Women's Experiences of Non-Invasive Prenatal Testing

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Declaration

This thesis contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text. I give consent to this copy of my thesis, when deposited in the University Library*, being made available for loan and photocopying subject to the copyright Act 1968.

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Acknowledgement of Collaboration

I hereby certify that the work embodied in this thesis has been done in collaboration with other researchers. I have included as part of this thesis a statement clearly outlining the extent of collaboration, with whom and under what auspices. I contributed to the development of the research question, the database search, the statistical analysis, the interpretation of results and editing of the manuscript. My supervisor, Dr. Linda Campbell contributed to the development of the research question, the formulation of the methodology, the interpretation of results, and editing of the manuscript. Taylah Armstrong assisted in the project development and data collection. Dr Tracy Dudding-Byth contributed to the development of the research project and editing of the manuscript. Dr Rina Fyfe assisted in the data collection.

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Women's Experiences of Non-Invasive Prenatal Screening

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Abstract

While the uptake of non-invasive prenatal testing (NIPT) continues to increase, the provision of pre-test genetic counseling remains unregulated in Australia. This study sought to characterise the experiences of women undergoing NIPT. We investigated participants' perceptions of informed choice, genetic counseling experiences and decision to undergo NIPT. Women who had been recently pregnant volunteered to complete an online survey which assessed their knowledge of and attitude toward NIPT; satisfaction with genetic counseling; satisfaction of their decision, and decisional conflict to undergo NIPT. The survey also gathered pregnancy-specific and demographic information, and allowed participants to provide qualitative information about their counseling experience and reasons for undergoing NIPT. A total of 94 participants were included in the analysis. Overall, participants had good knowledge of and positive attitudes toward NIPT, experienced low decisional conflict and were overall satisfied with their genetic counseling experience and decision to undergo NIPT. Some participants however, expressed dissatisfaction with the lack of information provided and biased language by pre-test genetic counseling providers. The desire to be informed was the most frequent reason for undergoing NIPT. This study highlighted the importance of providing accurate and objective information in pre-test genetic counseling to reduce decisional conflict and improve satisfaction with the decision to undergo NIPT.

Key Words: Genetic Counseling; Decision Making; Genetic Testing

Women's Experiences of Non-Invasive Prenatal Testing

Due to technological advances, women have an increasing ability to access powerful information regarding their unborn baby via non-invasive prenatal testing (NIPT). NIPT using cell free fetal DNA is a newly established screening method for identifying chromosome anomalies by way of a maternal blood test (Harraway, 2017). NIPT has become increasingly available in Australia, with a variety of laboratories offering the screen to women with and without risk factors for fetal abnormalities (Hui & Hyett, 2013). Women are asked to decide whether to undergo NIPT, but information provided to women regarding NIPT is not regulated in Australia. Furthermore, little is known about Australian women's experiences of NIPT, informed choice, decision-making and provision of counseling.

Since its introduction to Australia in 2012, NIPT has been well received by women, despite its commercial nature and out-of-pocket expenses (Metcalfe, 2018). Over time, NIPT has become increasingly sophisticated allowing relatively reliable screening of fetal aneuploidies such as Down syndrome (trisomy 21), Edwards' syndrome (trisomy 18) and Patau syndrome (trisomy 13) (Vanstone, Yacoub, Giacomini, Hulan, & McDonald, 2015). The number of conditions detectable by NIPT is increasing and now extends to micro-deletion syndromes, such as 22q11.2 deletion syndrome (22q11), and sex chromosome abnormalities, such as Turner syndrome (Ravi et al., 2018; Vanstone et al., 2015). The accuracy of NIPT is continuing to improve with advances in technology, hence increasing its ability to screen for a growing number of conditions. The uptake of NIPT however, does not necessarily reflect the facilitation of informed choice or patient's knowledge of conditions being screened for (Ames, Metcalfe, Archibald, Duncan, & Emery, 2015).

The World Health Organisation's (WHO) genetic screening guidelines recommend that not only analytical and clinical validity of screening tools be evaluated, but also the ethical and psychosocial aspects, such as informed choice and decision-making (WHO, 1998). Although NIPT has been found to be a clinically sound method (Harraway, 2017), health care professionals have expressed concern that due to its simplicity and availability, not all women who elect to undergo prenatal testing are appropriately informed of whether the benefit of the test may outweigh the potential psychological harm in receiving a high risk result (Ames et al., 2015). The available research regarding women's informed choice relating to NIPT is varied and inconsistent in outcomes definitions and methodology across a variety of settings. For example, a study conducted in Hong Kong found that 80% of women were well informed about NIPT (Lo et al., 2017) while Piechan et al. (2016) found only 44% of women to have good knowledge of NIPT in the United States of America. From these findings, it would appear that concerns regarding the introduction of NIPT and inconsistent pre-test counseling and informed choice may be warranted (Silcock, Liao, Hill, & Chitty, 2015).

The effectiveness of NIPT is likely to enable further expansion, commercialization and routinization of the test, causing additional concern for the erosion of careful attention to detail in the informed consent process (Minear, Alessi, Allyse, Michie, & Chandrasekharan, 2015). A review conducted by Ames et al. (2015) found that most women (82%) believed prenatal testing to be compulsory, demonstrating the lack of perceived autonomy in reproductive screening tests. Similarly, over 92% of health professionals and over 90% of pregnant women reported that NIPT testing should be offered routinely to all pregnant women (Silcock et al., 2015), further contributing to the normalisation of NIPT. Piechan et al. (2016)

outcomes suggest most women (91%) who undergo NIPT perceived themselves to have good knowledge of NIPT and felt they were well informed in their decision making process. The powerful information NIPT has the ability to provide should not be undervalued. It is important for patients to understand the benefits as well as potential limitations and consequences of electing to undergo NIPT (Buchanan, Sachs, Toler, & Tsipis, 2014).

The aim of NIPT is to screen for chromosomal abnormalities, which can then be confirmed via diagnostic testing (Hewison, 2015). The results of the diagnostic test can then be used to either avoid or prepare for the birth of a baby with a potentially disabling condition and to facilitate autonomous reproductive choices (Metcalfe, 2018). While the expansion of screening abilities of NIPT may be perceived as beneficial for early pregnancy management or neonatal care, patients may not have prior knowledge of the conditions being screened for, creating additional ethical considerations (Long & Goldblatt, 2014). Therefore, it is essential women are provided with not only information about NIPT itself, but complete, accurate and unbiased information regarding the genetic conditions tested for and the potential severity and phenotypic variability of the condition (Minear et al., 2015).

The provision of this information is not only vital for deciding whether to undergo NIPT, but also for informed decision-making of pregnancy management following a high-risk NIPT result. This challenging decision-making process can cause significant psychological distress, especially when the fetal abnormality detected is not well known to the patient (Long & Goldblatt, 2014). Armstrong, Cornell, Campbell, Fyfe and Dudding-Byth (2019) found that women who received a high-risk NIPT result reported significantly more symptoms of depression, anxiety and stress compared to women who received a low-risk result. These findings further

stress the responsibility of genetic counseling providers to ensure women are well informed and supported in their decision to undergo NIPT.

Although pre-test counseling is recommended to ensure patients are well informed, the provision of counseling regarding NIPT is not regulated in Australia (Metcalfe, 2018). While genetic counselors are specifically trained in genetic counselling (assisting people to understand the medical, psychological and familial implications of genetic contributions to disease, Metcalfe, 2018), genetic counseling may be conducted by a number of other professions. As NIPT is becoming more commercialised, general practitioners, obstetricians and midwives are also tasked with the role of counselling patients (Minear et al., 2015; Metcalfe, 2018). It is recommended that pre-test genetic counseling regarding NIPT comprises of objective information such as the accuracy of the test, possibility of false positive results, incidental findings, information regarding potential quality of life for the child and parent, the potential variety of expressions of the syndrome and informing patients that NIPT is elective (Allen, Stoll, & Bernhardt, 2016; Metcalfe, 2018; Sachs, Blancford, Buchanan, Norwitz & Bianchi, 2015). Similarly, women's perceived importance of information should also be considered to facilitate interactive discussion with women prior to screening (Dane, Peterson & Miller, 2018).

However, considering the provision of pre-test counseling is not monitored, it is likely that the information provided to women will differ depending on the professional providing the counseling, impacting overall informed decision-making (Metcalfe, 2018). For example, Allen et al. (2016) suggested that women who receive counseling from a genetic counselor are likely to receive more thorough information (due to the level and specificity of their professional training) and therefore more likely to make more informed choices regarding their pregnancy. Decisional conflict

(the extent to which a person feels uncertain about their decision) is experienced less by women who make informed choices (Lewis, Hill, & Chitty, 2017). Similarly, Hartwig, Borregaard Miltoft, Malmgren, Tabor, and Jorgensen (2019) found high satisfaction with counseling also resulted in low decisional conflict (regarding their decision to undergo NIPT), acknowledging counseling plays a significant role in making informed choices and overall decision-making processes. The absence of standardised procedures for pre-test counseling therefore demonstrates the potential for variability in patients' experiences, decisional conflict, and overall satisfaction with their decision to undergo NIPT.

The information delivered to patients by health-professionals is highly valued and can significantly affect how women may choose to manage their pregnancy. The number of pregnancy terminations and social stigma associated with conditions detected by screening can be influenced by how information is presented to parents (Metcalfe, 2018). For example, a recent review found most practitioners provide reactive recommendations for post-abortion care, suggesting a presumption in favour of abortion (Sullivan & de Faoite, 2017). Similarly, a review conducted by Marteu and Dormandy's (2001) suggests that in the context of prenatal testing, the provision of information about specific conditions to pregnant women is often too brief and more negative compared to information provided to parents at other times or to a parent of an affected child. The provision of genetic counseling to pregnant women can significantly influence their pregnancy management decisions, conflict in decision-making, satisfaction with genetic counseling and overall satisfaction of their decision.

Purpose of the Study

Although existing literature discusses the ethical implications of the introduction of NIPT, limited studies characterize women's experiences and consequential satisfaction, specifically in the Australian context. The aim of this study is to explore and characterise the experiences of women undergoing NIPT. The expected outcomes of the study aim to inform future health policies regarding the treatment and care of pregnant women and the provision of genetic counseling regarding NIPT in Australia.

Method

Participants

The target population were women who had undergone NIPT. Participants were recruited primarily through local health professionals, such as obstetricians, general practitioners, the Maternal Fetal Medicine Unit of the John Hunter Hospital and Hunter Genetics in Newcastle, NSW, as well as via social media. While an "open survey" format was used, where any visitor to the survey website had access to complete the survey without barrier, screening questions were presented to ensure suitability for the study. Judgement sampling was used to target women who had chosen to undergo NIPT via health experts, though respondent driven sampling may have occurred over the course of the study. Participation in the study was voluntary. Participants under the age of 18, not proficient in the English language, who had not recently been pregnant or who did not provide implied consent were excluded from the study via pre-screening questions.

Instrumentation

The survey was developed as a joint effort among several researchers and other relevant health professionals affiliated with the participating recruitment sites. The

survey questions presented to participants were dependent on answers to previous questions, requesting only information relevant to their experience and therefore eliminating possibly distressing questions (e.g., regarding terminations). Demographic data, such as age, income and education were gathered at the beginning of the survey. Additional qualitative data specific to participants' experiences of NIPT and the provision of counseling were gathered throughout the survey via optional open-ended questions. More specifically, participants were presented with the opportunity to provide additional comments regarding their genetic counseling experience prior to undertaking NIPT and reasons for accepting and undergoing NIPT. Outcome measures assessed knowledge of and attitude toward NIPT (Multidimensional Measure of Informed Choice – NIPT [MMIC-NIPT], Lewis, Hill, Skirton & Chitty, 2016), decisional conflict (Decisional Conflict Scale, O'Connor, 1995), decision satisfaction (Satisfaction with Decision Scale, Holmes-Rovner, et al., 1996) and genetic counseling satisfaction (Genetic Counseling Satisfaction Scale; DeMarco, Peshkin & Tercyak 2004). While additional measures and demographic questions were provided to participants as part of a larger research project, only measures relevant to the current study are outlined.

The MMIC-NIPT (Lewis et al., 2016) is an adaptation of the original Multidimensional Measure of Informed Choice (Marteau, 2001) and comprises of three scales assessing knowledge, attitude and deliberation. The deliberation scale was removed to remain consistent with the original MMIC measure (Marteau, 2001) for the purpose of the larger research project. The knowledge scale includes 12 multiple-choice questions while the attitude scale includes five questions rated on a Likert scale from 0-4 on which participants rate how they feel about each statement (e.g., beneficial – harmful) (Cronbach's $\alpha = .69$) (Lewis et al., 2016). Scores above

nine on the knowledge scale indicate good knowledge, whereas scores below 8 indicate poor knowledge (Lewis et al., 2016). Similarly, scores on the attitude scale equal to or below six indicated a positive attitude, scores between seven and 13 indicated neutral attitude and scores between 13 and 20 indicated a negative attitude (Cronbach's α = .84) (Lewis et al., 2016).

The Decisional Conflict Scale comprises five subscales measuring personal perceptions of uncertainty in choosing options (uncertainty), feeling informed (informed), being clear about personal values (values clarity), feeling supported in decision-making (support) and effective decision making (O'Connor, 2010). The traditional 16-item measure was used in this study, where participants are asked to rate how much they agree or disagree with each statement from 0 (strongly agree) to 4 (strongly disagree) (Cronbach's α = .81) (O'Connor, 2010). Higher scores indicate higher conflict in decision-making.

Both the Satisfaction with Decision Scale (Cronbach's α = .88) (Holmes-Rovner, et al., 1996) and Genetic Counseling Satisfaction Scale (Cronbach's α = 0.80) (DeMarco, et al., 2004) each comprise 6-item Likert-scales asking participants to rate how much they agree or disagree with each statement from 1 (strongly disagree) to 6 (strongly agree). Higher scores on both scales indicate higher satisfaction (Holmes-Rovner, et al., 1996; DeMarco, et al., 2004).

Procedures

After securing Human Ethics approval from Hunter New England Health and the University of Newcastle, information pamphlets were distributed to potential participants via local health professionals (general practitioners, obstetricians, genetic counsellors and midwives). These professionals also received their own information statement about the purpose of the research and their objective role in this process.

The pamphlets outlined the aims of the study and how to participate. Advertisements were also posted on social media platforms with information about the study and how to participate. Third parties did not receive any incentives for recruitment and were not directly involved in the research project.

Participants provided online consent after reviewing the participant information statement. As the survey was anonymous, participants were unable to withdraw their data after submitting responses. However, participants were notified that they were able to discontinue the survey at any time. The survey took participants approximately 30 minutes to complete. Participants were reminded that they were able to exit the survey at any time and contact details for support services were provided should they feel distressed. The survey was presented via the Qualtrics survey platform with data analysis conducted using SPSS software.

Data and Analysis

A cross-sectional correlational survey design was used to investigate informed choice, decisional conflict, decision satisfaction to undergo NIPT and genetic counseling satisfaction. An exploratory analysis was also conducted to examine the provision of counseling offered to women who undergo NIPT. Correlation analyses were used to examine the relationships between genetic counseling satisfaction, knowledge of NIPT, attitude toward NIPT, decisional conflict and decision satisfaction to undergo NIPT. Qualitative analysis was also performed using an interpretative content analysis method (Patton, 2001). The first author reviewed the responses to the open-ended survey questions to identify common themes and subthemes. The second and third authors conducted audits of the qualitative analysis. Discrepancies were discussed amongst the authors until resolved and then frequencies were calculated. Participants were included in the analysis if data was completed for

at least one standardized scale. Analysis of missing data was conducted as per instructions for each outcome measure.

Results

A total of 208 participants accessed this survey between April and July 2019. Seventy-five (36%) participants were excluded as they completed a prenatal screen other than NIPT, and 15 (7.2%) were excluded as they chose not undertake any prenatal screening. A further 15 (7.2%) participants were excluded as they had not been offered prenatal screening. Of these 15 participants, 3 (1.4%) identified that their pregnancy was not planned, but was accepted, and 2 (0.1%) identified that their pregnancy was not planned and not accepted (indicating a possible termination). Nine participants (4.3%) were excluded as they did not complete at least one outcome measure. Data from the total remaining 94 participants were used for analyses. There was no significant difference between the included and excluded participants in regard to age, F (1, 169) = 0.14, p = 0.90, education level, F (1, 169) = 0.36, p = 0.85, income, F (1, 169) = 0.62, p = 0.80 or presence of a mental health condition, F (1, 169) = 0.01, p = 0.94.

Sociodemographic characteristics of participants are presented in Table 1. Women's mean age was 32 years (range 19 - 56). The majority of women were university educated (71.3%) and had a yearly household income above $80,000 (64.9%). Participants who indicated a current or previous mental health diagnosis (9.6%) included diagnoses such as anxiety (n=6), depression (n=3), panic (n=2) post-traumatic stress (n=1) and post-natal depression (n=1). Of those who participated, 28 (29.8%) had non-invasive prenatal testing only and 66 (70.2%) had both combined first trimester screening (CFTS) and NIPT. Of the participants' pregnancies that were not planned (18.1%), all women intended on carrying out the pregnancies (100%).

Most participants obtained counseling regarding NIPT by obstetricians (29.8%), followed by general practitioners (25.5%), with 23 (24.5%) participants obtained counseling from more than one health professional. Five participants (5.3%) indicated they were not provided with any counseling prior to their NIPT, or they were unsure who provided them with the counseling. Frequencies of counseling providers are presented in Table 2.

Table 1. Sociodemographic characteristics of participants.

Characteristic	M(SD)
Age (Years)	32.39 (6.06)
Education	n (%)
High School	13 (13.8)
Diploma	14 (14.9)
University (Bachelor Degree)	41 (43.6)
University (Post Graduate Degree)	26 (27.7)
Yearly Household Income	
$0-$18,200	1 (1.1)
$18,201-$37,000	6 (6.4)
$37,001-$80,000	7 (7.4)
$80,001-$180,000	61 (64.9)
$180,001 and over	19 (20.2)
Diagnosed Mental Health Disorder	
Yes	9 (9.6)
No	85 (90.4)
Planned Pregnancy	
Yes	77 (81.9)
No	17 (18.1)
Type of Prenatal Screening	
Non-Invasive Prenatal Testing only	28 (29.8)
Both CFTS and NIPT	66 (70.2)

Table 2. Frequencies of genetic counseling providers.

Genetic Counseling Provider	n (%)
Genetic Counsellor	4 (4.3)
Neonatologist	1 (1)
General Practitioner	24 (25.5)
Midwife	1 (1)
Nurse	1 (1)
Obstetrician	28 (29.8)
More than one health professional	23 (24.5)
Other	5 (5.3)
None/Don't know	5 (5.3)
Missing	2 (2.3)

All participants were presented with the Multidimensional Measure of Informed Choice – NIPT (MMIC-NIPT; Knowledge and Attitude), Decision Satisfaction Scale, Decisional Conflict Scale and Genetic Counseling Satisfaction Scale. Means and standard deviations are found in Table 3 and frequencies of MMIC–NIPT categorical scores are found in Table 4. Participant numbers differ between scales as some participants did not complete the survey in full. Decision satisfaction, decisional conflict and genetic counseling satisfaction mean scores were all within one standard deviation of the norms (Holmes-Rovner, et al., 1996; O'Connor, 1996; DeMarco, et al., 2004). Decisional conflict (total score above 37.5) was present in seven (8.14%) participants.

Table 3. Outcome measure scores.

Outcome Measure	n	Mean	Min	Max	SD
*MMIC - NIPT Knowledge	94	10.41	2.5	12	1.60
*MMIC - NIPT Attitude	94	3.10	0	20	4.88
Decision Satisfaction	78	23.17	15	25	2.92
Decisional Conflict (Total)	86	15.10	0	58.33	15.94
Uncertainty	86	13.47	0	75	17.63
Informed	86	15.11	0	91.67	18.28
Values Clarity	86	14.53	0	58.33	16.63
Support	86	14.73	0	91.67	18.86
Effective Decision	86	16.16	0	83.33	19.89
Genetic Counseling Satisfaction	80	24.1	6	30	5.36

Note: *Multidimensional Measure of Informed Choice

Table 4. Frequencies of categorical MMIC – NIPT categories.

MMIC - NIPT	n (%)
Knowledge	
Good knowledge	83 (88.3)
Poor knowledge	11 (11.7)
Attitude	
Positive attitude	76 (80.9)
Neutral attitude	12 (12.8)
Negative attitude	6 (6.4)

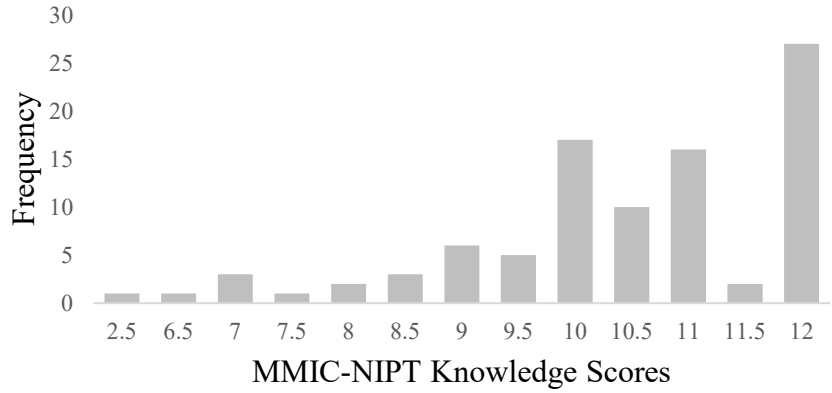

Figure 1. Frequencies of MMIC-NIPT Knowledge scores

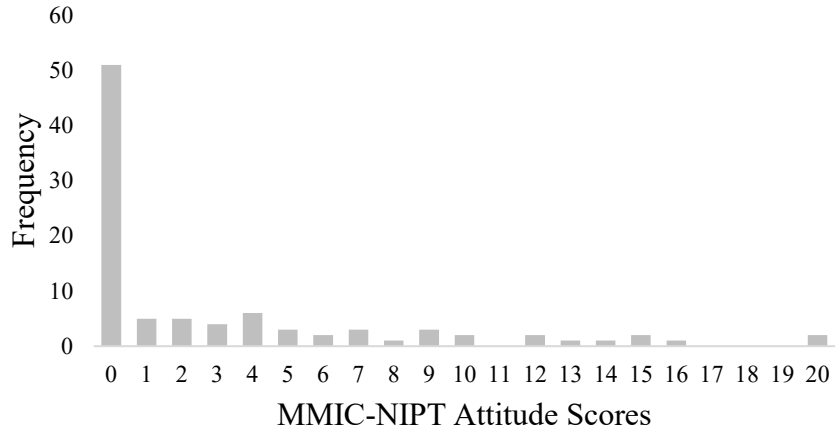

Figure 2. Frequencies of MMIC-NIPT Attitude scores

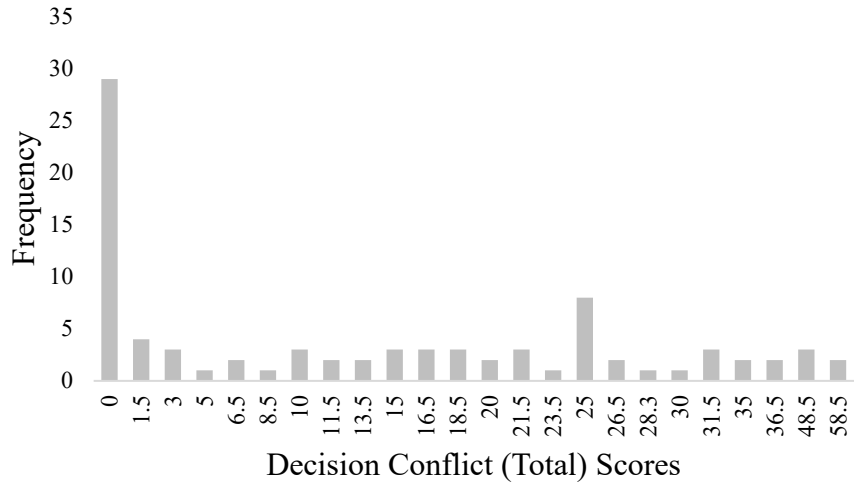

Figure 3. Frequencies of Decisional Conflict (Total) scores

The majority of participants' responses indicated overall satisfaction with the content of genetic counseling. Most participants reported the information was easy to understand (62.5%), they received the right amount of information (90%), strongly agreed that the information was presented well (53.8%) and covered things participants wanted to know (50%), agreed that the counselor provided them with new information (43.8%) and assisted in their decision to undergo NIPT (82.5%). Furthermore, 70 (87.5%) participants reported they would make the same decision to undergo NIPT in future pregnancies. See Table 5. Of the women who participated, 22 (23.4%) did not know the difference between NIPT and CFTS prior to entering the survey, indicating participants were unaware of the difference between a routine risk assessment (CFTS) and an elective screen for fetal abnormalities (NIPT).

Table 5. Frequencies of satisfaction with genetic counseling content.

Survey statement/question	n (%)				
	Easy	Somewhat easy	Somewhat hard	Hard	
How easy was the information to understand?	50 (62.5)*	29 (36.3)	1 (1.3)	1 (1.3)	
	Too much	Too little	The right amount		
The amount of information was	1 (1.3)	8 (10)	72 (90)*		
	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree
The information:					
was presented in a way that I could understand	43 (53.8)*	33 (41.3)	3 (3.8)	1 (1.3)	1 (1.3)
provided me with new information	27 (33.8)	35 (43.8)*	12 (15)	5 (6.3)	2 (2.5)
covered things I wanted to know	40 (50)*	35 (43.8)	2 (2.5)	4 (5)	0
Assisted in Decision Making (missing = 3)	Yes	No			
	66 (82.5)*	12 (15)			

* Most frequent option* Table based on 80 participants, with 14 participants not completing the scale

A correlation analysis revealed a significant positive correlation between education and NIPT knowledge scores, indicating that higher education was associated with more knowledge about NIPT ($r = 0.29$, $p = 0.005$). A significant positive correlation was also found between income and decision satisfaction, indicating higher income was associated with higher decision satisfaction ($r = 0.29$, $p = 0.011$). Significant negative correlations were found between income and decisional conflict subscales uncertainty ($r = -0.28$, $p = 0.008$), support ($r = -0.25$, $p = 0.02$) and effective decision ($r = -0.28$, $p = 0.009$), indicating higher income was associated with less conflict in decision making. Furthermore, education was significantly positively correlated with age ($r = 0.35$, $p = 0.00$) and income ($r = 0.35$, $p = 0.00$).

A significant negative relationship was found between decisional conflict and NIPT knowledge scores ($r = -0.26$, $p = 0.018$), indicating greater NIPT knowledge was related to less decisional conflict. Furthermore, a significant positive relationship was found between decisional conflict and NIPT attitude scores ($r = 0.26$, $p = 0.015$), indicating negative attitudes toward NIPT were related to higher decisional conflict. Similarly, a significant positive relationship was found between the support subscale of decisional conflict and NIPT attitude ($r = 0.42$, $p = 0.00$), indicating negative attitudes toward NIPT were associated with less support. A significant negative correlation was found between NIPT attitude and decision satisfaction ($r = -0.24$, $p = 0.032$), indicating more positive attitudes toward NIPT were associated with higher decision satisfaction.

A significant negative relationship was found between decision satisfaction and total decisional conflict ($r = -0.76$, $p = 0.00$), indicating higher decisional satisfaction was associated with lower total decisional conflict scores. Further correlation analyses identified significant negative relationships between decision satisfaction and all decisional conflict subscales (uncertainty: $r = -0.70$, $p = 0.00$; informed: $r = -0.54$, $p = 0.00$; values clarity: $r = -0.59$, $p = 0.00$; support: $r = 0.63$, $p = 0.00$; effective decision: $r = -0.81$, $p = 0.00$).

A significant negative correlation was found between genetic counseling satisfaction and total decisional conflict ($r = -0.43$, $p = 0.001$). However, significant relationships were only found

between genetic counseling and the informed (r = -0.44, p = 0.00), support (r = -0.60, p = 0.000) and effective decision (r = -0.27, p = 0.038) subscales. These relationships indicate that lower genetic counseling satisfaction was associated with higher decisional conflict in the informed, support and effective decision subscales only. A significant positive relationship was found between decision satisfaction and genetic counseling satisfaction (r = 0.33, p = 0.018), indicating higher decision satisfaction was associated with higher genetic counseling satisfaction. Correlation matrix is presented in Table 6.

Table 6. Correlation matrix between outcome measures.

	NIPT Knowledge	NIPT Attitude	Decision Satisfaction	Counseling Satisfaction	Decisional Conflict	Uncertainty	Informed	Values Clarity	Support	Effective Decision	Age	Income	Education
MMIC - NIPT Knowledge	1	-	-	-	-	-	-	-	-	-	-	-	-
MMIC - NIPT Attitude	-.13	1	-	-	-	-	-	-	-	-	-	-	-
Decision Satisfaction	-.16	-.24*	1	-	-	-	-	-	-	-	-	-	-
Counseling Satisfaction	-.11	-.24	.33*	1	-	-	-	-	-	-	-	-	-
Decisional Conflict (Total)	-.26*	-.26*	-.76**	-.43**	1	-	-	-	-	-	-	-	-
Uncertainty	-.15	.26*	-.70**	-.24	-.88**	1	-	-	-	-	-	-	-
Informed	-.33**	.12	-.54**	-.44**	-.85**	.59**	1	-	-	-	-	-	-
Values Clarity	-.18	.13	-.59**	-.21	-.82**	.60**	.74**	1	-	-	-	-	-
Support	-.24*	.42**	-.63**	-.60**	-.83**	.71**	.64**	.52**	1	-	-	-	-
Effective Decision	-.14	.24*	-.81**	-.27*	-.88**	.90**	.59**	.64*	.68**	1	-	-	-
Age	.18	.16	-.11	.08	.11	.11	.02	.12	.26	.09	1	-	-
Income	.14	.01	.29*	-.10	-.20	-.28**	-.02	-.04	-.25*	-.28**	.07	1	-
Education	.29**	.01	.09	.20	-.12	-.09	-.16	-.03	-.16	-.07	.35**	.35**	1

*Note. *p < .05, **p < .01, ***p< .001*

Twenty-seven participants responded to the open-ended survey question "are there any further comments you would like to make?" presented at the end of the Genetic Counseling Satisfaction Scale. Sixty-one participants responded to the open-ended survey question "what were your main reasons for undergoing NIPT?" presented at the end of the survey. Written response themes, frequencies and examples of responses are outlined in Tables 7 and 8. Some responses span more than one category. Furthermore, 70 (74.5%) participants reported they would make the same decision to undergo NIPT in future pregnancies, seven (7.4%) reported they would not make the same decision and data was missing from 17 participants (18.1%).

Table 7. Qualitative Analysis for open-ended survey question presented after genetic counseling satisfaction scale

Written response themes	n (%)	Example
Negative feedback regarding provision of information provided	11 (40.7)	
Felt pressured	1 (3.7)	"I felt the pressure to undergo both first trimester screening and NIPT was based on the medical professionals desire to control the outcome of my pregnancy"
Unsatisfied with provision of information	5 (18.5)	"I had to explain what [NIPT] was to my GP" "[GP] just gave me a pamphlet"
Biased information	5 (18.5)	"There should be positive information given about [name of syndrome], not just negative" "… more information is needed about if the results are positive … and how the child can have a fulfilling life"
Negative feedback regarding process of screening	1 (3.7)	
More mental health support required	1 (3.7)	"…More support from a mental health perspective while waiting for results may have been beneficial"

General positive feedback	7 (25.9)	"It helped dramatically to speak to a genetic counsellor before any of the tests" "I felt it was paramount to moving forward with my pregnancy"
Positive autonomy	5 (18.5)	"I was grateful to be informed about existence of [NIPT], but I didn't perform it"
Cost/billing	1 (3.7)	"It's expensive but worth it"
Neutral/Other	4 (14.8)	"I just wanted the results" "I did not carry out NIPT in the end"

***** *Table is based on 27 participants, with 87 participants not providing responses to the open-ended question*

Table 8. Qualitative Analysis for open-ended survey question "what were your main reasons for undergoing NIPT?"

Written response themes	n (%)	Example
Reassurance/increased knowledge	21 (27.63)	"… I wanted to have all the information and be able to make sure there was no major concerns with the baby" "To ensure I was carrying a healthy baby"

Identified increased risk of fetal abnormality	17 (22.37)	"Recommended from obstetrician after previous stillbirth" "My brother having 22q"
Test for a specific condition	2 (2.63)	"To find out if our baby had Down syndrome"
Safety of test	7 (8.05)	"I would want to have information about possible genetic abnormalities, but I wouldn't risk miscarriage to obtain that information" "Safe compared to [invasive] tests"
Accuracy of test	13 (17.11)	"Test was more accurate for assessing risk of Down syndrome/other genetic anomalies than combined screening test"
Test for sex	9 (10.34)	"To determine the sex of the baby" "Benefit of finding out sex early"
Assist in decision making process for termination	5 (5.74)	"…was to be used as determining factor whether to proceed with pregnancy or not" "… giving us the chance to terminate if required"

Prepare for a baby with an abnormality	12 (13.79)	"So I could prepare [for fetal abnormalities] with no surprises" "… to prepare for the possibility of a baby with chromosomal addition"
Expectation to undertake test	1 (1.32)	"…thought I should do it"

** Table based on 61 participants, with 33 participants not providing responses to the open-ended question*

Discussion

To the extent of the authors' knowledge, this is the first study to investigate the characteristics of women's experiences of the decision making process to undergo NIPT. We sought to assess women's knowledge and attitudes of NIPT, satisfaction with genetic counseling, satisfaction of their decision and decisional conflict to undergo NIPT. In addition, the qualitative portion of the survey was designed to capture a broader understanding of women's counseling experiences and reasons for deciding to undergo NIPT.

The results of our study indicated most women had good knowledge of and positive attitudes toward NIPT and were satisfied overall with the content and experience of genetic counseling. While participants' knowledge of NIPT in this study is consistent with some studies such as Lo et al. (2017), less recent studies suggest knowledge of NIPT and prenatal screening to be significantly lower (Piechan et al., 2016; Gourounti & Sandall, 2008). The apparent increase in knowledge over time may reflect the growing uptake and recognition of NIPT, but may also illustrate differences between countries and cultures (Asia, America and Europe). However, as the sample size of this study is quite small in comparison to other studies, it is possible that these results are unable to be generalised across the population. The results also indicated that most participants had experienced little conflict in their decision making process and were mostly satisfied with their decision to undergo NIPT. The majority of the sample population earned moderate-high incomes and were well educated. It is possible that the higher knowledge scores reported in this study could be attributed to participants' high education levels. However, as NIPT incurs an additional cost in Australia (i.e., not funded by Medicare) unlike other countries (e.g., The Netherlands), generalisation of this sample is assumed and comparisons with overseas studies may not be reasonable.

Sociodemographic

The reason for the association between higher income, higher decision satisfaction and less decisional conflict is unclear. As income and education commonly increase with age, the reported

links between age, income and education are expected. Women with lower educational levels were less likely to have good knowledge of NIPT. Therefore, it is important to consider how information is provided to and accessed by women across a range of educational levels to ensure all women undertaking NIPT are well-informed in their decision making process.

Decisional conflict

A significant finding from this study is the relationship between decisional conflict and genetic counseling satisfaction. Consistent with research conducted by Hartwig et al. (2019), women who were more satisfied with the counseling they received were less likely to feel conflicted in their decision to undergo NIPT. Of note, women who reported more satisfaction with their counseling also reported feeling more supported and informed in their decision making process. Similarly, women who had higher knowledge of and a more positive attitude toward NIPT also reported feeling more supported and informed in their decision. Women who are not supported or informed are at risk of making uninformed choices and possible consequential psychological distress. These results provide further endorsement that feeling supported and being provided with accurate and objective information is essential in reducing uncertainty in decision-making.

Satisfaction with Counseling

Overall satisfaction with the counseling process and content was high. Although previous research has suggested reported satisfaction of counseling does not necessarily reflect participant knowledge (Piechan et al., 2016), the results from this study indicate women were generally highly satisfied with counseling and well informed about NIPT. No significant relationship was found between satisfaction with counseling and NIPT knowledge in this study. Therefore conclusions cannot be made regarding the relationship and future researchers should continue to measure these domains independently. Furthermore, satisfaction with counseling was not compared with participant NIPT results in this study. It is possible that the majority of the sample achieved low-risk NIPT results, which may have influenced their satisfaction with the counseling process.

While genetic counselors have been suggested to facilitate more informed decisions (Metcalfe, 2018), only four participants reported receiving counseling by a genetic counselor. It is possible though, that participants who received counseling from multiple professionals may have included counseling with a genetic counsellor. The routinization of NIPT has been suggested to reduce participants' informed choice by counseling conducted by a range of professionals. This study has indicated that the majority of this sample achieved good knowledge of NIPT, representing appropriate provision of clinical information across counseling professionals. Importantly, while the knowledge subscale of MMIC-NIPT measures clinical aspects of NIPT (e.g., validity), it does not assess participants' understanding of psychosocial implications of the test, such as the variability of expressions of disorders NIPT can screen for (e.g., 22q11.2 deletion syndrome). Therefore, while clinical information is being provided in pre-test counseling, it is difficult to establish which counseling providers, if any, are providing such important psychoeducational information.

Qualitative Analysis

Although quantitative data found the majority of participants were satisfied with their counseling experience, the 27 women who provided qualitative responses regarding their pre-test counseling experience were more critical about their experiences. These responses captured spontaneous, voluntary information, indicating women who reported negative pre-test counseling experiences felt more strongly about their experience. It is also possible that these women may have received high-risk NIPT results, influencing their overall satisfaction of the NIPT process. Dissatisfaction with the lack of information provided and the counseling providers' biased language were the most frequently reported response themes. Women expressed the need for more balanced, accurate information, including more information about living with the disorders that NIPT screens for (e.g., Down Syndrome). The identification of biased language is consistent with previous research (Marteau, 2001; Sullivan & de Faoite, 2017; van Schendel et al., 2017) and highlights the importance of providing neutral and objective information throughout the counseling process.

The qualitative responses regarding women's reasons for undergoing NIPT recognised women's desire to be informed as the most common, followed by its safety and accuracy. However, women's preference to be informed does not necessarily translate to understanding the limitations of NIPT and the risks associated with the powerful knowledge NIPT can provide. For example, while women wish to be informed, they may feel a false sense of security by over-generalising a low-risk result, perceiving it as a guaranteed outcome. Women's desire to be informed also indicates the possibility that women may make the decision to undergo NIPT prior to receiving counseling. Therefore, it is essential to prioritise counseling and the provision of accurate and objective information regardless of their perceived current knowledge.

Furthermore, eight women identified testing for the sex of the baby as their reason for undergoing NIPT. While testing for the sex is possible via NIPT, it is not the predominant aim of the test. Although the sex of the baby may be identified, other incidental information pertaining to fetal abnormalities may also be reported. This could put women at an increased risk of psychological distress if they are not informed regarding other consequences of undergoing NIPT (i.e., potential high risk result of a fetal abnormality), providing further evidence for the significance of comprehensive genetic counseling to support women in their decision-making process to undergo NIPT.

Study Limitations

Limitations of this study are that it was self-report, retrospective and participants were not excluded based on time since undergoing NIPT. Similarly, while the sample is considered to be generalizable to the Australian context, the high education and socio-economic background of participants may not accurately reflect all women who elect to undergo NIPT should the uptake of NIPT change over time (e.g., becomes funded by Medicare). Furthermore, the findings of this study are limited by excluding women who decided not to undergo NIPT. As such, it is acknowledged that conclusions cannot be made regarding women's decisions or informed choices to decline NIPT.

The sample size of this study also limited further analyses of subgroups, such as women with poor knowledge scores, therefore limiting inferences regarding these populations.

However, as NIPT has only been offered in Australia for approximately seven years, all participants' pregnancies were included and considered recent. A longitudinal study would be beneficial to assess possible changes in women's decision-making processes and satisfaction with counseling across various pregnancies. This study did not control for women who had children with a disability. These women may have had a heightened awareness to biased information or language used within the pre-test counseling process compared with other women. While women were predominantly recruited via local, Australian health professionals, it is possible women from overseas may have participated due to the availability of the online survey via social media. Comparisons between counseling providers were not possible due to sample size and inadequate comparison requirements. While a larger sample size may have been beneficial, this study succeeded in establishing common experiences of women undergoing NIPT. Furthermore, it is acknowledged that causation cannot be implied from these results.

Practice Implications

As the uptake of NIPT continues to increase, it is essential that women are provided with neutral, objective and accurate information at the time of pre-test counseling. It is recommended counseling providers use disability inclusive language such as "high chance" instead of "high risk", which implies a harmful or negative result/experience, to reduce the stigma associated with disability. Similarly, it is recommended that counseling providers also offer disability inclusive information, such as available support for families of children with disabilities and positive qualities of individuals with the disorders screened for. Based on the findings from the qualitative data, it is clear that pre-screening counseling can have a significant effect on womens' experiences of NIPT. As such, the addition of a decision aid is recommended to further clarify preferences and reduce decisional conflict for all women who undergo NIPT, which have been reported to assist in informed decision making regarding NIPT uptake in the Netherlands (Beulen et al, 2016).

Research Recommendations

This study was designed to explore women's experiences of undergoing NIPT. Further research is recommended to investigate differences in counseling satisfaction, decisional conflict and informed choice between counseling providers. Similarly, it is recommended to explore differences in counseling satisfaction between women who receive high or low risk NIPT results. In addition, further qualitative study regarding decision-making processes is also recommended to determine the most important components of pre-test counseling to ensure patients are well informed, experience low decisional conflict and are satisfied with their counseling experience and decision to undergo NIPT. Similarly, further study exploring the provision of information received by participants may provide a more complete picture of the level of understanding of those undergoing NIPT. More specifically, it is recommended that future research focus on women who have lower levels of education and to build on existing findings of the usefulness of low literacy decision aids (Smith et al, 2018), in order to establish effective ways to improve their knowledge of NIPT to make informed decisions regarding prenatal screening. Comparisons between counseling providers would also be valuable to depict any differences in patients' experiences and information provided. The outcomes of these research recommendations will continue to inform future health-care policies regarding NIPT and the provision of genetic counselling in Australia.

Conclusions

By undergoing NIPT, women are at risk of experiencing significant psychosocial implications and ethical challenges. However, this study indicates women are satisfied overall with their decision to undergo NIPT, are well informed about NIPT, have positive attitudes toward NIPT, are satisfied with their pre-test genetic counseling and experience low decisional conflict. It is concluded that the majority of women appear to have positive NIPT experiences. While our qualitative analysis provides rich data regarding the importance of neutral, objective and accurate pre-test counseling, it also provides a basis for future studies to further explore patient understanding and differences between counseling providers. Similarly, while women desire to be

informed about possible fetal abnormalities, it is not well understood whether women recognize the possible psychosocial implications associated with being more informed. The relationship between decisional conflict and genetic counselling satisfaction, as well as the rich qualitative data reported in this study reinforces the significance of pre-test genetic counseling in ensuring patients are informed in decision-making, experience low decisional conflict to undergo NIPT and are satisfied with their decision to undergo NIPT

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Conflict of Interest Statement

I declare that I have no conflict of interest.

Human Studies and Informed Consent

All procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and standards, laid down in the 1964 Helsinki Declaration. Ethical approval of the study was granted by the Hunter New England Health's Research Ethics Committee and UoN's Human Research Ethics Committee. Informed consent was obtained from all individual participants included in the study.

Animal Studies

No non-human animal studies were carried out by authors of this thesis.

Appendix A: Journal of Genetic Counseling – Submission Guidelines

Original Articles

The Journal of Genetic Counseling seeks papers reporting exciting, timely, original research in the discipline and practice of genetic counseling. The Journal considers papers using a form of systematic study or inquiry to address a question to be original research. Systematic study can be approached using a variety of methods, such as empirical methods, systematic literature review methods, normative or conceptual research methods. Original articles:

- include an abstract and key words;
- are no more than 25 double-spaced pages in length for quantitative studies and no more than 35 double-spaced pages in length for qualitative or non-empirical studies (excluding Supplemental Information);
- have no more than 5 display items (tables + figures), and any additional display items will need to be submitted as Supplemental Information. Large tables should always be published as online only material;
- report relevant information per appropriate methodologic guideline (see Research Reporting Guidelines below).

Abstract

Please provide an unstructured abstract of no more than 300 words containing the major keywords summarizing the article. The abstract should include a description of the study's objective, methods or methodological approach, sample, measures or main outcome variables, main results, and conclusion.

Keywords

Please provide three to six keywords to be used for indexing the article.

Main Body

For Original Research articles, all major sections should carry section headings (such as Introduction, Methods, Results, Discussion, Conclusions, etc.) type centered. Side headings in Methods section should include, as appropriate: Participants, Instrumentation, Procedures, and Data Analysis. The Discussion should begin with a very succinct summary of the major conclusions of the paper and then go on to focus on the interpretation and significance of the findings with concise objective comments that describe their relation to other work in the area. It should not repeat information in the results. Side headings in Discussion should include: Study Limitations, Practice Implications, and Research Recommendations. The journal uses US spelling.

Footnotes should be avoided in the main text. When their use is absolutely necessary, footnotes should be numbered consecutively using Arabic numerals and should be typed at the bottom of the page to which they refer. Place a line above the footnote, so it is set off from the text. Use the appropriate superscript numeral for citation in the text.

Author Contributions

Please include a statement delineating the contributions of each author using the criteria recommended by the International Committee of Medical Journal Editors (ICMJE). The statement should mention each author separately by name. ICMJE criteria are:

- Substantial contributions to the conception or design of the work; or the acquisition, analysis, or interpretation of data for the work; AND
- Drafting the work or revising it critically for important intellectual content; AND
- Final approval of the version to be published; AND
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

If the study includes original data, at least one author must confirm that he or she had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Please include this statement in the cover letter.

Acknowledgements

Contributions from anyone who does not meet the criteria for authorship should be listed, with permission from the contributor, in an Acknowledgments section. Financial and material support should also be mentioned. Authors should list all funding sources and are responsible for the accuracy of their funder designation.

Conflict of Interest Statement

The Conflict of Interest Statement should mention each author separately by name. Recommended wording is as follows:

Author X declares that she has no conflict of interest.

Author Y has received research grants from Drug Company A.

Author Z has received a speaker honorarium from Drug Company B and owns stock in Drug Company C.

If multiple authors declare no conflict, this can be done in one sentence:

Author X, Author Y and Author Z declare that they have no conflict of interest.

Submitting authors should ensure they liaise with all co-authors to confirm agreement with the final statement.

Human Studies and Informed Consent

For manuscripts reporting studies that involve human participants, a statement identifying the ethics committee that approved the study and confirmation that the study conforms to recognized standards is required. It should also state clearly in the text that all persons gave their informed consent prior to their inclusion in the study.

The Journal requires that all appropriate steps be taken in obtaining informed consent of any and all human subjects participating in the research comprising the manuscript submitted for review and possible publication, and a statement to this effect must be included in the Human Studies and Informed Consent section of the manuscript. Participant anonymity should be preserved and all identifying information should be excluded in the manuscript.

Photographs need to be cropped sufficiently to prevent human subjects being recognized (an eye bar must not be used because of insufficient de-identification). Images and information from individual participants will only be published where the authors have obtained the individual's free prior informed consent. If any identifying information about participants is included in the article, the following sentence should also be included:

'Additional informed consent was obtained from all participants for which identifying information is included in this article.'

Authors do not need to provide a copy of the consent form to the publisher; however, in signing the author license to publish, authors are required to confirm that consent has been obtained.

Animal Studies

The Journal of Genetic Counseling does not publish non-human animal studies. To affirm that this is the case for your submission, please include the following sentence under this subheading in the manuscript:

'No non-human animal studies were carried out by the authors for this article'

References

The accuracy of references is the responsibility of the authors. Only published papers and those in press may be included in the reference list. The Journal has a strong preference against the inclusion of conference abstracts (published or unpublished) or unpublished data in manuscripts. However, if done, unpublished data and submitted manuscripts must be cited parenthetically within the text. Personal communications should also be cited within the text; permission in writing from

the communicator is required. References should be prepared according to the *Publication Manual of the American Psychological Association* (6th edition).

Appendix B: Ethics Approval

29 November 2018

Dr Linda Campbell
School of Psychology
University of Newcastle

Dear Dr Campbell,

Re: The impact of non-invasive prenatal testing on parents (18/10/17/4.01)

HNEHREC Reference No: 18/10/17/4.01
NSW HREC Reference No: HREC/18/HNE/269

Thank you for submitting the above application for single ethical review for a multi-centre study. This project was first considered by the Hunter New England Human Research Ethics Committee at its meeting held on **17 October 2018.** This Human Research Ethics Committee is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research (2007)* (National Statement) and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Further, this Committee has been certified under the National Health and Medical Research Council's *National Certification Scheme for the Ethical Review of Multi-Centre Human Research*. The Committee's Terms of Reference are available from the Hunter New England Local Health District website.

I am pleased to advise, the Hunter New England Human Research Ethics Committee has determined that the above protocol meets the requirements of the *National Statement on Ethical Conduct in Human Research* and following acceptance of the requested clarifications and revised Information Statements and Survey by Dr Nicole Gerrand Manager, Research Ethics & Governance, under delegated authority from the Committee, grants ethical approval of the above project.

The *National Statement on Ethical Conduct in Human Research (2007),* which the Committee is obliged to adhere to, include the requirement that the Committee monitors the research protocols it has approved. **Ethics Approval will be for 5 years and subject to the following conditions:**

- A report on the progress of the above protocol is to be submitted at 12 monthly intervals. A proforma for the annual report will be sent at the beginning of the month of the anniversary of approval. Your review date is **November 2019.**
- All variations or amendments to this protocol must be forwarded to, and approved by, the Hunter New England Human Research Ethics Committee prior to their implementation.
- A final report must be submitted at the completion of the above protocol, that is, after data analysis has been completed and a final report compiled.
- Adherence to the safety reporting requirements of the with the NHMRC Safety Monitoring and Reporting Guidance for Therapeutic Goods Trials (November 2016) available at https://www.nhmrc.gov.au/_files_nhmrc/file/publications/16469_nhmrc_-_ahec_position_statement-web.pdf

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http://www.hnehealth.nsw.gov.au/ethics/Pages/Research-Ethics-and-Governance-Unit.aspx

- If for some reason the above protocol does not commence (for example it does not receive funding); is suspended or discontinued, please inform Dr Nicole Gerrand as soon as possible.
- If the study has not been completed by **November 2023,** a Renewal Application will be required.

The following documentation has been reviewed and approved by the Hunter New England Human Research Ethics Committee:

Document	Version	Date
HREA [Submission Code: AU/1/A298312]		
Project Description	Version 1	12 November 2018
Demographic Questionnaire	Version 2	5 November 2018
Standardised Questionnaires	Version 2	14 November 2018
Reliability and Validity of Standardised Measures	Version 2	9 November 2018
Information Statement – For Health Practitioners	Version 2	12 November 2018
Participant Information Statement	Version 2	12 November 2018
Consent Form (file name Version 1, 9 November 2018)	undated	no date
Recruitment - Social Media Blurbs	Version 1	11 September 2018
Information Pamphlet	Version 2	5 November 2018

Approval has been granted for this study to take place at the following sites:

- **Hunter Genetics**
- **John Hunter Hospital**

You are reminded that this letter constitutes ethical approval only. You must not commence this research project at a site until separate authorisation from the Chief Executive or delegate of that site has been obtained.

A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

Should you have any concerns or questions about your research, please contact Dr Gerrand as per the details at the bottom of the page. The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Please quote **18/10/17/4.01** in all correspondence.

The Hunter New England Human Research Ethics Committee wishes you every success in your research.

Yours faithfully

For: Ms M Hunter
Chair
Hunter New England Human Research Ethics Committee

Hunter New England Research Ethics & Governance Office
Locked Bag No 1
HRMC NSW 2310
Telephone: (02) 49214950
Email: HNELHD-HREC@hnehealth.nsw.gov.au
http://www.hnehealth.nsw.gov.au/ethics/Pages/Research-Ethics-and-Governance-Unit.aspx

25 February 2019

Dr Linda Campbell
School of Psychology
University of Newcastle

Dear Dr Campbell

Re: The impact of non-invasive prenatal testing on parents (18/10/17/4.01)

HNEHREC Reference No: 18/10/17/4.01
NSW HREC Reference No: HREC/18/HNE/269
SSA Reference No: SSA/19/HNE/19

Thank you for submitting an application for authorisation of this project. I am pleased to inform you that authorisation has been granted for this study to take place at the following sites:

- **Hunter Genetics**
- **John Hunter Hospital**

As part of the process of the governance review process for this protocol, the following documents were reviewed for use at the **Hunter Genetics and John Hunter Hospital** site:

Document	Version	Date
Project Description	Version 1	12 November 2018
Demographic Questionnaire	Version 2	5 November 2018
Standardised Questionnaires	Version 2	14 November 2018
Reliability and Validity of Standardised Measures	Version 2	9 November 2018
Information Statement – For Health Practitioners	Version 2	12 November 2018
Participant Information Statement	Version 2	12 November 2018
Consent Form (file name Version 1, 9 November 2018)	undated	no date
Recruitment - Social Media Blurbs	Version 1	11 September 2018
Information Pamphlet	Version 2	5 November 2018

The following conditions apply to this research project. These are additional to those conditions imposed by the Human Research Ethics Committee that granted ethical approval:

1. Proposed amendments to the research protocol or conduct of the research which may affect the ethical acceptability of the project, and which are submitted to the lead HREC for review, are copied to the research governance officer;
2. Proposed amendments to the research protocol or conduct of the research which may affect the ongoing site acceptability of the project, are to be submitted to the research governance officer;

Hunter New England Research Ethics & Governance Office
Locked Bag No 1
HRMC NSW 2310
Telephone: (02) 49214950
Email: HNELHD-HREC@hnehealth.nsw.gov.au
http://www.hnehealth.nsw.gov.au/ethics/Pages/Research-Ethics-and-Governance-Unit.aspx

3. Annual Report submitted to the lead HREC for review and the acknowledgment, are copied to the research governance officer;
4. Final Report submitted to the lead HREC for review and the acknowledgement, are copied to the research governance officer.

Yours faithfully

Dr Nicole Gerrand
Research Governance Officer
Hunter New England Local Health District

Hunter New England Research Ethics & Governance Office
Locked Bag No 1
HRMC NSW 2310
Telephone: (02) 49214950
Email: HNELHD-HREC@hnehealth.nsw.gov.au
http://www.hnehealth.nsw.gov.au/ethics/Pages/Research-Ethics-and-Governance-Unit.aspx

RESEARCH INTEGRITY UNIT

Registration of External HREC Approval

To Chief Investigator or Project Supervisor:	**Doctor Linda Campbell**
Cc Co-investigators / Research Students:	**Miss Paige Cornell** **Miss Taylah Armstrong** **Dr Tracy Dudding-Byth**
Re Protocol:	**The impact of prenatal testing on parents**
Date:	**27-Mar-2019**
Reference No:	**H-2019-0106**
External HREC Reference No:	**18/10/17/4.01**

Thank you for your **Initial Application** submission to the Research Integrity Unit (RIU) seeking to register an External HREC Approval in relation to the above protocol.

Your submission was considered under an **Administrative Review** by the Ethics Administrator.

I am pleased to advise that the decision on your submission is **External HREC Approval Noted** effective **27-Mar-2019**.

As the approval of an External HREC has been noted, this registration is valid for the approval period determined by that HREC.

Your reference number is **H-2019-0106**.

PLEASE NOTE:
As the RIU has "noted" the approval of an External HREC, progress reports and reports of adverse events are to be submitted to the External HREC only. In the case of Variations to the approved protocol, or a Renewal of approval, you will apply to the External HREC for approval in the first instance and then Register that approval with the University's RIU, via RIMS.

Linkage of ethics approval to a new Grant

Registered External HREC approvals cannot be assigned to a new grant or award (ie those that were not identified in the initial registration submission) without confirmation from the RIU.

Best wishes for a successful project.

Mr Alan Hales
Manager, Research Compliance, Integrity and Policy

For communications and enquiries:
Human Research Ethics Administration

Research & Innovation Services
Research Integrity Unit

The University of Newcastle
Callaghan NSW 2308
T +61 2 492 17894
Human-Ethics@newcastle.edu.au

RIMS website - https://RIMS.newcastle.edu.au/login.asp

Linked University of Newcastle administered funding:

Funding body	Funding project title	First named investigator	Grant Ref

Appendix C: Participant Information Statement

Dr Linda Campbell
School of Psychology
University of Newcastle
Science Offices
Ourimbah
NSW 2258
Ph: (02) 43494404
Linda.e.campbell@newcastle.edu.au

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Prenatal Screening Study Information Statement – For Participants
The Impact of Prenatal Screening on Parents

Investigating the Relationship between Prenatal Screening, Informed Decision Making, Counselling and Decision Satisfaction and Psychological Well-being

Dr Linda Campbell, Dr Tracy Dudding, Dr Frida Carswell, Dr Rina Fyfe, Miss Paige Cornell, and Miss Taylah Armstrong

You are invited to take part in a research survey for the project identified above, which is being conducted by Master of Clinical Psychology students Paige Cornell and Taylah Armstrong, under the supervision of Dr Linda Campbell, at the University of Newcastle.

Before you decide whether you would like to take part, it is important for you to consider why the research is being done and what it will involve. Please read this information sheet carefully.

Why is the research being done?

Researchers at the University of Newcastle are trying to find out more about the experiences of pregnant women following prenatal screening, to better inform the care provided to these women in the future. Prenatal screening tests include non-invasive prenatal testing (NIPT), also known as non-invasive prenatal screening (NIPS), and combined first trimester screening (CFTS). First trimester screening combines the results of biochemical blood tests with the structural findings measured under ultrasound to predict the chance that the baby has a chromosomal or other structural abnormality. In comparison, NIPT is a genetic blood test that analyses the baby's DNA fragments that are circulating in the mother's bloodstream to detect the most common chromosomal abnormalities. By directly analysing the baby's DNA, NIPT results have been shown to be more accurate and have fewer false positives (i.e. abnormal results that are incorrect) than CFTS in identifying Down syndrome cases (Sonic Genetics, 2015).

This study aims to investigate women's satisfaction of their experience with prenatal screening and associated counselling, as well as their psychological wellbeing following the outcomes of the prenatal screening test. This research is expected to inform future health policies regarding the treatment and care of pregnant women, and the provision of information and counselling regarding prenatal screening in Australia.

Who can participate in the research?

Women who have previously been offered prenatal screening are invited to participate in our online survey. Participating in this research is suitable for you if you are fluent in English, as the survey is only available in English.

What choice do you have?

Participation in this survey is entirely voluntary. Should you not wish to take part you may do so without explanation. If you do take part in the survey, you can discontinue the survey at any time without having to give a reason. If you do discontinue, the questions you have answered may be used in this study. If you received information about this survey from a health care professional, please be assured that your decision regarding participation will not be communicated to your doctor and will not affect your medical treatment or your relationship with staff who are caring for you.

What would you be asked to do if you agree to participate?

If you agree to participate in this study, you will be asked to complete an online survey regarding your experience of prenatal screening. This survey is expected to take approximately 30 minutes. The survey includes questions about your satisfaction regarding the decision to undergo prenatal screening or not, informed choice, and the associated genetic counselling you received. You will also be asked about your personal values, and your psychological wellbeing following this decision. Additionally, demographic questions about your education and income will be asked to establish potential impacts on access to services.

What are the risks and benefits of participating?

Participation in this survey will require you to answer questions about sensitive topics, including your choice to undergo or not to undergo prenatal screening. Additionally, you will be asked questions about your psychological well-being, and satisfaction with your decision making. Some participants may find these topics upsetting, and may experience emotional discomfort and distress as a result of participating.

Should you have any concerns, or feel distressed as a result of participating in this study, please contact your GP, or any of the following services who can provide timely and professional support to people experiencing distress.

Beyond Blue 1300 224 636 www.beyondblue.org.au	Lifeline 13 11 14 www.lifeline.org.au

Will the study cost you anything?

Participation in this study will not cost you anything, nor will you be paid. Participants may find satisfaction in the knowledge that research into experiences following prenatal screening may assist in making important changes regarding care provided to pregnant women in the future.

How will your privacy be protected?

The University of Newcastle is committed to protecting and preserving a participant's right to confidentiality. No personal information will be collected, and questionnaire responses will be collated anonymously. All responses received in the survey will be handled with strict confidentiality. The study results may be presented at a conference or in a scientific publication, but individual participants will not be identifiable in such a presentation.
Your unidentified data from this research project will be retained for possible use in future research conducted by other researchers within the University of Newcastle.

What do I do now?

Thank you for reading this information sheet and for considering taking part in this research. If you are happy to participate please follow the link below to continue to the survey.

http://www.findlab.net.au/the-impact-of-prenatal-screening.html

Further Information

Should you have any queries regarding this study, you can contact Linda Campbell using the details provided at the beginning of this statement. If you wish to find out about the results of this study, you can check our website, or follow us on Facebook, with these details being provided below.

Website	Facebook page
www.findlab.net.au	Family Interaction & Neurodevelopmental Disorders Lab

Complaints about this research

This research was reviewed and approved by the Hunter New England Human Research Ethics Committee, Reference number 18/10/17/4.01 Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to Dr Nicole Gerrand, Manager, Research Ethics and Governance Unit, Hunter New England Human Research Ethics Committee, Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305, telephone (02) 49214950, email HNELHD-HREC@hnehealth.nsw.gov.au.

Appendix D: Health Practitioner Information Statement

Dr Linda Campbell
School of Psychology
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Ourimbah
NSW 2258
Ph: (02) 43494404
Linda.e.campbell@newcastle.edu.au

THE UNIVERSITY OF NEWCASTLE AUSTRALIA

Prenatal Screening Study Information Statement – For Health Practitioners
The Impact of Prenatal Screening on Parents

Investigating the Relationship between Prenatal Screening, Counselling Satisfaction, Decision Satisfaction and Psychological Well-being

Dr Linda Campbell, Dr Tracy Dudding, Dr Frida Carswell, Dr Rina Fyfe, Miss Paige Cornell, and Miss Taylah Armstrong

You are invited to distribute information regarding a research survey for the project identified above, which is being conducted by Master of Clinical Psychology students Paige Cornell and Taylah Armstrong, under the supervision of Dr Linda Campbell, at the University of Newcastle. We request that you distribute information regarding this project to patients who have undergone prenatal screening.

Before you decide whether you would like to distribute information regarding this project to your patients, it is important for you to consider why the research is being done and what it will involve. Please read this information sheet carefully.

Why is the research being done?
Researchers at the University of Newcastle are trying to find out more about the experiences of pregnant women following prenatal screening to better inform the care provided to these women in the future. Prenatal screening tests include non-invasive prenatal testing (NIPT), also known as non-invasive prenatal screening (NIPS), and combined first trimester screening (CFTS).
First trimester screening combines the results of biochemical blood tests with the structural findings measured under ultrasound to predict the chance that the baby has a chromosomal or other structural abnormality. In comparison, NIPT is a genetic blood test that analyses the baby's DNA fragments that are circulating in the mother's bloodstream to detect the most common chromosomal abnormalities. By directly analysing the baby's DNA, NIPT results have been shown to be more accurate and have fewer false positives (i.e. abnormal results that are incorrect) than CFTS in identifying Down syndrome cases (Sonic Genetics, 2015).

This research project aims to investigate women's satisfaction of their experience with prenatal screening and associated counselling, as well as their psychological wellbeing following the outcomes of the prenatal screening. This research is expected to inform future health policies regarding the treatment and care of pregnant women, and the provision of information and counselling regarding prenatal screening in Australia.

Who can participate in the research?
We are seeking women who have previously been offered prenatal screening to participate in our online survey. Participating in this research is suitable for participants who are fluent in English, as the survey is only available in English.

What choice do you have?
Participation in this survey is entirely voluntary. Should your patient not wish to take part, she may do so without explanation. If your patient does take part in the survey, she can withdraw at any time without having to give a reason. It is important to assure your patient that any information she

receives about this survey from you as her health-care professional or her decision to participate will not influence her medical treatment or relationship with staff who are caring for her.

What would you be asked to do if you agree to distribute information to patients?
If you agree to distribute information about this study, the researchers request that you provide objective information regarding the project and its aims to your patients. Those who wish to participate will be asked to complete an online survey regarding their experience of prenatal screening. This survey is expected to take approximately 30 minutes.

What are the risks and benefits of your patients participating?
Participation in this survey will require your patients to answer questions about sensitive topics, including their decision about whether or not to undergo prenatal screening, their satisfaction with this decision, informed choice and associated counselling, and their psychological wellbeing. Some participants may find these topics upsetting, and may experience emotional discomfort and distress as a result of participating.

As NIPT is a recent introduction in Australia, several considerations to its use are yet investigated. By participating in this study, your patients will be contributing to more informed care for women undergoing prenatal screening. Participants have the opportunity to express their satisfaction/dissatisfaction with current health care procedures surrounding prenatal screening and consequently identify possible links to psychological wellbeing.

Should your patients have any concerns, or feel distressed as a result of participating in this study, they will be advised to contact their GP, or any of the following services who can provide timely and professional support to people experiencing distress

Beyond Blue	Lifeline
1300 224 636	13 11 14
www.beyondblue.org.au	www.lifeline.org.au

While we intend that this research study will improve the care provided to women who undergo NIPT in the future, it may not be a direct benefit to you or your patients.

Will the study cost your patients anything?
Participation in this study will not cost you anything, nor will your patients be paid. Participants may find satisfaction in the knowledge that research into experiences following NIPT may assist in making important changes provided to pregnant women in the future.

How will you and your patients' privacy be protected?
The University of Newcastle is committed to protecting and preserving a participant's right to confidentiality. No personal information will be collected from health care professionals or participants, and questionnaire responses will be collated anonymously. All responses received in the survey will be handled with strict confidentiality. The study results may be presented at a conference or in a scientific publication, but individual participants will not be identifiable in such a presentation.

What do I do now?
Thank you for reading this information sheet and for considering distributing information to patients to consider participating in this research. If you are happy to distribute information to your patients, please provide your patients with the Information Statement for Parents or our pamphlet/brochure where they will find additional information, including how to participate.

Further Information
Should you have any queries regarding this study, you can contact Linda Campbell using the details provided at the beginning of this statement. A link has been provided below which includes

information regarding the use of non-invasive prenatal testing. If you wish to find out about the results of this study, you can check our website, or follow us on Facebook, with these details being provided below.

Website	Facebook page	NIPT
www.findlab.net.au	Family Interaction & Neurodevelopmental Disorders Lab	https://www.racgp.org.au/afp/2017/october/non-invasive-prenatal-testing/

Complaints about this research

This research was reviewed and approved by the Hunter New England Human Research Ethics Committee, Reference number 18/10/17/4.01 Should you have concerns about this research, or you have a complaint about the manner in which the research is conducted, it may be given to the researcher, or, if an independent person is preferred, to Dr Nicole Gerrand, Manager, Research Ethics and Governance Unit, Hunter New England Human Research Ethics Committee, Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305, telephone (02) 49214950, email HNELHD-HREC@hnehealth.nsw.gov.au

Appendix E: Participant Recruitment Advertisement

Have you recently been pregnant?

Have you recently undergone a pre-natal test (non-invasive prenatal testing or combined first trimester screening) to screen for chromosomal abnormalities? We would like to know more about your experience.

We are interested in finding out more about women's decision making, counselling satisfaction, informed choice and psychological well-being following prenatal screening. We invite you to complete an online survey examining these issues.

For more information, and to participate, please follow the link below
http://www.findlab.net.au/the-impact-of-prenatal-screening.html

Participants must have undergone prenatal screening, and be fluent in English. Participation is completely voluntary. All data will remain confidential and anonymous, though may be used for publication. This research may help to improve the care provided to pregnant women in the future.

If you have any further concerns or queries, please visit our website
www.findlab.net.au

This research is being conducted by Linda Campbell, Frida Carswell, Tracy Dudding, Paige Cornell, and Taylah Armstrong.

For more information, please contact Linda Campbell (Clinical Psychologist)
linda.e.campbell@newcastle.edu.au

This project has been approved by the Hunter New England Human Research Ethics Committee (Approval number: 2019/ETH01243)

Appendix F: Social Media Recruitment Advertisement

The above photos will be used with the BELOW blurbs:

Social Media Blurbs Version 1, 5 July 2018

1. Have you recently been pregnant? Did you have a blood test to screen for chromosomal abnormalities like Down Syndrome?

Researchers at the University of Newcastle are seeking volunteers to participate in a study investigating non-invasive prenatal testing (e.g. Harmony test) and its impacts on parents. Your experience can make a difference! To find out more, please go to: www.findlab.net.au/NIPT/

2. Have you recently made the decision to terminate your pregnancy? Did the results of prenatal testing contribute to this decision?

Researchers at the University of Newcastle are seeking volunteers to participate in a study investigating non-invasive prenatal testing (e.g. Harmony test) and its impacts on parents. Your experience can make a difference! To find out more, please go to: www.findlab.net.au/NIPT/

Appendix G: Consent Questions

1. I have read the Information Statement for Participants and consent to participate in this stud.
    a. Yes, I consent to participate in this study
    b. No, I do not consent to participate in this study

2. Do you consent to your unidentified data from this research project to be retained for possible use in future research conducted by the research team at the University of Newcastle?
    a. Yes
    b. No

Appendix H: Demographic Questions

1. What is your current age in year?
    a. [participant entered age]

2. What is your sex?
    a. Male
    b. Female
    c. I would prefer not to disclose
    d. Other (please specify)

3. What is your total yearly household income?
    a. $0 - $18, 200
    b. $18, 201 - $37, 000
    c. $37, 001 - $80, 000
    d. $80, 001 - $180, 000
    e. $180, 001 and over

4. What is your highest level of education?
    a. Year 10 or less
    b. Year 12 or equivalent
    c. Diploma
    d. Bachelor degree
    e. Postgraduate degree

5. Do you have any diagnosed mental health conditions?
    a. Yes (please specify)
    b. No

6. What your most recent pregnancy planned?
    a. Yes
    b. No

7. Were you offered any prenatal screening* at any time during your most recent pregnancy? (*prenatal screening tests your baby's overall development and checks to see if your baby is at risk of genetic conditions, such as Down syndrome)
    a. Yes
    b. No [exited out of survey]
    c. I don't know [exited out of survey]

8. Which prenatal screening test(s) did you undertake?
    Note: Combined First trimester Screening (CFTS) involves ultrasound and a maternal serum blood test for the purpose of screening for early-onset pre-eclampsia and fetal abnormalities such as Down Syndrome. This is usually conducted at 10-13 weeks gestation. This test is Medicare funded.
    Non-Invasive Prenatal Testing (NIPT) involves a blood test for the purpose of screening for fetal abnormalities such as Down syndrome. This test has a higher accuracy rate than the CFTS (at 99% accuracy for Down syndrome). This test is NOT Medicare funded.
    a. Combined First Trimester Screen only
    b. Non-invasive Prenatal Testing only
    c. Combined First Trimester Screening AND Non-Invasive Prenatal Screening

   d. Other [free text]
   e. I don't know [exited out of survey]
   f. None

9. Did you know the difference between non-invasive prenatal testing (NIPT) and combined first trimester screening (CFTS) before beginning this survey?
   a. Yes
   b. No

Note: The following questions are about women's prenatal screening tests. Women who underwent both CFTS and NIPT, were asked questions about both tests, with wording adjusted within survey.

10. Why were you offered prenatal screening for your most recent pregnancy?
    a. Increased risk of fetal anomaly
    b. Standard practice
    c. Recommended by a health professional
    d. Testing was conducted without an explanation
    e. Other (please specify)

11. How long has it been since your prenatal screening?
    a. Less than one month
    b. 1 – 3 months
    c. 3 – 6 months
    d. 6 – 12 months
    e. More than 12 months

12. How long did it take for you to be made aware of your prenatal screening results?
    a. Less than 1 week
    b. 1 – 2 weeks
    c. More than 2 weeks
    d. I have not yet received my results

13. Who delivered your prenatal screening result?
    a. Geneticist
    b. Genetic counsellor
    c. Neonatologist
    d. General Practitioner
    e. Midwife
    f. Nurse
    g. Obstetrician
    h. I don't know
    i. Other (please specify)

14. How was the outcome of your prenatal screening result delivered to you? Please select all applicable options.
    a. Face to face (verbal information only)
    b. Face to face (verbal and written information)
    c. Email
    d. Over the phone
    e. Post
    f. Other (please specify)

15. Did you receive a high-risk/positive result for a fetal anomaly?
    a. Yes
    b. No
    c. I don't know

16. Were you offered any further follow-up testing to confirm your prenatal screening result?
    a. Yes (please specify)
    b. No
    c. I don't know

Note: The following questions were only asked to women who had NIPT

17. If you received a high-risk result, what condition was identified by NIPT?
    a. 22q11.2 deletion syndrome
    b. Down syndrome
    c. Edwards syndrome
    d. Patau syndrome
    e. Turner syndrome
    f. Triple X syndrome
    g. Klinefelter syndrome
    h. Other (please specify)
    i. Not known/disclosed

18. Did you have follow-up diagnostic testing to confirm your NIPT result?
    a. Ultrasound (specific for visual examination of physical abnormalities)
    b. Diagnostic testing (CVS, amniocentesis, or other diagnostic test)
    c. I did not have follow-up testing
    d. Other (please specify)

Note: The follow questions were only asked to those who did have follow-up testing

19. Did the follow-up diagnostic testing confirm the NIPT result?
    a. Yes
    b. No

20. After receiving your diagnostic testing results, what decision did you make regarding this pregnancy
    a. I decided to continue with my pregnancy
    b. I decided to terminate my pregnancy
    c. I am still deciding whether to continue or terminate my pregnancy

21. At what stage of your pregnancy did you make this decision?
    a. 1 – 12 weeks (1st trimester)
    b. 13- 26 weeks (second trimester)
    c. 27 – 40 weeks (third trimester)

Note: The following question was asked to all participants within the survey

22. If you were offered prenatal screening again, would you make the same choice (to undergo screening)? Please elaborate on your response.
    a. Yes [provide elaboration]
    b. No [provide elaboration]

Note: The following questions will have free text responses and will be asked at the end of the survey.

23. What were your main reasons for choosing to undergo or not undergo NIPT?

24. Do you have any further comments that you feel are relevant and have not been covered in this survey?

Appendix I: Standardised Measures

Decisional Conflict Scale (O'Connor, 1995)

Think about the decision you made to undergo prenatal screening. Please how strongly you agree or disagree with each statement in regard to your decision to undergo prenatal screening.

0 = strongly agree 1 = agree 2 = neither agree nor disagree
3 = disagree 4 = strongly disagree

1. I knew which options were available to me	0	1	2	3	4
2. I knew the benefits of each option	0	1	2	3	4
3. I knew the risks and side effects of each option	0	1	2	3	4
4. I was clear about which benefits mattered most to me	0	1	2	3	4
5. I was clear about which risks and side effects mattered most to me	0	1	2	3	4
6. I had enough support from others to make a choice	0	1	2	3	4
7. I chose without pressure from others	0	1	2	3	4
8. I had enough advice to make a choice	0	1	2	3	4
9. I was clear about the best choice for me	0	1	2	3	4
10. I felt sure about what to choose	0	1	2	3	4
11. The decision was easy for me to make	0	1	2	3	4
12. I felt I had made an informed choice	0	1	2	3	4
13. My decision showed what is important to me	0	1	2	3	4
14. I expected to stick with my decision	0	1	2	3	4
15. I am satisfied with my decision	0	1	2	3	4

Genetic Counselling Satisfaction Scale (DeMarco, Peshkin, Mars, & Tercyak, 2004)

Please read each statement below and select the how much you agree or disagree with each statement regarding your genetic counselling experience.

*Genetic counselling involves the provision of objective information about NIPT, what it screens for, its clinical features (variability of conditions tested), and the accuracy of the test. Genetic counselling also involves the provision of objective information in regard to the neurodevelopmental disorders that NIPT screens for.

*In the following questions, genetic counsellor refers to the health professional that delivered information about the screening test.

1 = strongly disagree 2 = somewhat disagree 3 = uncertain
4 = somewhat agree 5 = strongly agree

1. My genetic counsellor seemed to understand the stresses I was facing	1	2	3	4	5
2. My genetic counsellor helped my identify what I needed to know to make decisions about what would happen to me	1	2	3	4	5
3. I felt better about my health after meeting with my genetic counsellor	1	2	3	4	5
4. The genetic counselling session was about the right length of time I needed	1	2	3	4	5
5. My genetic counsellor was truly concerned about my wellbeing	1	2	3	4	5
6. The genetic counselling session was valuable to me.	1	2	3	4	5

Multidimensional Measure of Informed Choice – Non-Invasive Prenatal Testing (Marteau, Dormandy & Michie, 2016)

Answer the following questions one by one. Please do not read through to the end of this section before you begin as this may give some of the answers away and not reflect your true understanding of the test. Please do not go back and change responses once you have completed the questions.

1. Which of these conditions does non-invasive prenatal test (NIPT) test the baby for? (tick one answer only)
   Spina bifida
   Anaemia
   Down's syndrome
   Down's syndrome (and 2 rarer chromosome conditions Edward's and Patau syndrome)
   All known genetic conditions
   Not sure

2. How is NIPT done? (tick one answer only)
   Saliva test from the mother
   Urine test from the mother
   Blood test from the mother
   Invasive test taking amniotic fluid from around the baby
   Not sure

3. What does a predicted to be affected NIPT result mean? (tick one answer only)
   The baby definitely has the condition
   It is highly likely that the baby has the condition, but invasive testing is needed to confirm the diagnosis
   Not sure

4. What does a highly unlikely to be affected NIPT result mean? (tick one answer only)
   The baby definitely does not have the condition
   It is highly unlikely that the baby has the condition, but as the test is not 100% accurate there is a very small chance the result is wrong
   Not sure

5. How does NIPT compare with standard Down's syndrome screening tests (ultrasound scan and/or blood test from the mother) currently offered during pregnancy? (tick one answer only)
   It is less accurate
   It has the same accuracy
   It is more accurate
   Not sure

6. How safe is NIPT (tick one answer only)
   There is no risk to you or the baby
   There is a risk of miscarriage
   Not sure

7. How long does it take to get an NIPT result? (tick one answer only)
The result will be available immediately after the blood is taken
It takes 24 hours to get a result
It takes 7-10 working days to get a result
Not sure

8. Will you always get a test result?
Yes, it is certain that you will receive a test result
No, in a small number of cases the laboratory can't give a result and the test can be repeated
Not sure

9. How safe are invasive tests (amniocentesis or CVS)? (tick one answer only)
There are no risks to you or the baby
There is a small (around 1%) risk of miscarriage
There is a high (20%) risk of miscarriage
None of these
Not sure

10. If it is confirmed that your baby definitely does have the condition, what will you be offered? (tick all that apply)
Immediate treatment for the baby
Support to prepare for a baby with the condition
The option of terminating the pregnancy if you want to
None of these
Not sure

11. Do you have to take any of these tests? (tick one answer only)
Yes, all women have to take these tests in pregnancy
No, it is my choice whether or not to take these tests
Not sure

12. What is Down's syndrome? (tick one answer only)
A life-long condition that causes learning difficulties
A condition that can be cured by surgery
A condition that children grow out of
Not sure

For each of the following five questions, please select the number from 0 to 4 on the scale that best describes how you feel at the moment.

13. For me, having NIPT would be:

Beneficial	0	1	2	3	4	Harmful

14. For me, having NIPT would be:

Important	0	1	2	3	4	Unimportant

15. For me, having NIPT would be:

A good thing	0	1	2	3	4	A bad thing

16. For me, having NIPT would be:

Reassuring	0	1	2	3	4	Not reassuring

17. For me, having NIPT would be:

Desirable	0	1	2	3	4	Undesirable

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

You have previously had to consider whether to or not to undergo NIPT. Answer the following questions about your decision. Please indicate to what extent each statement is true for you at the time of making your decision.

1 = strongly disagree 2 = somewhat disagree 3 = uncertain
4 = somewhat agree 5 = strongly agree

1. I am satisfied that I was adequately informed about the issues important to my decision	1	2	3	4	5
2. The decision I made was the best decision for me personally	1	2	3	4	5
3. I am satisfied that my decision was consistent with my personal values	1	2	3	4	5
4. I am satisfied that this was my decision to make.	1	2	3	4	5
5. I am satisfied with my decision	1	2	3	4	5

Appendix J: Scope of Journal of Genetic Counseling

The Journal of Genetic Counseling (JOGC), published for the National Society of Genetic Counselors, is a timely, international forum addressing all aspects of the discipline and practice of genetic counseling. The journal focuses on the critical questions and problems that arise at the interface between rapidly advancing technological developments and the concerns of individuals and communities at genetic risk. The publication provides genetic counselors, other clinicians and health educators, laboratory geneticists, bioethicists, legal scholars, social scientists, and other researchers with a premier resource on genetic counseling topics in national, international, and cross-national contexts.

As a crucial resource for genetic counselors and associated professionals, the Journal's primary purpose is to report original research in the following areas:

- **Genetic Counseling Theory, Methods, and Practice**: addresses genetic counseling in clinical or non-clinical settings;
- **Public Health, Public Policy, and Access and Genetics Service Delivery**: addresses public health genomics, health behaviors, legal or policy aspects related to genetic counseling and genetic testing, precision medicine, health disparities, models of genetics services delivery;
- **Education and Genetics Professional Workforce Issues**: addresses educational training, professional development, and workforce topics related to genetic counseling;
- **Ethical, Legal, Psychological, and Social Issues**: addresses ethical, legal, psychological, and/or social issues related to genetic counseling, genetic services, and/or genetic information regarding individuals, communities, and the public
- **Risk Assessment**: addresses algorithms, theoretical models, or empirical data for use in genetic counseling risk assessment.

In addition to research articles, regular features of the Journal of Genetic Counseling include case presentations, editorials, rapid publications, and letters to the editor. Note: The Journal does not publish non-human animal studies.