Identification, Classification, and Frequency of Medical Errors in Outpatient Diabetes Care

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Abstract

Objectives: Diabetes-related medical errors in outpatient practice are common and costly. This study attempts to accurately identify, classify, and interpret patterns of diabetes-related medical errors in primary care settings using diagnostic, laboratory, and pharmacy data. **Methods:** Automated diagnostic, laboratory, and pharmacy data were used to evaluate outpatient care received from 5,729 adults with an established diagnosis of diabetes, who received care at a single large medical group over a 12-month period of time. A subset 4,152 adults with diabetes who were (a) younger than 80 years; (b) had a Charlson comorbidity score of 2 or lower; (c) had pharmacy coverage; and (d)were linked to a primary care physician, were classified as having a glycemic-control error, a lipid-control error, or a pharmacy error. **Results:** Among the subset of 4,152 patients, 62.3 percent had one or more medical errors during the 1-year study period. Errors related to glycemic-control care occurred in 22.1 percent; errors related to low-density lipoprotein-cholesterol (LDL) care occurred in 58.3 percent. Inappropriate or risky drug prescribing occurred in 9.9 percent of the 5,729 patients. Metformin was used by 27.2 percent of those with congestive heart failure, and by 16.6 percent of those with a measured serum creatinine value greater than 1.5 mg/dl. **Conclusions:** Medical errors in adults with diabetes are the norm rather than the exception. Passive surveillance for medical errors can be done accurately and inexpensively using automated data routinely available in many primary care settings. These observed patterns of medical error define specific clinical domains and patient subgroups for whom aggressive efforts to reduce medical errors are most urgently needed.

Introduction

In diabetes care, achieving recommended glucose, blood pressure, and lipid treatment goals significantly reduces the risk of subsequent adverse events including heart attacks, strokes, renal failure, and premature death.[1–3] However, at present, less that 20 percent of adults with diabetes have simultaneously achieved glycated hemoglobin (A1c) less than the recommended level of 7 percent, systolic blood pressure (SBP) less than 130 mm Hg, and -cholesterol (LDL) less than 100 mg/dl.[4] It is noteworthy—and somewhat discouraging—that for SBP and A1c, there has been little improvement in levels of care in the past 10 years, despite a steady stream of more effective medications and monitoring technologies.[5, 6]

Recent work has suggested that medical error rates in outpatient care, especially for those who are elderly or on multiple medications, are substantial.[7, 8] Medical errors in outpatient care often involve drug therapy. Among the categories of drug-related medical errors are those related to drug-drug interactions, use of contraindicated drugs, or failure to obtain recommended safety laboratory monitoring tests.[9] In addition to medical errors related to misuse or overuse of drugs, errors related to the under use of drugs or procedures is also common in outpatient practice[10] Errors of omission in diabetes care include failure to provide evidence-based diabetes tests, procedures, or treatments in a timely fashion.[11] In this paper, we focus on development of methods to identify, classify, and interpret medical errors related to diabetes care.

In outpatient settings, follow-up of patients is often incomplete, and most medical errors are not recognized as errors by either physicians or patients. Thus, error surveillance strategies that rely on active reporting of errors by physicians or patients are a poor fit for identifying medical errors in outpatient chronic disease care. In theory, the best way to obtain surveillance for medical errors related to outpatient chronic disease care would be to monitor and interpret ongoing streams of automated diagnostic, laboratory, and pharmacy data.[12] This strategy—while conceptually simple—poses a number of technical challenges related to data availability, data accuracy, and creation of computer programs to appropriately acquire, process, and interpret available data.

Since the landmark report of the Institute of Medicine, *To Err Is Human: Building a Safer Health System,*[13] more attention has been given to inpatient than outpatient medical-errors research. However, patients with chronic diseases typically receive the vast majority of their care in outpatient office settings. Increasing availability of automated clinical data in outpatient settings enhances our ability to identify medical errors and reduce adverse events related to such errors. The magnitude of adverse events related to medical errors in outpatient chronic disease care is often underestimated. Recent clinical trials and other studies indicate that the rate of major cardiovascular events in adults with diabetes can be reduced more than 50 percent, and possibly as much as 80 percent, by aggressive and effective outpatient management of A1c, SBP, and lipids.[14, 15] Each heart attack or stroke preceded by uncontrolled chronic diseases, and each associated premature death, represents an adverse event related, in part, to outpatient medical error.

We conducted this study to estimate the frequency of selected medical errors in the outpatient care of adults with diabetes mellitus. To achieve this goal, we developed automated methods to passively identify and classify diabetes-related medical errors, including both errors of omission and errors of commission. Further, we validated this error identification method, and classified diabetes-related medical errors in a large and well-defined group of adults with diagnosed diabetes mellitus.

Subjects and methods

Study site and study subjects

This study was conducted at a multispecialty medical group that in 2003 provided care for an estimated 170,000 adult patients at 18 clinics. About 120 internists and family physicians provide the majority of adult diabetes care, and 113 of these physicians provide regular care to 10 or more adults with diabetes. In this medical group, about 10 percent of patients with diabetes see an endocrinologist each year, and about 30 percent see a diabetes educator each year.

Identification of diabetes patients

A diabetes diagnosis was assigned to any patient who, in a defined 12-month period of time, had either (a) two or more International Classification of Diseases (ICD)-9 250.xx codes assigned at inpatient or outpatient encounters; or (b) had filled a prescription for a diabetes-specific medication. This method of diabetes identification has previously been validated and has an estimated sensitivity of 0.91, specificity of 0.99, and positive predictive value of 0.94.[16] Of the 5,729 patients with an established diagnosis of diabetes, a subset of 4,152 patients who were younger than 80 years, had a Charlson comorbidity score of 2 or lower, had pharmacy coverage, and were linked to a primary care physician was identified. Data from the study site suggest that the quality of diabetes care as judged by glycemic control, lipid control, eye and microalbuminuria screening, and aspirin use steadily improved from 1994 to 2003. Details of the innovations and their impact on outcomes and more detailed description of the study site and study subjects can be found elsewhere.[17, 18]

Data collection

Diagnostic data from inpatient and outpatient clinical encounters were used to identify adults with diabetes or congestive heart failure (CHF). A congestive heart failure diagnosis was assigned to any adult patient with diabetes who had two or more inpatient or outpatient ICD-9 codes for CHF (428.xx) separated by at least a six-month period during the study year. An audit of a sample of these charts showed that 95 percent had a confirmed diagnosis of CHF based on standard tests or procedures. The New York Heart Association staging system for CHF was not applied.

In addition, dates and results of all glycated hemoglobin (A1c), LDL, serum creatinine (CREAT), creatinine clearance (CRCL), alanine aminotransferase (ALT), aspartate aminotransferase (AST), and creatine kinase (CK) results were retrospectively abstracted from laboratory databases for all study subjects. These data were used to identify study subjects who had renal insufficiency (serum creatinine $\geq$ 1.5 mg/dl), lipid disorders (LDL > 100 mg/dl, or triglycerides > 200 mg/dl after a minimum 12-hour fast), abnormal liver function enzymes (ALT or AST > 3 times upper limit of normal), or abnormal muscle-related enzymes (CK > 3 times upper limit of normal).

Automated pharmacy data was used to ascertain names, dates, dose, and days supplied for all oral glucose-lowering agents (sulphonylureas, metformin, thiazolidenediones, non-sulfonylurea secretogogues, and alpha-glucosidase inhibitors), insulin, and lipid-lowering agents (statins or fibrates). Diagnostic, laboratory, and pharmacy data were linked at the patient level using unique study identifiers to create an integrated database. After necessary linkages were accomplished, the database was purged of identifying information.

Definition and classification of diabetes-related medical errors

A panel including three clinicians with diabetes and chronic disease expertise, a computer scientist, and an expert in decision science constructed an initial algorithm to identify diabetes- related medical errors based on clinical logic and decision science principles. Each error identification algorithm was iteratively tested for validity against chart audits and revised at least six times. The algorithm was then applied to the patient databases and used to classify each patient over a 12-month period of time, as having or not having each of the following kinds of medical error: (a) glycemic-control error; (b) lipid-control error; or (c) pharmacy error.

An experienced physician (Sperl-Hillen) reviewed the charts of iterative samples of about 20 patients in each error classification to verify that the error assigned to the case by the automated protocol was in fact accurate, based on explicit clinical criteria. Cases in which discrepancies were possible were resolved by group discussion that included the entire research team, to assure consensus classification of errors from both the clinical and decision science point of view.

Counts of the number of diabetes patients who had each type of error were obtained, and percentages of patients with each type of error were calculated. For some types of errors, such as drug-related errors, denominators that included only those patients taking a particular medication were used. Analysis was performed to quantify the degree of correlation between errors of different types within patients. The study was reviewed in advance, approved, and monitored by the HealthPartners Institutional Review Board.

Results

Table 1 presents data on the demographics and health status of the 4,152 study subjects with an established diagnosis of diabetes mellitus who met all of the following criteria: (a) age 80-years or younger; (b) Charlson comorbidity score of 2 or lower; (c) pharmacy coverage; and (d) able to be linked to a primary care physician. These data indicate that current levels of A1c and LDL control of adults with diabetes at this medical group are quite good compared with the national diabetes care surveys.[19, 20] A relatively high proportion of diabetes

patients also receive regular monitoring of A1c and LDL, which increases our ability to accurately classify patients' error status.

Table 1. Demographic and clinical characteristics of the 4,152 study subjects

Characteristic	Measure
Population size	4,152
Mean age in years (SE)	56.5 (0.19)
Median age in years	56
Age > 64 Years	27.33%
Female	46.1%
At least one A1c test in one year	92%
Mean A1c value (SE)	7.7% (0.03)
Median A1c value	7.4%
At least one LDL test in one year	77%
Mean LDL value (SE)	109 mg/dl (0.58)
Median LDL value	104 mg/dl

Table 2 shows the final classification of patients by glycemic-control error status. The error rates are based on the subset of 4,152 study subjects. Descriptive definitions of the type of errors are also provided in Table 2. We found that 33 percent (N=1,371) of all study subjects had A1c at the recommended level of less than 7 percent, and 27.2 percent (N=1,129) had A1c between 7 percent and 7.9 percent. We did not classify those in the latter group as having a glycemic-control medical error, because with A1c in this range, advice or educational interventions that emphasize physical activity or nutrition therapy only may be clinically appropriate for many patients—and our data could not provide information on lifestyle interventions or advice. Among those with A1c ≥ 8 percent, 491 of 1,225 (40.1 percent) failed to receive active management of A1c to move toward evidence-based goals. If the 379 subjects on insulin alone are removed from the denominator (because we had insufficient data to assess insulin intensification), then 491 of 846 subjects with A1c greater than 8 percent (58 percent) had a medical error.

Table 3 provides similar data on lipid management for the same group of study subjects. In those with diabetes, 32.6 percent had LDL less than 100 mg/dl. Among those with LDL ≥ 100 mg/dl, or triglycerides > 400 mg/dl, only 376 of 1,887 (19.9 percent) had active lipid therapy, while 1,511 of 1,887 (80.1 percent) had no changes in lipid drug therapy. In addition, 984 subjects, or 21.9 percent of all subjects, had no LDL test within a year; of these 73 LDL values were missing because the concurrent triglyceride value was greater than 400 mg/dl and LDL could not be calculated.

Table 2. Classification of 4,152 adults with diabetes by A1c status and glycemic-control pharmacotherapy over a 12-month period of time

No Error	N	%	Error	N	%	Error status unknown	N	%
A1c < 7% At goal	1,371	33.0%						
A1c 7 – 7.9% Goal reachable without drugs	1,129	27.2%						
A1c 8 – 10.9% With drug intensification	293	7.1%	A1c 8 – 10.9% No drug intensification	436	10.5%	A1c 8 – 10.9% On insulin; cannot assess changes in dose.	328	7.9%
A1c ≥ 11% With insulin initiation	62	1.5%	A1c ≥ 11% No drug intensification	55	1.3%	A1c ≥ 11% On insulin; cannot assess changes in dose.	51	1.2%
			No A1c test in 12 months	427	10.3%			
Total no error	2,855	68.8%	Total error	918	22.1%	Cannot classify	379	9.1%

Table 3. Classification of 4,152 adults with diabetes by lipid levels and lipid-lowering drug therapy over a 12-month period of time

No error	N	%	Error	N	%
LDL < 100 mg/dl At goal	1,354	32.6%			
LDL 100 – 129 mg/dl With drug intensification	165	4.0%	LDL 100 – 129 mg/dl No drug intensification	902	21.7%
LDL ≥ 130 mg/dl With drug intensification	159	3.8%	LDL ≥ 130 mg/dl No drug intensification	536	12.9%
Triglycerides > 400mg/dl on fibrate or medication intensification	52	1.3%	Triglycerides > 400 mg/dl no fibrate or medication intensification	73	1.8%
			No LDL test within 12 months	911	21.9%
Total no error	1,730	41.7%	Total error	2,422	58.3%

Table 4 presents the frequency of medication-related errors related to glucose-lowering or lipid-lowering agents among all the 5,729 adults with diabetes. Two rates are estimated. Column C provides the error rate in the subgroup at risk, while column D provides the error rate in the total population of 5,729 adults with diabetes included in this analysis. In general, fewer medication-related errors were related to lipid care than to glucose care. Metformin or thiazolidinediones (TZDs) were frequently used by patients with relative contraindications to their use—like renal insufficiency, congestive heart failure, liver function abnormalities, or chronic lung disease.

Table 4. Frequency of selected medical errors or risky prescribing practices among 5,729 adults with diabetes

A Denominator (Subgroup of Patients)	B Numerator (Number of Occurrences)	C Subgroup error rate (B divided by A)	D Population error rate (B divided by N= 5,729)
3,258 patients on statins*	282 with no ALT/AST Test	8.7%	6.7%
3,258 patients on statins	**6 with ALT or AST > 3x upper limit of normal+**	**0.2%**	**0.1%**
3,258 patients on statins	**10 with CK > 3x upper limit of normal+**	**0.3%**	**0.2%**
568 patients on fibrate	375 with no CK test in one year	63.8%	6.5%
568 patients on fibrate	**4 with CK > 3x upper limit of normal**	**0.7%**	**0.1%**
388 patients on fibrate plus statin	230 with no CK test in one year	59.3%	4.0%
2,675 patients on metformin	190 with no serum creatinine in one year	7.1%	3.3%
2,675 patients on metformin	**75 with serum creatinine > 1.5 mg/dl+**	**2.8%**	**1.3%**
2,675 patients on metformin	**111 with two or more CHF ICD-9 codes in last year++**	**4.1%**	**1.9%**
2,675 patients on metformin	**130 with two or more COPD ICD-9 diagnosis codes in last year++**	**4.9%**	**2.3%**
79 patients age 80+ and on metformin	2 with no serum creatinine test in last year	2.5%	< 0.1%
79 patients age 80+ and on metformin	**10 with serum creatinine test > 1.5 mg/dl+**	**12.7%**	**0.2%**
79 patients age 80+ and on metformin	75 with no creatinine clearance test in last year	94.9%	1.3%
408 patients with CHF	**111 on Metformin++**	**27.2%**	**---**
350 patients with COPD	**130 on Metformin++**	**37.1%**	**---**
408 patients with CHF	**46 on TZD (rosiglitazone or pioglitazone)++**	**11.3%**	**---**
626 patients on TZD	**46 with two or more CHF ICD-9 codes in last year++**	**7.3%**	**0.8%**
626 patients on TZD	76 with no ALT or AST test in 12 months	12.1%	1.3%
626 patients on TZD	**1 with ALT or AST > 3x upper limit of normal+**	**0.2%**	**< 0.1%**

Table 4. Frequency of selected medical errors or risky prescribing practices among 5,729 adults with diabetes, cont.

A	B	C	D
		Subgroup error rate	**Population error rate**
Denominator (Subgroup of Patients)	**Numerator (Number of Occurrences)**	**(B divided by A)**	**(B divided by N= 5,729)**
5,729 patients with diagnosed diabetes mellitus	566 known to have 1 or more of the above errors	9.9%	9.9%
408 patients with CHF	130 known to have 1 or more of the above errors	32.5%	2.3%
378 patients age 80+ and older	80 known to have 1 or more of the above errors	21.2%	1.4%

* Errors related to omission of safety laboratory monitoring are in regular type. Errors related to inappropriate use of medications are in bold type.
+Drug-fill date more than 4 weeks after test date.
++Drug-fill date more than 4 weeks after second of two or more diagnostic codes for CHF or COPD.
CK=creatine kinase, an enzyme that often reflects muscle status.
ALT/AST=liver alanine and aspartate transaminase enzyme measurements that reflect liver status.
Serum Creatinine=a blood test that reflects kidney function.
Creatinine Clearance=a more accurate measure of kidney function, requires a 24-hour urine collection.
CHF=congestive heart failure.
COPD=chronic obstructive pulmonary disease (emphysema).
ICD=International Classification of Disease.
TZD=thiazolidenedione.

When all the errors were considered simultaneously, we found that 3,571 of the 5,729 study subjects (62.3 percent) had 1 or more errors, and 38.7 percent were free of errors during the 1-year study period. Of those with errors, 1,796 had one error, 1,570 had 2 errors, 191 had 3 errors, and 14 had 4 errors in the 1-year period of time.

Table 5 provides data on the relationships among three differing types of errors for patients relative to glucose and lipid errors. Odds ratios indicate whether a patient with one type of error is more likely or less likely to have another type of error. Overall, patients with glucose errors are significantly more likely to have analogous lipid errors. Patients with missing A1c tests are 22 times more likely to be missing an LDL test also, relative to patients that have an A1c test. This clustering of errors within patients could be related to patient, physician, or patient-physician interaction factors.

Table 5. Interrelationships among glucose and lipid errors at the level of individual patients[#]

	Lipid-error type 1+ Odds ratio (P-value)	Lipid-error type 2++ Odds ratio (P-value)	Lipid-error type 3+++ Odds ratio (P-value)
Glucose-error type 1*	1.398 (0.0012)	1.709 (0.2004)	0.792 (0.0721)
Glucose-error type 2**	1.468 (0.0777)	6.196 (0.0002)	0.735 (0.2630)
Glucose-error type 3***	0.154 (<0.0001)	NA[##]	22.989 (<0.0001)

#Estimates adjusted for age and gender.
*Type 1 glucose error is inadequate drug treatment when a patient's A1c ranges 7% to 10.9%.
**Type 2 glucose error is inadequate drug treatment when a patient's A1c is   11%.
***Type 3 glucose error is having no A1c test for a year.
+Type 1 lipid error is inadequate drug treatment when LDL ranges 100-129 mg/dl.
++Type 2 lipid error is assigned when LDL is not calculated because triglyceride is greater than 400.
+++Type 3 lipid error is having no LDL test for a year.
It is difficult to accurately assess the clinical significance of elevated triglyceride levels in the presence of poor glycemic control.

Discussion

In this study, conducted at a medical group recognized by the American Diabetes Association for high-quality diabetes care, medical errors in adults with diabetes were the norm rather than the exception. Inadequate control of A1c or LDL was commonly observed and is especially pernicious because the impact of inadequate control may be delayed for years to decades. Inappropriate or risky medication use was also common and some medication errors had the potential to rapidly lead to adverse clinical events. For example, among the 451 subjects with serum creatinine greater than 1.5 mg/dl, 16.6 percent were taking metformin. Among the 408 subjects with CHF, 27.2 percent were on metformin, which may cause lactic acidosis; and 11.3 percent were on a TZD, which may exacerbate CHF, due to fluid retention or other factors. If error rates are similar at other practice sites, then common outpatient medical errors may contribute to many potentially preventable adverse clinical events each year in adults with diabetes.

Although our estimate of medical error rates seems high, it is likely to be a conservative estimate for several reasons:

- We examined only selected errors, namely, those related to management of blood glucose or blood lipids. Moreover, if we had more complete data on insulin therapy, additional errors would likely have been identified. Also, many of these patients have other diseases; if we had considered errors related to treatments for these conditions, error rates would inevitably be higher.

- Median A1c was 7.4 percent and median LDL was 104 mg/dl at the study medical group at the time of the study. If our error identification algorithms were applied to medical groups with higher A1c or LDL values, the proportion of patients with errors would likely be higher.

Diabetes care in the study setting was substantially better than diabetes care described in several recent national studies.[19–21]

- Our error rates were computed over a 12-month period. If we had computed errors of omission based on a shorter window of time, such as the time between office visits, to the proportion of patients classified as having errors of omission over a 12-month period would have been substantially higher.

Error rates were higher with respect to lipid management (58.3 percent of all patients) than glucose management (22.1 percent) in these diabetes patients. A number of recent studies suggest that many adults with diabetes may derive more benefit from aggressive lipid-lowering therapy (a 20 percent to 25 percent reduction in mortality risk) than from aggressive glucose-lowering therapy.[3] Moreover, the cost-effectiveness of lipid treatment is better than glucose treatment for patients over age 50 years.[22] These data reinforce the need for clinicians to focus more attention on lipid control (and blood pressure control) in diabetes patients in order to maximize reduction in cardiovascular complications of diabetes. The importance of this is underscored by the fact that more than 70 percent of all deaths and the majority of excess health-care charges in adults with diabetes are related to heart attacks and strokes.[23]

Passive identification of errors can be done by searching integrated outpatient laboratory, pharmacy, and diagnostic databases. Such databases are already available to many medical groups or health plans, and will become more widely available as more health-care delivery organizations invest in better information systems.[24] Passive identification of errors is simple, relatively cheap, can be done iteratively over time, and the thresholds for action can be easily modified as evidence-based clinical guidelines change, or to meet local needs or preferences. Passive identification of errors is likely to be more complete than provider-initiated error identification.[25] Careful analysis of error information may ultimately suggest effective intervention strategies to reduce medical errors and improve the health outcomes of adults with diabetes. For example, we have now developed physician learning interventions that significantly reduce clinical inertia and drug-related errors for diabetes care.[26]

A significant limitation of the study is our inability to reliably capture errors related to insulin management, because automated data are insufficient to identify changes in insulin doses. Insulin prescriptions do not include dose information, and patients are advised to discard unused insulin one month after opening a vial. These factors make it difficult to systematically capture information on changes in insulin dose using pharmacy data. Such data may be difficult to obtain even from electronic medial records, because many well-educated patients with diabetes self-adjust insulin doses based on acute illness or on daily variations in exercise, eating, and home glucose test values.

Despite the limitations, the results of this study are interesting and important. In adults with diabetes, medical errors are the rule rather than the exception, even in medical groups recognized for excellence in diabetes care. Errors of omission

and overuse of potentially risky medications in those with CHF or renal insufficiency are two errors of particular concern. Moreover, the occurrence of glucose errors is significantly correlated with lipid errors in these patients. These findings justify the urgent development of interventions designed to reduce high medical error rates experienced by adults with diabetes. An ongoing stream of passive surveillance data would likely provide additional important insights on the epidemiology of medical error in diabetes patients that may guide the development of novel and effective interventions to reduce errors in diabetes care.

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