Protocol Management of Dysuria, Urinary Frequency, and Vaginal Discharge

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A protocol to be administered by nurses for the management of dysuria, frequent urination, and vaginal discharge was validated. In a randomized, controlled trial, 146 women were seen by both nurse and physician and then assigned to either the nurse-protocol treatment plan or the physician treatment plan. The clinical data collected by the nurse showed no important differences from the physicians' data. The protocol recommended that 89 percent of the patients be sent home without seeing the physician. The physicians agreed with the protocol-recommended disposition in all but two cases. All patients with complications were appropriately referred to the physician. In follow-up, more than 95 percent of both groups reported symptomatic improvement, and repeat urine cultures were negative. We conclude that the protocol can be accurately administered, makes sound recommendations, is safe, and efficiently saves physician time.

Several groups in the United States are testing protocols (also called clinical algorithms) for common clinical problems. The protocol is a form that combines a data collection section with a decision logic pattern to direct the practitioner in history taking, diagnosis, therapy, and disposition appropriate to a particular patient. Protocols can be used as aids to train and guide nurses, nurse-practitioners, and physician's assistants, and to audit diagnostic and therapeutic decisions. By facilitating the delegation of clinical care responsibilities to providers other than physicians, protocols conserve physician time. Protocols assure highest quality care both by guiding performance and by providing a system to audit effectiveness.

Komaroff and associates[1] developed and used protocols for the return visits of patients with diabetes mellitus and hypertension. Sox, Sox, and Thompson[2] have extensive experience with the computerized audit of clinical algorithms for acute minor illnesses as part of a physician's assistant training program. We did an uncontrolled validation study[3] of a protocol for upper respiratory infections that included some measurements of the quality of care delivered. We report here a randomized, controlled, clinical trial of a protocol for the management of frequent and painful urination, vaginal discharge, and vaginal irritation. The performance of a nurse using the protocol was compared with that of a group of physicians; process and outcome criteria for quality of care and efficiency were measured.

We tested three hypotheses: (1) the nurse could accurately collect the clinical data (history, physical examination, laboratory tests) required by the protocol; (2) the protocol could assist the nurse in making correct diagnostic assumptions, recommending appropriate therapy, and referring the complex and high-risk patients to the physician; and (3) use of the protocol by the nurse could save physician time.

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Materials and Methods

Description of the Protocol – This protocol provides a rational, logical, and medically sound approach to the diagnosis and treatment of women with the symptoms of frequent or painful urination, vaginal discharge, and vaginal irritation. It directs the user to collect relevant data (history, physical examination, and laboratory tests), and then it guides the user through a sequence of decisions to a diagnosis of uncomplicated urinary tract infection; urethritis; monilial, trichomonal, or nonspecific vaginitis; or a combination of these. For each of these diagnoses the protocol specifies therapy and disposition. The protocol identifies pathologic entities, such as gonorrhea, diabetes, and hypertension, that may be related to the presenting complaints either as causes, results, or complicating factors. If the nurse suspects these more complex pathologic entities, the protocol directs referral of the patient to a physician.

The protocol is a single-page form that combines a data collection form with the decision logic pattern necessary to direct data gathering, diagnosis, therapy, and disposition appropriate to the particular patient.

The medical judgments in the protocol were subjected to consultant review. The protocol is described here and shown diagrammatically in Figure 1. If the patient has dysuria or frequent urination or both, relevant history is obtained, physical examination and urinalysis are done, and the urine sample is cultured. If the urinalysis shows at least 20 or more leukocytes or 2+ bacteria per high power field in a centrifuged sediment, the patient is treated for urinary tract infection.[4,5] If the urinalysis results are negative, then a pelvic examination is done to rule out vaginitis. If vaginitis is not present the patient is considered to have urethral syndrome or urethritis. The patient is informed about the condition but is not treated with antibiotics until culture results are evaluated.[6,7] A patient complaining of ei-

ther vaginal discharge or irritation of the vulva receives a pelvic examination, including inspection for gross abnormalities and tests for monilia or trichomonas. If neither are detected, the patient is treated for non-specific vaginitis.

To check for gonorrhea, the protocol directs inspection and palpation of the cervix for purulent discharge and tenderness. If either is present, a Gram's stain and culture are done. At the UCLA Student Health Service, where the study was conducted, a culture for gonorrhea is taken routinely with each pelvic examination, regardless of the clinical findings.

Patients are automatically referred to the physician if they are on a return visit for any of the symptoms listed above, are older than age 45, have had a recent gynecologic procedure, are pregnant, or have diabetes, severe abdominal pain, back pain, incontinence, vomiting, nausea, fever or chills, proteinuria, glycosuria, hypertension, significant fever, or any vaginal abnormalities. A history of recurrent urinary tract infection, chronic kidney disease, or medications recently administered vaginally are reasons for verbal consultation by the nurse with the physician, after the examination is completed, but the physician need not see the patient.

Urinary tract infections are treated with sulfisoxazole.[6] If the patient is allergic to sulfonamide, then tetracycline or ampicillin is used. Nystatin (Mycostatin®, E. R. Squibb and Co., Inc.) suppositories are prescribed for the treatment of monilia infection and metronidazole for the treatment of trichomonas infection. Vaginal suppositories of sulfonamide are used in the treatment of nonspecific vaginitis.

The accuracy of the initial diagnosis is checked by the culture test results, and treatment is modified if necessary. Patients are advised to return if rash, fever, chills, or vomiting develop or if the symptoms continue for more than three days with urinary tract infection and more than seven days with vaginitis.

Study Design — The study conducted between March 1, and May 31, 1973, compared the effectiveness of a protocol-guided nurse to the effectiveness of a group of physicians with respect to history taking, physical examination, simple laboratory observa-

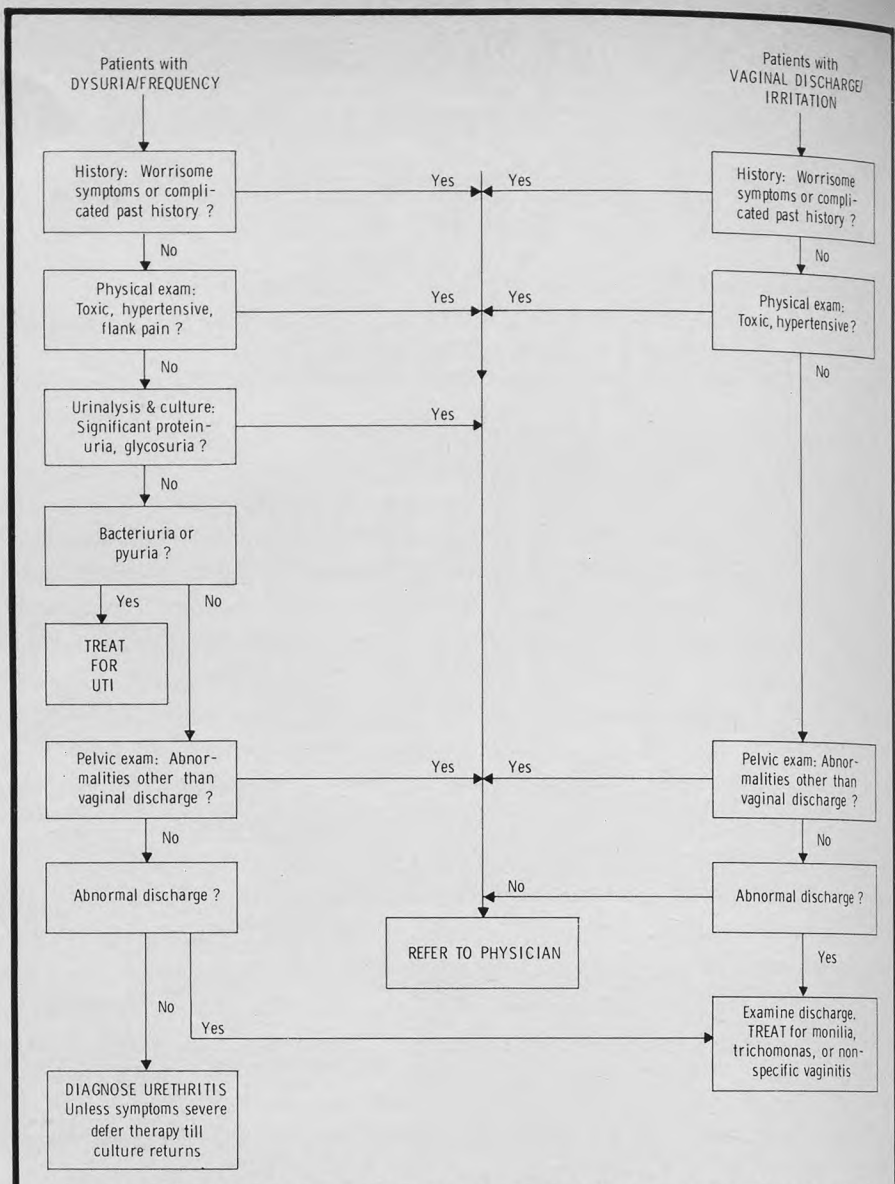

Figure 1. Major logic pathways through the urinary tract infection (UTI) and vaginitis protocol. The protocol specifies what is meant by phrases such as "worrisome symptoms" and "toxic." Beside this logic, the protocol contains many other minor pathways and logic branch points.

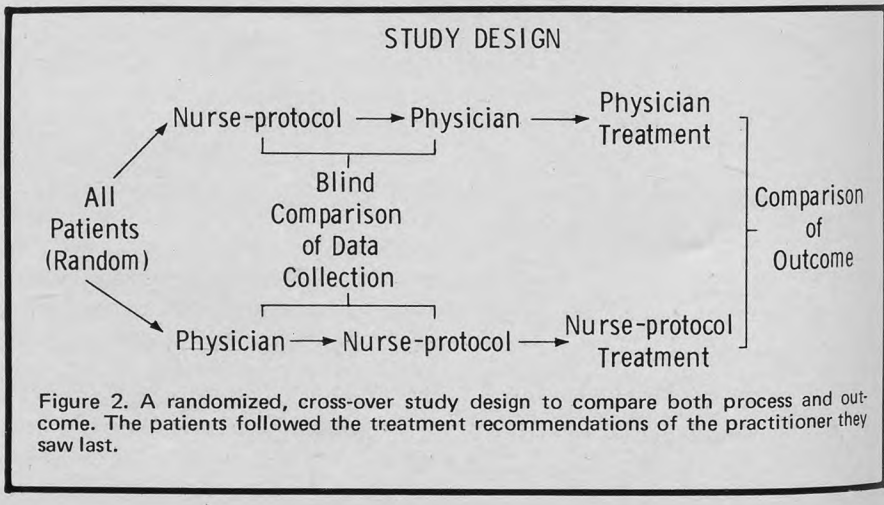

Figure 2. A randomized, cross-over study design to compare both process and outcome. The patients followed the treatment recommendations of the practitioner they saw last.

tions, and management (Figure 2). Women who had either dysuria, frequency of urination, vaginal discharge, or vaginal irritation were randomly allocated to one of two groups.

One group was seen first by a nurse, an RN without practitioner experience, and then by one of 13 participating physicians. Eight of the 13 physicians were regular staff members of the Student Health Service, and five were part-time residents at the UCLA Hospital in the departments of pediatrics, radiology, and surgery. The physicians knew the study goals and design, and all inquiries were answered; however, the protocol was not reviewed with any of these physicians.

Patients assigned to the other group were seen first by a physician and then by the nurse. Neither the physician nor the nurse knew the other's findings. The order of patient contact was reversed to control for the patient's sensitization to the history and physical examination by the first observer. The nurse examined the urine sediment and the vaginal smear without knowing the results of the Student Health Service laboratory examination of the same specimen.

The nurse (on the protocol form) and the physician (on a similar form that did not include the protocol outline) recorded their history and physical examination findings, and after ascertaining the laboratory results they committed themselves to a presumptive diagnosis and plan. The patients seen last by a physician followed the physician's recommendations (physician group). Those patients seen last by the nurse followed the protocol-recommended disposition and therapy (nurse-protocol group). The nurse gave the physician the protocol recommendations, for treatment or for referral to a physician, and requested the physician to indicate on a special sheet a judgment on these protocol-recommended decisions. The physician was asked whether the protocol recommendation was *reasonable*, not whether it corresponded exactly to what he or she had recommended or would recommend. If the physician was opposed to the nurse-protocol disposition or therapy, the physician's decisions prevailed. The information on these patients was removed from the analysis of outcome results.

The patients were asked to telephone two days later for the results of the urine culture. If the urine culture was positive the patient was asked to return for a repeat culture one week after termination of therapy. Within a week after the clinic visit all patients were contacted by telephone and questioned about the presence, absence, or alleviation of symptoms and about complications.

Each protocol report was reviewed by Dr. Greenfield to verify that the protocol was followed accurately.

Table 1. Data Collection Concordance Between Physicians and Nurse-Protocol (N-P)*

	Identical	Physician Error	N-P Error
	←	*no.*	→
History	139	6 (4)	1 (0)
Physical Exam	137	0	9 (0)

* ( ) = Resulting in altered diagnosis or management.

Results

Five of the 151 patients admitted to the study did not complete the study because they refused to be examined twice or because of an error in triage. The data were analyzed for the remaining 146 patients.

Table 2. Diagnosis Concordance Between Nurse-Protocol (N-P) and Physician for 130 Patients*

N-P Diagnosis	Physician Diagnosis						
	UTI	Urethral Syndrome or Urethritis	Monilia	Nonspecific Vaginitis	Trichomonas	UTI and Vaginitis	Other†
Urinary tract infection	28						
Urethral syndrome or urethritis		6					
Monilia			37				
Nonspecific vaginitis			1	41			
Trichomonas					1		
Urinary tract infection and vaginitis	2					8	
Other†							6

*UTI = urinary tract infection.
†Includes no pathology found, trichomonas and monilia together, and suspected allergic reactions to vaginal insertions.

There were five patients over 30 years old; the others were 18 to 22 years old. The full-time Student Health Service physicians saw 99 patients. The remaining 47 patients were seen by the five part-time residents.

Concordance between physicians and the nurse with respect to the patient's medical history is recorded in Table 1. Of the 146 histories, 139 were essentially identical. Of the seven discrepancies, there were six cases of error by physicians. In four cases, the physicians concurred that they had erred in not pursuing symptoms suggesting either vaginitis or urinary tract infection, and management was altered when either condition was found. In two cases, physicians agreed that they had not acquired a presumptive history of urinary tract problems. The nurse did not detect a past history of significant urinary tract infection in one patient.

Concordance on the results of physicial examination was similar. Of 146 cases, 137 were virtually identical. In nine cases the nurse made an error, based on concurrent physician assessment. These nine errors were not independently verified. In no case did any of these physical examination errors result in a different management decision: in five cases the nurse did not recognize monilia in vaginal discharge, but monilia was shown by laboratory tests; in four cases physicians noted costovertebral angle tenderness that the nurse had not noted, but they did not specifically diagnose pyelonephritis or alter management of routine urinary tract infection.

Evaluation of the laboratory work done by the nurse indicated that the Health Service's laboratory findings agreed with the nurse's in 54 of 58 urinalyses. In the four cases of disagreement, the physician who had seen the patient examined the sediment and confirmed the nurse's observation. The laboratory failed to note the presence of monilia in vaginal secretions in nine cases of the 39 in which the nurse had detected monilia. In all of these cases, the nurse's findings were confirmed by the physician. The nurse failed to note monilia on one specimen found to be positive by the laboratory. There was no independent judgment made on the specimens reported as negative by both nurse and laboratory.

The protocol's diagnostic accuracy was evaluated in those cases in which the patient would have gone home without seeing a physician. The protocol directed that the patient be referred to the doctor in 16 (11 percent) cases. Concordance of diagnosis in the remaining 130 patients is seen in Table 2. The diagnoses were made after review of the laboratory tests results; agreement was virtually complete. In two cases a diagnosis of vaginitis was confirmed by the nurse when the physician had noted only urinary tract infection; in both instances, on review, the physician agreed with the nurse-protocol diagnosis and therapy. In one case the laboratory found monilia on a Gram's stain of vaginal discharge of a woman who had been diagnosed by the nurse as having nonspecific vaginitis.

There was virtually complete agreement on therapy. In one case the physician agreed with the nurse-protocol diagnosis but preferred another treatment. In the 129 other cases, physicians judged the protocol treatment plan to be "reasonable." Physicians concurred with the nurse-protocol diagnosis and management (specific therapy or referral) in 144 of the 146 cases.

Beside advising specific treatment, the protocol recommended a review by a physician in 11 cases, nine for a suspected history of urinary tract disease and two because the patient had recently taken medication potentially interfering with diagnosis and therapy. There was agreement on the need for review of all 11 records.

All 16 patients referred to the physician by the protocol-directed nurse were referred appropriately, according to the physicians. Of the 16 referrals, seven were for either a return visit for the same complaint or recently taken medication interfering with the diagnosis and therapy, three were for symptoms of generalized toxicity, and the remainder were for miscellaneous reasons. The protocol did not fail to recommend referral for any patient the physicians felt had to be examined by a physician.

The outcome of symptoms was evaluated in the nurse-protocol-treated and physician-treated groups. Of 76 patients allocated to the nurse treatment group, eight did not receive nurse-protocol management because of referral (six cases), physician disagreement (one case), or no identifiable pathology (one case). Similarly, five patients of the 70 assigned to the physician treatment group were excluded from analysis of specific therapy because of referrals to subspecialists or other complications. The outcome of symptoms for the remaining 68 patients treated by nurse-protocol and 65 patients treated by physicians are recorded in Table 3. Of the 65 physician-treated patients all but two reported alleviation or improvement of their symptoms. Similarly, only two of the 68 nurse-protocol patients reported no improvement. The three patients with unimproved vaginitis were thought to have nonspecific vaginitis on the first visit and were later treated for monilia infection. One patient who had a urinary tract infection (treated by the physician) had an allergic reaction to sulfisoxazole.

Results of treatment with antibiotics of urinary tract infection are shown in Table 4. Nine of the physicians' 15 culture-positive patients had repeat cultures one week after treatment terminated. Eight of nine cul-

Table 3. Symptomatic Outcome by Treatment Group and Diagnosis

	UTI/US*		Vaginitis		Both	
	Total	Improved	Total	Improved	Total	Improved
Nurse-protocol	16	16	49	47	3	3
Physician	23	22	35	34	7	7

*Urinary tract infection/urethral syndrome.

Table 4. Culture Results of Antibiotic Treatment for Urinary Tract Infection

Group Patients	Positive Before Treatment	Total Recultured	Culture Sterile After 3 Weeks
Physician	15	9	8
Nurse-protocol	14	12	10
Total	29	21	18

tures were sterile. Similarly, of the 14 positive cultures in the nurse-protocol patients group, 12 were recultured and ten of these were sterile within three weeks.

As determined by review of the protocols, very few minor errors and no substantive errors were made in following the logic.

Discussion

The study seems to support the three hypotheses tested: the nurse accurately collected the relevant clinical data; the protocol made appropriate diagnostic, therapeutic, and disposition recommendations; use of the protocol by the nurse saved physician time. Thus the protocol met the two essential requirements for its widespread use: the quality of care was good, as reflected by both process and outcome criteria, and use of the protocol introduced the anticipated efficiency of care.

Because urinary tract symptoms, vaginitis symptoms, and bacteriuria can be self-limited, laboratory cultures and outcome of symptoms are not sufficient criteria to validate protocol decisions. It is also necessary to evaluate the *process* of medical care – to compare the nurse-protocol with the physicians' procedure regarding the thoroughness and accuracy of the clinical data collected and the diagnosis, therapy, and disposition. The study design permitted independent evaluation of these aspects of the process.

The results were favorable regarding the thoroughness and accuracy of the clinical data collected by the nurse. The concordance between the nurse and physicians in the history, physical examination, and laboratory data indicates that a nurse can be trained in the specific skills required for the management of the specific complaints we studied. The few "errors" in physical examination made by the nurse were not verified by an independent observer, and, even if real, they did not prevent her from reaching a proper diagnostic conclusion because of the built-in checks of the protocol. As with all clinical medicine, decisions are seldom made on the basis of a single branch in logic.

That the nurse did as well in the laboratory determinations as the Student Health Service laboratory is to be expected. The nurse learned a few laboratory procedures very well and became expert at them while the laboratory technicians were doing many procedures, without emotional investment in a given procedure or in any patient. This concentration also pertains to the accuracy in following the protocol. The nurse (S. S.) was doing only this study at the time, and she worked closely with one of the physicians (S.G.).

The quality of the diagnostic, therapeutic, and disposition recommendations of the protocol was also good, as reflected by both process and outcome measurements. Diagnostic impressions by the nurse-protocol were in almost complete concordance with those of the physicians. The protocol's provisions for a detailed history allowed the nurse to make slightly more accurate diagnoses than the physicians. Physicians agreed that the nurse-protocol treatment plan was reasonable in virtually all cases.

Perhaps most important, consideration of the reasons for physician referral for 16 patients indicated that the protocol was conservative, as intended, and entirely safe. Those patients who would have been sent home by the protocol rules without seeing a physician had no complications as ascertained by our follow-up and by physician estimation of the complexity of the problem. All potential complications were referred to physicians, and we anticipate that the protocol is conservative enough to continue this degree of safety with larger numbers of patients.

Study of the outcome of care also supported these conclusions. Patients treated by the protocol-directed nurse obtained the same high degree of symptom relief as those treated by the physician, which is not surprising. Most urinary tract infections are self-limited diseases in terms of symptoms.[6] The problem with vaginitis is not difficulty in diminishing symptoms but recurrence that is troublesome and chronic. It is accepted, however, that any given episode is not difficult to treat symptomatically.

At this point the most significant indicator of outcome for urinary tract infections is a negative urine culture after treatment. Although the controversy as to whether symptomatic and asymptomatic bacteriuria lead to chronic pyelonephritis is unsettled, we adopt the conservative approach that bacteria should be eradicated. Eight of the nine physicians' patients and ten of the 12 nurse-protocol patients had sterile urine cultures at three weeks. Although the numbers are small, these results compare favorably with previous studies.[6,8,9]

Beside providing care of demonstrably high quality, the nurse using the protocol showed a significant potential for saving physician time. Almost 90 percent of the patients could have been managed completely by the nurse. For those patients referred to the physician, a nurse's completing a preliminary examination would have saved considerable time, depending on the complexity of the problems and the physician's style of practice.

The study had several possible shortcomings. One is that the protocol was tested with only one nurse. This affects solely the question of how well nonphysicians collect clinical data and not the question of how appropriate the protocol was in recommending treatment or referring patients to the physician. We feel that the skills required for the protocol are so explicit and circumscribed that a nurse with moderate ability should be able to master them. Further, as indicated earlier, the protocol is so constructed that individual data collection errors will have only a small effect on decisions.

A second possible shortcoming is the restricted age group of the patients. Use of the protocol in older patients more prone to chronic diseases might increase the number of patients referred to the physician, thus reducing the protocol's efficiency. It is unlikely that, when used with a different patient population, the protocol would be less effective in directing treatment or referral. This particular aspect should be investigated further.

It can also be argued that bias among the physicians may have affected their judgments about the protocol's diagnostic, therapeutic, and disposition decisions. The physicians were not instructed on the logic behind the protocol decisions. In each case the physicians committed themselves to a diagnostic, therapeutic, and disposition plan *before* knowing the nurse-protocol plan. Over time, however, the physicians may have made proper inferences about the protocol, which would introduce a bias. This bias could have affected the physicians' agreement with the appropriateness of the referrals. Two of us (S. G. and S. S.) involved in the daily aspects of the study ascertained from informal conversations with the physicians that they were clearly disposed to accept the protocol recommendations on referral to a physician when they realized that the protocol had been developed after careful review of the literature and analysis by specialist consultants. If the physicians were influenced toward higher quality medical care, this bias adds to the value of the protocol rather than detracts from it.

The use of protocols to train, guide, and audit the performance of various health care professionals has been rejected by some people as being too constraining, cumbersome, time-consuming, and limited, because of the diversity of clinical problems, and productive of mindless, mechanical, and potentially dangerous behavior. We have discussed some of these concerns elsewhere.[1,10] Our experience in this study and with other protocols does not support these concerns; nevertheless, additional carefully evaluated experience is required.

We conclude that this protocol met the criteria for quality and can be used by appropriately trained health professionals other than physicians to manage complaints of urinary tract infections and vaginitis. The protocol saves physician time, allows ease of evaluation of medical care, and facilitates teaching the management of these complaints without sacrificing high standards of medical care.

Acknowledgments

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