Fecal occult blood tests: a cost-effectiveness analysis

Gyrd-Hansen D

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
Population screening programmes in older adults using fecal occult blood (FOB) tests for the detection of colorectal neoplasms.

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
Asymptomatic individuals, aged between 50 and 74. Cancer patients or individuals at high risk were not included in the analysis.

Setting
The study setting was a hospital. The economic study was carried out in the USA.

Dates to which data relate
The data for the effectiveness analysis were taken from studies published between 1985 and 1998. The estimation of resource use was based on the population of the Danish county of Funen (no dates were provided). 1993 prices were used.

Source of effectiveness data
The evidence/estimate for the final outcome was derived from a review of completed studies and from the authors' opinion.

Modelling
Model-simulated costs and effects were used. The purpose of the model was to estimate the cost-effectiveness of alternative FOB tests. All costs and effects were based on screening an unscreened population. Hence, in the initial years after a programme's introduction the cancer detection rate would be higher, while after the introduction of the programme it would fall to a constant rate. A long period of 36 years was chosen to simulate the cost and effects of a screening programme that was introduced in a population on a permanent basis.

Outcomes assessed in the review
The outcomes assessed in the review were the specificity and sensitivity of the FOB tests under investigation.
Study designs and other criteria for inclusion in the review
Studies were not included in the review if the sensitivity of the screening test was dependent on preclinical detectability of the diagnostic test or if the study sample included cancer patients or individuals at high risk. The age range for the unhydrated H-II test was 55 to 74 years and for the group of alternative FOB tests the age range was 50 to 74 years. The follow-up periods were 1 or 2 years.

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
Five studies (two randomised controlled trials and three studies of unspecified designs) were directly cited as the sources of the data included in the analysis. At least three more studies were cited indirectly.

Methods of combining primary studies
The results of studies were not combined and each study had a separate input in the analysis.

Investigation of differences between primary studies
Not stated.

Results of the review
The specificity and sensitivity of the tests were:

H-II unhydrated: specificity, 99.5%; sensitivity, 72% (1 year) and 52% (2 years) according to the Funen study;

H-II rehydrated: specificity, 95.7%; sensitivity, 88% (1 year) and 82% (2 years) according to the Gothenburg study;

H-II unhydrated: specificity, 97.7%; sensitivity, 80.0% according to the Minnesota trial;

H-II rehydrated: specificity, 90.4%; sensitivity, 92.2% according to the Minnesota trial;

H-II unhydrated: specificity, 97.7% (cancer) and 98.1% (polyps 1cm or larger); sensitivity, 37.1% (cancer) and 30.8% (polyps 1cm or larger) in Allison et al;

HemeSelect: specificity 94.4% (cancer) and 95.2% (polyps 1cm or larger); sensitivity, 68.8% (cancer) and 66.7% (polyps 1cm or larger) in Allison et al;

H-II Sensa: specificity, 86.7% (cancer) 87.5% (polyps 1cm or larger); sensitivity, 79.4% (cancer) and 68.6% (polyps 1cm or larger) in Allison et al.

Methods used to derive estimates of effectiveness
Estimates of effectiveness were also based on the authors’ assumptions.
Estimates of effectiveness and key assumptions
The model assumed that there was no difference in the stage distribution of cancers detected by the respective tests. Consequently, the excess survival rate for patients with screen-detected cancers was identical to that which had been observed in the Funen trial. The authors included the potential effect of increased sensitivity for the detection of adenomas by assuming that the adenoma sensitivity of the Danish study was approximately 10% and that 2-year follow-up sensitivities of 60%, 70%, and 80% would increase the adenoma detection rate by 50%, 100%, and 150%, respectively. This assumption corresponded well with data from the Gothenburg trial where the adenoma detection rate was 2.7 times higher than in the Funen trial. No effects of detection of small adenomas were included, since, for such patients, surveillance is thought to have little effect.

Measure of benefits used in the economic analysis
The benefit measure used in the economic analysis was life-years gained. Benefits were discounted at 5%. Effects were estimated for a population equivalent to the Funen population in size and age distribution. Danish incidence rates were applied.

Direct costs
Costs were discounted, but no justification was provided for the choice of the discount rate. Quantities were not reported separately from costs. Costs included the costs of manufacturing, distributing, and analysing the test. The cost of the test included mailing expenditures as well as the cost of test analysis. The estimation of resource use was based on the population of the Danish county of Funen. The estimation of unit costs was based on the published literature and assumptions made by the authors. 1993 price data were used.

Statistical analysis of costs
No statistical analysis of costs was reported.

Indirect Costs
Indirect costs were not considered.

Currency
Danish kroner (DKr). The exchange rate was DKr1.00 = US$0.17.

Sensitivity analysis
A set of one-way sensitivity analyses was performed varying the costs of colonoscopy and an FOB test, to examine the robustness of the results. Two iso-cost curves were used to depict the combinations of follow-up sensitivity and specificity required to maintain the average cost of screening 55-74 year olds every 2 years at DKr 17,500. This sum was approximately the average cost per life-year of this programme when the unhydrated H-II test was used in the Funen trial. The second iso-curve maintained the average cost of screening 55-74 year olds every year at DKr 21,000, which was the estimated average cost per life-year gained using the unhydrated H-II test. An efficiency curve was also used to plot 15 mutually exclusive screening scenarios according to the costs and benefits they would incur over a 36-year period. The robustness of the results was tested by varying the sensitive parameters in the frameworks of iso-cost and efficiency curves.

Estimated benefits used in the economic analysis
Not reported.

Cost results
The costs were discounted at a rate of 5%. The total costs of the screening programmes were not given.
Synthesis of costs and benefits
Costs and effects were combined in three different ways: depicting iso-cost curves, plotting efficiency curves, and by calculating cost per life-year gained. An incremental analysis was performed.

One of the set of results attained in the iso-cost study maintaining the average cost per life-year of DKr 17,500 was that, if a screening interval of 1 year were chosen, a specificity of well over 97% was required to sustain the average cost per life-year. A specificity of under 97% was allowed if the screening interval were 2 years. Shorter screening intervals would, all things being equal, tighten the requirement for a high specificity. Hence, programmes with a low specificity may be significantly more cost-effective if administered less frequently. <SYNTHESIS OF COSTS AND BENEFITS> The analysis based on an efficiency curve revealed that, if the Gothenburg trial's results hold, the rehydrated test is a cost-effective option and should be used in screening programmes that are intensified beyond screening 55-74-year-olds every two years.

The incremental cost per life-year (subject to the Minnesota results) using the unhydrated H-II test (55-74 year-olds every two years) was DKr17,500.

The average cost-per life-year using the unhydrated H-II test (55-74 year-olds every year) was DKr30,000.

The average cost-per life-year using the unhydrated H-II test (50-74 year-olds every year) was DKr39,000.

The average cost-per life-year using the HemeSelect test(50-74 year-olds every year) was DKr71,300.

The average cost-per life-year using the rehydrated H-II test(50-74 year-olds every year) was DKr138,100.

Authors' conclusions
The unhydrated H-II test proved a very cost-effective option and preferable to alternative tests such as the HemeSelect and the Hemoccult Sensa. The rehydrated H-II test may be a viable alternative to the unhydrated test, but evidence of that test's characteristics is unclear.

CRD COMMENTARY - Selection of comparators
A justification was given for the comparator used. The unhydrated hemoccult II test every two years is the most used in controlled trials and screening programmes. However, in the economic analysis, incremental cost-effectiveness ratios suggested that a “do-nothing” alternative was used as the comparator.

Validity of estimate of measure of effectiveness
The estimation of the effectiveness was based on a review of the literature, which may not have been systematic. Details of the methods used to search for primary studies, and inclusion/exclusion criteria used to select the primary studies were not reported. It was not clear why the authors did not conduct an appropriate data synthesis to combine the results of different studies. The authors carried out a sensitivity analysis to handle issues of uncertainty.

Validity of estimate of measure of benefit
The estimate of benefit was based on the effectiveness results from the literature and on a simulation model. The choice of the benefit measure appears to be justified. Benefit outcomes associated with each screening strategy were not reported.

Validity of estimate of costs
The validity of the cost results may have been hindered by insufficient details about the sources of resource use and costs and the fact that quantities were not reported separately. The perspective adopted in the cost analysis was not reported and it is not clear whether the cost data was based on true costs or on charges. Only health service costs were
included in the analysis, while costs to others in society such as patients were not considered. The total cost outcomes associated with each screening strategy were not reported. These factors may also limit the generalisability of the cost results to other settings or countries. However, the price year and the exchange rate adopted in the analysis were reported and sensitivity analyses were performed on cost results.

Other issues
Exploring the cost-utility of the screening programmes would have been helpful. Appropriate comparisons with other studies were made and the authors addressed the issue of generalisability to other settings and countries. It was acknowledged that the results presented in the study were based on the population in the Danish county of Funen. However, the authors believed that the conclusions would hold for other settings and population sizes, as the major proportion of overhead costs was assumed to be variable in this analysis, under the assumption that resources can be adjusted in the long run to conform with the size of the programme. The authors noted that country-specific incidence may vary and influence absolute cost-effectiveness ratios, but average as well as incremental costs will increase proportionately to a decrease in cancer incidence, thereby maintaining the relative cost effectiveness of the presented programmes.

Implications of the study
The authors noted that their study illustrates the impact of specificity on the economics of a screening test. They recommend biannual or annual screening of 50-74 year-olds using the unhydrated-II test. The authors suggested that more sensitive tests should be introduced only if it is wished to increase performance beyond that of annual unhydrated H-II screening of the 50-74-year-olds.

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