Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Twenty-eight office-based strategies for the evaluation and management of dysuria were compared. The strategies comprised all reasonable combinations of urinalysis, urine culture, pelvic examination, chlamydia and gonorrhoea cultures, and empiric treatment with trimethoprim-sulfamethoxazole (tmp-smx).

Type of intervention
Screening and treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised a hypothetical cohort of healthy women aged less than 65 years old presenting to the office with fewer than 7 days of dysuria, accompanied by urgency or frequency. Women who appeared to have vaginal discharge, fever, flank pain, nausea or vomiting were not included. Pregnant women and those with diabetes, immunosuppression, or a history of urinary tract abnormalities were also excluded.

Setting
The setting was a primary care practice. The economic study was carried out in the USA.

Dates to which data relate
The effectiveness data were derived from studies published between 1965 and 2001. The cost data were derived from sources published between 1996 and 2003. The price year was stated to be 2002.

Source of effectiveness data
The effectiveness data were derived from a review and synthesis of completed studies, augmented by some authors’ assumptions. It was not apparent from the paper that the review was systematic.

Modelling
The authors constructed a recursive decision tree using a standard computer program (Decision Maker 7.06, Pratt Medical Group, Boston) to analyse the expected outcomes of the 28-office-based strategies. Further details of the model were not reported.

Outcomes assessed in the review
The input parameters used in the model were numerous. They included:
the probabilities of etiologic agents;

test characteristics such as sensitivity and specificity;

antibiotic efficacy;

natural history; and

the probabilities of adverse events.

Study designs and other criteria for inclusion in the review
Not reported.

Sources searched to identify primary studies
Not reported.

Criteria used to ensure the validity of primary studies
Not reported.

Methods used to judge relevance and validity, and for extracting data
Not reported.

Number of primary studies included
Forty-two studies provided the effectiveness data.

Methods of combining primary studies
In many cases the authors do not appear to have combined the results of the primary studies. Where the study results were combined, the methods used were not reported.

Investigation of differences between primary studies
Not stated.

Results of the review
The authors fully reported all input variables for the model.

The probabilities of etiological agents were 0.67 for cystitis, 0.07 for chlamydia, 0.07 for vaginitis, 0.03 for gonorrhoea, and 0.02 for herpes.

The authors also reported the probabilities of bacteriuria and of pyuria in cystitis, chlamydia, vaginitis, gonorrhoea, herpes, and urethral syndrome.

Antibiotic efficacy was as follows:

for cystitis, tmp-smx 0.96, quinolones 0.96, no treatment (per 2 days) 0.05;

for acute urethral syndrome (AUS), overall antibiotics 0.86, no treatment (per 2 days) 0.35;

for AUS (and pyuria), antibiotics 1.00, no treatment (per 2 days) 0.12;
for AUS (without pyuria), antibiotics 0.76, no treatment (per 2 days) 0.51;
for bacteria resistant to tmp-smx, 0.16;
for bacteria resistant to quinolones, 0.02;
for antibiotics against resistant organisms, 0.50;
for symptoms improving despite antibiotic failure, 0.59;
for systems persisting despite bacterial eradication, 0.05.
The probabilities of adverse events were also reported.

**Methods used to derive estimates of effectiveness**
The authors made assumptions to derive some estimates of effectiveness.

**Estimates of effectiveness and key assumptions**
As far as the antibiotic efficacy was concerned, the authors assumed that women with nonbacterial urethritis and vaginitis would not respond to antibiotics. In addition, some diseases (e.g. chlamydia) were assumed not to improve without treatment.

**Measure of benefits used in the economic analysis**
The primary outcome measure used was the symptom-day avoided. This was derived directly from the model.

**Direct costs**
The costs were estimated from the perspective of the medical payer (patient or insurer) and were derived from various published sources. The costs included in the analysis could be categorised as physicians’ fees, cost of tests, hospital fees, cost of drugs for treatment, and cost of allergic reactions. Physicians’ fees covered office visits, emergency room, intramuscular injection, intravenous therapy, inpatient consultation, and the physician bill for subsequent hospital days. The drug costs reflected the average wholesale price, but the price year was not reported. All the costs were adjusted to 2002 levels, but details of the adjustment were not reported. Discounting was not carried out, which was appropriate since the costs appear to have been incurred in less than 2 years.

**Statistical analysis of costs**
The costs were treated deterministically.

**Indirect Costs**
The indirect costs were not included.

**Currency**
US dollars ($).

**Sensitivity analysis**
A one-way sensitivity analysis was carried out on each variable in the model, using ranges derived from the literature. In addition, a two-way sensitivity analysis was conducted by running each one-way analysis against the published prevalence of disease from four actual settings (two walk-in clinics, university health service, family practice), as derived from published studies.
The authors acknowledged that their base-case analysis used conservative cost estimates derived from the Medicare fee schedule and average wholesale prices for drugs. Therefore, they tried to substitute costs from the physicians’ fee reference (published in 1996) and neighbourhood pharmacy charges. The price year for the neighbourhood pharmacy charges was not reported.

**Estimated benefits used in the economic analysis**
The average symptom-days ranged from 4.72 in the empiric treatment group (treat all patients without testing) to 4.04 in the routine testing without urinalysis group (i.e. pelvic examination, urine culture, gonorrhoea and chlamydia cultures, and treatment). The side effects of medication were considered in the economic analysis.

**Cost results**
The total costs were not explicitly reported, whereas the average costs for each of the 28 strategies were reported.

The average cost ranged from $90.92 per episode in the empiric treatment group to $147.58 per episode in the routine testing without urinalysis group.

**Synthesis of costs and benefits**
Three urinalysis strategies and two non-urinalysis strategies dominated all other strategies. These strategies included empiric antibiotics with tmp-smx for undiagnosed patients at the end of the initial visit. All three urinalysis strategies began with pelvic examination and urine culture for patients with normal urinalysis. Compared with empiric antibiotics alone, this basic strategy resulted in a marginal cost of $3.96 per symptom-day avoided. Adding urine culture for patients with pyuria resulted in a marginal cost of $64 per symptom-day avoided, while including gonorrhoea and chlamydia cultures at the pelvic examination resulted in a cost of $126 per symptom-day avoided. Strategies without urinalysis were less cost-effective.

The authors used sensitivity analyses to examine the potential effects of local variables on the cost-effectiveness of the different strategies. The most sensitive parameters appear to have been the probability of cystitis, antibiotic resistance, aversion to pelvic examination, and sulphur allergy. When the authors substituted costs from the physicians’ fee reference and neighbourhood pharmacy charges the order of the strategies did not change, but the marginal cost-effectiveness per symptom-day avoided was increased as much as 10-fold for some strategies.

**Authors’ conclusions**
The authors reported that the findings of their study indicated that the value of any test depends on its context in the larger management strategy. For instance, the cost-effectiveness of urine culture depends, for example, on whether it is performed on all women or only on those with normal urinalyses, whether a pelvic examination is performed, whether the patient receives empiric antibiotics while awaiting culture results, and whether gonorrhoea and chlamydia cultures are also performed.

**CRD COMMENTARY - Selection of comparators**
The authors evaluated a total of 28 office-based strategies for the evaluation and management of dysuria. The interventions chosen comprised all reasonable combinations of urinalysis, urine culture, pelvic examination, chlamydia and gonorrhoea cultures, and empiric treatment with tmp-smx. The rationale of the study was the variation observed among researchers and the lack of consensus about the most appropriate and cost-effective management strategy for dysuria. You should decide which of the comparators represents current practice in your own setting.

**Validity of estimate of measure of effectiveness**
The source of the effectiveness data was a review and synthesis of published studies. The authors did not state that a systematic review of the literature was carried out. It is therefore possible that the data from the available studies were used selectively. The authors did not note any differences between the efficacy estimates from the primary studies.
There was little comment on the quality of the retrieved studies, making it difficult to comment on the quality of the efficacy estimates. However, the authors carried out a number of sensitivity analyses relating to the efficacy estimates. These analyses help to improve both the internal validity and the generalisability of the study by demonstrating the robustness of the results to changes in the base-case estimates. However, without better reporting on how the effectiveness evidence was identified and retrieved, it is difficult to make a firm judgement.

**Validity of estimate of measure of benefit**
The estimation of benefits (symptom-day avoided) was modelled. The authors estimated, from the model, the average number of symptom-days associated with each strategy. The rationale for this choice was the fact that patients with dysuria seek medical attention primarily to alleviate symptoms.

**Validity of estimate of costs**
The authors conducted their economic analysis from the perspective of the medical payer. As such, it seems that all the categories of cost relevant to the perspective adopted have been included. In some categories (e.g. hospital fees) the use of summary costs makes it impossible to determine what aspects of costs were included within the category. All the costs were derived from published sources and were adjusted to the year 2002, but no details of the adjustment were reported. The cost of drugs reflected average wholesale prices, but the price year was not reported. For the physicians’ fees, the authors used the Medicare fee schedule and reported that these cost estimates might be fairly conservative. Subsequently, they tried to substitute them with costs from the physicians' fee reference and neighbourhood pharmacy charges, which resulted in a 10-fold increase of the marginal cost-effectiveness per symptom-day avoided. No further sensitivity analysis of the prices was conducted. The authors reported the unit costs but the quantities of resources used were not reported separately. Since all the costs appear to have been incurred in less than 2 years, discounting was unnecessary and, appropriately, was not undertaken.

**Other issues**
The authors did not make appropriate comparisons of their finding with those from other studies, as other decision models and analyses had limited themselves to the assessment of a single study. The cost estimates and efficacy data appear to have been based on US estimates and evidence. This may limit the generalisability of the study beyond the USA for settings with different demographic and epidemiological characteristics in their population. However, the issue of generalisability to other settings was addressed, as the authors used their model to derive an algorithm to take local conditions (e.g. antibiotic resistance, prevalence of disease, and patient preferences) into consideration, given a value for a day of dysuria avoided. Two algorithms were constructed. The first applied to women with dysuria, but no vaginal symptoms, presenting to a physician's office or to a university health service. The second applied to a family practice environment, which also includes those patients with some vaginal symptoms. The effects of local factors are quite important. The authors stressed the need to collect local clinical information, such as data about the clinical setting and its prevalence of disease (walk-in clinic versus family practice versus university health service), antibiotic resistance patterns, and how much it is reasonable to spend to prevent one day of dysuria.

**Implications of the study**
The authors concluded that empiric therapy is never preferred. In addition, they mentioned that their model highlights the importance of collecting local clinical information. The authors did not make any recommendations for changes in policy or practice. However, they stated that any doctor or clinic could generate a locally tailored algorithm by entering local clinical information into their model, provided that relevant data (clinical setting, prevalence of disease, antibiotic resistance patterns, etc.) are available at the local level.

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