Performance Failure of an Evidence-Based Upper Respiratory Infection Clinical Guideline

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BACKGROUND. We evaluated an upper respiratory infection (URI) clinical guideline to determine if it would favorably affect the quality and cost of care in a health maintenance organization.

METHODS. Patients with URI symptoms contacting 4 primary care practices before and after guideline implementation were compared to ascertain what proportion of all patients with respiratory symptoms were eligible for treatment in accordance with the URI guideline; what proportion of eligible patients were managed without an office visit; and what proportion of eligible patients were treated with antibiotics, before and after guideline implementation.

RESULTS. A total of 3163 patients with respiratory symptoms were identified. Of these, 59% (n = 1880) had disqualifying symptoms or comorbid conditions for URI guideline care, and 28% (n = 1290) received disqualifying diagnoses on the day of first contact, leaving 13% (n = 408) who received a diagnosis of URI and were eligible for care in accordance with the guideline. Among this group of patients, the proportion who received guideline-recommended initial telephone care was 45% preguideline and 47% postguideline ($\chi^2 = 0.40$; $P = .82$). Likelihood of a subsequent office visit increased from pre- to postguideline ($\chi^2 = 17.1$; $P < .01$), although the majority of patients had no further diagnoses other than URI. Antibiotic use for the initial URI diagnosis declined from 24% preguideline to 16% postguideline ($\chi^2 = 3.97$; $P = .046$), but antibiotic use during 21-day follow-up did not change ($F = 0.46$, $P = .66$). The mean cost of initial care was $37.80 preguideline and $36.20 postguideline ($P > .05$).

CONCLUSIONS. Only 13% of primary care patients with respiratory symptoms were eligible for URI guideline care. Among eligible patients, use of the guideline failed to decrease clinic visits, decrease antibiotic use during a 21-day period, or reduce cost of care to the health plan.

KEY WORDS. Practice guidelines; respiratory tract infections; treatment outcome; health care costs; antibiotics.
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Clinical guidelines are widely believed to be a key element in improving the quality of health care.[1] However, it has become clear that guideline implementation can be quite challenging, especially when many of them are published in a short period of time. The clarity and brevity of guidelines, as well as the availability of simple tools to support their use, such as visual aids, chart shingles, or standing orders, may increase the likelihood of successful implementation.

The Institute for Clinical Systems Integration (ICSI) developed an evidence-based upper respiratory infection (URI) guideline in 1994. This guideline, its supporting documentation, and a detailed description of the methods used to develop it were published in 1996.[2] URI was deemed an appropriate topic for a clinical guideline because it is an important health problem with high prevalence and high direct and indirect costs.[3] Further, although the treatment of URI is imperfectly understood, there is substantial scientific evidence to support a conservative approach to care that could reduce practice variation, resource use, and inappropriate use of antibiotics.[4-8]

The URI guideline recommends that eligible patients with respiratory symptoms be initially assessed by telephone, using a carefully constructed clinical algorithm (Figure). When a presumptive diagnosis of URI is established, treatment advice is given by telephone, with the instruction that the patient come to the office for further evaluation if the condition worsens or if symptoms persist or change. The guideline strongly recommends against the use of antibiotics for the treatment of URI. Only generally healthy patients without any underlying conditions, prolonged or severe symptoms, or evidence of other specific diagnoses were eligible for care in accordance with the guideline.

We evaluated the guideline's impact on the quality and cost of URI care delivered to children and adults from birth to age 65 years who were within the clinical domain defined by the guideline. Because abundant literature supports the clinical approach outlined in the

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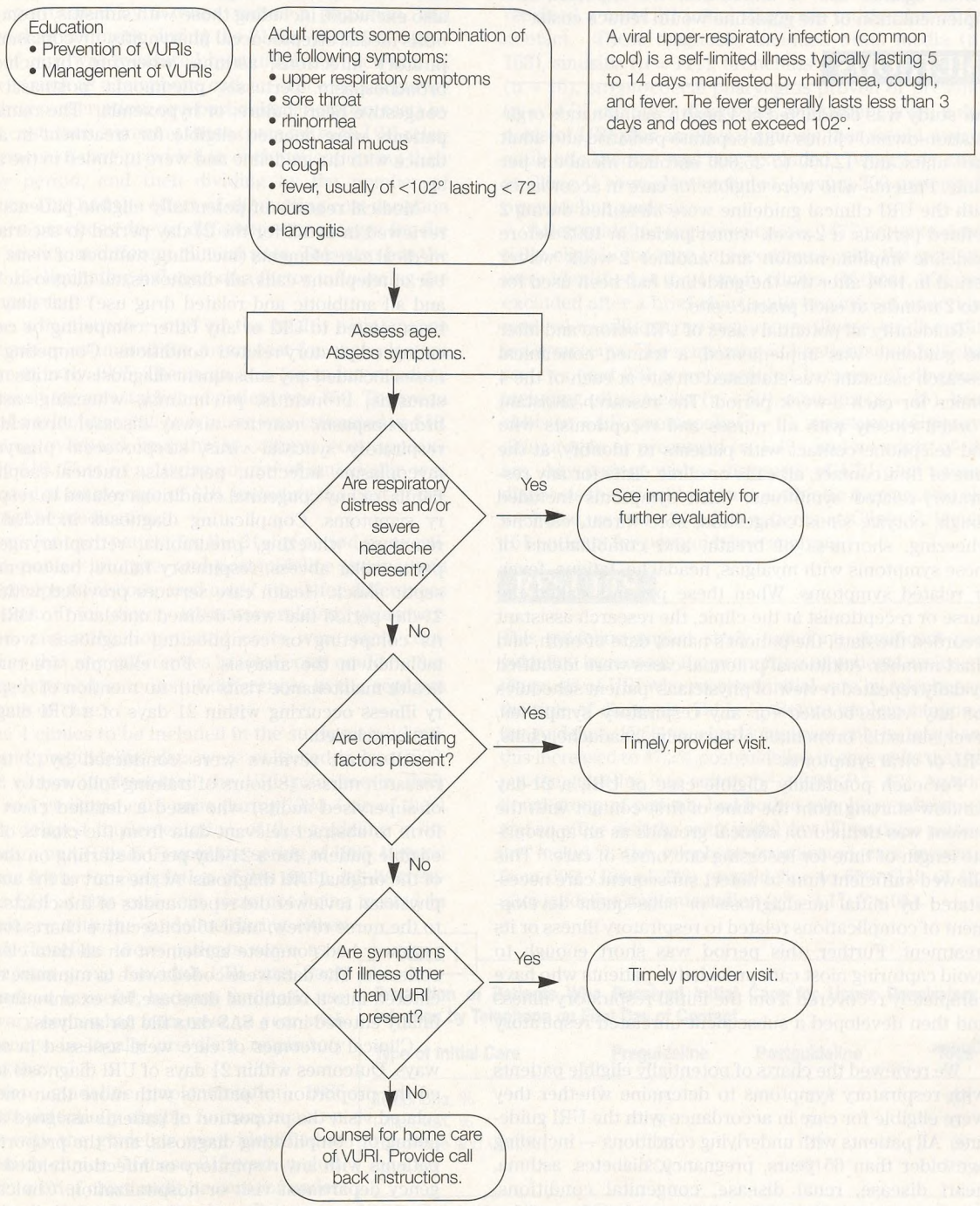
FIGURE

The clinical algorithm for the upper respiratory infection treatment guideline.



guideline,[4-8] we expected good clinical outcomes. Because the guideline recommends telephone care rather than office care for eligible patients and recommends against use of antibiotics, we expected that implementation of the guideline would reduce costs.[9-12]

METHODS

Our study was conducted at 4 health maintenance organization-owned clinics with separate pediatric and adult care units and 12,000 to 25,000 enrolled members per clinic. Patients who were eligible for care in accordance with the URI clinical guideline were identified during 2 defined periods: a 2-week winter period in 1993 before guideline implementation and another 2-week winter period in 1994 after the the guideline had been used for 1 to 2 months at each practice site.

To identify all potential cases of URI before and after the guideline was implemented, a trained nonclinical research assistant was stationed on site at each of the 4 clinics for each 2-week period. The research assistant worked closely with all nurses and receptionists who had telephone contact with patients to identify, at the time of first contact, all calls or clinic visits for any respiratory-related symptoms. Such symptoms included cough, coryza, sinus congestion, sore throat, earache, wheezing, shortness of breath, and combinations of these symptoms with myalgias, headache, fatigue, fever, or related symptoms. When these patients called the nurse or receptionist at the clinic, the research assistant recorded the date, the patient's name, date of birth, and chart number. Additional potential cases were identified by daily repeated review of physicians' patient schedules for any visits booked for any respiratory symptoms, fever, sinusitis, bronchitis, otitis media, headache, chills, URI, or viral symptoms.

For each potentially eligible case of URI, a 21-day window starting from the time of first contact with the patient was defined on clinical grounds as an appropriate length of time for assessing outcomes of care.[13] This allowed sufficient time to detect subsequent care necessitated by initial misdiagnosis or subsequent development of complications related to respiratory illness or its treatment. Further, this period was short enough to avoid capturing most care provided to patients who have completely recovered from the initial respiratory illness and then developed a subsequent unrelated respiratory illness.

We reviewed the charts of potentially eligible patients with respiratory symptoms to determine whether they were eligible for care in accordance with the URI guideline. All patients with underlying conditions — including age older than 65 years, pregnancy, diabetes, asthma, heart disease, renal disease, congenital conditions, immunocompromise, sickle cell disease, lymphoproliferative disorders, or neurologic conditions — were excluded from consideration. Also excluded were those with prolonged or severe symptoms or symptoms suggestive of a specific diagnosis other than URI at the time of first contact. Of the remaining patients, those with specific non-URI diagnoses assigned at initial evaluation were also excluded, including those with sinusitis, bronchitis, otitis media, streptococcal pharyngitis, mycoplasma respiratory infections, asthma, wheezing, bronchiolitis, bronchospasm, pertussis, pneumonia, postnasal drip, congestive heart failure, or hypoxemia. The remaining patients were deemed eligible for treatment in accordance with the guideline and were included in the analysis.

Medical records of potentially eligible patients were reviewed in detail for the 21-day period to ascertain all medical care elements (including, number of visits, number of telephone calls, all diagnoses, all diagnostic tests, and all antibiotic and related drug use) that may have been related to URI or any other competing or complicating respiratory-related conditions. Competing diagnoses included any subsequent diagnosis of otitis media, sinusitis, bronchitis, pneumonia, wheezing, asthma, bronchospasm, reactive airway disease, bronchiolitis, respiratory syncitial virus, streptococcal pharyngitis, mycoplasma infection, pertussis, tracheal-esophageal fistula, or any congenital conditions related to respiratory symptoms. Complicating diagnoses included drug reactions, wheezing, pneumonia, retropharyngeal or peritonsillar abcess, respiratory failure, bacteremia, or septic shock. Health care services provided within the 21-day period that were deemed unrelated to URI or to its competing or complicating diagnoses were not included in the analysis. For example, fractures or health maintenance visits with no mention of respiratory illness occurring within 21 days of a URI diagnosis were excluded.

All chart reviews were conducted by 2 trained research nurses (8 hours of training followed by 3 days of supervised audits) who used a detailed chart audit form to abstract relevant data from the charts of each eligible patient, for a 21-day period starting on the date of the original URI diagnosis. At the start of the audits, a physician reviewer did repeat audits of the charts, blind to the nurse review, until 15 consecutive charts for each reviewer had complete agreement on all data elements collected. The data were coded twice to minimize errors, entered into a relational database for examination, and finally entered into a SAS data file for analysis.

Clinical outcomes of care were assessed in several ways. Outcomes within 21 days of URI diagnosis included the proportion of patients with more than one URI-related visit, the proportion of patients assigned a competing or complicating diagnosis, and the proportion of patients with any respiratory or infection-related emergency department visit or hospitalization. Clinical outcomes of care were compared before and after guideline implementation using the chi-square statistic for difference in proportions.[14]

Adherence to the URI guideline was measured in several ways. These included the proportion of patients with an initial diagnosis of URI who received their initial diagnosis by telephone versus an office visit, received initial care coordinated by a nurse versus a physician, and received an antibiotic during the 21-day period of care. Cost of care was measured by multiplying each unit of service (such as a telephone call, an office visit, a particular drug prescription, or a particular laboratory test) by a unit cost, then summing these costs for each URI-related element of care provided to each patient during their 21-day period, and then dividing by the number of patients. This had the effect of eliminating cost variation between practices due to differences in charges for the same service at different clinical sites. This also has the effect of eliminating inflation as a factor influencing the cost analysis.[15-16]

The administrative staff of the health maintenance organization estimated the mean cost for each element of care in early 1995. The mean cost for an intermediate office visit for an established patient was $50. The mean cost of a telephone call to a nurse was estimated at $10, including overhead, and throat cultures cost approximately $10. Cost of a 10-day course of amoxicillin was estimated at an average of $10, including the cost of dispensing the medication.

Costs for each patient for the 21-day period were estimated, pooled into pre- and postguideline groups, and the 2 groups were compared using *t* tests for differences in means. Total direct, laboratory-related, pharmacy-related, and utilization-related costs were each compared so that any differences in total costs could be further understood in terms of differences in the separate elements of care.

The 4 clinics to be included in the study were identified, and preguideline data were collected in late 1993. These clinics implemented the URI guideline in their adult and pediatric care units during 1994. One of the 4 clinics delayed implementation of the guideline in its adult care unit (Clinic C) until the spring of 1995, beyond the time frame for completion of this study. Adults treated for URI at this care unit were not being treated in accordance with the guideline during either period, therefore these patients serve as a comparison group for adult URI care. Such comparison is useful, because antibiotic use may vary somewhat from year to year with differences in locally prevalent respiratory pathogens.

Before guideline implementation, 1686 patients potentially eligible for care in accordance with the guideline were identified at the 4 study clinics. Of these, 916 were excluded after a brief chart audit because of underlying medical conditions (such as diabetes or asthma), the reason for contact was not respiratory illness (rash, nausea and vomiting, and so forth), or the type or severity of their symptoms disqualified them for treatment in accordance with the guideline. The remaining 770 patients had full-chart reviews, and another 544 were excluded because they received a non-URI initial diagnosis on the day of first contact. These diagnoses included otitis media (n = 163), sinusitis (n = 111), bronchitis (n = 68), pneumonia (n = 10), streptococcal pharyngitis proven or presumed (n = 147), and other diagnoses. Any patient given a diagnosis of URI plus another diagnosis that would warrant antibiotic therapy was also excluded. Twenty-six adults at Clinic C were also excluded, leaving 200 patients for preguideline analysis.

After guideline implementation, 1477 patients potentially eligible for care in accordance with the guideline were identified at the 4 study clinics. Of these, 964 were excluded after a brief chart audit because of underlying medical conditions, no respiratory illness, or disqualifying symptoms. The remaining 513 patients had full-chart reviews, and 331 were excluded because of diagnoses including otitis media (n = 80), sinusitis (n = 45), bronchitis (n = 46), pneumonia (n = 3), streptococcal pharyngitis proven or presumed (n = 42), and a variety of others. Any patient with a diagnosis of URI plus another diagnosis that would warrant antibiotic therapy was also excluded, as were 21 adult patients at Clinic C, leaving 161 patients for postguideline analysis.

RESULTS

This guideline impact study found no significant postguideline increase in the proportion of patients assigned a diagnosis of URI who received initial care by telephone at the time of diagnosis (Table 1). Before implementation of the guideline, 45.5% received initial care only by telephone; this increased to 47.2% postguideline in care units that had put the guideline into action ($\chi^2 = 0.04$; $P = .82$). An additional group of patients had both a telephone assessment and an office visit the same initial day. When these patients are included, the telephone-coordinated care increased from 60% (136 of 226) preguideline to 65% (119 of 182) after guideline implementation ($\chi^2 = 1.17$; $P > .05$).

TABLE 1

Proportion of Patients Who Received Initial Care for Upper Respiratory Infection by Telephone on First Day of Contact

Type of Initial Care	Preguideline	Postguideline	Total
Telephone, %	45	47	167
Office visit, %	36	33	167
Telephone and visit, %	19	20	69
Total, no.	200	161	361

Note: Patients were among 361 eligible upper respiratory infection cases in 7 care units that implemented the guideline. $\chi^2 = 0.40$. $P = .82$.

TABLE 2

Proportion of Patients Who Received an Antibiotic on the Day of First Contact

Antibiotic Status	Preguideline	Postguideline	Total
Yes, %	24	16	73
No, %	76	84	288
Total, no.	200	161	361

Note: Patients are among 361 eligible upper respiratory infection cases in 7 care units that implemented the guideline, $\chi^2 = 3.97$, $P = .046$.

Of 200 preguideline patients, 54% had at least one office visit within 21 days of the first day of the episode. At these subsequent visits, the diagnosis of URI was assigned in approximately 65% of encounters. Of 161 postguideline patients, 75% had at least one office visit within 21 days of the first day of the episode. At these subsequent visits, a URI was diagnosed in approximately 50% of cases. The proportion of patients who progressed to pneumonia was 1% both preguideline and postguideline ($\chi^2 = 0.04$; $P = .83$).

With regard to antibiotic use, the proportion of patients with a diagnosis of URI who received antibiotic treatment on the day of first contact decreased significantly from 24% preguideline to 16% postguideline ($\chi^2 = 3.97$; $P = .046$) in the 7 care units that had implemented the guideline, but rose from 23% to 29% in the adult care unit that had not. (Table 2). This strongly suggests that the guideline was effective at achieving one of its major goals: the reduction of inappropriate antibiotic use at the time of initial contact for patients with URI.

During the entire 21-day follow-up period inclusive of the day of first contact, the cumulative proportion of patients who received an antibiotic was 43.5% before and 54.6% after guideline implementation in the 7 care units that put the guideline into action. The care unit that did not implement the guideline had an even larger increase in antibiotic use during the 21-day period, from 38% to 57%. Analysis of covariance was used to compare antibiotic use in the care units that had implemented the guideline with the care unit that had not. The results showed that guideline implementation did not have a significant impact on cumulative antibiotic use during the 21-day follow-up period ($F = 0.46$; $P = .66$). However, in a direct preguideline versus postguideline comparison of the 7 complying care units, the increased use of antibiotics was significant ($\chi^2 = 4.47$; $P = .035$).

During the 21-day follow-up period, the proportion of patients with at least one subsequent office visit following initial evaluation increased from 54% in the preguideline period to 75% in the postguideline period ($\chi^2 = 17.1$, $P < .01$).

Emergency department visits for respiratory symptoms were made by 1 patient preguideline and 2 patients postguideline ($\chi^2 = 0.59$; $P = .44$). There were no hospital admissions related to respiratory symptoms or to complicating or competing diagnoses associated with respiratory conditions before guideline implementation, and there was one admission after the guideline was put into action ($\chi^2 = 1.24$; $P = .26$). The equivalence of emergency department visits, hospitalizations, and diagnoses of pneumonia during the 21 days after an initial diagnosis of URI suggest that quality of care was as good after the implementation as it was before.

Costs

The guideline did not appear to significantly reduce resource use at the time of initial evaluation. The antibiotic most often used to treat URI was the inexpensive antibiotic amoxicillin, so changes in antibiotic use did not translate into significant cost savings. The proportion of patients managed by telephone, a major factor in lowering the cost of URI care, increased only by approximately 2% after guideline implementation. There was no change in the amount of test ordering, which was fairly low (less than 25% of patients had any laboratory tests) (Table 3). Of those laboratory tests, the vast majority were throat cultures that are relatively inexpensive and are often clinically indicated in the care of respiratory illness. Using these data and health plan estimates of cost, the guideline reduced costs of initial URI care by $1.60 per case managed. The average cost of initial care was $37.80 preguideline and $36.20 postguideline, for an insignificant net savings of 4.2% ($P > .05$). These figures do not take into account the costs of implementing the guideline, which required a series of meetings at each clinic that were attended by physicians, nurses, and other staff.

The costs of care during the entire 21-day follow-up period were not formally estimated, because the preponderance of subsequent care delivered was for condi-

TABLE 3

Proportion of Patients with Initial Treatment of Upper Respiratory Infection Undergoing Various Laboratory Tests During Initial Care

Test	Percent with Test	
	Preguideline	Postguideline
Complete blood count	3.3	5.0
Erythrocyte sedimentation rate	0.9	0.7
Blood culture	0.9	0
Mono spot	1.8	0.7
Throat culture	20.4	23.6
Positive throat culture	21	21
Sputum culture	0.5	0

TABLE 4

Relationship of Initial Antibiotic Use to Whether a Patient with Upper Respiratory Infection Returned for Further Clinic Evaluation

	Preguideline* (N = 226)		Postguideline† (N = 182)	
Subsequent Visit	Initial Antibiotic	No Initial Antibiotic	Initial Antibiotic	No Initial Antibiotic
Yes	28	94	27	110
No	26	78	4	41

* $\chi^2 = 0.13$, $P > .05$.
† $\chi^2 = 2.80$, $P > .05$.

tions (such as otitis media, sinusitis, and bronchitis) beyond the scope of the guideline. However, during this period, both antibiotic use and the proportion of patients having at least one subsequent office visit increased significantly from the preguideline period to the postguideline period. Thus, it is likely that mean costs during the 21-day period increased after guideline implementation.

DISCUSSION

Implementation of this evidence-based guideline failed to decrease antibiotic use during a 21-day period, failed to increase initial telephone care, and failed to significantly decrease cost of initial URI care to the health plan. Increases in rates of follow-up office visits were noted in the postguideline period, and costs of care for patients given a URI diagnosis appear to have increased during the 21-day period of care.

These results are especially disappointing because URI appears to be a condition ideally suited to guideline-directed care. It is a common and costly condition, and there is a substantial evidence base to support clinical recommendations. Why, then, did this guideline fail?

There are 3 factors that may have contributed to this performance failure. First, the guideline implementation may have been flawed or inadequate. Second, microbial patterns in the 2 study periods may have differed. Third, the guideline may have misjudged patient expectations related to URI care.

Prior to implementation, each clinic had a series of meetings to familiarize front desk staff, telephone care nurses, and primary care providers with the guideline. A chart shingle was designed (one for adults and another for children) with eligibility algorithms and treatment protocols embedded in it. Telephone triage nurses in many of the clinics appeared to adopt this tool willingly, although the first version of the shingle was streamlined for greater efficiency following the completion of this study.

Most of the study clinics were concurrently implementing a number of other clinical guidelines, however, and the amount of training and support needed to sustain the use of each guideline is high, especially when staff turn over, other guidelines appear, or staffing patterns shift. There was considerable variation in the amount of energy and time each clinics needed to implement the URI guideline; one clinic was unable to implement this particular guideline in time to be fully included in the postguideline data analysis.

It is possible that if clinics had done more intensive implementation of the guideline — devoted more time to staff training or hired additional nurses to cover the increased demand for nursing time, for example — it may have been more effective. However, this would substantially increase the cost of implementing the guideline both initially and on an ongoing basis. The ability of primary care clinics to put multiple clinical guidelines into action simultaneously has not received much attention, and what we do know is not encouraging.[17] Studies of long-term maintenance of guideline-driven care are also needed.[18] It is possible that a series of condition-specific guidelines is not the best strategy to improve care in primary care settings.[19] It may be better to develop office systems that can support improved care for a larger number of conditions, rather than developing systems and implementation strategies for a long sequence of individual guidelines.[20]

There is always a variation in types of respiratory infections circulating in a community each winter; the severity of the associated clinical syndromes could affect the performance of the URI guideline. In the winter of 1994, during the postguideline measurement period, a media-publicized outbreak of mycoplasma respiratory illness occurred in the Minneapolis metropolitan area. Treatment of mycoplasma with macrolide or tetracycline-family antibiotics was recommended, but no rapid test to confirm mycoplasma infection at the time of

TABLE 5

Relationship of Type of Initial Contact to Whether a Patient with Upper Respiratory Infection Returned for Further Evaluation

	Preguideline* (N = 226)		Postguideline† (N = 182)	
Subsequent Visit	Initial Office Visit	No Initial Office Visit	Initial Office Visit	No Initial Office Visit
Yes	27	95	31	106
No	63	35	32	13

* $\chi^2 = 39.2$, $P > .001$.
† $\chi^2 = 35.2$, $P > .001$.

a visit was available. Although the use of erythromycin and doxycycline rose from 8.8% of cases in the preguideline winter to 14.8% in the postguideline winter, mycoplasma was rarely recorded as a diagnosis — either in dictated notes or by ICD-9 code. So it remains uncertain whether microbiologic variation influenced antibiotic use.

Patient Expectations

Patient expectations of office visits or of treatment with antibiotics may have limited the effectiveness of the guideline. This guideline functions on the assumption that patients would accept telephone care of URI. However, among those who received initial telephone care, 61% preguideline and 88% postguideline had an office visit for respiratory symptoms within 21 days. At these subsequent visits, most received no diagnosis other than URI. This suggests that patient desire to have a hands-on clinical evaluation may have been responsible for the failure of the guideline to decrease utilization or costs. Subsequent office visits were not related to whether an antibiotic had been prescribed (Table 4), but were strongly and consistently related to having an initial telephone evaluation rather than an initial hands-on office visit (Table 5).

Several studies have shown that patients' expectations influence drug prescriptions,[21,22] antibiotics in particular.[23,24] Further, physician belief that patients expect antibiotics also leads to increased antibiotic prescription,[23,24] but physician assessments of which patients want antibiotics has been shown to be inaccurate.[24] The assumed relationship between patient satisfaction and antibiotic prescription has been studied 3 times with no association noted.[24-26] One study concluded that the most important predictors of satisfaction for URI patients were the amount of time a physician spent explaining the illness and whether the patient understood the physician's choice of treatment.[24]

Limitations

One study documented physician diagnosis shifting to justify antibiotic use. In that study, physicians' belief that a parent wanted antibiotics for a child's cough increased the likelihood of a diagnosis of bronchitis (rather than URI), with a concomitant increased prescription of an antibiotic.[23] It is possible that this type of diagnosis-shifting could have occurred in our study and that this could have introduced bias. If so, the effect of this bias would be to lower the proportion of postguideline URI cases treated with antibiotics, because antibiotic-treated patients may have been assigned diagnoses of otitis media or sinusitis rather than URI, to avoid violating guideline recommendations. This could explain the initial apparent drop in antibiotic use postguideline, but is not consistent with the overall unchanged or increased use of antibiotics postguideline during the 21-day period of care. Other studies have also shown a 10% to 20% use of antibiotics in patients with diagnoses of URI.[27-29] Such antibiotic overuse may accelerate the emergence of resistant organisms.[30]

CONCLUSIONS

The evidence used to craft this evidence-based guideline was primarily drawn from clinical trials. There was no recognition that qualitative studies that assess patient expectations for care may contribute important, even critical insights that could increase the effectiveness of guidelines. If many patients with URI desire hands-on assessment and an assurance that nothing more serious is wrong, then a clinical strategy that encourages brief office visits may be more successful than a strategy that discourages office visits altogether.

Improvements in URI care may be difficult to achieve until we better understand patients' perceived needs and expectations. The way to advance our understanding is by conducting well-designed qualitative studies.[31-33]

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