

Title	Immunochemical Fecal Occult Blood Testing (iFOBT)
Agency	INESSS, Institut national d'excellence en santé et en services sociaux 1195 Avenue Lavigerie, bureau 60, Québec, QC G1V 4N3; Tel: 418 643-1339, Fax: 418 644-8120, inesss@inesss.qc.ca , www.inesss.qc.ca
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Aim

This report proposes a positivity threshold for the immunochemical fecal occult blood test (iFOBT) in the upcoming screening phase (Phase II) of the demonstration projects under Québec's colorectal cancer screening program (*Programme québécois de dépistage du cancer colorectal – PQDCCR*).

Conclusions and results

In light of the selected performance data from the scientific literature examined, INESSS has reached the following conclusions, in the case of a single fecal sample (per participant):

1. The estimated sensitivity for detecting significant colorectal lesions (SCL) and the number of cases referred for colonoscopy increase when the positivity threshold is decreased.
2. The iFOBT may detect up to 3 times more SCLs and from 2 to 2.5 times more colorectal cancers (CRC) than the guaiac fecal occult blood test (gFOBT).
3. Increasing the positivity threshold to 175 ng/ml would reduce the use of confirmation colonoscopies by approximately 25% without significantly affecting the number of CRCs detected, compared with the threshold recommended by manufacturers, which is 100 ng/ml.
4. A threshold lower than 175 ng/ml is liable to reduce the positive predictive value (PPV) of iFOBT for CRC. This may lead to an increase in the number of participants referred for colonoscopy to detect one case of CRC, compared with gFOBT.
5. The estimated specificity of a threshold of 175 ng/ml for detecting CRC attains the minimum value of 95% recommended for CRC screening programs.

Taking into account the available scientific and contextual data and to ensure that PQDCCR managers are able to make the best use of colonoscopy resources without compromising patient safety and CRC screening benefits, INESSS has concluded that the best positivity threshold for iFOBT on a single fecal sample (per participant) is **175 ng/ml**. This positivity threshold applies only to asymptomatic patients at average risk for CRC invited to participate in the PQDCCR demonstration projects.

Methods

A literature review of publications from January 2000 to December 2011 inclusive and of other ad hoc research was performed in databases. For the purpose of determining the positivity threshold for the iFOBT to be selected in launching the pilot projects under Québec's colorectal cancer screening program (PQDCCR), five primary studies carried out with OC-Sensor technology were selected for analysis. In addition, the websites of advisory bodies or of other organized screening programs were consulted to discover and compare the arguments in favour of recommending a positivity threshold or those underpinning the choice of an iFOBT modality. An examination of the references included in the relevant studies completed the literature review.

Written by

Éric Potvin, INESSS, Canada