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ORIGINAL RESEARCH

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A nurse driven care management program to engage older diabetes patients in personalized goal setting and disease management

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Abstract

Background and Aims: Multiple diabetes care guidelines have called for the personalization of risk factor goals, medication management, and self-care plans among older patients. Study of the implementation of these recommendations is needed. This study aimed to test whether a patient survey embedded in the Electronic Healthcare Record (EHR), coupled with telephonic nurse care management, could engage patients in personalized goal setting and chronic disease management.

Methods: We conducted a single-center equal-randomization delayed comparator trial at the primary care clinics of the University of Chicago Medicine from 2018.6 to 2019.12. Patients over the age of 65 years with type 2 diabetes with an active patient portal account were recruited and randomized to receive an EHR embedded goal setting and preference survey immediately in the intervention arm or after 6 months in the delayed intervention control arm. In the intervention arm, nurses reviewed American Diabetes Association recommendations for A1C goals based on health status class, established personalized goals, and provided monthly telephonic care management phone calls for a maximum of 6 months. Our primary outcome was the documentation of a personalized A1C goal in the EHR.

Results: A total of 100 patients completed the trial (mean age, 72.51 [SD, 5.22] years; mean baseline A1C, 7.14% [SD, 1.06%]; 68% women). The majority were in the Healthy (59%) followed by Complex (30%) and Very Complex (11%) health status classes. Documentation of an A1C goal in the EHR increased from 42% to 90% ($p < 0.001$) at 6 months in the intervention group and from 54% to 56% in the control group. Across health status classes, patients set similar A1C goals.

Mengqi Zhu and Michael Cui these two authors contributed equally to this work.

Conclusions: Older patients can be engaged in personalized goal setting and disease management through an embedded EHR intervention. The clinical impact of the intervention may differ if deployed among older patients with more complex health needs and higher glucose levels.

Trial Registration: ClinicalTrials.gov Identifier: NCT03692208.

KEYWORDS

diabetes, glycated hemoglobin, goal setting, nurse care management, older adults

1 | INTRODUCTION

In the United States, approximately 40% of adults living with diabetes are over 65 years of age and the vast majority (>95%) have type 2 diabetes.[1] This population of older adults with diabetes is expected to double in the next two decades with the aging of the baby boomer generation and high rates of obesity.[2] Compared with their peers without diabetes, older patients with diabetes have a much higher risk of microvascular and cardiovascular disease[3] as well as geriatric conditions, such as chronic pain,[4] depression, and dementia.[5] Older patients with diabetes also unfortunately experience some of the highest rates of hypoglycemia, a consequence of diabetes treatments. Older patients with diabetes are a very heterogeneous population in terms of comorbid conditions, diabetes complications, and functional status. As a result, the risk of future events such as microvascular complications, cardiovascular complications, hypoglycemia, and mortality is quite different across major subgroups (i.e., age groups, duration of diabetes, and comorbid conditions).[6] The complications of diabetes will contribute to an expected tripling of Medicare costs for diabetes care in the next 25 years due to the aging of the US population combined with high rates of obesity and diabetes.[2]

Clinical trials of intensive glycemic control have demonstrated long-term benefits but short-term harms.[7–9] In light of the mixed trial results and the heterogeneity among older adults with diabetes, multiple organizations such as the American Diabetes Association (ADA) and the Endocrine Society have called for the personalization of risk factor goals, medication management, and self-care plans among older patients.[10,11] The general concept is that more lenient glycemic goals are assigned to older adults with more complex health status as they are less likely to benefit from a strategy of intensive glucose control. Since 2012, the ADA[12] has promoted recommendations urging individualized glycemic (hemoglobin A1C [A1C] < 7.5% vs. <8.0% vs. <8.5%) and blood pressure control targets (<140/80 vs. <150/90 mmHg) and statin use for three strata of the health status of older patients (Healthy, Complex, and Very Complex). The strata of health status were defined by the presence and number of comorbidities or impairments of functional status. With greater medical complexity, the guidelines also emphasize the importance of developing care plans that are sensitive to the burdens and risks of polypharmacy. In the 2024 Standards of Care chapter on Older Adults, the guidelines authors emphasize the importance of developing care plans that are not overly complex for the older adult. This requires weighing the benefits of additional drugs, monitoring against the likelihood that the harms of polypharmacy and irregular adherence.[13]

Despite the release of these guidelines, multiple studies have demonstrated that the care of older patients is not currently being personalized based on health status.[14–16] The failure to personalize care may lead to both overtreatment of the sickest patients and undertreatment of healthy patients. The lack of differentiation of diabetes care by health status may be due to a lack of geriatric care support interventions that can be integrated into busy clinical practices. Many clinical organizations have diabetes quality improvement systems in place, but these efforts typically do not promote individualized goals and do not have a geriatric orientation.

Trying to answer the question of whether or not personalized glycemic goal setting benefits older adults was one of the major motivations behind our trial. This requires a first step of developing a protocol to encourage personalized goal setting with shared decision-making principles. In other clinical contexts, goal setting has been found in a systematic review to have potential health benefits in a variety of dimensions including helping patients identify what goals were important to them, align their goals with clinician goals, and achieve improved health outcomes.[17]

The Managing Diabetes to Gain Opportunities for a more Active Life (My Diabetes GOAL [MDG]) trial was conducted to test whether a patient-facing disease management intervention embedded in the Electronic Healthcare Record (EHR) can engage patients in personalized goal setting and chronic disease management.

2 | METHODS

2.1 | Trial design

The MDG trial was a 6-month single-center single-masked delayed comparator pilot trial conducted at the University of Chicago Medicine located in Chicago, IL of the United States. The trial protocol was approved by the institutional review board at the University of Chicago Medicine, and all participants provided written informed consent. Patients were randomly assigned in a 1:1 ratio to either intervention or delayed intervention control arm. A blocked randomization scheme

with randomly permuted block sizes (unknown to the investigative team) was conducted by the study statistician. No stratification factors were considered for this single-center study. Whereas patients and registered nurses (RNs) assigned to the intervention arm were aware of the allocated arm, data analysts and chart abstractors were masked to the allocation. Study data were collected and managed using Research Electronic Data Capture (REDCap) tools.

2.2 | Participants

Participants were all over the age of 65 years, had an active MyChart account, and were seen in the outpatient clinic in the past year. MyChart is a free online service provided by the healthcare organization that offers patients a secure access to their health records. Due to the general purpose of this intervention, no patients with comorbid conditions or functional impairment were excluded. Participants were recruited from primary care clinics of the University of Chicago Medicine located in Chicago, IL, from June 2018 to December 2019. The University of Chicago Medicine is a large urban academic medical center, which serves a primarily Black population.

2.3 | Intervention and procedures

A previously created web-based decision support application designed to encourage goal setting based on patient prognosis and treatment preferences was converted into a MyChart questionnaire.[18] The original web-based application included education regarding the interpretation of A1C levels, a complex simulation model to predict individual risks of events, treatment preference elicitation, and geriatric condition screening. The new intervention was simplified to focus on gathering inputs for a single prediction model and treatment preferences. Participants were provided informed consent and randomized to either the intervention or delayed intervention control arm. After a patient was consented, the research coordinator clicked on the randomization button in REDCap to reveal the patient's study arm. Participants in the intervention arm were e-mailed a link to complete the questionnaire via MyChart the same day of their enrollment into the study. Participants in the delayed intervention control arm were e-mailed a link to complete the questionnaire 6 months after their enrollment date.

The questionnaire (Supporting Information Appendix questionnaire) included an embedded risk score calculator, which was based on the well-established and externally validated 4-year mortality prediction model that has been translated into life expectancy predictions.[19,20] The risk score incorporated age, sex, six self-reported comorbid conditions (diabetes, cancer, lung disease, heart failure, current tobacco use, and body mass index <25), and four functional measures (difficulty with bathing, walking several blocks, managing money, and pushing large objects). It was used to stratify older patients into three classes (Healthy, Complex, and Very Complex), corresponding to different life expectancy ranges (>10, 5–10, and <5 years). This classification of patients was based on the three-tiered scheme proposed by the ADA.[12] Two registered diabetes nurse educators (RN) would review participant responses and document their personalized goals, treatment preferences, and hypoglycemic events.

In the questionnaire, patients were also asked about their experiences with low blood sugar, A1C goals, side effects of diabetes medications, preferences for diabetes medications, and health literacy. Each RN utilized the responses from the questionnaire to assist in personalizing the care management phone calls. During the initial phone calls, the RN had shared decision-making conversations with each patient regarding the A1C goals that were selected. The RN would share the ADA-recommended goal based on each patient's personalized comorbidity and life expectancy and help each patient adjust their personal A1C goal if the patient wanted. Patient preferences and goals were recorded by the RN and embedded into the EHR. During the initial and subsequent conversations, the RN would address any barriers that may negatively impact A1C control. Some of the barriers include medication, physical activity, lack of diabetes education, mental health, and social barriers. The RN would also refer patients to services, such as diabetes education, self-care resources, and electronic resources. Patients received monthly follow-up calls with a maximum duration of 6 months. Each month the RN would attempt to reach the patient three times.

To complement survey data, we also performed an abstraction of the EHR to collect additional information. EHR data included documentation of personalized goals in the EHR, A1C test results, medication changes, emergency room (ER) visits, and hospitalizations. The documentation of personalized goals in the EHR was abstracted at baseline and at 6 months after the intervention. A1C test results, medication changes, ER visits, and hospitalizations were abstracted from a period of 6 months before the randomization to the 6 months after the randomization for both control and intervention.

2.4 | Outcomes

The primary outcome was documentation of a personalized diabetes A1C goal in the medical record in 6 months. There were three secondary outcomes that included each patient's: (1) selection of a personalized diabetes goal, (2) ability to reach their personalized diabetes goals at 6 months, and (3) healthcare utilization 6 months before and after the intervention, which included medication changes and resources, such as ER visits and hospitalizations.

2.5 | Statistical analysis

An intention-to-treat analysis was used to include all patients who were randomized. Quantitative outcomes from survey and EHR data were summarized by basic descriptive statistics. Chi-squared tests, Fisher's exact tests, and Wilcoxon rank-sum tests were utilized to assess the outcomes between study arms or health status groups. McNemar's tests were used to assess the outcomes within the study

arm. For all testing, a two-sided significance level was set at 0.05. All analyses were performed in R Studio (v.3.6.1).

The primary outcome was the documentation of personalized goals for diabetes care at 6 months. We expected that at baseline, in both groups, there would have <5% patients whose charts have been documented their personalized goals. We assumed that the intervention group would have more than 50% of patients with personalized goals at 6 months. Using Fisher's exact test, a total sample size of 44 subjects (22 per group) was needed to obtain at least 90% power to detect the difference of 45% between the two groups at a two-sided significance of 5%. With a total sample size of 100, the power would be 99%.

3 | RESULTS

Of 110 enrolled patients, 57 were assigned to the intervention group and 53 to the delayed intervention control group. After accounting for withdrawals and deaths during the course of the study, there were a total of 50 patients for analysis in each study arm (Figure 1). Patients had a mean age of 72.51 (SD, 5.22) years and a mean baseline A1C of 7.14% (SD, 1.06), 68% were women, 25% were White non-Hispanic, and 70% were Black. The majority were in the Healthy (59%), followed by Complex (30%) and Very Complex (11%) health status classes. The baseline characteristics between the two groups were similar (Table 1). The control and intervention groups had similar levels of diabetes control, comorbidities, healthcare utilization, medication use, and documentation of A1C goals. Patients in both arms had well-controlled diabetes.

Among intervention patients, the documented goal in the chart increased significantly from 42% to 90% of patients during the course of the trial ($p < 0.001$). For control patients, the documentation of goals did not change during the same period (54% and 56%, $p > 0.99$) (Figure 2). The proportion of patients who had documentation of goals was not significantly different at baseline ($p = 0.32$) between the two groups, and was significantly different at 6 months ($p < 0.001$).

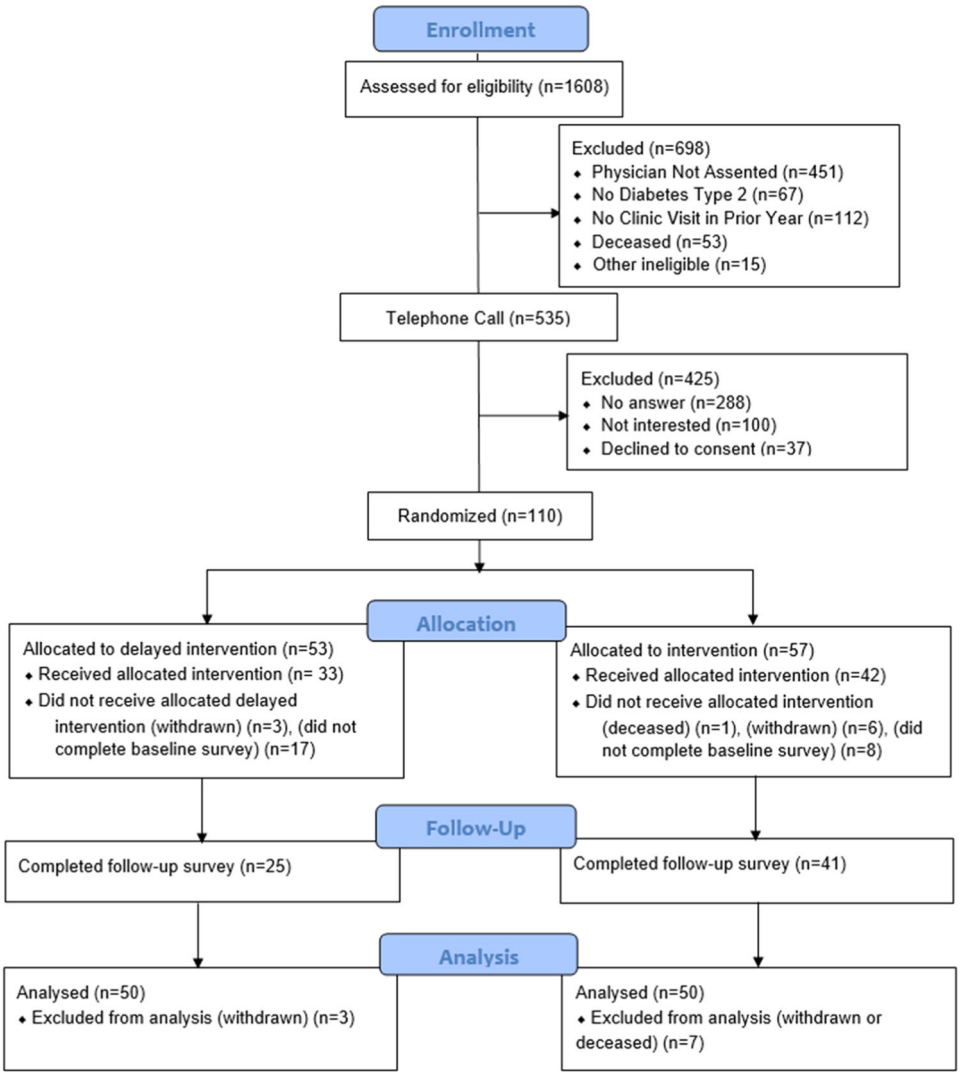

FIGURE 1 CONSORT diagram.

TABLE 1 Baseline patient characteristics.

Patient characteristics	Intervention (*N* = 50)	*N* missing	Control (*N* = 50)	*N* missing	*p* Value
Age, Mean ± SD, year	72.4 ± 5.0	0	72.7 ± 5.5	0	0.98
Female	58	0	78	0	0.05
Race/ethnicity		0		0	0.13
White	34		16		
Black	62		78		
Other	4		6		
A1C value, Mean ± SD, %	7.1 ± 0.8	8	7.2 ± 1.3	4	0.86
>9.0%	2		7		0.62
>8.0%	10		22		0.15
<6.5%	21		30		0.47
SBP, Mean ± SD, mmHg	132 ± 18	0	134 ± 15	0	0.38
DBP, Mean ± SD, mmHg	70 ± 9	0	68 ± 10	0	0.40
Mortality index score, Mean ± SD	7.6 ± 2.8	0	7.4 ± 2.9	0	0.82
Health status class		0		0	>0.99
Healthy	60		58		
Complex	30		30		
Very Complex	10		12		
Glucose lowering medications		0		0	
Metformin	66		62		0.83
Sulfonylureas	18		22		0.80
Insulin	30		34		0.83
Statin	86	0	84	0	>0.99

Note: Values reported are the percentage of patients, unless otherwise indicated. *p* Values were calculated using Chi-squared tests, Fisher's exact tests, and Wilcoxon rank-sum tests.

Abbreviations: DBP, diastolic blood pressure; SBP, systolic blood pressure.

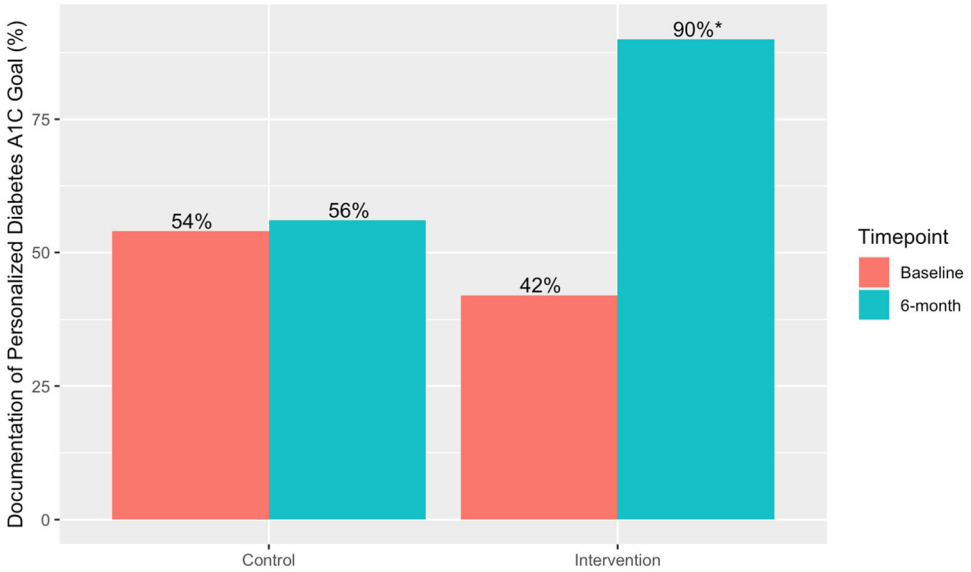

FIGURE 2 Documentation of personalized diabetes A1C goal in the medical record. *Indicates significant difference from baseline.

Across the three different health status classes in the intervention group, there was no significant difference in patients' self-reported A1C goals (Healthy 6.47 ± 0.67, Complex 6.93 ± 0.55, and Very Complex 6.37 ± 1.10, respectively). Even after the goal-setting discussion with the RN and learning about ADA recommendations guidelines, only five patients chose to revise their A1C goals. Most patients selected A1C goals lower than recommended by the ADA guidelines. No significant difference in baseline A1C across the health status categories was also observed (7.02 ± 0.83, 7.12 ± 1.17, and 7.08 ± 0.92, respectively) (Figure 3).

The baseline A1C and 6-month A1C of intervention and control patients were statistically similar. Neither the intervention nor the control group had any statistically significant change in A1C at 6 months (Supporting Information Appendix Table 1).

At baseline in the intervention group, 31% patients had lab-documented A1C lower than their selected goal and 84% had lab-documented A1C lower than the ADA-recommended goal. At 6 months in the intervention group, 33% patients had lab-documented A1C lower than their selected goal and 86% patients had lab-documented A1C lower than the ADA-recommended goal. There were missing data as a result of patients missing lab-documented A1C at baseline (missing $N = 8$ and 4 for the intervention and control groups, respectively) and at 6-month intervention (missing $N = 5$ and 13 for the intervention and control groups, respectively).

There was no significant difference in treatment preferences by intervention patient health class (Table 2). Most (79%) patients were willing to take more oral medications to lower their blood glucose compared with only 36% of patients who were willing to take injections. Few (12%) patients were willing to take less medication if it would result in higher blood glucose. The majority (90%) of patients wanted to be involved in making decisions about their diabetes goals as well as knowing how well their diabetes was controlled.

Patients in both arms had similar levels of healthcare utilization before and during the study (Supporting Information Appendix Table 2). During the 6 months before the intervention, 21% of patients had at least one hospitalization, and 12% of patients had at least one ER visit. During the 6 months of the intervention, 22% of patients had at least one hospitalization, and 11% of patients had at least one ER visit (Supporting Information Appendix Table 2). There was no ER visit or hospitalization that was due to hypoglycemia or hyperglycemia during our study period. Patient utilization of medication and medication categories did not change in the intervention and control groups at baseline or at 6 months (Supporting Information Appendix Table 3).

4 | DISCUSSION

This study demonstrates that a patient-facing disease management intervention embedded in the EHR can engage older patients in personalized goal setting and chronic disease management. Patients in the intervention arm increased the documentation of personalized

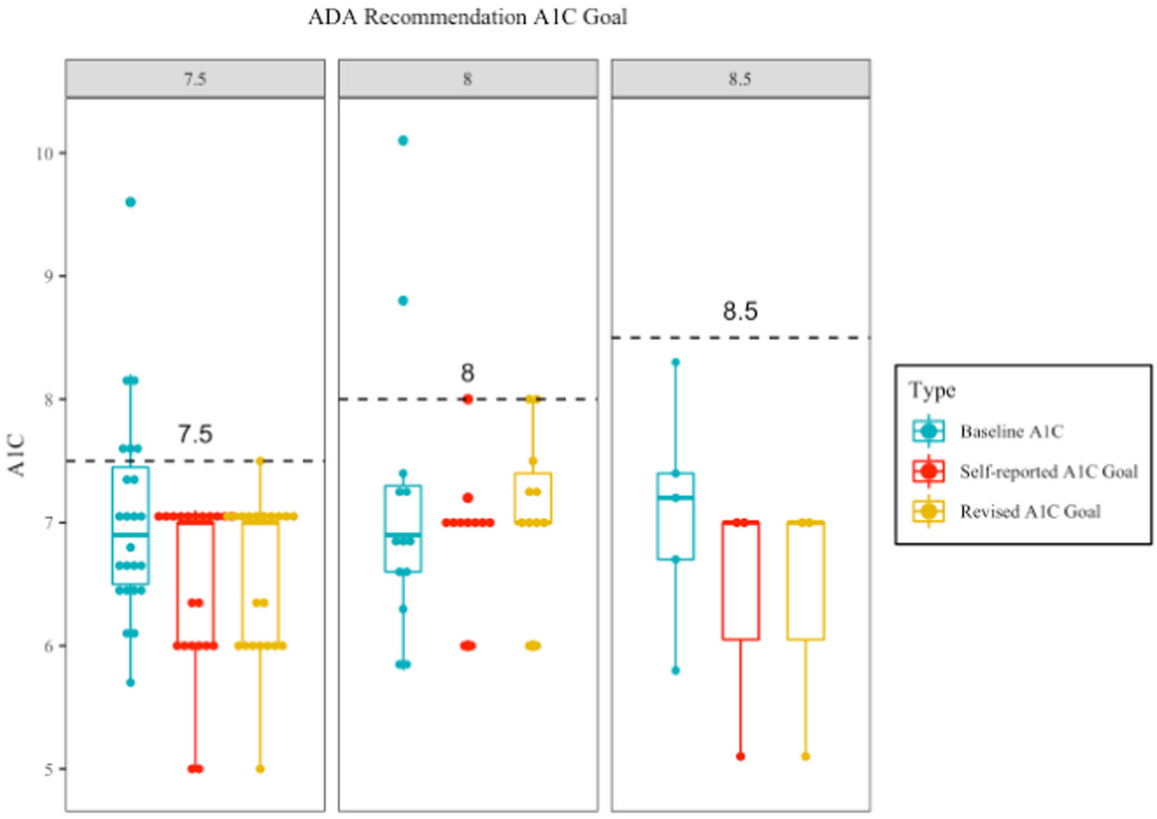

FIGURE 3 Patient selection of personalized diabetes goal by ADA recommendation. ADA, American Diabetes Association.

TABLE 2 Treatment preferences of intervention patients by health status.

	Overall (*N* = 50)	Healthy (*N* = 30)	Complex (*N* = 15)	Very Complex (*N* = 5)	*p* Value
Treatment preferences (combined agree/strongly agree)					
Would you be interested in taking less diabetes medications, even if your sugars will be higher?	12	15	0	33	0.13
I am willing to take oral medication (pills, tablets) to help lower my sugars	79	85	75	33	0.13
I am willing to take injections to help lower my sugar	36	44	25	0	0.25
I want to be involved in making decisions about my diabetes goals	90	93	83	100	0.69
Knowing how well my diabetes is controlled is important to me	90	89	92	100	>0.99

Note: Values reported are the percentage of patients, unless otherwise indicated. *p* Values were calculated using Fisher's exact tests.

diabetes A1C goal in the EHR by more than double, from less than half to the vast majority. Almost all patients in our study wanted to be part of the discussion regarding their diabetes goals. When engaged in shared decision making with a nurse regarding setting A1C goals, patients in the study selected lower A1C goals than the risk-stratified upper threshold recommended by ADA. Regarding medication preferences, our study again redemonstrated older patients' preference for taking oral medication when compared with injectable medications.[21,22]

Our EHR-based intervention was successfully deployed in an older primarily Black population. The survey was embedded into the EHR and sent out to participants via a patient portal. Having an active patient portal account appeared useful as a screener for patients who may be able to use electronic questionnaires. Of note, for some patients, team members or family members had to assist the patient to complete the survey. The primary challenges patients experienced included difficulty remembering their password to the portal, difficulty resetting their password, and difficulty navigating the embedded survey link in the MyChart e-mail. The trial also allowed care management to be personalized based on patients' questionnaire responses. With survey responses, nurse care managers could spend time on areas of patient need. Lastly, patient preferences and goals were embedded into the EHR for all care members to utilize. The integration with the EHR made the goals easily accessible to a patient's care team.

A secondary outcome of our study was to understand how older patients would personalize their A1C goals after being presented with ADA recommendations by a nurse. Nurses were trained to utilize a shared decision-making approach to goal setting with data exchange, preference elicitation, and deliberation. They had different protocols for patients with A1C goals above and below the ADA recommendations. In cases where the A1C was below the ADA recommendation, nurses specifically inquired about hypoglycemia. Following shared decision-making principles, nurses ultimately encouraged patients to be the decision maker in setting their A1C goals. We found that the majority of patients selected A1C goals that were below the upper threshold of their risk-stratified A1C recommendation. We also found no real differentiation in selected goals by health status. An A1C of 7% was the most reported goal. We suspect that the results related to A1C goal setting may be partially due to the nature of shared decision-making interventions, which emphasizes the process of decision making and not the actual decision choice. More likely, the A1C goal results may be a reflection of the clinical characteristics and psychological biases of the patients in the study. Many of the patients in this study had long-standing diabetes that was well controlled. Patients likely had anchored on the A1C goal of 7% that may have been discussed with them early at the time of diagnosis and throughout their experience with diabetes management. This anchor is incredibly hard to adjust even with further education. Only five patients stated that they would be willing to decrease diabetes medications if it meant higher glucose readings, which suggests many patients may be resistant to higher A1C goals and treatment deintensification may not be acceptable to them. In future research, efforts to study deintensification would require an intervention explicitly designed to produce this change in goals and behavior.

Our trial differs greatly from prior studies of personalized goal setting with diabetes in terms of the age of the population as well as the general purpose of the intervention. In prior trials of goal setting, patients were younger and had elevated A1Cs at baseline.[17] In these trials, goal setting was associated with reductions in achieved A1C. In our trial, the older patients had baseline levels of A1C that were frequently below thresholds, such as an A1C < 7.0%. As a result, the general purpose of personalized goal setting is quite different as older patients were permitted to select less stringent goals.

A limitation of our study is the unique characteristics of the trial population. The patients enrolled in this study were relatively healthy with well-controlled diabetes. The same intervention might have different effects in a population with worse health status and less control of their diabetes. Another limitation was that the patients already had, or were willing to create, an active patient

portal. This self-selects the patients into a higher technology literacy group. This group could fundamentally be different than those without access to a patient portal. Future versions of the intervention should allow the inclusion of patients across the spectrum of technology literacy.

Despite these limitations, this study is an important first step in operationalizing an approach to personalized medicine that incorporates patient engagement, risk prediction, and shared decision making within the electronic health record. An electronic questionnaire is more readily updated and easier to scale. Serial questionnaires, which is a logistical nightmare, are more easily conducted with electronic questionnaires. Analytics can also be embedded in the questionnaire to interpret their results. The use of an electronic medium also minimizes user errors. An electronic questionnaire is easier to deploy, analyze, and manage which reduces the overall cost of administration.

In summary, this study demonstrates that older patients can be engaged in personalized goal setting and chronic disease management through an embedded EHR intervention. Patients in our study selected lower A1C goals than recommended by the ADA guidelines, which suggest goal setting is complex and more research is needed to identify effective strategies for communicating about personalization and deintensification. Future care guidelines may need to acknowledge the practical challenges of implementing goal setting and shared decision making in clinical practice.

AUTHOR CONTRIBUTIONS

Mengqi Zhu: Data curation; formal analysis; visualization; writing—original draft; writing—review and editing. **Michael Cui**: Data curation; writing—original draft; writing—review and editing. **Aviva G. Nathan**: Conceptualization; methodology; project administration; writing—review and editing. **Valerie G. Press**: Writing—review and editing. **Wen Wan**: Conceptualization; methodology; writing—review and editing. **Cristy Miles**: Investigation; writing—review and editing. **Rabia Ali**: Investigation; writing—review and editing. **Mariko Pusinelli**: Investigation; writing—review and editing. **Megan Huisingh-Scheetz**: Investigation; writing—review and editing. **Elbert S Huang**: Conceptualization; data curation; funding acquisition; supervision; writing—review and editing.

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CONFLICT OF INTEREST STATEMENT

The authors declare is no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

TRANSPARENCY STATEMENT

The lead author Elbert S. Huang affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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