Mechanism of action and impact of a cystitis clinical practice guideline on outcomes and costs of care in an HMO

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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
Cystitis clinical practice evidence-based guideline (including the use of specified antibiotics for three days without obtaining urine culture) in the treatment of uncomplicated cystitis in female patients aged 18 to 64 years.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
Female patients aged 18 to 64 years with uncomplicated cystitis (i.e. having one of the following symptoms of cystitis: dysuria, urinary frequency, and urinary urgency).

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

Dates to which data relate
The study was carried out in 1995 and involved the review of records related to effectiveness and resource use data corresponding to patients treated during two three-month periods (1 August - 31 October 1993, and 1 August - 31 October 1994). The price year was 1995.

Source of effectiveness data
Effectiveness data were derived from a single study.

Link between effectiveness and cost data
Costing was retrospectively performed on the same patient sample as that used in the effectiveness analysis.

Study sample
Power calculations were not used to determine the sample size. The study sample consisted of 201 patients in the pre-guideline group (from a total of 342 charts available for 355 women potentially eligible to be treated under the cystitis guideline) as compared to 241 patients in the post-guideline group (from a total of 431 charts available for 487 women potentially eligible to be treated under the cystitis guideline). Patients with pregnancy, diabetes mellitus, immunocompromise, renal calculi, renal insufficiency, known urologic abnormalities, urinary tract catheterisation within the previous 2 weeks, hospitalisation or nursing home stay within the previous 2 weeks, 4 or more episodes of
urinary tract infection within the previous 2 weeks, nausea, vomiting, abdominal pain, symptoms of cystitis for more
than seven days, shaking chills, fever of more than 100 degrees F, flank pain, abnormal vaginal discharge, dyspareunia,
or high-risk behaviours for sexually transmitted diseases, were excluded from the study sample.

Study design
Retrospective cohort study, carried out in 5 out of 19 primary care practices of a staff-model health maintenance
organization (HMO). The duration of the follow up was 21 days. Only patients whose follow-up data was available were
included in the sample. Two experienced research nurses reviewed the medical records.

Analysis of effectiveness
The analysis of effectiveness appears to have been based on treatment completers only. The clinical outcome measures
were the proportion of patients receiving a second course of an antibiotic within a 21-day period for cystitis or its
complicating or competing diagnoses, the proportion of patients with more than one cystitis-related visit in the 21-day
period, the proportion of patients assigned a competing or complicating diagnosis within 21 days of the initial cystitis
diagnosis, and the proportion of patients with a cystitis-related emergency room visit or hospitalisation within 21 days.
The results related to the key elements of the guideline were also reported. Those were: use of specific recommended
antibiotics, use of three-day course of antibiotics, non-use of urine culture, and nurse co-ordination of care under the
direct supervision of a physician. The percentage of patients initially receiving from zero to four of the above-
mentioned recommended components was also reported. The authors did not discuss comparability of groups.

Effectiveness results
The effectiveness results were as follows:

10.9% of patients in the pre-guideline group received a second course of an antibiotic within 21-day period for cystitis
or its complicating or competing diagnoses versus 9.6% in the post-guideline group (p>0.05).

Patients with more than one cystitis-related visit in the 21-day period were 12.4% in the pre-guideline group versus
16.5% in the post-guideline group (chi-square 0.89, p>0.05);

patients assigned a competing or complicating diagnosis within 21 days of the initial cystitis diagnosis, 0 in the pre-
guideline group versus 1 in the post-guideline group (p>0.05);

patients with a cystitis-related emergency room visit or hospitalisation within 21 days, 1 in the pre-guideline group
versus 0 in the post-guideline group (p>0.05).

The results related to the use of specific recommended antibiotics were 83% in the pre-guideline group versus 86% in
the post-guideline group (chi-square 0.91, p=0.34).

The values for the use of a three-day course of antibiotics were 28% in the pre-guideline group versus 52% in the post-
guideline group (chi-square 25.01, p<0.001);

use of urine culture, 70% in the pre-guideline group versus 37% in the post-guideline group (chi-square 48.19,
p<0.001);

and nurse co-ordination of care under the direct supervision of a physician, 21% in the pre-guideline group versus 78%
in the post-guideline group (chi-square 142.93, p<0.001).

The percentages of patients initially receiving from zero to four of the components of the guideline (nurse co-ordinated
care, no urine culture, use of a recommended antibiotic, and/or use of a three-day antibiotic course) were as follows:

Zero: Pre-guideline, 9%; Post-Guideline, 3%,

One: Pre-Guideline, 35%; Post-Guideline, 13%,
Two: Pre-Guideline, 44%; Post-Guideline, 24%.
Three: Pre-Guideline, 12%; Post-Guideline, 28%.
Four: Pre-Guideline, 0%; Post-Guideline, 32%.

Clinical conclusions
Although the cystitis clinical guideline appears to have achieved all it was designed to do, a closer analysis of the results of the guideline showed that desired changes in use of antibiotics and urine cultures were limited to cases co-ordinated by nurses. When physicians managed patients with cystitis, there was no significant change in use of three-day antibiotic treatment or in use of urine cultures despite guideline recommendations.

Measure of benefits used in the economic analysis
No summary benefit measure was identified in the economic analysis, and only separate clinical outcomes were reported.

Direct costs
Costs were not discounted due to the short time frame of the study. Quantities were reported separately from the costs and cost items were reported separately. Cost analysis covered the costs of a cystitis physician visit at the HMO, cystitis care managed by a nurse, urine culture, a urinalysis with microscopic exam, and a three-day and 10-day course of generic trimethoprim-sulfamethoxazole. The perspective adopted in the cost analysis was not explicitly specified. The source of cost data was the HMO. The chief economist of the HMO and his staff calculated the average cost for each cystitis-related element of care in order to eliminate the variation between practices. The date of the price data was 1995. The study did not cover the costs of implementing the cystitis guideline.

Statistical analysis of costs
A T-test was used to compare the study groups in terms of mean cost per patient and cost components.

Indirect Costs
Not considered.

Currency
US dollars ($).

Sensitivity analysis
A series of one-way sensitivity analyses was performed on the cost of drugs, recommended drugs, and accounting practices used to estimate the cost of nursing time.

Estimated benefits used in the economic analysis
Not applicable.

Cost results
The mean cost per patient for the post-guideline group was $25.08 less than for the pre-guideline group, leading to about 35% savings due to the use of the guideline.
Synthesis of costs and benefits
Not combined.

Authors' conclusions
Use of the guideline was associated with desirable changes in antibiotic use, nurse co-ordination of care, costs of care, and comparable clinical outcomes. Clinics that used clinical systems and tools to support nurse co-ordinated cystitis care had greater guideline adherence than clinics that did not support nurse co-ordinated care.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator is clear, as it was the usual practice before the implementation of the guidelines in the authors' setting.

Validity of estimate of measure of benefit
The internal validity of the effectiveness results cannot be guaranteed due to the retrospective nature of the study design. Only patients with completed medical records were included in the analysis and it is not clear whether patients groups were comparable or not in their baseline characteristics.

Validity of estimate of costs
Quantities were reported separately from the costs and adequate details of methods of cost estimation were given. As acknowledged by the authors, indirect costs could have been included in the analysis (e.g. time lost from work). The cost results may not be generalisable to other settings, as acknowledged by the authors. As the effectiveness study showed similar effectiveness for the comparator and the intervention the study may be classified as a cost-minimisation analysis.

Other issues
The authors' conclusion should be interpreted in the light of the potential biases arising from the study design. Further details of the sensitivity analyses would have been helpful. The issue of generalisability to other settings or countries was not systematically addressed. However, appropriate comparisons were made with other studies.

Implications of the study
The results observed should be tested for their durability over longer periods, in other care system, and with different provider group and patient populations.

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