A qualitative study looking at informed choice in the context of non-invasive prenatal testing for aneuploidy

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ABSTRACT
Objective To explore women’s attitudes towards non-invasive prenatal testing (NIPT) and determine factors influencing their decisions around uptake of NIPT.

Method We conducted qualitative interviews to assess knowledge, attitude and deliberation amongst women offered NIPT in a public health service. In total, 45 women took part in telephone interviews (79% participation rate).

Results Most women could recount the key aspects of NIPT discussed during pre-test counselling but had variable knowledge about Down syndrome. Analysis of women’s attitudes towards undergoing NIPT revealed three dominant factors they considered when reflecting on the test: (1) how NIPT compared with alternative testing options, (2) reflections on coping and (3) moral or religious values. Exploring the deliberative process revealed the different paths women take when making decisions. For some, it was an extension of the decision to have Down syndrome screening; some considered it early on following the booking-in appointment; others made step-wise decisions about NIPT when it became relevant to them.

Conclusion Our findings support the importance of personalised counselling, whereby women and their partners have the opportunity to reflect on the implications of the test results in the context of their own lives and values. Our data highlight the influence of personal circumstances on decision-making. © 2016 The Authors. Prenatal Diagnosis published by John Wiley & Sons, Ltd.

INTRODUCTION
Most Western countries have established prenatal screening programmes for Down syndrome (DS), with first trimester combined DS screening or second trimester serum screening followed up by invasive testing for women at increased risk.1–3 This approach to prenatal screening for DS is, however, rapidly changing following the introduction of non-invasive prenatal testing (NIPT), which is based on the analysis of cell-free DNA in maternal plasma and can be used to screen for DS and major trisomies with detection rates as high as 99.2% and low false positive rates (0.09%).4 Although highly accurate, NIPT is still a screening test and requires invasive testing for confirmation of a positive NIPT result.5

Regardless of the approach to testing, if DS is diagnosed during pregnancy, women are faced with the difficult decision to either continue or terminate their pregnancy. As such, it is vital that women who are offered DS screening are supported in their decision-making process to facilitate making an informed choice, a view emphasised by professional bodies in the UK and USA.6,7 Despite this, research studies have shown that pregnant women do not always make informed choices about traditional DS screening.7–9 Moreover, one of the key concerns associated with the implementation of NIPT in clinical practice relates to the potential for routinisation and undermining of informed choice.10–13

One of the most widely used measures of informed choice is the Multidimensional Measure of Informed Choice (MMIC) developed by Marteau et al. for women undergoing DSS.14 The MMIC is based on informed choice being defined as one made with sufficient knowledge, in line with the person’s values and attitudes to testing and behaviourally implemented. We have recently developed and validated it to measure informed choice (the Informed Choice study) amongst women offered NIPT in our public sector maternity healthcare system.15 Whilst quantitative measures of informed choice are valuable, they do not provide an in-depth understanding
of decision-making. Accordingly, the addition of a qualitative arm to the quantitative assessment of informed choice is considered ideal. We have previously reported the quantitative work conducted to measure informed choice for NIPT in which 89% of women were judged to have made an informed choice. Here, we describe the detailed findings from our qualitative work.

**METHOD**

Approval for the NIPT Evaluation Study was obtained from NHS Research Ethics Committee London – Camden and Islington (13/LO/0082) in February 2013.

**Sample and recruitment**

Recruitment into the RAPID NIPT Evaluation Study is described in detail in the study protocol. In brief, women with a standard DS screening risk > 1/1000 were offered NIPT as a contingent test. Those with a risk of > 1/150 were considered ‘high risk’ and those with a risk of 1/151 to 1/1000 intermediate risk. A consecutive sample of approximately 100 women at each of eight participating centres were invited to take part in the Informed Choice study which consisted of two questionnaires (T1 (containing the adapted MMIC) after accepting or declining NIPT and T2 one month later). A subset of T1 responders (with varying MMIC scores, pregnancy pathways, DS screening risk, NIPT uptake and demographic backgrounds) were purposively selected to take part in an interview. In this paper, we report only the findings from T1 interviews which focused on exploring the different dimensions of informed choice (knowledge, attitude and deliberation). The findings of the interviews at T2 exploring the impact of the test results and overall reflections on NIPT are reported elsewhere.

**Interviews and data analysis**

Following consent, interviews were digitally recorded and transcribed verbatim. Data analysis was conducted using thematic analysis and facilitated by NVIVO version 10 software (QSR International, Pty Ltd). Transcripts were read repeatedly and broken down into small meaningful units of texts (codes). Codes were generated both deductively (using key topics from the interview guide) and inductively (themes emerging from the discussion). The text in each code was then reviewed allowing for revision, combination or separation of codes. Revised codes were then clustered to form broader categories which were then placed under one of the key dimensions of informed choice (knowledge, attitude, deliberation and behaviour). Recruitment of interview participants ceased once saturation had been reached.

**FINDINGS**

**Participant characteristics**

Forty-five women took part in a telephone interview between December 2013 and September 2014 (79% response rate). Interviews lasted between 12 and 38 min. The sample characteristics of the participants are described in Table 1. Thirty-two women (71%) were intermediate risk, and the majority (n = 39; 87%) had NIPT. Most (n = 33; 73%) were White or White British and highly educated (n = 32; 71%).

**Knowledge**

Most women could recount the key aspects of NIPT that were discussed during pre-test counselling. Testing procedure (that NIPT was a blood test), the high accuracy rate and the safety of the test were frequently cited when participants were first asked about their understanding of NIPT, highlighting the importance placed on these aspects. In around one third of cases, women had heard of NIPT prior to being invited to take part in the Evaluation Study, either through friends and family, or through the media or on the internet.

All the women interviewed were aware that NIPT tested for Down syndrome. Nevertheless, when asked about their understanding of the condition, this was found to be variable. Most participants were aware that the condition was incurable, and that those affected had learning difficulties but only a
small number were aware that affected individuals could also have physical health problems. Information about the condition had been acquired either at school, through the media or via the information provided at the booking-in appointment. A small number had experiential knowledge, such as a family member having Down syndrome or a friend having a child with the condition.

Whilst the majority of women knew that NIPT also tested for Edwards and Patau syndrome, the interviews highlighted that most participants had no knowledge of these conditions prior to being informed about them either at the booking-in appointment, or when they were offered NIPT. Most women recollected that these conditions were much more severe than Down syndrome.

Although the majority of women demonstrated good knowledge about NIPT in the interview, some inaccuracies or misunderstandings became apparent. This included that NIPT tested for spina bifida; that NIPT was 100% accurate; that there was ‘a 1% chance that the result could be incorrect’, that NIPT was more accurate than CVS and the turnaround time for NIPT results was quicker than for invasive testing. In most cases, these misunderstandings had been addressed and corrected during pre-test counselling.

Attitudes
We identified three dominant factors that shaped women’s attitudes towards NIPT. Frequently, women would consider a combination of these factors when formulating their decisions about testing. We also identified an important sub-theme – ambivalence towards undergoing NIPT – which occurred in a minority of cases.

Comparing NIPT to alternative prenatal testing options
Women frequently discussed NIPT in comparison with undergoing traditional DS screening, saying they found traditional screening to be difficult to interpret largely because of the way the results are reported and in one case because the complexity of the algorithm used to calculate risk was confusing. NIPT, in contrast, was frequently described as ‘reassuring’ because it was more accurate; the way the result was reported (as either ‘highly likely’ or ‘highly unlikely’) was easier to understand, and because the test looked at material originating from the baby. Thus, for the majority of women, NIPT enabled them to have reassurance that the baby was not affected by one of the three main trisomies and reduced anxiety for the remainder of the pregnancy.

Whilst most women’s attitudes towards DS screening supported their decision to have NIPT, in a small number of cases, the opposite occurred. For two women, screening results were perceived to be sufficiently reassuring that there was no need for follow-up NIPT.

“I was low risk from screening and felt secure with that result” P54: intermediate risk, declined NIPT

Women also framed their views of NIPT through comparing it with invasive testing, particularly those women who were found to be high risk through DS screening. Although they acknowledged the test was not diagnostic, for most women, the accuracy rate was considered high enough to deliver ‘a clear indication’ without risk of miscarriage.

“Its chances of miscarrying are nonexistent with this test and the fact that then we’ll know for sure, well almost for sure, but I think it will be good enough for us.” P22: high risk, had NIPT.

Test safety was found to be key. NIPT enabled women to make decisions based purely on whether they wanted to know whether the baby had Down syndrome, rather than having to weigh this up against the fear of miscarriage. The risks of invasive testing compared with the non-existent risks of NIPT were therefore pivotal in the decision-making process.

Whilst most women were encouraged by the high accuracy rates associated with NIPT, the small false positive and negative rates were the reason why three high-risk women opted for invasive testing.

“I think the tricky thing for me is how it’s used at the moment and so therefore in the context of how I decided to use it myself in decision-making as to invasive testing or not. Because I think largely, at the moment, although it is very sensitive and specific, it is seen as a screening test rather than a definitive test.” P80: high risk, had NIPT.

Personal experiences and reflections on coping
Women’s perceptions of whether they felt physically and mentally able to take on the challenges of caring for a child with Down syndrome were found to play a significant role in influencing their attitudes towards undergoing NIPT. During these considerations, some reflected on the extent to which they perceived themselves to be at risk as a result of their age, for example, ‘I’m anxious about Down’s [syndrome] with the risk at my age’. Some also considered their current care responsibilities including children and partners, current health issues, and what it would mean to care for a child with the condition in the context of their families’ lives at that particular time as highlighted by the following quote:

“I think, for me, in particular, my husband has multiple sclerosis and I’ve got two children already and I’m a bit older and so it was very important for me... I was quite clear about the fact that I couldn’t take on caring for something knowing that I might have to care for my husband in the future.” P21: intermediate risk, had NIPT.

Another woman who had declined screening in her first pregnancy because she felt she could ‘take on the world’, then opted for screening and NIPT in her second pregnancy as her views about raising a child with disabilities had changed significantly:

“Second time round it felt like we weren’t 100% sure that we would necessarily go through with having a child who had disabilities...and that’s partly linked to our older son who was very ill between 18 months and two and a half and I think that made us realise quite how enormous having a very ill child is emotionally and in terms of how that affects your life.” P15: intermediate risk, had NIPT.
These examples highlight how past experiences can play a significant role in the way people think about the future, and the level of uncertainty they are prepared to accept, irrespective of their particular demographic risk.

Participants also reflected on their ‘future lives’, for example, one participant with a high-risk reflected on what the long-term future of parenting a child affected by Down syndrome would look like and the implications for her own children.

“It’s not just thinking about the here and now…When you think your average child sort of 18/19/20 is really sort of, pretty independent…we would never have that. We would have still had a very dependent child that needed us. That has really played a decision.” P44: high risk, had NIPT and invasive testing

Moral or religious values

Moral or religious views around termination of pregnancy and perceived quality of life of a child with Down syndrome (or Edwards or Patau) were frequently cited when women reflected on their attitudes towards NIPT. The vast majority of women did not have any moral or religious objections to termination per se. Thus, they considered the quality of life of that child, and whether the condition was severe enough to warrant termination of pregnancy. Most women agreed that the quality of life of a child with Edwards or Patau was so poor that it did justify termination of pregnancy.

“If it was Down syndrome I would want to know so that I could prepare myself…If it was something like Edwards syndrome or something where the quality of life is pretty horrendous and the baby wouldn’t live particularly long I think it would be too upsetting for everybody and I’d probably want to end it.” P11: intermediate risk, had NIPT

For a small number of women, however, termination was considered unacceptable, irrespective of what the condition was.

Interviewer: “Would termination be an option for you?”
Interviewee: “No, for me it’s not an option. You must have what God gives you.” P34, intermediate risk, declined NIPT

Nevertheless, the vast majority of women who had moral or religious objections to termination of pregnancy still had a positive attitude towards NIPT, because it gave women reproductive autonomy and enabled them to prepare for the birth of the child.

“The benefit I think would be the fact that yes we can be prepared for it. We can find out more information on Down’s Syndrome and plan ahead.” P14, intermediate risk, had positive NIPT result, declined invasive testing and continued pregnancy

Ambivalence towards undergoing NIPT

In a small number of cases, it became apparent that there were mixed feelings or ambivalence towards undergoing NIPT. In these cases, the decision regarding NIPT uptake was less cut-and-dry, with arguments both for and against testing. One woman spoke of her desire for information about the health of the baby, but at the same time acknowledged the potential for additional anxiety whilst waiting two weeks for the test results. Another woman acknowledged concerns around ‘over-testing’ in pregnancy, yet found it difficult to ‘decline a test that was offered by trusted health professionals’. These examples demonstrate that there are likely to be women for whom decisions around NIPT are particularly challenging, and who may need additional support during decision-making.

Deliberation

A key finding from our analysis was that, for many participants, decision-making was a multistep process. The initial consideration occurred when they first encountered NIPT at the booking-in appointment. These women made an initial judgement about whether NIPT was relevant to them but were not yet required to make a decision until they received the DS screening result and were considered eligible for the study. The way that the study was conducted, with multiple points at which to consider NIPT, was found to facilitate this process, as highlighted in the following quote:

“We had plenty of time because it was discussed at several different points so that was absolutely fine.” P18: intermediate risk, had NIPT

This multistep deliberative process was not evident in all cases. In a number of cases, women commented that they did not give NIPT much consideration early on in the process as it was not yet fully relevant to them. It was only once they found to have a risk >1/1000 that the decision became relevant.

“The first I heard about [NIPT] was when they sent all the information about my booking in appointment…And at the time I read it, but I dismissed it because I thought oh I won’t be in that group…so I heard about it then but then I didn’t really consider it until I actually went for my [NIPT] test and got the results.” P15: intermediate risk, had NIPT

In another example, the majority of the deliberative process was focused on decision-making around DSS, and NIPT was seen as an extension of this decision. This woman described her decision about NIPT as being ‘a no-brainer’ with the ‘only difficulty being the initial decision about whether to have screening done.’

In a small number of cases, it was less clear as to whether participants had given sufficient deliberation to NIPT. For example, one woman described NIPT as being a routine test – ‘It’s something that you do…’ and had not considered the potential outcomes. The potential for routinisation of testing was evident in another comment from one woman who described NIPT as ‘just another blood test so there wasn’t much to think about’. These comments underscore the complexity of ensuring informed decision-making when a
new technology is masked behind a seemingly old technology – a blood test.

**DISCUSSION**

As far as we are aware, this is the first study to use a qualitative approach to look at the multiple components of informed choice in the context of NIPT. Research into informed decision-making for NIPT is now beginning to emerge; however, these have predominantly been quantitative in scope. The findings from this study must be viewed with some degree of caution given that NIPT is unlikely to be offered in clinical practice with the same emphasis on written information and lengthy pre-test counselling as was provided in this pilot study. Nevertheless, our study has revealed the complexities of the decision-making process whereby participants frequently used a combination of clinical information, personal experiences and moral values to guide action. Moreover, we observed a deliberative process in which there may be multiple steps to deciding whether to accept or decline NIPT. This concurs with most health behaviour theories which consider health decisions to be the end result of a decision-making process that is based on deliberative processing of the available information. Women’s initial unfamiliarity with NIPT, coupled with an increased risk result, may have led them to think through the decision more consciously and find more relevance in the decision that led to them becoming more informed, a key aspect of Adult Learning Theory, whereby individuals explore the basis for assumptions and reframe preconceptions in the presence of new information. Re-examining informed choice once NIPT is offered routinely in clinical care would be important to ensure rates of informed choice remain high.

Reflections on personal experiences, coping, quality of life and views towards termination were identified as dominant factors when women formulated their attitudes towards NIPT. These reflections were considered in conjunction with the clinical information provided by the health professional. These findings chime with our previous research on NIPT where quality of life, coping and beliefs around termination of pregnancy were identified as important factors when making decisions around prenatal testing. Other studies looking at decision-making for both DS screening and invasive testing have identified similar findings. This suggests that the experience of decision-making around NIPT is not significantly different from other types of prenatal tests where personal experiences are key factors. Nevertheless, it could be argued that the decision-making process is easier because women do not also have to consider these factors against the risk of miscarriage.

One aspect where women had less knowledge was with regard to DS itself. Archibald and McClaren highlight the importance of incorporating the role of experiential knowledge into the development of educational materials and genetic counselling approaches. This could include providing insight into the ‘lived experience’ of the condition through vignettes or videos of people with the condition and their families, and thereby potentially improve understanding of DS.

In general, women were judged to have sufficient knowledge about the test and testing procedure to enable them to make an informed decision about NIPT. Nevertheless, comments such as understanding fetal material to originate from the baby (it originates from placental trophoblasts) and the high accuracy rate enabling women to be ‘almost sure’ and that there was a 1% chance the result could be incorrect (positive predictive value for NIPT has been shown to be as low as 50% for NIPT) does indicate that some of the limitations of the technology may not have been fully comprehended. These findings highlight the need for health professionals to have a good understanding of the limitations of NIPT and be aware that women may come with pre-existing views that have been influenced by the media or commercial NIPT providers and misconceptions and misunderstanding may need to be addressed.

Women were found to not only have sufficient knowledge of the test and an attitude reflected in their decision regarding NIPT but also had the opportunity to consider the implications of the test results. This is consistent with our quantitative findings where rates of informed choice were high with most women having deliberated on the decision. This emphasizes the importance of allowing women’s time to have this reflective dialogue. Implementation of NIPT as a contingent test is one way that this deliberative process may be facilitated as decisions can be made in a stepwise manner. Nevertheless, NIPT in clinical service is likely to be offered very differently with much less time dedicated to pre-test counselling and explanation of the different options available. Whether women will have adequate time to make decisions in a stepwise manner remains to be seen and should form the basis of further research when NIPT is introduced into routine practice. Our findings also demonstrate the different paths women take when making decisions about NIPT and the possibility for ambivalence around testing. It is imperative that health professionals support women not only by ensuring they have sufficient knowledge about NIPT but also through facilitating a dialogue whereby women and partners reflect on the implications of the test results guided by individual values and preferences.

**STUDY LIMITATIONS**

A key limitation of this study is that the women received extensive written and verbal information from a dedicated research midwife, which may not to reflect the reality of how NIPT will be offered in a routine clinical practice. Furthermore, the population were highly educated and well informed. Understanding some of the complexities associated with NIPT may be more challenging for people with lesser levels of education or lower literacy in English. The majority of women in this study accepted NIPT and may therefore be more likely to hold positive attitudes towards NIPT than women who declined. This may have
positively skewed our findings. Of note, a number of women (n = 13) who had NIPT and received a diagnosis of DS chose to continue the pregnancy, supporting the observation that women with a positive attitude towards NIPT may use it to prepare for the birth of a child with DS.\textsuperscript{18}

**CONCLUSION**

Our study has highlighted the multiple factors that influence women’s attitudes towards testing including how NIPT compares with alternative prenatal testing options, reflections on coping, personal experiences and circumstances, quality of life and attitudes towards termination of pregnancy. As the diagnostic capabilities of NIPT increase, there will be new challenges to address in order to prepare pregnant women to make informed choices. Ensuring healthcare providers who are providing pre-test counselling are aware of the myriad of factors that influence decision-making and the different ways in which women perceive and respond to these factors is critical.

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