Implementation Science

RESEARCH

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The UPFRONT project: tailored implementation and evaluation of a patient decision aid to support shared decision-making about management of symptomatic uterine fibroids

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Abstract

Objective To evaluate implementation of a patient decision aid for symptomatic uterine fibroid management to improve shared decision-making at five clinical settings across the United States.

Methods We used a type 3 hybrid effectiveness-implementation stepped-wedge design and the Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) planning and evaluation framework. We conducted clinician training, monthly reach tracking with feedback to site clinical leads, patient and clinician surveys, and visit audio-recordings. Implementation strategies included assessment of organizational readiness for shared decision-making, synchronous clinician training, audit and feedback of decision aid reach, and access to multiple decision aid formats. Outcomes and analyses included patient-level reach, clinician-level adoption, and associations of patient-reported decision aid exposure (as treated) and setting-level implementation (intention-to-treat) with patient-reported (collaboRATE measure) and observed (OPTION-5 measure) shared decision-making. We also designed and assessed setting-level plans for sustainability and other factors impacting sustained decision aid use.

Results The decision aid was adopted by 72 of the 74 eligible gynecologists (97%) and reached 2553 patients across five settings. CollaboRATE scores improved among patients who reported receiving the decision aid (as-treated analysis, 69% vs. 59%; OR 1.6, 95% CI 1.16–2.27). CollaboRATE scores remained consistent before and after setting-level decision aid implementation (intention-to-treat analysis, 64% vs. 63%; OR 0.86, 95% CI 0.61–1.22). Participants would prefer to receive a decision aid at multiple time points (91.9% before the visit, 90.7% during the visit, 86.5% after the visit). Shared decision-making experiences did not improve when comparing pre vs. post-implementation collaboRATE scores across included settings (intention-to-treat, 64% vs. 63%; OR 0.86, 95% CI 0.61–1.22).

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Conclusion When patients with symptomatic uterine fibroids are given decision aids, they report higher shared decision-making scores. However, the differences we observed between the as-treated and intention-to-treat results suggest that unaddressed implementation challenges continue to limit the extent to which patients receive decision aids and likely hinder their overall impact. Future efforts to implement decision aids should explore enhancing their integration into clinical workflows and standard operating procedures, supported by organizational incentives that prioritize shared decision-making.

Trial registration ClinicalTrials.gov NCT03985449; registered 6 June 2019.

Keywords Shared decision making training, Patient decision aid, Conversation aid, Symptomatic uterine fibroids, Implementation science

Contributions to the literature

- In this study, we identified patient preferences surrounding decision aid implementation, including timing and mode of decision aid delivery.
- This study supports existing research demonstrating the effectiveness of patient decision aids when they are used in clinical care.
- Challenges remain when implementing patient decision aids into routine clinical practice, including a lack of organization-level prioritization and difficulty incorporating decision aids into routine clinical workflows.

Introduction

Symptomatic uterine fibroids are a common condition and have many treatment options with varied functional trade-offs. This makes fibroids an ideal condition for preference-sensitive care, that is, treatment that is based on individual patients' values and preferences [1, 2]. Patient decision aids support evidence-based, patient-centered decision-making [3–6]. The American College of Obstetricians and Gynecologists recommends the use of patient decision aids to support decision-making conversations between patients and clinicians [7].

Option Grid® decision aids, designed for use within clinical encounters during conversations between patients and clinicians, have demonstrated effectiveness by improving shared decision-making (SDM) in randomized controlled trials [8–10]. However, the positive effects of decision aids on SDM and resulting cognitive-affective outcomes are not yet achieved at scale, as implementation of patient decision aids in routine clinical practice remains challenging [11].

Barriers to routine use of patient decision aids include disruption of established clinical workflows, lack of clinician buy-in, and misalignment between organizational incentives and decision aid use [12, 13]. More attention toward broad implementation of patient decision aids is needed, along with investigation of what implementation strategies are most effective. We initiated the Uterine Fibroids Options for Treatment (UPFRONT) project to investigate the impact of a multi-component implementation strategy bundle on decision aid delivery in gynecology settings. In this study, we aimed to evaluate implementation of the Option Grid patient decision aid for symptomatic uterine fibroids at five health systems in the United States using the RE-AIM framework.

Methods

Design

We conducted a type 3 hybrid study [14] combining evaluations of intervention effectiveness (e.g., impact on patient outcomes) and implementation. We used the Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) planning and evaluation framework [15, 16]. Reporting follows the Standards for Reporting Implementation Studies (StaRi) [17].

Detailed intervention, implementation strategy, and evaluation methods are reported in a published protocol [18]. The Option Grid patient decision aid was rolled out one setting at a time according to a randomized stepped-wedge schedule. Relevant outcome data were collected throughout each setting's pre-implementation and active implementation phases (Fig. 1).

Ethics approval and registration

The study was registered at ClinicalTrials.gov (NCT03985449) and approved by the Dartmouth College Committee for the Protection of Human Subjects (study #31464) and the Washington University Human Research Protection Office.

Intervention

The Option Grid patient decision aid for symptomatic uterine fibroids presents answers to frequently asked questions about available medical and procedural treatment options in a tabular format, available in English or Spanish, using text at a sixth-grade reading level. Adaptations made during the study led to two versions of the decision aid, covering medication and procedure-based options. Options included watch and wait, medicine with

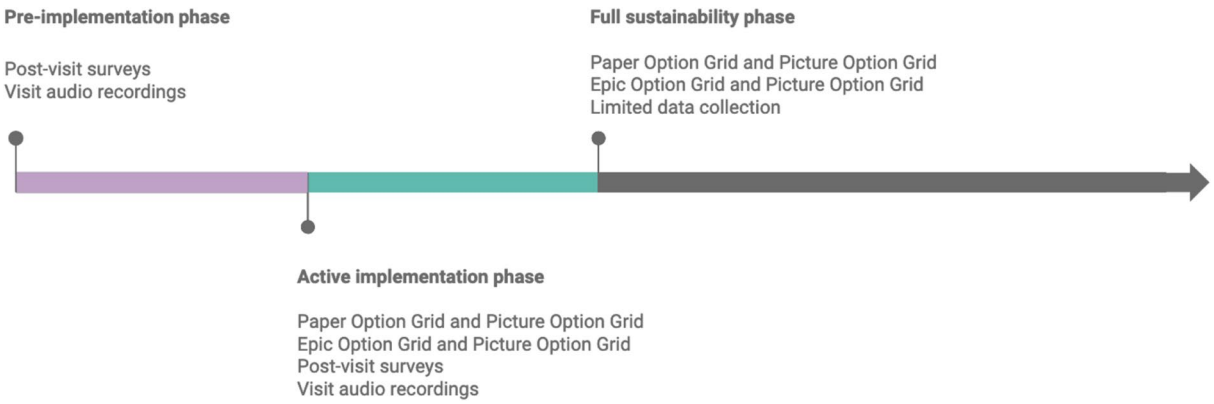

Fig. 1 Study phases

hormones, medicine without hormones, uterine artery embolization, endometrial ablation, radiofrequency ablation, myomectomy, and hysterectomy. We also created Picture Option Grid versions of the medication and procedural Option Grids, which include the same text supplemented by images that illustrate key information. An online, interactive version allowed users to select various options for comparison in a tailored Option Grid file downloaded to their computer.

Implementation strategy

The multi-component implementation strategy was guided by the Consolidated Framework for Implementation Research (CFIR) [19, 20]. The strategy comprised assessing organizational readiness for SDM at each site; providing access to the Option Grid in multiple modalities and formats, including access for clinicians through the electronic health record; conducting brief training for clinicians on SDM and how to use the decision aids; presenting monthly audit and feedback to each site's clinical lead on reach of the decision aid; and planning for sustainability at each site (see Table 1) [18, 21]. Individual settings developed different methods to deliver the decision aids to patients (see Appendix 1 process maps). Throughout the project period, core project staff held weekly check-in meetings with site-based project team members to plan implementation processes and monitor progress at each site. Beyond the initial iterative planning discussions, these meetings provided regular opportunities for troubleshooting implementation-related issues over the course of the project. Clinician training sessions (synchronous, 1 h at each setting) were tailored to strengths, resources, and opportunities identified at each site through the Measure of Organizational Readiness for Patient Engagement [21].

Settings

The five implementation settings were situated in academic medical centers. They included gynecology practices in: (1) a rural area of the Northeast United States (US); (2) an urban area of the Midwest; (3) an urban area of the Northeast; (4) an urban area of the Northeast focused on reproductive endocrinology and minimally invasive gynecologic surgery; and (5) a small city in the Midwest focused on minimally invasive gynecologic surgery.

Participants

Clinician participants included attending physicians, residents and fellows, nurse practitioners/midwives, and physician assistants who cared for patients with fibroids at the five gynecologic settings. We included patients

Table 1 Multi-component implementation strategy bundle

Implementation strategy	Relevant CFIR domains
Assessment of organizational readiness for SDM, informing tailored training and workflows at each site that address organizational barriers to implementation	Inner setting, Implementation process
Online or in-person training of all participating clinical teams, including feedback and coaching	Individuals
Monthly audit and feedback of setting-level decision aid reach	Individuals
Access to multiple formats of Option Grid decision aids (text, picture, and online interactive versions; in English and Spanish)	Innovation
Create plans for sustained decision aid use at each site	Inner setting, Implementation process

of reproductive age (i.e. premenopausal) with new or recurrent symptoms of uterine fibroids (e.g., heavy menstrual bleeding, pelvic pressure, or pain) who were seeking treatment and met the following inclusion criteria: (1) assigned female sex at birth, (2) 18 + years of age, (3) spoke English or Spanish, and (4) could complete short surveys online independent of assistance. We did not exclude pregnant patients. We excluded postmenopausal patients because they are less likely to experience fibroid-related symptoms.

Outcomes

Table 2 summarizes study outcomes.

Reach

Measure We evaluated reach as the total number of patients who received the Option Grid or Picture Option Grid. While reach is typically presented as a proportion, the non-specific symptoms associated with uterine fibroids (e.g., heavy bleeding, pain) posed challenges for systematic identification of eligible patients presenting for uterine fibroid evaluation and decision-making. Unable to fully rely on diagnosis codes or other reporting mechanisms within clinic scheduling software and electronic health records to estimate the total number of eligible patients, participating sites enlisted clinical, administrative, and/or research staff to conduct manual monthly tracking of eligible patients. These tracking methods had limited reliability due to the introduction of telehealth visits (in response to COVID-19 onset) early in the implementation phase and the limited involvement of clinical and administrative support staff in clinicians' telehealth workflows. We therefore chose not to present proportions as the likely undercounting of eligible patients inflates these reach estimates.

Data collection Throughout each setting's active implementation phase, we conducted monthly email and/or teleconference outreach to research staff employed at each setting to tally the total number of paper decision aids distributed to patients. Research staff determined usage by monitoring their setting's visit schedule to identify eligible patients and tracking their inventory of decision aids. Uses of the online decision aids, accessed through the Epic electronic health record at each setting [18], were automatically tracked electronically by the publisher and reported to the study team each month. No honoraria or incentives were offered to clinicians, patients, or research staff to evaluate decision aid reach.

Analysis We summed the total number of paper decision aids distributed and the number of times the electronic health record-based decision aids were accessed at each of the five settings.

Effectiveness

Measures We measured effectiveness using the collaboRATE patient-reported measure of SDM, adopting top-box scoring (i.e. a binary indicator of whether a respondent marked the highest possible score on all three items) [23–25].

Data collection We collected electronic surveys from a convenience sample of eligible patients throughout pre-implementation and active implementation phases at two time points: (T1) immediately post-visit and (T2) three months after the visit. Surveys were hosted in Qualtrics software. Participants received a $20 gift card after completion of each survey. Before the onset of the COVID-19 pandemic in March 2020, research staff at each setting collected T1 surveys on-site by offering eligible patients the survey on a tablet computer. After the pandemic's onset, survey data collection was paused for five months. Upon re-initiation in August 2020, surveys were collected through a combination of tablet computers in the settings and survey links sent to eligible patients via email or secure electronic message.

Analysis Using mixed effects logistic regression, adjusting for patient characteristics as fixed effects and setting as a random effect, we conducted an as-treated analysis [26] of the association between patient-reported decision aid use and collaboRATE shared decision-making scores (i.e. comparing collaboRATE scores among those who reported receiving the decision aid vs. those who reported they did not receive the decision aid). Descriptive statistics compared intended versus selected treatments.

Adoption

Measure We defined adoption as the total number and proportion of eligible clinicians who agreed to use the decision aid with patients.

Data collection Prior to the study's pre-implementation phase, we tallied the number of eligible clinicians at each setting. We confirmed this number at the end of the study. At the beginning of each setting's active implementation period, we conducted initiation visits to

Table 2 RE-AIM Outcomes and analysis

	Definition (from Glasgow et al.[12])	Measures	Analysis
Reach	"The absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative, intervention, or program."	Total number of patients who received the decision aid	Count
Effectiveness	"The impact of an intervention on important outcomes."	CollaboRATE shared decision-making score (top box)	As-treated analysis: Association of collaboRATE scores and patient-reported decision aid receipt
Adoption	"The absolute number, proportion, and representativeness of a) settings and b) intervention agents (people who deliver the program) who are willing to initiate a program."	Total number and proportion of clinicians who agreed to use the decision aid with patients	Count; Proportion
Implementation	"Intervention agents' fidelity to the various elements of an intervention's protocol."	CollaboRATE shared decision-making score (top box)	Intention-to-treat analysis: Association of collaboRATE scores and setting implementation phase
		Observer OPTION-5 shared decision-making rating	Intention-to-treat analysis: Descriptive statistics comparing pre-implementation and active implementation phases
[Factors contributing to] **M**aintenance	"The extent to which…a program or policy becomes institutionalized or part of the routine organizational practices and policies."	ADOPT measure of clinician attitudes about patient decision aids	Descriptive statistics comparing pre-implementation and active implementation phases
		Preferred methods and timing of decision aid delivery (patient-reported)	Descriptive statistics
		Weekly site monitoring and planning meetings	Content analysis according to Schalock et al. [22] systematic approach to sustainability

present the decision aids to the participating clinicians and provide brief training on their effective use. At these visits, we obtained written informed consent from clinicians who agreed to use the intervention. Throughout the study, as new clinicians were hired at the participating settings, we obtained their agreement to use the intervention. Initiation visits were conducted in person at setting 1 and, given COVID-19 travel restrictions, virtually at the other four settings.

Analysis We calculated the proportion of eligible clinicians at each setting who agreed to use the intervention [15].

Implementation fidelity

Measures We collected patient-reported information on when and how the decision aid was delivered and used by the clinical team; we accepted multiple responses on these survey items, allowing for the possibility that a patient received the decision aid more than once. We also assessed the collaboRATE patient-reported measure of SDM top-box scores [23–25] and the Observer OPTION-5 measure of SDM [27].

Data collection For patient-reported data, we collected Qualtrics electronic surveys from a convenience sample of eligible patients at two time points: (T1) immediately post-visit and (T2) three months after the visit. Full survey administration details are described under "Effectiveness" above.

Audio recordings were collected from a convenience sample of visits between eligible patients and clinicians, who had previously provided written informed consent. Research staff provided each participating patient with a handheld digital audio recorder and started the audio recorder as the visit was initiated. Two independent raters used the Observer OPTION-5 measure to assess the level of SDM observed during each audio recorded visit.

Analysis We used intention-to-treat analysis [26] to evaluate setting-level scores on measures of SDM during the pre-implementation and implementation phases. We used mixed effects logistic regression adjusting for patient characteristics as fixed effects and setting as a random effect to evaluate the association between setting-level intervention implementation and collaboRATE SDM scores.

Using the mean of the two raters' Observer OPTION-5 scores, we calculated descriptive statistics comparing scores in pre-implementation vs. implementation phases.

Factors contributing to maintenance

Measures We evaluated clinician attitudes about patient decision aids using the ADOPT measure, which asks participants to select from a list of ten adjectives that clinicians might use to describe patient decision aids – five positive and five negative [28]. ADOPT sum scores range from -5 to 5, with higher scores representing more positive attitudes toward patient decision aids. Survey measures of patients' preferred methods and timing of decision aid delivery were also collected.

We planned for sustained decision aid use at each site using Schalock and colleagues' systematic approach to sustainability, identifying organizational drivers focused on accountability, leadership, and process [22]. The Schalock et al. framework addresses factors that promote sustained quality improvement within human service organizations, including "maintaining sound outcomes, generating knowledge, building capacity, experiencing stable funding and staffing patterns, and providing value-based services and supports in an effective and efficient manner" [22].

Within the post-visit patient survey, we collected bespoke measures of patients' preferred decision aid delivery modality (i.e., by mail, through the online patient portal, via a paper copy in the clinic, and/or viewed on a clinic computer) and timing (i.e., before, during, and/or after a visit).

Data collection The principal investigators distributed Qualtrics survey invitations by email to all eligible clinicians at two time points: (1) the beginning of their employer's active implementation phase and (2) the end of their employer's active implementation phase. The Qualtrics-hosted survey included a consent form and the ADOPT measure.

During weekly site check-in meetings between core project staff and site-based project team members in year 3 of the 4-year project, we discussed key drivers and barriers of sustained decision aid use, brainstormed strategies to support sustainability, and took detailed field notes.

Patient survey measures: Full patient survey details are reported under "Effectiveness" above.

Analysis We used descriptive statistics to compare mean ADOPT sum scores across all settings between

the beginning vs. end of the implementation phase. Core project team members formalized sustainability plans in written reports according to Schalock and colleagues' framework [22] and shared those reports with site-based project team members for member checking. We calculated frequencies and proportions for patient reports of preferred methods and timing of decision aid delivery.

Results

Reach

Option Grid decision aids reached 2553 total patients across the five settings (Table 3).

Effectiveness

Patient survey participant characteristics

Among the subsample of eligible patients who completed a post-visit survey across pre-implementation and active implementation study phases ($n=781$), most were women between 31–50 years old who spoke English at home. Health insurance types varied across settings. Most survey participants reported private health insurance coverage through an employer or purchased individually. Table 4 presents patient survey participant characteristics across the five included settings.

Patient-reported shared decision-making

In adjusted mixed effects logistic regression analysis (Table 5), patients who reported receiving the decision aid were more likely to report high-quality shared decision-making experiences than those who did not receive the decision aid (collaboRATE top box score 69% vs. 59%; OR 1.6, 95% CI 1.16–2.27).

Adoption

There was near-universal decision aid adoption at the clinician level (see Table 1). Clinicians who chose to use the decision aid varied by subspecialty, ranging from general gynecologists to reproductive endocrinologists and minimally invasive gynecologic surgeons. Settings 1, 2, and 3 had universal agreement among attending gynecology generalists to use the decision aid, though eligible patient volumes varied significantly across these participating clinicians according to their clinical practice patterns. At Setting 4, adoption was more limited (80% of targeted reproductive endocrinology and minimally invasive gynecologic surgery clinicians). At Setting 5, all targeted minimally invasive gynecologic surgery (MIGS) specialists adopted the intervention (10/10). Across all settings, a total of 72 clinicians adopted the intervention.

Implementation fidelity

Patient survey participant characteristics

See Table 3 above.

Patient-reported decision aid delivery: modality and timing

Most patient survey participants who received a decision aid ($n=322$, 65% of active implementation phase survey participants) reported receiving it during their visit (63.7%, $n=205$), compared to before the visit (34.8%, $n=112$) or after the visit (9.9%, $n=32$).

Among those participants receiving the decision aid *before* the visit ($n=112$), half had it delivered electronically, e.g., through the clinic's online patient portal (50.9%, $n=57$). Others had it delivered by postal mail (23.2%, $n=26$), received a paper copy when they arrived for their visit (14.3%, $n=16$), or viewed it on a practice computer (6.3%, $n=7$).

Participants receiving the decision aid *during* the visit ($n=205$) primarily had it delivered via a paper copy (84.4%, $n=173$). Others viewed it on a practice computer (11.2%, $n=23$) or had it delivered through the online patient portal (1.5%, $n=3$).

Among participants receiving the decision aid *after* the visit ($n=32$), most received a paper copy in the office (65.6%, $n=21$). Very few participants viewed it on a practice computer (12.5%, $n=4$), received it through the online patient portal (9.4%, $n=3$), or were mailed a copy (3.1%, $n=1$) after their visits.

Patient-reported shared decision-making

In adjusted mixed effects logistic regression analysis, patients who attended clinical visits before decision aid implementation occurred at their setting reported shared decision-making experiences similar to those of patients

Table 3 Patient reach and clinician adoption across implementation settings

	Implementation setting	Number of patients reached at each setting	Number of clinicians adopting at each setting, of those targeted (%)
1.	Rural Northeast	136	20 of 20 (100%)
2.	Urban Midwest	307	12 of 12 (100%)
3.	Urban Northeast	1147	22 of 22 (100%)
4.	Urban Northeast	161	8 of 10 (80%)
5.	Small city in Midwest	802	10 of 10 (100%)

Table 4 Patient survey participant characteristics by setting[a]

	Setting 1 % (*n* = 55)	Setting 2 % (*n* = 111)	Setting 3 % (*n* = 418)	Setting 4 % (*n* = 38)	Setting 5 % (*n* = 159)
Gender [b]					
Female	87.3% (48)	100% (111)	89.7% (375)	78.9% (30)	86.2% (137)
Male	–	–	0.4% (2)	–	0.6% (1)
Non-binary, Transgender, or Something else	–	–	0.2% (1)	–	–
Prefer not to say	1.8% (1)	–	1.2% (5)	–	0.6% (1)
Age					
18–30 years	6.1% (3)	4.5% (5)	7.8% (29)	6.7% (2)	5.8% (8)
31–40 years	22.5% (11)	40.5% (45)	31.1% (119)	46.7% (14)	33.3% (46)
41–50 years	49.0% (24)	42.3% (47)	51.4% (197)	36.7% (11)	55.8% (77)
51–60 years	20.4% (10)	12.6% (14)	8.6% (33)	–	3.6% (5)
61 years or older	2.0% (1)	–	–	10.0% (3)	0.7% (1)
Prefer not to say	–	–	1.3% (5)	–	0.7% (1)
Primary language					
Speaks English at home	95.9% (47)	97.3% (108)	84.5% (317)	86.7% (26)	94.9% (129)
Speaks another language at home	4.1% (2)	2.7% (3)	15.5% (58)	13.3% (4)	5.2% (7)
Symptom severity mean (SD)[c]	26.3 (8.6)	26.2 (7.5)	28.6 (8.0)	24.6 (8.4)	25.5 (6.9)
Health insurance					
Private (including supplemental coverage)	81.6% (40)	68.5% (74)	53.1% (197)	72.4% (21)	86.7% (117)
Public (no supplemental coverage)	12.2% (6)	13.9% (15)	34.2% (127)	13.8% (4)	1.5% (2)
Other/Not sure	6.1% (3)	17.6% (19)	12.7% (47)	13.8% (4)	11.9% (16)
Limited health literacy[d]	17.3% (9)	23.4% (26)	25.2% (97)	31.3% (10)	23.7% (33)

[a] Sample sizes vary by item due to non-response

[b] Multiple responses accepted; participants were asked to select all that apply

[c] UFS-QOL Symptom Subscale ranges 8–40; higher scores indicate more severe symptoms

[d] Assessed using the Chew et al. [29] single item health literacy screener and top-box scoring [25]

who attended clinical visits after their setting implemented the decision aid (collaboRATE top box score 64% vs. 63%; OR 0.86, 95% CI 0.61–1.22; see Table 6).

Observed shared decision-making

In the convenience sample of audio-recorded visits across settings ($n = 57$), the mean Observer OPTION-5 score prior to setting-level decision aid implementation was 17% ($n = 28$). After decision aid implementation, the mean Observer OPTION-5 score was 16% ($n = 29$).

Factors contributing to maintenance

Clinician attitudes about patient decision aids

During the pre-implementation phase, ADOPT scores ranged -2 to 5 (on a scale of -5 to 5) across settings with a mean of 1.6 (SD 1.6), indicating neutral to slightly positive attitudes about patient decision aids. Attitudes toward patient decision aids remained relatively unchanged as clinicians gained more experience with the decision aid, with ADOPT scores during the active implementation phase ranging -2 to 5 with a mean of 1.9 (SD 1.8).

Sustainability plans

We present a representative sustainability plan in Table 7, describing common factors identified in all sites.

Patients' preferred decision aid delivery

Patient survey participants who had experience with the decision aid ($n = 322$) were open to its delivery before

Table 5 Mixed effects logistic regression results: Adjusted association between patient-reported decision aid exposure and collaboRATE shared decision-making scores

	Odds ratio (OR)	**95% Confidence Interval (CI)**	
Patient-reported decision aid exposure	**1.62 ***	**1.16**	**2.27**
Age			
18–30 years	(reference)		
31–40 years	0.93	0.46	1.88
41–50 years	1.14	0.57	2.27
51–60 years	0.95	0.40	2.24
61 years or older	0.86	0.12	6.20
Speaks English at home	0.92	0.53	1.59
Health insurance status			
Private (including supplemental coverage)	(reference)		
Public (no supplemental coverage)	1.25	0.81	1.93
Other or unsure	0.98	0.59	1.64
Limited health literacy	0.62 *	0.42	0.91
	Random effect estimate	**95% Confidence Interval**	
Setting	0.26	0.05	1.23

* $p < 0.05$

Table 6 Adjusted mixed effects logistic regression results: association between decision aid implementation phase and collaboRATE shared decision-making scores

	Odds Ratio (OR)	**95% Confidence Interval (CI)**	
Setting-level decision aid implementation phase: Pre-implementation vs. Active implementation	**0.86**	**0.61**	**1.22**
Age			
18–30	(reference)		
31–40	0.97	0.48	1.97
41–50	1.16	0.58	2.32
61 or older	0.99	0.42	2.32
Prefer not to say	0.90	0.13	6.42
Speaks English at home	0.96	0.55	1.65
Health insurance type			
Private (including supplemental coverage)	(reference)		
Public (no supplemental)	1.35	0.87	2.08
Other or unsure	1.02	0.61	1.69
Limited health literacy	0.59 *	0.41	0.87
	Random effect estimate	**95% Confidence Interval**	
Setting	0.21	0.04	1.05

* $p < 0.05$

(91.9%, $n = 296$), during (90.7%, $n = 292$), and after (86.6%, $n = 279$) their visits.

Among those open to receiving the decision aid *before* a visit ($n = 296$), many wanted to receive a copy through the online patient portal (42.6%, $n = 126$) or be handed a paper copy in the office (30.7%, $n = 91$). Others were open to receiving a copy by mail (18.6%, $n = 55$). 8.1% of all survey participants who received decision aids ($n = 26$ of 322) said they would not want to have it delivered before their visit.

Among those open to receiving the decision aid *during* a visit ($n = 292$), most wanted to be handed a paper copy (74.7%, $n = 218$). Few others were open to viewing it on a practice computer (11.3%, $n = 33$) or receiving it through the online patient portal (9.6%, $n = 28$) during a visit. Only 2.8% of all survey participants who received

Table 7 Sustainability plan overview according to Schalock et al. [22] framework: Common factors across sites

Domains	Sustainability plans
Organization Drivers	
High performance teams "Horizontally structured work groups who focus on teamwork, synergy, raising the performance bar, "us" accountability, and promoting a learning culture. Such teams are characterized by being involved, informed, organized, accountable, and empowered"	The high performance teams include the schedulers, flow staff, nurses, and providers who work to sustainably implement the Option Grid in practice. Providers can use a smartphrase to send the Option Grid to patients using the online patient portal (myChart). Nurses can also scan the schedule and remind providers to use the tool for potentially eligible patients. Even without the reminder, clinicians can efficiently access the tools via Epic in the encounter, or quickly identify a paper version that is located in the clinic workroom. Further, an important component of the high performance team is the presence of a clinic champion (site principal investigator) who serves as a role model by using the tools in their practice. They are also mentors to residents and can set an important example for how to implement a patient-centered approach.
Quality improvement (QI) "An integrative, sequential, participative, and continuous process that is based on best practices and whose primary purpose is to enhance an organization's effectiveness, efficiency, and sustainability from a multiple, performance-based perspective"	The principal investigators will generate monthly or quarterly (frequency will be determined by the investigator) reports to determine the number of eligible patients that were eligible to receive the Option Grid (denominator data). The principal investigator, or a member of their team, will count the number of paper versions of the text and Picture Option Grids that have been used in a specific timeframe (numerator data). The principal investigator will also receive a weekly automated report on the number of uterine fibroids Option Grid tools generated through Epic. These quantitative data will help us gauge whether our implementation effort was sustainable.
Accountability Drivers	
Effectiveness ("the degree to which an organization's intended results are achieved from the perspective of the customer and the organization's growth") and Efficiency ("the degree to which the organization produces its planned results from the perspective of its financial analyses and internal processes")	Integration of Option Grid into the EHR: The Option Grid has been integrated into a clinician-facing menu in Epic, so that providers can pull up the Option Grid on their screen when conversing with patients in the clinical encounter. The integration will increase efficiency and sustained use of the tools in the workflow Toward automation of Option Grid delivery to patients: We are currently working on a standard language for communication (e.g., smartphrase) that can be used by scheduling staff that will automatically attach an Option Grid to the pre-visit reminder that is sent to patients who have a myChart patient portal account. This will give the patient the opportunity to read the content of the Option Grid and prepare for the clinic visit. The smartphrase can also be used by clinicians post-visit to deliver the tools to patients using the patient portal. Presence of a clinic champion: The site principal investigator represents the clinical champion who has advocated for using patient decision aids to facilitate a SDM process. Several have used patient decision aids in the past in their practice. They are role models for their colleagues, and mentor residents on how to implement a patient-centered approach, using decision aids, in their practice Provision of training materials as part of standard operating procedures to initiate new staff and residents: The training tools explain SDM and how to use a tool like Option Grid in practice to facilitate a SDM approach. Effectiveness and efficiency will depend on training new staff on the purpose of the Option Grid and how to operationalize them in practice.
Leadership Drivers	
Transformational "Communicating a shared vision, mentoring and directing, coaching and instructing, inspiring and empowering, and collaborating and partnering"	The clinic champions have facilitated the use of the Option Grid in workflows. They have advocated for using the tools, and have led usage to set an example for colleagues. They mentor residents and share a vision for patient-centered care. Several site PIs are also part of other patient-centered initiatives and have used patient decision aids in their clinical work in the past. These examples will be instrumental to sustained use of the Option Grid.
Strategic Execution "Demonstrating highly visible and maintained support of the change/transformation, communicating progress to all stakeholders, and considering the adoption of the change/transformation as a top organization priority"	We will rely on the site principal investigator/clinic champion to gauge the level of use of the tools, and we will attempt to include the Option Grid training in standard operating procedures for the induction of new staff. We will also provide updated versions of the text and Picture Option Grids as the evidence-based content is updated according to the latest data. Further, we plan to keep the location of Option Grid consistent in the workrooms so that all providers are aware of their location.

decision aids ($n=9$ of 322) would prefer not to receive one during their visit.

Among those open to receiving the decision aid *after* a visit ($n=279$), most wanted to receive it through the patient portal (36.2%, $n=101$) or be handed a paper copy (34.4%, $n=96$). Others were open to receiving it by mail after the visit (18.6%, $n=52$). 6.5% of survey participants who received decision aids ($n=21$ of 322) would not want to receive the decision aid after their visit.

Discussion

Key findings

Through its adoption by 72 clinicians across five clinical settings, the Option Grid decision aid reached 2553 patients with symptomatic uterine fibroids. Four of the five settings had all eligible clinicians adopt the decision aid.

Where patients reported receiving the decision aid, it was effective in improving their experiences of shared decision-making. However, we did not observe an overall difference in shared decision-making between pre-implementation and implementation phases at the setting level. This result indicates that the effect of the decision aid is limited to its effect in specific encounters where the patients received the tool; the effect does not extend beyond those encounters, suggesting the possibility of variation in the extent to which the decision aid was systematically given to eligible patients and integrated into the decision-making discussion.

Patients said they would have liked to receive the decision aid in a variety of ways, such as at different times and in different formats. Inconsistencies in how decision aids were delivered – and missed opportunities to deliver and use them in ways that patients preferred (e.g., before the visit, a paper copy during the visit, and a copy sent after the visit) – likely limited shared decision-making implementation efforts at the setting level. However, context-sensitive delivery likely facilitated settings' efforts to deliver and use the decision aid. Efforts to match decision aid delivery timing and format to patients' delivery preferences may support their sustained use and impact.

Results in context

In other implementation efforts, several organizations have successfully achieved patient decision aid use [30, 31]. Others confirm the challenges of implementing patient decision aids to facilitate shared decision-making [13, 32, 33]. In addition to technical implementation challenges [34], misalignment between financial incentives and organizational priorities has historically been a key barrier to implementing SDM and decision aids in routine care [13]. One successful recent implementation effort has involved the Centers for Medicare and Medicaid Services (CMS), the largest payer organization in the United States, requiring shared decision-making using a patient decision aid for certain patients with an abnormal heart rhythm who are considering placement of an implantable cardioverter defibrillator (ICD) device [35]. This highlights the importance of aligned organizational and policy incentives in promoting shared decision-making using patient decision aids.

Using decision aids can add work for clinicians and their organizations, requiring awareness, acceptance, and adoption of tools that inform patients about treatment choice. Identifying eligible patients, locating and then using the tools add extra steps to the normal visit routine. Nevertheless, when accomplished, even outside randomized trials, studies show that the impact of patient decision aid use on shared decision making is promising [36], as the current study confirms. To date, most implementation strategies have combined availability of patient decision aids with clinician training and technical support. It remains to be seen whether innovations such as learning collaboratives, feedback dashboards, and linkages with professional associations lead to more sustainable results [37].

Strengths and limitations

This study benefited from regional variation in participating settings and from including general gynecologists as well as subspecialists. The decision aid was adapted to include new treatment options over the course of the study and kept up to date with emerging evidence. The substantial patient reach in this study represents efforts at academic centers that were able to leverage administrative support and integrate the tools into EHRs; this level of adoption may not be generalizable to other settings. Limitations include interruption of the planned stepped-wedge design and reduced patient volumes for a period of time because of the COVID-19 pandemic, use of a convenience sample for patient-reported measures, and an inability to consistently identify eligible patients – which prevented us from reporting the proportion of eligible patients that were given the patient decision aids. In this implementation-focused study, we also lacked complete records of the number of patients approached with survey invitations; we therefore cannot calculate a survey response rate. Finally, the bounds of our study design and data collection processes (due in part to COVID-19 research restrictions) precluded detailed attention to the comparative effectiveness of different components of our multi-component implementation strategy and to fidelity to specific core elements of the decision aid intervention.

Implications

It remains uncommon for organizations to fully integrate decision aids into their workflows and standard operating procedures. Sustained use of patient decision aids is possible where there is strong clinical leadership, especially when shared decision-making becomes part of medical education and resident training. Future implementation research should evaluate innovations that embed the use of decision aids in operational policies using integration into electronic health records and patient portals, and through audit, feedback and communal learning facilitated by learning collaboratives.

Conclusion

Where patients have access to patient decision aids, these tools can improve experiences of shared decision-making. Implementation of patient-facing decision aids remains a challenge. Policy changes to prioritize access to patient decision aids and shared decision-making as part of routine gynecologic care are needed.

Supplementary Information

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Supplementary Material 1.

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Authors' contributions

Conceptualization: M-AD, GE. Methodology: M-AD, GE, RCF, DS. Formal analysis: RCF. Investigation: RCF, DS, JE, AL, RG, MS, MT, JZ, SA, AS. Funding acquisition: M-AD, GE. Writing – initial draft: GE, RCF. Writing – review and editing: RCF, M-AD, DS, JE, RMA, EB, TF, SKL, TM, MP, AL, RMG, MS, MT, JZ, SA, SA, AS, JWMA, GE.

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Data availability

Deidentified datasets generated during the study are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

The study was registered at ClinicalTrials.gov (NCT03985449) and approved by the Dartmouth College Committee for the Protection of Human Subjects (study #31464) and the Washington University Human Research Protection Office. Participants in research activities (surveys, audio recordings) provided informed consent prior to participation.

Consent for publication

Not applicable.

Competing interests

Financial

Glyn Elwyn has edited and published books that provide royalties on sales by the publisher: the books include *Shared Decision Making* (Oxford University Press) and *Groups* (Radcliffe Press). He currently is Founder and Director of &think LLC which owns the registered trademark for Option Grids™ patient decision aids. Marie-Anne Durand has contributed to the development of the Option Grid™ patient decision aids, which are licensed to EBSCO Health. She receives consulting income from EBSCO Health and royalties. Shannon K. Laughlin-Tommaso authors UpToDate articles related to fibroids; she receives royalties.

Non-financial

Glyn Elwyn's academic interests are focused on shared decision making and coproduction. He owns copyright in measures of shared decision making and care integration, namely collaboRATE, integRATE, Observer OPTION-5, and Observer OPTION-12. These measures are freely available for use by researchers.

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