A Protocol for Minor Respiratory Illnesses

An evaluation of its use by nurses in a prepaid group practice

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THE PRESSING HEALTH NEEDS of our society are being met increasingly by specially trained nurses and physician's assistants, who are now carrying out some of the tasks of diagnosis and treatment previously restricted to physicians (*1–5*). One approach to facilitating this delegation of responsibility has been the development of protocols (also called clinical algorithms) for common clinical problems. For a given complaint, a protocol specifies a set of data to be collected—history, physical examination, and laboratory work—and recommends specific diagnostic, therapeutic, and disposition decisions.

The potential advantages of protocols include their educational value (*6*), their role in reducing the need for physicians (*7,8*), and their ability to improve auditing, recordkeeping, and compliance with standards (*9*).

However, there also may be potential problems with a given protocol. Its clinical logic may not be sound. It may lead to important missed diagnoses, inappropriate treatment, or inappropriate referral to the physician. Often there are no clear indications in the literature as to how a particular problem should be evaluated and treated. There may be resistance to protocols based on the anticipation that they will be time-consuming to use and bothersome to fill out. They may be resented as restricting or inhibiting the full capabilities of the user.

We have investigated the advantages and disadvantages of a specific protocol in a specific practice. Building on a previously reported protocol for viral upper respiratory infections and streptococcal pharyngitis (*9*), we developed a protocol for a broader spectrum of upper respiratory infections and related illnesses (URI protocol). The URI protocol is applicable to persons 16 years of age or older with the following presenting complaints:

"Cold"	Post-nasal drip
Congestion	Runny or stuffy nose
Cough	Sinus pain
Earache	Sneezing
Ears stuffed	Sore throat
Exposure to strep	Strep throat
"Flu"	Swollen glands

Ache all over (with any of the above)
Fever (with any of the above)
Throat culture request (with any of the above)

Diseases treated according to the protocol include viral pharyngitis and rhinitis, streptococcal pharyngitis, acute bacterial sinusitis, otitis media, otitis externa, and viral bronchitis.

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This URI protocol was used by three nurses in a prepaid group practice for 12 weeks, and the safety and efficiency of the care delivered by these nurses when using the protocol was evaluated. For comparison, the care given by two nurses using only standing orders was evaluated by criteria similar to those used for the other nurses.

The performance of the nurses who used the protocol was audited to (*a*) determine the accuracy with which they collected clinical data by a comparison of their physical findings with those of the backup physicians and (*b*) determine deviations in decision making from the protocol recommendations. The checklist format of the protocol made this audit possible. A comparable audit could not be performed for the nurses who were using the general guidelines.

MATERIALS AND METHODS

The Protocol

The protocol shown is the latest version. It differs slightly in format, but not in logic, from the one used in the study. The protocol specifies the history, physical examination, and laboratory data to be collected, and it recommends appropriate diagnosis, therapy, and disposition decisions based on the data collected. The checklist format has a branching logic that directs data collection and decision making built into the checklist through the use of symbols and colors in boxes and directions adjacent to questions.

The clinical logic was based on standard texts (*10–12*) and selected journal articles (*13–17*), supplemented by reviews and comments of members of the medical staffs of the Beth Israel Hospital and the Harvard Community Health Plan. A detailed discussion of the medical rationale of the entire protocol has been published (*18*).

Study Setting

We conducted the study at the Harvard Community Health Plan (HCHP), a health maintenance organization (HMO) in the Boston metropolitan area. HMOs have been cited as one answer to the burgeoning health costs (*19,20*). Before the study, the HCHP had expanded the role of the nurses in an attempt to decrease costs and increase availability of care to its members without sacrificing quality (*21*). At the HCHP, each internist works closely with a particular registered nurse. During the initial visit, the physician takes the history, does physical and laboratory evaluations, and discusses these with the nurse if continuing problems are anticipated. Then the nurse becomes the first contact for that patient if acute problems arise. When a problem is one that the nurse has been trained to manage according to standing orders, the nurse may elect to treat the patient without consulting the physician.

The Nurses

The three nurses in one of the internal medicine areas of HCHP (henceforth called the protocol area) agreed to use the protocol, largely because of its anticipated educational value to them; all had been examining patients for less than 7 months. The two nurses in a second area (non-protocol area) continued to see patients according to general standing orders, but did not use protocols; one had been examining patients for 4 months, the other for 3 years. No nurse in either area had completed a formal nurse practitioner course. The nurses in the non-protocol area constitute a "comparison group," but not a true control group since there was no random assignment of protocol use. No baseline data of performance were obtained for any of the nurses before the study.

Study Design

The study was carried out during 12 weeks from March to June 1973, at the Kenmore Center of the Harvard Community Health Plan. All patients who came either to the protocol area or non-protocol area with one of the chief complaints listed earlier were entered into the study; there was therefore no randomization of patient assignment. However, the two populations turned out to be similar in age, sex, and diagnoses. All patients were seen first by a nurse in each area. Nurses in the protocol area recorded the clinical data on the protocol and recorded the diagnosis, therapy, and disposition in the computerized record system at HCHP (*22*). Nurses in the non-protocol area recorded the diagnosis, therapy, and disposition in the computerized record. Physicians in both areas saw only those patients referred to them by nurses. When the physician saw a patient, he or she (rather than the nurse) entered the diagnosis, therapy, and disposition into the computerized

URI Protocol ►

The colors which appear on the actual protocol are as follows:

red  yellow 

Questions are answered "yes" or "no" with a check mark in the appropriate box. A check mark in a red box indicates grounds for referral to a physician after completion of the protocol. A yellow box indicates a procedure or action to be carried out. A period denotes stopping and moving to the next block of boxes. A letter in a box denotes skipping to that box below with the letter adjacent.

URI PROTOCOL© (12/73)

Chief Complaint(s) _____

_____

Name:
Birthdate:
Unit #:
Date:
Phone #:
Provider:

yes no HISTORY

- Duration ≥ 6 weeks _____

- A Cough
- Age ≥ 60
- Diabetic
- Hx of smoking > 30 pack years
- Duration of cough > 10 days
- Improving

- Productive of green/brown sputum Throughout the day?
  Get sputum culture, Gram stain

A

- Sore throat? *Get throat culture*
- Swollen glands? *Get throat culture*
- Strep exposure in past week?
  Get throat culture

- Runny/stuffy nose
- Stuffed ear(s)
- Earache
- Severe pain

- Ache all over
- New skin rash
- Taking antibiotics
- Hx of rheumatic fever

PHYSICAL

- Temperature ≥ 102
- Stiff neck

- Throat culture ordered
- Palpable posterior neck nodes?
  Get mono spot
- Exudate
- Tender neck nodes
- Temp ≥ 100
- All 3 greys? *Dx strep throat*
- Any 2 greys?
- Symptoms present for > 6 days?
  Dx strep throat

- Sinus pain by history
- Tender sinus(es) on exam
- Purulent nasal discharge?
  Culture and Dx sinusitus
- Temp ≥ 100? *Dx sinusitis*

right	left	
		Ear stuffiness/ache
		Normal on exam
		Canal red/swollen? *Dx otitis externa*
		Exudate in canal? *Dx otitis externa*
		Drum obscured
		Drum perforated
		Drum red? *Dx otitis media*
		Landmarks obscured? *Dx otitis media*
		Dx of both types of otitis?
		Dx of either type otitis?
		Earache

- Cough
- Pulse ≥ 100 or ≤ 50 _____
- Resp ≥ 30 or ≤ 10 _____
- Abnormal chest exam _____

PLAN

- STOP Any reds? *Consult MD*
- STOP Will consult MD for other reasons

- Dx strep, sinusitis, or otitis media?
- Hx of penicillin allergy?
  Rx Penicillin V 250 mg qid X 10d or
  Rx Benzathine penicillin
  1.2 million U IM
- TO MD Hx of erythromycin allergy? *Consult MD*
  Rx of Erythromycin 250 mg qid X 10d

- Dx sinusitis or otitis media:
  Rx antihistamine-decongestant and nasal spray decongestant

- Dx otitis externa?
  Rx antibiotic-steroid ear drops

Also palliate as per standing orders

_____

_____

_____

_____

_____

_____

record. All patients participating in the study gave written informed consent. Use of antibiotics and telephone followups were compared by means of the Fisher exact test, two-tailed (the one-tailed P values were doubled); referral rates were compared by the chi-squared method; and timing was compared by Student's t test.

RESULTS

Clinical Logic of the Protocol

Appropriate use of antibiotics for sore throat. Accuracy in prescribing penicillin for presumed group A beta hemolytic streptococcal pharyngitis was determined before culture results were obtained. Specifically, protocol directives were compared with actual performance by nurses in the non-protocol area. Nurses performed throat cultures with cotton swabs plated within 2 hours on poured sheep agar plates. Beta hemolysis and Bacitracin ® disk sensitivity were the criteria for group A beta hemolytic streptococcal colonies (*17*). To reduce inappropriate use of penicillin without eliminating early treatment in patients likely to have streptococcal disease, the protocol allows initial use of penicillin only for those with all three of the following: temperature above 100° F, tonsillar or pharyngeal exudate, and tender anterior cervical adenopathy (indicated as "greys" in the protocol).

The following table compares penicillin treatment according to culture results in the protocol and non-protocol areas.

	Number of patients	
Treatment	*Protocol area*	*Non-protocol area*
Positive culture:		
Start penicillin	5	11
Wait	10	9
Negative culture:		
Start penicillin	2	15
Wait	138	122

Sensitivity was 33 percent for the protocol patients and 55 percent for the non-protocol patients; the difference was not significant ($P = 0.35$). Specificity was 99 percent for the protocol patients and 89 percent for the non-protocol patients; the difference was significant ($P = 0.0023$).

The protocol was successful in reducing inappropriate use of penicillin. On the other hand, in the protocol group fewer patients with streptococcal pharyngitis received penicillin at the time of their initial visit. The protocol was significantly more specific, but slightly less sensitive in identifying patients with positive cultures. In both groups, all patients with streptococcal disease not initially treated received penicillin after the results of the throat cultures were known.

Outcome Measurements

Two to three weeks after the initial encounter, about half of the patients from each area were selected at random for followup by telephone and a review of their medical records. They were asked three questions: Were the symptoms gone? Had they returned to HCHP or gone to an outside physician for treatment of their URI symptoms? Had any serious illness or hospitalization related to the initial minor respiratory illness developed? The results were as follows:

	Protocol area (101 patients)		*Non-protocol area (113 patients)*	
Followup	*Number*	*Percent*	*Number*	*Percent*
Return visit [1]	17	17	24	21
Persistent symptoms [2]	30	30	42	37

[1] Difference not significant ($P=0.52$).
[2] Difference not significant ($P=0.31$).

There were no subsequent hospitalizations or serious illnesses related to the initial minor respiratory illnesses in either group. Although the protocol patients had a lower rate of return and persistence of symptoms, the differences were not significant.

Efficiency of Protocol Use

In both areas, total encounters and encounters generated by minor respiratory complaints (URI encounters) were tallied from the copies of patients' records and consent forms. In the protocol area, the protocol was used for 212 of 242 encounters for minor respiratory illnesses (88 percent). There was no difference in the diagnostic spectrum of encounters handled without the protocol, and it is unclear why protocols were not used in these cases. The percentage of URI patients referred to the physician after the nurse evaluation was measured, and the reasons for referral to the physician were determined from the protocol form. The time spent with patients by nurses in both areas was measured during randomly chosen visits. Timing began when the nurse entered the room with the patient and ended when the nurse left the room; the timing data included the time taken to complete the protocol.

There were 2,378 nursing encounters in both areas during the study; 472 or 19.8 percent were for minor respiratory complaints. As mentioned, the protocol was not used for 30 of the 242 encounters in the protocol area. The referral rates were as follows:

Encounters	Protocol area Number	Protocol area Percent	Non-protocol area Number	Non-protocol area Percent
URI encounters:				
Patients referred to physician [1]	64	30	50	22
Total encounters	212	...	230	...
Non-URI encounters:				
Patients referred to physician [2]	344	41	318	30
Total encounters	833	...	1,073	...

[1] $P=0.055$.
[2] $P<10^{-6}$.

The protocol area nurses had higher referral rates for both URI and non-URI encounters. This finding suggests that the higher rates had more to do with differences of style between the two groups of nurses than with the use of the protocol. The difference was less significant for protocol encounters.

The reasons for referral of the 64 patients to the physician in the protocol area were:

Reason	Patients Number	Patients Percent	Major complaint
According to protocol	28	44	Chest, 19
Unsure of history, physical	14	22	Ear, 10
Non-URI problem [1]	14	22	Various
Mistrust of protocol	7	11	Throat, 5
Patient request	1	1	....

[1] An additional 9 patients were not referred.

Of these 64 referrals, 28 (44 percent) were directed specifically by the protocol rules—primarily because of findings suggesting serious lower respiratory tract pathology. An additional 36 patients were referred to the physician for reasons not directed by the protocol rules, for example, the nurse was uncertain of a physical examination finding, or the patient volunteered significant symptoms unrelated to a URI, or the nurse wished to deviate from the protocol directive. One patient was referred because of a specific request to see a physician.

The following table shows the results of time studies.

Nurses	Number of encounters	Time [1] (minutes, mean ± S.D.)
Protocol area:		
Nurse A	11	9±3
Nurse B	17	11±4
Nurse C	12	22±8
Total	40	14±7
Non-protocol area:		
Nurse D	14	12±5
Nurse E	15	10±3
Total	29	11±4

[1] $P=0.053$.

The average time in the protocol area was 14 minutes, and in the non-protocol area it was 11 minutes; the difference was not significant. Nurse C in the protocol area accounted for the difference.

Quality of Care Audit

Accuracy of data collection. Nurses in the protocol area sometimes requested that the physician also examine a patient, guided by either the protocol recommendation to do so or by their experience. Physicians did not spot check randomly selected patients other than those referred to them by the nurse. When both the nurses and physicians performed the same aspect of the physical examination, the nurses first committed themselves in writing on the protocol and then noted whether the physicians agreed with their finding. The nurses asked the physicians to do an examination when they were unsure of a finding or, in the case of the chest examination, when they thought there was an abnormality. Occasionally a physician was consulted to perform one particular aspect of the examination and also checked another aspect of the examination that was not the focus of the consultation.

The physicians' agreement with the nurses' physical findings, by part of the body examined, was complete for 74 percent of the cases, as shown in the following table. Agreement ranged from 82 percent for ear examinations to 50 percent for sinus examinations. Most of the disagreement occurred in instances when the nurse thought that a finding might be abnormal but the physician considered it to be normal. Individual nurses also were audited, and their personal agreement rates with the physicians ranged from 68 to 80 percent.

Part examined	Number of patients	Physician agreement Number	Physician agreement Percent
Ear	22	18	82
Chest	12	8	67
Throat	5	3	60
Sinus	2	1	50
Other	4	3	75
Total	45	33	74

Deviations from protocol recommendations. The protocol logic included rules for including and excluding the recording of certain clinical information. The protocol also made specific recommendations regarding the appropriate diagnosis, therapy, and disposition. The protocols were audited by one person and checked by a second according to explicit criteria to determine completeness of data collected

and extent to which the protocol's diagnostic, therapeutic, and disposition recommendations were followed. The nurses were given the freedom to deviate from protocol directives, but they were asked to explain their reasons for doing so in the comments section of the protocol.

The results of the audit of the nurses' compliance with the protocol recommendations were as follows:

	Patients	
Nurses' compliance	*Number*	*Percent*
Perfect	130	61
Minor deviations	50	24
Major deviations	32	15
Omissions	15	7
Failure to refer	13	6
Departures in therapy	4	2
Total	212	100

Of the 212 protocols, 61 percent were correctly followed in all respects. Those with minor deviations included some with extra information not called for and some with information missing from its proper place on the protocol but recorded elsewhere on the protocol sheet or in the permanent medical record. These "minor" deviations were so named because they had no bearing on decision making—many were strictly clerical. The protocols with "major" or potentially significant deviations had omissions of data called for by the protocol logic that might have affected decision making (7 percent), failures to consult the physician when indicated by the protocol logic (6 percent), or departures from the protocol recommendations regarding treatment (2 percent). Regarding major omissions, we could not determine whether the data were collected and not reported or whether they were not collected.

DISCUSSION

The major benefits of protocol use have been described in a variety of publications. Protocols have been used as effective educational tools in a physician's assistant program (*6*). They have facilitated rapid training of health workers to care for patients with diabetes and hypertension (7) and with many kinds of acute conditions in a large teaching hospital (*8*) and in an army hospital (*23*). They have been shown to improve compliance with standards of care in managing pharyngitis in a university health service (*24*). The pharyngitis study (*24*) included physicians, and they were found to deviate from standards to a greater extent than physician's assistants before protocols were introduced. Although physicians resisted use of protocols, their performance improved significantly after introduction of protocols, as did that of the physician's assistants. Goetzl and associates (*25*) pointed out the difficulties of retrospectively auditing a handwritten record. By contrast, protocols with a checklist format can be audited easily.

We believe that the quality of a protocol is a large determinant of its success in actual practice. Quality includes both safety and efficiency. For this reason, we have undertaken clinical trials of several protocols. Protocols for urinary tract infection and vaginitis in females (*26*), low back pain (*27*), headache (*28*), male genitourinary infections (*29*), and diabetes and hypertension (*7,30*) have been developed and tested (*31*).

The present study tested the applicability of the URI protocol to a particular practice setting. The results show that the protocol is safe, as determined by followup studies of patients cared for according to the protocol; medically sound in the management of sore throat when its performance was examined closely; and efficient in that it led to a referral rate to the physician of only 30 percent and that encounters took an average of 14 minutes. Although in all of these parameters the URI protocol did not lead to care superior to that given by a comparison group of nurses using general guidelines, it did not compromise care either.

Several limitations of the study must be acknowledged. The experience reported is limited because it included relatively few nurses from one particular setting. The comparison group nurses in the nonprotocol area were not a true control group; therefore, only limited inferences can be drawn about the contribution of the protocol to performance. Physical examination findings were not randomly checked by independent examiners, so that conclusions about reliability of nurse findings must be qualified. In that regard, it should be pointed out that a protocol is not a substitute for sound clinical skills in history taking and physical examination. The standard of care embodied in the protocol is totally dependent on accuracy in collection of clinical data, and this must be considered in any evaluation of protocol-based medical care. Moreover, any educational program based on protocols must also provide training in clinical skills.

Despite the limitations of the study, some advantageous features of this particular protocol were demonstrated. The protocol directives in management of sore throat reduced unnecessary antibiotic administration elevenfold. In addition, a careful audit of clinical performance was made possible by

the explicit directives of the protocol and the checklist format. Certain aspects of the physical examination were done uniformly under well-defined conditions and recorded. Although the physical examinations by the nurses were not always checked by the physicians, they frequently were, and the agreement between observers determined. It is reassuring to note that the correlation was good between the nurses' findings on physical examination and those of the physicians. The overall rate of inter-observer agreement in physical findings was 74 percent, similar to that in previous reports. In a blind study of physical signs of the respiratory system, Smyllie and associates found that agreement between physicians was about 75 percent (*32*), and Kaku and associates found agreement between nurses and physicians in 80.6 percent of the observations made during routine health appraisals (33). Without the protocol, the various parts of the physical examination would not have been done or recorded under uniform conditions by different nurses, and there would have been no assurance that the findings of both nurse and physician were recorded. Therefore, assessment of this aspect of nurse performance would have been difficult or impossible.

The checklist format enabled us to perform a detailed audit of the process of care. We did not insist on slavish conformance to the protocol, but asked that deviations be explained in the comments section. Any reasonable explanation was accepted for purposes of the audit. The audit uncovered "major" deviations that potentially might have had a deleterious effect on patient care. Fortunately, outcome studies did not reveal long-term ill effects of these deviations, and identification of the deviations was beneficial educationally. The audit also demonstrated reasons for referral to the physician that could in time be eliminated, such as uncertainty in the history taking or physical examination and mistrust of the protocol. In this way, audit could be used to improve efficiency of care.

This study addresses directly the following arguments frequently advanced against protocols: (*a*) doubt about the clinical logic and safety of the particular protocol, (*b*) belief that the protocol will be time-consuming and bothersome to fill out, and (*c*) fear that the protocol may introduce other inefficiencies into a practice, such as increased referrals by the user to the physician. None of these arguments appear valid with respect to the URI protocol in this study.

The nurses who used the protocol stated that they learned a great deal from its use. Because of this positive experience with a protocol, several protocols were used in a formal nurse practitioner course at the Harvard Community Health Plan. Training manuals have been prepared to facilitate education in the use of the protocols, and a textbook of common acute illnesses based on the protocols and training manuals has been written (*18*).

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SYNOPSIS

WINICKOFF, RICHARD N. (Harvard Community Health Plan), RONIS, AIJA, BLACK, W. L., and KOMAROFF, ANTHONY L.: *A protocol for minor respiratory illnesses. An evaluation of its use by nurses in a prepaid group practice. Public Health Reports, Vol. 92, September-October 1977, pp. 473–480.*

A study carried out in 1973 at the Kenmore Center of the Harvard Community Health Plan tested the applicability to a particular practice setting of a written upper respiratory infection (URI) protocol. Developed for the management of a broad spectrum of URI infections and related illnesses, the protocol was used for 12 weeks by 3 nurses in a prepaid group practice. The safety and efficiency of the care these nurses provided using the protocol was evaluated and compared with the care given by two other nurses who only followed standing orders.

The directives in the protocol for the management of sore throat reduced unnecessary antibiotic administration elevenfold. In addition, the protocol's explicit directives and its checklist format made a careful audit of clinical performance possible. Also, certain aspects of physical examinations were done uniformly under well-defined conditions, and the observations were recorded. The physical examinations performed by the nurses under the protocol were not always checked by the physicians, but when they were, the correlation between the physicians' and the nurses' findings was good (overall agreement 74 percent).

The audit of the protocol nurses' performance uncovered some deviations that potentially might have a deleterious effect on patient care. Nevertheless, outcome studies revealed no long-term ill effects from these deviations, and their identification was beneficial educationally. Fewer patients with streptococcal pharyngitis in the protocol group than in the non-protocol group received penicillin upon their initial visit. The protocol was found to be significantly more specific, but slightly less sensitive, in identifying patients with positive cultures. Nevertheless, all patients in both groups with streptococcal disease who were not initially treated received penicillin once the results of their throat cultures were known.

The audit identified some referrals to physicians that could in time be eliminated. The protocol nurses had higher referral rates for both URI and non-URI encounters, but this difference was believed to be related more to differences in style between the two groups of nurses than to use or nonuse of the protocol.

Followup studies of patients treated according to the URI protocol demonstrated that safe care could be provided under its directives. The management of sore throat according to the protocol appeared to be sound. Care provided under the protocol directives also was efficient: only 30 percent of the cases encountered were referred, and each encounter took on the average only 14 minutes of the nurse's time. Although the URI protocol did not lead to care that was superior to the care given by the comparison group of nurses using general guidelines, neither did it compromise care.