

**Title** Immunochemical Faecal Occult Blood Test (IFOBT) for Colorectal Cancer (CRC) Screening

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**Reference** Health Technology Assessment Report, MOH/P/PAK/232.12(TR), online:  
<http://www.moh.gov.my/v/hta>

## Aim

To assess the diagnostic accuracy, effectiveness, safety and cost-effectiveness of the various types of IFOBTs used for CRC screening among general population.

## Conclusions and results

There was fair level of evidence to suggest that the sensitivity and specificity of IFOBT varies with the cut-off points or positivity threshold of haemoglobin. The sensitivity of IFOBT (cut-off point between 100 ng/ml to 150 ng/ml) is around 89.0% for CRC whereas specificity around 97.0%. Several studies have revealed that the performance of IFOBT was influenced by two important factors: high temperature and lag time before the faecal sample is analyzed because of haemoglobin stability. A two-day faecal collection method was found to be more cost-effective compared to three-day faecal collection method for use in IFOBT as a means of screening for CRC. A screening programme using IFOBT can be effective for prevention of advanced CRC (risk of developing advanced CRC was reduced from 28.0% to 46.0%) and reduced mortality from 23.0% to 60.0%. There was no retrievable evidence on the safety of IFOBT for CRC screening. However, several test methods on IFOBT have United States Food & Drug Administration (US FDA) approval. There was evidence to suggest that IFOBT or FIT was cost-effective in comparison with no screening. The generated incremental cost-effectiveness ratios (ICERs) were USD\$905 and CAN\$611 per quality-adjusted life year in Taiwan and Canada, respectively. An economic evaluation in Canada also revealed that annual FIT with mid-range

testing characteristics, was more effective and less costly compared to all strategies (including no screening). By using this modality, it was postulated that the number of CRC could be reduced to about 71.0% and the numbers of CRC deaths to about 74.0%, while saving CAN\$68 per person.

## Recommendations

IFOBT can be used in Malaysia as a screening test for CRC. The use of fully automated IFOBT assay would be highly desirable should a screening programme is to be introduced because of the large number of tests to be done and involving large number of laboratories. Automation allows time to be saved and could reduce the number of staff required to perform analysis, better standardization of results, and the application of very strict quality control criteria. However, one has to take cognizance of the staff with the skills required to use the automated equipment that they must be well trained.

## Methods

Electronic databases such as MEDLINE, PubMed, EBM Reviews-Cochrane Database of Systematic Reviews, EBM Reviews-Cochrane Central Register of Controlled Trials, EBM Reviews-Health Technology Assessment, EBM Reviews-Cochrane Methodology Register, EBM Reviews-NHS Economic Evaluation Database, Database of Abstracts of Reviews of Effects (DARE), Horizon Scanning database, INAHTA database, HTA database and FDA database were searched. No limits were applied to the search. Additional

articles were identified from bibliographies of retrieved articles and hand-searching of journals. All relevant literature was appraised using the Critical Appraisal Skills Programme (CASP) and evidence was graded based on guidelines from U.S./Canadian Preventive Services Task Force and NHS Centre for Reviews and Dissemination (CRD) University of York, Report number 4 (2nd Edition), March 2001 for test accuracy studies.

#### **Further research/reviews required**

Organizational issues such as training, manpower, good referral centre or system, and funding as well as sample collection, storage condition, sample analysis, and transportation need to be addressed at all levels. One must recognized methods to minimise the effect of high temperature and lag time before the faecal sample can be analysed.

#### **Written by**

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