Diabetes Outcomes in the Indian Health System During the Era of the Special Diabetes Program for Indians and the Government Performance and Results Act

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Objectives. We reviewed changes in blood glucose, blood pressure, and cholesterol levels among American Indians and Alaska Natives between 1995 and 2001 to estimate the quality of diabetes care in the Indian Health Service (IHS) health care delivery system.

Methods. We conducted a cross-sectional analysis of data from the Indian Health Service Diabetes Care and Outcomes Audit.

Results. Adjusted mean Hemoglobin A1c (HbA1c) levels (7.9% vs 8.9%) and mean diastolic blood pressure levels (76 vs 79 mm Hg) were lower in 2001 than in 1995, respectively. A similar pattern was observed for mean total cholesterol (193 vs 208 mg/dL) and triglyceride (235 vs 257 mg/dL) levels in 2001 and 1995, respectively.

Conclusions. We identified changes in intermediate clinical outcomes over the period from 1995 to 2001 that may reflect the global impact of increased resource allocation and improvements in processes on the quality of diabetes care, and we describe the results that may be achieved when community, health program, and congressional initiatives focus on common goals. (*Am J Public Health.* 2005;95:1518–1522. doi:10.2105/AJPH.2004.053710)

Rates of morbidity and mortality among people with diabetes mellitus can be improved by controlling blood glucose, blood pressure, and lipid levels.[1–5] Health care systems can help people better control their diabetes by allocating resources to and ensuring the quality of a broad array of population-based and individually targeted education, nutrition, and medical therapies.[6–9] Glucose, blood pressure, and lipid control can therefore be used globally as an indicator of the quality of diabetes care services within a particular health care delivery system.

The Indian Health Service (IHS) is a federally operated system that provides health care, along with tribal and urban programs, to more than 1.5 million American Indians and Alaska Natives, of whom approximately 100 000 have been diagnosed with diabetes. Assessing the quality of diabetes care in the IHS health care delivery system is important for 2 major reasons. First, in addition to this population's disproportionately heavy burden of diabetes, American Indians and Alaska Natives with diabetes appear to be at particularly high risk of developing complications.[10–13] Thus, delivery of high-quality care is an important strategy to eliminate the health disparities that result from diabetes in this population.

Second, in the past decade, a substantial refocusing on diabetes has been undertaken by communities, health systems, and Congress. This focus has resulted in an increased interest in federal agency performance measurement and reporting as a means of judging effectiveness and maintaining accountability. We estimated quality of diabetes care in the IHS health care delivery system by examining system-level changes in blood glucose, blood pressure, and lipid control over the period from 1995 to 2001.

METHODS

Setting and Design

Because the IHS is an integrated health services delivery system, individual Indian tribes have the opportunity to become involved in developing and managing health care programs that target locally defined needs. IHS services are provided through both federally managed and tribally contracted and operated health programs. The federal system consists of 36 hospitals, 61 health centers, 49 health stations, and 5 residential treatment centers. American Indian and Alaska Native tribes are responsible for managing 13 hospitals, 158 health centers, 28 residential treatment centers, 76 health stations, and 170 Alaska village clinics. In addition, a variety of health and referral services are provided through 34 urban Indian health projects.[14] We examined selected intermediate clinical outcomes of IHS diabetes care between 1995 and 2001.

IHS Diabetes Program

The IHS National Diabetes Program (NDP), now known as the IHS Division of Diabetes Treatment and Prevention, was established in 1979, initiated as a result of the Indian Health Care Improvement Act of 1976. The NDP was charged with combating the diabetes epidemic in American Indians and Alaska Natives by using models of diabetes care and prevention that were based on medical, public health, and community models. In the mid-1980s, the NDP, in conjunction with clinicians, created guidelines designed to improve care and outcomes among patients with diabetes seen in IHS, tribal, and urban program facilities.[15]

The NDP also identified key variables to measure patient care, track intermediate clinical outcomes, and provide ongoing surveillance of care practices. In 1986, these guidelines and measures became the IHS Standards of Care for Diabetes. Simultaneously, the annual Diabetes Care and Outcomes Audit, which monitored key variables

at local facilities, was created and implemented.[16] Both the IHS Standards of Care for Diabetes and the Diabetes Care and Outcomes Audit measures have been revised periodically to reflect new scientific findings and improvements in clinical practice.

Special Diabetes Program for Indians

The Special Diabetes Program for Indians was established by Congress as part of the Balanced Budget Act of 1997. Built up in stages by additional legislation, it currently provides $150 million per year to the IHS to establish grants aimed at preventing and treating diabetes. Tribes and tribal leaders, urban Indian organizations, and IHS staff were included in the development of the grant program. A tribal leaders diabetes committee, formed as a partnership between tribes and the IHS, provided guidance on diabetes and grant program issues. Grants were awarded to 318 programs under 286 administrative organizations within the 12 IHS areas. Twenty-seven grants were awarded to IHS programs, 33 were awarded to urban programs, and 258 were awarded to tribal programs.

Approximately two thirds of grant activities focused on primary and secondary prevention, with the remaining activities focused on tertiary prevention. Examples of the wide range of grant activities included use of traditional approaches, such as story-telling and talking circles, and use of traditional herbs or medicines to help support and influence positive diabetes self-management behaviors. Most grantees established new or improved existing diabetes teams and clinics, created diabetes registries and related data systems, and augmented health care staff, including nutritionists and case managers, supplies (such as pharmaceuticals), and equipment (such as meters for self-monitoring blood glucose). Funds were first allocated to programs in October 1998.

Government Performance and Results Act

The Government Performance and Results Act of 1993 (GPRA) requires federal agencies to demonstrate that they are effectively using their funds to meet their missions. Agencies are required to have a 5-year strategic plan in place and to submit annual performance plans and reports with their budget requests. In the case of the IHS, a GPRA coordinating committee guides the agency's annual performance plan development and implementation and oversees annual performance reporting. GPRA performance indicators specific to diabetes include blood glucose, blood pressure, and cholesterol measures.

The data source for the IHS GPRA annual performance report is the IHS Diabetes Care and Outcomes Audit. The measures used in the audit are comparable to the measures used for national health outcome indicators such as the indicators implemented in the National Committee for Quality Assurance's Health Plan Employer Data and Information Set and the Centers for Disease Control and Prevention's *Healthy People 2010.* Given the importance of measuring diabetes care outcomes in response to the GPRA, the IHS has implemented a number of processes, including systemwide training, to increase the accuracy and amount of audit data reported.

IHS Diabetes Care and Outcomes Audit

Data for this study were derived from the 1995–2001 Diabetes Care and Outcomes Audits. IHS and tribal clinic facilities are encouraged to maintain diabetes registries for all individuals with diabetes, and a systematic, random sample of records is selected for review each year. The randomization and sample collection methods used provide an estimate of performance for each facility within 10% of the true rate with a power of more than 90%.[17] Local professional staff members, supported by regional diabetes consultants, review paper-based, electronic medical records, or both, using a uniform set of inclusion and exclusion criteria and measurement definitions. Abstracted data are then entered (for manual audits) or exported (for electronic audits) into a general-purpose, microcomputer-based software program. Data from participating sites are combined regionally and then aggregated nationally to establish systemwide performance values.

Although national validation studies of the audit have not been published, several IHS regional administrative areas have used different reviewers to audit the same charts and assess accuracy of the data entry procedures. An evaluation comparing paper-based and electronically based data collection showed good agreement (κ values of 0.78–1.00) at 1 facility (C. Wilson, MD, Phoenix Indian Medical Center, Indian Health Service, unpublished data, January 2004). Although the audit includes patients of all ages, we limited our evaluation to individuals aged 18 years or older, because diabetes care standards currently are available only for adults.

Data Collection

Outcome variables. We focused our evaluation on yearly results associated with 3 systemwide diabetes care clinical outcomes—blood glucose, blood pressure, and lipid control—from the period 1995 to 2001. The final value for each variable within the performance year was recorded.

We assessed glucose control by examining Hemoglobin A1c (HbA1c) levels recorded for patients included in the audit. HbA1c was determined at local or regional IHS or commercial laboratories throughout the nation using standard, clinically available assays.

We obtained systolic and diastolic blood pressure measurements from the recorded audit measurements. Measurements we obtained as a result of emergency medical care visits were excluded. We calculated mean systolic and diastolic levels using the 3 most recent blood pressure recordings included in each record.

We determined lipid control using total cholesterol and triglyceride values, data for which were widely available throughout the study period. We obtained these values from local or regional laboratories throughout the nation that used standard, available clinical assays. Missing values precluded assessment of high-density and low-density lipoprotein cholesterol levels.

Covariates. Demographic and clinical data of interest collected through the audit included gender, age, height, weight, duration of diabetes, and treatment type. Age was calculated as date of audit minus date of birth. Body mass index (BMI) was calculated from recorded height and weight. Duration of diabetes was recorded as time in years since diagnosis. Treatment type was recorded as diet and exercise alone (no medication), oral agent, insulin, or oral agent in combination with insulin (we combined the latter category with the insulin group for analysis purposes).

TABLE 1—Selected Demographic and Clinical Characteristics of American Indians and Alaska Natives With Type 2 Diabetes: Indian Health Service Diabetes Care and Outcomes Audit, 1995–2001

	1995 (n = 7110)	2001 (n = 15 537)
Gender, No. (%)		
Male	2783 (39.1)	6463 (41.6)
Female	4327 (60.9)	9074 (58.4)
Treatment type, No. (%)		
Diet and exercise alone	1009 (14.2)	2262 (14.6)
Oral agents	3952 (55.6)	9112 (58.6)
Insulin (with or without oral agents)	2149 (30.2)	4163 (26.8)
Age at audit, y, mean (SD)	55.6 (13.4)	54.9 (13.7)
BMI, mg/kg^2, mean (SD)	32.1 (6.7)	33.5 (7.4)
Diabetes duration, y, mean (SD)	9.2 (7.6)	8.3 (7.4)

Note. BMI = Body mass index.

Data Analyses

We conducted a descriptive analysis of variation in terms of the intermediate clinical outcomes according to the demographic and clinical variables between 1995 and 2000. We used analysis of covariance techniques to estimate mean HbA1c, blood pressure, and cholesterol values. All trend analyses were adjusted for age, gender, treatment type, and facility from which patient data were collected. Analyses of HbA1c trends also were adjusted for BMI and duration of diabetes. Analyses of triglyceride trends were adjusted for BMI, because of the positive association between triglyceride levels and BMI observed in univariate analyses of these variables.

None of the adjustments resulted in statistically significant changes of the primary outcome measure, but we included them to help decrease potential bias. The final analyses were limited to patients with complete data for each covariate. SAS software was used in conducting all analyses.[18]

RESULTS

The IHS Diabetes Care and Outcomes Audit included 87 048 records of patients with diabetes who were at least 18 years old at the time their record was audited. The number of clinical programs participating in the audit in a given year varied as a result of the voluntary nature of the audit, ranging from 227 to 235 over the 7-year period. Regarding the outcome measures, 57 942 patients (66.6% of all patients) had both a HbA1c (i.e., glucose control level) and complete information on covariates, 65 646 patients (75.4% of all patients) had systolic and diastolic blood pressures and complete information on covariates, and 55 170 and 51 974 patients (63.3% and 59.7% of all patients, respectively) had total cholesterol and triglyceride levels and complete information on covariates.

Table 1 summarizes selected demographic and clinical measures. In 2001, patients' mean age was 54.9 years, and the mean diabetes duration was 8.3 years. Throughout the study period, most patients were treated with a single oral agent or a combination of oral agents (55.6% in 1995 and 58.6% in 2001), although use of combination hypoglycemic therapy increased over time.

We found that HbA1c, diastolic blood pressure, and total cholesterol and triglyceride levels significantly improved between the 1995 audit and the 2001 audit (Table 2). Adjusted mean HbA1c levels decreased significantly ($P<.0001$), from 8.9% to 7.9%. Systolic blood pressure did not decrease over the period of the study ($P>.05$), but mean diastolic blood pressure decreased by 3 mm Hg, from 79 to 76 ($P<.0001$). Mean total cholesterol and triglyceride levels decreased from 208 mg/dL to 193 mg/dL ($P<.0001$) and from 257 mg/dL to 235 mg/dL ($P<.0001$), respectively.

DISCUSSION

Using data collected between 1995 and 2001 from the IHS Diabetes Care and

TABLE 2—Adjusted Mean HbA1c, Blood Pressure, Total Cholesterol, and Triglyceride Levels: Indian Health Service Diabetes Care and Outcomes Audit, 1995–2001

	Year, Mean (SE)							
	1995	1996	1997	1998	1999	2000	2001	*P* (1995 vs 2001)
HbA1c, %[a]	8.9 (0.04)	8.7 (0.04)	8.4 (0.04)	8.3 (0.03)	8.3 (0.03)	8.2 (0.03)	7.9 (0.03)	.0001
Systolic blood pressure, mm Hg[a]	134 (0.24)	134 (0.24)	133 (0.25)	134 (0.23)	134 (0.21)	133 (0.21)	132 (0.20)	>.05
Diastolic blood pressure, mm Hg[a]	79 (0.14)	78 (0.14)	78 (0.15)	78 (0.13)	77 (0.12)	76 (0.12)	76 (0.12)	.0001
Total cholesterol, mg/dL[b]	208 (0.87)	204 (0.86)	202 (0.89)	204 (0.80)	197 (0.77)	195 (0.77)	193 (0.73)	.0001
Triglycerides, mg/dL[b]	257 (5.02)	238 (5.00)	261 (5.10)	258 (4.65)	246 (4.44)	240 (4.37)	235 (4.16)	.0001

Note. HbA1c = Hemoglobin A1c
[a]Adjusted for age, gender, body mass index, treatment type, duration of diabetes, and facility.
[b]Adjusted for age, gender, body mass index, treatment type, and facility.

Outcomes Audit, we identified changes in HbA1c, diastolic blood pressure, and total cholesterol and triglyceride levels among patients in the IHS health care system. These changes occurred during an era in which systemwide improvements in diabetes care were implemented, special congressional appropriations for diabetes treatment and prevention were made, and an increased emphasis on federal agency performance measurement and reporting was applied. Few health care systems or populations possess this quantity of data over such a long period with which to evaluate systemwide changes in diabetes care. This overall health system view provides a unique opportunity to evaluate the potential effects of certain laws along with the policies, procedures, and partnerships used to implement those laws.

The magnitude of the improvement in outcomes over the study period is likely to have an important public health impact. Epidemiological studies conducted in several American Indian communities have demonstrated strong relationships between morbidity and mortality and blood glucose, blood pressure, and lipid control,[19–21] and intervention trials involving other populations have demonstrated the benefits of lowering glucose, blood pressure, and lipid levels.[1–4,22–27] Comparable clinical trial data are not currently available for American Indians and Alaska Natives with diabetes; however, for those who might question whether clinical trial results can be generalized to this patient population, it should be reassuring to note that American Indians and Alaska Natives taking part in the Diabetes Prevention Program benefited to the same extent as did other ethnic groups.[28]

To continue to improve the quality of diabetes care, efforts will need to be sustained and expanded. Congress recently extended the Special Diabetes Program for Indians for 5 additional years and increased the total funding amount for each fiscal year from $100 million to $150 million. Performance measurement procedures also have improved systematically. Beginning in fiscal year 2003, a new software application, GPRA+ (Clinical Reporting System, Office of Information Technology, Indian Health Service, Albuquerque, New Mexico), was deployed throughout the IHS to support passive retrieval of clinical data. Congressional performance reporting now includes both Diabetes Care and Outcomes Audit data and GPRA+ results. Continued funding of diabetes programs and evolution of data collecting systems are important steps toward sustaining and systematizing diabetes care efforts.

Our study involved some limitations. Participation in the Diabetes Care and Outcomes Audit is voluntary; as a result, the facilities that participated may not be representative of all facilities. For example, if facilities providing poorer quality care chose not to participate, we may have overestimated the health effects. Also, the audit does not collect information on income, employment status, mobility, educational attainment, activity level, or frequency of medical visits. Changes in these unmeasured patient-level factors could have affected the trends we observed. Because our analysis involved cross-sectional data, it is appropriate to use caution when generalizing the differences observed here. To help minimize potential bias, we analyzed differences after adjustment for age, gender, treatment type, and diabetes duration. We also analyzed trends in the data collection process that may have had an influence on the results observed, including the use of different laboratory assays to measure glucose control.

In the past, casual glucose determinations were used to assess glucose control, but this method has been replaced by HbA1c assays. The percentage of patients with measured HbA1c levels increased from 55% in 1995 to 90% in 2001. To reduce the potential bias introduced by these changes in percentages, we conducted several analyses using both casual glucose values and HbA1c values. We used the formula

$$(1)\ \text{HbA1c} = (60.16 + \text{mean glucose}) / 30.9$$

to calculate HbA1c values from available casual glucose values.[29] We then examined glucose control trends among those patients for whom only a calculated HbA1c was available. We found the same statistically significant downward trend when we used only calculated HbA1c values as we did with measured HbA1c values. No changes were observed in the percentage of patients with measured blood pressure levels or lipid values over the study period.

In summary, using IHS Diabetes Care and Outcomes Audit data collected between 1995 and 2001, we identified improvements in diabetes-related health indicators over time. The IHS health system data used in this report offered a unique picture of diabetes care quality during a period of increased legislation, partnership, and policy efforts aimed at improving care of this disease. The outcomes observed in this article demonstrate the improvements that can be achieved when community, health program, and congressional initiatives focus on common goals. Despite these positive outcomes, the continued epidemic growth of diabetes,[30] as well as increases in other chronic diseases and conditions, will require ongoing dedication to effective resource allocation, program accountability, and partnership among tribes, tribal leaders, and federal programs. ■

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Contributors

C. Wilson and S. Gilliland contributed to study conception and to the data analysis. T. Cullen, K. Moore, and Y. Roubideaux contributed to the data analysis. L. Valdez and W. Vanderwagen contributed to study conception. K. Acton contributed to study conception and to the data analysis. All of the authors contributed to the writing of the article.

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Human Participant Protection

No protocol approval was needed for this study.

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