Development and Evaluation of a Computer-Assisted Management Protocol (CAMP): Improved Compliance with Care Guidelines for Diabetes Mellitus

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ABSTRACT

Disease-specific standards for directing patient management are becoming increasingly important. These standards, however, are often not followed because they are not sufficiently integrated into the clinical care setting. In this study we describe the development and evaluation of a Computer-Assisted Management Protocol (CAMP) of care guidelines for diabetes mellitus. While other studies have shown improved compliance with rule-based reminders, the CAMP customizes disease-specific care guidelines to individual patients over time. We evaluated the effect of the CAMP on compliance with guidelines in a prospective, randomized controlled study. The study was performed at a family practice clinic where much of the patient record is maintained electronically on The Medical Record (TMR). The management protocol was developed from standards published by the American Diabetes Association. Fifty-eight providers were randomized to either receive or not receive the CAMP for diabetes. Compliance with standards was assessed by chart audits of all encounters with diabetic patients during the study interval. The following conclusion was made: the Computer-Assisted Management Protocol resulted in a statistically significant improvement in compliance with diabetes care standards.

INTRODUCTION

Limited financial resources and increasing emphasis on primary care in a managed care environment are driving medical care delivery to become more efficient and cost-effective without sacrificing quality. One major approach to achieving the goals of efficiency and quality is through the standardization of care for specific diseases [2,3,5,10]. Care standardization efforts have included development of care maps, critical pathways, and care guidelines [14]. While the standardization efforts are laudable, they often fail to have the desired effect because they are not sufficiently integrated into the clinical setting. Non-compliance with care standards can have both adverse medical and legal consequences [6]. While many factors contribute to this compliance failure, a primary cause is the limitation of the human care provider as an information processor [8]. Computerization of medical knowledge can be used to augment provider information processing. Several previous studies have shown that computer-generated, rule-based reminders can improve compliance with individual guidelines [4,8,9,11], but others have shown that reminders alone are insufficient to effect compliance [7,13]. No studies to date, however, have computerized an existing set of disease-specific care guidelines for use in the clinical setting. In this study we describe the development and evaluation of a Computer-Assisted Management Protocol (CAMP) for the continuing care of patients with diabetes mellitus. The CAMP provides a novel way to computerize domain-specific medical knowledge from disease-specific care guidelines and integrate this knowledge into the clinical setting. It allows customization of recommendations based on data in a patient's electronic medical record and evolution of these recommendations over time. Diabetes mellitus was selected for the prototypic CAMP for several reasons. Diabetes is a common disease affecting more than 5% of the adult population in the United States. Its diagnosis is quantitative and relatively unambiguous. Chronic management of diabetes requires monitoring of several laboratory parameters and serial physical examinations common to all patients. Care guidelines have been published by the American Diabetes Association (ADA) and are relatively well accepted as standards [1,5]. Lastly, encounters with diabetic patients are relatively time- and information-intensive leading to an increased need for efficient information processing. In this study we evaluated the impact of a CAMP for diabetes mellitus on provider compliance with guidelines in a primary care setting.

METHODS

Study Design

The effect of the CAMP on compliance with disease-specific guidelines was evaluated in a controlled, prospective, randomized study conducted from September 1993 through February 1994 at the Duke Family Medicine Center (DFMC). Retrospective data was obtained from the 6 months prior to the start of the study (March 1993 through August 1993) to determine baseline compliance levels. DFMC is a free-standing, full service primary care clinic and site of the Family Medicine Residency Program affiliated with Duke University Medical Center. The clinic had a total of 74,738 patient visits

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in fiscal year 1993. At the start of the study, the clinic employed 58 primary care providers and 6 specialists. The primary care providers included 25 faculty (21 physicians, two physician assistants, and two nurse practitioners), and 33 family medicine residents. All the primary care providers were randomly assigned to either receive or not receive the CAMP by standard randomization techniques. The randomization was not constrained by level of training since there is no evidence to suggest that training level alone affects compliance with care guidelines [13]. Providers in neither group were aware that they had been randomized in order to study the effect of the CAMP on their compliance with guidelines. At the start of the study, providers who were designated to receive the CAMP were sent a letter informing them that the CAMP developed from the practice consensus guidelines would be printed on the encounter forms for their diabetic patients. This letter also described how the CAMP functioned and solicited feedback about incorrect recommendations. Prior to the initiation of the study, a representative level of exposure to diabetic patients and diabetes care was defined. In order to consider a provider's compliance score a valid representation of their practice patterns for diabetes, the provider had to have contact with at least six unique diabetic patients and to have assessed diabetes care in at least 12 encounters during the study period. The CAMP was designed to integrate into the DFMC electronic medical record system, The Medical Record (TMR). TMR is a comprehensive electronic medical record system that supports a complete database of patient information [12]. TMR modules in operation during the study included demographic information, scheduling, accounting, problem lists, subjective and physical findings, encounter summary, medications, quality assurance, and laboratory orders/results.

Development of the Computer-Assisted Management Protocol

To diminish non-compliance with care standards due to provider disagreement with the standards themselves, consensus guidelines were developed among the providers at DFMC. The continuing care guidelines for diabetes published by the ADA were used as the initial template [1]. Faculty and resident consensus was obtained from the responses to two surveys and through discussions at practice management meetings. The consensus guidelines were completed three months prior to the initiation of the study, lessening the effect of recent exposure to care guidelines on provider practice patterns.

The consensus guidelines, summarized in Figure 1, were encoded in the existing Quality Assurance module of TMR. The the output from the program for the diabetes CAMP was printed on the first pageof an encounter form. Encounter forms at DFMC were

1. Foot examination every month in patients with diabetic neuropathy or history of lower limb ulcers
2. Annual complete physical examination
3. HgbA1c 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

Figure 1. *DFMC Care Guidelines for Diabetes Mellitus*

generated for each patient prior to the visit. These forms served as order/billing sheets, as well as summary lists for patient problems, medications, and health maintenance data. Initially the CAMP program identified all patients with diabetes listed as a problem in their electronic record who were scheduled to see a primary care provider. It then customized the guideline recommendations for the scheduled visit based on data in the electronic record. Laboratory and immunization data were historically available in TMR. CAMP providers could add data about the foot exam or physical exam in the feedback section of the CAMP (see below) to have this data also available to the CAMP. The patient's name, identification number, and CAMP were stored in a master file as a source list for encounters to be audited. The CAMP was then selectively printed only on the encounter forms of patients scheduled to see providers randomized to receive the CAMP.

A sample CAMP is shown in Figure 2. It lists the customized diabetes guideline recommendations and provides an area for written feedback/updating by the provider. The guideline feedback section also allowed the provider to indicate if the recommendation was offered but *declined* ("D") by the patient or *never* ("N") to be performed. When "never" was entered, a given guideline recommendation was permanently shut off for that patient. Feedback/updates from providers that were not automatically captured by TMR (e.g., a laboratory test performed at another facility) were manually entered into the patient's electronic record.

Data Collection and Analysis

Compliance with CAMP recommendations was determined by chart audit. Chart audits were selected as the "gold standard" for compliance since direct evaluation of the written documentation of the encounter was necessary to determine if diabetes care was assessed and if the recommendations were addressed during the encounter. Providers were considered compliant with a guideline if they performed the recommendation, commented that the

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 2. *Sample Format for the Computer-Assisted Management Protocol for Diabetes Mellitus*

recommendation had been done in the past or was scheduled at a definite time in the future, or stated why a guideline was not being followed (e.g., financial limitations). Compliance was based solely on data derived from the paper chart. 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 sections of a progress note not specifically addressing diabetes. In order to standardize chart auditing, an audit protocol was used for every chart. Chart evaluations were recorded on an audit form generated from the encounter list in the master file described above. Data from these forms were entered into an electronic database (Paradox, Borland International, Inc., Scotts Valley, CA) for analysis. Comparison of patient demographic data between groups was done using a t-test for mean ages and Chi square tests for gender and race. Provider compliance scores were calculated as the number of required guidelines followed over the total number of required guidelines, and expressed as percent compliance. Comparison of compliance scores between the CAMP and No-CAMP groups was done with a two-tailed Wilcoxon rank sum 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 provider enrolled in the study. Four hundred eighty-three (97%) of these charts were available for auditing after up to 5 chart requests were submitted for each chart. In 81 (17%) of the audited charts, the diagnosis of diabetes was incorrect. Most of these reflected errors in data entry, i.e. coding "family history of diabetes" (#250) as "diabetes" (#91) modified by "family history of." Forty-three (9%) of the charts were for patients who were not followed primarily at DFMC for diabetes. Every encounter in the remaining 359 charts (72%) that occurred during the study period with a study provider was assessed for compliance with guidelines. This resulted in 1265 encounters being audited. In 884 (70%) diabetes was addressed. In addition, for the 6 months prior the the start of the study, all encounters with study providers in which diabetes was a focus problem for the encounter were scored for compliance with guidelines. For the purposes of analysis, only compliance data from the encounters in which diabetes was a focus problem were used to derive provider compliance scores. Patients seen by CAMP versus No-CAMP providers did not differ significantly by age, race, or gender. The exposure to diabetic patients during the study is shown in Figure 3. The experience of the 58 providers is represented as a function of the number of diabetic patients seen versus the number of encounters in which diabetes was addressed. Based on the predefined criteria for minimum exposure to diabetic patient care, 16 providers of the CAMP group and 14 providers of the No-CAMP group qualified for further evaluation. The CAMP group consisted of 11 faculty members, 2 third-year residents, and 3 second-year residents. The No-CAMP group consisted of 9 faculty members, 3 third-year residents, and 2 second-year residents.

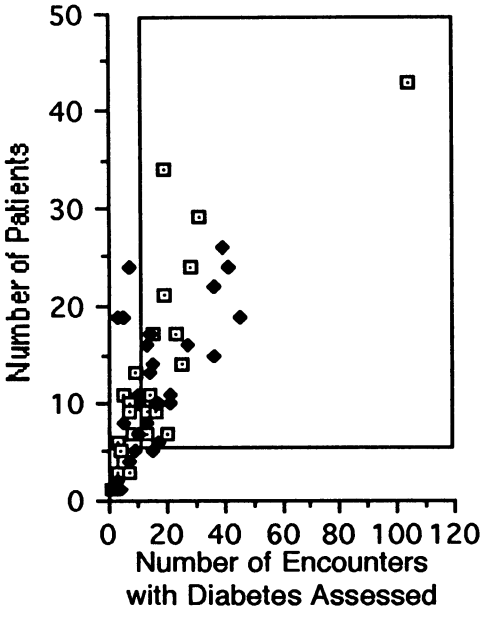

Figure 3. *Provider exposure to diabetes care. Diamonds represent CAMP providers. Squares represent No-CAMP providers.*

Comparison of Compliance Levels

Comparison of the compliance scores for qualified providers from both the CAMP and No-CAMP groups during the study is depicted in Figure 4. The providers receiving the diabetes CAMP had a

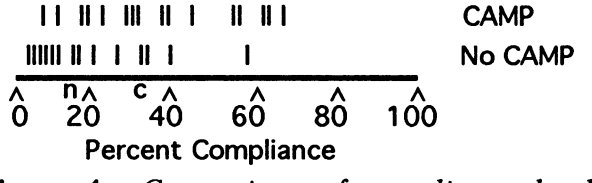

Figure 4. *Comparison of compliance levels between groups after introduction of the CAMP. Each "\|" represents the compliance score for one provider.*

statistically significantly greater median level of compliance than the providers not receiving the CAMP (p=0.02) (32.0% versus 15.6%). Comparison of compliance scores between the same provider groups prior to the study were not statistically significantly different. The median baseline compliance levels during the 6 month prior to the implementation of the CAMP were 21.2% for the CAMP group and 18.0% for the No-CAMP group.

DISCUSSION

The significant difference in compliance levels between providers randomized to receive the diabetes CAMP and those who did not receive it demonstrates the effectiveness of the Computer-Assisted Management Protocol for improving compliance with diabetes care guidelines. The lack of difference between these two groups prior to the introduction of the CAMP underscores that the primary factor effecting the change in compliance was the CAMP.

A discussion of potential biases introduced into the study is warranted. The effect of not collecting encounter data from 3% of the patient charts initially identified could be a source of bias. However, this only slightly limited the total amount of data that could be collected, and there is no reason to suspect that compliance levels in the unevaluated charts were any different than those in the charts that were evaluated. Furthermore, the unavailable charts were relatively evenly distributed among the CAMP and No-CAMP providers. If this lack of chart availability suggests anything of significance, it is the limitation of a paper medical record as the primary repository for clinical data. The discovery that 17% of the study patients were incorrectly classified as diabetic reflects the cumulative errors in data entry by non-medical personnel and the lack of attention paid to updating and correcting patient problem lists by providers. While this finding should not bias the evaluation of provider compliance, it does underscore the need for greater accuracy in data entry and in data surveillance by providers. In order to drive medical knowledge modules, such as the diabetes CAMP, from data in the electronic patient record, the data must be accurate. The lack of difference in the demographics of the patients seen by the two study groups effectively eliminates the potential bias of patient age, gender, or race. 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 provider was focussed on other medical problems. This approach was felt to optimize a provider's opportunity to be compliant with the standards. The number of providers (55% of the CAMP group and 48% of the No-CAMP group) fulfilling the predefined requirements for exposure to diabetic patients was less than initially anticipated. These smaller numbers are due in part to the lack of availability of charts for auditing and the disqualification of some patients because they were wrongly labelled as diabetic or were primarily followed for diabetes at another facility. While the exposure criteria limited the sample size, these criteria were necessary to assure that the compliance score accurately reflected a provider's true practice pattern. Since the factors limiting the number of qualifying providers applied equally to both the CAMP and No-CAMP groups, there is no evidence to suggest introduction of bias at this level. Because providers in neither group were aware that their compliance with diabetes care guidelines was

being studied, the Hawthorn effect was not considered to have had a significant impact on the study outcome.

The findings of this study have important ramifications for the delivery of health care in the United States. Computer-Assisted Management Protocols provide a mechanism to electronically represent medical knowledge and deliver this knowledge to the clinical setting. As the focus of the health care system shifts from a specialist-based, private payor system to a primary care-based, managed care environment, the primary care provider will be expected to see an increasing volume of patients and master an increasing breadth and depth of medical knowledge. No longer will domain experts (specialists) be the first level of care for most diseases. The development of care standards for specific diseases can assist the primary care provider in delivering high quality health care. Already, there has been an increasing effort to create such care standards. However, clinical standards are of little use unless they are available to providers in a timely, efficient way. As shown in this study, the CAMP as a computerized representation of medical knowledge is one effective tool by which practice guidelines can be integrated into the clinical setting. The CAMP also has a potentially important role in the evaluation of the care standards themselves. Many standards are assumed to favorably affect patient outcome but have never been proven to do so. By significantly increasing provider compliance with care standards, the use of CAMPs could allow direct evaluation of the efficacy of the standards in outcomes research.

In the future, it is anticipated that CAMPs similar to this prototypic diabetes CAMP will be developed. Further computerization of the patient record will also allow for real-time application of CAMPs during the actual clinical encounter. As shown in this study, now and in the future, CAMPs have great potential to improve compliance with care standards and ultimately enhance the quality and efficiency of health care delivery, by bringing care standards to the point of patient contact.

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