



Quality assurance for FIT in the Dutch colorectal cancer screening programme

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Expert Working Group
'FIT for screening'



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CRC screening started January 2014

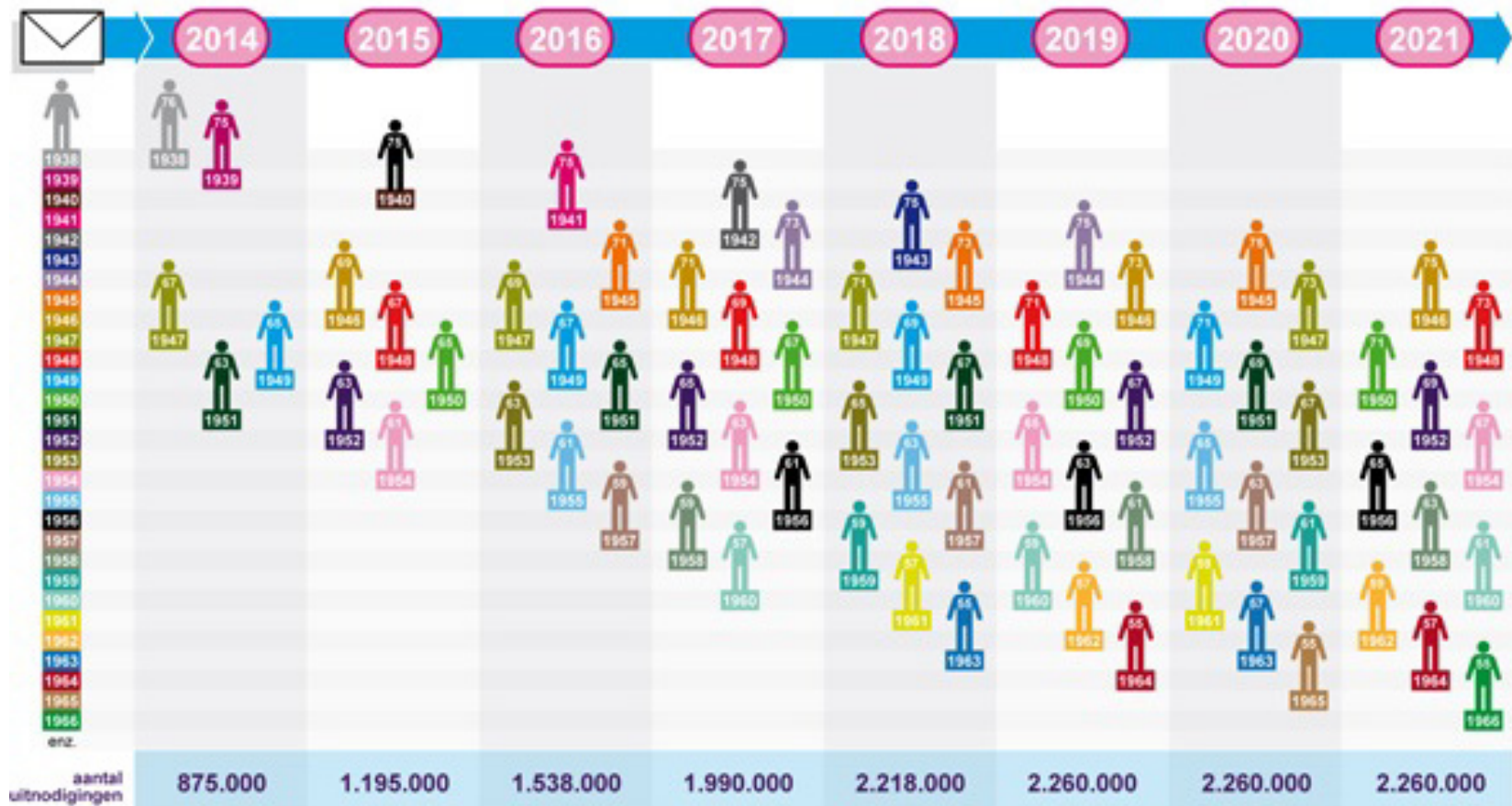
Expected effects (in 2020)

| | |
|---|-------------|
| Scope of target group (men & women 55-75 years old) | 4.4 million |
| No. of invitations per year (at an invitation frequency of every 2 years) | 2.2 million |
| Number of screening tests (FIT) per year (expected participation: 60%) | 1.3 million |
| Number of unfavourable results (positive FIT) per year | 85,000 |
| Number of colonoscopies after positive FIT per year (85% of positive FIT) | 72,000 |

FIT + colonoscopy



Phased introduction





Quality control

- 3 labs to spread the risks and to compare results

Each lab

- uses same method and same analyser
 - is unconditionally accredited to ISO 15189
 - has an comprehensive total quality management system
 - has a certified clinical chemist
-
- Aim: 3 labs should work as if they were one lab
 - National coordinator monitoring FIT from SKML, the Dutch external quality assurance scheme organiser



Start of quality control: European tenders

- Legal obligation
- Opportunity to select by quality and price

1. FIT + analyser:

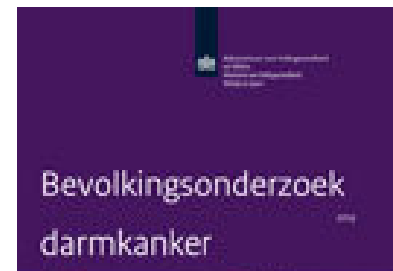
Sysmex, subcontracting Sentinel (FOB Gold) + DiaSys (BioMajesty van Jeol) + Inpeco (track)

2. Screening laboratories:

Orbis Medical Centre, Isala and Star Medical Centre

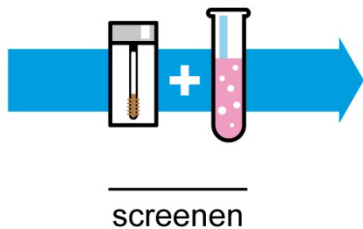


5 screening organisations send the invitations





Screening laboratories



The screening lab:

- opens the return envelopes
- scans the return forms that are electronically read
- examines stool for the presence of blood
- reports results electronically to the screening organisation





Return envelopes





Unwrapping & scanning

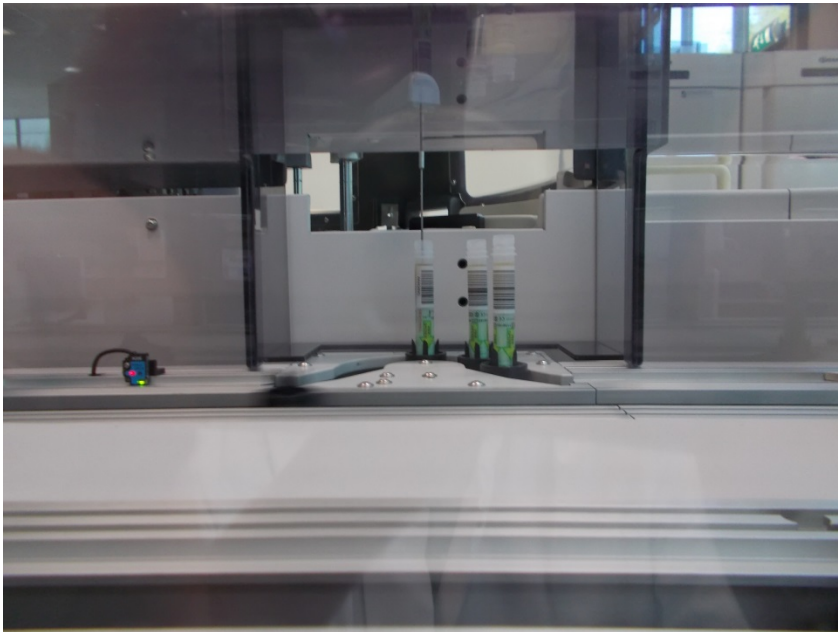




Identical
configuration
in 3 labs



Identical configuration in 3 labs





Components of quality assurance

1. Internal quality control samples (from Sentinel and SKML)
2. External QC samples (SKML and ?)
3. Check by national coordinator monitoring FIT
4. Internal audit
5. External audit
6. Use of protocols and SOPs (made together during **pilot phase**)
7. Structural consultation (SKML, clinical chemists, screening organisations)
8. Entry check tubes, calibrators, QC samples Sentinel



1. Internal QC samples

- In BioMajesty, Sentinel
 - 50 ng/ml
 - 70-80 ng/ml
 - 300 ng/ml

Before and after each analytical run

- If 2 or 3 results don't meet the analytical requirements which are determined before taken in production: actions under authority of the clinical chemist according to SOP
- If not able to get results in accordance with the analytical requirements, the national coordinator is in the lead and responsible for tuning between the laboratories



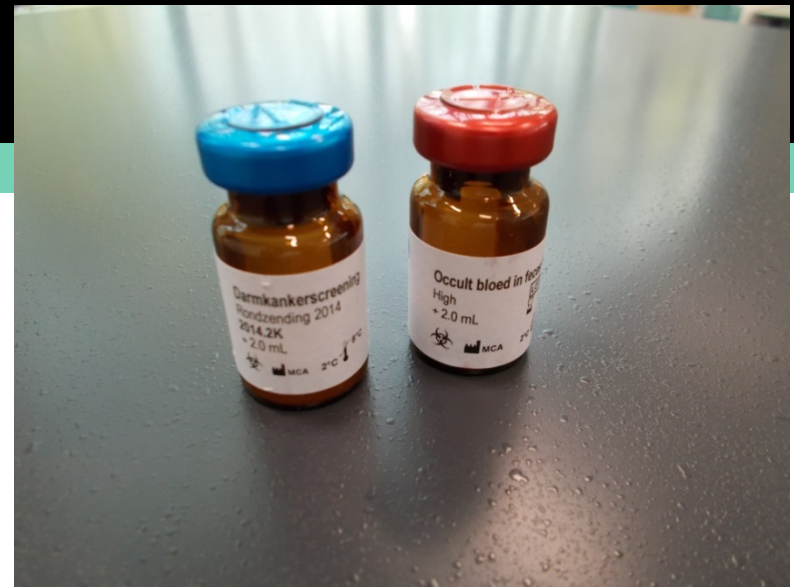


2. SKML QC samples

- Via track, SKML
 - 65 ng/ml
 - 120 ng/ml

Daily one of these two as internal QC sample

- Twice per week, 10-15 levels, unknown to lab, as external QC sample
- **Commutable material = same matrix as client samples:** mixed feces samples suspended as client samples in buffer, spiked with known amounts of Hb, lyophilised, reconstitution in water





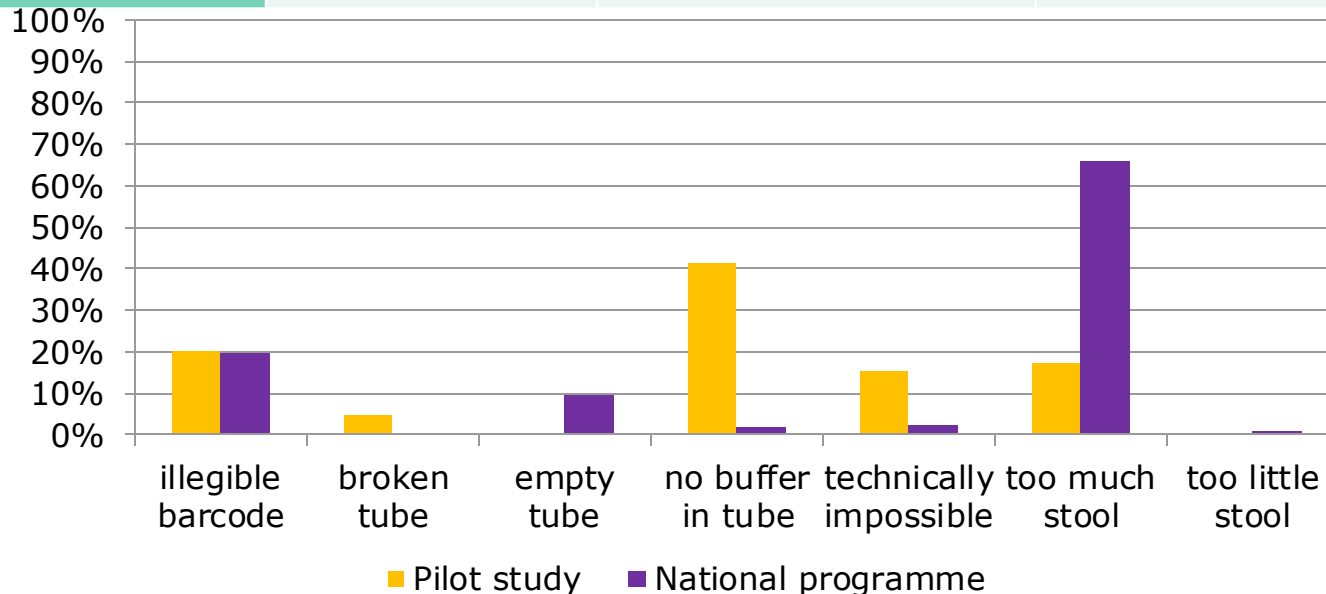
3. Check by national coordinator

- Results from internal and external QC samples
- After approval of client results by the clinical chemist, these are sent electronically to the central database
- The following results are available for national coordinator (3 labs) and clinical chemist (own lab):
 - Percentage positive results \geq (88 ng/ml)
 - Percentage results below detection limit (< 20 ng/ml)
 - Percentage results ≥ 20 and < 88 ng/ml
 - Daily average + SD calculated on the basis of binomial statistics



Rejected samples (data until March 12)

| | Number of FiT | Number rejected samples | Percentage rejected samples |
|-----------------------------|---------------|-------------------------|-----------------------------|
| Pilot of national programme | 3219 | 137 | 4,26% |
| National programme | 76235 | 380 | 0,50% |





Further information

www.rivm.nl/en/Topics/B/Bowel_cancer_screening_programme

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