“Act on Threes” Paradigm for Treatment Intensification of Type 2 Diabetes in Managed Care: Results of a Randomized Controlled Study with an Educational Intervention Targeting Improved Glycemic Control

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ABSTRACT

BACKGROUND: Clinical inertia, which has been defined as the recognition of a problem with a patient's management but failing to act, is a concern in type 2 diabetes (T2D) because it places the patient at risk of diabetes-related complications. Despite managed care organizations making significant investment in this area, little is known about the impact of educational programs aimed at aligning patients and their physicians with diabetes guidelines and thus overcoming clinical inertia.

OBJECTIVE: To assess the impact of an educational intervention specifically designed to align patients and their physicians with 2012 American Diabetes Association (ADA) guidelines on glycated hemoglobin (A1c) testing frequency and insulin initiation.

METHODS: The “Act on Threes” educational intervention was a 12-month, randomized controlled prospective study that included Medicare Advantage patients aged 18-85 years with T2D, who received ≥ 3 oral antidiabetes drugs (OADs) and/or had A1c not at goal and/or had no recent A1c evaluation over 12 months, as identified through the analysis of administrative claims data (May 1, 2011-April 30, 2013) from the Humana database. Identified patients were randomized 3:1 to receive the Act on Threes educational intervention in conjunction with standard care (intervention group) or standard care alone (control group). For the educational intervention, patients and physicians were simultaneously mailed general and targeted information aimed at aligning them to 3 vital aspects of A1c control: timely measurement of A1c every 3 months; timely treatment intensification to meet A1c goals with treatment intensification every 3 months if A1c is not at goal; and insulin initiation when appropriate, including patients receiving ≥ 3 OADs with A1c not at goal. Control patients were only enrolled if the treating physician was not involved in the care of any patients in the intervention group. The primary outcome measures were A1c testing frequency based on the ADA standard for compliance of ≥ 2 tests per year and insulin initiation in the 12-month postintervention period. A1c levels were evaluated for the subgroup of patients with available A1c measurements in the pre- and postintervention periods. Descriptive statistics were used to analyze differences between the intervention and control groups. Multiple logistic regression analysis was used to identify determinants of insulin initiation in the full study cohort.

RESULTS: 6,243 patients (mean age 70 years; 43.5% female) were identified; 4,555 were randomized to the intervention group and 1,688 to the control group. The percentage of patients with ≥ 2 A1c tests per year was not significantly different postintervention for patients in the intervention and control groups (47.7% vs. 46.8%, respectively; $P=0.995$). Intriguingly, the frequency of A1c testing increased significantly from pre- to postintervention in the intervention and control groups. Change in A1c level from pre- to postintervention was also similar for the 2 groups ($P=0.240$). A similar percentage of patients in the intervention and control groups initiated insulin during the postintervention period (6.3% vs. 7.6%, respectively; $P=0.059$).

CONCLUSIONS: This randomized controlled study demonstrated that, compared with standard care, the Act on Threes educational intervention combined with standard care did not result in any significant differences in the frequency of A1c testing or in the initiation of insulin in patients with T2D. These findings are in contrast to uncontrolled comparative studies showing significant improvements in outcomes postintervention and reinforce the importance of study design in evaluating the effectiveness of educational programs.

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What is already known about this subject

- A low proportion of patients with type 2 diabetes (T2D) experience care that aligns with the American Diabetes Association (ADA) position statement regarding glycated hemoglobin (A1c) testing frequency; the average patient has an A1c level $>7.0\%$ for approximately 10 years and $>8.0\%$ for approximately 5 years before insulin initiation.
- Positive effects on diabetes-related outcomes have been reported from studies that evaluated interventions aimed at improving diabetes management delivered in the form of educational mail-outs that targeted patients and physicians.
- The majority of intervention studies used a pre- versus postintervention comparison without the inclusion of control groups.

What this study adds

- This randomized controlled study showed that, compared with standard care, an educational intervention program such as “Act on Threes” did not result in a significant difference in treatment intensification with insulin and glycemic control in high-risk patients with T2D, despite an increase in A1c testing frequency in both cohorts during the study period.
- An intervention that would increase awareness among physicians and patients of the long-term outcomes of an A1c level $>8.0\%$ and delayed insulin initiation may be better able to help overcome clinical inertia and promote insulin initiation in alignment with the current ADA recommendations.

What this study adds (*continued*)

- The lack of effect of the Act on Threes educational intervention challenges the validity of other studies of educational interventions that have shown significant changes in diabetes-related outcomes based on a pre- to postintervention design without the use of appropriate control groups.

Optimal glycemic control is critical in order to reduce the risk of diabetes-related morbidity and complications, as well as to reduce medical costs and health care utilization. However, optimal management of patients with type 2 diabetes (T2D) is a significant clinical challenge for any general practitioner or specialist physician.^{1,2} Despite extensive research demonstrating the clinical benefits of glycemic control—and, notably, the benefits of early insulin initiation^{3,4}—at least 60% of U.S. patients with T2D enrolled in commercial or Medicaid health maintenance organization plans who are appropriate candidates for stringent glycated hemoglobin (A1c) goals fail to attain the American Diabetes Association (ADA) recommended A1c goal of 7.0% or less.^{1,5,6} Even considering the recent emphasis of the ADA on patient-centered care and the appropriateness of less stringent A1c targets such as in older patients with comorbidities, an estimated 54.5% of Medicaid patients, 41.1% of patients on a commercial insurance plan, and 34.5% of Medicare patients fail to achieve an A1c goal of 8.0% or less.^{5,6}

For patients with good glycemic control and who meet treatment goals, A1c testing is recommended twice a year, with quarterly testing for those not at goal and whose therapy has changed.⁷ Yet, in a large U.S. cohort of adult patients with T2D, just 7% were adherent for 1 year to ADA guidelines for A1c testing frequency, and therapy was modified in accordance with guidelines in just 39%.⁸ Another study indicated that from T2D diagnosis, the average patient spent approximately 10 years with an A1c level >7.0% and approximately 5 years with an A1c level >8.0% before initiating insulin.⁹

Patient and physician concerns, particularly in relation to insulin initiation, contribute to delays in treatment intensification in patients with T2D¹⁰; this clinical inertia may put patients at risk of diabetes-related complications.^{1,2} Managed care organizations and the pharmaceutical industry invest heavily in physician- and patient-targeted educational outreach programs to overcome clinical inertia and patients' reluctance to initiate insulin, but little is currently known about the impact of such programs. Positive results from studies that have evaluated pre-versus postintervention outcomes of educational initiatives that targeted patients and physicians via mail-outs have encouraged similar interventions in managed care. However, these studies did not employ a randomized controlled study design to evaluate

the impact on outcomes in those exposed versus those not exposed to the interventions.^{11,12}

The objective of the "Act on Threes" educational intervention was to align patients with T2D and their physicians with the 2012 ADA position statement on T2D management⁵ and to assess 3 vital aspects of A1c control: the timely measurement of A1c levels every 3 months; timely treatment intensification to meet A1c goals, with treatment intensified every 3 months if A1c is not at goal; and insulin initiation when appropriate, including in patients already receiving ≥ 3 oral antidiabetes drugs (OADs) with A1c not at goal. Unlike previous studies, the Act on Threes intervention used a rigorous, randomized design with the objective of evaluating the impact of the educational intervention on A1c testing frequency and insulin initiation in patients with T2D who had not received A1c testing or had suboptimal control of their A1c ($\geq 8.0\%$) according to the 2012 ADA position statement.⁵ The secondary objective was to identify factors that predict insulin initiation in patients with T2D enrolled in the study.

Methods

Study Design

This was a 12-month, prospective, randomized, and interventional study of adult patients with T2D that evaluated the effects of the Act on Threes educational intervention on A1c testing frequency and insulin initiation through the analysis of administrative claims data from the Humana database. Humana is a for-profit health insurance company with more than 13 million U.S.-based customers. Following retrospective identification of patients with high-risk status using medical, pharmacy, laboratory, and enrollment indices of A1c screening frequency; number of noninsulin antihyperglycemic medications; and/or A1c test results as per ADA criteria for A1c testing frequency and antidiabetic treatment modifications⁸ (identification period May 1, 2011–April 30, 2013), patients were randomized 3:1 to receive either the Act on Threes educational intervention in conjunction with standard care (intervention group) or standard care alone (control group; Figure 1). Controls were eligible only if the treating physician was a different physician from that of any intervention patient. The full study period included a 12-month pre-intervention (baseline) period and a 12-month postintervention (follow-up) period, with the index date being the date of the most recent diagnosis of T2D during the identification period.

Patients and Physicians

High-risk Medicare Advantage with prescription drug coverage (MAPD) members were eligible if they were aged 18–85 years with ≥ 1 inpatient or 2 physician visits dated ≥ 30 days apart with a primary or secondary diagnosis of T2D using *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) codes 250.x0 or 250.x2. Patients were

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FIGURE 1 Patient Selection and Cohort Attrition in Humana MAPD Dataset

^aIneligible or unreachable based on provider feedback and returned mailings.

A1c = glycated hemoglobin; MAPD = Medicare Advantage Plan D; T2D = type 2 diabetes.

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TABLE 1 Patient Demographic and Baseline Clinical Characteristics

Characteristic	Intervention Patients N = 4,555	Control Patients N = 1,688	P Value	Standardized Difference
Age, years, mean [SD]	70.3 [8.3]	70.7 [8.2]	0.062	0.053
Female, n (%)	2,002 (44.0)	716 (42.4)	0.277	0.031
Race, n (%)			0.826	
White	3,580 (78.6)	1,325 (78.5)		0.002
Black	717 (15.7)	275 (16.3)		0.015
Hispanic	107 (2.4)	34 (2.0)		0.023
Other	151 (3.3)	54 (3.2)		0.007
Low-income subsidy, n (%)	893 (19.6)	334 (19.8)	0.872	0.005
MAPD plan type, n (%)			0.790	
Standard (HMO)	2,084 (45.8)	764 (45.3)		0.010
Enhanced (PPO)	1,948 (42.8)	737 (43.7)		0.018
Complete (FFS)	523 (11.5)	187 (11.1)		0.013
A1c, mean [SD], %	8.66 [1.5]	8.53 [1.4]	0.043	0.098
A1c category, n (%)			0.537	
<6%	9 (0.5)	5 (0.8)		0.020
6.0%-6.9%	128 (7.6)	53 (8.8)		0.019
7.0%-7.9%	353 (21.1)	136 (22.7)		0.011
8.0%-8.9%	652 (38.9)	232 (38.7)		0.016
9.0%	534 (31.9)	174 (29.0)		0.045
Deyo-Charlson Comorbidity Index, mean [SD]	2.63 [2.1]	2.57 [2.0]	0.237	0.034
Comorbidities, n (%)				
Hypertension	3,521 (77.3)	1,298 (76.9)	0.736	0.010
Dyslipidemia	2,454 (53.9)	896 (53.1)	0.576	0.016
Neuropathy	996 (21.9)	334 (19.8)	0.075	0.051
Depression	334 (7.3)	114 (6.8)	0.431	0.023
Amputation/ulceration	254 (5.6)	83 (4.9)	0.306	0.030
Retinopathy	250 (5.5)	86 (5.1)	0.540	0.018
Hypoglycemia	245 (5.4)	90 (5.3)	0.942	0.002
Obesity	243 (5.3)	71 (4.2)	0.070	0.053
Nephropathy	108 (2.4)	40 (2.4)	0.996	0.000
Physician visit, n (%)				
General practitioner	4,017 (88.2)	1,483 (87.9)	0.718	0.010
Specialist ^a	554 (12.2)	212 (12.6)	0.671	0.012
Endocrinologist	199 (4.4)	65 (3.9)	0.366	0.026

^aSpecialist includes endocrinologist, geriatrician, and nephrologist.

FFS=fee for service; HMO=health maintenance organization; MAPD=Medicare Advantage Plan D; PPO=preferred provider organization; SD=standard deviation.

required to have continuous enrollment in the MAPD plan with medical and pharmacy coverage for ≥ 12 months before (baseline) the most recent T2D diagnosis (index date) and current enrollment at the time of identification. Additionally, patients were required to meet 1 of the following high-risk selection indicators: (a) have no A1c evaluations in the 12 months before the index date; (b) concurrent use of ≥ 3 non-insulin antihyperglycemic agents without insulin at any time in the 12 month period before the index date, but without evidence of a medical claim for an A1c test; (c) at least 1 A1c value $\geq 8.0\%$ that occurred ≥ 6 months before the index date, without any A1c evaluations within the previous 6 months; (d) taking ≥ 3 noninsulin antihyperglycemic agents and having ≥ 1 A1c value $\geq 8.0\%$ in the 12 months before the index date; (e) at least

1 A1c value $\geq 8.0\%$ in the 12 months before the index date with no subsequent change in therapy over the course of 3 A1c measures $\geq 8.0\%$ regardless of current therapy. Patients with a prescription claim for insulin in the pre-intervention period were excluded. Patient selection was fully anonymized and compliant with Health Insurance Portability and Accountability Act regulations. Physicians targeted for the intervention were those involved in the treatment of the selected patients.

Act on Threes Intervention

The Act on Threes educational intervention had a 2-pronged approach that incorporated general and targeted T2D educational materials and cover letters, which were simultaneously mailed to patients and their treating physicians twice (see

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FIGURE 2 Proportion of Patients with at Least 2 A1c Tests Annually in the Pre- and Postintervention Periods

^a $P < 0.001$ for the pre- versus postintervention comparison.
A1c = glycated hemoglobin.

Appendices A-D, available in online article). The educational materials were concise and used language at a level considered appropriate for patient and physician groups. The materials were developed in association with Humana’s in-house clinical task force and communications team and were consistent with ADA clinical guideline recommendations for A1c testing frequency and treatment modification in patients with T2D. General T2D educational materials included patient and physician brochures (Appendices B and D, available in online article). A simple brochure encouraged patients to see their doctors for an A1c test every 3 months until A1c is at goal, then at least every 6 months to maintain goal A1c; talk to their doctors about their medications every 3 months if A1c is not at goal; and talk to their doctors about using insulin if they are on ≥ 3 diabetes medications, and A1c is not at goal. Another brochure was sent to physicians encouraging them to measure their patients’ A1c every 3 months; intensify treatment every 3 months for patients not at goal A1c; and consider starting insulin for patients using ≥ 3 noninsulin antihyperglycemic drugs. Targeted educational materials were sent to physicians in the form of patient-specific profiles, outlining the reason why the patient was classified as high risk, together with relevant diabetes-related information such as comorbidities, hospitalizations, medication use, and laboratory A1c results (Appendix E, available in online article). The profiles were presented with 1 patient per page so the data could be easily incorporated into the patient’s chart. Follow-up letters were sent to physicians

and patients 3 months after the initial mailing. The control group received standard care and did not receive any messaging as part of the study.

Outcome Measures

The primary outcome measures were A1c testing frequency, as recorded in the medical claims, and based on the ADA standard for compliance of ≥ 2 tests per year and insulin initiation in the postintervention period, as recorded in the pharmacy claims. A1c testing frequency was measured in the entire study cohort, which was composed of patients remaining on the same treatment regimen and patients who changed treatment regimen (including those who initiated insulin therapy). A1c levels were examined for the subgroup of patients with available A1c measurements in the pre- and postintervention period.

Act on Threes campaign-related measures during the postintervention period were secondary outcomes and included the following: the number of T2D patients who had ≥ 1 A1c measure; the number of patients who had A1c measures every 3 months; the number of patients who initiated insulin; the number of patients who switched to insulin; and the number of patients with any change in treatment. Other secondary outcome measures were the frequency and proportion of patients who discontinued any OAD used in the 30 days before switching to insulin, with discontinuation defined as a 90-day gap in receipt of medication and including refills, and diabetes therapy intensification, defined as the number of class-level OADs added during the postintervention period in addition to those received in the pre-intervention period. Hypoglycemic events in any setting were identified by ICD-9-CM codes 250.8, 251.0, 251.1, and 251.2.

Statistical Analyses

Descriptive statistics were used to analyze differences in demographic and clinical characteristics between the intervention and control groups. Differences in the proportions of patients with ≥ 2 A1c tests in the pre- and postintervention periods were evaluated for each group using the McNemar test; the Student’s t-test was used to evaluate between-group differences. Bivariate comparisons of outcome measures in the intervention and control groups were made using X^2 tests to evaluate for statistical significance of differences in proportions of patients. Multiple logistic regression analysis of the entire study cohort was used to assess predictors of insulin initiation in the post hoc analysis. All analyses of data were conducted using SAS software, version 9.1 (SAS Institute, Cary, NC).

The a priori alpha level for all inferential analyses was set at 0.05, and all statistical tests were 2-tailed. For the secondary objective of examining predictors of insulin initiation, an analysis of the data was conducted to evaluate insulin initiation in patients with T2D who had available A1c measures in the pre- and postintervention periods. During the 12-month postintervention period, insulin initiation was examined in

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FIGURE 3 Act on Threes Campaign-Related Measures Among Patients Stratified by High-Risk Selection Indicators 1 to 5

^aT2D patients who have had no A1c evaluations in the 12 months before the most recent T2D diagnosis.

^bT2D patients concurrently on ≥3 noninsulin antihyperglycemic agents without insulin at any time in the 12-month period before the most recent T2D diagnosis, but no evidence in the medical claims that an A1c test was performed.

^cT2D patients with ≥1 A1c value recorded that occurred 6 months or more before the most recent T2D diagnosis at a value of ≥8.0% and with no A1c evaluations in the 6 months before the most recent T2D diagnosis.

^dT2D patients who are on ≥3 noninsulin antihyperglycemic agents and with ≥1 A1c value ≥8.0% in the 12 months before the most recent T2D diagnosis and therefore represent potential candidates for insulin.

^eT2D patients with an A1c value of 8.0% in the 12 months before the most recent T2D diagnosis with no subsequent change in therapy over the course of 3 A1c measures, regardless of current therapy.

A1c = glycated hemoglobin; T2D = type 2 diabetes; q3 mo = every 3 months.

the entire cohort using pharmacy claims, and its determinants were identified from patients' pre-intervention demographic and clinical characteristics.

Results

Patient Demographics and Baseline Characteristics

Patient attrition is summarized in Figure 1. A total of 6,243 patients with a mean age of 70 years (43.5% female) were identified in this study; 4,555 patients were randomized to the intervention group and 1,688 patients to the control group. Patients in the intervention group had a significantly higher mean A1c level at baseline compared with the control group (8.66% vs. 8.53%, respectively; $P=0.043$). Otherwise, patient demographics and baseline characteristics were similar for the 2 groups (Table 1).

Primary and Secondary Outcomes

The percentage of patients with ≥2 A1c tests per year was significantly higher postintervention compared with pre-intervention in the intervention and control groups ($P<0.001$; Figure 2). However, when the pre- to postintervention change was compared for intervention and control patients, there was no significant difference between the groups in the proportion of patients who received ≥2 A1c tests ($P=0.995$). For patients with pre- and postintervention A1c measurements (intervention group: $n=1,503$; control group: $n=539$), A1c levels were similar for the intervention (mean [SD]: pre-intervention, 7.94% [1.47] vs. postintervention, 7.98% [1.45]; $P=0.540$) and control groups (mean [SD]: pre-intervention, 7.98% [1.57] vs. postintervention, 7.94% [1.52]; $P=0.630$). There was also

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TABLE 2 Proportion of Patients with Intensification of Diabetes Therapy Stratified According to Number of Class-Level OADs Added During PostIntervention Period

Outcome	Intervention Patients N=4,555	Control Patients N=1,688
Patients on 1 OAD medication during pre-intervention period, n (%)	1,194 (26.2)	445 (26.4)
0	1,035 (86.7)	383 (86.1)
1	139 (11.6)	53 (11.9)
2+	20 (1.7)	9 (2.0)
Patients on 2 OAD medications during pre-intervention period, n (%)	1,008 (22.1)	371 (22.0)
0	894 (88.7)	329 (88.7)
1	111 (11.0)	40 (10.8)
2+	3 (0.3)	2 (0.5)
Patients on ≥ 3 OAD medications during pre-intervention period, n (%)	1,045 (22.9)	380 (22.5)
0	966 (92.4)	352 (92.6)
1	77 (7.4)	27 (7.1)
2+	2 (0.2)	1 (0.3)

OAD=oral antidiabetic drug.

no difference in the A1c level when comparing the pre- to postintervention change for patients in the intervention and control groups ($P=0.240$).

The proportion of patients who initiated insulin therapy postintervention was similar for the intervention and control groups (6.3% vs. 7.6%, respectively; $P=0.059$). When patients were stratified according to predefined high-risk selection indicators, there were no statistically significant differences in Act on Threes campaign-related measures between the study groups ($P>0.05$; Figure 3). Diabetes therapy intensification during the 12-month postintervention period was comparable for the study groups, with most patients not having their OAD therapy intensified during the postintervention period (Table 2).

Characteristics and Predictors of Insulin Initiation

Determinants of insulin initiation were examined in a subgroup of 2,042 patients with available A1c measures in the pre- and postintervention periods. Of these, 220 (10.8%) patients initiated insulin during the postintervention period. Compared with patients who did not initiate insulin ($n=1,822$), patients who initiated insulin ($n=220$) had a higher mean Deyo-Charlson Comorbidity Index score (3.46 vs. 2.77; $P<0.001$) and a higher prevalence of diabetic nephropathy (11.8% vs. 5.7%; $P<0.001$) and hypoglycemia (8.6% vs. 5.4%; $P=0.049$) during the pre-intervention period. Compared with patients who did not initiate insulin, a higher proportion of patients who initiated insulin were receiving ≥ 3 OADs (62.3% vs.

49.6%; $P<0.001$) and treatment with a glucagon-like peptide-1 receptor agonist (GLP-1 RA; 8.2% vs. 4.5%; $P=0.015$). During the pre-intervention period, patients who initiated insulin had more outpatient visits than those who did not initiate insulin (mean = 11.1 vs. 9.6 per patient; $P<0.001$) and were more likely to have an A1c level of $\geq 9.0\%$ (38.6% vs. 17.8%; $P<0.001$).

Table 3 summarizes the findings of logistic regression analyses used to examine predictors of insulin initiation in this population. The Act on Threes educational intervention had no impact on insulin initiation in either the unadjusted or adjusted models. Significant predictors of insulin initiation in the final adjusted model were Deyo-Charlson Comorbidity Index score ($P<0.001$); use of ≥ 3 OADs ($P=0.050$); GLP-1 RA use ($P=0.029$); and A1c of 8.0%-8.99% ($P=0.029$), 9.0%-9.99% ($P<0.001$), and $\geq 10\%$ ($P<0.001$). A1c $<7.0\%$ significantly reduced the likelihood of insulin initiation in the adjusted model ($P<0.001$).

Discussion

Act on Threes was a novel study with a rigorous randomized design aimed at prospectively evaluating the effects of a targeted educational program directed to patients with high-risk T2D and their treating physicians. Act on Threes specifically targeted patients with either no A1c evaluations or those with A1c $\geq 8.0\%$ and, to our knowledge, is the first randomized study of patients with T2D that compared the effects of a targeted educational program between the intervention and control groups in addition to comparing pre- and postintervention results. The main findings of this study were that the Act on Threes intervention, compared with standard care, did not result in any significant differences in the frequency of A1c testing or in the initiation of insulin among high-risk patients with T2D. Also, the Act on Threes intervention did not result in any differences between the intervention and control groups in terms of campaign-related measures. However, in the intervention and control groups, A1c testing was conducted significantly more frequently postintervention compared with pre-intervention.

Although it is difficult to speculate on the reasons for an increase in A1c testing frequency in the control group, there is confidence in our finding of a lack of a between-group effect because no treating physician was involved in the care of intervention and control group patients. Therefore, control group patients would not have been directed to intervention-based measures. We speculate that the absence of an intervention effect was a result of the higher cost of care associated with additional physician visits and A1c testing in a group of Medicare patients assigned to the intervention group. The intervention group, and particularly those on insulin, would be more likely than control patients to experience the Medicare

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TABLE 3 Predictors of Insulin Initiation Among Patients with at Least 1 A1c Lab Result (N=2,042)

Characteristic	Unadjusted Model		Adjusted Model	
	OR (95% CI)	P Value	OR (95% CI)	P Value
Intervention				
Control (reference)	1.00		1.00	
Act on Threes Intervention	0.86 (0.63-1.17)	0.337	0.84 (0.61-1.16)	0.300
Age groups				
<65 years (reference)	1.00		1.00	
65-74 years	0.86 (0.59-1.26)	0.444	0.97 (0.64-1.46)	0.880
>75 years	0.77 (0.50-1.18)	0.225	0.81 (0.51-1.29)	0.368
Gender				
Male (reference)	1.00		1.00	
Female	1.00 (0.76-1.33)	0.991	0.98 (0.73-1.32)	0.891
U.S. geographic region				
Northeast (reference)	1.00		1.00	
Midwest	0.31 (0.08-1.17)	0.082	0.34 (0.08-1.47)	0.151
South	0.61 (0.17-2.13)	0.436	0.60 (0.15-2.45)	0.482
West	0.58 (0.16-2.14)	0.414	0.60 (0.14-2.54)	0.486
Race				
White (reference)	1.00		1.00	
Black	0.82 (0.56-1.20)	0.311	0.79 (0.52-1.18)	0.245
Hispanic	0.43 (0.15-1.18)	0.101	0.36 (0.12-1.03)	0.055
Other	0.59 (0.25-1.38)	0.222	0.53 (0.22-1.29)	0.160
MAPD plan type				
Standard (HMO) (reference)	1.00		1.00	
Enhanced (PPO)	0.77 (0.55-1.08)	0.134	0.97 (0.67-1.41)	0.876
Complete (FFS)	0.65 (0.34-1.22)	0.179	0.84 (0.43-1.66)	0.617
Deyo-Charlson Comorbidity Index score	1.14 (1.08-1.21)	<0.001	1.14 (1.06-1.23)	<0.001
Comorbidities				
Diabetic retinopathy	1.23 (0.72-2.13)	0.451	0.90 (0.50-1.62)	0.725
Diabetic nephropathy	2.21 (1.41-3.49)	0.001	1.61 (0.97-2.67)	0.069
Diabetic neuropathy	1.31 (0.97-1.77)	0.082	1.61 (0.97-2.67)	0.736
Hypertension	1.22 (0.83-1.80)	0.314	1.20 (0.80-1.81)	0.387
Dyslipidemia	1.14 (0.84-1.57)	0.404	0.98 (0.70-1.38)	0.894
Hypoglycemia	1.66 (0.99-2.78)	0.052	1.44 (0.70-1.38)	0.211
Number of OADs				
0/1 (reference)	1.00		1.00	
2	1.72 (1.06-2.78)	0.028	1.18 (0.70-1.98)	0.558
≥3	2.35 (1.52-3.63)	0.000	1.63 (0.99-2.67)	0.050
GLP-1 RA use	1.92 (1.13-3.26)	0.016	1.91 (1.07-3.41)	0.029
Health care resource utilization				
Outpatient visits	1.05 (1.03-1.07)	<0.001	1.03 (1.00-1.06)	0.073
Inpatient visits	1.08 (0.87-1.34)	0.479	0.99 (0.77-1.27)	0.922
ED visits	1.11 (0.98-1.26)	0.101	1.08 (0.93-1.27)	0.073
Endocrinologist visits	1.30 (0.77-2.18)	0.321	1.12 (0.64-1.96)	0.689
A1c				
7.0%-7.9% (reference)	1.00		1.00	
<7.0%	0.30 (0.17-0.53)	<0.001	0.36 (0.20-0.65)	<0.001
8.0%-8.9%	1.38 (0.94-2.01)	0.099	1.54 (1.04-2.28)	0.029
9.0%-9.9%	2.01 (1.30-3.11)	0.000	2.26 (1.43-3.56)	<0.001
≥10%	3.26 (2.13-4.99)	<0.001	3.84 (2.45-6.01)	<0.001

A1c=glycated hemoglobin; CI=confidence interval; ED=emergency department; FFS=fee for service; GLP-1 RA=glucagon-like peptide-1 receptor agonist; HMO=health maintenance organization; MAPD=Medicare Advantage Plan D; OAD=oral antidiabetic drug; OR=odds ratio; PPO=preferred provider organization.

coverage gap or "donut hole," which would require patient out-of-pocket expenses to fund the increased level of care. The changes seen pre- and postintervention are consistent with other studies reporting the results of educational interventions. A recent study examining the number of patients with diabetes who received retinal screening after a printed, mailed educational intervention was sent to physicians found no effect for intervention.¹³ Another study investigating the impact of point-of-care A1c testing on provider compliance and A1c levels in a primary care setting reported a significant difference in pre- to postintervention A1c levels (mean A1c 6 months pre-intervention: 8.1%; 6 months postintervention: 7.7%), but unlike the present study, it did not include a control group.¹² Indeed, the lack of effect between the intervention and control groups in the present study challenges the validity of other studies that have shown significant changes in diabetes-related outcomes based on pre- to postintervention design.^{11,12} A cluster randomized controlled trial evaluating the effects of peer support on T2D-related outcomes similarly found no impact of the intervention relative to a control group, but unlike the present study, this study did not employ a pre- versus post-intervention comparison.¹⁴

Another possible reason for the lack of intervention effect in the present study relates to resistance encountered from physicians during the educational intervention. A total of 122 calls from providers were received in response to the mailings for reasons that included reporting that a patient was no longer seen in the practice and that the patient/physician pairing listed on the profile was inaccurate (38.5%); calls were also received to provide updated information on the patient's A1c testing frequency or results and to relay information about a positive change in care (32.0%). A few providers also called to request that they not be sent these types of communications and that reading such materials would be "wasting their time," as they did not require help caring for their patients. Although few in number ($n=3$; 2.5%), these calls may represent a widely held but unexpressed sentiment that any intervention that distracts physicians from their current focus or approach is unhelpful and time consuming. This resistance, if it is widespread, is of potential concern because it suggests that the delivery of patient-centered care may be a step too far for some physicians; it may also be a contributor to clinical inertia in the case of insulin initiation. Reasons for inertia in the management of T2D previously identified include patients being reluctant to add new medications, especially insulin, to already complex treatment regimens, as well as a lack of familiarity with insulin therapy initiation and failure to intensify on the part of the primary care physician.^{15,16} Yet, there is a need to further investigate the reasons for inertia in insulin initiation among the physician community. Possible resistance from the

physician aside, it is important to acknowledge that this study made no attempt to measure patient or physician engagement with the educational materials. Thus, it is possible that the physician participation rate was sufficiently low as to affect the observable outcomes and may better explain the absence of an intervention effect.

The Act on Threes initiative tried to influence insulin initiation in a positive way; however, only a small proportion of patients initiated insulin therapy during this study. This outcome suggests that clinical inertia, in conjunction with patient and/or physician reluctance to initiate insulin treatment, remains a problem in the managed care setting. The findings of this study in relation to the use of an educational intervention emphasize that simply increasing A1c testing frequency does not promote treatment intensification. This highlights the complexity of clinical inertia and shows that multiple approaches may be required to address clinical inertia in the managed care setting. The A1c threshold of 9.0% seemed to be a much stronger motivator for treatment intensification, with a 2- to almost 4-fold greater likelihood of insulin initiation associated with an A1c of 9.0% or higher. Other studies have previously reported an association between increasing A1c level and decreasing clinical inertia.¹⁷⁻¹⁹ Other significant predictors of insulin initiation in the present study were the Deyo-Charlson Comorbidity Index score, which is a proxy for comorbidities, and use of ≥ 3 OADs or a GLP-1 RA during the pre-intervention period. A potential reason why the use of a GLP-1 RA predicted treatment intensification with insulin may be that such patients are already experienced with injectables and therefore more willing to initiate insulin.

The development and availability of new classes of OADs may further increase the length of time to insulin initiation. In addition to raising the awareness of ADA-recommended A1c testing, an intervention that would increase awareness among physicians and patients regarding the effect on long-term outcomes of an A1c level $>8.0\%$ and delayed insulin initiation may be better able to overcome some of the inertia and promote insulin initiation at lower A1c thresholds.

Limitations

The Act on Threes educational intervention included Medicare T2D patients from the Humana administrative claims database only. Therefore, the results may not be representative of, or generalizable to, all patients with T2D. Further, it is not known what other concomitant interventions the patients received that were not related to this study. For example, managed care organizations are focused on improving quality measures and providing other educational initiatives, with such initiatives potentially affecting the pre- and postintervention outcomes in this study. Although it is unlikely that the 2 arms were affected

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unequally, any impact of such initiatives may have "shadowed" the overall effect of the intervention. As already indicated, no efforts were made to measure patient or physician engagement, which may have been inadequate to achieve an intervention effect. Furthermore, although the educational materials conveyed simple messaging of the ADA, no external testing or validation of the materials was conducted to determine their utility for patients and physicians alike. Finally, personalized A1c goals may be more appropriate because they consider factors such as patient age and health status with the aim of balancing the benefits of glycemic control with its possible risks.²⁰ In this study, the less aggressive treatment goals may have affected patient and physician responses to educational intervention.

Conclusions

The Act on Threes study is the first randomized study comparing pre- and postintervention results in an interventional and a control group. Our findings did not demonstrate an overall significant effect for the educational intervention on outcomes of A1c testing and the campaign measures. Importantly, these findings highlight a major drawback of numerous previous studies that used a pre- versus postintervention comparison without a control group. Given the significant postintervention increase in A1c testing observed in the intervention and control groups, our findings indicate the potential of such studies to generate flawed conclusions with the risk of inappropriately influencing the management of diabetes. Indeed, had we relied on a similar study design, we would have mistakenly concluded that the intervention resulted in a significant improvement in the primary outcome of percentage of patients with ≥ 2 A1c tests per year. As it was, a similar improvement in the control group negated any intervention effect, leaving us to speculate why.

We suggest that future studies are warranted to determine the effect of educational interventions in aligning physicians and their T2D patients with ADA recommendations. The use of pre- versus postintervention comparisons remains a valid method for determining the effect of an intervention and is particularly relevant for database studies. However, such studies should also use a randomized design that incorporates a control group and focus on a broader segment of the patient population in keeping with the possibility that cost restraints associated with the Medicare model detrimentally affect patient care and the ability of educational interventions to achieve desirable outcomes. Further profiling of determinants of insulin intensification may be helpful in designing and targeting appropriate interventions for patients who are likely to benefit most.

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Reynolds and Uribe provided expertise and key clinical insights for the study design and methodology, provided interpretations of the data, contributed to the discussion, and reviewed the manuscript. Bieszk and Wei codeveloped the study design, researched data, contributed to discussion, and reviewed the manuscript. Davis and Kamble collected the data, provided study design, clinical insights, statistical and analytic reflections of the data, drafted the study reports, and reviewed the manuscript. All authors had full access to all the data in the study. Reynolds is the guarantor of this work and, as such, takes responsibility for the integrity of the data and the accuracy of the data analysis.

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REFERENCES

1. Stolar MW, Hoogwerf BJ, Gorshow SM, Boyle PJ, Wales DO. Managing type 2 diabetes: going beyond glycemic control. *J Manag Care Pharm*. 2008;14(5 Suppl B):S2-S19. Available at: <http://www.jmcp.org/doi/abs/10.18553/jmcp.2008.14.S5-B.1>.
2. Shogbon AO, Levy SB. Intensive glucose control in the management of diabetes mellitus and inpatient hyperglycemia. *Am J Health Syst Pharm*. 2010;67(10):798-805.
3. Hanefeld M. Use of insulin in type 2 diabetes: what we learned from recent clinical trials on the benefits of early insulin initiation. *Diabetes Metab*. 2014;40:391-99. Available at: [http://www.diabet-metabolism.com/article/S1262-3636\(14\)00139-6/pdf](http://www.diabet-metabolism.com/article/S1262-3636(14)00139-6/pdf). Accessed July 18, 2016.
4. Smolen HJ, Murphy DR, Gahn JC, Yu X, Curtis BH. The evaluation of clinical and cost outcomes associated with earlier initiation of insulin in patients with type 2 diabetes mellitus. *J Manag Care Spec Pharm*. 2014;20(9):968-84. Available at: <http://www.jmcp.org/doi/10.18553/jmcp.2014.20.9.968>.
5. Inzucchi SE, Bergenstal RM, Buse JB, et al. Management of hyperglycemia in type 2 diabetes: a patient-centered approach. *Diabetes Care*. 2012;35(6):1364-79. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3357214/pdf/1364.pdf>. Accessed July 18, 2016.

"Act on Threes" Paradigm for Treatment Intensification of Type 2 Diabetes in Managed Care: Results of a Randomized Controlled Study with an Educational Intervention Targeting Improved Glycemic Control

6. National Committee for Quality Assurance. The state of health care quality 2014. Available at: <http://store.ncqa.org/index.php/2014-state-of-health-care-quality-report.html>. Accessed August 1, 2016.
7. American Diabetes Association. Standards of medical care in diabetes—2015. *Diabetes Care*. 2015;38(Suppl 1):S4-93. Available at: http://care.diabetesjournals.org/content/suppl/2014/12/23/38.Supplement_1.DC1/January_Supplement_Combined_Final.6-99.pdf. Accessed July 18, 2016.
8. Lian J, Liang Y. Diabetes management in the real world and the impact of adherence to guideline recommendations. *Curr Med Res Opin*. 2014;30(11):2233-40.
9. Brown JB, Nichols GA, Perry A. The burden of treatment failure in type 2 diabetes. *Diabetes Care*. 2004;27(7):1535-40. Available at: <http://care.diabetesjournals.org/content/27/7/1535.full.pdf+html>. Accessed July 18, 2016.
10. Ng CJ, Lai PS, Lee YK, Azmi SA, Teo CH. Barriers and facilitators to starting insulin in patients with type 2 diabetes: a systematic review. *Int J Clin Pract*. 2015;69(10):1050-70. Available at: <http://onlinelibrary.wiley.com/doi/10.1111/ijcp.12691/epdf>. Accessed July 18, 2016.
11. Weber V, Bloom F, Pierdon S, Wood C. Employing the electronic health record to improve diabetes care: a multifaceted intervention in an integrated delivery system. *J Gen Intern Med*. 2008;23(4):379-82. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2359509/pdf/11606_2007_Article_439.pdf. Accessed July 18, 2016.
12. Egbunike V, Gerard S. The impact of point-of-care A1C testing on provider compliance and A1C levels in a primary setting. *Diabetes Educ*. 2013;39(1):66-73.
13. Zwarenstein M, Shiller SK, Croxford R, et al. Printed educational messages aimed at family practitioners fail to increase retinal screening among their patients with diabetes: a pragmatic cluster randomized controlled trial [ISRCTN72772651]. *Implement Sci*. 2014;9:87. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4261896/pdf/13012_2013_Article_826.pdf. Accessed July 18, 2016.
14. Smith SM, Paul G, Kelly A, Whitford DL, O'Shea E, O'Dowd T. Peer support for patients with type 2 diabetes: cluster randomised controlled trial. *BMJ*. 2011;342:d715. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3039437/>. Accessed July 18, 2016.
15. Shah BR, Hux JE, Laupacis A, Zinman B, van Walraven C. Clinical inertia in response to inadequate glycemic control: do specialists differ from primary care physicians? *Diabetes Care*. 2005;28(3):600-06. Available at: <http://care.diabetesjournals.org/content/28/3/600.full.pdf+html>. Accessed July 18, 2016.
16. Bolen SD, Bricker E, Samuels TA, et al. Factors associated with intensification of oral diabetes medications in primary care provider-patient dyads: a cohort study. *Diabetes Care*. 2009;32(1):25-31. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2606824/pdf/25.pdf>. Accessed July 18, 2016.
17. McEwen LN, Bilik D, Johnson SL, et al. Predictors and impact of intensification of antihyperglycemic therapy in type 2 diabetes: translating research into action for diabetes (TRIAD). *Diabetes Care*. 2009;32(6):971-76. Available at: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2681018/pdf/zdc971.pdf>. Accessed July 18, 2016.
18. Balkau B, Bouée S, Avignon A, et al. Type 2 diabetes treatment intensification in general practice in France in 2008-2009: the DIAttitude Study. *Diabetes Metab*. 2012;38(Suppl 3):S29-35. Available at: <http://www.em-con-sulte.com/showarticlefile/709574/main.pdf>. Accessed July 18, 2016.
19. Mata-Cases M, Benito-Badorrey B, Roura-Olmeda P, et al. Clinical inertia in the treatment of hyperglycemia in type 2 diabetes patients in primary care. *Curr Med Res Opin*. 2013;29(11):1495-502.
20. Inzucchi SE, Bergenstal RM, Buse JB, et al. Management of hyperglycemia in type 2 diabetes, 2015: a patient-centered approach: update to a position statement of the American Diabetes Association and the European Association for the Study of Diabetes. *Diabetes Care*. 2015;38(1):140-49. Available at: <http://care.diabetesjournals.org/content/38/1/140.full.pdf>. Accessed July 18, 2016.

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APPENDIX A Act on Threes Patient Cover Letter

Brochure to Help You Understand Your Diabetes Care

Dear [Humana Member Name],

Thank you for having a Humana plan.

Our records show you have diabetes, which is a disease that requires a lot of care. We understand that caring for your diabetes isn't always easy.

We've enclosed a brochure to use when discussing your care with your doctor. It's full of helpful information, especially if you don't know your target A1c goal. The brochure explains an “A1c goal.”

The more you understand about your diabetes and how to keep it controlled, the fewer problems it may cause.

Please use this brochure to help you talk to your doctor during your next visit. If you have questions please call [xxx-xxx-xxxx].

APPENDIX B Act on Threes Patient Brochure

Now is the time to ACT ON 3s for my diabetes

- See your doctor for an A1c* test every 3 months until you are at your goal, then at least every 6 months to make sure you stay there.
- Talk to your doctor about your medications every 3 months if your A1c score is not at your goal. Your doctor may need to increase the dose of the medication you are on, or add another medication.
- If you are on 3 or more medications for your diabetes, and your A1c score is not at your goal, then it is time to talk to your doctor about using insulin.

*The A1c test is a special blood test (not like your home blood sugar testing machine) that gives your doctor a good idea of how controlled your blood sugar has been over the last 3 months. For most patients, the goal A1c is 7%. High blood glucose levels can harm your heart, kidneys, feet, and eyes. The sooner your A1c score gets to goal, the less harm your diabetes might cause you.

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APPENDIX C Act on Threes Provider Cover Letter

Dear Physician or Health Care Provider,

Our records indicate that you have a patient with diabetes who is considered high risk based on A1c screening frequency, number of non-insulin antihyperglycemic medications and/or A1c test results. In an effort to help support the well-being of your patients, we have enclosed a brochure that includes the latest American Diabetes Association recommendations for management of diabetes, published in April 2012.

Also enclosed, please find a profile of the patient (or patients) who have been identified as high risk, including the reason for their high-risk classification. We respectfully request that you consider this data when treating or monitoring escalation, if appropriate for the individual patient. Humana also encourages coordination of care between patients' primary physicians and specialists.

If you have questions about this information, please contact me at [xxx-xxx-xxxx].

Thank you for your continued care of our members.

APPENDIX D Act on Threes Provider Brochure

Now is the time to ACT ON 3s for diabetes^a

Follow A1c every 3 months in patients whose therapy has changed or who are not meeting glycemic goals^{1,2}

Intensify treatment every 3 months if A1c is not at goal²

Consider insulin for patients using 3 or more noninsulin glucose-lowering drugs if A1c is not at goal^{2,3}

A reasonable A1c goal for most patients with type 2 diabetes is <7.0%. More or less stringent goals may be appropriate for some patients.¹

Insulin is likely to be more effective than most other agents as a third-line therapy, especially when A1c is $\geq 9.0\%$.²

For patients presenting with A1c $\geq 10.0\%$ -12.0%, insulin should be considered from the outset.²

^aBased on the ADA/EASD 2012 Position Statement for the Management of Type 2 Diabetes and the ADA Standards of Medical Care in Diabetes–2012.^{1,2}

References: **1.** American Diabetes Association. Standards of medical care in diabetes–2012 (position statement). *Diabetes Care*. 2012;35(suppl 1):S11-S63. **2.** Inzucchi SE, Bergenstal RM, Buse JB, et al. Management of hyperglycemia in type 2 diabetes: a patient-centered approach. Position statement of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) *Diabetes Care*. 2012;35(6):1364-79. **3.** Rodbard HW, Jellinger PS, Davidson JA, et al. Statement by an American Association of Clinical Endocrinologists/American College of Endocrinology consensus panel on type 2 diabetes mellitus: an algorithm for glycemic control. *Endocr Pract*. 2009;15(6):541-559.

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APPENDIX E Sample Patient Profile

Patient Profile

Reason for Classification as High Risk Diabetic Patient:

[reason]

Patient Name	Date of Birth	Address
[First Name] [Last Name]	[mm/dd/yy]	[123 Main St., Anywhere, USA 12345]

Providers and Visits:	Provider Name	Provider Type	Date of Last Visit
	[Provider 1]	[Type]	[mm/dd/yy]
	[Provider 2]	[Type]	[mm/dd/yy]

A1c Trends in the Last 12 Months According to Claims and Lab Data:

A1c Test Date	A1c Test Result
[mm/dd/yy]	[x.x%]
[mm/dd/yy]	[x.x%]
[mm/dd/yy]	[x.x%]
[mm/dd/yy]	[x.x%]
[mm/dd/yy]	[x.x%]
[mm/dd/yy]	[x.x%]
[mm/dd/yy]	[x.x%]
[mm/dd/yy]	[x.x%]
[mm/dd/yy]	[x.x%]
[mm/dd/yy]	[x.x%]
[mm/dd/yy]	[x.x%]

Presence of Diabetes-Related Comorbid Conditions According to Claims Data:

[comorbidity 1]	[comorbidity 2]	[comorbidity 3]	[comorbidity 4]
[comorbidity 5]	[comorbidity 6]	[comorbidity 7]	[comorbidity 8]

Diabetes-Related Emergency Department Visits:

Total Number in Past 12 Months [number]
Dates of Visits [Date 1] [Date 2] [Date 3] [Date 4]

Diabetes-Related Hospitalizations:

Total Number in Past 12 Months [number]
Dates of Visits [Date 1] [Date 2] [Date 3] [Date 4]

Use of Non-Insulin Anti-Hyperglycemic Agents in the Past 12 Months

Medication	Date of Last Fill	Days Supply of Last Fill	Prescribing Physician
[Medication 1]	[Date]	[Date]	[First Name] [Last Name]
[Medication 2]	[Date]	[Date]	[First Name] [Last Name]
[Medication 3]	[Date]	[Date]	[First Name] [Last Name]
[Medication 4]	[Date]	[Date]	[First Name] [Last Name]
[Medication 5]	[Date]	[Date]	[First Name] [Last Name]
[Medication 6]	[Date]	[Date]	[First Name] [Last Name]
[Medication 7]	[Date]	[Date]	[First Name] [Last Name]
[Medication 8]	[Date]	[Date]	[First Name] [Last Name]
[Medication 9]	[Date]	[Date]	[First Name] [Last Name]
[Medication 10]	[Date]	[Date]	[First Name] [Last Name]