Cost-effectiveness analysis of fecal occult blood screening for colorectal cancer
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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 study examined a biennial faecal occult blood test (FOBT) for the screening of colorectal cancer (CRC).

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised a hypothetical cohort of asymptomatic individuals aged 50 to 74 years.

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

Dates to which data relate
The effectiveness data and most resource use data were derived from studies published between 1987 and 2001. The price year was 2002.

Source of effectiveness data
The effectiveness evidence was derived from a synthesis of completed studies.

Modelling
A published Markov model was used to model the clinical and economic outcomes associated with biennial FOBT screening in a hypothetical cohort of 100,000 asymptomatic individuals aged 50 to 74. The population was monitored over a 20-year period, or until the age of 85 or until death. The five health states included in the model were absence of CRC or adenoma, CRC, adenoma larger than 1 cm in diameter, death from CRC, and death from another cause. Other details of the model were not reported.

Outcomes assessed in the review
The outcomes assessed from the literature were mainly epidemiological parameters. The outcomes included:

CRC mortality,
the screening acceptability rate,
the proportion of positive tests,
the positive predictive value for adenoma greater than 1 cm in diameter,

the distribution of CRC by stage in screen-detected cancers,

the age- and gender-specific incidence rates for CRC,

the number of cancers arising in adenomas, and

the sensitivity and specificity of the screening tests.

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

It appears that the primary studies have been identified selectively, rather than through a systematic review of the literature. Most of the evidence came from a clinical trial carried out in Burgundy (France). This trial studied 45,642 screened patients and 45,557 control patients over an 11-year period. The age- and gender-specific incidence rates of CRC were derived from a French national registry.

**Sources searched to identify primary studies**

Not relevant.

**Criteria used to ensure the validity of primary studies**

The use of a clinical trial ensures the validity of most primary estimates.

**Methods used to judge relevance and validity, and for extracting data**

Not stated.

**Number of primary studies included**

Four primary studies provided the clinical data.

**Methods of combining primary studies**

The primary estimates were not combined since each source provided a series of estimates.

**Investigation of differences between primary studies**

Not stated.

**Results of the review**

CRC mortality was significantly lower in the screening population than in the control population. The mortality ratio was 0.84 (95% confidence interval, CI: 0.71 - 0.99).

The acceptability rate of the test was 55% in the base-case. It varied between 52.8 and 58.3% according to the screening campaign.

The FOBT had a sensitivity of 60% (70% in an alternative analysis) for CRC and a specificity of 99% (90% in an alternative analysis).

The acceptability of colonoscopy was 87%. The proportion of positive tests was 2.1% initially and 1.4% in successive rounds.

The positive predictive value for adenoma greater than 1 cm in diameter was 17%.
Other data used in the model were not reported.

**Measure of benefits used in the economic analysis**
The summary benefit measure used was the number of life-years gained (LYG). This was derived from the decision model. The rate of mortality was also reported as a model output. An annual discount rate of 3% was applied to the LYG.

**Direct costs**
The cost analysis took the perspective of the French health care insurance system. The health services included were:

- the cost of the structure organising the screening programme, including labour costs and equipment;
- the cost of inviting the population, including conception and printing of the invitation letter and of the information leaflet sent at the beginning of each screening campaign, the labour costs for preparing the mailing, the cost of postage, and the cost of training the general practitioners and informing the entire medical profession;
- the distribution cost of the screening test, including the cost of the test, remuneration of general practitioners for offering the test, and the cost of mailing the test or the reminder letter;
- the cost of the test analysis performed in a centralised analysis centre, including overhead costs, capital expenditure, running costs and labour costs;
- the cost of a colonoscopy in the case of a positive screening test; and
- the cost of CRC care, which depended on cancer stage.

The unit costs were not presented separately from the quantities of resources used for all items, but some unit costs were reported. The costs associated with different stages of CRC were reported as macro-categories. Much of the resource use data were derived from the clinical trial that was the main source of clinical evidence used in the model. The costs came from different sources (i.e. the clinical trial and other published studies). Discounting was relevant, given the long timeframe of the analysis, and an annual rate of 3% was applied. The price year was 2002.

**Statistical analysis of costs**
The costs were treated deterministically.

**Indirect Costs**
The indirect costs were not considered.

**Currency**
Euros (EUR).

**Sensitivity analysis**
Several univariate sensitivity analyses were carried out to assess the robustness of the base-case cost-effectiveness ratios to variations in the model inputs. Such model inputs included the acceptability rate of FOBT, the diagnostic performance of FOBT, most economic parameters, and age at the start and end of screening. The authors appear to have chosen the alternative values.

**Estimated benefits used in the economic analysis**
The estimated LYG with screening over no screening were 2,888 (3,891 if undiscounted) with a time horizon of 20
years and 1,458 (1,712 if undiscounted) with a time horizon of 10 years.

The reduction in mortality was 17.7% over 20 years and 15.1% over 10 years.

Cost results
The total costs were not reported.

Synthesis of costs and benefits
Incremental cost-effectiveness ratios (ICERs) were calculated to combine the costs and benefits of CRC screening in comparison with no screening.

The incremental cost per LYG with FOBT screening over no screening over 20 years was EUR 3,375 (EUR 4,705 if the time horizon of the study was 10 years). The corresponding undiscounted results were EUR 2,492 at 20 years (EUR 4,007 at 10 years).

The sensitivity analysis showed that the ICERs were strongly related to the acceptability rate. For example, with a 10% absolute increase in the acceptability rate, the ICER was reduced by 20.1%. A 20% decrease in the acceptability rate resulted in an 86.0% increase in the ICER.

The diagnostic accuracy of FOBT had a slight impact on the ICER, whereas changes in the costs of an FOBT kit and colonoscopy had a stronger impact. For example, a decrease in the cost of an FOBT kit from EUR 3.20 to EUR 1.60 led to an 11.1% reduction in the ICER. The ICERs ranged from EUR 2,929 to EUR 3,817 according to the lowest and highest costs of colonoscopy.

The analysis of the starting age showed that very close ICERs were found in the 50 - 74 and 55 - 74 age groups, whereas the 60 - 74 and 65 - 74 age groups showed higher ICER values. However, the number of LYG was higher for a starting age of 50 than for a starting age of 55. The 55 - 64 age group presented the lowest ICERs but a very small number of LYG in comparison with the 50 - 64, 50 - 69, or 50 - 74 age groups.

Authors' conclusions
A biennial faecal occult blood test (FOBT) was a cost-effective screening strategy for colorectal cancer (CRC) in France for asymptomatic individuals aged 50 - 74 years. The analysis highlighted the importance of acceptability rates on the cost-effectiveness of the FOBT.

CRD COMMENTARY - Selection of comparators
The selection of no screening as the basic comparator was appropriate as it represents the actual standard of care in several countries. Biennial FOBT is often advocated as the first screening option for the mass detection of CRC before the introduction of more invasive screening strategies (i.e. colonoscopy). You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness data were estimated from published studies. It was not stated whether a systematic review of the literature was undertaken to identify primary studies. The primary studies appear to have been included selectively. The evidence on treatment efficacy came from a French clinical trial, which had a high internal validity due to its randomised design and large sample size. Some information on the studies used to derive other clinical estimates was provided. The impact of the primary estimates on the results of the study was addressed in the sensitivity analysis. However, it was not stated whether the primary studies were comparable.

Validity of estimate of measure of benefit
The use of LYG as the summary benefit measure was appropriate since they capture the impact of the intervention on survival, which is the most relevant dimension of care. Further, the use of LYG enables comparisons with the benefits of other health care interventions. Discounting was applied, as economic evaluation guidelines recommend.

**Validity of estimate of costs**
The analysis of the costs was consistent with the perspective adopted in the study. Some unit costs were reported but, in general, information on the unit costs and quantities of resources used was not presented separately. This limits the possibility of replicating the results of the study in other settings. The source of the costs was unclear. Statistical analyses were not carried out, but the impact of variations in the cost estimates was investigated in the sensitivity analysis. The price year was reported, which makes reflation exercises in other time periods straightforward.

**Other issues**
The authors reported the results from other European economic evaluations of FOBT, the results of which were quite consistent with those of the current study. Some explanations for the small differences (mainly associated with different costs among countries) across the three studies were provided. The issue of the generalisability of the study results to other settings was not explicitly addressed, but the extensive use of sensitivity analyses enhances the external validity of the study. There was little information on model parameters such as transition probabilities. The study referred to asymptomatic individuals aged 50 to 74 years and this was reflected in the authors' conclusions.

**Implications of the study**
The study results supported the implementation of a CRC biennial screening programme targeted at asymptomatic individuals aged 50 to 74 years.

**Source of funding**
Supported by the Ministry of Health (PHRC), the Burgundy Regional Council and INSERM.

**Bibliographic details**

**PubMedID**
15609792

**Other publications of related interest**


**Indexing Status**
Subject indexing assigned by NLM
MeSH
Aged; Colorectal Neoplasms /diagnosis /epidemiology; Cost-Benefit Analysis; Humans; Markov Chains; Mass Screening /economics; Middle Aged; Occult Blood

AccessionNumber
22004008424

Date bibliographic record published
31/05/2006

Date abstract record published
31/05/2006