

Feasibility of a Primary Care Intervention to Decrease Oral Antibiotics for Acute Upper Respiratory Tract Infections: A Pilot Study

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Abstract

Background: Antimicrobial resistance in common respiratory tract pathogens is a growing public health threat, especially in the southeastern United States. The excessive use of antibiotics for common infections is a major contributing factor in the emergence of antibiotic resistance. We report results from a multi-site outpatient pilot project in North Carolina to reduce antibiotic prescriptions for acute nonbacterial upper respiratory tract infections (URIs).

Methods: Primary care practices were provided education and symptom therapy kits for patients with URIs, as an alternative to antibiotics, in a project to reduce the overuse of antimicrobial therapy. The feasibility of this approach was evaluated with interviews and surveys. A methodology for claims-based evaluation of intervention efficacy in reduction of antibiotics use was developed as part of this project.

Results: Of eight contacted practices, four agreed to participate and three participated fully. Physicians reported that symptom therapy kits were useful for patients with URIs and resulted in a meaningful change in antibiotic prescribing behaviors. A claims-based approach is a feasible and promising method to evaluate efficacy in subsequent post-pilot large-scale implementations.

Limitations: Due to the small number of outpatient practices and the lack of controls in this pilot study, the efficacy of the intervention in reducing antibiotic use could not be determined.

Conclusions: Education combined with symptom therapy kits as an alternative to oral antibiotics is a feasible intervention that warrants additional studies to evaluate the efficacy of this approach in the reduction of antibiotic use for URIs.

Keywords: antibiotics, upper respiratory tract infection, outpatient care.

Introduction

Resistance to antimicrobial agents is a growing public health threat, especially in the southeastern United States.¹⁻⁶ Antibiotic overuse contributes to resistance, yet antibiotics are commonly administered to treat conditions such as nonbacterial acute upper respiratory tract infections (URIs) for which they are not proven effective.⁷⁻¹¹

The American College of Physicians-American Society for Internal Medicine, American Academy of Family Physicians,

Infectious Diseases Society of America, and the Centers for Disease Control and Prevention have endorsed a campaign to promote appropriate antibiotic use for the treatment of acute respiratory tract infections in adults. Clinical Practice Guidelines providing evidence-based recommendations have been published.¹² They provide practical strategies for limiting antibiotic use to the patients who are most likely to benefit.

Among the frequently cited causes for antibiotic overuse are physician perceptions of patient expectations, patients' actual expectations, lack of knowledge of the dangers and limitations

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of antibiotic therapy, and inadequate communication during physician-patient encounters.¹³⁻¹⁷ To maximize effectiveness, interventions to reduce antibiotic use will need to address as many of these factors as possible.

We developed a multi-pronged approach to reduce the outpatient use of antibiotics for URIs that focuses on patient and physician education and understanding while enhancing patient-physician communication through the use of symptom therapy kits. In this report, we describe a pilot project to evaluate the feasibility and uptake of this approach. We report promising findings supporting the need for a large scale study to evaluate the effectiveness of educational interventions combined with symptom therapy kits to reduce the use of antibiotics for URIs.

Methods

Pilot Project Overview

Internal medicine, general practice, and family medicine providers treating large numbers of patients were identified as potential project participants. Of eight invited practices, one practice declined because the physician felt that patients seen at the practice were particularly high-risk and likely required antibiotics for treatment of URIs. Three other practices declined due to time constraints. Of the four practices that entered the project, one failed to complete the intervention because the practice physically relocated and intervention materials were misplaced. Three practices successfully completed the project interventions.

Physicians in four participating practices received a project introduction consisting of training related to antibiotic resistance and current treatment guidelines provided by a physician specializing in infectious disease. Intervention materials provided in January 2002 to each practice included 100 symptom therapy kits, 15 posters, and 10 symptom relief prescription pads. Symptom therapy kits and symptom relief prescriptions offered patients the alternative of symptom control with reassessment in consultation with their physician should symptoms not improve.

Physicians and their staff were contacted routinely throughout the cold and flu season of early 2002 to identify problems and successes related to the project, assess practice adherence with project protocols, and identify the need for additional intervention materials. A formal interview and questionnaire were administered to participating providers in April 2002.

Because this was intended to be a pilot project for the development of the intervention, the number of participating practices was limited and no controls were identified. Thus, intervention efficacy could not be determined. However, in anticipation of a large-scale implementation of the intervention, this project also included a component to develop an evaluation methodology using administrative claims.

North Carolina Medicaid outpatient and pharmacy claims were reviewed to characterize antibiotic use for acute nonbacterial URIs. Methods and results are described in detail elsewhere.¹⁸ Data were provided by the Division of Medical Assistance of the North Carolina Department of Health and Human Services, the administrators of the state's Medicaid program.¹⁹ Pre-intervention

analyses of Medicaid claims revealed high levels of antibiotic use, justifying the development of this pilot project to reduce outpatient antibiotic use for acute nonbacterial URIs.

This project was sanctioned by the North Carolina Medicaid program due to its potential to prevent drug-related adverse events, protect public health, and reduce costs. It was approved by the Institutional Review Board of the University of North Carolina School of Medicine.

Interventions

Educational materials were distributed to participating physicians at no charge. Some materials were obtained from the Campaign for Appropriate Antibiotic Use in the Community sponsored by the Centers for Disease Control and Prevention.²⁰ These included an educational poster for examination and waiting rooms, a prescription pad for symptomatic relief of URIs,²¹ and "A new threat to your health: Antibiotic Resistance" pamphlet.²² Clinical practice guidelines were distributed to all participating practices. These were adapted from "Principles of Antibiotic Use for Treatment of Acute Respiratory Tract Infections in Adults" created by the American College of Physicians-American Society of Internal Medicine.¹² The guidelines included information concerning the syndrome, etiology, course of illness, and treatment recommendations for common adult URIs including nonspecific URIs, acute pharyngitis, acute rhinosinusitis, and acute bronchitis.

In addition to the above materials, The Carolinas Center for Medical Excellence developed a symptom relief kit known to patients and providers as the "self-care kit." This kit consisted of an assortment of items used for education and symptomatic relief in a custom-designed 6x4x1.5 inch box (Figure 1). Each kit cost approximately \$6. Providers were encouraged to distribute the kit and other intervention materials, in place of antibiotics, to patients with URIs. Practices were encouraged to distribute these materials to all patients with URIs regardless of insurance status and payer. The kit included a postcard survey returned via mail to assess patients' impression of the usefulness of kit contents. The response rate (2.6%) was too low to be meaningful, and the patient survey results are, therefore, not reported here.

It was recognized that recommended treatment approaches for URIs may differ among professional societies. Although the American College of Physicians guidelines were distributed, the adoption of these guidelines versus others was not specifically requested. The main focus during educational meetings with physicians was to describe and encourage the use of the symptom therapy kit as an alternative to antibiotics when, in the physician's judgment, the likelihood of a bacterial infection was low.

Project Evaluation

Interviews and surveys completed by participating physicians were used to evaluate the feasibility of this approach. The prevalence of filled prescriptions for oral antibiotics following index patient-physician encounters for URIs occurring during baseline (January 1, 2001-March 31, 2001) and intervention (January 1, 2002-March 31, 2002) measurement periods was determined from Medicaid pharmacy claims as a model for the evaluation of a large-scale implementation of this intervention

beyond the pilot phase. Antibiotics were identified using the *Physician's Desk Reference* and the *National Drug Code (NDC) Directory*. NDC numbers for oral antibiotics in the Medicaid pharmacy claims database were obtained from the Multum Lexicon™ database (Multum Information Services, Inc., Denver, CO, 2001). The number of days from the date of the index patient-physician encounter for URIs to the first pharmacy service date for an oral antibiotic prescription was evaluated as a potential indicator of intervention efficacy.

Patient Populations

Patient populations for this project consisted of all adult patients with nonbacterial URIs seen at any of the participating practices. Complete information regarding these populations is not available. Medicaid administrative claims were used for limited practice characterization.

According to our claims-based evaluation protocol, a Medicaid recipient must have had at least one face-to-face outpatient encounter with a family medicine, general practice, or internal medicine physician for acute nonbacterial URIs during the measurement period. Qualifying outpatient physician-patient encounters were identified based on *Current Procedural Terminology (CPT)*²³ and *International Classification of Disease, 9th Revision, Clinical Modification (ICD-9-CM)*²⁴ codes in Medicaid claims.

In our claims-based evaluation protocol, the conditions and diagnosis codes for acute nonbacterial URIs were acute nasopharyngitis (460), acute pharyngitis (462), acute upper respiratory infections (465.9), acute bronchitis (466.0), and influenza (487.1). Index encounters must have occurred in the baseline or intervention measurement periods. Patients with acute nonbacterial URIs encounters less than 90 days prior to the index encounter were excluded. Patients with chronic respiratory conditions were also excluded: chronic bronchitis (491), emphysema (492), asthma (493), and chronic obstructive pulmonary disease (496). These conditions were identified from claims for outpatient services occurring during an observation period beginning 90 days prior to the index visit. To exclude a patient for chronic conditions, there must have been two or more claims at least six days apart specifying at least one of the chronic respiratory condition diagnosis codes.

Analysis

All analyses were performed at The Carolinas Center for Medical Excellence. Data from physician interviews and surveys were recorded and analyzed using electronic spreadsheets. Our

Figure 1.
Self-Care Kit



- Chicken Soup
- Tea
- Saline nasal spray
- Lozenges
- Chest Patch
- Thermometer
- Facial Tissues
- CDC pamphlet
- Survey

pilot methodology for claims-based evaluation used Medicaid data provided by the North Carolina Department of Health and Human Services Division of Medical Assistance. Statistical and claims analyses were performed using SAS v9.1 statistical software (SAS Institute, Inc., Cary, NC).

Results

Intervention Uptake

Surveys completed by all participating physicians (n=14) in late April and early May 2002 indicated an overall positive view of project interventions and their effect on prescribing patterns. Results suggest that most physicians frequently felt pressured to prescribe antibiotics. On average, physicians reported that they would prescribe antibiotics for acute nonbacterial URIs 39% of the

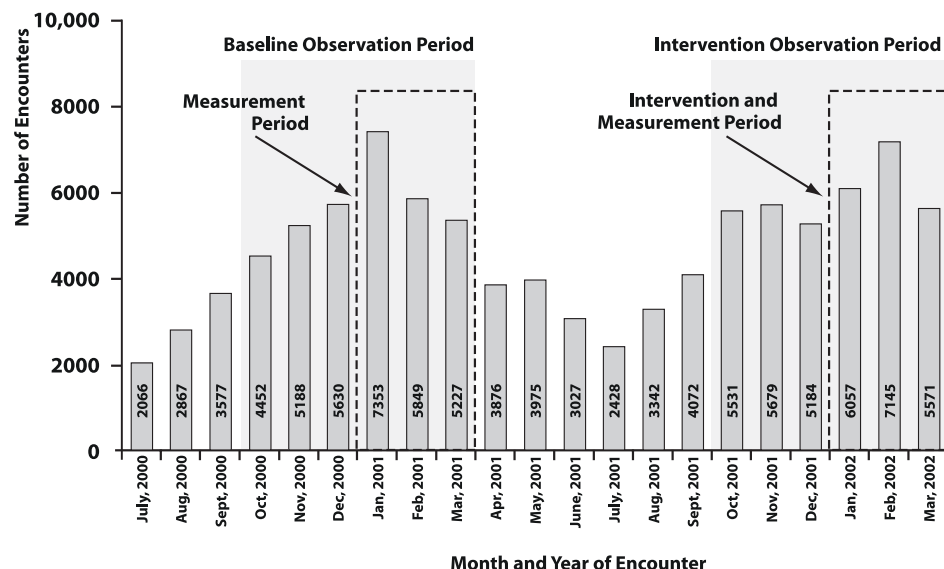
time before the intervention and 20% of the time after the intervention. All physicians surveyed thought the kits were helpful, and most believed their patients also found the kits useful. On average, physicians reported they had given kits to 44 patients, and about a third of patients who received the kits were enrolled in Medicaid. Posters and printed guidelines were also used by almost all physicians. In contrast, the symptom relief prescription pads were used by less than half the physicians.

Claims-based Findings

A claims-based approach is a feasible method to characterize patient populations and to assess efficacy of this intervention in large-scale studies designed for this purpose. Statewide in the Medicaid population 18 to 64 years of age, there were 98,096 patient-physician encounters for acute nonbacterial URIs from July 1, 2000 through March 31, 2002. These involved 55,614 patients seen by 1,739 providers. The number of encounters varied seasonally, as expected (Figure 2), with the highest monthly counts occurring in January 2001 and February 2002. During the baseline measurement period there were 18,429 encounters involving 14,960 patients and 1,210 providers. During the intervention measurement period there were 18,773 encounters involving 15,439 patients and 1,269 providers. The distributions of specific URIs diagnoses were similar during the baseline and the intervention measurement periods, with approximately 2% of encounters for acute nasopharyngitis; 17-18% for acute pharyngitis; 32-33% for acute upper respiratory infections; 43% for acute bronchitis; and 4-5% for influenza.

The state population was mostly female (78%) and Caucasian

Figure 2.
Number of patient-physician encounters by month and year for acute nonbacterial upper respiratory tract infection among Medicaid recipients 18 to 64 years of age in North Carolina.



(59%). African Americans were the largest minority group (31%). Almost three quarters (73%) were less than 50 years of age. Participating practices differed substantially from the state and among each other with respect to Medicaid patient population size, age, sex, and race/ethnicity composition (Table 1).

In the Medicaid claims analysis for this pilot project, there were 15,628 and 16,020 pharmacy claims for oral antibiotics during the baseline and intervention measurement periods, respectively, in the statewide population of Medicaid patients seen for URIs. Among patients filling an antibiotic prescription for URIs, about 79% of pharmacy claims occurred by the day following the patient-physician encounter, and 84% occurred within 5 days. More than half of the statewide population filled a prescription for antibiotics within 5 days of seeing a primary care provider for acute nonbacterial URIs. The prevalence of pharmacy claims for antibiotics declined slightly, from 59% to 58% statewide, comparing baseline and intervention measurement periods. Rates also decreased in the intervention practices (Table 2). The extent to which these declines were related to the intervention cannot be determined due to limitations in the study design in this pilot study. Nevertheless, these effectiveness measures can be readily determined from adminis-

trative claims supporting a claims-based methodology for the evaluation of an efficacy study.

25%.³ The southeastern United States has demonstrated the lowest susceptibility of all regions, with up to one third of pneumococci isolates demonstrating antibiotic resistance.^{3,4,26}

The excessive use of antibiotics in the outpatient setting has contributed to the increase in antimicrobial resistance.^{5,27} In one study, antibiotics were prescribed for 51% of patients diagnosed with colds, 52% with upper respiratory tract infections, and 66% with bronchitis.⁹ The progression of antimicrobial resistance can be reversed. For example, in Finland, nationwide reductions in the use of macrolides resulted in a significant decline in resistance among Group A streptococci.⁸

Discussion

Antimicrobial resistance has increased at an alarming rate, both in hospitals and in the community. During the five-year period from 1994–1995 to 1999–2000, penicillin susceptibility decreased from 76% to 66%, and erythromycin susceptibility from 90% to 74%.²⁵ The overall proportion of penicillin non-susceptible pneumococci within a population-based surveillance program across the United States in 1997 was

Table 1.
Characteristics of Medicaid patients with acute nonbacterial upper respiratory tract infection during the intervention period for North Carolina and participating practices.*

	State	Intervention Practice		
		1	2	3
Jan 1, 2002-March 31, 2002	n=13,295	n=41	n=25	n=128
Age				
18-34	41	54	16	55
35-49	33	32	32	34
50-64	27	15	52	11
Sex				
Female	78	85	84	82
Race/Ethnicity				
African American	30	34	12	11
Caucasian	59	46	88	81
Other	11	20	0	8

*All numbers are a percent of the column-specific total.

Table 2.
Percent of patients filling antibiotic prescriptions within 5 days of index encounter for acute nonbacterial upper respiratory tract infection among Medicaid recipients without chronic respiratory conditions during the baseline and intervention measurement periods in participating practices.*

	Intervention Practice % (total Number of Patients with URI)		
	1	2	3
Baseline Period			
Jan 1, 2001-March 31, 2001	62 (40)	67 (33)	64 (101)
Intervention Period			
Jan 1, 2002-March 31, 2002	39 (41)	60 (25)	60 (128)

*These descriptive data are not useful for evaluation of intervention effectiveness due to limitations in study design and statistical power.

Results from our pilot project suggest that physicians respond favorably to interventions aimed at reducing antibiotic use for nonbacterial URIs. The symptom therapy kits were especially well received. An expanded study to test the efficacy of this approach could be supported by our findings. Furthermore, the claims-based evaluation methodology created as part of this project appears to be a feasible method to evaluate intervention efficacy in a study designed for this purpose. The availability of Medicare pharmacy benefits starting in 2006 offers the potential for expansion of this evaluation into the Medicare population.

We have reported that the North Carolina Medicaid program paid more than \$1.5 million for 33,061 oral antibiotic prescriptions filled for acute nonbacterial URIs from October, 2000- March, 2001.¹⁸ The average prescription cost of \$45 during this period well exceeds the \$6 cost of the self-care kit. Healthcare payers may find such kits a cost effective alternative to antibiotics. Providers interviewed during the project suggest that, when the kit is offered during outpatient office visits, it serves as a catalyst to foster better patient-physician communications, promotes increased knowledge, and enhances awareness of expectations.

Important strengths of this study include a multi-site implementation, pre-post quantitative evaluations, qualitative evaluations, and the inclusion of diverse patient populations commonly seen by primary care providers throughout North Carolina. The extent to which project practices represent the "typical" North Carolina practice is not known. Characteristics of Medicaid patient populations for some project practices differed substantially from those of the state. This should be considered when evaluating the generalizability of our findings. Patient populations seen in these practices include Medicaid

and minority populations common to other practices throughout the state. In this respect, the project practices may share similar barriers related to URI treatment with other practices statewide. A limitation is the low response rate to patient surveys. As a result, the acceptability of this intervention to patients could not be directly determined.

Medicaid claims-based evaluation of efficacy may be limited by several factors. Medicaid patients generally have good access to medications through the program's pharmacy benefit, and information about this access is readily available through the Medicaid program; however, these patients are not necessarily representative of the overall patient population. The effect

of interventions cannot be determined for patients not in Medicaid. Our inability to distinguish between patients who were not prescribed medications from those who were prescribed but did not fill prescriptions is another limitation of claims-based evaluation.

In conclusion, our multi-pronged approach to reduce antibiotic use for URIs in the outpatient setting by targeting barriers related to understanding and communication shows much promise. We have found that these efforts are feasible and welcome in outpatient practices. We have also shown that physicians are very receptive to symptom relief kits, especially when combined with patient education. Unfortunately, a statistically rigorous proof of effectiveness was not possible, nor was it our goal, given the limited nature of a pilot project. Nevertheless, it is reassuring to find that antibiotic use rates declined for all participating practices. These findings suggest that an expanded study to test the effectiveness of this approach is warranted. **NCMedJ**

Acknowledgements: The investigators acknowledge and thank participating physicians, their patients, and their staff for making this project possible. We also thank the North Carolina Division of Medical Assistance and its staff for their guidance in project development and for the provision of the Medicaid claims data used for project evaluation. We are grateful to Anna Cook, Senior Associate for Corporate Information at The Carolinas Center for Medical Excellence, for the graphic design of the symptom therapy kits. This project and manuscript (Internal Tracking Number 7SOW-NC-PUB-O5-02) was conceived and funded by The Carolinas Center for Medical Excellence, formerly known as Medical Review of North Carolina, Inc.

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