Quality-assured immunochemical testing – proposal for a pilot project in the Czech Republic

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CRC screening in the Czech Republic

CLIENT aged 50-54 years

Screening Test FOB

GP/GYNAECOLOGIST

negative

positive

Screening Colonoscopy

Return to Regular Screening in 1 year

GASTRO-ENTEROLOGIST

DATABASE

REPORTING

CLIENT aged over 55 years

Screening Test FOB

GP/GYNAECOLOGIST

negative

positive

Primary Screening Colonoscopy

Return to Regular Screening in 2 years

GASTRO-ENTEROLOGIST

negative

positive

Return to Regular Screening in 2 years

Screening Colonoscopy

Treatment / Surveillance

DATABASE

REPORTING

Return to Regular Screening in 10 years

Treatment / Surveillance
Legislative setting

- Regulation of the Ministry of Health, 70/2012: preventive check-ups
  - examination of faecal occult blood by a special test

- Standard for providing and reporting of colorectal cancer screening procedures (Bulletin of MH, 1/2009)
  - initial screening method is a faecal occult blood test

- Regulation of the Ministry of Health, 350/2015: catalogue of medical procedures including valuation
  - Determination of occult blood in stool with a special test within colorectal cancer screening
    - using immunochemical test with cut-off 75-100 ng per ml in an asymptomatic individual
FOBT positivity in Czech districts

Men and women over 50

Year 2016, N = 662,347 examinations
Source of data: Healthcare payers

FOBT positivity [%]

Total positivity (2016): **7.2 %** (range between districts: 4,0-13,3 %)
Situation in the Czech Republic

- there is a substantial variability in FOBT positivity and types of tests used in practice
- results of a survey performed in 2014:
  - types of FOBT test in use by individual GPs
    - 66% cassette immunochemical test (8 different types)
    - 23.5% POCT FIT analyser (3 different types)
    - 3% gFOBT
    - 7.5% laboratory examination

Time trends in types of FOBTs

June 2015–2016, 29,414 FOBT+ colonoscopy examinations, CRC screening registry

Proportion of individual FOBT type

Month
Project and institutional background

- National Action Plan for the Development of Medical Screening Programmes, including the strategic area ‘Ensure innovations of screening programmes according to the current scientific evidence’

- ESF project ‘Czech National Coordination Centre for Prevention of Serious Diseases’

- Institute of Health Information and Statistics established the Czech National Coordination Centre for Prevention of Serious Diseases (PreSeD), which provide governance, expertise and administrative support for piloting of early detection and prevention activities
Pilot project: Aims

1. To create *methodology* for realization of the project for quantitative evaluation of faecal occult blood at the national level

2. To verify *practical setting and logistics* of the process of quantitative evaluation of faecal occult blood

3. To *assess feasibility, outcomes and cost-effectiveness* of the proposed process for the project for quantitative evaluation of faecal occult blood, in relation to the benefits for the target population
Pilot project: Working group

- Representatives of
  - General practice
  - Gastroenterology
  - Biochemistry
  - Epidemiology
  - Healthcare payers
  - Ministry of health

- Secretariat provided by
  - Institute of Health Information and Statistics – Czech National Coordination Centre for Prevention of Serious Diseases
## Pilot project: Indicative timetable

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Pilot project: Implementation

- project will recruit patients coming for their usual colorectal cancer screening examination (age over 50)
- patients will be recruited by their GP, who will include defined type of quantitative FOBT in their screening testing
- the project will include centralized evaluation for faecal occult blood, and will allow to test for feasibility and acceptability of the centralized testing
- the project should include approximately 1000-1500 patients
- if tested positive, the participants will continue with usual care defined within the screening programme
- results will be recorded in an electronic data capture system
Open questions: to be solved by the working group

- Appropriate size of the study (patients, providers) (scientific objectives?)
- Role of gastroenterologists – actively involved or only included as experts within the working group?
- Comparison with usual practice – cross-over study or comparison with general population? (monitoring and reimbursement mechanisms in question)
- Inclusion of different quantitative FIT technologies (centralised vs. POCT)?
- Centralised distribution of FIT tests?