HEALTH CARE REFORM

The Diabetes Mellitus Medication Choice Decision Aid

A Randomized Trial

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Background: Patient involvement in the choice of antihyperglycemic agents could improve adherence and optimize glycemic control in patients with type 2 diabetes mellitus.

Methods: We conducted a pilot, cluster randomized trial of Diabetes Medication Choice, a decision aid that describes 5 antihyperglycemic drugs, their treatment burden (adverse effects, administration, and self-monitoring demands), and impact on hemoglobin A_{1c} (HbA_{1c}) levels. Twenty-one clinicians were randomized to use the decision aid during the clinical encounter and 19 to dispense usual care and an educational pamphlet. We used surveys and video analysis to assess postvisit decisional outcomes, and medical and pharmacy records to assess 6-month medication adherence and HbA_{1c} levels.

Results: Compared with usual care patients (n=37), patients receiving the decision aid (n=48) found the tool more helpful (clustered-adjusted mean difference [AMD] in a 7-point scale, 0.38; 95% confidence interval [CI], 0.04-0.72); had improved knowledge (AMD, 1.10 of 10 questions; 95% CI, 0.11-2.09); and had more involvement in making decisions about diabetes medications (AMD, 21.8 of 100; 95% CI, 13.0-30.5). At 6-month follow-up, both groups had nearly perfect medication use (median, 100% of days covered), with better adherence (AMD, 9% more days covered; 95% CI, 4%-14%) and persistence (AMD, 12 more days covered; 95% CI, 3-21 days) in the usual care group, and no significant impact on HbA_{1c} levels (AMD, 0.01; 95% CI, –0.49 to 0.50).

Conclusion: An innovative decision aid effectively involved patients with type 2 diabetes mellitus in decisions about their medications but did not improve adherence or HbA_{1c} levels.

Trial Registration: clinicaltrials.gov Identifier: NCT00388050

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THE SUCCESSFUL MANAGEMENT of type 2 diabetes mellitus requires attention to glycemic control and appropriate nutrition, exercise, and preventive care.[1] Improved diet and increased levels of physical activity alone are often insufficient for glycemic control. Thus, patients require medications to enhance glycemic control.[2]

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The extent to which antihyperglycemic agents favorably reduce the risk of diabetes complications is largely unclear.[3] Clearer are the varying adverse effects and the burden these agents impose on patients—a burden that some patients may perceive as greater than that of future diabetes complications.[4] Therefore, for a given patient, the balance of benefits and harms when choosing among available diabetes medications remains unclear. To cope with this uncertainty, expert groups have published treatment algorithms based largely on pathophysiologic considerations.[2] An alternative approach is to consider how patients view the potential benefits, harms, costs, and burdens of the available agents.

Video available online at www.archinternmed.com

While desirable, patient involvement in choosing diabetes medications is challenging. Not all patients and clinicians may desire or be comfortable with patient par-

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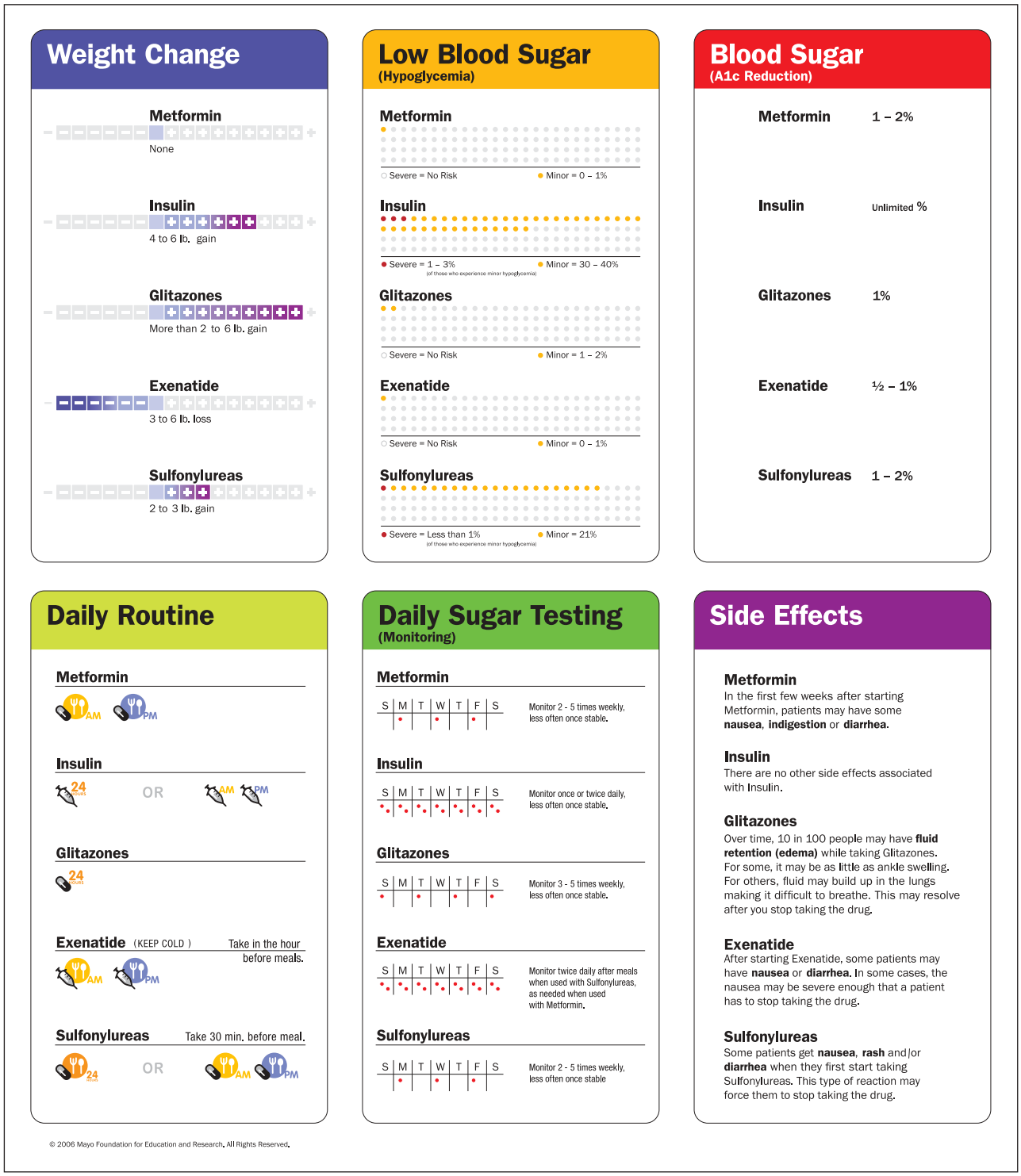

Figure 1. The Diabetes Medication Choice decision aid cards (reproduced with permission from the Mayo Foundation for Education and Research).

ticipation in diabetes medication choice.[5-7] Several barriers can make the task seem daunting, including the technical language used to describe the goals of treatment based on hemoglobin A_{1c} (HbA_{1c}) levels and the number and combinations of available medications.[8,9] Clinicians seeking to involve patients may not have the skills, time, or tools (eg, decision aids) to do so effectively and efficiently. Furthermore, despite the affirming policy statements, clinicians often lack incentives to invest time and effort to involve patients in the choice.[10] Finally, the evidence is inconclusive for better patient outcomes resulting from greater patient involvement in treatment decision making.[11-13]

With the goal of enabling patient involvement in diabetes treatment decision making, we developed the decision aid Diabetes Medication Choice (**Figure 1**). The tool was designed for use by clinicians during the clinical encounter and describes for patients the features of the avail-

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able antihyperglycemic medication options.[14] To evaluate the efficacy of this tool in the care of patients with type 2 diabetes mellitus, we conducted a cluster randomized pilot trial in primary care. Specifically, we sought (1) to determine the ability of the decision aid to promote patient involvement in choosing antihyperglycemic agents and (2) to evaluate the effects of this strategy on medication adherence and patient outcomes compared with usual care.

METHODS

SETTING

The trial took place at 11 primary care and family medicine sites within the Mayo Clinic Health System and Olmsted Medical Center, all in southeast Minnesota. The institutional review boards of each site approved the trial.

PARTICIPANTS

Eligible clinicians included physicians, physician assistants, and nurse practitioners managing diabetes in adults at participating sites. Eligible patients were adults with a diagnosis of type 2 diabetes mellitus for at least 1 year who had a scheduled appointment with an enrolled clinician and were able and willing to give informed consent to participate in the trial. The informed consent document kept participants blind to the study goals.

To ensure that patients would need to make a decision about diabetes medications, we sought to enroll patients with incomplete glycemic control who had remaining antihyperglycemic medication options. Thus, eligible patients had HbA_{1c} tests conducted less than 6 months prior to enrollment and results between 7.0% and 9.5% while taking 3 or fewer antihyperglycemic medications and not using insulin.

INTERVENTION

We have previously described the development of the Diabetes Medication Choice decision aid tool,[14] including how patients, clinicians, educators, and designers participated in its iterative development and extensive field testing. Briefly, the tool is designed to enable clinicians to discuss with patients the potential advantages and disadvantages of adding an agent from 1 of the following antihyperglycemic classes to their regimen: metformin, insulin, thiazolidinediones, exenatide, and sulfonylureas. The tool consists of 6 cards that describe the possible effects of the medications on 6 outcomes: "Weight Change," "Low Blood Sugar (Hypoglycemia)," "Blood Sugar (A1c Reduction)," "Daily Routine," "Daily Sugar Testing (Monitoring)," and "Side Effects" (Figure 1).

Ideally, the clinician presents all 6 cards to the patient and asks which of the cards the patient would like to discuss first. After reviewing and discussing the cards that the patient and the clinician choose to discuss (they do not need to discuss all 6 cards), they arrive at the medication that best matches the patient's circumstances and preferences (video supplement, http://www.archinternmed.com). The patient receives a copy of the cards in the form of a take-home pamphlet. While empirically developed, the decision aid is consistent with contemporary theories of choice and reflects a "noncompensatory" form of decision making.[15] Gigerenzer[16] found that this approach, based on fast and frugal heuristics, best reflects how people make optimal decisions in an information- and time-constrained environment.

Clinicians randomized to the intervention arm received a brief demonstration from the study coordinator on how to use the decision aid prior to meeting the first enrolled patient. The training usually lasted less than 3 minutes (as seen in the video) and occurred only once, unless the clinician requested further training.

Participants in the usual care arm discussed antihyperglycemic medication in the usual manner. In addition, patients received a professionally produced (by the Mayo Clinic Patient Education Center) 12-page general pamphlet on oral antihyperglycemic medications to take home. While distributing this pamphlet is not considered usual care, we provided it to patients in the usual care arm to control for the specific take-home material we distributed in the intervention arm.

ALLOCATION PROCEDURE

We randomized clinicians to either use the decision aid with all of their eligible patients (intervention) or discuss antihyperglycemic medications in their usual manner (control) during a regularly scheduled clinical visit. A computer-generated allocation sequence, unavailable to personnel enrolling patients or clinicians, randomized clinicians to intervention (decision aid) or usual care and was accessed by the study coordinators via telephone. The sequence was stratified by practice type (eg, family medicine or primary care) and practice location, with a block size of 4. Consequently, patient eligibility was assessed prior to randomization for the first patient a clinician saw while enrolled in the trial, but any subsequent patients the clinician saw were assessed for eligibility without being blind to the study arm.

OUTCOMES AND DATA COLLECTION

Postvisit Surveys

Outcome data included a self-administered written survey completed by patients immediately after the visit. The survey (eFigure, http://www.archinternmed.com) included five 7-point Likert-type scales to explore patients' perceptions of acceptability of the information.[17] The survey included 15 knowledge questions to assess patient understanding of the attributes of the different diabetes medications. Ten of these questions were addressed in the decision aid, and 5 were not. We used the 16-question Decisional Conflict Scale[18] to evaluate participant confidence in their knowledge of the information received and the resulting decisional efficacy and satisfaction (ranked 0, strongly agree, to 5, strongly disagree). We used the 9 question Trust in Physician Scale[19] to ascertain this construct (ranked 1, completely trust, to 5, not at all trust).

To assess patient involvement in decision making, we used a validated pictorial instrument that offered responders 7 options depicting levels of patient involvement in decision making.[20] We invited patients to identify both the level of involvement they perceived they had during the visit and the level of involvement they would have preferred.

We surveyed clinicians after each clinical encounter regarding the decision to add another antihyperglycemic medication and their perception of patient involvement in that decision. On completion of the trial, we surveyed those clinicians who had used the decision aid about the tool's helpfulness and appropriateness.

Visit Video Recordings

In both study arms we video recorded the clinical encounter (1) to assess the fidelity with which the decision aid was used and (2) to compare how clinicians and patients discussed diabetes medications with or without use of the decision aid. Trained observers applied the OPTION[21] instrument to these video recordings to measure the degree to which the clinician involved the

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patient in the process of deciding how to optimize glycemic control. The instrument addresses 12 observable clinician behaviors that promote patient involvement, and the clinician is rated from 0 (behavior not observed) to 4 (behavior observed and executed to a high standard) on each dimension. Rated clinician behaviors include the following: (1) the clinician identifies the problem(s) needing a decision-making process; (2) the clinician states that there is more than 1 way to deal with the identified problem(s); (3) the clinician explains the advantages and disadvantages of the options to the patient; and (4) the clinician explores the patient's expectations (or ideas) about how the problem(s) will be managed. Two raters watched each video in duplicate and independently until they achieved near perfect agreement (intraclass correlation for total OPTION score of 0.99), rating the remaining videos separately.

Follow-up Telephone Interviews and Review of Pharmacy Records and Clinical Charts

Research staff telephoned patients at 1, 3, and 6 months after the visit to assess adherence to diabetes medications. Patients were asked a single question: "People often have difficulty taking their pills for one reason or another. How many times do you think you may have missed taking your pills in the last week?" Any patient reporting a missed dose was considered to be nonadherent.[22,23] During the same telephone call, we asked patients to rate their health as excellent, very good, good, fair, or poor.[24]

We collected the patients' pharmacy records for all diabetes medications 6 months after their clinical visit as another measure of adherence to prescribed antihyperglycemic regimens. Patients continuing to take the medications that they were using before the visit were presumed to have enough medication to cover the time until their first prescription fill after the visit, up to a 100-day supply. A gap of longer than 90 days was considered *discontinuation*, rather than a *temporary suspension*, of the medication regimen. *Adherence* was defined by the proportion of days covered during the 180 days after the visit, crediting overlapping supply. *Persistence* was defined as the number of days from the first prescription fill to the last fill in the 180 days after the visit, giving credit for overlapping supply and the number of days supplied at the last fill, truncating at 180 days after the visit.[25,26]

Review of the medical record provided information about the baseline glycemic control (HbA_{1c} levels), medications, and comorbidities as well as follow-up visits, and HbA_{1c} levels closest to the 6-month point after the clinic appointment.

STATISTICAL ANALYSIS

Considering clustering by physician using intraclass correlations (ICC) for each outcome in 85 patients, we had greater than 99% power to show a 1-point difference in the 7-point helpfulness of the information question (ICC, 0.05); greater than 88% power to show a 15-point difference in the total OPTION[21] scale (ICC, 0.20); and greater than 99% power to show a 20% difference in adherence to any antihyperglycemic medication (ICC, calculated conservatively, 0.10). Statistical analysts and statisticians used generalized estimating equations to estimate the association between intervention and outcomes. These equations allowed us to adjust for clustering at the clinician level when assessing the impact of the intervention on the outcomes.[27] We chose to estimate the effect of the association between intervention and continuous outcomes by estimating adjusted mean differences and 95% confidence intervals (CIs) using generalized estimating equations with a normal distribution and identity link so the standard errors of the resulting model estimates could be adjusted for within-physician clustering. Residual analysis showed that the normal distribution assumption was met for most of the outcomes. For those that did not meet the normal assumption, analyses using the gamma distribution with the log or inverse link yielded similar results. For dichotomous and categorical outcomes, we present estimates of association using odds ratios (ORs) and 95% CIs.

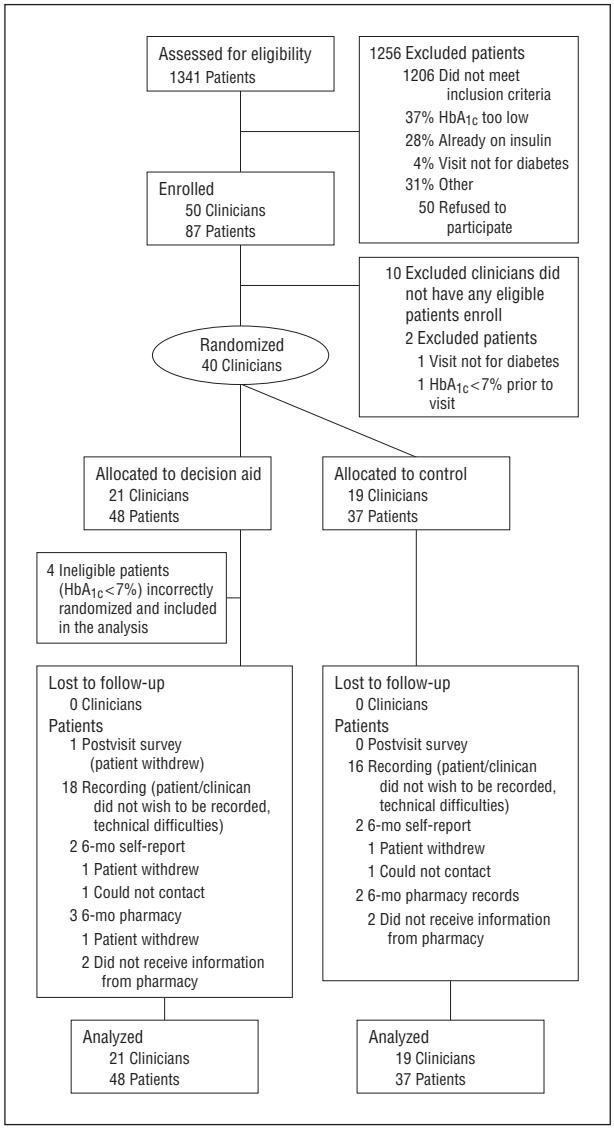

Figure 2. Participant flow diagram. HbA_{1c} indicates hemoglobin A_{1c} level.

RESULTS

Enrollment began in November 2006 and finished a year later. We enrolled 50 clinicians from the 11 locations participating in the trial: 40 clinicians had at least 1 eligible patient and were randomized, 21 to deliver the decision aid to 48 patients and 19 to provide only usual care to 37 patients (**Figure 2**). Most of the ineligible patients had either well-controlled diabetes (37%) or were using insulin (28%). **Table 1** summarizes the characteristics of the participants at baseline. Most patients were well educated and had HbA_{1c} levels lower than 8%.

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Table 1. Clinician and Patient Baseline Characteristics[a]

Characteristic	Decision Aid	Usual Care
Total Clinicians	**21 (100)**	**19 (100)**
Physicians	17 (81)	13 (68)
Nurse practitioners	3 (14)	1 (5)
Residents	1 (5)	5 (26)
Total Patients	**48 (100)**	**37 (100)**
Age, mean (SD) median, y	62.1 (10.9) 63.0	62.2 (12.4) 62.0
Women	22 (46)	18 (49)
Annual income, median (range), US$ × 1000	50 (<20 to >100)	50 (<20 to >100)
High school education completed	46 (96)	34 (94)
Hemoglobin A_{1c}, mean (SD) median, %	7.47 (0.58) 7.30	7.63 (0.65) 7.40
Duration of diabetes mellitus, mean (SD) median, y	7.47 (7.18) 6.00	8.24 (6.87) 6.00
Medications, mean (SD) median, No.	6.0 (2.8) 5.0	5.7 (3.4) 5.0
Antihyperglycemic medications, mean (SD) median, No.	1.31 (0.75) 1.00	1.51 (0.69) 2.00
Taking a statin	35 (73)	23 (62)
Taking aspirin	34 (71)	29 (78)
Self-rated health score, mean (SD) median	74.3 (17.8) 80.0	71.4 (18.4) 75.0

[a] Unless otherwise indicated, data are given as number (percentage) of clinicians or patients.

Table 2. Scores of Acceptability and Effect on Decisional Conflict, Trust, and Knowledge[a]

Characteristic	Decision Aid	Usual Care	AMD (95% CI)[b]
	Acceptability		
Amount of information	6.59 (0.91) 7.00	6.37 (1.14) 7.00	–0.01 (–0.29 to 0.28)
Clarity of information	6.20 (0.96) 6.00	6.20 (0.87) 6.00	–0.01 (–0.38 to 0.36)
Helpfulness of the information	6.15 (0.94) 6.00	5.74 (1.04) 6.00	0.38 (0.04 to 0.72)[c]
Would recommend to others	6.16 (1.51) 7.00	5.89 (1.82) 7.00	0.38 (–0.28 to 1.05)
Would want to use for other decisions	6.04 (1.55) 7.00	5.69 (1.75) 6.00	0.34 (–0.39 to 1.08)
	Conflict, Trust, and Knowledge		
DCS	14.10 (17.89) 7.81	14.95 (12.68) 14.06	–0.89 (–5.37 to 3.59)
Informed subscale of DCS	13.65 (19.84) 0.00	15.28 (15.49) 12.50	–2.49 (–7.21 to 2.23)
Trust in Physician Scale[19]	94.69 (7.14) 97.22	93.06 (9.58) 97.22	2.06 (–1.78 to 5.89)
	Knowledge Questionnaire		
Specific to DA (10 questions)	6.35 (2.44) 7.00	5.30 (1.82) 6.00	1.10 (0.11 to 2.09)[c]
Nonspecific to DA (5 questions)	2.83 (1.65) 3.00	3.14 (1.57) 3.00	–0.38 (–1.03 to 0.27)

Abbreviations: AMD, adjusted mean difference; CI, confidence interval; DA, decision aid; DCS, Decisional Conflict Scale.[18]
[a] Unless otherwise indicated, all data are mean (SD) median scores.
[b] Positive AMD favors DA group except for the DCS, for which a lower number means less conflict and so a negative AMD favors the DA group.
[c] Statistically significant results.

Eighty-four patients (99%) completed the postvisit survey. We recorded 51 encounters (60%): 30 decision aid visits (63%) and 21 control visits (57%). The main reasons for missing recordings were technical difficulties with the recording equipment and patient refusal. We obtained 6-month survey responses for 81 participants (95%) and pharmacy records for 80 participants (94%).

ACCEPTABILITY

The decision aid was acceptable and helpful to patients and physicians (**Table 2**). Of the 21 physicians who used the decision aid, 18 considered it helpful (86%) and 19 indicated their desire to use the decision aid again if given the opportunity (90%). Of note, the physicians' enthusiasm for the decision aid was related to the clinical context: while 19 physicians would use the decision aid with patients whose HbA_{1c} levels fluctuated between 7.0% and 9.5% in the last 6 months (90%), only 9 would use the decision aid with patients with steady HbA_{1c} levels whose condition was improving (43%).

KNOWLEDGE, DECISIONAL CONFLICT, AND TRUST

Patients who used the decision aid scored significantly and slightly higher on knowledge questions pertaining to information on the decision aid than patients in the control arm (Table 2). Both groups scored similarly high in the Trust in Physician Scale[19] and similarly low in the Decisional Conflict Scale.[18]

PATIENT INVOLVEMENT

The decision aid was effective in promoting patient involvement in the decision-making process as documented by independent assessors using the OPTION[21] scale on encounter recordings. The overall OPTION score was significantly higher in decision aid encounters than

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in usual care ones: a mean (SD) of 49.7 (17.74) of 100 for the decision aid group compared with 27.7 (11.75) for the control group (adjusted mean difference, 21.8; 95% CI, 13.0-30.5). All but 2 of the 12 items significantly favored the decision aid.

Use of the decision aid also shifted the focus of the conversation in the decision aid arm: weight change was the card picked first most often (33% of the time) and the card most commonly picked overall (67% of the time) (**Table 3**) (clinicians did not use the cards during 2 visits). When patients and clinicians discussed weight change in the usual care arm, it was generally in the context of a glycemic control rather than as a potential adverse effect of the medications.

MEDICATION DECISION

While marginally more patients in the decision aid arm chose a new agent, most patients in both arms of the trial chose to continue their medication regimen, either at the same or an increased dose (**Table 4**).

OUTCOMES AT 6 MONTHS

Judged by pharmacy records, median persistence and adherence to diabetes medications were near perfect in both groups and significantly better in the control group. Judged by patient self-report, there was no difference between groups, but the trend again favored the control group. The decision aid did not affect glycemic control or patient-reported health status at 6 months (**Table 5**).

SENSITIVITY AND SUBGROUP ANALYSES

Four patients, all of whom were enrolled at a site that enrolled patients a few days before the visit and were randomly assigned to the decision aid arm, had HbA_{1c} levels at enrollment that were within the eligible range but lower and ineligible HbA_{1c} levels by the time they attended their visit. Analyses excluding these 4 patients yielded similar results and identical implications (data not shown).

Post hoc subgroup analyses limiting comparisons to patients who at baseline had unchanged or worsening HbA_{1c} levels, HbA_{1c} levels higher than 7.5%, and who were using maximum doses of their existing therapy (n=9 in the decision aid arm and 10 in the control arm) found that a larger and similar proportion of both groups started treatment with new agents (n=4 and n=5, respectively). All other results were similar to those in the main analysis (data not shown).

Table 3. Use of the Issue Cards in the 30 Recorded Decision Aid Visits[a]

Card Title	Picked First	Picked at All
Blood Sugar (A1c Reduction)	7 (23)	20 (67)
Daily Sugar Testing (Monitoring)	3 (10)	13 (43)
Daily Routine	2 (7)	15 (50)
Low Blood Sugar (Hypoglycemia)	4 (13)	16 (53)
Side Effects	2 (7)	16 (53)
Weight Change	10 (33)	19 (63)

[a] All data are reported as number (percentage) of decision aid patients.

Table 4. Medication Choice Made During the Visit (Medical Record)[a]

Medication Choice	Decision Aid (n=48)	Usual Care (n=37)
Continue taking current medications	32 (67)	29 (78)
Start taking metformin	5 (10)	3 (8)
Start taking sulfonylureas	6 (13)	1 (3)
Start taking glitazones	2 (4)	1 (3)
Start taking exenatide	3 (6)	0
Start taking insulin	0	2 (5)
Other	0	1 (3)[b]

[a] All data are reported as number (percentage) of patients.
[b] One patient started sitagliptin.

COMMENT

MAIN FINDINGS

The Diabetes Medication Choice cards were helpful to patients and clinicians and improved patient involvement in making decisions about diabetes medications. Participants in both groups had high scores on knowledge, low scores on decisional conflict, were improving their glycemic control, and exhibited near perfect medication adherence. Very few participants in either group started treatment with new medications. Thus, the tool, while effective in increasing patient involvement, had limited opportunity to improve outcomes in the population studied.

WEAKNESSES AND STRENGTHS OF THIS STUDY

This pilot study has several weaknesses. The population who agreed to participate had good geographic access to primary and specialty care and only moderate lack of diabetes control. It is possible that a different, less-adherent patient population with deteriorating glycemia control might have greater benefit from involvement in decision-making.[28]

Another limitation of the study is that physicians used the diabetes decision aid with their patients only once. Glycemic control is an issue that patients and clinicians repeatedly revisit, and patients and clinicians can defer decisions and try different lifestyle interventions and treatments.[29] Also, there may be a learning curve for the patient-clinician dyad in using decision aids during the clinical encounter, and outcomes might improve with repeated use.

Given the difficulties in blinding a decision aid trial, we designed patient involvement to be measured by 2 researchers observing the videos independently and in duplicate with adequate reproducibility, but these safeguards might not have been sufficient to prevent bias in favor of the decision aid. Furthermore, because only 60% of the encounters were recorded, there is potential for

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Table 5. Six-Month Outcomes

Characteristic	Decision Aid	Usual Care	AMD (95% CI)[a]
Adherence: Self-report, No. (%) of Patients			
Did not miss a dose in last week	31 (76)	25 (81)	0.74 (0.24 to 2.32)[b,c]
Adherence: Pharmacy Records			
Persistence, days covered, No. (range)	180 (0-180)	180 (180-180)	−11.8 (−21.0 to −2.67)[c]
Adherence, days covered, % (range)	97.5 (0.0 to 100)	100 (73.9 to 100)	−8.88 (−13.6 to −4.14)[c]
Adherence: HbA_{1c} Values, Mean (SD) Median			
HbA_{1c} at 6 months	7.31 (0.99) 7.10	7.37 (1.21) 6.95	−0.01 (−0.50 to 0.49)[d]
HbA_{1c} decrease	0.16 (0.99) 0.10	0.24 (1.04) 0.50	0.01 (−0.49 to 0.50)[d]
Self-reported health status	3.30 (0.87) 3.00	3.34 (0.94) 3.00	−0.03 (−0.44 to 0.39)

Abbreviations: AMD, adjusted mean difference; CI, confidence interval; HbA_{1c}, hemoglobin A_{1c} level.
[a] Positive AMD favors decision aid arm; odds ratio >1 favors decision aid arm.
[b] Reported here as odds ratio rather than AMD.
[c] Statistically significant finding.
[d] Adjusted for baseline HbA_{1c} levels.

selection bias; however, this seems unlikely because none of the measured baseline characteristics were different across participants with and without recorded visits.

The decision aid itself may require further modification. For example, the decision aid cards did not describe the effect of reducing HbA_{1c} level on patient-important outcomes, but rather it assumed that clinicians and patients would have set an HbA_{1c} level goal prior to deciding to intensify treatment and use the cards. Perhaps evidence from some recently published trials could help patients and clinicians choose a glycemic target.[30-32] The cards limited the discussion to drug treatment intensification; future iterations may incorporate a discussion of lifestyle interventions. Also the cards did not include cost information because we could not summarize the vast range of out-of-pocket costs patients would incur under the existing drug benefit programs; this might be a feasible addition in health systems in which the relative or absolute costs are predictable.

Strengths of the study include a rigorous randomized trial design that addressed the efficacy of one of the first decision aids for patients with diabetes and the first decision aid designed to facilitate patient involvement in diabetes medication choice. Our decision aid is innovative in that it departs from the traditional model of an all-encompassing stand-alone tool to prepare patients for the consultation; it was designed for efficient use during the consultation (ie, for cooperative decision making between the clinician and the patient); and it was designed to help the patient to work through the decision using the most salient or relevant attributes of the available options. The strong endorsement from clinicians indicates the success of the decision aid design in achieving efficiency in primary care.

The study showed that our decision aid could favorably affect patient involvement in what has been heretofore considered a technical decision in primary care practices. Despite the additional demand on patients to take part in a complex decision, the decision aid increased involvement without negative effect on patient satisfaction with decision making. Finally, the decision aid allowed primary care clinicians to present insulin as an alternative, a challenge in primary care practices.[33]

IMPLICATIONS FOR RESEARCH AND POLICY

Further work is necessary to overcome the limitations of this pilot study. Evaluation of costs, HbA_{1c} level targets, and the use of the cards over time will require exploration as will evaluation of the decision aid in patients with worsening diabetes control, limited health literacy, and limited subspecialty access and support. Also, the decision aid can be used as an instrument to study the role patient and clinician preferences might play on clinical inertia and nonadherence, not in thought exercises (eg, surveys of perceptions and beliefs) but rather in actual clinical care.

Our findings, while preliminary, may begin to inform policy about patient involvement. Many policymakers, including the Institute of Medicine in the United States[34] and the National Health Service in the United Kingdom,[35] and specific legislation, such as the Medicare Modernization Act of 2003 and the State of Washington health care reform bill of 2007 (ESSB 5930),[36] promote patient involvement in making decisions. These initiatives are based, at least in part, on the assumption that increased patient involvement will improve outcomes. The present study reminds us that this assumption requires further empirical evaluation. Are these organizations ready to consider patient involvement on principle alone or as a right as in the new British National Health Service constitution,[35] or is evidence of positive downstream effects of involvement necessary? If unwilling to promote patient involvement on principle, then these organizations may want to postulate and test circumstances in which greater patient involvement yields downstream positive consequences. They should also be ready to consider that greater patient involvement may increase practice variation, move care away from recommended care, and increase cost.

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Additional Information: An eFigure and a video supplement are available at http://www.archinternmed.com.

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Correction

Error in Abstract and Introductory Paragraph of the Main Article. In the article titled "Outcomes Associated With Tiotropium Use in Patients With Chronic Obstructive Pulmonary Disease" by Lee et al, published in the August 10/24 issue of the *Archives* (2009;169[15]: 1403-1410), part of the first paragraph of the article was published in the "Conclusions" section of the abstract. The last sentence of the abstract should have read "However, this result was not consistent in other medication regimens that included tiotropium." (The last 4 sentences of the abstract "Conclusions" should have been the first 4 sentences of the main article.)

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