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Evaluation of a fertility awareness-based shared decision-making tool part 2: Patient experiences

Marguerite Duane [a,*], Virginia Martinez [a], Meghan Berry [a], Sarah Gilpatrick [a], Michael D. Manhart [b]

[a] FACTS, 1020 Kearny St NE, Washington, DC 20017, USA
[b] Fertility Science Institute, Couple to Couple League International, 5440 Moeller Avenue Suite 149, Cincinnati, OH 45212, USA

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ABSTRACT

Objective: To assess patient experiences using a Shared Decision-Making (SDM) Tool for fertility awareness-based methods (FABMs) of family planning.
Methods: The study employed a prospective crossover design to evaluate impact of the SDM tool compared to usual practice when discussing FABMs with patients. Patients completed pre- and post-office visit surveys and an online survey six months later. The primary outcomes evaluated the effect of the SDM tool on patient satisfaction and FABM continuity of use rates.
Results: There was no significant difference in likelihood of changing family planning methods immediately after the office visit; however, by six months a significantly larger proportion of patients had started or changed FABMs in the experimental group (52%, 34/66) compared to the control group (36%, 24/66) ($p = 0.04$). Significantly more patients who used the tool and changed their FABM after their visit reported increased satisfaction with their FABM compared to control (50% vs. 17%, $p = 0.022$).
Conclusions: Use of the SDM tool increased persistent use of and satisfaction with chosen FABMs at six months.
Innovations: The novel SDM tool can enhance patients' understanding and facilitate the selection of a more suitable method leading to increased satisfaction.

1. Introduction

Shared decision-making (SDM) tools have been utilized in many aspects of healthcare and have been shown to be valuable to the patient experience [1,2]. Research shows using a shared decision-making process when choosing a family planning method increases satisfaction with and continued use of the method [2,3].

With fertility awareness-based methods of family planning (FABMs), which may also be referred to as natural family planning, people may use the physiological signs of a woman's cycle—cervical fluid secretions, basal body temperature, and/or urinary hormones—to identify the fertile window: the days in her cycle when she can become pregnant [4-6]. This information is empowering as couples can choose whether to engage in sexual relations based on their family planning goals. Despite their growing popularity among women, knowledge of evidence-based FABMs among clinicians is limited [4,7-9]. This lack of knowledge may contribute to the fact that few SDM tools concerning family planning include information about the different types of FABMs. Given that FABMs can be used effectively to prevent pregnancy and have no medical side effects, it is important to include these among the range of family planning options offered to women and couples [4,5].

Accordingly, our group has developed and tested a FABM SDM tool for use by clinicians or their staff when having a conversation about family planning options. We have previously reported on the impact of the use of the SDM Tool among clinicians [10]. We demonstrated the SDM tool had a significant beneficial effect on clinician knowledge of FABMs. In this study, we evaluate the impact of the use of the SDM tool as part of a relevant office visit on patients' selection and satisfaction with FABMs and assess its ongoing impact at six months in comparison to usual practice.

2. Methods

A detailed description of development and testing of the SDM tool as well as the study design employed to evaluate its utility in comparison to current practice among FABM knowledgeable clinicians has been presented [10]. [The overall study design is illustrated and the SDM tool as tested is

Abbreviations: SDM, Shared decision making; FABMs, Fertility awareness-based methods.

* Corresponding author.
E-mail addresses: DrDuane@FACTSaboutFertility.org (M. Duane), info@FACTSaboutFertility.org (V. Martinez), sarah.gilpatrick@mmnfp.com (S. Gilpatrick), mmanhart@ccli.org (M.D. Manhart).

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available in Appendix A and B respectively]. The study was fully reviewed and approved by the Georgetown School of Medicine IRB.

Briefly, patients visiting one of the 26 enrolled clinicians were invited to participate in the study if they were: i) 18 to 44 years of age, ii) scheduled for an office visit for a well woman exam, new patient visit, post-partum family planning visit, natural family planning (NFP) counseling, or OB-family planning visit. Patients who met these eligibility criteria at the time of their visit were provided with a consent form. Patients that agreed to participate then needed to indicate if they had started a new family planning method in the previous six months or were considering starting, changing, or re-starting an FABM in the next six months. If yes, these patients then completed a pre-office visit and a post-office visit survey and were contacted via email six months later to do an online follow-up survey.

We employed a simple crossover design to evaluate the impact of the SDM tool. Patients enrolled in the control group had an office visit conducted by the clinician as they normally would, and patients enrolled in the experimental period experienced use of the SDM tool during the office visit. Participating clinicians received general training on FABMs and on use of the tool itself between the control and experimental periods.

We evaluated the usefulness of the SDM tool for patients by two pre-specified measures. First, we compared "fit" of the chosen FABM by evaluating patient satisfaction ratings in the post-office visit and six months follow-up surveys, hypothesizing that integration of the SDM tool should increase overall satisfaction ratings.

Second, we evaluated continuity of use rates for patients starting or changing FABM methods between the control and experimental groups. We assumed that 25% of women in the control group who adopted a new FABM would continue to use that FABM for at least six months based on the "current practice" office visit discussion. We hypothesized that as many as 35% of women in the experimental group exposed to the SDM tool by a trained clinician would adopt a new FABM and continue to use it for at least six months. In a simple random sample, with a two-sided Type I error rate, and 80% power, we would need 155 women in each of the treatment and usual care groups to detect a significant difference in proportions of women still using adopted FABMs after six months.

Additionally, we sought to gain insight about knowledge levels, FABM use patterns, and patients' reasons for starting or changing FABMs using information from the patient surveys. A comparison of proportions test was used to compare the distribution of patient-selected FABMs between control and experimental groups, and a Student *t*-test was used to compare patient satisfaction and level of understanding with their FABMs.

3. Results

Over the six month follow-up, patients who used the SDM tool were more likely to start or change an FABM and those who changed FABMs reported higher rates of satisfaction.

3.1. Baseline characteristics of study groups

Twenty-six clinicians contributed patients in both the control and experimental phases of the study. A total of 196 patients were screened during the control period with 56% ($n = 109$) meeting eligibility criteria and consenting to participate. In the experimental phase 206 patients were screened with 59% ($n = 122$) eligible. Thus, both groups were undersized in comparison to the prospective assumptions made for statistical power. Further eroding the study's power not everyone eligible completed the pre- and post-office surveys, and online follow-up at six months. Our response rate, while good for online surveys [11], was less than comprehensive; 62% and 53% of patients provided a survey in the control and experimental groups respectively (Table 1).

Overall, the two groups were well balanced with no differences in mean age, mean number of children, race, educational level, etc. (Table 2). Patients in both groups were generally married, Caucasian, well educated, and on average had less than two children at the time of the study: typical demographics for subjects in FABM studies of effectiveness in preventing pregnancy [12].

Table 1
Patient Accounting by treatment group. Shown are the number of patients screened, the proportion meeting the entrance criteria, and the number completing each of the surveys used in the study for both the control (usual practice) and experimental groups (SDM tool used).

	Control	Experimental
No. patients screened	196	206
Met eligibility criteria (% eligible)	109 (56%)	124 (60%)
Completed pre- office visit questionnaire	107	124
Completed post- office visit questionnaire	107	122
No. completing six months follow-up (% of those with complete post-office visit)	66 (62%)	66 (53%)
No. changed, started, or restarted FABM	37	41

Table 2
Patient demographics. Demographics such as age, marital status, race, educational level, etc. for both groups are shown and demonstrate the two groups were comparable with no important demographic differences.

	Control	Experimental
Mean Age (yrs)	28.9	31.8
% Married (n)	72% (77)	82% (102)
% Non-Hispanic Caucasian (n)	72% (77)	77% (95)
% With some college or higher (n)	80% (86)	87% (108)
Avg. Number of Children	1.6	1.76
% Without Children (n)	26% (28)	32% (40)
% Already using FABM (n)	58% (62)	47% (59)

In the control group, 58% reported they were currently using an FABM at study entry, compared to 47% in the experimental group. Current barrier use, sometimes in combination with FABMs, was reported by 25% and 23% of the control and experimental groups, respectively. Twenty-three percent and 20% reported use of no method of family planning in the control and experimental groups, respectively. Both groups felt the physician answered their questions about FABMs; 84% of the control group and 92% of the experimental group indicated their questions were answered "very well" or "fairly well" ($p = 0.30$).

Among those already using a FABM, the distribution of type of FABM used was comparable between the control and experimental group. Mucus-only methods (Creighton & Billings) were the most popular, followed by calendar-based methods, multi-indicator methods (Symptothermal or Marquette), and multiple methods (see Fig. 1).

3.2. Impact of the use of FABM SDM tool

Use of the FABM SDM tool increased the satisfaction and likelihood that a patient would start or change FABMs. When asked immediately after the office visit about the likelihood of changing family planning methods (scored as Very Likely + Somewhat Likely to change), there was no significant difference between the Control and Experimental groups (48% and 52% respectively $p = 0.48$). However, among those with sufficient follow-up, by six months a significantly larger proportion of patients had started or changed FABMs in the Experimental group (52%, 34/66) compared to the control group (36%, 24/66) ($p = 0.04$). This underscores that change is a process and not necessarily instantaneous. This also indicates the SDM tool facilitates the change process and may improve continuity rates.

Among those who changed or started an FABM after the study visit and graded their satisfaction, 45% of those who used the Tool had increased satisfaction with their new method compared to 35% in the control group ($p = 0.22$). Among only patients who changed FABMs (excluding patients new to FABMs), those in the experimental group had a 50% increase in satisfaction versus only 17% increase in satisfaction in the control group

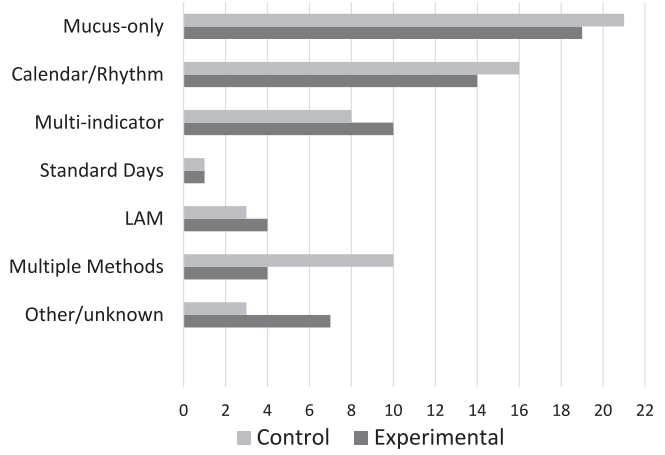

Fig. 1. Distribution of type of FABM currently using at baseline. The frequency of current FABM at baseline for each group is shown. Mucus-only methods include Creighton, Billings, & FEMM. Calendar/ Rhythm includes any calendar based FABM excluding Standard Days method (reported separately). Multi-indicator methods include Symptothermal and Marquette model. Multiple methods include any combination of the named FABMs.

($p = 0.022$). This suggests the tool was especially helpful for clinicians to assist patients select the method best suited for them.

Beyond these primary outcome measures, the tool influenced the decision-making process in additional ways. First, among those who stated they would choose a new FABM there was a trend toward more diversity in the new methods chosen with a higher proportion of patients selecting a method other than a mucus-only method (Creighton or Billings) in the experimental group compared to control (56% vs 42% respectively $p = 0.14$) (see Fig. 2). This trend was most pronounced in those patients selecting an FABM for the first time; just 22% of patients new to FABMs (2 of 9) in the control group selected a method other than mucus-only as compared to 60% of patients new to FABMs (12 of 20) in the experimental group ($p = 0.03$).

Second, use of the tool seemed to improve patient understanding of FABMs. Among those with six months follow-up, 68% of control patients felt they understood their FABM moderately well or very well; whereas 82% of experimental patients had this high level of understanding

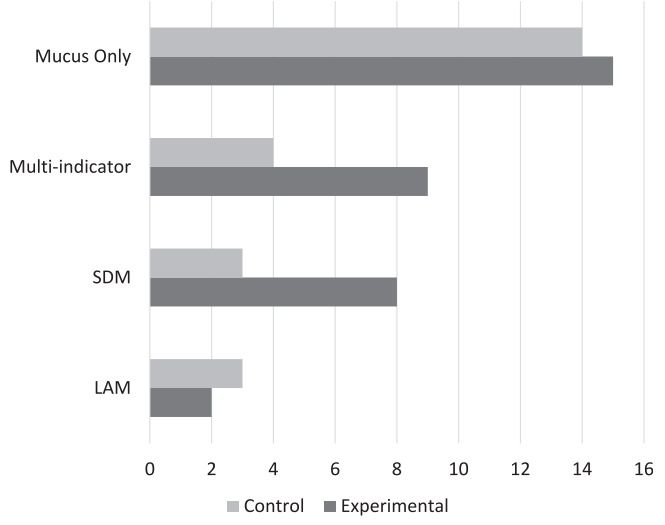

Fig. 2. Distribution of FABMs selected as new or changed by patients. FABM methods chosen after 6 months for both control and experimental groups are shown. Mucus-only methods include Creighton or Billings; Multi-indicator methods include Symptothermal and Marquette. Standard Days method (SDM) and Lactational amenorrhea method (LAM) represent the remaining choices made.

($p = 0.07$). Among those with follow-up surveys who had changed, started, or restarted a FABM, 82% and 89% of control and experimental patients, respectively, scored their level of understanding as high ($p = 0.17$). Taken together, these trends indicate the tool provided important information that was likely missing in discussions and contributed to patients enhanced understanding of FABMs.

3.3. Comparison of FABM users to non-users in combined groups

Given the baseline similarity of the control and experimental groups, we combined the two cohorts in a *post-hoc* analysis to explore perceptions and attitudes about FABMs between current FABM users and non-users. FABM users reported a higher percentage of perceived or experienced benefits than non-users. When asked to indicate the benefits of FABMs (perceived or experienced) both users and non-users provided the same top five benefits with differences only in frequency of the named benefit. The rank ordered benefits of FABMs, with frequency of response for users and non-users respectively in parenthesis, named were “natural” (79%,45%), “no harmful side effects” (70%,42%), “accuracy of knowing my fertile window” (47%,26%), “cost” (affordable) (39%,23%), and “partner involvement or support” (39%,23%).

The perceived or experienced challenges also had a high degree of overlap between users and non-users with both groups citing “low confidence in the method” (19%) and “low accuracy of knowing my fertile window” (17%) as the top two challenges. Users ranked “lacks confirmation of ovulation” (16%), “other” (15%) and “cannot be used with irregular cycles” (14%) as #3–5 challenges. For non-users the next most important challenges were “too time consuming to learn” (13%), “seems complicated” (10%) and abstinence period too long (9%).

Taken together, this suggests many current non-users may be interested in learning and using FABMs if their perceived challenges can be addressed and discussed with accurate information.

3.4. Satisfaction with current method of family planning (combined groups)

Prior to the office visit patients were asked to rate their satisfaction with their current methods of family planning on a four-point scale (completely-, mostly-, somewhat-, not at all-satisfied). Current FABM users were significantly more satisfied (74%, 69/93) than current condom users (51%, 27/53) ($p = 0.04$). They were also much more satisfied than long-acting reversible contraceptive (LARC) users (33%,4/12), followed by those using no method (54%, 13/24), and short acting hormone users (60%, 6/10).

4. Discussion and conclusion

4.1. Discussion

This study shows that use of a FABM SDM tool, when used as part of a physician-patient discussion, can enhance patients' understanding and facilitate the selection of a more suitable method leading to increased satisfaction. Despite the study being underpowered with respect to patient follow-up, we found among those who were new to or changed FABMs, use of the SDM tool resulted in significantly improved persistent use at six months and a trend toward increased satisfaction compared to the previous method used. This is consistent with previous studies showing that SDM tools increase patient knowledge, decrease decisional conflict, decrease appointment length, and may increase patient satisfaction with the chosen contraceptive method [13-15]. Further, patients who used the tool tended to show higher levels of understanding of FABMs and selected a wider diversity of methods in comparison to control patients. Given that women are more likely to continue a family planning method when they have access to their preferred method, it is important for medical professionals to provide accurate information about the full range of family planning options, including FABMs, to help patients find the method best suited for them [16].

Importantly, these patient benefits were seen among a group of physicians who were already knowledgeable about FABMs prior to enrolling in the study and in a patient cohort with an already high rate of FABM use. It would be of interest to test the tool in a group of physicians caring for reproductive-age women who are not as knowledgeable of FABMs to see if the frequency of choosing an FABM by patients is increased.

In this cohort, the perceived benefits and challenges of FABMs were consistent among users and non-users of FABMs. This implies current non-users may be interested in using FABMs if they knew more about them. The higher satisfaction ratings among FABM users at the study start compared to more commonly used family planning methods implies that more widespread evidence-based discussion of FABMs in all family planning visits may improve patient satisfaction.

This trial underscores the need for clinicians to be aware of and confident in discussing FABMs with their patients and a FABM SDM tool may assist with this interaction. In fact, some of the control patient participants stated that their office visit would have been improved with the use of a chart of FABMs.

This study has several strengths including implementation in a non-academic medical setting, increasing generalizability to general practice settings which patients commonly encounter. Another strength is the study's comparative design which allows patient experience with the SDM tool to be appraised against that of the clinician's usual practice.

There are important limitations to this study, including the study's small size and lack of power for six month follow-up. As mentioned previously, the study was conducted with a group of clinicians who are highly knowledgeable about FABMs with a patient population with a high rate of use, limiting the generalizability to the wider population. In addition, we found that the process of starting or changing FABMs was longer than expected. The Stages of Change Model has been used to describe contraceptive choice in the literature and this model is also relevant to the choice of a FABM [17]. Patients move through the four stages at varying rates, with the preparation and action stages potentially being quite lengthy as the patient investigates various methods, considers options for instruction, schedules a class, and possibly waits for a new cycle to begin using the new method. Our study period was insufficient to capture the full process in all cases.

4.2. Innovation

This study is the first effort to examine the patient experience with a novel SDM tool presenting fertility awareness-based methods in a non-academic setting. As noted previously, implementation of the tool in a non-academic setting is innovative as the results are more readily generalizable. Though shared-decision making is a well-established concept, this decision tool is the first of its kind in relation to evidence-based FABMs. More importantly, it provides detailed information about the five most commonly used, evidence-based FABMs, including how they work, their effectiveness rates, advantages and disadvantages which studies show patients prefer to receive, particularly via the use of visual models [18]. By providing critical information on different FABMS, the SDM tool facilitated selection of the FABM best suited to each patients' needs as evidenced by the increased satisfaction and persistence of use we observed in the study.

4.3. Conclusion

In conclusion, use of the SDM tool during FABM counseling increased patient continuity with their chosen method and increased satisfaction with the chosen method among those changing FABMs. Our results suggest that the tool gives patients a wider diversity of methods to choose from and increases patient understanding of FABMs. Overall, the SDM tool was well-received by patients and assisted clinicians in helping patients find the right "fit" of FABM to meet their needs.

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Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

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