Decision-making about mode of delivery after previous caesarean section: development and piloting of two computer-based decision aids

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Abstract

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Objective To develop and pilot two computer-based decision aids to assist women with decision-making about mode of delivery after a previous caesarean section (CS), which could then be evaluated in a randomized-controlled trial.

Background Women with a previous CS are faced with a decision between repeat elective CS and vaginal birth after caesarean. Research has shown that women may benefit from access to comprehensive information about the risks and benefits of the delivery options.

Design A qualitative pilot study of two novel decision aids, an information program and a decision analysis program, which were developed by a multidisciplinary research team.

Participants and setting 15 women who had recently given birth and had previously had a CS and 11 pregnant women with a previous CS, recruited from two UK hospitals. Women were interviewed and observed using the decision aids.

Results Participants found both decision aids useful and informative. Most liked the computer-based format. Participants found the utility assessment of the decision analysis program acceptable although some had difficulty completing the tasks required. Following the pilot study improvements were made to expand the program content, the decision analysis program was accompanied by a training session and a website version of the information program was developed to allow repeat access.

Conclusions This pilot study was an essential step in the design of the decision aids and in establishing their acceptability and feasibility. In general, participating women viewed the decision aids

as a welcome addition to routine antenatal care. A randomized trial has been conducted to establish the effectiveness and cost-effectiveness of the decision aids.

Introduction

Caesarean section (CS) rates are rising throughout the developed world. In the United Kingdom, the CS rate rose from 9% in 1980 to 21% in 2001,¹ and similar increases have been recorded in the United States and Australia.^{2,3} Determining the optimal mode of delivery for women who have had a previous CS may be difficult as it requires balancing the risks of repeat CS with those of vaginal birth after caesarean (VBAC). With the increasing rates of primary CS (CS for the first time) a growing number of women face this decision when planning a subsequent birth.

Women's decision-making about delivery after CS often involves a complex interplay of medical, psychological and practical considerations.^{4,5} In addition, decisions are made within a context of differing opinions and on-going debate amongst health professionals.⁶ Some are concerned that CS rates are too high, yet interventions developed to influence women in favour of vaginal delivery have been unsuccessful.^{7,8} By contrast, some commentators suggest that women should be able to request elective CS, even where there is no medical indication.^{9,10} This is a view which, although likely to result in a further increase in CS rates, is more consistent with the recent emphasis on women's choice in decisions concerning pregnancy and childbirth.¹¹ Policy-makers in the United Kingdom advocate measures such as counselling and referral for second opinion to minimize requests for primary CS, but maintain that for women with a previous CS, decision-making should consider maternal preferences and priorities as well as a discussion of risks.¹² It seems unlikely that controversy concerning the safest mode of delivery for mother and baby will be resolved without a randomized-controlled trial (RCT) to compare vaginal birth with elective CS. However, a survey of health professionals revealed that although most wished they had the results

of such a trial, only a minority felt it was feasible, ethical or desirable.¹³ This context, along with the growth in health-care litigation, puts health-care professionals in an increasingly difficult position with respect to how they advise and support women with a previous CS in their decision-making. There is evidence that health-care professionals may resolve this by placing a greater level of responsibility onto the woman.¹⁴ Although many women may feel comfortable taking this responsibility, there is also a suggestion that they may be doing so without the provision of adequate information about health risks and benefits.^{5,15}

Decision aids have been used to assist patients and health-care professionals with a variety of complex health-related decisions. Decision aids are defined as 'interventions designed to help people make specific and deliberative choices amongst options by providing information about the options and outcomes that are relevant to a person's health status'.¹⁶ A systematic review of health-related decision aids found evidence for improved knowledge of options, reduced decisional conflict and increased participation in decision-making, without increased anxiety.¹⁷ The review also suggested that more detailed decision aids could provide greater benefits when compared with simpler versions, but concluded that more research evidence was needed to comprehensively examine the relative merits of complex decision aids. Given the emphasis on maternal involvement in pregnancy-related decisions it is unsurprising that a number of decision aids have been developed in this area, including aids for decision-making about prenatal testing, management options for breech presentation and pain management in labour.^{18–20} A RCT of a paper-based decision aid for women with a previous CS conducted in Australia reported increased knowledge and decreased decisional conflict for those receiving the intervention compared with the usual care control group. However, these changes were not

accompanied by evidence of differences in planned or actual mode of delivery.^{21,22}

Technology, and particularly the widespread use of personal computers and the Internet, offers new opportunities for the design and distribution of decision aids. Compared with paper-based decision aids, computer programs can be more interactive, containing a greater variety of information in different formats, from which the user may easily select only the information relevant to them. Computerized decision aids can also make increasingly sophisticated and individualized decision modelling accessible to patients using techniques such as decision analysis. Decision analysis provides an explicit and systematic approach to decision-making in situations where human cognitive ability is insufficient to consider all relevant variables. It has previously been used to model the potential population impact of choice of delivery after CS,^{23–25} but has yet to be applied to individual women's decision-making. Although a number of potential conceptual and practical issues have been identified with the application of individualized decision analysis,²⁶ it has been shown to aid patient decision-making in other contexts.^{18,27} Given the complexity of the outcomes and associated probabilities to be considered, and the limited availability of specifically targeted information, decision-making after CS is a highly applicable context in which to design a decision analysis-based decision aid.

This study describes the development and piloting of two novel computer-based decision aids for women with a previous CS to assist with decision-making about their subsequent mode of delivery. The aim was to utilize the latest technology to design innovative, usable and acceptable decision aids which could be evaluated in a subsequent RCT.²⁸

Methods

Process of decision aid development

The development team comprised a consultant obstetrician, a clinical academic training fellow in obstetrics, a midwife, a general practitioner, a

research scientist with experience using decision analysis and designing decision aids, a health psychologist, applied computing specialists and a software engineer. Development activity was focused on three broad areas; content, interface design and software development. The content of the decision aids was derived from best practice protocols, extensive literature review (including systematic reviews) and from clinical experience of the issues salient to women. The content was also discussed with pregnant women from the earliest stage and revised according to their comments. The aim was to provide comprehensive and neutral presentation of the potential outcomes of the different delivery options and procedural issues using accessible language. The interface design aspect of the development involved consideration of the usability, layout, screen sequence, colours and fonts. Various issues were discussed with respect to the software development particularly relating to the method of utility assessment and interaction between the user interface and the decision analysis software. The programs were developed through 12 iterations over a period of 9 months with successive versions of the programs being created by the software engineer following detailed discussion with the development team.

Outline of the decision aids

Two computer-based decision aids were developed: (i) an information program and (ii) a decision analysis program that includes a utility assessment exercise and individualized decision analysis. Both programs begin with a login screen, followed by an introductory screen, which provides a brief description of the background to the research and aim of the program. On the main screen the information is arranged under seven tabbed menu options; introduction, frequently asked questions, complications for mother, complications for baby, non-medical benefits, special circumstances and glossary. More detail of the information provided under each of these menu options is given in Table 1.

Table 1 Outline of decision aid content

Menu	Summary of information provided	Subheadings
Introduction	Describes the information found in each of the other menus.	
Frequently asked questions	Gives descriptions of the delivery choices and information about how the pregnancy and delivery will be managed given a previous caesarean section delivery.	What are the delivery choices? Who will decide? When will the delivery method be decided? How likely am I to succeed if I try for a vaginal birth? Will it be a normal vaginal birth? What are the implications for further pregnancies? What happens if I go past my due date? What happens if I labour early? What kinds of pain relief are suitable during labour? What type of anaesthetics are used during caesarean section?
Complications for mother	Gives descriptions of possible health problems for the mother during or after delivery, providing general information about each complication as well as specific implications relating to the different delivery types if appropriate. The descriptions DO NOT provide an indication of the likelihood of the complications occurring (this information was provided separately in the information program and website only).	Hysterectomy Incontinence Surgical damage Severe perineal damage Haemorrhage Uterine rupture Infection Blood clots Delayed conception Death of mother
Complications for baby	Gives descriptions of possible complications for the baby during or after birth as outlined for the complications for mother section above.	Baby breathing difficulties Infant brain injury Death of baby Baby in poor condition
Non-medical benefits	Gives information about the practical, social and emotional benefits of the delivery choices.	Vaginal birth Elective caesarean section
Special circumstances	Describes medical problems or other situations that could arise during the pregnancy which may influence the type of delivery that is possible.	Placenta praevia/accreta Twin pregnancy Breech presentation Home birth Growth restricted baby Emergency delivery Pre-eclampsia
Glossary	Gives definitions of many of the terms used in the program.	

Information program

In addition to the descriptive information about the potential health complications outlined in Table 1, the information program includes presentation of the probability of each complication for VBAC, elective CS and emergency CS delivery. These probabilities were obtained from the best-published evidence available at the time of development. A complete list of the references

used is available from the corresponding author.

The probability information is presented in accordance with guidelines on health risk communication suggested in the literature.^{29–31}

Absolute risks are presented in number, figure and pie chart formats so women can choose to view the format(s) they find most useful. Dual representation, including both possible loss and gain, is employed to avoid framing effects and all risks are

presented using a common denominator (one thousand). Examples of the presentations formats can be viewed in Figure 1 at <http://www.phc.bris.ac.uk/phcdb/pubpdf/Diamond.pdf>. This program was designed to be simple and easy to use. By including information only, it is closer in format to other sources of information, such as leaflets or books, which woman are routinely provided relating to other aspects of their pregnancy.

Decision analysis program

The purpose of the decision analysis program is to provide each woman with an individualized suggested optimal mode of delivery. This is achieved by calculating the sum of the woman's utilities for the various possible health outcomes for each delivery choice, weighted according to the estimated probabilities of those outcomes. Assessment of utilities must be completed independently of any knowledge of the estimated probabilities. Therefore, our decision analysis program does not explicitly present probability data (in contrast to the information program described above). Instead a woman viewing the program has an opportunity to read the descriptive information outlined in Table 1 before proceeding to the utility assessment. Here, the woman is presented with a graphical rating scale from 0 to 100, and a number of pointers each labelled with a possible health complication for herself (mother) or her baby. She is instructed to move the pointers and position them between 0 (which represents her own worst possible outcome) and 100 (which represents her best possible outcome). To do this the woman is asked to consider how she would feel if each health complication actually occurred. An example screen print of the health complications ratings scale can be viewed in Figure 2 at <http://www.phc.bris.ac.uk/phcdb/pubpdf/Diamond.pdf>.

The user is then asked to consider her 'preference' for achieving or not achieving the mode of delivery she plans. There is likely to be variability across individuals in the level of disutility associated with not achieving the delivery planned, therefore it is important to incorporate

this, along with the associated estimated probability, into the individualized decision analysis. On a second rating scale the woman is asked to rate the four most common combinations of planned and actual mode of delivery (planned VBAC and actual VBAC or actual emergency CS, planned elective CS and actual elective CS or actual emergency CS). She is asked to imagine that each of the delivery combinations is what occurred and place the pointers on the scale between her best and worst outcome. These ratings are made on the same scale used for the health complications. To remind the woman of this the outcomes she rated as best and worst on the first rating scale are displayed on the second to give upper and lower anchor points.

Following the utility assessment a results screen is displayed which provides the suggested best planned method of delivery for each women (either attempted VBAC or elective CS). This result reflects the ratings given during the utility assessment combined with the estimated probabilities of each outcome within the decision tree. Each woman is provided with a printout detailing her best-suggested delivery method. This program was designed to incorporate more sophisticated decision modelling techniques along with the information content. It is therefore more complex and likely to be novel and unfamiliar to users.

Piloting of decision aids

Setting

Women were recruited from two University-affiliated teaching hospitals, located in Bristol and Dundee, UK. The units deliver 4660 and 4245 babies per year and have total CS rates of 23% and 24%, respectively. Delivery of care to women with a previous CS is similar in both locations, with women being referred to the hospital outpatient clinic to discuss delivery with an obstetrician at least once during their pregnancy.

Participants

Piloting sessions were conducted with a sample of postnatal ($n = 15$) and antenatal ($n = 11$) women. A consecutive sample of 41 postnatal

women were identified from computerized maternity unit records as delivering a live birth in the period of 2–8 months prior to recruitment and whose previous child was delivered by CS (i.e. women who had recently made the decision between VBAC and repeat elective CS). Fifteen women responded to the written invitation to participate in the study by returning a completed consent form to the research team.

The 11 participants in the antenatal sample were consecutive attendees at the hospital antenatal clinic over a 3-week period, identified from maternity unit records as having had one previous CS delivery in their last pregnancy (i.e. pregnant women who were currently making the decision between VBAC and repeat elective CS). Women in either sample who had limited ability to speak or understand English were excluded. Eligible women were provided with an information sheet and consent form, which they returned to the research team if they wished to take part. All eligible women approached agreed to participate in the study. Table 2 details characteristics of the study participants.

Recruitment and data collection took place between February and April 2004. This was

prior to commencement of recruitment into the subsequent RCT, in which none of the pilot study participants was included. All participants gave informed written consent to participate and the study was approved by the South West Multi-centre Research Ethics Committee.

Data collection and analysis

The piloting interviews were conducted by CE or MM and took place in the women's own homes. The interviews were semi-structured according to a pre-defined topic guide. Women were first asked to provide some background information about themselves and their previous childbirth experiences. The computer program was then set up. Women were observed using the program, to establish how well instructions for the navigation of the programs were understood and followed, and were encouraged to comment as they went through. Finally, they were asked about their experience of using the program. Sessions were audio-recorded and the researcher made notes during the observation to record contextual information on how women used the program. The audio-recorded interview data were reviewed by CE and sections relevant to the

Table 2 Participant characteristics

	Postnatal sample (<i>n</i> = 15)	Antenatal sample (<i>n</i> = 11)
Location, <i>n</i> (%)		
Bristol	7 (47)	8 (73)
Dundee	8 (53)	3 (27)
Decision aid used, <i>n</i> (%)		
Decision analysis program	10 (67)	5 (45)
Information program	5 (33)	6 (55)
Age, mean (range)	34.2 (20.3–39.4)	32.5 (22.4–40.4)
Parity, <i>n</i> (%)		
1	–	11 (100)
2	12 (80)	0 (0)
> 2	3 (20)	0 (0)
Type of previous CS, <i>n</i> (%)		
Elective	2 (13)	4 (36)
Emergency	13 (87)	7 (64)
Gestation in weeks, mean (range)	–	19.1 (14.1–25.9)
Age of baby in months, mean (range)	4.6 (2.4–7. 4)	–
Mode of recent delivery		
VBAC	3 (20)	–
Elective CS	9 (60)	–
Emergency CS	3 (20)	–

decision aid evaluation were transcribed. A content analysis approach was used to generate descriptive themes concerning the content of the program, the acceptability of the computer-based format, the presentation of health risks and benefits, the usability of the programs and repeat access to the programs. Generation of the themes was guided by the aims of the study and the content of the interview topic guide. The purpose of this analysis of the interview data, in combination with the notes from the observations (which were not formally analysed) was to highlight areas for discussion by the development team and to inform improvements to the programs and the protocol for use in the planned RCT.

Results

Data arising from the pilot study provided insight into women's views of the acceptability and usability of the programs and the feasibility of their investigation in a randomized trial. A number of modifications were made to the programs as a result of the pilot study. The themes arising from the data are outlined below and illustrated with verbatim quotes taken from the transcripts of the piloting sessions.

Program content

Most women found the content of both programs informative and useful.

Yeah, it's very good, it explains it all very well, saying what can happen (Antenatal participant 3, Decision analysis program).

I wish I'd had it. Yeah. Especially, you know the benefits and stuff, the wider issues (Postnatal participant 10, Information program).

I thought it was really good actually, really helpful ... all the information that you needed was on there really (Antenatal participant 1, Information program).

basically, what it says there is what the doctors had said or what I'd been through ... But seeing it there, it makes you understand better, because when a doctors telling you, you're in, sort of, shock (Postnatal participant 11, Information program).

it would have been useful, I think it would be useful for people beforehand ... I can see you are telling them what sort of complications there could be, they might not of thought of things like that (Postnatal participant 9, Decision analysis program).

However, one woman expressed that she did not believe the program would have been helpful to her and another felt language used was sometimes patronizing and over-simplified.

I think for me that probably is something that I would choose not to be reading ... I don't really think that anything there would have made it any easier for me (Postnatal participant 13, Decision analysis program).

I am not so keen on this 'out of every thousand women *like you*', the repetition of it, it's a bit like ... it sounds a bit patronising (Antenatal participant 5, Information program).

It's good to have it simplified, because you don't want to be trying to wade through complicated medical jargon, but you want to come away feeling like you've been informed, not just fobbed off (Antenatal participant 5, Information program).

The language was deemed to be at an appropriate level for most women and explanatory 'pop-up' information boxes were included to explain the medical terms.

Easy to understand ... its not medical terms, kind of straightforward talking terms and easy facts (Antenatal participant 6, Information program).

It's useful having that information box, because ... just so you can double check ... what the condition is (Antenatal participant 4, Decision analysis program).

However, some medical terms identified by women as unclear were replaced following piloting, for example, 'Perinatal death' was replaced with 'Death of baby'.

Perinatal, that's child is it? (Antenatal participant 8, Information program).

In the special circumstances menu an additional subheading was included to discuss issues surrounding home birth after CS, this was in response to one participant in the antenatal pilot who had a strong preference for a home

birth and felt the program was lacking in this area.

The main thing for me is the gaping hole as concerns to home birth ... its bad to leave that out you know (Antenatal participant 5, Information program).

Acceptability of computer-based format

Most women found the computer-based format of the programs acceptable and could recognize the benefits of this mode of presentation.

I like computers anyway. I don't have one, but I like them (Postnatal participant 9, Decision analysis program).

It's quite nice, you know, because you might not be interested in lots and lots of it. So the fact that you can sort of flick about [is good] (Postnatal participant 1, Information program).

I like the way, it's ... like this 'Complications for the Mother', I think that's very, very ... I mean I can see exactly where I want to go, I can see exactly where I want to navigate on that page (Postnatal participant 2, Information program).

However, the computer format was not every participant's preference.

I prefer that sort of information in a leaflet format rather than on a computer screen, because I can sit down on the sofa and browse through it ... but that would be a big leaflet wouldn't it! (Postnatal participant 4, Decision analysis program).

Presentation of health outcomes

The two versions of the program presented women with information concerning potential outcomes of different modes of delivery in different ways. In the information program descriptions of the health risks and benefits was supplemented with presentation of their probabilities in several formats. The decision analysis program provided only the descriptive information about health risks and benefits. The probability information was embedded within the decision tree used for the individualized decision analysis, and was not available for women to view.

Participants using the information program found the different presentation formats useful. A preference was expressed for each of the different formats.

I find that's very clear ... the number format. The figure format, that wouldn't be the way I would choose to view it ... and probably not the pie chart format either (Postnatal participant 1, Information program).

I really like that, I really like that pictorial representation of all the people. That really makes it very clear for me (Postnatal participant 2, Information program).

That's quite good how they've done that [figure format], it sort of grabs your attention more and it's a lot easier to understand (Antenatal participant 1, Information program).

[I liked] the pie charts ... If you see 2 in a 100 you think oooh, but on the grand scale of a pie chart, you think, oh yeah it is small (Antenatal participant 6, Information program).

Several women said they found the probability information reassuring, because it showed that the absolute risks were small.

Certainly having the figures this is reassuring, very much so, because it makes you notice what a small chance there is (Postnatal participant 1, Information program).

By contrast, others felt discussion of health risks was a source of anxiety. There was a suggestion that this anxiety may have been heightened for women using the decision analysis program, where descriptions of the risks were provided without an indication of how likely they were to happen.

It's interesting reading it but you probably don't want to dwell on it ... You could get yourself quite wound up about it all (Antenatal participant 4, Decision analysis program).

Sometimes the more information you know, kind of, the more you think about it and then you'd be a bit, kind of, well a bit scared really (Postnatal participant 7, Decision analysis program).

I think if you are going to give them the information, then you need to give the statistics as well ... That's not giving me any information that helps me make a decision (Antenatal participant 7, Decision analysis program).

Despite these reservations, some participants found the decision analysis program's utility assessment exercise was beneficial.

It just makes you focus on what you want to happen and what you don't want to happen (Antenatal participant 7, Decision analysis program).

I think its very clever how it comes out. Its not asking you directly, I don't think, what you'd want ... its very clever how it prioritises things, what it tells you to ... and then it gives you an idea (Antenatal participant 3, Decision analysis program).

Usability

In general, the participants found both programs easy to use. However, it was evident that some of the navigation instructions were not sufficiently clear, as during the observations it became apparent that some women unintentionally overlooked some sections of the program. Following piloting the introductory screens were extended to address this problem. In addition, some problems arose with the utility assessment in the decision analysis program. Although the participants seemed comfortable with the concept of the rating tasks, some had difficulty using the rating scales correctly. While they were using this program most women asked the researcher for clarification of the instructions as some stage. Several women rated the outcomes in reverse (i.e. putting their best outcome at 0, and their worst at 100), some found assigning the outcomes a number on 0–100 scale challenging and one woman would have preferred Likert-type scales (e.g. five or seven points between strongly agree and strongly disagree).

Participant: Am I doing that the right way round?
Researcher: No, the other way round ... yeah
Participant: So 100 is good then?
Researcher: Yeah, 100 is good (Postnatal participant 13, Decision analysis program).

I knew what I wanted to put at zero and I knew what I wanted to put at a hundred, but a number for the others, it was just more descending or ascending order ... whether it was 70 or 50 didn't

matter really. I was just ranking them, as it were, in an order (Postnatal participant 6, Decision analysis program).

I am hopeless at these sort of scales things ... I don't know how people are on those kind of scales. I like the Likert scales or like strongly agree, agree, I like that scale, because this gives me too many choices. Other people might feel differently (Postnatal participant 4, Decision analysis program).

Despite these problems, all 15 participants were able to successfully complete the ratings task.

It did take me a minute or two, to sort of ... once I'd got the hang of it, it was quite easy ... because its different to anything else you've sort of looked at (Postnatal participant 6, Decision analysis program).

In response to the issues raised in the pilot study it was decided that the decision analysis program should be accompanied by a 10- to 15-min training session. This would supplement the on-screen instructions and ensure participants understood the utility assessment. The information program was accompanied by a much briefer training session (3–5 min) to ensure participants knew how to navigate through the screens. After the training session both programs were used autonomously.

Repeat access

Some women found the quantity of information too much to absorb in one session and would have preferred the option to refer back to it. Some women felt their partners would also like access to the information.

there's an awful lot of information to take in (Postnatal participant 5, Decision analysis program).

I think it would be really nice to be able to print it out, or come with it ready printed out to leave as reference material. Because it would be difficult to remember all the statistics wouldn't it, because there's quite a lot in there ... Yeah, I think a printed version would be good, or putting it on the web so you could print your own (Antenatal participant 8, Information program).

A lot of people would probably want to just go in ... have a document there that's perhaps five or six pages long, print it out and then have look at it more slowly, perhaps with their husbands as well (Antenatal participant 7, Decision analysis program).

Rather than provide a paper copy, as some women suggested, it was decided to preserve the computer format of the decision aid and make the information program available for repeat access via a password-protected Internet site. This would also allow us to monitor the extent to which participants in the RCT utilized the repeat access option.

Discussion

Women participating in the pilot study found both the computer-based decision aids useful and informative. Most liked the computer-based format, which was beneficial in allowing more information to be presented in a variety of formats, and enabled the user to choose which sections they wanted to view. Participants made a number of suggestions to clarify and expand the content that were incorporated into later program versions. Some women expressed a desire for a means of repeat access to the programs in order that they could refer back to the information or share it with their partner. To facilitate this a password-protected website version of the information program was developed. The main contrast in views concerning the two decision aids related to the difficulty some users of the decision analysis program experienced correctly completing the ratings task. This is perhaps to be expected given the additional complexity and novel nature of the program. It was therefore proposed that in the subsequent RCT, the decision analysis program be accompanied by a training session to provide extra explanation about the use of the rating scales. Further, the RCT will explore whether the additional complexity of the decision analysis program provides users with added benefit, in comparison with the simpler information program.

The strength of this study is that it reports the development and piloting work required to successfully create a new patient decision aid. The processes used were consistent with the United Kingdom Medical Research Council framework for the design and evaluation of complex interventions to improve health,³² and the decision aids produced conform with the quality criteria framework for patient decision aids published in 2006.³³ The iterative development phase, involving a multidisciplinary team and input from service users, served to define the relevant intervention components. The pilot study included postnatal women with previous CS, who had recently made their delivery choice, to ensure all information that women felt in hindsight they had needed to inform their decision could be incorporated into the decision aids. Antenatal women with previous CS were those who fulfilled the intended inclusion criteria for the RCT. This allowed us to assess the acceptability of the interventions with the target population and identified feasibility issues that could be addressed ahead of the RCT. Conducting this study has also allowed us to address some of the challenges associated with designing decision aids. In particular, we found it was important to gain the support of local health-care providers, and to produce decision aids that are both flexible and based on the best possible evidence.³⁴ The pilot study, along with a qualitative interview study conducted concurrently and reported elsewhere,⁵ has provided insight into the context in which decisions are being made,³⁵ and highlighted the differences in women's preferences for the type and amount of information they receive.³⁶ This knowledge will inform interpretation of the results of the RCT and guide inquiry in the qualitative evaluation which accompanies it. Finally, the study highlights a need to provide more information to women with previous CS (the benefit of which was shown by a previous study)²² and the advantages of using a computer-based format with these women (an approach novel to our study).

The study was conducted with limited time and resources. It was therefore only possible to conduct piloting sessions with a relatively small number of participants and meant it was not feasible to employ a maximum variation sampling strategy to ensure the inclusion of women from a diverse range of socio-demographic backgrounds. It was also not possible to develop alternative versions of the programs in order to make them accessible to women unable to read English or unable to use a computer. These limitations may have resulted in some issues salient to women in the target population being overlooked. Women using the decision analysis decision aid experienced some difficulties with the utility assessment that has been the source of criticism in the literature. These included difficulty assigning numerical values rather than a rank order and frustration concerning the lack of explicit probability information.²⁶ However, many of the problems experienced seemed attributable to insufficient instruction rather than conceptual difficulty and several women found the decision analysis program particularly useful. These issues will be explored further during the RCT.

Conclusion

It has been established that pilot studies are essential to ensure that health-related interventions are acceptable to patients and feasible to deliver. This is equally true for the design of new patient decision aids. These activities are likely to contribute to a more successful subsequent RCT and to benefit future implementation. For the women with a previous CS participating in our pilot study the computer-based decision aids were viewed as a welcome addition to routine antenatal care. In general, they were found to be acceptable, informative and user-friendly. Women's views of the program resulted in improvements to the content and language used. In addition the instructions were clarified, a training session was introduced and a repeat access option was developed. A randomized trial will establish the effects of the decision aids on decisional conflict and mode of delivery in a

large sample of women with previous CS and the cost-effectiveness of implementation within the health service.

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References

- 1 Royal College of Obstetricians and Gynaecologists Clinical Effectiveness Support Unit. *The National Sentinel Caesarean Section Audit Report*. London: RCOG Press, 2001.
- 2 Hamilton BE, Martin JA, Sutton PD. Births: preliminary data for 2002. *National Vital Statistics Report*, 2003; **51**: 4–5.
- 3 Nassar N, Sullivan E. *Australia's Mothers and Babies 1999*. Sydney: Australian Institute of Health and Welfare National Perinatal Statistics Unit, 2001.
- 4 Eden KB, Hashima JN, Osterweil P, Nygren P, Guise J-M. Childbirth preferences after cesarean birth: a review of evidence. *Birth*, 2004; **31**: 49–60.
- 5 Emmett CL, Shaw ARG, Montgomery AA, Murphy DJ. Women's experience of decision-making about mode of delivery after a previous caesarean section: the role of health professionals and information about health risks. *BJOG: An International Journal of Obstetrics and Gynaecology*, 2006; **113**: 1438–1445.
- 6 Anderson GM. Making sense of rising caesarean section rates. *British Medical Journal*, 2004; **329**: 696–697.
- 7 Fraser W, Maunsell E, Hodnett E, Moutquin J-M, the Childbirth Alternatives Post-Cesarean Study Group. Randomized controlled trial of a prenatal vaginal birth after cesarean section education and support program. *American Journal of Obstetrics and Gynecology*, 1997; **176**: 419–425.
- 8 Walker R, Turnbull D, Pratt N, Wilkinson C. The development and process evaluation of an information-based intervention for pregnant women aimed at addressing rates of caesarean section. *BJOG: An International Journal of Obstetrics and Gynaecology*, 2005; **112**: 1605–1614.
- 9 Paterson-Brown S, Amu O, Rajendran S, Bolaji II. Education and debate: should doctors perform and elective caesarean section on request? *British Medical Journal*, 1998; **317**: 462–465.
- 10 Minkoff H, Chervenak FA. Elective primary cesarean delivery. *New England Journal of Medicine*, 2003; **348**: 946–950.

- 11 Department of Health. *Changing Childbirth: Part I. Report of the Expert Maternity Group*. London: HMSO, 1993.
- 12 National Institute of Clinical Excellence. *Caesarean Section: Clinical Guideline 13*. London: National Institute of Clinical Excellence, 2004.
- 13 Lavender T, Kingdon C, Hart A, Gyte G, Gabbay M, Neilson JP. Could a randomised trial answer the controversy relating to elective caesarean section? National survey of consultant obstetricians and heads of midwifery. *British Medical Journal*, 2005; **331**: 490–491.
- 14 Kamal P, Dixon-Woods M, Kurinczuk JJ, Oppenheimer C, Squire P, Waugh J. Factors influencing repeat caesarean section: qualitative exploratory study of obstetricians' and midwives accounts. *BJOG: An International Journal of Obstetrics and Gynaecology*, 2005; **112**: 1–7.
- 15 York S, Briscoe L, Walkinshaw S, Lavender T. Why women choose to have a repeat caesarean section. *British Journal of Midwifery*, 2005; **13**: 440–445.
- 16 O'Connor AM, Stacey D, Entwistle V *et al.* *Decision Aids for Patients Facing Health Treatment or Screening Decisions (Cochrane Review)*. The Cochrane Library, Issue 1. Chichester, UK: John Wiley & Sons, 2004.
- 17 O'Connor AM, Rostim A, Fiset V *et al.* Decision aids for patients facing health treatment or screening decisions: systematic review. *British Medical Journal*, 1999; **319**: 731–734.
- 18 Bekker HL, Hewison J, Thornton JG. Understanding why decision aids work: linking process with outcome. *Patient Education and Counseling*, 2003; **50**: 323–329.
- 19 Roberts CL, Raynes-Greenow CH, Nassar N, Trevena L, McCaffery K. Protocol for a randomised controlled trial of a decision aid for the management of pain in labour and childbirth. *BMC Pregnancy and Childbirth*, 2004; **4**: 24.
- 20 Roberts CL, Nassar N, Barratt A, Raynes-Greenow CH, Peat B, Henderson-Smart D. Protocol for the evaluation of a decision aid for women with a breech-presenting baby. *BMC Pregnancy and Childbirth*, 2004; **4**: 26.
- 21 Shorten A, Chamberlain M, Shorten B, Kariminia A. Making choices for childbirth: development and testing of a decision-aid for women who have experienced previous caesarean. *Patient Education and Counseling*, 2004; **52**: 307–313.
- 22 Shorten A, Shorten B, Keogh J, West S, Morris J. Making choices for childbirth: a randomized controlled trial of a decision-aid for informed birth after caesarean. *Birth*, 2005; **32**: 252–261.
- 23 Chuang J-H, Jenders RA. Trial of Labor versus Elective Repeat Cesarean Section for the Women with Previous Cesarean Section: a Decision Analysis. *Proceedings of the AMIA Annual Symposium*, 1999: 226–230.
- 24 Mankuta DD, Leshno MM, Menasche MM, Brezis MM. Vaginal birth after caesarean section: trial of labor or repeat caesarean section? A decision analysis. *American Journal of Obstetrics and Gynecology*, 2003; **189**: 714–719.
- 25 Shy KK, Legerfo JP, Karp LE. Evaluation of elective repeat caesarean section as a standard of care: an application of decision analysis. *American Journal of Obstetrics and Gynecology*, 1981; **139**: 123–129.
- 26 Elwyn G, Edwards A, Eccles M, Rovner D. Decision analysis in patient care. *Lancet*, 2001; **358**: 571–574.
- 27 Montgomery AA, Fahey T, Peters TJ. A factorial randomised controlled trial of decision analysis and an information video plus leaflet for newly diagnosed hypertensive patients. *British Journal of General Practice*, 2003; **53**: 446–453.
- 28 Montgomery AA, the DiAMOND Study Group. The DiAMOND trial protocol: a randomised controlled trial of two decision aids for mode of delivery among women with a previous caesarean section. *BMC Pregnancy and Childbirth*, 2004; **4**: 25.
- 29 Edwards A, Elwyn G, Mulley A. Explaining risks: turning numerical data in meaningful pictures. *British Medical Journal*, 2002; **324**: 827–830.
- 30 Paling J. Strategies to help patients understand risks. *British Medical Journal*, 2003; **327**: 745–748.
- 31 Wills CE, Holmes-Rovner M. Patient comprehension of information for shared treatment decision making: state of the art and future directions. *Patient Education and Counseling*, 2003; **50**: 285–290.
- 32 Campbell M, Fitzpatrick R, Haines A *et al.* Framework for design and evaluation of complex interventions to improve health. *British Medical Journal*, 2000; **321**: 694–696.
- 33 Elwyn G, O'Connor AM, Stacey D *et al.* Developing a quality criteria framework for patient decision aids: online international Delphi consensus process. *British Medical Journal*, 2006; **333**: 417.
- 34 Feldman-Stewart D, Brundage MD. Challenges for designing and implementing decision aids. *Patient Education and Counseling*, 2004; **54**: 265–273.
- 35 Charles C, Gafni A, Whelan T, O'Brien MA. Treatment decision aids: conceptual issues and future directions. *Health Expectations*, 2005; **8**: 114–125.
- 36 Dowie J. The role of patients' meta-preferences in the design and evaluation of decision support systems. *Health Expectations*, 2002; **5**: 16–27.