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## **Helicobacter pylori screening for individuals requiring chronic NSAID therapy: a decision analysis**

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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**

The use of *Helicobacter pylori* (Hp) screening for chronic users of non-steroidal anti-inflammatory drugs (NSAIDs).

### **Type of intervention**

Screening.

### **Economic study type**

Cost-effectiveness analysis.

### **Study population**

The study population included all NSAID users at an average risk of peptic ulcer disease. More detailed characteristics of the patient population were not reported.

### **Setting**

The setting was the community. The economic study was carried out in Michigan, USA.

### **Dates to which data relate**

The effectiveness data were derived from studies published between 1988 and 1999. The dates over which resource use data were collected, and the price year, were not reported.

### **Source of effectiveness data**

The effectiveness data were derived from a review of published studies.

### **Modelling**

A Markov model was used to simulate the natural history and health care expenditures of chronic NSAID users over a 1-year period. A "symptom-driven" management approach was adopted to reflect actual medical care delivery, and to allow a realistic estimate of resource utilisation.

### **Outcomes assessed in the review**

The clinical inputs used in the model were the outcomes assessed in the review. The outcomes assessed were:

Hp prevalence;

the overall probability of endoscopic ulcer in infected and non-infected patients;

the probabilities that the endoscopic ulcer was symptomatic or complicated;

the probability that there were non-ulcer symptoms;

the effectiveness of eradication therapy;

the sensitivity and specificity of Hp serology; and

the sensitivity and specificity of the urea breath test.

### **Study designs and other criteria for inclusion in the review**

The authors selected studies of different designs, such as randomised controlled trials and case-control studies. The selection criteria were not reported.

### **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 reported.

### **Number of primary studies included**

Approximately 23 studies were included in the review.

### **Methods of combining primary studies**

The method by which primary studies were combined was unclear.

### **Investigation of differences between primary studies**

Not reported.

### **Results of the review**

The Hp prevalence was estimated to be 50%.

The probability of developing an endoscopic ulcer over a one month period was 1.75% overall, 1.4% in non-infected patients, and 2.1% in infected patients.

The probability that the ulcer was symptomatic was 13% and the probability that it was complicated was 50%. The probability that there were non-ulcer symptoms was 4.2%.

The effectiveness of eradication therapy was 85%.

The sensitivity and specificity of Hp serology were both 85%.

The sensitivity and specificity of the urea breath test were both 95%.

### **Measure of benefits used in the economic analysis**

Two measures of benefits were used in the economic analysis: the number of months over which symptomatic ulcer disease was prevented, and the number of months over which ulcer complications were prevented.

### **Direct costs**

The costs were not discounted since they were incurred over one year. The costs and quantities were not reported separately, but unit costs were presented. The following medical costs were included in the analysis: serology, eradication therapy, NSAID, H2-antagonist, proton-pump inhibitor, urea breath test, physician visit, endoscopy, and hospitalisation for ulcer complications. The costs were based on payments made for medical services by a large private insurer. The costs of out-patient pharmaceuticals were based on average prices determined from an ongoing survey of retail pharmacies. The overall estimation of the quantities and costs for each strategy was derived using modelling. The dates over which the resource data were obtained, and the price year, were not reported. The cost/quantity boundary was that of health services.

### **Statistical analysis of costs**

No statistical analysis was carried out.

### **Indirect Costs**

Indirect costs were not included, given the perspective adopted in this study.

### **Currency**

US dollars (\$).

### **Sensitivity analysis**

A broad range of model inputs was investigated, given that the values were obtained by a non-systematic review of the literature. One-way sensitivity analyses were carried out on the effectiveness of Hp eradication, the costs and effectiveness of antisecretory drugs and non-drug services, and the risk of ulcer. Two-way sensitivity analyses were performed to demonstrate the trade-off between ulcer risk and the protective effect of Hp eradication.

### **Estimated benefits used in the economic analysis**

Compared with no screening, the model estimated that the Hp screening strategy led to fewer months with symptomatic ulcers: 5.4 per 100 patient-years for no screening and 4.6 per 100 patient-years for Hp screening. Hp screening also led to fewer ulcer complications: 2.6 per 100 patient-years for no screening and 2.3 per 100 patient-years for Hp screening.

### **Cost results**

The Markov model provided an estimate of the cost per patient treated for both strategies. Over the one year period, the cost per patient treated was slightly greater for the screening strategy, compared with the no screening approach: \$556 versus \$435. However, the large differential in the cost of Hp testing and eradication therapy (\$8 and \$149 per patient for no test and Hp test respectively) was offset by a reduction in expenditures for adverse events (\$268 and \$230 per patient for no test and Hp test respectively).

### **Synthesis of costs and benefits**

The incremental cost-effectiveness ratios of the Hp screening strategy, compared with the no screening option, were calculated. In the base-case, the incremental costs per symptomatic and complicated ulcer prevented were \$16,805 and \$31,842 respectively. The one-way sensitivity analysis indicated that the results were sensitive only to the ulcer risk and the effect of Hp eradication. As the values of these variables both increased, the difference in the cost per patient treated between the two strategies narrowed.

The two-way sensitivity analyses showed that for low-risk patients (risk lower than 1%) the no screening option was always cost-effective, no matter what the efficacy of Hp eradication. This was due to the fact that the cost-savings associated with the relatively few NSAID-related complications prevented, do not offset the significant incremental cost of Hp testing and eradication. In the case of an ulcer risk greater than 1%, the Hp screening strategy became progressively more cost-effective. Ulcer risk and effect of Hp eradication therapy were the most important inputs into the model.

### **Authors' conclusions**

The authors concluded that, according to the model results, Hp screening had the potential to decrease ulcer-related adverse events at an incremental cost, especially in patients at high risk of ulcer.

### **CRD COMMENTARY - Selection of comparators**

The no screening option seemed to represent a clear alternative to Hp screening in the current management of chronic NSAID users.

### **Validity of estimate of measure of effectiveness**

The methods used to combine the effectiveness estimates derived from the literature were unclear. A systematic review may have increased the robustness of the results. However, a broad range of sensitivity analyses was undertaken in order to address this issue. The authors did not mention the criteria used to select the primary studies and to ensure their validity.

### **Validity of estimate of measure of benefit**

The benefit estimates were based on a model that appeared to represent the natural course of the disease and the clinical approach to the management of Hp infection.

### **Validity of estimate of costs**

All the costs relevant to the perspective adopted were included in the analysis. However, the cost estimates were likely to be specific to the US setting, as they were based on the actual payments of both a US private insurer and Medicare.

### **Other issues**

The robustness of the model was assessed by sensitivity analyses. The issue of generalisability to other settings was not specifically addressed.

As the authors stated, the economic analysis could have been improved both by the inclusion of indirect costs, i.e. productivity losses, and by the adoption of benefit measures based on patients' perception of quality of life.

### **Implications of the study**

The authors suggested that decision-makers should decide whether the incremental cost-effectiveness values of Hp screening, namely \$31,842 per complicated ulcer prevented and \$16,805 per symptomatic ulcer prevented, is worthwhile in the broad context of allocation of health care resources. The authors also recommended that future research should be based on study designs with high internal validity, for example, randomised controlled trials.

### **Source of funding**

None stated.

### **Bibliographic details**

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