver's role in the disclosure process, but would be considered an adjunct to the process.

Encouraging results were seen with the pilot phase of this study. Although the sample is small and limited to a descriptive analysis only, it would appear that the supplementary pamphlet improved women's understanding of ultrasound in most areas of the knowledge domain. The overall mean knowledge index scores increased from 5.6 (95%CI: 4.80-6.30) to 8.4 (95%CI:7.69-9.05), respectively over the interval of the two questionnaires. The mean post-intervention score was also considerably higher than the mean score of Group 1. There were no sociodemographic differences between the two groups suggesting that the intervention may have contributed to the differences seen.

In spite of the intervention, some women still answered a number of questions incorrectly. Four of the 24 women remained uncertain about risks of ultrasound exposure to the fetus, 5 women could not correctly identify fetal problems detectable by ultrasound and 6 could not identify fetal problems not detectable by ultrasound. Although there was a considerable increase from 4 to 8 women who considered the implications of detecting a fetal anomaly and how that relates to the management of their pregnancy, this number still remains small. The pamphlet was direct in laying out the psychological implications of testing should a suspected or confirmed abnormality be detected, but only 33% of women correctly identified this as a drawback. Although women were informed of the consequences of testing, they remained reluctant to discuss this openly.

The intervention pamphlet was well received by all the women. It was concise and considered informative and easy to read. It would appear that the pamphlet had a positive effect on women's view of the disclosure process. A greater proportion of the post-intervention Group 2 women strongly agreed that their health provider gave them information that helped them better understand ultrasound testing as compared with women of Group 1 (25.0% versus 15.9%).

5.4 Strengths and Limitations of the Study

The results of this study described an area of knowledge that is deficient in the literature. The findings presented have raised valuable questions and generated theoretical hypothesis for further research. Because knowledge is limited in this area, this preliminary work provides the basis for further research.

For the purpose of internal validity, questionnaire scales require a comprehensive evaluation in terms of their validity and reliability. The validity of the questionnaire and information pamphlet was rigorously tested. Content validity, the adequacy of subject items covered, was carefully addressed through coverage of the different aspects of ultrasound that were identified and through several reviews by a broad range of health professionals. Further validity testing on larger and more diverse populations would be required. Reproducible results with other studies would provide support for the validity of the questionnaire and of the results.

Inherent to quasi-experimental designs are specific threats to internal validity. "Pre-test sensitization" is a problem whereby the experience of the first questionnaire influences a change in responses to the second questionnaire. Women of Group 2 may have realized their lack of knowledge and sought information from sources outside of the information pamphlet. Related to this is the "Hawthorne Effect," whereby the knowledge the Low Risk Maternity Clinic physicians had of the study directly influenced how they provided information to their patients. "Recall bias or "test-effect" could occur as a result of women gaining familiarity with the test instrument, whereby women remember their responses from the first testing and apply that memory to their second test. As a result of these threats the effect of the intervention would be over-inflated.

Threats to validity existed with the Group 1 population as well. Women of Group 1 were recruited at the Ultrasound Department 15 to 20 minutes prior to their scan. Under these circumstances, women may have experienced considerable anxiety about their imminent scan, which in effect would influence the manner with which they answered the questions. This could potentially

result in a measurement bias, whereby an underestimate of women's knowledge was attained. Although it is difficult to exclude a selection bias, it was considered to be a minimal threat. It was believed that women were not systematically selected by the receptionists to participate in the study. It appeared that women were arbitrarily chosen to participate. This was dependent on who was at the front desk and how familiar they were with the study and the researcher, and the schedule and load of the day. One method of determining a risk of selection bias would be to compare the sociodemographic characteristics of the participants with women who did not participate. Unfortunately, the EFW did not keep a database that allowed the researcher to review the demographics of women 18-20 weeks in pregnancy receiving a prenatal ultrasound.

The pilot study had considerable limitations due to the select population of women recruited and its small sample size. Ideally, a population-based study with randomization should be attempted in order to obviate the possible biases in using a select group such as the Low Risk Maternity Clinic. Alternatively, a larger sample size from a collaboration of low risk maternity facilities could be attempted. With larger numbers and diverse centres, more confidence could be placed on the results.

Lastly, the generalizability of this study's findings is limited in that the population was of a higher sociodemographic status than is true of the general population. As well, it should be noted that the sample consisted of women who had made up their minds to have ultrasound testing. The number of women who were not offered or chose to refrain from second trimester ultrasound testing may have an entirely different understanding of ultrasound testing. Generalizability is also limited in view of the conditions of the Obstetrician's fee dispute with the Alberta Government. One cannot make an assumption that the dispute had not introduced a confounding variable.

5.5 Implications for Prenatal Care

The findings of this study can be of assistance to pregnant women, their prenatal care providers and the Alberta Clinical Practice Guidelines Working Group for Prenatal Ultrasound.

As ultrasound technology becomes increasingly advanced, counselling has to be correspondingly improved. Formulating guidelines that help prenatal care providers address and evaluate methods of achieving the goal of fully informing women about ultrasound testing is a required step in improving prenatal testing services. The blueprint, questionnaire, and information pamphlet prepared for this study may provide the content necessary for the development of guidelines for care providers, as well as the evaluation of those practice guidelines.

This study found that a significant predictor of knowledge is maternal age and education. Focus, therefore, needs to be placed on younger and less educated women. Innovative means of providing women with information using supplementary tools modified according to women's needs and expectations may be an effective way to disseminate the necessary information to different populations of women.

5.6 Implications for Future Research

This study raises a set of issues and questions regarding disclosure of information. The question of women's expectations regarding the scope of disclosure have been raised. Related questions for further research include:

What are women's expectations of the disclosure process?

From low-risk pregnant women's views, how important is it to be fully informed about all aspects of ultrasound testing?

What is the best way to help women make informed choices?

Regarding the determinants of knowledge, further research is required to best address the following questions:

How can different information needs of different people be met to equal levels of satisfaction?

What methods are most effective in enhancing informed choice?

This study was not designed to evaluate whether the information understood by women was provided by health professionals. In view of the misconceptions outlined in this study, it would be crucial to evaluate what prenatal care providers understand about ultrasound testing and how they view the possible implications of detecting a fetal anomaly.

5.7 Conclusion

Knowledge of prenatal ultrasound was measured utilizing a blueprint (guideline) designed specifically for this study. Categories within the blueprint included women's understanding of the purpose, benefits, limitations and consequences of second trimester ultrasound testing.

Only 54.0% considered screening for birth defects as an objective of a second trimester ultrasound. Thirteen percent of women were uncertain of the risks of ultrasound exposure to the woman or her developing fetus. Twenty-four percent of women could not correctly provide examples of fetal problems an ultrasound could detect or fail to detect at 18-20 weeks in pregnancy. Fifty two percent did not openly identify any drawbacks to ultrasound testing. Based on these responses, women participating in this study failed to comprehend all the relevant information necessary to meet the requirements of informed choice. Younger and less educated women in particular, were less knowledgeable about ultrasound testing than their counterparts.

Supplementing women with written information specific to ultrasound screening appeared to have a benefit in improving women's understanding of ultrasound and their views on the disclosure process in the pilot phase of this study. A larger and true experimental study would be required to confirm this finding.

Eighty-six percent of women claimed to have received information from at least one health care source. Fifty-five percent of women claimed to have received no additional information from their care provider, apart from scheduling information. In spite of this, 69% of women stated that their care provider gave them information to help them make a decision about ultrasound testing. It is therefore unclear if women received, but failed to retain the relevant information on ultrasound, or simply did not receive the information prior to their test.

An interesting dichotomy surfaced regarding women's interest in learning about possible fetal problems in pregnancy. Eight percent of women considered it a benefit to learn about a fetal problem in pregnancy, and 4.4% considered the detection of an anomaly a drawback to testing. The dichotomy would best be explored qualitatively.

The results of this study raise very important questions. What are women's expectations of their prenatal care providers in regards to the informed choice process? Do women wish to be as fully informed about ultrasound testing as outlined in the guidelines presented in this study? Where is the balance between maintaining the ethical principles related to informed choice, and respecting women's wishes regarding full disclosure?

As Alberta Health has endorsed second trimester ultrasound screening of all low-risk healthy pregnant women, it will soon become a standard of care in Alberta. This study reveals gaps in women's understanding of the purpose, benefits, limitations and implications of ultrasound testing. Further studies addressing issues of concerns raised in this study are required to ensure we are providing the best prenatal care possible to women.

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APPENDIX A

Summary of Brent, Jensh and Beckman's review of the *Reproductive Effects and Risks of Medical Sonography* (1991).

The rationale for providing a summary of this particular article is that their thorough evaluation of the possible risks associated with prenatal ultrasound exposure, follow closely, the criteria outlined for establishing a cause-effect relationship (outlined in Hennekens, 1987). A summary of Brent, Jensh and Beckman's findings will be guided by Henneken's outline.

Strength of Association: Consistency with Other Investigations

Brent and colleagues address the strength of association with the question: "Are there repeatable epidemiological findings, whether they related to congenital malformation, neurobehavioral effects, or other reproductive risks? To approach this question, Brent, Jensh and Beckman reviewed the results of 21 epidemiological studies, including cohort, cases control, randomized clinical trials and case reports. These studies evaluated outcomes including fetal growth, congenital malformations, stillbirth, physiological effects, postnatal neurological and behavioral effects, postnatal cancer occurrence and chromosome abnormalities. They state that, although many of the studies examined, have intrinsic methodological problems, it could be concluded that the "available studies are reassuring because most of the parameters that have been studied are unaffected by diagnostic ultrasound." Two important parameters in determining biologic effect are the dose and length of exposure. Brent and colleagues emphasize that "an increase in newer technology and systems that enhance resolution and imaging by increasing output and intensity also increase the fetal exposure." This suggests that as the sonographic technology changes, studies re-examining the effects of higher exposures are warranted.

Time Sequence

Hennekens points out that there should be clear evidence that the exposure precedes the outcome. Brent and colleagues address this with the questions: "Do secular trends of the frequency of reproductive risks correlate with the frequency of exposure? And, "Has there been an increase or decrease in reproductive risks when the agent was introduced or removed?"

To address this criteria for assessing causality, Brent, Jensh and Beckman examined the incidences of four malformations (anencephaly, spina bifida, hydrocephalus and limb reduction defects) from the period of 1970 to 1982, correlating the with time when the use of ultrasound was exponentially increasing. These four malformations were selected, as hyperthermia has been suggested as one of their etiologies. They noted that the malformation rates did not correlated with the increase in population exposure. They also found that most other malformation rates had not varied over this time period.

Brent et al are sensitive to the fact that secular trend data alone cannot disprove a teratogenic effect and also acknowledge that although a high proportion of pregnant women are exposed, only a smaller proportion of women are exposed at the vulnerable period of organogenesis.

Animal Studies

The question raised in this review is: "Have animal models been developed that reproduce the findings reported in human reproductive studies, at the same exposure or does used in human?"

Higher therapeutic exposures of ultrasound are known to result in embryonic effects, including malformations and embryonic death, as higher doses result in hyperthermia, a proven experimental teratogen (Lyons, Dyke, Toms, and Cheang, 1988; Hande and Devi, 1995). Brent and colleagues presented the results from approximately 40 laboratories that had studied the reproductive risks of ultrasound in mammals and concluded overall that many of the studies failed to

follow the basic principles of developmental biology and teratology. Overall, Brent et. al. conclude that the good animal experiment (they outline the definition of one in their review) are consistent with the human studies which indicate that diagnostic ultrasound is a relatively safe modality. They caution, that as new equipment is introduced that substantially raises exposure, especially if it results in hyperthermia, will require further review.

Dose-response

Based on animal studies, the higher the dose, the higher the incidence of more serious reproductive effects. This threshold effect means that below certain exposures, no deleterious effects will occur. According to Brent et. al., most papers that utilized exposures in the human diagnostic range, did not report reproductive effects.

Biologic Credibility

Brent, Jensh and Beckman addressed this item with this question: "Is there a biologically plausible explanation for the reproductive effects reported or hypothesized? Do the findings make biologic sense?"

The only clearly defined effect of ultrasound that can be certain to produce reproductive risks is hyperthermia (Brent, Jensh and Batemen, 1991). The conclusion of their thorough review of accumulated data on hyperthermic effects, is that: "temperatures of 39 degrees Celsius in the human may not present measurable risks to the human embryo."

Summary

Brent, Jensh and Bateman summarize their evaluation by stating that diagnostic exposure to ultrasound "presents nonmeasurable risks to the developing embryo."

APPENDIX B

To: Healthy pregnant women

I am a registered nurse employed as a genetic counsellor at the Alberta Children's Hospital and a graduate student in the Department of Community Health Sciences at the University of Calgary. In collaboration with my supervisor, Dr. Love, we are conducting a survey in an attempt to determine women's knowledge of prenatal ultrasound. The information gained from this to plan prenatal testing education tailored to meet the needs of pregnant women. Your response to the enclosed questionnaire is important to the success of the study. The questionnaire should take approximately 10-15 minutes to complete. We ensure you that all the information you provide will be held strictly confidential. Once you complete the questionnaire, please place it in the envelope provided, seal the envelope, and return it to the receptionist. In order to ensure your privacy, all questionnaires will be received by me at the University and kept secured in a locked cabinet. The responses will be entered into a computer without any identifiers. The Information about you will not be shared with others. The information from all participating women, when combined and evaluated, will be used in the final reporting of the study.

You are under no obligation to complete the questionnaire. However, as stated earlier, the more information we receive from women undergoing a prenatal ultrasound, the more we can gain an understanding of women's current knowledge of prenatal ultrasound. This could ultimately benefit you in the future, as there may be a possibility of developing prenatal education materials better suited to meet your needs (in your future pregnancies!).

If you wish a summary of the results of the survey, please detach the last page of the questionnaire and send it to myself, care of the Department of Community Health Sciences, The University of Calgary.

Should you have any questions or concerns about the survey or questionnaire, please feel free to contact myself, Ruth Kohut at 220-4286 or Dr. E.J. Love at 220-7368. We would be available to answer any questions you might have. If you chose not to participate in the study, please take a minute to complete the enclosed postcard and return it with the package to the ultrasound receptionist. Your decision to complete and return this questionnaire will be interpreted as an indication of your consent to participate.

Thank you for your time and assistance,

Ruth Kohut, R.N. BSc.

MSc Candidate

Dr. E. J. Love M.D., PhD

Professor Dept. of Community Health Sciences

University of Calgary

APPENDIX C

Department of Community
Health Sciences
University of Calgary

WOMEN'S
UNDERSTANDING
OF
PRENATAL ULTRASOUND

Most of the questions in this survey can be answered by simply checking (✓) the statement that most closely describes your responses. (There are some questions where more in-depth input is requested).

Please answer all questions to the best of your ability

Our first questions provide us with information on who you are seeing during your pregnancy and the reasons why.

1a) Who are you currently seeing for prenatal care in this pregnancy?

- ☐ My regular family physician
- ☐ A physician working the **Low Risk Maternity Clinic** at the Foothills Hospital (Main floor, University of Calgary Medical Clinic)
- ☐ A physician working in the Low Risk Maternity Clinic at the Peter Lougheed Hospital
- ☐ My obstetrician
- ☐ An Obstetrician working in the **Low Risk Obstetrics' Clinic** (2nd floor, North Tower, Foothills Hospital)
- ☐ An Obstetrician working in the **High Risk Obstetrics' Clinic**, Foothills Hosp.
- ☐ Midwife
- ☐ Other (please specify)

1b) If you are attending the **Low Risk Maternity Clinic** or **Low Risk Obstetrics Clinic**, please indicate why:

- ☐ My family physician referred me to the clinic.
- ☐ I was referred with my previous pregnancy and chose the same clinic for this current pregnancy.
- ☐ A friend or relative recommended the clinic.
- ☐ Other. Please specify the reason _____

2a) Have you had a prior prenatal ultrasound in this pregnancy?

- ☐ No
- ☐ Yes

2b) If your answer to question (2a) was Yes, what do you understand was the Main reason for your earlier ultrasound?

- ☐ I am not sure
- ☐ To determine the due date
- ☐ To determine the cause for some vaginal bleeding
- ☐ To determine if I was carrying twins
- ☐ Other reason (please specify) _____

Our next few questions are about how prenatal ultrasound testing was presented to you by your prenatal care provider (person you are seeing for your prenatal care) and how informed you feel about this procedure.

3) What do you understand is the reason for your ultrasound today?
(you may check more than one answer)

- ☐ I am not sure
- ☐ To determine my due date
- ☐ To find out if my baby has a birth defect
- ☐ Other (please provide further information)

4) From which of the following sources, if any, have you received on information prenatal ultrasound?

Did you receive information from:			Information provided was:			
	Yes	No	Very helpful	Somewhat helpful	Somewhat unhelpful	Not at all helpful
Family doctor						
Obstetrician						
Midwife						
Genetic counsellor						
Nurse						
Friend / relative						
Prenatal classes						
Newspaper						
Magazines						
Television						
Internet						
Books						
Other (specify)						

5) At your early prenatal visits before this appointment, what information on ultrasound did your prenatal care provider give you? (check all that apply)

- ☐ Appointment time and instructions on where to go and what fluid to drink
- ☐ Written information specifically about prenatal ultrasound
- ☐ Discussion about prenatal ultrasound. If a discussion was provided, what information did you receive?

Please indicate how much you agree with each of the following statements:

- 6) My care provider gave me information on prenatal ultrasound that helped me understand its benefits and limitations.

Strongly	Somewhat	Somewhat	Strongly
Agree	Agree	Disagree	Disagree

7) It is currently a woman's choice as to whether or not to proceed with prenatal ultrasound.

Strongly	Somewhat	Somewhat	Strongly
Agree	Agree	Disagree	Disagree

8) In general, how important is it to you to get information about medical tests before having the tests done?

Very	Somewhat	Somewhat	Not at all
Important	Important	Unimportant	Important

9) Do you regard ultrasound as a routine part of your prenatal care?

- ☐ No
- ☐ Yes
- ☐ I am not sure

10) Were you specifically told that prenatal ultrasound is an *optional* test?

- ☐ Yes
- ☐ No
- ☐ I do not remember

11) What specific information do you expect will be provided to you about your prenatal ultrasound result?

12) Have you been informed as to how the results of your ultrasound will be relayed to you?

- ☐ No
- ☐ Yes if Yes, how the results will be provided?
- ☐ by phone
- ☐ at my next prenatal visit
- ☐ other (specify)

The next few questions are about what prenatal ultrasound is and how it works. If you are unsure how to answer a question, please give the best answer you can.

13) Which answer best describes how ultrasound works? (check all that apply)

- ☐ uses sound waves to take a picture of the baby in the womb
- ☐ uses X-rays to take a picture of the baby in the womb
- ☐ none of the above
- ☐ I am not sure

14) What is the main use of ultrasound? (check all that apply)

- ☐ To see what sex the baby is
- ☐ To test for blood disorders
- ☐ To check age, growth and development of the baby
- ☐ None of the above
- ☐ I am not sure

15) Is there a medical risk to the mother from an ultrasound?

- ☐ No
- ☐ Yes if Yes, what is the risk?
- ☐ I am not sure

16) Is there a risk to the baby from a prenatal ultrasound?

- ☐ No
- ☐ Yes if Yes , what risk?
- ☐ I am not sure

17) True or False:

A "normal" ultrasound result guarantees that the baby will be born free of birth defects.

- ☐ True
- ☐ False
- ☐ I am not sure

18) Do you know of any problems an ultrasound can identify in the baby?

- ☐ No
- ☐ Yes if Yes please list as many as you can:

19) Do you know of any problems an ultrasound may fail to identify in the baby?

- ☐ No
- ☐ Yes if Yes please list as many as you can:

20) How will having an ultrasound benefit you?

21) Can you think of any drawbacks to having an ultrasound?

The final questions are to identify overall characteristics of women who have participated in this study.

22) What is your date of birth?

Year _____ Month _____

23) Is English your first language?

- ☐ Yes
 - ☐ No if No please indicate your first language
-

24) What is your current marital status?

- ☐ Married
- ☐ Single (never married)
- ☐ Separated
- ☐ Living common law
- ☐ Divorced ☐ Widowed

25) Is this your first pregnancy?

- ☐ No
- ☐ Yes. If Yes, please proceed to question #31

- 26) In this (current) pregnancy, have you experienced
☐ a threatened miscarriage
☐ other complications (specify)

- 27) Have you ever given birth?
☐ No If No, proceed to question # 29
☐ Yes If Yes, when were your children born (year of births) _____

- 28) Were your children born with any birth defects?
☐ No
☐ Yes (please specify) _____

- 29) Have you ever lost a pregnancy (miscarried or aborted)?
☐ No
☐ Yes If Yes was the loss(s)::
☐ early in the pregnancy (before 3 months)
☐ after 3 months

- 30) Have you had ultrasound(s) in a previous pregnancy?
☐ Yes
☐ No

- 31) What is the highest grade or level of education you have ever completed?
☐ No High School ☐ Some College ☐ Some University
☐ High School ☐ Completed College ☐ Completed University

- 32) Have you had training in the health care industry
(ie. Physician, nurse, nurse's aid, radiology experience etc.)
☐ No
☐ Yes if Yes, please specify your training

- 33) Are you presently:
☐ Employed. If so, please specify your occupation
☐ Unemployed
☐ Full-time at home with children
☐ Student
☐ Other (specify)

- 34) If you have a partner, is he:
☐ Employed. Please specify his occupation
☐ Unemployed
☐ Full-time at home with children
☐ Student
☐ Other (specify)

APPENDIX D

If you are interested in a summary of the results of the survey, please detached this blue page from the questionnaire and return it to the front desk, or return by mail to:

Ms R. Kohut
Department of Community Health Sciences
University of Calgary
3330 Hospital Drive N.W.
Calgary, Alberta
T2N-4N1

Name:

Address:

City:

Postal Code:

Telephone:

APPENDIX E

POSTCARD

Declining participation in the study: Women's understanding of ultrasound

I have declined participating in this study because:

☐ I am not interested

☐ I do not have the time

☐ personal or moral issues

☐ other (specify)

We would appreciate if you take a minute to answer five questions.

1. What is your date of birth?

Year Month

2. What is your current marital status?

Married Divorced or separated Widowed

Common law Single (never married)

3. Is this your first pregnancy?

☐ No

☐ Yes

4. What is your highest level of education you have ever completed?

No High School Some College Some University

High School Completed College Completed University

5. Are you presently:

Employed outside the home

Unemployed

Full-time at home with children

Student

Thank you!

APPENDIX F

The pre- intervention knowledge questionnaires provided to Group 2 women was presented in an identical format to the Group 1 questionnaire presented in Appendix C, with exception to the following differences :

Pre-Intervention knowledge questionnaire

A number of question items presented in Appendix B were not provided in the Pre-intervention knowledge questionnaire. Questions excluded were:

Question item # 3) What do you understand is the reason for your ultrasound today?
(you may check more than one answer)

- ☐ I am not sure
- ☐ To determine my due date
- ☐ To find out if my baby has a birth defect
- ☐ Other (please provide further information)

Question item # 5) At your early prenatal visits before this appointment, what information on ultrasound did your prenatal care provider give you? (check all that apply)

- ☐ Appointment time and instructions on where to go and what to drink
- ☐ Written information specifically about prenatal ultrasound
- ☐ Discussion about prenatal ultrasound. If a discussion was provided, what information did you receive?

Question item # 6) Please indicate how much you agree with each of the following statement:

My care provider gave me information on prenatal ultrasound that helped me understand its benefits and limitations.

Strongly Agree Somewhat Agree Somewhat Disagree Strongly Disagree

Question item # 10) Were you specifically told that prenatal ultrasound is an *optional* test?

☐ Yes

☐ No

☐ I do not remember

Question item # 12) Have you been informed as to how the results of your ultrasound will be relayed to you?

☐ No

☐ Yes

APPENDIX G

TO HEALTH PREGNANT WOMEN:

Are you interested in completing a second questionnaire (at the time of your 18-20 week ultrasound, should you proceed with this option)?

☐ No

☐ Yes if Yes,

I (R. Kohut) will leave the second questionnaire in an envelope addressed to you at the Ultrasound Department (EFW, Foothills Professional Building)

I would like to contact you by phone to obtain the date of your ultrasound.

Name (please print)

Signature

Date

Phone numbers:

(home)

(office)

Convenient time to call:

Please ask for this questionnaire when you arrive for your ultrasound appointment.

Thank you.

APPENDIX H

The post- intervention knowledge questionnaires provided to Group 2 women was presented in an identical format to the Group 1 questionnaire presented in Appendix C, with exception to the following differences :

Post-intervention knowledge questionnaire

A. On the first page, following the discussion of the research, women were asked:

To assist us in matching your two questionnaires, please complete the following:

Your name	Year of birth	Month of birth
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B. On the final page of the questionnaire, women were asked the following additional questions:

Would you recommend providing the prenatal ultrasound information pamphlet to women early in their pregnancy?

☐ No, if No, please explain

☐ Yes if Yes, would you have any recommendations for improvement?

C. The demographics section was excluded from this post-intervention questionnaire.

APPENDIX I

Prenatal Ultrasound Pamphlet

The prenatal ultrasound pamphlet was presented as a question-answer booklet format.

Prenatal**Ultrasound Screening**

Ultrasound has become an increasingly important part of prenatal care.

This information will provide you with answers to common questions asked about prenatal ultrasound.

Should you have any questions regarding this information, or any additional questions, please address your questions to Ruth Kohut at 220-4286.

Take-home messages:

1. The majority (97-98%) of babies are born healthy, without birth defects-whether or not prenatal testing was performed
2. Prenatal ultrasound is a screening test, not a diagnostic test. This means that some birth defects can go undetected. Additionally, some findings detected may ultimately have no impact on the child's health and development.
3. Prenatal ultrasound is an optional test available to you through your doctor. As with any test, the choice should be made only after you have reviewed the advantages, limitations and potential consequences of your decision. It is recommended that you be your own advocate and ask any questions you may have about prenatal ultrasound.

What is a prenatal ultrasound?

Prenatal ultrasound is a method used to visualize the fetus and placenta in the mother's uterus. It is important to emphasize that ultrasound uses sound waves to produce this picture and is not an X-ray.

How does ultrasound work?

Firstly, you may be asked to drink a few glasses of water about two hours prior to your test. This is to fill up your bladder. A full bladder brings the uterus closer to the abdominal wall, which also assists in providing a clearer picture. To provide a clearer picture, the technician will apply a gel over the woman's abdomen prior to the test. A small hand-held device called the 'transducer' is placed on the woman's abdomen and rubbed back and forth. Sound waves are sent out through the transducer. The sound waves travel through the abdomen and uterus and bounce off different surfaces. When the sound waves reach the fetus, echoes from the waves are converted into an image, then onto a TV monitor to produce a picture of the fetus and the placenta.

How long does ultrasound take?

An ultrasound can take as short as 10 minutes to as long as an hour. Sometimes, the fetus is lying in a position which makes it difficult to get a clear view of all the organs. If the woman has a larger body size, it may also be more difficult to get a clear picture. Situations like this prolong the ultrasound procedure.

When is ultrasound used?

A prenatal ultrasound exam has many uses during pregnancy. The more common uses are described at the back of this pamphlet.

Who performs the ultrasound?

In most cases, it is an Ultrasound Technologist. The technologist takes several pictures of the fetus. These pictures are later reviewed by a Radiologist (physician with training in diagnostic imaging), who then provides a written summary to your prenatal care provider (person responsible for your prenatal care).

If there is difficulty in viewing the fetus completely, or a question raised in regards to the fetal anatomy, a Radiologist may wish to perform the scan personally.

The presence of the Radiologist at your scan does not mean that there is a problem with your pregnancy.

How do I receive the results?

The written summary is mailed to your prenatal care provider. This summary should be available within 1-2 weeks. If a concern is raised at the time of the scan, the radiologist will contact your prenatal care provider sooner. You would then be contacted directly by your prenatal care provider.

Is ultrasound a safe procedure for the mother and the fetus?

Ultrasound has been used for over 25 years without any risks being identified.

It is, therefore, considered to be a safe procedure to both the mother and the fetus.

I am healthy with no family history of concern. Am I at risk for delivering a child with a birth defect?

All women regardless of their age, health or family history are at a 2-3% risk for delivering a child with a birth defect. Problems can range from mild conditions which have minimal impact on the child's overall health and development to more serious and life threatening problems.

Can all birth defects be identified by a prenatal ultrasound?

No. Ultrasound performed after 17 weeks of pregnancy can detect most serious birth defects, but some minor defects and occasionally more serious defects can be missed by this screen. Furthermore, ultrasound cannot diagnose chromosome problems such as Down Syndrome. It can, however, detect fetal abnormalities which may suggest a possible chromosome problem. Amniocentesis is a test used

to diagnose chromosome problems, and would be an option available if a chromosome problem was suspected. Although ultrasound is useful in assessing the development of the baby's organs (heart, kidneys and brain for example), it will not necessarily be able to comment on the function of the organs.

Can the problems diagnosed by ultrasound be treated?

We can not provide you with a general answer to this question. Information obtained from an ultrasound is used to better manage prenatal care and provide parents with as much information as possible, should there be an identified fetal problem.

Does a problem identified by ultrasound definitely mean that the baby will have problems once delivered?

No. It is important for you to recognize that prenatal ultrasound can detect findings in the fetus that may be a 'variation of normal.' Ultrasound has

improved so dramatically over the years that subtle “variations” in organ development can be seen by a skilled Radiologist.

Some of these findings may be ‘variations of normal.’ Other findings may suggest an actual problem with the fetus. It is difficult at times to distinguish between the two. Couples are, therefore, informed of the suspected findings and offered alternative options of management. (eg. amniocentesis). About 1% of ultrasounds performed will identify such a ‘finding.’ This can result in anxiety and distress.

If not all problems are detectable or treatable, and some findings picked up ultimately do not have an impact on my child’s health, what is the advantage of a 17-20 week ultrasound?

Most women have prenatal testing for the purpose of reassurance. If your 17-20 week ultrasound reveals no fetal abnormalities, chances are far in your favor of a normal outcome. 17-20 weeks is the best time for an ultrasound as the fetal organs are well visualized. It is also early enough to provide women with further management options should a problem be suspected.

If a problem is identified, are there going to be further tests?

It depends on what the problem is. If it is a suspected heart problem for example, the option of a special fetal heart ultrasound will be provided to you to further evaluate the heart. If there are findings to suggest a chromosomal problem in the baby, the option of an amniocentesis would be discussed with you.

Be assured that all information will be provided to you prior to performing further tests. Your questions should never go unanswered.

Table: Common indications for prenatal ultrasound in the first 16 weeks of pregnancy.

Purpose	Advantage
Dating of pregnancy if menstrual dates are uncertain	An early ultrasound is accurate in estimating the due date
Identify causes for early pregnancy complications (bleeding, cramping, etc.)	Rule out/ manage serious causes for complications
Assess for multiple gestations (twins, triplets or more)	Appropriate management of the pregnancy and delivery can be well planned.
Assess for placenta location	

Limitation

An ultrasound performed in the first 16 weeks of pregnancy is not as accurate in the identification of birth defects as later in the pregnancy.

Table: Common indications for prenatal ultrasound performed between 17-20 weeks of pregnancy

Purpose	Advantage
In addition to what is outlined in the first table, an ultrasound at 18-20 weeks:	Most useful time to screen for birth defects.
Identifies the development of fetal organs by examining the baby from head to toe.	An ultrasound identifying no fetal problems does not provide women with 100% guarantee, but chances are in their favor of a child without serious birth defects. This can provide reassurance.
Looks at all major organs such as the heart, brain, kidneys etc.	

Limitations

Structure of organs can be seen, but an ultrasound cannot identify how the organs function.

An ultrasound where no problems have been identified in the baby, does not guarantee a perfectly healthy baby as some birth defects can go undetected.

An unexpected finding can raise considerable anxiety and distress.

Certain birth problems may not become evident until later in pregnancy.

APPENDIX J

Data Analysis of the pretest sample

The questionnaire was tested on a group of healthy low risk pregnant women. Below is the data analysis performed on this population.

I. Description of Sample

The following section provides a description of the pre-test sample with respect to sociodemographic variables including age, marital status, parity, education and employment status. A summary table of the socio demographic variables is provided in Table 1.

The age distribution as expected is positively skewed. The median age was 36 years (Q1 35 years; Q3 39 years). The majority of women (11/13) were married with some secondary education (8/13) and employed (13/13).

Sixty nine per cent (9/13) of women were multiparous. Of that group, 30% (4/9) had an ultrasound in their prior pregnancy(s). None of these respondents reported having delivered a child with a birth defect.

Four women in this pretest sample had an ultrasound in this current pregnancy.

All four were multiparous with a history of early pregnancy losses.

Table 1: Summary figure of demographics: Characteristics of pretest sample
Pretest sample (n = 13)

	No (%)
Median age of woman (years)	36 yrs.
Married	11(85)
Nulliparous	4(31)
Secondary education (attended or completed college or university)	8(61)
Health field experience	2(15)
Employed (Working outside the home)	13(100)
Ultrasound in current pregnancy	4(33)
Family physician as primary care provider	11(85)

Analysis of Study Objectives

Objective 1:

Explore what information women receive about prenatal ultrasound.

To meet this objective, 5 questions were addressed:

Q1 - How do women receive information?

Q2 - How do they view the usefulness of the information received?

Q3 - What information did they receive from their own care provider?

Q4- Are women aware of the indication for their ultrasound?

Q5-How do women expect to be informed of their test results?

Q6 -What information do women expect to receive from the ultrasound?

Objective 2:

Evaluation of the information received.

To meet this objective the following questions were addressed:

Q1- Do women receive information as to the benefits of prenatal ultrasound?

Q2-Do women receive information as to the limitations of prenatal ultrasound?

Q3- What do women perceive as the potential consequences of prenatal ultrasound?

Objective 3:

Explore women's view of prenatal ultrasound and informed choice.

To meet this objective the following questions were addressed:

Q1-Do women view ultrasound as an optional test?

Q2-Do women strongly agree that their prenatal care provider helped them understand required information to make an informed choice?

Q3-What is the relationship between women who view prenatal ultrasound as routine and those who are aware that they have a choice about prenatal ultrasound testing?

Q4-Are there variables which can be identified as determinants on women's position on prenatal ultrasound as a routine practice of their prenatal care?

Objective 1:

The first two questions of objective 1: 'how do women receive information?' and 'how do they view the usefulness of the information received from those sources?' are presented in the table below.

Table: sources and perceived usefulness of pretest information received by pretest sample.

Sources of information:	Usefulness of information			
	No.	Very helpful	Less than very helpful	No response
Family doctor alone	3	1	1	1
Midwife and obstetrician	1		1	
Books alone	1		1	
Family doctor and books	2	1(books)	2	
Family doctor and friends	1	1		
Family doctor, friends and books	2	1 (doctor, books)	1(friends)	
No response	3			

Overall, only 30% of sources were considered 'very helpful' to this population of women. Eight of the thirteen women claimed that their family physician (with or without other sources) were a source of pretest information, however, only 3 of the eight (37%) claimed that the information received was useful to them.

Extending from this, is the third question of this objective: 'what information did women receive from their own care provider?' In the table presented below, it can be seen that nearly half of the pretest sample did not complete this question. From this, one could assume that, quite possibly, their primary care providers had not yet discussed prenatal ultrasound testing with them at their prenatal visits.

Table: Information received from primary care provider

Information received from primary care provider	No.(%)
No additional information apart from when and where to go	3(23)
Written information specific to US	0
Discussion about US	4(31)
No response	6 (46)

Of the 6 women who received a discussion from their primary care providers, the responses to the question, what did they receive, included:

"what was involved into it"

"when an ultrasound is normally performed"

"I was told I should have an ultrasound at the appointment - the reason why I should have it done."

"mostly to determine how many babies present, and development."

There may be several variables that may have an influence on what information is relayed to women. These may include maternal age, language and education, parity, family history and physician. As an example, the table below presents the relationship between information provided and parity. This relationship could not be analyzed due to the small sample size, however, in the formal study, it may be worthwhile to examine these relationships more closely.

Table: Relationship between parity and information provided

Parity	Time & location only	discussion
Nulliparous	1	2
Multiparous	2	2

Q4- Are women aware of the indication for their ultrasound?

It is concerning that 30% of women did not respond or were not sure of the indication for their ultrasound (Table below). Interpreting this result must be guarded. The question is worded: What do you understand is the reason for your ultrasound today? These women were not having an ultrasound scan on the day of this pretest, therefore, it cannot be considered a valid question for this population of pretest women.

Table: women's understanding as to the indication for their ultrasound

Reason for ultrasound	N (%)
I am not sure	1
To determine my due date	1(7)
To find out if the baby has a birth defect	2(14)
Other reasons: check for twins	2
to make sure everything is ok	2
To determine my due date and make sure the baby is healthy	2 (14)
No response	3 (23)

Q5-Have women been informed as to how they would be informed of their test results?

Fifty four per cent (7/13) affirmed that they had been informed, and the remaining women either denied that they had not been informed or did not respond to the question item.

Q6 - What information do women expect to receive from the ultrasound?

Of the eight women that responded, some general comments received from this open ended question included: I don't know as I never had one, the size, confirmation of due date, birth defects, and general concerns about the health of the baby.

Of these eight women, three expressed strongly that the information received from their prenatal care providers helped them understand the benefits and limitations of ultrasound, and the remaining five either did not respond or support that statement.

Summary findings from Objective 1.

The sample size was too small to make any conclusive statements. It appears that a sizeable minority do not receive sufficient information about prenatal ultrasound from their primary care providers, and what information that is received, is not necessarily considered useful by women. Women who expressed their expectations as to what they hope to receive in terms of the results of their ultrasound provided very accurate comments.

Objective 2:

Evaluation of the information received.

Q1- Do women receive information as to the benefits of prenatal ultrasound?

This question will be addressed by considering individually, each of benefits of prenatal ultrasound outlined in Appendix II and reiterated below.

Main use of prenatal ultrasound

All women reported that the main use of prenatal ultrasound is to check for the age, growth and development of the baby. Three women also suggested that the fetal gender is a second use. In view of this, one may suggest a possible bias in the questionnaire item.

It is interesting that nearly one quarter of the women also believed that prenatal ultrasound is useful in the assessment of fetal gender, as this in fact, is not the case. The diagnosis of fetal gender can not be made with absolute confidence at until later in pregnancy. It appears therefore, that some women may have a misunderstanding about this issue, and do not consider this as a possible limitation of prenatal ultrasound at this particular gestation.

Reported risks to the mother or baby, associated with ultrasound testing.

How this population of women view ultrasound, in terms of 'medical risk' to either the mother or the fetus, is presented in the table below.

Table: Perceived medical risks of prenatal ultrasound

Medical risk to mother: [nos (%)]

Yes	No	uncertain
1	8(62)	4(31)

Medical risk to fetus: [nos (%)]

Yes	No	uncertain	No response
1	6(46)	5(38)	1

Sixty two and 46 per cent of women believed that there was no associated risk to the mother or fetus (respectively) from prenatal ultrasound exposure. However, 31% (4/13) and 38% (5/13) of women respectively, were uncertain. The one subject who regarded prenatal ultrasound as a medical risk argued that "there could be unknown long term effects to both the mother and fetus," and furthermore, she alluded to the possible risk of "psychological harm" to the mother. This latter comment raised the important issue of the possible consequences of prenatal ultrasound testing. This will be further addressed shortly.

The benefit of reassurance from prenatal ultrasound testing was addressed with the open ended question: How will having an ultrasound benefit you?.

There were two themes drawn out of the responses to this item, reassurance (n=5), and the benefit of evaluating the baby's growth and development (n=6). The latter response may have been influenced by a prior question pertaining to the main use of ultrasound ("to check age, growth and development of the baby"). Nonetheless, it would appear that most women see prenatal ultrasound as a means of assessing fetal growth and development, and in turn, providing reassurance and peace of mind.

A corresponding question regarding benefits asked was: What specific information do you expect will be provided to you about your prenatal ultrasound result? This question is correlative in that it is asking women what they hope to receive from their test. The themes drawn from this question were addressed previously. There were no responses that provided insight into the possible consequences of the test should the ultrasound reveal an abnormality.

Responses to the item: "Do you know of any problems an ultrasound can identify in the baby?" revealed that 41% of women were uncertain as to what problems could be identified. Four of the seven women who acknowledged their awareness of problems that can be identified, provided very legitimate responses, commenting on such fetal abnormalities as spina bifida, limb defects and heart problems.

Q3- Do women receive information as to the limitations of prenatal ultrasound?

Diagnostic limitations of prenatal ultrasound

Twelve of the thirteen women (92%) correctly responded to the question item that a "normal" ultrasound result does not guarantee that the baby will be born free of birth defects. The fact that this number is not 100% raises suggests that women are not fully aware of the difference between diagnostic and screening tests.

Are there determinants that can be identified to better understand why some women are not aware that ultrasound is not diagnostic of all birth defects?

The woman who provided the incorrect response was multiparous,

with experience with prenatal ultrasound in her prior pregnancies. She was seeing a family physician for her care, and considered that the information she received from her doctor was less than sufficient. Her first language is Cantonese. Her highest level of education was high school and she had no training in the health industry. With a larger sample size, such determinants as maternal age, education, language and physician may be explored.

A correlated item asked in an open ended question is: Do you know of any problems an ultrasound can fail to identify in the baby?

Two thirds (36%) of respondents were not aware of problems that can either go missed by prenatal ultrasound or are simply not detectable by this test. Four of the 7 respondents who affirmed that there are problems that can go undetected provided sound accurate examples of such problems. These examples included Down Syndrome and cognitive defects.

The fact that cognitive defects was included suggests that this minority are aware that although development can be evaluated, a prenatal ultrasound does not provide information on how those organs function.

Q4- What do women perceive as the potential consequences of prenatal ultrasound?

This important issue was approached with discretion, as there is a fine balance between asking women of their understanding of the test and frightening them unnecessarily. It was therefore chosen to address this issue with a question open to several interpretations: Can you think of any drawbacks to having an ultrasound?

Seven women responded 'No' to this question and 5 chose not to respond at all. Of the one individual who responded, her drawback was related to the discomfort of lying on her back. This was the same individual who commented on the maternal "psychological harm" associated with ultrasound.

The lack of desired responses to this question is somewhat concerning.

One could conclude that either the question was too vague, or women truly have not considered the drawbacks or consequences to prenatal ultrasound testing.

Objective 3:

Women's view of prenatal ultrasound and informed choice.

Q1-Do women view ultrasound as an optional test?

This question was approach by examining the term 'optional' from three perspectives presented in the table below.

Table: Question items correlating to women's views of prenatal ultrasound as an optional test.

	Yes Nos.(%)	No Nos.(%)	Uncertain Nos.(%)
1.Do women regard ultrasound as a routine part of their prenatal care?	10(76)	3(23)	
2. Do women strongly agree that it is currently their choice as to whether or not to have an ultrasound?	6(50)	6(50)	
3. Were women specifically told that prenatal ultrasound is an optional test?	4(40)	5(50)	1(10)

These three questions raised some very interesting results. It would appear that the majority of women (76%) do regard prenatal ultrasound as routine and there is an equal split among women regarding the issue of personal choice. Statistical analysis on a larger sample size could be performed.

Q2-Do women strongly agree that their prenatal care provider helped them understand required information to make an informed choice?

This question was directly asked to women. The responses were presented with a four point Likert scale.

Table: Characteristics of subjects who strongly do or do not support the following statement: My care provider gave me information of prenatal ultrasound that helped me understand its benefits and limitations.

Characteristics of women	N (%)		
	Strongly agree	Do not strongly agree	No response
Age:			
15-19			
20-24			
25-29			
30-34			
35-39			2
40 and over	3	7	
Marital status			
married or common law	2	6	2
never married	1	1	
divorced/ separated/ widowed			
Parity			
nulliparous	0	3	2
multiparous	3	4	0
Level of education			
secondary school and university graduates	2	5	2
lower level of education	1	2	
Primary care provider			
family physician	3	6	2
obstetrician			
low risk physician			
midwife		1	
Employment			
outside the home	3	7	2
full time with children			
student			

Q3. What is the measure of agreement between women who view prenatal ultrasound as routine and are also aware that they have a choice about prenatal ultrasound testing?

Do you consider ultrasound a routine part of your care?	It is a woman's choice whether or not to have an ultrasound.	
	Strongly agree	Do not strongly agree
Yes	5	4
No	1	2

The variables are both categorical, therefore analysis using a Fisher Exact Test or chi square test would be the statistical test of choice, however the assumption that none of the expected values are less than 5 cannot be made in this small sample.

What is the measure of agreement between women who value the information received from their care provider, and whether this test was presented to them as an option.

I was specifically told that ultrasound is an optional test	My care provider gave me information that helped me understand the benefits and limitations	
	Strongly agree	Do not strongly agree
Yes	2	3
No	2	2

What is the measure of agreement between women who value the information received from their care provider and whether they view it as their choice to proceed or not with testing?

		My care provider gave me information that helped me understand the benefits and limitations	
It is a woman's choice whether or not to have an ultrasound		Strongly agree	Do not strongly agree
	Yes	2	2
	No	2	4

Appendix K

Description of Knowledge Index Scale

The purpose of the knowledge index scale relates directly to the primary research question: Do women receive and retain information as to the purpose, benefits, limitations and potential consequences of prenatal ultrasound, sufficient to enable them to make an informed choice about prenatal testing?

To assess women's understanding of prenatal ultrasound, an index of overall knowledge was constructed on the basis of the questionnaire items. Scores were obtained by summing the number of items answered correctly for a maximum score of nine. Similar test measures have been reported measuring women's understanding of other types of genetic testing (Faden, et al, 1985; Mareau, Johnston, Plenicar, Shw and Slack, 1988; Green, Shatham and Snowdon, 1993; Ormond Pergament and Fine, 1996; Decruyenaere, Evers-Kiebooms, Denayer and Van den Berghe 1992).

To assure that all main points were covered, items of the knowledge index scale were developed based on the information blueprint and the contents of the knowledge questionnaire. A detailed description of the knowledge index is outlined in the proceeding table.

Table K1: Knowledge index items and method of scoring

1	2	3	4	5	6	7	8	9	score
Purpose	Advantage (i)	Advantage (ii)	Advantage (iii)	Benefit	Limitation (I)	Consequences	Limitation (iii)	How ultrasound works	

Knowledge item/related question	Correct response(s)	Score
<p>Purpose (column 1)</p> <p>Question item: What is the main use of ultrasound?</p> <p>Women should be aware that the primary use of an 18-20 week ultrasound is to check age, growth and development of the fetus. Ultrasound is limited at 18-20 weeks in accuracy regarding fetal gender.</p>	<p>Correctly answers "to check age, growth and development of baby"</p>	<p>0= incorrectly answers: "to test for blood disorders," "to see what sex the baby is." 0= selects "none of the above," or "I am not sure." 0 = no response 1= correctly answers "to check age, growth and development." Will accept "gender" with the correct response.</p>

Table K1 (continued): Knowledge index items and method of scoring

<p>Advantages (column 2)</p> <p>Question item (i): Do you know of any problems an ultrasound can identify in the baby?</p> <p>Women should be aware that ultrasound can detect many anatomical fetal defects at 18-20 weeks gestation.</p>	<p>Answers "yes" to the question <u>and</u> provides examples of problems that are correct</p>	<p>0 = answers 'no' 0 = answers 'yes' but gives incorrect or no examples 0 = uncertain 0=no response 1 = answers 'yes' and provides correct examples</p>
<p>Advantages (column 3)</p> <p>Question item (ii): Is there a medical risk to the mother ultrasound?</p> <p>Women should be aware that there are no confirmed medical risks to the mother from prenatal ultrasound exposure.</p>	<p>There is considerable misinformation regarding ultrasound risk.</p> <p>Accept the answer 'no risk' only</p> <p>As above. Accept 'no' to risk</p>	<p>0= unsure 0=no response 1= answers 'no risk'</p> <p>Scoring criteria as in last item above.</p>
<p>Advantages (column 4)</p> <p>Question item (iii): Is there a medical risk to the baby from ultrasound?</p> <p>Women should be aware that based on current information , prenatal ultrasound is not considered to be harmful to the baby.</p>		

Table K1 (continued): Knowledge index items and method of scoring

Knowledge item/related question	Correct response(s)	Score
<p>Advantages (column 5)</p> <p>Question item (iv): How will having an ultrasound benefit you?</p> <p>Reassurance is the primary benefit most women receive when undergoing prenatal testing.</p>	<p>Open-ended response equating to 'reassurance'</p> <p>Other benefits would be related to providing an evaluation of the pregnancy that may affect management.</p>	<p>0= no response 1= reassurance 1= answer related to influence of ultrasound on the management of pregnancy. 1= evaluation of fetal growth & development seen as a benefit</p>
<p>Limitations (column 6)</p> <p>(i) Question item i: True or False: A "normal" ultrasound result guarantees that the baby will be born free of birth defects.</p> <p>Women should be aware that an anatomically normal scan at 18-20 weeks gestation does not guarantee a normal outcome.</p>	<p>Answers 'false' to this question item</p>	<p>0 = answers incorrectly 0= uncertain 0 = no response 1= answers correctly</p>

<p>Limitations (column 7)</p> <p>(ii) Question item ii: Do you know of any problems an ultrasound can <u>fail</u> to identify in the baby?</p> <p>Women should be aware that some fetal anomalies are not detectable by prenatal ultrasound at 18-20 weeks.</p>	<p>Answers 'yes' <u>and</u> provides examples that are correct</p>	<p>0 = answers 'no'</p> <p>0 = answers 'yes' but gives incorrect or no examples</p> <p>1= answers 'yes' and provides correct examples</p>
<p>Consequences (column 8)</p> <p>Question item: Can you think of any drawbacks to having an ultrasound?</p> <p>This question is aimed at addressing the 'what if' issue. Do women consider the possibility of the emotional or psychological costs to prenatal testing prior to proceeding with the test?</p>	<p>An acceptable answer to this open-ended question would be one that eludes to the:</p> <ul style="list-style-type: none"> -possibility of identifying an abnormality -possibility of false negative/positive -anxiety and/or psychological sequela <p>considers some consequence of the test to the outcome of the pregnancy</p>	<p>0 = uncertain</p> <p>0=no response</p> <p>0= discusses possible long term effects on the baby (i.e. Hearing problems)</p> <p>1= identifies one of the possible consequences outlined</p>
<p>General knowledge of ultrasound (column 9)</p> <p>Question item: Which answer best describes how ultrasound works?</p> <p>Women should be aware that ultrasound uses sound waves not X-rays in the production of the images.</p>	<p>answers correctly</p>	<p>0= no response</p> <p>0= uncertain</p> <p>0= uses X-rays(will be noted)</p> <p>0= incorrect response (answers 'none of the above')</p> <p>1= correct response</p>

Appendix L:

Sociodemographic comparisons were made with Group 1 (n=113) and the combined Group 2 (n=26) and Group 2 Q1 participants (n=17). This is presented in the proceeding table (Table L.1).

No statistically significant differences were seen between the two groups with respect to age, parity, marital status, education or health training. There was, however, a difference seen in employment status, in that more women of the Group 2 combined subjects were either employed outside the home or students (90.6% versus 76.1%), and more women of Group 1 were likely to be either unemployed or at home with their children (21.2% versus 6.9%). A possible explanation for this difference is not clear. In view of the fact that no difference was seen in education, this difference was not considered to be of clinical importance.

Sociodemographic information was compared among the 23 Low Risk Maternity Clinic subjects of Group 1 with the Group 2 and Group 2 Q1 subjects (n=26 and n=17). The mean maternal ages of Group 1 LRMC subjects, Group 2 participants and Group 2 Q1 participants was 30 years (95%CI: 28.7, 31.3), 31.4 years (95%CI: 28.6, 32.1) and 31 years (95%CI: 28.8, 33.9) respectively. An overlap of the 95% confidence intervals in the means suggest no significant difference in maternal age. An analysis of variance of the mean ages concurs with this finding ($F(2,59,61)=0.574$, $p=0.57$). There were no statistical differences seen in the demographic characteristics of marital status, education, health training, parity or, quite interestingly, employment status between the LRMC subjects (Table L.3). As no significant differences were seen in the sociodemographic variables between Group 2, Group 2Q1 and the LRMC subjects of Group 1, they were combined (n=66) and compared to the Group 1 less the LRMC subjects (n=90) to provide a more uniform comparison between subjects (Table L.3). The only difference found was the employment status. Women seeking prenatal care outside of the LRMC were more likely to be employed outside of the home or a student, then clients of the LRMC (90.6% versus 76.1%).

Table L.1: Comparison of sociodemographic information between Group 1 (n=113) and the combined Group 2 and Group 2Q1 participants (n=43)

	Group 1 (n=113) N (%)	Group 2 and Group 2Q 1 (n=43) N(%)	Difference
Maternal age: Mean (95%CI)	30.4 yr.	30.7yr.	ANOVA: Not significant $F(2,109,43) = 0.173$ $p = 0.68$
Marital status Married or common-law No response	109 4	43	Not significant
Education: Less than or completed high school Some/ completed post-secondary No response	16 (14.2) 92 (81.4) 5 (4.4)	5 (11.6) 37 (86.1) 1 (2.3)	Not significant $\chi^2(1) = 0.213, p = 0.65$
Health care training No response	30 (26.5) 5 (4.4)	9 (20.9) 1 (2.3)	Not significant $\chi^2(1) = 0.634, p = 0.43$
Parity Nulliparous Multiparous No response	50 (44.2) 60 (53.1) 3 (2.7)	22 (51.7) 20 (46.0) 1 (2.3)	Not significant $\chi^2(1) = 0.585, p = 0.44$
Employment status Employed outside of home or student Unemployed/ at home raising children No response	86 (76.1) 24 (21.2) 3 (2.7)	39 (90.6) 3 (6.9) 1 (2.3)	Significant $\chi^2(1) = 4.48, p = 0.03$

Table L.2 Comparison of the sociodemographic characteristics between Group 1 Low Risk Maternity Clinic subjects (n=23) with Group 2 (n=26) and Group 2 Q1 (n=17)

	Group 2 Participants (n=26) N (%)	Group 2 Q1 Participants (n=17) N(%)	Group 1 LRMC subjects (n=23) N(%)	Test statistic
Maternal age:				
Mean (95%CI)	30.3(28.6-32.1)	31.4(28.8-33.9)	30.0(28.7-31.3)	ANOVA:
≤ 25 years	3 (11.5)	1 (5.9)	2 (8.7)	Not significant
26-30 years	8 (30.8)	6 (35.3)	10 (43.5)	$F(2,59,61)=0.574$
31-35 years	11 (42.3)	4 (23.5)	9 (39.2)	$p=0.57$
≥ 36 years	3 (11.5)	4 (23.5)	1 (4.3)	
No response	1 (3.9)	2 (11.8)	1 (4.3)	
Marital status:				
Married or common-law	26 (100)	17 (100)	23 (100)	Not significant
No response	0	0		
Education:				
High school	1 (3.8)	4 (23.5)	2 (8.7)	FET, $p= 0.228$
Post secondary	25 (96.2)	12 (70.7)	21 (91.3)	Not significant
No response	0	1 (5.8)	0	
Health care training:	6 (23.1)	3 (17.6)	10 (43.5)	Not significant
No response	0	1 (5.8)	1 (4.3)	$\chi^2(1)=0.917, p=0.$
Parity:				
Nulliparous	15 (57.7)	7 (41.2)	11 (47.8)	$\chi^2(2)=0.894, p=0.$
Multiparous	11 (42.3)	9 (53.0)	12 (52.2)	Not significant
No response	0	1 (5.8)	0	
Employment :				
Outside of home or student	24 (92.3)	15 (88.4)	20 (91.3)	$\chi^2(2)= 0.642, p=0.$
Unemployed or e raising children	2 (7.7)	1 (5.8)	3 (8.7)	Not significant
No response	0	1 (5.8)		

Table L.3 Comparison of the sociodemographic characteristics between Group 1 less Low Risk Maternity Clinic subjects (n=90) with 'Group 2 combined' (Group 1 LRMC subjects, Group 2 participants and Group 2 Q1 participants: n=66)

	Group 1 less LRMC n=90 N (%)	Group 2 combined n=66 N(%)	Difference
Maternal age:			ANOVA:
Mean (95%CI)	30 (28.7, 31.3)	30.5 (29.5, 31.5)	F(1,147)=-.000
≤ 25	14 (15.5)	6 (9.1)	p=0.99
26-30	28 (31.3)	24 (36.4)	
31-35	31 (34.4)	24 (36.4)	
≥ 36	14 (15.5)	8 (12.1)	
No response	3 (3.3)	4 (6.)	
Marital status			
Married or common-law	90 (100.0)	66 (100.0)	Not significant
No response	0		
Education:			
Less than or completed high school	14 (15.5)	7 (10.6)	X ² (1)=0.994, p=0.32
Some/ completed post-secondary	71 (78.9)	58 (87.9)	Not significant
No response	5 (5.6)	1 (1.5)	
Health care training	20 (22.2)	19 (28.8)	X ² (1)=0.789, p=0.37
No response	4 (4.4)	2 (3.0)	Not significant
Parity			
Nulliparous	38 (42.2)	33 (50.0)	X ² (1)=0.527, p=0.47
Multiparous	49 (54.5)	32 (48.5)	Not significant
No response	3 (3.3)	1 (1.5)	
Employment status			
Employed outside of home or student	66(73.3)	59 (89.4)	X ² (1)= 5.66, p=.017
Unemployed/ at home raising children	21 (23.3)	6 (9.1)	Significant
No response	3 (3.3)	1 (1.5)	

Table L.4 Differences in correct responses to knowledge index items between Group 1 subjects (n=113) and pre-intervention Group 2 and Group 2 Q1 subjects (n=43)

	Group 1 (n=113)		Pre- intervention Group 2 and Group 2Q1 (n=43)		Test of significance:
	N	%	N	%	
Purpose: Main use of ultrasound No response	107 1	94.7 0.87	36 0	83.7	Not significant: $\chi^2(1)= 6.07, p=0.14$
General knowledge How ultrasound works No response	97 2	85.8 1.8	39 0	90.7	Not significant: $\chi^2(1)= 0.329, p=0.57$
Benefits Problems identifiable by ultrasound No response	81 3	71.7 2.6	23 0	53.5	Significant: $\chi^2(1)= 5.76, p=0.02$
No medical risk to the woman No response	92 1	81.4 0.87	41 0	95.3	Significant: $\chi^2(1)= 4.45, p=0.03$
No medical risk to fetus No response	77 2	68.1 1.8	26 1	60.5 2.3	Not significant: $\chi^2(1)= 0.772, p=0.38$
Personal benefits (reassurance/ affect on pregnancy management)	70 12	61.9 10.6	18 6	41.9 13.9	Significant: $\chi^2(1)= 5.00, p=0.02$
Limitations Diagnostic limitations No response	103 2	91.1 1.8	31 0	72.1	Significant: $\chi^2(1)= 11.75, p=0.01$
Limitations in identifying all fetal anomalies No response	64 7	56.6 6.2	16 0	37.2	Significant: $\chi^2(1)= 6.60, p=0.01$
Consequences Drawbacks, implications of testing No response	18 20	15.9 17.7	5 3	11.6 2.6	Not significant: $\chi^2(1)= 0.919, p=0.34$

Table L.5 Differences in correct responses to knowledge index items between Group 2 pre-intervention subjects (n=26) and Group 2 Q1 subjects (n=17)

	Group 2 Q1 (n=17)		Group 2 Pre-intervention (n=26)		Test of significance: p value (95%CI)
	N	%	N	%	
Purpose: Main use of ultrasound	15	88.2	21	80.8	Not significant: p=0.49 (-0.139, 0.289)
General knowledge How ultrasound works	16	94.1	23	88.5	Not significant: p=0.72 (-0.511, 0.741)
Benefits					Not significant:
Problems identifiable by ultrasound	7	41.2	16	61.5	p=0.27 (-0.671, 0.187)
No medical risk to woman	16	94.1	25	96.1	p=0.78 (-0.111, 0.147)
No medical risk to fetus	10	58.8	16	61.5	p=0.89 (-1.04, 0.916)
Personal benefits (reassurance/ affect on pregnancy management)	11	64.7	15	57.7	p=0.64 (-0.443, 0.332)
Limitations					Not significant:
Diagnostic limitations	10	58.8	21	80.8	p=0.13 (-0.498, 0.059)
Limitations in identifying all fetal anomalies	6	35.3	10	38.5	p=0.15 (-0.443, 0.332)
Consequences					Not significant:
Drawbacks, implications of testing	1	5.9	4	15.4	p=0.73 (-0.242, 0.170)

Table L.6 Differences in correct responses to knowledge index items between Group 1 LPMC subjects (n=23), Group 1 pre-intervention subjects (n=26) and Group 2 Q1 subjects (n=17)

	Group 1 LPMC (n=23)	Group 2 pre- intervention (n=26)	Group 2 Q1 (n=17)	Test of significance
	N (%)	N (%)	N(%)	
Purpose: Main use of ultrasound	22 (95.6)	21 (80.8)	15 (88.2)	Not significant $\chi^2(2, n=65)=4.610$ $p=0.10$
General knowledge How ultrasound works	21 (91.3)	23 (88.5)	16 (94.1)	Not significant: $\chi^2(2, n=65)=0.927$, $p=0.63$
Benefits				
Problems identifiable by ultrasound	16 (69.5)	16 (61.5)	7 (41.2)	Not significant: $\chi^2(2, n=66)=3.365$ $p=0.19$
No medical risk to woman	22 (95.6)	25 (96.1)	16 (94.1)	Not significant: $\chi^2(2, n=66)=0.101$ $p=0.95$
No medical risk to fetus	17 (73.9)	16 (61.5)	10 (58.8)	Not significant: $\chi^2(2, n=65)=0.961$ $p=0.62$
Personal benefits (reassurance/ affect on management)	7 (30.4)	15 (57.7)	11 (64.7)	Not significant: $\chi^2(2, n=5)=3.055$ $p=0.22$
Diagnostic limitations	21 (91.3)	21 (80.8)	10 (58.8)	Significant: $\chi^2(2, n=66)=6.271$ $p=0.04$
Limitations in identifying all fetal anomalies	12 (52.2)	10 (38.5)	6 (35.3)	Not significant: $\chi^2(2, n=66)=1.416$ $p=0.49$
Consequences				
Drawbacks, implications of testing	7 (30.4)	4 (15.4)	1 (5.9)	Not significant: $\chi^2(2, n=60)=4.605$ $p=0.10$