The cost-effectiveness of placing urinary tract infection treatment over the counter
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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
Urinary tract infection treatment (UTI) available over-the-counter.

Type of intervention
Treatment (mode of service delivery).

Economic study type
Cost-effectiveness analysis.

Study population
A hypothetical cohort of women with symptoms of UTI. High-risk subpopulations such as diabetics, pregnant women, women with AIDS, and women with structural abnormalities of the urinary tract, were not considered in the study.

Setting
Primary care. The economic study was carried out in Michigan, USA.

Dates to which data relate
The main effectiveness data were extracted from published studies dated 1990, 1991, and 1994. Resource use and cost data were mainly derived from studies published in 1978-1995. The price date was 1994.

Source of effectiveness data
Estimates of effectiveness were based on a review of previously published studies.

Modelling
A probability model was used to estimate costs and benefits over a 20-year time period. The model incorporated costs associated with drug treatment (a 3-day regimen of oral antibiotics, trimethoprim-sulfamethoxazole) and doctors' visits as well as the costs associated with over-the-counter diagnostic test tools. The model thus aimed to provide insights into the implications of greater access and convenience for resource use and health benefits and risks (increased resistance to antibiotics) of UTI treatment. The intended perspective was that of society.

Outcomes assessed in the review
The main outcomes were UTI prevalence, incidence, diagnosis, misdiagnosis and treatment for uncomplicated UTI in ambulatory cases.

Study designs and other criteria for inclusion in the review
Sources searched to identify primary studies
Not stated.

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

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

Number of primary studies included
Approximately 12 studies.

Methods of combining primary studies
Where relevant the authors used the median value from the studies considered. The median was used in order to avoid estimates skewed by a few extreme cases.

Investigation of differences between primary studies
Not stated although the above shows that the authors considered these differences in utilising the median value.

Results of the review
The prevalence of urinary symptoms was 5.8%. 50% of women reporting symptoms at any one time have UTI and the remaining 50% represent the number who could potentially misdiagnose and therefore incorrectly treat their symptoms. The total annual urinary symptoms were estimated to be 6.3 million (3.6 million actual and 2.7 million misdiagnosed). Doctor visits were estimated to be 3.14 million/year. Cases using drug treatment were estimated to be 2.4 million (1.6 million actual and 0.8 million misdiagnosed). Symptom days were estimated to be 18.9 million. The days of restricted activity was estimated to be 7.5 million. Bed days were estimated to be 2.5 million. The resistance to treatment was estimated to be 18% and the growing resistance was assumed to be a 5.55% change each year. A 20% reduction in doctor visits for UTI each year was assumed.

Methods used to derive estimates of effectiveness
Authors' opinions, likely to be based on manufacturers's test specifications.

Estimates of effectiveness and key assumptions
In the second scenario the authors assumed a sensitivity and specificity for the diagnostic test (Meridian Diagnostics, Cincinnati, OH) of 96.5% and 79.7%, respectively.

Measure of benefits used in the economic analysis
The measure of benefits was the number of restricted activity days, bed days, and symptom days avoided. Also, the number of resistant cases avoided (incurred) was reported. These benefits were estimated using a model which covered a 20-year period and discounted the corresponding annual flow benefits accruing to the intervention. The model reported benefits only for the assumed 57% proportion of symptomatic women actually having UTI.
**Direct costs**
Doctor visits (assuming that in most cases a urine culture is not ordered), and oral antibiotic treatment for UTI were included in the costing exercise. Major quantities were reported separately from the costs. Treatment costs were based on average wholesale prices from 1995. Total costs were estimated using a model covering a 20-year time period, with those costs being discounted. The quantity/cost boundary adopted was the hospital/clinic, the patient (out-of-pocket expenditures) and the third-party payer (insurer). The resource use data were derived from data from a 1994 study on the effects of over-the-counter availability of yeast infection remedies in terms of doctor visits and the number of annual doctor visits from a 1981 study (both were US studies). The price date was 1994.

**Currency**
US dollars ($).

**Sensitivity analysis**
A one-way sensitivity analysis was performed on the proportion of women visiting a doctor, the proportion of mistreated cases, the proportion of women who would still see a doctor if treatment were available over-the-counter, and the price of the dipstick (diagnostic test kit) as part of the over-the-counter treatment package. A threshold analysis (point at which the net costs would be zero) was used to report the results associated with the most influential parameters.

**Estimated benefits used in the economic analysis**
The intervention (over-the-counter) including the dipstick diagnostic kit in the treatment package would result in an overall reduction of 54.8 million total symptom days, assuming no increased resistance to drug therapy, and 78.2 million reduced total symptom days, assuming an increase in resistance to drug therapy of 5.55% per year. The second scenario investigated, namely that of the proper use of the diagnostic kit, was associated with 52.1 million and 75.4 million reduced total symptom days, respectively, for the same assumptions regarding resistance. In all the above calculations, a discount rate of 3% was applied and a hypothetical cohort of 6.3 millionsymptomatic women per year served as the basis for the corresponding results.

**Cost results**
As above, based on a hypothetical cohort of 6.3 million of symptomatic women and using a 5% annual discount rate, the intervention antibiotic treatment sold along with a dipstick was associated with incremental costs of +$301 million for the intervention without proper use of the dipstick and +$103 million for the intervention in combination with proper use of the diagnostic test.

**Synthesis of costs and benefits**
The cost per total symptom day avoided (combined bed days, restricted activity days and symptom days avoided) at 1994 prices and using discount rates of 5% and 3%, respectively, was used to synthesise costs and benefits associated with the intervention. The corresponding estimate was $5.50 for the scenario of an intervention with no proper use of the dipstick test and $1.97 assuming an intervention with a proper use of such a diagnostic tool. The sensitivity analysis showed that, only if doctors' visits were reduced to 64.6% of current levels, would the net costs of the over-the-counter treatment policy be zero. The results were most sensitive to the parameter representing the proportion of women experiencing symptoms who present to a doctor.

**Authors' conclusions**
The costs of over-the-counter distribution of UTI treatment, particularly those due to the risk of decreasing the time until standard treatments become ineffective due to bacterial resistance ("antibiotic resistance sweeps geographic areas seemingly overnight"), outweigh the short-term gains of decreased symptom days and increased access to treatment.
CRD COMMENTARY - Selection of comparators
The reason for the choice of comparator(s) is clear. The delivery of UTI treatment by medical prescription is the standard of practice in the USA. UTI therapy is an attractive candidate for over-the-counter sale because of the possibility of UTI self-diagnosis and treatment.

Validity of estimate of measure of benefit
The estimate of benefit used in the economic analysis was based on a review of the literature and median values. It is not possible to judge if all relevant literature were identified as the authors did not describe their search strategy. Other methods of combining the findings of studies such as meta-analysis were not considered although the potential pitfalls of combining data were presumably taken into account through the approach adopted.

Validity of estimate of costs
Adequate details of methods of quantity/cost estimation were given. It seems, however, that the costs associated with the treatment of recurrences were not included in the analysis or, at least, that they were assumed to be common. In that case this may represent a source of bias in the results.

Other issues
The authors’ conclusions were justified in terms of the sensitivity analysis, given the uncertainties in the data. The issue of generalisability to other settings was not addressed, although appropriate comparisons were made with other studies.

Implications of the study
Further prospective studies may help in validating the results reviewed here.

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