Diagnostic accuracy and cost-effectiveness of faecal occult blood tests (FOBT) used in screening for colorectal cancer: a systematic review

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CRD summary
This review found that direct comparisons indicated better performance from immunochemical faecal occult blood tests, compared with guaiac faecal occult blood tests, but the evidence was low quality. Indirect comparisons found no difference. Poor reporting of the evidence limited the scope of the review.

Objectives
To determine the diagnostic accuracy and cost-effectiveness of different types of faecal occult blood test (FOBT) in screening for adenomas, colorectal cancer or both in average-risk people.

Review methods
Seventeen databases, including MEDLINE, EMBASE, DARE, and Dissertation Abstracts, were searched. The Internet, contents of key journals, and references of included studies and relevant systematic reviews were searched. Experts were asked to identify further studies.

Studies of any design, comparing FOBT with any reference standard, were selected by two reviewers at the title and abstract stage. Full papers were assessed by one reviewer; a random selection of rejected papers was checked by a second reviewer. Studies of flushable FOBTs or FOBTs that were under development, and studies conducted in high-risk patients, were excluded. Studies had to report data for 2x2 tables of performance; adverse events were recorded. The data were extracted by one reviewer and checked by another; studies in languages other than English were assessed and had data extracted by one reviewer with help from a translator. Quality was assessed by two independent reviewers using QUADAS. Disagreements were resolved by discussion or with a third reviewer.

Heterogeneity was assessed using $I^2$. Sensitivity, specificity, positive and negative likelihood ratios and diagnostic odds ratios with 95% confidence intervals, were combined in a narrative synthesis for each test, for all neoplasms, colorectal cancer, adenomas and adenomas of 1cm or larger.

Results of the review
Fifty-nine studies provided data on diagnostic accuracy (range 44 to 97,205 patients); 21 were diagnostic case-control studies, 17 were diagnostic cohort studies, 16 were screening studies, five were randomised controlled trials. Most of the studies had methodological limitations and were poorly reported; studies of immunochemical FOBTs had more methodological flaws than guaiac studies. Reference standards varied.

Guaiac FOBTs: Over the 33 studies, the sensitivity of guaiac FOBTs reported in diagnostic cohort studies for the detection of all neoplasms was low, ranging from about 6% to 46% for Haemoccult. Accuracy seemed better for the diagnosis of colorectal cancer, with sensitivity ranging from about 25% to 96% for Haemoccult, 62% to 79% for Haemoccult Sensa, and 27% for Shionogi B. Sensitivity for Haemoccult ranged from about 4% to 19% for the detection of all adenomas, and 4% to 33% for the detection of adenomas of 1cm or larger. Specificity was 80% or higher for all tests on all measured outcomes.

Immunochemical FOBTs: Over the 35 studies, the sensitivity of immunochemical FOBTs reported in diagnostic cohort studies for the detection of all neoplasms varied between about 5% for OC Light and 63% for Immudia HemSp. For the diagnosis of colorectal cancer, sensitivity ranged from about 2% for Flexsure to 98% for MonoHaem. For all adenomas it ranged from 4% for OC Light to 63% for Immudia HemSp, and for adenomas of 1cm or larger it ranged from 28% for Flexsure to 67% for Immudia HemSp. Specificity was 89% or higher for all named immunochemical FOBTs on all measured outcomes.

Direct comparisons of guaiac and immunochemical tests were contradictory, but indicated better performance from immunochemical tests; indirect comparisons found no difference. Only three studies reported adverse events. The seven cost-effectiveness studies were too varied for any reliable conclusions.
Conclusions
The direct test comparisons indicated better performance from immunochemical tests, but the evidence was low quality. Indirect comparisons detected no difference. Poor reporting of the evidence limited the scope of the review. Further research was required to fully evaluate the comparative diagnostic accuracy of FOBTs.

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This is a high quality systematic review involving CRD that meets the criteria for inclusion on DARE. This structured abstract presents a brief summary of the review methods, the results and conclusions.