

USING INTERACTIVE 'HEALTH IT' TO SUPPORT WOMEN'S CHOICES FOR BIRTH AFTER CESAREAN

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Abstract

Purpose: To design a new web-based *Birth Choices* decision aid to support shared decision making (SDM) about birth after previous cesarean, and explore the feasibility of implementation within ethnically diverse outpatient settings.

Scope: This represents new work translating static and generic decision aids into web-based tools with interactive elements using learning design principles. Meeting an urgent need to develop tools that promote risk communication about birth after cesarean, health information technology (IT) supports interaction with evidence-based information, information tailoring, values clarification, and communication of preferences.

Methods: A two-phase sequential mixed-methods design was used: Phase I: An iterative and participatory research approach engaged targeted users in decision aid design and development. Phase II: Feasibility of integrating the decision aid into two busy urban outpatient settings using SDM was assessed using a before and after design.

Results: The web-based *Birth Choices* decision aid was acceptable for targeted users and demonstrated preliminary efficacy in practice. It is feasible to translate and adapt decision aids to meet the needs of ethnically diverse pregnant women. Identification of strategies to facilitate patient access, consistent utilization and seamless integration into the system of care are important next steps for future implementation research.

Key Words:

Decision Aids

Health IT

Shared Decision Making

Vaginal Birth after Cesarean (VBAC)

Cesarean

Birth Choices

Purpose

The purpose of this study was to use health information technology (IT) to translate, adapt and build upon a best-practice decision aid booklet, *Birth Choices...what is best for you?*¹, originally developed in Australia by PI Allison Shorten, to support women making choices about mode of birth after previous cesarean. We adapted the decision aid content to a web-based format, designed for use within the context of the United States health care system. We then explored the feasibility of using the new web-based interactive decision aid within busy, ethnically diverse outpatient clinical practice settings. The study aims were:

Aim 1: To translate the best-practice *Birth Choices* paper-based decision aid into an interactive web-based decision aid to support women making decisions about mode of birth after prior cesarean.

Aim 2: To assess the feasibility of integrating the *Birth Choices* interactive decision aid into busy urban outpatient pregnancy care settings using a Shared Decision Making Framework.

This study represents foundation work on translating static and generic decision aids into interactive decision aids using electronic learning design principles. Further, the study addresses the feasibility of integrating decision aids into the reality of busy ethnically diverse clinical practice environments. We were able to explore usability of the decision aid and the potential to support women to gain knowledge about their options and clarify their personal values and preferences about their options for birth after previous cesarean (planned vaginal birth after cesarean (VBAC) versus elective repeat cesarean section (ERCS)).

Scope (Background, Context, Settings, Participants, Incidence, Prevalence)

Background and Context

More than one in three women experience cesarean surgery for birth each year in the United States yet fewer than 10% experience VBAC in subsequent pregnancies.²⁻⁴ This is despite clear evidence that confirms the safety of planned VBAC for the majority of women as an alternative to ERCS surgery³ and growing evidence of inferior outcomes associated with ERCS.^{3,5} The most recent systematic review of the evidence on birth after cesarean found that VBAC is safe for the majority of women and their babies.³ The decline of VBAC has been associated with fear of scar rupture, even though rates are reported to be as low as 325 per 100,000 women.³ Less attention has been paid to risks of repeated surgery. Maternal mortality is 4 to 6 times greater for repeat cesarean surgery than for VBAC.³ Multiple cesareans can increase the chance of life-threatening complications for women. Higher risks for newborns associated with repeat cesarean surgery include admission to intensive care, respiratory distress and persistent pulmonary hypertension (RR = 2.0; IC 95% = 1.3 to 3.1).⁶⁻⁹

Opportunities for women to participate actively in decisions about birth depend on the ability of providers to support shared decision making (SDM), the availability of effective decision support tools for women and effective ways to integrate decision support tools into busy clinical practice settings. Women will make different choices for birth based on individual perception of risk for themselves and their infants, previous birth experience, fears surrounding birth, and personal values on what is important to them. To do this effectively they need balanced and consistent information to help them weigh the benefits and potential harms of both options, and to develop a plan with clinicians about the type of birth that is best for them.

Setting

This study took place within two urban multi-disciplinary outpatient pregnancy care clinics at Yale-New Haven Hospital (YNHH) in New Haven, Connecticut.

Participants

Women who participated in the study were attending one of the two outpatient clinic services of YNHH, were over the age of 18 years, English-speaking, with a history of one prior low transverse cesarean section with no indications excluding them from making a choice between planning VBAC or scheduling repeat cesarean.

Providers who participated in the study were providing pregnancy care at one or both of the two outpatient clinic services involved in the study.

Methods (Study Design, Data Sources/Collection, Interventions, Measures, Limitations)

A mixed-method sequential exploratory design was utilized to develop and evaluate the *Birth Choices* interactive decision aid. The study had two phases: Phase I used an iterative and participatory approach engaging targeted users (pregnant women and pregnancy care providers) in the decision aid design to ensure acceptability to pregnant women and providers. Phase II assessed the usability of the decision aid and feasibility of integrating the interactive decision aid into busy urban outpatient pregnancy care settings.

Aim 1: To translate the *Birth Choices* best-practice paper-based decision aid into an interactive decision aid to support women making decisions about mode of birth after prior cesarean.

Phase 1: Decision aid translation and health IT development:

The ADDIE Model of Instructional Design (Analyze, Design, Develop, Implement, and Evaluate) was used as the framework for the tool design and evaluation. Our process steps were: (1) Brainstorm by conducting focus groups and interviews with pregnant women (n=9) and pregnancy care providers (n=10) at YNHH; (2) Develop prototype of *Birth Choices* interactive web-based decision aid (3); Think aloud procedure for women (n=4) and providers (n=6) to evaluate the *Birth Choices* interactive web-based decision aid; (4) Revision of the *Birth Choices* interactive decision aid based on ‘think aloud process’ in preparation for Phase 2 evaluation. A published manuscript details the process for development, review, revision and product outcomes for Phase 1.¹⁰ Figure 1 illustrates the framework used for the web-based design and evaluation process adapted from Elwyn et al.¹¹ Table 1 summarizes the main features and functions of the new web-based decision aid. These key features and functions were prioritized according to input from providers and targeted users.¹⁰

Figure 1: Framework for Design, Development and Evaluation of the Birth Choices Decision Aid

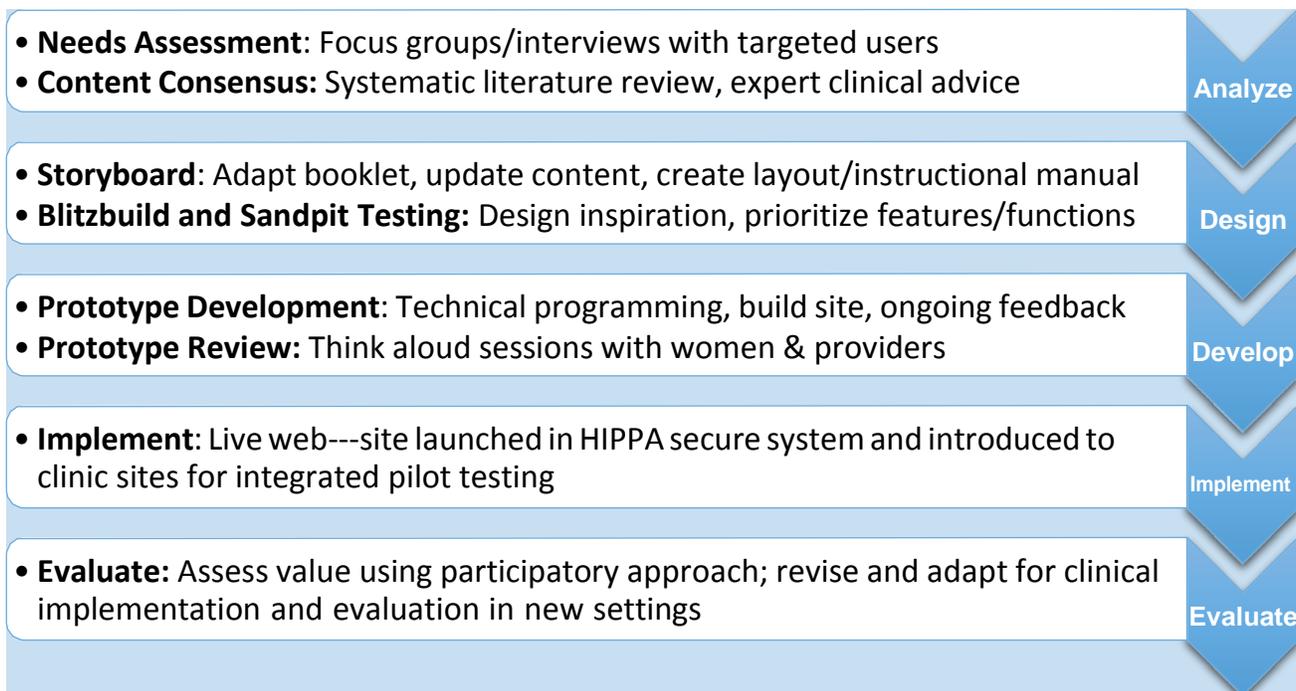


Table 1 Features and Functions of Birth Choices Web-based Decision Aid

Features and Functions
Evidence-based educational content describing risks and benefits of birth options
Pictorial representation of probabilities of risks and benefits
Interactive values clarification exercise
VBAC success calculator using personal risk factor assessment with integrated personalized probability pictograph
User control over information sequence and depth based on level of interest for higher complexity and depth
Integrated quiz questions and answers at conclusions of key option sections
Interactive values clarification exercise and question generator produces “My Birth Choices” summary to save or print. Includes values, goals, birth preferences and questions for decision discussion with provider
Bookmark function for pages of interest
Multimedia formats to engage learner
Mobile web-based technology (computer, tablet and phone) for flexibility and access.
Audio in English and Spanish to accommodate low-literacy and Spanish speakers.
Password HIPAA compliant system protects access to site, stores inputs, bookmarks, values clarification, summary.
Easy editing platform using Drupal software for ongoing revision and update by project team.

Aim 2: To assess the feasibility of integrating the *Birth Choices* interactive decision aid into busy urban outpatient pregnancy care settings using a Shared Decision Making Framework.

Phase 2: We assessed the usability of the interactive web-based decision aid and feasibility of integrating the decision aid in the two outpatient clinical practice settings at YNHH.

Feasibility Assessment: Study Protocol

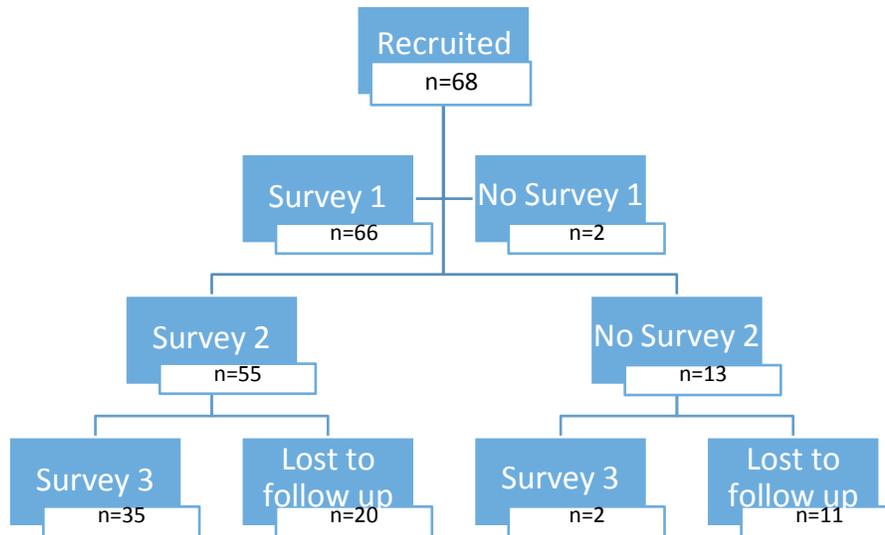
Using a before and after design, women receiving pregnancy care within the YNHH clinics who had experienced one previous cesarean and were eligible to choose between planned VBAC or ERCS were recruited at their first pregnancy care visit (approximately 12-28 weeks of pregnancy). Participants were given a personal username and password for secure access to the decision aid and shown its features and functions for use at home on their personal computer or mobile device. They were also invited to use the decision aid in the clinic if they did not have Internet access at home. Participants were followed up once by phone call or text prior to Survey 2 to remind them to use the decision aid and to offer support if they were having any problems accessing the web-site. Providers were informed about the study prior to roll out were reminded to encourage participants to use the decision aid as part of routine care. Participants were followed up at 32-38 weeks gestation, to evaluate their knowledge of options, levels of decisional conflict, to assess decision aid usability and birth choice. Participants completed a one-page “My Birth Choices” summary and values clarification exercise, consistent with the web-site values clarification exercise, and were encouraged to share this with their provider during the next clinic consultation. At 4-6 weeks post birth, participants were followed up to assess satisfaction with decision making, features and functions of the decision aid and birth outcomes.

Sample Recruitment

The recruitment target was set at 70 women across the two clinics. Eligible women were identified by the research assistant, clinic nurse or physician at the first antenatal care visit or at the first visit to the study site and asked if they would be willing to participate in the study. The informed consent process was conducted by the research assistant and not by the nurse or attending physician at the clinic providing their care. There were 83 women who met the eligibility criteria for the study and were invited to participate. A total of 71 (85.5%)

expressed willingness to participate, and of these 68 (81.9%) completed the informed consent process and were recruited. Of the 68 women recruited initially, 66 (97.1%) completed Survey 1, which consisted of a baseline assessment of ‘before’ measures prior to being given access to the decision aid; 55 (80.9%) completed Survey 2 which consisted of ‘after’ measures; and 37 (54.4%) completed Survey 3 following the birth. Figure 2 illustrates the flow of participants through the study. There were two women who were recruited but did not complete Survey 1, although they completed Survey 2, with one also completing Survey 3 follow up. There were 31 women lost to follow up after completing both Survey 1 and Survey 2, and two participants who did not complete Survey 2 yet completed Survey 3.

Figure 2 Flow of Participants



Sample Characteristics Women in the sample were racially diverse with most participants identifying as either Black (46.2%) or Hispanic (35.4%). Mean age was 29.3 years, 37 women (55.8%) had either attended trade school (18.2%) or college (37.6%), and 42 (63.6%) were currently in paid employment.

Table 2 Demographic Characteristics of the Sample (n=66)*

Characteristics		n (%)
Race (Missing = 1)	Black	30 (46.2)
	Hispanic	23 (35.4)
	White	9 (13.8)
	Asian	2 (3.1)
	American Indian	1 (1.5)
Education	Middle School	3 (4.5)
	High School	26 (39.4)
	Trade	12 (18.2)
	College	25 (37.6)
Current Employment	Full Time (Paid)	20 (30.3)
	Part Time (Paid)	22 (33.3)
	Unemployed	9 (13.6)
	Home Duties	15 (22.7)
Age (Mean 29.3 yrs)	20-24	10 (15.2)
	25-29	25 (37.9)
	30-34	20 (30.3)
	35+	11 (16.6)

*Excludes n=2 who did not provide demographic characteristics (Survey 1)

Table 3 Summary of Sample Feasibility Metrics

Feasibility Measures	n/target (%)
Recruitment Total	68/71 (96%)
Recruitment Rate	68/83 (82%)
Before and After Measures Completed*	53/68 (78%)
Decision-aid Utilization	39/55 (71%)
Post-Birth Follow-up	37/68 (54%)

Note *53 participants completed both Survey 1 and Survey 2 for matched pairs comparison

Characteristics of the Sample Utilizing the Decision Aid

The plan was for all women to have an opportunity to access and utilize the decision aid either at the time of recruitment, at another convenient time before or after their scheduled clinic appointment, and/or at home, at a time prior to Survey 2 when the birth decision would be discussed with their provider. As there were multiple possible opportunities for accessing the web-site, utilization was assessed at Survey 2, where women were asked to evaluate the decision aid web-site. There were 55 women who provided responses to Survey 2 and of these 39 women provided feedback on the decision aid and 16 women indicated that they had not accessed it. Table 4 provides a summary of characteristics for the 55 women who completed Survey 2 and who indicated whether they had used or not used the decision aid. Specific reasons for ‘non-use’ were written in the free survey space by only 5 participants. Reasons given included that they *had not had time to access the web-site* (n=2), and they felt they *already had enough information to make a decision* (n=3). One participant had experienced difficulty accessing the site at home (n=1).

Although most of the differences are not statistically significant, likely due to small sample size (especially for women who did not access the decision aid web-site), they are nevertheless suggestive in terms of pointers for further research regarding strategies for implementation. Racial differences in use of the decision aid were evident. Women who identified as black were less likely to use the decision aid (44.4% of women accessing the decision-aid were black, compared to 62.5% of those who did not use the decision aid). Hispanic women constituted 41.7% of participants using the decision aid compared with only 25.0% of those who did not use the decision aid. There is no evidence of any important differences in decision aid use due to either education level or current employment status. There was some evidence that women who reported that they had already discussed birth options with their provider prior to completing Survey 1 were less likely to access the decision aid. Women who were leaning toward planning VBAC at recruitment (Survey 1) were much more likely to use the decision aid (over 61% of women who used the decision aid were initially leaning toward planned VBAC, compared to only 37.5% of women who did not use the decision aid). A similar pattern was evident for Survey 2 (post-intervention) preference, and it is also of note that women who did not use the decision aid seemed to be more likely prefer ERCS at Survey 2. There is evidence that women who used the decision aid were younger than those who did not. There is no apparent link between decision aid use and gestation at recruitment. Women who did not use the decision aid had a higher mean REALM-R literacy score¹² than those who did access the decision aid. Note, however, that there were only 12 women who did not use the decision aid who provided literacy score data. Although there was no difference in use according to perceived numeric ability, there was a very large and statistically significant difference in decision aid use according to perception of numeric usefulness score¹³ (p<0.02). Women who used the decision aid reported significantly higher levels of interest in numeric presentation of information¹³.

Table 4 Characteristics of Women Who Did (n=39) Or Did Not (n=16) Access the Decision Aid

Characteristics	Did Not Access		Accessed		Total		X2 (t) p value
	n	%	n	%	n	%	
Race							
Black	10	62.5	16	44.4	26	50.0	
Hispanic	4	25.0	15	41.7	19	36.5	
Other	2	12.5	5	13.9	7	13.5	
Total	16	100.0	36	100.0	52	100.0	0.454
Education							
Middle/High School	6	37.5	15	40.5	21	39.6	
Trade	4	25.0	7	18.9	11	20.8	
College	6	37.5	15	40.5	21	39.6	
Total	16	100.0	37	100.0	53	100.0	0.882
Employment							
Full time	5	31.3	10	27.0	15	28.3	
Part Time	6	37.5	13	35.1	19	35.8	
Unemployed	2	12.5	5	13.5	7	13.2	
Home Duties	3	18.8	9	24.3	12	22.6	
Total	16	100.0	37	100.0	53	100.0	0.969
S1 Discussed Options							
Yes	13	81.3	26	70.3	39	73.6	
No	3	18.8	11	29.7	14	26.4	
Total	16	100.0	37	100.0	53	100.0	0.405
S1 Preference							
Planned VBAC	6	37.5	22	61.1	28	53.8	
ERCS	5	31.3	7	19.4	12	23.1	
Unsure	5	31.3	7	19.4	12	23.1	0.289
Total	16	100.0	36	100.0	52	100.0	
S2 Preference							
Planned VBAC	8	50.0	25	64.1	33	60.0	
ERCS	7	43.8	11	28.2	18	32.7	
Unsure	1	6.3	3	7.7	4	7.3	
Total	16	100.0	39	100.0	55	100.0	0.536
Age n(mean)	16	(31.3)	39	(29.0)	55	(29.6)	(0.169)
S1 Gestation n(mean)	15	(19.1)	35	(20.0)	50	(19.8)	(0.618)
REALM-R Score n(mean)	12	(7.42)	35	(6.74)	47	(6.91)	(0.167)
Numeracy Ability n(mean)	15	(2.95)	36	(2.95)	51	(2.95)	(0.997)
Numeracy Usefulness n(mean)	15	(2.51)	36	(3.41)	51	(3.14)	(0.018)

Note: Total number of women may not sum to 55 due to missing data on characteristics

ERCS = elective repeat cesarean section; S1 = Survey 1; S2 = Survey 2

Results (Principal Findings, Outcomes, Discussion, Conclusions, Significance, Implications)

Principal Findings

Acceptability of the Decision Aid in Practice

Women were asked about their use of the decision aid during Survey 2 and asked to respond to statements about the role the decision aid played in their process of decision making. The results are reported for women who indicated that they had used the decision aid web-site and who completed Survey 2 (n=39).

The following information confirms that the *Birth Choices* web-based decision aid was an acceptable tool for women in decision making. The majority of women found the decision aid helped a lot/a great deal as they made decisions about their birth after cesarean. Table 5 provides a summary of 9 survey items regarding decision aid use. Women responded to statements about the degree to which the web-site helped them to prepare for decision making and make their decision. For seven of the nine items between 66% and 72% of respondents reported that the decision aid had helped them “A Lot” or “A Great Deal”.

Table 5. Decision Aid Acceptability Survey (n=39)

How much did the Birth Choices web-site...	Not at all/ a little n (%)	Somewhat n (%)	A lot/ a great deal n (%)
1. help you organize your own thoughts about your birth decision?	7 (17.9)	11 (28.2)	21 (53.8)
2. help you consider the pros and cons of each option?	5 (12.8)	7 (17.9)	27 (69.2)
3. help you identify the questions you needed to ask?	3 (7.9)	12 (31.6)	23 (60.5)
4. help you consider how involved in the decision you wanted to be.	4 (10.5)	7 (18.4)	27 (71.1)
5. help you discuss your options with your family?	7 (17.9)	6 (15.4)	26 (66.7)
6. help you discuss your options with your doctor/ midwife?	5 (12.8)	6 (15.4)	28 (71.8)
7. prepare you to make a decision?	6 (15.4)	7 (17.9)	26 (66.7)
8. help you know what to expect from your birth choice?	5 (12.8)	6 (15.4)	28 (71.8)
9. help you feel satisfied with the birth decision?	5 (12.8)	6 (15.4)	28 (71.8)

When asked whether they would recommend the Birth Choices web-site to other women the overwhelming response was in the affirmative, with 35 women responding “Yes” and none responding in the negative. In the free response section, positive attributes noted about the web-site were that it was “easy to navigate” that it provided information on “*the pros and cons of options*”, that it was “*informative*”, it “*helped to answer questions*” they had. There were no recommendations for improvements or things they would like to change or add.

Decision Aid Content Evaluation

Of the 68 women recruited to the study, 37 (or 54.4%) completed Survey 3 approximately 6 weeks after the birth. Of the 37 women completing Survey 3, 31 had used the web-based decision aid. To assess women’s perceptions of how satisfied they felt with the decision making experience we used the satisfaction with decision (SWD) scale questions adapted for post birth after cesarean. This scale is based on a series of six questions which assess satisfaction with birth decision, with each question scored on a scale of 1 (Strongly Disagree) to 5 (Strongly Agree). For 29 women who answered all questions (missing=2), the mean SWD score was 4.50 out of 5 (standard deviation = 0.60) (median = 4.67). We also asked women to rate the different sections and components of the web-site, using a four point Likert scale from Poor to Excellent. We have combined the categories into Poor/Fair and Good/Excellent for the analysis (Table 6). The web-site rated highly for all content and features. Areas to be explored for potential future improvements include web-site instructions (n=3) and VBAC problems (n=3) and the VBAC success calculator (n=2).

Table 6 Rating for Birth Choices Web-site Components

Content and Features	Poor/Fair n (%)	Good/Excellent n (%)
Web---site Instructions	3 (10.0)	27 (90.0)
Information about VBAC	0 (0.0)	30 (100.0)
VBAC Benefits	1 (3.3)	29 (96.7)
VBAC Problems	3 (10.7)	25 (89.3)
VBAC Success Calculator	2 (7.4)	25 (92.6)
Information about C---section	0 (0.0)	29 (100.0)
C---section benefits	1 (3.4)	28 (96.6)
C---sections Problems	1 (3.4)	28 (96.6)
Quizzes to check your facts	1 (3.4)	28 (96.6)
My Birth Choices Summary (What is important to you)	1 (3.3)	29 (96.7)

Preliminary Efficacy of the Decision Aid in Practice

Measures to establish preliminary efficacy were administered before (Survey 1) and after (Survey 2). As the focus of this study was on the feasibility and preliminary efficacy use of the decision aid in practice, the analysis firstly provides a matched pairs before and after comparison for the total sample who completed both Survey 1 and Survey 2 (n=53), and secondly refines the focus on women who had indicated at the time of Survey 2 that they had used the decision aid. Where possible, matched measures comparing women who had used the decision aid (n=37) with those who had not (n=15), are provided.

Knowledge of risks and benefits of birth options was measured using a 15-item Shorten Knowledge of Birth after Cesarean test, adapted for this study (Cronbach's alpha = 0.69).¹⁴The 15 items comprise statements about risks and benefits of planned VBAC versus ERCS, requiring a response of true, false or unsure. The Decisional Conflict Scale (Birth) was used to measure level of conflict in decision making according to five subscales.¹⁵ This scale assesses levels of decision *certainty*, whether the choice is *informed*, consistent with *values*, *supported*, likely to be implemented and if women are *satisfied* with the decision. Women were asked to indicate their preference for mode of birth (Planned VBAC, Planned Cesarean or Unsure) which was compared with actual plans enacted as well as the outcome for birth.

Change in Knowledge Scores

There is evidence that Knowledge scores improved from Survey 1 (S1) to Survey 2 (S2). Matched pairs methodology was used to compare before and after scores individually for women who completed the knowledge test in both surveys (n=52), Mean knowledge scores increased from 6.54 to 9.12 (p<0.01).

Table 7 Mean Matched Pairs Pre and Post-Intervention Knowledge Score /15 (n=52)

Before (S1)	After (S2)	p value	95% CI for Knowledge Increase
6.54	9.12	<0.01	1.76-3.40

As this was not a randomized controlled trial, we cannot be confident that changes in scores were linked to the decision aid given the many sources of information available to women during their pregnancy including pregnancy care providers. We could be more confident that improvements in knowledge are linked to use of the web-site if it can be demonstrated that those who actually used the decision aid web-site posted larger improvements than those who did not. However, self-selection bias must be considered in this context, and analysis suggests that women who used the decision aid may be systematically different to those who did not, as discussed below and also in Table 4.

Women who subsequently used the decision aid actually demonstrated higher knowledge at baseline (6.89) when compared with women who had not used the decision aid (5.57) ($p=0.23$). Similarly, mean scores at Survey 2 were 9.49 for those who had used the decision aid and 8.20 for those who had not ($p=0.10$). Neither difference was statistically significant at conventional levels, and indeed the study was not powered for such a comparison, with the original expectation being that all women would access the decision aid either in the clinic or at home.

To gain more clarity on the potential efficacy of the decision aid web-site we explored the variable of change in knowledge score (S2 – S1 score) for each woman. For the 52 women completing before and after surveys, knowledge score increased for 42 women (80.8%), decreased for five women (9.6%) and remained the same for five women (9.6%). Mean increase was 2.58 questions ($p<0.01$) (median = 3).

Table 8 Knowledge Change and Decision Aid Usage (n=52)

Decision aid use	S1 Mean Knowledge Score/15	S2 Mean Knowledge Score/15	Mean Change
Yes (n=37)	6.89	9.49	2.60
No (n=15)	5.67	8.20	2.53
Total (n=52)	6.54	9.12	2.58

Women who used the decision aid web-site had higher pre-intervention scores and also showed greater increases in mean knowledge scores (2.60 questions versus 2.53). However, the differences in knowledge increase were not found to be statistically significant in this small sample of women.

Change in Decisional Conflict (DCS)

For 52 women who provided decisional conflict information at both Survey 1 and Survey 2, DCS declined for 34 of these women (65.4%), was unchanged for seven women (13.5%) and increased for 11 women (21.2%).

Table 9 Change in Mean DCS Scores from Survey 1 to Survey 2.

Mean DCS Score (out of 4)	Survey 1	Survey 2	Change	p value
Used Web-site (n=36)	0.77	0.39	-0.38	0.001
Did Not Use (n=16)	1.05	0.44	-0.61	0.003
Total (n=52)	0.86	0.41	-0.45	0.000

The baseline DCS scores were lower than for other Birth Choices decision aid research.¹⁴ Despite this, there was a highly statistically significant reduction in mean DCS scores from Survey 1 to Survey 2 (from 0.86 to 0.41 overall). As with knowledge quiz scores, there was a noticeable difference in mean baseline DCS scores between women who used the decision aid web-site and those who did not (0.77 versus 1.05), again suggesting that women who used the decision aid web-site were systematically different to those who did not. However, the difference was not found to be statistically significant, perhaps due to the small sub-sample sizes. DCS scores were also lower at Survey 2 for women who had used the web-site (0.39 versus 0.44), but mean decrease in DCS was in fact greater for women who did not use the web-site (0.61 versus 0.38), perhaps in part because they had greater scope for reduction, having exhibited higher baseline scores. Again, this difference was not statistically significant ($p=0.27$).

Summarizing, there was a statistically significant decrease in mean DCS score for women completing both Survey 1 and Survey 2, from 0.86 to 0.41 on a scale of 0 to 4. There were indications that women who most needed information about their birth options (in the sense of having higher conflict levels and lower knowledge scores at baseline) were in fact less likely to have accessed the decision aid. However, overall mean DCS

level at Survey 2 was extremely low (0.41) compared to other studies^{14,15} despite evidence that measured knowledge of issues regarding birth mode options was still only modest (Table 8). This will be an interesting area of exploration for future research.

Birth Choices and Outcomes

As there was support for the framework of SDM at the study sites, it is not surprising that women were not only satisfied with the decision making experience, but, most importantly, most women were able to enact their choice for birth. Of those for whom birth data was available and who had completed Survey 1 and Survey 2 (n=52), there were 30 (57.7%) women who at Survey 2 had decided to attempt VBAC, of whom 26 (87%) went on to experience labor. For the 18 women who preferred ERCS at Survey 2, 14 (78%) experienced scheduled caesarean. Of four women still unsure at Survey 2, three attempted VBAC and one had scheduled repeat caesarean. Higher than the national rates of VBAC, this is a testament to the commitment of the providers within the sites to support women in shared decision making about birth after cesarean. The VBAC success rate was 66.7% (22 of 33 women), well within the expected range of 60-80%³

The study intent was not to increase one mode of birth over the other but to support SDM. The decision aid evaluation provided evidence that women who used the decision aid felt that it played a role in their decision making process. Low levels of decisional conflict indicate that women perceived they were informed, felt certain, supported and that their decisions were consistent with their values. They also expected to carry out their birth choices. High levels of adherence to choice indicate that they did indeed carry out their choices.

Study Limitations

This was a small feasibility study which took place within one geographical area within a clinical setting where patient education is supported and shared decision making is an integral part of routine care. The before and after design is suggestive of trends which should be explored in future research.

Conclusion

Based on the results of this pilot study, we conclude that the web-based decision aid is acceptable and was appealing to the majority of women participating in this study. It demonstrated feasibility as a potentially useful tool for decision support. The majority of women in the study used the web-based decision aid and reported high satisfaction with content and ease of use. In addition, most women who participated in the study experienced significant improvement in knowledge of their options for birth and reduced levels of decisional conflict.

It is feasible to use a web-based decision aid within a framework of SDM to enhance decision making experiences for women who have experienced previous cesarean, particularly in environments where planned VBAC is supported by providers. The fact that our sample was obtained in an urban setting and consisted almost entirely of women from higher risk vulnerable groups in terms of race and other characteristics, also indicates that it is feasible to integrate the decision aid web-site into the reality of pregnancy care within urban, ethnically diverse clinic settings. However, there is still work to be done in identifying effective strategies to ensure all women have convenient access to the decision aid in a format that meets their individual needs and at a time and place that will facilitate their access and utilization of the decision aid.

Implications for Future Research

This study provided evidence about the feasibility of comprehensively testing the effectiveness of the interactive decision aid in a future multi-site study. A proposal for a R01 grant has been designed around more sophisticated development of the health IT component to include interaction with the patient portal function in the electronic medical record so that women can access the decision aid through a central, integrated HIPPA compliant portal increasingly utilized by patients. This will also enable women to provide information about their

decision process during pregnancy and submit questions and preferences remotely to their provider. This would be evaluated using a multi-site implementation study within a more complex inter-professional shared decision making framework (IP-SDM), and including use of broader applications for use with a range of mobile communication devices. We will be able to then test whether the interactive decision aid embedded in a SDM framework is more effective in improving women's knowledge, reducing conflict and supporting women to reach shared birth decisions that are consistent with their values. We will also assess whether clinicians perceive health IT can support them in providing consistent, up to date, evidence-based information to women, documenting shared decision making, and coordinating outpatient pregnancy care. If effective, this IT Health strategy of integrated decision support system has the potential to be used to support a wider range of pregnancy decision topics. Future research is also needed to examine the robustness of decision aid effects in a larger randomized sample and to explore effective strategies for seamless service integration and implementation of the decision aid in a broader array of clinical settings.

Decision Aid Format Choice: Access to both paper-based and web-based format may be one possible solution to address the issue of inconsistent access and use of the decision aid. It is important to account for different learning styles of women and personal comfort in using either paper-based or web-based materials.

Addressing Time Constraints: Even though women were invited to use the decision aid at a time while they were in the clinic waiting room, prior to their pregnancy care appointments, they were sometimes called into their appointments early or arrived late to their scheduled appointment and did not have sufficient time to use the decision-aid prior to their appointment. Others left soon after seeing their provider and did not remain in the clinic to use the decision aid. Some participants indicated verbally to research assistants that they preferred to use the decision aid when they were at home and had more time to read. To account for the time constraints within pregnancy care visits, purposeful, scheduled time, designated for education and decision support would be another possible strategy to explore in the future.

7. Publications and Presentations

Shorten, A., Fagerlin, A., Illuzzi, J., Kennedy H.P., Lakehomer, H., Pettker, C., Saran, A., Witteman, H., Whittemore, R. (2015). Developing an Internet-based decision aid for women choosing between vaginal birth after cesarean and repeat cesarean birth. *Journal of Midwifery and Women's Health*. 60(4), 390-400.

Shorten A. (2016) Creating tools to improve opportunities for shared decision making during pregnancy. *Evidence Based Nursing* (BMJ Group Blog) <http://blogs.bmj.com/ebn/2016/04/21/>

Products

Shorten, A. (2014) Birth Choices: What is best for you...vaginal or caesarean birth, Yale University, USA, interactive Internet based edition (*Including English and Spanish audio*).

Conference Abstracts/Podium Presentations/Posters

Shorten, A. (2015, October) *Using Health Information Technology to Transform Decision Support Tools for Pregnant Women*, YSN Scholar Day, "Making a Difference with Scholarship", Yale University, Orange, Connecticut, USA.

Shorten, A., Fagerlin, A., Illuzzi, J., Kennedy, H., Lakehomer, H., Pettker, C., Saran, A., Witteman, H., Whittemore, R. (2015, July). *Using health information technology to transform a decision aid for pregnant women in an ethnically diverse primary care setting* (Research Paper) 7th International Shared Decision Making Conference, Sydney, Australia.

Shorten, A., Fagerlin, A., Illuzzi, J., Kennedy, H., Lakehomer, H., Pettker, C., Saran, A., Witteman, H.,

Allison Shorten R21HS022114 Final Report October 2016

Whittemore, R. (2015, July). *Using health information technology to transform a decision aid to support shared decision making about birth after cesarean* (Research Paper) International Confederation of Midwives Asia Pacific Regional Conference, Yokohama, Japan.

Shorten, A., Fagerlin, A., Illuzzi, J., Kennedy H.P., Lakehomer, H., Pettker, C., Saran, A., Witteman, H.,Whittemore R. (2015, October). *Using Health Information Technology to Support Shared Decision Making in an Ethnically Diverse Primary Care Setting*, Advancing Science, Improving Lives, The National Institute of Nursing Research's 30th Anniversary Scientific Symposium and Poster Session, Bethesda, Maryland.

Shorten, A., Fagerlin, A., Illuzzi, J., Kennedy H.P., Lakehomer, H., Pettker, C., Saran, A., Witteman, H.,Whittemore R. (2015, June). *Using health information technology to transform a pregnancy decision aid to support shared decision making for birth after cesarean*, 19th Annual Nursing Research Conference New York University Langone Medical Center, New York, New York.

Invited International Lectures

Shorten A. (2016 July). *From Inspiration to Implementation: Using health information technology to support shared decision making during pregnancy* (Invited Lecture), Kobe University, Kobe, Japan.

Shorten, A. (2015, July). *Using health information technology to transform a decision aid for birth after cesarean* (Invited Lecture), Niigata University, Niigata, Japan.

8. References

1. Shorten A. *Birth Choice: What is best for you...vaginal or caesarean birth? A Decision-aid for women making choices about after caesarean section*. University of Wollongong Printery, Wollongong, Australia, 2007.
2. Hamilton BE, Martin JA, Ventura SJ. *Births: Preliminary data for 2010*. National vital statistics reports web release; vol 60 no 2. Hyattsville, MD: National Center for Health Statistics. 2011.
3. Guise J-M, Eden K, Emeis C, et al Vaginal Birth After Cesarean: New Insights. Evidence Report/Technology Assessment No.191. (Prepared by the Oregon Health & Science University Evidence-based Practice Center under Contract No. 290-2007-10057-I). Rockville, MD: Agency for Healthcare Research and Quality. March 2010. AHRQ Publication No. 10-E001.
4. National Institutes of Health Consensus Development Program, *Vaginal Birth after Cesarean: New Insights*, Final Statement, March 8-10 2010, Bethesda, Maryland, <http://consensus.nih.gov>.
5. Cahill AG, Stamilio DM, Odibo AO, et al. Is vaginal birth after cesarean (VBAC) or elective repeat cesarean safer in women with a prior vaginal delivery? *Am J Obstet Gynecol* 2006;195:1143-7.
6. Steer PJ, Modi N. Elective caesarean sections--risks to the infant. *Lancet* 2009; 374:675-6.
7. Hook B et al. Neonatal morbidity after elective repeat cesarean section and trial of labor. *Pediatrics* 1997; 100:348-353.
8. Kamath BD, Todd JK, Glazner JE, Lezotte D, Lynch AM. Neonatal outcomes after elective cesarean delivery. *Obstet Gynecol* 2009; 113:1231-8.
9. Winovitch KC, Padilla L, Ghamsary M, Lagrew DC, Wing DA. Persistent pulmonary hypertension of the newborn following elective cesarean delivery at term. *J Matern Fetal Neonatal Med* 2011 Nov; 24(11):1398-402.
10. Shorten, A., Fagerlin, A., Illuzzi, J., Kennedy H.P., Lakehomer, H., Pettker, C., Saran, A., Witteman, H., Whittemore, R. (2015). Developing an Internet-based decision aid for women choosing between vaginal birth after cesarean and repeat cesarean birth. *Journal of Midwifery and Women's Health*. 60(4), 390-400
11. Elwyn, G. et al. 1999. Shared decision-making in primary care: the neglected second half of the consultation. *Br J Gen Pr* 49(443), pp. 477-482.
12. Agency for Healthcare Research and Quality. Health literacy measurement tools. Rockville, MD. January 2009. <http://www.ahrq.gov/populations/sahlsatool.htm>
13. Fagerlin et al. Measuring numeracy without a math test: Development of the subjective numeracy scale. *Medical Decision Making* 2007; Sept-Oct:672-680.
14. Shorten A, Shorten B, Keogh J, West S, et al. Making Choices for Childbirth: A Randomized Controlled Trial of a Decision-aid for Informed Birth after Cesarean. *Birth* 2005; 32(40): 252-261.
15. O'Connor AM. Validation of a decisional conflict scale. *Medical Decision Making* 1995; JanMar;15(1):25-30.