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Individualizing Hemoglobin A1c Targets for Patients with Diabetes: Impact of an Automated Algorithm within a Primary Care Network

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Abstract

Aims—To develop glycemic goal individualization algorithms and assess potential impact on a health care system and different segments of the diabetes population.

Methods—Cross-sectional observational study of diabetes patients in a primary care network age >18 years with an HbA1c measured between January 1 and December 31, 2011. We applied diabetes guidelines to create targeted algorithms 1 and 2, which assigned HbA1c goals based on age, duration of diabetes (<15 years or <10 years), diabetes complications, and Charlson comorbidity score (<6 or <4) (targeted algorithm 2 was designed to assign more patients a goal <64 mmol/mol [8.0%] than targeted algorithm 1). Each patient's HbA1c was compared to these targeted goals and to the 'standard' goal <53 mmol/mol (7.0%). Agreement was tested using McNemar's test.

Results—Overall, 55.7% of 12,199 patients would be considered controlled under the 'standard' approach, 61.2% under targeted algorithm 1, and 67.5% under targeted algorithm 2. Targeted algorithm 1 reclassified 1,213, or 23.6%, patients considered uncontrolled under the standard approach to controlled, $p < 0.001$. Targeted algorithm 2 reclassified 1844, or 35.2%, patients, $p < 0.001$. Compared to those controlled under the standard goal, there was no significant difference in the proportion of those controlled using targeted goals who had Medicaid, had less than a high school diploma, or received primary care in a federally qualified health center.

Conclusions—Two automated targeted algorithms would reclassify one quarter to one third of patients from uncontrolled to controlled within a primary care network without differentially affecting vulnerable patient subgroups.

Landmark trials such as ACCORD,[1] ADVANCE,[2] and VADT,[3] have demonstrated that the benefits and harms of glycemic control are not equally distributed across all patient groups. There is increasing consensus that glycemic control goals should be based on individual patient factors.[4] However, quality reporting and pay-for-performance programs commonly evaluate diabetes outcomes using “one-size-fits-all” goals.[5] This approach may promote more aggressive management among older, sicker patients with less expected benefit and more expected harm from therapy[6], while discouraging aggressive management early in the disease course when therapy is safest and most effective. Recent American Diabetes Association (ADA) guidelines for control of hyperglycemia in type 2 diabetes explicitly abandon the use of a single glycemic goal for all patients.[4] Instead, drawing on an approach proposed by Ismail-Beigi et al.,[7] the ADA endorses a system of individualizing goals based the expected benefits and harms of therapy.[8]

Recently, an analysis of data from a U.S. national population sample created an algorithm with the potential to individualize glycemic control goals.[9] However, this algorithm relied upon data from in-person interviews. This time-consuming method cannot be applied on a large scale for population level management in clinical care settings. Furthermore, the implication of individualizing goals for a large panel of patients within a health care system is unknown. For example, there is concern that performance measurement strategies may negatively affect certain clinic settings, such as “safety net” federally-qualified health centers, or vulnerable patient sub-groups, such as those with low socioeconomic status, and those for whom English is not their first language.[10, 11] This differential reclassification could divert resources from those who need it most. Finally, racial/ethnic minorities such as Hispanic and non-Hispanic Black patients may experience earlier diabetes onset[12] and have worse diabetes outcomes,[13] suggesting that optimal glycemic control is not achieved early in the disease course. Strategies that highlight more stringent diabetes control soon after diabetes diagnosis may be useful in combating disparities in diabetes outcomes[14].

To address these issues, we sought to individualize HbA1c goals using an automated health information technology process and to assess how these goals would reclassify diabetes patients in a large healthcare delivery system. We hypothesized that reclassifying patients from uncontrolled to controlled by individualizing glycemic goals would not negatively affect safety-net health centers or vulnerable populations.

Methods

Study Setting and Sample

The study was conducted in an 18-practice primary care network affiliated with an academic medical center in the United States. Eligible patients had at least one visit to a study practice within the 3-year period ending December 31, 2011.[15] Inclusion criteria included adults (age >18 years) diagnosed with diabetes (type 1 or type 2) identified using a previously validated algorithm.[16] Patients were excluded if they had died or did not have a hemoglobin A1c (HbA1c) level performed between January 1 and December 31, 2011. The Partners Healthcare Human Research Committee approved this study.

Creating Tailored Glycemic Target Levels

Based on current ADA recommendations,[4] we used 4 patient factors to create individualized HbA1c goals: age, duration of diabetes, presence of macrovascular or microvascular complications, and comorbidity (Figure 1). Depending on the combination of these factors, the algorithm generated one of three HbA1c goals: <48 mmol/mol (6.5%), <53 mmol/mol (7.0%), or <64 mmol/mol (8.0%). This operationalization was similar to that used in prior studies of National Health and Nutrition Examination Survey (NHANES) participants.[9, 17] Guidelines suggest[4, 8, 18] that in addition to patients for whom an HbA1c goal of <53 mmol/mol (7.0%) is appropriate, there are some patients for whom more stringent (HbA1c goal <48 mmol/mol [6.5%]) glycemic control is beneficial and some for whom less stringent (HbA1c goal <64 mmol/mol [8.0%]) glycemic control is more appropriate[4]. However, controversy exists regarding what patient factors might lead a clinician to assign an HbA1c goal <64 mmol/mol (8.0%), with some clinicians thinking this is appropriate for a greater percentage of patients than others. In order to accommodate this disagreement, we developed two algorithms, which, while both consistent with guideline proposals, would be expected to vary the percentage of patients for whom the less stringent goal would be assigned.

First, age was calculated as the age at the date of HbA1c measurement. Similar to prior work,[9] we considered age ≥ 75 years to represent advanced age for both algorithms, because of the declining expected benefits from tighter glycemic control in older patients.[6] Presence of advanced age led to an HbA1c goal <64 mmol/mol (8.0%).

Second, duration of diabetes was calculated as the date the diagnosis of diabetes was first assigned to the patient subtracted from the date of most recent HbA1c measurement. This approach results in a conservative estimate of duration of diabetes, because a patient may have joined the primary care network after having been previously diagnosed outside of our system, or may have been diagnosed with diabetes prior to the start of electronic data collection. The earliest recorded diabetes diagnosis date in our cohort was April 2, 1991. Based on characteristics of trial participants,[2, 3] a duration <5 years was considered a short duration[19] for both algorithms. A long duration of diabetes was considered either ≥ 15 years (targeted algorithm 1 - fewer patients assigned an HbA1c goal <64 mmol/mol [8.0%]) or ≥ 10 years (targeted algorithm 2 - more patients assigned an HbA1c goal <64 mmol/mol [8.0%]). A duration of <5 years was necessary, but not sufficient, to yield an HbA1c goal <48 mmol/mol (6.5%), while a 'long' duration would lead to an HbA1c goal of <64 mmol/mol (8.0%).

Third, macrovascular and advanced microvascular complications were determined using validated algorithms derived from electronic health record data (Supplemental Tables S1 & S2), and were treated the same way for both algorithms. Any macrovascular or advanced microvascular complication would lead to an HbA1c goal of <64 mmol/mol (8.0%). Macrovascular complications included diagnosis of coronary heart disease or cerebrovascular disease; advanced microvascular disease included Stage 5 chronic kidney disease (CKD-5, defined as an estimated glomerular filtration rate (eGFR) <15 ml/min on two occasions 90 days apart[20]). To calculate eGFR, creatinine values from the electronic health record were entered into the CKD-EPI equation.[21] We did not consider

macroalbuminuria without CKD-5, or earlier stages of chronic kidney disease, to represent an advanced microvascular complication because a clinician may still strive for tighter glycemic control in these patients in order to avoid the need for renal replacement therapy. Similarly, we did not consider diabetic neuropathy or retinopathy to be an indication for less stringent HbA1c goals because clinicians may continue aggressive glycemic control in order to prevent worsening of these conditions.

Finally, we used the Charlson score[22] as an index of comorbidity. For targeted algorithm 1, we used a cutpoint of 6 to indicate significant comorbidity, while in targeted algorithm 2, we used a cutpoint of 4. The presence of significant comorbidity generated an HbA1c goal of < 64 mmol/mol (8.0%), because a longitudinal study of patients with diabetes reported approximately 20% mortality over 3 years of follow up for patients with a Charlson score of 4, and approximately 40% mortality over 3 years of follow up for scores 6, indicating little expected benefit from stricter glycemic control.[23]

Demographic and Clinical Factors

Information regarding age, gender, self-reported race/ethnicity, insurance, whether a patient received primary care at a federally-qualified health center, spoken language preference, educational attainment (less than high school diploma vs. diploma or greater) as an indicator of socioeconomic status, and glucose-lowering medications prescribed from January 1, 2011 to December 31, 2011 was obtained from self-report patient registration data and an electronic central data repository at Partners Healthcare.[24]

Outcomes

Moving from a standard to an individualized approach would most significantly impact health care systems by reclassifying patients currently considered to have uncontrolled to controlled glycemia. Therefore, our primary outcome was the percentage of patients reclassified from uncontrolled to controlled hyperglycemia based on an HbA1c goal from either targeted algorithm, compared to the 'standard' goal of <53 mmol/mol (7.0%) for all patients. We also examined reclassification from controlled to uncontrolled hyperglycemia, and reclassified group demographics.

Statistical Analysis

Following the algorithms depicted in Figure 1, we assigned each patient individualized HbA1c goals. Next, we ascertained whether each patient would be considered controlled or uncontrolled based on the two targeted algorithms or the 'standard' <53 mmol/mol (7.0%) goal. We tested for agreement as to whether a patient's hyperglycemia was under control between the 'standard' and either targeted algorithm using McNemar's test. We then examined the effect of adopting the targeted algorithms from two perspectives: that of the health care system, and that of the patient. From the health care system perspective, we compared demographic, social, and clinical characteristics of patients considered controlled under the standard strategy and under the targeted strategies. We used logistic regression with generalized estimating equations (SAS PROC GENMOD) to account for repeated measures of patients considered controlled under both strategies. Finally, to examine reclassification from the patient's perspective, we used chi-squared tests to evaluate

differences between patients whose glycemic control status was reclassified by the targeted algorithms and those whose status was not reclassified.

Analyses were performed using SAS version 9.3 (Cary, NC).

Results

In our primary care network, there were 12,199 patients with diabetes during 2011 (Table 1).

Targeted algorithm 1 (duration of diabetes 15 years, Charlson 6), designed to assign fewer patients a goal of <64 mmol/mol (8.0%), assigned 23.8% of patients a goal HbA1c of <48 mmol/mol (6.5%), 29.7% a goal of <53 mmol/mol (7.0%), and 46.5% a goal of <64 mmol/mol (8.0%). Targeted algorithm 2 (duration of diabetes 10 years, Charlson 4), designed to assign more patients a goal of <64 mmol/mol (8.0%), assigned 17.7% of patients a goal HbA1c of <48 mmol/mol (6.5%), 14.4% a goal of <53 mmol/mol (7.0%), and 67.9% a goal of <64 mmol/mol (8.0%).

Overall, 55.7% of patients were considered controlled under the 'standard' approach, 61.2% were considered controlled under targeted algorithm 1, and 67.5% were considered controlled under targeted algorithm 2. Under targeted algorithm 1, 1,213, or 23.6%, patients considered uncontrolled under the 'standard' strategy were re-classified as being controlled, $p<0.0001$. Under targeted algorithm 2, 1,844, or 35.2%, patients considered uncontrolled under the 'standard' strategy were re-classified as being controlled, $p<0.0001$ (Tables 2a & 2b).

From the perspective of the health care system, the demographic, social, and clinical characteristics of the controlled population using the targeted algorithms was similar to that of the controlled population under the standard strategy (Tables 3a and 3b). There was no significant difference in the proportion of the controlled population who had Medicaid, less than high school diploma educational attainment, or received primary care in a federally qualified health center.

We then looked at the subsets of reclassification from the patient's perspective. Compared to patients considered controlled under both the standard and targeted approach ('not reclassified'), there was no significant difference in the proportion of patients considered uncontrolled under the 'standard' approach and controlled under a targeted algorithm goal ('reclassified') who were non-Hispanic Black (9.4% vs. 9.5% of total patients in 'reclassified' vs. 'not reclassified' groups, using targeted algorithm 2, $p=0.84$), Hispanic (9.2% vs. 10.0%, $p=0.30$), had Medicaid (10.1% vs. 9.7%, $p=0.59$), had no insurance (7.9% vs. 7.2%, $p=0.29$), had less than a high school education (17.0% vs. 16.6%, $p=0.66$), had a primary language other than English (17.9% vs. 16.6%, $p=0.66$), or received primary care in a federally qualified health center (5.9% vs. 5.9%, $p=0.99$). Results were similar using targeted algorithm 1 (data available upon request).

When looking at those whose status changed from in control under the standard approach to out of control under a targeted algorithm, results were similar. There was little difference in the proportion of those considered in control under the standard approach and out of control

under targeted algorithm 2 with regard to having less than a high school education (16.1% vs. 16.6%, $p=0.77$), being seen in a federally qualified health center (5.0% vs. 6.0%, $p=0.99$), having Medicaid (11.8% vs. 9.8%, $p=0.15$), or having no insurance (5.2% vs. 7.2%, $p=0.10$). In contrast, slightly more non-Hispanic Black (12.5% vs. 9.6%, $p=.044$) and Hispanic (16.3 vs. 10.1%, $p<.0001$) patients were reclassified from controlled to uncontrolled (i.e. now assigned a HbA1c goal of $<6.5\%$ [48 mmol/mol]), likely due to younger age at diagnosis (non-Hispanic Black mean age 60.8 years vs. 63.6 years for all other patients, $p<0.001$; Hispanic mean age 56.5 years vs. 64.2 years for all other patients, $p<0.001$) and less comorbidity (non-Hispanic Black mean Charlson score 3.9 vs. 4.5 for all other participants, $p<0.001$; Hispanic mean Charlson score 3.6 vs. 4.5 for all other participants, $p<0.001$).

Discussion

Using an automated health information process, we were able to assign individualized HbA1c targets consistent with guideline recommendations to a large population of diabetes patients within a health care system. Both targeted algorithms reclassified as “controlled” a substantial number of patients who would otherwise be classified as “uncontrolled” using a ‘standard’ strategy.

Making the final determination that a particular HbA1c goal is appropriate for a particular patient is an exercise in clinical judgment—the application of general medical principles to a specific case. Though the glycemic control goals generated by our algorithms represent good starting points, additional factors, such as the risk and riskiness of hypoglycemia, social circumstances, and patient preferences are also very important to consider.[4, 7] We explicitly chose not to include these factors in the algorithms as current electronic health records do not yet capture such information in sufficient detail to be useful to clinicians. In addition, treatment intensity is an important consideration. Because greater number of glycemic lowering medications may increase risk of side effects with diminishing impact on HbA1c lowering, clinicians could consider a less stringent goal for patients not controlled despite multiple medications[4]. Therefore, we believe that our algorithms, which yield a starting point that combines multiple sources of readily available patient data but leaves the final determination to the treating clinician, supports clinical decision-making, unlike the standard ‘one-size-fits-all’ approach.

We recognize that a $<6.5\%$ goal is controversial, and not applicable to patients with established comorbidities and polypharmacy, in light of evidence of harm in patients who achieved HbA1c $<6.5\%$ in the ACCORD trial in all pre-specified subgroups[1]. Some health care systems may wish to use $<7.0\%$ and $<8.0\%$ goals only. This can easily be accomplished using our algorithms by simply removing the criteria for the $<6.5\%$ goal and assigning those patients a goal of $<7.0\%$. However, the ADA and European Association for the Study of Diabetes[8], as well as the American Association of Clinical Endocrinologists[18] and many clinicians, do advocate a $<6.5\%$ goal for some patients on the basis reduced microvascular complications[25, 26]. Because of this, we have included this goal in our analysis. If using this goal, clinicians should pay careful attention to the chance for benefit and the risk for harms. For example, if the target can be achieved using

benefit for less stringent targets, our strategy is consistent with the best currently available clinical evidence. Secondly, we have focused here on glycemic control, which may be less important overall to major clinical outcomes in diabetes patients than blood pressure or cholesterol control.[28] However, since goals for these parameters are less controversial and less in need of individualization than those for glycemic control,[4] creating a system which produces HbA1c goals better fit to a patient's clinical circumstances may free up a clinician to focus on blood pressure or cholesterol control, rather than pursuing a lower HbA1c level unlikely to result in patient benefit. The patients included in this study come from a single urban health care delivery system and may not be generalizable to all settings. However, this system does include a diverse set of practice sites including federally qualified health centers, a large academic teaching practice, and several community practice sites. Next, our algorithms rely on data from an electronic health record repository. Current medication regimen was not available. Additionally, despite using a validated algorithm[15] incorporating both billing and clinic data, inaccuracies in these data may lead to an inaccurate estimation of the Charlson score. Finally, our method of determining duration of diabetes calculates known duration of diabetes, and can underestimate the true duration of diabetes when patients who already have diabetes enter the primary healthcare network. This shorter estimated duration could increase the number of patients assigned lower HbA1c goals, such as <48 mmol/mol (6.5%). Clinicians should be aware of this limitation, and, as noted above, clinicians should ensure that patients assigned stringent targets are likely to benefit from these HbA1c goals, especially if they cannot be achieved without significant side effects [8]. We also recommend routine collection of duration of diabetes for entry into the electronic health record, as this is an important consideration in setting glycemic goals.

In conclusion, we applied evidence-based glycemic goal individualization algorithms to diabetes patients within a large primary care network. If applied, this would result in reclassifying one quarter to one third of patients from uncontrolled to controlled, but without adversely reclassifying vulnerable subgroups. Future research should focus on testing these individualized goals in order to determine their efficacy, safety, and efficiency in guiding population management of diabetes patients.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

SAB and DJW designed the study and co-authored the manuscript. SAB analyzed the data. RWG and SJA substantially contributed to the design of the study and revised the manuscript for critical intellectual content.

Seth A. Berkowitz had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. He will serve as the guarantor.

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Novelty Statement

- Individualizing glycemic control goals will require the ability to automate target assignment
- The implications of individualization on vulnerable populations are unknown
- We introduce a novel automated glycemic goal individualization process that would:
 - Allow for reclassification of patients across health care systems
 - Reflect the current state of the science regarding uncertainty of optimal glycemic control targets
 - Allow for local customization
 - Not adversely affect vulnerable subgroups

HbA1c goals assigned under targeted algorithm 1

Goal	Patient Characteristics
<48 mmol/mol (6.5%)	Age ≤ 75 and duration < 5 years and Charlson < 6 and no complications (CHD, CVD, or CKD5)
<53 mmol/mol (7.0%)	Age ≤ 75 and duration between 5 and 15 years and Charlson < 6 and no complications (CHD, CVD, or CKD5)
<64 mmol/mol (8.0%)	Age > 75 or Duration ≥ 15 years or Charlson ≥ 6 or presence of a complication (CHD, CVD, and/or CKD5)

CHD = Coronary Heart Disease

CVD = Cerebrovascular Disease

CKD-5 = Chronic Kidney Disease, Stage 5

HbA1c goals assigned under targeted algorithm 2

Goal	Patient Characteristics
<48 mmol/mol (6.5%)	Age ≤ 75 and duration < 5 years and Charlson < 4 and no complications (CHD, CVA, or CKD5)
<53 mmol/mol (7.0%)	Age ≤ 75 and duration between 5 and 10 years and Charlson < 4 and no complications (CHD, CVA, or CKD5)
<64 mmol/mol (8.0%)	Age > 75 or Duration ≥ 10 years or Charlson ≥ 4 or presence of a complication (CHD, CVA, and/or CKD5)

Figure 1. Targeted Hemoglobin A1c goal assignment algorithm

Table 1
Demographics and criteria for reclassifying HbA1c targets

Characteristic	% or Median (IQR) N=12,199
Age (y)	64 (54 – 73)
% >75 years old	22.1
Female	47.4
Race/Ethnicity	
White	68.7
Black	10.3
Hispanic	12.3
Other/Multi	8.7
Insurance	
Private	46.5
Medicare	32.2
Medicaid	12.0
None	9.3
<HS Diploma	17.5
Non-English Primary Language	19.9
Received Primary Care in Federally Qualified Health Center	6.1
Charlson Score	4 (2 – 6)
% 4	51.1
% 6	27.6
Duration of Diabetes (y)	6.0 (3 – 10)
% < 5 years	37.5
% 5-10 years	37.2
% 10 years	25.3
% 5-15 years	62.3
% 15 years	0.3
Presence of Diabetes Complication	26.1
Coronary Heart Disease	20.3
Cerebrovascular Disease	9.1
Chronic Kidney Disease-Stage 5	1.8
Prescribed Insulin	42.2
Prescribed SFU	40.8

SFU = sulfonylurea

Table 2a
Reclassification of glycemic control using standard approach vs. targeted algorithm 1

		Tailored HbA1c Target			p-value
		Controlledn (%)	Uncontrolledn (%)	Total	<.0001
Standard HbA1c Target	Controlled	5928 (50.8)	604 (5.2)	6532 (56.0)	
	Uncontrolled	1213 (10.4)	3922 (33.6)	5135 (44.4)	
	Total	7141 (61.2)	4526 (38.8)	11667 (100)	

532 patients missing data to calculate Charlson score excluded (4% of total)

Table 2b
Reclassification of glycemic control using standard approach vs. targeted algorithm 2

		Tailored HbA1c Target		Total	p-value
		Controlledn(%)	Uncontrolledn(%)		
Standard HbA1c Target	Controlled	6130 (51.9)	447 (3.8)	6577 (55.7)	
	Uncontrolled	1844 (15.6)	3394 (28.7)	5238 (44.3)	
	Total	7974 (67.5)	3841 (32.5)	12072 (100)	

384 patients missing data to calculate Charlson score excluded (3% of total)

Table 3a
Characteristics of patients considered controlled under targeted algorithm 1

Characteristic	Controlled under Standard Strategy(%) N=6,532	Controlled under Targeted Algorithm 1(%) N=7,141	p-value
Female	48.0	46.9	0.37
Race/Ethnicity			
White	71.5	73.7	<.001
Black	9.8	9.3	0.10
Hispanic	10.6	9.5	0.005
Other/Multi	8.2	7.5	<.001
Insurance			
Private	42.9	38.4	<.001
Medicare	35.6	39.8	<.001
Medicaid	9.9	9.6	0.15
None	7.0	7.2	0.01
<HS Diploma	16.6	16.9	0.12
Non-English Primary Language	15.8	15.3	<.001
Received Primary Care in Health Center	27.7	26.8	0.24
Using Insulin	28.9	35.6	<.001
Using SFU	30.7	35.6	<.001

Table 3b
Characteristics of patients considered controlled under targeted algorithm 2

Characteristic	Controlled under Standard Strategy(%) N=6,532	Controlled under Targeted Algorithm 2(%) N=7,974	p-value
Female	48.0	47.1	0.27
Race/Ethnicity			
White	71.5	73.1	<.001
Black	9.8	9.5	0.11
Hispanic	10.6	9.9	0.01
Other/Multi	8.2	7.5	<.001
Insurance			
Private	42.9	40.1	<.001
Medicare	35.6	37.5	<.001
Medicaid	9.9	9.8	0.52
None	7.0	7.4	0.04
<HS Diploma	16.6	16.7	0.33
Non-English Primary Language	15.8	16.3	<.001
Received Primary Care in Health Center	27.7	27.0	0.33
Using Insulin	28.9	36.6	<.001
Using SFU	30.7	36.7	<.001