Improving initial management of lower urinary tract symptoms in primary care: costs and patient outcomes

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
The study examined a distance learning programme for general practitioners (GPs) for the treatment of lower urinary tract symptoms (LUTS) in middle-aged to elderly men. The distance learning programme contained a package for individual learning (PIL) as well as the following:

- consultation-supporting materials;
- the guidelines summarised in the form of a decision tree and a short explanation; and
- two information leaflets for patients, one on prostate-specific antigen (PSA) testing and the other on the treatment for LUTS.

The comparator was the existing national guidelines on LUTS.

Type of intervention
Other: Information and education in health.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised male patients with LUTS over 50 years of age, with or without indications for benign prostatic hyperplasia, who visited their GP. The exclusion criteria were patient in the terminal phase of a disease, patient unable to complete a questionnaire because of cognitive problems, known prostate carcinoma, a urostomy, or bladder catheterisation.

Setting
The setting was primary care. The economic study was carried out in the Netherlands.

Dates to which data relate
The dates to which the effectiveness evidence and resource use referred were not reported. However, they might have been reported in two published studies on the distance learning programme (Wolters et al. 2004 and 2005, see 'Other Publications of Related Interest' below for bibliographic details). The price year was 2002.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same patient sample that provided the effectiveness data.
Study sample
The study was designed to detect a 20% decrease in PSA test requests. Assuming that each GP would be able to recruit 3 patients, 180 patients from 60 GPs were required. A 30% loss to follow-up was assumed, meaning that 86 GPs would in fact be required. A random sample of 1,500 GPs was invited to take part in the study. Of these, 142 GPs showed some level of interest and were allocated to one of the two groups. There were 70 GPs in the intervention group and 72 in the control group. Then, 45 GPs in the intervention group returned the PIL and formed part of the study, while 44 GPs in the control group returned notes. Finally, 32 GPs in the intervention group recruited 95 patients and 31 GPs in the control group recruited 92 patients.

Study design
The study was a cluster, randomised controlled trial that was conducted in multiple centres. Details of the method of randomisation and blinding were not given, although they might have been described in the earlier studies (Wolters et al. 2004 and 2005). The duration of follow-up was 3 months. By the time of the initial consultation, the loss to follow-up was 36 in total (20 in the intervention group and 16 in the control group). At the 3-month consultation, the loss to follow-up was 65 in total (39 in the intervention group and 26 in the control group).

Analysis of effectiveness
The primary health outcome of the study was the patient-reported urinary symptom level, assessed using the International Prostate Symptom Score (IPSS). The basis of the analysis appears to have been treatment completers only, but this was not explicitly stated. The groups were shown to be comparable at baseline.

Effectiveness results
At baseline, the number of patients reporting minor, moderate and severe LUTS were 10 (13%), 49 (65%) and 16 (21%), respectively, in the intervention group and 9 (12%), 48 (63%) and 19 (25%) in the control group.

At 3 months, the number of patients remaining was 122 (56 in the intervention group and 66 in the control group). The numbers reporting minor, moderate and severe symptoms were 15 (27%), 37 (66%) and 4 (7%), respectively, in the intervention group and 19 (29%), 40 (61%) and 7 (11%) in the control group.

Clinical conclusions
The authors concluded that patient-reported urinary symptoms at 3 months did not differ between the study groups.

Measure of benefits used in the economic analysis
The measure of benefit used in the economic analysis was a one-point movement on the urinary symptom scale.

Direct costs
The study reported the direct costs to the health service. These comprised the material costs, GP time relating to the distance learning programme or reading of the guidance, initial consultations, and costs of health care received. The costs of developing the clinical guideline and educational programme were not included, as both had been developed for the total population of GPs in the Netherlands. The cost estimates were based on reimbursement prices, while quantities were based on physician (GP time and use of health care) or patient (number of follow-up consultations) reports. The costs were reported as the mean cost per patient. The costs were not discounted. The price year was 2002. Where necessary, price information was extrapolated to 2001 using an inflation rate of 4% per year.

Statistical analysis of costs
Between-group differences in mean total costs were examined using a t-test and non-parametric Mann-Whitney U-test.
Indirect Costs
Productivity costs were not considered.

Currency
Euro (EUR). An exchange rate of EUR 1.00 = 2.21 Dutch guilders was used when necessary.

Sensitivity analysis
The examination of uncertainty was restricted to the bootstrapping (with 1,000 iterations) of the incremental cost-effectiveness ratio (ICER).

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The mean cost per patient was EUR 93.11 in the intervention group and EUR 121.26 in the control group. The difference (EUR 28.15) was statistically significant, (p=0.04 with the non-parametric test).

Synthesis of costs and benefits
The costs and benefits were combined using an ICER.

The ICER was EUR 111.98 per point on the urinary symptom scale (-0.25 points on the IPSS scale divided by EUR -28.15).

The bootstrap analysis provided an estimated 95% confidence interval of EUR -423 to EUR 329. It also showed that 60% of the estimated ICERs found the intervention to dominate the control, as it reduced symptoms and was less costly.

Authors' conclusions
The distance learning programme did not change health outcomes, but it reduced costs in the first 3 months after an initial consultation, compared with written guidelines.

CRD COMMENTARY - Selection of comparators
The reason for the choice of the comparator was clear. It was chosen because it reflected current practice in the authors' setting. You should decide if it represents current practice in your own setting.

Validity of estimate of measure of effectiveness
The analysis was based on a cluster, randomised controlled trial. With the exception of the lower number of solo practices in the study sample, the study sample of GPs was said to be representative of the study population. The patient groups were shown to be comparable at baseline. Details of the method of randomisation were not provided, although they might have been described in earlier studies. The nature of the intervention would have prevented the blinding of the clinicians, but blinding of the patients and researchers who collected the outcome information should have been possible. However, the process was not discussed. Although a randomised controlled trial was conducted, the outcomes were analysed for treatment completers only and this could make the intervention look more or less effective than it actually is. Power calculations were reported and an appropriate sample size was used.

Validity of estimate of measure of benefit
A one-point movement on the urinary symptom scale was used as the summary benefit measure. It was obtained directly from the effectiveness analysis.

Validity of estimate of costs
The analysis of the costs was performed from the perspective of the health care system. It appears that all the relevant categories of costs have been included in the analysis. The costs developing the clinical guideline and educational programme were not included. However, their omission is unlikely to have affected the authors’ conclusions. Discounting was not performed, but it was not necessary given the short duration of follow-up. The authors evaluated uncertainty in the cost data jointly with the effectiveness by using a non-parametric bootstrap method to explore the variability around the ICER. The costs and the quantities were reported separately, which increases the generalisability of the study results. Adjustments for inflation and the price year were all reported.

Other issues
The authors made some limited comparisons of their findings with those from other studies, but the outcome measures in the studies were not the same so direct comparisons were not possible. The authors did not address the issue of the generalisability of their results to other settings. The results of the study do not appear to have been presented selectively and the conclusions would appear to be an adequate reflection of the scope of the analysis. The authors reported a number of further limitations to their analysis. First, the drop-out of patients. Second, the short follow-up period. Finally, the authors noted that they did not know whether all diagnostic procedures were performed as planned, or whether treatment decisions were changed after the initial consultation.

Implications of the study
The authors indicated that larger trials with longer follow-up are required to examine the issue in more detail.

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Other publications of related interest
Because readers are likely to encounter and assess individual publications, NHS EED abstracts reflect the original publication as it is written, as a stand-alone paper. Where NHS EED abstractors are able to identify positively that a publication is significantly linked to or informed by other publications, these will be referenced in the text of the abstract and their bibliographic details recorded here for information.


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