Importance  For antidepressants, the translation of evidence of comparative effectiveness into practice is suboptimal. This deficit directly affects outcomes and quality of care for patients with depression. To overcome this problem, we developed the Depression Medication Choice (DMC) encounter decision aid, designed to help patients and clinicians consider the available antidepressants and the extent to which they improved depression and other issues important to patients.

Objective  Estimate the effect of DMC on quality of the decision-making process and depression outcomes.

Design, Setting, and Participants  We conducted a cluster randomized trial of adults with moderate to severe depression considering treatment with an antidepressant. Primary care practices in 10 rural, suburban, and urban primary care practices across Minnesota and Wisconsin were randomly allocated to treatment of depression with or without use of the DMC decision aid.

Intervention  Depression Medication Choice, a series of cards, each highlighting the effect of the available options on an issue of importance to patients for use during face-to-face consultations.

Main Outcomes and Measures  Decision-making quality as judged by patient knowledge and involvement in decision making, patient and clinician decisional comfort (Decisional Conflict Scale) and satisfaction, encounter duration, medication adherence, depression symptoms, and the Patient Health Questionnaire for depression (PHQ-9).

Results  We enrolled 117 clinicians and 301 patients (67% women; mean [SD] age, 44 [15] years; mean [SD] PHQ-9 score, 15 [4]) into the trial. Compared with usual care (UC), use of DMC significantly improved patients’ decisional comfort (DMC, 80% vs UC, 75%; P = .02), knowledge (DMC, 65% vs UC, 56%; P = .03), satisfaction (risk ratio [RR], from 1.25 [P = .81] to RR, 2.4 [P = .002] depending on satisfaction domain), and involvement (DMC, 47% vs UC, 33%; P < .001). It also improved clinicians’ decisional comfort (DMC, 80% vs UC, 68%; P < .001) and satisfaction (RR, 1.64; P = .02). There were no differences in encounter duration, medication adherence, or improvement of depression control between arms.

Conclusions and Relevance  The DMC decision aid helped primary care clinicians and patients with moderate to severe depression select antidepressants together, improving the decision-making process without extending the visit. On the other hand, DMC had no discernible effect on medication adherence or depression outcomes. By translating comparative effectiveness into patient-centered care, use of DMC improved the quality of primary care for patients with depression.

Trial Registration  clinicaltrials.gov Identifier: NCT01502891
Depression is a common, debilitating, and costly chronic mental illness affecting 17% of Americans.\textsuperscript{1-4} Depression burdens patients, their families, and the health care system.\textsuperscript{1-4} Fortunately, treatment can effectively mitigate this burden.\textsuperscript{5,6} Of the available treatments, pharmacotherapy has become the main modality, particularly for patients with moderate to severe depression.\textsuperscript{7,8} Unfortunately, the efficacy of antidepressants is reduced by low patient adherence rates (13%-60%) and premature discontinuation (33%-42%) that contributes to avoidable disability, increased risk of relapse, and higher health care use.\textsuperscript{9-11} Patients stop taking antidepressants because of unrealistic expectations, lack of treatment efficacy, or unacceptable adverse effects.\textsuperscript{12,13} It would seem critical, therefore, to improve the process by which patients and clinicians select and implement antidepressants.

Choosing the right antidepressant is difficult because of limitations in the evidence of their comparative effectiveness.\textsuperscript{14,15} More certain are their effects on other important outcomes (ie, weight gain) that matter to patients. However, clinicians struggle to present this information to patients in meaningful ways and have a difficult time parting from their preferred antidepressants.\textsuperscript{16,17} Clinicians and patients have more to gain by identifying which agent is preferable given the patient’s circumstances and preferences, rather than selecting what might be deemed the clinically most effective choice. This shared decision making (SDM) approach cultivates informed preferences that lead to patient-centered choices. To arrive at informed preferences, patients and clinicians must access and make sense of the best research evidence, which unfortunately has not effectively reached the point of care.\textsuperscript{18,19} This suboptimal translation of evidence into practice directly affects outcomes and quality of care for patients with depression.\textsuperscript{18-20}

Decision aids are evidence-based interventions designed to engage patients and clinicians in an SDM process and translate research evidence into patient-centered care.\textsuperscript{21-24} A body of evidence (II5 randomized trials) demonstrates that decision aids increase patients’ knowledge and engagement in and comfort with the decision-making process.\textsuperscript{24} Most of this evidence reflects the use of educational tools distributed to patients before making a decision with the goal to empower patients to participate in decision making through information.\textsuperscript{24} Yet, only a minority of these trials sought to determine if SDM actually took place. An evolving body of evidence, on the other hand, is finding that decision aids can effectively promote SDM when used during the clinical encounter.\textsuperscript{25}

In collaboration with patients, clinicians, and stakeholders, we developed an encounter decision aid, Depression Medication Choice (DMC), to support pharmacotherapy choices when this approach is being considered in the primary care of patients with moderate to severe depression.\textsuperscript{26} We hypothesized that its use would improve patient engagement, the quality of decision making as perceived by patients and clinicians, and depression outcomes.

**Methods**

**Study Design**

We conducted a cluster randomized trial in which we randomly allocated primary care practices to treat depression with (intervention) or without (control) DMC. Patients and clinicians were surveyed regarding the quality and outcome of the decision-making process, and patient adherence and clinical outcomes were followed for 6 months after the encounter. Mayo Clinic institutional review board, IRB of record for participating practices, and the Hennepin County Medical Center Human Subjects Research Committee approved the study procedures. The trial is registered at clinicaltrials.gov (NCT01502891); details of the study procedures are found elsewhere,\textsuperscript{26} and the trial protocol is given in Supplement 1.

**Study Setting and Participants**

This study took place between December 2011 and November 2013 in 10 rural, suburban, and urban primary care practices across Minnesota and Wisconsin. Primary care practices were eligible for the study if they had at least 2 clinicians interested in participating, a clinical champion (ie, outstanding clinician who has earned the respect of their peers and is willing to build support for and actively promote the current project), eligible patients, and the willingness to have an on-site study coordinator for the duration of the trial.\textsuperscript{26} Clinicians were invited to participate if they cared for patients with depression. Eligible adult patients (>18 years of age) had moderate to severe depression and a Patient Health Questionnaire (PHQ-9)\textsuperscript{27} score of 10 or higher, no bipolar disorder, an appointment with a member of their primary care team, and no major barriers to providing informed consent. Eligibility criteria (ie, severity of depression, PHQ-9 score) were set so that chosen eligible patients, whether on a medication or not, were most likely to engage in conversations concerning antidepressants (ie, start, increase, or switch treatment).

**Stakeholder Engagement**

We developed DMC in close collaboration with 2 patient advisory groups and with an External Advisory Council comprised of 24 stakeholders (ie, patients, clinicians, policy makers) from 12 different organizations. We further engaged these groups throughout the set-up and conduct of the trial, seeking insights primarily on eligibility criteria, choice of outcomes, and recruitment strategies (ie, identifying respectful ways to recruit patients with depression).

**Recruitment**

We invited practices that were part of the External Advisory Council to participate in the trial, and then we extended our reach to Mayo Clinic and Mayo Clinic Health Systems practices. Clinicians were approached for participation during an initial on-site meeting or, afterward, by the study coordinator.\textsuperscript{26} On-site study coordinators identified potentially eligible patients from the appointment schedules of clinicians and approached them during their respective
appointments. Clinicians and patients both provided written informed consent and neither received financial incentives to participate in the trial.

Allocation Procedure
We had initially set to stratify practices according to their number of clinicians as an indicator of their potential for enrollment but later replaced it with their history of accrual (low vs high) in past studies, an indicator we deemed more effective in addressing recruitment rate per arm. The lead study statistician (J.H.) therefore stratified practices by their history of accrual and the presence of the Depression Improvement Across Minnesota, Offering a New Direction (DIAMOND) program (a practice redesign initiative to improve depression care present in numerous Minnesota practices at the time of the study) and centrally randomized practices within these strata to either care with or without DMC. Study team members, practices, and clinicians were aware of the assigned arms. Patients were kept unaware of the study hypothesis and nature of the intervention.

Intervention and Control
We described the development of DMC elsewhere. The decision aid, laminated 10.16×25.40-cm cards, presents general considerations about antidepressant efficacy and then adverse effects in terms that matter to patients: weight change, sleep, libido, discontinuation, and cost (Figure I). We briefly (<10 min) demonstrated to clinicians how to use the decision aid prior to enrollment of their first patient. A video clip and storyboard demonstrating the basic use of the decision aid re-
mained available, as well as a leaflet for patients to take home (eFigure 1 and eFigure 2 in Supplement 2).

Clinicians in the intervention group were to use the decision aid during the consultation with their patients, whereas clinicians in the control arm did not have access to the decision aid (usual care).

Outcomes and Data Collection
The evaluation of the study was guided by the Reach, Effectiveness, Adoption, Implementation, Maintenance framework. This article focuses on the effectiveness of DMC to improve decision making and clinical outcomes.29

Patient Level Outcomes
Decision-Making Quality Outcomes
Decisional conflict, defined as personal uncertainty about which course of action to take when choosing among competing options while considering risks or challenges to personal life values, was our primary outcome. Patients completed the Decisional Conflict Scale (DCS) immediately after the clinical encounter.30 We report results as level of comfort with the decision (0 = conflict, 100 = comfort). Other measures of decision-making quality were obtained from patients postencounter: knowledge and acceptability of information sharing (ie, satisfaction).31-33

Clinical Outcomes
Patients completed the PHQ-9, a measure of depression symptoms, at entry into the study, 3 months, and 6 months.27 We extracted PHQ-9 records from the medical records of patients during the trial period to be used as proxy for unreturned ones if completed within 2 weeks of the 3- and 6-month period.

Adherence
Patients reported medication usage at the time of appointment and after the clinical encounter. We collected pharmacy records and reviewed medical records for the trial period. For patients with pharmacy data, we calculated primary medication adherence as proportion of patients who filled their prescription within 30 days and secondary adherence as the proportion of patients with a percentage of days covered (PDC) greater than 80%.34 For each antidepressant prescribed, PDC was defined as the number of days a patient had a supply of each medication divided by the number of days of eligibility for that medication.34

Clinician Level and Encounter Level Outcomes
Decision-Making Quality Outcomes
Clinicians completed a clinician version of DCS and an acceptability of information sharing (ie, satisfaction) scale following each encounter with a participating patient.32,33,35 We video recorded encounters in which both patient and clinician gave us consent to record. From these recordings, we assessed the extent to which clinicians sought to engage patients in the decision-making process using the Observing Patient Involvement in Decision Making (OPTION) scale.36 We also assessed, via a fidelity checklist, the extent to which they used the decision aid as intended.26,37 Study coordinators captured the number of minutes patients remained in the consultation room as a proxy for the effect of using the decision aid on encounter duration and disruption of clinic flow.

Sample Size
We used a formula for a cluster-adjusted t test to estimate that the recruitment of 300 patients (30 per practice) would give the study a power of 90% to detect a difference of 9.8 points or greater on the DCS with a 2-sided a level of .05.38 Assumptions were based on results from trials of similar design and outcomes: DCS variances are as reported in the Statin Choice Trial (16.9, 14.1); there is a modest correlation of outcomes across practices (intracluster correlation coefficient [ICC] of 0.05); and a 10% average attrition rate.32,33,39,40 Assuming a similar ICC and attrition rate for other outcomes, this sample size would have 99% power to detect a 1.0-SD difference in any continuous measure and 80% power to detect a 30% difference in 6-month adherence rates assuming a control adherence rate of 50%.

Statistical Analysis
All outcomes were analyzed according to the intention-to-treat principle.38 Because clinicians and patients were randomized in clusters (practices), we used cluster-adjusted t tests, χ2 tests, and hierarchical generalized linear models (HGLMs) to compare variables between groups.30 In particular, HGLMs allowed us to account for the correlation of patient outcomes within clinicians and practices explicitly by modeling the intercept as a 3-level effect, with random effects at clinician and practice level.40

We summarized patient and clinician characteristics by arm, testing for differences using cluster-adjusted tests or HGLMs with random effects for practice for patient characteristics and χ2 tests for clinician characteristics. We summarized outcomes by arm, and then to assess the effect of the intervention on outcomes, we estimated a series of HGLMs with logit or linear response, with random effects for clinician and practice and including randomization group as a binary independent variable. We then tested whether there was an intervention effect by testing whether the coefficient of the group indicator was significantly different from null and reported the P value for this test for all outcomes. Patient prescription, filled status, and adherence outcomes were compared only among those with pharmacy data. Analysis and data management were conducted using SAS 9.2, Stata 13.1 (StataCorp), and REDCap (Vanderbilt University) Management system statistical software.

Results
Participant Flow and Characteristics
Figure 2 shows the flow of participants and completeness of data. A total of 177 clinicians (median [range], 7 [4-30] per practice) and 297 patients (34 [15-40] per practice and 2 [1-14] per clinician) from 10 practices (1 rural, 1 suburban, 8 urban) were included in the analysis. There was no difference in the attrition of participants or completeness of the data across arms.
(Figure 2). Characteristics of participants are summarized in Table 1. Although sex and ethnicity differed moderately, there were no significant differences in participant characteristics across arms.

**Patient Decision-Making Quality and Clinical Outcomes**

After the encounters with their clinicians, patients in the decision aid arm reported significantly higher comfort with the decision (mean difference [MD], 5.3 out of 100; 95% CI, 1.1–9.5; P = .01) and were more knowledgeable (odds ratio [OR], 9.5; 95% CI, 0.8–18.2; P = .03) and satisfied (ranging from risk ratio [RR], 1.25 [P = .81] to RR, 2.40 [P = .002]) compared with patients in the control arm (Table 2). There was no observed difference across arms in control of depression symptoms (mean PHQ-9 score), remission rate (PHQ-9 score <5), or responsiveness (>50% PHQ-9...
improvement) at 3 and 6 months or in medication use or adherence (Table 2).

**Clinician Decision-Making Quality and Encounter Outcomes**

Table 3 shows that clinicians are more comfortable with the decisions made (MD, 11.4 out of 100; 95% CI, 17.1-5.7; \( P < .001 \)) and more satisfied with the process when they used the decision aid (RR, 1.64; \( P = .02 \)). In available video-recorded encounters (n = 96), clinicians assigned to the use of the decision aid involved patients significantly more in the decision-making process (MD, 15.8 out of 100; 95% CI, 6.5-25.0; \( P < .001 \)) (Table 3). Clinicians in the intervention arm reported actual use of the decision aid in 128 (81%) of the encounters, and of those with video recordings (n = 57) reached, on average, 54% of the targeted fidelity items (ie, used the decision aid as intended). There was no difference in the duration of clinical encounters (mean [SD] minutes: control arm, 48 [27]; intervention arm, 44 [22]; \( P = .47 \)).

**Discussion**

**Main Findings**

In this randomized trial, the use of DMC by primary care clinicians and patients with moderate to severe depression during clinical encounters was feasible and effectively improved patient knowledge and engagement in the decision-making process, as well as patient and clinician satisfaction with that process. Use of the decision aid, on the other hand, had no discernible effect on encounter duration, depression control, and medication use and adherence.

**Limitations**

Our study is at risk of bias. Lack of blinding of participants may have affected questionnaire responses, and lack of blinding of analysts, particularly those reviewing videos, may have biased video-based outcomes. There was substantial loss to follow up (about 20%) for our primary endpoint, mainly due to logistical issues at the beginning of the study where study coordinators were still adapting to the recruitment and follow-up process. While these issues may increase the risk of bias in favor of the intervention, other limitations may bias it toward no difference. Because most clinicians used the decision aid with only 2 patients, it is possible that our trial underestimates the efficacy of the decision aid when used repeatedly and expertly. We did...
## Table 2. Patient Decision-Making Quality and Clinical Outcomes

<table>
<thead>
<tr>
<th>Decision-Making Quality Outcomes (Continuous Outcomes, Mean [95% CI])</th>
<th>Usual Care (n = 139)</th>
<th>Decision Aid (n = 158)</th>
<th>Mean Difference (95% CI)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Decisional conflict (0 = conflict, 100 = comfort)</strong>&lt;sup&gt;a&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Informed subscale</td>
<td>72.1 (68.5 to 75.7)</td>
<td>79.6 (76.4 to 82.7)</td>
<td>7.8 (1.9 to 13.6)</td>
<td>.009</td>
</tr>
<tr>
<td>Clarity subscale</td>
<td>73.3 (69.6 to 76.9)</td>
<td>81.3 (78.2 to 84.4)</td>
<td>8.4 (3.3 to 13.5)</td>
<td>.001</td>
</tr>
<tr>
<td>Support subscale</td>
<td>79.3 (75.6 to 83.0)</td>
<td>83.4 (80.3 to 86.4)</td>
<td>4.5 (~1.4 to 10.4)</td>
<td>.13</td>
</tr>
<tr>
<td>Uncertainty subscale</td>
<td>71.7 (67.5 to 75.9)</td>
<td>74.6 (71.0 to 78.1)</td>
<td>2.9 (~2.5 to 8.3)</td>
<td>.30</td>
</tr>
<tr>
<td>Effectiveness subscale</td>
<td>75.8 (72.3 to 79.3)</td>
<td>79.1 (76.3 to 81.9)</td>
<td>3.3 (~1.1 to 7.7)</td>
<td>.14</td>
</tr>
<tr>
<td>Overall</td>
<td>74.5 (71.4 to 77.6)</td>
<td>79.7 (77.0 to 82.5)</td>
<td>5.3 (1.1 to 9.5)</td>
<td>.01</td>
</tr>
<tr>
<td>Missing, No. (%)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>25 (22.7)</td>
<td>20 (14.9)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Knowledge</strong> (0 = no correct, 100 = all correct) OR (95% CI)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tailored to information in the decision aid</td>
<td>46.6 (42.6 to 50.5)</td>
<td>58.1 (53.6 to 62.6)</td>
<td>13.2 (6.4 to 19.9)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Generic (ie, depression in general)</td>
<td>72.4 (67.3 to 77.5)</td>
<td>72.5 (68.0 to 77.0)</td>
<td>2.8 (~3.9 to 14.8)</td>
<td>.65</td>
</tr>
<tr>
<td>Overall (ie, both tailored and generic)</td>
<td>56.3 (52.9 to 59.6)</td>
<td>63.5 (59.9 to 67.1)</td>
<td>9.5 (0.8 to 18.2)</td>
<td>.03</td>
</tr>
<tr>
<td>Missing, No. (%)&lt;sup&gt;b&lt;/sup&gt;</td>
<td>23 (20.9)</td>
<td>21 (15.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Categorical Outcomes, No. (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Satisfaction&lt;sup&gt;c&lt;/sup&gt; OR (95% CI)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right amount of information given</td>
<td>102 (91.9)</td>
<td>124 (92.5)</td>
<td>1.25 (0.21 to 7.52)</td>
<td>.81</td>
</tr>
<tr>
<td>Information given was extremely clear</td>
<td>64 (58.7)</td>
<td>92 (68.7)</td>
<td>1.77 (0.92 to 3.38)</td>
<td>.09</td>
</tr>
<tr>
<td>Information given was extremely helpful</td>
<td>57 (52.8)</td>
<td>92 (69.2)</td>
<td>2.01 (1.18 to 3.40)</td>
<td>.01</td>
</tr>
<tr>
<td>Strongly desire to receive information this way for other treatment decisions</td>
<td>55 (50.5)</td>
<td>90 (68.2)</td>
<td>2.10 (1.25 to 3.55)</td>
<td>.005</td>
</tr>
<tr>
<td>Strongly recommend the way information was shared to others</td>
<td>65 (59.1)</td>
<td>104 (77.6)</td>
<td>2.40 (1.38 to 4.19)</td>
<td>.002</td>
</tr>
<tr>
<td>Missing&lt;sup&gt;b&lt;/sup&gt;</td>
<td>30 (27.5)</td>
<td>26 (19.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Clinical Outcomes</strong> (Continuous Outcomes, Mean [95% CI])</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression symptoms</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PHQ-9 score, 3 mo&lt;sup&gt;d&lt;/sup&gt;</td>
<td>9.0 (7.7 to 10.2)</td>
<td>9.2 (8.0 to 10.3)</td>
<td>0.4 (~2.5 to 3.4)</td>
<td>.78</td>
</tr>
<tr>
<td>Missing, No. (%)&lt;sup&gt;e&lt;/sup&gt;</td>
<td>38 (34.5)</td>
<td>44 (32.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PHQ-9 score, 6 mo&lt;sup&gt;e&lt;/sup&gt;</td>
<td>9.3 (8.2 to 10.5)</td>
<td>8.9 (7.8 to 10.0)</td>
<td>~0.2 (~2.9 to 2.6)</td>
<td>.91</td>
</tr>
<tr>
<td>Missing, No. (%)&lt;sup&gt;e&lt;/sup&gt;</td>
<td>38 (34.5)</td>
<td>49 (36.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Categorical Outcomes, No. (%)</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Depression symptoms</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remission, 3 mo</td>
<td>26 (18.7)</td>
<td>31 (19.6)</td>
<td>NA</td>
<td>.85</td>
</tr>
<tr>
<td>Response, 3 mo</td>
<td>43 (30.9)</td>
<td>53 (33.5)</td>
<td>NA</td>
<td>.77</td>
</tr>
<tr>
<td>Missing</td>
<td>38 (34.5)</td>
<td>44 (32.8)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Remission, 6 mo</td>
<td>20 (14.4)</td>
<td>34 (21.5)</td>
<td>NA</td>
<td>.18</td>
</tr>
<tr>
<td>Response, 6 mo</td>
<td>38 (27.3)</td>
<td>55 (34.8)</td>
<td>NA</td>
<td>.15</td>
</tr>
<tr>
<td>Missing</td>
<td>38 (34.5)</td>
<td>49 (36.6)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adherence to medication</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>On medication at time of encounter</td>
<td>90 (64.7)</td>
<td>93 (58.9)</td>
<td>NA</td>
<td>.93</td>
</tr>
<tr>
<td>On medication after the encounter</td>
<td>110 (79.1)</td>
<td>142 (89.9)</td>
<td>NA</td>
<td>.15</td>
</tr>
<tr>
<td>Pharmacy record available</td>
<td>93 (66.9)</td>
<td>113 (71.5)</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Primary adherence (filled prescription)&lt;sup&gt;f&lt;/sup&gt;</td>
<td>82 (93.2)</td>
<td>94 (86.2)</td>
<td>NA</td>
<td>.19</td>
</tr>
<tr>
<td>Missing</td>
<td>5 (5.7)</td>
<td>4 (3.7)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Secondary adherence&lt;sup&gt;g&lt;/sup&gt;</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% PDC &gt;80% (of filled prescription)</td>
<td>85 (97.7)</td>
<td>96 (98.0)</td>
<td>NA</td>
<td>.25</td>
</tr>
<tr>
<td>% PDC &gt;80% (of all patients)</td>
<td>91 (97.8)</td>
<td>107 (94.7)</td>
<td>NA</td>
<td>.67</td>
</tr>
</tbody>
</table>

Abbreviations: OR, odds ratio; PDC, proportion of days covered; PHQ-9, Patient Health Questionnaire for depression.

*Reported variance $\sigma^2$(site) = 5.7, $\sigma^2$(clinician) = 0.00; $\sigma^2$(patient) = 254.1.

*Seven-point Likert scale, reporting proportion of agree/strongly agree.

*Reported variance $\sigma^2$(site) = 0.0; $\sigma^2$(clinician) = 3.5; $\sigma^2$(patient) = 35.2.

*Calculated out of available pharmacy records.

<sup>a</sup>Reported variance $\sigma^2$(site) = 0.0; $\sigma^2$(clinician) = 3.5; $\sigma^2$(patient) = 35.2.
not access the content of patient-clinician interactions outside the index encounter, yet patients had an average of 3 or more appointments (range, 1-10) during the trial period (data not shown). We did not capture use of or adherence to interventions (ie, psychotherapy).

This trial also yielded imprecise clinical outcome estimates, which limited our ability to detect meaningful differences in these secondary endpoints across arms. This was due to greater than anticipated ICC and loss to follow-up (30%) affecting both PHQ-9 measures and medication adherence data, and higher adherence rates in the trial (>80%) than the initial estimated rate (50%). Hence, estimates of the effect of the decision aid on clinical outcomes and adherence are favorable to the decision aid arm but too imprecise to draw definitive conclusions about their effect.

Comparison With Other Studies

This trial shares the strengths of our other practical real-world decision aid trials.32,33,39,42 We used a rigorous trial design with optimal allocation concealment and high recruitment rates for clinicians and patients. It was conducted in rural, suburban, and urban; academic and nonacademic; and small and large practices caring for patients of various ethnic and sociodemographic backgrounds.

This trial is the first to assess the effectiveness of an encounter decision aid for antidepressants and one of a few assessing the effect of SDM in mental health.43 The magnitude of our findings, including effect on clinical outcomes, is consistent with the results of other trials of encounter decision aids in other contexts.32,33,42 Moreover, this trial is one of a few that can directly link the use of decision aids to improvements in observed decision-making quality.25 We also assessed the fidelity with which clinicians and patients used the decision aid as intended during clinical encounters, a rare feature in the SDM literature.24,44 This is also the first study, to our knowledge, to assess clinicians’ comfort with the decision-making process in the context of mental health. Importantly, clinicians were more satisfied with encounters that used the decision aid with those that did not, and the use of the decision aid did not add to the duration of the encounters, a key finding for promoting implementation.

Implications for Practice, Policy, and Research

There is substantial policy support for SDM. Although there are significant investments in generating comparative evidence of treatment for various conditions,45 including depression, there is limited information about methods for incorporating this evidence meaningfully in routine clinical practice.18-20 Depression Medication Choice offers 1 effective patient-centered method. Our results, however, do not support the notion that SDM will improve the efficacy or efficiency of care, an assumption policy makers often make when they advocate for patient involvement.46,47

Several practice guidelines call for SDM in the management of depression under the premise that for treatment to be effective, patients need to actively participate and adhere to these treatments despite their side effects, cost, and burden.10,11 This remains one of their least translated recommendations.46,49 Depression Medication Choice, with its effect on patient decision-making process, efficient design (ie, user friendly, easy to update evidence), straightforward implementation (minimal training and support), and clinician buy-in, could provide a means to meet this recommendation.

Involving patients in fateful health care decisions is an integral component of patient-centered care, a necessary feature of high-quality health care.50 When confronted with our findings—which are consistent with the systematic review of 115 randomized trials and with our own previous trials—policy makers will have to decide whether the value of decision aids as promoters of patient-centered care and informed patient engagement, as demonstrated in this trial, argue on their own merits for priority.
Further work in this area is necessary. The ideal decision support should include nonpharmacological options. A larger and longer trial to study the effect of the decision aid on adherence to therapy in patients selected because of nonadherence may be more informative.\(^5\) Larger studies are needed to identify subgroups (ie, socioeconomic status)\(^5\) that may benefit more from using the decision aid. Identifying the amount and type of support needed to effectively embed the use of this decision aid in the routines of primary care practices to support its longitudinal use also remains to be determined.

**Conclusions**

Depression Medication Choice is a novel and efficient SDM tool. It effectively helps patients with moderate to severe depression and their primary care clinicians engage in collaborative deliberation by using evidence about the comparative effectiveness of antidepressants. Depression Medication Choice can help patients and their clinicians identify and implement treatment that best fits the patient’s values, preferences, and goals in a timely way—a path to higher-quality health care.

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**REFERENCES**


The Role of Decision Aids in Depression Care

Kurt Kroenke, MD

Clarion calls about enhancing detection and management of depression in primary care have reiterated several truisms: Depression is as prevalent as many common medical disorders, treatable yet frequently undertreated, responsible for enormous occupational and social impairment as well as adverse effects on the costs, treatment outcomes, and morbidity of comorbid medical diseases. Depression is second only to low back pain in years lived with disability (YLD), a metric that incorporates disease prevalence, age of onset, chronicity, and impairment. The YLDS attributable to depression exceed those accounted for by diabetes, ischemic heart disease, stroke, and chronic kidney disease combined. The primary care setting is where the majority of patients with depression first present with their symptoms and where many receive their initial and often only treatment.

Pharmacotherapy for depression, like that for hypertension and numerous other medical disorders, relies on a discrete number of equally effective drug classes. Step 1 antidepressants include 5 main classes: selective serotonin reuptake inhibitors (citalopram, escitalopram, sertraline, paroxetine, fluoxetine), serotonin-norepinephrine reuptake inhibitors (venlafaxine, duloxetine), bupropion, mirtazapine and, to a lesser degree currently, tricyclic antidepressants. Adding bupropion, buspirone, or an atypical antipsychotic (aripiprazole, quetiapine, olanzapine) to the regimen of a patient who is only partially responding to antidepressants. Adding buproprion, buspirone, or an atypical antipsychotic (aripiprazole, quetiapine, olanzapine) to the regimen of a patient who is only partially responding to antidepressants may provide further improvement. Several types of psychotherapy are also effective, including cognitive behavioral therapy, interpersonal psychotherapy, and problem-solving therapy. These are important not only as first-line therapy in patients preferring a nonpharmacological approach but also in patients inadequately responding to