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The role of focus groups in a randomised controlled trial: the ADEPT study

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Background
In a recent study we developed a decision aid for prenatal testing of fetal abnormalities. The effectiveness of the decision aid compared with a pamphlet in increasing women’s informed choice and decreasing conflict was evaluated using a cluster randomised controlled trial, A Decision aid for Prenatal Testing for fetal abnormalities (ADEPT) [ISRCTN22532458].² Challenged with the need to ensure that the decision aid best suited the needs of women and health professionals involved General Practitioners (GPs), we explored the potential of both quantitative and qualitative methodologies to inform the development phase. In this article we discuss our rationale for, and provide some insights regarding our experience of, using qualitative methods during the development phase of the decision aid.

In the ADEPT study, we used the enhancement model in which the qualitative data is thought to add something further to the quantitative research. This may be in two ways, dependent on whether the qualitative research precedes or follows the quantitative research. Firstly, qualitative research data may inform quantitative tools to be used in quantitative research, as in the ADEPT study. Secondly, qualitative research may explain some findings from quantitative research. This may be as simple as using open-ended questions in a survey to elaborate on responses to a preceding multi-choice question or using in-depth interviews with target populations to further explore outcomes established from quantitative research.³

Our rationale for using qualitative, rather than quantitative methodology in the development phase was the need to explore the feasibility of designing a decision aid and if necessary, to learn about the prenatal testing information needs of women from the perspectives of both women and GPs. In particular, we sought a detailed understanding of what information was considered useful and how this information should be presented. Collecting data through focus groups provided us with the flexibility to explore these issues in depth with participants and to learn from the interaction between participants, which would not have been possible using quantitative methods.

Our experience
Between June 2003 and August 2003, five focus groups were conducted involving 35 women. Four GP focus groups were conducted between May 2003 and July 2003 with 27 GPs participating. The focus groups were conducted in targeted metropolitan, regional and rural settings in Victoria. Women participants were recruited through maternal and child health centres, community organisations and professional settings and GPs were recruited through Divisions of General Practice, publicly available telephone listings and professional networking. A range of strategies including fliers and letters inviting participation were used to recruit participants. As the decision aid was to be trialled with primiparous and multiparous women it was important to learn of the information needs of women yet to experience pregnancy as well as women who had had children. While women could share their personal and collective experiences and thoughts, involving health professionals who consulted with a wider population was also considered important.

The interaction between participants is a unique feature of focus groups.¹ In an effort to foster dialogue, a sense of group identity and trust, we grouped the women participants by whether or not they had had children and according to their geographical location. The topic of prenatal testing for fetal abnormalities can be a sensitive topic to discuss with others and the use of homogenous grouping was particularly important to assist women feel more comfortable to share their thoughts and experiences. GP groups were conducted on the basis of geographical location.

The focus groups were conducted using two facilitators and establishing ground rules prior to discussions that were led using a question guide. All groups were audio-taped and professionally transcribed. The groups were conducted until informational redundancy was reached. Analysis followed reading and re-reading of the transcripts and the content was analysed using a pre-specified coding schedule.

Four topics were coded: content of information, amount of information, level of information and format of information. This information underpinned the design of the decision aid. It could be argued that similar information could have been collected using a questionnaire. While this is true for the factual material that was gathered, focus groups provided a much richer understanding of issues than the more conventional quantitative method allowed such as why certain information should be included. We felt that knowing the ‘why’ would facilitate the implementation of the decision aid into clinical practice, if found to be effective.
The GP experience of providing complex information to women, how they filtered this information and how they reacted to time pressures were important insights from the focus groups that would not have been revealed as a collective using other approaches. In providing information about screening tests to women, GPs identified the negative impact of providing this information early in pregnancy when women presented, happy with the confirmation of their pregnancy, and the GP needed to introduce the topic of testing (Box 1).

Box 1: Quotations from GPs experience of introducing prenatal tests for fetal abnormality

“It’s very hard to explain statistics if you have a 1 in 400 chance of having a Down syndrome baby – what does that mean to a woman? 1 in 400? Well, that sounds like a low risk, why what’s all the fuss? It’s really hard to explain...it’s hard to explain the statistics – that’s why I say the damn statistics, how do you get this concept of risk over to them? It’s a very difficult issue.”

“Pressure – they’ve just come to tell you that they’re pregnant and immediately you start with a story about Down syndrome which probably they’ve never even heard of – pressure on them to decide whether or not they want to test. They may not want to, they’ve got lots of other things they want to ask about, not just Down syndrome and the time it takes to explain...”

“...in fact you feel like a bit of a spoilsport bringing it up because they’re really happy and you know– and then y'ou're sort of saying, oh well you know, I hate to bring it up but, have you thought about...”

“A lot would come in, they're overjoyed to be pregnant... and the thought of then throwing in testing for all those things that might be wrong with the pregnancy. It’s a bit of a downer.”

Consistently women across all groups wanted information on the practical aspects of testing including accuracy, safety, availability, cost, how to access tests and recovery time. Again this information could be collected in a variety of different ways however, the use of focus groups uncovered many valuable insights into women’s thoughts, attitudes and experiences that we used to tailor the decision aid.

There was common agreement within the groups of multiparous women that the amount of information provided in pregnancy was overwhelming. As described by one woman “...there’s so much information that you are presented with when you’re pregnant and there are so many things to think about that you just end up swimming.” A range in amount of information required was evident across the women’s groups and this challenged our team to develop a decision aid that had the flexibility to cater for this range at the same time as presenting the information in a concise eye catching way to stand out from the other information provided in pregnancy.

Through the process of using qualitative methods, new information was generated and as a result we included information within the decision aid that we may otherwise have missed. This included information on termination of pregnancy and hypothetical scenarios to describe some of the different decision making processes of women in response to comments like this one: “I think (I would like) anecdotes, a story which people have gone through having to make a difficult decision – why they chose – to make that decision and what the outcomes were and how they feel about the decision they made, personalise it a bit.”

In the development of decision aids, focus groups play a valuable role in ensuring that the developers have a more complete understanding of the decision making process and gain valuable insights to issues that may not be accessed without dialogue within a group environment.

Lessons we learnt

Compared to a survey design, there were additional cost implications in audio taping the focus groups and the transcription of tapes. Another important consideration was the additional time we required for recruitment, data analysis and interpretation compared to using traditional quantitative methods. The use of quantitative methods would have been less resource intensive. However, the use of focus groups in our study was planned and budgeted for and in our experience the benefits of using qualitative methods in the development phase of the ADEPT study outweighed the negative aspects associated with costs and time.

We collaborated with experienced qualitative and quantitative researchers on our project team and this was important in ensuring that our mixed methods approach was robust. In addition, many thoughts, feelings and experiences arise in focus groups that can challenge the way we think as researchers. This required for us to develop a particular skill set and the qualitative expertise of our project team provided invaluable support. The collaborative nature of the project team also gave us the opportunity to ‘cross pollinate’ between both approaches, benefiting all.

Developing a resource for women on prenatal testing for fetal abnormalities requires an understanding of women’s information needs, values and preferences. Seldom are the nuances of such complex areas of study completely understood and qualitative methods allow the opportunity for the generation of new information, which can then be tested using a quantitative design.

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