Effects of Clinical Nutrition Education and Educator Discipline on Glycemic Control Outcomes in the Indian Health Service

CHARLTON WILSON, MD^{1,2} TAMMY Brown, MPH, RD, BC, ADM, CDE²

Kelly Acton, MD, MPH 2 SUSAN GILLILAND, PHD, MPH, RN³

OBJECTIVE — We used the Indian Health Service (IHS) Diabetes Care and Outcomes Audit to assess the effectiveness of clinical nutrition education in reducing HbA_{1c} levels and to test the relative effectiveness of clinical nutrition education when it was delivered by a registered dietitian (RD) compared with an educator from another discipline (non-RD).

RESEARCH DESIGN AND METHODS — We examined clinical care data collected by the IHS Diabetes Care and Outcomes Audit of 7,490 medical records during 2001. Glycemic control was assessed by using the difference between the two most recent HbA_{1c} levels during 2001. Age, BMI, duration of diabetes, type of treatment, proteinuria, and facility were included as covariates. Clinical nutrition education was defined as documentation in the record of any diet instruction and educator discipline classified as RD or non-RD. ANCOVA methods were used to assess the effects of diet education and educator discipline on differences between the two HbA_{1c} measurements and to adjust for differences in the distribution of covariates among the education groups.

RESULTS — After adjustment for age, sex, type of treatment, duration of diabetes, BMI, initial HbA_{1c} level, and clinical facility, clinical nutrition education and educator discipline were each associated with changes in HbA_{1c} levels (P < 0.001). Those receiving clinical nutrition education from an RD or from an RD as well as a non-RD had the largest improvements in HbA_{1c} levels (-0.26 and -0.32, respectively) compared with those receiving either only non-RD or no clinical nutrition education (-0.19 and -0.10, respectively).

CONCLUSIONS — Clinical nutrition education in the IHS is associated with favorable trends in glycemic control. To be effective, clinical nutrition education should be delivered by an RD or a team that includes an RD.

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linical nutrition education is a key component of medical nutrition therapy and diabetes self-management practices (1). Several research studies have documented the effectiveness of clinical nutrition education when delivered as a component of a comprehensive

plan of care by a multidisciplinary team, and current expert consensus suggests that the primary instructors on the diabetes team should have specialized diabetes and educational training at or beyond basic academic preparation (2–5). This consensus opinion has been used to shape

From the ¹Indian Health Service, Phoenix Indian Medical Center, Phoenix, Arizona; the ²Indian Health Service, National Diabetes Program, Albuquerque, New Mexico; and the ³University of Southern California, Department of Preventive Medicine, Statistical Consultation and Research Center, Los Angeles, California. Address correspondence and reprint requests to Charlton Wilson, Indian Health Service, Phoenix Indian Medical Center, 4212 N. 16th St., Phoenix, AZ 85016. E-mail: charlton.wilson@pimc.ihs.gov.

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Abbreviations: IHS, Indian Health Service; RD, registered dietitian; non-RD, educator from another

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A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

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policy for reimbursement of Diabetes Self- Management Education and Medical Nutrition Therapy programs (6), although empiric evidence for the effectiveness of clinical nutrition education in a national health care system and the role of discipline of the educator has yet to be documented.

We used the Indian Health Service (IHS) Diabetes Care and Outcomes Audit to assess the effectiveness of clinical nutrition education in reducing HbA_{1c} when delivered as a component of multidisciplinary diabetes care in this large national health care organization and to test the relative effectiveness of clinical nutrition education when it was delivered by a registered dietitian (RD) compared with an educator from another discipline (non-

RESEARCH DESIGN AND **METHODS**

Data collection

We examined clinical care data collected by the IHS Diabetes Care and Outcomes Audit of medical records performed at 218 different facilities during 2001. Methods for the audit have been described previously (7-9). Briefly, IHS and tribal clinic facilities are encouraged to maintain diabetes registries of all individuals with diabetes. Regional diabetes coordinators and professional staff members, trained by the coordinators, perform an audit of clinical care on a randomly selected sample of records of patients on the local registries. Data from the medical record are abstracted using standardized protocols and data collection forms. In addition to manual record abstraction, in 2001, 11% of sites collected patient encounter information using an electronic audit application that retrieved data from clinical and administrative databases of the Resource and Patient Management System (RPMS). Data are then entered or imported into a generalpurpose microcomputer-based software program. Although validation studies of the audit have not been conducted to assess interobserver variation on documentation of education between facilities, we did find a moderate agreement between manual chart reviewers and electronically created audits at one large facility with respect to the presence or absence of documentation of clinical nutrition education (observed agreement 0.73, κ 0.36).

Glycemic control

The two most recent HbA_{1c} values, collected as a part of routine clinical practice, are recorded in the audit. We assessed improvement in glycemic control by calculating the difference between the two HbA_{1c} levels measured during the 2001 audit period. The IHS Standards of Care recommend testing of HbA_{1c} every 3 months; however, the audit does not record the time interval between the two values. Therefore, we performed a focused study of the interval between HbA_{1c} values at one large IHS facility included in the audit where computerized laboratory data were available for analysis. Among 1,125 patients with diabetes who met the same inclusion criteria, the mean number of days between HbA_{1c} measurement was 132 ± 63 days (mean \pm SD) and there was no statistical difference in the mean number of days between the two most recent HbA1c values for people who received instruction by an RD (123 \pm 49 days), for patients instructed by both an RD and a non-RD $(132 \pm 62 \text{ days})$, for patients instructed only by a non-RD (130 \pm 68 days), or for patients with no documentation of dietary instruction (136 \pm 69 days) (P = 0.44, ANOVA).

Clinical nutrition education

Clinical nutrition education was defined as documentation in the medical record of diet instruction. The audit identifies whether the education was provided by an RD, a non-RD, by both an RD and a non-RD, or none. The timing of the education relative to the interval HbA_{1c} measurements was not documented in the audit; however, the education and the HbA_{1c} measurements must have occurred within the year before the audit.

The IHS follows the Commission on Accreditation for Dietetics Education of the American Dietetic Association in identifying an RD as an individual who has completed the minimum of a baccalaureate degree granted by a U.S. regionally accredited college or university or

foreign equivalent, has met current minimum academic requirements and completed preprofessional experience, has successfully completed the Registration Examination for Dietitians, and has accrued 75 h of approved continuing professional education every 5 years (10). non-RDs could include, but would not be limited to, physicians, physician assistants, nurse practitioners, nurses, or health educators. In addition to the professional training and accreditation of the educator, clinical nutrition education instruction by an RD typically differs from that of a non-RD. Clinical nutrition education encounters by an RD are generally longer in duration and involve a nutrition assessment, goal setting, intervention, and plans for follow-up. Clinical nutrition education instruction by a non-RD provider typically comes in response to a patient request or upon identification of a clinical problem during the course of delivering medical care. non-RD instructions on clinical nutrition are often brief and focused on the transfer of generally available verbal or written information.

Covariates

In addition to HbA_{1c} values and clinical nutrition education documentation and clinical nutrition educator discipline, additional demographic, clinical, and standard of care variables were collected in the audit and include facility, sex, age, height, weight, duration of diabetes, diabetes classification, type of treatment, diet instruction, and urinary protein assessments. Age was calculated at the date of audit. BMI was calculated from recorded height and weight $[(703 \times \text{weight in})]$ pounds)/(height in inches \times height in inches)]. Duration of diabetes was recorded as time since diagnosis in years. Type of treatment was recorded as diet alone (no medication), oral agent (used singly or in combination with other oral agents), or insulin. For purposes of analysis, when oral agents were used in combination with insulin, the patient was included with the insulin treatment group. Proteinuria was defined as having 1+ (30 mg/dl) or greater protein on a urine dipstick in the past year.

Data analyses

The primary study end point, the difference between the two most recent HbA_{1c} values, was conducted for all people with two measured HbA_{1c} values. To test

whether the differences in HbA_{1c} level varied by diet instruction and to adjust for covariates that might affect the relationship, we used ANCOVA (11). The chosen covariates for adjustment included age, sex, BMI, duration of diabetes, type of treatment, and facility. For this report, we restricted our analysis to patients older than 18 years of age who did not have proteinuria. Effect modifiers were assessed using significance tests for interaction terms or by fitting nested models. All statistical analyses were performed using SAS statistical software (SAS Institute, Cary, NC) (12).

RESULTS— Of 10,685 patients aged 18 years or older with a diagnosis of type 2 diabetes and without proteinuria who were included the 2001 IHS Diabetes Care and Outcomes Audit, 8,826 (83%) had two HbA_{1c} values recorded. Data on duration of diabetes, BMI, treatment type, and diet instruction were incomplete for 1,336 patients, resulting in a remaining 7,490 patient audit record dataset available for analyses. The demographic and selected clinical measurements of selected participants are summarized in Table 1. Consistent with sex differences in the prevalence of diabetes in American Indian/Alaska Natives, more women than men were included in the sample. The mean age of the patients was 55.2 years, mean duration of diabetes was 7.9 years, and mean BMI was 33.7 kg/m². The mean HbA_{1c} level was 8.0%. Most patients were treated with oral agents (63%), followed by insulin (25.4%) and diet and exercise (11.6%). Patients excluded from the analysis because they had only one HbA_{1c} level were similar to those included, except that they had a shorter mean duration (6.3 years), a greater proportion of treatment by diet and exercise oral agents (21.4%), and smaller proportion treated with insulin (18.4%).

We found that, overall, clinical nutrition education was associated with improving HbA_{1c} values during 2001 (Table 2). After adjustment for age, sex, type of treatment, duration of diabetes, BMI, initial HbA_{1c} level, and clinical facility, there was statistically significant improvement in HbA_{1c} values among patients receiving clinical nutrition education compared with those who did not (-0.09 vs. 0.06, respectively). In addition, there was a statistically significant improvement in HbA_{1c} value among those receiving clini-

Table 1—Selected demographic, clinical, and standards of care variables among American Indian/Alaska Native people with type 2 diabetes (Indian Health Service, 2001)

	n	Mean (SE) or percentage
Age at audit (years)	7,490	55.2 (13.3)
Duration of diabetes (years)	7,490	7.9 (6.9)
BMI	7,490	33.7 (7.3)
HbA _{1c} (%)	7,490	8.0 (2.0)
Sex		
Male	2,901	38.4%
Female	4,645	61.6%
Type of treatment		
Diet alone	868	11.6%
Oral agents	4,720	63.0%
Insulin (with or without oral agents)	1,902	25.4%
Delivery of clinical nutrition education		
RD	1,630	21.4%
Both RD and non-RD other	863	11.6%
non-RD	2,474	32.2%
None	2,402	33.2%
Refused	121	1.6%

cal nutrition education from an RD and both an RD and a non-RD (-0.26 vs. -0.32, respectively; P < 0.0001). The difference between RD instruction and both RD and non-RD instruction was not statistically significant (P > 0.05). Among those receiving clinical nutrition education from only non-RD educators, HbA_{1c} values improved (-0.19); however, the change was not statistically different from those having no documentation of education (-0.10).

When analyses were stratified by type of treatment, all clinical nutrition education groups had improvements in HbA_{1c} levels compared with those receiving no education among patients treated with diet and exercise alone or oral agents (Table 3). This difference was statistically sig-

nificant for those receiving oral therapies (P < 0.0001). Among those receiving diet therapy, the mean decrease in HbA_{1c} level was -0.23 for RD and -0.18 for both RD and non-RD. The mean decrease in HbA_{1c} level was -0.10 for diet instruction by a non-RD and was not statistically significant (P = 0.09). For those patients receiving oral agent therapies, the mean decrease in HbA_{1c} value was -0.23 for RD, -0.33 for both RD and non-RD, and -0.12 for non-RD. The improvement in HbA_{1c} value among those receiving clinical nutrition education from an RD and from both RD and non-RD was statistically significantly different from those who did not receive clinical nutrition education. In addition, the improvement in HbA_{1c} value for those receiving clinical

Table 2—Adjusted* HbA_{1c} level mean differences (SE) and clinical nutrition education

Clinical nutrition education	N = 7,490	HbA_{1c} mean difference (SE)	95% CI
Nutrition education			
Yes	4,967	$-0.09(0.04)^{a}$	-0.17, -0.02
No	2,523	0.06 (0.04) ^b	-0.03, 0.14
RD	1,630	$-0.26 (0.10)^{c}$	-0.45, -0.07
Both RD and non-RD	863	$-0.32(0.11)^{c}$	-0.53, -0.11
non-RD	2,474	-0.19 (0.09)	-0.38, -0.01
None	2,402	$-0.10 (0.09)^{d}$	-0.29, 0.08
Refused instruction	121	-0.07 (0.17)	-0.40, 0.26

Data are n or means (SE). *Adjusted for age, sex, type of treatment, duration of diabetes, BMI, initial HbA $_{1c}$ level, and clinical facility; a,b and c,d are statistically significantly different by Tukey's studentized range (honestly significant difference).

nutrition education from both an RD and a non-RD was statistically significantly different from those receiving clinical nutrition education from another educator. The difference between RD instruction and both RD and non-RD instruction was not statistically significant (P > 0.05). In contrast, none of the clinical nutrition education groups showed improvements in HbA_{1c} values among patients receiving insulin therapy.

CONCLUSIONS— We found that documentation of clinical nutrition education provided in the IHS was associated with improvements in HbA_{1c} values. In this setting, in which care is delivered by a multidisciplinary team, HbA_{1c} values improved when the education team included an RD but not when clinical nutrition education was provided by a non-RD. This observation provides evidence that the effectiveness of clinical nutrition education found in clinical trials is translatable into routine clinical practice in a large national health care program. Our observation also uniquely confirms the relative importance of the RD compared with the non-RD in achieving desired glycemic control outcomes from the clinical nutrition education process.

There is reason to believe that the observed effect of clinical nutrition education on the difference between the two most recent HbA_{1c} values in this study is clinically and statistically significant. The IHS Standards of Care for Diabetes Mellitus recommends measurement of HbA_{1c} quarterly and clinical nutrition education annually. For the purpose of analysis, we have assumed that clinical nutrition education occurred before or during the measurement interval. We have estimated, from a large sample of patients at a single institution, that the measurement interval was \sim 132 days and was comparable between the education groups. If the differences observed over this 132-day period were projected over a year, this would result in an \sim 0.27-unit decrease in HbA_{1c} for patients receiving clinical nutrition education compared with a 0.18-unit increase in HbA_{1c} for individuals not receiving clinical nutrition education. The comparable improvement in HbA_{1c} value when an RD was a part of the instruction team was of a greater magnitude. If projected over a year, RD instruction would result in a 0.78-unit decrease and instruc-

Table 3—Adjusted* HbA_{1c} level mean differences (SE) by clinical nutrition education for those receiving diet therapy and oral agent therapies

	N =	HbA _{1c} mean difference	
Clinical nutrition education	7,490	(SE)	95% CI
Diet therapy			
Diet instruction			
Yes	568	-0.14(0.07)	-0.28, -0.01
No	300	-0.02 (0.88)	-0.15, 0.20
RD	163	$-0.23 (0.12)^{a}$	-0.47, -0.02
Both RD and non-RD	95	$-0.18(0.15)^{a,c}$	-0.48, 0.13
non-RD	310	-0.10 (0.09) ^d	-0.27, 0.07
None	285	0.04 (0.09) ^b	-0.13, 0.22
Refused	15	-0.30 (0.35)	-0.98, 0.40
Oral therapy			
Diet instruction			
Yes	3,156	$-0.19(0.04)^{a}$	-0.27, -0.11
No	1,564	$-0.02 (0.05)^{b}$	-0.12, 0.08
RD	1,018	$-0.23 (0.06)^{a}$	-0.35, -0.10
Both RD and non-RD	544	$-0.33 (0.08)^{a,c}$	-0.49, -0.17
non-RD	1,594	$-0.12 (0.05)^{d}$	-0.22, -0.02
None	1,487	$-0.01 (0.05)^{b}$	-0.11, 0.09
Refused	77	-0.17 (0.19)	-0.54, 0.20

Data are n or means (SE). *Adjusted for age, sex, duration of diabetes, BMI, initial HbA $_{1c}$ level, and clinical facility; a,b and c,d are statistically significantly different by Tukey's studentized range (honestly significant difference).

tion by both an RD and a non-RD would result in a 0.96-unit decrease. This magnitude is comparable to the decrease in HbA_{1c} seen in clinical trials of education in diabetes and would be comparable to some medication interventions (5). Because this data comes from audits of actual clinical practice, the quality of documentation, the timing and intensity of the education process itself, and the interval of HbA₁₆ measurement are likely much more variable than we have assumed. This variability would likely bias against the finding of an association between the education groups. Therefore, we believe that the differences observed may be conservative estimates of overall magnitude and an underestimate of the relative effect of RDs compared with non-RDs.

Interestingly, we did not see an improvement in the subset of patients treated with insulin. The reasons for this are not known. However, we suspect that insulin therapy is a marker for more advanced diabetes where, because of progressive metabolic deterioration and β -cell dysfunction, even appropriate dietary therapies would be less effective than medication therapies in achieving glycemic control (13). In support of this hypothesis, when we looked at a different

set of patients with proteinuria, another marker of more advanced diabetes, there were no differences in ${\rm HbA_{1c}}$ values among any of the clinical nutrition education groups (data not shown). We do not suggest that clinical nutrition education is not valuable in patients with more advanced diabetes but that the effect on glycemic outcomes is not or is at least less demonstrable.

Although our data are consistent with the possibility that dietary education by an RD results in improved glycemic control outcomes in patients with diabetes, this was an observational study, and we cannot assign causality to the associations identified. Patient characteristics and behaviors may have significantly influenced whether an RD was involved in the educational process. Such patient-specific differences may have influenced changes in HbA_{1c} value during the study period. We did attempt to account for some patient level differences by adjusting the HbA_{1c} difference for age, sex, type of treatment, duration of diabetes, BMI, and initial HbA_{1c} level. Facility level differences may also have played a role. For example, facilities that have RDs as members of the education team could potentially differ in a variety of ways from facilities without RDs, which in turn may

have influenced the patient outcomes. Therefore, we sought to adjust for such differences by including a variable for the facility in our models. Finally, we cannot determine what quantitative or qualitative differences in the educational process between RD and non-RD clinical nutrition educators might reasonably be associated with the observed outcomes. Further research and data gathering will be needed to better understand these associations.

In summary, documentation of clinical nutrition education as delivered in this large health care organization is associated with favorable trends in glycemic control during a 1-year audit period. Our data support the concept that clinical nutrition education should be delivered by an RD or a team that includes an RD to be effective in achieving better glycemic control and reducing the risk for future complications.

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