Colorectal cancer screening in Italy: feasibility and cost-effectiveness in a model area
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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
Five types of screening programmes for colorectal cancer (CRC): annual faecal occult blood testing (FOBT), sigmoidoscopy (SIGM) (every 5 years), FOBT plus SIGM (every 1 and 5 years), colonoscopy (every 10 years) (all in the age group 55-69 years, last examination at 70 years), and 'filter' colonoscopy (FC50). The latter had to be performed in persons at 50 years of age and repeated every 10 years until the age of 70. The age group of 55-69 years was chosen because approximately 60% of cases occur within this age range.

Type of intervention
Screening.

Economic study type
Cost-effectiveness analysis.

Study population
A hypothetical cohort of individuals aged 55-69 for the CRC screening strategies of FOBT, SIGM, FOBT+ SIGM; individuals at age 70 for colonoscopy and individuals at age 50 for FC50.

Setting
The study setting was hospital. The economic analysis was carried out in Italy.

Dates to which data relate
Effectiveness data were based on studies published between 1991 and 1997. The price year was not explicitly specified.

Source of effectiveness data
The evidence for the effectiveness outcomes was based on a literature review and assumptions made by the authors.

Outcomes assessed in the review
The review assessed the proportion of patients who will require colonoscopy and polypectomy (true negatives), and the proportion of patients who are diagnosed with early and advanced cancer.

Study designs and other criteria for inclusion in the review
Not reported.

Sources searched to identify primary studies
Not reported.
Criteria used to ensure the validity of primary studies
Not reported.

Methods used to judge relevance and validity, and for extracting data
Not reported.

Number of primary studies included
A total of 4 studies were included in the review.

Methods of combining primary studies
Not reported.

Investigation of differences between primary studies
Not reported.

Results of the review
It can be predicted that approximately 95% of non-rehydrated FOBTs executed for screening purposes will turn out negative. Of the remaining 5% of patients who will be subjected to colonoscopy:

- approximately 0.5% will be diagnosed with an 'early' cancer; and
- 1% will present one or more polyps.

Of those screened with SIGM, 85% will have no apparent pathological findings. However, the truly negative subjects will be 70%. Of the remaining 30%:

- half will present a polyp which will require a full colonoscopy, which in turn will yield an early cancer in one out of 30 examinees; and
- half will have a lesion higher in the colon that will go unnoticed (absence of 'sentinel polyp' at SIGM) and will present later as an advanced cancer.

Of those screened with colonoscopy and FC50, polypectomy will be required in 30% of those screened and approximately 1% will be diagnosed with early cancer.

Methods used to derive estimates of effectiveness
Assumptions about effectiveness were also made by the authors.

Estimates of effectiveness and key assumptions
For the case of a 'no screening' strategy, it was reported that the patient with an 'early' CRC has an asymptomatic cancer discovered incidentally or by an occasional FOBT required by his/her general practitioner; usually this type of cancer is diagnosed before metastases have occurred and (in more than 70% of cases) the patient recovers after surgery, which, in 5% of cases, is conducted using colonoscopy. The patient with a 'late' CRC has local or systemic symptoms at the time of diagnosis; the cancer carries a 5-year mortality greater than 40% in the case of local metastasis and greater than 90% in the case of widespread dissemination.
Measure of benefits used in the economic analysis
The benefit measure was the number of lives saved (deaths prevented) compared with the 'no screening' strategy.

Direct costs
Costs were not discounted. Resource use data for the treatment of CRC in the 'no screening' strategy were reported separately from the costs. Some cost items were reported separately. Cost analysis covered the costs of screening procedures, surgery with and without complications, chest X-ray, physical check-ups, neoplastic markers, routine blood tests, abdominal ultrasounds, radio/chemotherapy, and admission to the hospital for palliative/antalgic treatment. The perspective adopted in the cost analysis was that of the Italian health care payer. Costs were calculated on the basis of the nominal fees paid by the Regional Health Office to the hospital/public structures performing the procedures and treatments. The price year was not reported; the cost data appear to have been taken from an Italian source published in 1996. Indirect costs were not discounted. Indirect cost analysis covered the costs of time lost from work by the patient and his/her relatives. No other details were reported.

Currency
US dollars ($). The conversion rate from Italian lira to US dollars was not reported.

Sensitivity analysis
A one-way sensitivity analysis was performed on the effect of a reduction in compliance to 50% and 75% on the total cost of various programmes.

Estimated benefits used in the economic analysis
For FOBT, it was calculated that 33% of would-be late cancers would be 'converted' into early ones: the lives saved would then be approximately 30% of the total. For SIGM, the protective effect derives in part from diagnosis at the precancerous level (the polyp stage) of approximately 50% of all lesions and from 'conversion' of half of the late CRCs into early ones with a net saving of approximately 75% of lives. For SIGM+FOBT, the saving of lives would be approximately 90%. For colonoscopy (both in the age range 55-69 and in individuals aged 50 years) the saving of lives would also be approximately 90%.

Cost results
All-inclusive 10-year costs per screenee were: $965 for FOBT, $436 for SIGM, $1,521 for SIGM+FOBT, $510 for colonoscopy, and $510 for 'filter' colonoscopy.

Synthesis of costs and benefits
All-inclusive 10-year costs per death prevented were: $77,200 for FOBT, $15,500 for SIGM, $35,000 for SIGM+FOBT, $15,100 for colonoscopy, and $14,000 for 'filter' colonoscopy.

Authors' conclusions
In Italy, screening programmes based on sigmoidoscopy/colonoscopy are more cost-effective than those based on faecal occult blood testing. 'Filter' colonoscopy at age 50 appears to be superior to the other types of endoscopy-based screening programmes because it utilises, at any point in time, a much smaller fraction of available resources.

CRD COMMENTARY - Selection of comparators
The 'no screening' strategy appears to have been regarded as the comparator; this allowed the active value of the CRC screening strategies to be evaluated. Furthermore, it was reported that due to wide variations in costs, compliance and other variables, a given type of screening might be cost efficient in one country but not in another. You, as a database user, should consider which CRC screening strategy is widely used in your own setting.
Validity of estimate of measure of effectiveness
The internal validity of the effectiveness results may be open to question as insufficient details were reported in the paper regarding the literature review, including the sources searched, the criteria used to ensure the validity of primary studies, and how differences between primary studies were dealt with. Furthermore, the outcomes attributed to the 'no screening' strategy does not appear to be supported by evidence from the literature.

Validity of estimate of measure of benefit
The estimation of benefits appears to have been based on the effectiveness analysis. No justification was given regarding why the benefit measures were restricted to the number of lives saved (deaths avoided); and not the number of life-years saved or the quality-adjusted life-years gained (especially with regard to the difference of CRC screening strategies in terms of invasiveness; which suggests that patients' preferences can be an important factor).

Validity of estimate of costs
Positive aspects of the cost analysis which contributed to its validity were as follows: resource use quantities for the treatment of CRC in the absence of any screening strategy were reported separately from the costs; adequate details of methods of cost estimation were given; the perspective adopted in the cost analysis was specified; the effects of alternative procedures on indirect costs were addressed. However, the price year and conversion rate from the Italian currency to US dollars were not reported; the cost data were based on fees paid by the regional health authority rather than true costs (it was acknowledged that the fee-for-service costs of the single exams/procedures utilised in this study were estimates since they did not fully reflect, for example, the nurse/physician time, cost and service of the equipment and so on); costs were not discounted despite the 10-year time frame of the cost analysis; the details of how indirect costs were calculated were not reported; and the robustness of the cost outcomes was not investigated using sensitivity analysis.

Other issues
The findings of the study offer useful information for those considering CRC screening programmes but some caution may need to be exercised in interpreting the study results. The issue of generalisability to other settings or countries was not systematically addressed; it was only reported that CRC screening programmes based on SIGM or colonoscopy are far cheaper than, for example, those in the USA. Appropriate comparisons were made with other studies.

Implications of the study
Other possible screening strategies, particularly CT Colography or "virtual colonoscopy" may become available in the future to provide a sensitive, non-invasive and well-accepted alternative. Until then, the findings of this study suggest CRC screening based on colonoscopy may be the most cost-effective alternative.

While they attempted to use reasonable estimates of the costs involved, the authors did recognise that only the actual implementation of the screening programme(s) and long-term follow-up may allow precise conclusions in this regard.

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