Is Patient Readiness to Change a Predictor of Improved Glycemic Control?

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OBJECTIVE — To test the hypothesis that patient readiness to change (RTC) predicts future changes in glycemic control in adults with diabetes.

RESEARCH DESIGN AND METHODS — We linked survey data with HbA_{1c} data for a stratified random sample of consenting adults with diabetes. Change in HbA_{1c} from baseline to the 1-year follow-up was computed and used as a dependent variable. Linear regression models assessed RTC and other patient variables as predictors of HbA_{1c} change.

RESULTS — Among 617 patients with baseline $HbA_{1c} \geq 7\%$ and complete data for analysis, RTC predicted subsequent improvement in HbA_{1c} for those with higher physical functioning (interaction $t = -2.45$, $P < 0.05$). Other factors that predicted HbA_{1c} improvement in multivariate linear regression models included higher self-reported medication adherence ($t = -4.41$, $P < 0.01$), higher baseline HbA_{1c} ($t = -15.08$, $P < 0.01$), and older age ($t = -2.61$, $P < 0.01$).

CONCLUSIONS — Diabetes RTC independently predicts change in HbA_{1c} for patients with high but not for patients with low functional health status. Customized use of RTC assessment may have potential to improve care.

Diabetes Care 27:2325–2329, 2004

The large gap between recommended levels of diabetes care and levels actually achieved in primary care or subspecialty practice is well recognized (1). Recent studies suggest that patient education and activation may be an especially important factor related to the control of glucose in those with diabetes. For example, improvement initiatives that include a patient-activation component are generally more effective than those that do not (2).

A patient's "readiness to change" (RTC) diabetes care provides a potentially useful metric of patient activation (3–7). RTC, which can be assessed by two brief questions, may indicate whether a patient is actively planning to make behavioral changes to improve their diabetes care. Behaviors related to medication adherence, nutrition therapy, physical activity, and home glucose monitoring are strongly related to the state of glycemic control in patients with diabetes. Moreover, a patient who is ready to change may be an ideal candidate for intensification of diabetes therapy.

Thus, if RTC is a valid predictor of improved glycemic control, its wider use in clinical practice could provide information useful to clinicians at the time of a diabetes office visit. This work tests the hypothesis that patient RTC is a significant predictor of subsequent change in glycemic control, measured by change in HbA_{1c} over time. The relationship of RTC to adherence to therapy and treatment intensification is also assessed.

RESEARCH DESIGN AND METHODS

— This report is based on data from a prospective cohort study, Project QUEST, designed to identify patient, physician, and other factors that predict quality of care provided to adults with diabetes or heart disease. This work focuses on patient-related factors that predict subsequent change in HbA_{1c} level in adults with diabetes.

To be included in this analysis, potential study subjects had to be enrolled in HealthPartners, a Minnesota health plan, and have an established diagnosis of diabetes in 1998 based on meeting at least one of the following two criteria: *1*) have one or more inpatient or two or more outpatient ICD-9 (*International Classification of Diseases*) diagnostic codes 250.xx for diabetes or *2*) have a filled prescription for a diabetes-specific drug, including insulins, sulfonylureas, biguanides, α-glucosidase inhibitors, thiazolidinediones, or meglitamides. This method of diabetes identification has been previously validated in the study population and has an estimated sensitivity of 0.91, a specificity of 0.99, and a positive predictive value of 0.94 (8).

In addition, study subjects had to meet all the following eligibility criteria: *1*) have health care insurance through HealthPartners in 1998, *2*) be at least 19 years old in 1998, *3*) receive care from a clinic that had a minimum of 10 HealthPartners-insured diabetic patients per primary care provider in 1998, and *4*) receive care from a clinic and medical group whose leaders were willing to participate in the study. We sought to recruit patients from 21 medical groups; 18 of these participated in the study. These 18 medical groups had 84 eligible clinics; 83 of these participated in the study. Because all study subjects had similar health insurance coverage, all had access to diabetes education, endocrinology referrals, and other diabetes-related services. We then randomly selected a sample of 10 adults with diabetes per primary care provider at each clinic. The complex sam-

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Received for publication 5 January 2004 and accepted in revised form 10 July 2004.
Abbreviations: RTC, readiness to change.
A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

pling strategy was designed to power the study to identify organizational characteristics of clinics and medical groups that may affect quality of care.

Following identification of subjects, a patient survey was sent to 4,780 adults with diabetes and returned by 2,832, for a response rate of 59.2%. To further screen out case subjects without diabetes, 83 patients who responded "no" to the baseline patient survey item "Has a doctor ever told you that you had diabetes?" were excluded from the study. Of the 2,749 survey respondents who reported having diabetes, 2,056 (74.8%) gave written informed consent for a medical record review, which was completed for 2,016 (98.1%). This report is based on the 1,794 adults with diabetes who had a medical record review and an HbA_{1c} measure in the baseline year. Predictive analyses were further limited to 746 of these patients who had a baseline $HbA_{1c} \geq 7\%$, which is above the currently recommended level of glycemic control (9,10), and who had HbA_{1c} measures available at both baseline and follow-up as well as the RTC measure.

Variable definition and measurement

Administrative data on health plan members was initially gathered to determine eligibility for the study. Information collected for this purpose included medical group and clinic membership, ICD-9 codes, CPT-4 (*Current Procedural Terminology*, Edition 4) codes, and pharmacy data.

Patients were surveyed in 2001 to obtain data on duration of diabetes, RTC for diabetes care, indicators of microvascular (numbness/tingling in feet or hands, foot ulcers/infections, retinopathy) and macrovascular (heart trouble, heart attack, stroke) complications, self-reported medication changes for diabetes in the past 12 months, perception of whether diabetes has been in good control for >6 months, self-reported medication adherence, belief that following the doctor's orders will help delay future problems, SF-12 physical function and mental function measures, height, weight, employment status, education level, and other information. Whenever possible, items and scales used were drawn from validated scales or from previously published studies (11–13). Medication adherence was assessed based on the response to a survey question: "In the past week how often have you not taken your medications as prescribed?" Those reporting not taking medications as directed once a week or more often were classified as having low adherence.

Patients were assigned to an RTC category on the basis of their responses to two items used in previous studies: "I am intending to make changes in my diabetes self-care in the (next 6 months)/(next month)" (14,15). Precontemplators were defined as those not intending to make changes in the next 6 months or in the next month. Contemplators were defined as those who intended to make changes in the next 6 months but not in the next month. Preparers were defined as those who intended to make changes in the next month. Due to the small percentage of patients in the contemplation stage (5.6%), individuals in this stage were combined with those in the preparation stage for all analyses. Thus, a single dummy code for stage of change used in the regression analyses contrasted patients in the contemplation and preparation stages with those in the precontemplation stage. The analysis was limited to the three stages of change relevant to patients with $HbA_{1c} \geq 7\%$.

HbA_{1c} levels done in the 12-month period before and the 12-month period after the patient survey were obtained from chart audits. When more than one HbA_{1c} measurement was available in a particular 12-month chart period, the HbA_{1c} test value closest to the end of the 12-month period was identified and used in the analysis. Although laboratories used by various clinics may have slightly different scales for HbA_{1c} assays, the normal range of HbA_{1c} was uniformly from a lower bound of 4.4 to 4.6% to an upper bound of 6.0 to 6.1%. We monitored laboratory arrangements of study clinics and did not identify any changes in laboratory assay for HbA_{1c} during the period of data collection. Although more formal standardization of HbA_{1c} could be done, the HbA_{1c} values reported here are those used to guide diabetes care in the community. The dependent variable used in the analysis consists of the difference score of HbA_{1c} level taken in the year after the survey minus the level in the year before the survey, so that in multivariate models a negative score represents an improvement in glycemic control over time.

Statistical analysis

Frequencies and χ^2 tests were used to describe sample attributes and to compare individuals with HbA_{1c} values <7% and those with values ≥7% as well as to compare individuals by RTC category. Ordinary least-squares methods were used throughout this work rather than a multilevel/nested approach due to the findings in previous work on this sample that clinic and medical group levels accounted for a negligible fraction of variance in HbA_{1c} change over time. Paired *t* tests were used to compare HbA_{1c} at baseline and follow-up for the entire sample of diabetic patients and for those with HbA_{1c} at baseline ≥7%.

To test the hypothesis that RTC category predicts HbA_{1c} change, a series of ordinary least-squares multiple linear regression equations was estimated. All equations included an a priori set of control variables that consisted of sex, age, education (college graduate or not), and duration of diabetes.

Multivariate models included predictor variables that showed empirical evidence of zero order correlation with change in HbA_{1c} at an $\alpha < 0.10$. These predictors included patient report of whether diabetes has been in good control in the past 6 months, self-reported medication compliance, and patient belief that following a doctor's advice will delay future problems. Other predictors evaluated included those considered to have theoretical importance, including presence of microvascular or macrovascular problems, patient-reported changes to diabetes medication in the past 12 months, patient-reported visits with a diabetes educator, satisfaction with medical care, trust of doctor, and mental and physical function scores from the SF-12.

The model-building strategy involved testing the predictive value of the dummy code for RTC in models containing one or more of the sets of predictors previously identified (a priori covariates, empirically promising, theoretically important). A priori covariates were included in all models. Items from the two other sets of predictors having at least marginally significant ($P < 0.10$) model parameters in the initial analysis were retained for entry into the final model. In order to test for potential moderators of the effect of RTC category on HbA_{1c} change, all predictors were individually entered in equations along with the a priori covariates, the

Table 1—*Characteristics of audited sample by HbA_{1c} level measured in the year of the baseline patient survey and by stage of change*

	All patients	Patients with baseline HbA_{1c} <7%	Patients with baseline HbA_{1c} ≥7%	Patients with HbA_{1c} ≥7% and in precontemplation	Patients with HbA_{1c} ≥7% and in contemplation or preparation
n	1,794	811	983	430	451
Women (%)	47.6	46.2	48.7	38.1*	56.3*
Age (years)	61.8 ± 13.0	62.3 ± 12.8	61.3 ± 13.1	64.7 ± 12.0*	56.8 ± 12.3*
Age <40 years (%)	4.7	4.0	5.3	1.9*	8.7*
Age >65 years (%)	41.3	43.3	39.7	48.1*	26.8*
College graduate (%)	28.3	30.2	26.7	25.7	28.6
Duration of diabetes (years)	10.4 ± 10.1	8.3 ± 9.2*	12.2 ± 10.4*	13.2 ± 10.8*	11.3 ± 9.7*
CHD per administrative data and self-report (%)	21.7	22.9	20.8	21.4	18.4
Employed full time (%)	40.6	38.7	42.2	34.8*	52.5*
Live alone (%)	18.4	18.3	18.5	18.0	18.0
BMI (kg/m^2)	31.2 ± 6.6	31.4 ± 6.6	31.1 ± 6.6	29.8 ± 6.0*	32.4 ± 7.0*
Diabetes in good control for >6 months, self-report (%)	75.0	90.1*	62.3*	82.2*	43.9*
Precontemplation (%)	57.5	67.9*	48.8*	—	—
Contemplation or preparation (%)	42.5	32.1*	51.2*	—	—
Baseline HbA_{1c} (%)	7.33 ± 1.44	6.18 ± 0.55*	8.28 ± 1.24*	8.01 ± 1.09*	8.52 ± 1.30*

Data are means ± SD, unless noted otherwise. *$P < 0.01$. CHD, coronary heart disease.

stage of change dummy code, and the two-way interaction of the predictor and the dummy code. Significant interactions from these single interaction term models were retained for entry into the final model.

The final model was first estimated with the set of a priori covariates, significant or marginally significant empirical and theoretical predictors, significant interaction terms, and the constituent items of these interaction terms. For the last estimation of the final model, the a priori covariates were retained as well as the dummy code for RTC category and all terms that were statistically significant from the initial estimation of this model.

Human subjects protection

The study protocol was reviewed in advance, approved, and monitored by the HealthPartners Institutional Review Board.

RESULTS — Some small but statistically significant differences exist by survey responder status among the 4,780 case subjects identified by administrative data as having diabetes. Survey responders were more likely than nonresponders to have heart disease according to administrative data (23.0 vs. 18.7%, $P = 0.0004$), to be women (47.9 vs. 43.9%, $P = 0.006$), and to be older (mean age 61.2 vs. 57.0 years, $P < 0.0001$). No other comparisons were made because additional data elements were not available from nonresponders.

Few differences were found by chart audit consent status among the 2,749 individuals who completed a survey and self-reported having diabetes. Individuals who consented to chart audits ($n = 2056$) and those who did not ($n = 693$) showed no differences in sex, living situation, education level, full-time work status, heart disease status, duration of diabetes, self-report of out of control diabetes, or stage of change. However, those who consented to a chart audit were older than those who did not consent (61.4 vs. 60.2 years, $P = 0.03$).

Some differences were found by baseline HbA_{1c} level. Individuals with HbA_{1c} ≥7% are more likely than those with HbA_{1c} <7% to have a longer duration of diabetes, are less likely to say their diabetes has been in good control for >6 months, and are more likely to be in the contemplation or preparation stage.

Characteristics of study participants by RTC category are shown in Table 1 for patients with HbA_{1c} ≥7%. Note that of 983 subjects with HbA_{1c} ≥7%, RTC category is classified for 881 with available data for RTC classification. When restricting the sample to just those patients with HbA_{1c} ≥7% in the baseline year of the study, differences by stage of change are numerous. Those in the contemplation or preparation stage are more likely than those in precontemplation to be women, younger, employed full-time, to have a shorter duration of diabetes, and higher BMI. Among those with HbA_{1c} ≥7%, 82.2% of precontemplators compared with 43.9% of contemplator/preparation patients reported that their diabetes is already in good control.

Among patients with a baseline HbA_{1c} ≥7%, mean HbA_{1c} was 8.23 ± 1.19% (±SD) at baseline and 7.86 ± 1.23% at follow-up. The mean change of −0.37% was statistically significant ($t_{829} = -8.79$, $P < 0.0001$).

When considering the entire sample of adults with diabetes and HbA_{1c} ≥7%, RTC was not a statistically significant predictor of change in HbA_{1c}. Specifically, RTC did not predict change in HbA_{1c} in preliminary regression models when entered along with a priori covariates (RTC $\beta = -0.012$, $P = 0.89$), with a priori and empirical covariates ($\beta = -0.027$, $P = 0.77$), or a priori and theoretical covariates ($\beta = -0.045$, $P = 0.65$). However, a significant interaction term in the final multiple regression model (described below) indicates that RTC relates signifi-

Table 2—*Final multiple linear regression analysis predicting change in HbA_{1c} for those (n = 677) with baseline HbA_{1c} ≥7% and at least one HbA_{1c} value available in the 12-month follow-up period: the variable coefficients, their standard error (SE), and the associated t test value and its statistical significance are shown*

	β	SE (β)	*t*
Sex (female)*	−0.147	0.087	−1.69
Age (years)	−0.010	0.004	−2.61†
College graduate*	−0.166	0.095	−1.75
Duration of diabetes (years)	0.002	0.004	0.50
Baseline HbA_{1c} value	−0.533	0.035	−15.08†
Compliant with medications*	−0.492	0.112	−4.41†
RTC‡	0.764	0.329	2.32§
SF-12 physical score	0.011	0.005	2.05§
RTC‡ × SF-12 physical score	−0.018	0.007	−2.45§

Details on model construction are provided in the text. Negative regression coefficients indicate a reduction in HbA_{1c}. *Variable coding: 0 = no, 1 = yes. †$P < 0.01$. ‡Variable coding: 0 = precontemplation, 1 = contemplation or preparation, $n = 617$, $F(9, 607) = 27.8$, $P < 0.0001$, $R^2 = 0.29$. §$P < 0.05$.

cantly to reduction in HbA_{1c}, but only for the subset of individuals with higher physical functioning at baseline.

The final multiple regression model incorporating a priori covariates is shown in Table 2 for adults with diabetes and baseline HbA_{1c} ≥7%. Negative model parameters indicate a reduction in HbA_{1c} from baseline to follow-up and improved glycemic control. Significant improvement in HbA_{1c} was found for individuals with higher HbA_{1c} at baseline, those who were older, and those who took medications as prescribed.

The significant effect for RTC must be interpreted in light of the significant interaction of RTC and SF-12 physical score. Figure 1 illustrates the form of this interaction in the prediction of HbA_{1c} improvement. For individuals with poorer health (SF-12 score <45, which is the 50th percentile of this distribution), RTC does not significantly predict improvement in HbA_{1c} ($\beta = 0.249$, $P = 0.07$). However, for individuals with higher physical functioning scores (SF score of ≥45), higher RTC significantly predicted improvement in HbA_{1c} ($\beta = -0.245$, $P = 0.046$).

CONCLUSIONS — Results indicate that RTC is a significant predictor of future HbA_{1c} change in those with HbA_{1c} ≥7% with high functional status at baseline. In these patients, assessing RTC using the question "Are you considering making changes in your diabetes self-care in the next 6 months" may be a good indicator of future improvement in HbA_{1c}. The fact that adherence to medication is an independent predictor of change in HbA_{1c} suggests that RTC and adherence may be complementary but distinct domains (16–20).

In an earlier study, Peterson et al. (15) found RTC to be strongly predictive of HbA_{1c} change in all diabetic patients. However, the earlier study included few study subjects, and multivariate covariate adjustment was precluded by the small sample size. Also, the functional health status of the patients in the Peterson study was not specified.

Our results partially support the hypothesis that RTC carries significant predictive information and can be used to maximize the effectiveness and efficiency of diabetes care delivered in office practice (18,21–23). Our data also suggest that RTC exerts effects beyond what may be mediated by adherence to medications, beliefs about diabetes, or even intensification of diabetes therapy, factors shown in previous reports to predict future changes in HbA_{1c} (24–26).

The factors that influence RTC, and its variation over time, are a topic of intensive research across a wide range of behavioral domains, many of them closely related to preventive care or health-related behaviors. A number of studies suggest that RTC for diabetes care and other behavioral domains is complexly determined by the balance of barriers and facilitators, some amenable to personal control, others environmentally determined (13,27,28). Moreover, there is evidence that diabetes care is a complex adaptive system in which both patient mental model and patient RTC evolve over time (13,27–29). For this reason, ongoing assessment of RTC and other patient-specific variables is important.

A number of factors limit the interpretation of our results. First, the analysis was limited to those with HbA_{1c} ≥7% and some of the observed improvement may have been related to regression to the mean. However, we have included baseline HbA_{1c} in the analysis to control for regression to the mean. Second, the data are inherently clustered at the physician and clinic level. However, other analyses suggest that the intraclass correlation coefficients related to the clustering are small, and thus we present results using standard multivariate methods. Third, some experts contend that RTC should be

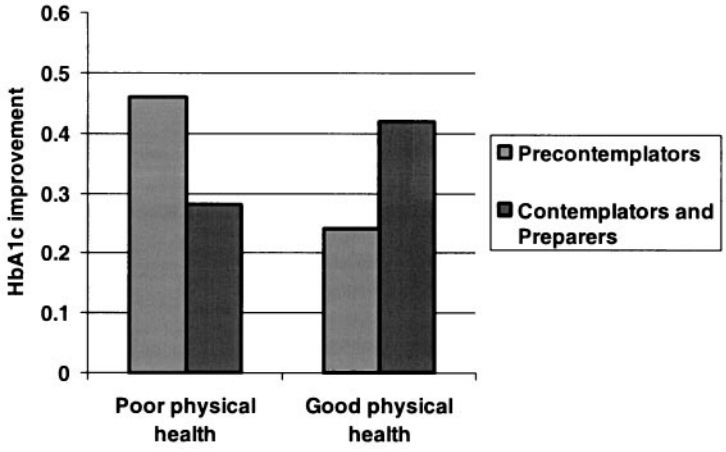

Figure 1—*Predicted improvement in HbA_{1c} by RTC and SF-12 physical score. Predicted values were evaluated at mean values for continuous predictors, modes for categorical predictors, and the 25th (poor health) and 75th (good health) percentiles on the SF-12 score.*

applied only to specific behaviors, such as smoking or exercise, and is not well suited for application to more complex patterns of behavior. Finally, there are limits on generalizability of results based on the design of the study and the community in which it was conducted.

Nonetheless, the results we observed are both interesting and important and have clinical implications that extend to the heart of how diabetes care is conceptualized and delivered.

Based on these data, we conclude that RTC and other factors, such as medication adherence, which are related to a patient mental model of diabetes, may act as important facilitators or barriers to improved diabetes care.

Acknowledgments— This research was supported by grant RO1 HS09946 from the U.S. Agency for Healthcare Research and Quality.

The authors thank the leaders of the 19 Minnesota medical groups who voluntarily participated in Project QUEST, motivated by the desire to improve the care they provide to their patients with diabetes.

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