SPECIAL ARTICLE

Computerized Decision Support Based on a Clinical Practice Guideline Improves Compliance with Care Standards

David F. Lobach, MD, PhD, MS, W. Ed Hammond, PhD, *Durham, North Carolina*

PURPOSE: Clinical guidelines are designed to assist in the management of specific diseases; however, these guidelines are often neglected in the delivery of care. The purpose of this study was to determine whether clinician use of a clinical practice guideline would increase in response to having, at the patient visit, a decision support system based on a practice guideline that generates a customized management protocol for the individual patient using data from the patient's electronic medical record.

SUBJECTS AND METHODS: In a 6-month controlled trial at a primary care clinic, 58 primary care clinicians were randomized to receive either a special encounter form with the computer-generated guideline recommendations or a standard encounter form. The effect of computer-generated advice on clinician behavior was measured as rate of compliance with guideline recommendations. Data from 30 clinicians were analyzed; data from 28 clinicians were excluded because these clinicians did not meet predefined criteria for minimum exposure to diabetic patient care.

RESULTS: Availability of patient management recommendations generated by the decision support system resulted in a two-fold increase in clinician compliance with care guidelines for diabetes mellitus ($P = 0.01$). Median compliance for the group receiving the recommendations was 32.0% versus 15.6% for the control group.

CONCLUSION: Decision support based on a clinical practice guideline is an effective tool for assisting clinicians in the management of diabetic patients. This decision support system provides a model for how a clinical practice guideline can be integrated into the care process by computer to assist clinicians in managing a specific disease through helping them comply with care standards. Use of decision support systems based on clinical practice guidelines could ultimately improve the quality of medical care. © 1997 by Excerpta Medica, Inc. ***Am J Med.* 1997;102:89–98.**

From the Division of Medical Informatics, Department of Community and Family Medicine, (DFL; WEH) Division of Endocrinology and Metabolism (DFL) Duke University Medical Center, and the Department of Biomedical Engineering, (DFL, WEH) Duke University, Durham, North Carolina.

Requests for reprints should be addressed to David F. Lobach, MD, PhD, MS, Division of Medical Informatics, Department of Community and Family Medicine, P.O. Box 3886, Duke University Medical Center, Durham, North Carolina 27710.

This work was supported in part by grant 1-T15-LM07071 from the National Library of Medicine.

Manuscript submitted May 24, 1996 and accepted in revised form October 8, 1996.

More than 1,600 clinical practice guidelines have been written to stipulate recommendations for the appropriate delivery of care in specific clinical situations.[1,2] These guidelines have little impact upon actual clinical practice unless they are effectively integrated into the clinical setting.[3–6] Novel approaches are needed to facilitate the use of guidelines in clinical practice. With the increasing use of electronic medical records, computer-based decision support systems could be used to integrate practice guidelines into the process of health care delivery.

In the past, computers have been programmed to generate patient-specific care reminders and to provide expert advice for managing a particular condition. Although studies using electronically stored data to generate reminders have demonstrated improved compliance with a series of rules concerning preventive care tests and procedures,[7–12] laboratory testing,[7,9] drug therapies,[7,9] and length of hospital stay,[13] none of these studies used a clinical practice guideline to manage a single disease over time. Furthermore, the impact of those studies was limited because the presentation of the recommendations was confusing,[14,15] the clinicians neglected to look at the recommendations,[9,14,15] or the clinicians disagreed with the recommendations.[14] Other computer systems have been programmed to capture the knowledge of expert clinicians to assist with the management of specific diseases.[16–20] Most of these expert systems were not directly integrated into the care process to provide management recommendations during a patient visit.[16,17] Systems that were available during the patient visit disrupted the routine care process by requiring the clinician to enter supplemental data into the computer.[18–20]

0002-9343/97/$17.00
PII S0002-9343(96)00382-8

In this study, we capitalized on the computer-generated-reminder approach of using existing electronic data to direct patient management during the patient encounter and on the rule-based approach used in expert systems to accommodate the management of a specific disease over time to create a decision support system based on a clinical practice guideline called the Computer-Assisted Management Protocol. The Computer-Assisted Management Protocol was designed to use medical knowledge contained in a clinical practice guideline to formulate disease-specific care recommendations for an individual patient based on data stored in the patient's electronic medical record. Because of the increasing availability and importance of clinical practice guidelines for improving efficiency and cost-effectiveness in medical care, we wanted to demonstrate that a practice guideline could be used as the source of the medical knowledge incorporated into the Computer-Assisted Management Protocol.

In this project, we selected, and subsequently modified, the care guideline for the continuing management of diabetes mellitus published by the American Diabetes Association.[21] Diabetes mellitus was selected because it is a common chronic disease affecting over 5% of the adult population, its diagnosis is quantitative and relatively unambiguous, and its management requires monitoring several laboratory tests and serial examinations which are common among all diabetic patients. Furthermore, approaches are needed to improve the quality of diabetes care in the United States.[22]

To assess the impact of the Computer-Assisted Management Protocol on the management of patients with diabetes mellitus, we conducted a randomized controlled trial to evaluate clinician compliance with care guidelines among clinicians with and without the availability of the Computer-Assisted Management Protocol.

METHODS

Study Design

The effect of the Computer-Assisted Management Protocol on clinician compliance with guidelines was evaluated in a 6-month, randomized, controlled trial conducted at the Duke Family Medicine Center at Duke University Medical Center. Duke Family Medicine Center is a free-standing, primary care clinic that offers on site laboratory testing, radiology studies, and pharmacy services. It is also the primary outpatient clinic site for the Duke University Family Medicine Residency Program. In 1993, the clinic had over 35,000 patient visits. All of the 58 primary care clinicians at Duke Family Medicine Center (20 family physicians, 1 general internist, 2 nurse practitioners, 2 physician's assistants, and 33 family medicine residents) were randomized either to receive (intervention group) or not to receive (control group) the Computer-Assisted Management Protocol. The randomization was not stratified by level of training since training level alone does not affect the extent of compliance with care guidelines.[8] The primary study measure was clinician compliance with guideline recommendations during an encounter. Clinicians in both groups were blinded to the study protocol. In only one encounter during the study, a control group clinician inappropriately received the Computer-Assisted Management Protocol; diabetes was not assessed during this visit so that the data from this visit was not eligible for inclusion in the calculation of compliance.

Development of Consensus Guidelines

The American Diabetes Association guidelines for the chronic care of patients with diabetes mellitus served as the starting point for the development of the Duke Family Medicine Center diabetes care protocol.[21] These guidelines represent an official opinion of the American Diabetes Association sanctioned by its Committee on Professional Practice and its Executive Committee of the Board of Directors; in short, the guidelines represent the opinions of experts defining optimal continuing care for patients with diabetes mellitus. These guidelines have been endorsed by several professional medical associations, but notably not by the American Academy of Family Physicians.

The American Diabetes Association guidelines were adapted to Duke Family Medicine Center through a consensus building process that allowed for input from all of the practicing clinicians to ensure that noncompliance with care guidelines was not the result of clinician disagreement with the guidelines.[23] Disagreement with the American Diabetes Association guidelines resulted from questions about their applicability in primary care. The consensus-building process utilized surveys of clinician practice patterns and discussions at practice management meetings over a three month period. The Duke Family Medicine Center consensus guidelines for the continuing care of diabetes mellitus were developed to apply to all diabetic patients as practice standards (**Table I**). They differed from the original American Diabetes Association guidelines in that the foot examination was required monthly only for patients with neuropathy or a history of lower limb ulcers instead of at every visit for all diabetic patients; the frequency of monitoring chronic blood glucose control was every 6 months for all patients instead of every 3 months for the type I diabetic patients; the lipid evaluation was limited to an annual cholesterol

TABLE I

Duke Family Medicine Center Care Guidelines for Diabetes Mellitus

1. Foot examination monthly in patients with diabetic neuropathy, peripheral neuropathy, or history of lower limb ulcers.
2. Annual complete physical examination.
3. Determination of chronic blood glucose control every 6 months.
4. Annual urine protein determination.
5. Annual cholesterol level.
6. Annual ophthalmologic examination.
7. Seasonal influenza vaccination (September-January).
8. Pneumococcal vaccination.

```
------------------------------------------------------------------------------------------
CATEGORY  TEST          RECOMMENDED              LAST DONE            F/U DATE
------------------------------------------------------------------------------------------
DIABETES  FOOT EXAM     AGE 18+ ONCE IN 1 MO                          *SUGGESTED*
          COMPLETE PE   AGE 18+ ONCE IN 1 YR                          *DUE NOW*
          HGBA1C        AGE 18+ ONCE IN 6 MO  9.1     09/10/92        *DUE NOW*
          URINE PROT    AGE 18+ ONCE IN 1 YR                          *DUE NOW*
          CHOLESTEROL   AGE 18+ ONCE IN 1 YR  257     09/10/92        DUE   09/10/93
          OPHTH EXAM    AGE 18+ ONCE IN 1 YR                          *DUE NOW*
          INFLUENZA     AGE 18+ ONCE IN 1 YR                          *DUE NOW*
          PNEUMOCOC     AGE 18+ ONCE                                  *DUE NOW*
------------------------------------------------------------------------------------------
QUALITY ASSURANCE DATA COLLECTION
TEST                    PLACE         DATE          RESULT
FOOT EXAM   __________________________________________________________ D     N ______
COMPLETE PE__________________________________________________________ D     N ______
HGBA1C      __________________________________________________________ D     N ______
URINALYSIS  __________________________________________________________ D     N ______
OPHTH EXAM  __________________________________________________________ D     N ______
INFLUENZA   __________________________________________________________ D     N ______
PNEUMOCOC   __________________________________________________________ D     N ______
```

Figure 1. Sample format for the computer-assisted management protocol for diabetes mellitus. "D" indicates that the recommendation was "declined" by the patient. "N" indicates that the recommendation was considered "never" appropriate by either the clinician or the patient.

level instead of a complete lipid panel; and a baseline electrocardiogram was not required.

Development of the Computer-Assisted Management Protocol

The Computer-Assisted Management Protocol was created to implement the Duke Family Medicine Center diabetes guidelines on The Medical Record, the computer-based patient record system in use at Duke Family Medicine Center. The Medical Record has been in development at Duke Family Medicine Center for more than 20 years. It is comprised of discrete modules that function together to support all aspects of a patient encounter electronically.[24,25] Modules in operation at the time of the study included demographic information, scheduling, accounting, problem lists, encounter summary, medications, quality assurance, laboratory orders/results, and medications/immunizations. Because the module for progress notes was not implemented at Duke Family Medicine Center and because consultants and laboratories outside the Center did not use The Medical Record, the computer-based medical record at Duke Family Medicine Center was supplemented with a paper medical record containing progress notes, outside study reports, and consultant notes. Summary lists of a patient's medical problems, medications, past encounters, and health maintenance information stored in The Medical Record were made available to clinicians during a visit as a printed sheet, known as an encounter form, that was attached to the patient's paper chart. Clinical information, prescriptions, and orders were communicated by clinicians to other clinic personnel by handwritten notes on the encounter forms. Demographic data, medical problems, appointments, and accounting data were entered in The Medical Record by receptionists as part of the patient registration and check-out processes.[26] Laboratory results were electronically transferred to The Medical Record from sample analyzing equipment. Information concerning medications was entered by pharmacy personnel.

The module developed to implement the consensus guidelines was modeled after the Quality Assurance module of The Medical Record which is described elsewhere.[24,25] The Computer-Assisted Management Protocol implemented the diabetes care guideline through a series of logic rules that performed temporal comparisons, mathematical calculations and/or logical comparisons using data selectively retrieved from the problem list, medications list (including immunizations), or studies section of a patient's electronic medical record. Following enactment of these rules, the program printed a set a patient-specific care recommendations. The program to create the Computer-Assisted Management Protocol was implemented by adding a call statement for the Computer-Assisted Management Protocol program to The Medical Record module that printed the encounter forms. The additional functionality provided by the Computer-Assisted Management Protocol beyond previous reminder programs was that the Computer-Assisted Management Protocol generated a set of disease-specific care recommendations customized to an individual patient that advised the clinician regarding which studies/procedures should be done during the current visit and which studies/procedures were next due in order to assist the clinician with managing the diabetic patient in accordance with a clinical practice guideline.

The output from the diabetes Computer-Assisted Management Protocol was printed on the first page of the paper encounter form immediately below the section that was used for capturing visit charges. A sample diabetes Computer-Assisted Management Protocol is shown in **Figure 1.** It provided the customized diabetes guideline recommendations based on practice standards and previously completed tests, and an area for handwritten updates by the clinician to capture data not previously stored in The Medical Record. Additional flexibility was included for the clinicians to designate that the recommendation had been declined by the patient ("D") or never to be done for the patient ("N"). If "never" was designated for a particular guideline, the guideline was shut off permanently for that patient. Despite their availability, however, the "D" and "N" designations were rarely used during the study. Users interacted with the printed Computer-Assisted Management Protocol information by reading which studies/procedures were due and ordering the appropriate studies/procedures on the encounter form in the space immediately above the Computer-Assisted Management Protocol or by performing the suggested examination(s). Users also interacted with the Computer-Assisted Management Protocol by writing information to update the Computer-Assisted Management Protocol on the blank data entry lines immediately below the recommendations. In the process of checking out of the clinic, patients carried a copy of the encounter form to the patient processors. Encounter forms on which Computer-Assisted Management Protocols were printed were selectively collected. These forms were then reviewed by clinic personnel for information that updated the Computer-Assisted Management Protocol. This information was then entered into the patient's electronic medical record by clinic personnel using a pre-existing data entry program in The Medical Record that had been expanded to include foot examination, complete physical examination, and ophthalmologic examination in the studies section, and to log performance of any Computer-Assisted Management Protocol studies/procedures that were performed at an outside facility.

The Computer-Assisted Management Protocol was generated by The Medical Record in the following way: when a command was entered to generate an encounter form, the Computer-Assisted Management Protocol program searched the patient's electronic problem list for the diagnosis of diabetes mellitus. If diabetes mellitus was found on the patient's problem list, the program then checked to see if the patient was scheduled to see one of the clinicians involved in the study. If the patient was scheduled to see a study clinician, the Computer-Assisted Management Protocol program then generated guideline recommendations that were customized for the patient based on a series of logic rules that utilized data in the patient's computer-based medical record. The program then stored a record of the patient encounter and a copy of the Computer-Assisted Management Protocol in a master file that later served to identify charts for audit. Finally, the program printed the Computer-Assisted Management Protocol recommendations on the encounter form of the diabetic patients who were seeing a clinician randomized to receive the intervention.

The Medical Record test system, a duplicate of The Medical Record program and database in use at Duke Family Medicine Center, was used to evaluate the Computer-Assisted Management Protocol module prior to implementation. The Computer-Assisted Management Protocol module was tested by the repeated creation and analysis of encounter forms using real patient appointments on The Medical Record test system. The module was not activated until the test encounter forms contained no errors.

At the initiation of the study, a letter was sent to all clinicians randomized to receive the Computer-Assisted Management Protocol. The letter described the function of the Computer-Assisted Management Protocol and encouraged clinicians to use it. A follow-up letter was sent to the same clinicians midway through the study to encourage continued use of the Computer-Assisted Management Protocol and clarify questions that had arisen.

Throughout the study period, the Computer-Assisted Management Protocol recommendations generated from information in The Medical Record were checked for correctness by comparing them with recommendations that theoretically would have been derived if information from both The Medical Record and the paper chart had been used. A recommendation was considered "correct" if the combined data from both the paper chart and the electronic medical record confirmed that a given recommendation was either due or not due. The overall reliability of the Computer-Assisted Management Protocol, calculated as the number of correct recommendations over the total number of recommendations, was 77% (4173 correct recommendations out of 5370 recommendations evaluated in 1098 encounters—86% of total encounters). The majority of incorrect recommendations resulted either from a transient disruption in Computer-Assisted Management Protocol functioning following the introduction of a new version of The Medical Record one month into the study (ie, systems errors: 86.8% of total errors) or from the presence of data in the paper chart which had not been captured electronically (ie, recording errors: 13.2% of total errors). More than 70% of the system errors were false positive recommendations in which the performance of studies/procedures was incorrectly suggested. Introduction of the new version of The Medical Record restructured the way in which study data was retrieved and hindered the Computer-Assisted Management Protocol's ability to detect data elements stored in The Medical Record and thus to update appropriately the recommendations regarding tests or interventions already performed. Specifically, the Computer-Assisted Management Protocol program selected the first occurrence of a study result instead of the most recent occurrence. This error resulted in the Computer-Assisted Management Protocol inappropriately recommending unnecessary tests or interventions when the most recent occurrence of a study was not detected. As errors were detected, the appropriate corrections were made. Clinicians appeared to have "overridden" or neglected the erroneous recommendations because the frequency of ordering the designated tests or vaccines did not significantly increase during this phase of the study. All of the errors caused by introduction of the new version of The Medical Record were eliminated by the end of the second month of the study. Throughout the remainder of the study the Computer-Assisted Management Protocol reliability was over 90%.

Data Collection

Compliance with Computer-Assisted Management Protocol recommendations was determined by review of computer-generated laboratory test summaries and by audits of paper-based medical records. Audits of paper charts were included because the paper record of the patient's visit was considered to contain the most complete information for determination of clinician compliance. All of the chart audits were performed by one physician (DL). In order to standardize chart auditing and to minimize observer bias, an audit protocol was used for every chart (**Figure 2**). The audit protocol explicitly outlined the process by which the components of each chart were to be reviewed systematically to collect compliance data. Using this protocol, intra-auditor consistency, evaluated by duplicate audits performed more than 2 weeks apart on 10% of the encounters, was greater than 90%. Review of clinicians' progress notes, nursing notes, immunization consent forms, ophthalmology consult notes, and computer-generated laboratory summaries were used to assess compliance during individual encounters. In this study, a complete physical was defined as a comprehensive health maintenance visit for which the clinician collected information on a special age- and gender-appropriate form.

-> Review patient problem list to determine if diabetes mellitus and/or neuropathy or lower extremity ulcers are on the list
-> Determine if note present for the encounter date
-> If present, read note to:
- confirm correct patient SSN, name, and encounter provider;
- determine if observed* encounter length is reasonable (less than 2 hours unless extenuating circumstances recorded in the note);
- determine if diabetes mellitus assessed as encounter problem*; and
- extract data relating to compliance with recommendations from note*
-> Decide if foot exam needed or done within past month
-> Find last complete physical exam form (colored paper) and note date performed
-> Review study result sheets to determine when last HgbA1c, urine protein, and cholesterol were performed
-> Review consult notes section for ophthalmology consult
-> Review vaccine consent forms for influenza and pneumococcal vaccines
-> Read previous notes for 1 year prior to encounter to find references to ophthalmologic referral, vaccinations, complete physical exam and studies
-> Determine if patient is primarily followed at DFMC for diabetes*
-> If documentation of pneumococcal vaccination or ophthalmologic examination in the past year have not been found, search entire chart for documentation of or reference to pneumococcal vaccination or ophthalmologic examination

* details explained in text

Figure 2. Protocol for chart audits.

Determination of Compliance

Prior to the initiation of the study, a minimum level of clinician exposure to diabetic patients and diabetes care was defined to insure that a clinician's compliance score was a valid representation of his/her practice patterns for diabetes. To achieve the minimum exposure criteria, the clinician had to have seen at least six different diabetic patients and to have assessed diabetes care in at least 12 encounters during the study period. A guideline was considered "due" if there was no evidence in the laboratory summary sheet or paper chart to suggest that the action recommended in the guideline had been done within the prescribed time interval. In order to evaluate compliance appropriately near the end of the prescribed interval for clinicians who fulfilled a guideline recommendation shortly before the recommended interval had expired, a guideline was also considered "due" if the clinician complied with a guideline (except for the monthly foot exam) within one month of its "due date." Because the time interval for the foot exam was one month, the foot exam was only considered "due" after the recommended time interval had lapsed.

By relying on chart audits of every encounter to evaluate compliance, we were able not only to detect whether or not recommendations had been completed but also to assess a clinician's intentions to comply with the guideline recommendations. In contrast to studies that used limited chart audits (8–12), we were able to expand the definition of compliance to provide a more true reflection of a clinician's behavior relative to the guideline recommendations. Clinicians were considered compliant with a guideline if they performed the recommendation, commented that the recommendation was scheduled to be performed at a definite time in the future, or stated why a guideline was not being followed (eg, financial limitations). This latter criterion for compliance accounted for less than 10% of the overall compliance rates in either group. Clinician compliance with Computer-Assisted Management Protocol recommendations was evaluated only if diabetes was assessed during the encounter in accordance with the practice standards. The restriction of compliance data to only encounters dealing with diabetes was done to avoid requiring compliance with diabetes care guidelines during encounters in which the clinician was focused on other medical problems. This approach was felt to optimize a clinician's opportunity to be compliant with the standards. Diabetes was considered assessed if it was listed as a problem heading in the encounter note, if it was checked on the encounter form as a focus problem for the visit, or if it was dealt with in any two of the four components (subjective, objective, assessment and plan) of a progress note not specifically addressing diabetes. Data from chart evaluations were recorded on audit forms and then entered into a relational database (Paradox, Borland International, Inc., Scotts Valley, CA) for analysis.

Statistical Analysis

Clinician compliance rates were calculated as the number of recommendations followed over the number of recommendations due during an encounter and expressed as percent compliance. This definition of compliance focused on the recommendations that needed to be completed and, thus, targeted the measure most likely to be affected by the Computer-Assisted Management Protocol. In order to provide a more global sense of how well clinicians were following the diabetes care guideline, adherence with the guidelines was also determined. Clinician adherence rates were calculated as the number of recommendations that were completed by the end of an encounter (ie, either done during the current encounter or done at previous encounters and not currently due) over the total number of recommendations. Adherence, thus, reflected the overall level at which clinicians used the diabetes guideline recommendations. Comparison of compliance rates and adherence rates between the intervention and control groups was done with a two-tailed Wilcoxon rank sum test. The Wilcoxon rank sum test was also used to compare compliance rates by individual recommendation between groups. Total encounter length was the time interval between the time when a patient checked into the clinic and the time when a patient checked out of the clinic. Encounter lengths were not available for encounters that were not processed at the actual time when the patient was registering in or checking out of the clinic. Comparison of encounter lengths between groups was done using a *t*-test.

RESULTS

Derivation of Compliance Data

Initially, 497 patients were identified for possible inclusion in the study based on a listing of diabetes on their electronic problem list and on having at least one encounter during the study period with a clinician enrolled in the study. Four hundred eighty-three charts (97.2%) were available for auditing. In 81 of the audited charts (16.8%), the diagnosis of diabetes incorrectly appeared on the patient's electronic problem list. Most of these incorrect diagnoses reflected errors in data entry, for example, coding "family history of diabetes" (#250) as "diabetes" (#91) modified by "family history of." Forty-three patients (8.9%) were not followed primarily for diabetes at Duke Family Medicine Center. These charts were excluded since clinicians may have felt no obligation to comply with diabetes care guidelines for patients who were followed for diabetes by another practitioner such as an endocrinologist. Every encounter in the remaining 359 charts that occurred during the study period with a study clinician was assessed for compliance with guidelines. This process resulted in 1,265 encounters audited. In 884 of these encounters (70%), diabetes was addressed. Patients seen by clinicians in the intervention and control groups did not differ significantly by age, race, or gender.

Because inclusion of the Computer-Assisted Management Protocol on the encounter form was based on the clinician scheduled to see the patient, the potential existed for contamination between groups if the patient saw a different clinician. In none of the four encounters in which contamination occurred was diabetes assessed. Therefore, the data from these encounters were not included in the analysis of clinician compliance.

Four encounters were insufficiently documented in the chart (eg, a dictated progress note that was lost) to evaluate adequately the clinician's compliance during the visit. Three of these encounters involved clinicians in the intervention group, and one involved a clinician in the control group.

Identification of Eligible Clinicians

Based on the predefined criteria for minimum exposure to diabetic patient care, 16 clinicians of the intervention group and 14 clinicians of the control group qualified for further evaluation. The extent of exposure of providers to patients with diabetes mellitus and to encounters in which diabetes was assessed is shown in **Figure 3.** The level of training in each of the study groups was similar. The intervention group consisted of 11 faculty members, 2 third-year residents and 3 second-year residents. The control group consisted of 9 faculty members, 3 third-year residents, and 2 second-year residents.

Comparison of Compliance Rates

A comparison of the compliance rates for qualified clinicians from both the intervention and control groups for all recommendations during the study is depicted in **Figure 4.** The clinicians receiving the diabetes Computer-Assisted Management Protocol

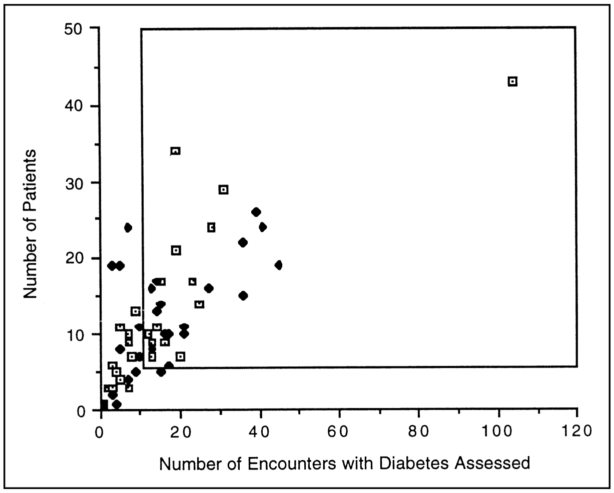

Figure 3. Clinician exposure to diabetes care. Solid diamonds represent clinicians in the intervention group. Open squares represent clinicians in the control group. Clinicians meeting the minimal exposure criteria lie within the rectangle.

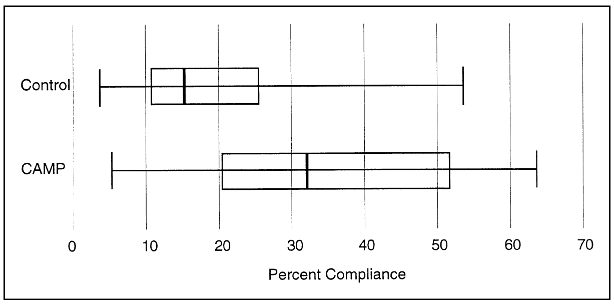

Figure 4. Effect of the computer-assisted management protocol on clinician compliance. Rectangles encase the 25th to 75th percentile for each group. The heavy vertical line inside each rectangle represents the group median. The horizontal lines capped with vertical cross bars delineate the range of values for each group. CAMP = computer-assisted management protocol.

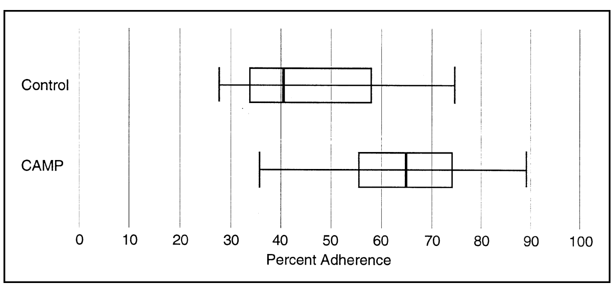

Figure 5. Effect of the computer-assisted management protocol on clinician adherence. Rectangles encase the 25th to 75th percentile for each group. The heavy vertical line inside each rectangle represents the group median. The horizontal lines capped with vertical cross bars delineate the range of values for each group. CAMP = computer-assisted management protocol.

had a statistically significant greater median level of compliance than the clinicians not receiving the Computer-Assisted Management Protocol ($P = 0.01$, two-sided). The median adherence rate of the clinicians receiving the Computer-Assisted Management Protocol was also statistically significantly higher than the median adherence rate for the control clinicians ($P < 0.01$, two-sided). The comparison of guideline adherence is shown in **Figure 5.** Compliance rates by individual recommendation are shown in **Table II.** Statistically significant differences were detected for the physical examination, the urine protein determination, and the cholesterol level. While the remaining recommendations failed to achieve statistical significance, they all showed a trend of increasing for the group receiving the intervention.

Effect of the Computer-Assisted Management Protocol on Encounter Length

Total encounter length was calculated for the 1002 (79.3%) encounters with any of the 58 primary care clinicians for which a time was recorded electronically as patients registered at and departed from Duke Family Medicine Center. No statistically significant difference existed between the mean length of encounters during which the Computer-Assisted Management Protocol was and was not supplied ($P > 0.1$) (95% confidence interval: −5.9 to 8.8). In contrast, a 10-minute increase was observed during encounters in which diabetes was assessed (93 ± 58 minutes) as compared with encounters in which diabetes was not assessed (83 ± 62 minutes) ($P = 0.02$, two-sided) (95% confidence interval: 1.6 to 18.5).

DISCUSSION

The Computer-Assisted Management Protocol significantly improved clinician compliance with care guideline recommendations for diabetes. This finding demonstrates that a clinical practice guideline can be used to assist directly with patient management and validates the Computer-Assisted Management Protocol as a tool to assist clinicians in the management of diabetes mellitus by integrating medical knowledge at the point of care. While this study has shown that the Computer-Assisted Management Protocol can improve the process of care delivery for diabetic patients by using a practice guideline, the study does not measure outcomes. A tool such as the Computer-Assisted Management Protocol could be used to facilitate the direct evaluation of guidelines for diabetes care on patient outcomes.

Despite the statistically significant difference between the experimental and control groups, the overall compliance rate even with the Computer-Assisted Management Protocol was still low. Informal questioning of Computer-Assisted Management Protocol recipients revealed that the Computer-Assisted Management Protocol recommendations were neglected because of time constraints, an overwhelming amount of other clinical information to process, insufficient time to document an intervention that was performed outside of the practice (oph-

TABLE II
Group Compliance by Computer-Assisted Management Protocol Recommendation

Recommendation	Group	Number of Instances*	Median % Compliance	*P* Value
Foot examination	control	31	30.0	$P > 0.1$
	intervention	43	55.6	
Complete physical examination	control	255	6.7	$P = 0.05$
	intervention	211	33.3	
Chronic glycemia monitoring	control	164	52.8	$P > 0.1$
	intervention	167	57.4	
Urine protein determination	control	162	3.9	$P = 0.01$
	intervention	117	73.3	
Cholesterol level	control	163	13.4	$P < 0.02$
	intervention	130	43.7	
Ophthalmologic examination	control	227	3.2	$P > 0.1$
	intervention	181	18.8	
Influenza vaccination	control	197	22.7	$P > 0.1$
	intervention	183	29.2	
Pneumococcal vaccination	control	244	0.0	$P > 0.1$
	intervention	200	19.8	

* Number of instances denotes the number of times that a recommendation was due.

thalmologic examination), an intervention was potentially painful or dangerous to a patient (pneumococcal vaccination), or because the recommendations were not considered appropriate for a given patient. These observations demonstrate that the Computer-Assisted Management Protocol in its current form is not the complete solution for improving compliance with clinical guidelines. The Computer-Assisted Management Protocol, like its computer-generated reminder predecessors, was still subject to neglect by clinicians. The adaptation of the diabetes guidelines to achieve consensus prior to implementation minimized the impact of disagreement with guideline recommendations on compliance.

On a more favorable note, the overall rate at which clinicians followed the diabetes guidelines rose above 50% with the introduction of the Computer-Assisted Management Protocol. While still allowing room for further improvement, the Computer-Assisted Management Protocol significantly enhanced utilization of the diabetes care recommendations. Ultimately, overall adherence to guideline standards will be the parameter by which the performance of a health care organization will be evaluated.

When the effect of the Computer-Assisted Management Protocol on individual recommendations was analyzed, the Computer-Assisted Management Protocol showed a trend of improved median compliance for all of the recommendations. The difference between groups, however, was only statistically significant for 3 of the 8 recommendations. Failure to detect statistically significant differences for 5 of the recommendations is in part due to the wide variation among compliance rates of individual clinicians in the same group and to the lack of statistical power derived from the relatively small sample size of each group.

The number of clinicians (55% of the intervention group and 48% of the control group) fulfilling the predefined requirements for exposure to diabetic patients was less than initially anticipated. These smaller numbers are due in part to the disqualification of some patients because they were wrongly labeled as diabetic or were primarily followed for diabetes at another facility. While exposure criteria limited the sample size, these criteria were necessary to assure that the compliance rate accurately reflected a clinician's true practice pattern. Since the factors limiting the number of qualifying clinicians applied equally to both the intervention and control groups, there is no evidence to suggest introduction of bias at this level. Since this project was considered an extension of routine quality assurance activities for the practice, neither group of clinicians was aware that their compliance with diabetes care guidelines was being specifically monitored. Consequently, the Hawthorne effect was not considered to have had an impact on the study's findings.

A potential source of bias in this study was the inability to blind the chart auditor to the assignment group of each clinician. While clinician assignment was not available to the auditor during the auditing process, the auditor could deduce from some progress notes which clinicians were following the Computer-Assisted Management Protocol recommendations. The use of the standardized audit protocol and the a priori definition of compliance were designed to assure that each chart was audited in the same fashion and, thus, minimize any tendency of the auditor to score compliance higher in the intervention group.

Encounter length, calculated as the difference between check-in and check-out times, serves only as a crude measurement of the length of time a clinician spent with a patient. A statistically significant difference in encounter length was noted only between visits when diabetes was addressed and when diabetes was not addressed regardless of whether the Computer-Assisted Management Protocol was available. This increased encounter length could be attributed to extra time spent managing the diabetes. The lack of difference between the encounter length of intervention and control clinicians indicates that the Computer-Assisted Management Protocol did not unduly prolong encounter length. If there were time savings from the use of the Computer-Assisted Management Protocol, these time savings may have been masked by an increased amount of patient time spent having studies performed.

The findings in this study are also limited because the Computer-Assisted Management Protocol was developed and evaluated for only a single guideline in an academic primary care practice. To validate the Computer-Assisted Management Protocol approach further, Computer-Assisted Management Protocols should be created from additional clinical guidelines and Computer-Assisted Management Protocol effectiveness should be evaluated in a variety of clinical settings. Even though the focus of this study was diabetes mellitus, the Computer-Assisted Management Protocol provides a framework though which guidelines for other diseases could be implemented. The structure of the Computer-Assisted Management Protocol decision support system can accommodate guidelines with branching logic; however, because the Computer-Assisted Management Protocol program is run prior to the patient encounter and presents its recommendations via paper encounter forms, the Computer-Assisted Management Protocol currently only supports guidelines for which the data on which the guideline logic is based is already stored in a patient's electronic medical record. Additional modifications to the implementation of the Computer-Assisted Management Protocol would be required to enable the Computer-Assisted Management Protocol to support real time data entry to traverse guidelines with branching logic based on data input during a patient encounter.

Another study limitation is the persistence of data "recording errors" arising from the discrepancy between data contained in the paper chart and data in the electronic patient record. As a consequence, false positive recommendations were made because the Computer-Assisted Management Protocol was uninformed about studies/procedures which were documented exclusively in the paper medical record. In spite of these persistent inaccuracies of the system, the Computer-Assisted Management Protocol still produced a significant change in clinician compliance with the diabetes care guideline. These recording errors will decrease as more clinical data is capture electronically. Fewer false positive recommendations should increase user confidence in the system which may serve to further boost compliance.

As the focus of the health care system shifts from a specialist-based, private payer system to a primary care-based, managed care environment, the primary care clinician will be expected to see an increasing volume of patients and master an increasing breadth and depth of medical knowledge. Primary care clinicians who use computers to implement care standards for specific diseases may deliver higher quality health care.

Future technological advances could further enhance the use of Computer-Assisted Management Protocols. Development of a computerized patient record that is used interactively during the patient encounter would allow direct prompting of the clinician during the clinical encounter.[27] Requiring a response and enabling the clinician to comply easily (eg, automated ordering of a recommended test) could be used to enhance compliance further.[28]

In summary, we have demonstrated that the Computer-Assisted Management Protocol can assist clinicians in the management of patients with diabetes mellitus by improving compliance with care standards. Use of the Computer-Assisted Management Protocol did not significantly prolong encounter length. In the future, Computer-Assisted Management Protocols may become a tool to enhance the quality, efficiency, and cost-effectiveness of health care delivery.

ACKNOWLEDGMENTS

The authors wish to thank James Collins, PhD, for programming assistance; Kimberly S. H. Yarnall, MD., for suggestions concerning the clinical implementation of the Computer-Assisted Management Protocol; and Jonathan Prather, BS, for assistance with database queries.

REFERENCES

1. American Medical Association. *Directory of Practice Parameters.* Chicago, IL: American Medical Association, 1995.

2. Committee to Advise the Public Health Service on Clinical Practice Guidelines, U.S. Institute of Medicine. *Clinical Practice Guidelines: Directions for a New Program.* Field MJ, Lohr KN, eds. Washington, DC: National Academy Press; 1990.

3. Headrick LA, Speroff T, Peleconanos HI, Cebul RD. Efforts to improve compliance with the National Cholesterol Education Program guidelines. Results of a randomized controlled trial. *Arch Intern Med.* 1992;152:2490–2496.

4. Czaja R, McFall SL, Warnecke RB, et al. Preferences of community physicians for cancer screening guidelines. *Ann Intern Med.* 1994;120:602–608.

5. Lomas J, Anderson GM, Dominick-Pierre K, et al. Do practice guidelines guide practice? The effect of a consensus statement on the practice of physicians. *NEJM* 1989;321:1306–1311.

6. Ellrodt AG, Conner L, Riedinger M, Weingarten S. Measuring and improving physician compliance with clinical practice guidelines. A controlled interventional trial. *Ann Intern Med.* 1995;122:277–282.

7. Grimshaw JM, Russell IT. Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. *Lancet.* 1993; 342:1317–1322.

8. McDonald CJ. Protocol-based computer reminders, the quality of care and the non-perfectability of man. *NEJM* 1976;295:1351–1355.

9. McDonald CJ, Hui SL, Smith DM, et al. Reminders to physicians from an introspective computer medical record: a two-year randomized trial. *Ann Intern Med.* 1984;100:130–138.

10. Rosser WW, McDowell I, Newell C. Use of reminders for preventive procedures in family medicine. *Can Med Assoc J.* 1991;145:807–812.

11. Garr DR, Ornstein SM, Jenkins RG, Zemp LD. The effect of routine use of computer-generated preventive reminders in a clinical practice. *Am J Prev Med.* 1993;9:55–61.

12. Chambers CV, Balaban DJ, Carlson BL, et al. Microcomputer-generated reminders: improving the compliance of primary care physicians with mammography screening guidelines. *J Fam Pract.* 1989;29:273–280.

13. Shea S, Sedeli RV, DuMouchel W, et al. Computer-generated informational messages directed to physicians: Effect on length of hospital stay. *J Am Med Inform Assoc.* 1995;2:58–64.

14. McDonald CJ, Wilson GA, McCabe GP. Physician response to computer reminders. *JAMA.* 1980;244:1579–1581.

15. Tape T, Campbell JR. Computerized medical records and preventive health care: success depends on many factors. *Am J Med.* 1993;94:619–625.

16. Barnett GO, Winickoff R, Dorsey JL, et al. Quality assurance through automated monitoring and concurrent feedback using a computer-based medical information system. *Med Care.* 1978;16:962–970.

17. McAlister NH, Covvey HD, Tong C, et al. Randomized controlled trial of computer assisted management of hypertension in primary care. *Br Med J.* 1986;293:670–674.

18. Coe FL, Norton E, Oparil S, et al. Treatment of hypertension by computer and physician—a prospective controlled study. *J Chron Dis.* 1977;30:81–92.

19. Deutsch T, Carson ER, Harvey FE, et al. Computer-assisted diabetic management: a complex approach. *Computer Methods Programs Biomed.* 1990;32:195–214.

20. Brownbridge G, Evans A, Fitter M, Platts M. An interactive computerized protocol for the management of hypertension: effects on the general practitioner's clinical behavior. *J Royal Coll Gen Pract.* 1986;36:198–202.

21. American Diabetes Association. Standards of medical care for patients with diabetes mellitus. *Diabetes Care.* 1992;15(supplement 2):10–13.

22. Weiner JP, Parente ST, Garnick DW, et al. Variation in office-based quality: a claims-based profile of care provided to Medicare patients with diabetes. *JAMA.* 1995;273:1503–1508.

23. Lobach DF. A model for adapting clinical guidelines for electronic implementation in primary care. In: Gardner RM, ed. *Proc. Nineteenth Annual Symp Computer Applications in Medical Care.* Philadelphia, Pa: Hanley & Belfus; 1995:581–585.

24. Stead WW, Hammond WE. Computer-based medical records: the centerpiece of TMR. *MD Comput.* 1988;5:48–62.

25. Yarnall KSH, Michener JL, Hammond WE. The Medical Record: A comprehensive computer system for the family physician. *J Am Board Fam Pract.* 1994;7:324–334.

26. Yarnall KSH, Michener JL, Broadhead WE, et al. Computer-prompted diagnostic codes. *J Fam Pract.* 1995;40:257–262.

27. Tierney WM, Hui SL, McDonald CJ. Delayed feedback of physician performance versus immediate reminders to perform preventive care. *Med Care.* 1986;24:659–666.

28. Litzelman DK, Dittus RS, Miller ME, Tierney WM. Requiring physicians to respond to computerized reminders improves their compliance with preventive care protocols. *J Gen Intern Med.* 1993;8:311–317.