Reuse of negative CLOtest kits in children
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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 reuse of negative CLOtests (rapid urease tests) for the diagnosis of Helicobacter pylori (H. pylori) infection in children.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised children who underwent diagnostic endoscopy at Cabell-Huntington Hospital. Those children that had been previously diagnosed with, or treated for H. pylori infection, were excluded.

Setting
The setting was a hospital. The economic analysis was carried out in West Virginia and Ohio, USA.

Dates to which data relate
The effectiveness evidence was collected between September 1997 and September 1998. The resource quantities were obtained from the number of endoscopies performed between January 1993 and December 1997. The price year was not given.

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

Link between effectiveness and cost data
The costing appears to have been performed retrospectively using resource quantities collected from the same institutions that provided the effectiveness data, but during an earlier period.

Study sample
No power calculations were performed to determine the sample size. All individuals in the study period were analysed. The study sample appears to have been appropriate, as demonstrated by the patients’ ages, the male-to-female ratio, and the numbers with gastritis and/or H. pylori infection. The mean age (+/- 1 standard deviation) of the patients was 10.3 (+/- 4.4), and the male-to-female ratio was 1.3:1. One hundred and twenty-two children were recruited into the study. Both tests were conducted on each child.
Study design
The study design was a diagnostic test accuracy evaluation performed in two hospitals with no follow-up. The laboratory technician who read the CLOtest was blinded to the clinical diagnosis and to the histopathologic test result.

Analysis of effectiveness
The outcome was measured in terms of the sensitivity and specificity of the new and reused CLOtests. The CLOtest results were compared with the 'gold' standard, histology. The biopsy specimens were taken from the gastric antrum and treated as described in the paper. Histologic tests were used to assess gastric inflammation (H and E staining) and/or the presence of H.pylori organisms (Giemsa staining). It was unclear how this information was combined to provide the diagnosis.

Effectiveness results
The specificity was 100% for both the new and reused tests.

The sensitivity was 63% for the reused test and 66% for the new test.

Only in one patient did the test results not agree. Both histology and the new CLOtest showed positive for H. pylori infection, whereas the reused CLOtest gave a negative result.

The prevalence was not given, although it can be calculated from the above results to be approximately 27%.

Clinical conclusions
The reused negative tests offered the same specificity as the unused tests, but slightly lower sensitivity.

Measure of benefits used in the economic analysis
No summary measure of effectiveness was used to compare the costs. A cost-consequences analysis was therefore conducted.

Direct costs
The costs were not discounted. This was appropriate given that the costs were incurred in less than one year. The price year was not given. The prices included the CLOtest kit ($6.00, or $3.00 per test if the kit was reused) and the charges for the professional and technical services per biopsy. The resource quantities were expressed as the 'average' (+/- standard deviation) by institution, and were derived from the institutional data obtained for each hospital between January 1993 and December 1997.

Statistical analysis of costs
The costs were not treated stochastically.

Indirect Costs
The indirect costs were not reported.

Currency
US dollars ($).

Sensitivity analysis
Not reported.
Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The total costs per patient tested were not given.

Using a prevalence of 15% and an annual number of endoscopies of 104 (±19), the total annual savings at Cabell-Huntington Hospital were estimated as $265.

Using a prevalence of 15% and an annual number of endoscopies of 768 (±102), the total annual savings at the Children's Hospital of Columbus were estimated as $1,985.

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
"Re-use of a negative CLOtest (rapid urease test) is reliable and may reduce costs, especially in facilities with a high volume of endoscopic procedures."

CRD COMMENTARY - Selection of comparators
The comparator selected was appropriate given its use in practice.

Validity of estimate of measure of effectiveness
Sensitivity and specificity were appropriate measures of effectiveness. The study design was appropriate for the study question. A good feature of the design was the blinding of the technicians. However, it was unclear how the results of the histologic tests were synthesised to make the definitive diagnosis. Also, the implications of a reused kit missing a positive test were not explored in terms of health and quality of life.

Validity of estimate of measure of benefit
Not appropriate, given the lack of a summary measure of benefit.

Validity of estimate of costs
Although some prices were given, the price year was not. In addition, some of the prices were charges, for which the breakdown in terms of resource quantities was unknown. Thus, the generalisability to other settings is hampered. The resource quantities were also taken from an earlier period and may not be valid for the test accuracy results. Finally, in order to calculate the savings, a prevalence of 15% was assumed since the total costs were not presented. However, there was no sensitivity analysis to account for differing prices, test accuracy or prevalence, which might occur in other settings. In fact, the present reviewer calculated the prevalence in the study to be much higher. It can be shown that the higher the prevalence, the more likely it is that false negatives will occur, and therefore the impact of any difference in sensitivity will increase.

Other issues
The results were compared with those of other studies. The authors also discussed the issue of generalisability in terms of the prevalence of H. pylori, and the accuracy of testing, which depends on several factors including previous medication usage. They do not seem to have reported their results selectively. The conclusions were consistent with the study population.
Implications of the study
The authors stated that histology should be the standard for the diagnosis of H. pylori in children due to the low sensitivity of the CLO test, whether reused or not. Cost-savings would be increased, and the probability of a false-negative decreased, by decreased prevalence. Nevertheless, any cost-saving must be weighed against the consequences of missing the diagnosis.

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