

Supporting the Patient's Role in Guideline Compliance: A Controlled Study

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Numerous studies have documented the slow dissemination of new medical knowledge^{1,2} and the failure of many patients to receive important evidence-based clinical services.^{3,4} Clinical alerts can accelerate the dissemination of new knowledge and increase the use of evidence-based services by providing information on important drugs, tests, or other services that appear to be missing from a patient's treatment.⁵⁻⁷ However, when alerts are sent only to physicians, these improvements often do not reach optimal levels.^{8,9} Busy physicians are inundated with messages from health plans and care management programs. Because of this, and the fact that messages from some sources may be perceived as unreliable, physicians may pay little attention to any clinical alerts. If physicians do take action based on alerts, their patients may not understand the recommendations or their importance, or may fail to fill the prescriptions or obtain the recommended tests.

These problems suggest that supplementing alerts to physicians with notices to their patients might be beneficial—encouraging patients to follow their physicians' advice or to remind their physicians about overlooked guidelines. Patients and health plan members increasingly want to play an active part in their own care.¹⁰ Yet few consumer decision support programs are designed to empower the consumer at a point in time when a potential problem of clinical quality or safety has been detected, and fewer still are integrated with systems of physician alerts. As Glasziou and Haynes pointed out, full implementation of improvements in medical care requires not just dissemination of abstract knowledge, but also application of that knowledge by physicians to individual patients and, in most cases, actions by the patients themselves.¹¹ It is not enough that a physician knows that medication X is now the drug of choice for condition Y. The physician must recognize that medication X is appropriate for patient Z and must write a prescription, and patient Z must fill and adhere to that prescription. Clearly, enhanced knowledge diffusion in the medical community alone is not enough. Clinical alerts to physicians concerning gaps in the care of specific patients can provide a useful reinforcement by directly addressing the applicability of new knowledge to individual patients. However, getting all the way to our goal may require including the patient in the system.

We studied the impact of a patient-messaging program designed to address these needs. Several previ-

Objective: Clinical messages alerting physicians to gaps in the care of specific patients have been shown to increase compliance with evidence-based guidelines. This study sought to measure any additional impact on compliance when alerting messages also were sent to patients.

Study Design: For alerts that were generated by computerized clinical rules applied to claims, compliance was determined by subsequent claims evidence (eg, that recommended tests were performed). Compliance was measured in the baseline year and the study year for 4 study group employers (combined membership >100,000) that chose to add patient messaging in the study year, and 28 similar control group employers (combined membership >700,000) that maintained physician messaging but did not add patient messaging.

Methods: The impact of patient messaging was assessed by comparing changes in compliance from baseline to study year in the 2 groups. Multiple logistic regression was used to control for differences between the groups. Because a given member or physician could receive multiple alerts, generalized estimating equations with clustering by patient and physician were used.

Results: Controlling for differences in age, sex, and the severity and types of clinical alerts between the study and control groups, the addition of patient messaging increased compliance by 12.5% ($P < .001$). This increase was primarily because of improved responses to alerts regarding the need for screening, diagnostic, and monitoring tests.

Conclusion: Supplementing clinical alerts to physicians with messages directly to their patients produced a statistically significant increase in compliance with the evidence-based guidelines underlying the alerts.

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ous studies documented the value of clinical alerts to physicians,^{5, 7,12} and this study did not reexamine that issue. Our focus was on the incremental impact of supplementing a physician clinical alert system with information sent directly to patients concerning possible gaps in evidence-based care for their condition, with the 2 messages coordinated to enable the patient and physician to collaborate in closing those gaps.

STUDY DESIGN

The alerting program we studied was built around a rule-based artificial intelligence expert system combined with a message generator that conveys clinical recommendations and supporting literature citations to treating physicians. More recently, as an option available to health plan sponsors (insurers and employers), messages also can be sent to patients. Health plans began to implement patient messaging in January 2006, providing the opportunity to conduct a controlled study of its incremental value.

The system develops an integrated patient record (reflecting a patient's care history across multiple providers) through frequently updated data that include physician, hospital, outpatient facility, laboratory, pharmacy, and medical equipment claims; laboratory test results; information reported by patients on health risk assessments and to dis-

ease management nurses; and physician responses to alerts they have received. The records are evaluated for potential gaps in care through identification of medical conditions, the presence or absence of appropriate diagnostic and therapeutic interventions, and clinical situations under which a specific alert should not be generated (eg, the presence of a contraindication).

Clinical issues for inclusion in the rules engine are identified by an in-house committee of clinicians and a multispecialty consultant panel of medical school faculty physicians, based on multicenter clinical trials, federal government and specialty society guidelines, and US Food and Drug Administration–approved pharmaceutical labeling.

The system's output—currently approximately 900 types of clinical alerts—represents patient-specific discrepancies between the care that is actually being received (as reflected in claims and lab data) and the care that patients should be receiving according to the evidence-based literature. These discrepancies fall into a variety of clinical categories, addressing various aspects of patient safety and the quality of care. These are listed, with examples, in **Table 1**.

Alerts vary in their clinical and temporal urgency. Level 1 alerts address potentially life-threatening situations and are communicated to treating physicians via telephone, followed up by fax. Level 2 alerts concern serious but not immediately life-threatening situations and are faxed to physicians. Level

■ **Table 1.** Categories of Clinical Alerts

Category	Examples
Add or intensify therapy	Consider adding ACE inhibitor therapy for a patient with congestive heart failure or a patient with cardiovascular risks who meets the criteria of the Heart Outcomes Prevention Evaluation (HOPE) trial
Condition or drug monitoring	Consider monitoring A1C in diabetic patients, or the level of anticoagulation in patients taking warfarin when monitoring appears to be absent or insufficiently frequent
Condition screening	Consider age- and sex-specific screening, and ongoing surveillance of those who have been treated in the past for Hodgkin's disease and cervical, prostate, bladder, or testicular cancers
Drug–drug interaction	Warnings about the interaction between seizure medications and other drugs that can increase or decrease their blood levels (as well as more basic drug interactions that often slip by pharmacy drug safety systems)
Interactions between prescription drugs and alternative medicine, products or foods	Cautions concerning the interactions between St. John's wart, ginkgo biloba, or grapefruit juice and a number of medications
Other reasons to stop or modify medication	Consider stopping or lowering the dosage of various medications that may be unsafe for the elderly or for pregnant women, or that can be toxic for those with abnormal liver function or kidney function tests
Diagnostic workup	Consider a workup for the presence of <i>Helicobacter pylori</i> in a patient with evidence of peptic ulcer disease
Vaccination	Consider pneumococcal vaccine for patients with sickle cell disease, and hepatitis vaccine for those on hemodialysis

A1C indicates glycosylated hemoglobin; ACE, angiotensin-converting enzyme.

3 alerts apply to routine monitoring and issues of a preventive/wellness nature and are distributed by mail.

At the option of the health plan, copies of the alerts, in lay language, also are mailed to their members—with a delay of 10 working days to allow physicians to contact their patients first, if they choose, or to indicate via fax or phone that there are clinical reasons why alerts do not apply (eg, an allergy not revealed by claims data). In such cases, the patient version of the message is not sent out and the new information is entered into the rules engine, so that that patient will never again trigger an alert suggesting the use of that medication. Examples of the physician and patient versions of an alert are shown in the **Figure**.

The study group consisted of 4 large employers that had physician alert messaging throughout 2005, implemented patient messaging on January 1, 2006, and maintained both physician and patient messaging throughout 2006. The control group comprised 28 employers that were matched as closely as possible to the study group employers. The control group employers also participated in physician messaging throughout 2005 and 2006, but did not choose to add patient messaging in 2006. This study is based on the secondary analysis of data from claims processed on behalf of these 32 employers, after removal of all data elements identifying individuals and employers. Therefore, the study was not submitted to an institutional review board.

The primary goals of the program are enhanced compliance with evidence-based clinical guidelines, a decrease in adverse events (eg, strokes, asthma attacks) that should follow from compliance with guidelines, a reduction in related healthcare utilization (especially emergency room visits and admissions), and a decrease in healthcare cost as a consequence. The magnitude of these sequential effects for alerts sent to *physicians* has been measured in a number of studies, including randomized controlled trials.^{9,12,13} The purpose of the current study was to measure any additional effects resulting from patient messages being added to this system of physician messages.

Given the study time frame, we used change in successful resolution of clinical gaps as a reasonable predictor of fewer clinical adverse events. There is strong support in the medical literature for a link between adherence to the guidelines underlying the system's alerts and reductions in adverse

■ **Figure.** Example of the Text in the Physician Version of a Clinical Alert

Your patient is at least 55 years old, has claims evidence for diabetes, has an additional cardiovascular disease risk factor (eg, history of cardiovascular disease, dyslipidemia, microalbuminuria), and has no claims evidence for an angiotensin-converting enzyme (ACE) inhibitor. The American Diabetes Association recommends that, in these patients, with or without hypertension, an ACE inhibitor be considered to reduce the risk of cardiovascular events. If your patient fits this clinical profile, and if not already done or contraindicated, consider starting an ACE inhibitor and titrating the dosage as tolerated.

Example of the text in the patient version of the same clinical alert:

- Our data show that you may have diabetes.
- If you have diabetes, it may help you to take a type of drug called an ACE inhibitor.
- You may not be taking this drug.
- Ask your doctor if you should take an ACE inhibitor.

event rates, utilization, and cost.^{3,12,13} The impact of patient messaging was assessed by comparing the changes in compliance from the baseline period to the study period in the group that added patient messaging versus the group that did not.

METHODS

Compliance with clinical alerts was based on claims evidence that the recommended actions (eg, to perform needed tests, to discontinue contraindicated medications) were actually carried out (eg, receipt of pharmacy claims documenting that patients filled prescriptions). For alerts suggesting the addition of a drug, test, vaccination, or other service, success was defined as claims evidence with a service date within 270 days after the alert was generated. For alerts recommending discontinuance of a drug, success was defined as the absence of a refill prescription between 60 and 150 days after generation of the alert.

The study was necessarily limited to “measurable” alerts, for which successful resolution could be determined from claims data. This excluded alerts recommending the avoidance of ginkgo biloba, or other outcomes knowable only from patient self-reports. Also eliminated from the study were newly implemented or discontinued alerts that were not in place during both the baseline and study years, and a small number of alert types that are never messaged to patients (eg, those that concern very sensitive topics such as HIV) or never messaged to physicians (eg, influenza immunizations that often are obtained from alternative sources).

■ MANAGERIAL ■

A strenuous attempt was made to select similar employer groups for inclusion in the study and control groups, matching their membership as of January 2006 (the first month of the study period) in terms of average age, percent female, average risk score, and prevalence of 4 chronic conditions: diabetes, asthma, heart disease, and cancer. All employers in both groups had the same health insurer, health benefit design, and disease management program, and the 2 groups were matched for mix of industry types, using Standard Industrial Classification codes. Despite these efforts, significant differences in demographic characteristics, distribution of alerts, and compliance did exist between the study and control groups during the baseline year (Table 2). Therefore, in analyzing the impact of member messaging, we used multiple logistic regression to control for these variables. Compliance rates varied widely among types of alerts. To control for any differential impacts that year-to-year shifts in the mix of alerts might have on compliance rates in our study and control groups, compli-

ance rates for each type of alert were included as independent variables in the regression. For the most stable estimates, we used the aggregate compliance rates for our entire client book of business, rather than rates for just the study and control group employers.

Members of the study and control groups who triggered alerts in the baseline year generated an average of 1.6 alerts each. Compliance with several alerts sent to the same patient (or the same physician) could not be considered independent. Therefore, our analyses used generalized estimating equations—the preferred method when analyzing correlated binary data—with clustering by both patient and physician.

RESULTS

During the study year (2006), more than 13,000 measurable alerts were issued to members of the study group, which added patient messaging, and almost 64,000 were issued to

■ **Table 2.** Characteristics of the Study Group (Physician and Patient Messaging) and Control Group (Physician Messaging Only) in the Baseline Year

Characteristic	Physician and Patient Messaging	Physician Messaging Only	P Value for Absolute Difference ^a
Membership	110,120	775,191	
Average age, y	34.4	33.4	<.001
Percent female	53.7	51.5	<.001
Percent receiving 1 or more measurable clinical alerts	6.1	5.1	<.001
Average number of measurable alerts per person receiving any	1.6	1.6	.023
Five most frequent alerts issued, in descending order	1. Heart protection study: add a statin 2. Women age ≥65 y: screen or treat for osteoporosis 3. Diabetes: do eye exam 4. High-risk diabetes: add an ACE inhibitor 5. Diabetes: test for microalbuminuria	1. Diabetes: do eye exam 2. Heart protection study: add a statin 3. Diabetes: test for microalbuminuria 4. Women age ≥65 y: screen or treat for osteoporosis 5. Diabetes: monitor A1C	
Compliance with clinical alerts			
• All measurable alerts	29.0%	30.0%	.045
• Add-a-drug alerts	26.7%	23.8%	<.001
• Stop-a-drug alerts	47.7%	43.0%	.004
• Do-a-test alerts	26.5%	30.0%	<.001
• Either/or alerts ^b	27.8%	38.2%	<.001

A1C indicates glycosylated hemoglobin; ACE, angiotensin-converting enzyme.

^aSignificance levels are based on 2-tailed *t* tests for comparisons of means and on χ^2 tests for all other comparisons.

^bEither/or alerts suggest that 1 of 2 things should be done (eg, *either* a potentially toxic medication should be discontinued *or* a test should be performed periodically to monitor for toxicity).

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Table 3. Characteristics of the Study Group (Physician and Patient Messaging) and Control Group (Physician Messaging Only) in the Study Year

Characteristic	Physician and Patient Messaging	Physician Messaging Only
Membership	167,120	836,322
Total alerts issued	14,760	69,537
Measurable alerts issued (rate per 1000 members)	13,364 (80.0/1000)	63,940 (76.5/1000)
By severity level		
• Level 1	298 (2.2%)	1427 (2.2%)
• Level 2	9439 (70.6%)	44,323 (69.3%)
• Level 3	3627 (27.1%)	18,190 (28.4%)
By outcome type		
• Add a medication	5823 (43.6%)	23,691 (37.1%)
• Discontinue a medication	1344 (10.1%)	6201 (9.7%)
• Do a test	5122 (38.3%)	26,751 (41.8%)
• Either/or ^a	1075 (8.0%)	7297 (11.4%)
Five most frequent alerts issued, in descending order	<ol style="list-style-type: none"> 1. Diabetes: do eye exam 2. Heart protection study: add a statin 3. High cholesterol: work on lifestyle changes 4. Diabetes: test for microalbuminuria 5. Diabetes: monitor A1C 	<ol style="list-style-type: none"> 1. Diabetes: do eye exam 2. Heart protection study: add a statin 3. Diabetes: test for microalbuminuria 4. High cholesterol: work on lifestyle changes 5. Diabetes: monitor A1C

A1C indicates glycosylated hemoglobin.

^aEither/or alerts suggest that 1 of 2 things should be done (eg, *either* a potentially toxic medication should be discontinued *or* a test should be performed periodically to monitor for toxicity).

members of the control group, which continued to have only physician messaging. The distribution of measurable alerts by severity level and outcome type is shown in **Table 3**. These outcome types are aggregations of the clinical alert types listed in Table 1, based on the types of evidence needed to determine compliance.

Overall, compliance with alerts in the study group increased from 29.0% in the baseline year to 31.0% in the study year, while decreasing from 30.0% to 29.0% in the control group. Controlling for age, sex, and the mix of alert severity levels and alert types, the addition of patient messaging increased compliance by 12.5% ($P < .001$). Spreading the impact over all the alerts that were issued for the study group employers—including alerts that were messaged only to physicians or only to patients—yielded an 11.4% increase in overall compliance.

The program's impact on compliance with each of the alert severity levels and outcome types is shown in **Table 4**. Statistically significant impact was limited to alerts of severity 2 (serious but not immediately life threatening) and 3 (routine monitoring and screening), and to those alerts recommending performance of a test. Changes in the mix of clinical alerts were seen to play a role; before the book-of-business compliance rate for each type of alert was entered into the regres-

sion analysis, the increase in compliance rates from baseline to study year for either/or alerts (which recommend that either 1 of 2 actions be taken) was larger (25.0%) and was also significant ($P = .023$). However, after these book-of-business compliance rates were added to the analysis, the increase in compliance for either/or alerts was reduced to 11.7% and was not statistically significant ($P = .309$).

We also examined the relationships among compliance, program impact, and patient demographics. In the study and control groups combined, men were 1.34% more likely than women to comply with alerts, but the addition of patient messaging did not have significantly different impacts on men and women. In the study and control groups combined, patients more than 50 years of age were 33.2% more likely than younger patients to comply with alerts, but again the impact of patient messaging did not differ significantly for patients of different ages.

DISCUSSION AND CONCLUSION

Supplementing clinical alerts to physicians with messages directly to their patients produced a statistically significant increase in compliance with the evidence-based guidelines underlying the alerts. The overall increase seems to be due

■ **Table 4.** Impact of Patient Messaging on Compliance With Clinical Alerts

Type of Alert	Compliance Rate, %		Absolute Year-to-Year Change, %	Relative Impact of Patient Messaging (95% CI), % ^a
	Baseline Year	Study Year		
All measurable alerts				+12.5 (+5.0, +20.4) P < .001
Physician and patient messaging	29.0	31.0	+2.0	
Physician messaging only	30.0	28.9	-1.0	
Severity level 1 alerts				+14.2 (-33.1, +94.9) P = .627
Physician and patient messaging	54.6	62.8	8.1	
Physician messaging only	61.6	61.2	-0.3	
Severity level 2 alerts				+11.9 (+1.4, +21.2) P = .006
Physician and patient messaging	29.5	32.8	+3.3	
Physician messaging only	29.6	29.9	+0.3	
Severity level 3 alerts				+14.8 (+0.9, +30.5) P = .036
Physician and patient messaging	25.6	23.8	-1.8	
Physician messaging only	28.6	24.2	-4.4	
Add-a-drug alerts				+5.9 (-4.9, +17.9) P = .294
Physician and patient messaging	26.7	27.4	+0.7	
Physician messaging only	23.8	24.1	+0.3	
Stop-a-drug alerts				-6.5 (-22.9, +13.5) P = .499
Physician and patient messaging	47.7	51.3	+3.5	
Physician messaging only	43.0	47.5	+4.5	
Do-a-test alerts				+26.4 (+12.5, +42.0) P < .001
Physician and patient messaging	26.5	29.5	+3.0	
Physician messaging only	30.0	28.2	-1.8	
Either/or alerts				+11.7 (-9.8, +38.3) P = .309
Physician and patient messaging	27.8	32.7	+5.0	
Physician messaging only	38.2	31.7	-6.5	

CI indicates confidence interval.
^aThese are the results of multiple logistic regression; the relative increase in compliance in the group with physician and patient messaging was compared with that in the group that had only physician messaging. Significance was based on 2-tailed t tests.

primarily to improved responses to advice regarding screening, diagnostic, and monitoring tests—advice that often is important but not temporally urgent. The improvement in compliance did not vary by patient age or sex.

Compliance with alerts is not the same as overall compliance with clinical guidelines. Alerts are issued only in those cases where evidence-based guidelines have not already been followed “spontaneously.” Apparent noncompliance can occur for clinically valid reasons, such as allergy to the recommended medication and other contraindications, which may be known to the treating physician but not recorded in claims data. A clinical guideline recommending anticoagulation therapy, for instance, is likely to be correctly ignored by a physician who knows that the patient falls frequently. However, noncompliance also may occur because of physician or patient lack of knowledge, understanding, or motivation.

Alerts should not produce compliance in situations where it is not clinically advisable, and it is probably not reasonable to expect even an ideal system of alerts to totally overcome the inappropriate barriers to compliance. It should be stressed that our study measured only apparent noncompliance because patients may receive therapies not recorded in claims data (eg, medication samples).

Many factors can affect rates of compliance with evidence-based medical guidelines. Chief among them is the influence of medical journals, direct-to-consumer advertising, and other media that disseminate information to physicians and the general public. The use of a large control group, in which patients and their physicians would presumably be exposed to the same information environment as those in the study group, is the most basic form of control for this influence. Matching study and control employers in terms of their

health insurance plan designs and the type of disease management program in which they participated (telephonic nurse counseling for chronic conditions) controlled for another group of factors known to affect compliance.

Compliance rates for some clinical alert outcome types were observed to decrease from the baseline year to the study year, mostly in the control group and markedly for either/or alerts. Compliance rates for specific alerts vary widely, especially within a heterogeneous category like either/or alerts. If an alert with a low compliance rate begins to be issued more frequently—or an alert with a high compliance rate begins to be issued less frequently—it can depress the average level of compliance for an entire alert category. The latter appears to have occurred in the control group in 2006 for alerts that recommended either screening women more than 65 years of age for low bone density or treating them to prevent osteoporosis.

There are at least 3 possible mechanisms behind the increase in compliance with evidence-based guidelines when patient messages were added. It may be that patient messages served to remind patients and to reinforce the instructions that their physicians have given them, so that they were more likely to follow these instructions. It is also possible that patients, armed with the messages they receive from the system, reinforced the clinical alerts that their physicians received, thereby making it more likely that the physicians would write the prescriptions and order the tests in question. A third explanation is that a physician alert was directed to the incorrect physician for that patient or for that aspect of the patient's care. The alerted patient, however, took the message to the correct caregiver. Our finding that the addition of patient messaging appeared to have its greatest impact on compliance with do-a-test alerts suggests that patient messages exerted most of their influence on the behavior of patients themselves, increasing the number who complied with physicians' orders that involved time-consuming or unpleasant actions (eg, going to radiologists or laboratories for the performance of tests). Lack of a similar effect for patient alerts related to adding or stopping medications suggests that significant effort by patients was less of a barrier to compliance with these types of recommendations, which are largely under the control of their physicians, and that patients urging their physicians to follow guidelines may not be an important factor.

Interestingly, a previous study of this same program measured the impact of physician messaging and found 24% compliance with clinical alerts advising physicians to add a drug.¹² The current study found remarkably similar levels of compliance with add-a-drug alerts in both the baseline and

Take-away Points

To maximize the impact on clinical quality and patient safety when clinical alerts are sent to physicians, they should be accompanied by similar messages to their patients.

- The results of a controlled study demonstrate that the addition of patient messages increased compliance with evidence-based guidelines by 12.5%.
- The overall increase was because of significantly improved compliance with guidelines recommending screening, diagnostic, and monitoring tests.

study years, in both the control and study groups, ranging from 23.8% to 27.4%. This finding would seem to lend support to the findings of the earlier study.

A clinically sound, evidence-based system for detecting possible gaps in care and bringing them to the attention of both patients and their physicians in a timely and constructive manner would benefit all segments of the population.¹⁴ As stated in *Crossing the Quality Chasm*,¹ “tens of thousands of Americans die each year from errors in their care, and hundreds of thousands suffer or barely escape from nonfatal injuries that a truly high-quality care system would largely prevent....”^{1,pg2} “In the area of effectiveness, there is considerable evidence that automated reminder systems improve compliance with clinical practice guidelines.”^{1,pg164}

Such a system can be developed by adding patient messaging to an existing program of clinically advanced physician alerts, as demonstrated in this study, or by adding physician alerts to a system that began with patient reminders. Whichever approach is taken, the result should be one in which the 2 sets of messages are coordinated to reinforce each other and to strengthen the patient–physician relationship.

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