

Upper-Respiratory Tract Complaint Protocol for Physician-Extenders

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A protocol for upper-respiratory tract complaints was administered to 226 patients in a walk-in clinic. The protocol, for use by a physician-extender in conjunction with a physician, specified the collection of data necessary for management. A decision-making algorithm separated the major causes of upper respiratory infection (URI) complaints and led to one of four plans: a physician referral, a culture only, antibiotic treatment, or symptomatic treatment only. Each patient was seen by a physician following the health assistant's interview. Of 226 patients, 96 (42 percent) would have been sent home by the protocol without seeing the physician. None of these had a complication of URI. Sixteen (seven percent) of the 226 had serious complications — all would have been referred to the physician. The protocol proved to be safe and efficient, acceptable to patients, and a reliable approach to physician-extender management of URI.

The role of physician-extenders in the delivery of medical care is still under debate. The question of whether anyone besides the physician can or should have decision-making authority in patient care cannot be separated from the question of who they are, what they do, how they will be trained, and how they will be monitored in practice. Each increment of

knowledge and skill in patient care can be looked at not only as an intermediate step to more complex training, but also as an end in itself for meeting health needs. Medical training can be viewed as a series of incremental stages, with each stage being a body of knowledge designed to accomplish a specific set of tasks. How much knowledge and skill health workers (including the physicians) need depends on the job they are required to do.

As an alternative to lengthy educational programs, a series of brief task-oriented training programs have been developed. Skills and knowledge required to manage high-frequency, chronic conditions or acute complaints such as upper-respiratory tract infection (URI) are defined, and the train-



ing of a physician-extender is keyed to the tasks identified.

The specification of such tasks is made explicit in a protocol — a printed instrument for this type of physician-extender to direct collection of the required historical, physical, and laboratory data, and to take specific action based on the data. We describe the development and validation of a protocol for the work-up and management of URI complaints.

Materials and Methods

Description of the Protocol. — This protocol, referred to hereafter as URI protocol, consists of three parts: (1) a list of chief complaints, (2) a data collection form, and (3) an algorithm.

The list of chief complaints indicates either a URI or a condition that

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Table 1. Relation of the Protocol Disposition to Physicians' Findings

Protocol Disposition	Physicians' Findings					
	Uncomplicated URI (Cultured, Palliated, Treated)		Complications ("Other Pathology")		Total	
	No.	%	No.	%	No.	%
Sent home	96	42	0	0	96	42
Referred to physician	114	51	16	7	130	58
Totals	210	93	16	7	226	100

must be differentiated from a URI and for which work-up by the URI protocol is appropriate. They are as follows:

- Acute cough (<one-week duration)
- "Cold"
- "Flu" or influenza
- Hay fever
- Hoarseness
- Postnasal drip
- Sinus trouble
- Sneezing
- Sore throat
- Streptococcal throat infection
- Stuffy or runny nose
- Tonsil trouble or tonsillitis
- Request for throat culture

The data collection form indicates the specific historical, physical, and laboratory data needed when a patient with these complaints arrives in an outpatient setting (Fig. 1). The completed data collection form can serve as the official record of the encounter.

Each group of related questions regarding symptoms or relevant history (subjective) and signs (objective) is designated as an "attribute." These attributes were chosen for their relation to the disease states to be identified and differentiated in the investigation of URI. For instance, one of the major medical reasons for accurate work-up of URI is the detection of streptococcal pharyngitis. Because there is no specific pathognomonic clinical characteristic of this disease as it presents itself initially, the physician

must consider not only the presence, absence, and severity of the symptoms and signs of streptococcal infection, but also the symptoms and signs of other conditions that may appear in a similar way, such as a viral infection. Thus, the data collection form requires the collection of essential clinical data that are weighed in making a differential diagnosis based on the assumption that clinical judgment flows from an analysis of many overlapping features that may be present to varying degrees.

In choosing what attributes are to be included for directing the protocol logic, decisions are derived from a combination of practical and purely medical considerations. These may not be universally acceptable to all physicians; however, if they are explicit, each can be rejected or modified to fit the view of the individual physician. Descriptions of the logic underlying the inclusion of attributes and the decisions made by the algorithm are too detailed to be outlined here. The general methods of protocol development have been described elsewhere,¹ and the particular logic of the URI protocol is available on request.

The algorithm (Fig. 2) determines the action to be taken by using probability considerations in assigning weights to the various data. The medical judgments contained in the algorithm were subjected to peer and consultant review. The logic is complete when one of the four heavily

Table 2. Correspondence of Physician and Protocol Treatment in 96 "Send Home" Patients*

Protocol Disposition	Physician Disposition		
	Palliation Only	Culture, Palliation	Penicillin
Palliation only	7†	0	0
Culture, palliation	1	57(3)†	9(1)
Penicillin	0	3(1)	19(6)†

*Numbers in parentheses indicate positive culture results for β -Streptococcus.
†Patients whose protocol-prescribed treatment agreed with that prescribed by the physicians.

outlined boxes recommending medical action is reached.

Patients with a productive cough, chest pain when not coughing, earache (with either a discharge or pain when not swallowing) or hearing impairment, new skin rash, headaches severe enough to restrict normal activities, tender sinuses, and mouth sores were sent immediately to the physician. This allowed the possibility of pneumonia, otitis media, aseptic meningitis, parameningeal infection, sinusitis, herpes infection, and agranulocytosis to be investigated further by the physician. Patients who had a history of rheumatic fever (but were not now under a physician's care), patients who had been seen before for the same complaint, and patients already taking antibiotics were also seen by the physician. Patients who had symptoms strongly suggesting allergy also went to the physician immediately so that further work-up could be considered.

Patients were treated with penicillin if they had the classic attributes of streptococcal infection. Those patients were treated who (1) were not referred to the MD by the above criteria; and

(2) have an exudate on their tonsils or tonsillar crypts; and (3) have at least one of the following: (a) streptococcal exposure (exposure to a person who by history had positive culture), (b) tender neck nodes (defined as tenderness in the anterior cervical region), and (c) temperature (oral) greater than 38.3 C; and (4) do not have two or more of the following (these attributes are thought atypical of a streptococcal throat infection they suggest, instead, a viral infection): (a) runny or stuffy nose, (b) hoarseness, (c) cough, and (d) ache all over; and (5) are not allergic to penicillin by history.

Antibiotic treatment was given at this point because (1) the presence of exudate with either adenitis or high fever gives the patient a greater chance of having a streptococcal infection than when these are not present²⁻⁴; and (2) if the patient does have a streptococcal infection, he might be at higher risk for rheumatic fever.^{4,5} An alternative action for these patients might be to take a culture and treat two days later if the culture is positive. Under ideal circumstances this would be acceptable, but lost cultures, lost patients, and a respectable rate of false-negative single cultures (about ten percent)⁶ make waiting hazardous. For these reasons we treat these patients immediately, in accordance with the practice of many,^{2,3,7,8} and in what we believe is a sound convergence of theoretical and practical considerations. Treatment in most cases was intramuscularly administered penicillin.

"Culture and palliate" patients constitute a group with overlapping features: those with classic streptococcal characteristics but also, at the same time, at least two attributes characteristic of viral infection. These patients were contacted several days later when the culture results were known.

Patients were sent home with palliative treatment alone if they had only coryza or hoarseness, or recent onset nonproductive cough, and the absence of suggestion of allergy, physician-referrable attributes, high fever, exudate, sore throat, and hoarseness for longer than two weeks.

Study Design. — This study was conducted in the walk-in clinic at the Beth Israel Hospital, Boston. This is a no-appointment clinic for adult

patients only. Some patients are referred by private physicians or triaged from other areas in the hospital, but most "walk in" on their own initiative. The physicians in the walk-in clinic are rotating senior assistant residents in medicine.

The protocol was administered to the patients by a nurse or health assistant. The health assistant was a high school graduate with no previous medical background, who has been trained over a four- to six-week period to administer the URI and other protocols. Details of this program have been presented elsewhere.¹

The health assistant completed the data collection form and determined the management plan from the algorithm on each patient. This information was presented to the physician, who then saw each patient himself and recorded his own clinical findings, impression, and management plan. The physicians were not asked to conform to the protocol-management plan.

It could be argued that in presenting the health assistant's findings to the physician, we biased the physician's subsequent evaluation of the patient's condition. If the physician had wanted the study to appear successful, he might have overlooked or failed to mention discrepancies between his findings and those of the health assistant; he might also have modified his impression and management plan to conform with the protocol. Conversely, if the physician had been biased against the study, he might have behaved in the opposite fashion.

While this argument cannot be refuted completely, we believe it is unlikely for the following reasons:

1. To suggest that physicians would have overlooked significant clinical findings because of bias toward the study is to suggest that they would have endangered patients for whose care they were solely responsible.

2. If physicians had been biased against the study, they would have recorded significant conditions that they claimed had been missed by the health assistant; the results show that this did not occur.

3. A preliminary evaluation of the health assistants' skills in data collection revealed a high degree of accuracy; it was, thus, unlikely that they would have missed significant clinical

findings that physicians biased in their favor would have also "overlooked."

4. The six physicians were not associated with the research project staff, and, thus, had no obvious vested interest in the project's success or failure.

Data collected included whether the protocol logic had been followed accurately by the health assistant and the protocol disposition (referral to the physician or, if no referral, recommended medical action); also collected were physician findings and diagnoses, plus physician-determined disposition. Within two weeks each record was reexamined to ascertain the results of throat cultures and to see if the patient had returned with a complication.

The test of safety was whether any patient would have been sent home by the protocol when the senior resident discovered a condition for which the patient should have been seen by a physician. It is, thus, a comparison of the protocol to the doctor with regard to false-negatives. Efficiency was expressed by the percentage of patients who would have been appropriately sent home, thus saving a physician visit.

Diagnosis or impression of conditions other than uncomplicated URI (hereafter referred to as "other pathology") was made by the physicians on a clinical basis only. Patients were asked to return or call the nurse if any problems ensued.

Bacteriologic Studies. — Cultures were taken by the nurse or health assistant. The posterior pharynx and tonsils, if present, were rubbed with a sterile cotton swab. All cultures were streaked within two hours on five percent sheep-blood agar plates and incubated. After 18 to 24 hours, colonies of β -hemolytic streptococci were picked. A presumptive identification of group A streptococci was made by bacitracin-disk sensitivity on subculture.

Results

Between May 1971 and February 1972 the protocol was administered to 226 adult patients who entered the walk-in clinic with the chief complaints as listed. The protocol was administered to the first 176 patients by a nurse and to the remaining patients by a health assistant. Because there were no differences between the nurse and health assistant with respect

UPPER RESPIRATORY COMPLAINTS

Name _____ Age _____ Sex _____ Date _____

Chief complaint _____

	Y	N	Subjective
Y →			Sore throat: duration _____
R →			Cough: duration _____ production, substantial or increased
			chest pain
R →			even when <u>not</u> coughing
Y →			Runny/stuffy nose: duration _____
B →			more than 3 times a year
B →			tearing with stuffy nose
B →			itchy eyes with stuffy nose
B →			itchy nose with stuffy nose
B →			attacks of sneezing with stuffy nose
B →			allergy in parents or siblings (not self)
			Ear ache: duration _____
R →			with discharge
R →			with hearing impairment
R →			pain even when <u>not</u> swallowing
Y →			Hoarseness (by observation): duration _____
R →			New skin rash
			Headaches
R →			severe (restrict normal activities)
Y →			Ache all over
R →			History of rheumatic fever
			Exposure to strep in past week
			History of penicillin reaction
R →			Return visit for same complaint _____

	Y	N	Rx
R →			Taking antibiotics
			Taking anything for chief complaint _____
			does it work

	Y	N	Objective
R →			Tender sinuses
			Tender neck nodes
R →			Lip/mouth sores
			Exudate
			Temperature _____

Code
 Y = yellow
 R = red
 B = blue

Impression: _____
 Plan: _____

 Signature _____

Figure 1. Data collection form on which information is denoted as present (Y) or absent. Arrows pointing to some boxes with letters Y (yellow), R (red), and B (blue) indicate the colors of these boxes used in decision-making algorithm described in text.

Decision-Making Algorithm

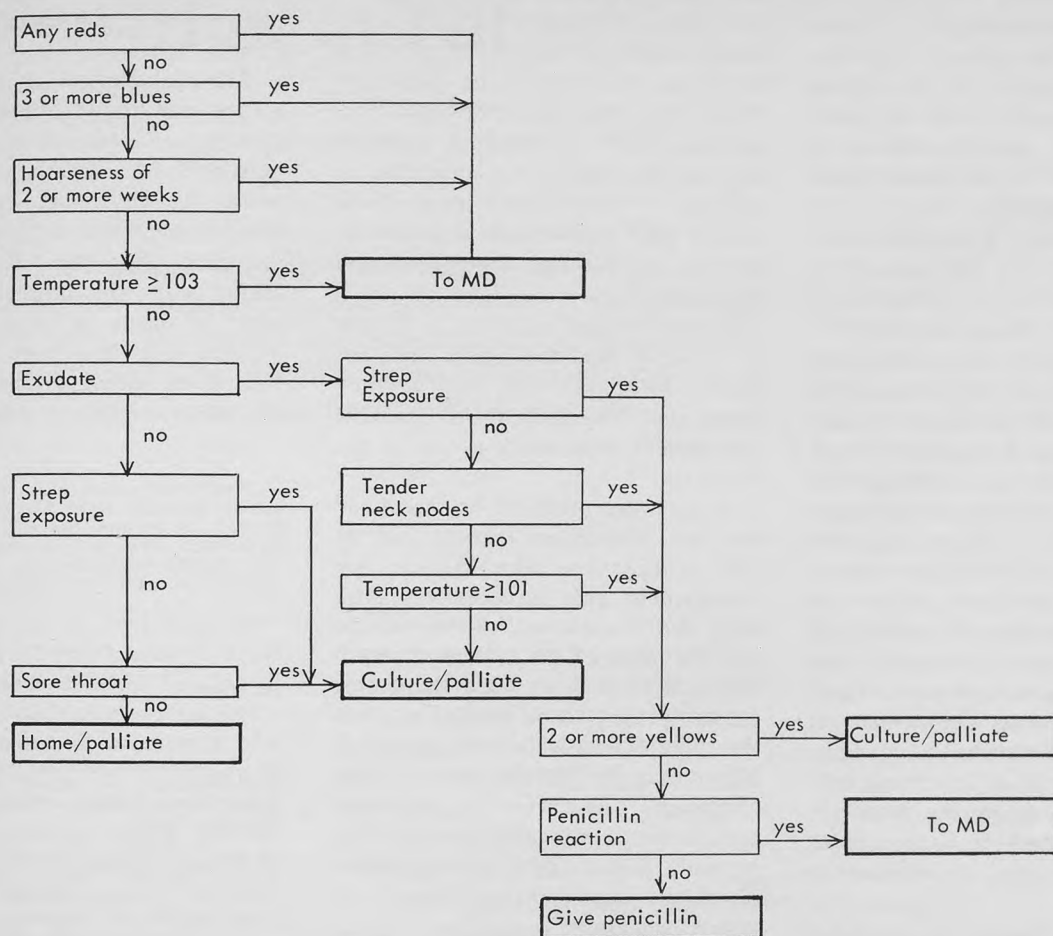


Figure 2. Decision-making algorithm, starting at the top "any reds" asks if there are checks in a yes box on the attribute list opposite red arrow (Fig. 1); the same procedure is followed for yellow and blue. Remaining items refer to uncolored boxes on the attribute list. The logic is complete when one of the four heavily outlined boxes that recommends medical action is reached.

to history, physical exam, and following protocol logic, the results were analyzed together. Sore throat was by far the most common chief complaint, presented by 79 percent of the 226 patients. Sore throat, "cold," "flu," or cough were presented by 99 percent of the patients.

As a measure of efficiency, 96 of the 226 patients (42 percent) would have been sent home by the protocol without seeing the physician (Table 1). In terms of safety, none of these patients had, according to the physicians who saw them subsequently, pathological conditions other than uncomplicated URI. Thus, there were no false-negatives.

Of the 96 patients who would have been sent home, the protocol-pre-

scribed treatment agreed with that prescribed by the physicians in 86 percent of patients (83 patients, Table 2). In the remaining 14 percent of patients, the protocol and physician disagreed as to whether antibiotic therapy was indicated. When the protocol and physician decisions were compared with throat culture results, the outcome favored the protocol decision (Table 2).

There were no patients in this study who returned to the Beth Israel Hospital within the subsequent two-week period with a complication of URI.

The protocol referred 130 patients (58 percent) to the physician (Table 1). Included in this number were all of the 16 patients (seven percent of the 226 patients) in whom pathological conditions other than uncomplicated URI

were found by the physician. The remaining 114 referred patients without confirmed "other pathology" were thought to have either streptococcal or viral infection. Thus the protocol, conservative and safe enough not to send any patients with complicated conditions home, included 114/130 (88 percent) false-positives, ie, patients who could have gone home safely but who were referred to the physician anyway.

Productive cough and earache when not swallowing comprised 25 percent of the reasons for referral (33 patients), although only three of these 33 patients had confirmed "other pathology." Severe headaches were accountable for another eight percent (ten patients) of the referrals; only one of these patients had a confirmed com-

plication, sinusitis.

Comment

Any departure from the one-to-one relationship of the physician and patient raises questions that should be addressed. In regard to this protocol, which is to be used in conjunction with a physician, the following issues must be dealt with.

1. Are the medical judgments reasonable and safe? The decisions about data-base collection and disposition are not made by the health assistant. They are made by the protocol, derived from local experience and peer consensus. In this study, physicians agreed with the protocol management plan in 83 of the 96 patients; in the remaining 13 patients the protocol manifested equal or better judgment (as determined by both our clinical estimation and by throat culture results). As an approximate measure of outcome, no patients returned within two weeks for a complication. Thus, the medical decisions were sound. As to the safety, there were no patients who would have been sent home who needed to be seen by the physician (false-negatives). All 16 patients with other conditions were correctly sent to the physician.

2. Does the use of the protocol make efficient use of physician time? For a chief-complaint protocol such as this to be really helpful means being able to manage a large fraction of the patients without their seeing or spending much time with the physician. This protocol as it now stands would have sent home 96 of 226 patients (42 percent). This is a considerable fraction and, as such, would allow a practice or clinic to treat considerably more URI patients. Moreover, substantial pre-physician work-ups have been done on the 114 patients who were sent to the physician but who could safely have gone home without seeing him. This also is an indication of efficiency, since this can reduce the physician's time spent with these patients. A revised protocol should theoretically be able to send home all the patients referred to the physician who did not have confirmed other pathology. Each reason for referral indicated what should be added to the protocol. Symptoms of productive cough, earache, and headaches, when evaluated

by the physicians in this study, showed little "other pathology." An expanded protocol that further evaluates these symptoms is under way.

3. Is the arrangement of a protocol-guided health assistant working with a physician acceptable to patients? While this was not specifically examined, there is abundant evidence that nonphysician care is acceptable to patients.^{9,10} Preliminary observations suggest that patients are very pleased to talk to someone other than the physician if they feel the person is authoritative and competent, if they are assured that the health assistant knows his limitations, and if they know that both the health assistant and patient have ready access to the physician.¹¹

4. Can the protocol be modified? No two physicians' management of URI is quite the same. Almost any management plan is necessarily arbitrary and needs modification both to suit the needs of the individual physician and to accommodate changes in causal factors, local conditions, and therapeutic and laboratory advances. Minor changes in the list of chief complaints, the data collection form, and the decision-making algorithm can be made quite easily by the individual physician. Major changes should be tested formally.

This type of protocol differs from other recently published "clinical algorithms"¹² in several important respects. One is that this protocol explicitly includes the decision to treat with antibiotics and the rationale behind that decision. The physician-extender does not have to check with the physician if there are no complications. Another difference is that the URI protocol has been subjected to both process and outcome study of its medical soundness. Protocol decisions were compared with those of physicians and the decisions of both were compared with respect to several outcome measures, ie, throat cultures and returns for complications.

Protocol validation may vary according to the nature and complexity of the complaint. For a dysuria and frequency protocol, which is currently being tested, not only outcome, but also the accuracy of history and physical exam, and the accuracy of individuals following the logic are being examined. We are thus attempting to

provide, protocol by protocol, complaint by complaint, sufficient data to allow use of these instruments in primary practice at the high level of quality care demanded by practitioners.

The problem-solving approach, concerned not only with diagnosis but also management, allows new health personnel to assist the physician and points the way toward rationalization of curriculum for all medical workers including physicians. It does so by asking what the physician does and what he needs to know in order to provide care. It brings together the process of individual patient care and the education of the health provider.

This investigation was performed pursuant to Contract HSM 110-73-335 with the Bureau of Health Services Research and Evaluation, Health Resources Administration, Public Health Service, Department of Health, Education, and Welfare.

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