

# Informed Choice Assistance for Women Making Uterine Fibroid Treatment Decisions: A Practical Clinical Trial

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**Background.** There is limited evidence about how to ensure that patients are helped to make informed medical care decisions. **Objective.** To test a decision support intervention for uterine fibroid treatments. **Design and Setting.** Practical clinical trial to test informed choice assistance in 4 randomly assigned gynecology clinics compared to 5 others providing a pamphlet. **Patients.** Three hundred women facing a treatment decision for fibroids over a 13-month period. **Intervention.** Mailed DVD and brochure about fibroid treatments plus the Ottawa decision guide and an offer of counseling soon after an index visit. **Measurements.** Mailed survey 6 to 8 weeks later asking about knowledge, preferences, and satisfaction with decision support. **Results.** In total, 244 surveys were completed for an adjusted response rate of 85.4%. On a 5-point scale, intervention subjects reported more treatment options

being mentioned (3.0 v. 2.4), had a higher knowledge score (3.3 v. 2.8), and were more likely to report being adequately informed (4.4 v. 4.0), and their decision was both more satisfactory (4.3 v. 4.0) and more consistent with their personal values (4.5 v. 4.2). Neither knowledge nor use of the intervention was associated with greater concordance between preferences and decisions. **Limitations.** Implementation of intervention may not have been well timed to the decision for some patients, limiting their use of the materials and counseling. **Conclusion.** It is difficult to integrate structured decision support consistently into practice. Decision support for benign uterine conditions showed effects on knowledge and satisfaction but not on concordance. **Key words:** group decision making; obstetrics; gynecology; women's health; decision aids. (*Med Decis Making* 2010;30:444–452)

Wennerberg and others<sup>1,2</sup> have identified preference-sensitive care as one of the 3 types of geographic variations in care utilization. They have noted that decisions about those medical treatments without a strong evidence base favoring particular alternatives should be based on informed patient choice and use shared decision making.<sup>3</sup> Because most

Received 25 February 2009 from HealthPartners, HealthPartners Medical Group, and HealthPartners Research Foundation, Minneapolis, Minnesota (LIS, SEA, NMT, JEM, KKK, LHA); Massachusetts General Hospital, Boston (KS); and Stillwater Medical Group, Stillwater, Minnesota (LM). Support for this study was provided by the Foundation for Informed Medical Decision Making (FIMDM). Revision accepted for publication 29 September 2009.

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DOI: 10.1177/0272989X09353947

physicians and physician associations seem to agree with this need to enhance shared informed decision making, it seems as though all that is needed is implementation.<sup>4–6</sup> However, as with many other desirable changes in medical practice, there is little research that is relevant to effective implementation strategies for decision support in clinical practice and no descriptions of a consistent delivery system under real-life care conditions with all of its variations.

To address this need, we conducted a practical clinical trial that tested the addition of consistent information and decision support for women facing a decision about treatment for uterine fibroids as an add-on to usual care. Practical clinical trials have been called for in this situation, trials for which the hypothesis and study design are developed specifically to answer the real-life questions faced by decision makers and clinicians.<sup>7,8</sup> This trial tested the

hypothesis that women who receive detailed information about the alternatives, along with an aid to decision making and an offer of counseling, will be more informed and will make decisions that are more consistent with their preferences. This combination is hereafter referred to as informed choice assistance (ICA). The trial grew out of a previous retrospective survey of women with fibroids that showed relatively low knowledge levels and little relationship between knowledge and the concordance between patient preferences and treatment choice.<sup>9</sup> In keeping with practical trials, we collected data on the reach, adoption, and impact on clinical personnel as well as effectiveness.

## METHODS

### Participants and Data Collection

This study was conducted in the gynecology clinics of a 600-physician multispecialty medical group in Minnesota. Twenty-five gynecologists care for patients in 8 clinics. The clinics were assigned to intervention and control arms of the study based on random allocation stratified by patient population size and type. First the 2 large central city sites were sorted into opposite study arms, followed by random allocation of the other sites to end up with similar patient sizes and characteristics. Patient allocation to intervention ( $n = 3$  clinics) or control arm ( $n = 5$  clinics) depended on the specific clinic where they received care.

The survey-eligible sample for this study consisted of all English-speaking, nonpregnant women between the ages of 18 and 65 years with a visit to a gynecology clinic with an ICD-9 diagnosis code for uterine fibroids of 218, 218.0, 218.1, 218.2, or 218.9 between February 2007 and February 2008. The medical records of these cases were reviewed by an experienced gynecologist (JM) or gynecology nurse to exclude cases unlikely to be in a decision-making situation, either because their fibroids were not clinically significant or because they had already chosen a treatment.

### Intervention

The ICA intervention included the following components:

1. *Patient decision aids:* DVD and booklet from the Foundation for Informed Medical Decision Making (FIMDM) describing the treatment options for

fibroids, the advantages and disadvantages of each, and illustrating how different women work with their doctors to choose the fibroid treatment that is best for them

2. *Decision worksheet:* Paper copy of a generic version of the Ottawa Decision Guide, designed to help identify the relevant options, the key pros and cons, values, and preferred decisions
3. *Nurse coach access:* The phone number to call to obtain help from a nurse counselor trained in using the Ottawa Guide with patients. If no call was received within 2 weeks, the counselor was to call each patient to facilitate access to counseling.

In the control clinics, similarly identified patients were given a pamphlet about fibroids, but there was no other decision support beyond whatever might be provided by usual care. Mailing of the intervention packets occurred within 2 weeks of the index visit, with a cover letter that was signed by the head of the gynecology department.

The intervention and patient identification methods described above were used for 11 months (April 2007–February 2008) of the 13-month trial. During the first 2 months of the study (February and March 2007), nurses at both intervention and control clinics identified patients making a decision about uterine fibroids. They then handed the patients either the packet of intervention materials (for intervention clinics) or usual care brochure (for control clinics) and faxed a weekly log of patients they had identified to the study team for follow-up surveys.

The identification of eligible patients for the clinics involved in the randomized trial was not easy. During the first 3 weeks of the intervention, electronic medical record (EMR) data identified 60 women with fibroid-related visits, but only 14 of these were identified by nurses in the clinics. Of the 14 identified by nurses, only 7 had been diagnosed with fibroids in the EMR. This finding led to the modification of the study to include weekly EMR-based identification of patients, followed by a clinician review to exclude cases with incidental findings of fibroids and women who had already made a treatment decision.

A follow-up questionnaire was mailed to all women in the study approximately 4 to 5 weeks after they had received their initial intervention or control fibroid information. Following a modified Dillman approach, those not responding after a mailed reminder and a subsequent repeat mailing of the questionnaire were called by a trained interviewer up to 6 times to conduct the survey by telephone.<sup>10</sup>

## Measures

The questionnaire included questions about demographics (age, education, race/ethnicity), fibroid problem history, treatment options offered by the doctor, and actual decision made. In addition, it included questions about the following:

- Satisfaction with the decision, her role in it, and relation to personal values on a Likert scale of 1 to 5.
- Knowledge: 5 multiple-choice questions about fibroids, the correct answers for which were summed to produce a knowledge score from 0 to 5. These items had been developed and tested in a previous study and included questions about what a fibroid is, who treatment is recommended for, what happens to fibroids after menopause, which treatments are permanent cures, and the effects of a hysterectomy.<sup>9</sup>
- Fibroid outcome preferences: patients rated on a scale of 0 to 10 how important 7 key health outcomes were to their decision. These items had also been developed and tested in a previous study.<sup>9</sup>

We were interested in the impact of ICA on clinical personnel satisfaction with this process and their relationship with patients. Therefore, we conducted a survey of physicians, midwives, nurse practitioners, nurses, and medical assistants at all sites to obtain their impressions of the approach used in their clinic. The personnel involved at each center received an e-mail in December 2007 that described the survey and contained a link to a Web-based survey. This survey asked about awareness of changes to the method of providing ICA to patients with uterine fibroids, satisfaction with the current and old system, suggestions for improving the approach, and the effect of the current approach on time spent with the patient and helpfulness to the patient. An e-mail reminder containing a survey link was sent out 1 week following the first mailing. Those who had not responded within 2 days of the reminder e-mail were called by the survey center to complete the survey by phone.

## Analyses

The hypotheses tested were whether fibroid knowledge and decision satisfaction differed by study arm, whether the concordance of preferences and treatment choice varied by study arm or knowledge level, and whether the use of specific ICA aids related to knowledge or satisfaction levels. In the staff survey, the hypothesis tested was whether staff reactions to use of the ICA differed by study arm.

Comparisons of survey items for patients in the control and intervention arm of the randomized trial used contingency tables and Pearson's chi-square for categorical variables and independent sample *t* tests for continuous variables. Continuous variables that showed significant differences by study arm were reanalyzed using general linear mixed models to take into account the clustering of individuals within intervention or control arm clinics. Because study arm effects in the general linear mixed models were similar to those for nonhierarchical analysis, the simpler nonhierarchical bivariate results are presented.

Concordance of individual treatment outcome preferences and treatment choice was computed separately by study arm using 1-way analysis of variance (ANOVA) to test for associations of preferences (on a 0–10 scale) with 4 treatment choices:

1. Decided to wait
2. Hormone or pain medications
3. Hysterectomy
4. Other surgical procedures (myomectomy, uterine artery embolization, intrauterine procedures)

Eta squared was used as an overall measure of association of preferences and treatment choice. The magnitude of eta squared was compared across study arm as an informal test of differential levels of concordance by study arm.

A formal test for differences in concordance between preferences and treatment choice by study arm was tested with multinomial logit regression, with an outcome of 4 treatment choices and predictors of study arm and the 7 preferences. A likelihood ratio test was used to test the significance of adding 7 interaction terms (study arm by each preference), which formally tested whether the concordance between preference and treatment choice varied by study arm. This analysis was repeated replacing study arm with the fibroid knowledge score to test whether concordance between preference and treatment choice varied by knowledge level.

This study was planned to be powered at 0.85 to detect a difference in the fibroid knowledge score of 49.0% correct responses v. 68.9% correct, assuming 108 complete survey responses from each study arm,  $\alpha = 0.05$ , and a 2-sided z-test of differences in proportions. The expected knowledge scores were the median effect sizes noted in a Cochrane review examining the effect of decision aids on patient knowledge.<sup>11</sup>

All research methods were reviewed, approved, and monitored by an institutional review board.

## RESULTS

During the trial period, 471 patients were identified from review of EMR visit information that fit the potential inclusion criteria. Of these, 245 appeared to be appropriate for inclusion after medical record review and were sent either the intervention or control materials, depending on the clinic visited. The same materials were also sent to 55 patients identified in the clinic during the first 2 months of the study. Among these 300 (245 + 55) individuals who were later sent the follow-up questionnaire, complete responses were obtained from 244 for a response rate of 85.4%, after removing 4 individuals with a language barrier. Figure 1 documents the flow of participants for the trial in accordance with the recommendations of CONSORT.<sup>12</sup>

### Controlled Trial

Table 1 documents information about the trial respondents by study arm from the research survey. Forty-four percent were nonwhite, 56% had a college education, most had been aware of their fibroids for over a year, and 67% reported being quite bothered (score of 7 or higher on a 0–10 scale) by at least one of the common symptoms of fibroids (data not shown). Nearly all reported wanting a major role in medical treatment decisions for fibroids, and 4 of the 7 outcome preferences were rated as being very important by at least half the respondents. There were no significant differences in any characteristic or preference between the study arms.

As Table 2 illustrates, intervention participants reported a larger number of treatment options being mentioned by their doctor, had a higher knowledge score, were more likely to report being adequately informed, and their decision was reported to be both more satisfactory and more consistent with their personal values. Nearly all (90%–94%) reported having made a treatment decision in the past few months, although the decision in nearly half the cases was not to treat at this time. Among those who made a treatment decision, 50.4% of control arm patients and 39.6% of intervention arm patients decided not to treat at this time ( $P = 0.11$ ).

Although 94% of the intervention participants recalled receiving fibroid informational materials, only 60% of control clinic participants did ( $P < 0.001$ ; see Table 3). Among intervention participants, 61% read the informational booklet, whereas 52% of control participants read the informational pamphlet ( $P = 0.16$ ). Relatively few of the

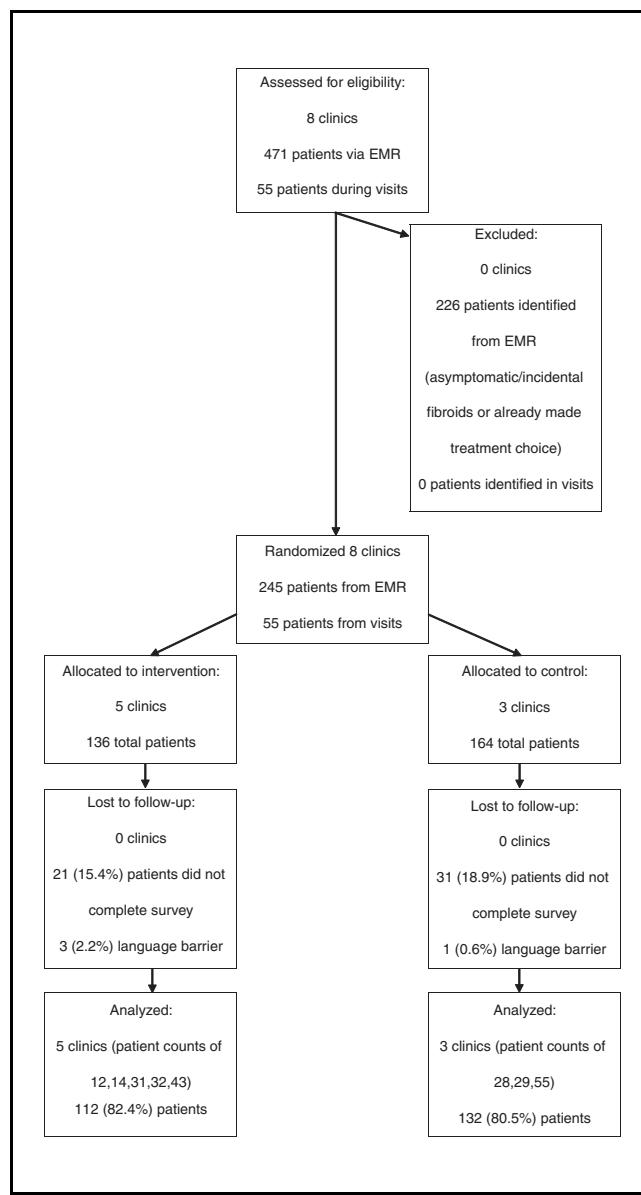


Figure 1 Flowchart of clinics and participants in the trial. EMR, emergency medical record.

intervention participants reported using either the decision guide or nurse counseling, and the counselor was only able to reach 24 patients, of whom half declined to participate in a structured facilitation of their decision.

Among patients in the intervention arm, the mean knowledge score was higher among those using the video than those who did not ( $\bar{x} = 4.0$  v.  $3.1$ ,  $t = 4.3$ ,  $P < 0.001$ ). Use of the booklet, decision guide, and nurse counseling were not associated with

**Table 1** Descriptive Information on Women with Fibroids by Study Arm

Characteristic	Control ( <i>n</i> = 132), % or <i>̄</i> ( <i>s</i> )	Intervention ( <i>n</i> = 112), % or <i>̄</i> ( <i>s</i> )
Age, y	46.3 (7.3)	45.8 (8.1)
Education		
Less than high school	0.8	4.6
High school or GED	12.4	13.9
Technical school or some college	31.0	25.9
College graduate	55.8	55.6
Race/ethnicity		
White	55.8	57.0
Black	32.6	34.6
Other	11.6	8.4
Preference for deciding about medical treatments for uterine fibroids		
I make the decision on my own or considering my doctor's opinion	52.0	53.7
I share responsibility with my doctor	41.6	42.6
My doctor makes the decision and may or may not consider my opinion	6.4	3.7
Confidence in filling out medical forms		
Extremely confident	68.5	64.8
Less than extremely confident	31.5	35.2
How long aware of uterine fibroids:		
Less than 1 year	36.5	32.1
1–2 years	12.7	19.3
3–5 years	22.2	20.2
More than 5 years	28.6	28.4
How bothered by symptoms in past few months (0 = <i>not bothered</i> , 10 = <i>extremely bothered</i> )		
Heavy bleeding	5.4 (4.0)	6.1 (3.8)
Pelvic pressure or pain	4.4 (3.5)	4.8 (3.8)
Urinary frequency	3.8 (3.2)	4.4 (3.5)
Infertility	0.9 (2.7)	1.2 (3.1)
Fibroid-related symptoms strongly interfere with daily activities (0 = <i>no interference</i> , 10 = <i>complete interference</i> )	4.4 (3.2)	5.1 (3.4)
Treatment outcome preferences (% very important) <sup>a</sup>		
Have a treatment with a low failure rate	78.3	76.3
Have a permanent treatment	60.4	55.7
Minimize the amount of time you would spend recuperating from a treatment	47.6	57.3
Do something right away to relieve symptoms	50.0	50.5
Avoid taking medication	47.1	43.3
Improve your sexual functioning	31.1	32.0
Keep your ability to have a baby	15.4	20.4

There were no statistically significant differences in this table by study arm.

a. Those rating a treatment outcome with a rating of 8 to 10 on a 0 to 10 scale with 0 = *not at all important* and 10 = *very important*.

knowledge score. Patients in the control arm who read the pamphlet completely had a higher mean knowledge score than those who did not read it or read only parts of it ( $\bar{x} = 3.3$  v.  $2.6$ ,  $t = 2.2$ ,  $P = 0.03$ ).

Associations between preferences and actual treatment choices in Table 4 illustrate that in one or both

study arms, there is statistical and patterned evidence of concordance between treatment choice and 4 of the 7 preferences: relieving symptoms right away, keeping the ability to have a baby, having a permanent treatment, and having a low failure rate. For example, those choosing hysterectomy rate the

**Table 2** Treatment Options, Treatment Choice, Knowledge, and Satisfaction

Characteristic	Control ( <i>n</i> = 112), % or $\bar{x}$	Intervention ( <i>n</i> = 103), % or $\bar{x}$
Treatment choices mentioned by doctor		
Hysterectomy	55.9	61.3
Not to treat at this time	59.8	50.5
Myomectomy**	35.4	55.0
Hormone medications**	32.3	49.6
Uterine artery embolization*	22.8	35.1
Pain relief medications	21.3	25.2
MRI-guided ultrasound	7.9	15.3
Other intrauterine procedures	3.2	5.4
Number of treatments mentioned by doctor, ** $\bar{x}$ ( <i>s</i> )	2.4 (1.6)	3.0 (1.8)
Treatment decision in the past few months		
Yes	44.4	56.5
Decided not to treat at this time	45.2	37.0
No	10.3	6.5
Treatment choice made <sup>a</sup>		
Hysterectomy	50.0	39.3
Myomectomy, uterine artery embolization, or other intrauterine procedures	26.8	34.4
Hormone and/or pain medications	17.9	24.6
Fibroid knowledge score** (0 = lowest score, 5 = highest score)	2.8 (1.5)	3.3 (1.3)
I was adequately informed about issues important to my decision** (1 = <i>strongly disagree</i> , 5 = <i>strongly agree</i> )	4.0 (1.1)	4.4 (0.8)
I am satisfied with my decision * (1 = <i>strongly disagree</i> , 5 = <i>strongly agree</i> )	4.0 (1.0)	4.3 (0.8)
I am satisfied that this was my decision to make (1 = <i>strongly disagree</i> , 5 = <i>strongly agree</i> )	4.2 (0.9)	4.5 (0.8)
My decision was consistent with my personal values** (1 = <i>strongly disagree</i> , 5 = <i>strongly agree</i> )	4.2 (0.9)	4.5 (0.8)

a. Excludes those who said they had not made a treatment decision and those who decided not to treat at this time.

\**P* < 0.05. \*\**P* < 0.01.

**Table 3** Decision Aids Used

	% (Proportion) Using the Aid among Those Who Recall Receiving It	% (Proportion) Using the Aid among All Respondents
Control arm ( <i>n</i> = 127)		
Remember receiving the pamphlet	59.8 (76/127)	
Read pamphlet	86.8 (66/76)	52.0 (66/127)
Intervention arm ( <i>n</i> = 103)		
Remember receiving information packet	94.2 (97/103)	
Read booklet	64.9 (63/97)	61.2 (63/103)
Watched video	45.4 (44/97)	42.7 (44/103)
Used the Ottawa decision guide	22.7 (22/97)	21.3 (22/103)
Used nurse counseling	17.5 (17/97)	16.5 (17/103)

\**P* < 0.05. \*\**P* < 0.01.

importance of having a permanent treatment higher than those choosing other treatments. Other patterns of association also suggest concordance between the content of preferences and the benefits and risks

associated with specific treatments. However, the magnitude of eta squared is higher for those in the intervention arm for only 4 of 7 preferences, suggesting that there is not a consistent pattern of higher

**Table 4** Importance of Individual Treatment Outcome Preferences by Treatment Chosen

Outcome Preference	Wait	Hormone and/or Pain Medication	Myomectomy, Uterine Artery Embolization, Other Intrauterine	Hysterectomy	Eta Squared	P
<b>Control arm</b>	(n = 54)	(n = 10)	(n = 15)	(n = 28)		
Avoid taking medications	6.1	4.4	6.1	6.8	0.036	0.32
Relieve symptoms right away	4.0	6.8	7.6	8.2	0.253	< 0.001
Keep ability to have a baby	1.5	1.9	4.6	0.7	0.128	0.004
Minimize recuperation time	6.1	5.0	8.3	6.5	0.067	0.10
Improve sexual function	4.3	3.7	5.7	5.6	0.035	0.33
Have a permanent treatment	6.4	5.6	8.4	8.8	0.149	0.001
Low failure rate treatment	7.5	7.3	8.9	9.5	0.113	0.008
<b>Intervention Arm</b>	(n = 38)	(n = 15)	(n = 20)	(n = 24)		
Avoid taking medications	5.4	3.5	6.2	6.5	0.067	0.10
Relieve symptoms right away	3.9	8.0	7.5	8.1	0.285	< 0.001
Keep ability to have a baby	2.5	2.7	3.6	0.9	0.062	0.12
Minimize recuperation time	6.6	7.1	6.7	7.8	0.025	0.52
Improve sexual function	3.5	5.5	3.9	6.0	0.077	0.06
Have a permanent treatment	5.6	6.4	7.6	9.1	0.211	< 0.001
Low failure rate treatment	7.7	8.0	8.7	9.3	0.064	0.11

Cell entry is the mean treatment outcome preference (0 = *not at all important*, 10 = *very important*) computed for those choosing a specific treatment. Eta squared and P value from 1-way analysis of variance.

association/discrimination of preferences by treatment chosen for patients in the intervention arm.

In a multinomial logistic regression analysis, there was no evidence that these patterns of association differed by study arm. A model predicting the 4 treatment choices from study arm and the 7 preference items had a likelihood ratio chi-square (168) = 148.9. When adding all 2-way interactions of study arm and preferences, the likelihood ratio chi-square (150) = 137.8. The likelihood ratio chi-square difference was not significant (18 df) = 11.1, *P* = 0.89. A similar analysis using high v. low knowledge tests scores instead of study arm had a likelihood ratio chi-square difference (18 df) = 10.0, *P* = 0.93, indicating that concordance of preferences and treatment choice also did not vary by knowledge level.

### Staff Survey

The staff survey was completed by 13/19 (68%) personnel in control clinics and 13/17 (76%) in intervention clinics. Of intervention clinic personnel, 85% reported awareness of a change to the delivery of ICA. Sixty-nine percent of intervention personnel and 85% of control personnel reported being satisfied or very satisfied with the approach used to help patients make treatment decisions about uterine fibroids. The most common complaint among the

dissatisfied was that the system of delivery for ICA was not fully understood. Twenty-two percent in the intervention arm were more satisfied with the new system than the one used in the previous year.

Belief that the current approach helped patients make a decision was directionally higher for clinicians in the control arm (82%) than in the intervention arm (44%). Most clinic personnel in the intervention sites reported that their relationships with patients stayed the same under the new approach, that the time they spent with patients was the same, and that the amount of time documenting care was the same. When asked about barriers to providing patients with information and assistance with treatment decisions, personnel in both intervention (60%) and control (100%) clinics cited limited physician time.

### DISCUSSION

This practical clinical trial demonstrated that intervention participants were aware of more treatment options, felt more informed, had more knowledge about fibroids, and were more satisfied with their decision and its relation to their preferences than were control participants. However, neither knowledge nor study arm was associated with more concordance between preferences and treatments. It seems likely that this inability to demonstrate an

effect on decision quality may have been related to the relatively small proportion of participants who actually used the intervention opportunities, especially the decision guide or counseling. It may also have been affected by the difficulty of implementing assistance at the optimal time and by the relatively high knowledge, concordance, and satisfaction levels already present in usual care in this medical group.

These results support previous work showing that it is important to do more than provide information and that facilitation of the decision-making process is important if we wish to improve the quality of decision making for preference-sensitive care. Krones and others<sup>13</sup> showed that providing a decision aid to men about prostate cancer screening in a randomized controlled trial did not affect their report of a collaborative decision, even though the intervention group did have greater knowledge and a greater feeling of being involved. These results also confirm that simply offering decision support in addition to information does not mean that many will make use of it. We had hoped to reduce this latter problem by incorporating the decision support directly into patient care but found it impossible to consistently achieve that, even when the physicians, nurses, and clinic leaders were supportive and actively involved in developing the intervention plan. The pressures of practice make it difficult to introduce seemingly optional additions, even when there is every intention to do so.

Perhaps the most important generalizable lesson from this study is the difficulty of delivering ICA outside the context of direct patient care, where timeliness, choice of cases, and synergy with the doctor-patient interaction are all going to be suboptimal. Closely integrating the use of these tools with the patient-provider interaction may be a critical element of successful implementation of decision-making support tools for any care decision. However, it is not clear how to do that consistently for all appropriate patients at the appropriate time. One third of clinical personnel in intervention clinics felt the new approach had improved their relationship with their patients, and none reported it had worsened it.

What are the barriers in practice to integrating ICA with care? The clinical personnel reported that the most important barrier was limited time, but only 1 physician and 3 other staff (out of 22 and 20, respectively) reported that lack of physician or patient interest in ICA was a problem. However, many physicians report feeling that ICA is their responsibility and that they are already doing it

pretty well. Both of those perceptions may be problems. In addition, our problems with efforts to integrate ICA into care suggest that several other issues not usually identified by those on the front lines are especially prominent for a problem such as uterine fibroids—infrequency and timing. Although fibroids are common and can cause considerable distress to patients, they develop slowly over years, are often asymptomatic, and rarely require urgent treatment. Thus, the right moment for assisting decisions is often both unclear and infrequent, and decisions to delay treatment are appropriate and common. When the right moment does arise in a busy practice, there may not be time to provide adequate impromptu assistance, and few practices have an organized way to provide it. One solution may be to always plan on a second visit, with ICA provided by staff between the visits.

Improving the delivery of other important clinical services with an important but indirect relationship to patient presenting complaints (e.g., preventive services, patient education, self-management support for chronic conditions) has required practice systems and delegation to other practice staff.<sup>7</sup> However, those services are predictable and can be addressed by nonphysicians at multiple visits or after/between visits. The problem for fibroids is to implement a delegatable system that is integrated with physician care, can be called into action consistently when the right moment arrives, and does not require the physician to remember to do so.

The principal limitation in our findings was the limited use of the intervention by the patients, perhaps aggravated by our inability to develop an intervention that could consistently provide the ICA at exactly the right time of need for it. Thus, another limitation was that survey questions addressed a variable number of doctor discussions, both before and after the intervention. In addition, patient selection could have been influenced by one of the reviewers (JM) who might have been aware of some of the clinic assignments; however, she expressed uncertainty about which clinics were in the intervention arm. Finally, even though we were able to consistently deliver the materials to patients in the trial by supplementing clinic operations, we lost the advantages that clinician involvement should produce, both in better timing and in integrating ICA into care. It seems likely that most of the intervention patients would have needed help working through their decision to show a difference in decision quality from usual care. Achieving greater integration into care on a consistent basis may require restructuring of

medical practice and changing the compensation system, but that was well beyond the scope of this study. In the meantime, we need further quality improvement efforts and practical clinical trials of more effective ways to integrate ICA into practice.

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