A Program to Improve the Management of Patients on Long-Term Acid Suppression Medication


Disease management programs typically focus on a few common chronic conditions for which it is possible to simultaneously improve care and reduce costs, such as asthma and diabetes. Insufficient attention has been paid to the management of upper gastrointestinal (UGI) disorders, including peptic ulcer disease, gastritis, dyspepsia, and gastroesophageal reflux disease (GERD), although there are some notable exceptions [1–3]. UGI conditions are both common and costly, particularly with respect to the increasing use of acid suppression medications [2,4,5]. In addition, recently published guidelines and studies have provided some standards necessary for the development of decision rules, which are used to disseminate population-based management strategies [6–12]. Therefore, UGI disorders may be an appropriate target for improving care through disease management.

The need for improved management of UGI disorders is especially clear among chronic users of acid suppression therapy. These patients may be symptomatic despite therapy or asymptomatic, and a large proportion may continue acid suppression therapy indefinitely without having received an adequate investigation of their symptoms [2,13]. Patients on long-term acid suppression medications can be easily identified from pharmacy billing data. Despite these potential opportunities, there are numerous obstacles to a systematic population-based approach to improving the management of UGI disorders. For example, physicians frequently treat UGI symptoms empirically, and the resulting diagnostic uncertainty makes the development of management recommendations challenging. In this paper, we describe a program designed to improve the management of UGI conditions in a large provider organization.

Setting

Partners Community HealthCare, Inc. (PCHI) is a network of approximately 1000 primary care physicians distributed throughout 250 physician groups in eastern Massachusetts. PCHI is affiliated with Partners HealthCare System. Approximately 50% of PCHI primary care physicians are employed at Massachusetts General Hospital, Brigham and Women’s Hospital, and North Shore Medical Center, the largest hospitals in the Partners HealthCare System.

PCHI supports physicians in managed care contracting, quality improvement, practice operations, and clinical management (including pharmacy, disease management, complex case management, and hospital discharge planning). PCHI’s clinical infrastructure includes pharmacists and care managers who utilize educational, technological, and medical management resources to support physicians. Each primary care physician group is assigned at least 1 case manager and a pharmacist. Each pharmacist supports approximately 200 physicians. PCHI clinical staff regularly attend weekly or biweekly medical management meetings where physicians discuss patient care issues and review utilization and pharmacy data. A minimum of 80% physician attendance is required at medical management meetings. PCHI data infrastructure includes a claims data warehouse that receives updated claims files monthly on all paid claims (including pharmacy) for patients cared for under global budgeting arrangements (capitation) from 3 insurers.

Clinical Problems

Several disorders of the upper gastrointestinal tract are commonly associated with acid suppression medication. These disorders include peptic ulcer disease, dyspepsia, and GERD [14,15]. In addition, chronic acid suppression is used as prophylaxis for patients requiring long-term use of non-steroidal anti-inflammatory drugs (NSAIDs) [10,16]. Determining the correct diagnosis for an UGI complaint based on symptoms alone has proven challenging, due in part to the overlap of symptoms associated with each diagnosis [17]. An accurate diagnosis of an UGI disorder often requires a variety of tests, including upper endoscopy. Primary care physicians frequently treat patients empirically with acid suppression therapy based on symptom history and a clinical examination. When initiating acid suppression therapy, physicians must monitor the patient’s regimen, adherence,
symptoms, and duration of treatment. Without follow-up, patients may continue acid suppression therapy for prolonged periods without a diagnosis or continue medication at doses that are larger than necessary for adequate symptom management [2,3,13,18,19].

While long-term acid suppression is an important element of the management of certain aspects of GERD [20–22], studies show acid suppression to be ineffective in nonulcer dyspepsia [8]. In addition, studies have found that 15% to 20% of dyspepsia patients may have undetected ulcer disease [23]. Since the discovery of Helicobacter pylori as the principal cause of ulcer disease (90% in duodenal ulcer disease and 80% in gastric ulcer disease), the overall approach to dyspepsia has been reevaluated [24,25]. Diagnosis and treatment of H. pylori infection may lead to cure of symptoms and prevention of ulcer disease complications. However, considerable uncertainty remains regarding which patients should be screened [26]. In the subset of patients whose symptoms are related to H. pylori, testing for and treatment of H. pylori may lead to resolution of symptoms and reduce the need for acid suppression.

H. pylori testing followed by anti–H. pylori therapy has a potential economic advantage because this approach may reduce the use of medical services by decreasing the number of complications that occur and shortening the duration of acid suppression therapy [4,9]. Patients whose symptoms are related to H. pylori will benefit from H. pylori testing and treatment, but there is little evidence on the outcomes of patients whose symptoms are unrelated to H. pylori who are subsequently tested and treated. Determining that H. pylori is a causal factor in UGI symptomatology is also challenging.

GERD, the most common diagnosis associated with chronic acid suppression, is defined as symptoms or tissue damage related to esophageal exposure to gastric contents. Heartburn and acid reflux are considered typical symptoms of GERD, and their presence is the basis for initiating medical treatment in many patients [6]. After approximately 6 to 8 weeks of acute treatment, physicians are advised to adjust the therapy to the minimal level sufficient to relieve the patient’s symptoms, although it is unclear what percentage of GERD patients remain on unnecessarily high levels of acid suppression therapy [6]. In addition, these patients may develop complications of GERD (eg, Barrett’s esophagus, strictures, or esophageal cancer) that would remain undiagnosed without additional investigation. Of significant concern is the continuance of maintenance acid suppression therapy without additional testing in patients with alarm symptoms, such as dysphagia, weight loss, or gastrointestinal bleeding [12].

The clinical issues discussed here developed in the context of rapidly expanding use of acid suppression medication. Analyses of pharmacy claims at PCHI identified a high prevalence of use of acid suppression therapy among patients receiving care from capitated providers. In 1999, the prevalence of acid suppression therapy was 7.4% in this population, and in 2000 the prevalence increased to 8.2%. These data, combined with the clinical issues, formed the basis for the development of the UGI Management Program.

Intention
Recognizing the challenges in the diagnosis of UGI conditions and the follow-up of patients on chronic acid suppression, we created a program to identify patients being treated for UGI disorders and to inform physicians regarding key aspects of care related to their patients’ UGI disorder. The program was designed to address the potential for underuse of H. pylori testing, acid suppression therapy, esophagogastroduodenoscopy, and invasive testing in patients with alarm symptoms and overuse of acid suppression medications and NSAIDs. Based on these areas of potential improvement, we identified the following goals: (1) increase H. pylori testing among patients with symptoms of dyspepsia or peptic ulcer disease; (2) increase acid suppression therapy for symptomatic patients requiring chronic therapy; (3) increase diagnostic testing of patients with symptoms and no definitive diagnosis; (4) decrease acid suppression medication use for asymptomatic patients; (5) increase testing of patients on chronic therapy with alarm symptoms; and (6) reduce unnecessary NSAID use.

The mechanisms used to achieve these goals had to meet the organization’s overall approach to disease management: First, primary care physicians should retain the primary role in clinical decision making for their patients. Therefore, the program would supply information and suggestions to physicians but would not attempt to manage or contact patients independently. Second, the program would cause only minimal imposition on physicians and their office staff. Third, the program would build upon the existing medical management infrastructure. To this end, we identified PCHI pharmacists as the most effective means for bringing patient-specific information to doctors at the previously established medical management meetings.

The program was implemented as a group randomized study; this approach allowed us to determine the true effectiveness of the program by comparing a control and an intervention group. Randomization occurred at a regional level in order to decrease the likelihood of contamination and to simplify the education of staff and the implementation process. The PCHI physician network included 14 clusters of physicians, called Regional Service Organizations (RSOs). Half of the RSOs were randomly assigned to the intervention and the other half to the control group. Therefore, patients were assigned to the treatment group based on their primary care physician’s group.

Program management included a team under the direction of the chief medical officer. The team included physicians
UGI MANAGEMENT PROGRAM

Program Staff
1. Identify patients
2. Approve enrollment
3. Complete survey
4. Compile data
5. Management decision
6. Follow PCP recommendations

PCP

Patients

Program Staff
PCP
Patients

Figure 1. Overview of program structure. Boxes indicate actions undertaken by the individuals involved in the program identified at the top of each column. Arrows indicate the flow of information through the program. PCP = primary care physician.

( generalists and specialists), a pharmacist, a program manager, a practice administrator, and data analytic support personnel. The UGI program design and operation was led by a physician clinical director (20% full time equivalent [FTE]), a program manager (master’s degree level, 50% FTE), and a program assistant (bachelor’s degree level, 50% FTE). Representatives from the program sponsor, a pharmacy benefits management organization, provided assistance with the program design.

Intervention

Using the clinical problems, guiding principles, and network infrastructure described above, we created a program that supported a flow of clinically meaningful, patient-specific information to physicians throughout the network (Figure 1). First, we created an interactive database (using Microsoft Access) that was directly linked to the PCHI claims data warehouse and allowed data entry from patient surveys and chart review. The program database permitted tracking of individual patients through the program to ensure timely interventions. This program database tracked more than 12,000 activities or tasks for the patients in the programs.

The population included patients of PCHI physicians who were enrolled in capitated insurance products. Patients enrolled in 2 local commercial insurance products were included in the sample. Only patients 18 to 64 years of age for which PCHI had medical and pharmacy claims data (approximately 175,000 patients) were eligible for the program. Patients were continuously identified for the program based on monthly analysis of pharmacy data. Patients’ billing history extended back in time from the program start date for a mean of 24.3 months (range 1–36 months; 72% of the population had at least 1 year of eligibility, and 53% of the population had 2 years of eligibility). Medication usage prior to a patient’s membership in the plan was not available. Eligibility criteria included pharmacy claims indicating more than 90 days of treatment with either a proton pump inhibitor or a histamine receptor antagonist within the most recent 6 months of claims data. Exclusion criteria included pregnancy, terminal diagnosis or other serious illness (including cancer), history of previous gastric surgery, asthma, end-stage renal disease, or Barrett’s/endoscopically documented erosive esophagitis.

After initial identification of patients through claims data, PCHI pharmacists confirmed each patient’s appropriateness for the UGI program in a meeting with the patient’s network physician. This meeting occurred on an ad hoc basis or during regularly scheduled medical management meetings. The pharmacist presented a 1-page report listing identified patients together with the name and dose of the acid-suppression medication that qualified him or her for the program. If the physician determined the patient was eligible for the program, the physician was asked to sign a recruitment letter.

A recruitment letter from the patient’s physician along with a 12-item symptom evaluation survey was sent to all eligible patients. Patients were sent 1 reminder letter if they did not return the survey within 4 weeks of the first mailing. The survey was used to determine current medication use, including over-the-counter medications, and frequency and severity of symptoms. The symptom evaluation questions were modified from instruments available in published articles [27,28]. An informational brochure regarding the etiology and management options available for people with UGI complaints was sent to all patients who returned a baseline survey. This information was provided to all patients regardless of study assignment (intervention or control).

Once the baseline data collection was complete, the logic embedded in the program database systematically evaluated each patient’s claims and survey data for indications for drug use, current symptoms, and H. pylori testing and treatment status. For patients in the intervention group, program staff compiled the data from the survey, chart review, and claims data into a 1-page patient profile (Table 1). PCHI pharmacists presented the profiles of patients in the intervention arm to the patients’ primary care physicians. A management recommendation for the primary care physician to consider was also
included in the patient profile. Using symptoms, diagnosis, and history of *H. pylori* testing, patients were categorized into 6 groups to determine whether the management recommendation would focus on medication dosing adjustment and/or further testing (Table 2). For example, for patients with a history of GERD who were asymptomatic according to their survey responses, the recommendation was to decrease the daily dose of the acid suppression medication. For patients with symptoms of peptic ulcer disease/dyspepsia and a history of testing and treatment for *H. pylori*, the recommendation was for the physician to consider further testing or referral to a gastroenterologist. Because it is possible for patients to have symptoms suggestive of both GERD and dyspepsia, management recommendations were weighted toward suggesting additional testing, including testing for *H. pylori*.

The program was completed when the physician made a decision regarding any action he or she might take in response to the program recommendations. A letter describing the recommended medication change for the patient was made available for the physician to sign. In addition, we asked physicians if they would like to have their pharmacist follow up with the patient by phone to answer any questions and assess adherence to the new management plan and assess symptom control. A patient-specific report summarizing the content of the pharmacist phone call was distributed to the patient’s physician.

### Implementation

The program was introduced to the physician network through a sequence of personal contacts and various media, including direct letters and newsletters. Considerable resources were invested in the program roll-out given the central importance of physicians in patient recruitment and follow through on clinical recommendations. Efforts to encourage physician participation and address physician concerns regarding the programs included placement of articles in internal PCHI publications and in-person presentations to leadership and all PCHI primary care physicians. For 7 months, the program manager and the clinical director conducted face-to-face meetings with more than 650 physicians at their medical management meetings. Each primary care physician was provided a binder of reference materials, including a review of pertinent medical literature, program goals and design overview, and copies of all patient letters, surveys, and reports.

We made several changes to the program after the initial design and implementation. Initially, some physicians resisted participation. While the overall physician participation was excellent (95% returned enrollment forms, and 65% of identified patients were approved by the PCP for enrollment), some physicians objected to the idea of management assistance. We implemented several strategies to improve physician participation in this voluntary program. First, we called the leaders of the physician groups the day before the program presentations to solicit their support of the program and to encourage the leader to state his or her support of the program during the discussion of the program the following day. We found this support of the leader to be crucial to

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<th>Table 1. Patient Profile Information</th>
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<td><strong>Information</strong></td>
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<td>Acid suppression medication</td>
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<td>Patient diagnosis</td>
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<tr>
<td>Symptom status, reported as PUD/dyspepsia, GERD/dyspepsia, GERD, or asymptomatic</td>
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<tr>
<td>Patient-reported use of nonsteroidal anti-inflammatory drugs</td>
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<tr>
<td>Results of chart review for <em>H. pylori</em> testing and treatment</td>
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<td>Specific management strategy (eg, suggested change in therapy) or additional testing</td>
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GERD = gastroesophageal reflux disease; PUD = peptic ulcer disease.

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<th>Table 2. Summary of Recommendations for Upper Gastrointestinal Management Program</th>
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<td><strong>Patient Data</strong></td>
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<tr>
<td>Group 1: Symptoms of PUD/dyspepsia and no history of <em>Helicobacter pylori</em> testing</td>
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<td>Group 2: Symptoms suggestive of GERD</td>
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<td>Group 3: No symptoms</td>
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<td>Group 4: Symptoms of PUD/dyspepsia and history of <em>H. pylori</em> testing</td>
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<td>Group 5: Alarm symptoms (eg, dysphagia)</td>
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<td>Group 6: Regular NSAID use</td>
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EGD = esophagogastroduodenoscopy; GERD = gastroesophageal reflux disease; NSAID = nonsteroidal anti-inflammatory drug; PUD = peptic ulcer disease; UGI = upper gastrointestinal.
physician participation. Second, we customized the program materials at physician’s request. For example, we formatted letters to patients to reference specific treatment needs as identified by the physicians. Third, a series of publications on the lack of benefit of testing for H. pylori in nonulcer dyspepsia published immediately before and during program implementation [29–33] created some concern regarding our decision to encourage H. pylori testing in patients with undiagnosed dyspepsia symptoms. Physicians were reminded that the published studies were performed in patients who had had endoscopy, unlike the patients in the program. Subsequent studies appeared to support our protocol [34,35] and we disseminated these to the physician community. Finally, we added a financial incentive for physician participation by including the distribution of withholds for capitated patients on achievement of quarterly participation goals. In the end, these strategies helped to address physicians’ concerns about the program and to encourage participation in the program.

Measurement
To evaluate the effectiveness of the disease management program, the investigators planned to compare the intervention and the control group patients in 5 key domains: use of acid suppression therapy, rates of diagnostic testing and visits to specialists, patient symptom burden, patient satisfaction, and physician satisfaction. Additionally, costs and utilization (eg, specialist visits and hospital inpatient utilization) were gathered for the intervention and control groups. Data to measure the effectiveness of the programs were collected from medical and pharmacy claims, patient survey, and chart review. Pharmacy data were analyzed to monitor continuation, discontinuation, or resumption of acid suppression therapy. Medical claims were analyzed to identify gastroenterology testing and specialist visits. Chart review was used to determine results of H. pylori testing and other gastroenterology testing or procedures. Finally, a symptom evaluation survey was mailed to all patients 6 months after the patient enrollment date to evaluate symptoms and over-the-counter medication use. This follow-up survey was similar to the baseline survey.

To assess physician satisfaction, we developed and distributed a 20-item survey to physicians. The survey assessed physicians’ overall satisfaction with the program and the impact on patient–physician communication and patient management. We used the Consumer Assessment of Health Plans Survey (CAHPS) to assess patient satisfaction. We compared satisfaction with care between the patients enrolled in the program and patients eligible for the program who chose not to enroll. In an attempt to capture patient experiences of care specific to the program, we included a 10-item addendum to the CAHPS survey. All outcomes were measured 6 months after patient enrollment date. Outcomes were measured both overall (all enrolled) and by each specific “track” (management recommendation).

Innovation
We consider several aspects of this program to be innovative. First, the clinical focus was unusual. The lack of clear evidence that the care of patients on long-term acid suppression therapy should be improved, the diagnostic complexity, and the lack of consensus on management of dyspepsia all likely serve as a deterrent to systematic population-based management of this set of conditions. Second, the deployment of disease management in an integrated delivery system with a diffuse geographic structure was also innovative. Integrated delivery systems were initially assembled in part to provide the capacities necessary for population-based management, but few reports describe successful implementation of condition management programs in these systems. Third, the commitment to a rigorous evaluation, including a group-randomized design and the measurement of physician and patient satisfaction, is unusual in disease management programs. This is due, in part, to accreditation requirements stipulating enrollment of all eligible patients within a defined population.

Applicability
The clinical algorithms and the information processing aspects of this program should be widely applicable to other settings. We used a combination of administrative data and survey instruments, both of which are common methods for disease management programs. Patient-specific reporting, whether alone or as a component of a broader physician education initiative, has proven effective in changing physician behavior [36].

However, there are some unusual aspects of the program and PCHI’s medical management infrastructure that will be difficult to replicate in other organizations. For this program, physicians endorsed or denied the recruitment of all identified patients. The hands-on approach, with intensive local PCHI support from professionals personally known to the treating doctors, likely had a significant beneficial impact on participation. The involvement of pharmacists helped secure physician involvement in the patient enrollment process.

Current Status
The enrollment phase for the randomized trial ended in June 2000, and follow-up data collection was completed in June 2001. Of the 1532 patients on chronic acid suppression therapy identified during the 14-month enrollment phase of the program, 531 (35%) were excluded. Of these, 256 (48%) were excluded by the primary care physician, and 161 (30%) met additional exclusion criteria. Of the 1001 eligible
patients, 473 (47%) were assigned to the intervention group. A baseline survey was returned by 537 (54%) control and intervention group patients. The outcomes data will form the basis of a future article for publication.

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References


