

Evaluation of Suspected Urinary Tract Infection in Ambulatory Women: A Cost-Utility Analysis of Office-Based Strategies

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BACKGROUND. The purpose of this study was to determine the most cost-effective strategy for managing suspected urinary tract infections in otherwise healthy adult women presenting to their primary care physician with dysuria and no symptoms or signs of pyelonephritis. Several office-based management strategies are considered: empiric therapy, use of dipstick analysis, use of complete urinalysis, and several strategies using office or laboratory cultures.

METHODS. We constructed a decision tree using model probabilities obtained from the literature. Where published probabilities were unavailable, we used extensive sensitivity analyses. Utilities were obtained from the Index of Well-Being. We obtained costs by surveying hospitals, physicians, and pharmacies.

RESULTS. The most cost-effective strategy is to treat empirically (\$71.52 per quality-adjusted life month, QALM). When the cost of antibiotics exceeds \$74.50 or if the prior probability of having a UTI is under 0.30, then treatment guided by the results of a complete urinalysis is preferred. While it was the preferred strategy, other strategies (complete urinalysis, culture and treat, and dipstick testing only) were associated with greater utility. The marginal cost-effectiveness of these strategies compared with empiric therapy ranged from \$2964 to \$48,460 per additional QALM.

CONCLUSIONS. The preferred strategy of empiric therapy is robust over a wide range of sensitivity analyses. While empiric therapy is associated with the best cost-utility ratio, doing a culture yields the greatest utility at greater incremental cost per QALM. Many primary care physicians already treat UTIs empirically with antibiotics. This study confirms that empiric therapy, while frowned upon by some, is a cost-effective strategy. Other strategies may be considered, but at greater marginal cost. Ultimately these findings need to be confirmed in clinical trials.

KEY WORDS. Urinary tract infections; female; treatment outcomes; decision trees; cost-benefit analysis. (*J Fam Pract* 1997; 44:49-60.)

In 1975 Calvin Kunin¹ published an algorithm for the management of outpatients with signs and symptoms of urinary tract infection (UTI). In addition to a complete urinalysis, he recommended that all patients have a

urine culture both before and after treatment. Twenty years later, his recommendations are no longer a standard of care for two reasons. First, an episode of uncomplicated cystitis would cost nearly \$200 using his guidelines. Second, subsequent research has shown that rapid screening tests for bacteriuria are accurate, follow-up cultures are not needed in uncomplicated cases, the majority of cases will respond to commonly used antibiotics, and symptoms in the presence of pyuria are highly predictive of infection.²

Komaroff² presents a simplified approach to the woman with dysuria, suggesting that treatment on the basis of pyuria alone is sufficient. Opinions, however, still differ on the optimal strategy for man-

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TABLE 1

Strategies Modeled in the Decision-Utility Analysis

Strategy	Description
1	Empiric therapy
2	Therapy based on urine dipstick results
3	Therapy based on a combination of results of urine dipstick and urine sediment results
4	Therapy based on results of culture performed in an office laboratory, with initial antibiotic treatment while awaiting culture results
5	Therapy based on results of culture performed in an office laboratory, without initial antibiotic treatment
6	Therapy based on the results of a culture performed in a reference laboratory, with initial antibiotic therapy while awaiting culture results
7	Therapy based on the results of a culture performed in a reference laboratory, without initial antibiotic therapy.

aging acute dysuria in ambulatory women. When presented with a clinical vignette of a patient with an uncomplicated UTI, 137 family physicians gave 82 separate management strategies.³ Some clinicians treat on the basis of symptoms alone, some on the basis of a urinalysis, and others prefer to culture first. At least one group⁴ recommends treatment on the basis of a leukocyte esterase and nitrite dipstick as the most cost-effective approach. Because most cases of acute UTI have an indolent course and because most antibiotics are benign and effective, each of these strategies seems reasonable. Nonetheless, in the current medical environment of cost consciousness and managed care, choosing the most cost-effective strategy is important.

This report presents a cost-utility analysis for determining the optimal office-based approach to diagnosis and treatment of suspected UTI in women. We compared seven strategies, including empiric therapy, strategies involving the use of dipstick and microscopic urinalysis, and strategies involving the use of office or laboratory cultures. Our analysis is limited to uncomplicated cases of dysuria in women because they represent the vast majority of patients presenting with this symptom in outpatient settings, and because strategies differ in men, children, and patients with underlying structural urinary tract abnormalities or recurrent infections. We also limit the analysis to office-based strategies. More creative strategies where the initial office visit is avoided are beyond the scope of this paper.

METHODS

Cost-utility analysis is a type of economic analysis that explicitly measures the costs and impact on quality of life (utility) of different strategies, with a primary outcome of dollars per level of utility (in this case quality-adjusted life months). This study uses decision analysis, a method for analyzing decisions under conditions of uncertainty, to develop a decision tree for each management strategy, and assigns specific probabilities, costs, and utilities to each intermediate and final outcome. The cost per quality-adjusted life month for each strategy and the marginal cost-effectiveness (dollars per additional quality-adjusted life month compared with the most cost-effective strategy) are then calculated.⁵

INDEX PATIENT

The index patient is a young (aged 18 to 50 years) healthy woman who visits her primary care physician for evaluation of dysuria of less than 1 week duration. She is experiencing no fever, chills, flank pain, nausea or vomiting, or vaginal discharge. She is not pregnant, has had no recent UTI, and has had no recent genitourinary tract instrumentation. The clinician suspects the woman has a UTI and now must consider one of several diagnostic and therapeutic options. Approximately two thirds of such patients will have a bacterial UTI. These patients generally do not have symptoms of vaginitis or risk factors for subacute pyelonephritis or urethritis.²

DECISION TREE

We constructed a decision model for the cost-utility analysis using a computer program (DATA by TreeAge, Boston, Mass, 1995). The seven strategies modeled are summarized in Table 1, and the decision tree for this analysis is shown in Figure 1. The branches represent the seven strategies and subsequent chance events and decisions. We identified the following clinical outcomes: cure without complication; pyelonephritis; persistent dysuria with reassessment; urethritis; vaginitis; and cure with medication-induced side effects. For this analysis, we used clinical response as the measure of treatment efficacy or cure and then performed a sensitiv-

TABLE 2

Sensitivity, Specificity, and Cost of Tests Used in the Cost-Utility Model

Test	Sensitivity (range for sensitivity analysis)	Specificity (range for sensitivity analysis)	Cost (\$) (range for sensitivity analysis)
Dipstick urinalysis*	0.65 (0.4 to 0.999)	0.75 (0.5 to 0.999)	5 (2 to 20)
Complete urinalysis†	0.90 (0.5 to 0.999)	0.72 (0.5 to 0.999)	7 (2 to 30)
Office culture	0.93 (0.75 to 0.999)	0.93 (0.5 to 0.999)	15‡ (2 to 50)
Lab culture	0.96§ (0.75 to 0.999)	0.96§ (0.5 to 0.999)	23 (5 to 50)

*A positive test is defined as the presence of either nitrites, leukocyte esterase, or both.

†A positive test is defined as the presence of one or more of the following: nitrites, leukocyte esterase, or pyuria. Pyuria is defined as the presence of 5 or more leukocytes per high-power field.

‡This information was unavailable locally. We contacted physicians in mid-Michigan and found that no local primary care physicians perform cultures in their offices due to managed care contracts and due to regulations imposed by the Clinical Laboratory Improvement Act.

§ Authors' estimate.

ity analysis over a wide range of probabilities. We also identified the following analytic outcomes: quality-adjusted life months (QALMs; on a scale of 0 to 1, the quality of life experienced by the patient over the 1-month period of the decision model); cost (from the payer's perspective); and cost per quality-adjusted life month (\$/QALM). Each clinical outcome is assigned a utility (a valuation of the patient's preference for the outcome). Costs accrue as office visits occur, medications are prescribed, and so on. Similarly, the utility of a strategy decreases as adverse events occur. The strategy with the lowest cost per expected utility is considered the most cost-effective.

Note that when a patient without UTI is treated (Figure 2), she would unnecessarily receive antibiotics and thus be exposed to a small risk of adverse events without any potential benefit. When patients with UTI are treated (Figure 3), they also experience antibiotic-induced side effects, but may also experience other complications and treatment failures. In the strategies guided by urinalysis, diagnostic errors caused by false-positive and false-negative results cause misclassification and result in initial mistreatment of the patient. Finally, in strategies where therapy is delayed pending results of culture (strategies 5 and 7), the patient either experiences greater duration of symptoms, spontaneous resolution of the UTI, or rarely, worsening of symptoms with progression to pyelonephritis.

PROBABILITIES

We used data from published studies to estimate test characteristics,^{2,4,6-37} and to estimate the probabilities of pyelonephritis, complications of therapy, and the treatment responses^{10,11,13,14,18,26,28-43} used in the model. Table 2 summarizes characteristics of the tests we used in the model.

DURATION OF THERAPY

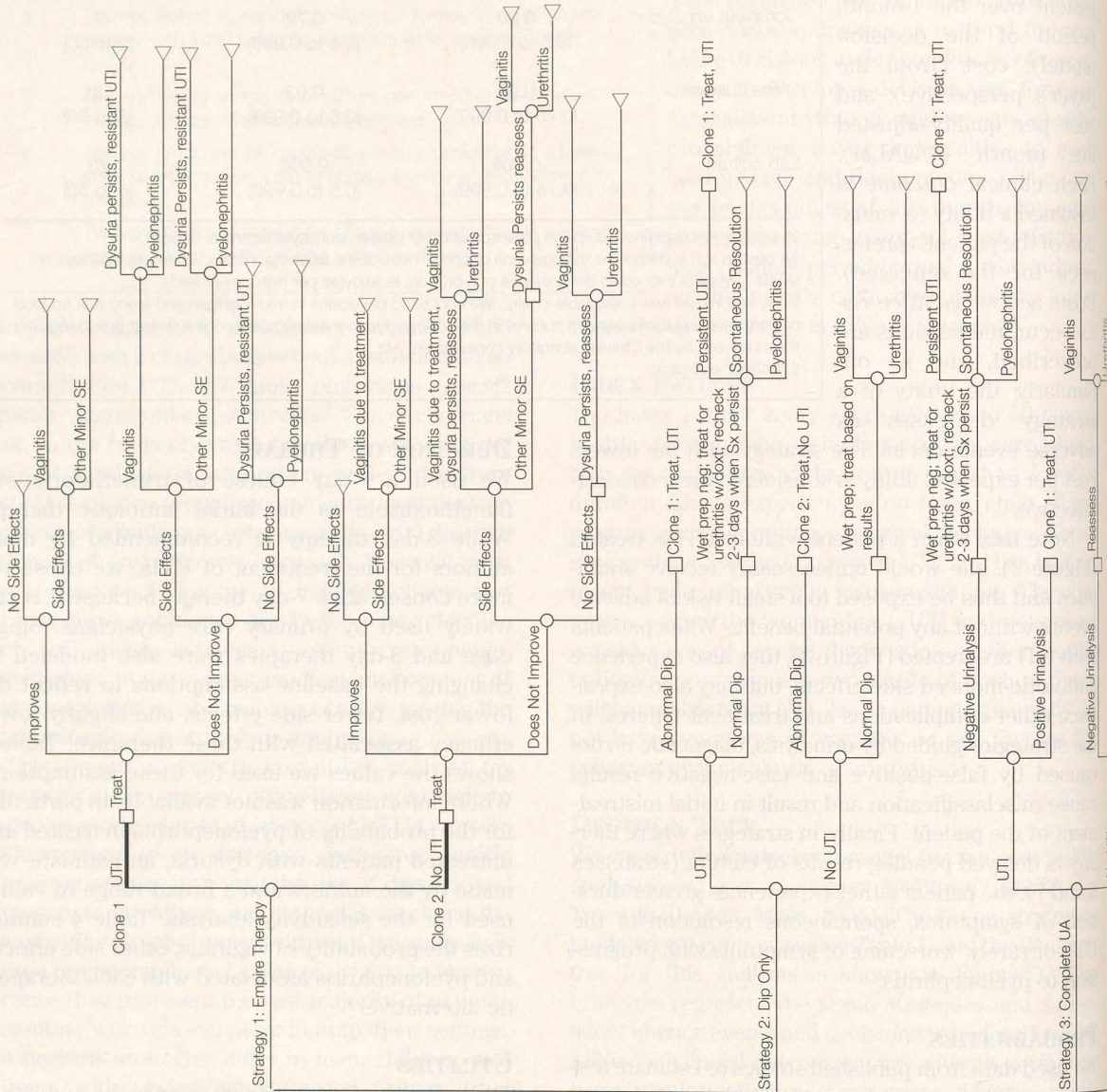
We used a 7-day course of trimethoprim-sulfamethoxazole as the initial antibiotic therapy. While 3-day therapy is recommended by many authors for the treatment of UTIs, we chose the more conservative 7-day therapy because it is still widely used by primary care physicians. Single dose and 3-day therapies were also modeled by changing the baseline assumptions to reflect the lower cost, fewer side effects, and slightly lower efficacy associated with these therapies. Table 3 shows the values we used for these assumptions. Where information was not available, in particular for the probability of pyelonephritis in treated and untreated patients with dysuria, an estimate was made by the authors and a broad range of values used for the sensitivity analysis. Table 4 summarizes the probability of vaginitis, other side effects, and pyelonephritis associated with each therapeutic alternative.

UTILITIES

The measure of effectiveness used is the number of QALMs experienced by patients. A QALM has a range of values from 0 to 1, where 0 is death and 1 is an optimal quality of life experienced for 1 month. One month was selected because all of the possible

FIGURE 1

Fully arborized decision tree.



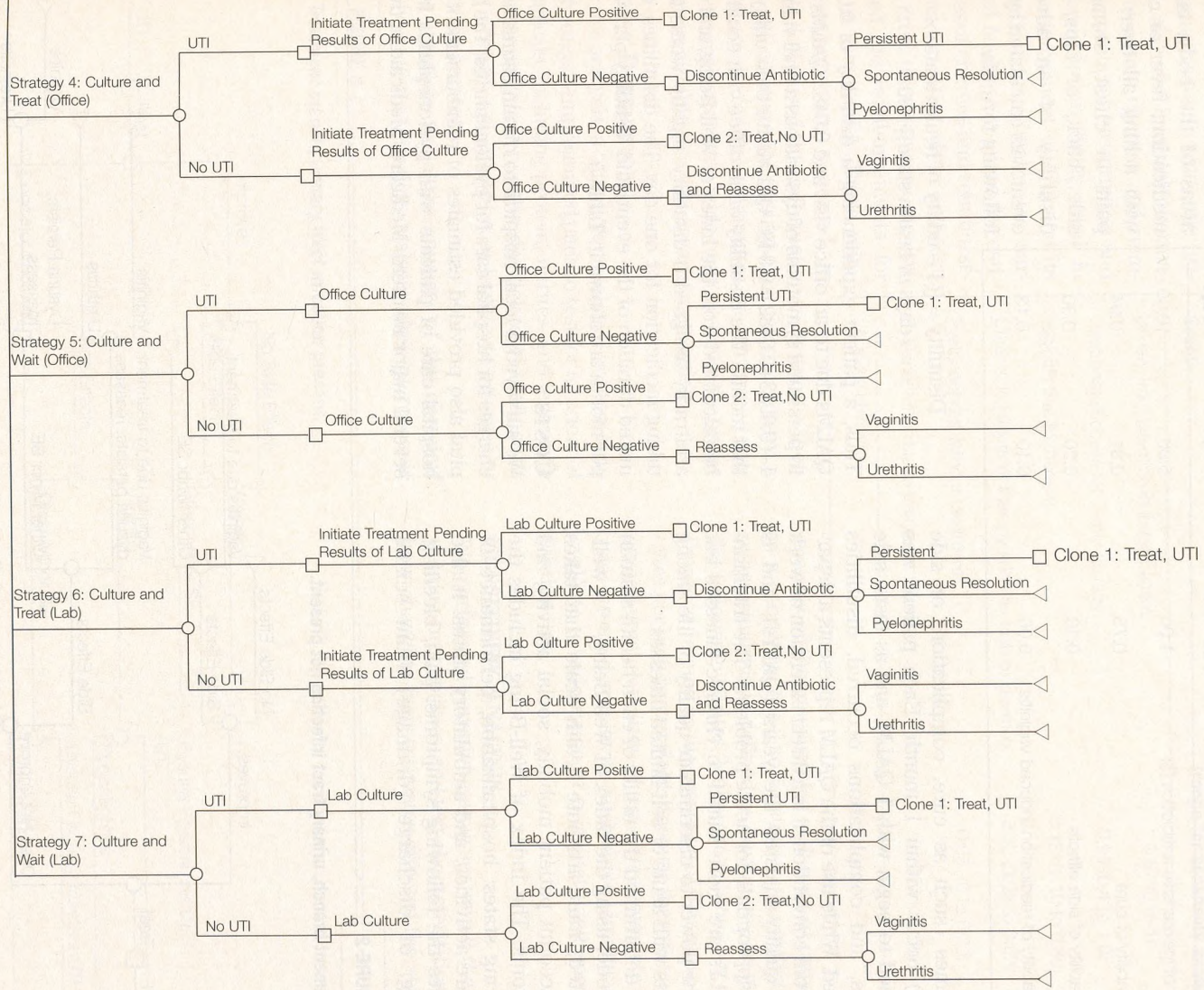


TABLE 3

Comparison of Varying Duration of Therapy

	Single Dose	3 Days	7 Days
Cost of inexpensive antibiotics (\$)	1.00	5.00	10.00
Probability of cure	0.75	0.81	0.94
Probability of side effects	0.10	0.20	0.30
Probability of medication-induced vaginitis	0.06	0.10	0.13

organs; painful, burning, or frequent urination; burning or itching rash on large areas of the body; taking medication; fever or chills with aching all over; and pain in chest, stomach, side, back, or hips. The disutility of an adverse event was calculated by the following formula:

$$\text{Disutility} = [(1 - \text{utility of health state}) \times (\text{days in health state})] / 30$$

outcomes (such as cure, complication, or side effect) occur within 1 month. Each patient was assumed to begin with 1 QALM, and as tests, side effects, and complications occurred, disutilities accrued. While use of the QALM represents a departure from convention, it is a direct extension of work using quality-adjusted life years (QALYs), and is more appropriate for acute problems. The traditional QALYs are more suited to chronic illnesses but lack the power to discriminate quality of life among patients with acute or self-limited illnesses.

We determined the utility of each health state in our model using the Index of Well-Being,⁴⁴⁻⁴⁷ a well-validated, multi-attribute health scale that takes into account patient mobility, social activity, and symptoms. The Index of Well-Being includes the following states: hospitalization, performance of self-care activities, and ambulatory status. It also includes the following symptoms: pain, bleeding, itching, or discharge (drainage) from sexual

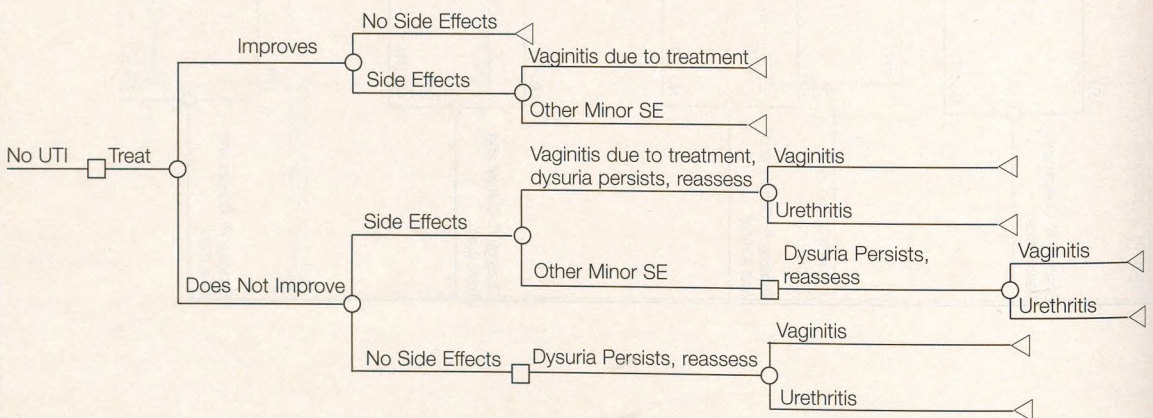
Thus, a patient experiencing a disutility of 0.0033 QALMs due to an office visit and 0.0482 QALMs due to persistent symptoms of dysuria has a final value of $1 - (0.0033 + 0.0482) = 0.9485$ QALMs for their utility for that month. The disutility of an office visit could not be calculated from the Index of Well-Being, and was arbitrarily assigned a disutility slightly worse than taking medication for one day. The disutilities, estimated duration of the event, and disutility per event per month are shown in Table 5.

COSTS

We surveyed a local hospital to obtain estimates of charges for hospital care for pyelonephritis. The hospital also provided estimates of reimbursement for hospital care of patients with pyelonephritis from several major insurers: Medicare, Medicaid, a tradi-

FIGURE 2

Treatment branch, urinary tract infection not present.



tional indemnity insurance plan, and a health maintenance organization. We also surveyed three pharmacies (one chain, one private, and one hospital pharmacy) to obtain charges and reimbursements for prescription and nonprescription drugs used in the management of UTI and its complications. Finally, we surveyed family physicians for estimates of charges and reimbursements for office visits and testing. From these sources, we estimated the reimbursements for use in our model. These reimbursements are reported in Table 6. We used this information to develop a "bottom up" estimate for cost of care. Since we used a small sample for these estimates, we performed sensitivity analyses over a wide range to make the analysis generalizable to a wider variety of settings.

OTHER DEFINITIONS

For this analysis, a "dipstick urinalysis" is a test strip with reagent-impregnated pads to test for a variety of chemicals, including protein, nitrites, and leukocyte esterase activity. A positive dipstick test is defined as one in which either nitrites or leukocyte esterase or both are present.

A complete urinalysis consists of the chemical analysis of the dipstick analysis plus microscopic

analysis of the resuspended sediment of urine spun in a centrifuge for 3 to 5 minutes. A positive complete urinalysis is defined as having one or more of the following: nitrites, leukocyte esterase, or pyuria. Pyuria is defined as the presence of 5 or more leukocytes per high-power field. Because there is no single agreed-upon definition of a positive complete urinalysis, we used sensitivity analysis to simultaneously evaluate a wide range of sensitivity and specificity for that test.

SENSITIVITY ANALYSIS

We performed sensitivity analyses on all the costs, utilities, probabilities, and test characteristics to see how changing their estimates affected the selection

TABLE 4

Probabilities Used in Model

Event	Probability (range for sensitivity analysis)
Urinary tract infection in index patient	0.67 (0 to 1)
Treatment success for 7-day therapy	0.94 (0.4 to 1.0)
Vaginitis due to therapy	0.13 (0.10 to 0.80)
Other side effects of therapy such as rash or diarrhea	0.22 (0.05 to 0.50)
Pyelonephritis without treatment*	0.05 (0 to 0.25)
Pyelonephritis due to treatment failure*	0.01 (0 to 0.5)

* Authors' estimate.

FIGURE 3

Treatment branch, urinary tract infection present.

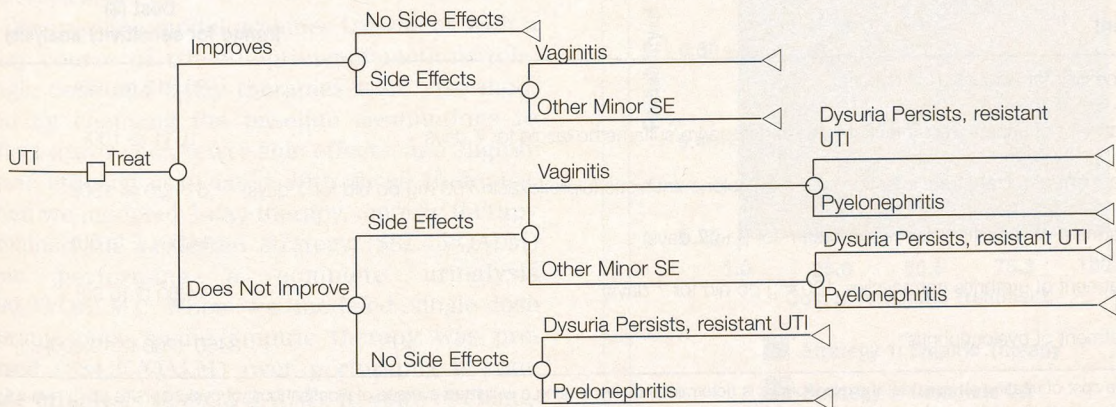


TABLE 5

Disutility, Duration, and Disutility per Month of Each Event in the Cost-Utility Model

Event	Disutility (1 - utility)	Duration of Health State (days)	Disutility per Month (range for sensitivity analysis)
Office visit	0.1	1	0.0033 (0 to 0.2)
Antibiotic treatment	0.01	7	0.0023 (0 to 0.2)
		3	0.001
		1	0.0003
Pyelonephritis	0.3732*	10	0.1244 (0.01 to 0.5)
Vaginitis	0.2894	5	0.0367 (0.01 to 0.2)
Persistent dysuria	0.2894	5	0.0367 (0.01 to 0.2)
Other side effects	0.2894	3	0.0289 (0.001 to 0.1)

* The disutility of pyelonephritis is determined by computing a weighted average of inpatient disutility of pyelonephritis (assuming a 4-day length of stay) followed by 6 days of intensive outpatient therapy.

of the optimal strategy. In one-way sensitivity analysis, the probability of an event is varied over a wide range of estimates. We also performed two-way sensitivity analyses for variables found to be of interest in the one-way analyses.

RESULTS

Table 7 summarizes the cost-effectiveness of each strategy and the marginal cost-effectiveness when

compared with empiric therapy. Using the outcome of cost per quality-adjusted life month (\$/QALM), the most cost-effective strategy was empiric therapy (strategy 1) at \$71.52 per QALM. This strategy is preferred over all others. While it was the lowest cost strategy, other strategies (complete urinalysis, culture and treat, and dipstick testing) were associated with greater utility. The "culture-and-wait" strategies (strategies 5 and 7) not only were

more expensive, they were also less effective and therefore were "dominated" by the preferred strategy. The culture-and-treat strategies (strategies 4 and 6) were associated with the greatest overall effectiveness, but at higher incremental cost.

We performed extensive sensitivity analyses. The decision model was robust because the preferred strategy was consistent over a broad range of values of key variables. Changing two variables modified the preferred strategy of empiric therapy.

TABLE 6

Cost of Events and Treatments in the Cost-Utility Model

Event	Cost (\$) (range for sensitivity analysis)
Office visit for evaluation of dysuria	35 (10 to 100)
Treatment of urinary tract infection with trimethoprim/sulfamethoxazole for 7 days	10 (1 to 100)
Treatment of urinary tract infection with a quinolone antibiotic (ciprofloxacin 750 mg po bid for 7 days)	57 (20 to 150)
Treatment of vaginitis (miconazole cream for 3 to 7 days)	14.50 (2 to 50)
Treatment of urethritis (tetracycline 100 mg po qid for 7 days)	14.50 (2 to 30)
Treatment of pyelonephritis*	3450 (200 to 10,000)

* The cost of treating an episode of pyelonephritis is determined by computing a weighted average of inpatient cost of pyelonephritis (assuming a 4-day length of stay) followed by 6 days of intensive outpatient monitoring and a total of 6 weeks of antibiotic therapy.

TABLE 7

Cost-Utility of Different Strategies for the Management of Acute Dysuria

Strategy	Cost (\$)	Marginal Cost (\$)	Effectiveness (QALMs)	Marginal Effectiveness (QALMs)	Cost-effectiveness (\$/QALM)	Marginal Cost-effectiveness*
Strategy 1: Empiric Therapy (7 days)	69.78	—	0.976	—	71.52	—
Strategy 3: Complete Urinalysis	84.60	14.82	0.981	0.005	86.24	\$2964.00
Strategy 5: Culture and Wait (Office)	96.03	11.43	0.966	-0.015	99.43	Dominated
Strategy 4: Culture and Treat (Office)	97.03	1.00	0.985	0.019	98.51	\$3027.78
Strategy 7: Culture and Wait (Lab)	99.87	2.84	0.967	-0.018	103.29	Dominated
Strategy 6: Culture and Treat (Lab)	100.87	1.00	0.986	0.019	102.29	\$3109.00
Strategy 2: Dipstick Only	118.24	17.37	0.977	-0.009	121.01	\$48,460.00

* The incremental cost for each additional quality-adjusted life month.

py. If the cost of medication exceeds \$74.50 or if the probability of having a UTI is less than 0.30, then performing a complete urinalysis is the preferred scheme.

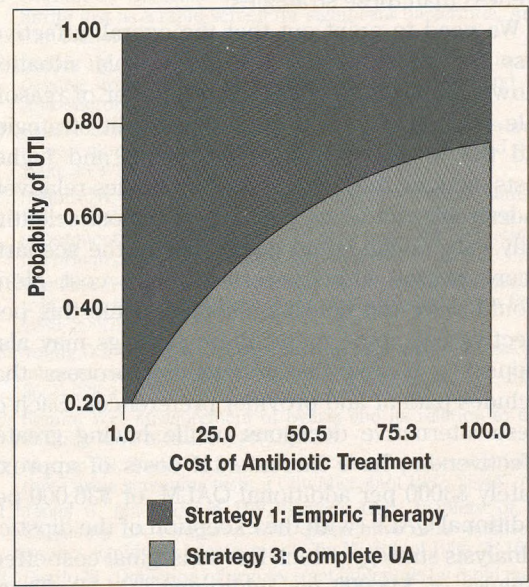
We also performed two-way analyses. The two-way sensitivity analyses were generally no more revealing than the one-way sensitivity analyses. The two-way sensitivity analysis on cost of antibiotic therapy and the probability of having a UTI (Figure 4) shows that as the cost of antibiotic therapy increases, a greater probability of having a UTI is needed for empiric therapy to remain the preferred strategy.

The baseline model assumes treatment with a 7-day course of trimethoprim-sulfamethoxazole. Single dose and 3-day therapies were also modeled by changing the baseline assumptions to reflect lower cost, fewer side effects, and slightly lower efficacy associated with these therapies. When we modeled 3-day therapy, empiric therapy remained the preferred strategy (\$81.45/QALM) over performing a complete urinalysis (\$96.03/QALM). When we modeled single-dose therapy, once again, empiric therapy was preferred (\$84.35/QALM) over performing a complete urinalysis (\$99.22/QALM). In spite of changing these baseline assumptions, 7 days of empiric

therapy appears to be the most cost-effective strategy. In all cases, empiric therapy was preferred over all other strategies.

FIGURE 4

Two-way sensitivity analysis on cost of antibiotic therapy and probability of UTI.



DISCUSSION

Empiric therapy for 7 days for all women aged 18 to 50 years who present with acute, uncomplicated dysuria was the most cost-effective strategy for a broad range of assumptions. The empiric therapy strategy in the management of uncomplicated UTIs, while representing a departure from prevailing recommendations, is consistent with recommendations of some authors.¹⁵ Clinicians should refer to the graph in Figure 4 to identify the most cost-effective strategy for their particular setting and patient population.

If we were to consider cost alone, as many insurers might, empiric therapy is a clear winner. UTIs account for over 7 million physician visits per year.⁴⁸ If only half of these visits fit our scenario, empiric therapy has the potential of saving over \$50 million each year (compared with performing a complete urinalysis). It is interesting to point out that performing a complete urinalysis was cheaper for a total episode of care than doing a dipstick test alone, although the latter is being advocated by several authors and several managed care organizations as a less expensive alternative. While the cost of the individual test is relatively inexpensive, the ramifications of misdiagnosis and subsequent treatment decisions make using dipstick testing more costly. Empiric therapy, however, had lower overall effectiveness than these strategies.

We need to point out that the overall effectiveness for all strategies was high. This situation allows clinicians to engage in a number of reasonable options. The two culture-and-wait strategies had the lowest overall effectiveness and higher costs, making these dominated strategies relatively undesirable (although probably the most scientifically valid). One could argue that in the scenario where overall effectiveness is high, cost alone should drive the decision-making. While this perspective has some merit, these findings may also support a shared decision-making process that includes patient and provider preferences. Each of these alternative decisions, while having greater effectiveness, have incremental costs of approximately \$3000 per additional QALM, or \$36,000 per additional QALY (with the exception of the dipstick urinalysis strategy, which has a marginal cost-effectiveness of \$48,000 per additional QALM). These

compare favorably with the marginal cost-effectiveness of other medical interventions such as caring for premature infants (weighing between 1000 and 1500 g) in neonatal intensive care units (\$8000 per QALY gained),⁴⁹ managing hypertension in a 40-year-old (\$16,500 per QALY gained),⁵⁰ or single vessel coronary artery bypass graft surgery (\$64,000 per QALY gained).⁵¹

Our analysis has several strengths. First, our model is quite robust. Extensive sensitivity analysis over a wide range of values had minimal effect on the preferred strategy as noted above. Second, the strategies we tested are realistic, and include strategies commonly used by family physicians. Third, we were able to obtain realistic estimates of charges and reimbursements from a variety of vendors and insurers. Fourth, we were able to obtain detailed information from the literature on the probabilities, sensitivities, and specificities used in the model. The exception: the test characteristics (sensitivity and specificity) of a full urinalysis. Most investigators have studied the accuracy of either the dipstick test or the microscopic examination not both together. Nevertheless, extensive sensitivity analyses of these test characteristics did not affect the preferred strategy.

Our study has several limitations. First, we did not address the issue of anaphylaxis or other serious reactions such as blood dyscrasias and Stevens-Johnson syndrome. We felt these to be rare events that would be approximately equally distributed across the strategies. Second, we used a payer perspective, which does not fully reflect opportunity and societal costs. Examples of other costs not included in this perspective are transportation, lost wages, and child care. Third, we did not address the issue of chronic pyelonephritis, which could result from delayed treatment; we included only short-term outcomes. If anything, consideration of the latter issue would be expected to favor a strategy of overtreatment such as empiric therapy. Fourth, this analysis is also unable to assess the potential long-range impact of altering the antibiotic resistance of the patient's microbial milieu. As such, the recommendations in favor of empiric therapy should be limited to the scenario where decisions are made in the context of an encounter with a health care provider. Finally, empiric therapy may not adequately treat sexually transmitted diseases, which may account for a significant proportion of women

presenting with acute dysuria. Stamm³² found no dysuric patients with *Neisseria gonorrhoeae*; however, up to 1 in 4 were infected with *Chlamydia trachomatis*. These women presented to either a university student health center or a Public Health Service walk-in clinic and were therefore at higher risk for sexually transmitted disease. While the sequelae of inadequately treating these conditions can be significant, empiric therapy would presumably be accompanied by a warning to return within 3 days if symptoms do not resolve or to return immediately if they worsen.

CONCLUSIONS

This analysis shows that the most cost-effective approach to an otherwise healthy woman aged 18 to 50 with a suspected UTI is empiric antibiotic treatment for 7 days. When the cost of a course of antibiotics is high (over \$74.50) or the probability of having a UTI is very low (less than 30%), a complete urinalysis should guide therapy.

Empiric therapy for acute dysuria, an approach traditionally used by many family physicians, is more cost-effective than more "scientific" strategies involving diagnostic tests. Future work will use this model to analyze the cost-effectiveness of approaches that do not involve an office visit, such as empiric therapy by telephone, or therapy based on a strategy where patients "drop off" a urine specimen. Such strategies may be preferred, especially in a managed care setting. Finally, clinical trials should compare patient-oriented outcomes among actual patients to confirm these results.

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