Do Clinical Practice Guidelines Improve Processes or Outcomes in Primary Care?

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Background: Clinical practice guidelines (CPGs) are common, but it is not clear whether they improve care. Methods: Quality indicators for processes and outcomes of care were obtained from a computerized system-wide database by patient administration and utilization management personnel unaware of this study and without connection to or interests in guideline implementation. These indicators were compared before and after guideline implementation. Results: After the asthma CPG, nebulizer treatments, emergency department visits, and admissions decreased significantly ($p < 0.001$ for all three) and education increased significantly ($p < 0.001$). Periodic measurements of lung function and controller medication prescriptions were unchanged. After the diabetes mellitus CPG, microalbumin screens and education increased significantly ($p < 0.001$). Angiotensin-converting enzyme inhibitor prescriptions and yearly foot examinations decreased significantly, along with the percentage of patients with blood pressure of ≤130/85 mm Hg ($p < 0.001$). Mean hemoglobin A_{1c} levels did not change significantly. After the tobacco cessation CPG, screening and education increased significantly ($p < 0.001$ and $p = 0.04$, respectively). Conclusions: The asthma CPG improved some processes and all outcomes. The diabetes CPG improved two of the eight measured processes but had no effect on outcomes. Education and screening, but not counseling, improved with the tobacco CPG. CPGs appear to improve diagnostic and educational processes more than provider-dependent treatment processes. Outcomes were improved after implementation of the asthma CPG but not after the diabetes CPG.

Introduction

Guideline-based medical practice pervades the delivery of health care.[1–7] As of 1997, there were more than 2,500 clinical practice guidelines (CPGs) available, and the number continues to increase.[8] Mandatory implementation of and compliance with an increasing number of CPGs are also becoming more common,[1,6,9] although the effectiveness of many CPGs in improving care remains uncertain.[1–3,10] A Cochrane systematic review of interventions to improve the care of diabetic patients recently concluded that the effect of guidelines for diabetes mellitus was unclear.[4] Although experts acknowledge the uncertainty of the effectiveness of CPGs, the experts encourage their implementation.[11,12] Studies that showed that CPGs improved the process or outcomes of care have been criticized as lacking strength or having minimal impact.[10] Furthermore, guidelines may be less effective in changing or improving practice in the primary care setting.[8,13]

The purpose of this study was to determine what effect asthma, diabetes, and tobacco CPGs have on processes of care and outcomes in a primary care setting.

Methods

Design, Setting, and Patients

The investigation was a before-and-after study in a primary care department of a managed care organization with approximately 68,000 beneficiaries of all ages. For the asthma portion of the study, only patients 6 years of age or older were included. For the diabetes and tobacco portions, only patients 18 years of age or older were included in the study.

Guideline Intervention

Evidenced-based CPGs derived from the National Heart, Lung, and Blood Institute and the American Diabetes Association were implemented through a series of required lectures for all primary care providers and the distribution of "tool kits" to all points of care. The tool kits consisted of full-sized and pocket-sized laminated management algorithms and other reference materials for each provider, along with educational materials for patients. Before the final implementation, local tailoring was performed using the Delphi method.[6] No decision point or recommendation in the guidelines that was based on good evidence was tailored. Guideline adherence was later encouraged at regular departmental performance-improvement meetings. Three separate guidelines were studied, to determine their impact on process and outcome measurements, i.e., asthma, diabetes, and tobacco cessation. All guidelines are available on the World Wide Web (http://www.qmo.amedd.army.mil).

Data Extraction

The Composite Health Care System is a computerized database that links scheduling (including all primary and consultative appointments), pharmacy, radiology, laboratory, and all other ancillary health care services throughout the entire military health care system. Physician orders for all outpatient services, including diagnostic tests and prescriptions, must be entered through this system. Patient visits for all outpatient care, including emergency department care, are recorded. Use of all ancillary health care services is also recorded. This results in the automatic generation of a computerized medical record that can be easily queried to determine such things as utilization, productivity, laboratory values, X-ray results, clinic appointments, and type and number of prescriptions. Patient and provider profiles can also be easily generated. For example, one can

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go to the database and query for all patients who were given prescriptions for insulin and who had protein in their urine. One can then see whether these patients were given prescriptions for an angiotensin-converting enzyme (ACE) inhibitor.

Personnel from the patient administration, information management, performance improvement, and utilization management departments, all of whom had no connection to the study or interest in guideline implementation, were asked to query the Composite Health Care System database to provide all of the data for this study, with two exceptions. Whether a patient was told to stop smoking was available only by review of the handwritten progress notes of the provider, and inpatient admissions were obtained from hospital admission records using the International Classification of Diseases, 9th Revision, codes.

Asthma Process and Outcome Measurements

Three process and three outcome measurements were used to assess the impact of the asthma CPG. These were the number of requests to respiratory service for nebulized albuterol treatments for asthma exacerbations, the number of emergency department visits, and the number of hospital admissions for asthma exacerbations 1 year before and 1 year after guideline implementation. For the subgroup of patients with persistent asthma, the percentage given appropriate long-term controller medications, the percentage receiving regular measurements of lung function tests (spirometry at each office visit), and the percentage receiving in-depth asthma education before and after guideline implementation were also compared.

Diabetes Process and Outcome Measurements

Eight process and two outcome measurements were used to assess the impact of the diabetes CPG. The percentages of patients with either type I or type II diabetes meeting indications for ACE-I or antihyperlipidemic therapy who actually received such therapy were compared. The percentages of patients receiving formal education, foot and eye examinations, and determinations of lipid, microalbuminuria, and glycohemoglobin levels at recommended intervals were also compared. The percentages of patients with blood pressure of ≤130/85 mm Hg 1 year before and after guideline intervention were compared. The mean hemoglobin A_{1C} levels for a subgroup of 277 patients were compared for 14 months before and after guideline intervention, following a 2-month "washout" period after the guideline was implemented.

Tobacco Process Measurements

The percentage of patients screened at each office visit for tobacco usage, the percentage receiving formal education about the dangers of tobacco, and the percentage counseled by a provider at least three times to stop before and after guideline intervention were compared.

Statistical Analyses

Because of the large *n* values, the *Z* test was used to determine whether the before and after data means were significantly different at the 95% confidence level.

Results

After implementation of the asthma CPG, there were statistically significant decreases in the frequency of nebulizer treatments, emergency department visits, and hospital admissions for asthma exacerbations. The percentage of patients receiving education increased significantly. The percentage receiving regular measurements of lung function and the number of prescriptions for controller medications did not change significantly (Table I). After the diabetes CPG, the percentages of patients receiving yearly microalbumin screens and recommended education increased significantly; however, the percentages of patients receiving recommended ACE inhibitor prescriptions or yearly foot examinations and the percentage with blood pressure at or below goal levels decreased significantly. The percentage receiving biyearly lipid profiles increased but not significantly. The percentage of patients given prescriptions for antihyperlipidemic drugs decreased but not significantly. The percentage of patients receiving yearly eye examinations and the percentage of patients receiving yearly glycohemoglobin assessments did not change significantly. The mean glycohemoglobin (hemoglobin A_{1C}) levels did not change significantly (Table II). Following the tobacco cessation CPG, the percentages of patients screened for tobacco use and receiving education increased significantly. The percentage counseled to stop decreased but not significantly (Table III).

Discussion

The asthma CPG appeared to improve educational and diagnostic processes along with several outcomes, such as the need for respiratory, emergency department, and inpatient assets.

TABLE I

EFFECT OF ASTHMA CPG ON PROCESSES AND OUTCOMES

Process or Outcome	Before (*n*)	After (*n*)	% Change	*p*
% Educated	51 (330)	65 (334)	+28	<0.001
% with pulmonary function tests	65 (330)	70 (334)	+7	0.15
% on controllers	66 (330)	67 (334)	+2	0.78
No. of nebulizer treatments	432	203	−54	<0.001
No. of emergency room visits	553	193	−65	<0.001
No. of total visits	16,844	16,579		
No. of admissions	56	23	−60	<0.001
% of Total admissions	8 (765)	3 (695)	−63	<0.001

TABLE II

EFFECT OF DIABETES CPG ON PROCESSES AND OUTCOMES

Process or Outcome	Before (*n*)	After (*n*)	% Change	*p*
% with ACE inhibitor	53 (427)	38 (584)	−28	<0.001
% with antihyperlipidemic	24 (427)	20 (584)	−17	0.14
% with yearly hemoglobin $A1_C$ test	83 (427)	81 (231)	−2	0.59
% with urinary microalbumin test	43 (421)	64 (226)	+45	<0.001
% with yearly foot examination	65 (318)	45 (235)	−30	<0.001
% with yearly eye examination	51 (309)	44 (226)	−14	0.09
% with lipid profile	67 (295)	72 (226)	+7	0.22
% educated	66 (395)	76 (404)	+15	0.002
Blood pressure <130/85 mm Hg	66 (342)	51 (221)	−23	<0.001
Mean hemoglobin $A1_C$ (%)	7.882 (277)	7.669 (277)	−3	0.074
Range (%)	5.0–15.2	5.0–14.9		

TABLE III

EFFECT OF TOBACCO CPG

Process	Before (*n*)	After (*n*)	% Change	*p*
% Screened for tobacco use	65 (692)	90 (153)	+38	<0.001
% Counseled three times to stop	23 (238)	13 (8)	−46	0.48
% Educated	84 (695)	90 (280)	+7	0.04

However, none of the CPGs increased provider compliance with specified treatment recommendations. The finding that provider behavior is less amenable to guideline intervention than other processes is not unique to our study.[14–18] Several factors might have been responsible for the failure of the diabetes CPG to influence outcomes. First, a podiatrist or diabetic foot-at-risk clinic is not continuously available in our setting; both are available on a quarterly basis. This may be one reason why the diabetes CPG did not improve that particular process. Second, diabetes, more often than asthma, is a comorbid condition with other associated variables that can affect processes and outcomes. Third, the diabetes guideline requires considerably more education on the part of the provider than does the asthma guideline, even with the help of the nurse educator or case manager. Furthermore, unlike patient education for asthma guidelines, patient education for diabetes is more akin to traditional education than to the newly recommended self-management education.[19] Whereas traditional patient education offers information and technical skills, self-management education teaches problem-solving skills and is generally more effective.[19] Fourth, patient compliance, not only with medication usage but also with diet and exercise, may be more important than application of management tools. In a previous study, simply making patients aware that guidelines existed helped increase patient compliance and improved outcomes.[2] In a systematic review of 15 studies, incorporating more patient-oriented interventions had a favorable effect on outcomes.[4] We have begun to make patients aware of the guidelines, and we recommend institutions consider doing this as part of their guideline implementation strategy. However, more research is needed to determine the extent to which that improves processes or outcomes.

It is unlikely that the implementation strategy was responsible for the failure of the diabetes CPG to improve outcomes, because it was the same implementation strategy as used for the asthma CPG, which did positively influence outcomes. Also, we attempted to mitigate the effect of population-specific factors on guideline impact through local tailoring before final implementation. It is also unlikely that population or provider instability contributed to guideline failure. Analysis of the population characteristics was performed using the Composite Health Care System database and showed that beneficiary enrollment and provider impanelment were stable and nearly unchanged during the preimplementation and postimplementation periods. Indeed, for the hemoglobin A_{1C} subgroup analysis, only patients with repeated measurements during both the preimplementation and postimplementation periods were included. Therefore, that population was not only stable but identical before and after implementation. All of the health care providers were the same in the preimplementation and postimplementation periods.

The finding that there was no negative impact on glycohemoglobin levels, despite the fact that the recommended guideline interventions were not applied, leads us to question the relevance of some of the processes recommended in the diabetes guideline, such as periodic measurement of hemoglobin A_{1C} levels. However, these are widely accepted processes and outcomes promoted by national authorities.[20] The outcome of lower blood pressure has also been called into question recently, because the rate of decline in glomerular filtration rate was no different for patients with usual mean arterial pressure (102–107 mm Hg), compared with patients with lower mean arterial pressure (≤92 mm Hg).[21] Finally, because hyperglycemia alone does not fully explain the pathogenesis of diabetic complications[22] and not all available data are consistent with the idea that diabetic complications are simply the result of glucotoxins produced by altered cellular glucose metabolism,[22] glycemic control may not be as sufficient an outcome or surrogate outcome measure as currently thought.

A limitation of this study was that we could not always determine whether there was an active decision to withhold an ACE inhibitor. However, this would not likely account for a significant number of patients because, in a non–tertiary-level care setting such as ours, one would encounter few contraindications for using an ACE inhibitor for a diabetic patient with proteinuria. We could and did account for the lack of an ACE inhibitor because of side effects or intolerance. Another limitation of this study was that patient compliance might have had more influence on outcomes than provider practice guidelines.

Because of inherent difficulties in accurately determining patient compliance, we were not able to measure it. We need to assess whether the mean HgA_{1C} level for the patients who experienced provider practice guideline efforts was different from that for the patients who did not. We also need to examine why high-level provider compliance with the established diabetes CPG was difficult to obtain in our setting. The CPGs were mandatorily implemented across our entire health care organization as part of performance improvement efforts. Because the intent was for all providers to follow the guidelines for every patient, we could not conduct a controlled before and after study by having a control group of patients who were not subject to guideline recommendations that we could compare with the study group. Prospective controlled studies are needed. If other institutions are aware beforehand that a guideline will be implemented, we encourage them to perform such a study, especially if implementation is not going to be uniformly mandatory.

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