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

FRAMEWORK FOR THE EXECUTION OF THE DUTCH BREAST CANCER SCREENING PROGRAMME

2021

Colophon

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Synopsis

Population screening for breast cancer consists of a chain of actions which begins with the invitation sent to the target group, and moves on to the connection with the subsequent stage in the healthcare system. 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 breast cancer screening. This is essential for the provision of optimal screening to the target group. The 'Framework for the execution of breast cancer population screening' describes who is responsible for the execution of breast cancer population screening together with the applicable rules and procedures. This report is written for all (medical) professionals involved in screening, including radiologists, 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 breast cancer population screening. Where relevant, the report refers to other related policy documents.

The framework for the execution of breast 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, breast cancer, quality, execution

Publiekssamenvatting

Uitvoeringskader bevolkingsonderzoek borstkanker

Het bevolkingsonderzoek borstkanker 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. 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 borstkanker' beschrijft hoe en door wie het bevolkingsonderzoek borstkanker moet worden uitgevoerd, en welke afspraken daarvoor gelden. Het Uitvoeringskader is geschreven voor alle (medisch) professionals, zoals de M(B)B'er, de radioloog en medewerkers van de screeningsorganisaties.

Het 'Uitvoeringskader bevolkingsonderzoek borstkanker' 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, borstkanker, screening, kwaliteit, uitvoering

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

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1 Introduction

1.1 Aim and scope of the Execution Framework

This Execution Framework describes how the breast 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 breast cancer screening programme, subsequent diagnostic testing and treatment/follow-up;
- quality assurance, monitoring and evaluation of the screening programme.

Suppliers of products used in the breast 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 Breast 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, some extra information can be found.

2 Breast cancer and the screening programme

This chapter starts with a description of the clinical picture of breast 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 breast cancer screening programme are also included. Finally, facts and figures on the screening programme are briefly mentioned.

2.1 Clinical picture of breast cancer

Breast cancer involves a malignant tumour in the breast. Breast cancer occurs mainly in women, but men can also get breast cancer. However, men are not included in the target group of the breast cancer screening programme.

Breast cancer can be divided into two types of tumours: non-invasive and invasive.

- Non-invasive (or 'in-situ') breast cancer concerns tumours that are initially confined to the mammary glands or glandular structures of the breast. Here, the cells do not grow through the wall of the mammary glands (a 'non-infiltrating' tumour). This usually concerns ductal carcinoma in situ (abbreviation: DCIS). Because the tumour cells have not or have not yet grown into the surrounding breast tissue, which contains blood and lymph vessels, there is not yet any risk of lymph node metastases or metastases elsewhere in the body. In the case of DCIS, 'microcalcifications' or 'calcium specks' are often visible on breast X-rays. These occur when the cancer cells in the glands get so crowded that some of them die and then calcify. Microcalcifications do not always indicate DCIS; they can also have a benign cause.
- Invasive breast cancer involves tumours that grow into the surrounding tissue. The cancer can then metastasise through the lymph nodes or the bloodstream.

Of all breast tumours, 75-80% originate in the milk ducts of the mammary gland (ductal carcinoma). In 10-15% of breast tumours, the tumour develops in the mammary glands and usually spreads throughout the breast (lobular type). The remaining 5-15% of breast tumours concern various, less common tumours.

2.1.1 Incidence / prevalence

Breast cancer is the most common form of cancer among women in the Netherlands. Each year, approximately 15,000 women in the Netherlands are diagnosed with invasive breast cancer and approximately 2,330 women with in-situ breast cancer. The average age at diagnosis is approximately 62 years. The risk of a woman developing breast cancer at any time during her life is 10-13%.(Source: NKR figures). Approximately 3,300 women die from the consequences of breast cancer every year. The survival rate for breast cancer is determined largely by the stage at which it is diagnosed. Of patients with stage I breast cancer, 99% are still alive after 5 years, whereas patients with stage IV (metastatic) breast cancer have a 5-year survival rate of 28% (Source: NKR figures).

For more information about breast cancer, see the national information leaflet about the breast cancer screening programme, the Fact sheet on the breast cancer screening programme or the websites www.borstkanker.nl or www.kwf.nl/borstkanker, www.kanker.nl/borstkanker or www.thuisarts.nl/borstkanker [Dutch only].

2.2 The breast cancer screening programme

The aim of the breast cancer screening programme is to reduce the mortality rate by detecting breast cancer early on, before women have symptoms. Early detection often offers more options in terms of the available treatment methods.

2.2.1 History of the screening programme

In the Netherlands, the introduction of a national screening programme for breast cancer started in 1988. By the end of 1996, the necessary capacity had been created to screen all women aged 50-69 by means of mammography once every two years. From 1998, the target group was expanded to include women up to 75 years of age. See **Chapter 3** 'Primary process' for information on how the breast cancer screening programme is currently set up.

2.2.2 Principles of the breast cancer screening programme

The execution of the breast 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 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, 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

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

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 breast 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.

2.2.4 Advantages and disadvantages of the breast cancer screening programme

The breast cancer screening programme has advantages and disadvantages. An important advantage is that participation in the programme reduces the chance of dying from breast cancer. Women who take part in the screening programme regularly are half (50%) as likely to die from breast cancer as women who do not take part. Thanks to the screening programme, breast cancer can be detected and treated at an early stage. This reduces the chance of metastases. In addition, the treatment may be less intensive and the chance of healing is greater.

There are also disadvantages. The screening does not provide complete certainty. Of every 100 cases of breast cancer, 25 cases are not detected by the screening programme.

In addition, overdiagnosis and overtreatment occur. It has been calculated that for every 1,000 women who take part in the screening programme, an average of four women are unnecessarily diagnosed with breast cancer and unnecessarily treated. However, at this time, it is not possible to determine beforehand to which women this applies.

Finally, women who turn out not to have breast cancer are also referred. Of every 1,000 women screened, 6 women are diagnosed with (early-stage) breast cancer and 14 women are referred (unnecessarily in retrospect) for further examination for what turns out to be a benign abnormality or no abnormality at all.
This average is higher for women participating in the programme for the first time. In retrospect, this results in unnecessary psychological and physical stress for the women concerned.

2.2.5 Facts and figures on the breast 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 breast cancer screening programme fact sheet [in Dutch], which contains the most important key figures.

3 Primary process of the breast cancer screening programme

This chapter describes the primary process of the breast cancer screening programme, including subsequent care (diagnostic testing, subsequent treatment and follow-up). A population 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 the breast cancer screening programme, participants with a BI-RADS 0, 4 or 5 result will be referred to regular health care. In each screening programme, the transition from health care back to screening takes place at some point (see Figure 3.1). The intention is that the normal invitation schedule is followed again from that time.

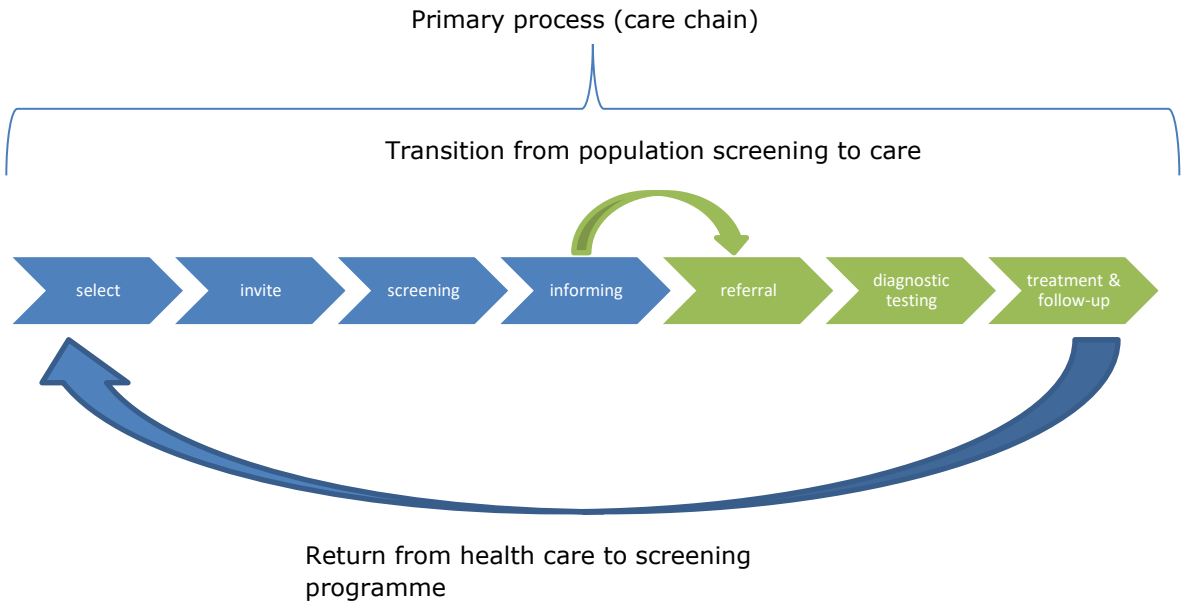


Figure 3.1. Diagram of phases in the primary process of the screening programmes (blue) and subsequent health care (green).

3.1 Phases in the primary process

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.

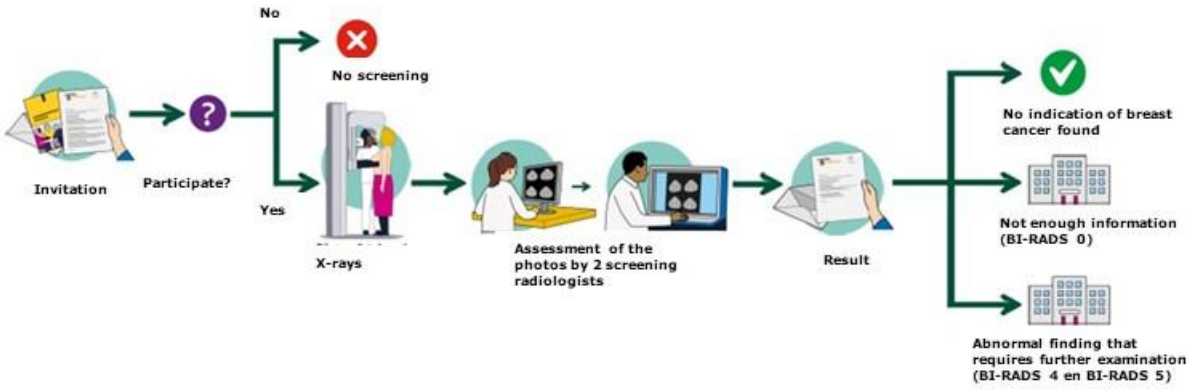


Figure 3.2. Diagram of breast cancer screening programme

3.2 Selection and invitation

Every two years, women aged 50 to 75 years are invited to take part in the screening programme. 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. Women who were referred to the hospital in the last screening round receive a letter asking them whether they want to participate in the screening programme.

The resulting target group is invited by the screening organisation. Some women receive an invitation with a date and time, and some receive an open invitation for which they can schedule their own screening appointment. The invitation letter includes information material, a questionnaire and a form that the woman can use to opt out of the screening programme once or permanently. Opting out permanently requires the woman's signature. The invited woman can change the date and time of the screening test. This can be done by telephone or via the websites of the screening organisations.

The invited woman can respond in three possible ways:
1. The woman takes part in the screening programme;
2. The woman opts out for this round;
3. The woman opts out permanently. In this case, the invitations for all subsequent rounds will be blocked. The woman can cancel the opt-out later if she likes.

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

If the invited woman does not respond, the screening organisation sends a reminder. The woman can then again respond in one the three ways described above. If the woman fails to respond again, no further action is taken by the screening organisation. The woman is invited again two years later, either with the date and time of the screening test, or with an open invitation. If she fails to respond to the invitation and the reminder again, she will receive an 'open invitation' in future. In this open invitation, the client is asked to contact the screening organisation herself to schedule an appointment.

Women who were referred in the previous round will receive an 'advance suspect letter' prior to the invitation, in which they are given the following options:
1. Op out once because they are receiving treatment.

2. Make an appointment to take part in the screening programme.

In Box 3.3, a number of specific situations are explained, for women with a breast implant and/or a medical device, women with disabilities and transgenders.

Box 3.3: Specific situations

Women with a breast implant and or a medical device/implant.
Women with a breast implant and/or a medical device/implant in the breast area (e.g. a pacemaker) are asked to contact the screening organisation. On request, women with a breast implant will then receive additional information about breast implant, on the basis of which they can decide whether to participate. Women with a medical device/implant are advised to wait at least six months after placement of the device/implant. More information about this can be found on the website of the screening organisations.

Women with disabilities
Women with disabilities who use a wheelchair are asked to contact the screening organisation. For women with disabilities, a separate appointment is made and a telephone questionnaire is used to determine whether the mobile unit is a suitable location. If the mobile unit is not suitable, the suitability of a static unit will be considered. The policy of the breast cancer screening programme aims to ensure that women with disabilities are, as much as possible, treated in the same way and examined according to the same quality criteria, and that this takes place in the same controlled and monitored environment as women who are able to be examined in a mobile or static screening unit. Therefore, in exceptional cases only, a mammogram may be taken at a health-care location in the vicinity, at the expense of the screening organisation. The X-rays taken in the hospital are assessed by a radiologist in the hospital. The woman receives the results from the hospital. The radiologists forward the results to the screening organisation so that the next invitation – if applicable – can again be sent on time by the screening organisation. The Dutch Society of Pathology (NVvR) already communicated this policy to hospital radiologists in the autumn of 2018. However, there are still a few points to be sorted out and organised. As this is still being worked on, this policy will not be finalised until all matters have been arranged.

Transgenders
In principle, transgender men who have registered a change of gender and transgender women who have not yet registered a change of gender will not or no longer receive an invitation for the breast cancer screening programme. If they do qualify for breast cancer screening and are between 50 and 75 years of age, they can contact their GP themselves for a referral to the hospital for a mammogram. When making an appointment, the client must indicate that the hospital bill is to be sent directly to the client, after which the costs can be claimed from the screening organisation. Other transgenders receive an invitation for the screening programme.

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

3.3 Screening

In most cases, the screening examination takes place in mobile screening centres. One or more static screening centres have been set up in each region. The examination is carried out by a radiographer (*Medisch Beeldvormings- en Bestralingsdeskundige*, *Medisch Beeldvormer* or Mammolaborant). A Mammolaborant has followed an in-service training programme to perform mammographic examinations independently). The woman reports to the radiographer, who verifies that the questionnaire is complete. During the examination, at least two images (mammograms) are taken of each breast in two different directions(mediolateral oblique (MLO) and craniocaudal (CC) views). Besides these four standard images, additional images may be taken. After the X-rays have been taken, the radiographer in the screening programme checks whether the images are technically suitable for proper assessment. If they are not, new X-rays are taken immediately. The radiographers look at the photos and mark any suspicious areas for assessment by the screening radiologists.

If a woman indicates that she has symptoms relating to the breasts – prior to or during the screening – the woman can still participate in the screening programme. The radiographer will make it clear to the woman that she needs to make an appointment with her GP to discuss her symptoms, regardless of the results of the screening programme. The radiographer has or has experienced symptoms (without differentiating according to medical relevance). If necessary, the GP refers the woman for further (indicative) examination.

The mammograms are assessed by two specially trained screening radiologists independently of each other, and assigned a BI-RADS (Breast Imaging Reporting and Data System) code. If the woman has already had mammograms taken in a previous screening round, these images will be compared with the new mammograms. If there is no consensus on the assessment result between the two assessing screening radiologists, the second radiologist assesses the mammogram again and can then choose between 'agreeing with the first interpretation' or 'upgrading' it. He or she cannot downgrade it. In the latter case, the mammogram is placed on an arbitration list. The arbitration list is assessed by a third radiologist, who first assesses it independently before seeing the assessment of the first two radiologists.

3.3.1 Secondary findings

It is possible that, while taking or assessing the mammogram, the radiographer or screening radiologist detects something that was not specifically being sought. This is called a secondary finding. This could concern: enlarged lymph nodes, loose wires from a pacemaker or ICD, or a leaking or ruptured breast implant; see Box 3.4 for more information.

Box 3.4: Secondary findings

Policy regarding enlarged lymph nodes
Enlarged lymph nodes are usually caused by an infection or damage to the hand or arm and are not a reason for referral for possible breast cancer. In exceptional cases, screening radiologists may see a lymph node which they think could eventually be seriously damaging or life-threatening. They then report this to the GP and register this contact with the GP and the reason for it in ScreenIT. The GP discusses this with the client.

Loose wires from a pacemaker or ICD
When a pacemaker is replaced, sometimes the old wires cannot be removed and are left behind. Loose wires from a pacemaker therefore do not need to be reported to the GP. If the woman has a pacemaker/ICD and is experiencing symptoms related to it, she should report this to her GP or cardiologist.

Leaking or torn breast implant
Breast implants do not last a lifetime. Checking implants is the responsibility of the woman herself and that of the plastic surgeon. Mammography, the examination applied in the screening programme, is not the right examination method for detecting problems with a breast implant. A possible tear and/or leak that is sometimes visible on the mammogram is not reported to the GP. In exceptional cases, the screening radiologists may decide to report a finding to a GP after all.

3.4 Informing and referral

The screening organisation sends the woman the results and the advice in writing within ten working days after the screening examination. There are four possible test results:

- No indication of breast cancer found (BI-RADS 1/2, no abnormal findings or a benign finding);
- The X-rays do not clearly show whether there are any abnormalities. A follow-up examination is needed in order to achieve a result (BI-RADS 0);
- Abnormal finding that requires further examination (BI-RADS 4/5, suspicious for malignancy but not typical, highly suggestive of malignancy).
- A proper assessment is not possible: this occurs occasionally if insufficient breast tissue is visible due to breast implants. These women are advised to contact their GP if they notice any symptoms or changes to their breasts.

If there is an abnormal finding or if the X-rays do not provide sufficient information to make a proper assessment, the screening organisation will send the result and the referral advice to the relevant GP practice two days before sending the result to the screened woman. The general practitioner also receives information in the form of the BI-RADS coding concerning the degree of suspicion. Since 1 July 2017, GPs have been advised to refer women with a BI-RADS 0 result to a hospital radiology department for additional imaging, while women with a BI-RADS 4 or 5 result are referred to a breast care clinic (*mammapoli*). The GP practice aims to inform the woman about the results before she receives the results letter. The GP practice consults with the woman about which hospital she will go to for further examination and refers the woman. The GP practice reports the referral to the screening organisation (NHG Standard for Breast Cancer).

3.5 Diagnostic testing, treatment & follow-up

3.5.1 Diagnostic testing in hospital

Women with a suspected malignancy (BI-RADS 4/5) can have an appointment made at the breast care clinic, while women with a BI-RADS 0 result can initially have additional imaging performed at the radiology department in a hospital of their choice[2], with 24-48 hours.

The maximum waiting time for the first appointment at the breast care clinic is one week (www.soncos.org). Screening organisations are responsible for providing the GP with information for the referral.

3.5.2 Treatment & follow-up

Treatment may follow, depending on the diagnosis. After treatment, the woman will be monitored (followed up) by the hospital for at least five years. After this monitoring period, the woman may participate in the breast cancer screening programme again. This is based on the recommendation of the health-care professional responsible for monitoring her at that time. Women who have opted out of the screening programme permanently must request an opt-out cancellation form from the screening organisation in order to be able to participate again. The opt-out can also be cancelled by telephone.

[2] The reason for this alternative routing for women with a BI-RADS 0 result is that in more than half of the cases, additional non-invasive imaging (mammogram and/or ultrasound) is sufficient to establish that no further treatment/examination is necessary. The number of false positives among BI-RADS 0 results is considerable. A fast BI-RADS 0 process minimises the psychosocial consequences for these women and is more efficient.

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 breast cancer screening programme and subsequent health care. The parties participating in the breast cancer screening programme are jointly responsible for the functioning of the entire 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, etc., of the breast cancer screening programme according to which these tasks and responsibilities 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 breast cancer screening programme, but not in the primary process.

Phases: / **Parties involved:**	Select-ion	Invi-tation	Screen-ing	Infor-ming	Referral	Diag-nostic tes-ting	Treat-ment & follow-up
Invitee or participant	•	•	•	•	•	•	•
Screening organisation	•	•	•	•			
Screening radiologist			•				
GP practice				•	•		
Hospital						•	•

Figure 4.1. Parties involved in the execution of the primary process

4.1 Role of the invitee or participant

The leaflet enclosed with the invitation for the primary test allows the women in the target group to make an informed decision about whether to participate in the breast cancer screening programme. The woman is responsible for deciding whether or not to take part based on the information provided. If she participates, the woman is responsible for keeping the appointment, filling in the questionnaire and visiting the screening centre. The woman undergoes the screening and receives the test result, after which action has to be taken (in the case of 'abnormal findings' or if 'the X-rays do not provide enough information to make an assessment') or not (in the case of 'no suspicion'). If the woman decides not to take part in the screening programme, she is responsible for opting out. If this concerns a one-off opt-out, this can be done via the client portal, the information number or by email. A permanent opt-out can be registered via the client portal or by filling in, signing and sending the enclosed form. Finally, the

invitee or participant must state whether she has any objections to the exchange of certain forms of information (see also **Chapter 8**).

4.2 Role of the screening organisation

The regional execution of the breast cancer screening programme rests with the five regional screening organisations. The screening organisations operate 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 breast cancer screening programme, regional coordination, and quality assurance for execution of the breast cancer screening programme.

Within the context of coordination and quality assurance, they have entered into agreements with PostNL, screening radiologist partnerships and parties for information management, imaging and hardware such as the mammography unit. 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 been placed with a national cooperation named Facility Cooperation for Population Screening (FSB). However, the Execution Framework generally refers to the screening organisations and not FSB.

To carry out the screening examinations, the screening organisations employ radiographers. The screening organisations are responsible for the continuity of the screening programme and take timely measures to maintain the capacity of the radiographers in the screening programme in the near future.

Within the context of executing the primary process of the breast cancer screening programme, the screening organisation is responsible for:
- selecting and updating the list of the target group that qualifies for an invitation or reminder;
- inviting the target group;
- execution of the screening examination (intake for the screening examination, taking the mammograms and assessing the technical quality of the mammograms); and
- communicating the results.

Selection

Core tasks:	Methods:
Selecting and updating the target group for the screening programme.	In accordance with the procedure used by the screening organisation. Legal framework - exchange of information from cancer screening programmes

Invitation

Core tasks:	Methods:
Scheduling the examination centres.	In accordance with the procedure used by the screening organisation.
Sending invitations, and reminders if applicable, to the	In accordance with the methods used by the screening organisation, using the documents:

target group of the screening programme.	• 'Breast cancer screening' leaflet • Invitation letter • Opt-out form • Client information on screening and breast implants • Client information on screening and cardiac implants

Screening

Core tasks:	Methods:
Arranging the intake for the screening examination.	In accordance with regional working instructions of the screening organisations (which include attention for clients in health-care institutions and/or extremely anxious or reluctant clients) And in accordance with nationally established documents specifically for the screening programme: • NVAVG guideline 'Breast cancer screening among women with an intellectual disability' • Procedure for Breast Implant • Quality document for radiographers in the screening programme

Taking the mammograms and assessing them in terms of technical quality.	In accordance with the methods used by the screening organisation and in accordance with nationally established screening programme-specific documents:
	• Quality document for radiographers in the screening programme
	• Measurements which the mammographs in the screening programme must meet
	• LRCB measurement protocol for physical-technical testing of mammography equipment in the Dutch Breast Cancer Screening Programme, version September 2018
	• Physical procedures and testing:
	  • type approval (of a new device)
	  • technical quality assurance
	  • acceptance test
	  • semi-annual test
	  • detector replacement
	  • weekly test
	• Procedure for Breast Implant
	
	Using the points for attention in the LRCB recommendation 'Options for pain reduction within the current force-based protocol', which is not a protocol but does offer scope for action. This is attached as Appendix 2 to the aforementioned

	'Quality document for radiographer in the screening programme'.
Sending the mammograms to the assessment unit of the screening radiologists for assessment.	In accordance with the procedure used by the screening organisation.

Informing

Core tasks:	Methods:
Receiving the authorised results from the screening radiologist and sending the results to the GP and participants in the screening programme.	In accordance with the methods used by the screening organisation, using the following documents: • Results letter 'No abnormal findings' • Results letter 'an abnormality has been detected' • Results letter 'not enough information' • Authorised report letter (BI-RADS 0, 4/5) from radiologists for GPs • Results letter 'poor interpretability due to breast implants' for client • Results letter 'poor interpretability due to breast implants' for GP

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

Core tasks:	Methods:
Answering questions from the public and invitees about the breast cancer screening programme.	In accordance with the procedure used by the screening organisation.
Registering and properly handling any complaints received.	In accordance with the procedure used by the screening organisation.
Registering and properly handling any incidents.	In accordance with national Risk Management Protocol.

4.3 Role of the screening radiologist

The screening radiologists, or their partnerships, are private care providers that are part of the care chain in that role. The screening radiologists are commissioned by the screening organisation, and a contract is in place with the organisation.

Within the context of executing the primary process of the breast cancer screening programme, the screening radiologist is responsible for the timely radiological assessment of the mammograms:

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

Screening (radiological assessment of the mammograms)

Core tasks:	Methods:
Receiving and assessing the mammograms from the screening organisation.	In accordance with the procedure in ScreenIT
Sending the authorised results of the radiological assessment to the screening organisation.	In accordance with the procedure in ScreenIT

4.4 Role of the GP practice

The GP practice is a health-care organisation that provides GP care and forms part of the care chain. In the case of a positive result, an employee of the screening organisation informs the GP and provide him or her with the relevant personal details. The employee shall state the client's citizen service number (BSN). The GP receives this message via the message box.

Within the context of executing the primary process of the breast cancer screening programme, the GP practice is responsible for:

- answering questions / providing information on the screening programme;
- communicating the results to participants with BI-RADS 0, 4 or 5 results; and
- advising and referring participants with BI-RADS 0, 4 or 5 results.

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

Informing

Core tasks:	Methods:
Receiving the authorised result from the screening organisation in the case of a BI-RADS 0, 4 or 5 result and entering data into the GP information system (HIS).	The following documents are generated automatically in ScreenIT: • Results letter 'No abnormal findings' • Results letter 'an abnormality has been detected' • Results letter 'not enough information' • Authorised report letter (BI-RADS 0, 4/5) from radiologists for GPs • Results letter 'poor interpretability due to breast implants' for client • Results letter 'poor interpretability due to breast implants' for GP
Contacting the woman before she receives the results letter.	In accordance with the NHG Standard for Breast Cancer 2016

Referral

Core tasks:	Methods:
Referring the woman to the hospital for further diagnostic testing and informing her of the procedure to be followed.	In accordance with the NHG Standard for Breast Cancer 2016

Reporting the referral of the woman to the screening organisation.	In accordance with the NHG Standard for Breast Cancer 2016

4.5 Role of the hospital

The hospitals are part of the care chain. 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 breast cancer screening programme, the hospitals are responsible for:

- performing additional imaging in a radiology department within a maximum of 24-48 for women with a BI-RADS 0 result;
- sending the GP and the screening organisation the letter with the results of the follow-up examination by the radiology department for women with a BI-RADS 0 result;
- prompt downstaging to a BI-RADS 1 or 2 result or upgrading to a BI-RADS 4 or 5 result for these women[3];
- performing further diagnostic testing in women with a BI-RADS 4 or 5 result in a mulitdisciplinary team; and
- treating patients in the health-care setting and monitoring after treatment.

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

Diagnostic testing

Core tasks:	Methods:
The hospital carries out the diagnostic testing.	In accordance with the guidelines and methods of the professional group.
Informing the woman of the results of the diagnostic testing.	
Informing the GP practice of the findings of further diagnostic testing, the treatment plan and the results thereof.	
Informing the screening organisation on the results of the diagnostic testing (preferably within three months).	

[3] If a result is upgraded to BI-RADS 4 or 5 and multidisciplinary care proves necessary, it should be available immediately. This means that the radiology department and the breast care clinic must be sufficiently attached or embedded within the hospital.

Treatment & follow-up

Core tasks:	Methods:
Treating and informing the woman.	In accordance with the documents established by the professional group.
Referring the woman back to the screening programme after the end of treatment and monitoring.	In accordance with the procedure used by the screening organisation.

4.6 Other parties involved

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

Involved parties	Explanation of role
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 breast cancer screening programme. The Minister for Health, Welfare and Sport is politically responsible for the breast 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 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 breast 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 breast 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.
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	Patient organisations represent the interests of patients and provide information to the public.
Professional groups	The relevant professional groups contribute their expertise (substantive and otherwise) and professional interest to national agreements. The representatives also provide information to the professional group.
Health insurers	Health insurers fund the diagnostic testing and treatment of women referred from screening.
Other parties (PALGA, IKNL, 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 (*data warehouse for cancer screening programmes*, DWH-BVOK).

5 Quality assurance

Quality assurance encompasses the entirety of planned and systematic actions required to provide sufficient confidence in the breast 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 breast 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.

In addition, in the breast cancer screening programme X-ray is used. The use of that equipment is subject to a license requirement under the Nuclear Energy Act (KEW), which furthermore includes special sets rules for medical use of and protection against radiation, whereby the breast cancer screening programme is explicitly mentioned.

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 breast 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 breast 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 breast cancer screening programme.

The national quality requirements for the breast 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, the screening radiologist, hospitals, LRCB, GP practers and the quality requirements related to communication can be found in **Appendix D**. 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 breast cancer screening programme. An overview is provided in **Appendix C**.

5.3.2 Monitoring of practical execution

For the screening tests, the monitoring of the practical execution focuses on the Mammography. 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. Table 5.1 shows the core tasks of the screening organisations to guarantee the quality of the practical execution.

Table 5.1: Core tasks of screening organisations in the field of monitoring the practical execution

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, Monitoring and Information Management

	(QMI), 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
Because the professionals carrying out the breast cancer screening programme are employed by the screening organisations or have concluded contracts with them, the quality control of the execution has been commissioned by RIVM-CvB to the Dutch Expert Centre for Screening (LRCB). The LRCB is the government-appointed institute for quality assurance of the breast cancer screening programme, where legislation and regulations also refer directly to the LRCB. The LRCB is commissioned annually by RIVM-CvB and is exempt from a tendering obligation. The general core tasks of the reference function are described in Table 5.2. A more detailed description of these tasks specifically for the breast cancer screening programme is provided in **Appendix E**.

Tabel 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.

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 breast 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, Monitoring and Information Management (QMI), 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 breast cancer screening programme. They must all keep up to date on relevant information and developments in order to optimise the execution of the breast cancer screening programme. The professionals involved in the breast 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 breast cancer screening programme;
2. providing information on the national agreements and quality requirements available to ensure that the breast 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 Radiographers

The screening organisations provide the practical part of the training for radiographers in the screening programme, which consists of being taught the positioning technique by instructional technicians and familiarisation with these skills by traineeship supervisors. The theoretical part of the training is provided by a contracted external party (LRCB) and the in-service radiographer training is provided by Erasmus MC. All (100%) Radiographers in the screening programme must be in possession of a LRCB test certificate.

After obtaining the LRCB certificate, radiographers are accredited to work in the screening programme and are automatically registered in the 'Accreditation Register of Radiographers in the Screening Programme' of the LRCB. Audits of assessment units are used to test (pseudonymised form) whether the work of the radiographers employed by the screening organisations meets the criteria defined in the Quality document for radiographers in the screening programme [dutch only]. The radiographers involved in

an audit are registered as having taken part in it. The audits are carried out in a three-year cycle in addition to an annual quality monitor.

The screening organisations also provide the extra training for radiographers in the screening programme:
- 100% of the radiographers in the screening programme have received at least 1 hour of extra training per year, or at least 3 hours of extra training every 3 years, on physics/radiation hygiene.
- 100% of the radiographers in the screening programme have received at least 4 hours of extra training per year, or 12 hours of extra training every 3 years, on mammography, of which at least 1/3 concerns positioning technique in practice.
- 100% of the radiographers in the screening programme have followed a review of images and/or clinical lesson with a screening radiologist at least 4 times per year, or at least 12 times every 3 years.

In addition, the screening organisations provide:
- Peer assessment and peer review in accordance with the Quality document for radiographers in the screening programme [dutch only], the national training plan for radiographers and the regional working instructions;
- Annual performance reviews
- Practical guidance of the radiographers in the screening programme;

And they promote the presence of radiographers in the screening programme at the subsequent discussion of the 3-yearly audits by the LRCB.

6.2.2 Screening radiologists

The LRCB is responsible for training, registration and re-registration of the screening radiologists. All (100%) of the screening radiologists working in the screening programme must be in possession of a breast cancer screening diploma/certificate from the LRCB. All (100%) of the screening radiologists working in the screening programme must be registered in the Quality Register for Screening Radiologists [dutch only] in the breast cancer screening programme in the Netherlands. By doing so they meet the registration and re-registration requirements as set out in the Regulations Concerning the Quality Register for Screening Radiologists in the Breast Cancer Screening Programme in the Netherlands, version 2020 [dutch only]. Re-registration is required every five years.

The screening radiologist may be asked to participate in scientific research approved by the LRCB/RIVM-CvB with the aim of improving screening performance. The screening radiologist must earn an average of eight continuing medical education (CME) credits per year for five years, relating to breast cancer diagnostics and screening, with a total of forty credits. Once every five years the screening radiologist must take part in a self-assessment offered by the LRCB. The screening radiologist must familiarise himself/herself with the results of most recent LRCB audit of the assessment unit with which he/she is affiliated, by participating in the audit or by reading the audit report. At the request of the screening radiologists, the LRCB can provide a refresher training evening within three months after the audit. The screening radiologist must also keep up to date on the latest indicators published in the national monitor.

The radiology group must organise internal meetings during which case histories are discussed, at least twice a year.

In addition, the screening organisations provide annual interviews with the screening radiologists and promote the presence of screening radiologists at the 3-yearly audits of the LRCB and the subsequent discussion of the audit. The screening organisations also ensure that each screening radiologist receives feedback at least four times a year on his/her personal referral rate for the findings from the subsequent diagnostic testing of the cases histories he/she has referred.

6.2.3 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 breast cancer screening programme take place. It starts with a description of the indicators used to monitor and evaluate the breast 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 Breast Cancer Screening Indicator Set was developed in order to uniformly implement the monitoring and evaluation of the breast 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 organizational unit level. 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 breast 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 breast 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 version of the monitor [dutch only] is available from the RIVM-CvB website. RIVM-CvB discusses this with the national Working Group on Quality, Monitoring and Information Management and the Breast 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.

7.3 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 Breast Cancer Screening (LETB), 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 breast cancer screening programme committee and may be published in scientific journals. In addition, a national evaluation of the screening programme 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, 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 breast 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 breast 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 breast 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.

8.2 Legal and regulatory aspects

National requirements apply to all parties involved in the execution of the breast 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

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 breast cancer screening programme, national evaluation, and providing personal information and data for the purpose of scientific research.

8.2.2 Privacy and objections

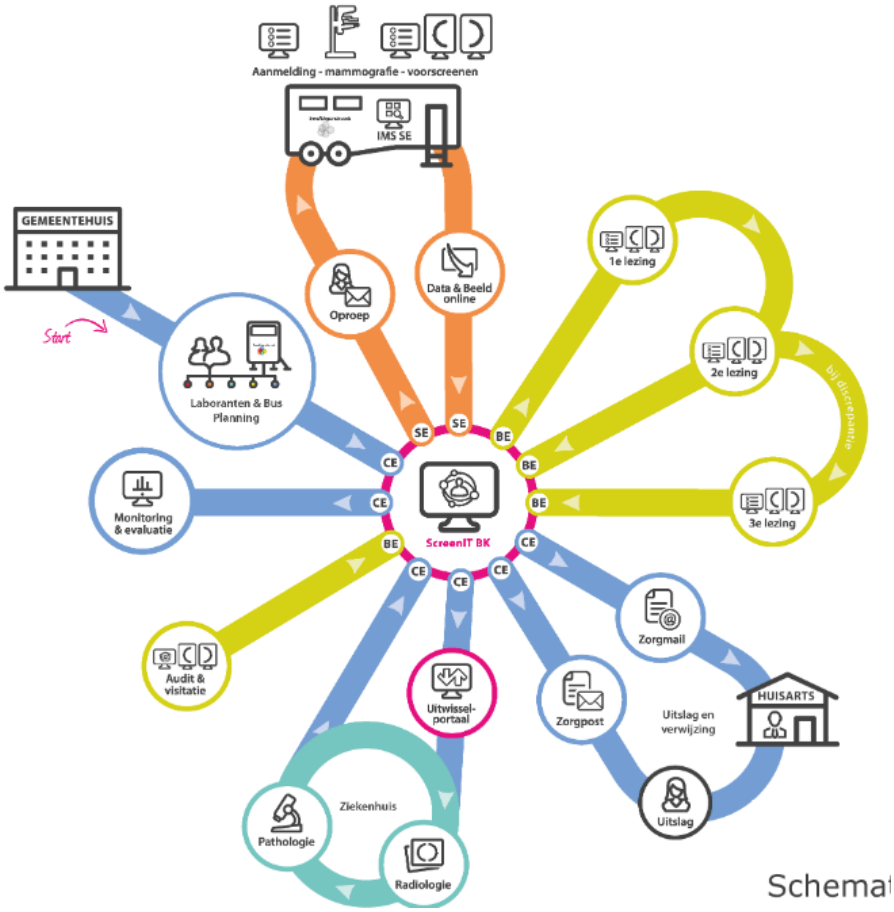
Individuals invited to take part in the screening programme must be informed about the registration, use and exchange of data, and should either give their explicit consent or be presumed to have given their consent for this, provided that they have been fully informed about the processing (registration, 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 breast 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.



Figuur 8.1: Data streams in the primary process [in Dutch only]

The mammograms of the women who take part in the screening programme are stored in the Image Management System (IMS) and subsequently reviewed by the screening radiologists. The assessment report is stored in ScreenIT. The images and the report are linked in the system.

In the event of an unclear or unfavourable result, the participant's GP is given a referral recommendation for further examination in the hospital. ScreenIT generates the results letter for the participant and the letter to the GP with the request to inform the woman in question and the referral request. The written letter is sent to the participant by post. The letter to the GP is sent digitally (slightly earlier) via a secure connection (Zorgmail).

The X-rays and screening reports of the participants in the screening programme are made available to the hospitals via an Exchange Portal. The radiologists in the hospitals can use their 'unique health-care provider identification' (UZI) pass to log in to this portal and download the images and reports.

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

In order to determine whether or not a referral for further examination or testing in the radiology department (BI-RADS 0) or to the breast care clinic (BI-RADS 4 or 5) was justified, feedback of the results of the diagnostic testing is indispensable. This includes results of additional imaging as well as pathology results. Until 2019, these results were entered manually into the client information system by employees of the screening organisations. The data came from reports of imaging or pathology examinations, or from letters to the GP.

The introduction of the BK2020 programme has made it possible to enter the results of additional imaging directly in the Exchange Portal, making them available to the screening organisations. This requires hospital staff to fill in a web form. If this web form is not used, the screening organisations still need to retrieve the results from reports/letters and enter them in ScreenIT manually.

The pathology results can be submitted digitally via PALGA. Thanks to an exchange of data between PALGA and ScreenIT via ZorgTTP, the results of diagnostic testing can be linked to the screening data for the woman in question in ScreenIT. This will probably become operational in 2020 for the results of diagnostic testing for women referred from the screening programme.

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 breast 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.

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.

9 Handling of bodily materials

Within the breast cancer screening programme, no bodily material is collected (X-rays are part of the medical file).

In the case of referral to hospital for further diagnostic testing, a participant with a BI-RADS 0 or BI-RADS 4 or 5 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 take place. 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.

10 Communication and information

Communication and information are an essential part of the breast 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 breast cancer screening programme, it is important to communicate with seven groups, namely:

- the target group for participation in the breast cancer screening programme: women aged 50 to 75 years;
- the actual participants in the breast 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 partici-pation	Partici-pants	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.bevolkingsonderzoekborstkanker.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 breast 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 breast 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 breast cancer screening programme follow largely from the identification of the risks of disrupting the continuity of the screening programme. The organisation of the breast 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 breast cancer screening programme is the entirety of powerful measures designed to ensure that the breast 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 breast 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 breast 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 breast cancer screening programme. Health-care professionals involved in executing the breast 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 breast 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 breast cancer screening programme.

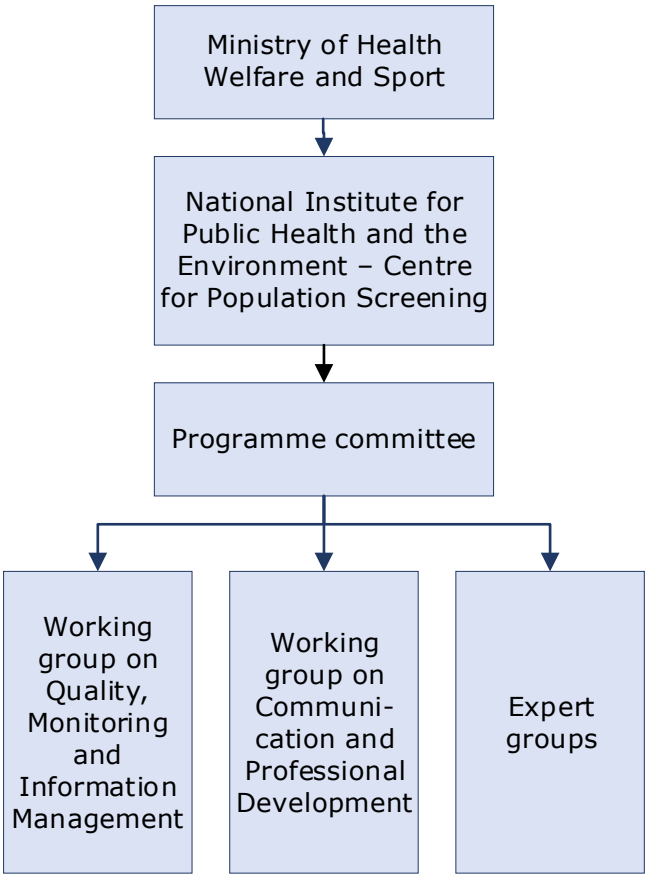


Figure 12.1: Consultation structure of the breast cancer screening programme

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 breast 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, Monitoring and Information Management (QMI). 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, Monitoring and Information Management

Enhancing the quality of the execution of the breast cancer screening programme is a key aspect of the activities of the CMI 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 breast 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;
- 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 breast 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 breast 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

Improvement of quality
Set of planned and systematic actions, aimed at increasing the possibilities to meet the requirements.

Monitoring
A more or less continuous activity aimed at safeguarding and improving the execution of the screening programme and subsequent diagnostic testing.

National quality requirements
The requirements which organisations, implementing parties or the execution must satisfy in order to guarantee uniform quality nationwide.

Public values
Values (sustainable views on the design of and activities in society) that affect the public interest. The public values in terms of population screening are: quality, accessibility and affordability.

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.

Quality
Meet the requirements

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.

Appendix B Abbreviations

Afkorting	Betekenis
AP	Authority for Personal Data *(Autoriteit Persoonsgegevens, AP)*
GDPR	General Data Protection Regulation (*Algemene Verordening Gegevensbescherming, AVG*)
B1-niveau	language that about 95% of the population can understand.
BI-RADS	Breast Imaging Reporting and Data System
BK2020	Project in which the entire client process, from invitation and screening to image exchange with hospitals, has been digitally renewed.
BRP	Personal Records Database (*Basisregistratie Personen*)
BSN	Burger Servicenumber
DCIS	Ductaal Carcinoma In Situ
DWH-BVOK	Data warehouse for cancer screening programmes (*Datawarehouse voor de bevolkingsonderzoeken naar kanker*)
GR	Health Council of the Netherlands (*Gezondheidsraad*)
HIS	GP Information System *(Huisartsen Informatie Systeem)*
ICD	Implantable Cardioverter Defibrillator
IT	Information Technology
IGJ	Health and Youth Care Inspectorate (*Inspectie Gezondheidszorg en Jeugd*)
IKNL	Netherlands Comprehensive Cancer Organisation
IMS	Image Management Systeem
ISO	Internationale Organisation for standardization
QMI (Working Group)	Working Group on Quality, Monitoring and Information Management (*Werkgroep Kwaliteit, Capaciteit, Monitoring en Informatiehuishouding*)
LETB	National Evaluation Team for Breast Cancer Screening *(Landelijk Evaluatie Team voor het bevolkingsonderzoek borstkanker)*
LRCB	Dutch Expert Centre for Screening *(Landelijk Referentiecentrum voor Bevolkingsonderzoek)*
MB'ers	Mammolaborant *(Medisch Beeldvormers)*
MBB'ers	Mammolaborant (Medisch Beeldvormings- en Bestralingsdeskundigen)
M(B)B'ers	Mammolaborant (Medisch Beeldvormings- en Bestralingsdeskundigen en Medisch Beeldvormers)
Ministry van VWS	Ministry of Health, Welfare and Sport
NABON	National breast cancer consultation (Nationaal Borstkanker Overleg Nederland)
NEN	Dutch Norm
NHG	Netherlands College of General Practitioners (*Nederlands Huisartsen Genootschap*)

NKR	Netherlands Cancer Registry (*Nederlandse Kankerregistratie*)
NVAVG	Dutch Association of Physicians for the Mentally Handicapped *(Nederlandse Vereniging van Artsen voor Verstandelijk Gehandicapten)*
NVMBR	Dutch Association of Medical Imaging and Radiotherapy *(Nederlandse Vereniging Medische Beeldvorming en Radiotherapie)*
NVvR	Radiological Society of the Netherlands (*Nederlandse Vereniging voor Radiologie*)
PALGA	The nationwide network and registry of histo- and cytopathology in the Netherlands (*Pathologisch Anatomisch Landelijk Geautomatiseerd Archief*)
pTNM	Pathological tumor-node-metastasis staging
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
SONCOS	the platform for interdisciplinary consultation and professional collaboration in oncological care between professional associations
WBO(-vergunning)	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*)
Wpg	Public Health Act *(Wet Publieke Gezondheid)*
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 breast cancer screening programme or parts thereof. Also listed are the frameworks and protocols drawn up specifically for the breast cancer screening programme. It has been decided not to mention the guidelines of the professional groups.

All documents are in Dutch.

Chapter	Document	From whom	Applicable to whom
Landelijke kaders			
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			
3, 4	NHG Standard for Breast Cancer 2016	NHG	GPs
4	NVAVG guideline 'Breast cancer screening among women with an intellectual disability'	NVAVG (Netherlands Society of Physicians for People with Intellectual Disabilities)	Professionals involved with people with intellectual disabilities.
4	NABON National Guideline: 'Breast Cancer'	Dutch Consultative Committee on Breast Cancer (NABON) working group	All parties involved
Quality documents specific to the screening programme			
	Execution framework for breast cancer screening	RIVM	All parties involved
4	Procedure for Breast Implants	LRCB	Screening organisations
4, 6, App. D, App. E	Quality document for radiographers in the screening programme	LRCB	Radiographers
4, 11	Complaints procedure	SOs	Screening organisations

4, 11 Bijl. E	Protocol risicomanagement	RIVM	Alle betrokkenen
6	Regulations Concerning the Quality Register for Screening Radiologists in the Breast Cancer Screening Programme in the Netherlands, version 2020	LRCB	Screening organisations and screening radiologists.
App. D, App. E	Audit protocol 2019	LRCB	Screening organisations
4, App. E	LRCB measurement protocol for physical-technical testing of mammography equipment in the Dutch Breast Cancer Screening Programme, version September 2018	LRCB	Screening organisations
4	Measurements which the mammographs in the screening programme must meet	LRCB	Screening organisations
4, App. E	Physical procedures and testing: • type approval (of a new device) • technical quality assurance • acceptance test • semi-annual test • detector replacement • weekly test	LRCB	Screening organisations

Appendix D National quality requirements screening organisations

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

Appendix E Reference function tasks

Reference task	Implementation
1) Assessment of equipment/implementing parties	
Admission of/requirements for implementing parties	Radiographers working in the screening programme must be accredited by the LRCB. This involves an entrance test aimed specifically at taking images for screening, with subsequent registration in an LRCB 'Accreditation Register of Radiographers in the Screening Programme'. Testing takes place on the basis of transparent protocols, specifically geared to the breast cancer screening programme. In addition, the LRCB manages a training register for radiographers in the screening programme. The general Quality Register of Allied Health Professions falls under the responsibility of the Dutch Society of Medical Imaging and Radiotherapy (NVMBR) and is not currently mandatory for radiographers in the screening programme. All screening radiologists working in the screening programme must be accredited by the LRCB. For this purpose, an induction program aimed specifically at assessing images in a screening setting, an entrance test aimed specifically at assessing images in a screening setting with registration in the 'Quality Register for Screening Radiologists', including subsequent accreditation. The Quality Register for Screening Radiologists is managed by LRCB on behalf of RIVM in close cooperation with the Dutch Society of Radiology (NVvR). (Note: the induction programme prior to the entrance test and accreditation is a responsibility of the LRCB because it is an essential part of finding the right balance between detection rates, false-positives and the number of interval carcinomas. This is a dynamic process which is continuously updated). In addition, the LRCB manages a training register for screening radiologists.
Admission of equipment	The equipment used in the screening programme must be accredited by the LRCB. This is done by means of a type examination/type approval and an acceptance test on site according to tests based on transparent protocols, specifically geared to national quality requirements of the breast cancer screening programme. The LRCB maintains a 'Quality register (type approval) for accepted screening equipment in the Breast Cancer Screening Programme in the Netherlands'.
2) Monitoring the quality of execution	
Audits/inspections by the reference function	The medical and physical-technical quality of the execution of the breast cancer screening programme are periodically tested against the national quality requirements and contractual requirements declared applicable to the breast cancer screening programme. The LRCB must carry out audits with regard to the medical expertise of the employees in the screening programme (radiographers in the screening programme and the screening radiologists) in a three-year cycle. The LRCB must carry out audits to assess the medical-technical quality of mammograms produced by the radiographers in the screening programme. The

	findings are reported for each organisational unit, based on peer review of the mammogram. The LRCB must carry out audits to assess the medical-technical quality of the screening/assessment by the screening radiologists. The findings are reported for each organisational unit, based on peer review of the assessed images. Audits must be carried out in accordance with the Audit Protocol. In addition, the LRCB must perform continuous quality control on the imaging systems by means of weekly artefacts and stability test, a semi-annual full functioning test and an overall assessment of the physical-technical quality of mammographs in the screening programme through audits. Quality tests must be performed in accordance with transparent protocols, geared to the national quality requirements of the breast cancer screening programme: LRCB measurement protocol for physical-technical testing of mammography equipment in the Dutch Breast Cancer Screening Programme, version September 2018 and Physical procedures and testing The LRCB must provide the screening organisation and RIVM-CvB with a report on each audit and test with concrete recommendations for improvement.
Annual monitoring of the quality of execution	In the years between visits, the LRCB carries out annual monitoring of indicators at assessment unit level. This will be set up in 2020.
Monitoring the quality of execution	Semi-annual quality tests of the equipment and a weekly stability check. Image reviews are used for the purpose of peer-review meetings. Benchmarking also takes place. Reporting takes place to the screening organisations and RIVM-CvB.
3) Professional development	
Induction and training programmes	The screening organisations provide radiographers with training on theory and on pre-screening by an external party. In practice this is the LRCB. The reference centre trains radiologists on the assessment of X-rays from a screening perspective.
Continuing education	The LRCB provides continuing education for radiologists. Professional development takes place in response to the feedback of the results of the audit of an assessment unit. The LRCB facilitates image reviews and provides re-registration in the LRCB training register for radiographers working in the screening programme. The LRCB carries out professional development on behalf of the screening organisation, RIVM-CvB or the professional associations. See **Chapter 6** for more details on professional development activities provided by the LRCB. The training of radiographers is the responsibility of employers, i.e. the screening organisations. As an assessing institution, the LRCB maintains a register. Training (theory and practice) can be purchased from LRCB by third parties.

4) Analysis of incidents/adverse events	
	Adverse events and inadequacies are immediately brought to the attention of RIVM-CvB and the relevant Screening Organisation, as described in **Chapter 11 'Risk Management'**. • The LRCB must inform RIVM-CvB in the event of adverse events and inadequacies in the screening programme. On the instruction of RIVM-CvB, the LRCB must carry out additional audits in places that deviate significantly from the performance indicators of the (short-cycle) monitoring, if the results of an audit or monitoring give cause to do so. • The LRCB must check the screening organisations and advise them on how to act in case of inadequacies and adverse events in the screening programme. In the case of adverse events, immediate action must be taken and this must be reported to RIVM-CvB. The LRCB must advise and support RIVM-CvB with regard to properly responding to questions from politicians and others.
5) Advising	
	The LRCB plays a role in advising with regard to information management. Naturally, this has to do with having access to the right data for quality control.
	The LRCB - has a national and international knowledge infrastructure in which new developments/innovations can be identified, initiated, tested and evaluated; - informs and advises RIVM on national and international developments in medicine and medical technology related to the breast cancer screening programme.

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 implementing 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 implementing 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 that 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 Overview of 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.

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 breast cancer screening programme.