MATERNAL SERUM SCREENING (MSS) IN NEWFOUNDLAND AND LABRADOR - KNOWLEDGE, OPINION AND PRACTICE

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MATERNAL SERUM SCREENING (MSS) IN NEWFOUNDLAND AND LABRADOR – KNOWLEDGE, OPINION AND PRACTICE

by

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Abstract

Objective To investigate maternal serum screening (MSS) in Newfoundland and Labrador.

Design Cross-sectional anonymous physician and post-partum women surveys conducted between September and December 2003. Aggregate laboratory data for 2003 were also assessed.

Population Physicians practicing antenatal care in Newfoundland and Labrador in the previous 12 months (n = 490). Women (n = 300) who had recently given birth.

Results The response rates for the physician and patient surveys were 60.4% (n = 293) and 66.7% (n = 200) respectively. Most physicians (88.8%) reported that they offer maternal serum screening to their patients. These physicians were divided among those who offered MSS to all women (63.5%) and those who offered MSS to selective groups of women (36.5%). Physicians who were younger, female and educated in Canada were more likely to offer MSS than physicians who were older, male and educated outside of Canada. Obstetricians were more likely to offer MSS and to offer the screening test to all women than family physicians. The majority of both physician groups reported that they would prefer a first trimester screening test.

The majority (62.9%) of patients surveyed reported discussing MSS with their physician. Less than half (46.2%) of these women chose to undergo the prenatal screen. Women who underwent MSS were significantly older than

women who did not undergo the screening test. Twenty seven percent of patients surveyed underwent MSS.

Data obtained from the Provincial MSS Program indicated that 22% of women undergo MSS. The overall false positive rate[1] associated with MSS in Newfoundland and Labrador was 13.1%.

Conclusion MSS is not being used as a population based screening test. It is being offered to and used by selected groups of women. Further education and promotion of this prenatal screening test are necessary.

[1] A screening result that shows evidence of a disease or an abnormal condition although it (the condition being tested for) is not present.

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List of Abbreviations

CME.....Continuing Medical Education

DS.....Down's syndrome

MSS.....Maternal Serum Screening

MSA.....Medical Service Aid

NTD.....Neural Tube Defect

Prov.....Provincial

SD.....Standard Deviation

SPSS.....Statistical Package for Social Science

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Chapter 1 - Introduction

1.1 Problem

The Provincial Medical Genetics Program of Newfoundland and Labrador introduced the Maternal Serum Screening (MSS) Program in the beginning of 2002. The goal of this program is to provide a risk estimate for Down's syndrome, Trisomy 18 and open neural tube defects for every pregnancy in Newfoundland and Labrador. The Canadian Task Force on the Periodic Health Examination (Canadian Task Force on Periodic Health Examination, 1994) has suggested that there is fair evidence to offer MSS to all pregnant women. This position is further supported by the Society of Obstetricians and Gynecologists of Canada (SOGC, 1999). MSS is therefore becoming the 'standard of prenatal care'.

After education and promotion throughout the province in July and August of 2002, the MSS rate was 19% in 2002 (Jennifer Moore, Personal Communication, June 22, 2004). There is little evidence to explain the low screening rate. The use of MSS is much higher in other parts of Canada, ranging from 48% in Ontario (Summers, 2003) to 68% in Manitoba (Karen MacDonald, Personal Communications, April 29, 2004).

1.2 Purpose and Objective

The goal of this study was to examine patterns of MSS use in Newfoundland and Labrador through a physician survey, patient survey and secondary analysis of laboratory data.

The objectives of the physician survey were:

1. to describe the characteristics of physicians who offered and did not offer MSS. Specifically, the study examined sociodemographic, practice, and training characteristics.

2. to assess physician knowledge of MSS.

3. to explore physician opinion of MSS and methods to improve the test.

The objectives of the patient survey were:

1. to describe the sociodemographic characteristics of women who have and have not been offered MSS as well as those who have undergone and not undergone MSS.

2. to describe the information provided to women regarding MSS as reported by women.

The objectives of the laboratory data analysis were:

1. to estimate the proportion of pregnant women in Newfoundland and Labrador who undergo MSS.

2. to describe the characteristics of the patients who have undergone MSS.

3. to describe the number of positive and negative test results.

1.3 Rationale

This topic is of particular interest to the people of Newfoundland and Labrador, as the province has the highest incidence of neural tube defects in Canada, affecting four per 1000 births (Crane et al., 2001). This statistic underscores the need to develop a better understanding of the low uptake of MSS in the province. By examining data from physicians, patients and the testing laboratory, this study provides a more complete picture of perceptions about MSS and actual MSS screening practices. The study also identifies facilitators and barriers to improving the use of MSS in Newfoundland and Labrador.

Finally, this study assesses the impact of MSS provincial implementation in September of 2001. With the introduction of the MSS Program, the Provincial Medical Genetics Program has conducted province wide educational and promotional sessions, including television, radio and newspaper spots. A public health nurse traveled across the province and held MSS education sessions in every hospital which performed deliveries. This study will describe current use, offering an assessment of the impact of the education and promotional activities that have taken place.

Chapter 2 – Review of Literature

2.1 Maternal Serum Screening

Maternal Serum Screening (MSS) is a prenatal genetic screening test completed in the second trimester and determines a woman's risk of carrying a fetus with Down's syndrome, Trisomy 18 or an open neural tube defect. With this blood test it is possible to assess the individual risk of fetal neural tube defects, Down's syndrome and Trisomy 18 for any pregnant woman, regardless of her age or medical history. Thus, invasive diagnostic tests (such as amniocentesis) can be offered more selectively to those screening positive and detection rates can be increased substantially (Wald et al., 1988). All definitive prenatal diagnostic techniques are invasive and are associated with risk of pregnancy loss and have significant financial cost. Therefore, it is appropriate to offer these invasive techniques only to patients at highest risk.

2.2 Down's Syndrome

Down's syndrome (DS) is a genetic abnormality consisting of three copies of chromosome 21. It is the most common form of (genetically) inherited developmental delay, occurring with an incidence of approximately 1 of 700 births in the general population (Ross & Elias, 1997). Down's syndrome is associated with a variety of congenital malformations including facial characteristics such as upslanting eyelids, protruding tongue and a flattened nasal bridge. Approximately 40% of infants born with Down's syndrome will have

congenital heart defects and all will have varying degrees of developmental delay (Ross & Elias, 1997). Other chronic health problems encountered by these individuals include gastrointestinal and musculoskeletal abnormalities, and increased rates of childhood leukemia and early Alzheimer's disease. Since the 1970s, the life expectancy and quality of life of persons with Down's syndrome have increased dramatically. The most current life expectancy for babies born with Down's syndrome is 58.6 years of age (Glasson et al., 2002).

2.3 Trisomy 18

Trisomy 18 is also a result of an extra chromosome; in this disease, there are three copies of the number 18 chromosome. It has an incidence of approximately 1 of every 6000 live births (Jorde et al., 2000). The abnormalities associated with Trisomy 18 are generally not compatible with more than a few months of life. Fifty percent of the affected infants do not survive beyond the first week of life and only about 10% are still alive at 12 months of age (Jorde et al., 2000).

A third copy of chromosome 18 causes numerous abnormalities. Most infants born with this disease are underweight and appear weak and fragile. Affected individuals have numerous problems with their internal organs. Problems often occur in the lungs, heart, diaphragm and blood vessels. The infant may also have malformed kidneys and abnormalities of the urogenital system.

2.4 Open Neural Tube Defects

Open neural tube defects are caused by an opening in the spinal cord or brain which is thought to arise from a combination of genetic and environmental factors. Normally the neural tube closes at about the fourth week of gestation. A defect in closure or a subsequent re-opening of the neural tube results in an open neural tube defect. Examples of open neural tube defects are spina bifida, anencephaly and encephalocele. This prenatal disorder is of particular importance to Newfoundland and Labrador as the latest statistics (Crane et al., 2001) show Newfoundland and Labrador has the highest rate of open neural tube defects in Canada, affecting approximately 4 in every 1000 live births (although the rate of neural tube defects has been decreasing throughout Canada since folic acid fortification was introduced).

Generally, the higher the defect occurs on the spinal cord and/or the larger the defect, the greater the disability. This disease can range from anencephaly which results in still birth or neonatal death to individuals with a neural tube defect who can lead productive lives. Associated conditions include paraplegia, bladder and bowel incontinence and other physical disabilities as well as mental impairment which occurs in approximately a quarter of the cases.

2.5 Risk Calculation

Risk is calculated in MSS by measuring three biochemical serum markers: alpha-fetoprotein, human chorionic gonadotropin and unconjugated estriol (in combination with maternal age for assessing down syndrome and trisomy 18

risk). An algorithm has been created in which a patient's risk is modified up or down depending on whether the results of each of the four factors are more typical of the unaffected population or more typical of the high risk population (women with a fetus with Down's syndrome, Trisomy 18 or open NTD). When a serum sample is sent to the lab, the three biochemical markers are measured and compared to the unaffected population median for the same day of gestation. Although exact reported population biochemical levels may differ among labs, all labs standardize their results by comparing them to the unaffected population median. Therefore, the 'average value' from any lab for each of the markers in the overall population will be 1.0 multiple of the median[1] (Carroll, 1997). For example, the median maternal serum alpha-fetoprotein level for a woman carrying a Down's syndrome fetus is approximately 0.8 multiples of the median of the normal pregnancy median (Ross and Elias, 1997). Median maternal serum alpha-fetoprotein is therefore about 20% lower in women carrying fetuses with Down's syndrome.

Each of the three multiples of the median values (for each biochemical marker) and maternal age are then fed into a computer program which calculates individual risk for each prenatal disease taking into account the impact of all four factors.

Using alpha-fetoprotein, human chorionic gonadotropin and unconjugated estriol, along with maternal age, MSS has a sensitivity of about 70% for Down's

[1] Once the blood test results are determined, a risk factor is calculated based on the "normal" blood tests for the testing laboratory. The average of normals is called the population median. Test results are reported to doctors as Multiples of the Median (MoM). The average value is therefore called 1.0 MoM.

syndrome, 75% for Trisomy 18 and about 80% for open neural tube defects. The specificity rates of MSS are 92% for Down's syndrome, 99.8% for Trisomy 18, and 98% for neural tube defects. (Haddow et al., 1992; MacDonald et al., 1991; Wald et al., 1988; Norgard-Pedersen et al., 1990; Cheng et al., 1993; Phillips et al., 1992). This means 70% of Down's syndrome cases screened will yield a positive MSS result and 30% of Down's syndrome cases will be missed. Also, with a 92% specificity rate, 92% of fetuses without Down's syndrome will be correctly identified as true negatives and 8% of people who have MSS done will have a false positive.

A blood test is considered to be "screen positive" for trisomy 18 or Down's syndrome when the sample contains unusual amounts of the three biochemical markers. The blood test is considered to be "screen positive" for an open neural tube defect when there is an abnormal amount of AFP. The patient's specific risk for each genetic anomaly is given as a ratio on the physician laboratory report. Screen positive for Down's syndrome is defined as when the chance of a baby being born with the disease is equal to or greater than 1/385. Trisomy 18 is determined to be screen positive when the chance of the baby being born with the disease is at least 1/25. Screen positive for an open NTD means that the result is equal to or greater than 2.2 multiples of the median.

If a screen positive result is the outcome, a physician following the guidelines of the provincial program is expected to arrange a detailed ultrasound to verify the weeks of gestation, to rule out multiple gestation, fetal death, and to examine the fetus for anomalies. If a follow up consultation is to be arranged, the

physician may meet with the patient to discuss the consequences of the screening test or he or she may have the patient meet with a genetic counselor. The counselor is specially trained to discuss the meaning of the screening results and possible further diagnostic testing to confirm the genetic abnormality. Amniocentesis is used to confirm DS and Trisomy 18, whereas, ultrasound is used to confirm a positive MSS screening result for an open NTD.

2.6 Genetic Counseling

Before a patient can consent to MSS they should receive pretest genetic counseling. Genetic counseling involves giving information regarding the available methods of prenatal diagnosis, risks and benefits of various techniques, timing of diagnostic procedures, conditions for testing, current management of relevant genetic disorders, and accuracy of prenatal test results, which would include implications of false negative and false positive test results (Society of Obstetricians and Gynecologists of Canada, 1999).

Counseling can be done by the physician or a person specially trained in genetic counseling. In Newfoundland and Labrador, physicians usually counsel their patients about MSS before they offer the prenatal screen. After the screening test is ordered, a negative screen result is sent directly to the physician, whereas a positive result is sent to the nearest genetic counselor who informs the physician of the screen result. The physician may counsel the patient about the test results and the options for further testing or they may send the patient to the nearest genetic center to meet with a genetic counselor. Trained genetic counselors are

located in the regional genetics centres in St. John's, Gander and Corner Brook.

2.7 Potential Problems with MSS

The three biochemical marker levels vary throughout a woman's pregnancy and can only be analyzed for maternal serum screening between 15 and 20 gestational weeks. The MSS blood test therefore operates within a narrow time window of a woman's pregnancy and requires unprecedented coordination among physicians, laboratories, genetics counselors, and prenatal diagnostic centers. Several potentially serious problems can arise with the use of MSS. These may include inadequate provider knowledge which may result in sub-optimal counseling or a complete lack of counseling and/or screening consent. There are also complaints of raised levels of anxiety among women who experience the delay in definitive diagnosis associated with MSS (Madlon-Kay et al., 1992). Another potential problem surrounding MSS is lack of timely follow-up of positive tests; in certain locations and regions there are problems with access to screening ultrasound, amniocentesis, specialized genetic counseling services, and services for pregnancy termination (Carroll, 1997). The timing surrounding the screening test is an issue for some physicians and patients as the screen requires that important decisions such as amniocentesis and the potential of pregnancy termination are made relatively late in a woman's pregnancy. Decisions surrounding pregnancy termination are especially controversial in Newfoundland and Labrador. The province has a large religious population which often have difficulty with the idea of pregnancy termination.

2.8 MSS in Newfoundland and Labrador

The most recent and relevant physician survey regarding MSS was done by Chandra et al. in 2000 (Chandra et al., 2003). In this study Newfoundland and Labrador physicians involved in prenatal care were contacted through a postal questionnaire. This survey was completed before the introduction of the Provincial Maternal Serum Screening Program and aimed to assess physician practice and knowledge of MSS. Chandra et al. found that 29% of respondents offered the screen to all pregnant women. A further 34% of respondents discussed it only with patients over 35 years of age at delivery. Of the physicians that ordered MSS, 30% did so outside of the correct screening time frame of 15 to 20 gestational weeks.

The study done by Chandra et al. (2003) discovered that physicians were not adequately informed about MSS. She found that physicians demonstrated a lack of overall knowledge of MSS. They were unaware of the appropriate gestational age at which MSS should be offered and the screening rates (e.g. false positives, true positives, etc.) associated with MSS. This is a cause for concern because if women are to provide consent for MSS, they should understand the purpose of the test, the likelihood of false positives and negatives, and the implications of the possible results. Moreover, it has also been suggested that it has been the lack of physician counseling time discussing MSS that has contributed to patients forgoing the screening test (Personal Communication, Claire Blight, Nova Scotia Department of Health, February, 2003).

In their 2000 study, Chandra et al. discovered that a number of physicians were offering MSS only to women over 35 years of age or to women with a family history of Down's syndrome or NTD. This is a cause of concern as this screening test uses population-based risk ratios and it is therefore inappropriate to recommend MSS solely to women in these higher risk groups.

2.9 Physician Opinion of MSS

Prenatal screening and MSS are complex and value-laden processes. Physician opinion of MSS has been studied in other parts of Canada (Carroll et al., 1997) and throughout the world (Hemminki et al., 2000; Green, 1994; Hemminki et al., 1999).

A study done in Ontario discovered that the majority of physicians surveyed recommended that their provincial MSS program should be changed or scrapped (Carroll et al., 1997). Reasons cited by physicians included "Too many normal pregnancies have positive MSS results," and "MSS causes too much anxiety for women". There were also studies done in Finland that surveyed health care providers regarding MSS. These studies found that there was support for such screening, but many physicians acknowledged the ethical and psychological implications of such testing (Hemminki et al., 1999; Hemminki et al., 2000). Another physician opinion study out of England found that physicians felt they did not have adequate training or resources to counsel all the women to whom screening was offered. The investigators suggested that the lack of available counseling was consistent with the high prevalence of problems associated with

women not understanding the test (Green, 1994). These surveys gave physicians an opportunity to suggest possible changes that could improve their MSS programs. For example, the physicians in England and Wales suggested that there was an urgent need to determine of what counseling should consist and who should undertake it. Newfoundland and Labrador physicians require the same opportunity to comment on improvements if the MSS program is to better suit the needs of the physicians and their patients.

An opinion often cited by physicians is that prenatal screening is offered too late in pregnancy (Madlon-Kay et al., 1992). Prenatal screening tests are constantly evolving and first trimester prenatal screening is now being offered in other Canadian provinces, most recently in Halifax, Nova Scotia (Personal Communications, Claire Blight, November, 2002).

2.10 Patient Acceptance of MSS

Physician acceptance and use of MSS have been well documented, but acceptance of MSS by patients has been less studied. Chandra et al. (2003) asked physicians if they were offering MSS to their patients but did not ask if patients generally accepted the screening test. Physicians may have concerns about the test and its limitations, which may be conveyed to their patients who then opt not to undergo the screening test. A 1992 survey of American physicians found that 87% of the physicians offered maternal serum alpha-fetoprotein testing. However, the physicians noted that relatively few patients chose to have the test done (Madlon-Kay, 1992). Therefore, asking patients about MSS may help us

determine whether it is patient or physician acceptance which is influencing the MSS rate in Newfoundland and Labrador.

2.11 Physician Factors Affecting Uptake

Factors that have been associated with early uptake of Maternal Serum Screening have been associated with the sex of the physician (Woodward et al., 1997). Woodward et al. (1997) completed a survey of physicians a year and a half after the Ontario Ministry of Health introduced a MSS program to be offered to all pregnant women as a province wide pilot. Woodward discovered that more female physicians offered MSS to all their patients and were more knowledgeable about MSS than male physicians. The number of deliveries performed per year by the physician has also been shown to influence MSS adoption. It has been found that the more deliveries a physician performs, the more likely they were to offer MSS (Yankowitz et al., 1996; Carroll et al., 1997). Also, the specialty of the physician has been shown to be a predictor of early MSS use. Obstetricians have been found more likely than family physicians to offer MSS (Sadler, 1997; Chandra et al., 2003).

Physician use of MSS has also been found to vary according to regional area. A study done in Ontario by Permaul-Woods et al. (1999) found that physicians in the northwest and rural regions of Ontario were less likely to routinely offer MSS to all women compared to physicians in urban centers. In Manitoba, physicians outside of Winnipeg were found to be less likely to do a

Down's syndrome prenatal screen [2] than physicians in the city (Chodirker & Evans, 1993). However, Chandra et al. (2003) found no such urban/rural difference in Newfoundland and Labrador.

[2] Maternal serum alpha-fetoprotein screening as a single biochemical marker was offered for Down's syndrome screening before the triple biochemical marker screening test became available.

Chapter 3 – Methods

This is a cross sectional study which used three data sources: a physician survey, a patient survey and aggregate laboratory data.

3.1 Physician Survey

The physician survey consisted of a postal survey of all obstetricians and family physicians[1] practicing in the province of Newfoundland and Labrador. Physicians who provided antenatal care during the preceding twelve months were included in the study.

3.1.1 Data Collection

The list of eligible physicians was created from the mailing list of currently licensed physicians from the Newfoundland Medical Board on August 15th, 2003. The list included 490 family physicians and 35 obstetricians practicing in the province, for a total physician study population of 525. The survey package sent to physicians included a questionnaire with return envelope and a postcard. The postcard and return envelope both had business reply postage stamps attached. Physicians were requested to separately mail back the completed survey and the reply postcard to permit anonymity of responses. The postcard displayed the corresponding physician's name and address. Its purpose was to distinguish physicians who had completed and returned the questionnaire so that subsequent mail-outs were sent only to non-respondents. To ensure anonymity neither the questionnaire nor its return envelope had the physician name or any traceable information attached.

[1] General practitioners and those who had family medicine specialty were grouped together as family physicians.

The physician survey consisted of four mail-outs between the period of September 23rd, 2003 and November 13th, 2003. To promote a higher response rate, the initial survey was followed up with three reminder surveys. The third followup was hand delivered to the offices of physicians on the Avalon peninsula, while physicians in the rest of the province were contacted by telephone.

3.1.2 Survey Instrument

The physician questionnaire was adapted from the questionnaire used by Carroll et al. (1997) to assess the Ontario Maternal Serum Screening program. The validity of this survey instrument had been achieved through focus groups and pilot testing which have been discussed elsewhere (Carroll et al., 1997). The questionnaire was shortened and some of the questions were altered to better represent the MSS Program in Newfoundland and Labrador. Questions regarding physician income, work hours and open-ended questions regarding patient and physician MSS brochures were omitted. Chandra et al. (2003) also used a version of the survey developed by Carroll et al. (1997). The questionnaire used in my study differed from that of Chandra et al. in that it was longer and it used more open-ended questions. Instead of asking whether the physicians' MSS practice had changed in the past 18 months, I asked how their MSS practices had changed in the past 18 months: whether they were offering MSS more often; less often; or the same amount. With regards to MSS information they have come across, Chandra et al. asked if they had read any material regarding MSS. I chose to ask exactly where they

had been exposed to MSS information (the internet, medical journals, newspapers, colleagues, etc.).

The first section of the survey contained questions regarding the physicians' personal and professional practice characteristics. These characteristics included age, gender, specialty, years in practice and the size of the community in which the physician practiced. The questionnaire also asked whether the physician provided antenatal care and included several questions regarding the physicians' antenatal practice. Questions included how many years the physician had been providing antenatal care, to what gestational week care was provided and the number of pregnant women cared for in the past twelve months. The questionnaire is presented in Appendix A.

The second section of the survey explored physician opinion and knowledge of MSS. Physicians were asked if they offered MSS, and if not, why. Physicians who offered MSS were asked to which groups of women they routinely offered the screening test, and to provide some MSS practice information. Practice information included the amount of time typically spent discussing MSS with a patient, the percentage of patients who chose to undergo the screening test as well as the turnaround time for notifying patients of positive and negative MSS results.

Questions posed to determine physician knowledge of MSS included the correct time frame to offer MSS; the false positive and the true positive rates for each genetic disease screened; whether the physician was aware of the Provincial MSS Program and a question regarding the sources of information pertaining to MSS knowledge. The questionnaire also asked whether the physician believed MSS could mislead patients to believe that physicians could guarantee a healthy baby and whether a first trimester

screening test was preferable. The questionnaire finished with an open-ended question regarding their opinion of the MSS program and whether they had any comments on MSS in Newfoundland and Labrador.

To ensure the clarity of the questionnaire, the questions were pre-tested with medical students, graduate students, faculty, genetic counselors and physicians. The questionnaire was deliberately kept brief to encourage a high response rate and utilized both open-ended and closed questions.

3.1.3 Data Management

The survey data were entered and analysed using SPSS software version 11.5 (Statistical Package for the Social Sciences). The data were cleaned by running frequencies and cross tabulations to identify data-entry errors and impossible responses. Errors were corrected by comparing the survey database with the original document.

Physicians who did not provide antenatal care were excluded from the analysis.

3.1.4 Data Analysis

The location of practice variable was initially recorded in five categories which were subsequently reduced to three: urban (>20,000), semi urban (10,000 – 19,999), town (5,000 – 9,999), small town (1,000 – 4,999) and rural (<999). In the final categorization the new rural category included the town, small town and rural responses.

Physician knowledge was determined by the physician identifying the correct gestational age to order MSS and the false positive and the true positive rates for each genetic disease screened. False positive and true positive rates were determined to be

correct if the physician's response was within 5% of the recorded literature value for each measure.

Frequencies were used to describe the characteristics of the sample as a whole. Chi square tests, t tests, ANOVA and, if applicable, Boneferroni tests were used to identify differences between specialty (family physicians versus obstetricians), gender, and MSS practice (whether MSS was offered to all patients, some patients or no patients, i.e. not offered). Frequencies were used to analyze responses from categorized open-ended responses including reasons for not offering MSS. Lastly, physician comments and opinion of the MSS program were analyzed, comparing the differences between the different MSS user types.

3.2 Patient Survey

The patient survey consisted of a self-administered written questionnaire completed by women within forty-eight hours of giving birth at the Women's Health Centre of the Health Care Corporation of St. John's in Newfoundland. The site was chosen due to the volume of patients seen, ensuring cost-efficient data collection. This setting is also the only tertiary care obstetric hospital in the province. The Women's Health Centre is not exclusive to pregnancies of high risk, but is visited by women living in St. John's and surrounding areas.

3.2.1 Sample

The sample frame consisted of a convenience sample of 300 women. Given that the Women's Health Centre has approximately 2100 births per year, this sample size

represents approximately 15% of the total population. Those who gave birth to a single baby (as MSS can only be used for single births) and who understood sufficient English to complete the questionnaire were eligible for the study.

3.2.2 Data Collection

The surveys were distributed and collected by Medical Service Aides (MSAs)[2] between October 8th and November 27th, 2003. Every two weeks I dropped off surveys to the MSAs, and collected completed questionnaires at this time. The MSA identified potential participants as women who gave birth within the last forty-eight hours on the maternity ward. The MSA visited the women in the morning to drop off the surveys and then returned later that day to collect the completed surveys. Women were asked not to sign the questionnaire or report any identifying personal information. Questionnaires were coded with a study number.

3.2.3 Survey Instrument

The survey asked applicable questions which were extracted from the physician MSS survey. Questions covered the patients' exposure to MSS, time spent discussing MSS with their physician and whether they chose to undergo the prenatal genetic screening test. Questions regarding patient age and the size of the community in which they lived were also asked.

This questionnaire was pre-tested on medical students, graduate students, faculty, genetic counselors and physicians to ensure clarity for participants. The questionnaire

[2] Medical Service Aides (MSAs) are support staff located throughout the hospital.

was kept deliberately brief as to minimize disruption to the new mothers. The patient survey presented in Appendix B.

3.2.4 Data Management

The survey data were entered and analysed using SPSS version 11.5 software (Statistical Package for the Social Sciences). The data were cleaned by running frequencies and cross tabulations to identify data-entry errors and impossible responses. Errors were corrected by comparing the survey database with the original document.

3.2.5 Data Analysis

The location of practice variable was initially recorded in five categories which were subsequently reduced to three: urban (>20,000), semi urban (10,000 – 19,999), town (5,000 – 9,999), small town (1,000 – 4,999) and rural (<999). In the final categorization the new rural category included the town, small town and rural responses.

Frequencies were used to describe the characteristics of the sample as a whole. Chi square tests, t tests, ANOVA and if applicable Boneferroni tests were used to identify differences (whether or not they had MSS) by age and place of residence. These groups of women were then analyzed for differences in sources of MSS information and the amount to time physicians typically spent discussing MSS.

3.3 Laboratory Information

Laboratory data were obtained from the Newfoundland and Labrador MSS Program with the permission of the Provincial Medical Genetics Clinic on March 5th,

2003. The data include the Provincial MSS uptake rate[3], geographic utilization rates of the screening test and screen positive [4] and screen negative rates[5] for the province for 2003. Also included was information regarding the age of women who were using MSS in 2003.

3.3.1 Data Analysis

Information was analyzed in aggregate form only.

3.4 Ethical Considerations

The study required the participation of physicians, and women delivering between October 8th and November 27th, 2003. The Human Investigation Committee at the Faculty of Medicine, Memorial University of Newfoundland (Appendix C) and the Research Proposal Approval Committee at the Health Care Corporation of St. John's (Appendix D) approved this study.

In order to provide questionnaire anonymity in the physicians' survey, identities were not requested and addresses were left off questionnaires and return envelopes. The reply post card sent separately permitted the responding physicians to remain anonymous, while allowing followup with non-responding physicians. Return of a completed questionnaire was considered implied consent for this group.

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[3] Uptake rate was defined as the number of women who underwent MSS screening divided by the number of women who gave birth in the calendar year.

[4] Screen positive rate was defined as number of samples per 100 that when analyzed had an unusual amount of the biochemical markers associated with it.

[5] Screen negative rate was defined as number of samples per 100 that when analyzed had the usual amount of the biochemical markers associated with it.

To protect patient confidentiality and ensure first contact with potential participants was by someone perceived to be a third party, a MSA, approached potential participants to identify those interested. These women were given a patient questionnaire and envelope and were asked not to sign or report any identifying personal information. The MSA returned later in the day to pick up the completed questionnaire in a sealed envelope. This gave the patients time to read over the questionnaire and decide if they wanted to participate in the study. Return of a completed questionnaire was considered implied consent.

To protect patient and physician confidentiality of MSS laboratory information, a third party, the Provincial Medical Genetics Program, provided statistical data. The data were kept in aggregate form and no identifying characteristics of either physician or patient were included in the data.

All data were kept in a password protected computer in password protected files in a secure room. I was the only person with access to the data.

Results are reported in aggregate form only. Individuals (physicians and patients) will not be identified in any publication or presentation.

I will distribute the results to family physicians and obstetricians practicing in Newfoundland and Labrador. I will also share my results with the Provincial MSS Program and the Women's Health Centre in the Health Care Corporation of St. John's.

Chapter 4 – Results

4.1 Physician Survey

4.1.1 Response rate and sample representativeness

Of the 525 eligible physicians listed on the Newfoundland and Labrador Medical Board mailing list, 40 physicians were ineligible because they had retired or moved. The remaining 485 physicians were found to be practicing family medicine or obstetrics. Of these 485 physicians, a total of 293 physicians responded to the survey, 270 family physicians and 23 obstetricians, for an overall response rate of 60.4% (60.0% and 65.7% respectively).

To assess representativeness, we compared the gender, specialty and location of practice of the respondents with the list provided by the Newfoundland and Labrador Medical Board (Table 4.1).

According to the Newfoundland Medical Board's mailing list, 93.3 % of physicians were listed as family physicians and 6.7 % were listed as obstetricians. These numbers were similar to those that responded to the survey, with 92.2 % reported practicing family medicine and the remaining 7.8 % reported practicing obstetrics (Table 4.1).

Table 4. 1 Representativeness of physicians who responded to the study

	NLMB n = 525	Respondents n = 293
	n (%)	n (%)
Gender:		
Male	386 (73.5)	189 (64.5)
Female	139 (26.5)	104 (35.5)
Specialty:		
Family Medicine	490 (93.3)	270 (92.2)
Obstetrician	35 (6.7)	23 (7.8)
Location of medical practice:		
Rural	197 (37.5)	125 (42.7)
Semi Urban	50 (9.3)	29 (9.9)
Urban	278 (53.2)	139 (47.4)

NLMB = Newfoundland and Labrador Medical Board

According to the mailing list there were 386 (73.5 %) males and 139 (26.5 %) female practicing family medicine or obstetrics in the province at the time of the first mail-out. A greater proportion of female physicians returned the survey compared to male physicians (104/139 compared to 189/386 respectively).

With regard to geographic distribution of the respondents, 125 (42.7 %) responses came from rural areas, 29 (9.9 %) came from semi-urban areas and the remaining 139 (47.4 %) came from urban areas. These numbers were found to be similar to those found on the mailing list obtained for the Newfoundland Medical Board ($p < 0.05$).

Eighty-eight of the respondents did not provide antenatal care in the past 12 months and were therefore ineligible for the study. The study reports on the remaining 205 physicians.

4.1.2 Physician Survey Respondents

Table 4.2 presents the characteristics of the sample by specialty. The majority of both physician groups were males and between the ages of 40 and 59 (Table 4.2). There was a significant difference in the location of medical education between the two groups ($p = 0.001$). The majority of family physicians attended medical school in Canada, whereas the majority of obstetricians attended medical schools outside of Canada. As expected, family physicians were more widely distributed throughout the province, compared to obstetricians, who were concentrated in more urban areas. Obstetricians cared for significantly more pregnant women and performed significantly more deliveries than family physicians ($p = 0.0001$). Obstetricians, on average, cared for 152 pregnant women per year, whereas family physician cared for 25 pregnant women per year. With regards to deliveries, obstetricians performed on average 139 deliveries per year, whereas family physicians performed an average of 40 deliveries per year.

Table 4.2 Characteristics of physicians providing antenatal care in Newfoundland and Labrador

Characteristic	Group; no. (%) of respondents: Family physicians n = 182	Obstetricians n = 23	p value
	n (%)	n (%)	
Sex			
	n = 180	n = 21	0.100
Male	101 (56.1)	13 (61.9)	
Female	79 (43.9)	8 (38.1)	
Medical Education			
	n = 182	n = 23	0.001*
in Canada	134 (73.6)	9 (39.1)	
outside Canada	48 (26.4)	14 (60.9)	
Age Group			
	n = 181	n = 20	0.409
<30	12 (6.6)	0	
30 – 39	50 (27.6)	3 (14.3)	
40 – 49	62 (34.3)	9 (42.9)	
50 – 59	48 (26.5)	8 (38.1)	
60+	9 (5.0)	1 (4.8)	
Mean years practicing in Canada (and SD)	n = 178 16.5 +/-11.2	n = 21 9.7 +/- 9.9	0.008*
Practice Location			
	n = 182	n = 23	0.042*
Urban	79 (44.6)	14 (60.9)	
Semi urban	20 (11.3)	4 (17.4)	
Rural	78 (44.0)	5 (21.7)	
Practice Characteristics			
Perform deliveries			
	n = 182	n = 23	0.000
No	155 (85.2)	1 (4.3)	
Yes	27 (14.8)	22 (95.7)	
# of deliveries (and SD)	40.3 +/- 35.8	139.5 +/- 47.9	0.000
Mean no. of pregnant women cared for in past year (and SD)	n = 173 25.4 +/- 25.9	n = 22 152.9 +/- 64.7	0.000
Mean no. of years providing antenatal care (and SD)	n = 175 16.0 +/- 10.0	n = 21 16.1 +/- 8.9	0.967

SD = standard deviation; * = statistically significant

4.1.3 Physicians who do not offer MSS

All the obstetricians who responded to the survey offered MSS to their patients. Of the 182 family physicians who provided antenatal care, 13.1% did not offer to MSS to their patients. Table 4.3 describes reasons chosen by physicians for not offering MSS. The majority of these physicians (58.3%) reported that they were unaware that MSS was available in Newfoundland and Labrador. Of the 23 family physicians who did not offer MSS, 60.9 % practiced in rural areas and the remaining 39.1 % practiced in urban areas.

Table 4.3 Opinion and practice location of physicians who provide antenatal care in Newfoundland and Labrador but who do not offer MSS.

	Group; no. (%) of respondents
MSS Practice Characteristic	Family physicians n = 23
	n (%)
Opinion of those who do not offer MSS	
Unaware MSS was available	14 (58.3)
Creates undo anxiety in patients	6 (25.0)
Follow up is difficult to coordinate	3 (12.5)
Too many false positives	1 (4.2)
Too difficult to explain test and outcomes	1 (4.2)
Incompatible with my religious beliefs	0
Too many false negatives/positives	0
Too costly	0
Too time consuming to explain	0
Practice location:	n = 23
Urban	9 (39.1)
Semi-Urban	0
Rural	14 (60.9)

4.1.4 Physicians who offer MSS

Table 4.4 describes the practice characteristics of physicians who offer MSS to their patients. A larger proportion of obstetricians (100%) than family physicians (86.8%)

offered MSS; 87.0% of obstetricians offered MSS to all patients, whereas 60.1% of family physicians reported offering MSS to all pregnant women. Overall, 46.7% of physicians were from urban areas, 13.9 % practiced in semi-urban areas and 39.4 % reported practicing in a rural area.

Family physicians who offered MSS to only some women offered the screening test more often to women over the age of 35 at their due date and women with a family history of Down's syndrome or neural tube defect. Obstetricians reported that more women under the age of 35 chose to undergo MSS when offered (46.6%), compared to the family physician group (34.6%). All obstetricians ordered MSS in the correct gestational time frame, as compared to 83.4% of family physicians. When communicating screening results to patients, obstetricians communicated both positive and negative MSS results to patients in a shorter timeframe than family physicians, but this difference did not reach statistical significance.

Table 4.4 MSS practice characteristics of physicians who provide antenatal care in Newfoundland and Labrador.

MSS Practice Characteristic	Group; no. (%) of respondents: Family physicians n = 158	Obstetricians n = 23	p value
	n (%)	n (%)	
Practice location	n = 155	n = 23	0.049*
Rural	66 (41.8)	5 (21.7)	
Semi-Urban	21(13.3)	4 (17.4)	
Urban	71(44.9)	14 (60.9)	
Women offered[1]	n = 155	n = 23	
All pregnant women	95 (60.1)	20 (87.0)	0.011*
Women age 35 or older	58 (36.1)	3 (13.0)	0.033*
Women under age 35	10 (6.3)	0	0.366
Women with family history of DS or NTD	58 (36.7)	3 (13.0)	0.032*
Women who asked to be tested	45 (28.5)	4 (17.4)	0.606
Mean time spent discussing MSS with patient (minutes and SD)	n = 155 7.7 +/- 5.2	n = 21 9.2 +/- 4.4	0.150
% of pregnant women <35 of age offered MSS chose to have it (% and SD)	n = 130 34.6 +/- 34.2	n = 20 46.6 +/- 31.4	0.130
Physicians who ordered MSS at the correct gestational age (%)	n = 145 121 (83.4)	n = 23 23 (100.0)	0.046*
Communication of positive MSS results to patients			
	n = 158	n = 23	0.091
Within 48 hours	110 (69.6)	21 (91.3)	
Within 1 week	26 (16.5)	0	
Within 2 weeks	7 (4.4)	2 (8.7)	
At next clinical appointment	5 (3.2)	0	
Communication of negative MSS results to patients			
	n = 158	n = 23	0.463
Within 48 hours	21 (13.7)	5 (21.7)	
Within 1 week	24 (15.2)	3 (13.0)	
Within 2 weeks	11 (7.0)	0	
At next clinical appointment	96 (60.8)	15 (65.2)	

DS = Down's syndrome; NTD = neural tube defect; SD = standard deviation; * = statistically significant

[1] Physicians could choose more than one group of women to whom they routinely offer MSS.

Table 4.5 describes the distance to MSS follow up services in hours. As expected family physicians reported longer distances to amniocentesis, level II ultrasound and genetic counseling follow up services, but these were not statistically significant.

Table 4.5 Distances of health care providers in hours to follow up services for Maternal Serum Screening (MSS)

	Group; % of respondents			
Hours to MSS follow up services (and SD)	Family physicians n = 165, 165, 160	Obstetricians n = 22, 21, 22	Total n = 187, 186, 182	p value
Amniocentesis	2.3 +/- 6.5	1.4 +/- 1.8	2.2 +/- 6.2	0.160
Level II ultrasound[2]	2.1 +/- 5.8	1.6 +/- 2.9	2.0 +/- 5.5	0.713
Genetic Counseling	2.9 +/- 6.9	2.1 +/- 2.9	2.7 +/- 6.5	0.347

Table 4.6 describes physician knowledge of the false positive rate for MSS and the detection rates for the three prenatal diseases screened. Fewer than half (42.5%) of the family physicians correctly identified the false positive rate associated with MSS, as compared to 61.1% of obstetricians. Significantly more obstetricians than family physicians correctly identified the detection rate for Down's syndrome. The total respondents varied by question.

[2] Level two ultrasound is used to measure gestational age and fetal growth. The brain, heart, kidney, cord insertion, amniotic fluid volume, placental position and obvious maternal pelvic organ abnormalities are also noted. Level one ultrasound captures information about fetal number, fetal presentation, documentation of fetal life, placental location, assessment of amniotic fluid volume, assessment of gestational age, survey of fetal anatomy for gross malformations and an evaluation for maternal pelvic masses.

Table 4.6 Family physician and obstetrician knowledge of Maternal Serum Screening (MSS) characteristics

MSS Knowledge	Group; % of respondents Family physicians n = 127, 129 131, 120	 Obstetricians n = 18, 20 17, 18	p value
	n (%)	n (%)	
Correctly identified MSS false positive rate (%)	54 (42.5)	11 (61.1)	0.138
Correctly identified MSS detection rate for DS	23 (17.8)	9 (45.0)	0.006*
Correctly identified MSS detection rate for open NTD	53 (40.5)	9 (52.9)	0.326
Correctly identified MSS detection rate for Trisomy 18	44 (36.7)	5 (27.8)	0.462

DS = Down's syndrome; NTD = neural tube defect; * = statistically significant

The following table (Table 4.7) describes where physicians reported hearing about MSS. A significantly larger proportion of obstetricians than family physicians reported hearing about MSS at hospital rounds and on the internet whereas, a significantly larger proportion of family physicians reported hearing about MSS from patients.

Table 4.7 Sources of information pertaining to Maternal Serum Screening (MSS) reported by physicians who provide antenatal care in Newfoundland and Labrador

MSS information	Group; no. (%) of respondents: Family physicians n = 182	Obstetricians n = 23	Total n = 205	p value
Medical Journals	113 (62.1)	19 (82.6)	132 (64.4)	0.053
Colleagues	98 (53.8)	14 (60.9)	112 (54.6)	0.524
NL Medical Genetics Clinic pamphlet	94 (51.6)	9 (39.1)	103 (50.2)	0.058
CME sessions	81 (44.5)	15 (65.2)	96 (46.8)	0.061
Hospital rounds	34 (18.7)	11 (47.8)	45 (22.0)	0.001*
NLMA newsletter	36 (19.8)	3 (13.0)	39 (19.0)	0.438
Patients	29 (15.9)	0	29 (14.1)	0.039*
Internet	18 (9.9)	6 (26.1)	24 (11.7)	0.023*
Newspapers	14 (7.7)	0	14 (6.8)	0.168

CME = Continuing Medical Education; NL = Newfoundland and Labrador; NLMA = Newfoundland and Labrador Medical Association; * = statistically significant

When obstetricians and family physicians were questioned about their practice of MSS in the past 18 months, the majority of both groups (63.6% and 69.6% respectively) responded that their MSS practice had not changed (Table 4.8). The majority of both groups (family physicians 70.8%, obstetricians 78.9%) also reported that they would prefer a first trimester screening test rather than the present second trimester MSS test. There were no differences between obstetricians and family physicians when the two groups were asked if MSS affects their medicolegal risk. Approximately equal proportions of each group (family physicians 33.1%, obstetricians 30.4%) believed that MSS misleads their patient to believe that physicians can guarantee a healthy baby. Significantly more obstetricians than family physicians knew about the Provincial MSS Program.

Table 4.8 Family physician and obstetrician practice and opinion of Maternal Serum Screening (MSS) in Newfoundland and Labrador

Characteristic	Group; no. (%) of respondents Family physicians n = 185	 Obstetricians n = 23	p value
	n (%)	n (%)	
MSS practice in the past 18 months			
	n = 173	n = 23	0.336
Offer MSS more in past 18 months	51 (29.5)	5 (21.7)	
Offer MSS less in past 18 months	5 (2.9)	2 (8.7)	
No change in past 18 months	110 (63.6)	16 (69.6)	
Not sure	7 (4.0)	0	
MSS and medicolegal risk			
	n = 170	n = 22	0.249
MSS increases medicolegal risk	41 (24.1)	7 (31.8)	
MSS decreases medicolegal risk	43 (25.3)	8 (36.4)	
MSS does not affect medicolegal risk	86 (50.6)	7 (31.8)	
Believe MSS misleads patients to believe physicians can guarantee a healthy baby	n = 163 54 (33.1)	n = 23 7 (30.4)	0.797
Would prefer a 1st trimester screening test	n = 161 114 (70.8)	n = 19 15 (78.9)	0.456
Aware of Provincial MSS program	n = 168 135 (80.4)	n = 23 23(100.0)	0.019*

* = statistically significant

I also looked for differences between male and female physicians. As seen below, in Table 4.9, male physician respondents working in the province are significantly older and have been providing antenatal care for a significantly longer time than female respondents. Also, significantly more male physicians attended medical school outside of Canada. The two groups did not differ significantly in the number of women cared for, number of deliveries in the past twelve months nor in location of their practice.

Table 4.9 Practice characteristics of male and female physicians who provide antenatal care in Newfoundland and Labrador

Characteristic	Group; no. (%) of respondents Female physicians n = 88	 Male physicians n = 115	p value
	n (%)	n (%)	
Medical Education			
	n = 88	n = 115	0.002*
in Canada	71 (80.7)	70 (60.9)	
outside Canada	17 (19.3)	45 (39.1)	
Age Group			
	n = 85	n = 115	0.000*
<30	4 (4.7)	8 (7.0)	
30 – 39	34 (40.0)	19 (16.5)	
40 – 49	34 (40.0)	37 (32.2)	
50 – 59	13 (15.3)	41 (35.7)	
60+	0 (0)	10 (8.7)	
Mean years practicing in Canada (and SD)	n = 87 12.8 +/- 9.1	n = 114 17.6 +/- 11.7	0.001*
Practice Location			
	n = 88	n = 115	0.343
Urban	45 (51.1)	46 (41.8)	
Semi urban	11 (12.5)	14 (12.7)	
Rural	32 (36.4)	50 (45.5)	
Practice Characteristics			
Perform deliveries			
	n = 88	n = 115	
No	68 (77.3)	87 (75.7)	
Yes	20 (22.7)	28 (24.3)	0.461
mean # of deliveries (and SD)	70.3 +/- 60.3	84.0 +/- 66.8	0.474
Mean no. of pregnant women cared for in past year (and SD)	n = 87 44.4 +/- 52.5	n = 115 34.7 +/- 49.0	0.192
Mean no. of years providing antenatal care (and SD)	n = 87 13.4 +/- 8.2	n = 113 17.8 +/- 10.5	0.002*

SD = Standard deviation; * = statically significant

When MSS practices were analyzed further, it was found that female physicians offered MSS significantly more often to all their pregnant patients (Table 4.10) and within the correct timeframe. Females also reported positive screening results significantly more quickly to their patients than their male colleagues. The two groups did not differ in the time spent discussing MSS with patients nor in the percentage of patients under the age of 35 choosing to undergo the screening test.

Table 4.10 MSS practice characteristics of male and female physicians who provide antenatal care in Newfoundland and Labrador.

MSS Practice Characteristics	Group; no. (%) of respondents: Female physicians n = 88	Male physicians n = 115	p value
	n (%)	n (%)	
Those who offer MSS:			
	n = 88	n = 115	
All pregnant women	64 (72.7)	65 (56.5)	0.000*
Women age 35 or older	21 (23.9)	39 (33.9)	0.125
Women under age 35	5 (5.7)	5 (4.3)	0.749
Women with family history of DS or NTD	20 (22.7)	41 (35.7)	0.063
Women who asked to be tested	16 (18.2)	33 (28.7)	0.099
Time spent discussing MSS with patient (min and SD)	n = 86 8.0 (5.5)	n = 90 7.9 (4.6)	0.875
% of pregnant women <35 of age offered MSS chose to have it (% and SD)	n = 72 33.1 (29.3)	n = 78 39.0 (38.3)	0.298
Physicians who ordered MSS at the correct gestational age (%)	n = 81 74 (91.4)	n = 87 70 (80.5)	0.049*
Communication of positive MSS results to patients			
	n = 87	n = 93	0.012*
Within 48 hours	69 (83.1)	60 (69.0)	
Within 1 week	13 (15.7)	14 (16.1)	
Within 2 weeks	1 (1.2)	8 (9.2)	
At next clinical appointment	0 (0)	5 (5.7)	
Communication of negative MSS results to patients			
	n = 84	n = 90	0.249
Within 48 hours	9 (10.7)	15 (16.7)	
Within 1 week	18 (21.4)	10 (11.1)	
Within 2 weeks	5 (6.0)	6 (6.7)	
At next clinical appointment	52 (61.9)	59 (65.6)	

DS = Down's syndrome, NTD = neural tube defect, SD = standard deviation; * = statistically significant

As seen below in Table 4.11, male and female physicians did not differ significantly in their knowledge of MSS screening rates. The majority of female physicians (50.7%) reported the correct false positive rate associated with MSS,

compared to 40.3% of male physicians. Male and female physicians scored very similarly with regard to correctly identifying the detection rates for the three genetic abnormalities screened for by MSS. Total respondents varied by question.

Table 4. 11 Male and female physician knowledge of Maternal Serum Screening (MSS)

MSS Knowledge Characteristic	Group; % of respondents: Female physicians n = 75, 63, 64, 64	Male physicians n = 67, 84, 82, 72	p value
Correctly identified MSS false positive rate (%)	38 (50.7)	27 (40.3)	0.240
Correctly identified MSS detection rate for DS	14 (22.2)	18 (21.4)	1.000
Correctly identified MSS detection rate for open NTD	25 (39.1)	36 (43.9)	0.614
Correctly identified MSS detection rate for Trisomy 18	23 (35.9)	26 (36.1)	1.000

When physicians were asked about their MSS practice in the past 18 months (Table 4.12), approximately one-quarter of male and female physicians reported that they offered MSS more often at the time of the survey (26.6% and 30.6% respectively). Both groups were evenly split on the influence MSS had on their medicolegal risk. Approximately half of physicians thought that MSS had no affect on their medicolegal risk, while the remaining physicians were split between whether MSS increased or decreased their risk. The two groups did, however, differ significantly on whether MSS misleads patients to believe that physicians could guarantee a healthy baby. A larger proportion of male physicians than female physicians reported that MSS misleads

patients. Lastly, a significantly larger percentage of female physicians were aware of the Provincial MSS Program than their male colleagues.

Table 4.12 Male and female physician practice characteristics and opinion of Maternal Serum Screening (MSS)

Characteristic	Group; no. (%) of respondents Female physicians n = 85	 Male physicians n = 115	p value
	n (%)	n (%)	
MSS practice in the past 18 months			
	n = 85	n = 109	0.088
Offer MSS more in past 18 months	26 (30.6)	29 (26.6)	
Offer MSS less in past 18 months	2 (2.4)	5 (4.6)	
No change in past 18 months	57 (67.1)	68 (62.4)	
Not sure	0	7 (6.4)	
MSS and medicolegal risk			
	n = 83	n = 108	0.692
MSS increases medicolegal risk	21 (25.3)	28 (25.9)	
MSS decreases medicolegal risk	19 (22.9)	30 (27.8)	
MSS does not affect medicolegal risk	43 (51.8)	50 (46.3)	
Believe MSS misleads patients to believe physicians can guarantee a healthy baby	n = 80 18 (22.5)	n = 104 42 (40.4)	0.011*
Would prefer a 1st trimester screening test	n = 75 55 (73.3)	n = 105 74 (70.5)	0.456
Aware of Provincial MSS program	n = 80 75 (93.8)	n = 109 81 (74.3)	0.000*

* = statistically significant

Table 4.13 describes the personal and practice difference between family physicians who offer MSS to all their patients, family physicians who offer MSS to some of their patients, and those family physicians who do not offer MSS to their patients. As

noted below, there was a significantly larger proportion of male family physicians who do not offer MSS as compared to their female peers. The two groups of family physicians that offer MSS are younger in age than the group of family physicians who do not offer MSS. A larger percentage of family physicians in rural areas offered the screening test less often than their urban peers.

Also, the family physicians who did not offer MSS cared for significantly fewer pregnant women in the past year and also delivered fewer babies. The Boneferroni test found that family physicians who offered MSS to some or all did not differ significantly ($p = 0.802$). There was also no difference ($p = 0.130$) between family physicians who offered MSS to some and those that did not offer the screening test to their patients. Those who offered MSS to all their patients did differ significantly ($p = 0.012$) to physicians who did not offer MSS.

Table 4.13 Demographic and clinical characteristics of family physicians who offer MSS to all, some, or none of their patients

	Group; no. (%) of respondents			
Characteristic	Family physicians who offer MSS to all patients n = 103 (%)	Family physicians who offer MSS to some patients n = 63 (%)	Family physicians who do not offer MSS to patients n = 24 (%)	p value
Sex	n = 95	n = 63	n = 24	0.000*
Male	39 (41.5)	39 (62.9)	23 (95.8)	
Female	55 (58.5)	23 (37.1)	1 (4.2)	
Medical Education	n = 95	n = 63	n = 24	0.000*
in Canada	81 (85.3)	41 (65.1)	12 (50.0)	
outside Canada	14 (14.7)	22 (34.9)	12 (50.0)	
Age Group	n = 94	n = 63	n = 24	0.048*
<30	3 (3.2)	7 (11.1)	2 (8.3)	
30 – 39	38 (40.4)	8 (12.7)	4 (16.7)	
40 – 49	26 (27.7)	31 (49.2)	5 (20.8)	
50 – 59	23 (24.5)	16 (25.4)	9 (37.5)	
60+	4 (4.3)	1 (1.6)	4 (16.7)	
Mean years practicing in Canada (and SD)	n = 92 14.3 +/-10.1	n = 62 15.9 +/- 10.0	n = 24 19.8 +/- 13.5	0.162
Practice Location	n = 93	n = 61	n = 23	0.046*
Urban	47 (50.5)	23 (37.7)	9 (39.1)	
Semi urban	11 (11.8)	9 (14.8)	0	
Rural	35 (37.6)	29 (47.5)	14 (60.9)	
Practice Characteristics				0.309
Perform deliveries	n = 95	n = 63	n = 24	
No	80 (84.2)	52 (82.5)	23 (95.8)	
Yes	15 (15.8)	11 (17.5	1 (4.2)	
# of deliveries (and SD)	42.3 +/- 40.9	41.2 +/- 28.7	1	0.345
Mean no. of pregnant women cared for in the past year (and SD)	n = 90 29.3 +/- 26.2	n = 61 24.6 +/- 28.1	n = 22 11.7 +/- 7.8	0.016*
Mean no. of years providing antenatal care (and SD)	n = 91 14.4 +/- 9.9	n = 61 17.0 +/- 9.0	n = 23 19.9 +/- 12.0	0.094
Time spent discussing MSS with patient (and SD)	n = 93 7.3 +/- 4.5	n = 62 8.2 +/- 6.1	n/a	0.318
% of pregnant women <35 of age offered MSS choose to have it (% and SD)	n = 91 46.2 +/- 34.2	n = 63 14.0 +/- 22.9	n/a	0.000*

SD = standard deviation; * = statistically significant

Table 4.14 compares the MSS practices and opinions of family physicians who offer MSS to all their patients, family physicians who offer MSS to some of their patients and those family physicians who do not offer MSS to their patients. There was a significant difference in MSS practice in the past 18 months among the family physician groups. A larger percentage of physicians who do not offer MSS had not changed their MSS practices in the past 18 months than the other two family physician groups. A larger percentage of family physicians who offered MSS to some or all patients were more likely to have reported offering MSS more in the past 18 months than those family physicians who did not offer MSS.

A larger proportion of family physicians (58.3%) who did not offer MSS were unaware of the Newfoundland and Labrador MSS Program. There was no difference in attitudes about medico-legal risks among the three groups of physicians.

Table 4.14 MSS practice and opinion characteristics of family physicians who provide antenatal care in Newfoundland and Labrador.

	Group; no. (%) of respondents			
Characteristic	Family physicians who offer MSS to all patients n = 103	Family physicians who do offer MSS to all patients n = 63	Family physicians who do not offer MSS to patients n = 24	p value
	n (%)	n (%)	n (%)	
MSS practice in the past 18 months				
	n = 103	n = 61	n = 22	0.026*
Offer MSS more	32 (31.1)	14 (23.0)	0	
Offer MSS less	14 (13.6)	4 (6.6)	0	
No change	57 (55.3)	40 (65.6)	19 (86.4)	
Not sure	0	3 (4.9)	3 (13.6)	
MSS and medicolegal risk				
	n = 89	n = 62	n = 19	0.943
MSS increases risk	23 (25.8)	13 (21.0)	5 (26.3)	
MSS decreases risk	19 (21.3)	21 (33.9)	3 (15.8)	
MSS does not affect risk	47 (52.8)	28 (45.2)	11 (57.9)	
Believe MSS misleads patients to believe physicians can guarantee a healthy baby	n = 85 22 (25.9)	n = 60 23 (38.3)	n = 18 9 (50.0)	0.132
Would prefer a 1st trimester screening test	n = 83 57 (68.7)	n = 57 40 (70.2)	n = 21 17 (81.0)	0.725
Aware of Provincial MSS program	n = 88 81 (92.0)	n = 59 47 (79.7)	n = 21 7 (33.3)	0.000*

* = statistically significant

The physician survey concluded with an open-ended question on the physicians' opinions of the MSS program. The majority of physicians (61.4%) took the opportunity to express their views and opinions on the MSS program; 45.2% of physicians who responded to this question thought that the MSS program was beneficial with many

describing the program as "excellent". Some physicians used this question to complain about MSS, 7.9% wrote that MSS distressed patients, 8.7% thought the false positive screening rate was too high, and 6.3% thought that patients had no interest in the screening test. Physicians were also asked if they had any comments they wanted to share. This second open-ended question had a very low response rate as the majority of physicians used the first open-ended question to express their thoughts and opinions of the Provincial MSS Program.

4.2 Patient Survey

Of the 300 surveys handed out, 200 patients returned the survey complete for a total response rate of 66.7%. The average age of mothers who delivered between October 8th and November 27th of 2003 was 29.1 years (Table 4.15).

Table 4.15 presents the demographic characteristics and MSS knowledge of the women surveyed. The majority of women were 35 years of age or younger (84.5%) and lived in urban areas (55.1%). Almost all women (95.5%) reported visiting a physician between 15 and 20 weeks gestation. Among women surveyed, 45.3% reported discussing the screening test with their family physician while 24.1% reported discussing MSS with their obstetrician.

Of the 117 women who discussed MSS with a physician, 54 (46.2%) chose to undergo MSS screening. Therefore, 54 of the 200 women surveyed underwent MSS, for an overall MSS uptake rate of 27.0%.

Table 4.15 Characteristics among women who gave birth and their experiences with MSS.

Characteristic	Group; no. (%) of respondents Patients n = 200
	n (%)
Age :	n = 200
< 25 years	45 (22.5)
25 – 30 years	56 (28.0)
31 – 35 years	68 (34.0)
> 35 years	31 (15.5)
average age (and SD)	29.1 +/- 5.2
Location of residence:	n = 196
Urban	108 (55.1)
Semi urban	15 (7.7)
Rural	73 (37.2)
Familiar with MSS:	n = 200 139 (69.5)
Source of information:	n = 200
Family Physician	92 (46.0)
Obstetrician	49 (24.5)
Not aware of MSS	52 (26.0)
Friends or family	24 (12.0)
Media	9 (4.5)
Public Health Nurse	5 (2.5)
Saw a physician between 15-20 weeks:	n = 200
No or Don't Know	11 (5.5)
Yes	189 (94.5)
MSS discussed	117 (62.9)
Time physicians spend discussing MSS (and SD)	8.6 +/-8.1
Underwent MSS	54 (31.8)
Underwent Amniocentesis	13 (6.4)
Underwent Ultrasound	197 (98.5)

SD = Standard deviation

As seen in Table 4.16 women undergoing MSS were significantly older than women who did not undergo the screening test. A larger percentage of these women

discussed MSS with their family physician or obstetrician between 15 and 20 weeks of their pregnancy.

Table 4.16 Characteristics of women who underwent MSS and who did not undergo MSS

Characteristic	Group; no. (%) of respondents: Patients who underwent MSS n = 53	Patients who did not undergo MSS n = 147	p value
	n = 53	n = 147	0.002*
Average age (and SD)	32.0 +/- 4.9	29.4 +/- 5.1	0.002*
Location of residence:	n = 52	n = 144	0.461
Urban	28 (53.2)	80 (55.6)	
Semi urban	6 (11.5)	9 (6.3)	
Rural	18 (34.6)	55 (38.2)	
Familiar with MSS	n = 53	n = 147	0.000*
	52 (98.1)	87 (59.2)	
Source of MSS Info:	n = 53	n = 147	0.006*
Family Physician	33 (62.3)	59 (40.1)	
Obstetrician	25 (47.2)	24 (16.3)	0.000*
Not aware of MSS	0	52 (35.4)	0.000*
Friends or family	6 (11.3)	18 (12.3)	0.859
Media	0	9 (6.1)	0.065
Public Health Nurse	0	5 (3.4)	0.174
Saw a physician between 15-20 weeks:	n = 53	n = 147	0.123
No or Don't Know	0	11 (7.5)	
Yes	53 (100)	136 (92.5)	
MSS discussed	50 (100)	67 (49.3)	0.000*
Minutes MSS was discussed	9.96 +/- 10.4	7.38 +/- 5.4	0.113
Would undergo MSS again	34 (79.1)	n/a	
Underwent Amniocentesis	6 (11.3)	7 (4.8)	0.097
Underwent Ultrasound	52 (98.1)	145 (98.6)	0.787
Screening result:	n = 52		
Don't know	1 (1.9)	n/a	
Screen negative	42 (80.8)	n/a	
Screen positive	9 (17.3)	n/a	
Underwent Counseling:	n = 53		
Genetic Counselor	7 (13.2)	n/a	
Family Physician	4 (7.5)	n/a	
Obstetrician	3 (5.7)	n/a	
Psychologist	0	n/a	

SD = Standard deviation; * = statistically significant

Table 4.17 describes the women surveyed by age categories. It was found that a larger percentage of women in the older age categories were familiar with and had undergone MSS. These older age categories reported that family physicians were an important source of MSS information. A larger percentage of women in the older age categories also reported undergoing amniocentesis than women in younger age categories.

4.17 Characteristics by age groups of the patient study population.

Characteristic	Group; no. (%) of respondents: < 26 years old n = 45	26-30 years old n = 55	31-35 years old n = 69	> 35 years old n = 31	p value
Location of residence:	n = 43	n = 54	n = 68	n = 31	0.600
Urban	24 (55.8)	24 (44.4)	40 (58.8)	20 (64.5)	
Semi urban	4 (9.3)	4 (7.4)	5 (7.4)	2 (6.5)	
Rural	15 (34.9)	26 (48.1)	23 (33.8)	9 (29.0)	
Familiar with MSS	22 (48.9)	35 (63.6)	56 (81.2)	26 (83.9)	0.001*
Source of MSS Info:	n = 45	n = 55	n = 69	n = 31	
Family Physician	10 (22.2)	26 (47.3)	38 (55.1)	18 (58.1)	0.002*
Obstetrician	11 (24.4)	9 (16.4)	17 (25.0)	12 (38.7)	0.148
Not aware of MSS	19 (42.2)	18 (32.7)	13 (18.8)	2 (6.5)	0.001*
Friends or family	5 (11.1)	8 (14.5)	8 (11.6)	3 (9.7)	0.910
Media	3 (6.7)	3 (5.5)	3 (4.3)	0	0.557
Public Health Nurse	3 (6.7)	0	2 (2.9)	0	0.141
Saw a physician between 15-20 weeks:	n = 45	n = 55	n = 69	n = 31	
No or Don't Know	8 (17.7)	3 (5.5)	0	0	0.002*
Yes	37 (82.2)	52 (94.5)	69 (100)	31(100)	
MSS discussed	14 (35.0)	26 (54.2)	50 (73.5)	27 (90.0)	0.000*
Minutes MSS was discussed (SD)	7.7 +/- 4.5	7.2 +/- 6.2	7.5 +/- 5.0	12.1 +/- 13.5	0.193
Chose not to undergo MSS	26 (66.7)	31 (63.3)	43 (65.2)	16 (53.3)	
Don't Know	7 (17.9)	5 (10.2)	1 (1.5)	1 (3.3)	
Underwent MSS	6 (15.4)	13 (23.2)	21 (30.9)	13 (41.9)	0.017*
Would undergo MSS in next pregnancy	5 (71.4)	10 (83.3)	15 (75.0)	8 (61.5)	0.667
Underwent amniocentesis	2 (4.4)	0	6 (8.7)	5 (16.1)	0.024*
Underwent ultrasound	44 (97.8)	53 (96.4)	69 (100)	31 (100)	0.337
Screening result:	n = 6	n = 13	n = 24	n = 13	0.129
Don't know	0	0	1(4.2)	0	
Screen negative	6 (100)	12 (92.3)	19 (79.2)	7 (53.8)	
Screen positive	0	1 (7.7)	4 (16.7)	6 (46.2)	
Underwent Counseling	0	0	4(100)	6 (100)	0.004*
Genetic Counselor	0	0	4(100)	4 (66.7)	0.011*
Family Physician	0	0	2(50.0)	3 (50.0)	0.027*
Obstetrician	0	0	2 (50.0)	2 (33.3)	0.141

SD = Standard deviation; * = statistically significant

Table 4.18 describes the women surveyed by the size of the community in which they reside. It was found that a larger percentage of women in semi-urban areas were unsure if they had undergone MSS.

4.18 Characteristics by size of residence community among women surveyed.

Characteristic	Group; no. (%) of respondents Urban n = 108	Semi-urban n = 15	Rural n = 73	p value
Average age (and SD)	n = 108 30.6 +/- 5.5	n = 15 29.6 +/- 5.3	n = 72 29.6 +/- 4.7	0.757
Familiar with MSS	n = 108 75 (69.4)	n = 15 10 (66.7)	n = 73 51 (69.9)	0.970
Source of MSS Info:	n = 108	n = 15	n = 73	
Family Physician	49 (45.4)	9 (60.0)	33 (45.2)	0.548
Obstetrician	26 (24.1)	3 (20)	19 (26.0)	0.875
Not aware of MSS	31 (28.7)	4 (26.7)	16 (21.9)	0.593
Friends or family	14 (13.0)	2 (13.3)	8 (11.0)	0.914
Media	5 (4.6)	0	3(4.1)	0.697
Public Health Nurse	3 (2.8)	1(6.7)	1 (1.4)	0.483
Saw a physician between 15-20 weeks:	n = 108	n = 15	n = 73	0.336
No or Don't Know	3 (2.8)	1 (6.7)	6 (8.2)	
Yes	105 (96.2)	14 (93.3)	67 (91.8)	
Underwent Amniocentesis	11 (10.2)	1 (6.7)	1 (1.4)	0.065
MSS discussed	65 (61.9)	9 (69.2)	41 (64.1)	0.861
Minutes MSS was discussed (and SD)	9.31 +/- 9.4	9.50 +/- 8.9	7.39 +/- 5.8	0.369
Chose not to undergo MSS	64 (66.0)	5 (33.3)	45 (65.2)	0.089
Don't Know	3 (3.1)	4 (26.7)	7 (10.1)	0.035*
Underwent MSS	30 (30.9)	6 (40.0)	17 (24.6)	0.461
Would undergo MSS in next pregnancy	24 (75.0)	1 (25.0)	12 (80.0)	0.080
Screening result:	n = 32	n = 6	n = 17	0.173
Don't know	1 (3.1)	0	0	
Screen negative	24 (75.0)	3 (50.0)	16 (94.1)	
Screen positive	7 (21.9)	3 (50.0)	1 (5.9)	
Underwent Counseling:	n = 7	m = 3	n = 1	
Genetic Counselor	5 (71.4)	2 (66.7)	1 (100)	0.094
Family Physician	3 (42.9)	1 (33.3)	1 (20.0)	0.483
Obstetrician	1 (14.3)	2 (66.7)	1 (100)	0.006*

SD = Standard deviation; * = statistically significant

As seen in the table below, a larger proportion of patients in every community size visited a family physician between 15 and 20 weeks of gestation as compared to those visiting obstetricians. Regardless of type of physician seen or where the patient lived, MSS was discussed with the majority of patients. Although a greater proportion of patients in each area reported discussing MSS with their obstetrician than with their family physician (Table 4.19).

Table 4.19 Patients who visited physicians between 15 and 20 weeks of their pregnancy and their experiences with Maternal Serum Screening (MSS) by place of residence

	Group; no. (%) of respondents				
Between 15 and 20 weeks of pregnancy	Urban	Semi-urban	Rural	Total	p value
Visited Family Physician	n = 77	n = 10	n = 52	n = 139	0.169
MSS discussed					
No or Can't remember	33 (42.8)	5 (50.0)	21 (40.4)	59 (42.5)	
Yes	44 (57.1)	5 (50.0)	31 (59.6)	80 (57.6)	
# of min(and SD)	8.0 +/- 6.7	12.5 +/- 11.9	7.0 +/- 5.4	7.7 +/- 6.5	0.284
underwent MSS	21 (47.7)	5 (100)	12 (38.7)	8 (47.5)	0.002*
Visited Obstetrician	n = 41	n = 9	n = 31	n = 81	0.613
MSS discussed					
No	10 (24.4)	1 (11.1)	6 (19.4)	17 (21.0)	
Can't remember	1 (2.4)	0	4 (12.9)	5 (6.2)	
Yes	30 (73.2)	8 (88.8)	21 (67.7)	59 (72.8)	
# of min(and SD)	10.8 +/- 11.1	6.6 +/- 3.5	9.1 +/- 6.0	9.6 +/-8.9	0.625
underwent MSS	14 (46.7)	5 (62.5)	10 (47.6)	29 (49.2)	0.447

SD = Standard Deviation; * statistically significant

4.3 Laboratory Data

The table below describes actual physician use of MSS in 2003, obtained from the Provincial MSS Program. A total of 355 different physicians ordered the screening test at least once. The majority of physicians (53.2%) practiced in rural areas, with a little over a third (37.5%) practicing in urban areas.

Table 4.20 Physician use of MSS reported by the Newfoundland and Labrador MSS Program for 2003

Practice Location	Physicians using MSS (%) n (%)
Urban	133 (37.5)
Semi-Urban	33 (9.3)
Rural	189 (53.2)
Total	355 (100)

There were 1049 samples received by the Provincial Maternal Serum Screening Program in 2003; 66 samples were received too early and 13 samples were received too late. Subtracting these 79 samples that were received outside the 15 to 20 gestational week timeframe of MSS, there were 970 (92.5%) samples that were ordered within the correct time and analyzed.

Using the total births of 2002[3] (Newfoundland and Labrador Centre for Health Information, 2003), 970 out of a possible 4860 possible women were analyzed, giving an overall 22% MSS uptake rate.

[3] The total births for 2003 are currently not available.

Table 4.21 describes the false positives associated with the MSS as reported by the Provincial MSS Program. There were no true positives encountered by the Program in the year of 2003 and the overall false positive rate was 13.1%.

Table 4.21 False Positives reported by the Newfoundland and Labrador MSS Program for 2003

Practice Location	False Positives n (%)
Open Neural Tube Defects	28 (2.9)
Down's Syndrome	95 (9.8)
Trisomy 18	4 (0.4)
Overall false positive rate	13.1
Samples from women < 35.5 years old	52 (5.9)
Samples from women > 35.5 years old	46 (32.6)

Chapter 5 – Discussion

5.1 MSS Rates

Our study found that 88.8% of physicians were offering MSS screening to their patients. Of the physicians who were offering MSS, 63.5% were found to be offering MSS to all patients. The remaining 36.5% were offering MSS to selective groups of patients (women who asked to be tested or groups of women considered to be "high risk").

Twenty-seven percent of the patients surveyed underwent MSS, 62.9% reported that they had discussed MSS when they visited a physician between 15 and 20 weeks and 46.2% of these patients chose to undergo MSS.

Information obtained from the Provincial MSS Program confirmed that the MSS uptake rate in Newfoundland and Labrador was 22%. This rate compares to 48% in Ontario (Summers, 2003) and 68% in Manitoba (Karen MacDonald, Personal Communications, April 29, 2004). Internationally, these uptake rates compare to 65% of pregnant women who underwent maternal serum screening in France in 1998 (Muller, 2002).

In a survey of Newfoundland and Labrador physicians in 2000, Chandra et al. (2003) found that only 29% of physicians were offering MSS to all patients. Our study found nearly 65% of responding physicians were offering MSS to all their patients. However, there are still fewer physicians offering MSS to all patients compared to other provinces in Canada. In a similar study done in

Ontario, Carroll et al. (1997) discovered that 88% of health care providers were offering MSS to all pregnant women, compared to 63% in Newfoundland and Labrador.

The overall improvement in the number of physicians offering MSS to women may be attributed to the MSS promotional and educational sessions held across the province in 2002. Promotion included television, radio and newspaper spots. MSS education was done by a public health nurse who traveled across the province holding MSS educational sessions in every hospital that performed deliveries.

There has been an improvement in the number of physicians offering MSS, but there are still many physicians offering the screening test selectively to only certain groups of women. There is, therefore, still much education and promotion to be done with this screening tool.

5.2 Who is being offered MSS

Our study discovered that there were three types of physicians with regard to MSS practice: those who offered MSS to all patients; those who offered MSS to selected groups of patients; and those who did not offer MSS. Eighty-seven percent of obstetricians offered MSS to all patients. Significantly fewer family physicians offered MSS to all their patients; 52.2% of family physicians offered MSS to all women and 34.6% offered MSS selectively to their patients. The remaining 13.2% of family physicians did not offer MSS.

Therefore, a total of 47.8% of family physicians reported either not using MSS or offering it to selected groups of women [including women who asked to be tested and/or those considered to be at "high risk" (women over the age of 35 years old and/or those with a family history of Down's syndrome or open NTD)].

Of all patients who visited a physician between 15 and 20 weeks, a total of 31.8% underwent the prenatal screening test. The concept of selective MSS screening was also seen in this portion of our study. There was a significant difference among the age categories of women who were familiar with MSS. Forty-eight percent of the women surveyed under the age of 26 were familiar with MSS; this compares to nearly 84% of women who were over 35 years of age. Significantly larger proportions of women in older age groups reported that their family physician discussed MSS with them and significantly larger proportions of older women chose to have the MSS test.

The relationship between knowledge of MSS and age was also found in a study done in Ontario (Goel et al., 1998). Goel et al. evaluated patient knowledge of MSS using a MSS knowledge questionnaire. The investigators discovered that MSS knowledge was correlated positively with age. A woman's likelihood of carrying a fetus with a genetic abnormality increases with age. This is well known among physicians and among women of child-bearing age. Women over the age of 35 therefore tend to be more informed regarding birth defects and the prenatal tests available.

MSS uses population-based risk ratios and it is therefore inappropriate to

recommend MSS solely to women in high risk groups. The results that nearly 50% of family physicians are offering MSS to selective groups of women are a cause of concern for the Provincial MSS Program, as MSS is intended to be a population based screening tool. Risk rates are calculated by comparing the analyzed biochemical marker levels to levels typically seen in the general population. It is, therefore, evident that the message that all women should be offered MSS screening is not known throughout the health care and general community.

5.3 Who is offering MSS

Our study found that a larger percentage of obstetricians than family physicians were offering MSS to all patients. Obstetricians cared for significantly more pregnant women and performed more deliveries, on average, than family physicians.

These findings are consistent with the two different fields of medicine. Obstetrics is the branch of medicine specializing in pregnancy, labour, and the period immediately following childbirth. Family physicians do not typically specialize in one aspect of medicine. They are primary care providers and often serve as the first point of contact patients have with the health care system. Obstetricians receive more education and experience in prenatal care and would therefore have more exposure to prenatal disease and high risk pregnancies.

Physicians who were offering MSS to all their patients were more often

younger, female and graduates of medical school in Canada. This would seem to make sense as MSS is a relatively new prenatal screening test, being first introduced in Canada in 1993. MSS would be more familiar to recent medical school graduates and, therefore, younger physicians. These advances in prenatal screening may not have been offered in foreign countries and therefore may not have been emphasized in foreign medical schools. Chandra et al (2003) similarly found in her 2000 survey of Newfoundland and Labrador physicians that female physicians were more likely to offer MSS.

Screening seemed to be related to how often the physician encountered the issues surrounding the screening test- how relevant prenatal diseases were to the physician's practice. Difference in MSS practice among obstetricians and family physicians is of particular importance in our province. Women in Newfoundland and Labrador are typically under the care of a family physician until the third trimester of pregnancy. Consequently, by the time a pregnant woman visits an obstetrician, it is too late to order MSS. The majority of patients will depend on their family physician for MSS screening. It is therefore essential that family physicians discuss all the available prenatal testing options with their patients.

5.4 Who is not offering MSS

Eleven percent of physicians were not offering MSS to their patients. All of these physicians (n = 23) were family physicians and accounted for 13.7% (n = 23) of the total family physician respondents providing antenatal care in the past

twelve months. These physicians more often attended medical school outside of Canada, were older and had cared for significantly fewer pregnant women in the past twelve months.

The majority (58.3%) of family physicians who reported not offering MSS to their patients reported that they were unaware that the screening test was available in Newfoundland and Labrador. We found that fewer physicians were not offering MSS since the study done by Chandra et al. (2003). Chandra discovered in her 2000 survey of physicians that 16% of physicians were not offering MSS to their patients.

Offering MSS may, therefore, be related to training. This point underscores the need for Continuing Medical Education for all physicians, specifically surrounding new tests that become available in the province.

5.5 Urban and rural differences

There was no difference in MSS use among women from urban and rural areas. However, among women who visited a family physician between 15 and 20 weeks, a significantly larger percentage of women living in semi-urban areas had MSS than women living in either urban or rural areas. This finding was supported in the physician survey of our study which found that all physicians in semi-urban areas providing antenatal care offered MSS.

This finding also suggests that the uptake of MSS is not an access issue. It may be explained by local physicians taking an active role in MSS promotion. A

theory proposed by Dixon (1990) explains that the adoption or promotion of a new genetic test by professional leaders in smaller communities may have a greater effect on diffusion in those communities than announcements of consensus on the part of nationally prominent physicians and scientists that a new technology should be adopted. This is of particular importance in Newfoundland and Labrador, as there are a large number of small communities located throughout the province. If MSS screening is to become widespread throughout the Newfoundland and Labrador, it would seem that local physicians should be of primary importance in the introduction and promotion of the screening test.

5.6 Physician knowledge and attitude towards MSS

Physicians did not know the particular detection rates or false positive rates associated with MSS. However, the physicians who used the screening test ordered it more often within the 15 to 20 gestational week timeframe and also reported positive screening results back to patients more quickly.

Obstetricians ordered MSS more often within the correct timeframe of 15 to 20 weeks. Obstetricians also reported positive MSS screening results back to patients more quickly than family physicians. The risk associated with MSS relies heavily on the correct dating of the gestational age of the fetus. Errors in gestational age estimates are the single largest contributor to inaccuracies of risk estimation (Carroll, 1997). Therefore ordering MSS within the correct timeframe and allowing patients enough time to have follow-up ultrasound (used to verify

the actual gestational age) is very important to this screening test.

The data obtained from the Provincial Medical Genetics clinic supported the point that most physicians were ordering MSS within the correct timeframe; 92.5% of samples obtained from physicians were within the acceptable time of 15 to 20 gestational weeks. This information also indicates that 7.5% of physicians are currently ordering the screening test incorrectly.

Chandra et al. (2003) found that in 2000, only 70.0% of physicians were ordering MSS within the correct range of 15 to 20 weeks. She also found that family physicians ordered MSS at the incorrect gestational age more often than obstetricians.

Physicians did not seem to differ with regards to how MSS affected their medicolegal risk. Approximately the same percentage of physicians thought that MSS increases their medicolegal risk as those which reported that MSS decreases their medicolegal risk; 48.4% of physicians reported that MSS had no effect on their medicolegal risk.

In the survey completed by Chandra et al. in 2000, 20.0% of respondents thought that MSS influenced their medicolegal risk and 41.0% thought that MSS did not alter their medicolegal risk. The physicians who felt that MSS affected their medicolegal risk in Chandra's study cannot be compared to our study, as the question posed by Chandra et al. did not specify a definition for the term "influenced". It could be taken to mean either increase or decrease in medicolegal risk.

When physicians in our survey were asked about the timing of prenatal screening, 70.8% of family physicians and 78.0% of obstetricians reported preferring a first trimester screening test. Prenatal screening is currently being offered throughout Canada, with many larger centers using a combination of first and second trimester screening to increase sensitivity and specificity screening rates. There is presently nobody trained in Newfoundland and Labrador to measure the ultrasound markers utilized in the current first trimester prenatal screening test.

These findings suggest that for the time being MSS is the only option for Newfoundland and Labrador physicians. There is still room for improvement with respect to physician MSS knowledge. More continuing medical education is needed on the topic of prenatal screening, as previous MSS education and promotion have been only moderately successful.

5.7 Patient familiarity with MSS

The most common source of MSS information among women surveyed was their family physician; 45.3% reported that they had discussed MSS with their family physician. This compares with 24.1% and 11.8% of women who discussed MSS with their obstetricians or family and friends respectively. There were no differences reported in sources of MSS information among women from different sized communities. Of the women in our study who discussed MSS with their physician, 53.8% chose not to undergo the screening test.

Exactly what women in Newfoundland and Labrador know about MSS is not known. Also unknown is why so many women decline MSS when it is offered by their physician. This is a potential area for further research. Education of women about MSS is also warranted.

5.8 False positive screening results

There were no true positive results reported by the Provincial MSS Program, ie. there were no open NTDs, DS, or Trisomy 18 babies born to women screening positive. The lack of open NTD true positives maybe partly explained by the recent fortification of food with folic acid throughout Canada.

The Provincial Maternal Serum Screening Program reported false positive rates of 2.9% (n = 28), 9.8% (n = 95) and 0.4% (n = 4) for open NTDs, Down's Syndrome and Trisomy 18 respectively among the women screened in 2003. This gave an overall false positive rate of 13.1% in 2003. This false positive rate is higher than that reported by the Ontario MSS Program which reported an overall false positive rate of 9.4% between October 1993 and September 2000. Ontario's rate was comprised of 2.0%, 7.2% and 0.2% false positive rates for NTDs, Down's Syndrome and Trisomy 18 respectively (Summers, 2003).

The high number of false positives associated with MSS was reported by physicians as a negative aspect associated with MSS. Reasons that were reported by physicians for not offering MSS were the large number of false positives associated with the test, the complexity of explaining the test and outcome to

patients and the undue anxiety that the test created in patients.

Similar rationales were reported in other studies which examined physician opinion of MSS. Green (1994) and Chodirker (1989) both found that patient anxiety was a common concern expressed by physicians. Physicians have often reasoned that MSS causes undue anxiety in their patients and, therefore, offering MSS does more harm than good. With this in mind Goel et al. (1998) completed a study on MSS and patient anxiety by following 2020 women who underwent MSS in Ontario. This study determined that MSS was not causing serious psychological harm to women and that women were not as concerned as practitioners thought.

In my study, of the women who underwent MSS screening and who received a false positive screening result, only 73% reported that they would not undergo MSS screening in their next pregnancy. This finding was also reported in a study published in 2000 by Rausch et al. In an age-matched comparison, 108 women who had a false positive in a previous pregnancy were significantly less likely than 108 women who were screen-negative to participate in maternal serum screening in their next pregnancy. The investigators proposed that reducing the false positive rate in prenatal serum screening would alleviate maternal anxiety and would probably lead to more stable participation among women undergoing MSS in subsequent pregnancies (Rausch et al., 2000).

The Provincial MSS Program reported that women over the age of 35 accounted for 13.9 % of the samples analyzed and had a false positive rate of

32.6%. Women under the age of 35 accounted for 86.1% of the samples and had a false positive rate of 5.9%. Older women are at an increased risk for carrying an affected fetus; this group would therefore be expected to have increased false positive and true positive rates associated with their pregnancy. The increased false positive rate associated with MSS in Newfoundland and Labrador may be explained by the large number of women over the age of 35 undergoing the screening test.

Normally, samples which are analyzed outside the 15 to 20 gestational week timeframe would give inaccurate risk assessments and inappropriate false positive rates. However, these samples are not likely to blame for the elevated false positive rate associated with the Provincial MSS false positive screening rate, as the Provincial MSS Program omitted these samples before calculating the overall rate. The high false positive rate in women over the age of 35 years of age is likely contributing to the overall false positive rate.

This is a potential problem associated with selective based screening. MSS uses population-based risk ratios and therefore offering the screening test to certain groups of women skews the overall false positive rate. Physicians complain that there is an extraordinarily high false positive rate associated with MSS but it may be their MSS practice which contributes to this problem. Physicians should understand that MSS benefits younger women, as well as, if not better than older women. Younger women experience the three prenatal diseases

screened by MSS, but do not have the high false positive rates associated with the screening test as compared to women in older age groups.

Also, the high false positive screening rate described in the study may be explained by the biochemical marker thresholds or cutoffs set by the screening program. In addition, there is the potential to lower the false positive rate by expanding the maternal serum screening program to include a fourth biochemical marker, inhibin A.

5.9 Limitations of study

There are several limitations to my study. Data from the physician component of our study came from self-reported questionnaires. This type of information relies on the individual to report his or her information and may select individuals who are more interested in the area being studied. It may also select individuals who are more likely to practice evidence based medicine and therefore would be more familiar with MSS.

Another negative aspect of self-reporting which may compromise the validity of our findings is that respondents may be more likely to report socially acceptable responses. Many consider MSS a controversial screening tool, as it involves identifying fetuses with genetic abnormalities with the possibility of pregnancy termination. Physicians may report offering MSS more because of its perceived importance to public health or anecdotal evidence suggests that they may offer MSS less because of religious reasons. Physicians may, therefore,

withhold their true MSS practices and beliefs and report more socially desirable responses.

In the patient section of our study, there would also be recall bias associated with the self-reported nature of the questionnaires. Women were surveyed up to 20 weeks after the screening window. Some women may have forgotten which tests were offered and ordered by their physician. Another limitation of the patient survey was that it did not encompass the entire province. Only women who gave birth at the Women's Health Centre in St. John's were surveyed. The Women's Health Centre is located in a major tertiary care hospital and would have serviced more high risk pregnancies. There might have been a selection bias associated with this aspect of my study. This somewhat different patient population was discovered when the Provincial MSS uptake rate was compared to the uptake rate reported by patient component of the study. The women in our study reported a MSS uptake rate of 27%, whereas the overall uptake rate for the province was 22%.

Lastly, a limitation associated with the laboratory data was that the information was only available in aggregate form (and the analysis was therefore somewhat limited).

5.10 Strengths of study

The main positive aspect associated with our study was that there were three sources of information regarding MSS in Newfoundland and Labrador.

Information came from each group involved in prenatal screening in the province: physicians, patients and the Provincial Medical Genetics Clinic. A more complete picture of MSS was available because of this triangulation of information.

Another strength associated with this study was the high response rates obtained from the physician and patient components of the study. The samples also seemed to be representative of each population.

Lastly, the impact of the new MSS Program in Newfoundland and Labrador was analyzed. This program was established after the survey of physicians done by Chandra et al. (2003) and therefore the impact of the Provincial MSS Program was examined in this study.

5.11 Recommendations

Since its introduction, the Provincial MSS Program has had modest success in physician awareness and uptake. This study found that there are still women not being offered MSS by their physicians. Some physicians still report being unaware of MSS in Newfoundland and Labrador. This was also reported by physicians in the 2000 survey of physicians done by Chandra et al. (2003). Since Chandra's study however, there has been a team which crossed the province conducting seminars to inform prenatal care providers of the government-funded MSS program.

This continued lack of awareness, especially in rural areas, could be explained by the high turnover rate of physicians in Newfoundland and Labrador.

New family physicians are continuously recruited to these areas, some of whom may not be familiar with the programs available in Newfoundland and Labrador.

Physicians in our study reported a definite lack of knowledge surrounding the details of the screening test. Continuing Medical Education sessions on MSS would benefit all physicians and may serve to increase the MSS uptake rate in the province. Professional organizations that represent physicians could also take a more active role in disseminating information on new practice guidelines. Special efforts could be made to reach older male physicians as our study found that this physician group was less likely to discuss and offer MSS.

Educating women of childbearing age about MSS may be another option to increase MSS screening. Workshops, public service announcements and distributing MSS brochures at baby clinics, community centers and family practices may serve to educate and inform pregnant women. Although the risk for Down's syndrome increases with maternal age, an estimated 75% of affected fetuses are born to mothers younger than 35 years of age because of the number of women giving birth at this time (Loncar et al., 1995). It is, therefore, important to inform women of these risks and to provide all pregnant women the option of noninvasive screening.

It is recommended that a further review of the Provincial MSS screening rates is warranted. The high number of false positives associated with the test was reported by physicians as a reason for not offering the test to all their patients. Upon analysis, it was discovered that the false positive rate for the province was

much higher than the recorded literature value. An investigation into this rate may be able to address one of the complaints physicians have with the MSS Program.

A cost benefit analysis of the program is also warranted. In 2003, there were a total of 1049 samples analyzed by the Provincial MSS Program, resulting in 127 false positives. There were 0 true positives. The Provincial MSS Program utilizes many different groups and resources throughout the health care system. In 2003 it did not discover one affected pregnancy. As developments and demands increase in the health care delivery system, new programs should be analyzed thoroughly to ensure their cost effectiveness.

More study on patient knowledge and attitude of MSS would also be useful. If repeated, the patient survey could be expanded in certain sections. Asking patients more specifically about their conversations about MSS with their physicians would give a more accurate account of how MSS information is presented to women in Newfoundland and Labrador. These additional results could be used to examine how information influences their decision to undergo screening. Other patient studies of maternal serum screening have indicated that the nature of the information given to women, and how it was presented, influenced whether screening was done (Marteau et al., 1992; Gekas et al., 1999). Also asking women more personal questions about their socioeconomic background may determine specific groups who are not being offered the screening test.

As this is the first prenatal genetic screening program in place in the province, further analysis of overall MSS knowledge and opinion is warranted. As genetic tests for diseases proliferate, the interest and attitudes of primary care physicians, specialists and the general public will be of paramount importance in the diffusion of new genetic tests (Holtzman, 1992).

Chapter 6 - Conclusion

Newfoundland and Labrador introduced a formal Provincial MSS Program in 2001. MSS is a blood test done in the second trimester of a woman's pregnancy which gives a risk assessment for carrying a fetus with Down's syndrome, open NTDs and Trisomy 18. A positive screening result identifies women who should have invasive testing such as amniocentesis, to definitively determine the status of the fetus. The goal of the Provincial MSS Program is to offer population based screening, as MSS is used widely across Canada and is considered the "standard of care". However, in Newfoundland and Labrador few women are undergoing the screening test. To examine this low MSS uptake rate we used a physician survey, patient survey and aggregate laboratory data to examine the knowledge of and attitudes towards MSS in Newfoundland and Labrador.

In October and November of 2003 we surveyed all physicians involved in antenatal care in the previous twelve months. In November and December of 2003 we completed a survey of 300 women who had given birth at the Women's Health Centre in St. John's, Newfoundland. The patient surveys were completed by patients in hospital within forty-eight hours of giving birth. In March of 2004 we collected the Provincial MSS Program's aggregate laboratory data from 2003. These data provided the uptake rate, screening rates and the age breakdown of women who ordered MSS in that calendar year.

With the introduction of the Provincial MSS Program a team crossed the Province on a MSS promotional and educational tour in the summer of 2002. These sessions seemed to influence physician MSS practice. The main finding of

the physician survey was that a greater number of physicians were offering MSS and more of these physicians were offering MSS to all pregnant patients. Chandra et al. (2003) reported that in 2000, 16.0% of physicians were not offering MSS and only 29.0% were offering it to all women. In our study the percentage of physicians that were not offering MSS had dropped to 11.2% and the number of physicians that were offering MSS to all women had increased to 56.1%.

Obstetricians were found more likely to offer MSS to all their patients, whereas, family physicians were more likely to offer the screening test only to women deemed to be at high risk. Obstetricians and family physicians did not differ significantly in their knowledge of the specific screening rates and false positive rates surrounding MSS. However, obstetricians did order MSS more often within the correct gestational timeframe and also reported positive screening results back more quickly to their patients.

A difference was also found between male and female physicians. Female physicians were more likely to offer MSS to all their patients and also ordered the test more often within the correct timeframe. Females were also more likely to report positive results back to their patients more quickly than their male colleagues. Female physicians were younger and had more likely to have graduated from a medical school in Canada.

The patient component of this study found that the older groups of women surveyed were more likely to be familiar with, and discuss MSS with their physician. Older patients in our study were also significantly more likely to undergo MSS and amniocentesis.

The Provincial MSS Program reported an overall MSS uptake rate of 22%. This uptake rate was found to be much lower than other MSS programs, inside and outside of Canada.

The Provincial MSS Program had an overall false positive rate that was much higher than that found in the literature and among other Provincial MSS programs.

Overall, a fairly extensive analysis was completed of the Newfoundland and Labrador MSS Program. My study found that MSS is still being used as a selective screening tool. This is a cause for concern as MSS is meant to be a population based screening tool. MSS uses population-based risk ratios; it is inappropriate to recommend MSS solely to women in high risk groups as it cannot give accurate risk estimates. This may explain the high false positive rate found in the province.

This raises an interesting ethical question for physicians. One of the concerns physicians had with MSS was the anxiety caused by the high false positive rate associated with the screening test. Physicians themselves are driving the false positive rate associated with MSS upwards by offering the test more often to older women who are more likely to screen positive.

Given these findings regarding physician MSS practices it is suggested that continuing medical education be implemented in this area. This study showed that educational sessions influence physician MSS practice and may improve prenatal screening in the province. Future educational sessions should particularly concentrate on older physicians, especially those who are male and practicing in

rural areas. Professional organizations that represent physicians could also take a more active role in disseminating information on new guidelines, especially to physicians new to the province.

A more extensive patient follow up survey is recommended. This more focused study may be useful in determining why so few women are choosing to undergo MSS screening when it is discussed with their physician. Examining the interaction between patient and physician may give more detailed information into this question. Another recommendation is education and promotion of MSS to women of childbearing age and physicians practicing family medicine in the province.

It is also recommended that further review is warranted with regard to the high false positive rate associated with the Provincial MSS Program.

Only 22 % of pregnant women in Newfoundland and Labrador underwent MSS screening. Only 63.5 % of physicians offered MSS to all their patients. This finding suggests selective screening still exists since the 2000 Chandra et al. survey and ensuing educational and promotional sessions throughout the province. There continues to be a need to educate both patients and physicians on the importance of screening all pregnant women.

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Appendix A

Memorial
University of Newfoundland

September 1, 2003

Dear Physician,

As you might be aware, Maternal Serum Screening (MSS) is currently offered in Newfoundland and Labrador. I am a M.Sc. student in the faculty of Medicine and am interested in physician practice, knowledge and opinion of this relatively new screening program. Attached you will find a questionnaire asking questions regarding these points.

There are no possible risks with this study and the time required is the few minutes that it takes to fill out and return the questionnaire in the enclosed envelope. You may contact the investigator at the below contact information at any time to inquire further about the study.

The results of this research study may be published but your name or identity will not be revealed. In order to maintain confidentiality of your questionnaire, your name and address have not been added to either the questionnaire or return envelope. As with any study of this size, we will be required to contact physicians who do not respond. Due to this fact a return postcard with your name and address will also be found in this package. Mail this postcard separately the same time the questionnaire is returned. This will ensure anonymity of responses while providing us with a list of physicians who have completed and returned the questionnaire.

Thank you for your attention in this matter, your response to the survey will assist in the identification of issues and concerns related to the Provincial Maternal Serum Program. If you would like information regarding this program please contact the MSS Coordinator at the Provincial Medical Genetics Program at (709) 777-4363. If you would like to receive the results of this study please contact me at the below address.

Yours truly,

Mr. John Cavanagh
Graduate Student
Division of Community Health
Faculty of Medicine
Memorial University of Newfoundland
St. John's NL A1B 3V6
phone: (709) 777-8384
fax: (709) 777-7382
email: jpcnfld@hotmail.com

Dr. Maria Mathews, PhD
Assistant Professor Health Policy/Health Care Delivery
Division of Community Health
Faculty of Medicine
Memorial University of Newfoundland
St. John's NL A1B 3V6
phone: (709) 777-7845
fax: (709) 777-7382
email: mmathews@mun.ca

SECTION I – Physician Personal and Practice Characteristics

Please answer each of the following questions by placing a tick (√) in the appropriate box.

1. What is your specialty? ☐ Family Medicine ☐ Obstetrician
   ☐ other (specify) : _____

2. What is your gender? ☐ female ☐ male

3. What is your age? ☐ <30 ☐ 30-39 ☐ 40-49 ☐ 50-59 ☐ 60 +

4. Where did you attend medical school? ☐ Canada
   ☐ United States
   ☐ other (specify): _____

5. How long have you practiced in Canada? ___ year(s)

6. What are your practice certifications? ☐ CCFP
   ☐ FRCP
   ☐ other (please specify): _____

7. How large is the community in which you practice? ☐ urban (>20 000)
   ☐ semi urban (10 000 – 19 999)
   ☐ town (5000 – 9 999)
   ☐ small town (1000 – 4999)
   ☐ rural (<999)

8. Do you provide antenatal care as part of your practice? ☐ yes
   ☐ no - ***if NO, PLEASE STOP HERE and go to the end of the questionnaire, thanks for your time.***

9. Approximately how many years have you provided antenatal care? ___ year(s)

10. Up to what gestational week do you provide antenatal care? ☐ 0-14 weeks
    ☐ 20 weeks
    ☐ 28 weeks
    ☐ 0 – term

11. Approximately how many pregnant women have you cared for in the past year? ___

12. Do you perform deliveries as part of your practice? ☐ Yes, about ___ deliveries per year
    ☐ No

The next few questions relate to your knowledge and opinion of maternal serum screening.

SECTION II – Knowledge and Opinions of Maternal Serum Screening

13. Do you offer pregnant women in your practice the opportunity to have Maternal Serum Screening (MSS)? (Please check one) ☐ yes – ***if Yes, skip to question 15.***
☐ no – ***if No, go to question 14.***

*Answer this question if answered **NO** to question 13.*

14. What are the reasons that you do not offer MSS? (Check all that apply)
- ☐ Too many normal pregnancies have positive MSS results
- ☐ MSS is incompatible with my religious beliefs
- ☐ I was unaware that MSS was routinely available in this province
- ☐ It is too difficult to explain the test and its possible outcomes
- ☐ Too many abnormal babies are missed, too many false positives
- ☐ MSS is too costly
- ☐ MSS is too time consuming to explain
- ☐ It is too difficult to coordinate testing and follow up services
- ☐ It creates undo anxiety for my prenatal patients.
- ☐ Other (please specify):_____

Please go to question #21.

*Answer these questions if answered **YES** to question 13.*

15. To which pregnant women would you routinely offer MSS? (Check all that apply):
- ☐ All pregnant women
- ☐ Women age 35 or older at their due date
- ☐ Women under age 35
- ☐ Women with a family history of Down syndrome or neural tube defect
- ☐ Any women who ask to be tested
- ☐ Other subgroup of women: _____

16. How much time do you typically spend discussing MSS with a patient? ___ minute(s)

17. What percentage of pregnant women <35 of age offered MSS chose to have it? ____%

18. At what gestational age do you order MSS? _____ week(s)

19. When do you communicate positive MSS results to patients?
- ☐ within 48 hours
- ☐ within 1 week
- ☐ within 2 weeks
- ☐ at next clinical appointment

20. When do you communicate negative MSS results to patients?
- ☐ within 48 hours
- ☐ within 1 week
- ☐ within 2 weeks
- ☐ at next clinical appointment

Please go to question #21.

The next few questions are some background questions regarding MSS.

21. How far away by automobile are follow up MSS services amniocentesis _____ hours
level II ultrasound _____ hours
genetic counselling _____ hours

22. What do you think is the false positive rate associated with MSS? _____%

23. What percentage of affected fetuses do you think MSS will correctly identify?
Down syndrome ____%
Neural Tube Defects ____ %
Trisomy 18 ____ %

24. Do you believe MSS misleads patients to believe that physicians can guarantee a healthy baby?
☐ yes
☐ no

25. Where have you read or heard information pertaining to MSS ? (Check all that apply)
☐ Medical journals ☐ Newspapers ☐ Colleagues
☐ NLMA newsletter ☐ Hospital rounds ☐ Patients
☐ Internet ☐ CME sessions
☐ Provincial Medical Genetics Clinic information pamphlets

26. Have you changed how you deal with MSS in the last 18 months? ☐ yes, I offer MSS more
☐ yes, I offer MSS less
☐ no change
☐ not sure

27. Would you prefer MSS be offered in the first trimester of pregnancy? ☐ yes ☐ no

28. Do you feel that the MSS test is altering your medicolegal risk? ☐ yes, ☐ no, ☐ unchanged
more risk less risk

29. Are you aware of a Provincial Maternal Serum Screening Program? ☐ yes ☐ no

30. What is your opinion of the MSS program?

_____

_____

_____

_____

31. Any comments:

_____

_____

Thank you. Please mail questionnaire in return envelope provided.

Appendix B

Newfoundland and Labrador Physician Practice, Knowledge and Opinion of Maternal Serum Screening

In-Hospital Patient Questionnaire

Date of Questionnaire Completion: _____ _____ _____
Month Day Year

The Faculty of Medicine along with the Provincial Medical Genetics Clinic is studying prenatal screening in Newfoundland and Labrador. We are asking patients who have recently given birth about the prenatal screening experiences during their pregnancy. We are questioning patients at the Health Sciences Centre to better understand the use of health care services. The questionnaire will take 2 to 5 minutes to complete.

This study has been approved by the Human Investigations Committee at Memorial University. You should also understand the following points:

You may choose not to answer a question and your participation is completely voluntary.

If you have any questions or comments please do not hesitate in contacting the primary investigator graduate student John Cavanagh of the department of Medicine at 777-8384 or Dr. Maria Mathews at 777-7845.

Please do not provide your name on the questionnaire, as your answers will be kept confidential and we will not identify you in any report or presentation. We will not share your answers with anyone including your doctor.

Whether or not you decide to participate, your care will not be affected in any way.

When the questionnaire is completed please seal in the envelope provided give to one of the medical services aid upon their return.

Memorial
University of Newfoundland

Appendix C

Human Investigation Committee
Research and Graduate Studies
Faculty of Medicine
The Health Sciences Centre
August 1, 2003

KEYED

Reference #03.62

AUG 0 1 2003

Mr. John Cavanaugh
c/o Dr. M. Mathews
Community Health
Faculty of Medicine

Dear Mr. Cavanaugh:

This will acknowledge receipt of your amendment form dated July 29, 2003, wherein you provide an amendment dated July 29, 2003 to your research study entitled "**Newfoundland and Labrador physician practice, knowledge and opinion of maternal serum screening**"

The Chairs' of the Human Investigation Committee reviewed your correspondence and granted approval of the amendment dated July 29, 2003 as submitted. This will be formally reported to the full Human Investigation Committee at the meeting scheduled for **August 7, 2003**.

Please be advised that the Human Investigation Committee currently operates according to the Good Clinical Practice Guidelines, the Tri-Council Policy Statement and applicable laws and regulations.

Sincerely,

Sharon K. Buehler, PhD
Co-Chair
Human Investigation Committee

Richard S. Neuman, PhD
Co-Chair
Human Investigation Committee

SKB;RSN\jd

C Dr. C. Loomis, Vice-President (Research), MUN
Mr. Wayne Miller, Director of Planning & Research, HCCSJ

St. John's, NL, Canada A1B 3V6 • Tel.: (709) 777-6974 • Fax: (709) 777-7501 • email: hic@mun.ca • www.med.mun.ca/hic

HealthCare

Appendix D

September 17, 2003

Mr. J. Cavanagh
Grad Student
Community Medicine
General site

Dear Mr. Cavanagh:

Your research proposal *"HIC # 03.062 – Newfoundland and Labrador Physician practice knowledge and opinion of maternal serum screening"* was reviewed by the Research Proposals Approvals Committee (RPAC) of the Health Care Corporation of St. John's at its meeting on September 16, 2003 and we are pleased to inform you that the proposal has been approved.

Ongoing approval of this project is dependent upon the continued support of the Director and Clinical Chiefs of the Children's and Women's Health Program.

This approval is based on the understanding that it has the necessary funding and that it is being conducted as outlined in the approved research proposal. Additionally, the Committee requires a progress report to be submitted annually.

If you have any questions or comments, please contact Lynn Purchase, Manager of the Patient Research Centre at 777-7283.

Sincerely,

Mr. Wayne Miller
Director, Planning and Research
Chair, RPAC

cc: Ms. Pamela Elliott, Vice President Quality and Planning
Ms. Lynn Purchase, Manager, Patient Research Centre

St. Clare's Mercy Hospital

154 LeMarchant Road, St. John's, NL, Canada A1C 5B8 Tel. (709) 777-5000 Fax (709) 777-5210
Website: www.hccsj.nf.ca

SITES: Health Sciences Centre (General Hospital, Janeway Children's Health and Rehabilitation Centre, Women's Health Centre) Dr. Leonard A. Miller Centre • St. Clare's Mercy Hospital • Dr. Walter Templeman Health Centre • Waterford Hospital

Patient Questionnaire

The first questions are to help describe your background.

1. In what year were you born? _____

2. Approximately how large is the community that you live in?
   - ☐ urban (greater than 20 000 people)
   - ☐ semi urban (10 000 – 19 999 people)
   - ☐ town (5000 – 9 999 people)
   - ☐ small town (1000 – 4999 people)
   - ☐ rural (less than 999 people)

3. Have you heard of Maternal Serum Screening (MSS)? ☐ yes ☐ no

The next few questions are to give us an idea of your experiences with prenatal genetic screening, specifically MSS. MSS stands for Maternal Serum Screening and is a blood test taken between 15 and 20 weeks of pregnancy. This screening test determines a woman's risk of carrying a fetus with Down's syndrome, Trisomy 18 or open Neural Tube Defect.

4. What prenatal tests did you undergo? (Check all that apply)
   - ☐ ultrasound
   - ☐ amniocentesis
   - ☐ MSS
   - ☐ other (please specify): _____

5. Where did you first hear about MSS? (Check all that apply)
   - ☐ family physician
   - ☐ media (newspaper, radio, internet, etc.)
   - ☐ obstetrician
   - ☐ public health nurse
   - ☐ never heard of MSS until now
   - ☐ friends or family

6. Did you see a physician between the 15 and 20th week (2nd trimester) of your pregnancy?
   - ☐ no
   - ☐ yes, if Yes which type of physician (check all that apply)
     - ☐ family physician
     - ☐ obstetrician
   - ☐ can't remember

7. Did your physician discuss MSS with you?

☐ yes, if Yes for approximately how many minutes? ____ minute(s)
☐ no
☐ can't remember

8. Did you choose to undergo MSS testing?

☐ yes, **if Yes please proceed to next question.**
☐ no, **if No this is the end of the questionnaire. Please seal questionnaire in the envelope provided and give to one of the medical service aids upon their return.**
☐ don't know, **if No this is the end of the questionnaire. Please seal questionnaire in the envelope provided and give to one of the medical service aids upon their return.**

9. Do you think you would choose to undergo MSS testing in your next pregnancy?

☐ yes
☐ no

10. What was the MSS result?

☐ screen positive (test positive), **if screen positive please proceed to next question.**
☐ screen negative (test negative), **if screen negative this is the end of the questionnaire. Please seal questionnaire in the envelope provided and give to one of the medical service aids upon their return.**
☐ don't know, **if don't know this is the end of the questionnaire. Please seal questionnaire in the envelope provided and give to one of the medical service aids upon their return.**

11. Did you receive counselling for your screen positive (test positive) result?

☐ yes, **if Yes please proceed to next question**
☐ no, **if No this is the end of the questionnaire. Please seal questionnaire in the envelope provided and give to one of the medical services aid upon their return.**

12. Who counselled you about your positive result?

☐ family physician
☐ obstetrician
☐ genetic counselor
☐ psychologist
☐ other (please specify): _____

This is the end of the questionnaire. Please seal questionnaire in the envelope provided and give to one of the medical service aids upon their return.