Linking Pharmacy and Laboratory Data to Assess the Appropriateness of Care in Patients With Diabetes

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OBJECTIVE — To use pharmacy and laboratory data to assess diabetes care within a medical group and between medical groups and to determine dispensing patterns and the extent to which providers change therapy based on HbA_{1c} results.

RESEARCH DESIGN AND METHODS — Participating groups submitted 1 year of data for continuously enrolled patients. Required data included date of birth, all diabetes-specific prescriptions (oral hypoglycemic agents and insulin), date of prescription, National Drug Code, all HbA_{1c} values, lower and upper normal limits, and date of testing.

RESULTS — Few changes in therapy were noted despite the large percentages of patients with suboptimal control. Nearly 90% of the patients treated with medications received a monotherapy regimen involving one of three therapeutic agents: sulfonylureas, metformin, or insulin. More than three-fourths of the patients remained on the same therapy during the observation period despite the fact that 27% of these patients had HbA_{1c} values $\geq$8%. Nearly one-fifth (18%) of patients had an HbA_{1c} level of $\geq$8% and no further testing for at least 90 days after the "actionable" HbA_{1c} result was obtained. Furthermore, 54% of patients with actionable HbA_{1c} results did not have a change in therapy initiated after the result was available.

CONCLUSIONS — The American Diabetes Association recommendations to act on HbA_{1c} values $\geq$8% and to follow up regularly on patients found to be in suboptimal control do not appear to be applied in a consistent manner based on the pharmacy and laboratory data analyzed in this sample.

Maintaining optimal glucose control is a stated goal of therapy in patients with diabetes. The Diabetes Control and Complications Trial and the U.K. Prospective Diabetes Study (UKPDS) demonstrated conclusively that glucose control in patients with type 1 and type 2 diabetes will reduce microvascular complications (1,2). The American Diabetes Association (ADA) guidelines encourage physicians to take action when the HbA_{1c} levels are >8% (3,4). Despite the ADA guidelines, considerable variations in diabetes care persist.

Provider profiling has been proposed as one way to hold a physician or medical group accountable for the care delivered and to reduce variation (5). Often these profiles represent aggregate data that examine a sample of total patients with a condition or data that address some utilization parameters without specific links to an outcome. This type of presentation lacks sufficient clinical details and therefore has limited usefulness in influencing or directing care (6). Furthermore, health plans and medical groups worry about the expense of profiling and potential hostile reactions from providers, who are often skeptical of the accuracy and reliability of the profiles (7,8).

The purpose of this study was to assess the extent to which two databases often available to health plans or medical groups (pharmacy and laboratory) could be linked to provide clinically useful data. By linking pharmacy utilization of antihyperglycemic therapy to an outcome (control of glycemia as reflected in HbA_{1c} values), information could be generated for providers that suggests specific actions to take to improve care within the medical group and potentially for individual patients. Physician acceptance of profiling data may increase if data feedback is not only nonpunitive and made available with peer or group comparisons but also adds value to the practice and helps physicians identify and track those patients in need of more aggressive care.

RESEARCH DESIGN AND METHODS — The American Medical Group Association (AMGA) is a trade association representing more than 300 multispecialty medical group members with ~40,000 physicians (9). The AMGA has members in 40 states; some members are stand-alone and fee-for-service entities, whereas others are integrated with hospitals and/or health plans and are highly involved in managed care. AMGA member groups were invited to participate. Groups were not offered incentives to participate other than the possibility of contributing to knowledge about the care of patients with diabetes. Participants were requested to provide the following data for at least 100 continuously enrolled patients with full pharmacy coverage for 1 year: demographic data including patient identification, date of birth, and primary care physician; pharmacy data including all diabetes-specific medications (oral hypoglycemic agents and

Table 1—*Percentage of patients by group and medication change category*

| Group | Change category* | | | | |
	1	2	3	4	*n*
1	72	26		2	51
2	40	36	3	22	2,475
3	46	28	5	21	108
4	43	23	4	30	127
5	36		21	43	14
6	86	11		3	37
7	42	25	5	28	80
8	44	12	11	33	9
9	55	23	4	18	144
Average	52	20	6	22	

Data are % unless otherwise indicated. *Change categories: 1, same oral monotherapy; 2, insulin only; 3, same combination therapy; and 4, any change (other than insulin dose or frequency).

insulin), date of prescription, and NDC code; and laboratory data including HbA_{1c} values, lower and upper normal limits, and date of testing.

Groups were encouraged to submit data from electronic databases using a specified format, but some had to use manual abstraction. Patient age was calculated as of the earliest HbA_{1c} test date or prescription date. SPSS software (SPSS, Chicago) was used for database manipulation and statistical calculations. Analysis of variance was used to test the differences in HbA_{1c} by age, and trend and deviation from linearity were also tested. The difference in average HbA_{1c} for those with and without prescriptions was tested with the independent group *t* test. HbA_{1c} values were standardized by subtracting the midpoint of the group's normal range from each value, dividing the result by one-half of the difference between the upper and lower normal limits, and then adding 5 to bring the final value into the accustomed range.

RESULTS

Participants
Nine multispecialty groups representing a diverse nationwide cross-section submitted data for patients receiving care between January 1996 and March 1998. The data sets provided had different beginning and end points for the various groups. Four groups did not identify primary care physicians. At least one data point was submitted for a total of 4,940 patients, but three groups did not reach the 100-patient goal. No HbA_{1c} or prescription data were available for 122 people, and these subjects were dropped from the analysis, which left

4,818 subjects. Of these subjects, 4,523 (94%) had at least one HbA_{1c} value, 3,886 (81%) had at least one prescription, and 3,590 (74%) had prescription, HbA_{1c}, and demographic data.

Sample description
The average age of patients included in the sample was 61.1 years, and 49.9% were female. Average age by group ranged from 55.3 to 70.7 years, and the percentage of female patients ranged from 40.2 to 59.5%. Although determining the type of diabetes from these data is impossible, only 2.9% of subjects were ≤30 years of age. Of subjects <31 years of age with prescription data, 91% were taking insulin only. Of subjects ≥31 years of age, 32% were taking insulin only, 65% used only oral medications, and 3% used both insulin and oral medications. As a result, we are confident that at least two-thirds of this sample have type 2 diabetes.

Pharmacy data
The pharmacy data included 37,062 prescriptions for 3,886 people. At least two different prescription dates were available for 3,595 (92%) people, and 77% of this group had ≥180 days between the first and last prescription dates.

Almost all (98.1%) of the prescriptions were from three major therapeutic classes: sulfonylureas, metformin, or insulin. Acarbose and troglitazone accounted for the remainder of the prescriptions. At least a two-fold difference is evident in group percentages for each medication class. The group with the highest use of glipizide had the lowest use of glyburide. The group with the highest percentage of metformin prescriptions also had the lowest percentage of

insulin usage. The group with the lowest percentage of "other" medications had the highest glyburide percentage. The group with the highest troglitazone prevalence also had the highest use of acarbose medications. Some groups did not use any acarbose or troglitazone. At the end of the data collection period, 88% of patients taking medications were receiving monotherapies, and only 12% were receiving combination therapy.

In addition to the variation in medications used by the groups, prescriptions for individual patients changed considerably during the course of 1 year. For the following analyses and those concerning HbA_{1c} that follow, patients needed to have at least two prescriptions of ≥180 days apart to be included. Two prescriptions within 60 days for different medications placed them in a combination therapy group. Four categories of medication usage can be defined as follows: *1*) monotherapy (other than insulin only) with no change, *2*) insulin only, *3*) combination therapy without change, and *4*) change in pharmacotherapy other than insulin dose or frequency. The percentages in the four categories by group are shown in Table 1. Overall, less than one-fourth had a change in medications, and only one group had >33% with changes. The prevalence of change was slightly higher for patients 40–69 years of age. Higher prevalence of insulin use was associated with a lack of change (Spearman correlation = −0.52).

HbA_{1c} data summary
A total of 9,789 HbA_{1c} test results was submitted for 4,523 people, and at least one follow-up was submitted for 2,892 people (63%). The average of the final group standardized HbA_{1c} means was 7.7%. HbA_{1c} declined with age ($P < 0.001$); the test of linearity was significant ($P < 0.001$), and a significant departure from linearity ($P < 0.001$) was evident with an unsustained drop in the fourth decade of life. Examining the percentages of patients that exceed various HbA_{1c} levels is more informative (Table 2). Only one group had <30% of their sample with HbA_{1c} levels >8%.

Interestingly, 932 subjects with HbA_{1c} data had no prescription data. The average final HbA_{1c} level for those with no prescriptions and those with at least one prescription was 7.0 and 7.8%, respectively ($P < 0.001$).

The ADA currently recommends that patients with HbA_{1c} levels ≥8% are in a range of glucose control that requires action. One might expect follow-up HbA_{1c} testing

Table 2—*Percentage of patients by group and HbA*$_{1c}$* category*

	HbA$_{1c}$ category (%)				
	<7	7–7.9	8–9.4	>9.5	n
Group					
1	26	39	22	13	87
2	24	21	29	26	3,478
3	48	19	17	15	93
4	58	22	16	4	317
5	47	23	18	12	105
6	29	22	27	22	41
7	47	17	20	16	106
8	31	35	19	15	94
9	29	30	21	20	202
Average	38	25	21	16	—

Data are % unless otherwise indicated.

in these patients within a reasonable time frame, such as 3 months. Therefore, we determined the percentages of patients with final HbA$_{1c}$ values ≥8% and ≥90 days remaining before the group's final laboratory and pharmacy data submissions (Fig. 1). Nearly one-fifth (18%) of the final HbA$_{1c}$ results are in this category. Considerable variation exists between groups. The results suggest that these patients did not have adequate provisions made to reassess their level of glycemic control in the 3-month time period recommended by the ADA.

Patients with elevated HbA$_{1c}$ levels are also candidates for changes in therapy. To assess change, we examined prescriptions for 90 days before and 90 days after a final HbA$_{1c}$ level ≥8%. Three categories of change were used: *1*) no change in prescriptions during the follow-up period, *2*) different medications or dosages after the test, and *3*) insulin only before and after the test (these patients may have had changes that cannot be detected from prescription data). Most patients had no changes, and considerable intergroup variation was evident (Table 3).

Another 19% of all patients had a final HbA$_{1c}$ level ≥8%, but <90 days were available for follow-up. If the experience of these patients is similar to the others with HbA$_{1c}$ levels ≥8%, then the percentage with inadequate follow-up may be >60%. Because of the small numbers of patients who had a change in therapy, we could not assess the effects of changes in therapy on subsequent HbA$_{1c}$ results.

CONCLUSIONS — Diabetes is a major health problem in the U.S. Clear evidence exists that good control can lessen

the effect of this disease, and new treatment modalities appear to make the goal of good control more feasible. However, a large body of literature has suggested that patients with diabetes are not receiving appropriate care (10–13). Efforts introduced by the National Committee for Quality Assurance (14) and the Diabetes Quality Improvement Project (15) to make health plans and medical groups more accountable for diabetes care have added pressure to address deficiencies in diabetes care. Health plans have responded in some cases with elaborate disease state management initiatives (16,17). Medical groups have begun using electronic medical records (18) and better information

systems but are finding implementation issues difficult and costs worrisome.

In this study, we assessed the drug-dispensing patterns in patients with diabetes and the extent to which providers change therapy based on HbA$_{1c}$ results. We found considerable intergroup variation in the medications used to control blood glucose in patients with diabetes. However, almost 90% of the patients treated with medications in this sample were receiving a monotherapy regimen involving one of three therapeutic agents. More than three-fourths of the patients remained on the same therapy during the observation period despite the fact that 27% of these patients had HbA$_{1c}$ values ≥8%. The ADA recommendations to act on HbA$_{1c}$ values ≥8% and to follow-up regularly on patients in suboptimal control do not appear to be applied in a consistent manner as evident from the pharmacy and laboratory data analyzed in this sample. Nearly one-fifth of patients with HbA$_{1c}$ levels ≥8% had no further testing during the next 90 or more days after the "actionable" HbA$_{1c}$ result was obtained. Furthermore, more than half of patients with actionable HbA$_{1c}$ results did not have a change in therapy initiated after the result was available, which suggests a lack of attention to the ADA guidelines.

We do not mean to imply that good diabetes care always equates to medication adjustment. Diabetes is a multifaceted condition that requires a great deal of patient participation and behavior change to be
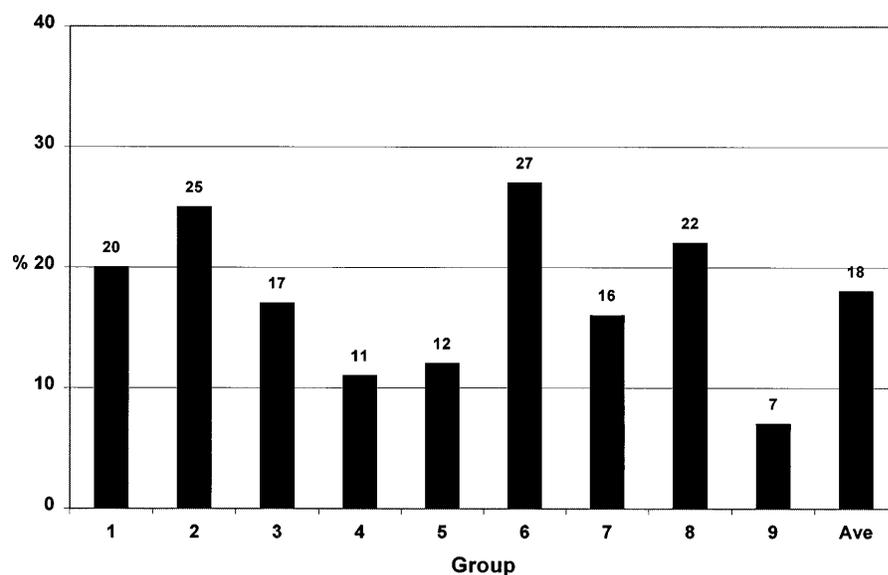

Figure 1—*Patients with HbA*$_{1c}$* values ≥8% with no further testing during the next 90 days or more (percentages by group and average (Ave) of group means).*

Table 3—*Prescription activity in patients with HbA$_{1c}$ levels ≥8% and no further testing for the next 90 days or more*

	No change	Change	Insulin only	*n*
Group				
1	53	41	6	17
2	42	33	24	883
3	13	81	6	16
4	100			36
5	69	31		13
6	46	54		11
7	35	41	24	17
8	86	14		21
9	43	57		14
Average	54	39	7	

Data are % unless otherwise indicated

managed successfully. Nevertheless, the UKDPS clearly demonstrated that combination therapy is the expected consequence of the natural history of this condition, even in patients who are closely monitored and adhere to their treatment plan (19). Moreover, our results may not reflect the actual diabetes care in a larger population because the sample did not represent a known population, and some of the group samples are small. Our goal was to demonstrate the usefulness of linking data that relate a clinical decision to a specific outcome.

Numerous explanations can be offered to explain why elevated HbA$_{1c}$ values are not pursued aggressively and why medication changes do not routinely follow findings of actionable HbA$_{1c}$ results. Some practitioners are still unaware of the ADA guidelines or do not agree with them. The UKPDS study was not yet published and widely discussed when these data were collected, and current pharmacy and laboratory data may provide an improved picture based on the effect of that study. Some providers may not pursue more aggressive regimens in certain patients because of age, comorbidities, or the adverse effect of medications. Some providers may be uncomfortable with insulin therapy or avoid insulin because of issues relating to patient acceptance or the patient education required to use insulin effectively. Inconsistent patient follow-up, nonadherence, or disagreement about a need to change therapy may also play a role. The often asymptomatic nature of diabetes can make accepting less-than-optimal control for several months or even years easier for patient and physician. Finally, most medical offices do not have systems that alert physicians to actionable results or systems that automatically initiate patient contact and close the

loop between data and care plans or treatment algorithms.

Physician profiling generally does not address these issues because it typically focuses on patterns of care instead of specific clinical decisions. In an effort to encourage further investigation into a different use of profiling data, we have described the potential benefit of linking pharmacy and laboratory data in assessing the quality of diabetes care. Profiling pharmacy and HbA$_{1c}$ data in the manner described by group or individual practitioners would help identify and characterize differences in practice style, and medical groups or individual physicians could respond based on ADA standards of care.

The initial reaction by some to the use of administrative or electronic data to assess the quality of care is to raise the now well-discussed concerns relating to validity, reliability, and accuracy of the data (20). Pharmacy data, for example, may not be complete because of the use of pharmacies outside the contracted pharmacy network, purchases with out-of-pocket money, or use of mail-order pharmacies. Profiling data are also seldom risk adjusted. One could suggest that the desired level of HbA$_{1c}$ control would vary for different patient groups depending on age, comorbidities, and type of diabetes. Some would even suggest that such data may lead to gaming the system (i.e., purposeful referral of high-risk or difficult-to-control patients in an effort to improve the data). All of these responses, of course, have some merit but are somewhat dysfunctional.

The more appropriate response is to ask "What sort of data presentation is most useful to the medical group or practicing physician?" What types of data have the potential to help the provider serve his or

her patients better, thereby adding value to the practice? Many health plans and some medical groups have structured integrated databases, a consistent process for reaching members or patients, and are able to close the data collection and feedback loop. By linking pharmacy and laboratory data in the manner illustrated in this report, the data are actionable and direct attention to those patients with persistently poor diabetes control who need modifications in their treatment regimens.

The potential value of this type of analysis and data presentation should be explored further. Information could be given to health plan members that would target those who need follow-up or intervention based on the ADA recommendations or locally accepted diabetes guidelines. Until physician offices are better equipped with information systems needed to manage chronic conditions like diabetes, health plans could also play a useful role in closing the data feedback and treatment loop. Obviously, medical groups capable of extracting these data electronically could use the same strategy in promoting better diabetes care throughout the group. Several of the medical groups participating in this project are now exploring implementation of this approach.

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