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en Milieu
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Welzijn en Sport

FRAMEWORK FOR THE EXECUTION OF THE DUTCH COLORECTAL CANCER SCREENING PROGRAMME

2021

Colophon

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Synopsis

Population screening for colorectal cancer consists of a chain of actions, which begins with the invitation sent to the target group, and ends at – if necessary – the transfer to subsequent treatment. The links in the chain should be firmly connected, and clearly defined. The chain is described by the roles and tasks of the organisations involved in colorectal cancer screening. This is essential for the provision of optimal screening to the target group. The 'Framework for the execution of colorectal cancer population screening' describes who is responsible for the execution of colorectal cancer population screening together with the applicable rules and procedures. This framework is written for all (medical) professionals involved in screening, including laboratory assistants, endoscopists, pathologists, and screening organisation employees.

The framework is based on the existing regulatory legislation and the policy framework for population screening. The framework provides a practical description of the execution and roles, tasks, and responsibilities of the organisations involved. It also includes descriptions of secondary processes, such as quality assurance, communication, and monitoring and evaluation of population screening. These secondary processes ensure the efficient and high quality execution of colorectal cancer population screening. Where relevant, the report refers to other related policy documents.

The framework for the execution of colorectal cancer screening is closely related to the Policy Framework for Cancer Population Screening. This document describes the regulatory legislative framework, the relation between cooperating organisations, and the preconditions required to ensure a high quality, attainable and affordable population screening process.

Keywords: Population screening, cancer, colorectal cancer, quality, execution

Publiekssamenvatting

Uitvoeringskader bevolkingsonderzoek darmkanker
Het bevolkingsonderzoek darmkanker bestaat uit een reeks van handelingen, die start met de uitnodiging van de doelgroep en doorloopt tot en met de aansluiting op een eventueel vervolgtraject in de zorg. Het betreft een sluitende keten met een helder beeld van de rollen en taken van de partijen die betrokken zijn bij de uitvoering van het bevolkingsonderzoek. Dit is essentieel voor een optimaal 'aanbod' voor de doelgroep van de bevolkingsonderzoeken.

Het 'Uitvoeringskader bevolkingsonderzoek darmkanker' beschrijft hoe en door wie het bevolkingsonderzoek darmkanker moet worden uitgevoerd en welke afspraken daarvoor gelden. Het Uitvoeringskader is geschreven voor alle (medisch) professionals, zoals de medewerkers van de FIT-laboratoria, de endoscopisten, de pathologen en de medewerkers van de screeningsorganisaties.

Het 'Uitvoeringskader bevolkingsonderzoek darmkanker' gaat uit van de wettelijke en beleidsmatige kaders die voor de bevolkingsonderzoeken gelden. Het Uitvoeringskader bevat een praktische beschrijving van de uitvoering en de rolverdeling (taken en verantwoordelijkheden) van de betrokken partijen.

Daarnaast worden de overige processen beschreven, zoals de kwaliteitsborging, communicatie en de monitoring en evaluatie van het bevolkingsonderzoek. Deze processen zijn van belang om de bevolkingsonderzoeken naar kanker doelmatig, efficiënt en met een hoge kwaliteit uit te voeren. Waar nodig wordt verwezen naar aparte documenten waarin de afspraken zijn vastgelegd.

Het Uitvoeringskader hangt nauw samen met het Beleidskader Bevolkingsonderzoeken naar Kanker. Hierin zijn de wettelijke kaders, de onderlinge verhoudingen van de samenwerkende partijen en de voorwaarden beschreven om te zorgen voor een hoge kwaliteit, een goede bereikbaarheid (laagdrempelig) én betaalbaarheid van de bevolkingsonderzoeken.

Trefwoorden: bevolkingsonderzoek, kanker, darmkanker, screening, kwaliteit, uitvoering

De volledige Nederlandstalige versie van het Uitvoeringskader bevolkingsonderzoek darmkanker is te vinden op de website.

Table of contents

1 Introduction

1.1 Aim and scope of the Execution Framework

This Execution Framework describes how the colorectal cancer screening programme should be carried out, ensuring that it proceeds effectively and within policy and legal frameworks. It describes the primary process, the allocation of roles (tasks and responsibilities) of the parties involved and the quality requirements for each party or the execution of the programme, in order to be able to provide the public with a reliable and high-quality screening programme. Where necessary, this Framework refers to separate documents in which these requirements are defined.

This Framework is aimed at all professionals involved in:
- coordination and execution of the colorectal cancer screening programme, subsequent diagnostic testing and treatment/surveillance;
- quality assurance, monitoring and evaluation of the screening programme.

Suppliers of products used in the colorectal cancer screening programme are also included in the target group.

The content of the Execution Framework is binding. This means that every professional involved in the execution of the screening programme is expected to be familiar with the content of the Execution Framework (relevant to him/her) and to put it into practice. For example, screening organisations use this Framework (or relevant parts of it) in their contracts with parties and suppliers who supply products for this screening programme. Where relevant, professional associations also bring this framework to the attention of their members. In addition, the care providers involved are themselves responsible for the quality of the care they provide. This Framework is a national standard according to which they can be held accountable.

1.2 Formation and maintenance

This 'Execution Framework for the Colorectal Cancer Screening Programme' has been compiled under the responsibility of the Centre for Population Screening of the National Institute for Public Health and the Environment (RIVM-CvB). RIVM-CvB is responsible for maintaining and distributing this Framework. Changes are adopted by RIVM-CvB following advice from the working group on Quality, Capacity, Monitoring and Information Management (QCMI) and the programme committee.

This Execution Framework is updated annually under the responsibility of RIVM-CvB in consultation with the QCMI working group and the programme committee. Questions and proposals for changes may be sent via email (CvB@rivm.nl). Updates to the Dutch Execution Framework will be announced in the (digital) cancer screening newsletter and the news reports on the RIVM website for professionals [Dutch only]. The latest version can also be found on this website.

1.3 Reading guide

This Execution Framework assumes that the reader is generally informed on the subject. Background information is only included insofar as it is required for a proper understanding of this Framework. **Appendices A and B** provide an overview of terminology and abbreviations. Various aspects of this Framework are detailed in related documents such as quality requirements, indicators, protocols, memoranda and model

agreements. These documents also apply to the screening programme and are included as appendices to this Framework (and/or are listed in **Appendix C**).

1.4 Extra information available in English

At the English webpage, among other information, three factsheets are published about the execution of the Dutch colorectal cancer screening programme: Lessons learned from the introduction of the colorectal cancer screening programme, Overview of programme structure colorectal cancer screening programme, and Overview of quality assurance in the colorectal cancer screening programme. At the same website, a video of the primary process is published.

2 Colorectal cancer and the screening programme

This chapter starts with a description of the clinical picture of colorectal cancer. This is followed by the goal and a brief description of the screening programme. The principles of the screening programme and the considerations involved in choosing whether to participate in the colorectal cancer screening programme are also included. Finally, facts and figures on the screening programme are briefly mentioned.

2.1 Clinical picture of colorectal cancer

Malignant colorectal tumours occur mainly in the colon (colon cancer) or in the rectum (rectal cancer). Malignant tumours of the small intestine and in the anus are very rare and are not detected through the colorectal cancer screening programme.

Colorectal cancer usually starts as a benign polyp. A small proportion of these polyps can grow over the years and form a malignant tumour that invades the intestinal wall and eventually metastasises via the lymph nodes or the bloodstream. This usually concerns a particular type of polyp, called adenomas (see Figure 2.1).

If any polyps are found during a colonoscopy, they will usually be removed immediately. Depending on the type of polyp, surveillance (monitoring) may take place. If colorectal cancer is diagnosed, treatment will be initiated.

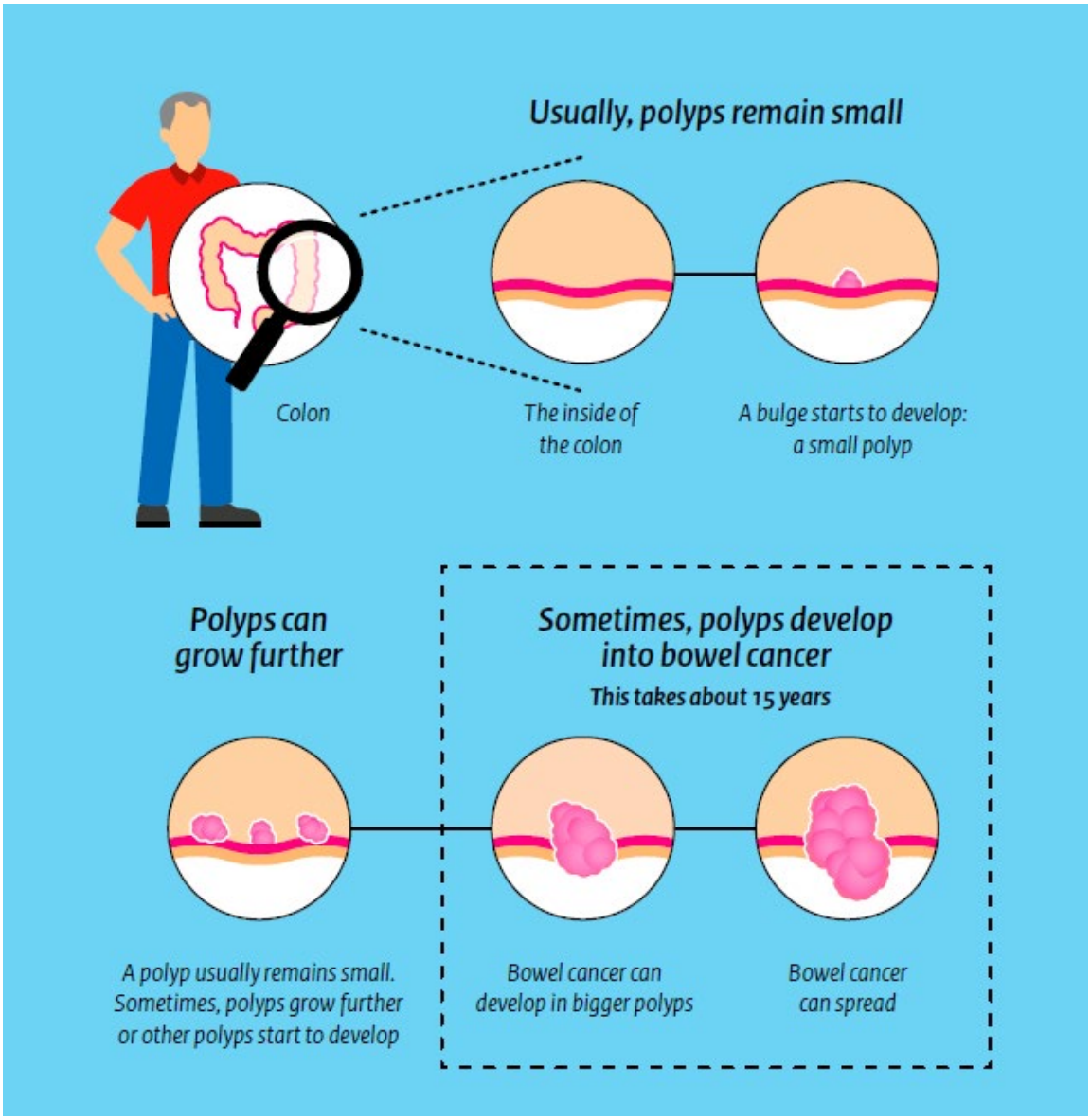

Figure 2.1: Development of polyps and colorectal cancer
Note: In communication aimed at the general public, the term 'large polyps' is used. For people familiar with the matter: This concerns high-risk polyps, in other words 'advanced adenomas'.

2.1.1 Incidence / prevalence

Approximately 30% of people over the age of 60 have polyps. In the Netherlands, about 1 in 20 people will develop colorectal cancer in their lifetime. Nine out of ten cases occur in people aged 55 years or older. Each year, about 13,000 people in the Netherlands are diagnosed with colorectal cancer and about 5,000 people die from this disease.

The five-year survival rate for colorectal cancer is 65%, but is highly dependent on the stage at which the tumour is detected (stage I: 85-95%; stage IV: <5%).

For more information about colorectal cancer, see the national information leaflet 'Invitation for bowel cancer screening programme', the colorectal cancer screening

programme fact sheet or the websites www.kanker.nl/darmkanker, www.kwf.nl/darmkanker, www.mlds.nl/kanker/darmkanker/ or www.thuisarts.nl/darmkanker [all in Dutch].

2.2 The colorectal cancer screening programme

The aim of the colorectal cancer screening programme is to reduce colorectal cancer mortality by detecting colorectal cancer and precancerous lesions of colorectal cancer early on. If colorectal cancer is detected early, there are generally more options for treatment.

2.2.1 History of the screening programme

In the Netherlands, the phased introduction of a national screening programme for colorectal cancer started in 2014. The phased introduction made it possible to build up the necessary capacity for diagnostic testing and treatment in subsequent care. In 2019, all men and women aged between 55 and 75 years received at least one invitation. See **Chapter 3** 'Primary process' for information on how the colorectal cancer screening programme is currently set up. More information in English can be found at www.rivm.nl/en/colorectal-cancer-screening-programme.

2.2.2 Principles of the colorectal cancer screening programme

The execution of the colorectal cancer screening programme must achieve an optimal balance between public values held by the government[1]: quality, accessibility and affordability. Parties optimise this balance within their own tasks and responsibility, taking the defined frameworks into account. At the national level, surveillance and decision-making regarding this optimal balance lies with the government (RIVM-CvB).

Good integration with diagnostic testing and treatment for the men and women referred from the screening programme is essential for a successful screening programme. The public values also apply to this follow-up care.

<u>The public value of quality:</u>

- The programme is effective in terms of the screening test used (test characteristics), target group participation and contribution to health gains.
- The programme is demand-based and takes the desires and needs of the target group into account.
- The programme is safe, justified and uniform at the national level. The continuity of the programme is guaranteed. The advantages outweigh the potential disadvantages for the target group.
- The programme is innovative. The available knowledge and experience of the parties involved are deployed in a structural manner to continuously improve the programme. Relevant innovations in methodology and screening methods, diagnostic testing and treatment are communicated in a timely manner. Potential consequences for the programme are discussed with the Dutch Ministry of Health, Welfare and Sport, ZonMw, the Dutch Health Council and other relevant parties.

<u>Public value 'accessibility':</u>

- The programme is accessible and organised in such a way that the target group experiences as few impediments to participation as possible. The programme is,

[1] Public values are values that everyone [in the Netherlands] believes deserve collective attention and protection (the government is the 'guardian' of these values).

among other things, physically feasible and financially accessible.
- The programme guarantees a timely execution of the required activities. The target group is invited to participate in the programme in a timely manner. The throughput times in the programme are acceptable, including the lead times for diagnostic testing and treatment.
- Participation in the programme is voluntary. Information for the general public and the target group is up to date, easy to understand, objective and balanced, and helps them make a well-informed decision.

Public value affordability:
- The costs of the programme are transparent, so that the government can weigh the public resources employed against their use for other governmental tasks.
- The programme is efficient. The programme is executed for the lowest possible cost while maintaining the required quality. The programme is also cost-effective.

2.2.3 Financing

Funding for the colorectal cancer screening programme is provided by the Grant Scheme for Public Health Care. The Grant Scheme for Public Health Care provides a legal framework for the funding. On behalf of the Dutch Ministry of Health, Welfare and Sport, RIVM-CvB grants subsidies to the screening organisations for carrying out the screening programme and quality assurance.

RIVM-CvB is financed by the Ministry of Health, Welfare and Sport to carry out its directive task.

The costs of diagnostic testing, treatment and surveillance are covered by the Healthcare Insurance Act and are therefore part of the insurance package.

2.2.4 Advantages and disadvantages of the colorectal cancer screening programme

Participating in the colorectal cancer screening programme has advantages and disadvantages.
An important advantage is that the screening programme makes it possible to detect colorectal cancer early. If colorectal cancer is detected early, treatment is often less intensive and the prognosis is better. In addition, screening may also detect possible precancerous lesions of colorectal cancer. The treatment of precancerous lesions can ultimately prevent colorectal cancer from developing.

There are also disadvantages. The stool test and colonoscopy in the screening programme do not provide complete certainty; therefore, there is always a chance that colorectal cancer is not detected.

In addition, overtreatment is possible. Some of the people referred for follow-up testing do not have advanced polyps or colorectal cancer (about 50%). In these cases, referral and further testing were unnecessary.

Polyps are almost always removed during colonoscopy. However, most polyps are benign. This could mean that polyps are removed even if they would not have caused any problems.

Finally, there is the psychological and physical stress caused by both the screening and the possible follow-up testing. The follow-up examination (the colonoscopy) can be unpleasant.

People may be worried if blood is discovered in the stool or if polyps are found. This stress may even be unnecessary if blood is detected in the stool test but follow-up testing reveals no clinically relevant abnormalities.

Finally, there is a risk of complications after colonoscopy. For every 1,000 colonoscopies, an average of two result in serious complications. There is also a risk of death following colonoscopy (between 1 in 40,000 and 1 in 10,000 colonoscopy participants). These fatal complications can occur, for example, as a result of perforation of the bowel or as a result of having to stop taking anticoagulants in order to undergo the colonoscopy.

2.2.5 Facts and figures on the colorectal cancer screening programme

Monitoring information is published annually in the national monitor (for more information, see **Chapter 7** 'Monitoring and evaluation'). RIVM-CvB uses this information in its annual Colorectal cancer screening programme fact sheet [in Dutch], which contains the most important key figures.

3 Primary process of the colorectal cancer screening programme

This chapter describes the primary process of the colorectal cancer screening programme, including subsequent care (diagnostic testing, follow-up treatment and surveillance). A screening programme can only achieve the desired effect if the entire chain of care – from invitation to any necessary follow-up care – is solid. In each screening programme, the transition from health care back to screening takes place at some point (see Figure 3.1). In the colorectal cancer screening programme, participants with a positive faecal immunochemical test (FIT) will undergo further diagnostic testing and receive treatment, if necessary, within the regular health-care system. They will receive a referral for this from the regional coordinating gastroenterologist.

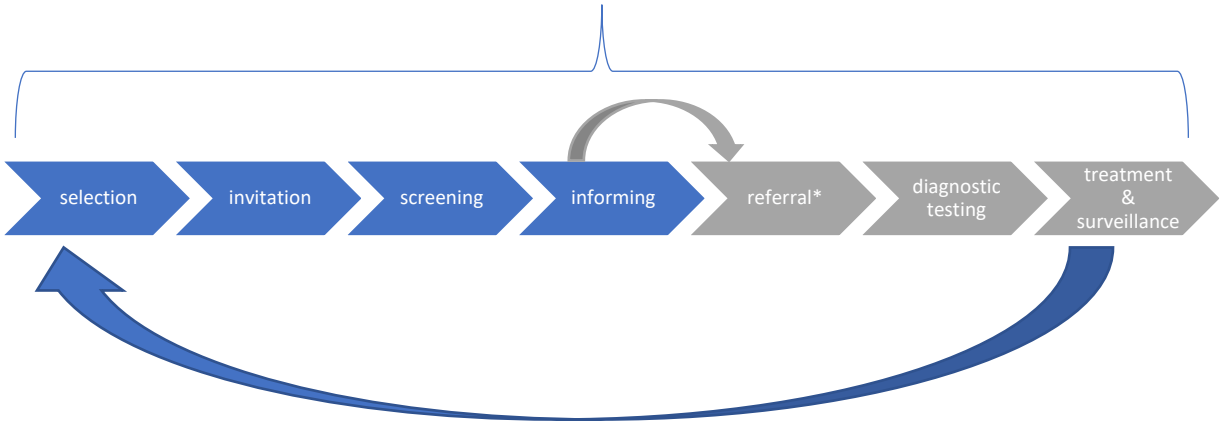

Figure 3.1: Diagram of phases in the primary process of the screening programmes (blue) and subsequent care (grey)

* For the colorectal cancer screening programme, the referral is also part of the screening programme.

3.1 Phases in the primary process of the colorectal cancer screening programme

A description of how the screening programme is executed is provided for each phase. A diagram of this in the form of a flowchart can be found in Figure 3.2.

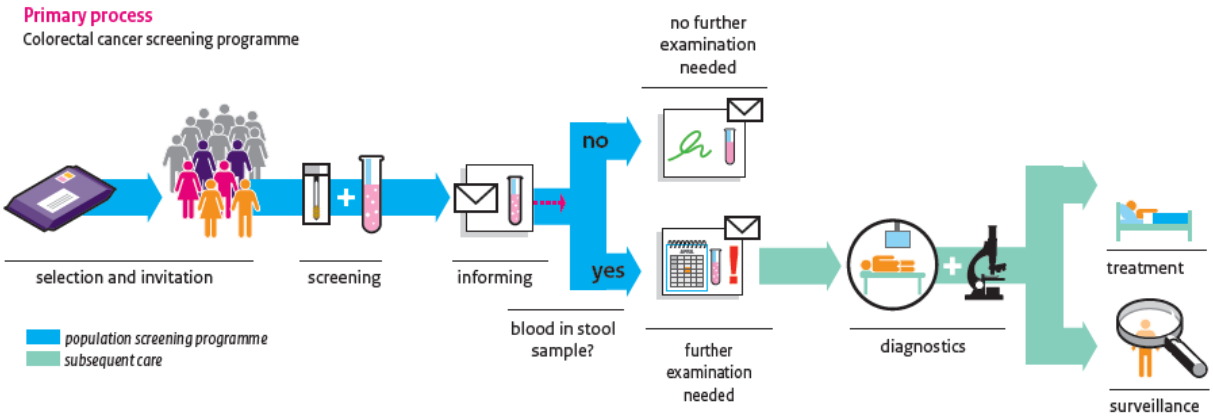

Figure 3.2: Diagram of the colorectal cancer screening programme

3.2 Selection and invitation

Every two years, people aged between 55 and 75 years are invited to take part in the screening programme. They are sent a self-sampling test kit (faecal immunochemical test, FIT), which they can send back for analysis themselves after taking a faecal sample.

The screening organisation selects the target group to be invited to take part in the screening programme for the year in question from the information provided by the Dutch Personal Records Database (*Basisregistratie Personen*, BRP). In subsequent rounds, the screening organisation removes from this selection those persons who have previously opted out or who can be excluded based on indications from diagnostic testing and care. Each year, half of the target group is invited. This means that every two years 4.4 million people receive an invitation for the screening programme.

Individuals invited for the first time receive an advance notification letter three weeks before the invitation. Besides an invitation letter to take part in the screening programme, the invitation pack consists of a leaflet explaining the purpose of the screening programme and how it works, as well as the advantages and disadvantages and information on the exchange of data. In addition, the target group receives the self-sampling test kit (FIT), instructions for use, a bag and a return envelope.

The invitee has then three possible responses:

1. The invitee takes part and sends back the return envelope with the faecal sample;
2. The invitee opts out for this round;
3. The invitee opts out permanently;

It is also possible that the invitee does not respond at all.

If the invitee opts out only for this round, the person in question will be invited again two years later. An invitee who opts out permanently receives a confirmation from the screening organisation. It is always possible to re-register again.

If the invitee does not respond, the screening organisation sends a reminder six weeks after the first invitation. The invitee can then again respond in one the three possible ways. If the self-sampling test kit (FIT) is lost, the invitee can request a new invitation

pack from the screening organisation (also via the ScreenIT client portal[2]). If the guest fails to respond again, no further action will be taken for this screening round. The person in question will be invited again two years later, unless he or she is older than 75.

When taking part in the screening programme, an invitee may file an objection to the exchange of certain data (see **Chapter 8** for more information) and/or bodily material (see **Chapter 9**) with the screening organisation (or via the ScreenIT client portal). The screening organisation processes the objection and sends the invitee a confirmation within one week of receipt.

3.3 Screening

The participant collects a faecal sample at home and uses the pre-addressed return envelope to sends the sample in the bag to the laboratory by regular mail. Sending the return envelope to the laboratory starts the screening procedure.

The screening laboratory analyses and assesses the faecal sample on the basis of the set standards and sends the results to the screening organisation electronically within 48 hours of receipt of the sample.

If the sample cannot be assessed, for example because too much stool has been put into the test, the screening organisation sends the participant a new invitation pack (see also **Section 3.2**). The participant responds by returning a new faecal sample or does not respond.

3.4 Informing and referral

The participant receives a letter with the test results and advice from the screening organisation based on the assessment in the screening laboratory. This takes place no more than five working days after the screening organisation has received the results from the laboratory. The following test results and follow-up steps are possible:

<u>No further examination or testing is needed following the FIT</u>
If no blood is found in the faecal sample (‘favourable result’), the screening organisation sends the participant a letter with the results; no further examination or testing is necessary. A new invitation to take part in the colorectal cancer screening programme will be sent after two years.

<u>Further testing or examination is needed following the FIT</u>
If the Hb value in the FIT is greater than or equal to the cut-off value (‘unfavourable result’), the screening organisation makes an appointment for the participant for an intake interview for a follow-up examination at a colonoscopy centre. This is done on the basis of the available time slots in the ScreenIT appointment module. The screening organisation sends the participant a letter with the results and a referral for an intake appointment for a colonoscopy, on behalf of the regional coordinating gastroenterologist. The letter contains the details of the appointment for the intake. A leaflet with information about follow-up testing and the advantages and disadvantages is enclosed. In the results letter, the participant is asked to contact his or her GP in the case of a past medical history, so that the GP can make sure that relevant information and medical

[2] The client portal is a web interface. The client has access to his/her information in ScreenIT to e.g. change the date of an intake appointment or request for a new FIT.

records are sent to the colonoscopy centre. In addition, the participant can also contact his or her GP for other questions about the test results.

The participant can inform the screening organisation who his or her GP is by telephone or via the client portal. If the GP is known, the screening organisation sends the test results to the GP at least two days before the screening organisation sends the results to the participant. This gives the GP the opportunity to contact the participant to inform him or her of an unfavourable result and to discuss which relevant medical records should be forwarded to the colonoscopy centre. If the participant and the GP do not contact each other before the intake, the participant attends the intake appointment for the colonoscopy without the involvement of the GP.

The participant can change or cancel the intake appointment (time and/or location) via the client portal or by telephone with the screening organisation. If the GP's name is known, he or she will be notified by the screening organisation regarding the change or cancellation.

3.5 Diagnostic testing

The intake appointment takes place no later than 15 working days after the results letter is sent. If the patient has a relevant past medical history and has been in contact with his or her GP, the GP is responsible for ensuring that the necessary medical records regarding relevant past medical history, genetic predispositionand medication are sent to the colonoscopy centre before the intake appointment. If a patient has not been in contact with his or her GP and it turns out during the intake that the colonoscopy centre needs additional medical records, the patient is asked during the intake to give the colonoscopy centre permission to request this additional information from the GP or other health-care professional. During the intake interview, for example, the advantages and disadvantages are discussed with the patient and the patient then decides whether or not to have a colonoscopy (intake conclusion):

- If the patient opts for a colonoscopy, the medical history is taken and the patient is further informed about the preparation and the colonoscopy. An appointment is also made for the colonoscopy. The colonoscopy takes place no later than 15 working days after the intake appointment, unless it is scheduled later at the patient's request. The colonoscopy centre notifies the screening organisation of the colonoscopy appointment via ScreenIT. This is necessary in order to monitor turnaround times.
- If the patient opts for a CT colonography (see **paragraph 4.6.3** for reasons), the colonoscopy centre registers this and notifies the screening organisation via ScreenIT. The colonoscopy centre requests a CT colonography. The radiologist forwards the results of the examination to the requesting physician at the colonoscopy centre. The colonoscopy centre then forwards the results to the GP and the patient. After a positive CT colonography, the patient often undergoes a colonoscopy as well. The results of this colonoscopy must be forwarded to the screening organisation.
- It is also possible that a colonoscopy does not have to be performed at this time for medical reasons, for example because a colonoscopy has already been performed in recent years. The client then returns to the screening programme, where the centre itself can indicate how many years after the positive stool test this should be (between two and ten years, unless the client has reached the age of 75 years by then). Other medical reasons may lead to the conclusion that returning to the screening programme is no longer useful, in which case the participant will be permanently excluded.
- If a follow-up examination does not take place at the client's request, he or she will

receive a new invitation for the screening programme two years after the date of the unfavourable results of the stool test. If the client no longer wants to participate in the screening programme at all, the client can opt out permanently through the screening organisation.

The colonoscopy centre registers the intake conclusion in ScreenIT.

If a participant fails to attend the intake appointment, this is registered by the colonoscopy centre (in ScreenIT). The screening organisation sends the participants a reminder letter within one week, asking the participant to make a new intake appointment via the screening organisation or the client portal. If the participant does not respond to the reminder, the screening organisation will only inform the GP (if known to the screening organisation) after six weeks. The GP can inform the participant of the importance of complying with the referral. Participants who do not respond to the invitation for follow-up testing will receive a new invitation pack two years after the unfavourable outcome, unless they are over 75 years of age at that time. This applies to participants who:

- cancelled the originally scheduled intake appointment;
- failed to attend the original intake appointment (no-show);
- wanted a different intake location, but then did not make a new intake appointment.

If the patient chooses to have a colonoscopy, the patient receives instructions and an explanation of the test on the day of the colonoscopy and, if agreed with the patient, a sedative and/or a painkiller. The colonoscopy is performed and the colonoscopy centre records the colonoscopy data. The colonoscopy centre informs the patient of the results verbally and in writing. If abnormalities are found during a colonoscopy, histological material (i.e. polyps or biopsies) is usually taken. The colonoscopy centre sends this material to a pathology laboratory that meets the quality requirements for the screening programme. The pathology laboratory analyses the material and communicates the results to the colonoscopy centre and to the screening organisation electronically within 5 working days after the histological material is received.

If the patient fails to attend the scheduled appointment for a colonoscopy, the colonoscopy centre will actively seek to contact the patient the same day to make sure he or she still attends. If, on medical grounds, the colonoscopy or CT colonography is cancelled, the centre registers in ScreenIT whether or not the client returns to the screening programme, where the centre itself can indicate how many years after the positive stool test this should be (between two and ten years, unless the client has reached the age of 75 years by then). Other medical reasons may lead to the conclusion that returning to the screening programme is no longer useful, in which case the participant will be permanently excluded. If the colonoscopy does not take place at the client's request, he or she will receive a new invitation for the screening programme two years after the date of the unfavourable results of the stool test. If the client no longer wants to participate in the screening programme at all, the client can opt out permanently through the screening organisation.

The steps taken after the examination depend on the findings (non-abnormal or abnormal result).

Non-abnormal result following the colonoscopy

No abnormalities were observed in the colon. The colonoscopy centre registers the results and informs the patient of the results verbally. The patient is also given a written confirmation of the results. The colonoscopy centre notifies the screening organisation of the findings and results of the colonoscopy electronically. ScreenIT is configured not to invite the patient to take part in the screening programme for another 10 years after the

unfavourable FIT result, unless he or she is over 75 years of age at that time. The colonoscopy centre also forwards the findings and the follow-up policy to the GP.

The colonoscopy centre phones the patient within one month after the colonoscopy to inquire about any complications. The colonoscopy centre registers any complications that may have occurred. The centre also verifies that the patient has fully understood the information given after the colonoscopy.

Abnormal result following the colonoscopy
During the colonoscopy, cancer was found or polyps were observed. The colonoscopy centre informs the patient immediately afterwards that a polypectomy has taken place or that biopsies have been taken. Once the results have been received (electronically) from the pathology laboratory, the colonoscopy centre informs the patient verbally. This is done no more than 10 working days after the colonoscopy. The colonoscopy centre sends the patient a written confirmation of the results no more than 5 working days after the verbal results (unless cancer has been diagnosed). The colonoscopy centre also informs the GP about the results. If desired, an appointment to discuss the results of the pathological findings is scheduled. During the appointment to discuss the results, the colonoscopy centre asks the patient whether there have been any complications and also asks the patient to report any complications in the weeks following the colonoscopy to the colonoscopy centre. The colonoscopy centre registers the complications. The colonoscopy centre notifies the screening organisation of the findings and results of the colonoscopy, further diagnostic testing and follow-up policy electronically.

If necessary, the colonoscopy will arrange for the patient to be referred to the hospital of his or her choice for further diagnostic testing and treatment and/or surveillance. If cancer is diagnosed, treatment will usually start within four weeks after the verbal explanation of the results, unless there are reasons to deviate from this in consultation with the patient.

3.6 Treatment & surveillance

Following an unfavourable result from FIT and colonoscopy, patients may be placed in a treatment or surveillance programme. A surveillance programme means that the patient goes to the hospital periodically for a follow-up colonoscopy. The screening organisation is notified of the fact that a patient is being placed in surveillance and for how long. The screening organisations process the intended surveillance period in ScreenIT. Depending on the surveillance period, the client will then not receive an invitation for the screening programme for 16, 18 or 20 years after the positive stool test.

4 Roles of parties involved

This chapter continues with the description of the primary process described in the previous chapter, and goes into further detail on the allocation of roles and responsibilities among parties involved in the colorectal cancer screening programme and subsequent care. The parties participating in the colorectal cancer screening programme are jointly responsible for the functioning of the chain of care. Good coordination of activities and timely and full mutual exchange of information are essential in this respect.

Figure 4.1 lists the parties that play an active role in the execution of the primary process. The following sections describe the core tasks and responsibilities for each of the parties involved with regard to the execution of the primary process. The tasks indicate the specific frameworks etcetera of the colorectal cancer screening programme according to which these are carried out (see **Appendix C** for an overview). No reference is made in this chapter to the generally applicable guidelines, etc., of professional associations and others. See **Chapter 5** (Quality assurance) for more information on working in accordance with guidelines and quality requirements.

The last section of this chapter names the parties that are involved in the colorectal cancer screening programme, but not in the primary process.

Phases / ***Parties involved***	**Selection**	**Invitation**	**Screening**	**Informing**	**Referral**	**Diagnostic testing**	**Treatment & Surveillance**
Invitee or participant	•	•	•	•	•	•	•
Screening organisation	•	•		•	•		
Packing centre	•	•					
Screening laboratory			•				
GP practice		•		•		•	•
Hospital/ independent treatment centre*						•	•

Figure 4.1: Parties involved in the execution of the primary process
* This concerns the colonoscopy centre, the pathology laboratory, radiology and oncology.

4.1 Role of the invitee or participant

The leaflet enclosed with the invitation for the primary test allows the target group to make an informed decision about whether to participate in the colorectal cancer screening programme. The invitee is responsible for deciding whether or not to take part based on the information provided. The participant is responsible for actually taking part in the screening programme. If the invitee decides to take part, he or she is responsible

for the correct collection of the faecal sample and for sending the faecal sample as soon as possible. Depending on the results of the FIT, the participant in the screening programme will or will not be referred as a patient for subsequent diagnostic testing and possible treatment or surveillance. If the invitee decides not to take part in the screening programme, the invitee is responsible for opting out. This can be done via the client portal, the information number or by email. If desired, the invitee can also use these lines to grant permission to notify his or her GP of the results of the screening programme. The GP will only be informed if the invitee has given explicit permission to do so. In the case of a colonoscopy, the patient is asked to report any complications in the weeks following the colonoscopy to the colonoscopy centre. Finally, the invitee or participant must state whether he or she has any objections to the exchange of certain forms of information (see also **Chapter 8**) and/or bodily material (see also **Chapter 9**).

4.2 Role of the screening organisation

The regional execution of the colorectal cancer screening programme rests with the five regional screening organisations. The screening organisations work under the direction of RIVM-CvB on behalf of the Ministry of Health, Welfare and Sport. The screening organisations are responsible for the regional execution of the colorectal cancer screening programme, regional coordination, and quality assurance for execution of colorectal cancer screening programme.

Within the context of coordination and quality assurance, they have entered into agreements with the four screening laboratories, the colonoscopy centres, PostNL, the packing centre for the FIT, the transport company, the supplier of the FIT and accompanying analytical equipment and reagents, and the suppliers involved in quality assurance of the FIT. In addition, they have entered into agreements with the coordinating professionals for independent reviewing of the quality of the screening programme (quality review coordinators). They are also chain partners of the GP and chain partners of and referrers to colonoscopy centres. Through these agreements and adherence to them, screening organisations ensure that contractors act in accordance with the legislation and regulations and the various frameworks (see **Chapter 5** Quality assurance. The screening organisations have placed the contract management with a national cooperative named Screening Facilities Cooperation (*Facilitaire Samenwerking Bevolkingsonderzoeken*, FSB). However, the Execution Framework generally refers to the screening organisations and not FSB.

Within the context of executing the primary process of the colorectal cancer screening programme, the screening organisation is responsible for:
- Selection and updating of the list of the target group that qualifies for an invitation or reminder;
- Inviting (and reminding) the target group to take part in the FIT;
- Sending the FIT;
- Communicating the results and referral, if applicable.

Selection

Core tasks:	Methods:*
Selection and updating of the information for the target group for the screening programme during based on information from the Dutch Personal Records Database, opt-outs and objections	In accordance with the procedure used by the screening organisation. Legal framework - exchange of information from cancer screening programmes

Invitation

Core tasks:	Methods:*
Sending invitations for the FIT to the target group of the screening programme.	In accordance with the methods used by the screening organisation, using the documents: • Advance notification letter • Invitation letter • 'Invitation bowel cancer screening programme' leaflet • Instructions for stool sample test
Sending a reminder for the FIT to the invitees who have not responded.	In accordance with the methods used by the screening organisation, using the documents: • Reminder invitation •
Timely ordering of self-sampling test kits and reagents for the FIT, based on a stock and management model.	In accordance with the procedures used by the screening organisation.

Informing

Core tasks:	Methods:*
Sending the results of the screening test to the participant.	In accordance with the methods used by the screening organisation, using the documents: • Results letters • In the case of a positive FIT, also 'Follow-up examination' leaflet and GP notification (if known)
Informing a participant if: 1. a faecal sample cannot be assessed; 2. the expiry date of the FIT has passed (faecal sample is unreliable). In these cases, the packing centre will send the participant a new invitation pack if possible.	National information materials: • Results of results letter unknown. • 'Invitation bowel cancer screening programme' leaflet • Instructions for stool sample test

Referral

Core tasks:	Methods:*
Referring the participant for subsequent diagnostic testing. Make an intake appointment for the participant, based on the timeslots made available by the colonoscopy centre in ScreenIT. Sending the participant a letter on behalf of the referring regional	In accordance with the procedures used by the screening organisation.

coordinating gastroenterologist (RCG) with the results and the referral for the colonoscopy intake appointment.	
Processing the opt-outs of participants who have indicated that they do not wish to participate in the colonoscopy intake appointment, including the reason for opting out. Sending the participant a confirmation of the opt-out from the intake for colonoscopy.	In accordance with the methods used by the screening organisation, using the document: • Letter regarding opting out of intake
Changing the colonoscopy intake appointment on request of the client. Sending the participant a confirmation of the changed appointment.	In accordance with the methods used by the screening organisation, using the document: • Letter regarding change of intake
Informing the GP (if known) about the unfavourable result of the stool test, changes to and opt-outs of intake appointments.	In accordance with the methods used by the screening organisation, using the document: • GP notification unfavourable result stool test • GP notification regarding change to intake • GP notification regarding opt-out of intake
Monitoring whether the participant follows the referral recommendation for an intake for a colonoscopy. Send a reminder if the participant fails to attend the intake appointment. Informing the GP (if known) when a participant does not respond to the reminder.	In accordance with the methods used by the screening organisation, using the documents: • Intake reminder • GP notification regarding no-show at intake
Making a new intake appointment for the participant, when the participant contacts the screening organisation in response to the reminder. Sending the participant a confirmation of the new intake appointment.	In accordance with the procedures used by the screening organisation, using the documents: • Letter regarding change of intake • GP notification regarding change to intake

In addition, the screening organisation is responsible for the following:

Core tasks:	Methods:*
Answering questions from the public and invitees about the colorectal cancer screening programme.	In accordance with the procedures used by the screening organisation.
Registering and properly handling any	In accordance with the procedures used by the screening organisation.

complaints received.	
Registering and properly handling any incidents.	In accordance with national Risk Management Protocol.

* Documents in Dutch only

4.3 Role of the packing centre

The packing centre is involved in the *selection* and *invitation* phases in the chain. The packing centre is responsible for putting together, packing and sending the invitation packs with the self-sampling test kits (FIT) and keeping the materials needed for this in stock. The packing centre works on behalf of the screening organisations. For the purpose of cooperation, the packing centre has a contract with the screening organisations. The packing centre complies with and works in accordance with the contractual and working agreements made with the screening organisations.

Selection and invitation

Core tasks:	Methods:
The packing centre is responsible for the design, production and stock of the packs. This applies to the invitation pack as well as the return pack.	In accordance with work process agreements between the screening organisations and the packing centre
The packing centre keeps sufficient stock of the components of the invitation pack: leaflet, test tube, instructions for use and paper/printed matter. The packing centre informs the supplier of the FIT when a new stock of test tubes is needed in a timely manner.	In accordance with work process agreements between the screening organisations and the packing centre
The packing centre agrees with the screening organisations which barcode range is used with which expiry date of self-sampling test kits. The packing centre prints the invitation letters in accordance with the agreed template. The packing centre submits in ScreenIT which self-sampling test kit is sent to which client.	In accordance with work process agreements between the screening organisations and the packing centre
The packing centre employee puts together the invitation packs based on the work list from ScreenIT. The packing centre transfers the invitation packs to the shipping company for delivery.	In accordance with work process agreements between the screening organisations and the packing centre
The packing centre informs the screening organisation about returned invitation packs and the reason for the return, by	In accordance with work process agreements between the screening organisations and the packing centre

means of registration in ScreenIT.	

4.4 Role of the screening laboratory

The screening laboratory is a private care provider and chain partner of the screening organisations, GP practices in their area, hospitals/independent treatment centres and other care providers. The screening laboratory is contracted by the screening organisation, and an agreement is in place between the organisations. Within the context of executing the primary process of the colorectal cancer screening programme, they receive the return envelopes with faecal samples via the transport company and the laboratory is responsible for:

- analysing faecal samples using a nationwide uniform FIT and analytical equipment, purchased by the screening organisations;
- notifying the screening organisations of the results (electronically).

The laboratory carries out the following core tasks for this screening programme.

Screening

Core tasks:	Methods:
Receiving, checking and registering the faecal sample with the corresponding data	In accordance with the procedures used by the screening organisation.
Analysing the faecal sample for human haemoglobin	In accordance with the procedures used by the screening organisation and the relevant professional group.
Notifying the screening organisation of the authorised results of the FIT via ScreenIT	In accordance with the procedures used by the screening organisation.

4.5 Role of the GP practice

The GP may have a role in the invitation, informing and referral, diagnostic testing and treatment & surveillance phases in the chain. At the request of the client, the GP is responsible for providing information about the screening programme and for advising participants with an unfavourable FIT result and/or abnormal colonoscopy. In addition, the GP is responsible for providing the necessary medical information for additional diagnostic testing (colonoscopy), in consultation with the client or at the request of the care provider. The GPs are private care providers and chain partners of the screening organisations, colonoscopy centres and other care providers.

Within the context of the screening programme, the GP carries out the following core tasks:

Invitation

Core tasks:	Methods:*
At the request of the invitee, informing the invitee whether participation in the screening programme is advisable, based on the usefulness of the screening programme and the invitee's symptoms, medical history and past history.	In accordance with the NHG Colorectal Cancer Screening Programme Practice Manual.

Informing

Core tasks:	Methods:*
The GP (if known) receives the results of an unfavourable FIT and the referral recommendation from the screening organisation minimally two days before the participant. This gives the GP the opportunity to decide to contact the participant himself or herself.	In accordance with the methods used by the screening organisation, using the document 'GP notification regarding unfavourable results'.
If desired by the participant: Advising the participant on the usefulness of the colonoscopy. If known, being notified by the screening organisation if the participant opts out of or changes the intake appointment.	In accordance with the NHG Colorectal Cancer Screening Programme Practice Manual, using the documents: • Nationally established exclusion criteria • GP notification regarding change to intake. GP notification regarding opt-out of intake.
Answering the participant's questions about the follow-up examination.	In accordance with the NHG Colorectal Cancer Screening Programme Practice Manual.

Diagnostic testing

Core tasks:	Methods:*
If there has been contact between the participant and the GP: Forwarding, on paper or electronically, of relevant medical records for the intake to the colonoscopy centre in a timely manner.	In accordance with the NHG Colorectal Cancer Screening Programme Practice Manual.
If a patient with a referral recommendation attends the intake appointment without the involvement of the GP: Providing the necessary medical records at the request of the colonoscopy centre, if the patient has given permission to do so.	In accordance with the NHG Colorectal Cancer Screening Programme Practice Manual.
If a patient with an unfavourable FIT does not follow the referral recommendation, the GP (if known) is notified by the screening organisation. The GP can inform the patient of the importance of complying with the referral. It is up to the GP whether he or she takes action. Registering an unfavourable FIT result in the patient's medical record. If a patient does not respond to the invitation for a follow-up examination, the GP can take	In accordance with the methods used by the screening organisation, using the document 'GP notification regarding no-show at intake'.

the results into account if the patient does develop symptoms later on.	
Receiving the results of the colonoscopy from the colonoscopy centre.	In accordance with the procedures used by the screening organisation.

Treatment & Surveillance

Core tasks:	Methods:*
At the patient's request, the GP supervises the follow-up treatment.	In accordance with the documents established by the professional group.

* Documents in Dutch only

4.6 Role of the hospital/independent treatment centre

Within the context of executing the primary process of the colorectal cancer screening programme, the hospitals/independent treatment centres are responsible for:
- Performing diagnostic testing;
- Treatment in a care context;
- Advising on surveillance after treatment.

These responsibilities translate to a number of core tasks for the hospital/ independent treatment centre. Within the hospital/independent treatment centre, the four parties below are responsible for follow-up after referral from the colorectal cancer screening programme:
1. Colonoscopy centre,
2. Pathology laboratory,
3. Radiology,
4. Oncology.

4.6.1 Colonoscopy centre

The colonoscopy centres (endoscopists, nurses and support staff) are involved in the diagnostic testing and treatment & surveillance phases in the chain. They are responsible for carrying out the intake, performing the colonoscopy and coordinating diagnostic testing, surveillance and referral to follow-up care. They also notify the screening organisations (electronically or otherwise) of how many intake interviews they can conduct at what times, taking into account their colonoscopy capacity and the agreed turnaround times. The colonoscopy centres are the commissioning clients for the pathology laboratories and radiology. The relationships to the laboratories may vary. The colonoscopy centres have concluded agreements with pathology laboratories, radiology departments and health insurers. For the purpose of cooperation, the colonoscopy centres have an agreement with the screening organisations. The colonoscopy centres ensure that every endoscopist involved in the context of population screening has signed a quality agreement with a screening organisation.

Within the context of the screening programme, the colonoscopy centre carries out the following core tasks:

Diagnostic testing (intake)

Core tasks:	Methods:*
Entering the available timeslots for intake interviews in ScreenIT.	In accordance with the procedures used by the screening organisation.
Recording in ScreenIT if a participant fails to attend the scheduled intake appointment.	In accordance with the procedures used by the screening organisation.
Taking the patient's history face-to-face to determine whether a colonoscopy can be performed on the patient in question. Checking whether the patient is taking anticoagulant medication. If a patient is taking anticoagulant medication, a modified procedure is used. Investigating whether the patient may have hereditary colorectal cancer and whether the genetic predispositionsuggests that intensive monitoring is desirable.	In accordance with the procedures used by the screening organisation and the guidelines of the professional group.
If the patient has a relevant past medical history and has had no contact with the GP prior to the intake: Asking for the patient's permission to request the additional information. Requesting the necessary additional information from a GP or other health-care professional (electronically or otherwise).	In accordance with the procedures used by the screening organisation.
Determining whether a colonoscopy is advisable and whether there are any obstacles to performing it, based on the patient's history and past medical history. Making an appointment for the colonoscopy with the patient. If a full colonoscopy is not possible, CT colonography can be requested.	In accordance with the procedures used by the screening organisation and the guidelines of the professional group.
Informing the patient about the preparations, procedure and risks of the colonoscopy. Giving the patient written information about the preparations and the colonoscopy.	In accordance with the procedures used by the screening organisation and the guidelines of the professional group.
Recording the necessary information from the intake in ScreenIT.	In accordance with the procedures used by the screening organisation and: • Technical dataset for colonoscopy

Diagnostic testing (colonoscopy)

Core tasks:	Methods:
Ensuring that the participant is prepared properly before the colonoscopy. Giving the patient a sedative and/or painkiller, if this has been agreed with him or her.	In accordance with the guidelines of the professional group.
Performing the colonoscopy or follow-up colonoscopy. If abnormalities are found during the colonoscopy: Performing (in principle) a polypectomy or taking biopsies. Sending the material taken for further testing to a pathology laboratory that meets the quality requirements of the screening programme.	In accordance with the procedures used by the screening organisation and the guidelines of the professional group.
Recording the necessary information from the colonoscopy in the gastroenterology system.	In accordance with the procedures used by the screening organisation.

Diagnostic testing (providing results and follow-up)

Core tasks:	Methods:*
Verbally providing the results of the colonoscopy to the patient. Sending written confirmation of the results to the patient, unless cancer has been diagnosed.	In accordance with the methods used by the screening organisation and the guidelines of the professional group, using the documents: • Results letter for colonoscopy without abnormalities (return to screening programme after 10 years, unless client is older than 75 years by then). • Results letter for colonoscopy with abnormalities (return to screening programme), • Results letter for colonoscopy with abnormalities (surveillance after 1, 3 or 5 years).
Forwarding the findings and the policy to the patient's GP. Electronically forwarding the results of the colonoscopy, any further diagnostic testing and the policy to the screening organisation.	In accordance with the procedures used by the screening organisation.
Calling the patient to ask about possible complications, within one month after a colonoscopy without abnormalities. Asking the patient whether there have	In accordance with the procedures used by the screening organisation and the guidelines of the professional group.

been any complications, during the results interview after a colonoscopy with abnormalities. Recording the complications in the DRCE.	
Periodically measuring the patient's experiences: what the patient thought of the quality, safety and comfort of care.	In accordance with the procedures used by the screening organisation.
Registering and properly handling any complaints received.	In accordance with the procedures used by the screening organisation.
Registering and properly handling any incidents and adverse events.	In accordance with the national Risk Management Protocol and in accordance with the Protocol for Admission and Auditing of Colonoscopy Centres and Endoscopists.

Treatment & Surveillance

Core tasks:	Methods:
Ensuring proper transfer of the patient and information to the relevant specialist if treatment is necessary.	In accordance with the guidelines of the professional group.
Electronically notifying the screening organisation of the fact that a patient is going into surveillance and for how long.	In accordance with the guidelines of the professional group.

* Documents in Dutch only

4.6.2 Pathology laboratory

The pathology laboratories are involved in the *diagnostic testing* phases in the chain. The pathology laboratory is responsible for the assessment of histological material from colonoscopies after referral from the screening programme. The pathology laboratories work on the instructions of the screening organisations. They have an agreement with the relevant colonoscopy centre for this purpose.

The pathology laboratory carries out the following tasks for this screening programme.

Diagnostic testing

Core tasks:	Methods:*
Receiving the histological material and the associated data from the colonoscopy centre.	
Recording the receipt and the date of receipt of the histological material.	In accordance with: • Technical dataset for pathology, • National PALGA Colon Biopsy Protocol-TEM(1)
Storing the material under proper storage conditions until processing takes place.	
Processing the histological material to make preparations for assessment.	
Assessment of the histological preparation. The pathologist does not routinely request immunohistochemical staining for this.	In accordance with the Protocol for Admission and Auditing of Pathology Laboratories.
Recording the necessary information from the assessment in the pathology system, as well as revisions and consultations.	In accordance with: • Protocol for Admission and Auditing of Pathology Laboratories. • Technical dataset for pathology, • National PALGA Colon Biopsy Protocol-TEM(1)
Ensuring the storage/destruction of the remaining residual material.	In accordance with hospital policy and the Memorandum Handling of bodily materials.
Within 5 working days after receipt of the histological material, delivering the pathology results authorised by a qualified pathologist.	• Protocol for Admission and Auditing of Pathology Laboratories. • Technical dataset for pathology, • National PALGA Colon Biopsy Protocol-TEM(1)
Forwarding the authorised results to the colonoscopy centre that requested the examination, within the context of the colorectal cancer screening programme.	In accordance with the Protocol for Admission and Auditing of Pathology Laboratories.
Forwarding the authorised results (electronically or otherwise) to the screening organisation.	• Protocol for Admission and Auditing of Pathology Laboratories. • Technical dataset for pathology
Registering and properly handling any complaints received.	In accordance with: • Risk management protocol, • Complaints procedure.
Registering and properly handling any incidents and adverse events.	In accordance with: • Risk management protocol, • Complaints procedure, • Protocol for Admission and Auditing of Pathology Laboratories

* Documents in Dutch only

4.6.3 Radiology department

The radiology departments are involved in the *diagnostic testing* phases in the chain. Colonoscopy is explicitly the diagnostic method of choice, because a relatively large number of abnormalities are expected in patients where blood has already been detected in the stool. These abnormalities can then usually be removed immediately during the colonoscopy.

A small proportion (approximately 1%) of participants with a positive FIT result can be offered CT colonography during the intake. Reasons to indicate a CT colonography are:
- a former incomplete colonoscopy due to a permanent reason,
- a psychological-medical reason (e.g. anxiety disorder or sexual abuse),
- the patient does by no means want a coloscopy.

The radiology department is responsible for performing and assessing the CT colonography and works on the instructions of the colonoscopy centres.

Diagnostic testing

Core tasks:	Methods:*
Performing and assessing CT colonography	In accordance with the guidelines of the professional group.
Forwarding the authorised results to the colonoscopy centre that requested the examination, within the context of the colorectal cancer screening programme.	In accordance with the procedures used by the screening organisation.
Registering and properly handling any complaints received.	In accordance with the procedures used by the screening organisation.
Registering and properly handling any incidents.	In accordance with the national Risk Management Protocol.

* Documents in Dutch only

4.6.4 Oncology

For the purpose of cooperation in the screening programme, the screening organisation has further written agreements with the hospitals.

Within the context of executing the primary process of the colorectal cancer screening programme, the hospitals are responsible for:
- treating patients in the health-care setting and surveillance after treatment.

These responsibilities translate to a number of core tasks for the hospital.

Treatment & Surveillance

Core tasks:	Methods:
Treating and informing the patient. After treatment, the patient is advised to receive ongoing monitoring in a hospital (length of time depends on the findings). Referring the patient back to the screening programme after the end of treatment and monitoring.	In accordance with the procedures used by the screening organisation and the guidelines of the professional group.

4.7 Other parties involved

The following parties are involved in the entire cooperation chain. An explanation of each party's role and responsibilities is provided.

Parties involved	Explanation of role
Dutch Ministry of Health, Welfare and Sport	The Ministry of Health, Welfare and Sport determines the policy and establishes the financial and legal frameworks for the colorectal cancer screening programme. The Minister for Health, Welfare and Sport is politically responsible for the colorectal cancer screening programme. The Minister decides on permit applications (following advice from the Health Council of the Netherlands) submitted by the screening organisations under the Population Screening Act (*Wet op het bevolkingsonderzoek*, WBO). The Ministry of Health, Welfare and Sport ensures that funds are made available for the execution of the screening programme. The Ministry is the commissioning client of RIVM-CvB, the Health and Youth Care Inspectorate (IGJ) and the Health Council of the Netherlands and grants the WBO permit to the screening organisations.
RIVM-CvB	RIVM-CvB is responsible for national management of the colorectal cancer screening programme. RIVM-CvB: • coordinates and directs the organisations involved, among other things by setting frameworks and quality requirements and facilitating the parties involved; • finances the screening programme through grants from the grant scheme for public health care; • stimulates and guarantees the quality and uniformity of execution; • monitors and evaluates the screening programme; • communicates with the public, professionals and stakeholders; • pools knowledge and innovates; • advises and informs policymakers. RIVM-CvB is a contractor and part of the Ministry of Health, Welfare and Sport. The Minister for Health, Welfare and Sport has commissioned RIVM-CvB with the national management and coordination of prevention programmes in the RIVM Act.
Health Council of the Netherlands	The Health Council is responsible for providing independent scientific advice to the Minister on: • changes to the colorectal cancer screening programme; • WBO permit applications by the screening organisations. The Health Council is a contractor and part of the Ministry of Health, Welfare and Sport.

Parties involved	Explanation of role
Netherlands Organisation for Health Research and Development (ZonMw)	ZonMw is involved in the entire cooperation chain and is responsible for funding innovation-oriented research (including prevention programmes). ZonMw is a contractor of the Ministry of Health, Welfare and Sport.
Patient organisations, such as the Digestive Diseases Foundation (*Maag Lever Darm Stichting*) and the Colorectal Cancer Working Group (Dutch Ostomy Foundation) (*Werkgroep Darmkanker*) (*Stomavereniging*))	Patient organisations represent the interests of patients and provide information to the public.
Professional groups	The relevant professional groups contribute their expertise (on the subject matter and otherwise) and professional interest to national agreements. The representatives also provide information to the profession group.
Health insurers	Health insurers fund the diagnostic testing and treatment of clients referred from screening.
Other parties (PALGA, IKNL, DRCE, etc.)	Other parties provide advice to RIVM-CvB on the screening programme, on request and voluntarily. They also provide data for quality control, monitoring and evaluation. IKNL: Also the organisation of a data warehouse on cancer screening programmes (*datawarehouse bevolkingsonderzoeken*, DWH-BVOK).

5 Quality assurance

Quality assurance encompasses the entirety of planned and systematic actions required to provide sufficient confidence in the colorectal cancer screening programme's current and continued compliance with set requirements.

The foundation for quality assurance is formed by the existing legislation and regulations, and measures taken by various organisations and professional groups in order to guarantee the quality of their actions.

In order to execute the colorectal cancer screening programme, a number of additional, nationally applicable quality requirements, frameworks and protocols have been established.

This chapter describes how quality assurance is organised at the various levels and how compliance is monitored.

5.1 Legal and regulatory aspects

In addition to legislation that keeps health care accessible and affordable, a key legal framework for promoting or protecting the health of the public at large is defined by the Public Health Act (Wpg) and the Population Screening Act (Wbo). Appendix 3 of the Policy Framework for Population Screening for Cancer gives an overview and brief explanation of the legislation and regulations that apply specifically to population screening for cancer.

The Health and Youth Care Inspectorate (IGJ) monitors compliance with a number of quality-related health-care laws and can give instructions, submit disciplinary complaints and take measures (including emergency measures) if necessary. With regard to screening for cancer, the IGJ investigates adverse events and incidents, assesses the measures taken by the health-care provider, takes measures itself if necessary, and advises the Minister for Health, Welfare and Sport about the observance of applicable legislation about population screening for cancer.

5.2 Quality assurance of organisations and professional groups

Based on the legal framework, the organisations and professionals involved in the colorectal cancer screening programme have established their own quality assurance systems. Quality certification and national guidelines safeguard the quality of execution and contribute to defining the professional standard and responsible care. The various professional groups are responsible for the development, management and implementation of guidelines. An overview of the guidelines that apply to the colorectal cancer screening programme is provided in **Appendix C**.

The practical execution is monitored by means of audits by both the professional associations and in the context of quality certification.

More information on quality assurance by the organisations and professional groups involved can be found on the websites of the relevant organisations and professional associations.

5.3 Quality assurance of execution of population screening

5.3.1 National quality requirements, frameworks and protocols

Additional quality requirements, frameworks and protocols have been drawn up to ensure uniform execution and optimal quality of the colorectal cancer screening programme.

The national quality requirements for the colorectal cancer screening programme have been developed by RIVM-CvB, in close cooperation with relevant executing parties. RIVM-CvB defined the requirements after being advised by the programme committee. The quality requirements for the screening organisations and the FIT laboratories[3] can be found in **Appendix D**. The Protocol for Admission and Auditing of Colonoscopy Centres and Endoscopists and the Protocol for Admission and Auditing of Pathology Laboratories [all documents in Dutch only] describe the quality requirements for the colonoscopy centres/endoscopists and for the pathology laboratories, respectively. Proposals for adjustments to the quality requirements for the colonoscopy centres and endoscopists are made by the regional coordinating gastroenterologists (RCGs) and the auditing professional of the screening organisation, and are discussed in the QCMI working group (see **Chapter 12** for more information about this working group). Proposals for adjustments to the quality requirements for the pathology laboratories are made by the regional coordinating pathologists (RCPs) and the auditing professional of the screening organisation. These are first discussed with the Committee on Quality and Professional Practice (CKBU) of the Dutch Society of Pathology (NVvP) and subsequently in the QCMI working group.

Indicators have been developed where possible in order to determine whether the quality requirements have been met (see **Chapter 7** 'Monitoring and evaluation').

In addition to national guidelines from professional groups, there are frameworks and protocols that apply specifically to the colorectal cancer screening programme. An overview is provided in **Appendix C**.

The frameworks and protocols of the RIVM-CvB are part of this Execution Framework. Screening organisation protocols are embedded in the Service Level Agreements between screening organisations and implementing parties/suppliers.

5.3.2 Monitoring of practical execution

For the screening tests, the monitoring of the practical execution focuses on the stool test and the colonoscopy. This quality control involves various parties, each with their own core tasks.

Screening organisations
The screening organisations are responsible for the quality of execution of the screening programme (see Table 5.1). For the purpose of quality assurance, the screening organisations conclude agreements with the parties that fulfil the reference function for the execution of quality control. They also take care of the design of a quality platform. The screening organisations have also concluded agreements with suppliers of equipment and materials for carrying out the screening programme. The quality requirements for equipment and materials are not discussed further in this Execution Framework.

[3] The Protocol Selecting and auditing FIT-laboratories, including quality requirements, will be published early 2021. From then on, the quality requirements in the Framework will be expired.

Table 5.1: Core tasks of screening organisations

Core task:	Description:
Monitoring the quality of execution	The screening organisation monitors the quality of the execution of the screening programme.
Organisation of quality control	The screening organisation organises the quality control of the execution by means of the reference function and the quality platform.
Early warning	The screening organisation identifies and reports bottlenecks in the quality of the execution and reports these in the advisory structure of the screening programme established for this purpose.
Advising	The screening organisation advises the Working Group on Quality, Capacity, Monitoring and Information Management (QCMI), the programme committee and RIVM-CvB on areas for improving the quality of execution.
Improvement	The screening organisation ensures the implementation of improvements in the execution of the screening programme that are consistent with legal frameworks and the WBO permit.

Reference function

A reference function provides an independent assessment of the quality of the screening tests at the national level. Within the colorectal cancer screening programme, the reference function has been set up for the screening part and the connection to health care, as well as for the colonoscopy that takes place in the care pathway and the assessment of removed tissue (the diagnostic testing). The general core tasks of the reference function are described in Table 5.2. A more detailed description of these tasks specifically for the colorectal cancer screening programme is provided in **Appendix E**.

Table 5.2: Core tasks of reference function

Core task:	Description:
Assessment of equipment/implementing parties	The reference function advises and assesses whether equipment and/or implementing parties can be admitted to the screening programme.
Monitoring the quality of execution	The reference function monitors the quality of execution of the screening programme.
Professional development	The reference function is partly responsible for the professional development of the professionals working in the screening programme.
Analysis of incidents/adverse events	The reference function identifies and advises on incidents and adverse events during the execution of the screening programme.
Advising	The reference function advises on various aspects related to the quality of the population screening programme.

Various coordinating professionals for independent reviewing of the quality of the screening programme (quality review coordinators) periodically perform independent quality assessments on the instructions of the screening organisations, geared to the audits of their professional group. The test coordinating gastroenterologists are

appointed nationally. They carry out the assessments to admit the endoscopists to the screening programme. The reference tasks related to the FIT analysis are carried out by one national officer. The national FIT monitoring officer (LFMF) is employed by the Dutch Foundation for Quality Assessment in Medical Laboratories (SKML), has no links to the contracted screening laboratories and has a cooperation agreement with the joint screening organisations. The reference functions for colonoscopy (regional coordinating gastroenterologist (RCG)) and pathology (Regional Coordinating Pathologist (RCP)) are filled by regional coordinating officers. The RCG is responsible for the independent quality assurance of the colonoscopy and coordination of diagnostic testing. The RCP assesses whether pathology laboratories can be admitted to the screening programme and then assesses them on the basis of the audit requirements. The screening organisations have cooperation agreements with the test coordinating gastroenterologists and Regional Coordinating Gastroenterologists, Regional Coordinating Pathologists and national expert officers. These officers are specialists from the relevant professional associations. Each screening organisation has concluded a cooperation agreement with specialists from the region to fill the RCG and RCP positions. The TCMDLs have a cooperation agreement with one of the screening organisations. They work nationally and are not tied to any region. The screening organisations report to RIVM-CvB on the execution and the findings of the audits once a year in accordance with a set template, with specific attention to matters that can optimise the screening programme.

Screening laboratories
The four screening laboratories are responsible for safeguarding their own quality systems. Additionally, the four screening laboratories execute a quality programme, specifically for the colorectal cancer screening programme. See the FIT Quality Assurance protocol for more information.

Quality platform
The four screening laboratories jointly participate in the quality platform for the purpose of ensuring uniform execution of the screening tests.

Quality platform core tasks

Core task:	Description:
Uniformisation of procedures	The quality platform ensures the creation and updating of protocols for the uniform practical execution of population screening activities. These form the foundation for the Standard Operating Procedures (SOPs) for the laboratories and are submitted to the screening organisations and RIVM-CvB. The protocols are managed by the screening organisations on the instructions of the quality platform.
Backup	The quality platform has a protocol for backup in the event of adverse events.
Monitoring execution	The quality platform monitors the execution of the screening tests (FIT analysis) by, among other things, discussing the results of verification samples, system performance and incidents.
Improving the quality of execution of screening tests	The quality platform discusses potential adjustments/improvements to screening tests (FIT analysis) and submits them to the screening organisations. After coordination, the platform drafts

	implementation plans for preauthorised adjustments/improvements.
Risk analysis	The quality platform discusses the main results and actions resulting from the individual prospective risk inventories carried out by the four screening laboratories.

5.4 Quality assurance of programme outcomes

5.4.1 Public values

The programme outcomes of screening programmes for cancer should fulfil the public values of quality, accessibility and affordability (see **Section 2.2.2** for more information on this). This is reported annually in the national monitor (see **Chapter 7** 'Monitoring and evaluation').

5.4.2 Monitoring of programme outcomes

One of the responsibilities of RIVM-CvB is to monitor the outcomes of the colorectal cancer screening programme. For the purpose of advising on this topic, RIVM appoints an expert group (or groups) and utilises the existing advisory structure of the programme commission and working groups (see **Chapter 12**).

RIVM-CvB core tasks

Core task:	Description:
Setting up advisory structure	RIVM-CvB is responsible for the appointment and agenda-setting of the programme committee, the Working Group on Quality, Capacity, Monitoring and Information Management (QCMI), the Working Group on Communication and Professional Development, and the expert group (or groups).
Monitoring	RIVM-CvB monitors the outcomes of the programme through a national monitoring programme and makes these results available to the public.
Improvement	RIVM-CvB identifies the options for improving the screening programme through, among others, the programme committee, working groups and expert groups, and monitoring and evaluation. RIVM-CvB ensures these matters are coordinated and that improvements are implemented by the appointed parties.
Coordination	RIVM-CvB ensures coordination with (boards of) professional organisations with regard to quality assurance and improvements.

6 Professional development

Many different professionals are involved in the colorectal cancer screening programme. They must all keep up to date on relevant information and developments in order to optimise the execution of the colorectal cancer screening programme. The professionals involved in the colorectal cancer screening programme must at least comply with the aspects of professional development as described in this chapter.

Professional development focuses on:
1. providing information on the content, organisation and process of the colorectal cancer screening programme;
2. providing information on the national agreements and quality requirements available to ensure that the colorectal cancer screening programme and the subsequent diagnostic testing are carried out uniformly and to a high standard nationwide; and
3. developing, enhancing and/or assessing new or existing knowledge and skills.

The above objectives are achieved by various means, such as information meetings and e-learning modules, newsletters and websites (for more information, see **Chapter 10** 'Communication and Information').

6.1 Professional development in general

Essentially, the responsibility for professional development lies with the individual professionals, their professional associations and employers. Individual professionals have a personal responsibility for their professional development and compliance with registration requirements, where applicable. Professional associations have a (legal) mandate to train/educate their members, based on applicable professional guidelines and standards. All organisations involved in the execution are responsible for the quality of the work carried out by their employees (see also **Chapter 5** 'Quality assurance').

For certain professional groups, additional training is offered or even made compulsory within the framework of the screening programme. Biennially updating the contents of the educational programmes is a shared responsibility of the parties involved and the quality review coordinators.

6.2 Professional development by professional group

6.2.1 Screening laboratory staff

Clinical chemists who participate in the execution of the screening programme are responsible for maintaining professional knowledge and experience by means of accredited annual training and refresher training and actively participating in (peer-to-peer) professional development. The clinical chemist responsible for the laboratory is registered in the register of the Netherlands Society for Clinical Chemistry and Laboratory Medicine (NVKC) (or has an equivalent registration) throughout the execution of the screening programme.

In addition, the laboratory should participate in circulation of control samples by the SKML, so that the quality of the laboratory can be assessed against the national standard.

6.2.2 Colonoscopy centres

Endoscopists must complete an admission procedure before they can work for the colorectal cancer screening programme. This admission process comprises three parts:

- Registration of 100 consecutive colonoscopies;
- Completion of three e-learning modules: 'Colonoscopy', 'Surveillance' and 'Genetic and hereditary colorectal cancer and anticoagulants'. These modules have been developed especially for endoscopists who wish to perform colonoscopies for the colorectal cancer screening programme; they also receive accreditation points for this purpose;
- A practical assessment.

This admission process is supervised and assessed by the TCMDL.

Nurses who assist during the endoscopy in the context of the screening programme must be in possession of the relevant qualifications (diplomas) for nursing and endoscopy nursing. They must be registered in the Individual Healthcare Professions (BIG) Register. They must also have a valid certificate of Basic Life Support+ (BLS+) or Advanced Life Support (ALS).

The intake is carried out by a qualified and competent staff member with the relevant expertise, who is registered in the BIG Register, such as a nurse, Nurse Practitioner, Physician Assistant or physician. A physician must be available for supervision and consultation.

Intake staff and endoscopy nurses may also follow the three e-learning modules if desired. However, they will not receive any accreditation points.

All admission and auditing requirements and information about professional development for the colonoscopy centres and endoscopists can be found in the Protocol for the admission and auditing of colonoscopy centres and endoscopists [in Dutch only]. This protocol describes the requirements according to which the RCG assesses the colonoscopy centres and endoscopists during the audits. If desired, the own results and performances are reported yearly (or quarterly) to the colonoscopy centres and individual endoscopists.

6.2.3 Pathology laboratories

Pathologists must successfully complete an assessment before they can work for the colorectal cancer screening programme. This assessment consists of an e-learning module. A second e-learning module must be completed within six months after admission.

This admission process is supervised and assessed by the RCP. All admission and auditing requirements and information about professional development for the pathologists and pathology laboratories can be found in the Protocol for the admission and auditing of pathology laboratories [in Dutch only]. This protocol describes the requirements according to which the RCP assesses the pathology laboratories and pathologists during the audits. Every three months the pathology laboratories receive reports about their individual performances concerning e.g. lead times and findings.

6.2.4 GP practices

The screening programme involves agreements that the GP and the GP assistants and practice nurse must be able to apply in contact with patients in connection with the colorectal cancer screening programme. RIVM-CvB, the screening organisations, the

Dutch College of General Practitioners (NHG) and the Dutch Association of Doctors' Assistants (NVDA) are responsible for the professional development of the GP practices. There is a Programme for Individual Continuing Education for GPs [in Dutch only]. The NHG Colorectal Cancer Screening Programme Practice Manual [in Dutch only] can also be used as training and refresher training material.

6.2.5 Screening organisation information line staff

Further education of information line staff is organised by the individual screening organisations on the basis of frequently asked questions and answers.

7 Monitoring and evaluation

Proper monitoring and evaluation of the execution of the screening programme is necessary in order to monitor the quality of the screening programme (for more information on quality assurance, see **Chapter 5**). This chapter provides insight into the way in which monitoring and evaluation of the colorectal cancer screening programme take place. It starts with a description of the indicators used to monitor and evaluate the colorectal cancer screening programme on the various aspects of public values (quality, accessibility and affordability). This is followed by a further explanation of the monitoring and evaluation process. The differences between monitoring and evaluation are shown in Table 7.1.

Table 7.1: characteristics of Monitoring & Evaluation

Monitoring	Evaluation
Periodic (annual)	Ad hoc (event driven) Periodic (every 4 years)
Standardised	Variable and standardised components
Indicators (predefined)	Questions (predefined)
Quantitative	Both quantitative and qualitative
Easy to calculate	Complex analyses/assumptions
Data already registered	Data often difficult to collect
Observational	Appraising
Quantitative overviews	Scientific methods
Identifying, directing, justifying, learning	Preparing, clarifying, directing, justifying, learning

7.1 Indicators

Within RIVM-CvB, indicators have been operationalised as (retroactively) measurable aspects of the provided screening and (its connection to) care. The Colorectal Cancer Screening Indicator Set was developed in order to uniformly implement the monitoring and evaluation of the colorectal cancer screening programme (here you can find the latest version [in Dutch only]). Each indicator is described according to a template based on the ECHI sheets of the European Core Health Indicators. To ensure that it is up to date, the set is checked and adjusted where necessary every five years and in the event of changes to the screening programme. The set of indicators can be applied at various aggregate levels so that indicators can be used at the national, regional (screening organisation) and local level (screening laboratory, pathology laboratory, endoscopy centre). The indicators are distributed across the entire care chain of the screening programme, subsequent diagnostic testing and further treatment. They can be subdivided into the public values (quality, accessibility and affordability) of national screening programmes.

7.2 Monitoring

Monitoring is a periodic activity focused on safeguarding and, if necessary, improving the execution processes within and outcomes of the colorectal cancer screening programme, and proper connection with subsequent care. Monitoring can take place at the national, local and regional level. In addition, there may also be short-cycle monitoring within a screening programme. In-depth analyses, such as cost-effectiveness studies, are performed by means of evaluations.

7.2.1 Monitoring at the national level

RIVM-CvB is responsible for national monitoring of the screening programme and subsequent care. The national monitor is provided annually by an external party (the monitoring party) on behalf of RIVM-CvB. RIVM-CvB uses the national monitor to monitor the quality of the colorectal cancer screening programme, to identify bottlenecks in the chain and elsewhere, to be able to make adjustments and also to account to the Ministry of Health, Welfare and Sport, the Health Care and Youth Inspectorate, the public and other partners.

For the national monitor, data is collected from the entire chain (screening programme and subsequent care). The defined national indicators provide information based on data routinely registered during execution. In order to facilitate monitoring of the screening programme, the organisations and professionals involved register and supply data to ScreenIT. From ScreenIT, the data is supplied to the data warehouse for screening programmes for cancer (DWH-BVOK; for more information see **Chapter 8** 'Data Management'). The organisations are also responsible for the quality of the supplied data. The monitoring party has access to the DWH-BVOK where the indicators and their numerators and denominators are ready for analysis.

The outcomes of the indicators in the monitor may indicate reasons for possible changes to the screening programme. An early warning may be detected if the outcome of the indicator:

- is compared over a number of years (trend); and/or
- is compared with the outcomes of e.g. other screening organisations or screening laboratories (benchmark); and/or
- is compared for different dimensions, such as age, gender, organisation, first versus follow-up screening, etc.; and/or
- is linked to and compared with a value, such as an early warning value, target value or standard (see **Appendix F** for definitions of standard, target and early warning value, comparison over time and benchmarking).

If these comparisons reveal unfavourable abnormalities, this will result in an action, such as a direct or indirect intervention or an evaluation.

The party providing the monitor publishes an annual report of the outcomes of the national indicators (the monitor). The most recent English version of the monitor is available from the RIVM-CvB website. RIVM-CvB discusses this with the national Working Group on Quality, Capacity, Monitoring and Information Management and the Colorectal Cancer Programme Committee. The working group and the programme committee advise RIVM-CvB on the interpretation of the results, the conclusions and any interventions and/or evaluations based on the outcomes of the monitor.

Monitoring party core tasks

Core tasks:	Methods:
Collecting data	Request data from DWH-BVOK administrator Contact with DWH-BVOK administrator
Data validation	Checking outcome level of indicators Contact with DWH-BVOK administrator in the event of unexpected outcomes
Data analysis	Calculate and analyse indicator outcomes Compare the outcomes with the early warning value, target value or standard, or over time
Reporting	The outcomes are presented in a concise monitoring report, a short

	and factual description of the results.
Making recommen-dations	Draw conclusions and make recommendations based on the presented results Discuss the results and recommendations in RIVM-CvB programme committee and working groups

7.2.2 Monitoring at the local and regional level

The screening organisations are responsible for monitoring the screening programme and subsequent care at the local (e.g. by laboratory) and regional (by screening organisation) level. The screening organisations should use the national set of indicators administered by RIVM-CvB, so that there are no differences at other aggregate levels (e.g. national versus regional). In addition, the screening organisations can also use their own indicators (e.g. for management information), which they manage themselves.

7.2.3 Short-cycle monitoring

When optimising or updating a programme, it is important to keep a close eye on developments within that programme (or parts thereof). Short-cycle monitoring is often used to monitor certain indicators more frequently than usual during the implementation phase or in the event of changes to the programme. This is done in order to be able to respond to any issues or unintended consequences in a timely manner.

For the colorectal cancer screening programme, a short-cycle monitor has been set up for the capacity of the colonoscopy centres. This short-cycle monitor is managed by the screening organisations.

7.3 Evaluation

A distinction can be made between national evaluation as a periodic activity – the epidemiological evaluation – and as a more incidental activity. The spectrum of topics addressed in evaluations encompasses both standard and variable items. Important standard items are effect evaluation (incidence/mortality reduction), a cost-effectiveness study, evaluation of informational products and in-depth analysis and interpretation of the outcomes of monitors across a specified multi-year period. These are often questions about which the monitor does not provide any information (indicators that are not available or, for example, why an indicator differs from previous years) and which are usually used for accountability purposes. Additional questions may also be answered. These can vary widely in terms of subject matter, but usually have their origin in a bottleneck or innovation.

RIVM-CvB assigns the mandate for the evaluation questions to an independent, expert contractor on a case-by-case basis.

The periodic evaluations are always carried out by the National Evaluation Team for Colorectal Cancer Screening (LECO), because these evaluation questions require a lot of knowledge (or prior knowledge).

The results of the evaluations are discussed in the relevant working groups, advisory groups and the colorectal cancer screening programme committee and may be published in scientific journals. In addition, a national evaluation of the screening programme [in Dutch only] is published every four years, containing the most important evaluations and findings.

In addition to the national evaluations on behalf of RIVM-CvB, the screening organisations also carry out evaluations based on the results of regional monitoring to further analyse differences in their regions. Where appropriate and in consultation with RIVM-CvB, the results are discussed in the Working Group on Quality, Capacity, Monitoring and Information Management. Where regional differences affect national policy, they are also discussed in the Programme Committee.

8 Data management

Data is registered, managed and exchanged as part of the execution of the colorectal cancer screening programme and subsequent health care. This includes (unique) personal details and test results. This chapter starts by describing the aims of registering and exchanging data. The applicable legislation and regulations, the ICT infrastructure and the structured recording of data are then discussed.

8.1 Aims

In executing the colorectal cancer screening programme, data is registered and exchanged for:

1. execution of the primary process: Data that professionals need in order to properly carry out their activities in the chain of care;
2. quality assurance of the primary process, including regional monitoring: Data that parties – such as screening organisations, professionals and reference function – need for this; and
3. national monitoring & evaluation: Data needed to calculate the indicators for monitoring of the screening programme and to be able to answer questions in the context of an evaluation.

Scientific research is not an aim of data collection. However, the data obtained with public funds should, in principle, also be made available for scientific research. The following considerations therefore apply to data from population screening for scientific research:

- Data processing must be carried out with due regard for the participants' say and the protection of their privacy.
- All data related to the colorectal cancer screening programme and the care chain concerns data obtained with public funds, and therefore must also be used to serve other public interests;
- Enrichment of data by linking to other relevant data sources is important and must be facilitated where possible.

For more information, see the web page Scientific research [in Dutch only].

8.2 Legal and regulatory aspects

National requirements apply to all parties involved in the execution of the colorectal cancer screening programme, based in part on relevant legislation and regulations such as the Medical Treatment Contracts Act (WGBO), the Healthcare Quality, Complaints and Disputes Act (Wkkgz), the Individual Health Care Professions Act (BIG Act), and the General Data Protection Regulation (GDPR). This includes agreements about access to data for the parties that may and must use this data, and a secure exchange of data between all parties providing data.

8.2.1 Agreements

When the colorectal cancer screening programme was introduced, a covenant on data exchange was drawn up and signed by the parties involved. The covenant provides transparency about the aim and principles of data processing in relation to the screening programme. It also describes the roles of parties in data collection and data management. In addition, the covenant contains agreements on how the contractor will obtain the data for the national monitor and evaluation from ScreenIT.

The agreements for the use of data are laid down in contracts between the parties involved. These contracts set out the roles, responsibilities and powers of authority of the parties with regard to the data. The contracts sets out the agreements concerning the registration of and access to data, and the exchange of data between different registration systems. This includes using and making data available for national monitoring of the colorectal cancer screening programme, national evaluation, and providing personal information and data for the purpose of scientific research.

Additionally, processing agreements have been drawn up between the screening organisations, the four screening laboratories and other relevant parties that need to use client or medical data for the execution of the primary process and quality assurance.

8.2.2 Privacy and objections

Individuals invited to take part in the screening programme must be informed about the registration, use and exchange of data, and should either give their explicit consent or be presumed to have given their consent for this, provided that they have been fully informed about the processing (registration, retention and exchange), can easily object and have not made use of that option to object. This is described in more detail for the screening programmes in the Policy framework for population screening for cancer. The invitees can find the national privacy regulations for the screening programmes at www.bevolkingsonderzoeknederland.nl/privacy [in Dutch only]. This is mentioned in the invitation leaflet.

8.3 ICT infrastructure

This section describes the applications and data streams related to the primary process, quality assurance and monitoring. More information about the applications can be found in **Appendix G**.

8.3.1 Exchange of data for the primary process

Data is registered and exchanged at various moments in the primary process of the colorectal cancer screening programme. The data streams within the primary process in relation to the ScreenIT information system are shown in Figure 8.1. As the first step, ScreenIT is fed with information from the Dutch Personal Records Database (*Basisregistratie Personen*, BRP). Based on this information, the screening organisations invite people to participate in the screening programme. There are various outbound and inbound processes for the planning, invitation and execution of the screening tests.

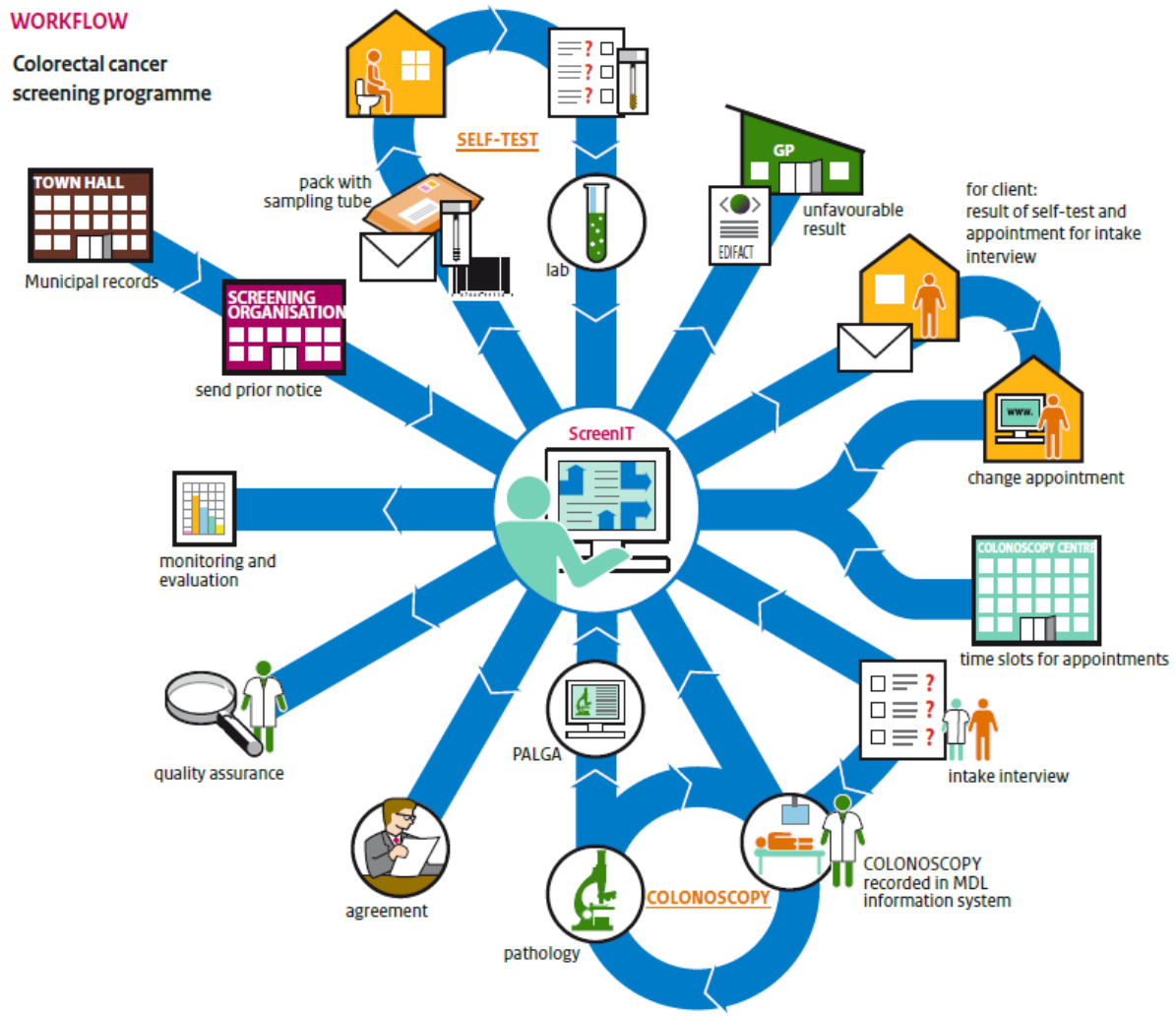

Figure 8.1: Data streams in the primary process

The participant receives the results of the FIT by mail and, in the event of an unfavourable result, an appointment for the intake for a colonoscopy. Invitations are based on the available time slots for intake appointments, which are indicated by the colonoscopy centres. These time slots are based on the available colonoscopy capacity, which is monitored by the screening organisations. In order to make the best possible use of the available capacity, the intake appointments are planned nationally in ScreenIT. In the event of an unfavourable result, the GP – if known – is also informed digitally. The report of the colonoscopy is recorded in the gastroenterology information system and the results are forwarded to ScreenIT. The pathology results are also sent to ScreenIT via PALGA, so that the findings of the screening programme can be monitored.

Clients can use their DigiD to access the client portal, a ScreenIT web portal, for example to file objections against various exchanges of data or to change an appointment.

8.3.2 Exchange of data for quality assurance

The data for regional monitoring and quality assurance for the screening organisations is primarily obtained from ScreenIT. The screening organisations have a reporting tool which can be used to display data from ScreenIT in standard reports. Information is also

available from ScreenIT and other systems (e.g. on finances and complaints), which the screening organisations and RIVM-CvB can use to monitor and safeguard the process. The reference function makes an important contribution to the identification of possible improvements in execution. In their audits, the coordinating professionals for independent reviewing of the quality of the screening programme (quality review coordinators) use data recorded in the context of the screening programme in order to test the quality requirements. The data streams used to determine the interval carcinomas can be found in the Interval Carcinomas Protocol [in Dutch only].

8.3.3 Exchange of data for national monitoring

The Data Warehouse for Cancer Screening Programmes (DWH-BVOK) was developed in recent years. Since 2019, indicators for the national monitoring of the colorectal cancer screening programme are obtained from the DWH-BVOK. Screening organisations provide data to the DWH-BVOK within the context of national monitoring. The data that can be obtained from the DWH-BVOK, for example by the monitoring party, is at an aggregate level and cannot be traced back to individual participants in the screening programme. RIVM-CvB has made agreements about what data will be supplied to the monitoring party within the framework of national monitoring. Further development of the DWH-BVOK for national monitoring and evaluation will take place in 2020.

In addition to being monitored nationally, the colorectal cancer screening programme is also monitored on a short-cycle basis. This data will be obtained through the ScreenIT reporting tool. The screening organisations will generate overviews for this purpose at the request of RIVM-CvB. This involves anonymous data.

8.4 Structured data registration

For a good exchange of data, it is important that the right data is recorded in a uniform, structured manner. Using the national indicator sets as a basis, data sets for the cancer screening programmes are made available. The data sets show which data must be recorded and by whom.

This data set has been developed on the basis of the indicators, in close consultation with the parties involved in various working groups and the Programme Committee. In the technical version of the data set, standardised (medical) terminology is used as much as possible, such as SNOMED CT and specific agreements from the field. The defined dataset is documented in Art-Decor. This online environment (Landing Page and technical datasets) [in Dutch only] contains the description of the dataset and the scenarios, the coding of the contents and the definition of the messages.

A governance structure [in Dutch only] has been designed for the management of the dataset. Each year, gastroenterologists, pathologists and other persons involved can request modifications to the dataset. An editorial board (chaired by the screening organisations) discusses and decides on these requests. In addition, it is important that RIVM-CvB is involved in the editorial board in connection with the possible impact of changes on the quality requirements and national indicators. The Dataset and messages governance memorandum [in Dutch only] describes the agreements and procedure used to manage the datasets and electronic messages from the screening programme.

The source codes of the ScreenIT software are publicly available at GitHub.

9 Handling of bodily materials

In the colorectal cancer screening programme, bodily material (faeces) is examined for the presence of blood. In addition, during a colonoscopy following an unfavourable FIT, polyps may be removed or biopsies may be taken for pathological examination (subsequent diagnostic testing).

Bodily material obtained in the colorectal cancer screening programme is or may – under certain conditions – be used for the purposes listed below:

1. Execution of the primary process: The assessment of the screening test;
2. Quality assurance of the primary process, such as verifications, circulation of samples, training of people involved;
3. Research in the context of quality improvement;
4. Further use for scientific research.

Participating men and women implicitly consent to performance of the screening test and quality assurance and training activities. If they object to these activities, they cannot take part in the screening programme.

The stool material remaining after testing and any activities in the context of quality assurance is destroyed, unless it is used in scientific research. Scientific research on bodily material obtained in the context of the screening programme will only take place with the explicit consent of the participant.

For the colonoscopy (including any pathology), a participant with a positive FIT result enters into a new treatment contract with the health-care institution where the subsequent diagnostic testing takes place. The handling of bodily material therefore falls outside the responsibility of the screening programme. The responsibility for the handling of bodily material therefore lies entirely with the health-care institution where the subsequent diagnostic testing takes place. This concerns handling of the bodily material (containers, paraffin blocks and sections) itself as well as the provision of information about this to the patient. This is subject to the policy of the relevant health-care institution with regard to bodily material. This policy is in line with current legislation, guidelines and codes of conduct in hospitals.

The memorandum Handling of bodily materials [in Dutch only] describes which materials can be used for which purposes and under which conditions. The memorandum will be updated in the future, in any case when the Control over Body Materials Act (*Wet zeggenschap lichaamsmateriaal*, Wzl) comes into force.

10 Communication and information

Communication and information are an essential part of the colorectal cancer screening programme. Various means of communication are used to inform the public, professionals and relevant organisations about the screening programme and any role they are expected to play in it. In addition, specific information is available for the target group for the screening programme; after all, people must be able to make informed decisions about whether or not to take part in the screening programme.

This chapter describes the target groups of communication, the communication resources and channels used, the principles that apply to each target group for communication, and how press inquiries, media attention and issue management are handled. The communication requirements defined for the cooperating parties are described in **Chapter 5** (quality assurance). For the sake of clarity, in this chapter the word 'communication' is used to refer to both communication and information.

10.1 Target groups

In the colorectal cancer screening programme, it is important to communicate with seven groups, namely:

- the target group for participation in the colorectal cancer screening programme: men and women aged 55 to 75 years;
- the actual participants in the colorectal cancer screening programme;
- the general public;
- professionals and organisations that work together in the screening programme;
- journalists (media/press/editorial staff);
- stakeholders (e.g. the Ministry of Health, Welfare and Sport as a commissioning client); and
- scientists/experts.

Communication with the first four target groups is described in more detail in this chapter. This is followed by a discussion of communication with regard to the media and issue management.

10.2 Communication resources and channels

The communication resources and channels used for each target group are shown in **Table 10.1**.

Table 10.1: Communication channels and resources for each target group

Target group / Communication resource or channel	Target group for participation	Participants	General public	Professionals, organisations
Letters with invitations and reminders	X			
Letters with confirmations and results		X		
Leaflets	X	X		
Instructions for stool sample test	X	X		
RIVM newsletters	X	X	X	X
Newsletters from the screening organisations	X	X	X	X
Visual material (photographs, videos, infographics, posters, animations, flowcharts)	X	X	X	X
Questions and answers	X	X	X	X
Presentations	X	X	X	X
Translations of basic information into English, Turkish and Arabic (depending on need)	X	X	X	
Fact sheets			X	X
Monitors, evaluations	X	X	X	X
Information lines of the screening organisations (telephone, website,[1] etc.)	X	X	X	X
RIVM website[2]	X	X	X	X
Social media accounts of RIVM and the screening organisations and webcare	X	X	X	X
Programme committee, working groups and expert groups of the screening programme				X
National meetings on screening programmes and/or specific groups	X	X		X
Presentations/participation in meetings/conferences/fairs	X	X	X	X
Communication resources of third parties	X	X	X	X

[1] www.bevolkingsonderzoeknederland.nl
[2] www.bevolkingsonderzoek-darmkanker.nl

10.3 Principles for each target group

The following principles apply to the communication about the screening programme with all the various target groups (as referred to in Section 10.1):

- The communication complies with the national quality requirements laid down in

the communication framework [in Dutch only] for all screening programmes;
- The Working Group on Communication and Professional Development, professional groups and relevant parties (in and outside the field) are involved in the development of communication resources. Additionally, the resources are presented to the target group;
- Clear and unambiguous information is jointly provided by professional groups, relevant parties (in and outside the field) and RIVM-CvB;
- RIVM-CvB is ultimately responsible for the content of the national information materials;
- The screening organisations are responsible for the distribution of information materials to the target group (i.e. the potential participants);
- The communication resources are designed in the government house style and meet the requirements of accessibility;
- Activities carried out to increase familiarity with and acceptance of the screening programme are coordinated by RIVM-CvB with relevant field parties.

If applicable, specific principles are defined for the target groups.

10.4 Communication with the target groups for participation in the screening programme

The goals related to communication with the target groups for participation in the screening programme are:
- Informing the target groups about the screening programme, such as informing about the primary process and the advantages and disadvantages;
- Informing the target groups about the developments/innovations in the screening programme;
- Responding to questions/comments from participants,

so that the target groups are informed about the screening programmes and invitees are able to choose whether or not to participate.

The government enables citizens to make informed decisions about participation in the screening programmes. This means that the information is:
- appropriate (geared to the target group);
- objective (advantages and disadvantages are mentioned);
- relevant (information on the right topics);
- offered in layers. This means that essential information for making an informed decision and participating in the screening programme is offered in writing. More in-depth information is presented on the website; and
- easy to understand (written at the B1 language level and supported visually where necessary).

10.5 Communication with the actual participants in the screening programme

The goals related to communication with participants are:
- Informing participants about all phases of the programme (from the invitation to the eventual result);
- Instructing participants (through instructions for the stool test);
- Informing participants about the results of the screening programme and possible subsequent steps;
- Ensuring good information during referral from the colorectal cancer screening programme to diagnostic testing in the health-care setting. This includes providing information about the possible consequences for the annual deductible (excess) in the event of follow-up testing or examination;
- Responding to questions/comments from participants and reassuring them if

necessary;
so that participants carry out the stool test correctly and are informed about the results of their test and about the subsequent steps to be taken.

In the communication with participants, the screening organisations are responsible for distributing national information materials to participants and for sending all letters (from invitation to results). The screening organisations are also the first point of contact for participants if they have questions or comments about the screening programme.

RIVM only communicates directly with (potential) participants on the initiative of the particular persons themselves (i.e. if they address questions, comments or complaints to RIVM). The frequently asked questions are then placed on the website.

10.6 Communication with the general public

The goals related to communication with the general public are:
- Informing the public about the screening programme;
- Keeping the public aware of developments;
- Responding to questions/comments about screening programmes,

so that the public is aware of the screening programmes and developments.

There are no specific principles for communication with the general public. Frequently asked questions are placed on the website.

10.7 Communication with professionals

The goals related to communication with professionals are:
- Informing professionals about the screening programmes (aims, background, including screening perspective, relevant developments);
- Informing professionals about and involving them in the national quality requirements/frameworks concerning their tasks within the screening programme;
- Ensuring (helping, facilitating) that professionals are able to provide the target group and the general public with good, clear and unambiguous information.

The following principles apply to communication with professionals:
- RIVM-CvB is responsible for the development and provision of communication about basic information relating to the screening programmes (aims, backgrounds, including screening perspective, etc.) and about national requirements/frameworks;
- screening organisations and professional associations are responsible for informing professionals and regional parties about national requirements/frameworks, what they mean for the activities of the professionals;
- in principle, RIVM-CvB does not actively communicate with individual professionals and regional parties about the basic information, national requirements/frameworks. This is done by the screening organisations and the professional associations.

10.8 Media and issue management

The cancer screening programmes receive regular media attention. The various cooperating parties may all be approached with press inquiries or contacting the press themselves.

RIVM-CvB wants to provide clarity to all parties about how to handle press inquiries or contacting the media/press themselves. A distinction can be made between:

1. press inquiries received by RIVM-CvB or other parties;
2. reports in the media about a development in or publication about a screening programme;
3. reports from the relevant or cooperating organisations themselves; and
4. an adverse event or crisis that threatens the continuity or credibility of the colorectal cancer screening programme, and which may result in political and/or social unrest.

10.8.1 Press inquiries

Press inquiries come in via the press officers of RIVM's Communication & Documentary Information Unit. Press inquiries that come in directly or indirectly in any other way must also be sent to the press office, or the press office is informed about the press inquiry. Press inquiries may concern answers, interviews, reactions and the like. Substantive experts are consulted about answering press inquiries. Depending on the type of question, the press officer answers questions from the press, or the press officer engages the substantive expert or spokesperson. If the question contains a political component, the press officer coordinates with the press officers of the Ministry of Health, Welfare and Sport, and the substantive expert of RIVM-CvB consults with the policy officers of the Ministry of Health, Welfare and Sport.

Press inquiries received by other parties involved are forwarded to the RIVM press office, which can advise on how best to respond and inform the right people. Press inquiries received by suppliers who have a contract with the screening organisations are discussed with the screening organisations. The screening organisations always notify the RIVM press office or the RIVM-CvB communications advisor and the programme coordinator.

10.8.2 Media reports

RIVM-CvB monitors offline and online media and social media on a daily basis. This ensures that reports about the screening programmes and trends are quickly identified. RIVM-CvB responds to questions and comments on social media (webcare). In the event of an issue (with a major impact) in the media or social media, RIVM-CvB informs the following parties:

- the director of the screening organisations charged with the communications portfolio;
- members of the programme committee;
- members of the Working Group on Communication & Professional Development and other working groups, if applicable;
- RIVM press office;
- policy officer of the Ministry of Health, Welfare and Sport.

10.8.3 Reports and media attention by parties involved in the screening programmes themselves

If organisations involved in the screening programme wish to publish news reports related to a screening programme themselves, they should inform RIVM-CvB of the content prior to publication and coordinate with RIVM-CvB on timing. Parties that develop a product (e.g. a scientific article) on behalf of RIVM-CvB and wish to draw attention to it should inform RIVM-CvB before seeking media attention. Suppliers contracted by the screening organisations inform the screening organisations in accordance with applicable contractual requirements. Who takes on the initial and

subsequent communication is decided in consultation. RIVM-CvB:

- determines whether there is a political component to the reports, which requires the Ministry of Health, Welfare and Sport to be informed. RIVM-CvB also assesses whether the timing of the report is politically favourable or unfavourable relative to the other screening programmes;
- informs relevant parties about reports early on;
- works with parties to determine whether a positive message can be reinforced by also deploying other parties or placing a news report on their own website;
- works with parties to determine whether additional background information is required, for example in the form of preparing and answering additional 'frequently asked questions'.

10.8.4 Adverse event or crisis

An adverse event or crisis can become visible from the primary process, regular media or social media. In the event of an incident or adverse event that requires scaling up to RIVM-CvB, RIVM-CvB is in charge of external communication. For scaling-up criteria, see **Chapter 11** 'Risk management'.

Depending on the adverse event or incident, a spokespersons guideline is drafted. A spokespersons guideline describes the situation, cause, solution, tactics, message and spokespersons. It is important to establish contact between relevant parties as quickly as possible, to ensure that the spokespersons guideline is clear and that agreements can be made regarding who speaks about what topics. Generally, the following distribution applies:

- The Ministry of Health, Welfare and Sport addresses matters pertaining to political choices or the role of the Minister;
- screening organisations or other partners address matters pertaining to the execution of the primary process;
- RIVM-CvB addresses other matters, unless decided otherwise.

If necessary, a crisis team is formed and the RIVM's general crisis communication plan comes into effect.

11 Risk management and complaints provision

Quality assurance, monitoring and evaluation of the colorectal cancer screening programme follow largely from the identification of the risks of disrupting the continuity of the screening programme. The organisation of the colorectal cancer screening programme is a complex network of cooperation and dependency. Risks to the continuity and quality of the screening programme may exist in various forms and phases of all processes (primary and supporting).

This chapter is about the risk management system and the complaints provision.

11.1 Risk management system (RMS)

The risk management system of the colorectal cancer screening programme is the entirety of powerful measures designed to ensure that the colorectal cancer screening programme can be executed as intended as quickly as possible after an undesirable situation (deviation) or that anticipated and unanticipated risks may be reduced or prevented. The system provides tools for dealing with risks (risk management).

The risk management protocol [in Dutch only] describes the procedure for preventing and dealing with deviations (minor deviations, incidents and emergencies), or the risk thereof, in the colorectal cancer screening programme. A distinction is made here between deviations that do not require scaling up, deviations that require scaling up to RIVM, deviations that require notification of the Health and Youth Care Inspectorate (IGJ) and deviations that require notification of the Data Protection Authority.

The method described in the protocol contributes to safeguarding the high quality of the screening programme (for more information on quality assurance, see **Chapter 5**), management of risks and potential risks, and providing insight into the decision-making process and responsibilities in the event of incidents and emergencies. The protocol also addresses crisis communication (see also **Chapter 10** 'Communication and Information').

The risk management protocol applies to all organisations involved in the management and execution of the colorectal cancer screening programme (see **Chapter 4**) and the suppliers. Risks and deviations can occur in all the activities mentioned.

11.2 Complaints provision

Complaints made by participants may also represent a risk to the colorectal cancer screening programme. Health-care professionals involved in executing the colorectal cancer screening programme are subject to the Health-care Quality, Complaints and Disputes Act (*Wet kwaliteit, klachten en geschillen zorg*, Wkkgz). Under this Act, they are required to draw up a written procedure for the effective and accessible handling of complaints involving them. The health-care provider must bring the procedure, as well as any changes to it, to the attention of its clients and client representatives in an appropriate manner (Section 13.4 of the Wkkgz). As part of the complaints procedure, the health-care provider has a complaints officer who meets the requirements (Sections 13.5 and 15 of the Wkkgz). The health-care provider decides on a complaint within six weeks (Section 17 of the Wkkgz) and is affiliated with a recognised dispute settlement authority (Sections 18.1 and 19.2 of the Wkkgz).

A complaint about a particular aspect of the execution of the chain is submitted to, and

handled by, the health-care provider with which the complainant has entered into a treatment contract at that time. In addition, complaints may relate to national policy and frameworks established by the Ministry of Health, Welfare and Sport and RIVM-CvB. These complaints are handled under the responsibility of the Ministry of Health, Welfare and Sport and RIVM-CvB, respectively. Within the framework of uniformity, complaints received by the screening organisations, the Ministry of Health, Welfare and Sport and/or RIVM Executive Board are shared anonymously with regard to the nature of the complaint and the manner in which it is handled.

If a participant has complaints about the colorectal cancer screening programme or the execution thereof, it must be clear where he or she can file those complaints. The complaints procedure [in Dutch only] of the screening organisations describes how this is arranged in the screening programme.

12 Programme organisation and consultation structures

On the instructions of the Ministry of Health Welfare and Sport, RIVM-CvB manages the execution of a number of national prevention programmes. These programmes are executed by specific executive organisations, health-care institutions and professionals. RIVM-CvB makes use of the knowledge and experience of these organisations and professionals in order to properly carry out its directive task. To this end, RIVM-CvB has established programme committees, working groups and expert groups to advise RIVM-CvB on the organisation and execution of these national programmes. See Figure 12.1 for the consultation structure for the colorectal cancer screening programme.

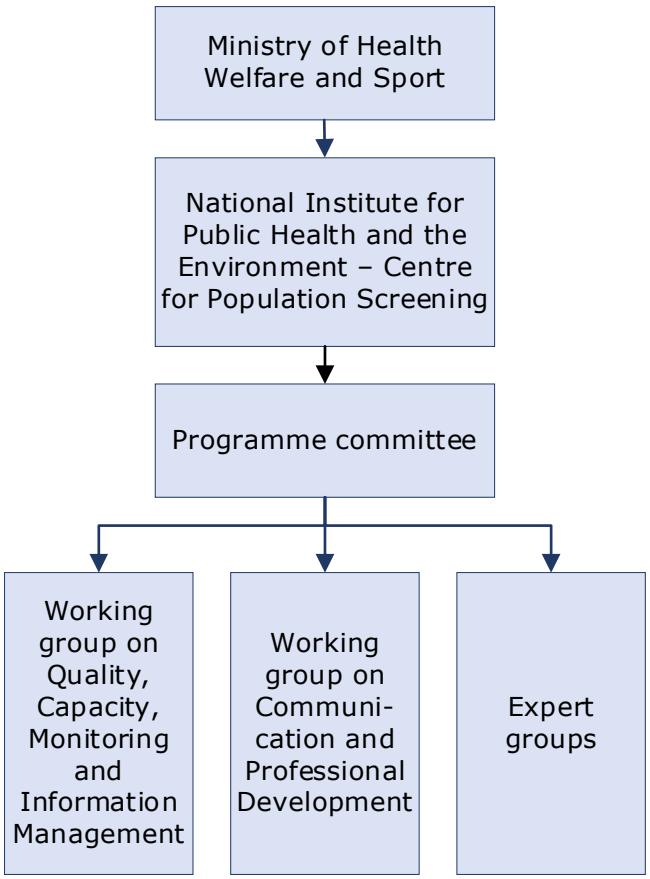

Figure 12.1: Consultation structure of the colorectal cancer screening programme

12.1 Programme committee and working groups

The programme committee and the working group are appointed by RIVM-CvB. The members are experts representing relevant professional groups, organisations and areas of expertise involved in the execution of screening and diagnostic testing for and treatment of colorectal cancer. They have authority in their field or network and relationships with the field of work. They represent the target group independently and are not bound by any instructions or mandate. Appendix H provides an overview of the participants in the programme committee and its working groups.

The programme committee and working groups meet structurally about three times a year. The programme committee and working groups are chaired by an independent technical chair. The programme coordinator acts as the secretary of the programme committee. A programme employee from RIVM-CvB focusing on quality acts as the secretary of the working group on Quality, Capacity, Monitoring and Information Management (QCMI). A communication programme employee from RIVM-CvB acts as the secretary of the working group on Communication and Professional Development.

12.1.1 Programme committee

The programme committee is the official advisory body for RIVM-CvB. The committee is tasked with identifying and discussing developments with regard to the programme and to advise on the design and execution thereof. If desired, the advice can extend to the entire chain from screening to diagnostics and treatment.

A recommendation by the programme committee may be both substantive and procedural in nature. The committee may provide advice on request or voluntarily. If a recommendation by the committee relates to a matter that does not fall within the remit of RIVM-CvB, the committee discusses how to deal with it. The programme committee also monitors the coherence of the recommendations from the various working groups and expert groups.

The programme committee's recommendations relate mainly to:

- communication,
- registration, evaluation and monitoring,
- training and professional development,
- programme quality,
- new developments and innovations,
- research related to the programme,
- logistics and processes within the programme,
- data management,
- execution of the programme relative to the goals,
- connection with the follow-up process,
- communication with the field, and
- appointment of working groups.

12.1.2 Working group on Quality, Capacity, Monitoring and Information Management

Enhancing the quality of the execution of the colorectal cancer screening programme is a key aspect of the activities of the QCMI working group. This translates to tasks that include:

- Discussing national areas for attention in the primary process and making proposals for improvements;
- Discussing the annual national monitor and identifying topics for further analysis/evaluation questions;
- Advising on adjustments based on annual monitoring and other relevant information;
- Advising on national quality requirements and indicators;
- Providing input and advising on updates to the items concerning quality and monitoring and evaluating of the Execution Framework;
- Advising on declaring parts of the guidelines applicable to the colorectal cancer screening programme.

- Sharing opportunities to improve the quality of the screening programme and advising on improvement proposals by parties that may affect the national screening programme and the associated public values;
- Monitoring the capacity of the execution of the screening programme and the subsequent diagnostic testing;
- Advising on the interpretation and coherence of quality control, monitoring and evaluation and, where relevant, considering this in relation to innovation and improvement and the necessary adjustments to the national ICT system;
- Identifying and listing points for attention/bottlenecks in the availability of data for the primary process, quality assurance, monitoring and evaluation and connection to the follow-up process and making proposals for solutions;
- Discussing relevant ICT procedures and sharing knowledge in these procedures, also in the case of bottlenecks.

The working group draws up recommendations for the programme committee on substantive and procedural matters relating to quality, monitoring, evaluation and information management. At the request of the programme committee, recommendations can be specified in further detail and rolled out under the supervision of the working group in cooperation with the parties involved.

12.1.3 Working group on Communication and Professional Development

This working group focuses on communication with and the provision of information to the target group, the general public and professionals, as well as on further developing the expertise of professionals. This translates to tasks that include:

- Advising on how targeted (e.g. letters and leaflets), untargeted (e.g. websites and magazines) and oral information and communication in the care chain to the target group and the general public can be improved.
- Advising on how targeted (e.g. newsletters) and untargeted (e.g. websites) communication aimed at professionals can be improved.
- Providing input for updating information and communication to the target group and professionals and advising on this.
- Discussing annual national activities/areas for attention that need to be communicated with the target group, professionals and the general public, and advising on the strategy and execution to follow.
- Coordinate communication activities about the colorectal cancer screening programme, which parties undertake or wish to undertake towards their target group or those they represent.
- Coordinate activities in the area of expertise relevant to the colorectal cancer screening programme undertaken by parties in their role.
- Providing input and advising on updates to the communication, information and professional development aspects of the Execution Framework.
- Advising on and, where necessary, elaborating and testing the desired organisation of the information and communication to the target group, professionals and the general public based on a vision on information and communication.
- Advising on how communication and information can be optimised in dialogue with the target group, the general public and professionals.

The working group draws up recommendations for the programme committee on substantive and procedural matters relating to information, communication and professional development. At the request of the programme committee, recommendations can be specified in further detail in information/communication

resources and rolled out under the supervision of the working group in cooperation with the parties involved.

12.2 Expert groups

Expert groups are consulted on an ad hoc basis. Depending on the form and the subject, the programme coordinator or a programme employee acts as the secretary and an external chair may or may not be selected. The members of the expert groups are selected on the basis of the necessary expertise geared to the subject for which they are being consulted at that time. Where appropriate, external scientific parties or foreign parties may be asked to participate.

Appendix A Definitions

Note: The definitions are shown as they apply in the colorectal cancer screening programme.

Adenoma	A benign tumour of the epithelial cells. Adenomas of the large intestine are often referred to as 'polyps', as many of them manifest as bulges in the intestinal mucosa. This terminology is not entirely correct, as other abnormalities in the intestinal wall can also present as polyps and not all adenomas are polypoid. Adenomas can also be 'flat or 'deep'.
Abnormalities	Polyps, adenomas and carcinomas found during the colonoscopy.
Medical history	(Intake interview about) the patient's past medical history, use of medication and/or relevant circumstances.
Anticoagulant	Medication to prevent the formation of blood clots. It causes the blood to clot more slowly.
Auditing	Periodic inspection or quality inspection of an organisation or professional as part of the quality assurance of the processes and activities to be carried out.
Screening programme	Medical examination or testing offered to people who do not have any symptoms, aimed at early detection (or exclusion) of an illness, a hereditary predisposition for an illness, risk factors that increase the risk of illness, or carrier status of a predisposition that can lead to illness in the individual's offspring.
Storage conditions	Conditions under which the FIT is to be stored.
Biopsy	A small piece of tissue removed for examination (diagnostic testing).
Test tube	See FIT.
Client portal	Web interface enabling the participant in the screening programme to access his/her data in ScreenIT, e.g. to reschedule an intake appointment or to request a new stool test.
Colon	Part of the large intestine. Consists of the ascending colon, transverse colon, descending colon and sigmoid colon.
ScreenIT	Working name of the national IT system for the colorectal cancer screening programme.
Colonoscopy	Visual examination of the large intestine.
Crisis communication	Communication at the time of a crisis or emergency: a situation that is or may be a threat to the continuity or credibility of the screening programme and which involves a risk of social unrest.
CT colonography	Radiological examination of the large intestine.
Colorectal cancer	Malignant tumour in the (large) intestine.
Participants	Men and women who have sent a faecal sample for the colorectal cancer screening programme.
Professional development	Training activities and transfer of information aimed at ensuring that all professional target groups involved in the execution have the knowledge and skills needed to carry out their tasks within the existing frameworks of the colorectal cancer screening programme.
Diagnostic testing	Further medical examination or testing after a positive FIT result.

Large intestine	Part of the intestines. Consists of the caecum, appendix, colon and rectum.
Target group	Men and women who are eligible for an invitation to take part in the screening programme.
Referred participants	Men and women who have been referred for further diagnostic testing after a positive FIT result.
Endoscopist	The specialist who performs the colonoscopy.
Evaluation	Considering specifically whether and to what extent the objectives of the policy are achieved. Evaluation may relate to the design, process or effects of the screening programme. Evaluation is a more incidental activity. See also Monitoring.
Exclusion criteria	Criteria on the basis of which a client or patient is excluded for a particular examination, test or treatment.
Genetic predisposition	Increased risk of a disease or condition occurring within the family.
Faecal sample	Small amount of faeces needed for a screening test. See also FIT.
FIT	FIT stands for Faecal Immunochemical Test: a test that shows small amounts of blood in stool material, which are not visible to the naked eye.
FIT laboratory	Laboratory that analyses FITs.
False negative	The result of the screening test is negative, while the disease is present. If the test has many false-negative results, this means that the test is not very sensitive (has a low sensitivity).
False positive	The result of the test is positive, while the disease is absent. If the test has many false-positive results, this means that the test is not very specific (has a low specificity).
Informed decision	People should be able to make a well-considered decision to participate in a screening programme. This is called an 'informed decision'. They need information in order to be able to weigh up the advantages and disadvantages of participation for themselves. The final decision whether or not to participate must be in line with their standards and values.
Invitee	An individual who has received an invitation to take part in the screening programme.
Favourable (negative) FIT result	No blood was found in the stool material. Within the framework of the population survey, there is no need for further testing or examination.
Histological material	Tissue material collected during the colonoscopy and processed for pathological diagnosis.
Human haemoglobin (Hb)	A protein found in human blood.
Indicators	Measurable aspects of the screening programme, which are used to monitor and evaluate the colorectal cancer screening programme at the level of individual organisations and professionals, at the regional level and at the national level.
Informing	Informing the participant in the screening programme about the results of the screening test.
Packing centre	Organisation responsible for putting together, packing and sending the invitation packs with the self-sampling test kits (FIT

	kits) and keeping the materials needed for this in stock.
Intake	Interview prior to examination, testing or treatment, in which the medical history is taken and the patient is informed about the examination, test or treatment.
Interval cancer	Colorectal cancer diagnosed after a negative screening test and before the next round of screening.
Clinical chemist	Laboratory specialist working in a clinical-chemical laboratory and responsible for the clinical-chemical analysis of blood or other bodily material.
Short-cycle monitoring	See Monitoring.
Quality assurance	The entirety of measures to ensure the quality of the process, including national frameworks, protocols, guidelines and procedures, audits, inspections and monitoring and evaluation.
Quality requirements	Requirements related to the quality of execution, implementing parties and materials of the colorectal cancer screening programme in order to guarantee the correct, uniform and good quality execution of the screening programme. See also Indicators.
National quality requirements	The requirements which organisations, implementing parties or the execution must satisfy in order to guarantee uniform quality nationwide.
Landing page	Technical overview of the releases of the datasets.
Bodily material	Human material from a participant in the screening programme.
Gastroenterologist	Physician who specialises in the diagnosis and treatment of diseases of the digestive organs.
Monitoring	A more or less continuous activity aimed at safeguarding and improving the execution of the screening programme and subsequent diagnostic testing. See also Evaluation.
Negative colonoscopy result	No advanced adenomas or carcinomas were found during the colonoscopy. However, polyps or non-advanced adenomas may have been found, which may result in an individual being included in a surveillance programme. See also Abnormalities.
Uninterpretable	When an FIT cannot be assessed, for example when a test tube is broken or filled incorrectly.
Unfavourable (positive) FIT result	A result of a test that deviates from the established standard. Specifically in the case of the FIT, this concerns a test result higher than 47 µg/g. In the case of an abnormal FIT result, a participant is referred for a colonoscopy. An abnormal rash does not necessarily mean that the participant has cancer. This can only be determined through further diagnostic testing (colonoscopy).
Stool test	See FIT.
Pathology laboratory	Medical speciality that investigates the causes and nature of diseases, including the examination of tissues for diagnostic purposes.
Polyp	A proliferation of the mucous membrane of the large intestine.
Polypectomy	Colonoscopic removal of a polyp.
Positive FIT result	The FIT analysis has demonstrated blood in the stool material;

	further testing or examination is necessary.
Positive colonoscopy result	Advanced adenomas or carcinomas were found during the colonoscopy. See also Abnormalities.
Radiology	Medical speciality that deals with locating the nature and location of a disease, injury or condition by means of rays or waves. See also CT colonography.
Reagents	Substances needed for chemical analyses.
Rectum	The terminal part of the intestine.
Reference function	Coordinating professionals for independent reviewing of the quality of the screening programme (quality review coordinators) who carry out periodic independent quality assessments on behalf of the screening organisations, geared to the inspections of their professional group and in accordance with the national quality requirements of the screening programme.
Risk management	The entirety of decisive measures designed to ensure that the screening programme can be executed as intended as quickly as possible following an emergency or that anticipated and unanticipated risks may be prevented.
Sedative	See Sedation.
Cooperation agreement	Agreement between screening organisations and a FIT laboratory or colonoscopy centre for the execution and quality assurance of the activities within the framework of the colorectal cancer screening programme and subsequent diagnostic testing.
Screening	See Population screening.
Screening laboratory	See FIT laboratory.
Screening organisation	The five screening organisations (*Bevolkingsonderzoek Noord, Bevolkingsonderzoek Midden-West, Bevolkingsonderzoek Oost, Bevolkingsonderzoek Zuid* and *Bevolkingsonderzoek Zuid-West*) are responsible for the regional execution, coordination and quality assurance of the screening programmes for breast cancer, cervical cancer and colorectal cancer. In the colorectal cancer screening programme, the screening organisations are also responsible for quality assurance of the subsequent diagnostic testing.
Sedation	Administration of anti-anxiety and soothing medication during a procedure or examination. See also Analgesia.
Selection	The selection of the target group to be invited for the screening programme based on age, using the Dutch Personal Records Database (*Basisregistratie Personen*, BRP).
Sensitivity	The frequency with which a test produces a positive result when a certain disease or risk factor is actually present, i.e. the number of true positive test results divided by the total number of persons who have the disease in question (true positives plus false negatives). A sensitive test produces few false negative results.
Specificity	The frequency with which a test produces a negative result when a certain disease or risk factor is actually absent, i.e. the number of true negative test results divided by the total number of persons who do not have the disease in question (true negatives

	plus false positives).
Stage	The extent of a cancer process. This is generally assessed on the basis of three characteristics (TNM): tumour size (T), spread to nearby lymph nodes (N) and spread (metastasis) to other organs (M).
Anticoagulant medication	See anticoagulant.
Surveillance	Periodic monitoring for colorectal cancer and precancerous lesions by means of colonoscopy in people from high-risk groups.
Technical dataset	Summary of data to be registered for the purposes of the screening programme.
Timeslot	Period within which an intake appointment for a colonoscopy can be made.
Invitation pack	Envelope with an invitation letter, leaflet, self-sampling test kit (FIT), instructions for use, bag and return envelope.
Execution framework	Document describing how the colorectal cancer screening programme and subsequent health-care should be carried out, ensuring that it proceeds effectively and within policy and legal frameworks.
Follow-up examination or testing	See Diagnostic testing.
Referral	If the screening test produces an unfavourable result, the participant is referred for follow-up testing.
Five-year survival rate	The chance that a person is still alive five years after discovery of the disease.
Inspection	Peer review of the health-care process on location.
Past history	The patient's relevant medical records and other data. See also Medical history.
Predictive value	The positive predictive value is the proportion of patients with a positive test result who actually have the disease. The negative predictive value is the proportion of patients with a negative test result who actually do not have the disease.
WBO permit	Permit within the framework of the Population Screening Act (WBO)
Self-sampling test kit	See FIT.

Appendix B Abbreviations

GDPR	General Data Protection Regulation (*Algemene Verordening Gegevensbescherming, AVG*)
BRP	Personal Records Database (*Basisregistratie Personen*)
CKBU	Committee on Quality and Professional Practice (*Commissie Kwaliteit en Beroepsuitoefening*) of the NVvP
CT (colonography)	Computed tomographic (colonography)
DCRA	Dutch Colorectal Audit
DICA	Dutch Institute for Clinical Auditing
DRCE	Dutch Registration of Complications in Endoscopy
DWH-BVOK	Data warehouse for cancer screening programmes (*Datawarehouse voor de bevolkingsonderzoeken naar kanker*)
FSB	Population Screening Facilities Cooperation (*Facilitaire Samenwerking Bevolkingsonderzoeken*)
GR	Health Council of the Netherlands (*Gezondheidsraad*)
FIT	Faecal Immunochemical Test
IGJ	Health and Youth Care Inspectorate (*Inspectie Gezondheidszorg en Jeugd*)
IKNL	Netherlands Comprehensive Cancer Organisation
IT	Information Technology
QCMI (Working Group)	Working Group on Quality, Capacity, Monitoring and Information Management (*Werkgroep Kwaliteit, Capaciteit, Monitoring en Informatiehuishouding*)
LECO	National Evaluation Team for Colorectal Cancer Screening (*Landelijk Evaluatieteam voor Colorectaal kanker bevolkingsonderzoek*)
LFMF	National Monitoring FIT Official (*Landelijke Functionaris Monitoring FIT*)
LHV	Dutch Association of General Practitioners (*Landelijke Huisartsen Vereniging*)
Gastroenterologist	Gastroenterologist
MGZ	Department of Public Health and Social Medicine (*Maatschappelijke Gezondheidszorg*) (Erasmus MC)
Ministry of VWS	Ministry of Health, Welfare and Sport
NFU	Netherlands Federation of University Medical Centres (*Nederlandse Federatie van Universitair Medische Centra*)
NHG	Netherlands College of General Practitioners (*Nederlands Huisartsen Genootschap*)
NIV	Dutch Society of Internal Medicine (*Nederlandse Internisten Vereniging*)
NKR	Netherlands Cancer Registry (*Nederlandse Kankerregistratie*)
NVDA	Dutch Association of Doctors' Assistants (*Nederlandse Vereniging van Doktersassistenten*)
NVKC	Netherlands Association of Clinical Chemistry and Laboratory Medicine (*Nederlandse Vereniging voor Klinische Chemie en Laboratoriumgeneeskunde*)
NVMDL	Dutch Association of Specialists for Gastroenterology-Hepatology

	(*Nederlandse Vereniging van Maag-Darm-Leverartsen*)
NVvH	Dutch Association of Surgeons (*Nederlandse Vereniging voor Heelkunde*)
NVvP	Dutch Society of Pathology (*Nederlandse Vereniging voor Pathologie*)
NVvR	Radiological Society of the Netherlands (*Nederlandse Vereniging voor Radiologie*)
NVZ	Dutch Hospital Association (*Nederlandse Vereniging van Ziekenhuizen*)
NZA	Dutch Healthcare Authority (*Nederlandse Zorgautoriteit*)
PA	Pathology
PALGA	The nationwide network and registry of histo- and cytopathology in the Netherlands (*Pathologisch Anatomisch Landelijk Geautomatiseerd Archief*)
RCG	Regional Coordinating Gastroenterologist (*Regionaal Coördinerend MDL-functionaris*)
RCP	Regional Coordinating Pathologist (*Regionaal Coördinerend Patholoog*)
RIVM-CvB	National Institute for Public Health and the Environment - Centre for Population Screening (*Rijksinstituut voor Volksgezondheid en Milieu – Centrum voor Bevolkingsonderzoek*)
ScreenIT	National information system for screening programmes
SKML	Dutch Foundation for Quality Assessment in Medical Laboratories (*Stichting Kwaliteitsbewaking Medische Laboratoriumdiagnostiek*)
SLA/DAP	Service Level Agreement/Dossier of Agreements and Procedures
SNOMED CT	A medical standard for the documentation and coding of medical records
SOW	Statement of Work
TCG	Test-coordinating Gastroenterologist (*Toetsingscoördinator MDL*)
V&VN	Dutch Nurses' Association (*Verpleegkundigen & Verzorgenden Nederland*)
VKGN	Netherlands Association of Clinical Genetics (*Vereniging Klinische Genetica Nederland*)
WBO	Population Screening Act (*Wet op het bevolkingsonderzoek*)
BIG Act	Individual Healthcare Professions Act (*Wet op de beroepen in de individuele gezondheidszorg*)
WGBO	Medical Treatment Contracts Act (*Wet op de geneeskundige behandelingsovereenkomst*)
Wkkgz	Healthcare Quality, Complaints and Disputes Act (*Wet kwaliteit, klachten en geschillen zorg*)
ZBC	Independent treatment centre (*zelfstandig behandelcentrum*)
ZN	Umbrella organisation of health insurers in the Netherlands (*Zorgverzekeraars Nederland*)
ZonMw	Netherlands Organisation for Health Research and Development (*Nederlandse organisatie voor gezondheidsonderzoek en zorginnovatie*)

Appendix C Overview of frameworks, guidelines and protocols

This appendix contains an overview of the national frameworks relating to cancer screening programmes. In addition, it contains an overview of the national guidelines that apply to the colorectal cancer screening programme or parts thereof. Also listed are the frameworks and protocols drawn up specifically for the colorectal cancer screening programme.
All documents are in Dutch.

Chapter	Document	From whom	Applicable to whom
National frameworks			
4, 8, App. D	Legal framework - exchange of information from cancer screening programmes	RIVM	All parties involved
5, App. D	Policy Framework for Population Screening for Cancer	RIVM	All parties involved
10	Communication framework	RIVM	All parties involved
Guidelines for professional groups			
4, 6	NHG Colorectal Cancer Screening Programme Practice Manual.	NHG	In its entirety: General Practitioners
4	National PALGA Colon Biopsy Protocol-TEM(1)	PALGA	In its entirety: Pathology Laboratories
Chapter	**Document**	**From whom**	**Applicable to whom**
Quality documents specific to the screening programme			
	Execution Framework for the Colorectal Cancer Screening Programme	RIVM	All parties involved
4, 8	Technical dataset for pathology	SO	All parties involved
4, 8	Technical dataset for colonoscopy	SO	All parties involved
4, 11	Complaints procedure	SO	Screening organisations
4, 11 App. E	Risk Management Protocol	RIVM	All parties involved
5, App. E	FIT Quality Assurance Protocol	SO	Screening laboratories
5, 6, App. E	Protocol for Admission and Auditing of Colonoscopy Centres and Endoscopists	SO	Colonoscopy centres and endoscopists
4, 5, 6, App. E	Protocol for Admission and Auditing of Pathology Laboratories.	SO	Pathology laboratories
7, App. D	National indicator set	RIVM	All parties involved
8	Covenant on data exchange	RIVM	
8	Memorandum Dataset and messages governance	SO	
8	Landing page for the Colorectal Cancer Screening Programme	SO	All parties involved that must register data
8, App. E	Interval Cancer Protocol	SO	All parties involved
9	Memorandum Handling of bodily materials	RIVM	All parties involved

Appendix D National quality requirements screening organisations and screening laboratories

The national quality requirements for the screening orqanisations and screening laboratories are only available in Dutch, and can be found in the Dutch framework for the execution of the colorectal cancer screening programme.[4]

[4] The Protocol Selecting and auditing FIT-laboratories, including quality requirements, will be published early 2021. From then on, the quality requirements in the Framework will be expired.

Appendix E Reference function tasks

Reference task	Execution*
1) Assessment of equipment/implementing parties	
Admission of/requirements for implementing parties	Before entering into an agreement or registration, the TCG assesses whether the implementing party meets the national quality requirements for admission to execution of the screening programme and further diagnostic testing. Based on the assessment, the reference function issues a recommendation to the screening organisation that will conclude the contract or registration for execution. The LFMF assesses whether screening laboratories meet the quality requirements. The quality requirements for the laboratories (FIT) are included in this Execution Framework. The RCGs assess whether colonoscopy centres and endoscopists meet the national quality requirements. Only colonoscopy centres and endoscopists that meet the national quality requirements receive referrals from the screening programme. The RCPs assess whether pathology laboratories meet the quality requirements. If they do, they can be placed on the list of laboratories to which endoscopists can send their material for assessment. See also the Protocol for Admission and Auditing of Colonoscopy Centres and Endoscopists), the Protocol for Admission and Auditing of Pathology Laboratories and the FIT Quality Assurance Protocol.
Admission of equipment / test materials	The invitation for tenders sets out the quality requirements for the screening equipment. The quality review coordinators advise on this.
2) Monitoring the quality of execution	
Audits/inspections by the reference function	Carrying out quality audits at the implementing parties of the colorectal cancer screening programme. See the Protocol for Admission and Auditing of Colonoscopy Centres and Endoscopists, the Protocol for Admission and Auditing of Pathology Laboratories and the FIT Quality Assurance Protocol. These audits are geared to the inspections of the relevant professional group as much as possible. Reporting takes place to the screening organisations.
Monitoring the quality of execution	With regard to the FIT laboratories and the pathology laboratories, sample panels or control samples are circulated in order to assess the quality and uniformity of the execution of the activities. The circulation of control samples is carried out by SKML. At the FIT laboratories, there is daily monitoring of FIT results, weekly monitoring of turnaround times and annual monitoring of interval cancers (see Interval Cancer Protocol). For the colonoscopy, there is annual monitoring of interval cancers, and annual benchmark reporting for pathology. Reporting takes place to the screening organisations and RIVM-CvB (annually in the QCMI working group). Peer consultation (via a quality platform for the FIT laboratories) and benchmarking take place in all three bodies.

3) Professional development	
Induction and training programmes	Endoscopy is a regular procedure, but performing endoscopies within the screening programme requires an e-learning course to be taken. The assessment of removed tissue is also a regular procedure. The FIT is an objective assessment, which does not require training.
Retraining and further education	The quality review coordinators are involved mainly in stimulating and facilitating professional development. They also contribute to this if necessary. The quality review coordinators for colonoscopy organise quality review meetings for endoscopists. The quality review coordinators for pathology organise quality review meetings for pathologists to discuss difficult preparations.
4) Analysis of incidents/emergencies	
	The Risk Management Protocol includes a limited description of the role of the reference function. The quality review coordinator is the first point of contact in the event of an emergency.
5) Advising	
	All quality review coordinators play a role in advising with regard to information management. This has to do with having access to the right data for quality control.
	All quality review coordinators have an advisory role with regard to national and international developments, opportunities for improvement, the adjustment of quality requirements and targets, and answering knowledge questions from politics and society. The quality review coordinators hold periodic peer-review meetings to discuss experiences and cases.

* All documents are in Dutch

Appendix F Definitions of the terms: standard, target value and early warning value, comparison over time and benchmarking

Some principles of use:

1. There is a hierarchy of professionalism and 'strictness': standards (calling to account, settling), target values (learning, motivating), early warning values (expressing concern). All lead to a certain intervention if the value is exceeded, which can range in hierarchy from a serious conversation, further evaluation, an action plan for improvement to reporting a problem to the inspectorate.
2. We will only develop a 'standard' for an indicator if it concerns a critical process within the execution and if we want to actively link an intervention to deviations from the standard.
3. It must be clear which parties are responsible if a standard, target value or early warning value is not met. This can be found in the description of the indicators. Several parties can be responsible simultaneously.
4. Quality requirements, standards, target values and early warning values are dynamic and are reviewed periodically and adjusted if necessary, especially in the event of changes to the programme.
5. Standards, target values and early warning values are explicitly not intended to be used primarily to judge the executive organisations. They are intended to be used as control instruments within the whole range of agreements and requirements.

Standard

Goal: To ensure that the programmes meet the requirements regarding the public values of quality, accessibility and affordability.
Definition: A minimum or maximum outcome of an indicator that has been shown to be feasible through monitoring, or is supported by literature (article and/or report).
Points for attention:

- Standards are usually linked to indicators for critical processes within the programme. For example, indicators are formulated on the basis of quality requirements if the execution of the programme is at risk. In that case, the quality requirements are usually the standard for the indicator;
- Failing to meet the standard has consequences for the executive party ('comply or explain'). Actions such as evaluation research and a step-by-step plan for improvement are possible interventions;
- IGJ often uses a different definition of 'standard' than the one used by RIVM-CvB, namely "a culpable error and/or culpable damage to health." Not all deviations from standards (RIVM-CvB definition) meet this definition, and therefore not all of them are reported to the IGJ.

Target value

Goal: To improve the programmes by making them meet higher requirements with regard to public values.
Definition: An achievable value of an indicator that is desired within an agreed time frame and gives direction to the outcome of an indicator to be achieved.
Points for attention:

- Setting targets concerns an effort related to the execution;
- Concrete activities are linked to the target value in order to achieve the value within an agreed time frame. Prioritisation of activities is necessary in time, and

execution depends on costs/resources in relation to benefits. Therefore, the target value must also be realistic;
- Target values cannot be developed until we know what is realistic or achievable (through monitoring or previous pilots).

Early warning value
Goal: Early identification of a possible deviation and/or risk in order to be able to make prompt and proactive adjustments.
Definition: A value of an indicator that emits a warning signal where the expected value for critical processes in the execution may be exceeded.
Points for attention:
- Early warning values can be developed if no standard or target value can be set;
- Early warning values are particularly important in large change processes where there is a great deal of uncertainty about the outcome of certain indicators;
- Early warning values can be temporary.

Comparison over time
Not every indicator requires a standard, target or early warning value. The outcomes of the indicators can also be compared over time for trend analysis or relative to each other (benchmarking).

Benchmarking
Instead of comparison over time, outcomes of indicators can also be compared to each other (e.g. between health-care providers or regions) (benchmarking).

Appendix G Applications

ScreenIT
In ScreenIT, the registration systems and associated databases for the three different screening programmes are separated. In addition, there is a generic database, where, for example, the Personal Records Database provides the data of individuals to be invited, which can then be used by the three individual parts of ScreenIT.

The data in ScreenIT is the responsibility of the screening organisations that also manage ScreenIT. ScreenIT is subject to strict access and security requirements, both for the authentication of users and for the set-up of the system components. Depending on a person's role in the screening programme, he/she has more or less rights in ScreenIT to view and edit certain information.

The screening organisations have registered ScreenIT with the Data Protection Authority. The administrative organisation of ScreenIT (FSB) is certified according to the ISO27001 and NEN7510 standards for information security. An external GDPR audit was also successfully completed. This included a data protection impact assessment (previously called a privacy impact assessment). In addition, a Data Protection Officer has been appointed, who is known to the Data Protection Authority.

The screening organisation, FSB and other relevant parties will not retain data longer than necessary for the purpose for which it was obtained and may be used.

ScreenIT is financed by the Ministry of Health, Welfare and Sport through RIVM-CvB.

Data Warehouse for Cancer Screening Programmes
The Data Warehouse for Cancer Screening Programmes (DWH-BVOK) was developed to have a central role in processing and calculating the indicators for cancer screening programmes by means of an automated process. The data linked from the screening and diagnostic process is stored at an anonymised and aggregated level. In particular, it provides results for national monitoring and, as necessary, for evaluation. Scientific research is not facilitated by the DWH-BVOK.

The DWH-BVOK was developed and is managed by IKNL. The DWH-BVOK is financed by the Ministry of Health, Welfare and Sport.

PALGA
PALGA (the nationwide network and registry of histo- and cytopathology in the Netherlands) consists of a database with all pathology results (even if no abnormalities have been found) and a computer network for data exchange with all pathology laboratories (about 58) in the Netherlands.

The data in the central system form the basis for the national cancer registry and for the evaluation and monitoring of the screening programmes. This data supports patient care and can be used for scientific research. The pathology laboratories are responsible for the data in the local databases. Laboratories must give individual permission to 'enable' their part of the database to be linked to another database, including ScreenIT.

The PALGA database does not contain any personally identifiable information. Personal data is already pseudonymised in the laboratory. After to the PALGA database by the laboratory, the personal details are pseudonymised for a second time (by a trusted third party).

PALGA is financed by the Ministry of Health, Welfare and Sport.

NKR
The NKR (Netherlands Cancer Registry) is a nationwide database with data of all cancer patients, from diagnosis to death, regardless of the treatment location. This includes information about diagnostic testing, tumour characteristics and initial treatment. The data is collected in the hospitals by specially trained IKNL data managers on the basis of information in the medical file.

The identification of the cancer diagnosis is sent to IKNL via PALGA, among other means. The database is used for scientific (epidemiological) research, clinical studies and research into the quality of health-care. IKNL reports the data from the NKR to hospitals, regional oncology networks and comprehensive cancer networks, health-care institutions, health-care professionals, patient organisations (health-care domain), researchers (public domain) and the Ministry of Health, Welfare and Sport and the National Health Care Institute (*Zorginstituut Nederland*) (political domain).

IKNL regularly produces overviews based on data in the cancer registry and publishes on topics such as incidence, survival and prevalence. This is published in professional journals and on www.iknl.nl.

The NKR contains data at the personal level. Data encryption ensures that data that is stored or sent is encrypted first. Two-factor authentication is required to log in. The NKR works by means of an opt-out system. Patients can inform IKNL if they do not want their data to be included in the NKR.

IKNL is financed mainly by the Ministry of Health, Welfare and Sport. Other sources of funding include grants from the Dutch Cancer Society (KWF) for trial support and research, and from ZonMw for improvement projects.

DICA
The DICA (Dutch Institute for Clinical Auditing) is an independent institute that carries out clinical quality registrations with the aim of improving quality, transparency and reducing costs in health-care. DICA originated in the workplace, for and by specialists, and facilitates them with information as an independent body. Registrations are started on the initiative of the scientific associations. Nearly 100% of hospitals and an increasing number of independent treatment centres take part in the DICA registrations.

MRDM (DICA's IT partner and hospital data processor, in the context of DICA registrations) is the information processor, needed for the DICA registrations. MRDM processes the patient data in such a way that DICA only receives coded (pseudonymised) data. DICA cannot trace this information back to individual patients.

The colorectal cancer screening programme cooperates with DICA (more precisely the Dutch Colorectal Audit, DCRA) in the context of quality assurance and monitoring and evaluation. DICA is financed by ZN.

Appendix H Programme committee and working groups

An overview of the participants in the programme committee and its working groups is only available in Dutch, and can be found in the Dutch framework for the execution of the colorectal cancer screening programme.