



National Institute for Public Health  
and the Environment  
*Ministry of Health, Welfare and Sport*

# Feasibility study into population screening

Feasibility study into population screening for bowel cancer

*Detection of bowel cancer put into practice*



National Institute for Public Health  
and the Environment  
*Ministry of Health, Welfare and Sport*

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Detection of bowel cancer put into practice

Report 225082001/2011

## Colophon

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People shopping in Kalverstraat, Amsterdam, 8 March 2011

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## Abstract

### **Feasibility study into population screening for bowel cancer**

Detection of bowel cancer put into practice

The introduction and implementation of nationwide population screening for bowel cancer in the Netherlands is certainly feasible. However, the population screening programme will require effective preparation and a phased introduction if the associated quality requirements are to be guaranteed. The same applies to the need for sufficient capacity to carry out any follow-up tests that may be required. This emerged from a so-called feasibility study into this population screening programme, carried out by the National Institute for Public Health and the Environment (RIVM). The Minister of Health, Welfare and Sport will use this study in reaching a decision on whether to proceed with the introduction of this population screening programme. A population screening programme for bowel cancer is cost effective, and can ultimately prevent 2400 deaths from this disease each year. Once a decision on the introduction has been made, the preparation of this population screening programme will involve at least two years.

The population screening programme is intended for individuals between 55 and 75 years of age (4.4 million people). The screening organisations contact these individuals every two years, and invite them to participate in the population screening programme. Home testing kits (iFOBT) are sent to the home addresses. After use, these kits are sent off for analysis. Those whose tests produce an abnormal result will be referred for further diagnosis (colonoscopy) and, if necessary, treatment.

The feasibility study was set up in cooperation with the relevant professional groups, patient organisations, the screening organisations, and other stakeholders. The introduction of screening enjoys broad support among these stakeholders.

Part of the feasibility study was to determine which preparatory activities should be carried out, and under what conditions. This study describes the guidelines and quality requirements that are needed, and how the quality of the programme can be monitored. Measures are proposed to compensate for the calculated capacity shortfalls, such as a shifting in the allocation of responsibilities and an efficient colonoscopy procedure. Steps must be taken to avoid long waiting lists for colonoscopy and subsequent treatment. If necessary, the phased introduction can be modified to this end. Appropriate consideration should also be given to communication, both in a general sense during the introduction of the population screening programme and, more specifically, with participants (concerning the programme's purpose and usefulness, and the processes involved). In addition, details of the major implementation activities are provided, together with a forecast of costs.

#### Key words:

population screening programme, colorectal cancer, implementation, colonoscopy, iFOBT, capacity, quality.

## Rapport in het kort

### **Uitvoeringstoets bevolkingsonderzoek naar darmkanker.**

Opsporing van darmkanker in praktijk gebracht

Het is mogelijk een landelijk bevolkingsonderzoek naar darmkanker in Nederland in te voeren en uit te voeren. Wel zijn een goede voorbereiding en een gefaseerde invoering vereist om de kwaliteitseisen van het bevolkingsonderzoek te garanderen. Het zelfde geldt voor voldoende capaciteit om eventueel vervolgonderzoek te kunnen uitvoeren. Dit blijkt uit een zogeheten uitvoeringstoets naar dit bevolkingsonderzoek, uitgevoerd door het RIVM. De minister van Volksgezondheid, Welzijn en Sport zal de toets gebruiken bij de besluitvorming of dit bevolkingsonderzoek wordt ingevoerd. Een bevolkingsonderzoek naar darmkanker is kosteneffectief en kan op termijn jaarlijks 2400 sterfgevallen voorkomen. Na de besluitvorming is minimaal 2 jaar aan voorbereidingen nodig om het bevolkingsonderzoek gefaseerd te kunnen invoeren.

Het bevolkingsonderzoek is bedoeld voor mensen van 55 tot en met 75 jaar (4,4 miljoen mensen). Zij worden door screeningsorganisaties elke 2 jaar uitgenodigd deel te nemen aan het bevolkingsonderzoek. Zij ontvangen daarvoor thuis een test (iFOBT), die zij zelf opsturen voor analyse. Bij een afwijkende uitslag zullen zij worden doorverwezen voor verdere diagnostiek (coloscopie) en zo nodig behandeling.

De uitvoeringstoets is in samenwerking met de betrokken beroepsroepen, patiëntenorganisaties, screeningsorganisaties en andere stakeholders tot stand gekomen. Onder hen is een breed draagvlak om de screening in te voeren.

Voor de uitvoeringstoets is in kaart gebracht welke voorbereidende activiteiten zouden moeten worden uitgevoerd, en onder welke voorwaarden. Zo is beschreven welke richtlijnen en kwaliteitseisen nodig zijn en hoe de kwaliteit van het programma kan worden bewaakt. Er worden maatregelen voorgesteld om de berekende capaciteitstekorten op te vangen, zoals taakverschuiving en een efficiënte uitvoering van de coloscopie. Verder moet erop worden toegezien dat er geen lange wachttijden ontstaan voor coloscopie en verdere behandeling; zonodig wordt de gefaseerde invoering bijgestuurd. Tevens moet er voldoende aandacht zijn voor communicatie, zowel in algemene zin bij de introductie van het bevolkingsonderzoek als voor de deelnemers over het doel, nut en proces ervan. Daarnaast zijn de belangrijkste implementatiewerkzaamheden en een prognose van kosten weergegeven.

#### Trefwoorden:

bevolkingsonderzoek, darmkanker, implementatie, coloscopie, iFOBT, capaciteit, kwaliteit.

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3. Communication on the Screening Programme  
M. Sobels, C-zicht
4. Indicators and minimum data set for national monitoring  
system and quality assurance for the bowel cancer screening  
programme  
F. van Hees et al., MGZ Erasmus Medical Center
5. Advisory report on the IT infrastructure for bowel cancer  
screening  
H. Mekenkamp, MedicalPHIT, B. Schapendonk, CvB
6. Capacity survey for the bowel cancer screening programme  
M. van Baalen, J. van Elteren, Berenschot
7. The additional capacity required in the care system, the cost  
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the introduction of a bowel cancer screening programme in the  
Netherlands  
F. van Hees et al., MGZ Erasmus Medical Center





## Summary

In 2009 the Health Council advised the Minister of Health, Welfare and Sport that there was sufficient evidence to introduce a bowel cancer screening programme on a regular basis. In response to the advisory report, and in preparation for the final decision on the introduction of a nationwide programme, the Minister asked the Centre for Population Screening (CvB) of the National Institute for Public Health and the Environment (RIVM) to conduct a feasibility study into a bowel cancer screening programme, the purpose of which was to ascertain the prerequisites for a bowel cancer screening programme and how it could be introduced successfully.

As the feasibility study shows, it is possible to introduce and implement a nationwide bowel cancer screening programme in the Netherlands using a self-administered test (iFOBT). There is broad support for the introduction of such a programme, which could eventually prevent 2,400 deaths a year. Once it is fully implemented, 4.4 million people aged 55 to 75 would be invited to take part in the programme every two years.

The feasibility study describes the primary process, the duties and responsibilities of the organizations involved in the screening programme. If the quality of the programme and capacity for its implementation, further diagnosis (colonoscopy) and care are to be guaranteed, proper preparations must be made for its introduction. As regards the implementation of the programme, the CvB recommends that this be phased in as proposed by the Health Council. This could result in shortages of capacity in gastroenterohepatology, gastroenterological surgery and to a lesser extent pathology. The professional groups involved, however, expect that the measures they propose will overcome any problematic shortages of capacity.

It will be important to monitor the quality of, and capacity for, the screening programme and follow-up care right from the start, so as to guarantee good diagnosis and care. If there is a risk of long waiting times developing for colonoscopy following an abnormal iFOBT or for the treatment of patients, the alternative scenarios for phased introduction set out in the study can be employed.

The cost of implementing the programme is set out in the feasibility study. In the initial years of the phased introduction the cost of follow-up care from the screening programme will increase, as the programme will result in bowel cancer being detected sooner and relatively large numbers of people with advanced stages of cancer will be found during that period. The Health Council's calculations indicate that the bowel cancer screening programme will be cost-effective.

The following are essential prerequisites for successful introduction:

- The professional groups will need to make preparations for the measures they propose to overcome shortages of capacity, also to improve expertise and develop guidelines.
- The health insurers, the Ministry of Health, Welfare and Sport and the professional groups concerned will need to reach agreement on the consequences for budgetary frameworks and the purchase of care.
- Monitoring of quality and capacity.
- Organization of communication about the screening programme and within it.
- A preparatory period of at least two years once it has been decided to introduce the programme.

The feasibility study was carried out with the involvement of appropriate stakeholders, who made recommendations in an advisory committee and working groups on information management and capacity and quality.

# 1 Introduction

Cancer of the large intestine<sup>1</sup> is common in Western countries. Bowel cancer was diagnosed in 12,117 people in 2008 and killed over 4,800 patients that year.<sup>(1)</sup> The preliminary stage of bowel cancer (adenoma) is protracted, and it is easy to recognize and simple to treat, enabling medical problems and mortality to be prevented (see Box 1).

In 2009 the Health Council produced an advisory report commissioned by the Minister of Health, Welfare and Sport on the desirability and feasibility of a bowel cancer screening programme in the Netherlands. In response to that advisory report, and in preparation for the final decision on the introduction of a nationwide programme, the Minister asked the Centre for Population Screening (CvB) of the National Institute for Public Health and the Environment (RIVM)<sup>2</sup> to conduct a feasibility study into a bowel cancer screening programme (see Appendix 1).

The Health Council's Bowel Cancer Screening Programme advisory report is briefly discussed in section 1.1. Section 1.2 summarizes the Minister's response to the Council's recommendations and describes the commission that the Minister awarded to the CvB for a feasibility study into a bowel cancer screening programme. Section 1.3 briefly recounts how the commission came about. The approach employed in the study is set out in section 1.4. Lastly, section 1.5 describes the organization of the present report.

## 1.1 The Health Council's advisory report

On 17 November 2009 the Health Council published its Bowel Cancer Screening Programme advisory report in response to a request by the Minister of Health, Welfare and Sport of 27 November 2008.<sup>(2)</sup> In its report the Council concluded that a bowel cancer screening programme was desirable and feasible, assuming that the required care capacity can be built up over the next few years. The Council found that with a participation rate of 60% the screening programme would prevent an average of 1,428 deaths per year (over the 2010-2039 period) and would have a favourable cost-effectiveness ratio of 2,200 euros per year of life gained. It recommended gradually introducing a two-yearly bowel cancer screening programme for men and women aged 55 to 75. The recommended screening test is the iFOBT (immunochemical faecal occult blood test), a self-administered test (see Box 2).

The Council further recommended providing good care to follow up the screening programme, as this will be needed if the programme is to achieve its desired effect. It also made suggestions on designing the organizational structure so as to ensure the good-quality, sustainable implementation of the programme and the follow-up care. The Council noted that introducing a nationwide bowel cancer screening programme is a major project, with a target group of over 4 million men and women being invited to take part every two years. It is essential that it be phased in so as to build up the required staffing and resources.

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<sup>1</sup> Where 'bowel cancer' (and the bowel cancer screening programme) is referred to in the remainder of this report this means cancer of the large intestine, the appendix, or the rectum.

<sup>2</sup> The RIVM's Centre for Population Screening is referred to in the remainder of this report as the CvB.

**Box 1: Bowel Cancer**

Bowel cancer develops from epithelial cells lining the interior of the large intestine. Important warnings of bowel cancer are an unexplained persistent change in bowel habit (constipation or diarrhoea), blood in the stool, persistent abdominal pain and/or weight loss for no apparent reason.

Bowel cancer usually starts as a polyp. A small proportion of these polyps can grow over the years into a tumour that invades the intestinal wall and eventually metastasizes via the lymph glands or the circulation. These are generally a particular type of polyp known as 'adenomas'. About 30% of the over-60s have adenomas. Adenomas only need to be treated if they are advanced. The risk of contracting bowel cancer at any time in your life is 4-5%. Nine out of ten cases occur in the over-55s. New cases of bowel cancer in 2008 in the Netherlands occurred in 12,117 persons.<sup>(3)</sup> As a result of the ageing population the annual number of cases is expected to rise to 14,000 in 2015.

The five-year survival rate for bowel cancer is approximately 59% at present, and it is highly dependent on the stage at which the tumour is detected (stage I: 94%; stage IV: 8%). The risk of death from bowel cancer is 2% for men and 1.5% for women. It killed about 4,800 people in 2008.

Most people with bowel cancer (about 80%) have no family history of the disease, hence the term 'sporadic bowel cancer'. Bowel cancer that runs in the family is found in 15-20% of bowel cancer patients. Hereditary syndromes are found in approximately 5%. The remainder of people with bowel cancer with family history of the disease have familial bowel cancer: this is the case if it is also found in one or more first-degree relatives. Carriers of bowel cancer genes and a proportion of people who have first-degree relatives with bowel cancer have a higher risk sufficient to warrant more frequent check-ups than the two-yearly check using a self-administered test (iFOBT).

**1.2 The Minister's response and the commission**

On 16 February 2010 the Minister of Health, Welfare and Sport wrote to the House of Representatives stating his position on bowel cancer screening.<sup>(4)</sup> He endorsed the Health Council's view that a major health benefit could be achieved by introducing a bowel cancer screening programme. He also referred to the reports of the National Cancer Control Programme (NPK), which are very useful.<sup>(5)</sup> Before a final decision can be made on the programme's introduction, the right conditions need to be created: this will involve finding funding from central government and under the health insurance schemes for both follow-up and aspects of implementation. The quality of implementation also needs to be assured and sufficient capacity must be available.

As regards the implementation aspects, in March 2010 the Minister asked the CvB to conduct a feasibility study into a bowel cancer screening programme (see Appendix 1), the purpose of which was to ascertain the consequences of introducing such a programme. In his letter the Minister asked the CvB to identify any problems and suggest how to deal with them.

The Minister expects the study to include at least the issues of capacity, communication, flexibility in the light of our growing understanding and new technological developments, the screening programme including the link with diagnosis and care, as well as monitoring and evaluation.'

Ministry would also like to receive a survey of support in the field in addition to a stakeholder analysis.

The results of the study will be used as input to the decision on the introduction of the screening programme. In addition to the feasibility study by the CvB, in 2010 the Ministry examined the question of funding the introduction of the screening programme. The Minister anticipates that a careful decision will be made in spring 2011.

### **1.3 History and background**

In 2001 the Health Council noted in a horizon scanning report on a bowel cancer screening programme that introducing such a programme merited serious consideration but a number of questions still needed to be answered. Reports by the Dutch Cancer Society (KWF Kankerbestrijding)(6) and the Netherlands Organisation for Health Research and Development (ZonMw)(7) in 2004 and 2005 urged the rapid introduction of the programme. In 2006 the then Minister of Health, Welfare and Sport concluded that serious consideration needed to be given to a bowel cancer screening programme.(8) Additional research was then done into good methods of screening for bowel cancer and the feasibility of a screening programme in the Netherlands in two pilot projects, which are discussed briefly below. In addition to these, three other pilot projects were carried out.

The FOCUS (Faecal OCcUlt blood Screening) trial started in 2006 as a joint project of Radboud University Nijmegen Medical Centre, the Academic Medical Centre (AMC) in Amsterdam, the Comprehensive Cancer Centre East (IKO) and the Comprehensive Cancer Centre Amsterdam (IKA). The FOCUS trial compared the gFOBT and the iFOBT based on pre-randomization and studied the effects of these different tests on participation and the yield of the screening programme.(9).

In 2006 the Erasmus Medical Center Rotterdam also began a trial screening programme called CORERO (Bowel cancer ROTterdam) in collaboration with the Comprehensive Cancer Centre Rotterdam and Stichting Bevolkingsonderzoek Zuidwest Nederland (the screening organization for the south-west of the Netherlands). CORERO compared three types of screening based on pre-randomization: sigmoidoscopy, iFOBT and gFOBT.(10) CORERO-II focused on the optimum time interval for screening, and on the effect on programme yield of submitting two iFOBT stool samples instead of one.

The results of the trial screening programmes were used in the Health Council's advisory report.

**Box 2: The screening programme for bowel cancer**

The bowel cancer screening programme screens men and women aged 55-75 using a self-administered test (iFOBT). A positive result is followed by colonoscopy to find out whether the participant in question has bowel cancer.

The iFOBT (immunochemical faecal occult blood test) is a test which can detect invisible traces of blood in the stool immunologically. The subject takes a sample of faeces at home and sends it in. It is examined in a laboratory. The antibodies used target human haemoglobin and are specific to human blood. The test does not involve any dietary restrictions. A positive iFOBT warrants further investigation in the form of colonoscopy.

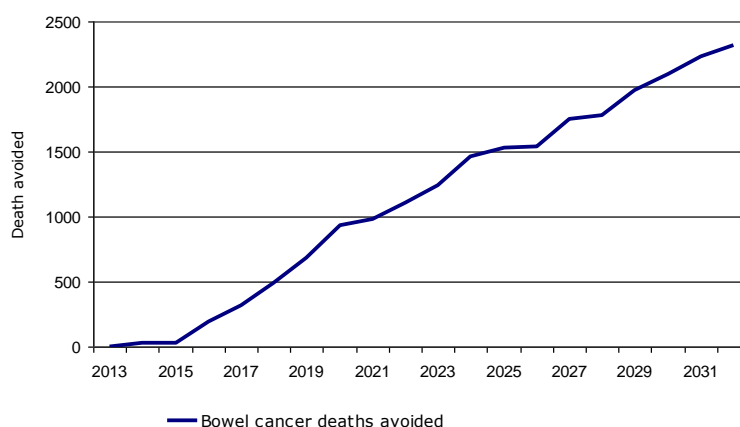
Colonoscopy is a technique enabling the whole of the large intestine to be examined using an endoscope or video endoscope. This requires extensive preparation: the subject has to take a strong laxative the day before. Colonoscopy is the gold standard for detecting bowel cancer and adenomatous polyps. Any polyps are removed immediately if possible, otherwise a sample of tissue is taken and examined by a pathologist.

The screening programme for bowel cancer in figures (reference date 2020-2030):

Target group	men and women aged 55-75
Size of target group	4.4 million
Interval between iFOBT screening invitations	every two years
Numbers of invitations per year	2.2 million
Expected participation	60%
Number of iFOBT analyses per year	1.3 million
Number of positive iFOBTs per year	78,000
Colonoscopies following a positive iFOBT	66,000

The five-year survival prognosis for iFOBT screening is 85%, i.e. substantially better than for the clinical control group without screening (59%).

The prognosis of the number of deaths avoided as a result of introducing the bowel cancer screening programme is shown in the graph below (source: report by Erasmus Medical Center Rotterdam). The number of deaths avoided rises gradually to 2,300 per year in 2032. It is then expected to stabilize at about 2,400 per year.



## 1.4 Feasibility study: approach

The CvB started work on the feasibility study in spring 2010. In order to identify the consequences of introducing a new screening programme the following activities were carried out, divided into two stages:

### A. Stakeholder analysis and preliminary survey:

- Stakeholder analysis: an overview of all the organizations involved in a possible bowel cancer screening programme, including a description of their aims and duties.
- Preliminary survey: interviews with experts in screening organizations, professional groups, patients' organizations and organizations that could play a role in the bowel cancer screening programme. Interviews were held with a total of 31 organizations. The list of organizations and interviewees can be found in Appendix 2. The results of the trial screening programmes in the Amsterdam, Rotterdam and Nijmegen regions were presented to the CvB.

Based on the stakeholder analysis and the preliminary survey, the CvB drew up an action plan for the remainder of the feasibility study, which was agreed with the Ministry of Health, Welfare and Sport.

### B. Drawing up recommendations on the feasibility study:

- Setting up a Bowel Cancer Screening Programme (Preparation) Advisory Committee, an Information Management Working Group and a Capacity and Quality Working Group. The Advisory Committee and the Working Groups advised the CvB on specific aspects of the feasibility study. An overview of the organizations represented on the Advisory Committee and the Working Groups can be found in Appendix 3.
- A number of issues were examined in depth based on interviews with stakeholders. It was decided that greater clarity was needed on these subjects for the purpose of decision-making. The subjects were capacity and phased introduction, indicators and information management, management and organization, quality and quality assurance.

At both stages of the feasibility study information was collected on the subjects specified by the Minister. The present report has been drawn up using this information.

## 1.5 Organization of this report

This report sets out the results of the feasibility study. A stakeholder analysis and the main findings from the interviews in the preliminary survey can be found in chapter 2. Chapter 3 contains a proposal on the organization of the primary process of the bowel cancer screening programme. Chapter 4 describes the duties and responsibilities of the organizations involved in the programme. Chapter 5 deals with communication on the screening programme. Chapter 6 discusses quality assurance policy, as well as the monitoring and evaluation of the programme, and the safeguarding of knowledge and innovation. Chapter 7 sets out various capacity aspects of the bowel cancer screening programme. The implementation process is described in chapter 8. Chapter 9 describes the funding of the programme. The report concludes with the key points in this feasibility study and recommendations on the nationwide introduction and implementation of a bowel cancer screening programme, set out in chapter 10.

The in-depth studies (in Dutch) carried out for the feasibility study can be found on the CD-ROM enclosed with this report.





## 2 Stakeholder analysis and preliminary survey

A large number of organizations will be involved directly or indirectly in the implementation of a bowel cancer screening programme, hence the CvB carried out a stakeholder analysis. This entailed first identifying the main organizations involved: the results of this stakeholder analysis are set out in section 2.1.

Interviews were then held with a total of 31 organizations during the April-December 2010 period, first and foremost so as to gain an impression of the support for and feasibility of a bowel cancer screening programme. The various organizations were also asked about their aims, activities and the contributions they could make to the programme, and they were questioned about important issues and problems that needed to be considered when implementing a possible bowel cancer screening programme. The project leaders of the three trial screening programmes talked at length about the knowledge and experience they had gained. The interviews yielded a good deal of information and understanding that could be used when introducing a bowel cancer screening programme. The main findings from the interviews as regards support and feasibility are set out in section 2.2, as well as other points that emerged during the interviews. The CD-ROM enclosed with this report includes an overview of the organizations that would be involved in the bowel cancer screening programme, including a brief description of their aims and activities (the 'stakeholder analysis').

### 2.1 Stakeholder analysis

The CvB identified the following categories of organizations that would be involved directly or indirectly in the bowel cancer screening programme and follow-up diagnosis and treatment:

- organizations involved in decision-making;
- organizations involved in management and funding;
- organizations involved in implementation;
- organizations involved in monitoring, evaluation and information management;
- organizations involved in quality control and improvement;
- organizations involved in knowledge development;
- the public, clients, patients, relatives, informal carers and their representatives;
- other organizations.

#### *Organizations involved in decision-making*

The Ministry of Health, Welfare and Sport is responsible for instituting a bowel cancer screening programme, taking advice from the Health Council and the CvB. The Health Council makes recommendations on current knowledge and the medical aspects of a screening programme; the CvB advises on the implementation aspects.

#### *Organizations involved in management and funding*

The CvB, acting on the instructions of the Ministry of Health, Welfare and Sport, is responsible for the management and funding of breast cancer and cervical cancer screening programmes and is expected to do this for the bowel cancer screening programme as well. Various organizations are responsible for the management and funding of care: in addition to the Ministry, these are the health insurers (as their association, Zorgverzekeraars Nederland), the Health Care Insurance Board, the Dutch Healthcare Authority and the Netherlands Competition Authority.

*Organizations involved in implementation*

These are first and foremost the five screening organizations involved in implementing the breast cancer and cervical cancer screening programmes. These will also be responsible for implementing the bowel cancer screening programme in their respective regions: this entails selecting and inviting the target group, carrying out the screening tests and referring patients to care. The actual testing is likely to be outsourced to suitably equipped laboratories and the clinical chemists working there, under the umbrella of the Netherlands Society for Clinical Chemistry and Laboratory Medicine (NVKC).

Important partners in diagnosis and treatment are the hospitals (university, general and specialist) under the umbrella of the Dutch Federation of University Medical Centres (NFU) and the NVZ Dutch Hospitals Association.

The main professional groups and umbrella organizations (in brackets) involved in diagnosis and treatment are the gastroenterohepatologists (Netherlands Association of Gastroenterohepatologists (NVMDL)), internists (Dutch Association of Internists (NIV)), pathologists (Dutch Pathology Association (NVVP)), surgeons (Netherlands Surgical Association (NVVH)) and anaesthetists (Netherlands Society of Anaesthetists (NVA)). The general practitioners (Dutch College of General Practitioners (NHG) and National Association of General Practitioners (LHV)) and clinical geneticists (Dutch Society for Clinical Genetics (VKGN)) also play an important role.

*Organizations involved in monitoring, evaluation and information management*

The CvB, acting on the instructions of the Ministry of Health, Welfare and Sport, is responsible for the national monitoring and evaluation of breast cancer and cervical cancer screening programmes and will be for the bowel cancer screening programme as well. The CvB will outsource the actual study of the national evaluations to an independent research institution. The breast cancer and cervical cancer screening programmes are currently under the auspices of the Erasmus Medical Center. The screening organizations will be responsible for recording the screening data and collecting the data needed for monitoring and evaluation.

Important records of pathology data are held by PALGA (the national histopathology and cytopathology data network and archive), the Comprehensive Cancer Centres (under the umbrella of the Netherlands Comprehensive Cancer Centres (IKNL)<sup>3</sup>) and Statistics Netherlands (CBS). Specifically regarding a new bowel cancer screening programme we should also mention the records of the Dutch Surgical Bowel Audit (DSCA).

As regards electronic exchange of information and the use of personal data the National IT Institute for Healthcare in the Netherlands (Nictiz) and the Dutch Data Protection Authority (CBP) respectively are important organizations.

*Organizations involved in quality control and improvement*

The Dutch Council for Quality of Healthcare set up by the Minister of Health, Welfare and Sport in 2009 is responsible for promoting good-quality care in collaboration with those working in the field. The Health Care Inspectorate promotes health by effectively maintaining the quality of care. The Comprehensive Cancer Centres (and the Dutch Institute for Healthcare Improvement (CBO)) are responsible, along with the professional groups, for developing and implementing oncological guidelines.

The focus of the National Expert and Training Centre for Breast Cancer Screening (LRCB) is on assuring the quality of breast cancer screening programmes. The RIVM's Laboratory for Infectious Diseases and Perinatal Screening (LIS) is the reference laboratory for newborn bloodspot screening. The knowledge and

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<sup>3</sup> Formerly the Association of Comprehensive Cancer Centres (VIKC)

experience acquired by the LRCB and LIS can be used when designing the bowel cancer screening programme.

#### *Organizations involved in knowledge development*

The Netherlands Organisation for Health Research and Development (ZonMw) funds health research and promotes the use of the knowledge developed to improve care and health. It does this partly on the instructions of the Ministry of Health, Welfare and Sport, which takes advice on the subject from the Health Council and the Advisory Council on Health Research (RGO).

Important research institutions are the University Medical Centres. Specialist studies in the area of bowel cancer screening are the FOCUS trial (Radboud University Nijmegen Medical Centre and AMC Amsterdam),<sup>(9)</sup> the CORERO project (Erasmus Medical Center),<sup>(10)</sup> the COCOS trial (Erasmus Medical Center Rotterdam and AMC Amsterdam), the DeCoDe project (VU University Medical Center in Amsterdam and Maastricht University Medical Centre) and the SCRIPT study (NDDO Institute for Prevention and Early Diagnostics (NIPED) in Amsterdam).

#### *The public, clients, patients, relatives, informal carers and their representatives*

The SPKS (Foundation for Patients with Cancer of the Alimentary Canal) is the patients' association for people with bowel cancer. It is a member of the Dutch Federation of Cancer Patients' Organisations (NFK). In addition to the SPKS and the NFK, the Dutch Cancer Society (KWF) and the Maag Lever Darm Stichting (Digestive Diseases Foundation) also represent the interests of bowel cancer patients.

#### *Other organizations*

Lastly, CvB interviewed the Capacity Board, the Foundation for the Detection of Hereditary Tumours (STOET) and the St. Antonius Academy, as a representative of a training centre in the care system.

## **2.2 Results of the preliminary survey**

### *Support*

None of the interviewers doubt the conclusion of the Health Council that this screening programme would produce a major health benefit. A large, broad basis of support for the introduction of a bowel cancer screening programme was found among the professional groups, screening organizations, health insurers and other stakeholders. The test proposed by the Health Council, the iFOBT, also commands broad support. Some possible future innovations in testing methods were however suggested by interviewees, especially stakeholders from academic centres (see section 6.6). Everyone also endorsed the broad outlines of implementation, quality control and organization proposed by the Health Council.

Public support has not been polled explicitly; the participation rates in the three pilot regions are known, however: 57% (Amsterdam), 61.5% (Rotterdam) and 62.2% (Nijmegen). In CORERO (Rotterdam) participation was lower among men aged 50-59, people with lower socioeconomic status and city-dwellers.<sup>(10)</sup> The initial results of the second screening show that participation in Amsterdam was lower than in the first screen, at 52%. Participation in the second round in Rotterdam went up, to 66%. We can conclude from this that, at least in the pilot regions, support in the group of invitees is reasonably large. As regards those invitees who did not take part, it is not clear whether this was due to lack of support or other factors.

Patients' organizations are very much in favour of introducing a bowel cancer screening programme, although they admit that there is little public awareness of the opportunities that such a programme could offer. This is confirmed by the Dutch Cancer Society and the Maag Lever Darm Stichting, which focus their activities raising public awareness of the risks of cancer and ways of preventing it. The same picture is gained from using the social media as a monitoring tool: this

shows that a bowel cancer screening programme is not a commonly discussed topic.

There does seem to be an increase in the availability of opportunistic screening or plans to carry this out, as shown by organizations that offer the iFOBT as a preventive activity or as part of a medical checkup or intend to do so. Questions have also been raised in the House of Representatives regarding a supplier that wished to offer the iFOBT.<sup>(11)</sup> The Health Care Inspectorate intervened in the case of a general practitioner offering the iFOBT to his clients over the age of 45, because of the Population Screening Act (WBO). Gastroenterohepatologists are noting an increase in patients' requests for opportunistic colonoscopy. These are signs of increasing public awareness that bowel cancer screening can produce benefits.

Support for bowel cancer screening in Europe is also on the rise: in November 2010 the European Parliament again passed a motion on reducing the number of deaths due to bowel cancer by means of early diagnosis. It is urging the Member States to introduce nationwide screening for bowel cancer.<sup>(12)</sup> Finland, Britain, France, Italy and the Czech Republic already have long-standing screening programmes, with nationwide (or virtually nationwide) coverage in the first four countries. Scotland is gradually introducing a nationwide screening programme and Ireland and Denmark have decided to introduce one.<sup>(13)</sup> A number of other countries provide individual screening, not as part of a programme: the participation rates there are low.<sup>(1)</sup>

#### *Feasibility*

As regards feasibility, interviewees particularly asked that possible discrepancies (national and/or regional) between the capacity available and required within the professional groups involved be looked at. Some interviewees foresaw capacity problems, not only in gastroenterohepatology but also in pathology, surgery and anaesthesia. The estimates of the various organizations and individuals differed widely on this point, however.

#### *Other points*

In addition to the comments on support and feasibility, interviewees mentioned many other points important to the introduction of a bowel cancer screening programme. The following topics were raised in many of the interviews:

- Good quality assurance to ensure that the desired effect can be achieved, including organizing a good reference function for the laboratories and appointing regional gastroenterohepatology coordinators and pathology coordinators.
- A well-considered choice of a limited number of laboratories, and the setting-up of specialist endoscopy centres.
- Organizing a good information management system to support the primary process, monitoring and evaluation of the screening programme and scientific research. This entails creating a good knowledge infrastructure and a research programme to make future innovations possible.
- The importance of allowing sufficient time to prepare for the launch of the programme: organizing the information management system, monitoring and evaluation, protocolization and tendering for the purchase of laboratory equipment in particular are relatively time-consuming.
- Deployment of endoscopy nurses and physician assistants to overcome potential capacity problems.
- Combining phased introduction by age with regional implementation.

These points have been included in this feasibility study wherever possible and appropriate.

### 3 Primary process

The bowel cancer screening programme will screen men and women aged 55 to 75 for bowel cancer and its preliminary stages. This chapter discusses the primary process of the screening programme including follow-up diagnosis and curative care.<sup>4</sup> Following a general description of the primary process, including the criteria, in section 3.1, the ensuing sections examine the main activities. Details in the form of a process description can be found in Appendix 4.

#### 3.1 Introduction

By the primary process of the bowel cancer screening programme including follow-up care we mean the activities directly involved in identifying participants with an increased risk of bowel cancer and the diagnosis, treatment and surveillance subsequently required. The primary process comprises the following steps (see also Figure 1):

1. selection;
2. invitation;
3. testing;
4. communication of results;
5. referral to care;
6. diagnosis;
7. treatment;
8. surveillance.

Diagnosis (including colonoscopy) and treatment take place in the health care system. An important consideration for the health care is the referral back to the screening programme, including the provision of the information on diagnosis and treatment.

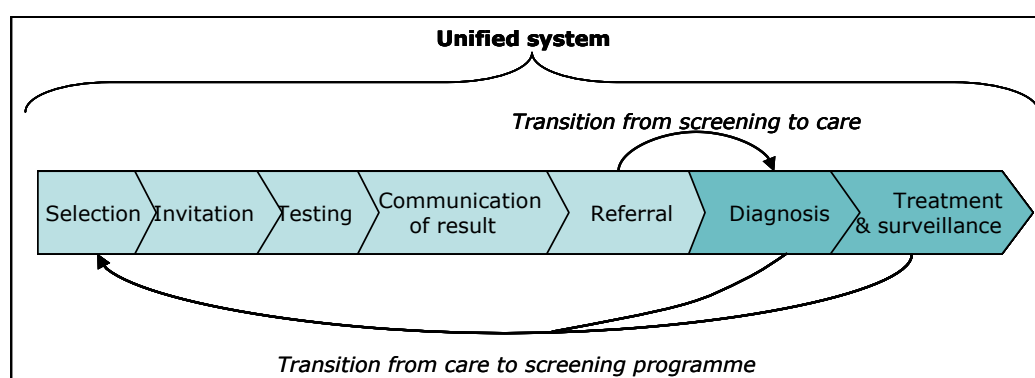


Figure 1: Diagram of the primary process of the bowel cancer screening programme, including follow-up care

<sup>4</sup> Where 'care' is referred to in the remainder of this report this means diagnostic and/or and curative care.

The description of the primary process of the possible new bowel cancer screening programme is based on the medical considerations and recommendations set out in the Health Council's Bowel Cancer Screening Programme advisory report(1) and the report Bowel Cancer Screening Programme: Scenarios for Effective Introduction by Working Group 2 of the National Cancer Control Programme (NPK).(5) The findings of the consultation with appropriate field practitioners carried out by the CvB and knowledge of the implementation of screening programmes (in particular for breast cancer and cervical cancer) acquired by the CvB have also been used.

The CvB has translated the medical considerations, recommendations, findings and knowledge items mentioned above into the following specific criteria for the design of the primary process:

1. The organization of the bowel cancer screening programme should be based on that of the existing breast cancer and cervical cancer screening programmes.
2. Selection and invitation should be done by the five screening organizations involved in the breast cancer and cervical cancer screening programmes.
3. The target group should be selected based on data from the municipal personal records database (GBA). Exclusion from the target group should be based on a request by the person being invited himself or on indications from diagnosis and treatment (for example if surveillance is indicated).
4. Invitation by screening organizations will promote uniform and good-quality implementation of this activity.
5. Announcing the screening to participants prior to the first invitation appears to have the effect of increasing the participation rate (by 3-4%) and is cost-effective.(14)
6. The screening should be carried out using an iFOBT. Invitees should be sent the invitation with the screening kit. Invitations should include information material so that invitees are well-informed and able to decide freely whether to accept the offer of screening.
7. The laboratory function should be centralized and accredited to ensure rapid processing of stool samples and assure the quality of the iFOBT.
8. General practitioners play a role valued by participants in communicating abnormal results and should therefore be informed promptly.
9. For the sake of quality assurance, colonoscopies should be carried out by a network of specialist centres. The referral procedure should be geared to this, with referral taking place directly through the screening organizations, which should only refer participants to colonoscopy centres that comply with the quality standards laid down (see section 6.1).
10. To ensure the quality of the pathology tests they must be carried out by laboratories that comply with the quality standards laid down (see section 6.1).
11. Following a negative colonoscopy the risk of developing bowel cancer in the next ten years is so small that bowel cancer screening is not required during that period.
12. The effectiveness and efficiency of the screening programme will depend inter alia on the effectiveness and efficiency of follow-up diagnosis, treatment and surveillance.

A detailed process description of the activities set out below can be found in Appendix 4.

### **3.2 Selection and invitation (criteria 1, 2, 3, 4 and 5)**

The screening organization should select the people in the target group from the municipal personal records database, excluding (for this screening or permanently) anyone who has previously deregistered or who can be ruled out based on indications from diagnosis and care. The screening organization should invite the remainder of the target group to participate in the screening programme: the

invitation should include information material, a screening kit, a laboratory form and a reply envelope. People being invited for the first time should be sent an announcement prior to the invitation.

The invitee has three possible responses. He can take part in the screening programme (see next section). He can deregister (for this screening or permanently): the screening organization should record this and not send out a reminder for this screening. Alternatively he can not respond at all, in which case the screening organization should send a reminder after a set time.

The invitee again has three possible responses to the reminder. He can go ahead and take part in the screening programme (see next section), deregister for this screening or permanently, or again not respond at all. If he does not respond, no further action should be taken, and he should be re-invited for the next screening.

### **3.3 Testing (criteria 1, 6 and 7)**

The screening test commences with the participant taking a stool sample, filling in the required information on the enclosed form, placing the sample and the form in the reply envelope and sending it to the designated laboratory by regular mail.

The laboratory analyses and assesses the sample based on the standards laid down and sends the result to the screening organization. If the sampling date is missing the laboratory should report this.

If the sample cannot be assessed, the screening organization should invite the participant to send in a fresh sample.

### **3.4 Communication of results and referral (criteria 1, 4 and 8)**

If there is an abnormal or normal result the screening organization should send the participant a letter stating the result and giving advice if necessary.

If the laboratory reports that the sampling date is missing and the result is normal, the screening organization should check whether the interval between sending the invitation and receiving the result exceeds a predetermined length of time: if so, the result may be unreliable. The screening organization should inform the participant of this and draw his attention to the options available (retaking the test or accepting the test result, depending on the time of sampling).

If the result is abnormal the screening organization, using a web application developed for the purpose, should schedule an appointment for an intake interview at a colonoscopy centre and send the participant a letter, on behalf of the regional gastroenterohepatology coordinator, stating the result and referring the patient to a colonoscopy centre. Prior to this the general practitioner should be informed of the result and the referral recommendation by phone and sent a copy of the result and the recommendation by post. Before the participant receives the results letter the general practitioner should inform him or her of the result by phone or during a consultation. The referred participant should confirm or change the appointment at the colonoscopy centre through the screening organization. The screening organization should check whether the participant has complied with the referral recommendation; if not, it should inform the general practitioner after a set time. The general practitioner should point out to the referred participant how important it is to comply with the referral.



### **3.5 Diagnosis and treatment (criteria 1, 8, 9, 10 and 11)**

The referred participant should be informed about the proposed procedure at the colonoscopy intake interview and a case history should be taken. Based on the case history the participant should either be excluded (if his state of health warrants this) or be prepared for colonoscopy. If he is excluded this must be recorded, stating the reason, by the colonoscopy centre and the information passed on to the screening organization, which should record it. The reason may warrant the participant's permanent exclusion from the bowel cancer screening programme.

The referred participant should report to the colonoscopy centre once he is prepared. Having been given instructions, and sedation if necessary, the participant undergoes the colonoscopy. The follow-up will depend on the findings.

If no abnormalities are found, the referred participant should be informed immediately verbally. The findings and the agreed quality parameters should be recorded and the participant sent written confirmation of the result and the consequences for screening. Two weeks after the colonoscopy the participant should be phoned to check whether there have been any complications and whether he took in the information given immediately after the colonoscopy (he may have forgotten it because of the sedation). The screening organization should be informed that the participant needs to be invited to take part in the screening programme again in ten years' time (if he is still in the target group) instead of two years. The screening organization should record this. The general practitioner should also be informed of the findings and the follow-up.

If any abnormalities are found, histological samples should be taken if possible. This can be done by means of a polypectomy and/or biopsy, depending on the type of lesion. Following the colonoscopy the referred participant should be informed verbally about the abnormalities found. The abnormalities and the agreed quality parameters should be recorded and an appointment made to communicate the result.

The histological samples, along with the relevant clinical data, should be sent to an anatomical pathology (AP) laboratory designated for the purpose. Once the AP specimens have been assessed the results should be sent back to the requesting colonoscopy centre.

The centre should inform the referred participant of the result and if necessary arrange for him or her to be transferred to his or her hospital of choice for further diagnosis (including at least a chest X-ray and a liver scan by CT or MRI), treatment and/or surveillance. The screening organization and the general practitioner should be informed of the result. They should also be sent information on the nature of the follow-up (further diagnosis and treatment, surveillance schedule, interval before re-inclusion in the screening programme).

### **3.6 Surveillance (criterion 11)**

If the participant is placed under surveillance the treating physician should draw his attention to the dates in the surveillance schedule provided. The treating physician should notify the screening organizations when the participant should be re-included in the screening programme.

## 4 Organization of duties and responsibilities

This chapter builds upon the description of the primary process in the last chapter and goes into more detail concerning the allocation of duties and responsibilities among the organizations involved in the screening programme. Section 4.1 outlines some criteria that the CvB applies regarding detailed duties and responsibilities for the implementation of the bowel cancer screening programme. Section 4.2 discusses how the bowel cancer programme will fit into the National Screening Programme (NPB) and the standards that the government lays down for screening programmes. Section 4.3 discusses the arrangement of follow-up care. Section 4.4 outlines the responsibilities and roles of certain organizations, and section 4.5 describes the allocation of responsibilities at each stage in the process. Section 4.6, lastly, outlines what legislation and regulations apply.

### 4.1 Criteria

The description of duties and responsibilities is based on the following criteria:

1. The guiding principles are outlined in the description of the primary process (chapter 3).
2. The bowel cancer screening programme will be part of the National Screening Programme (NPB) and organized nationwide on a regular basis.
3. As it forms part of the NPB, the same criteria will apply as to other screening programmes (see section 4.2).
4. The CvB, acting on behalf of the Minister, will be responsible for the national management of the bowel cancer screening programme, taking advice from a Bowel Cancer Screening Programme Committee.<sup>5</sup>
5. The screening organizations will be licensed for the bowel cancer screening programme under the Population Screening Act (WBO).
6. Funding for the screening programme will be provided under the Public Health (Subsidies) Regulation.
7. The existing legislation and regulations lay down the requirements for the organization of the screening programme.

### 4.2 The National Screening Programme

The Minister of Health, Welfare and Sport's Framework Letter on Screening(15) includes a description of the government's responsibility regarding the National Screening Programme (NPB), which the Minister formulates as follows:

*The government has a constitutional obligation to take measures to promote health. Reducing the burden of disease and premature deaths in the Dutch population is therefore an important government objective. A programme to detect diseases in at-risk groups by means of a National Screening Programme is a tool that successfully contributes to achieving this objective. It is not without a reason in the policy document Being Healthy, Staying Healthy, which I sent to the House in September 2007, I refer to the tool of disease prevention as the 'dyke watchman' of our health care system.*

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<sup>5</sup> The Bowel Cancer Screening Programme Committee is referred to in the remainder of this report as the 'Bowel Cancer Programme Committee'.

The NPB produces a health benefit by detecting diseases at an early stage, thus enabling them to be treated. It differs fundamentally from curative care in that it is offered to people who are essentially healthy: in other words they are not requesting help with the disorder that is the subject of the screening programme.

Because of these aspects the framework letter highlights the importance of a programmatic approach and central management of screening programmes:

*The government offers a screening programme if a major health benefit at group level can be achieved at a reasonable cost. Other criteria are that it should be evidence-based and that there should be a balance between benefit and risk. The programmatic approach enables access and availability to all, irrespective of socioeconomic background, to be guaranteed from a health point of view. It also provides quality safeguards as regards availability, information and counselling, recording and evaluation. Lastly, a programmatic approach results in a higher participation rate, which is essential, as cost-effectiveness is an important criterion. Wilson and Jungner's<sup>6</sup> internationally accepted criteria provide the framework for decision-making on the NPB. Dutch screening programmes are held in high regard internationally.*

The Ministry of Health, Welfare and Sport has commissioned the CvB, acting on behalf of the Minister, to provide central management of the NPB screening programmes. In carrying out this remit the CvB guarantees the following criteria to the best of its ability:

1. Effectiveness: the screening programme should be effective in terms of the testing system used, coverage in the target group, the health benefit and/or the options offered.
2. Efficiency: the government (the client), and the public (the taxpayers) have an interest in the efficient use of public funds.
3. Reliability and quality:
  - The screening programme should be of good quality and carried out carefully in a standardized manner throughout the country.
  - The screening programme should be accessible. This includes providing information that enables people to make an informed choice.
  - There should be continuity in the availability of the screening programme.
  - It must be clear to the public that this is a government programme.
4. Follow-up care: if the test results are abnormal, good follow-up care must be provided, with further diagnosis and treatment where necessary.

### 4.3 Screening and good follow-up care

A screening programme can only produce the desired effect if the entire chain, from invitation to treatment and surveillance, is watertight. In any screening programme at some point there will be a transfer from screening to further diagnosis and treatment. In the case of the screening programme, for those participants whose iFOB tests prove abnormal, further diagnosis will be provided in the regular health care system, i.e. in this context funded under the Health Care Insurance Act (ZVW).

This means that both the screening itself and the subsequent diagnosis and treatment must be of good quality and properly coordinated logistically and in terms of capacity. A number of points have been identified, both in the Health Council report and in the interviews conducted by the CvB, that need to be properly

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<sup>6</sup> For the Wilson and Jungner criteria see Appendix 5.

covered. These include:

- Implementing various multidisciplinary medical guidelines more widely (uniform implementation).
- Rapid availability of iFOBT results (certainty of quick results for participants).
- Adequate capacity and national distribution of colonoscopy facilities (no waiting lists or long journey times).
- Maximizing and standardizing the quality of colonoscopies.
- Mutual exchange of information.

Ensuring that these points are complied, the implications for the allocation of duties and responsibilities are described.

#### **4.4 General allocation of duties and responsibilities**

Based inter alia on the recommendations of the National Cancer Control Programme and the Health Council, the interviews for the feasibility study and experience from the National Screening Programme, the CvB arrives at the following general allocation of duties:

1. Commissioning, funding and licensing of the bowel cancer screening programme: Ministry of Health, Welfare and Sport.
2. Central management of the screening programme: CvB.
3. Advice on the screening programme from representatives of the stakeholders: a new Bowel Cancer Programme Committee.
4. Representing the interests of the public and patients: patient/consumer organizations.
5. Regional coordination and implementation of the bowel cancer screening programme: the five screening organizations.
6. iFOB testing: a limited number of laboratories.
7. Colonoscopy: designated centres.
8. Quality assurance of iFOBTs, colonoscopy and pathology: by assigning a reference function (see section 6.2).
9. Taking out contracts with and funding colonoscopy centres that comply with national quality standards laid down by health insurers.

This allocation of duties is discussed below.

##### *Ministry of Health, Welfare and Sport*

The Minister of Health, Welfare and Sport has political responsibility for the bowel cancer screening programme. He or she decides on licence applications (having taken advice from the Health Council) made by the screening organizations under the Population Screening Act. The Ministry ensures that funds are made available to implement the screening programme.

##### *CvB*

The CvB is commissioned by the Ministry to manage the bowel cancer screening programme, acting on behalf of the Minister, to which end it performs the following tasks:

1. Coordinating and managing the organizations involved, including by laying down frameworks and assisting those organizations.
2. Funding for the screening programme under the Public Health (Subsidies) Regulation.
3. Promoting and ensuring the quality of implementation.
4. Monitoring and evaluating the screening programme.
5. Communicating with the public, professionals and stakeholders.
6. Pooling and sharing knowledge, spotting innovations and implementing them if appropriate.
7. Advising and informing policy-makers.

*Bowel Cancer Programme Committee*

The CvB has set up a programme committee for each of the screening programmes. These committees advise the CvB on the implementation of the programme and the quality of follow-up care, i.e. such matters as quality standards to complement professional guidelines, communication with the public and professionals, information management, innovations and programme evaluation. During the preparatory stage the CvB takes advice from an advisory committee, which is transformed into a programme committee once actual implementation of the screening programme begins.

Offering a bowel cancer screening programme will give rise to responsibilities in terms of the availability not only of good-quality screening but also of follow-up diagnosis and high-quality care. The Bowel Cancer Programme Committee lays down national quality standards for the primary process of the screening programme and follow-up diagnosis and care. Specific topics are discussed in working groups. The Bowel Cancer Programme Committee is chaired by an independent chairperson and comprises representatives of the professional groups involved and other stakeholders. Participation is on the basis of expertise: members are not bound by a mandate or required to consult their rank and file. In this way the CvB is supported in its management role by a broad representation of knowledge and experience in the field and the reference function.

*Screening organizations*

The screening organizations will be responsible for carrying out duties in the areas of selection, invitation, implementation of screening tests, results and referral. They are also responsible for carrying out duties in the areas of communication (with the target group and professionals) and supplying data for monitoring and evaluation. Screening organizations will be responsible for assuring the quality of the primary process of the screening programme, including referral for diagnosis, so that it complies with the quality standards laid down for the programme. To assure the quality of the screening programme and follow-up care a reference function should be assigned. The screening organizations will be responsible for assigning and taking out contracts for the reference function. On the basis of this responsibility they will apply for a licence under the Population Screening Act to implement the bowel cancer screening programme.

*Patient/consumer organizations*

The CvB is keen to have input from patient/consumer organizations on all screening programmes, which is obtained partly through their representation on the various programme committees. Ultimately it is a question not only of the health benefit that can be achieved among the screening programme participants but also of limiting the adverse effects that the programme could have. When organizing the programme and drawing up guidelines and quality standards the interests of the public are paramount: this should be reflected inter alia in the development of balanced, easy-to-understand and comprehensive information to the public.

*The hands-on professional groups and the organizations they work for*

The success of this screening programme will depend to a large extent on the efforts of the hands-on professionals. The health care providers will be responsible for ensuring the good quality of their work, to which end they should receive appropriate updates and additional training. Their professional groups will be responsible for developing quality assurance policy in their respective disciplines. Together they will be responsible for coordinating their quality assurance policies to ensure a smooth-running health care chain. The Bowel Cancer Programme Committee promotes the development of field standards and can lay down requirements for the screening programme and the quality of the diagnosis to which participants in the programme are referred.

*Reference function*

The purpose of the reference function is to assure the quality of:

- iFOB testing;
- colonoscopy;
- pathology for diagnosis.

The screening organizations will be responsible for organizing the regional reference function, for which purpose they should take out contracts with a clinical chemist, regional gastroenterohepatology coordinators and regional pathology coordinators. The screening organizations should organize the reference function in a standardized manner (see section 6.2) so as to assure the quality of the screening programme, on top of existing inspections by the respective professional groups.

*Health insurers*

Health insurers have a duty of care towards the people they insure and will act as purchasers and funders of colonoscopy and further health care and surveillance. They should support the quality of diagnosis and care by only paying for colonoscopy and pathology carried out by centres that comply with the quality standards laid down for the screening and health care chain.

**4.5 Responsibilities at each stage***4.5.1 Selection and invitation*

The screening organizations will be responsible for selecting and inviting the target group. They should ensure that this is done in a standardized manner throughout the country, using information material developed nationally.

*4.5.2 The test*

The invitee is responsible for deciding whether or not to participate, using the information sent along with the invitation.<sup>7</sup> If so, he will be responsible for taking the sample, filling in the data and sending in the sample as quickly as possible.

The laboratories will be responsible for analysing the iFOBT and reporting the findings to the screening organizations. It is advisable to limit the number of laboratories from both a quality perspective (so as to build up experience, routine and speed with large volumes and have the ability to detect abnormalities more quickly) and an administrative perspective. A large-scale operation is also conducive to efficiency. The CvB therefore proposes that three to five laboratories should be made responsible for iFOB testing, so as to provide backup capacity in the event of one laboratory being temporarily unavailable. It is important to follow a transparent tender procedure based on objective functional requirements and with the professional group itself explicitly involved.

The screening organizations should purchase the iFOB tests from three to five laboratories, based on quality standards and rules laid down nationally.

*4.5.3 Communication of iFOBT results to participants*

The screening organizations will be responsible for communicating the iFOBT results to participants. They should ensure that this is done by means of a standard national results letter. In the event of an abnormal test result the screening organization should first inform the general practitioner by letter or phone. The general practitioner should then inform the participant of the result.

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<sup>7</sup> If invitees require more information, they can find it from national websites, the screening organizations, patients' organizations and/or their general practitioners.

The screening organizations will be responsible for setting up a telephone helpline for queries relating to the screening programme, so as to provide easy access, enabling most questions to be answered. Participants can put more specific questions, for example going beyond the screening programme or relating to their medical records, to their general practitioners.

#### 4.5.4 *Referral to care*

The screening organizations will be responsible for referring participants with abnormal results to colonoscopy centres that comply with the national quality standards. These standards will be drawn up in consultation with the professional groups on the Bowel Cancer Programme Committee and published by the CvB. The screening organizations will enter into partnership agreements with colonoscopy centres that include these quality standards. The regional gastroenterohepatology coordinators contracted by the screening organizations will act as formal referrers to the colonoscopy centres. The gastroenterohepatology coordinators referring participants on the instructions of the screening organizations will oversee the transfer and the quality of the curative care, including overseeing compliance with the national quality standards for colonoscopy. The feedback of records from the health care system, which is needed to assess the effect of the screening programme and evaluate cut-off values for the iFOBT, can take place through the gastroenterohepatology coordinator.

#### 4.5.5 *Diagnosis*

The colonoscopy centres will be responsible for carrying out colonoscopy. Referred participants will be informed of the colonoscopy procedure and it will be decided in each individual case whether colonoscopy can be carried out. It may be decided that this is not appropriate (or not yet) based on medical indicators. Immediately following the colonoscopy the referred participant will be informed of the result and any follow-up procedure.

To be certain of the quality of diagnosis, colonoscopy needs to be carried out by colonoscopy centres that comply with national quality standards. The screening organizations will enter into partnership agreements with these centres. The regional gastroenterohepatology coordinator, working under a contract with the screening organizations, will perform a quality-enhancing and oversight role in relation to colonoscopy and review of interval carcinomas. This will require proper coordination between the regional gastroenterohepatology coordinators, the professional group of gastroenterohepatologists and the existing accreditation system in the professional group. The screening organizations' contracting policy means that participants will only be referred to colonoscopy centres that comply with these conditions. The contracts will specify the standards that quality assurance at these centres must comply with.

The pathology (AP) laboratories will be responsible for examining the biopsies taken in the course of colonoscopy. They will record the results in PALGA and communicate them to the colonoscopy centre and the screening organization. The AP laboratories will work in accordance with national quality standards and requirements in connection with the screening programme, e.g. concerning records.<sup>8</sup>

The colonoscopy centres will take out contracts with the AP laboratories. They will only use laboratories that comply with the national quality standards. Given the standards laid down for quality, standardization, capacity and records, this may have consequences for the number of AP laboratories used for the screening programme. Proper coordination with AP will be needed later at the surgical treatment stage.

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<sup>8</sup> The quality standards that the screening organization applies in connection with referral relate not only to colonoscopy itself but also to the quality of and recording of pathology contracted out by the colonoscopy centre.

The screening organization will take out a contract with the regional pathology coordinator, who will be responsible for the promotion of expertise, quality control and oversight of records in accordance with quality standards laid down nationally.

Standard national records are very important to enable the bowel cancer screening programme to be evaluated. These must provide information from the entire chain, i.e. including any pathology at the treatment stage.

#### 4.5.6 *Treatment*

Bowel cancer care comprises hospital treatment and aftercare. This involves a variety of medical professionals, such as surgeons, radiotherapists and oncologists. They are responsible for feeding back treatment data – needed for the monitoring and evaluation of the screening programme – to the screening organization.

Although the screening programme has minimal formal responsibility for this care, the information collected there – insofar as it is relevant to assessing the programme's effects – needs to be fed back properly to the screening organizations, as the effects of the programme will be felt to a large extent in the care system. Explicit attention will need to be paid to linking up with sources of information in the care system when developing the information management system for the bowel cancer screening programme. It will need to be clear at the outset what data and indicators should be fed back and how the feedback can be standardized so as to enable nationwide comparisons (see sections 6.4 and 6.5).

It is advisable, in line with the Guide to Allocation of Responsibilities for Collaboration in Care,<sup>(16)</sup> in the case of follow-up treatment (following a positive colonoscopy) to make a single care provider responsible for the further treatment process. This provider can also play a role in promoting correct record-keeping at the treatment stage of data fed back for the monitoring and evaluation of the screening programme.

## 4.6 Legal framework

Screening programmes are subject to the Population Screening Act (WBO), the aim of which is to protect participants against the risks of screening. Cancer screening programmes must be licensed: the Minister of Health, Welfare and Sport can grant a licence to one or more organizations implementing such a programme, and licences may be made subject to conditions. Thus the screening organizations are licensed for the breast cancer and cervical cancer screening programmes, and these licences are subject to conditions concerning the quality of the programmes.

The breast and cervical cancer screening programmes are subsidized by the CvB, acting on behalf of the Ministry, under the Public Health (Subsidies) Regulation. This feasibility study proposes using the same Regulation for the bowel cancer screening programme. The subsidy may be made subject to conditions within the limitations laid down under the General Administrative Law Act (AWB) so as to exert control over the work of the screening organizations and assure the quality of the diagnosis to which participants are referred.

The diagnosis and care following the screening programme is at least as important in the case of the bowel cancer screening programme. The work of the colonoscopy centres and pathology laboratories is subject to the Care Institutions (Quality) Act (KWZi) and the Individual Health Care Occupations Act (BIG). The expectation is that the KWZi will in due course be incorporated in the Client Rights (Healthcare) Act (WCZ), which will mean that far less direct control will be possible. As regards the criteria for proper care the KWZi (and in future the WCZ) relies heavily on 'field standards', in other words protocols, guidelines and quality conditions that



determine a professional standard of proper care. The Health Care Inspectorate (IGZ) bases its inspection regime on this, albeit it can lay down rules that must be complied with where these are absent.

The patient in the meaning of the Medical Treatment Contracts Act (WGBO, which in future will be incorporated – to a large extent – in the WCZ, where 'patients' are referred to as 'clients') is entitled to care in line with the professional standard, i.e. in accordance with the 'field standards' mentioned above. The screening organization similarly enters into a treatment contract with an invitee who accepts the offer. That organization must act in accordance with the professional standard. The screening organization's gastroenterohepatology coordinator will only refer participants to a colonoscopy centre that complies with field standards and additional quality standards laid down by the Bowel Cancer Programme Committee.

In the absence of such field standards quality control cannot be assured or overseen. This is also the case where there is an absence (or partial absence) of guidelines that apply specifically to the screening programme, such as standards for initial diagnosis and follow-up diagnosis at colonoscopy centres for patients referred from the programme. The government, in this instance the CvB, can initiate the development of field standards and quality standards, and the CvB can declare them applicable to referral for diagnosis from the screening programme by the screening organizations. These standards should be based on the multidisciplinary consensus in the field. The Bowel Cancer Programme Committee could be a good forum for this, as these field standards and quality standards can then be drawn up in the context of the screening programme and it can be ensured that they are in line with screening programmes as defined by the WBO, i.e. those of the screening organizations.

Neither competition law nor tender law presents an obstacle to the screening organizations entering into contracts with all the colonoscopy centres that comply with the field standards, as these are objective standards and the screening organization is not choosing between particular providers. The contracts can include agreements on e.g. giving notification of waiting times at the centres, which can be taken into account when referring participants. It can also be agreed how the centres are to demonstrate that they are complying with the field standards; this could also apply to pathology laboratories that either fall under the health care provider which the colonoscopy centre represents (the provider – the legal entity – that is party to the contract) or acting as contractors to the provider.

It goes without saying that the screening programme must comply with the conditions regarding informed consent that follow from the WGBO (at present). As the invitation from the screening organizations relates to an unsolicited offer, stringent requirements apply here, as in the case of other screening programmes. Chapter 5, Communication and information, deals with this in more detail.

The legal requirements for exchange of information for the purpose of monitoring and scientific research are laid down mainly in the WGBO and the Personal Data Protection Act (WBP), and these are no different for the bowel cancer screening programme than for other screening programmes. It needs to be examined to what extent the proposed data processing can be carried out using privacy-enhancing technologies, and possibly a trusted third party, without processing personal data on the invitees or patients. Where this does take place, the informed consent of the person concerned is required in principle. Limited exemptions can be made for scientific research under §7:458 of the Civil Code (WGBO) and §23 (2) of the WBP, subject to the condition that the person concerned has been informed and has not raised any objection in advance.

There are no special conditions regarding feedback on the results of further diagnosis to the screening organization's gastroenterohepatology coordinator; this is part of the normal exchange of information between the referrer and the care provider. This process must however be transparent for the patient, who can object

to it if he or she so desires. This will have to be included in the informed consent procedure.

More detail on the legal framework for the screening programme is given in the document *Background study on the legal aspects of assuring the quality of bowel cancer screening*, which can be found in Dutch on the CD-ROM enclosed with this report.

#### **4.7 Funding system**

The bowel cancer screening programme could be funded by the Ministry of Health, Welfare and Sport under the Public Health (Subsidies) Regulation in the same way as the other screening programmes. The cost of the iFOB testing would be included in the subsidy to the screening organizations, which would enter into contracts with the laboratories concerned and fund them from their subsidy. This approach is in line with that used for the breast cancer and cervical cancer screening programmes, where the screening organization's costs are reimbursed in the form of an overall price per head. The cost of the bowel cancer screening programme and how it is to be funded still needs to be examined in detail. Informing participants of abnormal test results by general practitioners and further diagnosis, treatment and surveillance care fall within the framework and funding system of the Health Care Insurance Act.



## 5 Communication and information

Communication and information are an essential part of screening programmes. The public, professionals and appropriate organizations are notified of the screening programme and any role that they are expected to play in it. There is also specific information material for the target group to enable them to make an informed choice on the steps in the programme that are relevant to them.

Section 5.1 outlines some criteria that the CvB applies regarding the details of communication about and within the screening programme and describes the communication target groups. Section 5.2 describes the communication and information in connection with the programme targeted at the general population. The communication and information in the programme, to people in the target group and the professionals involved, is described in section 5.3. Details of communication and information are outlined in the report *Communication on the Bowel Cancer Screening Programme*, which can be found on the CD-ROM enclosed with this report.

### 5.1 Criteria and target groups for communication and information

#### *Criteria for communication and information*

The CvB applies a number of criteria as regards communication:

1. The government should enable members of the public to make an informed decision on whether to participate in the bowel cancer screening programme. The information<sup>(17)</sup> must be:
  - appropriate (attuned to the target group);
  - objective (it must mention benefits and disadvantages); and
  - relevant (on the right subjects).
2. The communication for this screening programme should be in line with the system applied to the other screening programmes:
  - The organization of communication on the programme should be based on the information system developed for the breast and cervical cancer screening programmes.
  - The information provided should be standardized nationwide and unambiguous.
  - The information provided to the public should comply with the CvB's rules on information.<sup>(18)</sup>
  - The screening organizations will distribute the information material to the population. The CvB will be responsible for the content of the information material (leaflets, websites, et cetera).
3. The public, professional groups and appropriate field practitioners should be involved in developing communication products.

#### *Communication target groups*

For the purpose of the screening programme it is important to communicate with three target groups:

- the screening programme target group: men and women aged 55 to 75;
- professionals and organizations involved in the screening programme;
- the general population.

## 5.2 Information on the screening programme

Proper communication on the screening programme will be needed if and when it is introduced. The aim of broad communication about the screening programme is twofold:

1. to ensure that the public are aware of the existence and purpose of the programme;
2. to increase acceptance of the programme among the population and help the target group make an informed decision on whether to participate.

Acceptance of and participation in the screening programme will be the decisive factors in its success. Good communication and information can contribute to its acceptance. When introducing the bowel cancer screening programme, the communication will need to take the following points into account:

- The Dutch public's knowledge of the symptoms and risks of bowel cancer and awareness of the opportunities that such a programme could offer is scanty.(19,20)
- Raising awareness of bowel cancer and the screening programme is likely to increase the demand for opportunistic screening.
- In a phased introduction of the programme only part of the target group of 55 to 75-year-olds will be invited in the initial phase. It is very important to communicate clearly why the programme is being phased in, which age groups will be invited first, and when other age groups can expect to be invited.
- Participation in the screening programme will include people who have a family history of bowel cancer. The communication should mention the importance of taking a family history and the fact that people can contact their general practitioner if bowel cancer does run in the family.
- There is not much known as yet about the factors that determine acceptance of and participation in screening programmes. Those factors that are known to play a part should be taken into account in the communication.
- Good communication on any incidents associated with the screening programme is important, both to those concerned and more widely. A special procedure will be devised for this, including who should be the spokesperson in a particular type of incident and what the message should be.

Activities to increase awareness and acceptance of the programme will be elaborated by the CvB in a communication plan and coordinated with appropriate field organizations, including the Dutch Cancer Society, the Dutch Federation of Cancer Patients' Organisations (NFK) and the Maag Lever Darm Stichting (Digestive Diseases Foundation). One of the possible activities is a national campaign to introduce the programme using the media. This will be done as far as possible in collaboration with the Dutch Cancer Society and the Maag Lever Darm Stichting.

## 5.3 Communication and information within the screening programme

This section deals with communication and information within the screening programme to people in the target group and professionals involved in its implementation.

### 5.3.1 *Information to people in the target group*

When providing information to people in the target group – men and women aged 55 to 75 – the main aims are as follows:

1. To ensure that they are aware of the existence and purpose of the screening programme.
2. To improve the knowledge of people in the target group to enable them to make an informed decision on whether or not to participate in the programme. This includes the appropriate subject areas on which

information should be supplied in the case of cancer screening programmes.(17)

3. Notifying and updating people in the target group at all stages of the process (from invitation to final results) of what is happening or will happen, reassuring them if necessary and informing them of possible subsequent steps.
4. Arranging follow-up diagnosis in the health care system.

Careful communication with the target group by the care providers involved in the screening programme and follow-up care is important at all times. In the programme's primary process, described above, there are three points at which communication to people in the target group needs to be supported particularly by communication products specific to these stages in the process:

1. the invitation;
2. the result of the iFOBt and any referral;
3. the result of diagnosis and any further referral.

In addition, there are general communication products that should be available at all stages of the screening programme.

### *Specific information stage*

#### *1. The invitation*

Everyone invited to participate in the screening programme (the invitees) will be sent a letter of invitation to the programme and a leaflet about it, along with instructions for carrying out the iFOBt test, a laboratory form and a screening kit. The letter of invitation will refer to general communications concerning the programme (see General communication tools). In-depth information will be provided on a website. The letter and leaflet will be translated into various languages so that they can also be used to target specific ethnic minority groups, who are known to have a lower participation rate than their Dutch fellow-countrymen.(21,22) In addition to leaflets in various languages, activities will be organized to make groups that are difficult to contact (such as ethnic minority and low socioeconomic status groups) aware of the bowel cancer screening programme.

A trial screening programme has shown that the participation rate goes up slightly if participants are sent a prior announcement before being invited to take part in the programme.(14) The prior announcement informs the invitees about bowel cancer, the programme and the option they have to participate. This is followed soon after by the letter of invitation. The best format for this prior announcement (letter, magazine as in the case of the cervical cancer screening programme, or some other format) will be examined later (during the preparatory stage).

#### *2. The result of the iFOBt and any referral*

The participants in the screening programme will in all cases be sent a letter stating the result of the iFOBt, with a copy to the general practitioner. If the result is abnormal it will be sent to the general practitioner first. The general practitioner should inform the participant before he or she receives his or her results letter. If the result is abnormal the letter will also contain (information on) referral to a colonoscopy centre and a leaflet describing the follow-up procedure. It is important that general practitioners adopt a standardized procedure so that all referred participants are given unambiguous information.

#### *3. The result of diagnosis and any further referral*

If further diagnosis will be carried out on referral, then the person undergoing the diagnosis will be informed of the result. It is very important that the result of the diagnosis – especially if it is positive – be communicated carefully. This should be done verbally, with written confirmation.

### *General communication tools*

In addition to the stage-specific information, information on the screening programme will be available at all times through the following channels:

- A national publicity campaign will take place at the start of the screening programme.
- Press releases and articles will be disseminated through the local and national media to draw attention to the launch of the programme (in the region) or to the addition of new age groups.
- A standard national leaflet on the bowel cancer screening programme.
- A standard national leaflet on all cancer screening programmes.
- A public website providing collected information on the screening programme: this will include animations on the sampling and colonoscopy procedures and a knowledge test on bowel cancer and the programme.
- Decision aids (interactive aids to decision-making) will help people to decide whether or not to participate and result in better informed decisions on the matter.(23,24) A decision aid is being developed to help people decide whether to participate in the bowel cancer screening programme: it will be available via the RIVM website for screening programmes and kiesBeter.nl (a government health care information web).
- A list of frequently asked questions and answers.
- Telephone hot lines where people can obtain more information.

### *Public involvement in the development of communication tools*

Members of the public play an important role. In order to respond properly to the public's need for information a survey will be carried out to answer the following three questions:

1. What do the public know about bowel cancer and a bowel cancer screening programme?
2. How would they like to be informed and when?
3. What do they need to make an informed choice?

The findings of the survey will be used to focus the communication goals and messages and choose the most efficient communication tools. The communication products developed will be tested by the public, and they may be revised based on the results of the pre-test.

### *5.3.2 Communication and information to professionals*

The main aims of the information to professionals are as follows:

1. to ensure that professionals are aware of the existence and purpose of the programme and how it is to be introduced;
2. to ensure that professionals are able to carry out their duties in the screening programme effectively, which is necessary to ensure the good quality of the programme;
3. to ensure that professionals are able to provide good information to the public;
4. to ensure that professionals are aware of the screening chain and their role in it.

### *Communication tools*

Various communication tools will be used to communicate with professionals:

- A website for professionals containing all the relevant information on the screening programme: background information, frequently asked questions and answers, interview protocols, guidelines, quality standards, policy framework, et cetera.
- A newsletter: paper and digital newsletters will inform professionals about important developments in the initial period once the screening programme has been introduced.
- Views of the professional groups: at the interviews the Dutch College of General Practitioners (NHG) reported that it is possible to develop and

disseminate a position document on the screening programme on behalf of the professional group. This will raise awareness of the programme and the role in it among general practitioners.

- Induction meetings: these will inform professionals about the reason for the programme, the methodology and their role in it. These meetings may be organized regionally or nationally.
- Communications from screening organizations to the care providers involved in a particular region – e.g. a digital newsletter and website – to inform them of aspects of the programme's introduction in that region.

### 5.3.3 *Organizations involved*

The CvB is responsible for the national management of communication about and within the screening programme. In this connection it will collaborate with appropriate field organizations (including the screening organizations, professional associations, patients' organizations, the Dutch Cancer Society and the Maag Lever Darm Stichting).

The various channels that the organizations have at their disposal can be used. The details of links with existing information systems will be decided at a later stage. The professional associations are also important partners when it comes to the content of the communication.

The communication strategy and quality standards for the information will be agreed with the new Bowel Cancer Programme Committee and its working groups.

The communication to professionals will have a major effect on assuring the quality of the screening programme. A substantial part of the information disseminated to professionals will concern quality aspects: protocols, guidelines and quality standards. These will be developed in collaboration with the professional groups. For more information on quality see sections 6.1 and 6.2.

The screening organizations have responsibilities in communicating with professionals, e.g. refresher and additional training. For more information on specific products relating to improving the expertise of professionals see section 6.3.





## 6 Quality, monitoring and evaluation, knowledge and innovation for the screening programme and follow-up care

A screening programme that the government offers to people with no symptoms requires a high quality of implementation. There must be a good ratio of desired to undesired effects (false positives, false negatives, overtreatment, et cetera), and this applies to every activity, from invitation to any treatment provided, so as to achieve the desired effect of the programme (the health benefit).

Section 6.1 of this chapter deals with quality assurance policy, discussing what tools are suitable, which areas of the new screening programme already have a quality assurance policy laid down, and where additions or modifications are needed before the bowel cancer screening programme can be launched. Section 6.2 discusses quality assurance. Section 6.3 considers the training of the professionals involved and improving the quality of implementation. Section 6.4 discusses the monitoring and evaluation of the programme and section 6.5 the information management system needed to support implementation, quality control and evaluation.

The Ministry specifically asked that the feasibility study consider a flexible infrastructure that can respond to new ideas and developments. Section 6.6 briefly discusses possible short and medium-term innovations, including the decision-making process required. It also looks at linking up the programme's information management system to the complementary research infrastructure and the importance of funding innovation research when the programme is introduced.

### 6.1 Quality assurance policy

#### 6.1.1 *The instruments*

##### *Legislation and regulations*

There are a number of laws that need to be taken into account when setting up a new screening programme. An important piece of legislation here is the Population Screening Act (WBO), which protects the population against risks associated with screening programmes. A WBO licence can include rules needed to protect the screening subjects against the risks of the programme.

The Public Health (Subsidies) Regulation is another important piece of legislation in the case of screening programmes. When granting a subsidy under it the Minister can impose requirements:

- regarding the quality of the screening programme;
- regarding the recording of data;
- relating to achieving the aim of the subsidy; or
- relating to the way in which the subsidized activity is carried out or the means employed.

Both these instruments are currently employed in ongoing screening programmes with reference to documents such as a guideline or policy framework setting out national standard quality undertakings.(25,26)

All the general statutes applicable to health care also apply to screening programmes: these are set out in section 4.6.

*Guidelines and protocols*

Guidelines and protocols help to define professional standards and satisfactory care. Their content is the responsibility of professionals and their organizations: they (or their professional groups) are responsible for developing and implementing guidelines and protocols, and determining their content. In terms of health law each care provider is required under the Medical Treatment Contracts Act (WGBO) to act in accordance with its responsibilities based on professional standards. Section 6.1.2.4 discusses guidelines relevant to bowel cancer.

*Quality standards*

Additional quality requirements may be laid down for the implementation of a screening programme to supplement the guidelines and protocols of professional groups, on the grounds that (a) implementation needs to be standardized nationwide or (b) it is considered necessary to lay down additional requirements because a screening programme is being offered to people who have no symptoms. These requirements are binding and are subject to conditions such as a licence under the Population Screening Act or the Public Health (Subsidies) Regulation. The CvB will lay down these national quality standards after obtaining advice from the Bowel Cancer Programme Committee. The conditions will refer to a guideline or policy framework setting out the quality standards in more detail. These instruments are updated annually where necessary. These additional quality standards are in principle compulsory. Quality of implementation should be assured and improved by means of a supporting quality system (see section 6.2).

*Guideline (script)*

A guideline will set out in detail how both the screening programme and the follow-up care should be implemented. It is a quality tool and it is binding for all health care providers involved. Its purpose is to make it clear to all the care providers involved who is responsible for what and what role each plays in the screening and follow-up care chain. It facilitates uniform implementation nationwide. The guideline can include references to both other guidelines and quality standards. It will also set target time limits for the various components, e.g. a target interval between referral and initial intake at a colonoscopy centre. The guideline will be laid down by the CvB, having obtained advice from the Bowel Cancer Programme Committee.

*6.1.2 Existing and new quality assurance policy*

Based on the steps in the primary process, the existing guidelines and protocols involved in a new screening programme are set out below. We also indicate where a national quality assurance policy still needs to be formulated.

*6.1.2.1 Selection and invitation*

The following protocols and quality standards are involved in selection and invitation:

- A standard national protocol for the use of data from the municipal personal records database, the selection and exclusion of persons and how invitations should be sent out.
- National standards for information products.
- A standard national set of instructions for invitees.
- Quality standards for the self-administered iFOB test.
- An informed consent procedure.

*National standards for information products*

Invitation must be based on the principle of informed decision-making (see section 5.1). When developing standard national information and instruction material, the information framework,(18) and the report by Agt et al.(17) listing the subjects on which information must be supplied in the case of cancer screening programmes will be used, as well as the experience gained from the pilot programmes. The CvB will pass the products developed after obtaining advice from the Bowel Cancer Programme Committee. The products to be used by the screening

organization for invitation, communication of results and referral in the bowel cancer screening programme will be laid down in accordance with the arrangements in the other cancer screening programmes.(27)

#### *A standard national set of instructions for invitees*

These instructions should be sent out with the invitation and should indicate how the invitee is required to take the iFOBT sample, store it and send it in. This guide should be pre-tested.

#### *Quality standards for the self-administered iFOB test*

These standards should be used in the tender procedure for the tests. Important requirements include a user-friendly screening kit and good instructions, as well as correct functioning.

#### *Informed consent procedure*

The arrangements for obtaining and recording informed consent to the use of data and material in the screening programme must be decided upon and communicated to invitees in the information material being developed.

#### *6.1.2.2 The test*

The sample sent in by the participant should be handled with care so as to produce a reliable result. The following points are essential here:

- quality standards for laboratories;
- laying down quality standards for the equipment and method used to measure iFOBT;
- a protocol on monitoring of sample quality and storage conditions;
- an incident handling protocol.

#### *Quality standards for laboratories*

For the sake of efficiency, uniform implementation and flexibility to adopt innovations it is recommended that the number of laboratories be restricted to a maximum of three to five. The final number will be decided based on the quality standards drawn up for the laboratories and the cost outline. The quality standards will include such matters as required expertise, logistical handling, number of samples per year and accreditation; there will also be quality standards for the equipment to be used and the treatment protocol for samples. They should also include the minimum data set (see section 6.4) that needs to be recorded and how data should be exchanged with the screening organization. A proposal on how the laboratories will be selected should be drawn up at an early stage of the preparations. It is important to follow a transparent tender procedure (see section 4.5.2).

#### *Quality standards for the equipment and method used to measure iFOB*

The quality standards for equipment and method will be drawn up in collaboration with the Tumour Markers Working Group of the Netherlands Society for Clinical Chemistry and Laboratory Medicine (NVKC). The Advisory Committee recommends opting for a dedicated system from a single supplier. Based on the new quality standards for equipment and method, a European tender procedure will be carried out for the selection of equipment (see also Quality standards for laboratories).

#### *Protocol on sample quality conditions*

The stability of the iFOBT is affected by such things as ambient temperature and the interval between sampling and laboratory testing. The procedure for sending in samples, the time taken for postal delivery and the handling of samples will be laid down in a laboratory protocol. A protocol will also set out how to deal with samples that cannot be measured.

#### *Incident handling protocol*

This will lay down how laboratories should record and report incidents.

### 6.1.2.3 *Communication of iFOBT results and referral*

The following protocols and quality standards will be developed on communicating iFOBT results and referral:

- quality standards for the communication of results;
- quality standards for referral.

#### *Quality standards for the communication of results*

These quality standards will be supported by a protocol for the phone call and/or consultation in the event of an abnormal iFOBT result, form letters to the participant on an abnormal or good result, a leaflet for abnormal results, a set of frequently asked questions and answers (FAQ) for general practitioners and staff of screening organizations, NHG (Dutch College of General Practitioners) letters to patients and an NHG position document on a bowel cancer screening programme for general practitioners.

#### *Quality standards for referral*

The quality standards for referral will lay down how referral data should be exchanged between screening organizations and colonoscopy centres. Participants will be referred to colonoscopy centres that comply with the quality standards and have entered into a partnership agreement with a screening organization.

### 6.1.2.4 *Diagnosis and treatment*

#### *Guidelines*

The following national and European guidelines on the diagnosis and treatment of bowel cancer have been or should be drawn up:

- National Guideline on Colon Carcinoma (2008).
- National Guideline on Polypectomy Follow-up (2000).
- European Guideline for Quality Assurance in Bowel Cancer Screening and Diagnosis (2010).
- European Guideline for Quality Assurance in Pathology in Bowel Cancer Screening and Diagnosis (2010).
- National Guideline on Bowel Hepatic Metastases (2006).
- National Guideline on Hereditary Bowel Cancer (2008).
- National Guideline on Sedation and/or Analgesia by Gastroenterohepatologists in Endoscopic Operations (2001).
- Draft Guideline on Sedation and/or Analgesia outside the Operating Theatre (PSA guideline).
- Multidisciplinary Guideline on Colon Carcinoma.

These guidelines are discussed briefly below.

#### ***National Guideline on Colon Carcinoma (2008)*** (28)

This guideline on policy on colon and rectal cancer has been developed by the National Working Group on Gastrointestinal Tumours of the Association of Comprehensive Cancer Centers (VIKC). It makes recommendations on diagnostic, treatment and follow-up procedures for adult patients with bowel cancer. The professional groups have pointed out that it needs to be tightened up as regards the definition of advanced adenoma, in both the section on gastroenterohepatology and that on pathology.

#### ***National Guideline on Polypectomy Follow-up (2002)*** (29)

This guideline provides a timetable for follow-up intervals after polypectomy. At present a large proportion of the colonoscopies available are used for surveillance (25-40%). The Health Council notes that the current guideline is unsatisfactory if a bowel cancer screening programme is introduced, and raises the question of whether surveillance is justified after the removal of one or two adenomas of less than 10 millimetres. It proposes referring these patients back to the screening programme.(1)

**European Guideline for Quality Assurance in colorectal cancer screening and diagnosis (2011)** (30)

This guideline sets out the medical, organizational and implementation standards that good-quality bowel cancer screening – including diagnosis, treatment and surveillance – needs to comply with. It is being developed with financial support from the European Community and will probably be finalized in 2011.

**European Guideline for Quality Assurance in Pathology in Colorectal Cancer Screening and Diagnosis (2010)** (31,32)

The European Guideline makes recommendations on the classification of biopsies and how external quality assurance could be carried out. The NVVP (Dutch Pathology Association) uses it as a basis for protocols and proposals on quality assurance and indicators for the bowel cancer screening programme.

**National Guideline on Bowel Hepatic Metastases (2006)** (33)

This guideline includes recommendations on preoperative diagnosis of colon cancer.

**National Guideline on Hereditary Bowel Cancer (2008)** (34)

This guideline makes recommendations on diagnosis, treatment, follow-up, regular tests and prophylactic operations in cases of hereditary and familial bowel cancer. It includes psychosocial care and information to patients.

**Guideline on Sedation and/or Analgesia by Gastroenterohepatologists in Endoscopic Operations (2001)** (35)

This guideline has been developed by the Netherlands Society of Gastroenterohepatology based on the Guideline on Sedation and/or Analgesia by Non-Anaesthetists issued in 1998 by the CBO (Dutch Institute for Healthcare Improvement) 1998.(36) It needs to be revised in line with the Draft Guideline on Sedation and/or Analgesia outside the Operating Theatre discussed below.

**Draft Guideline on Sedation and/or Analgesia outside the Operating Theatre** (37)

This draft guideline is a revised edition of the Guideline on Sedation and/or Analgesia by Non-Anaesthetists issued in 1998 by the CBO (Dutch Institute for Healthcare Improvement).(36) The appendix to the guideline deals with the procedures for the specialism, including those of gastroenterohepatologists.

**Multidisciplinary guideline**

The Health Council recommends developing an integrated multidisciplinary guideline for the screening programme, including diagnosis, treatment and surveillance.(1) The CvB and the Bowel Cancer Advisory Committee endorse this recommendation. The guideline should be drafted by the professional groups.

**Quality standards**

On top of guidelines, it is important to assure the quality of follow-up care for patients referred from the screening programme with appropriate quality standards so as to guarantee uniform quality nationwide. In addition to the guidelines discussed above, the following national quality standards are important:

- quality standards for colonoscopy centres;
- quality standards for endoscopists;
- quality standards for pathology laboratories;
- quality standards for pathologists;

**Quality standards for colonoscopy centres**

These relate to e.g. gastroenterohepatology staffing, the setting in which the colonoscopy centre operates, the requirements for equipment used in colonoscopy, the requirements for the room where colonoscopy takes place, the arrangements that the colonoscopy centre should have with hospitals regarding the treatment of any perforations, waiting times for intake interviews/endoscopy, and the supply of data to the screening organization for the purpose of quality assurance and evaluation.

**Quality standards for endoscopists**

These include the number of colonoscopies carried out, training standards for the accreditation of endoscopists, observing the National Guideline on Colon Carcinoma and the recording and supply of data for monitoring, evaluation and quality assurance. Standards could be laid down on the following points: completion rate, adenoma detection rate, number of colonoscopies carried out and keeping a register of complications.

Similar standards should also be formulated for pathologists and anatomical pathology (PA) laboratories.

**Protocols**

The professional groups mentioned a number of protocols where they consider that standard national agreements are required:

- a protocol for intake interviews and exclusion criteria;
- a protocol for the preparations for colonoscopy;
- waiting time targets (see 8.3.7);
- a protocol for the information to be provided in the event of abnormal colonoscopy results: the proposal is to draw up a telephone script and a specimen results letter;
- a protocol for arrangements on returning participants to the screening programme from the various stages of diagnosis, treatment and surveillance;
- a protocol for incident handling for both colonoscopy and pathology;
- an input protocol for pathologists using the local PALGA system;
- a protocol for the handling of residual material;
- a framework for contact with patients based on Dutch Federation of Cancer Patients' Organisations (NFK) standards.(38)

**6.1.2.5 Quality assurance**

Those responsible for the reference function (clinical chemists, regional gastroenterohepatology coordinators and regional pathology coordinators) will monitor quality. How this quality assurance is to be carried out should be laid down in a quality assurance protocol. The components of this quality assurance are discussed in section 6.2.

**6.2 Quality assurance**

Screening programmes require well-organized quality assurance to guarantee good-quality and sustainable screening. This section discusses the criteria for quality assurance, followed by a recommendation on how to implement the reference function.

**6.2.1 Quality assurance criteria**

The quality assurance criteria are as follows:

1. Responsibility for quality and quality assurance is held at various levels.
2. The monitoring of quality is important to the whole process, from invitation to treatment.

**1. Responsibility for quality and quality assurance is held at various levels.****a. The care provider**

The care provider is responsible for the good implementation of the screening programme and/or follow-up care, observing the national guidelines and quality standards laid down. The care provider, or the organization employing him, should set up and maintain an internal quality assurance system. The care provider is responsible for improving his own expertise and registering on the professional group's quality register. To enable the quality of the programme to be monitored the care provider must record data and supply it to the screening organization (see section 6.4).

b. Quality assurance by means of the reference function

Quality assurance of implementation will be provided at regional level by the reference function in the screening organizations. The clinical chemists, regional gastroenterohepatology coordinators, regional pathology coordinators and the reference laboratory will carry out this quality assurance so as to enable independent assessment of quality to take place. The reference function will be performed by specialists from the respective professional associations (NVKC, NVMDL and NVVP). The aim of this quality assurance is to improve the quality of implementation: instructions can be issued where necessary to improve the quality of care within a certain period (see section 6.2.2).

c. Inspection committees from professional associations

The professional associations' inspection committees will organize inspections of their particular specialism. These inspection committees have a broader remit than just inspecting diagnosis following on from a screening programme. The work of an inspection committee and external quality assurance will need to be coordinated.

d. National quality assurance

Quality assurance for the programme as a whole and monitoring of the screening organizations will be carried out at national level by the CvB/the Bowel Cancer Programme Committee. National monitoring and evaluation will provide information on the areas where quality assurance policy needs to be revised or what measures need to be taken to increase the programme's effectiveness (see sections 6.4 and 6.5). On top of this the Health Care Inspectorate will act as a general watchdog.

*2. Assuring the quality of the entire chain*

Assuring quality applies to the whole process, from invitation, screening tests and diagnosis to treatment and surveillance. Quality standards and risks therefore need to be set out for all parts of the process, so that a good system of external quality control, monitoring and evaluation can be set up. The method of quality assurance needs to be laid down and implemented in each part. The Bowel Cancer Programme Committee will play an important role in identifying problems and coordinating the entire chain.

Part and parcel of the quality assurance carried out by the laboratories conducting the iFOBT will be organizing comparative tests among laboratories to assess sample quality. In the case of the breast and cervical cancer screening programmes the screening organizations comply with certification by the Expertise Centre on Quality Review in Health Care (HKZ); this HKZ certification could also be used for the bowel cancer screening programme.

The Health Council has asked for attention to be paid specifically to the quality of follow-up diagnosis.<sup>(1)</sup> It is known that the performance of endoscopists can differ substantially.<sup>(39,40)</sup> A recent study of indicators for the quality of endoscopists shows that if an endoscopist has a low adenoma detection rate this is an independent risk factor for interval carcinomas.<sup>(41)</sup> Research shows that systematic quality assurance of colonoscopy and having colonoscopies carried out by endoscopists who perform well in tests can result in a major improvement in the quality of implementation.<sup>(42)</sup> The NVMDL organizes inspections to improve the quality of the work done by gastroenterohepatologists. The details of external quality assurance of colonoscopy are discussed in the next section.

To assure the quality of pathological diagnosis the system of comparative tests among pathology laboratories currently used by the Foundation for Quality Assessment in Clinical Laboratories (SKML) will be employed. The aim of the SKML is to improve the quality of clinical laboratory testing for diagnosis and treatment, to bring the testing up to the highest possible standard and keep it there.

Recent research shows that not all patients in the south of the Netherlands with (suspected) bowel cancer are checked for metastases.<sup>(43)</sup> The interval between



diagnosis and the start of treatment in current bowel cancer patients in that region also fails to comply with the standard laid down by the Dutch Cancer Society (15 days).(44) Recording, feeding back and publishing data on bowel cancer operations can help to improve the quality of care. The Dutch Surgical Bowel Audit (DSCA) has therefore set up a databank to promote this.(45)

It is clear from the foregoing that recording relevant data and indicators from the whole care screening and follow-up care chain, from invitation to treatment and surveillance, is important so as to monitor quality. The CD-ROM of in-depth studies (in Dutch) enclosed with this report includes a proposed indicator set.

#### *6.2.2 Quality assurance by means of the reference function in the screening organizations*

Those responsible for the reference function (clinical chemists, regional gastroenterohepatology coordinators and regional pathology coordinators) will provide quality assurance. The screening organizations (WBO licence-holders) will take out contracts with laboratories and enter into partnership agreements with colonoscopy centres and endoscopists working there, and colonoscopy centres will only take out contracts with pathology laboratories and pathologists who comply with the quality standards laid down (see section 4.5.5). The contracts and partnership agreements should refer to the observance of the guidelines and national quality standards.

Quality assurance by means of the reference function falls into six areas:

##### *1. Taking out contracts with contractors*

The reference officer will check whether the contractor is able to comply with the national standards before entering into a contract or agreement. The contractors will be the laboratories conducting the iFOBT, the colonoscopy centres and endoscopists, and the pathology laboratories and pathologists. The standards could include such things as training requirements, requirements for equipment and data storage, target handling times, availability, participation in comparative tests among laboratories, and the recording and supply of data (see section 6.1).

##### *2. Checking capacity before the launch of the screening programme and during its introduction*

Before the screening programme is introduced the screening organization will gauge the capacity that is available and needs to be contracted out in its region. The contractors will be asked to give an estimate of the maximum capacity they can supply over the various calendar years.

The screening organization will check, using a checklist drawn up for the purpose, whether the contractors are ready to go. It will carry out a trial run to test whether all parts of the entire chain are properly coordinated. It will also check whether the capacity monitoring system to monitor the progress being made with introduction has been implemented (see chapter 7). Before the programme can be rolled out to additional age groups there must be adequate capacity for this and/or the expected waiting times following referral based on a positive iFOBT must be within the limits laid down.

##### *3. Regular audits*

The reference laboratory, the gastroenterohepatology coordinator and the pathology coordinator will carry out regular audits to check contractors against the national quality standards and indicators. They will check that agreements are being complied with and discuss opportunities for improvement. Protocols will need to be drawn up by the Bowel Cancer Programme Committee for the auditing of the care activities concerned. Aspects that the audit protocol needs to deal with include the following:

- Announcement of audits.
- Providing data in advance: this could take the form, for example, of filling in a prior questionnaire, supplying data (indicator information) or images.

- Design of the audit: in addition to auditing implementation, possible improvements in implementation should be discussed in the light of any communication problems, unclear or incorrect results, et cetera. identified by the care provider, and any complaints made or incidents that have occurred should be discussed.
- Reporting by the reference function once an audit is complete: this should include submitting draft reports suggesting possible improvements, with an opportunity to respond. These reports should include programmes for improvements where necessary and note any areas where functioning is unsatisfactory. They could also include indications of areas where national protocols, guidelines and quality standards could be improved, which the reference officer should raise at national level.

#### *4. Discussion of interval carcinomas*

An important part of the regional gastroenterohepatology coordinator's reference function is discussing interval carcinomas with the health care provider based on negative colonoscopies prior to diagnosis. The aim of this discussion is to learn lessons. In order to be able to discuss interval carcinomas, proper arrangements need to be made for the storage of and access to colonoscopy images. A link to the Dutch Cancer Registry also needs to be provided in a data warehouse (see sections 6.1 and 6.5).

#### *5. Performance benchmarking*

The performance of care providers and centres should be benchmarked based on appropriate indicators obtained through the standardized recording and supply of data (see section 6.4). The purpose of benchmarking is to learn from one another by comparing results and discussing them with one another. The appropriate indicators for benchmarking will be decided nationally by the Bowel Cancer Programme Committee in consultation with the professional groups. It will also be decided explicitly who will have access to these internal benchmark data and what data will be used for external reporting. The ColonIS system will support benchmark reporting (see section 6.5). The reference officer will encourage discussion.

#### *6. Encouraging and facilitating the improvement of expertise*

The screening organizations will organize regional meetings to share knowledge and know-how in attractive programmes with expert speakers, also for the providers in the care chain to get to know one another and one another's work.

### **6.3 Training and Improving expertise**

By 'improving expertise' here we mean 'the set of activities designed to maintain and increase the skill level of staff involved professionally in the screening programme and follow-up care'.

For some of the participants the screening programme will generate a demand for care in the form of referral for further diagnosis. Thus the introduction of a bowel cancer screening programme will give rise to responsibilities in terms of the availability of high-quality follow-up diagnosis and care. The quality of the programme and the follow-up care will depend on the knowledge, skills and conduct of individual care providers. This justifies a role for the screening programme in setting standards for the training and improvement of expertise of medics and paramedics involved in the programme and follow-up care: if this is not in order the anticipated health benefit for participants will not be achieved.

Care providers involved in the screening programme and follow-up care should comply with attainment targets, professional registration/re-registration and quality standards laid down by the programme. The bowel cancer screening programme should also encourage the improvement of expertise in areas where gaps in knowledge or skills are identified.

### 6.3.1 *Training*

The attainment targets for the care providers performing the various activities in the bowel cancer screening programme and follow-up care should be laid down, based on the skills they require. All specialist medical courses have laid down discipline-specific targets or are in the process of doing so. General attainment targets regarding knowledge and skills in such areas as communication, collaboration and psychosocial care are being developed centrally (CanMEDS 2000). On top of this, professional associations such as the NVMDL and NVVP lay down compulsory requirements for training in particular subject areas.

Training requirements for those involved in the screening programme and follow-up diagnosis will be laid down based on proposals from the professional groups of medical specialists concerned. In the case of gastroenterohepatologists, anatomical pathologists and clinical chemists it can be presumed that registration on the professional register means that the training requirements laid down in the screening programme have been met. As regards performing colonoscopies, the training for internists does not comply with the requirements laid down for gastroenterohepatology registration. A number of internists, especially those working in hospitals that do not have a specialist gastroenterohepatologist, meet the knowledge and skills requirements for the gastroenterohepatology specialism on the basis of a supplementary course.

When the bowel cancer screening programme is introduced, as well as using medical specialists the roles of endoscopy nurses and physician assistants need to be redefined; the endoscopy nurses can carry out parts of colonoscopy and the physician assistants can carry out work in the AP laboratory (see section 7.4). Thus endoscopy nurses could perform defined tasks such as parts of the intake procedure, colonoscopy and referral. Research shows that it is possible to use specialist nurses for the diagnostic investigation and follow-up of patients with gastrointestinal conditions.<sup>(46)</sup> Research is taking place, funded by the Netherlands Organisation for Health Research and Development (ZonMw), to examine whether the quality of work in terms of outcomes (reliability and safety), patient satisfaction and cost using specialist nurses is comparable with that when using specialist gastroenterohepatologists.

If endoscopy nurses and specialists other than gastroenterohepatologists and physician assistants are to be used, the national training requirements must be properly defined, and a national appraisal and registration system will need to be developed. The register should be available to the regional gastroenterohepatology coordinators and pathology coordinators who check the quality standards and enter into agreements for referral to colonoscopy centres and pathology laboratories that comply with these standards (see section 6.2).

The professional groups have been advised to draw up training plans for endoscopy nurses and physician assistants in 2011, setting out the training requirements, appraisal and registration system for areas of the work done by endoscopy nurses and physician assistants. There is also a recommendation to carry out a survey of training institutions' interest in placing the required course on the market and the feasibility of doing so: here the CvB could identify problems and provide encouragement.

### 6.3.2 *Improving expertise*

A health care provider is responsible for improving his or her own expertise so as to provide good-quality care. Care providers will only be successful in improving their expertise if they are willing to take a critical look (with other people) at the way they work and gauge the value of new developments and incorporate them in the existing care. Professional associations are responsible for the quality level of their respective professional groups, and organizations working on the ground (e.g. screening organizations) for the quality of the work done by their staff.

The bowel cancer screening programme should encourage the improvement of expertise in areas where gaps in knowledge or skills are identified. The principle here is that responsible partners should be brought in and optimum coordination sought when organizing the improvement of expertise. In addition to national training activities organized by the professional groups or the bowel cancer screening programme, those responsible for the reference function (the regional gastroenterohepatology/pathology coordinator and the reference laboratory) should play a role in improving expertise (see section 6.2, Quality assurance).

When the bowel cancer screening programme is introduced it will be necessary to improve expertise. Care providers will need to be informed of and given additional training on the national agreements and quality standards so as to ensure that the programme is implemented uniformly nationwide and is of high quality. The guidelines, protocols, quality standards and master plans set out in section 6.1 will provide the basis for this improvement programme, which will be supplemented where necessary with skills training courses.

It is recommended that an action plan for the improvement of expertise be drawn up in collaboration with screening organizations and the professional groups concerned. Tried and tested activities relating to innovations in other screening programmes under the National Screening Programme that could be included in this action plan are:

- regional or national training seminars;
- e-learning;
- an Individual Refresher Training Programme or position document for the professional groups;
- instructional videos;
- articles in periodicals;
- skills training courses (e.g. on manning a telephone line, interviewing participants with abnormal results).

The communication tools described in section 5.3.2 will be used to support this.

#### **6.4 Monitoring and evaluation**

If screening programmes are to be carried out properly it is essential to monitor and evaluate the quality of implementation. This involves both monitoring the quality of the primary processes (quality assurance) and evaluating effectiveness and efficiency nationwide. Monitoring and evaluation will contribute to an ongoing process of improving the programme.

In its advisory report the Health Council noted that the national evaluations of the breast and cervical cancer screening programmes were found to be important in supporting the management of both programmes and improving them step by step.(47-50) The Health Council explicitly recommended monitoring attendance, quality of information and informed choice. It also noted that it is important to link up with international standards and networks (the International Bowel Screening Network) that exchange knowledge and experience of indicators, monitoring and evaluation.(1)

The Health Council's recommendations were endorsed by the interviewees consulted out for this feasibility study. They stressed that a standard national indicator set and a minimum data set need to be developed for the quality assurance and evaluation of the screening programme. Coordinated record-keeping in the screening programme and the care system, with ample attention to the standardization of data recording, is very important to the quality of the programme and the follow-up care.

#### 6.4.1 *Monitoring and evaluation*

By 'monitoring' the CvB means a regular activity designed to assure and improve the quality of the primary processes in the screening programme and good follow-up care. Each partner in the chain, from invitation to referral in the screening programme, and from follow-up diagnosis and any treatment and surveillance in the care system, is responsible for the quality of its part of the chain. The responsibilities are set out in chapter 4. Quality assurance and the supporting quality (assurance) system in the implementing organizations is discussed in section 6.3.

As regards the national monitoring system, an important point is that data will be needed from the entire chain to enable the identification of any problems there (e.g. transfer from the screening programme to the care system). It is important that data be recorded once only at source and that it be linked to the primary process as far as possible (see also section 6.5, Information management). The CvB commissions national monitoring reports annually as a rule. In the case of the introduction of the bowel cancer screening programme it may be necessary to carry out more frequent monitoring reports of parts of the programme so as to make timely adjustments if problems occur.

National evaluation is a more ad hoc activity, generally taking place over a three to five-year cycle. The spectrum of topics for evaluation includes both standard and variable topics. An important standard topic is an in-depth analysis and interpretation of the results of the monitoring reports over a period of several years. Additional questions may also be answered, originating in the results of previous national monitoring reports or evaluations, indications from the implementing organizations' regional monitoring reports, contacts with the professional groups, questions posed by the CvB and the Ministry of Health, Welfare and Sport, and questions raised by various new developments concerning the screening programme. These evaluation questions are not so standard. The answers can be based on the data recorded for monitoring or on data that requires relatively major efforts to obtain (for example questionnaires). A good knowledge of research methods and analytical techniques is essential to a proper evaluation, especially if comparisons are being made (e.g. between screening organizations). The independence and expertise of evaluators must also be guaranteed.

A good (local/regional/national) monitoring report and evaluation is based on indicators and the data collected and/or recorded for this purpose.

#### 6.4.2 *Indicator set and data set*

Indicators are measurable aspects of the screening programme and the care provided as follow-up. They give an indication of e.g. how reliable and efficient the programme is. It is important to have indicators for the entire chain, including transfer from the screening programme to diagnosis (referral), so as to identify any problems. The Health Council also mentions indicators such as referral rate, referral compliance and tumour characteristics. A data set will be needed to determine the indicators.

A distinction is made between indicators for internal quality assurance by the contractors and care providers and those for external reporting. The first set will be mainly monitoring data from their own quality systems; the second will be mainly for national monitoring reports and/or evaluations, which can also be used by the Health Care Inspectorate for public reporting.

The Information Management Working Group and the Advisory Committee recommend selecting a set of indicators to detect any problems at the implementation stage as quickly as possible through monthly monitoring. An example of a possible problem and associated indicator is the waiting list for colonoscopy in a particular region: this could contribute to adjustments in the

programme during the phased introduction (see chapter 7). It is recommended that these indicators be decided upon at an early stage in the preparations.

The Public Health Department of Erasmus Medical Center Rotterdam was asked to make a start on defining important indicators and the minimum data set required. The report by Erasmus MC, *Indicators and minimum data set for national monitoring system and quality assurance for the bowel cancer screening programme*, can be found in Dutch on the CD-ROM enclosed with this report. The selected indicators are in line with the primary process activities set out in chapter 3: selection and invitation, implementation of the programme, communication of results, referral to care, diagnosis and treatment and surveillance. In addition, as recommended by the Health Council, an indicator has been developed for informed choice. The report distinguishes between process indicators, quality indicators and effect indicators. Following the feasibility study a further distinction will be made, in consultation with those working in the field, between indicators for quality assurance and indicators for the national monitoring report and national evaluation, including the further development of the data set.

## 6.5 Information management

The introduction of a bowel cancer screening programme will need to be supported with adequate information management. This is the totality of provisions (people, resources and measures) needed to enable data to be stored, managed and supplied to authorized persons and authorities. Properly organized and professionally used, information management provides the foundation for various processes:

1. the primary process and regional quality assurance;
2. the national monitoring system;
3. national evaluation and and/or public reporting on the programme;
4. scientific research.

Proper information management presupposes a good indicator set and a minimum data set (see section 6.4).

Essential criteria for information management are:

- once-only recording of data at the source;
- uniform definitions and data recording (standardized language) by all contractors and care providers, structured (based on a protocol) and encoded (using an international code);
- electronic data transfer;
- using existing information flows wherever possible;
- use of an encrypted BSN (Dutch acronym: A unique identifier, also known as a Citizen service number);
- legal aspects (such as privacy) need to be dealt with properly.

To provide administrative support for the bowel cancer screening programme a central screening information system (ColonIS) with a modular design is proposed. The modular structure of ColonIS (the central system in the care chain) makes the application more manageable and flexible in use, so that future changes will be easier to implement. Looking at the flow of information throughout the implementation chain, within which ColonIS needs to function optimally, many interrelations/links with other systems will need to be made to meet the information needs at various levels (from management information to evaluation) and to fully support the primary process described in chapter 3. Figure 2 shows the interplay between the various organizations and systems in the care chain.

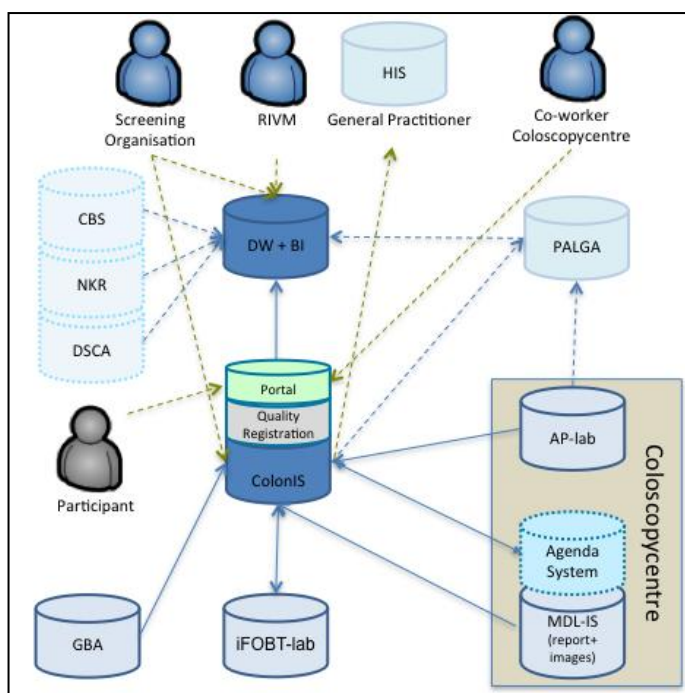


Figure 2: IT infrastructure for the bowel cancer screening programme

Particular attention will need to be paid to the following essential modules in ColonIS:

- Laboratory module, which records the results of iFOBT analysis (including sampling date, date of receipt and any samples that cannot be assessed) and additional data from ColonIS (if not recorded directly in ColonIS or by means of an electronic message from the laboratory system).
- Colonoscopy and pathology follow-up module.
- Planner module: ColonIS will need to be linked to the appointments system for intake to the colonoscopy centre.
- Contract module for the records of contracted care providers.
- Standard report module for management information from the screening programme.
- Quality assurance module.
- Monitoring, evaluation and scientific research module.

Data for monitoring and evaluation will generally need to be anonymous. ColonIS is not suitable for these purposes, because it contains medical client/patient information. A solution is to set up a data warehouse (DW) which is populated with anonymised data from ColonIS on a regular basis, and with data from records such as PALGA, the DSCA (Dutch Surgical Bowel Audit), the NKR (Netherlands Cancer Registry) and Statistics Netherlands (causes of death). This could possibly be done under a trusted third party construction. Legal aspects, management and access rights to the data warehouse will need to be dealt with in an agreement and a user manual. The Information Management Working Group stressed the need to take complementary (scientific) research into account: this should be included as far as possible in the design of ColonIS and the data warehouse.

It is recommended that the following activities (broadly speaking) be tackled so as to fully introduce the infrastructure outlined:

1. Deciding upon and implementing a technical dataset (including encoding) based on the minimum data set in the various gastroenterohepatology source systems, local PALGA, treatment systems of surgeons and internist oncologists, and laboratory systems.

2. Drawing up a workflow description setting out data interchange (transactions) between organizations (actors) in an abstract manner.
3. Checking whether the statutory obligations (under the Personal Data Protection Act, Medical Treatment Contracts Act and Citizen Service Number (BSN) Act) regarding data storage and interchange are complied with. Reaching agreements with the various participants on the use of the data ('drawing rights'). Arranging for informed consent for the transfer of data. The question of 'whether persons not participating in the screening programme should be allowed to remain in the database' also needs to be examined and a ColonIS partnership agreement needs to be drawn up.
4. Drawing up a Statement of Requirements for ColonIS in collaboration with those working in the field, European tender for ColonIS, proof of concept for ColonIS.
5. Defining and implementing links between the various systems defined (including electronic transfer of diary appointments between ColonIS and the colonoscopy centre appointments system, feedback of follow-up data, et cetera).
6. Adapting source systems.
7. Developing ColonIS.
8. Testing and acceptance of ColonIS.
9. Implementation of ColonIS release 1 (trial region).
10. Implementation of ColonIS release 1.1 (broad roll-out).
11. Organizing the management of ColonIS and further development of functionality.

It is recommended that a new modular system be built and development of the existing iColon system (which was used in the trial screening programmes) halted. In the long run this would make it easy for the screening organizations to use various modules for the breast cancer and cervical cancer screening programmes. Also, two-thirds of the required functionality is currently absent from iColon and would therefore need to be developed afresh anyway. The estimated period from the start of development to implementation is at least two years. So that this does not become a bottleneck in the introduction of the screening programme, it is recommended that preparatory work on the European tender (including the statement of requirements) begins as soon as possible. More information on the recommendations on information management can be found in Dutch on the CD-ROM enclosed with this report, *Recommendations on IT infrastructure for bowel cancer screening*.

## 6.6 Knowledge and innovation

Timely innovation is essential in the bowel cancer screening programme so as to guarantee the effectiveness of the programme and follow-up care in the long term. Possible innovations were mentioned by both the Health Council and the interviewees: these are discussed briefly below. We also consider the flexibility of the proposed infrastructure for the screening programme to enable the incorporation of innovations and other essential prerequisites.

### 6.6.1 Possible short and medium-term innovations and decision-making

As regards possible new innovations the Health Council notes the following:

- No results can be expected within ten years from trials of the effectiveness of colonoscopy and colonography as primary screening tests.
- Suitable biomarkers should be examined in a randomized trial, which could be organized as part of the screening programme.
- A feasibility study into offering a choice between sigmoidoscopy and iFOBT should be considered, since trials in Britain and Italy using MISCAN simulation confirm a reduction in mortality.<sup>(52)</sup>
- It considers the infrastructure with an iFOBT screening programme to be future-proof. It recommends designing the programme in such a way that



trials of better testing methods can take place as complementary research within the context of the current screening programme.(1)

A number of possible innovations were mentioned in the interviews with stakeholders. These are set out below, with a brief account of what major modifications to the programme they would require.

- *More than one iFOBT in a short space of time*:(53) possible increase in sensitivity; modifications to invitation, laboratory analysis and logistics.
- *Measuring other relevant biomarkers in faeces as well as iFOBT*: possible increase in sensitivity and specificity, additional laboratory testing and modification to logistics.
- *Modification to the programme for persons with a family history of bowel cancer*: optimizing detection of familial bowel cancer; change in invitation criteria.
- *Combining iFOBT with sigmoidoscopy*: possible positive effect on participation; inclusion of sigmoidoscopy in screening organization licences; introduction of sigmoidoscopy would have consequences for communication, the invitation system, quality assurance policy and capacity.

Research into innovations that could improve the implementation of a screening programme could interfere with its regular implementation. Experience in other screening programmes shows that it is therefore advisable, before the launch of a pilot, to reach suitable agreements between the CvB, the screening organizations and the researchers on how the pilot (for which a licence under the Population Screening Act will generally need to be granted) can be incorporated in the programme.

The proposed organization and infrastructure does not seem to present an obstacle to implementing most of the proposed innovations in the programme, following pilots and proper scientific review by the Health Council and recommendations on introduction by the CvB. Combining the iFOBT with sigmoidoscopy, however, would require major modifications to the programme.

The reference team and the Bowel Cancer Programme Committee will play a major role in identifying potentially feasible innovations in the screening programme. The CvB could inform the Ministry of Health, Welfare and Sport about promising innovations. Decisions on future innovations in the programme rest with the Ministry, generally after taking advice from the Health Council, especially if they relate to the effectiveness of the programme. Before a final decision is made it is important to identify the consequences of introduction and implementation. Minor modifications and improvements in implementation can perhaps be made within the structure of the screening programme (the licence) or after obtaining advice from the Health Council's Population Screening Act Licensing Committee.

#### 6.6.2 *Information management, monitoring and evaluation, and complementary research infrastructure*

Allowance should be made when designing the bowel cancer screening programme for complementary research that could be relevant, especially linking up the two information management systems. If they are correctly designed and linked up, researchers will be able to use data recorded in a standard form nationwide for monitoring and evaluation quickly and efficiently, as well as data from the programme, biobanks and imaging et cetera. It is recommended that national developments concerning the complementary research infrastructure be monitored closely, so as to create synergy wherever possible.

#### 6.6.3 *Funding of research into implementation and innovation*

The funding of the complementary research required was regularly mentioned as a problem in the interviews with stakeholders. So far the bowel cancer screening pilots have been funded by the Netherlands Organisation for Health Research and Development (ZonMw) under the Prevention Programme. In certain areas (e.g.

measuring public acceptance, pre-testing communication tools et cetera) research into implementation will be needed prior to the introduction of the screening programme. It is also important, once a decision has been made to introduce the bowel cancer screening programme, that funding should be made available for any innovation research considered necessary in connection with it, so that the evidence required for future improvements is available in good time.

The CvB advises the Ministry and ZonMw to include innovation research for the bowel cancer screening programme as a priority in the ZonMw programme and to provide sufficient funds for it.



## 7 Capacity

The Ministry asked for the feasibility study to address possible problems of capacity for the screening programme and follow-up diagnosis and treatment that could arise if the programme is introduced, and recommendations to be made on measures to overcome these problems. Both the National Cancer Control Programme and the Health Council have pointed out the need for additional colonoscopy capacity if a bowel cancer screening programme is introduced. The CvB has commissioned additional research from the Department of Public Health of Erasmus University and the consulting firm Bureau Berenschot, so as to gain a good idea of the magnitude of the shortages and ways of dealing with them. The reports of these additional studies can be found on the CD-ROM (in Dutch) enclosed with this report. Section 7.1 describes the phased introduction proposed in the Health Council's advisory report. The capacity required and available for the screening programme is discussed in section 7.2, and the capacity required and available in the health care system is outlined in section 7.3. Section 7.4 discusses possible measures to overcome shortages of capacity, i.e. measures to alleviate any capacity problems on the supply side and measures that could reduce demand during the phased introduction. The conclusions and recommendations on phased introduction and capacity are set out in section 7.5.

### 7.1 Phased introduction

A screening programme is part of a care chain. If a subject's test results are abnormal, he is referred to the care system for further diagnosis and treatment if necessary. The introduction of the bowel cancer screening programme will thus have consequences for the processes that take place in the care system. The number of referrals for colonoscopies will increase and remain higher. Operations and adjuvant therapy as a result of these colonoscopies will increase initially but probably decrease again after a number of years. The increase in the demand for care may cause problems with the available capacity.

One of the Health Council's considerations is that it will take time to build up care capacity, which is why it recommends phased introduction (see also Figure 3). The timetable entails inviting only 65 and 75-year-olds in the first year of introduction; in the next year 63, 65, 67 and 75-year-olds will be invited, in the following year 61, 63, 65, 67, 69 and 75-year-olds, and so on. Under this timetable all age groups will be invited in year 6, in line with the estimation that adequate care capacity will be available by then. In year 7 another age group not previously invited will be included, namely those who turn 57 that year and were not invited as 56-year-olds in year 6. In this way everyone aged 55 to 75 will have been invited to take part in the screening programme at least once by year 7.<sup>9</sup> This phased introduction timetable is taken as the reference scenario in the remainder of this chapter.

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<sup>9</sup> Absolute figures for the annual target group are specified in the report by Erasmus Medical Centre Rotterdam, *The additional capacity required in the care system, the cost and the prevention of mortality from bowel cancer following the introduction of a bowel cancer screening programme in the Netherlands* and can be found on the CD-ROM enclosed with this report (in Dutch).

	Phased introduction					All age-categories included	Target group at least once invited
	1 2013	2 2014	3 2015	4 2016	5 2017	6 2018	7 2019
Year of birth	Age at invitation for the screening						
1964							55
1963						55	
1962							57
1961						57	
1960					57		59
1959						59	
1958					59		61
1957				59		61	
1956				61	61		63
1955				61		63	
1954			61		63		65
1953				63		65	
1952			63		65		67
1951		63		65		67	
1950			65		67		69
1949		65		67		69	
1948	65		67		69		71
1947		67		69		71	
1946			69		71		73
1945				71		73	
1944					73		75
1943						75	
1942					75		
1941				75			
1940			75				
1939		75					
1938	75						
<b>Number of invitations (*1000)</b>	338	762	1.195	1.538	1.990	2.218	2.260


 invited age-category

Figure 3: Health Council scenario (reference scenario) for the phased introduction of the bowel cancer screening programme

## 7.2 Capacity required and available for the screening programme

The introduction of a bowel cancer screening programme will have consequences for the capacity required for regional implementation by the screening organizations and national management by the CvB.

### 7.2.1 Capacity for regional implementation by the screening organizations

Any future bowel cancer screening programme will have many features in common with the existing cervical cancer screening programme as regards the screening organization's work processes. The projections of capacity are based on more or less equal staffing for the corresponding work processes. On top of this, capacity will be needed for the additional work, including packing the screening kits, and at the implementation stage capacity will need to be set aside for the new project organization.

*Invitation*

The self-administered test will be offered to people in the target group. The samples will be analysed at a small number of laboratories. We assume that invitations and screening kits will be packed by hand in the initial years, as in the pilots currently in progress.

*Referral by the screening organization*

The role of the screening organization in referring clients still needs to be examined in detail, but informing clients of abnormal results and organizing referral will certainly require more manpower than the current referral system in the cervical cancer screening programme.

*Quality assurance*

When it comes to performing the reference function the screening organization will be dependent on the availability of gastroenterohepatologists, clinical chemists and pathologists (see chapter 4). It is difficult to gauge at present whether the capacity problems in these professional groups will also result in reduced availability for these tasks in the screening organizations. Experience from the cervical cancer screening programme shows that recruiting people to carry out these tasks from the select group of reference specialists has not given rise to any problems so far.

*Phased introduction*

The target group will grow gradually once the bowel cancer screening programme is phased in. The manpower needed to pack the invitations and refer clients to the care system will need to grow in step with the target group. Support staff for communication (information officer) and the quality system (regional specialist coordinators) will need to be appointed at the start of the programme, however, as most of the work involved in communication and setting up a quality system will be at the start of implementation and will be independent of the size of the target group.

The screening organizations do not envisage any problems as regards the required capacity.<sup>10</sup> There are no posts that will be difficult to fill.

*7.2.2 iFOB testing capacity*

The CvB recommends having the iFOBT carried out by a maximum of three to five laboratories. Each laboratory will presumably require 1-2 FTE of analysts for this largely automated test and 0.1 FTE of a clinical chemist for coordination work. Recruiting additional analyst and clinical chemist capacity is not expected to be a problem.

*7.2.3 Capacity for national management by the CvB*

The CvB is currently running eight national programmes, for each of which it has appointed a programme coordinator supported by a team of professionals, namely:

- Advisers and programme staff (medical, financial, business, quality, monitoring and evaluation, communication, ICT, account management and internal coordination).
- Programme support staff and secretarial office.

If the CvB is commissioned to take on the introduction and national management of the bowel cancer screening programme, the team will need to be expanded by a number of FTEs for implementation and programme coordination, including advisers, programme staff and support staff. Once the programme has been implemented the required capacity will gradually fall back to the level required for the CvB's other major screening programmes. The CvB does not envisage any problems in recruiting the required staff, unless remits or funding cuts get in the way of expanding the staff complement.

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<sup>10</sup> Memorandum from Administrative Consultation Committee (BOS), Capacity of Screening Organizations, 5 October 2010.

#### 7.2.4 *Conclusions on capacity required for the screening programme in the reference scenario*

There are not expected to be any shortages of capacity as regards implementing and managing the screening programme for which additional measures would be needed.

### 7.3 **Capacity required and available in the care system**

#### 7.3.1 *Criteria for research into capacity in the care system*

The capacity required and available in the care system, as regards colonoscopy, AP analysis and gastroenterological operations, has been examined by Erasmus Medical Center Rotterdam and Bureau Berenschot. Adequate capacity also needs to be available for support functions such as operating theatres. The projections of required capacity are based on the participation rate of 60% found in the trial screening programmes and the estimated capacity available in the 2013-2020 period.

When interpreting the results of the studies and seeking solutions to shortages of capacity the CvB applied the following criteria and preconditions:

1. The phasing-in of the bowel cancer screening programme proposed by the Health Council (the reference scenario) is the preferred introduction scenario.<sup>11</sup> Switching to alternative implementation scenarios that are more in line with the capacity available in the 2013-2020 period is only acceptable if the measures to increase capacity (or distribute it better among the regions) do not overcome the shortages of capacity.
2. A shortage of capacity would result in an increase in waiting times for follow-up diagnosis and treatment, which is undesirable. A shortage of capacity for a limited period during the phased introduction is acceptable provided it remains confined to a maximum of 5,000 colonoscopies (approximately 2.5% of total colonoscopies, or the number carried out nationwide in six or seven days of production).
3. Organizations are not likely to maximize their efforts to overcome the projected shortages of capacity and reduce waiting times until a decision has been made on the introduction of the bowel cancer screening programme.
4. Uniform implementation nationwide is to be preferred for reasons of access. The five screening regions must not be allowed to have unnecessary differences in approach.
5. Any alternative implementation scenario must be acceptable to the public and must be able to respond flexibly to the capacity available; nor must it adversely affect the monitoring and evaluation of the programme needed for good quality control.

#### 7.3.2 *Design of the study*

The methodology of the study carried out by Erasmus Medical Center Rotterdam and Bureau Berenschot was as follows:

- The capacity required without the introduction of the screening programme (the baseline) as regards colonoscopy and surgery has been calculated based on the number of procedures carried out in 2008, basing the number of procedures in each age group on the forecast population size for 2013-2025 (Statistics Netherlands).
- The number of colonoscopy procedures in 2008 was determined on the basis of appropriate Diagnoses Related Group (DRGs).<sup>12</sup> The projections for the number of surgical interventions are based on the total number of tumours of the large intestine and rectum in 2008.<sup>(3)</sup> The number of

<sup>11</sup> The phased introduction proposed by the Health Council is the most cost-effective scenario (see the report in Dutch by Erasmus Medical Center Rotterdam on the enclosed CD-ROM).

<sup>12</sup> Source: Inquiry into DRG maintenance.

surgical interventions has been checked against the number of procedures (operations) carried out in 2008 as part of a DRG. Because of the complexity of mutually reinforcing growth factors, the historical trend is not reliable enough to forecast the capacity required for pathology procedures, so these have been based on the calculations by the Capacity Board (see section 7.3.3).(51)

- The capacities required to carry out the screening programme have been calculated using the MISCAN model<sup>13</sup> also used by the Health Council to make projections in its advisory report.
- The size of the screening programme target group has been determined from Statistics Netherlands forecasts (2010) for demographic structure over the 2013-2025 period. The numbers of colonoscopies are based on the participation rate found in the trial screening programmes (60%) and referral rates. The numbers of pathology procedures are based on the average number of polypectomies per colonoscopy(1) plus the estimated number of pathology procedures as a result of subsequent surgery. The basis for the number of surgical interventions is the expected number of tumours of the large intestine and rectum(1) plus the estimated number of adenomas requiring surgical removal following colonoscopy.<sup>14</sup>
- The total capacity required (for colonoscopy, AP and gastroenterological surgery) has been calculated by adding the capacity required without the screening programme (the baseline) and the additional capacity required for the programme.
- The capacity available is based on the average number of procedures per medical specialist in 2008 (the number of procedures in 2008 divided by the number of medical specialists working in that year): this average multiplied by the expected number of medical specialists in a particular year gives the capacity available for the procedure in question in that year. The number of specialists in a particular year is based on estimates by the Capacity Board and the interviews with the professional groups.
- For colonoscopy procedures, AP analysis and bowel cancer surgery the difference between the capacity available and required over the 2013-2025 period has been calculated.
- Possible developments that could affect the shortages of capacity warned of, and ways of reducing them, were considered in consultation with representatives of the professional associations of gastroenterohepatologists, pathologists and gastroenterological surgeons. These effects and measures were identified, and quantified wherever possible, by the Working Groups and the Bowel Cancer Screening Programme Advisory Committee.

Further evidence for the criteria used and how they were applied can be found in the report by Bureau Berenschot *Capacity survey for the bowel cancer screening programme* and the report by Erasmus Medical Center Rotterdam *The additional capacity required in the care system, the cost and the prevention of mortality from bowel cancer following the introduction of a bowel cancer screening programme in the Netherlands*, which can be found on the CD-ROM enclosed with this report.

### 7.3.3 Results of the study

#### *Colonoscopies*

500,000 gastrointestinal tract endoscopies were carried out in 2008, including 178,000 colonoscopies.<sup>15</sup> Of these colonoscopies 123,000 (69%) were performed by gastroenterohepatologists, 44,000 (25%) by internists and 8,000 (4%) by surgeons. This amounts to just under 500 colonoscopies per year per gastroenterohepatologist. Internists and gastroenterological surgeons carry out far fewer colonoscopies per person, namely 28 and 20 per year respectively. Thus

<sup>13</sup> Microsimulation SCreening ANalysis, a mathematical model for predicting costs and effects of screening strategies.

<sup>14</sup> Source: Erasmus Medical Center Rotterdam records, Bowel Cancer Pilot Screening Programme (Rotterdam region).

<sup>15</sup> These figures, used by Berenschot to calculate the baseline, tally with the figures presented at the NVGE spring meeting by Prof. C.J.J. Mulder of VU University Medical Center.



gastroenterohepatologists are by far the most common colonoscopy practitioners. Given the demographic trend we can expect the number of colonoscopies to have risen to over 190,000 by 2013.

The number of additional colonoscopies required for the fully implemented screening programme would be about 70,000 (see Figure 4).

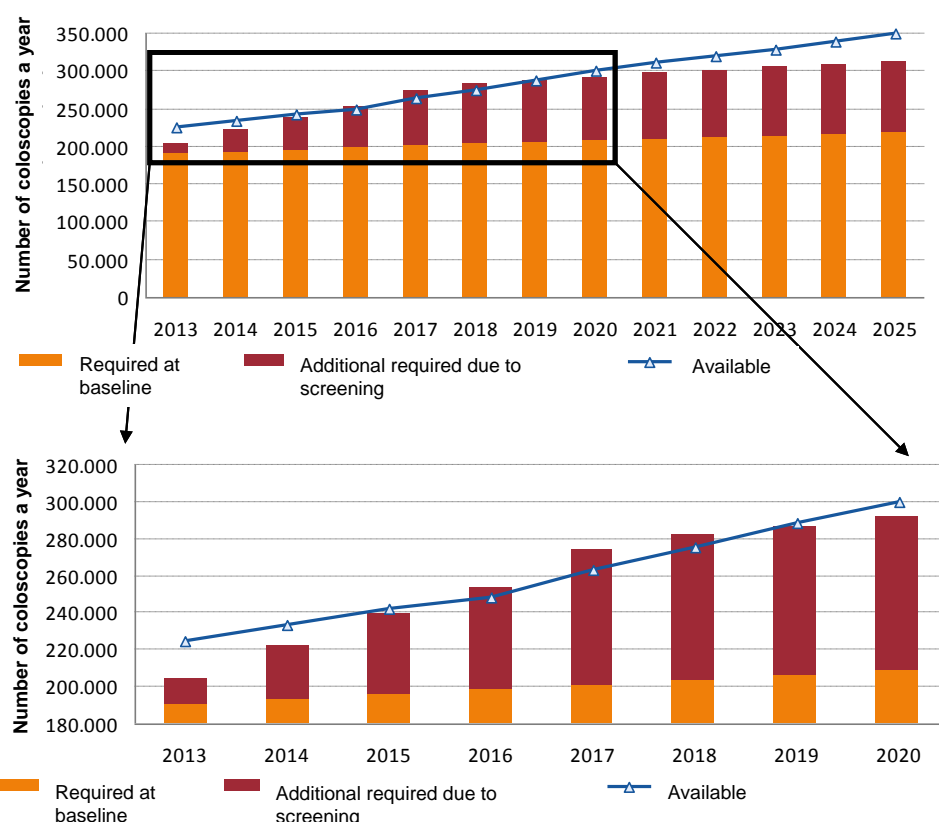


Figure 4: Colonoscopy capacity required and available. The second chart zooms in on the period where a shortage of colonoscopy capacity develops.

Analysis of the colonoscopy capacity required and available shows that until 2015 there is adequate capacity to cope with additional colonoscopies resulting from the phasing-in of the screening programme; in 2016, 2017 and 2018, however, there will be a shortage of colonoscopy capacity (see Figure 4). The biggest problem<sup>16</sup> will be in 2017, with a shortage of approximately 11,500 colonoscopies, or the number carried out nationwide in 15-16 days of production. This will increase waiting times between an abnormal iFOBT result and follow-up diagnosis by about three weeks. After 2019 there will be adequate colonoscopy capacity again.

Although the number of gastroenterohepatologists is growing (from 250 in 2008 to 335 in 2013 and 400 in 2017, partly in anticipation of a possible bowel cancer screening programme), a large number of hospitals are currently having difficulty filling vacancies for gastroenterohepatologists. This is due to a longstanding absolute shortage of gastroenterohepatologists and the fact that those who are available prefer to work in large practices with lower workloads and more opportunities for job differentiation. Furthermore, any expansion of capacity in a hospital is often soon taken up with work that used to be left undone or that has been introduced recently as a result of new treatments for chronic illnesses (e.g. Crohn's disease and viral hepatitis). In reality the surplus colonoscopy capacity projected for 2013 and 2014 will be invisible, as it will be taken up with other appropriate gastroenterohepatology work. The allocation of

<sup>16</sup> Based on introducing the screening programme in 2013 (baseline).

gastroenterohepatologists' colonoscopy capacity, then, is subject to a certain degree of flexibility. At present they spend about 20-25% of their working time on colonoscopies. Any shortages of capacity could be overcome temporarily by prioritizing work differently, but taking advantage of this flexibility is not a suitable structural solution to the shortages of capacity in the peak years following the introduction of the programme.

It should be noted that a day treatment place must be available for a colonoscopy to be carried out in hospital. If this capacity does not grow in step with the additional colonoscopies resulting from the screening programme there could be problems here. Hospitals agree the numbers of day treatment places with health insurers annually.

On top of the direct increase in colonoscopies due to the screening programme outlined above, some indirect effects can be expected. It is likely that the introduction of the programme will result in more individuals with a positive family history of hereditary bowel cancer being detected.<sup>17</sup> According to the guideline they should undergo colonoscopy every six years. It is difficult to gauge how many additional colonoscopies this will entail.

#### *Pathology procedures*

Approximately 1.47 million pathology procedures were carried out in 2008, and demand for them is expected to grow faster – as a result of various developments in medical technology – than projected based on purely demographic trends. This will also increase the numbers of pathology procedures per medical condition and per head of population. The Capacity Board has included these trends in medical technology and demography (and a few others) in its projections and adjusted the number of training places accordingly.

On full implementation it is estimated that some 65,000 additional pathology procedures will be carried out as a result of the bowel cancer screening programme (see Figure 5). Thus the growth in pathology procedures as a result of the programme amounts to about 4% of the total number per year. This ratio means that the increase due to the programme will have less impact on pathology than on colonoscopy (and surgery).

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<sup>17</sup> The umbrella organization of clinical geneticists (VKGN) said that introducing the screening programme might cause a slight increase in waiting times for consultations with a clinical geneticist.

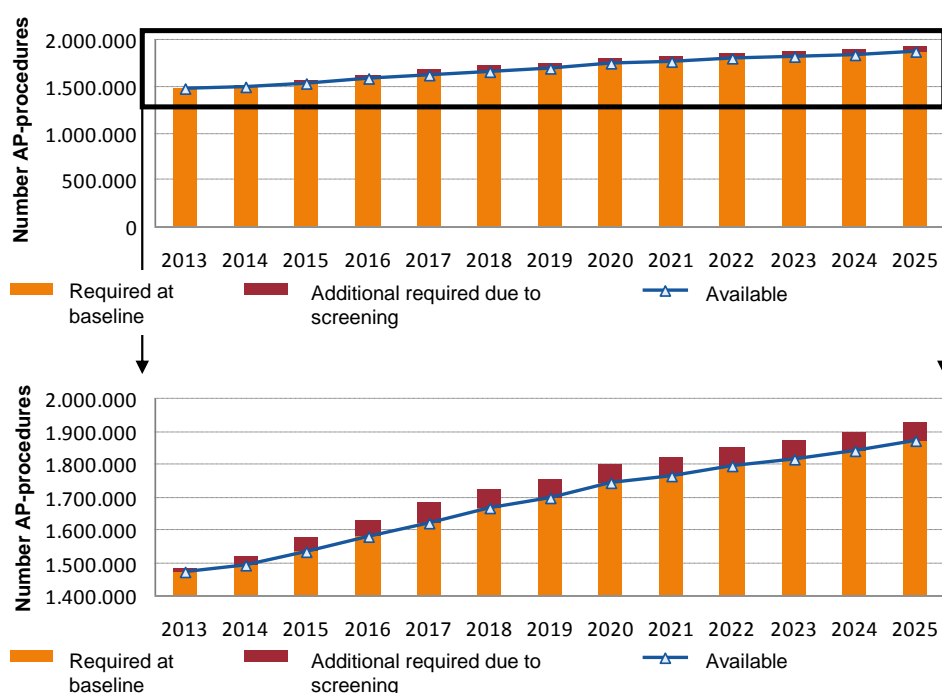


Figure 5: Pathology capacity required and available. The second chart zooms in on the additional pathology procedures required as a result of introducing the bowel cancer screening programme.

Of the 65,000 pathology procedures mentioned, about 60,000 are related to the assessment of adenomas removed during colonoscopy. The remaining 5,000 are the result of surgery: these are more complex in nature and will be carried out mainly in the initial years following the launch of the screening programme. The more complex procedures are expected to become fewer in parallel with the number of surgical procedures due to the programme. Pathologists are well distributed among Dutch hospitals.

#### *Surgical interventions*

The number of surgical interventions includes not only operations to treat bowel cancer but also operations to remove adenomas that cannot be removed during colonoscopy. Approximately 14,000 such interventions were carried out in 2008. Operative treatment of bowel cancer is the domain of gastroenterological surgeons, i.e. surgeons who specialize in treating disorders of the gastrointestinal tract, including bowel cancer. Discussions with the NVVH (Netherlands Surgical Association) and the Capacity Board indicate that the capacity for gastroenterological procedures is already limited. The main reasons for this lack of capacity are health insurers' procurement policies, the way hospitals are run and existing shortages in operating theatre staff; it is not due to a shortage of gastroenterological surgeons, indeed there is a small surplus of these. Surgical capacity is well distributed throughout the Netherlands.

The number of operations will increase once the screening programme is introduced. More bowel cancers will be diagnosed initially as a result of the programme, giving rise to a surge in the surgery workload in the initial years following its introduction. The increase is expected to peak in the 2014-2018 period, with some 3,000 additional operations per year in those years (see Figure 6), an increase of 20% on the baseline. After that period the number of bowel cancers in the population will go down, as the preliminary stages will be detected in the screening programme and treated. As a result of the number of

bowel cancer operations is expected to be reduced in the long run.(1) Because of the programme, operations will eventually become less radical: this change in treatment is not included in the capacity projections, as the data required was not available.

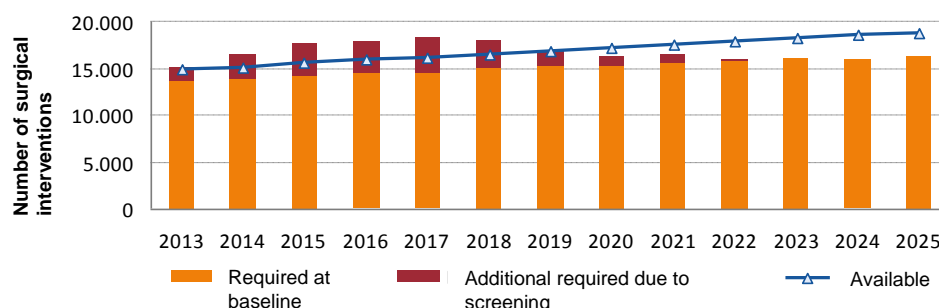


Figure 6: Surgical capacity required and available.

#### 7.3.4 Conclusions on the capacity required and available in the care system under the reference scenario

The introduction of a bowel cancer screening programme in line with the reference (Health Council) scenario, if no additional measures are taken, would result in temporary shortages of capacity in gastroenterohepatology, pathology and gastroenterological surgery. The largest shortage would appear to be of gastroenterohepatologists – the main practitioners of colonoscopy. The shortage of capacity in pathology is relatively small. Although the additional surgical capacity required is substantial, there is no shortage of gastroenterological surgeons. Issues in surgery are health insurers' procurement policies, the way hospitals are run and how they deal with existing shortages of operating theatre staff.

It should be noted that the underlying calculations do not take into account any changes in opportunistic screening due to the screening programme (there could be either an increase or a decrease) and any increase in the demand for care on the part of people with a positive family history. Although the magnitude of these effects on full implementation would be relatively limited, they could have a strong distorting effect, especially at the start of the programme.

An important criterion in all the projections is a participation rate of 60%, as observed in the trial screening programmes. The rate varies somewhat among the pilot regions. Nor can we rule out the possibility that an effective national introduction campaign could immediately result in higher participation, though an initial rate of more than 70% seems unlikely. 70% participation on full implementation in the peak years would mean an additional 12,000 colonoscopies, a similar number of additional pathology procedures and 500 more operations. Conversely, if attendance remained at 50%, this would mean 12,000 fewer colonoscopies and pathology procedures and about 500 fewer operations: there would then be no shortage of colonoscopy capacity, and the shortage of pathology and surgical capacity would be less and therefore easier to overcome.

As already indicated, the introduction of a bowel cancer screening programme in line with the reference scenario would most probably result in shortages of capacity in the care system, which could be larger or smaller depending on the assumptions made. The effects of various trends that could affect the size of the shortages are also difficult to gauge. The ensuing sections discuss measures to overcome shortages of capacity.

## 7.4 Measures to overcome shortages of capacity

There is a shortage of capacity when demand exceeds supply. The shortage is remedied when demand decreases and/or supply increases. If supply is determined primarily by the availability of a particular medical specialism, it can be increased by increasing the number of specialists. A solution to a shortage of capacity on the demand side would be to reduce the number of referrals from the screening programme, by inviting fewer people to participate, and/or inviting people less often, and/or referring fewer people from the programme (e.g. by increasing the cut-off value for the test). Measures could be taken on both the supply side and the demand side to reduce an expected shortage of capacity in good time. Possible measures on the supply side are discussed in section 7.4.1. Section 7.4.2 discusses alternative scenarios to reduce demand during the phased introduction.

### 7.4.1 Measures to reduce shortages of capacity on the supply side

#### *Gastroenterohepatologists*

Apart from training more gastroenterohepatologists, various alternative measures could be envisaged to overcome shortages during the 2016-2019 period. According to the professional association of gastroenterohepatologists it should be possible to overcome the shortage of capacity identified in the reference scenario in the 2016-2019 period using the following measures:

1. Transferring less complex clinical endoscopies to endoscopists/endoscopy nurses.
2. Increasing the capacity available for the screening programme by stepping up the throughput rate (streamlining the colonoscopy process, e.g. by analogy with care pathways) by using support staff (e.g. specialist nurses, case managers and sedation staff).

Revising the existing guideline for endoscopic surveillance following removal of adenomatous polyps would also reduce the number of colonoscopies required, but this measure is already included in the Erasmus Medical Center Rotterdam projections.

Employing foreign gastroenterohepatologists has also been considered as a way of overcoming shortages of capacity, but experience with foreign gastroenterohepatologists has not been an unqualified success. In addition to possible language problems, which are important in such a multidisciplinary area with a lot of direct contact with patients, their endoscopic training is often of significantly lower quality (this is the case, for example, with gastroenterohepatologists trained in Belgium and Germany). Their approach is often different too. On top of this, their average length of stay is usually short, with the result that they derive only limited benefit from the induction period and they are not included in the quality programmes customary in the Netherlands, such as quality inspection.

An increase in colonoscopies might in fact require more day treatment places in hospital, and this would also affect the respective care budgets.

An issue that needs to be considered when preventing or dealing with shortages of capacity is the development of regional imbalances. There are no shortages at present – or only minor ones – in the metropolitan areas, for example, whereas the shortages are relatively large in the more rural areas, especially Zeeland (province in Southwest) and the tip of Noord-Holland (province in the Northwest). In practice, gastroenterohepatologists, as already indicated, prefer to work in larger practices (which have lower workloads and more opportunities for job differentiation). The expectation is that the less than ideal distribution of gastroenterohepatologists will be remedied if the capacity available increases. There are in fact indications that, in regions with relatively few gastroenterohepatologists, internists make up for the resulting shortage of colonoscopy capacity (at least partly). In practice, less than

ideal distribution does not generally cause major problems, as patients have recourse to hospitals in nearby towns and cities. In the event of regional shortages a national planning and appointments facility could meet patients' wishes to receive colonoscopy and treatment sooner outside their particular region. The expectation is that regional shortages in colonoscopy capacity could also be resolved by having gastroenterohepatologists carry out colonoscopies at other locations.

#### *Pathologists*

Introducing a bowel cancer screening programme would cause a limited increase in total pathology procedures of about 4%. This would take place mainly in the initial years following its introduction, with complex pathology procedures increasing as a result of surgery. The expectation of the umbrella organization of pathologists (NVVP) is that this shortage could be overcome with the following measures:

1. An efficiency gain from technological and IT innovations in pathology operations (including laboratory technology, digital microscopy, standard reports, and so on).
2. Transferring duties to other echelons (analysts/physician assistants).
3. Training a number (to be decided) of additional pathologists immediately following a positive decision by the Minister, so as to cope with the relatively large peak in complex pathology procedures following surgery that is expected to occur at the start of the screening programme.

Here again the employment of foreign pathologists has been considered. Most Western European pathologists have a similar level of knowledge and could be employed immediately, provided there is no language barrier. Whether there are surplus pathologists in Western Europe is not known, however.

In the case of pathology too the respective budgets may need to be adjusted to meet the growth in volume generated by the screening programme.

#### *Gastroenterological surgeons*

The current shortage of bowel cancer operation capacity is not due to a shortage of gastroenterological surgeons: as already noted, there is even a surplus of these. Any shortages of surgical capacity may be due to limited procurement of this service by the health insurers and the relatively scarcity of operating theatre staff. The capacity available is determined for the most part by market factors and the way health insurers and hospitals are run. There are various mechanisms that could produce a temporary increase in bowel cancer surgery capacity:

1. Hospitals could increase the availability of support staff such as operating theatre nurses and anaesthetists for bowel cancer surgery.
2. Health insurers could take the increase due to the screening programme into account when purchasing bowel cancer surgery.

In the case of surgery too the respective budgets may need to be adjusted (temporarily) to meet the growth in volume generated by the screening programme.

#### *Measures on the supply side: conclusion*

In this section we have discussed measures that could offset shortages of capacity caused by a bowel cancer screening programme. The measures have been identified for each discipline and discussed with the three professional groups, which are all motivated to take measures to overcome the shortages of capacity. The CvB concludes from this that the proposed measures and associated preconditions provide an adequate basis for phasing in the programme in line with the reference scenario. Regional shortages of colonoscopy capacity could develop, but these will not be insurmountable. This supposition is shared by the professional associations of gastroenterohepatologists, pathologists and gastroenterological surgeons.

The projections of capacities available and required are based on a number of assumptions, including a participation rate of 60%. Also, as already noted, the

effects of various trends are difficult to gauge in advance, above all more or less opportunistic screening and the influx of people with a family history into the colonoscopy screening prescribed by the guideline. Another possibility is that the measures described above to adjust capacity to demand might not be effective enough. Alternative scenarios have therefore been developed to influence the demand side.

#### *7.4.2 Alternative scenarios for phased introduction*

In this feasibility study, in addition to the reference scenario put forward by the Health Council (Figure 7A), we have developed three alternative scenarios to reduce demand during the phased introduction. Colonoscopy capacity has been taken as the starting point for all the scenarios, regarding a shortage of no more than 5,000 colonoscopies per year as acceptable. The phasing or cut-off value has then been geared to this.

##### *7.4.2.1 The scenarios developed*

1. *Implementation with alternative invitation of age groups (see also Figure 7B)*  
Scenario where the implemented timetable is geared to nationwide colonoscopy capacity, subject to the following preconditions:
  - a. The implemented sequence is in line with the Health Council scenario as far as possible but slower.
  - b. Age groups once invited continue to be invited.
  - c. Individuals once invited continue to be invited in line with the Health Council scenario (every two years).
2. *Implementation with alternative screening interval (see also Figure 7D)*  
Scenario where the implemented timetable is geared to nationwide colonoscopy capacity, subject to the following preconditions:
  - a. The implemented sequence is in line with the Health Council scenario as far as possible, but starts with invitation every four years; invitation of intermediate age groups begins once there is adequate capacity.
  - b. Age groups once invited continue to be invited.
  - c. Individuals once invited continue to be invited in line with the Health Council scenario (first every four years, then every two years).
3. *Implementation with alternative cut-off value (sensitivity threshold for the iFOB test) (see also Figure 7C)*  
Scenario where the implemented timetable is geared to nationwide colonoscopy capacity, subject to the following preconditions:
  - a. Implemented in line with the Health Council scenario.
  - b. Adjustment/variation of iFOBT cut-off values permitted.

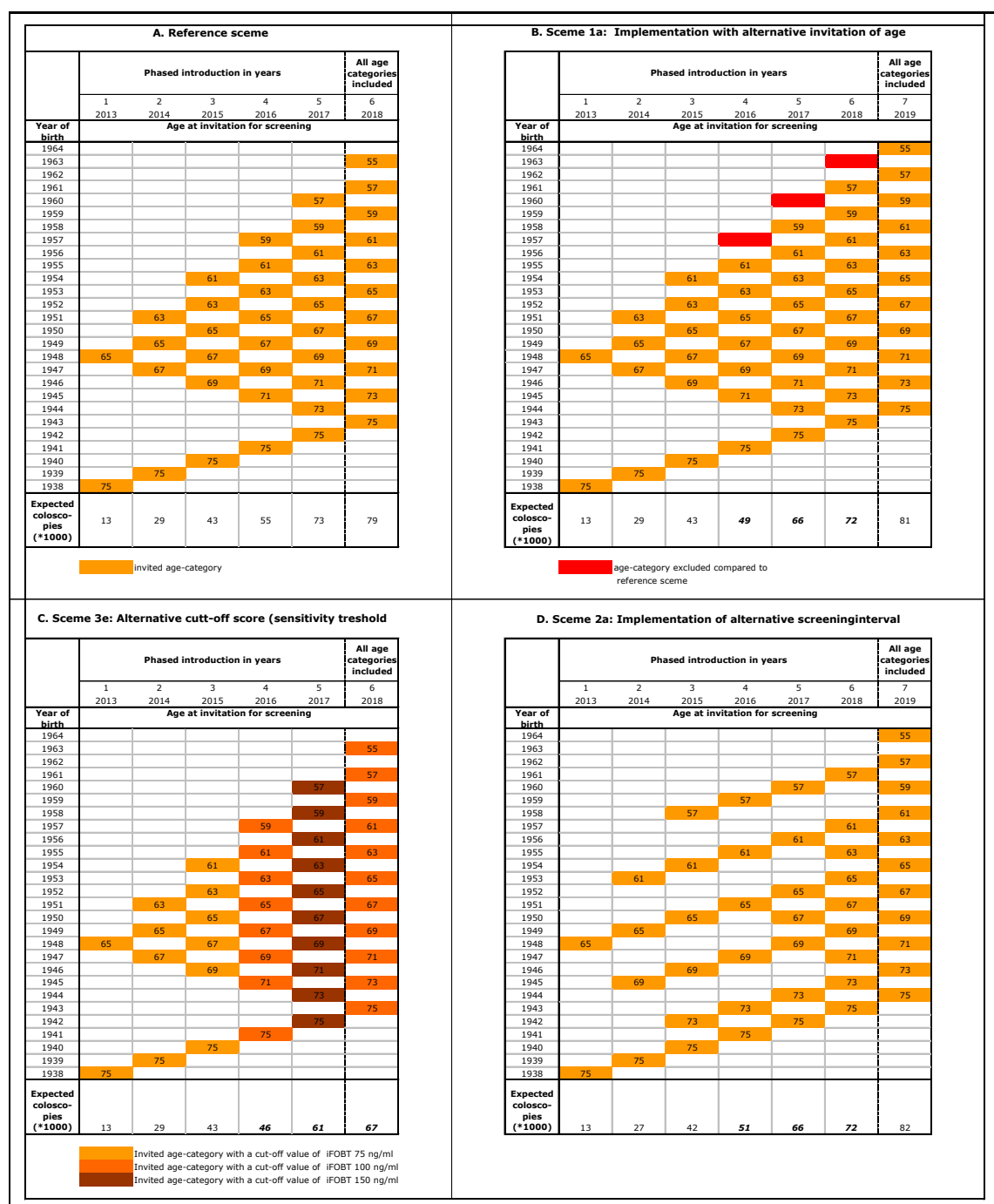


Figure 7: Timetables for the phased introduction of the bowel cancer screening programme and expected numbers of colonoscopies required. A: Reference (Health Council) scenario. B: Example of alternative phasing with deferred invitation of particular age groups. C: Example of alternative scenario with adjustment of iFOBT sensitivity threshold.<sup>18</sup> D: Example of alternative phasing starting with a four-year screening interval.

A fourth scenario with a three-yearly invitation system was considered but rejected because of a number of problems. First of all, it is not possible to distribute the age groups to be invited properly over the 55-75 age interval. Also, within the age interval only seven age groups could be invited, instead of the eleven proposed by the Health Council. This would mean switching from a three-year timetable to a two-year timetable during implementation. This would be complicated, especially if

<sup>18</sup> The cut-off point for the iFOBT used here applies to the OC-Sensor test.



the capacity required during the changeover is to grow gradually in step with the capacity available. A complicated changeover timetable would make it more difficult to respond flexibly to hiccups in the growth of capacity, and it would be more difficult to explain to the public. It would also hamper the proper monitoring and evaluation of the screening programme.

#### 7.4.2.2 *Effect of scenarios*

Study and analysis of these alternative scenarios shows that they all have variants that would adequately adjust the colonoscopy capacity required on implementation to the capacity available. Most of them achieve this with acceptable concessions to cost-effectiveness vis-à-vis the Health Council scenario. More information on the scenarios can be found in the report by Erasmus Medical Center Rotterdam on the CD-ROM enclosed with this report.

#### 7.4.2.3 *Pros and cons of alternative scenarios*

The pros and cons of each scenario vis-à-vis the reference scenario are as follows:

- Scenario 1: Implementation with alternative phasing of invitation of age groups (see Figure 7B)
- Method: Three years after introduction no new age groups are invited for three successive years, thus levelling out the peak in the care system.
- Effect: Reduces the shortage to no more than 4,000 colonoscopies in the peak year 2017.
- Advantages: This scenario could be implemented at such time as shortages of capacity cause problems and would thus be suitable as an ancillary tool.
- Disadvantages: It would take at least one year longer for the whole population to be included. People might feel disadvantaged by the deferred implementation scheme and have recourse to opportunistic screening.
- 
- Scenario 2: Implementation with alternative screening interval (see Figure 7D)
- Method: The screening interval is four years at the start of the programme; after four years it changes to two years.
- Effect: Reduces the shortage to just over 4,000 colonoscopies in the peak year 2017.
- Advantages: The entire target group is first invited before certain age groups are invited for a second time.
- Disadvantages: The risk of interval carcinomas is higher as a result of the longer screening interval.  
This scenario is not suitable as an ancillary tool: people might feel inadequately protected as a result of the longer screening interval and have recourse to opportunistic screening.  
This scenario would be difficult to explain to the participants, as the screening interval would differ depending on the year they join the programme during its phased introduction.
- 
- Scenario 3: Implementation with alternative cut-off value(s) (see Figure 7C)
- Method: From year 3 the cut-off value is adjusted to reduce the number of referrals from the programme.
- Effect: Adjusting the cut-off values to the colonoscopy capacity required would prevent a shortage.
- Advantages: This is the most cost-effective alternative scenario. It is suitable as an ancillary tool, as the reference scenario remains intact.
- Disadvantages: High cut-off values mean that fewer abnormalities are detected. They would also change the case mix, with relatively more carcinomas and fewer adenomas being found. The risk of interval carcinomas would be higher, and the degree of protection would be lower.

It would cause problems as regards clear monitoring and evaluation. People might feel unprotected as a result of the high cut-off value and have recourse to opportunistic screening. It would be difficult to explain to the public, as changing the cut-off values would have a semblance of arbitrariness.

All the alternative scenarios, if implemented, would place heavy demands on communication to the public. A combination of scenarios 1 and 3 is a possibility. Another possibility is, when the time comes, to seek alternatives within any scenario/system that are more in line with actual developments.

#### *7.4.2.4 Conclusion*

Capacity problems could be minimized by changing the implementation timetable or the cut-off value. Workable models have been developed in the form of three alternative scenarios. Two of these (1 and 3) are suitable as measures during implementation and could be applied if introduction in line with the reference scenario (in the Health Council advisory report) results in unacceptable problems. If scenario 2 were to be adopted this would have to be before implementation begins, when it would not yet be clear that the reference scenario is going to cause problems.

Adopting an alternative scenario would mean making concessions to the degree of protection for the population as a whole and the cost-effectiveness of the screening programme. Whether this is acceptable is a political decision, which could be backed up to some extent by further research into support and necessity in the initial years of the programme.

The Bowel Cancer Screening Programme Advisory Committee expressed its preference for scenario 1 as an ancillary tool on 3 February 2011. In the Committee's opinion this scenario would have the least adverse effect on the reference scenario and on the test characteristics used as a basis for the forecasts. The Committee therefore recommends including the participation rate, the waiting times between referral from the screening programme and colonoscopy, the handling time for AP procedures and the waiting time from diagnosis following colonoscopy to surgery as indicators in the short-cycle capacity monitoring system. The Committee advises the CvB to decide on targets and limits for waiting times and handling times in consultation with the professional associations and patients' associations concerned during the preparatory period. The CvB agrees with the Committee's recommendations and suggests using the Treek targets.<sup>19</sup>

## **7.5 Conclusions and recommendations on phased introduction and capacity**

### *7.5.1 Conclusions*

The introduction of the bowel cancer screening programme in line with the Health Council's advisory report will cause substantial temporary shortages of capacity nationwide, especially in gastroenterohepatology and gastroenterological surgery. The maximum shortage of gastroenterohepatology capacity is estimated at 11,500 colonoscopies, and of surgery capacity at 3,000 bowel operations.

The expectation of the gastroenterohepatologists is that the projected shortage can be overcome by role reallocation, efficiency measures and increasing the intake to training programmes. The shortage of capacity in gastrointestinal surgery is not due to a shortage of gastroenterological surgeons; it is the result of the policies of health insurers and hospitals and as such can be resolved if funding is available.

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<sup>19</sup> Targets for waiting times in the care system: there are two types of target, maximum acceptable waiting times for everyone and acceptable waiting times within which 80% of patients must be dealt with.

Any regional shortages of capacity that occur could be overcome temporarily by means of agreements between hospitals and specialists in other regions, and if necessary by referring patients to hospitals outside their region. A national planning and appointments facility will be required to achieve this.

The increase in the demand for pathology caused by the screening programme is relatively small, but it will take place in the initial years of the phased introduction. The NVVP considers that the increased demand can be accommodated with the proposed measures.

No shortages of capacity are expected within the screening programme itself, i.e. the laboratories analysing the iFOBTs, logistical support by the screening organizations and national management by the CvB.

Given the uncertainties in the capacity projections it will be important to monitor the capacity effects closely. If necessary, measures can be taken to defer the introduction of the bowel cancer screening programme based on monitoring of capacity and waiting times. Scenarios 1 and 2 entail slowing down intake by deferring the addition of new age groups. Scenario 3 entails adjusting the cut-off value of the iFOB test during the course of implementation. As these scenarios have drawbacks (also of an ethical nature), the decision should be made by the Minister.

#### *7.5.2 Recommendations*

The CvB recommends:

- Phasing in the screening programme in line with the timetable proposed by the Health Council. The shortages of capacity that are likely to occur in the care system will encourage the professional groups to take suitable measures. If insurmountable shortages of capacity in the care chain develop in spite of these measures, one of the alternative scenarios could be adopted.
- Deciding in advance which scenario/system for intake is to be preferred so as to limit unacceptable shortages of capacity. This would entail measuring support for the various scenarios among patients/consumers and professional groups before the decision is taken.
- Revising the appropriate care budgets so that the temporary additional costs to the care system resulting from the screening programme are covered.
- Urging the professional groups, hospitals and health insurers to take advantage of the preparatory and implementation period to take the measures to increase capacity. It would be advisable to initiate a national consultation system for this purpose.
- To develop and set up a short-cycle capacity monitoring system (national and regional). The speed of introduction could be adjusted if necessary, based on a number of critical quality and access parameters such as waiting times and handling times for colonoscopy and treatment.
- To create a national planning and appointments facility that oversees capacity available throughout the Netherlands, so as to deal with regional discrepancies in waiting times and handling times in the care system (diagnosis and treatment). It would be advisable here to reach prior agreement with the professional groups and hospitals on how regional discrepancies can be dealt with, for example by deploying specialists in regions where shortages develop.

## 8 Implementation of the national bowel cancer screening programme

This chapter discusses how a bowel cancer screening programme could be organized and what preparations need to be made before it can actually be launched, based on the preconditions formulated in the preceding chapters. Following a section on the decision to introduce the programme (section 8.1) and one explaining the various stages to full implementation (section 8.2), sections 8.3 and 8.4 discuss the activities relevant to the various stages, noting potential risks that could present an obstacle to proper preparation or introduction. The chapter concludes with a general timetable (section 8.5).

### 8.1 Decision to introduce the programme

#### *Communication on the Minister's decision*

The Minister is to make a final decision in spring 2011 on whether to introduce a national bowel cancer screening programme.<sup>(4)</sup> We would advise the Ministry of Health, Welfare and Sport to communicate the decision to both the public and the professionals and organizations concerned, so that everyone is correctly informed of the Ministry's decision in good time. If the decision is positive, the time required for preparation and the date and rate of implementation should be communicated at the same time, so as to avoid any misunderstandings.

### 8.2 Stages

A positive decision to introduce the bowel cancer screening programme will be followed by three stages. It is anticipated that, following such a decision, one or two months will be needed for instructions to be issued before preparations can get under way.

#### *The preparatory stage*

This stage commences when the Minister has given instructions for the implementation of the bowel cancer screening programme to begin. It will entail organizing all the processes and products required for the good-quality implementation of a national bowel cancer screening programme (see section 8.3). It will end after a predetermined period (see section 8.5).

#### *Phased introduction*

The phased introduction will begin with the implementation of the bowel cancer screening programme in certain age groups and end once the entire target group has been invited. How long this stage lasts will depend on the invitation timetable adopted (see chapter 7), but it will take at least six years.

#### *Full implementation of the bowel cancer screening programme in the 55-75 age group*

By this stage the programme has been fully implemented and some 4.4 million people aged 55 to 75 are being invited every two years (2.2 million per year).

### 8.3 Preparing for introduction

Generally speaking, the following activities will need to take place at the preparatory stage:

- setting up the programme management team;
- setting up the organization and implementation;
- setting up programme funding;
- setting up communication and information;
- setting up quality of screening and follow-up care, including quality assurance;
- setting up training and improvement of expertise;
- setting up monitoring, evaluation and information management;
- setting up phased introduction and capacity monitoring;
- setting up knowledge and innovation.

The implementation table in Appendix 6 gives more details of the activities that need to be organized. It will take at least two years to prepare for introduction (i.e. until the first age group is invited). Section 8.5 discusses the preparation timetable in more detail.

#### 8.3.1 *Setting up the programme management team*

At the implementation stage an implementation team at the CvB will coordinate the preparations for introduction. It will draw up a detailed action plan for implementation, including planning and funding based on this feasibility study. The programme management team will ensure that the appropriate organizations involved in the screening programme and follow-up care start working on their share of the preparatory work in good time. A Bowel Cancer Screening Programme Implementation Advisory Committee<sup>20</sup> and working groups under it will also be set up. The Committee will advise the CvB on relevant aspects of implementation and quality standards. Representatives of the organizations involved will sit on the Committee, which will launch the following working groups:

- Organization, Implementation and Reference Functions Working Group;
- Funding Working Group;
- Quality Working Group;
- Capacity, Training and Improvement of Expertise Working Group;
- Communication and Information Working Group;
- Monitoring and Information Management Working Group;
- Research and Innovation Working Group.

The working groups will start work once their remits have been approved by the Advisory Committee. The CvB will coordinate their work and check that they are working in a coordinated fashion.

#### 8.3.2 *Setting up the organization and implementation*

Chapter 4 sets out the proposed organizational structure. Introducing the programme will entail specific work in a number of areas, including:

- drawing up a basic document on duties, responsibilities and powers;
- embedding reference functions in the organization and taking out contracts by the screening organizations;
- drawing up quality standards to be included in the financial frameworks and the Population Screening Act licence<sup>21</sup>;
- linking colonoscopy and pathology quality frameworks to the screening organizations' quality assurance role;
- drawing up a Population Screening Act licence application to be used by the screening organizations.

The working group will draft and implement an Implementation Organization Action Plan for the organization of the screening organizations' work.

<sup>20</sup> The Advisory Committee uses the Bowel Cancer Programme Committee model as referred to in Chapter 4.

<sup>21</sup> E.g. including quality standards for the iFOBT in contracts between laboratories and screening organizations, quality standards for screening organizations linked to the subsidy scheme, Population Screening Act licence, etc.

### 8.3.3 *Setting up programme funding*

Setting up the funding of the programme will entail the following activities at this stage:

- Developing the scale of charges for the screening organization, both for the selection, invitation and referral work and for the implementation of the reference function.
- Setting up a macro framework for the funding of the programme.
- Amending the Public Health (Subsidies) Regulation.
- Contracting out laboratory diagnosis for the iFOBT.
- Advising the Ministry of Health, Welfare and Sport and Zorgverzekeraars Nederland (the umbrella organization of health insurers) on the hospital and general practice budget frameworks for the introduction of the screening programme.

Work on contracting out laboratory diagnosis will need to begin immediately the decision is taken. The tender procedure, delivery and organization of laboratory diagnosis for the iFOBT will take two years. These and other activities will be developed in consultation with the Funding Working Group.

### 8.3.4 *Setting up communication and information*

The Communication Working Group will develop the existing report *Communication on the Bowel Cancer Screening Programme* (see the CD-ROM enclosed with this report, in Dutch) into a specific plan of activities. It will carry out the following activities at the preparatory stage:

- a study of the public need for information;
- developing the information material to be used in the screening programme: both stage-specific information (e.g. a leaflet and letter of invitation and a leaflet on abnormal results) and general communication tools (e.g. website, organization of telephone lines and publicity campaign);
- using communication tools such as newsletters, meetings and websites to inform the professionals and stakeholders of the preparations for the introduction of the screening programme and the agreements reached on its implementation;
- ensuring that the communication to the public and professionals is embedded in the organization.

### 8.3.5 *Setting up quality of screening and follow-up care, including quality assurance*

Section 6.1 sets out in detail what quality assurance policy needs to be set up for the introduction of a bowel cancer screening programme and follow-up diagnosis and treatment. This entails developing quality standards, protocols and guidelines for such things as laboratory diagnosis, colonoscopy centres and communication in the event of abnormal results. A Bowel Cancer Screening Programme Guideline (script) will also be drawn up setting out the implementation process along with the duties and responsibilities involved, with reference to guidelines and quality tools. The Quality Working Group will play an important role in drawing up the quality standards, protocols and the guideline (script). The CvB and the Advisory Committee will play a stimulating and facilitating role where necessary in the drafting of a multidisciplinary guideline.

A number of activities will need to begin immediately once the decision on introduction has been taken:

- To develop the quality standards and protocols for laboratory diagnosis: these will provide the basis for the tendering criteria;
- To develop the quality standards for colonoscopy centres;
- Pathology recording by pathology laboratories using input protocols;
- The polypectomy and surveillance guideline: the existing guideline is out of date and will need to be updated, based on the new European guideline, before the start of the screening programme.

These activities are expected to require a considerable time to develop or implement.<sup>22</sup> Most tools will need to be in place before the screening programme begins. Development of a multidisciplinary guideline on colon carcinoma is recommended. As there are already monodisciplinary guidelines, this could alternatively be developed and implemented during the phased introduction.

### 8.3.6 *Setting up training and improvement of expertise*

#### *Training*

Care providers involved in the screening programme and follow-up care will need to comply with attainment targets and professional registration/re-registration. If other professional groups that require additional training to be qualified (e.g. endoscopy nurses, physician assistants and possibly internists) are used, the training requirements must be clearly defined, and a national appraisal and registration system will need to be available, linking up with existing systems if possible. An action plan setting out how training, appraisal and registration can be organized should be drawn up as soon as possible after the decision is taken, so as to start actually training practitioners during the second year of the preparatory period if possible and thus have additional capacity at an early stage in the phased implementation.

#### *Improvement of expertise*

Once the screening programme is introduced it will be necessary to improve expertise. Care providers will need to be given additional training on the national agreements and quality standards to ensure that the programme is implemented uniformly nationwide and is of high quality. An action plan for the improvement of expertise will be drawn up in the first year of preparatory work. Activities in this plan (e-learning, instruction seminars, skills training courses et cetera) will be carried out in the second year of the preparatory period and the first year of the phased implementation.

### 8.3.7 *Setting up monitoring, evaluation and information management*

A monitoring and evaluation system will need to be set up in good time to monitor both the quality of programme implementation and capacity and waiting times during the phased implementation. A good indicator set will need to be developed, backed up by an ICT infrastructure ensuring that data for monitoring, quality control and evaluation are available for the implementation of the first age group.

At the preparatory stage the following activities, among others, will need to be carried out to ensure that monitoring and information management are in order:

- Drawing up indicators and a data set to provide information on the development of capacity and waiting times, so as to support ongoing decisions on the phased introduction.
- Developing an indicator set, with separate indicators for quality assurance and for the national monitoring system and national evaluation.
- Developing the data sets into a technical data set, which should be incorporated in the source systems.
- Setting up/linking up with existing source systems that record data.
- Drawing up a statement of requirements for the ColonIS tender procedure.
- Building and trialling ColonIS.
- Creating links between ColonIS and source systems.

An informed-choice measuring tool will need to be developed to monitor this aspect.

The short-cycle capacity/waiting time and quality monitoring system will need to be implemented before the start of the screening programme; without it it will be impossible to check whether implementation is progressing satisfactorily and

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<sup>22</sup> Work on updating the polypectomy and surveillance guideline could begin before the decision is taken, as it is in need of updating anyway.

therefore to make adjustments in good time. It is recommended that the further development of indicators, the formulation of the technical data set and the preparatory work on the European tender procedure for ColonIS (including the statement of requirements) should begin as soon as possible. We estimate that the work required to put effective monitoring systems for both quality and capacity in place will take at least two years.

### *8.3.8 Setting up implementation and capacity monitoring*

The introduction of the bowel cancer screening programme will cause substantial temporary shortages of capacity nationwide, especially in gastroenterohepatology and gastroenterological surgery. The professional groups have proposed measures to overcome the projected shortages, such as reallocation of roles, efficiency measures, increasing the intake to training programmes and agreements on the budgetary framework for indicated care. Proposals have also been put forward to overcome any regional shortages of capacity that might occur, including setting up a national planning and appointments facility. Given the uncertainties in the capacity projections it will be important to monitor the capacity effects and waiting times closely with a short-cycle monitoring system. If problematic shortages occur a decision could be taken to employ one of the alternative scenarios proposed.

A number of activities will need to start as soon as possible:

- Drawing up indicators for the short-cycle capacity monitoring system (see section 8.3.7).
- Setting up the information system for monitoring and the appointments facility (see section 8.3.7).
- Organizing the measures proposed by the professional groups, such as:
  - o training and reallocating duties to endoscopists and physician assistants (see section 8.3.6);
  - o implementing colonoscopy efficiency measures or technical and IT innovations in pathology operations.

It will be up to the professional organizations to implement these measures. The CvB can provide support in the form of a national consultation system.

- Reaching agreement between the health insurers, the Ministry and the professional groups concerned on the consequences for budgetary frameworks and the purchase of care of an increase in indicated care due to the introduction of the screening programme.

### *8.3.9 Setting up knowledge and innovation*

The proposed infrastructure for the programme will be designed to respond flexibly to future innovations. The CvB recommends giving priority to the national introduction of the screening programme in the initial years and only then introducing possible innovations. A number of preconditions for future innovation will need to be met, however, and it is recommended that:

- Money should be set aside in the budget for the preparatory work on the programme for investigating any problems with implementation.
- The CvB should be used to build up international contacts with coordinating bodies in other European countries where bowel cancer screening programmes are being introduced or implemented.
- Research into innovations in bowel cancer screening programmes should be made a priority in the programme of the Netherlands Organisation for Health Research and Development from 2013.
- Developments in relevant complementary research should be monitored so as to create synergy between the screening programme's information system and the information system for complementary research where this is worthwhile.
- A Knowledge and Innovation Working Group should be set up at the preparatory stage to monitor knowledge development and innovation and advise the Bowel Cancer Programme Committee and the CvB. The CvB could inform the Ministry of Health, Welfare and Sport of promising innovations.



### 8.3.10 Risks at the preparatory stage

Introducing a nationwide bowel cancer screening programme is a major project, with a target group of over 4 million people who will be invited to take part every two years. Many professionals and organizations will be involved in implementing the programme and providing follow-up diagnosis and care.

The following risks to the introduction of the programme and the start of implementation could occur at the preparatory stage:

- *Delays in completion and insufficient commitment*  
A large number of organizations will be involved in the preparatory work, and the cooperation of all of them is essential if everything needed for implementation to start is to be ready in time. Lack of commitment on the part of any of them (even if only temporarily) will directly affect the timely completion of activities at the preparatory stage, which could directly affect the length of that stage. Conversely, delays in decision-making will affect their commitment. A facilitating programme structure will encourage cooperation between the organizations involved.
- *Capacity measures do not provide the additional capacity expected, or provide it later than expected.*  
The professional groups have indicated their willingness to take measures to increase capacity in the care system in the coming years. Measures such as using endoscopists/endoscopy nurses or temporarily expanding surgical capacity will depend on a host of factors, and assumptions have been made in the capacity projections that may not correspond to the actual situation. The feasibility of the various measures to increase capacity cannot therefore be predicted with certainty. This risk will be monitored to permit adjustment to the phased implementation if necessary.
- *Inadequate purchase (or temporary purchase) of care*  
The introduction of the screening programme will result in an increase in care procedures (consultations, colonoscopies, surgical interventions, pathology, day treatment et cetera), which will create additional costs that are not yet included in the budgetary frameworks (e.g. for general practice and hospital care). Several of the professional groups (including the National Association of General Practitioners and the Netherlands Surgical Association) said that support for the introduction of the screening programme will be contingent upon revising the budgetary frameworks in line with this cost increase. The purchase of care by the health insurers will also need to be adjusted in line with the increase in care caused by the programme.
- *Initiatives on the part of care organizations and public demand*  
As a result of increasing awareness of the screening programme, people who have not yet been invited may exert pressure to be included in the programme sooner. They may also use different routes to access iFOB testing or colonoscopy. Then again, suppliers of tests might deliberately play on the market of 'the willing public', as is already occasionally happening. This would have direct effects not only on colonoscopy capacity but also on the efficiency, quality and reliability of the screening programme. Opportunistic screening could be curbed by clear communication on how and why the programme is being phased in and enforcement of the Population Screening Act.
- *Public resistance to the introduction of the screening programme*  
Conversely, it is impossible to foresee whether events will take place and/or interest groups spring up that have an effect on support for the programme.
- *Capacity and quality monitoring system not in place at the start of the programme*  
The ICT information system must be delivered and data supplied to it in time for proper monitoring and quality control of the programme to take place. This too will be dependent on various factors, such as standardized language usage in the data recorded, the cooperation of suppliers of existing care ICT systems and a strict registration system for gastroenterohepatologists, pathologists, surgeons and screening organizations. These activities should begin as soon as the decision to introduce the programme is taken, so that ICT suppliers know what is expected of them in good time.

- *Insufficient funding*  
A large number of things need to be in place before introduction can begin. If insufficient resources are available to carry out the preparatory work and create the products, there is a risk that the programme cannot start, or quality will be unsatisfactory when it is introduced.
- *European tenders*  
A tender procedure provides opportunities but it takes a long time to complete. It helps to ensure that funds are spent efficiently: proper preparation often pays back at a later stage. A number of things need to be put out to tender, for example the purchase of screening kits and laboratory diagnosis for iFOB testing/analysis and ColonIS. A tender can give rise to unforeseen procedures (often lawsuits) that cause delays.

Both the Health Council's Population Screening Act Committee and the CvB will advise the Minister on the progress of the preparatory stage and the readiness of the implementing organization. Risks that are not properly covered at this stage of the preparations could result in introduction of the programme being postponed.

## 8.4 Phased introduction

### 8.4.1 Important considerations regarding phased introduction

The programme needs to be phased in so as to build up capacity and avoid waiting lists. This will provide an opportunity to deal with teething problems in the implementation of the bowel cancer screening programme. Under the reference scenario this stage will take six years.

Considerations during the phased introduction:

- *Communication*  
Awareness will need to be raised that the screening programme has started, and it will be important to pick up any signals of a negative image developing as soon as possible. The communication will need to pay ample attention to the way in which the programme is being phased in.
- *Implementation by the screening organizations*  
The screening organizations will need to grow in step with the increasing numbers during the phased implementation. This must be anticipated in plenty of time for the expansion, so that sufficient capacity is available. Production processes such as packing screening kits and sending out mailshots will need to be carried out as efficiently as possible.
- *Capacity*  
The capacity/waiting times monitoring system will be used to survey the capacity available and required nationally and in each region. It will be used for ongoing decision-making on the national implementation of the next age group. This could result in additional stimulus measures in regions where capacity is lagging behind.
- *Quality assurance*  
The general organization of quality assurance will need to be developed during the initial years of implementation.

### 8.4.2 Risks during phased introduction

The following risks could occur once the screening programme starts:

- *Increase in diagnosis and treatment vis-à-vis budgetary frameworks*  
Budgetary frameworks, e.g. for hospital and general practice care, place maximum limits on total annual costs. If the increase in care – e.g. more GP consultations or surgical interventions – is to be covered within the framework this will effectively result in reducing the budget, as the same budget will have to cover a larger number of declarable activities. It is important to reach agreement on the budgetary framework when the screening programme is introduced, so as to maintain support for its introduction on the part of the care providers. It will be important to monitor developments in costs, not only to

- enable the cost-effectiveness of the programme to be assessed but also because of the care agreements between the Ministry and the care providers.
- *Insufficient diagnosis and treatment capacity: waiting lists develop.*  
Attendance at the screening programme may be higher than expected, or the proposed measures to provide the capacity required for the phased introduction may not have the desired effect, with the result that waiting lists for diagnosis and treatment develop. Available and required capacity and waiting times will be actively monitored, so as to enable adjustments to be made in good time. On this basis the Minister can decide to adopt an alternative scenario for phased introduction or take additional stimulus measures in regions where capacity is lagging behind.
  - *Public demand*  
The introduction of the screening programme and the communication on the subject could create additional public demand, for example from people in the target group who are to be invited at a later stage of the phased implementation. This could have effects not only on colonoscopy capacity but also on the efficiency, quality and reliability of the programme. Opportunistic screening could be curbed by clear communication on how and why the programme is being phased in and enforcement of the Population Screening Act.
  - *Quality not yet uniform at the desired level*  
There will always be teething problems in the early stages of a major programme. Also, not all care providers will comply with the agreed quality assurance policy, or they will still need to develop expertise in certain areas. The quality of the screening programme and follow-up care will need to be stepped up gradually during the initial years. During that period additional resources will be needed for the improvement of expertise, audits and inspections, along with discussion of best practice to improve both the quality of individual care providers and agreements on quality targets.
  - *Colonoscopy deaths*  
One of the most serious incidents – which cannot be ruled out – is the death of a person with no symptoms<sup>23</sup> during colonoscopy. This risk cannot be ruled out even at the phased introduction stage, and the result could be media hype, possibly with a reduction in participation in the programme and/or a knock-on effect on screening programmes in general. An incidents procedure, including incident communication, will need to be developed before the programme starts.
  - *Negative image in the media*  
A negative image of the screening programme could develop, and this could spread very rapidly in today's social media. It will be advisable to monitor discussion of the programme in the social media and anticipate it where possible with an appropriate communication policy.
  - *Risks at the preparatory stage*  
The risks mentioned at the preparatory stage could also occur at this stage, e.g. insufficient commitment, inadequate procurement, initiatives on the part of care organizations/the public, or insufficient funding.

## 8.5 Timetable

Activities that are prerequisites for the bowel cancer screening programme to get off to a good start are set out in section 8.3. Figure 8 shows the timetable for the various stages in the introduction of the programme.

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<sup>23</sup> This amounts to approximately one death per four years, based on 100,000 screening colonoscopies per year.

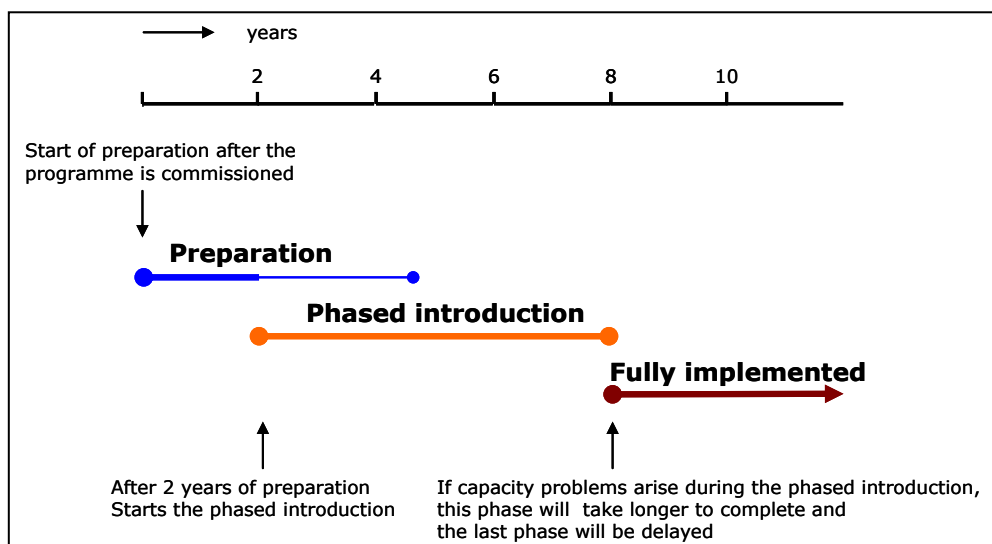


Figure 8: Timetable for the various stages in the introduction of a bowel cancer screening programme

It will take at least two years of preparatory work before the phased introduction can begin. This period cannot be reduced by deploying more staff, as critical activities here are the European tender and the setting-up of laboratory diagnostic facilities for iFOB testing/analysis, ColonIS to supply information, and good monitoring. Activities such as developing quality tools and improving expertise will also need to take place in sequence, and the proposed measures to provide sufficient diagnostic and treatment capacity during the phased introduction will need to be instigated as soon as possible once the decision has been taken. Such preparatory work as can take place after the start of the phased introduction will not be carried out until then, so as to enable introduction to begin as soon as possible (see also Figure 8).

Section 8.4 sets out the activities during the phased introduction stage, when possible capacity problems will need to be monitored closely. Shortages of capacity (resulting in growing waiting times) could be overcome by switching to an alternative implementation scenario. The duration of the phased introduction will depend on this, but it will take a minimum of six years. Any teething problems in the implementation of the screening programme will also need to be dealt with at this stage.

The screening programme will have been fully introduced once the phased introduction is complete. Possible innovations to improve the programme will become apparent at this stage (see also section 6.6).

Below is a list of activities that must be started once the decision has been taken to introduce the bowel cancer screening programme.<sup>24</sup> A number of introductory/exploratory activities could begin before the decision is taken, in view of the critical completion time for these activities within the tight two-year schedule for the preparatory work. These activities are as follows:

- Programme management
  - Drawing up an implementation plan and budget based on this feasibility study (first half of 2011).
  - Continuation of the advisory work by the ad hoc advisory committee and working groups.
- Funding
  - Drawing up a budget for the screening organization's running costs, for both the preparatory stage and the phased implementation (first half of 2011).

<sup>24</sup> For a full overview of all the preparatory activities see Appendix 6.

- Preparing the tender procedure for laboratory diagnosis for iFOB testing/analysis.
- Communication
  - Organizing communication on the decision (Ministry of Health, Welfare and Sport).
- Quality
  - Drawing up quality standards for laboratory diagnosis (needed for the tender procedure).
  - Drawing up quality standards for colonoscopy centres and endoscopists.
  - Promoting the revision of the polypectomy and surveillance guideline.
- Training and improving expertise
  - Plan for the training, appraisal and registration of endoscopy nurses (first half of 2011).
  - Action plan for the improvement of expertise.
- Monitoring and ICT infrastructure
  - Further development of a minimum data set into a technical minimum data set (first half of 2011).
  - Drawing up a statement of requirements for ColonIS.
- Capacity
  - Drawing up indicators and a data set for the capacity monitoring system (first half of 2011).
- Knowledge and innovation
  - Learning from our neighbours: working visits to a country or countries where screening has been introduced nationwide (first half of 2011) to learn from experience gained there.

## 9 Funding

This chapter discusses the estimated cost of the implementation and management of the bowel cancer screening programme and the estimated cost to the care system of introducing such a programme.

Once the Minister decides to introduce the bowel cancer screening programme the preparatory work can begin. During the preparatory period and the initial years of the phased introduction there will be implementation costs, so an implementation budget will be needed for this period (see section 9.1). The screening organizations will start to incur running costs, and the CvB management costs, when the first age group is invited. After a minimum of six years all the age groups in the target group will have been invited and the running costs will settle down to a regular level. These costs are outlined in section 9.2. Section 9.3 briefly discusses the costs that will be incurred in the care system once phased introduction begins. Erasmus Medical Center Rotterdam has carried out an in-depth study to supplement the more general analyses it has conducted for the Health Council: the report (in Dutch) can be found on the CD-ROM enclosed with this report.

### 9.1 Cost of implementation

Before phased implementation can begin, activities such as those set out in section 8.3 will need to be planned and implemented, which will require a preparatory period of at least two years. In addition to sorting out the proper organization, implementation and funding of the programme within conditions laid down by the Ministry of Health, Welfare and Sport, specific products will have to be made. These include information products, both for the screening programme itself and more general products (leaflets, websites), and quality assurance products (e.g. guidelines and products for the improvement of expertise). Investment will also be needed in the setting-up of a satisfactory information system for the start of the phased implementation and making it operational, so that implementation can be monitored and evaluated and appropriate adjustments can be made during the phased introduction. The length of the preparatory period is due partly to the need to organize the screening programme carefully and partly to processes that by nature take a long time but are necessary to the launch of a screening programme (e.g. setting up monitoring and tender procedures). The lion's share of the preparatory work will take place in the two-year preparatory period. Table 1 shows a cost estimate.

During the initial years of the phased introduction other preparatory activities associated with this will be carried out, such as additional public information and short-cycle monitoring of attendance, available capacity and waiting times for diagnosis and treatment. These activities do not necessarily have to take place before the first invitations are sent out to the target group, but they are a prerequisite for the proper and full introduction of the screening programme. The inevitable teething problems will also require special attention and efforts during the initial years of the phased introduction. Table 1 shows an estimate of the costs involved here.

The cost of implementation in the preparatory period and the initial years of the phased introduction is estimated at a total of € 11.3 million, based on the activities shown in the Table Implementation of the screening programme

(Appendix 6). A more precise estimate of the screening organizations' costs during the implementation stage, along with the rationale, will need to be made based on further research (see also section 9.2).

*Table 1: Cost of implementation (see also Appendix 6)*

<b>Cost of implementation</b> (* € 1,000)	<b>Preparatory period</b>		<b>Initial years of phased introduction</b>		
	1	2	3	4	5
National programme management	400	400	200	75	38
Setting up organization and implementation	725	675	125	80	50
Setting up programme funding	125	104	0	0	0
Communication and information	528	753	258	55	20
Quality of screening and follow-up care	312	322	196	111	50
Training and improving expertise	322	322	211	10	0
Monitoring, evaluation and information management	577	2,057	376	375	0
Knowledge and innovation	50	125	125	75	35
10% unforeseen	304	476	149	78	19
<b>Total per year</b>	<b>3,341</b>	<b>5,231</b>	<b>1,639</b>	<b>858</b>	<b>212</b>
<b>Total implementation budget</b>	<b>11,281</b>				

## 9.2 Cost of implementing and managing the screening programme

### *Criteria*

The following criteria were applied when calculating the financial forecasts for the implementation of the bowel cancer screening programme:

1. The cost of implementing the programme was based on the rate given in the Health Council's advisory report (€ 17.48, price level as at 2008).
2. The costs are non-indexed in all the forecasts.
3. The projected cost of implementation is based on phased introduction in line with the reference scenario as outlined in chapter 7.
4. 60% of invitees actually attend the screening (based on participation in the pilot projects).
5. The purchase of the iFOBT and analysis will be put out to tender.
6. The costs of notifying participants of abnormal iFOBT results by general practitioners, colonoscopy, treatment and surveillance are covered under the Health Care Insurance Act.

### *Development of costs*

The phased introduction will begin with the invitation of two age groups (65 and 75-year-olds), adding age groups gradually in subsequent years until the whole target group is included. Because of this phasing-in, the cost of implementation will be relatively small in the first year, going up as the size of the invited target group increases. Once the programme is fully implemented the cost of implementation will stabilize, being determined solely by the size of the target group, which will be influenced by demographic factors, as is the case with all the screening programmes.

### *Rationale behind the costs of the screening programme*

During the screening programme the following activities will generate costs, which will be incurred to a large extent by the screening organizations.

### Selection and invitation

Most of the cost of selection relates to screening organization staffing<sup>25</sup> and the cost of the underlying system (the link to the municipal personal records database). In addition to staff costs, there will be costs of supplies for the invitations (printing, envelopes and postage for envelopes and reply envelopes). Packing the letter and the screening kit in a single envelope will require an efficient system in the screening organizations.

### Testing

In order to carry out the iFOBT, screening kits will need to be purchased and sent to the target group. Some laboratories will need to purchase analytical equipment to analyse the stool samples. The laboratories involved will also incur staffing costs for the storage and analysis of the material and quality assurance. The purchase of the iFOBT (material, storage, analysis, et cetera) will be put out to tender.

### Notification, referral and reference functions

In addition to staff costs, there will be costs of supplies for notifying the participants (printing, envelopes and postage). In the case of abnormal results there will also be the cost of notifying the general practitioner and referral to the follow-up procedure, which will be done by the screening organizations. They will also perform reference functions which will generate costs. Clinical chemists, regional gastroenterohepatology coordinators and regional pathology coordinators will provide and oversee quality assurance.

### Cost forecast

Figure 9 gives a cost forecast based on the criteria for the activities mentioned above (see also the report in Dutch by Erasmus Medical Center Rotterdam on the CD-ROM enclosed with this report). As the figure shows, the cost of implementing the screening programme will stabilize from 2018 at approximately € 38 million; it will then drop slightly as a result of a slight decrease in the size of the target group.

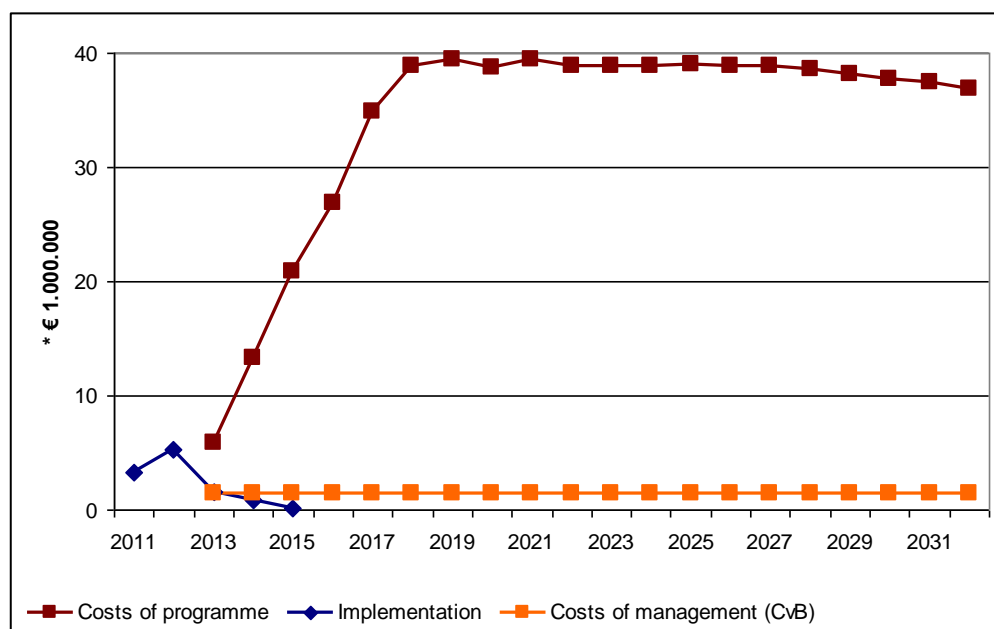


Figure 9: Cost forecast for the bowel cancer screening programme

### Funding method

As set out in chapter 8, the Funding Working Group will work out the details of the various rates and the funding system for the primary process of the bowel cancer

<sup>25</sup> Including overheads such as costs of accommodation, ICT, etc.



screening programme. The actual cost of the preparatory work will also need to be ascertained. As the screening organizations will be incurring preparatory costs in the initial years, and the target group to be invited during the phased introduction will still be small, these can best be funded on a budget basis. An auditor's report will be a prerequisite for subsequently ascertaining the actual costs and funding on that basis. After a few years, when there is a better idea of the cost and most of the target group has been invited, the programme can switch to the funding system used for the other two current cancer screening programmes. This involves a fixed rate per participant (Price) and a costing based on actual numbers (Quantity: hence the term 'PxQ' funding).

#### *Cost of management*

The estimate of the cost of managing the bowel cancer screening programme is based on the current cost to the CvB of managing the breast cancer and cervical cancer screening programmes, which is € 1.5 million per year. This figure includes the costs of national management, administering the subsidy scheme (insofar as applicable), quality assessment and assurance, communication and information including national leaflets, monitoring and evaluation, pooling knowledge and possible innovations relating to the screening programme and implementing changes in it. The cost of management will begin in the first year of phased implementation (see also Figure 9).

### **9.3 Cost to the care system**

The estimated costs set out below are based on the cost-effectiveness analysis from a social perspective conducted for the Health Council's *Bowel Cancer Screening Programme* advisory report. The Department of Public Health of Erasmus Medical Center Rotterdam carried out the analysis again, with the following differences from the Health Council report:

- The start of the phased introduction was set for 2013 instead of 2010.
- The cost of notifying participants of abnormal iFOBT results by general practitioners was included.
- Endoscopic removal of a proportion of tumours was taken into account.
- Surgical removal of a proportion of adenomas was also taken into account.
- As regards surveillance, it was assumed that this would not take place if only one or two small adenomas were detected.

The criteria applied also included the following:<sup>26</sup>

- The costs are non-indexed in all the forecasts (Health Council advisory report, price level as at 2008).
- The projected cost of implementation is based on phased introduction in line with the reference scenario as outlined in chapter 7.
- 60% of invitees actually attend the screening and 85% of participants with a positive iFOBT undergo colonoscopy (in line with the findings from the pilots).
- The cost of colonoscopy is based on the findings from the pilots.

#### *Current cost to the care system of bowel cancer*

Based on this analysis, the forecast is that, with no bowel cancer screening programme, € 270 million would be spent on detecting and treating bowel cancer in 2013 (see Figure 10). Based on extrapolation, the expectation is that population ageing will cause the cost to rise to € 365 million by 2030. This extrapolation does not include some developments expected in the cost of treating bowel cancer, as these trends are not yet quantifiable: they include up-and-coming methods of treating bowel cancer, especially the severe stages (III and IV), which are much more expensive than those used hitherto.<sup>(54)</sup> There is also likely to be

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<sup>26</sup> A more detailed set of criteria can be found in the report (in Dutch) by Erasmus Medical Center Rotterdam on the CD-ROM enclosed with this report.

an increase in opportunistic screening, which will generate additional costs that cannot be quantified at present. Opportunistic screening is expected to increase if the screening programme is not introduced.

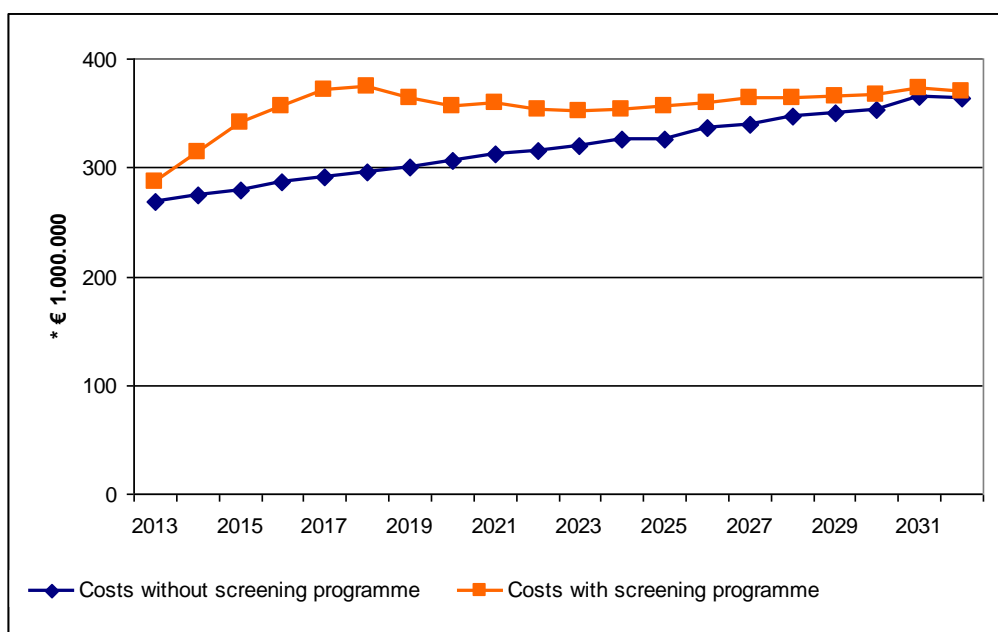


Figure 10: Forecast of the cost to the care system of bowel cancer (source: report by Erasmus Medical Center Rotterdam)

#### Costs due to introducing the screening programme

Introducing a new screening programme will not only generate costs for the implementation of the programme itself; general practitioners will incur costs for notifying participants, colonoscopy centres for the intake and diagnosis of participants with abnormal iFOBT results, pathology laboratories for procedures to assess histological samples, hospitals for treating bowel cancer and surveillance.

Figure 10 shows the forecast costs to the care system due to the introduction of the bowel cancer screening programme. As the figure shows, the cost to the care system will peak in 2017, partly as a result of the fact that at the start of the programme a lot of people will be being screened for the first time and a relatively large number of people with abnormalities (adenomas and bowel cancer) will be found at that point, as people can be walking around for many years with abnormalities that are detectable by screening but no symptoms as yet. The cost of follow-up diagnosis and any treatment will be brought forward in the case of these people. Furthermore, the group being screened for the first time will include a relatively large proportion of people with a relatively late stage of bowel cancer, which is expensive to treat. The cost of follow-up diagnosis and treatment will go down after a few years, when a higher proportion of people will be invited for a second or subsequent screening, resulting in fewer abnormalities being detected. The bowel cancer screening programme will also ensure that bowel cancer is detected at an earlier stage. Lastly, the removal of adenomas will prevent bowel cancer developing.

The ultimate effect of a screening programme is not financial, however, but a reduction in the number of deaths and a lesser burden of disease due to bowel cancer. As outlined in Box 2 in chapter 1, the bowel cancer screening programme should eventually prevent 2,400 deaths per year.



## 10 Key Points and Recommendations

### 10.1 Introduction

Bowel cancer is one of the most common causes of death in the Netherlands: in 2008 it killed some 4,800 patients and was diagnosed in about 12,000 people. Owing to the ageing population the annual number of cases is expected to rise to 14,000 in 2015. The five-year survival rate for bowel cancer is approximately 59% at present, and it is highly dependent on the stage at which the tumour is detected. Bowel cancer has a protracted preliminary stage and therefore lends itself to screening: the chances of survival are better if it is detected at an early stage (94% at stage I).

In 2009 the Health Council produced a report commissioned by the Minister of Health, Welfare and Sport on the desirability and feasibility of a bowel cancer screening programme in the Netherlands. The Council indicated that there is sufficient evidence to implement such a programme on a regular basis using the iFOBT. The five-year survival rate following screening is 85%, and the expectation is that eventually 2,400 fewer people a year would die of bowel cancer in the Netherlands. The Council recommends phasing in a bowel cancer screening programme, assuming that the required care capacity can be built up over the next few years.

In response to the report, and pending the final decision on the introduction of a nationwide programme, the Minister of Health, Welfare and Sport has asked the Centre for Population Screening to conduct a feasibility study into a bowel cancer screening programme.

The purpose of the study is to ascertain the prerequisites for a bowel cancer screening programme and how it can be introduced successfully.

### 10.2 Methodology

The feasibility study began with a stakeholder analysis and discussions with thirty organizations. A Bowel Cancer Screening Programme Organization Advisory Committee, an Information Management Working Group and a Capacity and Quality Working Group were then set up and in-depth discussions held. In-depth studies were also carried out into the subjects of capacity and phased introduction, indicators and information management, management and organization of quality: these can be found in Dutch on the CD enclosed with this report.

### 10.3 Exploratory study

A large, broad basis of support for the introduction of a bowel cancer screening programme was found among the professional organizations, patients' organizations, screening organizations, health insurers and other stakeholders. The test proposed by the Health Council, the iFOBT, also commands broad support. The European Parliament is urging the Member States to introduce nationwide screening for bowel cancer. Various European Member States, e.g. the UK, France, Italy, Finland and the Czech Republic, already have bowel cancer screening programmes (regional or otherwise). Other countries such as Germany, Austria and Poland offer private individuals the option of being screened under their health

insurance, and a number of Member States such as Ireland and Denmark have recently decided to start organizing screening programmes. Support among the Dutch public has not been polled explicitly, although it is known that attendance in previous pilots on screening was around 60%. There would seem to be little public awareness as yet of bowel cancer and the opportunities afforded by screening. The Dutch Cancer Society, the Maag Lever Darm Stichting (Digestive Diseases Foundation) and patients' organizations are working hard to raise awareness.

The main concern that emerges from the Health Council report and the exploratory study is the capacity available and required in the areas of gastroenterology and hepatology, pathology, surgery and anaesthesia. The estimates of the various people and organizations concerned differ on this point, and an in-depth study was carried out as part of the feasibility study.

#### 10.4 Organization of the screening programme

The primary process involves screening men and women aged 55 to 75 for bowel cancer and its preliminary stages, the activities being as shown in the figure below.

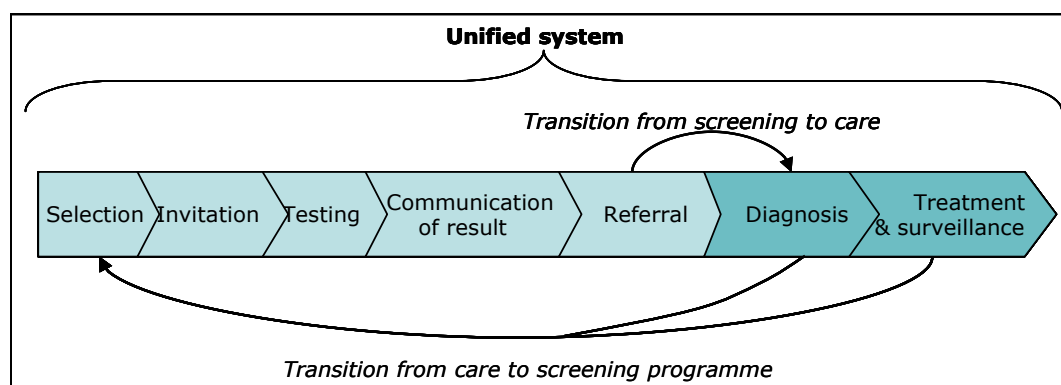


Figure 11: Diagram of the primary process of the bowel cancer screening programme, including follow-up care

Based on current knowledge and the discussions held, the following criteria were formulated for the design of the primary process:

- The Health Council's report is endorsed.
- The implementation of the bowel cancer screening programme should be based as far as possible on the organization of existing cancer screening programmes.
- The screening will be carried out using the immunochemical faecal occult blood test (iFOBT).
- The laboratory facilities for iFOBT screening should be centralized so as to maximize quality and efficiency.
- In the event of a positive iFOBT, colonoscopy should be carried out for a conclusive diagnosis.

#### Allocation of responsibilities

Broadly speaking, the following allocation of responsibilities is proposed for the bowel cancer screening programme:

- Award of contracts, funding and regulation under the Public Health (Subsidies) Regulation and licensing under the Population Screening Act: Ministry of Health, Welfare and Sport.
- Central management of the screening programme: Centre for Population Screening (RIVM).
- Advice from representatives of the stakeholders: a new Bowel Cancer Programme Committee.

- Representing the interests of the public and patients: patient/consumer organizations.
- Regional implementation and coordination: the five existing screening organizations for cancer screening programmes.
- In the event of a positive iFOBT the participant should be informed by his or her general practitioner.
- Analysis of the iFOBTs should be carried out by three to five laboratories.
- Screening organizations should refer patients for colonoscopy to centres that meet national quality standards.
- Quality assurance of iFOBTs, colonoscopy and pathology should be provided by setting up a standard position in screening organizations.

#### Communication

Adequate, objective, relevant information in line with the information requirements for the other cancer screening programmes is essential to inform the target group – men and women aged 55 to 75 – about the programme, so that they can make informed decisions and be aware of the relevant steps in the programme.

Communication with participants in the programme involves invitations, iFOBT results, referral where appropriate, results of other diagnostic procedures and any further referral. The keywords here are meticulousness, avoidance of unnecessary anxiety and promptness.

Broad-based communication on bowel cancer and the opportunities afforded by screening should be organized in collaboration with the Dutch Cancer Society, the Maag Lever Darm Stichting and patients' organizations, the aim being to raise public awareness of the existence and purpose of the screening programme and acceptance.

Professionals should also be informed about the existence and purpose of the programme and how it is to be introduced, so that they can perform their duties under the programme and provide good follow-up diagnosis and care.

#### Quality assurance

A screening programme offered to people with no symptoms requires a high quality of implementation, and this applies to every activity, from invitation to any treatment provided, so as to achieve the desired effect of the programme (the health benefit). Participants are entitled to expect uniform quality nationwide. To achieve and assure that high quality, professional guidelines and protocols are needed to define professional standards and appropriate care. These are not yet fully developed. The Centre for Population Screening has identified what professional guidelines already exist and where a national quality assurance policy still needs to be formulated. It recommends developing an integrated multidisciplinary guideline/care standard for the bowel cancer screening programme.

Additional compulsory quality requirements may be laid down for the implementation of a screening programme to supplement the guidelines and protocols. They will be linked to rules such as licensing under the Population Screening Act or the Public Health (Subsidies) Regulation. There will be a master plan setting out how the programme and follow-up care should be implemented. This will provide guidance on quality assurance and will need to be developed in detail before the programme can begin.

For some of the participants the screening programme will generate a demand for care in the form of referral for further diagnosis. Thus the introduction of a bowel cancer screening programme will give rise to responsibilities in terms of the availability of follow-up diagnosis and high-quality care. The quality of the programme and the follow-up care will depend on the knowledge, skills and conduct of individual care providers. The expertise of medics and paramedics involved in both the programme and follow-up diagnosis will need to be improved.

### Monitoring, evaluation and information management

The new bowel cancer screening programme will need to be subject to quality control, both to monitor the quality of the primary processes (quality assurance) and to evaluate effectiveness and efficiency nationally. Monitoring and evaluation will contribute to an ongoing process of improving the programme.

A set of indicators for monitoring and evaluating the screening programme system and follow-up care was developed as part of the feasibility study. The Centre for Population Screening recommends using a short-cycle capacity, waiting list and quality monitoring system to enable adjustments to be made to the phased introduction as necessary. The guiding principle is that data should be recorded once only and uniformly at the source; the information management of the primary process should avoid duplication of registry. As regards the information management to support the screening process, monitoring and evaluation, the Centre recommends putting out a request for tender for a new modular information system.

### Innovation

The proposed organization and infrastructure should support the implementation of possible innovations in the programme, following pilots and proper scientific review by the Health Council. These could be short and medium-term innovations relating to such things as improving testing methods, test characteristics and logistics, combining tests and/or other biomarkers and optimizing the detection of familial bowel cancer. Wherever possible the information management of the screening programme should be coordinated with flanking research so that data can be used quickly and efficiently (within the rules laid down in the data protection legislation).

## 10.5 Capacity and waiting lists

The Achilles' heel of the programme will be providing adequate capacity. The introduction of the bowel cancer screening programme will have consequences for the processes that take place in the health service. The number of referrals for colonoscopies will increase and remain higher. Operations and adjuvant therapy as a result of these colonoscopies will increase initially but probably decrease again after a number of years. This increase in the demand for care may cause problems with the available capacity, hence longer waiting lists.

Based on background studies by Erasmus Medical Center Rotterdam and the consulting firm Berenschot, the capacities required have been compared with the expected growth in colonoscopy, pathology and bowel cancer surgery capacity and solutions have been sought to make up the difference.

The introduction of the bowel cancer screening programme will cause substantial temporary shortages of capacity nationwide, especially in gastroenterology, hepatology and gastrointestinal surgery. There is no shortage of gastrointestinal surgeons, however; the limitations lie in the availability of people in the supporting professions. The shortage of capacity in pathology is relatively small.

The professional organizations have come up with measures and agreements that could overcome the shortages, in particular reallocation of roles, efficiency measures, increasing the intake to training programmes and agreements on the budgetary framework for indicated care. The NVMDL (Netherlands Association of Gastroenterologists and Hepatologists), NVVP (Netherlands Pathology Association) and NVVH (Netherlands Surgical Association) expect the measures they propose to overcome problematic shortages of capacity. It is up to the professional organizations to implement these measures. The Centre for Population Screening can provide support in the form of a national consultation system. The Ministry of Health, Welfare and Sport, the health insurers and the professional organizations need to reach agreement on the budgetary framework.

Proposals have also been put forward to overcome any regional shortages of capacity that might occur: a national planning and coordination point is required to achieve this.

Given the uncertainties in the capacity estimates it will be important to monitor the capacity effects closely with a short-cycle capacity and waiting list monitoring system. If problematic shortages occur and waiting lists become longer, the Minister could decide to implement one of the alternative scenarios proposed in the feasibility study so as to reduce demand from the screening programme.

## **10.6 Implementation and funding**

Following a positive decision by the Minister of Health, Welfare and Sport to introduce the screening programme, we can identify three phases, namely organization, phased introduction and full implementation. These are shown in detail in an implementation table, which shows that the minimum time needed to organize the programme is two years. Critical activities here are the request for a European tender and the setting-up of laboratory diagnostic facilities for iFOBT analysis and the information system. The proposed measures to provide sufficient diagnostic and treatment capacity during the phased introduction also need to be instigated as soon as possible once the decision has been taken. Potential risks at the organization stage and during the phased introduction have been identified: for example, the development of waiting lists owing to various factors such as higher attendance, public demand, inadequate effects of measures or agreements on budgetary frameworks. How adjustments can be made is set out in section 10.5.

The Centre for Population Screening recommends that, once a positive decision has been made, the time required to organize the programme and the rate of phased introduction should be communicated so as to avoid misunderstandings.

The cost of introducing and running the screening programme and the cost to the health service have been forecast. The cost of implementing the programme is estimated at approximately € 11.3 million. As a result of the phased introduction, the annual cost of running the programme will rise over five years to € 38 million. The annual management cost is estimated at € 1.5 million. In the initial years of the phased introduction the cost of follow-up care from the screening programme will rise, as the programme will result in bowel cancer being detected sooner and relatively large numbers of people with advanced stages of cancer will be found during that period. The additional cost to the health service will reach a peak in 2017, after which it will decrease. The bowel cancer screening programme will produce a substantial structural health benefit in a cost-effective manner.

## **10.7 Recommendations**

As the feasibility study shows, it is possible to introduce and run a bowel cancer screening programme in the Netherlands. There is broad support for its introduction. Once it is fully implemented, 4.4 million people aged 55 to 75 will be invited to take part in the programme every two years, eventually enabling 2,400 deaths to be avoided annually. The introduction of the programme needs to be organized properly to guarantee the quality of, and capacity for, its implementation of the screening, further diagnosis and care.

The Centre for Population Screening recommends that the bowel cancer screening programme should be organized nationally in line with the duties and responsibilities set out in this report. As regards the implementation of the



programme, the Centre recommends that this needs to be phased in as proposed by the Health Council. This will result in temporary shortages of capacity in gastroenterology and hepatology, gastrointestinal surgery and to a lesser extent pathology. The professional organizations (the NVMDL, NVVP and NVVH), however, expect the measures they propose will overcome any problematic shortages of capacity.

It will be important to monitor the quality of, and capacity for, the programme and follow-up care right from the start. Adjustments will need to be made as required to guarantee quality and/or the required capacity. If necessary the demand for colonoscopy and follow-up treatment could be influenced using the alternative scenarios for phased introduction proposed in this report: this will be the case if there is a risk of long waiting lists for colonoscopy developing following positive iFOBTs or for the treatment of patients. In addition to capacity monitoring, quality needs to be monitored and controlled so as to guarantee good diagnosis and follow-up care and to maximize the health benefit.

The following are essential prerequisites for the introduction of the programme:

- The activities mentioned in this report to organize the introduction of the screening programme must be completed before introduction begins. Once it has been decided to introduce the programme, an organization period of at least two years will be needed to carry out and complete the activities.
- It is up to the professional organizations to organize the measures they propose to overcome shortages of capacity during the phased introduction, to improve expertise and to develop guidelines.
- The introduction of the screening programme will result in additional activities and costs in diagnostic and/or curative care. The health insurers, the Ministry of Health, Welfare and Sport and the professional organizations concerned will need to reach agreement on the consequences for budgetary frameworks and the purchase of care, e.g. hospital care and general practice care.
- The Centre for Population Screening will need to organize good communication about the programme and within it in collaboration with other stakeholders.
- Once the phased introduction begins, capacity and quality monitoring needs to be in place so that adjustments can be made as required and the programme can be evaluated so as to improve its quality where necessary.

The main effect of introducing this bowel cancer screening programme will be a structural decrease in deaths from bowel cancer by 2,400 per year in the long term.

## Acknowledgements

The present report could not have been written without the assistance of various people.

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In addition to those working in the field, other people have made important contributions to the report. Berenschot, Erasmus Medical Center Rotterdam, MedicalPhit, C-zicht and Medlaw contributed to the specialist reports in Dutch on the CD-ROM enclosed with this report. We should like to thank Pepita Groeneveld and Annemarieke Rendering of the Ministry of Health, Welfare and Sport for their faith in awarding us this commission and their involvement. We should like to thank our colleagues at the RIVM for reviewing and commenting on earlier drafts of this report, in particular Loek Stokx, who not only read it critically but also helped with editing. Lastly a special word of thanks goes to Brigitte Kallendorf, who has supported the whole process with secretarial work, and Esther Brouwer, who drew up the process description.

On behalf of the authors  
Harriët van Veldhuizen, Project Leader



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## Glossary

### *Abnormal result*

A result of a test that departs from the norm. In the specific case of the iFOBT this is a test result higher than 75 ng/ml. In the event of an abnormal iFOBT result, the participant is referred for colonoscopy. An abnormal result does not necessarily mean that there is cancer: this can only be ascertained by further diagnosis (colonoscopy).

### *Adenoma*

A benign tumour of the epithelial cells of the intestinal mucosa. Adenomas of the large intestine are often referred to as 'polyps', as many of them manifest as bulges in the intestinal mucosa. This term is not entirely correct, as other abnormalities in the intestinal wall can also present as polyps and not all adenomas are polypoid; they can be 'flat' or 'deep'.

### *Cancer biomarker*

A characteristic at DNA, RNA or protein level that can be measured objectively in cells or body fluids and is used e.g. as an indicator of cancer risk and as a screening test.

### *Carcinoma*

Malignant growth, cancer.

### *Colon*

The longest part of the large intestine, comprising the ascending colon, the transverse colon, the descending colon, and the sigmoid colon. In this report, we use the term bowel for colon.

### *Day treatment*

Hospital admission for a therapeutic intervention and/or diagnostic test and discharge on the same day.

### *False negative*

A negative result produced by the screening test when the disease is actually present. If the test produces a lot of false negative results this means that it has a low sensitivity.

### *False positive*

A positive result produced by the screening test when the disease is absent. If the test produces a lot of false positive results this means that it has low specificity.

### *FOBT (or iFOBT)*

Faeces occult blood test (i stands for immunochemical).

### *Improvement of expertise*

The set of activities designed to maintain and increase the skill level of staff involved professionally in the screening programme and follow-up care.

### *Interval carcinoma*

Cancer detected after a negative or false positive screening test and before the next screening.

### *Invitees*

Men and women selected for the bowel cancer screening programme from the municipal personal records database.



*Large intestine*

Comprises the appendix (caecum) and the colon.

*MISCAN*

MIcrosimulation SScreening ANalysis, a mathematical model for predicting costs and effects of screening strategies.

*Occult blood (loss)*

E.g. in the faeces, only detectable by means of chemical reactions.

*Participants*

Men and women who have sent in a sample.

*Patients*

Men and women who undergo further diagnosis and treatment in the health care system.

*People in the target group*

Men and women eligible for invitation.

*Polyp*

See Adenoma

*Polypectomy*

The removal of polyps.

*Positive test result*

An unfavourable outcome of the screening test, indicating an increased risk of having or contracting the disease.

*Rectum*

The final portion of the large intestine.

*Referred participants*

Men and women who have a positive iFOBT result and are referred for diagnosis.

*Sensitivity*

The frequency with which a test produces a positive result when the disease or risk factor concerned is actually present, or the number of true positive test results divided by the total number of persons with the disease (true positives plus false negatives). A sensitive test produces few false negatives.

*Specificity*

The frequency with which a test produces a negative result when the disease or risk factor concerned is actually absent.

*Stage*

The extent to which a cancer has developed. This generally involves three characteristics: the size of the tumour (T), metastases (secondary tumours) in nearby lymph nodes (N) and remote metastases in other organs (M).

*Stool sample*

The quantity of faeces required for a screening test.

*Surveillance*

Regular colonoscopy check-ups for people in high-risk groups.

*The public*

All men and women of all ages.

## Abbreviations

AMC	Academic Medical Centre Amsterdam
AP	Anatomical pathology
ASP	Application Service Provider
AWB	General Administrative Law Act (Algemene wet bestuursrecht)
BBK	Cancer Screening Programme Policy Framework (Beleidskader Bevolkingsonderzoek naar Kanker)
CBO	Dutch Institute for Healthcare Improvement (Centraal BegeleidingsOrgaan)
CBP	Dutch Data Protection Authority (College bescherming persoonsgegevens)
CBS	Statistics Netherlands (Centraal Bureau voor de Statistiek)
CEA	Cost-effectiveness analysis
COCOS trial	COlonoscopy or COlonography for Screening trial
ColonIS	Colon Information System
CORERO	Bowel carcinoma ROTterdam trial screening programme
CRC	Bowel cancer
CSN	Citizen Service Number
CvB	Centre for Population Screening (Centrum voor Bevolkingsonderzoek) of the RIVM
DeCoDe	Decrease in Bowel cancer Death (one of the pilots)
DRG	Diagnosis Related Group
DSCA	Dutch Surgical Bowel Audit
FAQ	Frequently Asked Questions
FOCUS trial	Faecaal OCcUlt blood Screening trial
GE surgeon	Gastroenterological/gastrointestinal surgeon
gFOBT	guaiac Faecaal Occult Blood Test
GRS	Global Rating Scale
HIS	GP Information System (Huisarts Informatiesysteem)
HKZ	Harmonization of Quality Review in Health Care (Harmonisatie Kwaliteitsbeoordeling Zorgsector)
ICD	International Code of Diseases
ICSN	International Bowel Screening Network
iFOBT	immunological Faecaal Occult Blood Test
IGZ	Health Care Inspectorate (Inspectie voor de Gezondheidszorg)
IKA	Comprehensive Cancer Center Amsterdam (Integraal Kankercentrum Amsterdam)
IKNL	Comprehensive Cancer Center Netherlands (Integraal Kankercentrum Nederland), formerly VIKC
IKO	Comprehensive Cancer Center East (Integraal Kankercentrum Oost)
KWF	Dutch Cancer Society (Koningin Wilhelmina Fonds Kankerbestrijding)
KWZi	Care Institutions (Quality) Act (Kwaliteitswet zorginstellingen)
LHV	National Association of General Practitioners (Landelijke Huisartsen Vereniging)
LIS	Laboratory for Infectious Diseases and Perinatal Screening (Laboratorium voor Infectieziekten en Screening) of the RIVM

LRCB	National Expert and Training Centre for Breast Cancer Screening (Landelijk Referentiecentrum voor Bevolkingsonderzoek)
MDL	Gastroenterology, digestive diseases
MDL-IS	Gastroenterohepatology Information System
Mdw	Market forces, deregulation and legislative quality operation
MLD-Stichting	Digestive Diseases Foundation (Maag Lever Darm Stichting)
MPRD	Municipal Personal Records Database (GBA, Gemeentelijke Basisadministratie persoonsgegevens)
MST	Minimal Standard Terminology
NFK	Dutch Federation of Cancer Patients' Organisations (Nederlandse Federatie van Kankerpatiëntenorganisaties)
NFU	Dutch Federation of University Medical Centres (Nederlandse Federatie van Universitair Medische Centra)
NHG	Dutch College of General Practitioners (Nederlands Huisartsen Genootschap)
Nictiz	National centre of expertise to facilitate the development of ICT in the care system
NIPED	NDDO (New Drug Development Organisation) Institute for Prevention and Early Diagnostics
NIV	Dutch Association of Internists (Nederlandse Internisten Vereniging)
NKR	Dutch Cancer Registry (Nederlandse Kankerregistratie)
NPB	National Screening Programme (Nationaal Programma Bevolkingsonderzoek)
NPK	National Cancer Control Programme (Nationaal Programma Kankerbestrijding)
NVA	Netherlands Society of Anesthesists (Nederlandse Vereniging voor Anesthesiologie)
NVKC	Netherlands Society for Clinical Chemistry and Laboratory Medicine (Nederlandse Vereniging voor Klinische Chemie)
NVMDL	Netherlands Association of Gastroenterohepatologists (Nederlandse Vereniging van Maag-Darm-Leverartsen)
NVMO	Dutch Association for Medical Oncology (Nederlandse Vereniging voor Medische Oncologie)
NVvH	Netherlands Surgical Association (Nederlandse Vereniging voor Heelkunde)
NVVP	Dutch Pathology Association (Nederlandse Vereniging voor Pathologie)
NVZ	Dutch Hospitals Association (NVZ vereniging van ziekenhuizen)
PALGA	The national histopathology and cytopathology data network and archive (Pathologisch Anatomisch Landelijk Geautomatiseerd Archief)
PSA	Procedural sedation/analgesia
RGO	Advisory Council on Health Research (Raad voor het Gezondheidsonderzoek)
RIVM	National Institute for Public Health and the Environment (Rijksinstituut voor Volksgezondheid en Milieu)
SCRIPT	One of the pilot projects (carried out by NIPED)
SES	Socioeconomic status
SKML	Foundation for Quality Assessment in Clinical Laboratories (Stichting Kwaliteitsbewaking Medische Laboratoriumdiagnostiek)
SPKS	Foundation for Patients with Cancer of the Alimentary Canal (Stichting voor Patiënten met Kanker aan het Spijsverteringskanaal)

STOET	Foundation for the Detection of Hereditary Tumours (Stichting Opsporing Erfelijke Tumoren)
TTP	Trusted third party
VIKC	Association of Comprehensive Cancer Centers (Vereniging van Integrale Kankercentra), now IKNL
VKGN	Dutch Society for Clinical Genetics (Vereniging Klinische Genetica Nederland)
VWS	(Ministry of) Health, Welfare and Sport (Volksgezondheid, Welzijn en Sport)
WBMV	Special Medical Procedures Act (Wet bijzondere medische verrichtingen)
WBO	Population Screening Act (Wet op het bevolkingsonderzoek)
Wbp	Personal Data Protection Act (Wet bescherming persoonsgegevens)
Wcz	Client Rights (Healthcare) Act (Wet cliëntenrechten zorg)
Wet BIG	Individual Health Care Occupations Act (Wet op de beroepen in de individuele gezondheidszorg)
WGBO	Medical Treatment Contracts Act (Wet op de geneeskundige behandelingsovereenkomst)
WKCZ	Health Service Clients (Right of Complaint) Act (Wet klachtrecht cliënten zorgsector)
WKZ	Quality of Care Institutions Act
WMCZ	Health Service Institution Clients (Consultation) Act (Wet medezeggenschap cliënten zorginstellingen)
Wmg	Health Care (Market Regulation) Act
WTZi	Care Institutions (Accreditation) Act
ZN	Umbrella organization of health insurers (Zorgverzekeraars Nederland)
ZVW	Health Care Insurance Act



## Appendices



## Appendix 1 The commission for a feasibility study of the colorectal cancer screening programme



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and the Environment  
Ministry of Health, Welfare and Sport

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**Our reference**  
PG/OGZ 2995414

**Appendices**  
TK-Letter

**Your letter**

*Any correspondence  
should be sent to the  
return address only,  
indicating the date and  
reference number of this  
letter*

Date 29 MARCH 2010  
Subject Commissioned feasibility study into population screening for  
colorectal cancer

Dear Ms Gravesteijn,

In writing this letter I am commissioning the Centre for Population Screening (CVB) to conduct a feasibility study into the options and conditions pertaining to a population screening programme for colorectal cancer.

### Background

On 17 November 2009, at my request, the Health Council of the Netherlands (HC) issued an advisory report on a population screening programme for colorectal cancer. The HC recommended that a population screening programme be introduced in phases. However, the advisory report highlighted various choke points, the most important of which concerned the capacity of the health service.

On 16 February 2010, the Minister of Health, Welfare and Sport sent details of his position on the HC's advisory report to the Lower House of the Dutch Parliament. The essence of this position is that a population screening programme for colorectal cancer would be of great significance for public health, but that no final decision on this matter can yet be taken. A number of important conditions have not yet been met. One pre-condition for the introduction of a population screening programme is that the available medical resources should be of sufficient quality and capacity to meet the diagnosis requirements, and, where necessary, to administer treatment. Capacity is currently a major choke point. Another condition concerns funding cover for the investments needed for the preparation, launch and implementation of a systemically integrated population screening programme. For a detailed explanation, I would refer you to the standpoint on a population screening programme for colorectal cancer that I have appended to this letter for information purposes. The coming year should be used to identify any choke points involved in a possible introduction, and to put forward proposals on how this should be handled. Based on the conditions, and on the results of various studies, the Minister expects to be able to reach a well-considered decision in the spring of 2011.

As discussed with you, and in accordance with the 2010 approval letter for the Centre for Population Screening (dated 22 December 2009; letter reference PG/JFB 2,978.566), the Centre for Population Screening at the National Institute of Public Health and the Environment will conduct a feasibility study on this matter. This evaluation, together with input from all of the parties involved, will provide important support in reaching a final decision on the possible introduction of a population screening programme for colorectal cancer.



Public Health Directorate

Our reference  
PG/OGZ 2995414

There is sufficient scope in your 2010 budget to fund the implementation of the feasibility study. This assignment will also take account of the impact on the Centre for Population Screening budget for 2011, in consultation with the relevant parties when preparing knowledge questions and quotations for the 2011 contractual year.

### Feasibility study

Since its 2006 launch, the Centre for Population Screening has gained considerable experience in the preparation and implementation of major changes to the national population screening programme. I expect the CVB to use this experience, together with the existing population screening checklist, as the basis for a feasibility study. Throughout the entire process, I would ask you to give all due consideration to communication and to ensuring that all relevant and affected parties and partners in the chain provide input. Each population screening programme is part of a larger chain, in which the link between screening and care is particularly vulnerable. This is certainly true for colorectal cancer screening, particularly in view of the bottleneck created by the health service's current capacity issues.

As I see it, the feasibility study consists of various phases that run parallel to the decision-making process. If a final decision on a population screening programme is to be taken in the spring of 2011, then the building blocks needed to underpin such a decision must be in place before November of this year. This involves an understanding of the major choke points, such as regional variations in health service capacity and options for task reallocation. Based on the available manpower (including that of the screening organizations), I expect a proposal for a rollout schedule with full financial details.

The assessment of topics of special relevance to the possible rollout schedule (e.g. a regional plan of action and communication with the public) may be deferred, but this work must be completed before the spring of 2011. Support from those in the field is of great importance. It is crucial to carry out a stakeholder analysis and a sphere-of-influence study involving the relevant actors. This would address their aspirations, expectations and possible roles, and how they relate to one another, to the screening, or to the follow-up procedure.

### Feasibility study topics

I feel that the feasibility study should at least address the topics described below, however this is by no means a definitive list. I expect you to make use of the knowledge and experience gained in the course of the current population screening programmes, together with any insights that may arise from the feasibility study, in consultation with the client.

### Capacity:

How many gastroenterohepatologists are available in each phase of the rollout? What are the options for task reallocation? Can the screening organizations cope with expansion (in the light of VIKS, DigiBOB)? Laboratory capacity (pathologists or reallocation of tasks)? And so on and so forth. Work with the professional groups involved and with the Capacity Board to obtain the necessary details concerning capacity.

**Communication:**

Communication and expectation management will be of the utmost importance throughout the entire process. Initially, this will be mainly focused on the professionals. The general practitioners, in particular, will have a lot of questions, and may not be aware of the latest developments. The potential participants in the population screening programme get an opportunity to contribute their views at a later stage. The Dutch public have a poor awareness of the risks of colorectal cancer. At the same time, assertive citizens who are not prepared to wait for the population screening programme will order or demand screening kits. Develop a plan of action.

**Flexibility:**

The technology is developing rapidly, and the infrastructure of population screening programmes must be capable of responding flexibly to new insights and developments. This places demands on the organization of the screening in terms of identifying such developments, adapting them for practical application, and implementing them. These requirements must be clearly identified.

**The population screening programme as part of the care chain:**

A population screening programme not only consists of a screening test, it involves an entire chain of consecutive and related activities, starting with effective and honest information in advance;

An invitation system that secures optimal participation without restricting the autonomy of those concerned (removing barriers, helping individuals to make well-informed choices);

A reliable test that meets the statement of requirements for home testing kits, as well as quality assurance in laboratories and monitoring; Communication of the results and referral to care: (e.g. results letter, direct referral by the screening organizations, and the role of the GP );

Rapid diagnosis and appropriate treatment: following a positive result, it is vital to check the diagnosis as quickly as possible and, where necessary, commence treatment. The practical aspects of care are primarily the responsibility of medical professionals. Caregivers have a collective responsibility to their clients to sound the alert if problems are encountered in the transition to care and in the follow-up care pathway. The quality of the entire chain must be properly secured. Screening and care are both crucial to the success of population screening programmes.

Highlight the various activities carried out in the chain and make suggestions concerning the optimal design and organization of quality assurance, link by link, throughout the entire chain. As part of this process, take into account various proposals made by the Health Council of the Netherlands, as well as the responsibilities of various parties, including care institutions, professional groups, and screening organizations.

**Monitoring and evaluation:**

It is vital that the screening results are presented effectively. The efficient exchange of information between screening and care is a prerequisite for this. This in turn requires effective coordination with professional groups and hospitals, as well as with other relevant parties such as patient organizations, the Health Care Inspectorate, and the Visible Care (Zichtbare Zorg) project. Prepare an action plan for the optimum monitoring and evaluation of the programme in question.

I would like you to draw up an action plan, in the form of a bid, for the feasibility study. With regard to the implementation of this assessment, you have agreed to provide monthly feedback to the client. Verbal modifications to the commission are possible, via a process of consultation.

I would like to take this opportunity to wish you every success with the work in hand.

Yours faithfully, on behalf of the Minister of Health, Welfare and Sport,  
Director-general for Public Health,

P.H.A.M. Huijts



Handwritten signature of P.H.A.M. Huijts, consisting of stylized, overlapping loops and a long horizontal stroke extending to the right.

drs. P.H.A.M. Huijts

**Public Health Directorate**

**Our reference**

PG/OGZ 2995414

## Appendix 2 Organizations and individuals consulted in the feasibility study

Organization	Contact	Position
Dutch Association of gastroenterologists (NVMDL)	Prof. E.J. Kuipers	President of NVMDL
	Prof. P. Fockens	President of Concilium
Capacity Board	Dr V.A.J. Slenter, Health and Society physician	Director
The national histopathology and cytopathology data network and archive (PALGA; Pathologisch Anatomisch Landelijk Geautomatiseerd Archief)	Dr E.H. Hofhuis	Board Secretary
	Dr A.T.M.G. Tiebosch	Chairman of the Board
	Mr A.M. van de Pol, MSc	Advisor
Umbrella organization of health insurers (ZN; Zorgverzekeraars Nederland)	Mr G.W. Saleminck	Medical advisor
Screening organizations (SOs)	Mr J.H. Sangers	Director of SO North
	Mr M.J.P. Steinbusch	Director of SO South
	Ms G.A. Bentvelsen	Director of SO East
	Ms A. Bartels-Kortland	Director of SO West Central
	Mr W.W.J. Spijker	Director of SO South-West
Elkerliek Hospital (pilot RUNMC; Radboud University Nijmegen Medical Centre)	Prof. J.B.M.J. Jansen	Research Project Manager
UMCU (pilot RUNMC; Radboud University Nijmegen Medical Centre)	Mr R.J.F. Laheij	Research Project Manager
Digestive Diseases Foundation (MLDS)	Ms. E. Mulder	Head of the Information Office
	Ms E. Kommer	Information Office staff member
National Reference Centre for Population Screening (LRCB)	Prof G.J. den Heeten	Director of the LRCB
Dutch Cancer Society (Koningin Wilhelmina Fonds Kankerbestrijding)	Ms M. op de Coul	Prevention Coordinator
	Ms F. Welles	Head of department
Academic Medical Center (AMC) - University of Amsterdam (UvA)	Prof. P. Fockens	Research Project Manager
	Dr E. Dekker	Research Project Manager
Dutch Federation of Cancer Patients' Organizations (NFK; Nederlandse Federatie van Kankerpatiëntenorganisaties)	Dr A. Snijders	Policy Officer
Netherlands Surgical Association (Nederlandse Vereniging voor Heelkunde)	Dr J.H.G. Klinkenbijl	Surgeon

Organization	Contact	Position
	Mr L.P.S. Stassen	Surgeon
	Prof. R. van Hillegersberg	Surgeon
	Dr J.W.D. de Waard	Surgeon
Erasmus MC, University Medical Center Rotterdam/Dutch Association of Gastroenterologists (NVMDL; CORERO Research Project)	Prof. E.J. Kuipers	Research Project Manager
Foundation for Patients with Cancer of the Alimentary Canal (SPKS; Stichting voor Patiënten met Kanker aan het Spijsverteringskanaal)	Ms A.L. van Erven	President of SPKS
	Dr J. Engelen	Secretary of SPKS
VU University Medical Center Amsterdam (VUmc)	Prof. C.J.J. Mulder	Dept. of Gastroenterology
Netherlands Society for Clinical Chemistry and Laboratory Medicine (Nederlandse Vereniging voor Klinische Chemie)	Dr Y.C.M. Kluiters-de Hingh	Clinical Chemist
	Dr D. Telting	Clinical Chemist
Dutch College of General Practitioners (NHG; Nederlands Huisartsen Genootschap)	Dr A. Drenthen	Team Leader
	Dr T.J. Wiersma	Guidelines Department
Comprehensive Cancer Centre of the Netherlands (IKNL)/Comprehensive Cancer Centre North East	Ms R. Otter	Chairman of the Board of VIKC (Association of Comprehensive Cancer Centers)
Dutch Pathology Association (NVVP; Nederlandse Vereniging voor Pathologie)	Dr F.J. van Kemenade	Secretary of the NVVP
National Institute of Public Health and the Environment (RIVM)/Centre for Infectious Disease Control Netherlands (CIb) - Laboratory for Infectious Diseases Diagnostics and Screening (LIS; Laboratorium voor Infectieziektendiagnostiek en Screening)	Dr J.G. Loeber	Head of LIS
	Dr A. de Vries	Deputy Head of GBO department
Netherlands Foundation for the Detection of Hereditary Tumours (STOET; Stichting Opsporing Erfelijke Tumoren)	Prof. H.F.A. Vasen	Medical Director
	Prof. J.A. Roukema	President of STOET
Antonius Academy	Dr P. de Jong	Director
	Dr M.J. Kaljouw	Former Director of the SSSV (Specific Nursing Training Foundation)

Organization	Contact	Position
	Ms C.M. Veldhuizen	Director
The Netherlands Colorectal Cancer Foundation	Ms A. Muller	President
Central Support Organization for Peer Review (CBO):	Dr G.A.H. Siemons	Board of Directors
	Prof. Swinkels	Board of Directors
VU University Medical Center Amsterdam (VUmc) (DeCoDe)	Prof. G.A. Meijer	Head of Pathology Department/
Dutch Society for Clinical Genetics (VKGN; Vereniging Klinische Genetica Nederland)	Dr F. Petreij	Secretary of VKGN
	Prof. N. Hoogerbrugge	Clinical geneticist Nijmegen
	Dr R.H. Sijmons	Clinical geneticist Groningen
Netherlands Society of Anaesthesiologists (NVA; Nederlandse Vereniging voor Anesthesiologie)	Mr J.W. Kallewaard	President
Dutch Association of Internists (NIV; Nederlandse Internisten Vereniging)	Dr F.H. Bosch	President
	Mr B.X. Oude Elberink	Director
Dutch Hospitals Association (NVZ vereniging van ziekenhuizen)	Dr R. Treffers, physician	Member of the Board
	Mr Dr S. Hofstede	Senior Policy Officer
National Association of General Practitioners (LHV; Landelijke Huisartsen Vereniging)	Mr C.F.H. Rosmalen	Head of Policy and Development
	Ms E.C. Romijn	Senior Policy Officer



### Appendix 3 Composition of advisory committee and working groups

<b>Advisory committee on the colorectal cancer population screening programme</b>	<b>Name of member</b>	<b>Position</b>
Screening organizations	Mr W.W.J. Spijker	Director/Administrator South-West population screening programme
Netherlands Society for Clinical Chemistry and Laboratory Medicine (NVKC)	Dr J.G. Boonstra	Clinical Chemist/Head of General Clinical Laboratory (AKL)
	Dr D. Telting	Clinical Chemist
	Dr Y.C.M. Kluiters – de Hingh	Clinical Chemist
Dutch Association of Gastroenterologists (NVMDL)	Prof. E.J. Kuipers	Gastroenterohepatologist, Erasmus MC, University Medical Center
	Dr M. van Haastert	Gastroenterohepatologist, Martini Hospital
Netherlands Surgical Association (NVvH)	Dr C. Rosman	Surgeon, Canisius-Wilhelmina Hospital
Dutch Pathology Association (NVVP; Nederlandse Vereniging voor Pathologie)	Prof. G.A. Meijer	Professor of Pathology, VU University Medical Center Amsterdam (VUmc)
	Dr N.C.T. van Grieken	Clinical pathologist
Dutch College of General Practitioners (NHG)	Prof. N.J. de Wit	Professor of General Practice Medicine
	Dr T. Drenthen (substitute)	Prevention Team Leader, Dutch College of General Practitioners (NHG)
Foundation for Patients with Cancer of the Alimentary Canal (SPKS; Stichting voor Patiënten met Kanker aan het Spijsverteringskanaal); Colorectal Cancer Patient Group	Ms J. Pon	President Colorectal Cancer Patient Group
ZN	Dr G.W. Salemink	Health and Society physician, Medical Advisor at Zorgverzekeraars Nederland(ZN; umbrella organization of health insurers)
National Reference Centre for Population Screening (LRCB)	Mr P.J.F. van Kalken	Director of the LRCB
Dutch Federation of Cancer Patients' Organizations (NFK; Nederlandse Federatie van Kankerpatiëntenorganisaties)	Dr A. Snijders	Policy Officer for Quality and Care
Dutch Society for Clinical Genetics (VKGN)	Dr R.H. Sijmons	Clinical geneticist and oncogeneticist, University Medical Center Groningen (UMCG)
Comprehensive Cancer Centre of the Netherlands (IKNL)	Dr R. Otter	Director/Administrator North-East Comprehensive Cancer Centre (IKNO)
	Dr S. Siesling	Head of Research at the North-East Comprehensive Cancer Centre (IKNO)

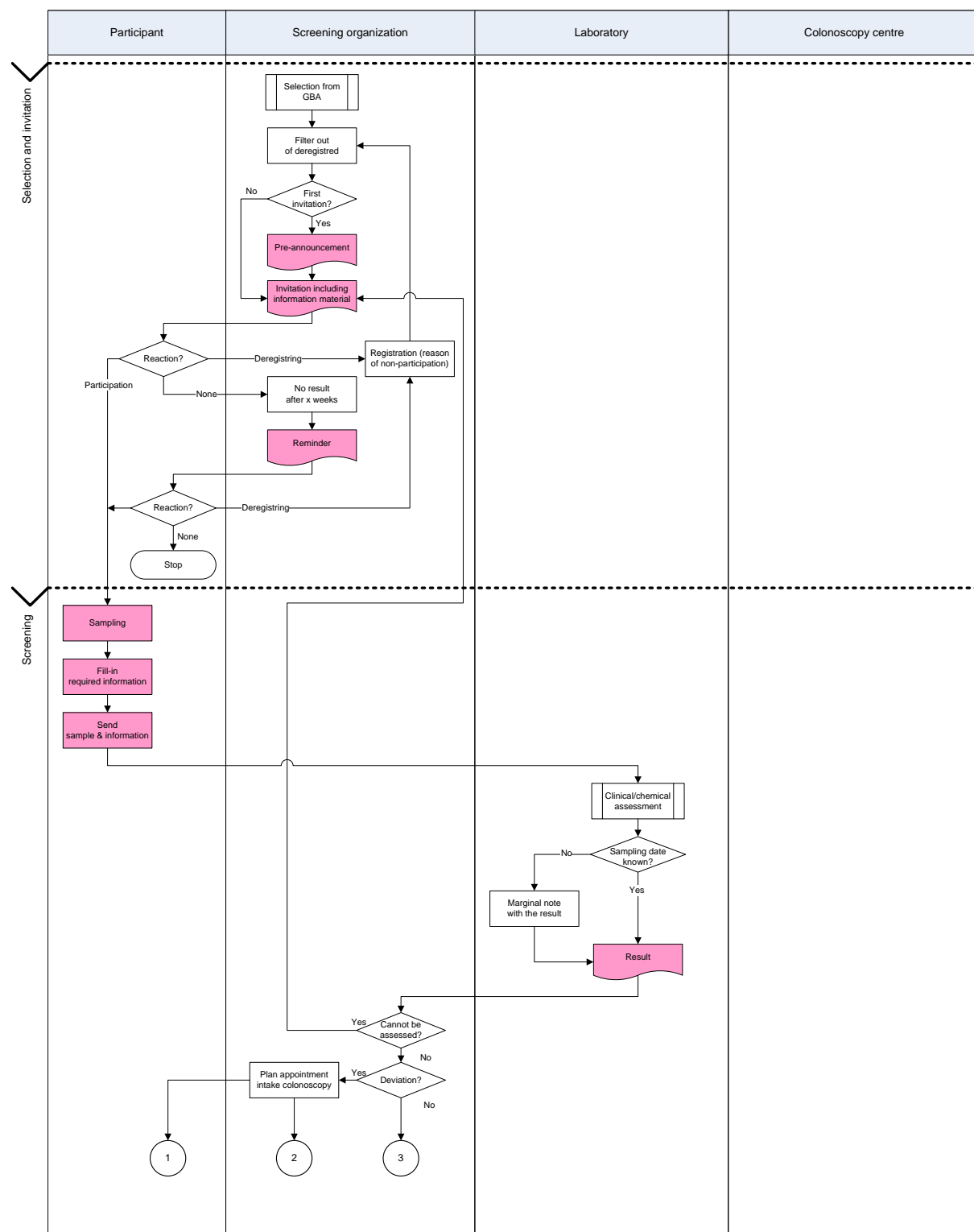


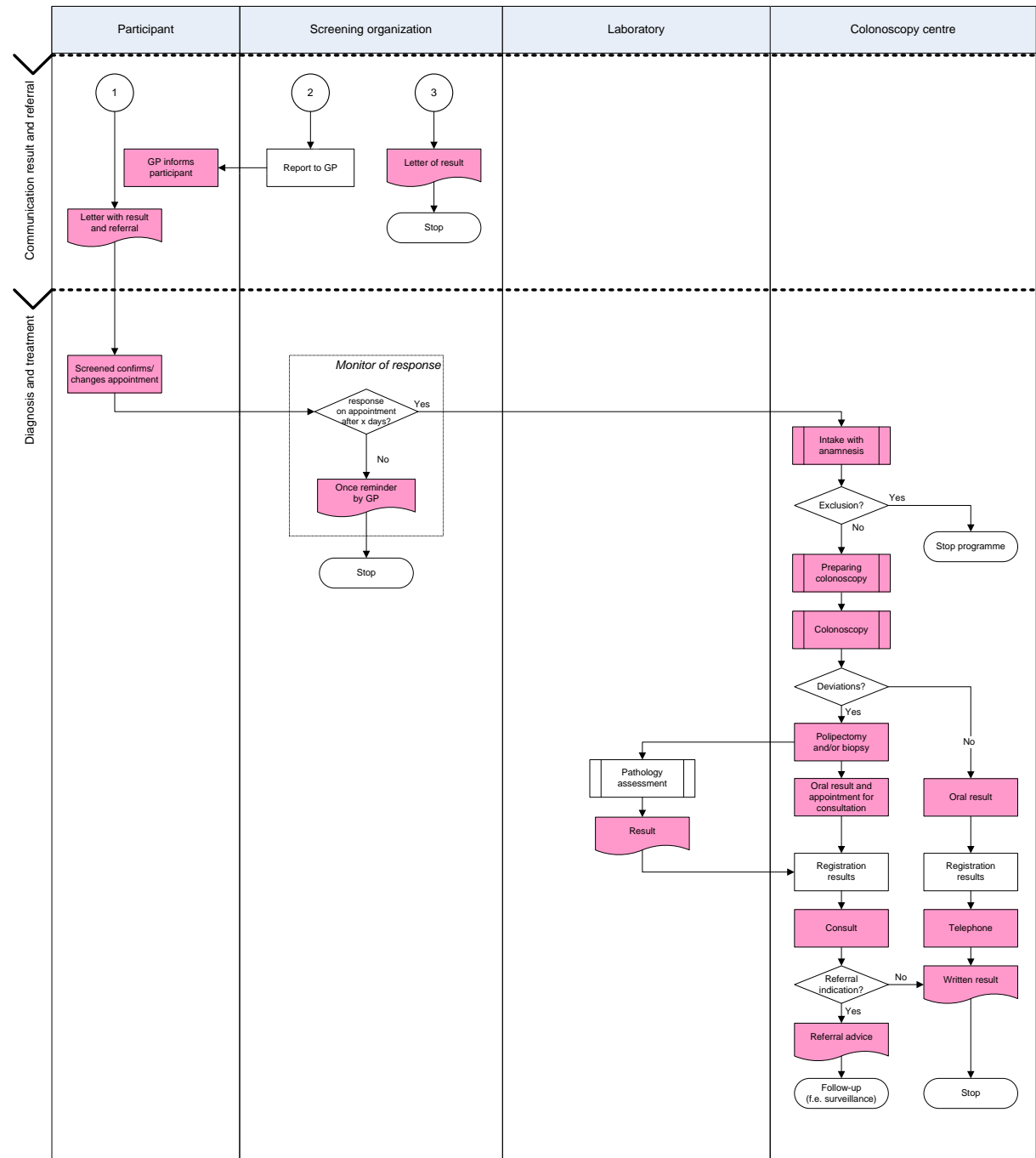
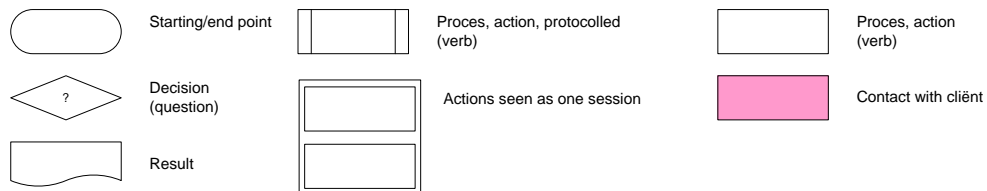
<b>Information Management Working Group</b>	<b>Name of member</b>	<b>Position</b>
Screening organizations	Mr A.V. van Peppen	Manager of West Central population screening programme
Netherlands Society for Clinical Chemistry and Laboratory Medicine (NVKC)	Dr J.L.S. Dols	Clinical Chemist, Academic Medical Center (AMC)
Dutch Association of gastroenterologists (NVMDL)	Dr M.E. van Leerdam	Gastroenterohepatologist, Erasmus MC, University Medical Center
Netherlands Surgical Association(NVvH) / Netherlands Society for Gastrointestinal Surgery (NVGIC) (subver.)	Dr W.M.U. van Grevensteijn	Gastrointestinal Surgeon at the University Medical Center Utrecht (UMCU)
Dutch Pathology Association (NVVP; Nederlandse Vereniging voor Pathologie)	Prof. G. Meijer	Professor of Clinical Pathology VU University Medical Center Amsterdam (VUmc)
Comprehensive Cancer Centre of the Netherlands (IKNL)	Dr S. Siesling	Head of Research at the North-East Comprehensive Cancer Centre (IKNO)
	Dr R. Damhuis Ms M. Elferink (replacements)	Cancer Registry Coordinator, Comprehensive Cancer Centre of the Netherlands (IKNL) Researcher at the North-East Comprehensive Cancer Centre (IKNO)
Dutch Surgical Colorectal Audit (DSCA)	Prof. R.A.E.M. Tollenaar	Professor of Surgical Oncology, Leiden University Medical Center (LUMC)
Pathological Anatomical National Automated Archive (PALGA)	Dr I.D. Nagtegaal	Pathologist, St. Radboud University Medical Centre, Nijmegen
<b>Capacity and Quality Working Group</b>	<b>Name of member</b>	<b>Position</b>
Screening organizations	Ms J. Reijerink	Director of management and innovation
Netherlands Society for Clinical Chemistry and Laboratory Medicine (NVKC)	Dr J.G. Boonstra	Clinical Chemist/Head of General Clinical Laboratory (AKL)
Dutch Association of gastroenterologists (NVMDL)	Prof. E.J. Kuipers	Gastroenterohepatologist, Erasmus MC, University Medical Center
	Mr M. van Haastert	Gastroenterohepatologist, Martini Hospital
Dutch Pathology Association (NVVP; Nederlandse Vereniging voor Pathologie)	Prof. G. Meijer	Professor of Clinical Pathology VU University Medical Center Amsterdam (VUmc)
National Reference Centre for Population Screening (LRCB)	Dr M. Broeders	National Reference Centre for Population Screening (LRCB)
Dutch Federation of Cancer Patients' Organizations (NFK; Nederlandse Federatie van Kankerpatiëntenorganisaties)	Dr A. Snijders	Policy Officer for Quality of Care
Dutch Society for Clinical Genetics (VKGN)	Dr R.H. Sijmons	Clinical geneticist and oncogeneticist, University Medical Center Groningen (UMCG)
Capacity Board	Mr J.G. Meeqdes	Senior Advisor
	Dr V.A.J. Slenter (replacement)	Director of the Capacity Board

Netherlands Foundation for the Detection of Hereditary Tumours (STOET)	Prof. H.F.A. Vasen	Internist, Leiden University Medical Center (LUMC)
Comprehensive Cancer Centre of the Netherlands (IKNL)	Dr S. Siesling	Head of Research at the North-East Comprehensive Cancer Centre (IKNO)
	Ms M. Elferink (replacement)	Researcher at the North-East Comprehensive Cancer Centre (IKNO)



## Appendix 4 Description of the primary process of the bowel cancer screening programme, including colonoscopy



**Legend**

Arrows show the proces of activities. After a decision, the arrow gives direction to the next activity.

## Appendix 5 Wilson and Jungner Criteria

**Wilson and Jungner criteria (WNO, 1968)<sup>(55)</sup>**

1. Relevant: the disease to be detected must be an acknowledged major health issue.
2. Treatable: the disease must be treatable using a generally accepted method of treatment.
3. Facilities: there must be sufficient facilities available to enable a diagnosis to be made.
4. Recognizable: there must be a recognizable latent stage to make detection worthwhile.
5. Natural course: the natural course of the disease must be known.
6. Who is ill? There must be agreement about who should be regarded as being ill.
7. Method of detection: a practical method of detection must already be available.
8. Acceptability: the detection test must be acceptable to the population.
9. Cost-Benefits: the costs involved should be proportionate to the benefits gained.
10. Continuity: The detection process should be continuous.



## Appendix 6 Table: Implementation of the population screening

<b>Setting up the programme management team</b>
Programme Coordination at the National Institute of Public Health and the Environment (RIVM)
Colorectal Cancer Programme Committee four times a year and various working groups which come under the Programme Committee; 20x
<b>Setting up organization and implementation</b>
Basic document primary process, roles, responsibilities and powers
Embedding reference functions in the organization and taking out contracts by the screening organizations
Translating quality standards to model agreements with endoscopy centre and with gastroenterohepatologists
Translate quality standards to policy framework, drafting policy framework for population screening programme, and amending the Subsidies Regulation
Population Screening Act (WBO) permit request
Implementation action plan per organization working on the ground
Implementation of action plan by screening organization (screening organization's preparations for implementation, such as organizing site, and tasks such as drawing up contracts with gastroenterohepatologists and iFOBT labs)
Making adjustments during the phased introduction, for further rollout schedule
<b>Setting up programme funding</b>
Setting SO's rates for invitation and reference (including reference function)
Setting up and maintaining macro framework programme
Amending the Public Health (Subsidies) Regulation
Preparation and supervising tender for iFOBT equipment/lab
Agreeing budgetary framework
<b>Setting up communication and information</b>
<i>The public (including testing of the products):</i>
Conducting survey to determine the public's need for information
Conducting public support survey
Developing information material for use within the population screening programme
Drafting Pre-announcement + letters (invitation, reminder, results) (cost to SO of implementing the programme)
Developing iFOBT instruction form + pre-test
Developing leaflets (leaflet with invitation and leaflet with abnormal result) + pretesting
Printing costs of leaflet for first target group
Developing Public Website (+ website professionals)
Establishing hotlines at various organizations; protocol development and drafting FAQ
Developing toolkit, regional awareness (announcements in newspapers/posters etc.)
Planning information dissemination activities and forms for special target groups + implementation
Developing animation
Developing film
Developing Decision Aid
Incident Communication Protocol and introduction
Communication regarding the introduction of the population screening programme, both for the public and for the professionals involved
Public Announcement by SOs and National Institute of Public Health and the Environment (RIVM)
<i>Professionals' products:</i>
Newsletter for professionals (paper/electronic)
National and regional introductory meetings



<b>Setting up quality of screening and follow-up care, including quality assurance</b>
<i>Drawing up quality standards for screening and follow-up care</i>
Drawing up, disseminating and implementing master plan
Disseminating and implementing master plan
Drawing up primary process for screening organizations (selection, invitation, referral, et cetera)
Drawing up quality standards for the self-administered iFOB test
Drawing up procedure for the use of residual material
Drawing up informed consent procedure
Drawing up quality standards for the equipment and method used to measure iFOB
Drawing up quality standards for laboratories
Drawing up quality monitoring protocol and sampling conditions
Drawing up an incident handling protocol for the iFOBT lab
Drawing up quality standards for the communication of results
Drawing up quality standards for referral
Modifying guideline on polypectomy
Drawing up quality standards for colonoscopy centres
Drawing up quality standards for endoscopists
Drawing up quality standards for pathology centre
Drawing up quality standards for pathologists
Drawing up quality standards for the colonoscopy room and associated equipment
Drawing up quality standards for the pathology equipment
Drawing up quality standards for the supply and recording of data
Drawing up protocol for intake interviews and exclusion criteria for colonoscopy
Drawing up colonoscopy preparation protocol
Drawing up information protocol for abnormal results
Drawing up protocol for return to population screening programme from care and surveillance
Drawing up an incident handling protocol for colonoscopy as pathology
An input protocol for pathologists using the local PALGA system
Drawing up multidisciplinary guideline on colon carcinoma
A framework for contact with patients based on Dutch Federation of Cancer Patients' Organizations (NFK) standards.(25a)
National quality assurance methodology both per organization and for the entire chain
Implementation and maintenance of quality assurance for primary process of population screening programme
<i>Education and professional development</i>
Drawing up training requirements for lab, endoscopist, pathologist
Action plan for the training of improvement of endoscopy nurses and physician assistants
Drawing up professional development action plan
Implementing professional development action plan, including:
Implementing action plan: e-learning:
Implementing action plan: articles in learned journals:
Implementing action plan: regional training seminars
Implementing action plan: standard for GPs, FAQ and telephone scripts for contractors
Implementing action plan: skill seminars

<b>Setting up monitoring, evaluation and information management</b>
<i>Further development of indicator set</i>
Drawing up indicators and data set, setting up monitor for interim decision-making on the phased introduction
<i>Organizing information management system, constructing information system</i>
Preliminary work on IT
1. Further elaboration of minimum dataset, together with professional groups
2. Workflow and technical dataset
3. Action plan and Functional design
4. Process supervision, preliminary work
IT tender
1. Process supervision
2. Purchasing
IT development
1. Process supervision
2. Building software in modules, including monitor
3. Working groups (attendance fees)
4. Adapting source systems
5. Define linkage
Testing IT
1. Process supervision
2. Legal assessment
3. Testing/acceptance
IT implementation
1. Process supervision
2. Communication
3. Training for screening organization/contractors
4. Create links
5. Partnership agreement, data access
<i>Management information system (helpdesk, hosting, application management, new functionality)</i>
<i>Monitoring</i>
Establishing regular monitoring (including data cleaning)
Establishing monitor for interim decision-making on the phased introduction
<i>Evaluation</i>
1. Establishing and implementing evaluation
2. Develop evaluation informed choice
<b>Setting up roll-out and capacity monitoring</b>
Capacity monitoring system (part of organizing information management system)
National appointments facility (part of organizing information management system)
Measures regarding additional capacity (see training, et cetera)
<b>Setting up knowledge and innovation</b>
Resolving problems with implementation

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L. Grievink | B. Hoebee | A.J.J. Lock | R. Reij

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