# Relation Between the Level of American Indian and Alaska Native Diabetes Education Program Services and Quality-of-Care Indicators

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American Indians and Alaska Natives experience a 2- to 3-times higher prevalence of diabetes compared with the US population overall.<sup>1</sup> Recent Indian Health Service (IHS) data indicate a doubling of the prevalence in American Indians and Alaska Natives younger than 35 years<sup>2</sup> who are at an increased risk for complications and death earlier in life.<sup>3</sup> American Indian and Alaska Native (AIAN) age-adjusted diabetes death rates are almost 4 times higher than the US all-races rate.<sup>4</sup>

Intensive diabetes management can reduce costly and debilitating complications.<sup>5</sup> The National Standards for Diabetes Self-Management Education define quality diabetes education that can result in improved health outcomes and emphasize the importance of evaluating the quality and effectiveness of diabetes education programs.<sup>6,7</sup> Among the AIAN population, receipt of diabetes education is associated with higher completion rates of diabetes care indicators, such as annual foot examinations, laboratory tests, and immunizations.<sup>8</sup>

In the 1990s, the IHS National Diabetes Program (now the IHS Division of Diabetes Treatment and Prevention [DDTP]) developed the Integrated Diabetes Education Recognition Program (IDERP) to evaluate the quality of diabetes education services provided in health programs serving American Indians and Alaska Natives. IDERP assesses the extent to which programs implement the 10 National Standards for Diabetes Self-Management Education.<sup>9,10</sup>

The IHS program is similar to the American Diabetes Association Diabetes Education Recognition Program<sup>11</sup> but is tailored to assess educational, clinical, and public health services specific to AIAN health programs. IDERP involves ranking programs in terms of successively more-comprehensive levels of services: level 1 is developmental, level 2 is

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*Objectives.* We examined the relation between the level of diabetes education program services in the Indian Health Service (IHS) and indicators of the quality of diabetes care to determine if more-comprehensive diabetes services were associated with better quality of diabetes care.

*Methods.* In this cross-sectional study, we used the IHS Integrated Diabetes Education Recognition Program to rank program services into 1 of 3 levels of comprehensiveness, ranging from lowest (developmental) to highest (integrated). We compared quality-of-care indicators among programs of differing levels with the 2001 IHS Diabetes Care and Outcomes Audit. Quality indicators included patients having recommended yearly examinations, education, and laboratory tests and achieving recommended levels of intermediate outcomes of care.

*Results.* Most of the 86 participating programs were classified at or below the developmental level; only 9 programs (11%) were ranked at higher levels. After adjusting for patient characteristics, program factors, and correlation of patients within programs, we associated programs that were more comprehensive with higher completion rates of yearly lipid and hemoglobin A1C tests (P<.05).

*Conclusions.* System-wide improvements in diabetes education are associated with better diabetes care. The results can help inform the development of diabetes education programs. (*Am J Public Health.* 2008;98:2079–2084. doi:10.2105/AJPH.2007.110478)

educational, and level 3 is integrated. IDERP seeks to improve the quality of diabetes care by increasing the number of AIAN health programs that volunteer to implement the criteria and achieve recognition to at least level 2, which renders them eligible to receive Medicare reimbursement for diabetes education services.<sup>12</sup> To our knowledge, no previous studies have evaluated IDERP to determine whether its implementation is associated with better diabetes care outcomes.

The aims of our study were to determine (1) the number of AIAN health programs ranked at each level of IDERP and (2) the association between the level of diabetes education services and the quality of diabetes care.

# **METHODS**

# Setting

The IHS provides health care to American Indians and Alaska Natives who are members of federally recognized tribes in the United States through a system of IHS-funded hospitals and clinics located on or near AIAN reservations in both urban and rural areas. In 1979, Congress directed the IHS to establish its National Diabetes Program, now the DDTP, to address the increasing prevalence of diabetes in AIAN communities. The DDTP serves as a network of resources for diabetes care, including a national office in Albuquerque, New Mexico; diabetes consultants in each IHS administrative area; and diabetes programs in local AIAN health facilities.

The DDTP sets standards for diabetes care, conducts routine surveillance on the prevalence of diabetes and the quality of diabetes care, and provides technical assistance to AIAN health programs. The DDTP also administers the Special Diabetes Program for Indians, which is a congressionally mandated grant program that has funded nearly 400 new diabetes care programs in AIAN communities since 1998; this has resulted in substantial improvements in diabetes

# Examples of Criteria for Each Program Level Under Standard 1 in the Indian Health Service (IHS) Integrated Diabetes Education Recognition Program

Standard 1—Structure: the Indian Health Service Diabetes Self-Management Education entity documents an organizational structure, mission statement, and goals and will recognize and support quality diabetes self-management education as an integral component of diabetes care.

# Level 1: Developmental

# Diabetes team

Members are identified, meetings are started; roles and responsibilities of team members are identified; required team composition (primary care provider, registered nurse, and registered dietician minimum) is in place

## **Diabetes registry**

Registry is in place; standard data guidelines used; annual update process identified

## Administration

Administration considers diabetes education program within the organizational structure

# **Program manual**

Program manual started, including (at a minimum): General description of the education program Policies Mission statement Goals and annual plan Organizational chart Team member roles and responsibilities Education program structure Forms

## Written statements

Written statements documenting
Team approach is integral component of diabetes education program
Administrative commitment and support for team meetings
Diabetes education instructors and staff; instructional time, preparation, implementation, and evaluation
Tribal commitment and support for diabetes education program

### Level 2: Educational

Team meets on a quarterly basis at minimum; team meetings are documented; team discusses and tracks diabetes education issues; team coordinates with appropriate departments

Diabetes team uses registry for annual planning

Organizational chart shows placement of diabetes education program in facility

Content (noted in level 1) is completed; signed by the appropriate personnel or departments; a process is in place for manual review and update

#### Level 3: Integrated

- Team membership is expanded to include clinical, educational, public health, and community representatives; there is a coordinated approach to diabetes management and education; integration of diabetes education and medical standards of care is documented
- Diabetes registry is expanded to include general registry and complications. Other registries are developed to help track target populations (e.g., endstage renal disease, hypertension, gestational)

Organizational chart shows placement of diabetes program in the organizational structure of the facility

Program manual is expanded to describe educational and clinical components for diabetes prevention and management; manual also includes written statements regarding team commitment to National Standards for Diabetes Self-Management Education and IHS Standards of Care for Patients With Type 2 Diabetes

Approval mechanism is documented for program and policy changes

Administrative commitment to National Standards for Diabetes Self-Management Education and IHS Standards of Care for Patients With Type 2 Diabetes; tribal commitment to address diabetes prevention and management

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processes of care and intermediate clinical outcomes.  $^{\rm 13}$ 

IDERP uses criteria to assess AIAN health programs with respect to the comprehensiveness of their diabetes education services. Programs are assessed for the extent to which they implement each of the 10 National Standards for Diabetes Education and are ranked into 1 of 3 levels, as described earlier.<sup>10</sup> The box on the previous page illustrates how criteria for standard 1 differ across the 3 levels.

To achieve recognition and eligibility to receive Medicare reimbursement for diabetes education services, programs must meet all criteria in level 1 (developmental) and level 2 (educational). This designation means that "quality diabetes education services" are in place. Level-3 (integrated) programs receive special recognition as offering "the best in diabetes care and education practices by integrating community-wide prevention programs, diabetes clinical systems, and educational programs for people with diabetes and their families."10 The IDERP is the only entity other than the American Diabetes Association Diabetes Education Recognition Program<sup>11</sup> that can certify a program eligible for diabetes education Medicare reimbursement. The number of programs applying for IDERP recognition has increased substantially over the last few years.

## Sample

In 2001, more than 300 IHS-funded hospitals and clinics nationwide offered services for diabetes care. For our study, the DDTP invited 138 of these IHS-funded programs to participate with the requirement that they have clinical services and had taken part in the IHS Diabetes Care and Outcomes Audit in the past year. Participating programs were asked to complete the IDERP checklist and indicate which criteria they met under each of the 10 national standards as of the year 2001.

Of the 138 invited programs, 88 (64%) completed the IDERP checklist. Two diabetes educators familiar with IDERP called each of the 88 participating programs to review completed checklists and verify the availability of evidence to support recognition criteria. This information was used to classify each program according to 1 of the 3 recognition levels.

We linked program-level data to patientlevel data from the 2001 IHS Diabetes Care and Outcomes Audit (hereafter "the 2001 audit"). The Diabetes Care and Outcomes Audit is an annual medical record review of more than 80 indicators of diabetes care in a systematic, random sample of patients from participating AIAN health programs.<sup>14</sup> Two of the 88 participating programs were excluded from analyses because they did not participate in the 2001 audit. Patients for whom key covariates, such as gender, age, and duration of diabetes were missing also were excluded from analyses. The final sample included 86 participating programs with a total of 7230 patient records in the 2001 audit.

## Measures

Program-level characteristics included facility type (i.e., hospital or clinic), number of patients in the diabetes registry, and recognition level assigned by the project diabetes educators. We dichotomized the 3 recognition levels into developmental (level 1 or below) and educational and integrated (levels 2 and 3) programs for this analysis to allow comparison between more- and lesscomprehensive programs. Levels 2 and 3 were combined because of the few facilities in the educational and integrated levels. Patient characteristics collected during the 2001 audit included gender, age, and duration of diabetes in years. We conducted additional analyses to determine whether participating programs differed from nonparticipating programs and found no significant differences in program or patient characteristics.

Patient-level outcomes were derived from the 2001 audit. Indicators of diabetes care included completion of annual foot, eye (e.g., dilated retinal), and dental examinations; receipt of annual general diabetes education, diet education, and education about exercise; completion of yearly laboratory tests, including creatinine, lipids (total cholesterol, low-density lipoprotein [LDL] cholesterol, high-density lipoprotein [HDL] cholesterol, and triglycerides), urinalysis, and glycated hemoglobin (hemoglobin A1C); and receipt of recommended influenza and pneumococcal vaccinations.

Intermediate outcomes of diabetes care were based on the IHS Standards of Care for Patients With Type 2 Diabetes<sup>15</sup> and included achievement of recommended levels of hemoglobin A1C, systolic and diastolic blood pressure, and LDL cholesterol.

### **Analysis**

We calculated descriptive statistics for continuous variables as mean  $\pm$ SD and computed percentages for categorical variables. We calculated the percentage completion of each diabetes care indicator and percentage achievement of recommended levels of intermediate outcomes to compare results in developmental programs with those in educational and integrated programs.

We used multivariate logistic regression to compare the odds of completion of each diabetes quality-of-care indicator in educational and integrated programs with those in developmental programs. We also used multivariate logistic regression to compare the odds of meeting recommended levels for intermediate outcomes in educational and integrated programs with those in developmental programs. Regression models were adjusted for age, gender, duration of diabetes, number of patients in the diabetes registry, and facility type. We present adjusted odds ratios with 95% confidence intervals for all outcomes.

# Accounting for the Correlated Data Structure

In this analysis, patients were clustered within health programs and were not treated as independent observations. To obtain appropriate statistical estimates for clustered data, we used generalized estimating equations (GEE) regression modeling. This method accounted for correlation among patients within the same health care facility.<sup>16</sup> The GEE method we used assumed an independent working correlation structure and the robust sandwich variance estimate. Use of this method is important in studies of programmatic interventions at the level of facilities. The ability to assess whether differences in patient outcomes according to program level are present requires a proper adjustment for patient clustering within facilities. Failure to adjust for this clustering can result in variance estimates that are too small and in resultant P values and confidence intervals that are incorrect.17

We underscore the importance of the GEE method to account for patient clustering by

TABLE 1—Characteristics of Programs Participating in the Indian Health Service (IHS) Integrated Diabetes Education Recognition Program and Their Patients: IHS Diabetes Care and Outcomes Audit, 2001

	% or	
	Mean (SD)	
Programs		
Facility type		
Hospital	30	
Clinic	70	
Program management type		
IHS	53	
Tribally managed	47	
Program ranking		
$\leq$ Level 1	89	
Level 2	5	
Level 3	6	
Patients in diabetes registry	651 (811)	
Patients		
Female	58	
Age, y	55 (14)	
Duration of diabetes, y	8 (8)	

*Note.* Number of programs = 86; number of patients = 7230.

presenting the design effect for the variance of the odds ratios associating the diabetesprogram level with our outcome measures. A design effect is a ratio showing the influence of clustering on the estimated variance for the odds ratios. We calculated the ratio by dividing the variance estimate for an odds ratio obtained from the GEE model by the comparable variance estimated for the same odds ratio obtained from a standard logistic regression model assuming all observations were independent. A design effect of 1.0 indicates that clustering has no influence on the estimated odds ratio variance, whereas effects greater than 1.0 suggest that standard logistic regression generates an incorrect variance that is too small. Analyses were performed with Stata 8.1 (Stata Corp, College Station, Texas).

# RESULTS

Most programs that participated in this project were clinic based (70%), and the remainder operated in hospital settings (Table 1). TABLE 2—Completion of Diabetes Quality-of-Care Indicators, by Indian Health Service (IHS) Integrated Diabetes Education Recognition Program Levels and the 2001 IHS Diabetes Care and Outcomes Audit

	Prograi			
	Educational and Integrated, <sup>a</sup> %	Developmental, <sup>a</sup> %	OR <sup>b</sup> (95% CI)	Desigr Effect <sup>o</sup>
Yearly examinations				
Foot	59	55	1.1 (0.6, 2.0)	13.7
Eye	52	48	0.8 (0.5. 1.1)	4.9
Dental	37	36	1.0 (0.6, 1.7)	10.1
Yearly education				
Diabetes	68	62	1.3 (0.5, 3.1)	27.7
Diet	66	51	1.8 (0.8, 4.0)	21.6
Exercise	59	45	1.4 (0.6, 3.4)	29.0
Yearly laboratory tests				
Creatinine	93	88	1.7 (0.9, 3.0)	4.7
Cholesterol	82	75	1.9 (1.3, 2.6)	3.2
Low-density lipoprotein cholesterol	75	59	2.2 (1.5, 3.2)	5.0
High-density lipoprotein cholesterol	79	62	2.7 (1.8, 4.0)	5.4
Triglycerides	82	70	2.4 (1.6, 3.7)	4.7
Urinalysis	86	83	1.4 (0.6, 3.2)	12.9
Hemoglobin A1C	98	89	4.2 (2.1, 8.4)	2.2
Immunizations				
Influenza vaccine	52	47	1.1 (0.8, 1.6)	6.0
Pneumococcal vaccine	72	65	1.0 (0.5, 1.9)	12.5

Note. OR = odds ratio; CI = confidence interval. Sample size for diabetes quality-of-care indicators varies as a result of missing data (range for n = 7146-7230).

<sup>a</sup>Unadjusted for covariates.

<sup>b</sup>Adjusted for age, gender, duration of diabetes, number of patients in program's diabetes registry, type of facility, and correlation of patients within programs.

<sup>c</sup>Design effects indicate the influence of data clustering on the variance of the ORs; substantial design effects that are much greater than 1 effectively reduce the sample size.

Programs were managed by either IHS (53%) or tribes (47%). The mean number of patients in program diabetes registries was 651 (SD=811). More than half (58%) of the patients were female; the mean age was 55 years (SD=14). The mean number of years diagnosed with diabetes was 8 (SD=8). According to IDERP criteria, 77 (89%) programs ranked at or below level 1, 4 (5%) at level 2, and 5 (6%) at level 3.

Table 2 illustrates completion of diabetes quality-of-care indicators according to the IDERP levels and the 2001 audit. A greater percentage of the patients in the educational and integrated programs (levels 2 and 3 combined) completed all of the quality-ofcare indicators compared with those in the developmental programs (at or below level 1). The greatest differences were seen in completion of certain yearly laboratory tests (i.e., LDL cholesterol, HDL cholesterol, triglycerides), diet and exercise education, and hemoglobin A1C tests. After adjustment for patient and program factors and clustering of patients within programs, the odds of completing 5 of the 15 indicators (e.g., total cholesterol, LDL and HDL cholesterol, triglycerides, and hemoglobin A1C tests) were significantly greater for higher-level programs. Design effects were all much greater than 1.0 for diabetes quality-of-care indicators (range=2.2–29.0), which shows the lack of independence of patients seen in the same facility.

Table 3 presents the achievement of recommended levels of intermediate outcomes of diabetes care (hemoglobin A1C, systolic and diastolic blood pressure, and LDL cholesterol) according to IHS treatment goals. The

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TABLE 3—Achievement of Recommended Levels of Intermediate Outcomes of Diabetes Care, by Indian Health Service (IHS) Integrated Diabetes Education Recognition Program Levels and the 2001 Indian Health Service Diabetes Care and Outcomes Audit

	Program Level			
Intermediate outcome <sup>a</sup>	Educational and Integrated, <sup>a,b</sup> %	Developmental, <sup>a,b</sup> %	OR <sup>c</sup> (95% CI)	Design Effect <sup>d</sup>
Hemoglobin A1C<7.0%	33	34	1.1 (0.8, 1.7)	5.8
Systolic blood pressure < 130 mm Hg	39	42	0.9 (0.7, 1.2)	3.8
Diastolic blood pressure < 80 mm Hg	72	67	1.1 (0.7, 1.6)	5.2
Low-density lipoprotein cholesterol <100 mg/dL	46	44	1.0 (0.8, 1.4)	2.6

Note. OR = odds ratio; CI = confidence interval.

<sup>a</sup>Sample size for intermediate outcomes varies as a result of missing data (range for n=4415-6669).

<sup>b</sup>Unadjusted for covariates

<sup>c</sup>Adjusted for age, gender, duration of diabetes, number of patients in program's diabetes registry, type of facility, and correlation of patients within programs.

 $^{d}$ Design effects indicate the influence of data clustering on the variance of the odds ratios; substantial design effects that are much greater than 1 effectively reduce the sample size.

percentage of patients achieving recommended levels was similar in both levels of programs, with the greatest difference seen in diastolic blood pressure control. After we adjusted for covariates and patient clustering, the odds of achieving recommended levels of intermediate outcomes were all close to 1.0. Design effects again were substantial, ranging from 2.6 to 5.8.

# DISCUSSION

This study represents the first use of IDERP to evaluate systemwide implementation of the National Standards for Diabetes Self-Management Education in AIAN health programs. The results indicate that only 9 of 86 participating programs met enough criteria (at least level 2) to receive official IDERP recognition. Most programs (77) ranked at level 1 or less, which is not surprising because IDERP requires an extensive documentation process and AIAN health programs are generally understaffed. The authority of the IHS to certify programs for Medicare reimbursement of diabetes education services also has been present only since 2002. Nonetheless, these results indicate the need for more education about IDERP and technical assistance to help programs achieve recognition.

This study provided a baseline assessment of the level of diabetes education services according to IDERP in programs throughout

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the AIAN health system against which future evaluations may be compared as more programs achieve recognition. Recognition is important because it renders programs eligible to receive Medicare reimbursement. Given that the IHS is funded at about only 40% of need, additional revenues can have an important effect on services at these already understaffed programs.<sup>18</sup>

Estimates for nearly all quality-of-care outcomes indicated that programs with a more comprehensive level of services tended toward better-quality diabetes care. Although most of the outcomes we examined were not significantly different by IDERP ranking, the pattern of findings across all outcomes was consistent with our original hypothesis that higher-level programs would have betterquality diabetes care. The greatest differences were seen in completion of diabetes qualityof-care indicators; differences in intermediate outcomes by program level were not statistically significant.

The number of patients (over 7000) in our study was substantial, but this sample size was somewhat deceiving because of the strong influence of patient clustering and the relatively few programs at the educational and integrated level. This led to large design effects and effectively reduced our sample size. Had we not used GEE methods to obtain adjusted variances, we might have concluded inappropriately that all odds ratios for completion of diabetes quality-of-care indicators were statistically significant. After we adjusted for the design effects, only 5 of the 15 quality-of-care indicators were significantly different by program level.<sup>19</sup> More generally, this illustrates the importance of understanding the substantial effect that clustered data structures can have on inference in program evaluation.

### Limitations

This study had several limitations. The data were drawn from participating programs in the AIAN health system, and our findings were likely an overestimate of results for all AIAN diabetes education programs. The results do not include data from AIAN patients in non-AIAN health systems and therefore are not generalizable outside the AIAN health system. Although we carefully checked the validity of responses to IDERP criteria by telephone, site visits to review evidence may have resulted in more-accurate results. IDERP now involves more-rigorous documentation and more site visits to verify results in person.

#### Conclusions

Despite these limitations, our study represents the first attempt to evaluate the quality of diabetes care in AIAN health programs according to the level of diabetes education services. Most studies of diabetes care review patient outcomes within individual programs at 1 level of service. The audit represents a unique source of annual outcome data at both patient and program levels, and IDERP allows comparison of outcomes by differing levels of diabetes-education services according to the National Standards for Diabetes Self-Management Education. On the basis of our review of the literature, this was the first evaluation of diabetes care as a function of the extent to which numerous programs have implemented the National Standards for Diabetes Self-Management Education.

Our findings are meaningful both programmatically and clinically. These data can help inform programs about the need for greater participation in IDERP. The trend toward better quality of care in higher-level programs is promising and provides incentive for more programs to implement the National Standards for Diabetes Self-Management Education.

# **RESEARCH AND PRACTICE**

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**Note.** Opinions expressed in this article are those of the authors and do not necessarily reflect the views of the Indian Health Service.

### Contributors

Y. Roubideaux originated the study and supervised and participated in all aspects of its design, conduct, and implementation and the analysis of the data, interpretation of results, and writing of the article. C. Noonan and J.H. Goldberg assisted with the design of the study, analysis of the data, interpretation of results, and writing of the article. S.L. Valdez assisted with the design and implementation of the study, interpretation of results, and writing of the article. T.L. Brown assisted with implementation of the study, interpretation of results, and writing of the article. S.M. Manson assisted with the design of the article. S.M. Manson assisted with the design of the article. K. Acton assisted with the design of the study, approval of the use of data, interpretation of results, and writing of the article.

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This study was approved by the University of Arizona and the University of Colorado at Denver and Health Sciences Center institutional review boards. The Indian Health Service institutional review board approved this article for publication.

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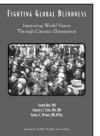
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