Impact of Baseline Insulin Regimen on Glycemic Response to a Group Medical Clinic Intervention

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OBJECTIVE—Group medical clinics (GMC) combine medication management and self-management training, and may improve diabetes outcomes. It remains unclear which patients benefit most from GMC. This secondary analysis examined the impact of baseline insulin regimen on GMC response.

RESEARCH DESIGN AND METHODS—We analyzed a trial of 239 veterans with type 2 diabetes randomized to GMC or usual care (UC). We categorized baseline insulin regimen as the following: no insulin; basal insulin only; or complex insulin (basal–prandial or mixed regimens). Using linear mixed models adjusted for clustering within GMC, we evaluated the differential impact of GMC relative to UC on hemoglobin A_{1c} (HbA_{1c}) and self-efficacy among patients on different baseline insulin regimens.

RESULTS—From linear mixed models, the effect of GMC on HbA_{1c} differed by baseline insulin regimen versus UC ($P = 0.05$); there was no differential effect on self-efficacy ($P = 0.29$). Among those using complex insulin regimens at baseline, GMC reduced HbA_{1c} by study end compared with UC (−1.0%; 95% CI −1.8 to −0.2; $P = 0.01$). We found no such HbA_{1c} difference between GMC and UC patients using no insulin ($P = 0.65$) or basal insulin only ($P = 0.71$). There were no clinically significant differences in hypoglycemia by baseline insulin regimen and intervention group.

CONCLUSIONS—We found that compared with UC, GMC lowered HbA_{1c} specifically among patients using complex insulin regimens at study baseline, which may relate to this group's demanding medication and self-management requirements. Implementing GMC among patients using complex insulin regimens may maximize this care delivery strategy's potential.

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Diabetes is increasingly prevalent (1), and the costs of poor glycemic control are increasing (2,3). Because improving hemoglobin A_{1c} (HbA_{1c}) leads to reduction in diabetes complications (4,5), addressing poor glycemic control is vital. Good self-care is a key predictor for attaining improved HbA_{1c} in patients with suboptimal glycemic control (6), so interventions that target deficiencies in diabetes self-management hold substantial promise.

Group medical clinics (GMC) offer an opportunity to provide patients with diabetes with both individualized medical management and self-management education in a manner that could potentially improve access and decrease costs compared with usual care (UC) (7). Randomized controlled trials (RCT) of GMC have reported conflicting results among patients with diabetes, with some studies showing a greater improvement in HbA_{1c} with GMC relative to UC, and with some studies showing no difference (8–19). It remains unclear whether certain subgroups of patients may derive greater benefit from diabetes GMC than others; for example, a recent systematic review demonstrated that baseline HbA_{1c} does not appear to be a significant predictor of GMC response (20). Selection of high-yield patient subgroups will be essential to efficiently implementing GMC.

Relative to patients using oral diabetes agents and/or basal insulin, patients using complex insulin regimens (defined for this study as multiple daily injections of either basal and prandial insulin or mixed basal–prandial insulin preparations) require careful insulin titration, which some primary care providers lack comfort in overseeing (21–25). Further, these patients have demanding self-management requirements, including regular blood glucose monitoring, frequent insulin administration, and nutritional restrictions (26). Consequently, self-management adherence is more challenging for patients using complex insulin regimens than for patients using simpler diabetes medication regimens (27). Because diabetes GMC appear to exert positive effects by providing both tailored medication management and self-management training (20), it is possible that GMC may have the greatest potential for impact among patients using complex insulin regimens.

Using data from a published randomized trial (16), we sought to evaluate the effect of a GMC intervention among patients with poorly controlled type 2 diabetes who at study baseline were prescribed no insulin (oral diabetes medications only), basal insulin only (in addition to any oral medications), or complex insulin regimens (in addition to any oral medications). Because of their higher medication complexity and more demanding self-management, we hypothesized that patients using complex insulin regimens at study baseline would derive greater benefit from GMC relative to UC than would patients using simpler diabetes treatment regimens.

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RESEARCH DESIGN AND METHODS

Group visits, population, and study design

The RCT (NCT00286741, ClinicalTrials.gov) on which this post hoc exploratory analysis is based evaluated the impact of a GMC intervention compared with UC among 239 patients at two Veterans Affairs Medical Centers (VAMC). Patients were eligible for the RCT if they were enrolled in primary care at either center, had poorly controlled type 2 diabetes (HbA_{1c} ≥7.5%) and hypertension (systolic blood pressure [BP] ≥140 mmHg or diastolic BP ≥90 mmHg), and used medication for diabetes and hypertension. Patients were excluded if they reported dual primary care outside of their VAMC, were enrolled in an endocrinology clinic in the past 6 months, were hospitalized for a psychotic illness in the past 3 years, were cognitively impaired, or had a reduced life expectancy from severe chronic illness. Both VAMC facilities' Institutional Review Boards approved the protocol.

Patients were enrolled between June 2006 and September 2007 and were randomized to either the GMC or the UC group in a 5:4 ratio (to account for clustering of patients in the GMC group). Randomization was stratified by site, baseline HbA_{1c} control (≥9.0 vs. <9.0%), and baseline systolic BP (≥150 mmHg vs. <150 mmHg). An unblinded individual with no responsibility for outcome ascertainment revealed study group allocation to patients. Trial duration was ~12 months, with assessments at study baseline, midpoint (median 6.8 months), and end (median 12.8 months). This trial's primary analysis showed that GMC improved BP but not HbA_{1c} relative to UC (16).

GMC intervention

The GMC intervention for the RCT on which this analysis is based is described in detail elsewhere (see Supplementary Appendix of parent trial) (16). Briefly, after collection of baseline information (including demographic and questionnaire data, baseline systolic BP, and baseline HbA_{1c}) at the initial study visit, patients randomly assigned to the GMC group chose a group that met on their preferred half-day. Groups each included 7–9 patients, met every 2 months (7 sessions of 120-min each over 12 months), and had a consistent care team comprising a primary care general internist, a pharmacist, and a nurse or certified diabetes educator. Different groups had different care teams, and each provider could be a member of more than one care team.

Each GMC session was divided into three phases. Phase 1 was devoted to intake and data collection. On presentation, each patient completed a brief medical questionnaire and had BP checked. A member of the care team collected blood glucose data brought by patients. Intake also allowed time for informal conversation among group members. Phase 2 was devoted to an interactive group educational session provided by the assigned educator. Group members selected the schedule of educational topics for subsequent visits at the initial group visit. Concurrently, the clinical pharmacist or internist or both reviewed medical records, BP, and home blood glucose readings for each patient and developed a medication and lifestyle management plan directed toward improving HbA_{1c} and BP. In phase 3, the clinical pharmacist or internist or both met individually with each patient to gather additional patient-specific information about medication use behavior, possible adverse drug events, or other changes in health care status that could alter the treatment plan. The provider and patient then negotiated a final plan for improved disease control, which was entered into the electronic medical record, and patients received an updated list of their medications with instructions for any medication or lifestyle changes. Telephone contact with patients between GMC sessions was limited to communicating the results of laboratory tests obtained during the GMC and any management changes based on those results.

Usual primary care

Patients in the UC group received their usual primary care but no active intervention. Intervention patients continued to receive their usual primary care in addition to the GMC sessions. Primary care providers were informed of any medication changes via the electronic medical record.

Definition of baseline insulin categories

We used medication data collected at baseline to create a categorical variable reflecting baseline insulin regimen. Patients were categorized as using the following: no insulin (oral diabetes medications only, including biguanides, sulfonylureas, or thiazolidinediones); basal (long-acting) insulin in addition to any oral medications; or complex insulin regimens in addition to any oral medications. Complex insulin regimens included basal–prandial insulin regimens (injection of basal insulin one to two times daily and short-acting or rapid-acting insulin with each meal) and mixed insulin regimens (including premixed preparations of basal and prandial insulin and regimens requiring the concurrent injection of basal and prandial insulin twice daily). Of note, no patients used noninsulin injectable medications, such as glucagon-like peptide-1 agonists, at study baseline. One patient used twice-daily U500 regular insulin at baseline along with aspart insulin three times daily with meals. Although U500 regular insulin is not a classic basal insulin, this patient was classified as using a complex insulin regimen based on the manner in which the two insulin types had been prescribed.

Outcomes

The primary outcome for this analysis was change in HbA_{1c} from study baseline to study end (HbA_{1c} measured at baseline, midpoint, and end). Clinical laboratories in each facility measured HbA_{1c} by using standard high-pressure liquid chromatography methods. A secondary outcome for this analysis was self-efficacy measured by the Perceived Competence Scale (PCS) at study baseline, midpoint, and end. The PCS assesses the general ability of participants to make or maintain a change toward a healthy behavior, participate in a health care program, or complete a treatment regimen. Research has shown that improved perceived competence increases the likelihood of making or maintaining change that leads to better health outcomes; the scale has been validated in patients with diabetes and has strong internal consistency (28–30). The PCS consists of four items in which the responses are summed and scores can range from 4 to 20 points. We also ascertained GMC attendance rates and rates of hypoglycemia (defined as a recorded blood glucose level <3.33 mmol/L [<60 mg/dL] or a self-report of symptomatic hypoglycemia and serious hypoglycemia as any such episode that required medical assistance).

Statistical analysis

All analyses were performed using SAS software (SAS Institute, Cary, NC). Descriptive statistics were used to characterize the sample, attendance at GMC

sessions, and hypoglycemic events by baseline insulin regimen. To assess differences in demographic and clinical characteristics between baseline insulin categories, one-way ANOVA was used for continuous variables and the Pearson exact χ^2 test was used for categorical variables. We used *t* tests to assess differences in the mean number of hypoglycemic events during the study between treatment groups by insulin regimen.

For HbA_{1c} and self-efficacy, we fit linear mixed models. Because these data are from an RCT, models were fit with a common baseline across treatment groups by insulin regimen (31–33). The primary predictors included baseline insulin regimen indicator variables, follow-up indicator variables, intervention group by follow-up indicator variables, baseline insulin regimen by follow-up indicator variables, and then the three-way baseline insulin regimen by intervention group by follow-up indicator variables. Contrasts of model parameters were set to estimate the differential effects of GMC compared with UC on outcomes by baseline insulin regimen between study baseline and follow-up.

A benefit of using a mixed-model framework for longitudinal analysis is that unbalanced or incomplete data are allowed and all patients with partial data for the outcome variables are included in the analyses (34). For the repeated measures over time, we used an unstructured covariance; we also fit a random GMC effect within the intervention arm to account for the clustering of subjects within the GMC. Models also included our stratification variables of site, baseline BP (systolic BP ≥150 mmHg vs. systolic BP < 150 mmHg) and baseline HbA_{1c} (HbA_{1c} ≥9.0 vs. <9.0%).

RESULTS

Patient characteristics

Two-hundred thirty-nine patients were enrolled in the study, with 133 patients randomized to GMC and 106 patients randomized to UC. Two-hundred fifteen patients (90%) completed midpoint study follow-up, and 211 patients (88%) completed the trial; we obtained 93% of data points. Table 1 provides patient characteristics by baseline insulin category. The study sample participants were predominantly male, African American or white, and had poorly controlled diabetes and hypertension. Of the 239 patients in the study, 41% (*n* = 98) used oral diabetes medications only, 26% (*n* = 62) used basal insulin in addition to any oral medications, and 33% (*n* = 79) used complex insulin regimens. The three insulin regimen groups were similar at baseline in terms of age, sex, race, marital status, education level, and baseline HbA_{1c}, systolic BP, and PCS.

GMC attendance by baseline insulin category

Overall, intervention patients attended 78.4% of the GMC sessions, and attendance was higher at the Richmond VAMC (86% of sessions attended) than at the Durham VAMC (70% of sessions attended). Attendance did not differ markedly between the three baseline insulin regimen groups; patients using no insulin (oral agents only) attended 79% of the sessions, patients using basal insulin in addition to oral agents attended 82% of the sessions, and patients using complex insulin regimens attended 74% of the sessions.

GMC intervention effects by baseline insulin category

From linear mixed models, we found evidence for a differential intervention effect by baseline insulin regimen on HbA_{1c} over time ($P = 0.05$). GMC patients using complex insulin regimens had a greater reduction in HbA_{1c} compared with UC from baseline to midpoint (−1.0%; 95% CI, −1.8 to −0.3; $P = 0.01$) and baseline to study end (−1.0%; −1.8 to −0.2; $P = 0.01$) (Table 2, Fig. 1). We found no HbA_{1c} difference between GMC and UC patients whose baseline regimens included no insulin or basal insulin only from baseline to midpoint ($P = 0.90$ and $P = 0.30$, respectively) or from baseline to study end ($P = 0.65$ and $P = 0.71$, respectively) (Fig. 1). Thus, whereas GMC patients using complex insulin regimens at study baseline showed significantly greater HbA_{1c} improvement during the study compared with UC, patients using simpler regimens (no insulin or only basal insulin) had

Table 1—*Baseline characteristics of the study population by insulin regimen category*

Demographics*	No insulin (*n* = 98)	Basal only (*n* = 62)	Complex (*n* = 79)	*P*†
Age (years), mean (SD)	62.0 (10.0)	63.2 (10.2)	61.2 (9.1)	0.5
Male, %	96.9	98.4	92.4	0.2
Race, %				
White	38.8	33.9	35.4	1.0
African American	57.1	61.3	59.5	
Other	4.1	4.8	5.1	
Marital status, %				
Married	56.1	54.8	64.6	0.2
Divorced or separated	31.6	22.6	21.5	
Widowed	6.1	9.7	10.1	
Never married	6.1	12.9	3.8	
Education, %				
High school or less	38.8	43.6	39.2	0.5
Some college	37.8	43.6	43.0	
College graduate or more	23.5	12.9	17.7	
Financial burden, %				
Can pay bills without cutting spending	69.9	75.8	57.1	0.06
Can pay bills only by cutting spending or cannot always pay bills	30.1	24.2	42.9	
Clinical data, mean (SD)				
HbA_{1c} (%)	9.0 (1.6)	9.1 (1.1)	9.3 (1.3)	0.4
Systolic BP (mmHg)	154.2 (16.0)	151.0 (11.8)	152.9 (13.6)	0.4
PCS, mean (SD)	14.0 (3.4)	14.4 (3.6)	14.1 (3.6)	0.8

*One patient in the complex insulin regimen group was missing data for education level. Five patients in the no insulin group and two patients in the complex insulin regimen group were missing data for financial burden. Five patients in the no insulin regimen category, three patients in the basal only regimen category, and two patients in the complex regimen category were missing a score for the PCS. Those with missing data were excluded from percentage calculations. †For continuous variables, a one-way ANOVA was conducted to test for differences in baseline characteristics between insulin treatment regimen groups. For categorical variables, exact Pearson χ^2 tests were conducted to test for differences between insulin treatment regimen groups.

Table 2—*Model estimates by baseline insulin category, study intervention group, and follow-up time*

Outcome or regimen category*	Baseline†	Follow-up: Midpoint GMC	Follow-up: Midpoint UC	Follow-up: End of study GMC	Follow-up: End of study UC	Difference in change (follow up–baseline) by diabetes regimen for GMC vs. UC (95% CI); *P* value: Midpoint GMC vs. UC	Difference in change (follow up–baseline) by diabetes regimen for GMC vs. UC (95% CI); *P* value: End of study GMC vs. UC
HbA_{1c}							
No insulin	9.2	8.8	8.8	8.3	8.2	0.0 (−0.6 to 0.7); 0.90	0.2 (−0.5 to .9); 0.6
Basal only	9.0	8.6	8.2	8.6	8.8	0.4 (−0.4 to 1.3); 0.30	−0.2 (−1.1 to 0.7); 0.7
Complex	9.2	8.4	9.4	8.0	9.1	−1.0 (−1.8 to −0.3); 0.01	−1.0 (−1.8 to −0.2); 0.01
PCS‡							
No insulin	13.9	15.8	14.5	16.6	14.5	1.3 (0.2–2.5); 0.02	2.1 (1.0–3.3); 0.0004
Basal only	14.4	15.8	15.8	15.8	15.4	0.0 (−1.4 to 1.3); 1.00	0.3 (−1.1 to 1.8); 0.7
Complex	14.0	15.5	14.7	15.7	13.8	0.8 (−0.4 to 2.1); 0.20	2.0 (0.6–3.3); 0.004

*Twenty-five patients were missing HbA_{1c} values at midpoint (GMC = 11; UC = 14) and 28 patients were missing HbA_{1c} at the end of the study (GMC = 10; UC = 18). Twenty-nine patients were missing PCS scores at midpoint (GMC = 13; UC = 16) and 30 patients were missing PCS scores at the end of the study (GMC = 11; UC = 19). †Common baseline across treatment groups by insulin regimen category. ‡The potential range of the PCS measure is 4 to 20, with higher scores indicating more confidence in managing their diabetes.

similar estimated change in HbA_{1c} regardless of intervention status (Fig. 1).

Although estimated mean self-efficacy scores did improve overall among GMC patients compared with UC, we found no evidence from linear mixed models of a differential intervention effect over time by baseline insulin regimen for self-efficacy ($P = 0.29$). Patients in the GMC group using either no insulin or complex insulin had higher mean scores on self-efficacy than UC at the end of study (2.1 points and 95% CI, 1.0–3.3 [$P = 0.0004$] and 2.0 points and 0.6–3.3 [$P = 0.004$], respectively), but self-efficacy did not differ significantly between GMC versus UC patients in the basal insulin only group ($P = 0.7$) (Table 2).

Hypoglycemia by baseline insulin category

Among those using no insulin at baseline, UC patients experienced a mean ± SD of 1.1 ± 0.9 hypoglycemic events during

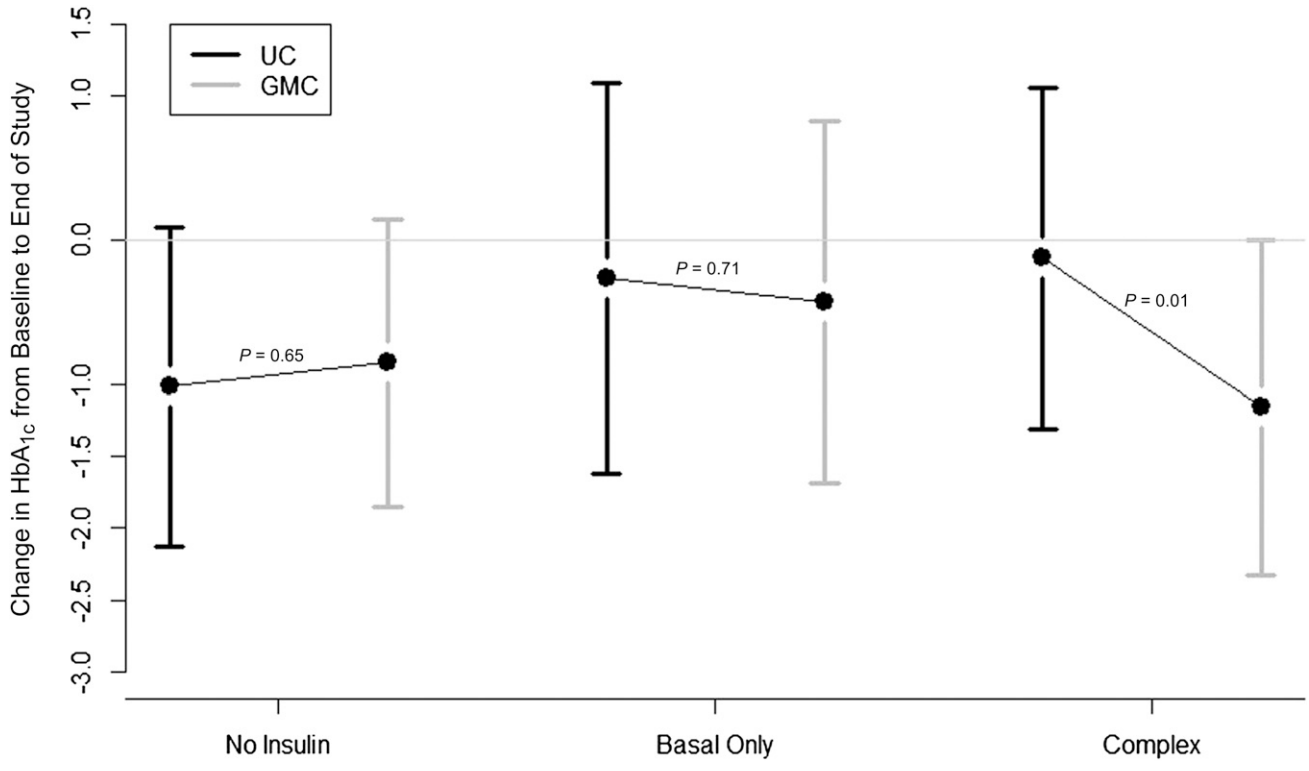

Figure 1—*Model estimates and 95% CI of change in HbA_{1c} from baseline to end of study by insulin regimen category and study intervention group. P values are from test of difference in change of HbA_{1c} between GMC and UC within diabetes regimen.*

the study, as opposed to 0.9 ± 0.9 in the GMC group (P = 0.86). Among those using basal insulin only, UC patients experienced a mean of 1.4 ± 1.0 hypoglycemic events, as opposed to 0.9 ± 0.6 in the GMC group (P = 0.04). Among those using complex insulin regimens, UC patients experienced a mean of 1.4 ± 1.0 hypoglycemic events, as opposed to 1.8 ± 1.0 in the GMC group (P = 0.96).

CONCLUSIONS—GMC show promise as a means to simultaneously address medication management and patient self-management deficiencies among individuals with diabetes and other chronic diseases. The randomized trial on which the current study is based demonstrated that GMC improved BP but not HbA_{1c} among veterans with poorly controlled type 2 diabetes and hypertension. However, it has remained unclear whether certain subgroups of patients with diabetes may derive greater HbA_{1c} lowering from GMC. This post hoc analysis indicates that patients using complex insulin regimens at study baseline had a significantly greater improvement in glycemic control with GMC as compared with UC. These findings stand in contrast to those for patients using simpler diabetes regimens (no insulin or basal insulin only) in which we found no difference in the degree of HbA_{1c} improvement between GMC and UC groups. Our finding that baseline insulin regimen appears to be a moderator for GMC response may have important implications for future research and implementation of GMC in clinical practice.

Two factors may explain the particular improvement in glycemic control we noted among GMC patients using complex insulin regimens at study baseline. First, management of complex insulin regimens requires a comfort with insulin titration that some primary care providers lack (21–25). Medication management by an experienced physician or clinical pharmacist, or both, through GMC therefore may yield greater potential for HbA_{1c} improvement than UC among patients using complex insulin regimens. Second, compared with patients using simpler diabetes regimens, patients using complex insulin regimens generally have a greater self-management burden, including more frequent blood glucose monitoring, more frequent medication administration, more stringent restrictions regarding meal timing and content, and a greater need for hypoglycemia monitoring and management (26). Studies have consistently demonstrated that diabetes self-management training from certified nurse educators, which GMC can provide, is more effective than UC in improving diabetes self-management (35), which may, in turn, translate to improved HbA_{1c} (36,37). Because treating patients using complex insulin regimens requires both complicated medication management and self-management training, it is logical that these individuals would exhibit superior outcomes with GMC, in which both medication management and self-management training are readily available, as compared with UC. GMC patients using complex insulin regimens achieved the observed improvements in HbA_{1c} without experiencing significantly increased rates of hypoglycemia.

We found no significant differential effect of the GMC intervention on PCS by baseline insulin regimen. However, the GMC intervention appeared to positively impact self-efficacy among patients using no insulin and complex insulin compared with UC. The PCS is a validated measure of general self-efficacy among patients with diabetes, and it was well-suited to assess self-efficacy pertaining to diabetes and hypertension for the purposes of the parent RCT. However, a detailed measure of diabetes-related self-efficacy (38), as well as additional measures such as diabetes-related emotional distress (39), would be more informative when examining the differential effect of the GMC intervention by insulin regimen. One might hypothesize that self-efficacy may, in part, mediate the effect of baseline insulin regimen by treatment group on HbA_{1c}, but a formal mediation analysis in a longitudinal framework is beyond the scope of this article. Future studies should evaluate whether self-efficacy and other psychometric variables may mediate the impact of baseline insulin regimen on GMC response.

Although individuals using oral diabetes medications only seemed to benefit from GMC in terms of HbA_{1c} lowering, our findings suggested that UC was equally effective in this regard among these patients. Patients using basal insulin with or without oral medications appeared to show less response to GMC and UC than did patients using oral medications alone. Although the current study cannot explain this finding, we could hypothesize that, despite their poor control, some in this group remained using basal insulin alone at study baseline because of resistance to further insulin intensification, and that this resistance limited the impact of GMC. The role of patient resistance to treatment intensification in modulating the effectiveness of GMC is another important area for further study. Because patients using oral diabetes medications with or without basal insulin did not appear to derive additional HbA_{1c} benefit from GMC relative to UC, baseline insulin regimen may be a key consideration when referring patients for diabetes GMC.

Limitations

In addition to the limitations detailed, this analysis has other limitations. The RCT on which this analysis is based was conducted in a veteran population that was predominantly male, which may affect the generalizability of our results. However, because Veterans Affairs is a generally high-functioning system with respect to diabetes outcomes (40), it is unlikely that we are overestimating the incremental benefit of GMC over UC. Because this is a secondary analysis, undetected covariate imbalance may exist between baseline insulin groups, so our results should be interpreted accordingly; however, our examination of available baseline factors suggests that the groups were similar in most respects. Our sample size required us to combine patients using different insulin regimens, such as basal–prandial insulin regimens and mixed insulin regimens, into a single "complex insulin regimen" category and, even with the categories used, our group sizes were relatively small. It is possible that distinct subpopulations within our complex insulin regimen group would have distinct responses to GMC and UC, and this should be a question for future study.

This analysis also is limited in that we lacked data to further explore treatment intensification among GMC and UC patients. In future studies, it will be informative to further explore patterns of diabetes medication intensification and to evaluate the relationship between treatment intensification and intervention response among patients randomized to GMC and UC in different baseline insulin regimen groups. However, because baseline insulin regimen easily can be determined at the time of referral to a GMC intervention, knowledge of how this factor relates to GMC response is valuable.

Despite our limitations, we demonstrated that GMC produced greater HbA_{1c} reduction than UC among patients with poorly controlled diabetes using complex

insulin regimens at study baseline. GMC hold promise as a strategy for care delivery redesign among patients with diabetes, and we are unaware of any previous analysis that has identified a patient subgroup deriving particular benefit from GMC. Our findings suggest that to maximize HbA_{1c} improvement relative to UC, diabetes GMC may be best-targeted toward poorly controlled patients using complex insulin regimens.

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M.J.C. researched data and wrote the manuscript. S.D.M. researched data and reviewed and edited the manuscript. C.J.C. analyzed data and reviewed and edited the manuscript. A.S.J. analyzed data and reviewed and edited the manuscript. D.E. was the principal investigator for the underlying trial, contributed to the discussion, and reviewed and edited the manuscript. M.J.C. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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