# QUALITY MANUAL FOR BREAST CANCER SCREENING

Published 18 April 2024

# CONTENTS

# EXPERT GROUP

## CHAIR

**Johanna Alanko**, Secretary of Finnish Breast Radiologists / Radiological Society of Finland, Specialist, Terveystalo

## MEMBERS

**Riitta Aaltonen**, Specialist, Turku University Hospital

**Kristiina Aittomäki**, D.Med.SC, Professor Emeritus, Specialist, University of Helsinki

**Maarit Bärlund**, D.Med.SC, Associate Professor, Specialist, Tampere University Hospital, University of Tampere

**Päivi Heikkilä**, D.Med.SC, Associate Professor, Specialist, Helsinki University Hospital, University of Helsinki

**Sirpa Heinävaara**, D.Soc.SC, Associate Professor, Research Director, Finnish Cancer Registry

**Ulla Karhunen-Enckell**, Specialist, Tampere University Hospital, University of Tampere

**Vesa Kataja**, D.Med.SC, Associate Professor, Senior Medical Officer , South Savo Wellbeing Services County

**Ilkka Käsmä**, Senior Medical Officer, Comprehensive Health and Social Services Centre, Central Finland Wellbeing Services County

**Milla Lehtinen**, Statistician, Finnish Cancer Registry

**Laura Niinikoski**, D.Med.SC, Specialist in breast cancer screening , Finnish Cancer Registry

**Minna Pöyhönen**, D.Med.SC, Professor, Helsinki University Hospital, University of Helsinki

**Anders Ståhls**, D.Med.SC, Specialist, Helsinki University Hospital, University of Helsinki

**Mazen Sudah**, D.Med.SC, Associate Professor, Specialist, Kuopio University Hospital

**Meri Utriainen**, D.Med.SC, Specialist, Helsinki University Hospital, University of Helsinki

## 1. SUMMARY

The aim of screening is to detect breast cancer at an early stage before it becomes symptomatic and to reduce mortality from breast cancer. Screening is a high-quality chain of interventions to ensure that as many breast cancers as possible can be diagnosed by mammography are detected early.

Around 5 000 women in Finland are diagnosed with breast cancer every year. Just over half of them are aged between 50 and 69 years and are invited for screening every two years. Around two-thirds of breast cancers in women of screening age are detected by screening. The mortality rate from breast cancer among screened women is about a third lower than it would be if there were no screening. Screening can also be harmful because a small proportion of cancers would not need treatment even if found. In addition, one in six women who are screened regularly will have at least one unnecessary follow-up examination.

The wellbeing services counties are responsible for the organisation of breast cancer screening for their residents. As things stand at present, a wellbeing services county can carry out screening on its own, in cooperation with other wellbeing services counties or by outsourcing. The screening programme must include an appropriate quality management and quality assurance procedure. The counties must also provide their residents with sufficient information on the objectives, organisation and effectiveness of screening examinations and the possible risks involved with them. The wellbeing services county is also responsible for screening follow-up examinations and specialised healthcare.

The wellbeing services counties must submit individual-level data on screening to the Mass Screening Registry maintained by the Finnish Cancer Registry, which can be used to assess the quality and effectiveness of screening. The Finnish Cancer Registry reports screening statistics with quality indicators on the performance of the screening chain.

## 2. TERMINOLOGY AND ABBREVIATIONS

| | |
|---|---|
| **ADH** | Atypical ductal hyperplasia |
| **DCIS** | Ductal carcinoma in situ |
| **DVV** | Digital and Population Data Services Agency |
| **ESP** | European Society of Pathology |
| **EUSOMA** | European Society of Breast Cancer Specialists |
| **IAP** | International Academy of Pathology |
| **LCIS** | Lobular carcinoma in situ |
| **MDT meeting** | Multidisciplinary team meeting |
| **MRI** | Magnetic resonance imaging |
| **OECI** | Organization of European Cancer Institutes |
| **PAD** | Pathological-anatomical diagnosis |
| **STUK** | Radiation and Nuclear Safety Authority |
| **TAD** | Targeted axillary dissection |
| **THL** | National Institute for Health and Welfare |
| **TNM classification** | International classification for the distribution of malignant tumours, based on the size of the tumour (T = tumour) and an estimate of the incidence of metastases in regional lymph nodes (N = nodes)and in other organs (M = metastasis). |
| **US** | Ultrasound |

## 3. INTRODUCTION

This Quality Manual for Breast Cancer Screening is intended to support decision-making and activity by those responsible for the organisation and practical implementation of breast cancer screening. It provides recommendations, based on research evidence and practical experience, for implementing an effective and cost-effective organised breast cancer screening programme. The treatment of breast cancer is not specifically addressed in this manual. More detailed information on treatment recommendations can be found, for example, in the national diagnostic and treatment recommendations of the Finnish Breast Cancer Group[1], (https://rintasyoparyhma.yhdistysavain.fi/hoitosuositus/).

At the beginning of 2023, the responsibility for organising screenings was transferred from municipalities to 21 wellbeing services counties and the City of Helsinki. In addition, the province of Åland is responsible for organising screening in its territory. The purpose of this quality manual is to clarify how high-quality breast cancer screening is organised. The detailed requirements for screening organisation are described in the chapters on the organisation and responsibilities of the screening programme, the screening protocol, the screening examination, interpretation of images and screening results, follow-up examinations or confirmatory screening, professional skills and training, data provision and reporting, monitoring of screening and quality assurance of the programme, and communication and information. The chapter on treatment in specialised healthcare sets out quality criteria for the professional competence of those working in this area.

# 4. BACKGROUND

- Breast cancer is the most common cancer in women.
- The first stage in breast cancer screening is a mammogram.
- Mammograms are interpreted independently by two radiologists.
- Anyone who needs further investigation will be invited to a confirmatory examination without delay.
- The steps in the chain are recorded in the Mass Screening Registry for quality and effectiveness monitoring and evaluation.
- Screening reduces mortality from breast cancer, but it also leads to overdiagnosis.

## 4.1 BREAST CANCER

Breast cancer is the most common cancer in women, affecting one in eight women in their lifetime. In 2021, more than 5 000 women were diagnosed with breast cancer and it caused nearly 1 000 deaths. The incidence of breast cancer has been increasing since the 1950s. The risk of breast cancer increases with age and 60% of breast cancers are diagnosed after the age of 60[2].

In addition to population ageing, changes in reproductive behaviour have contributed to the increased risk of breast cancer: the age at first birth has increased, the number of children has decreased as well as duration of breastfeeding. Long-term hormone replacement therapy for menopausal symptoms increases the risk of breast cancer, especially if it contains both oestrogen and progestin. Being overweight and drinking too much alcohol also increases the risk of breast cancer. Current estimates suggest that 5-10% of breast cancers are explained by hereditary predisposition[1].

## 4.2 BREAST CANCER SCREENING

Screening aims to find breast cancer at an early stage before it causes symptoms and to reduce mortality from the disease.

Finland was one of the first countries to start breast cancer screening, in 1987. During the first five years, 1987–1991, randomisation based on birth year was carried out in the selected screening population. In this case, only some of the women in the target population were invited for screening, with some acting as controls. The initial results of the randomised follow-up study indicated that the programme was as effective as anticipated by previous studies[3,4].

The national breast cancer screening programme started in Finland in 1992. Municipalities were responsible for organising screening. At that time, women aged 50–59 years were invited for screening every 20-26 months. Following the Government Decree on Screenings that entered into force in 2007, breast cancer screening was gradually extended to the female population aged 60–69 across the country between 2007 and 2016. Some municipalities also invited women aged 60–64 to be screened from the start of the programme[4].

Breast cancer screening is a high-quality chain of actions to ensure that as many breast cancers as possible that can be diagnosed from a mammogram are found in time. The first test is a mammogram, to which women of screening age are invited.

Mammograms are taken by a radiology nurse so that the whole breast is evenly visible on the image. The images are interpreted independently by two radiologists. Women who need further investigations are invited to follow-up examinations without delay. Confirmatory examinations are carried out by a radiologist, who is also responsible for informing the patient and making a referral to specialised healthcare. The steps in the chain are recorded at the Mass Screening Registry for quality monitoring and effectiveness evaluation. The quality of each phase in the chain needs to be maintained and monitored in order to achieve the objectives.

### 4.2.1 Benefits and harms

In breast cancer screening, mammography is the only method of examination that has been shown to have an impact on breast cancer mortality. In Finland, screening has reduced breast cancer mortality by about 20% among those invited compared to the situation without screening[5]. Breast cancer mortality in those who have received screening has been reduced by about one-third compared to the situation without screening[6].

Screening targets a healthy population, so there are unavoidable physical and psychological harms. They may also be felt at a societal level, such as the additional costs of overdiagnosis. In cancer screening, overdiagnosis generally refers to the detection of a cancer that would not have caused harm to a person during their lifetime if it had not been diagnosed.

Of those participating regularly in breast cancer screening between the ages of 50 and 69, 18% receive at least one unnecessary invitation for a follow-up examination[7]. According to one international study, overdiagnosis in women aged 50–69 years invited for screening is estimated to be at most 10%[8]. According to a national study, the overdiagnosis rate in women aged 50–59 invited for screening is 5-7%[9]. Breast cancer screening prevents about 100 breast cancer deaths per year but results in about 150 unnecessarily diagnosed breast cancers[4].

In the national screening programme, the benefits and harms of the programme must be weighed up at the population level, and an acceptable balance must be achieved. The harms of screening, as well as the benefits, should also be clearly communicated to the invited persons.

## 5. ORGANISATION AND RESPONSIBILITIES OF THE SCREENING PROGRAMME

- Wellbeing services counties are responsible for the organisation and quality control of screening activities in their area.
- Screening must be carried out every 20–26 months for women aged 50–69 years.
- The wellbeing services county must appoint a person in charge of breast cancer screening, who is a radiologist specialised in breast radiology. This person shall be responsible for the implementation and quality control of screening.
- The wellbeing services county must regularly monitor and evaluate the quality of the screening process and the reliability of the screening tests, and submit individual-level data on screening to the Mass Screening Registry maintained by the Finnish Cancer Registry.
- The National Cancer Screening Steering Group provides guidance on the initiation, implementation and development of cancer screening.
- For each cancer screening programme, the National Cancer Screening Steering Group has appointed a group of experts to provide more detailed guidance on the implementation of cancer screening.
- The primary responsibility for monitoring the screening programme lies with the wellbeing services counties themselves.

### 5.1 LEGISLATION

According to § 14 of the Health Care Act, a wellbeing services county must organise screenings for permanent residents in accordance with the national screening programme[10]. The screening regulation[11] and its amendments[12,13] specify that breast cancer screening must be carried out every 20–26 months for women aged 50–69 years. In addition, the screening regulation[14] provides that breast cancer screening is also to be carried out for persons whose sex has been determined to be male or female under sex determination legislation and for persons who are long-term users or have been users of hormonal products that increase the risk of breast cancer. Participation in the screening test and any follow-up examinations is free of charge.

At the beginning of 2023, the responsibility for organising screenings was transferred from municipalities to 21 wellbeing services counties and the City of Helsinki. In addition, the province of Åland is responsible for organising screening in its territory. The screening is organised according to a programme decided in advance by the wellbeing services county, and the wellbeing services county must appoint a person responsible for breast cancer screening who is a radiologist with expertise in breast radiology. This person shall be responsible for the implementation and quality control of the screening.

Wellbeing services counties can either carry out the screening themselves or outsource it to a service provider of their choice. In either case, the programme must include an appropriate quality management and quality assurance procedure. The wellbeing services county is also responsible for organising follow-up examinations and specialised healthcare.

The wellbeing services county must regularly monitor and assess the quality of the entire screening process and the reliability of the screening tests, and submit individual-level data on screening to the Mass Screening Registry maintained by the Finnish Cancer Registry, which can be used to assess the quality and effectiveness of screening. The Finnish Cancer Registry has been commissioned by the National Institute for Health and Welfare (THL) to monitor and evaluate, in cooperation with other actors in the field, ongoing screening programmes and the methods used.

In order to organise screening other than in accordance with the national screening programme

(for example, when expanding the age groups for screening), a wellbeing services county must assess the requirements and impact of screening on the health care service system before starting screening.

### 5.1.2 Screening unit

The screening unit responsible for conducting screening must have suitable facilities, equipment and staff to send out screening invitations and results and to take and read mammograms. In addition to this primary phase, the screening unit is also responsible for the transmission of individual-level data for the whole screening chain (invitations, tests and their results, follow-up examinations and their results, specialised healthcare and its results) to the Mass Screening Registry of the Finnish Cancer Registry[12].

The screening unit must have supporting information systems that provide for the collection of data from the entire screening chain and the transmission of data to the mass screening register in accordance with the data model and parameters defined by the Finnish Cancer Registry.

## 5.2 SCREENING GUIDANCE AND SUPERVISION

The National Cancer Screening Steering Group provides guidance on the initiation, implementation and development of cancer screening and prepares regulations and laws related to cancer screening in cooperation with the Ministry of Social Affairs and Health. The steering group consists of expert members of the regional cancer centres and the Finnish Cancer Registry and a representative of the Ministry of Social Affairs and Health. For each cancer screening programme, the Cancer Screening Steering Group has appointed an expert group to provide more detailed guidance on the implementation of cancer screening and the wellbeing services counties are responsible for the implementation of this guidance.

The primary responsibility for monitoring the screening programme lies with the wellbeing services counties themselves. The Regional State Administrative Agencies are also responsible for supervising the screening organised by the wellbeing services counties, just like the rest of the health care system. The Regional State Administrative Agencies also deal with complaints, except in cases of suspected malpractice resulting in the death or serious permanent disability of a patient.

## 6. SCREENING PROTOCOL

- The target group for breast cancer screening under the screening decree is women aged 50–69 years every 20–26 months.
- At the beginning of each calendar year, the Finnish Cancer Registry sends a list of the personal identification numbers of those invited for screening to the screening operators designated by the wellbeing services counties.
- The screening provider can use the paid call service provided by the Finnish Cancer Registry.
- The invitation letter cannot be sent to people subject to non-disclosure for personal safety reasons or who have confirmed their sex as male, but they should be instructed to contact the screening provider themselves.
- Invitations should be sent and images taken evenly throughout the year, taking into account holiday periods, to ensure a steady flow of referrals to specialised healthcare.
- Those invited to screening are entitled to participate until the end of March of the following year.
- The screening invitation must be addressed to the invitee in person and must be in writing.
- The invitation letter must be in the invitee's mother tongue, Finnish or Swedish, or bilingual. If there are significant linguistic minorities in the wellbeing services county, consideration should be given to translating the invitation into other languages.
- If the screening invitee does not attend the screening, the screening operator sends a reminder six weeks after the first invitation.

### 6.1 SCREENING TARGET POPULATION

The target group for breast cancer screening is women aged 50–69 years every 20–26 months, according to the Government Decree on Screenings. In addition, the decree[14] states that breast cancer screening shall also be provided for persons whose sex has been established as male or female under sex confirmation legislation and for persons who are long-term users or have been users of hormonal products that increase the risk of breast cancer.

No separate invitations to the screening are sent to people who have confirmed their sex as male, as the invitations are based on the gender marker in the Digital and Population Data Services Agency (DVV). However, these persons are eligible to participate in the screening.

### 6.2 SELECTION OF INVITEES AND SELECTION DATES

The birth year cohorts to be invited to the screening are extracted from the DVV. At the beginning of each calendar year, the Finnish Cancer Registry sends a list of the personal identification numbers of those to be invited for screening to the screening providers designated by the wellbeing services counties. To facilitate the organisation of screening, it is possible to use the paid invitation service provided by the Finnish Cancer Registry, where, in addition to the personal identification numbers, the screening provider is provided with name and address information for sending screening invitations. The contact details are extracted from the DVV. Persons subject to a valid non-disclosure for personal safety reasons, or who have confirmed their gender as male, are not included in this sample. However, the wellbeing services county should also provide these groups with sufficient information about screening and easy access to book an appointment for screening. In addition, the screening provider must issue instructions on its website on how eligible persons can participate in the screening even if they have not received an invitation letter.

The screening service must send invitations so that the 20–26-month screening interval required by the Government Decree is met for each person, regardless of any change of screening provider. For quality assurance purposes, information on the invitations sent is submitted to the Mass Screening Registry maintained by the Finnish Cancer Registry.

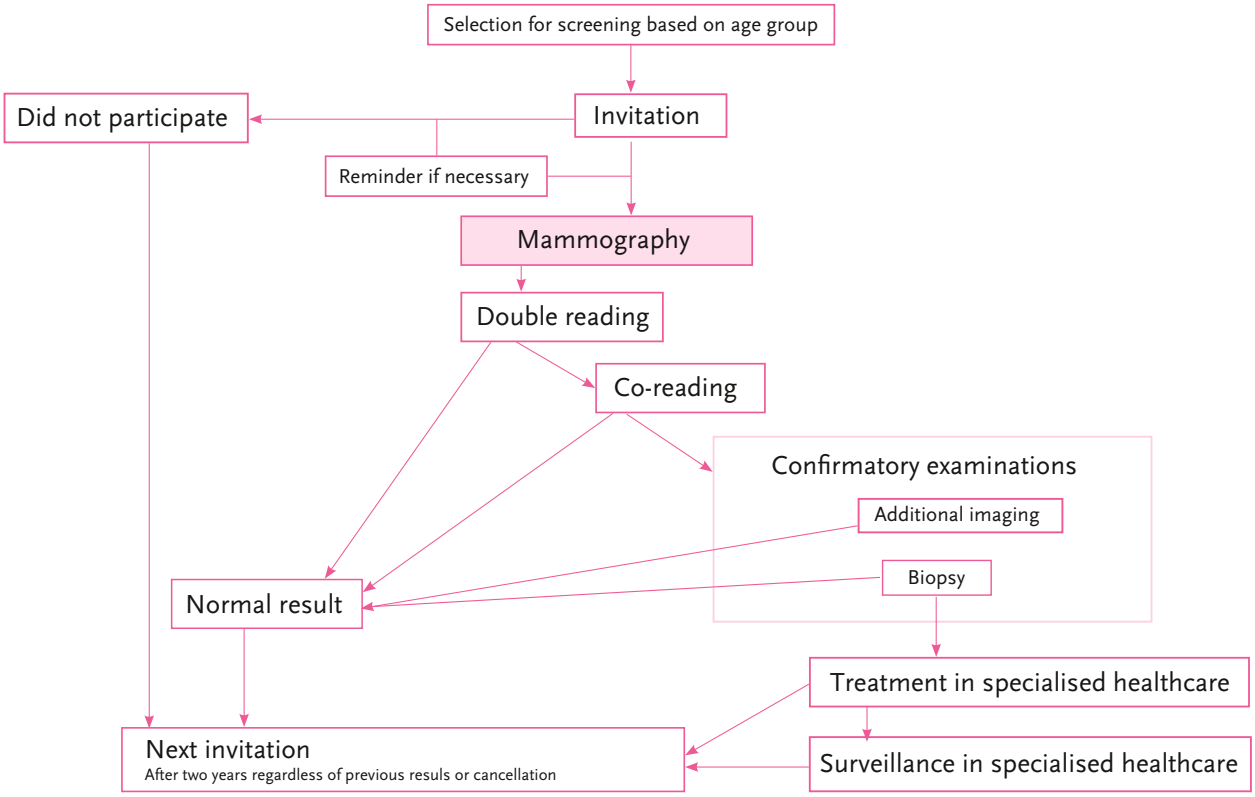


**Figure 1. Screening protocol of breast cancer screening.**

The first screening invitations are sent out in January of each year so that imaging can start from the beginning of February. Screening invitations should be sent out and screening images should be performed evenly throughout the year, taking into account holiday periods, to ensure a steady flow of referrals to specialised healthcare. This will prevent backlogs in breast cancer surgery and oncology units. Those invited to screening are entitled to participate until the end of March of the following year. This means that even those invited at the end of the year have at least three months to participate in screening.

## 6.3 CONTENT OF THE INVITATION

The invitation is sent to the target population in paper or electronic form via the suomi.fi service or another similar channel requiring strong authentication that the person has adopted. The invitation letter is either bilingual or in the recipient's own mother tongue if Finnish or Swedish is the mother tongue. If there are significant linguistic minorities in the well-being services county, consideration should be given to translating the invitation into other languages.

**The invitation must contain the following information:**

- Date and place of the mammography
- Possibility to change the screening appointment time. It must be possible to change the screening time easily and securely. Sufficient time for screening must also be available in the evenings and/or at weekends.

**To make a decision on participation, the invitation letter must contain the following information:**

- The purpose of screening
- The screening procedure
- The importance of early detection of disease

- The benefits and harms of screening
- On follow-up examinations, how those are performed and about their relevance
- On the existence of screening quality monitoring

**The letter must also include:**

- Information on how the screening result will be communicated to the participant
- Information on how quickly the screening result will be provided (TARGET 2 weeks, 3 weeks after screening at the latest)[15]
- Contact for further information
- Indication of the address source (DVV Population Information System)

There are invitation letter templates (language versions in Finnish, Swedish, English, Northern Sami and Russian) produced and maintained by the Finnish Cancer Registry, which can be used as a basis for or as an invitation letter. The invitation templates, as well as other screening materials of the Finnish Cancer Registry, can be found on the website[16] of the Finnish Cancer Registry, https://cancerregistry.fi/screening/organising-cancer-screening/.

## 6.4 REMINDER INVITATION

If the person invited to the screening has not attended the screening, the screening officer will send a reminder invitation six (6) weeks after the first invitation was sent. A model reminder letter is available in Finnish, Swedish and English on the website of the Finnish Cancer Registry, as are other invitation and reply letter templates for breast cancer screening[16].

# 7. SCREENING DESCRIPTION

- Mammography is the primary screening method.
- The imaging includes two imaging projections of both breasts: craniocaudal and mediolateral oblique.
- The screening operator must organise quality assurance of the activities that expose the workers to radiation.
- During the imaging session, any symptoms and clinical examination findings are recorded.

## 7.1 DIGITAL MAMMOGRAPHY

Mammography is the primary screening method for breast cancer and direct digital mammography is the preferred imaging modality.

The technical characteristics of the imaging equipment and its peripheral devices (including imaging plates and image reader, if used) and imaging software must be suitable for mammography examinations. The equipment and the peripheral equipment and instruments associated with its use must meet the in-service acceptance requirements specified in the Radiation and Nuclear Safety Authority (STUK) decision on radiation safety in mammography[17].

The imaging includes two imaging projections of both breasts: craniocaudal and mediolateral oblique[15]. As a rule, the area of a removed breast does not need to be imaged. Images should aim to meet the criteria for good image quality[18]. Radiologists interpreting screening images are ultimately responsible for the quality of the images. If it is not possible to see the whole breast tissue in sufficient detail, the client should be invited for a technical repeat mammogram.

## 7.2 QUALITY CONTROL OF SCREENING IMAGING

The operator must organise quality assurance of the activities that expose the workers to radiation. A quality assurance programme must be drawn up to this end[11,17]. Internal quality assurance includes monitoring and self-assessment[19]. It is good practice to provide a self-evaluation plan and report annually to the wellbeing services counties so that quality performance can be monitored (e.g. staff qualifications and training, amount and quality of activities).

## 7.3 IMAGING SESSION

During the imaging session, symptoms reported by the woman/client and the findings of the examination (inspection) and manual palpation are recorded. These should be recorded in the pre-screening information so that the radiologists interpreting the images can take them into account[15].

The preliminary questionnaire, examination and response to any questions should take place in an unhurried manner in appropriate premises at a reasonable distance from the subject's place of residence.

- Screening should be carried out either in the subject's own municipality or in a neighbouring municipality that is easily accessible by public transport.
- You should allow at least 5+5 minutes for interviewing and imaging.

The client's consent (or refusal) to the transfer of screening data must be recorded in the patient record. Consent entitles the obtaining of comparative images from other screening units and feedback from the place of follow-up treatment to the screening provider.

## 8. INTERPRETATION OF IMAGES AND SCREENING RESULT

- The images are interpreted independently by two different radiologists.
- If necessary, a co-reading is made.
- If necessary, the person will be invited to a technical repeat mammogram.
- Cases where a malignant finding cannot be ruled out or is suspected, or where symptoms may be suggestive of cancer, are invited for confirmatory examinations on the basis of co-diagnosis.
- The result must be delivered in person no later than 3 weeks after the screening.

Interpretation of images is organised in a double-blind: images are interpreted by two different radiologists independently of each other[15]. If necessary, the co-reading will be carried out either in a combined session or remotely.

- Interpretation of images should be done on monitors with at least five megapixels.
- Before the images are interpreted, it is ensured that the client's previous mammograms are available. Comparison with previous images is very important, as a change in the findings (especially lesion growth tendency) is one feature that may indicate the possibility of malignancy.

Each radiologist interprets the images of the screening examination independently, and assesses

- whether the images are sufficient to assess the result or whether a (technical) repeat mammogram is needed,
- the nature of the image and decide whether to forward the images for co-reading.

In assessing the nature of the findings, attention is paid to nodular changes, architectural distortions, asymmetries and microcalcifications, especially their change or increase from the previous one, and radiological features that suggest possible malignancy.

Preliminary data recorded by the radiology nurse who took the images are also taken into account in the interpretation and should lead to a co-reading of the images (e.g. lump, retraction, bloody discharge from the nipple), even if no changes are detected in the screening images.

The screening assessment is graded on a scale of 0–5

- Failed = 0
- Normal = 1
- Benign = 2
- Malignancy not excluded = 3
- Suspected malignancy = 4
- Almost certain malignancy = 5

### 8.1 NORMAL RESULT

*"The result of the screening is negative, the individual result from both radiologists is negative"*

If both readers score 1 or 2 on the screening and neither has referred the images for co-reading, the client will be informed and will receive the next screening invitation in the future according to their age group.

### 8.2 GUIDING CO-READING

*"The radiologist's individual result is positive"*

If the radiologist is in doubt about the benign nature of the finding, he or she may refer the results to 1 or 2 co-reading for joint consideration. Findings 3, 4 or 5 of one or both radiologists are always referred for a co-reading.

The radiologists who interpreted the images in the joint lecture will decide on the cases,

- that do not require further screening (co-screening result 1 or 2) and are sent a normal result
- invited for confirmatory examinations (co-reading outcome 3, 4 or 5)

## 8.3 INVITATION TO A TECHNICAL REPEAT MAMMOGRAM

*"Still no result in screening, no result in radiologist's interpretation"*

If the result of the reading is a failure, i.e. 0, the reading can be cancelled before the result is given, in which case the subject is called for a technical repeat mammogram. Alternatively, in a co-reading session, it may be decided to invite the subject for a technical repeat mammogram, in which case the result of the co-reading session is also 0. The technical repeat mammogram is subject to a double reading as with the screening.

If the subject's condition does not allow the mammogram images to be taken, the reading is defined as failed and is assigned a value of 0. In this case, the screening is not performed and the screening result cannot be given.

## 8.4 INVITATION TO CONFIRMATORY EXAMINATIONS

*"The result of the screening is positive"*

Invitations for confirmatory examinations take place when

- cases decided at co-screening on the basis of mammograms require further follow-up examinations, i.e. in co-reading results 3, 4 or 5.
- women who have complained of symptoms suggestive of cancer at the time of screening (see preliminary data) or if the radiology nurse has noticed a lump in the subject's breast during the imaging.

## 8.5 REPORTING THE SCREENING RESULT

The result must be delivered in person by the deadline indicated in the invitation, but no later than 3 weeks after the screening[15]. The result will be sent by post in paper or electronic form via the suomi.fi service or any other equivalent channel requiring strong authentication that the person has adopted. If the result of the screening is positive, the person will receive an invitation for further examination.

## 9. FOLLOW-UP OR CONFIRMATORY SCREENING TESTS

- Women are referred for follow-up examinations if breast cancer cannot be ruled out on the basis of mammograms or if cancer is suspected.
- The aim is that follow-up examinations are done within a month of the screening.
- Supplementary imaging will be done as necessary during confirmatory examinations.
- If possible, a biopsy will be taken during the same visit.
- The doctor who performed the confirmatory examinations will inform the patient of the results and, if necessary, make an urgent referral to specialised healthcare.

If the result of the screening is positive, i.e. cancer cannot be ruled out on the basis of the mammography images or the imaging raised suspicion of cancer, the radiologist responsible for the screening examination makes an urgent referral for follow-up examinations, which are carried out in accordance with the current national diagnostic and treatment guideline[1,20].

The aim is that follow-up examinations are done within a month of the screening, i.e. within about a week of the co-reading[15].

The venue of the follow-up examination must be within a reasonable distance from the subject's home (at most the same distance as to the place of specialised healthcare).

Follow-up or confirmatory examinations are carried out in the screening unit by a radiology specialist with a special qualification in screening mammography.

Supplementary imaging will be made as necessary during the confirmatory examinations. Confirmatory examinations are to be performed with monitors of at least 5 megapixels to ensure adequate and appropriate diagnostic accuracy, especially when interpreting supplementary images.

Confirmatory examinations always include a supplementary ultrasound (US) scan. The ultrasound machine used for the scan can be up to 10 years old. The ultrasound machine must contain software for breast imaging and an imaging sensor frequency range, preferably 15 MHz and 18–24 MHz for superficial changes.

The confirmatory examination radiologist makes a radiological diagnosis (BI-RADS 1–5)[21], deciding whether the change requires a needle biopsy and how suspicious the change is radiologically. If possible, the sample will be taken at the same visit. The purpose of sampling is to establish the extent of the disease in both breast and axillary regions so that, after confirmatory investigations, the patient can proceed directly to surgery if necessary.

The doctor who performs the confirmatory examinations will inform the person being examined of the result. If the result of the examination is benign without biopsy, the subject will be told so immediately. If the result of the examination requires biopsy, an appointment will be made to hear the result of the examination when the biopsy is done. On receipt of the result of the specimen, the radiologist conducting the examination will summarise the radiological and pathological results and inform the subject of the result of the examination. If necessary, the doctor who performed the confirmatory examinations will make an urgent referral for specialised healthcare.

### 9.1 SUPPLEMENTARY MAMMOGRAPHY

Confirmatory examinations include, if necessary, additional mammograms, targeted imaging, targeted enhancement, tomosynthesis imaging or contrast-enhanced mammograms in the directions considered best.

- In lateral direction a tomosynthesis or an additional image is taken in the first instance. This is particularly important in the case of a small

mammographic lesion, as it makes it easier to determine the size of the lesion.

- Supplementary images are taken of the target if more than 25% of the tumour edge is obscured. Images are taken to assess the nature of the lesion (whether real or not) and its margins and the extent of any microcalcifications associated with the lesion.
- If cancer is not suspected in the first instance and the benign nature of the lesion can be confirmed by ultrasound (cyst), a complementary mammogram may not be performed. If a cyst is not confirmed by ultrasound, additional images should be taken before sampling.
- Tomosynthesis imaging generally replaces target images for nodules, architectural distortions and/or asymmetries.
- Lateral and craniocaudal target magnifications are taken of microcalcifications.

The mammogram images are used to classify the features of the change in the radiologist's opinion, and these are used to assess the risk of the lesion being either benign or malignant.

- Nodule
  - Shape: round, oval or irregular
  - Margin: circumscribed, obscured, microlobulated, indistinct or spiculated
  - Density compared to breast tissue: more dense, equally dense, less dense or fatty
- Microcalcifications
  - Appropriate as benign
  - Suspicious for malignancy
    - Amorphous
    - Coarse heterogeneous
    - Fine pleomorphic
    - Fine linear or branched
- Architectural distortion
- Asymmetries
  - Asymmetry: the discovery of a single projection
  - Global asymmetry: at least one quadrant
  - Focal asymmetry: less than one quadrant
  - Developing asymmetry: new, increasing or more intense

Based on the screening images and the supplementary mammography, the statement will indicate the size of the radiological lesion, the possible multicentricity and the location of the lesion in terms of breast quadrants and depth:

- Upper outer quadrant, upper inner quadrant, lower inner quadrant, lower outer quadrant, central or extending into several quadrants
- Anterior, middle, posterior

## 9.2 ULTRASOUND IMAGING

Confirmatory examinations always include a supplementary ultrasound scan, which must include both breasts and armpits. The ultrasound examination also includes palpation of both breasts.

In ultrasound imaging, the location of the lesion is marked on the ultrasound still images.

The size of the lesion, the location according to clock-face notation (1–12) and the distance from the nipple must be noted on the radiologist's report and referral.

To ensure quality, an ultrasound still image of both breasts and a still image of the axillary lymph node on both sides may be required if it is suspected that the instructions for their inclusion in the examination are not being followed.

The suspect nature of ultrasound findings is assessed in the radiologist's report, as with mammography images, according to the BI-RADS classification[21]. The report describes the general structure of the tissues: flat adipose tissue, flat glandular tissue, uneven/hard to interpret and

- Orientation of the lesion: parallel to the tissue or in the opposite direction
- The echo pattern structure, shape and margins of the lesion finding
- Whether the lesion is hyperechoic or causes a shadow
- Whether the lesion contains microcalcifications or macrocalcifications
  - that can be located in a duct and stretches it

- Whether the lesion contains both anechoic and solid parts = complex mass

A more detailed definition of the findings can be found in the Guide to Breast Diagnostics, 4th edition[20], BI-RADS textbook[21], The Radiology Assistant: BI-RADS[22].

## 9.3 OTHER CONFIRMATORY EXAMINATIONS

An abnormal breast discharge is examined by galactography (ductography) in confirmatory examinations to assess whether the appearance of the duct is normal, benign or suspected to be malignant. In ambiguous or symptomatic cases, the cyst is drained by aspiration.

## 9.4 RADIOLOGICAL SUMMARY

Based on the confirmatory imaging, a radiological diagnosis (BI-RADS 1-5[21]), is made to decide whether the lesion requires a biopsy and how suspicious the lesion is radiologically.

BI-RADS:

- Normal = 1
- Benign = 2
- Probably benign = 3
  - In screening, benignity is usually confirmed by biopsy (the purpose of screening is to exclude cancer), but in some cases a control is done between screenings. The proportion of controls should be less than 1% of cases who went through follow-up examination, TARGET 0%).
- Suspicion for malignancy = 4
  - A biopsy must be done, but a benign results that explains the finding is acceptable.
- Highly suggestive of malignancy = 5
  - A biopsy must be done and a benign result is unacceptable. If necessary, new biopsies must be taken or percutaneous/surgical removal must be performed.

## 9.5 BIOPSIES

The purpose of taking a biopsy is to determine the extent of the disease in both breasts and in axillary lymph nodes so that the patient can go straight to surgery after the confirmatory examinations.

### 9.5.1 Biopsies of breast lesions

For solid masses and architectural distortions of the breast, at least 3 to 4 14-gauge core needle samples are taken under ultrasound, stereotactic or tomosynthesis guidance. Lesions visible on ultrasound are usually sampled under ultrasound guidance.

- A sufficient number of samples and a transverse rotation of the US probe with respect to the needle should be used to ensure that the needle biopsy hits the target.
- To ensure quality, an ultrasound still image with the needle in the target may be required if there is too frequently a discrepancy between the radiological and histological findings.
- When biopsying, small lesions that cannot be guaranteed to be discernible after sampling should be marked with a marker/clip.
- If the US shows separate lesions more than 1 cm apart, both should be biopsied in their own containers. If there are more than 2 suspicious lesions, those furthest from each other are biopsied.

For microcalcifications suspicious for malignancy, at least 6 vacuum-assisted biopsies (with a minimum 10 g needle) are taken under stereotactic or tomosynthesis guidance.

- Stereotactic or tomosynthesis-guided biopsies are taken under the screening contract, either at the screening unit or at the hospital where the breast cancer is diagnosed.
- The presence of calcifications in the biopsy samples should be confirmed by an x-ray of the sample pieces and, if necessary, taking further samples at the same time if no calcification is present in the samples.
- For calcified clusters larger than 3 cm, 2 samples should be taken from different edges if the area is not completely uniform, and all multicentric clusters should also be biopsied separately.

### 9.5.2 Biopsy of axillary lymph nodes suspicious for breast cancer on the same side

In the case of suspicious breast findings of malignancy, the axillary lymph nodes of the same side

should be biopsied according to the current national diagnostic and treatment guidelines[1].

Biopsies are taken from the cortex of the suspicious lymph node using either a 14–16-gauge core needle or a fine needle aspiration.

### 9.5.3 Histopathological/cytological examination of biopsy samples

**Referral to a pathologist**

The radiologist must record in the referral: where the sample was taken (which breast, which quadrant or which axilla), the size of the tumour, whether it is multifocal, whether it is a mass an architectural distortion or calcification and the degree of radiological suspicion. The referral should also include any medical conditions in the history, such as a history of cancer and radiotherapy to the breast, and if the lesion has been previously biopsied.

**Pathologist's examination**

The pathologist will interpret the samples within one week (5 working days) and it must not take more than two weeks (10 working days) to obtain the results of any additional staining required.

**Additional staining**

When diagnosing ADH (atypical ductal hyperplasia), the pathologist should confirm the diagnosis by performing the recommended immunostaining, estrogen receptor staining (ERalpha) and cytokeratin staining CK5/6.

Myoepithelial staining (p63 and SMMHC) is recommended when interpreting the glandular structures of a sclerotic lesion as invasive ductal carcinoma.

The distinction between LCIS (lobular carcinoma in situ) and the solid growth variant of DCIS (ductal carcinoma in situ) is based on E-cadherin immunostaining.

When diagnosing in situ papillary carcinoma, the pathologist should perform myoepithelial staining (p63 and SMMHC) to confirm the absence of myoepithelial cells in papillary structures.

**Core needle, vacuum-assisted and fine-needle aspiration sample report**

The pathologist will describe the histology of the specimen in their report the core needle/vacuum-assisted sampling and will determine the pathological anatomical diagnosis (PAD), including SNOMED M and T codes, ICD-O-3 codes or SNOMED CT codes.

A fine-needle aspiration biopsy is classified as

- Failed = 0
- Normal = 1
- Good quality = 2
- Malignancy not excluded = 3
- Suspected malignancy = 4
- Almost certainly malignant = 5

## 9.6 REPORTING ON CONFIRMATORY EXAMINATIONS AND REFERRAL FOR SPECIALISED HEALTHCARE

### 9.6.1 Communicating the results

The radiologist who performed the confirmatory examinations will inform the subject of the result.

If the result of the follow-up test is benign without biopsy, the subject will be told immediately.

An appointment will be made at the time of the biopsy for a consultation about 1 week (5 working days) in advance, by which time the results of the needle biopsy must be ready. If the sample requires additional staining, after the initial result, the final result must be ready in 2 weeks.

After receiving the report on the biopsy, the radiologist conducting the examination must decide on the next steps and inform the subject of the result.

- Benign, no conflict with radiological findings, no further intervention.
- Malignant or high-risk lesion recommended for removal, referral to specialised healthcare.

- Discrepancy between the radiological findings and the biopsy result, urgent re-sampling or referral for further investigation in a specialised healthcare.

If the result of the follow-up examinations remains unclear and a control is needed, the radiologist who performed the confirmatory examinations will agree with the person on the time and date of the control.

### 9.6.2 Referral to specialised healthcare

If necessary, the doctor who performed the confirmatory examinations will make an urgent electronic referral to specialised healthcare.

**The referral must contain**

- relevant medical history (diseases, surgeries, family history, smoking yes/no, height and weight)
- clinical findings (palpation, inspection; possible redness of the skin of the breast, puckering or dimpling and nipple discharge)
- radiological findings
- pathologist's report and pathological anatomical diagnosis / diagnoses

Images from the screening and follow-up examinations are sent to the specialised healthcare.

Pathology specimen blocks (at least for cancers and indeterminate cases) are sent to the specialised healthcare.

Subjects who are admitted to hospital are monitored to ensure that they receive appropriate examinations and treatment. The electronic referral system should have a feedback system to ensure this.

Under the Act on the Status and Rights of Patients, a patient must be asked to consent to the transfer of data, images and samples between the screening provider and the hospital providing treatment. Consent should be requested and recorded in the medical record at the initial stage of screening.

### 9.6.3 Feedback from specialised healthcare to the screening unit

Information on treatments performed in specialised healthcare and the final histological finding must be submitted as described below to the screening provider, who will forward the information to the Mass Screening Registry of the Finnish Cancer Registry[12]. The wellbeing services county is responsible for transferring the data to the screening system of the screening provider and from there to the Mass Screening Registry. The physician in charge of the screening unit can also view the specialised healthcare data from the registry if the patient has not refused to do so.

**For all referrals to specialised healthcare, the following are needed:**

- PAD (pathological anatomical diagnosis with SNOMED M and T codes (or SNOMED CT codes))
- Date of procedure or date of decision to treat with neoadjuvant therapy, if applicable
- Code number(s) of the procedure
- If no treatment is given, but further tests have been carried out in a specialised health care (MRI, vacuum-assisted imaging), their date and result.
  - 0 Not known
  - 2 Suitable for benign
  - 3 Suspected malignancy
  - PAD
- Date of decision, if no treatment is given and no imaging or new sampling was done in specialised healthcare.

**And concerning cases of cancer:**

- Tumour size (mm) on surgical specimen or MRI, if neoadjuvant treatment
- Possible multifocality on surgical specimen or MRI if neoadjuvant treatment
- Location of tumour on surgical specimen or MRI if neoadjuvant treatment
- Tumour grade
- Local lymph node involvement both in sentinel lymph node biopsy and in axillary lymph node dissection separately: number of metastatic lymph nodes and number of all lymph nodes removed
- TNM-classification

# 10. TREATMENT IN SPECIALISED HEALTHCARE

- Treatment in specialised healthcare is carried out in accordance with the national diagnostic and treatment recommendations of the Finnish Breast Cancer Group.
- Multidisciplinary team meetings, or MDTs, are the gold standard for cancer care and diagnostics.
- Screening radiologists and pathologists should be enabled to attend MDT meetings and are encouraged to attend MDT meetings on a regular basis.

Treatment and follow-up in specialised healthcare is carried out in accordance with the national diagnostic and treatment recommendation of the Finnish Breast Cancer Group[1].

## 10.1 RADIOLOGY

- Any additional imaging needed, such as MRI or contrast-enhanced mammography
- Additional biopsies required
- Marking the surgical site
- Vacuum-assisted excision of selected lesions

## 10.2 SURGERY

Available surgical techniques in all breast cancer units

- Breast-conserving surgery
  - If necessary, oncoplastic techniques are used to conserve the shape and size symmetry of the breast.
- Mastectomy
  - For patients suitable for full breast reconstruction, the option of immediate reconstruction is offered.
- Axillary surgery
  - Sentinel lymph node biopsy or axillary dissection depending on the axillary lymph node involvement
  - For neoadjuvant-treated patients, targeted axillary dissection (TAD), if treatment response has been achieved by imaging

## 10.3 PATHOLOGY

- Histological examination of tissue samples and pathological and anatomical diagnosis/diagnoses
- Estimate of adequate surgical margins

## 10.4 ONCOLOGY

- Neoadjuvant therapy
- Adjuvant therapy

## 10.5 MULTIDISCIPLINARY TEAM MEETINGS (MDTS)

- Multidisciplinary team meetings (MDTs) are the internationally recognised gold standard for cancer care and diagnostics[23].
- According to the quality criteria of the European Society of Breast Cancer Specialists (EUSOMA) and the Organisation of European Cancer Institutes (OECI), all or more than 95% of patients with early breast cancer should have a treatment recommendation at the MDT meeting, both before and after surgery[24,25]
- Doctors in training, junior specialists and nurses should attend MDT meetings for training purposes and should be given the opportunity to do so.
- Screening radiologists and pathologists from the wellbeing services county should be enabled to attend MDT meetings and are encouraged to attend MDT meetings regularly.
  - Data protection rules must not prevent this from happening, but a confidentiality/non-disclosure agreement policy must be put in place.
- Procedure code WZC15 is used for the MDT meeting
- The method of detection of screening-age cancers should be taken into account and the assessment of possible interval cancers should be carried out in accordance with Annex I in the context of quality control and training[15]. The registration of this assessment in a secure manner must be agreed in the wellbeing services county (Annex I).

## 11. SKILLS AND TRAINING

- A radiology nurse who performs screening imaging must have completed the Society of Radiographers in Finland mammography course (certificate of competence issued by the Society of Radiographers in Finland) or an equivalent national or foreign course.
- At least one of the radiologists interpreting the screening images must have a special competence in screening mammography.
- Persons performing screening mammography examinations and interpreting images must undergo appropriate continuing education.
- Persons performing screening mammography examinations and interpreting images must maintain competence by performing sufficient imaging/image readings each year.
- The person performing or responsible for the confirmatory examinations must have a special competence in screening mammography.
- Pathologists, surgeons and oncologists are also required to have adequate knowledge of breast cancer treatment and diagnosis, attend MDT meetings and undergo continuing education.

### 11.1 PROFESSIONAL COMPETENCE, TRAINING, AND SELF-ASSESSMENT OF RADIOLOGY NURSES

The person performing the screening imaging must be a radiology nurse with experience in clinical mammography, and who has attended continuing education on screening. The radiology nurse performing the screening imaging must have completed the Society of Radiographers in Finland mammography course (certificate of competence issued by the Society of Radiographers in Finland) or an equivalent national or foreign course[17].

- A radiology nurse must have taken at least 200 mammograms, or 50 clinical mammograms, before moving on to screening mammograms[18].
- To maintain their competence, they must perform screening mammography examinations as follows: at least 400 images, i.e. 100 examinations per month. They must work at least four full working days per month, preferably one full working day per week. On an annual basis, this means 3 000 mammograms, including holidays, or 750 clients[18].
- Persons carrying out the imaging must undergo appropriate continuing education (two training days per year, national or foreign training in breast and radiation protection).
- Self-evaluation annually, see Annex II.

### 11.2 PROFESSIONAL COMPETENCE, TRAINING, AND SELF-ASSESSMENT OF RADIOLOGISTS

Screening mammography images must be interpreted by two radiologists with experience in mammography and image interpretation. At least one of them must have a special competence in screening mammography. Persons interpreting mammograms shall undergo continuing education and training[17].

- Radiologist interpreting mammograms must be a licensed physician in Finland and be able to work independently as a licenced professional in Finland.
- The Finnish Medical Association or the Radiological Society of Finland Special Competence Advisory Board provides a special competence in screening mammography[26].
- At least one of the two image readers (READER 1) must have a special competence in screening mammography and TARGET: more than 3500, MINIMUM: 2000 screening readings per year in previous years.
  - According to the EU recommendation, the best quality is achieved when the interpreter performs 3500–11000 screening reads/year (low degree of research evidence)[27].
  - Screening requirements must be proportionate to the need and the availability of experienced interpreters in the area.
- Before starting the screening work, the second image reader (READER 2) must have performed a sufficient number of mammography examinations under the supervision of an experienced radiologist in the hospital and/or screening unit participating in the reading as a third reader.

- A minimum of 6 months is considered sufficient, including any months spent in the specialisation period.
- While under supervision, must have attended pre-operative and post-operative breast cancer MDT meetings organised by the university or central hospital MINIMUM: once a month, TARGET: at least every two weeks.

- The person performing or responsible for the confirmatory examinations must have a special competence in screening mammography.
- The person performing the confirmatory examinations should attend pre- and post-operative breast cancer MDT meetings organised by the university or central hospital on a regular basis.
  - MINIMUM once a month TARGET at least twice a month, excluding holiday periods.
  - Remote access is practical and should be organised.
  - Data protection rules must not prevent this from happening, but a confidentiality/secrecy agreement must be put in place.
- Experienced radiologists in the screening unit should be required to participate in training for new interpreters of mammography images.
  - Procedures and compensation to be agreed locally.
- Screening radiologists must attend at least 3 days of continuing education/training in breast radiology in Finland or abroad per year, of which 1 day could be replaced by radiation protection training.
- Screening radiologists aim to achieve at least 85% sensitivity and 85% specificity in their work.
  - This is the pass mark for the exam required to obtain the special competence in screening mammography.
  - In practice, good practices for self-evaluation and quality control need to be developed. For details, see Annex II.

## 11.3 PROFESSIONAL COMPETENCE OF PATHOLOGISTS

The aim is that the analysis of breast samples (core and fine needle biopsies and surgical biopsy) should be carried out by a pathologists with sufficient knowledge of breast cancer pathology who has maintained their skills in clinical work and through participation in further training in the field (Finnish branch of the International Academy of Pathology IAP, and ESP, the European Society of Pathology).

The aim is that the surgical specimen is examined by a pathologist who has sufficient knowledge of breast cancer pathology and who has maintained his/her skills through clinical work and participation in further training in the field (Finnish IAP and ESP).

## 11.4 PROFESSIONAL COMPETENCE OF SURGEONS

The aim is for breast cancer to be operated on by a specialist surgeon with comprehensive knowledge of breast cancer diagnosis, treatment and different surgical techniques, or a surgical resident under the supervision of a specialist[28].

- Surgeons maintain their skills in clinical work, and by attending MDT meetings and continuing education in the field in Finland and abroad.
- Residents are trained by specialists in breast cancer surgery , and also residents have the opportunity to participate in national and international training courses.

According to the Government Decree on the division of tasks and the centralisation of certain tasks in specialised healthcare, breast cancer surgery is to be performed in units where at least 150 breast cancer operations are performed per year and each surgeon performs at least 50 breast cancer operations per year.

## 11.5 PROFESSIONAL COMPETENCE OF ONCOLOGISTS

The aim is that the planning and implementation of adjuvant therapy of breast cancer should be carried out by a medical oncologists with expertise in breast cancer diagnosis, drug therapy and the management of possible side effects of treatment, or a resident under the guidance of a specialist. The planning of

radiotherapy should be carried out by an experienced radiation oncologist or a resident under his/her supervision.

- In addition to their clinical work and MDT meetings, oncologists and residents should regularly participate in continuing education provided by their employer, as well as other training courses in Finland and abroad.

## 12. DATA TRANSMISSION AND REPORTING

- The screening operator is responsible for collecting data on all stages of the screening chain for reporting to the Mass Screening Registry of the Finnish Cancer Registry.
- The register of patient data generated during screening is kept by the wellbeing services county, even if it purchases the service from an external service provider.
- The data submitted to the Finnish Cancer Registry will be used to assess the quality and effectiveness of screening.

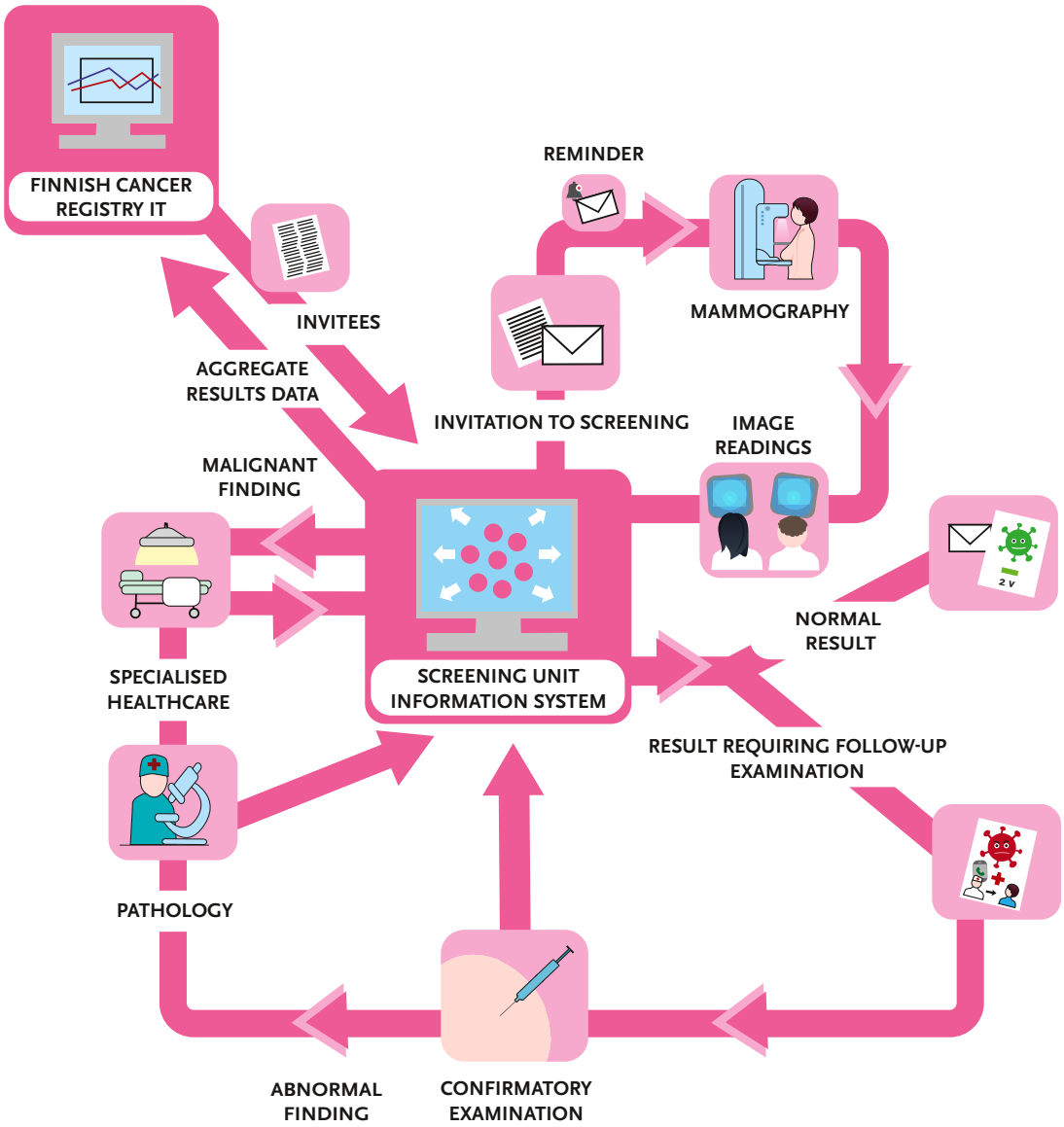


**Figure 2. Information flow between the screening centre and other actors.**

## 12.1 REGISTRATION OF SCREENING DATA

It is the responsibility of the screening provider, i.e. the wellbeing services county or its outsourced service provider, to collect data on all stages of the screening chain for reporting to the Finnish Cancer Registry (Figure 2). It is also essential that the different steps in the process (e.g. referral, sampling and analysis, follow-up examinations) remain linked so that the data can be analysed as a coherent screening chain.

The controller of the patient data, including samples and images, generated during the screening process is the wellbeing services county, even if it purchases the service from an external service provider. Screening data are patient records and are confidential. However, the screening provider has a legal right to process all screening data, including data for follow-up examinations and specialised healthcare. Likewise, the units providing the latter have a statutory right to transmit this data to the screening provider.

Patient records from previous screening rounds (such as findings and reports from previous screenings) and screening images should be available for interpretation at the next screening round. It would be good practice for the wellbeing services county itself to archive the documents, samples and images so that they are most readily available and accessible.

If the archiving of documents, images and samples is outsourced to a screening provider:

- The place where the screening data is archived and stored must be agreed and their availability ensured.
- When storing and transferring mammograms, the diagnostic quality of the images must remain unchanged.
- The costs and potential risks of data transfer must be taken into account in the purchased service contract.
- It must also be agreed how screening images will be made available free of charge if the subject changes or needs images between screenings.

The cancer screening provider must ensure that individual-level data on the different stages of screening are submitted to the Mass Screening Registry of the Finnish Cancer Registry. The quality and effectiveness of the screening will be assessed on the basis of the data submitted to the Finnish Cancer Registry. It is advisable that data submission is automated periodical routine, but the data should be submitted latest by the end of August of the year following the screening year.

To ensure smooth data collection, screening providers must provide a reporting system for reporting follow-up and treatment data. The specialist who performs the follow-up examinations shall report the follow-up examination data to the screening provider's electronic reporting system.

According to the THL administrative decision (https://thl.fi/aiheet/tiedonhallinta-sosiaali-ja-terveysalalla/maaraykset-ja-maarittelyt/hallintopaatokset), in Finnish), individual-level screening invitation and screening data and data on the first treatment offered must be submitted in accordance with the data model and parameters defined by the Finnish Cancer Registry. More detailed instructions and a description of the data model and parameters are available on the website of the Finnish Cancer Registry[29].

The Act on the Processing of Client Data in Health Care and Social Welfare (703/2023)[30] obliges the archiving of new image data in the Kanta archive. The Act entered into force on 1 January 2024 and applies, among other things, to image data generated from screening examinations. The deadline for archiving new image data is 1.10.2029.

# 13. SCREENING MONITORING AND PROGRAMME QUALITY ASSURANCE

- Quality assurance in breast cancer screening includes self-assessment by radiology nurses and radiologists and quality control by the screening unit.
- The Finnish Cancer Registry assesses the quality and effectiveness of screening and reports statistics on the quality indicators of the screening chain.
- The wellbeing services counties and the HUS Group in Uusimaa must ensure the quality assurance of the follow-up examinations and screening process in accordance with the national screening programme.
- The wellbeing services county must appoint a person responsible for breast cancer screening.
- The wellbeing services counties should ensure the training and further training of screening experts to enable high-quality breast cancer screening that meets the targets.
- Each screening unit must have a designated quality manager.

Quality assurance in breast cancer screening includes self-assessment by radiology nurses and radiologists and quality control by the screening unit. Recommendations on the principles and criteria for quality control are set out in the Quality Control Annex (Annex II). Quality assurance includes an annual self-assessment at an individual level, and in addition, the wellbeing services county must monitor the quality of the screening units in its area. The Finnish Cancer Registry is responsible for quality control of screening activities nationwide.

## 13.1 THE FINNISH CANCER REGISTRY

The Finnish Cancer Registry assesses the quality and effectiveness of screening. It reports on the quality of screening through screening statistics, which include screening quality indicators on the performance of the screening chain. The screening statistics are published annually at national level and by wellbeing services counties with a delay of about two years[31]. The Finnish Cancer Registry's screening statistics report quality indicators in accordance with international recommendations as time series, so a comparison between screening years is possible. The quality indicators reported have been set at recommended and target levels[15], which are defined in detail in the annex on quality control (Annex II).

## 13.2 WELLBEING SERVICES COUNTIES

The screening regulation[11] and in accordance with the guidelines of the Ministry of Social Affairs and Health, the wellbeing services counties operating a university hospital and the HUS Group in Uusimaa province must ensure the quality assurance of follow-up examinations and the screening process in accordance with the national screening programme.

The wellbeing services county must appoint a person responsible for breast cancer screening, who is a radiologist specialised in breast radiology. This person shall be responsible for the implementation and quality control of screening and shall have sufficient time to carry out this task.

Wellbeing services counties should take quality indicators into account in their quality monitoring in as many ways as possible. Thus, in addition to the indicators reported by the Finnish Cancer Registry, the wellbeing services counties should take into account the proportion of malignant findings in screening, possible variations between different screening providers, the proportion of small cancers and DCIS, as well as interval cancers between screenings. Attention should also be paid to the quality of interpretation of screening samples and feedback should be provided to pathologists interpreting screening samples. Objectives and guidelines can be found in Annex II and a model form for the assessment of cancers in screen-aged women can be found in Annex I. An appropriate plan for the registration of these data should be drawn up.

The screening contract should set out the quality standards, how they will be monitored and what will be done if the guidelines or targets are not met.

Wellbeing services counties should ensure the training and continuing education of screening experts to enable high-quality breast cancer screening that meets the targets.

The aim should be a quality monitoring and quality improvement programme for each screening unit, radiology nurse and radiologist.

Each screening unit should have a designated quality manager, who is responsible for monitoring screening results, self-assessment and providing feedback to screening radiologists and radiology nurses[15].

# 14. COMMUNICATION AND INFORMATION

- Communication on screening is primarily the responsibility of the wellbeing services counties.
- Communication should give a good idea of the purpose of the screening and the screening process.
- Good information is needed at all stages of the screening chain: from invitation to screening to screening results and possible follow-up examinations.
- Particular attention should be paid to those with an abnormal result in the information provided.
- Communication should also aim to reach people who have not participated in the screening programme.
- Information material may need to be tailored to suit different audiences, taking into account, for example, socio-economic, linguistic and cultural differences and specific groups.
- The screening invitation letter is an important first contact with the person to be screened.
- Radiology nurses should also be trained in communication skills.

## 14.1 THE AIM OF COMMUNICATION

Screening has significantly reduced breast cancer mortality. The benefits of screening have also been estimated to outweigh the harms. To ensure that screening continues to be effective, the programme should be communicated to the target population with the aim of achieving the highest possible screening uptake.

The communication should give a good understanding of the purpose of the screening and the screening process. It should also increase a sense of security at different stages of the screening chain. Good communication and information can minimise the potential psychological harms caused by screening. At the same time, it is necessary to communicate to healthcare staff and women seeking mammography that imaging asymptomatic younger and older women than the screening target age should be avoided[32].

Communication on screening is primarily the responsibility of the wellbeing services counties. The wellbeing services county must ensure that its residents have access to sufficient information on the objectives and effectiveness of screening, the potential risks associated with screening and the organisation of screening[11].

## 14.2 COMMUNICATION CONTENT

Good communication is needed at all stages of the screening chain: from invitation to screening, to screening results and possible follow-up examinations. The person invited for screening must have access to clear and accurate written information at all times.

Both summarised basic information and more detailed information on the different stages of screening should be available. Screening invitations and materials should contain the same information throughout the country to ensure regional parity. The Cancer Registry provides and updates materials (e.g. leaflets, invitation letters, result letters) freely available to screening providers[16]. Materials are available in different languages.

Particular attention should be paid to those with an abnormal result in the information provided.

## 14.3 IMPROVING PARTICIPATION

Communication should also aim to reach people who have not participated in the screening programme. Reminders are key to improving participation and should be used routinely throughout the country[33]. In areas where screening participation is lower than average, regional communication activities and campaigns can be implemented where appropriate.

Communication must emphasise the need for screening but in a way that does not compromise the right to self-determination and the ability to opt out of screening.

## 14.4 SPECIAL GROUPS

A major challenge in communicating about the screening programme is the variety of recipients of such information. Information material may need to be tailored to suit different audiences. For example, socioeconomic, linguistic and cultural differences need to be taken into account. Information should be available through different channels and in different languages and, where appropriate, cooperation can be established, for example with different ethnic communities[34].

Care must also be taken to ensure that transgender people and people who have used hormone therapy over a prolonged period that increases the risk of breast cancer know that they are entitled to free screening, even if the invitation no longer comes after the change of personal identity number[14]. Information can be provided, for example, by the services coordinating sex reassignment therapy.

The right to screening for other specific groups, such as people with reduced mobility, hearing and vision impairment, and people with intellectual disabilities, must also be ensured through appropriate and accessible communication. For those who relocate during the screening year, a contact channel should be provided to ensure participation in screening.

## 14.5 INFORMATION AND COMMUNICATION CHANNELS

The screening invitation letter is an important first contact with the person to be screened. It should be concise and clear and include a pre-allocated time and place for the screening, with instructions on how to change these. It should be possible to change the time online and by telephone. The invitation should also indicate where more detailed information is available.

Comprehensive and up-to-date information is available on the internet, for example on the following websites:

- Health Village House hub[35]: https://www.terveyskyla.fi/tutkimukseen/kuvantamistutkimuksia/mammografia-ja-muut-rintarauhasen-tutkimukset (in Finnish)
- Cancer Society of Finland[36]: https://www.freefromcancer.fi/check-your-body/breast-cancer-screening-or-mammography/
- Finnish Breast Cancer Group treatment guidelines[1]: https://rintasyoparyhma.yhdistysavain.fi/hoitosuositus/ (in Finnish)

Radiology nurses are in direct contact with the people being screened, so they should also be trained in communication skills. Radiology nurses can answer questions from the people being screened or tell them where more information is available. This will increase confidence in the screening programme. Written materials such as screening leaflets should also be available at the screening sites.

A person with an abnormal screening result should be able to contact a healthcare professional in person for further information if they wish. Contact details for this purpose can be included, for example, in the result letter. The health professional should stress that an abnormal screening result does not mean cancer or even a precursor cancer. Psychological support is available, for example, from the Cancer Society's advice service.

Wellbeing services counties should inform about any changes to the screening programme. It is recommended to use a variety of channels, such as press releases and social media.

# 15. FUTURE OBJECTIVES OF BREAST CANCER SCREENING

- The European Commission updated its recommendation on cancer screening in December 2022.
- Digital mammography or digital tomography is the recommended screening method.
- It is recommended that the target group for breast cancer screening be extended from 50–69 years to 45–74 years.
- The recommendation also calls for consideration of personalised screening, taking into account hereditary breast cancer susceptibility and breast density.
- The use of artificial intelligence (AI) in breast cancer screening is being explored.

## 15.1 NEW EUROPEAN CANCER SCREENING RECOMMENDATION

European Commission updated its recommendation on cancer screening in December 2022[37]. According to the recommendation, digital mammography or digital tomography can be used as a screening method. Breast MRI is recommended as a screening test only for justified reasons. The recommendation also commented on the age range for screening and on personalised risk-based screening.

### Age group recommendations

The current EU Commission recommendation proposes that the target group for breast cancer screening should be extended from 50–69 years to 45–74 years. Dutch[38] and Finnish cost-effectiveness studies[39] support extending the screening target age from the current one, especially to younger women aged 45–49. An ongoing study at the Finnish Cancer Registry is currently evaluating in more detail the cost-effectiveness of expanding the age range of breast cancer screening. Preliminary results will be available in 2024 and will feed into a discussion on age group expansion in the Cancer Screening Steering Group and the Expert Group on Breast Cancer Screening.

### Risk-based monitoring of asymptomatic people

The current recommendation also calls for consideration of personalised approaches to breast cancer screening. Personalised breast cancer screening is based on an individual assessment of breast cancer risk, which is influenced by factors such as hereditary breast cancer susceptibility and breast density.

### Hereditary risk-based monitoring

One of the main risk factors for breast cancer is the hereditary risk of developing breast cancer. With hereditary risk being actively investigated through gene panel testing, a growing number of women at hereditary risk are identified each year.

Hereditary risk differs from population risk in several ways. Significant differences include a remarkably higher lifetime risk of breast cancer than the general population, the onset of the risk from younger age groups, and a different distribution of breast cancer subtypes. Risk-reducing strategies are considered for women at highest risk. On the other hand, hereditary risk is similar to age risk in that it is concentrated in healthy women without any external risk factors that can be identified at individual level. As with women screened on the basis of age risk, women at hereditary risk also need regular breast imaging monitoring.

Women at high risk of breast cancer are currently monitored in the healthcare service system, see in more detail the national diagnostic and treatment guidelines for breast cancer[1].

### Individualised complementary imaging based on breast density

The density of the connective tissue on mammograms is an independent risk factor for breast cancer and can mask the appearance of cancer on mammograms. It is recognised that mammographic screening is not sufficiently effective for women with dense breasts and individualised complementary screening with other methods based on breast density is recommended in Europe and worldwide[40]. Breast den-

sity can be assessed either computer-assisted or visually. Breast density assessment is not yet routine in breast cancer screening and its distribution in Finnish women of screening age is not known. It is therefore important to find out in a comparable way how many Finnish women have dense breasts and how to screen them in an appropriate and cost-effective way.

## 15.2 DIGITAL TOMOSYNTHESIS

Digital breast tomosynthesis imaging has been studied as a screening method for breast cancer, but there are no clear results on its superiority over mammography[41]. One disadvantage of tomosynthesis is the increased time required for the imaging procedure and image interpretation. The higher radiation dose of tomosynthesis must also be taken into account. According to the guidelines of the Radiation and Nuclear Safety Authority of Finland (STUK), the average dose of an image should not exceed the specified reference level[17]. If tomosynthesis were to be envisaged as a screening method, the reference levels would probably have to be increased. According to the Government Decree on Screenings, the programme for the implementation of screening must take a position on the suitability of the screening method, but the decree does not actually specify which method is to be used for breast cancer screening.

## 15.3 ARTIFICIAL INTELLIGENCE

In the Nordic countries, Sweden, Norway and Denmark have explored the potential of AI in population screening in retrospective studies[42-44]. These studies have used an AI application called Transpara, which classifies cases with a risk score of 1–10 at around 10%/value. Based on these retrospective studies, it could potentially reduce the screening workload by selecting low-risk cases identified by AI to be read by a single radiologist or even not read at all. Depending on the cut-off value,  a very few cancers of probably low aggressiveness would be missed. It could also be possible to find some of the interval cancers in the high-risk cases classified by AI already at screening. Promising results have recently been published from an ongoing randomised trial in Sweden, which are in line with these findings[45]. Studies elsewhere, therefore, suggest that the use of AI in breast cancer screening is worth exploring in Finland as well.

## 16. REFERENCES


1. Suomen Rintasyöpäryhmän ry:n valtakunnallinen diagnostiikka- ja hoitosuositus [Internet]. Suomen Rintasyöpäryhmä ry; Available from: https://rintasyoparyhma.yhdistysavain.fi/?x118281=178858

2. Finnish Cancer Register: Cancer Statistics [Internet]. Available from: https://cancerregistry.fi/statistics/cancer-statistics/

3. Hakama M, Pukkala E, Heikkila M, Kallio M. Effectiveness of the public health policy for breast cancer screening in Finland: population based cohort study. BMJ. 1997 Mar 22;314(7084):862-7

4. Rintasyövän seulonnan vuosikatsaus 2018 [Internet]. Finnish Cancer Register; Available from: https://syoparekisteri.fi/assets/files/2018/12/

5. Sarkeala T, Heinävaara S, Anttila A. Organised mammography screening reduces breast cancer mortality: A cohort study from Finland. Int J Cancer. 2008 Feb 1;122(3):614–9.

6. Heinävaara S, Sarkeala T, Anttila A. Impact of organised mammography screening on breast cancer mortality in a case–control and cohort study. Br J Cancer. 2016 Apr;114(9):1038–44.

7. Singh D, Pitkäniemi J, Malila N, Anttila A. Cumulative risk of false positive test in relation to breast symptoms in mammography screening: a historical prospective cohort study. Breast Cancer Res Treat. 2016 Sep;159(2):305–13.

8. Puliti D, Duffy SW, Miccinesi G, De Koning H, Lynge E, Zappa M, et al. Overdiagnosis in Mammographic Screening for Breast Cancer in Europe: A Literature Review. J Med Screen. 2012 Sep;19(1_suppl):42–56.

9. Heinävaara S, Sarkeala T, Anttila A. Overdiagnosis due to breast cancer screening: updated estimates of the Helsinki service study in Finland. Br J Cancer. 2014 Sep;111(7):1463–8.

10. Terveydenhuoltolaki 30.12.2010/1326 [Internet]. Oikeusministeriö; Available from: https://www.finlex.fi/fi/laki/ajantasa/2010/20101326

11. Valtioneuvoston asetus seulonnoista 6.4.2011/339 [Internet]. Oikeusministeriö; Available from: https://www.finlex.fi/fi/laki/ajantasa/2011/20110339

12. Valtioneuvoston asetus seulonnoista annetun valtioneuvoston asetuksen muuttamisesta 908/2018 [Internet]. Oikeusministeriö; Available from: https://www.finlex.fi/fi/laki/alkup/2018/20180908

13. Valtioneuvoston asetus seulonnoista annetun valtioneuvoston asetuksen muuttamisesta 1243/2022 [Internet]. Oikeusministeriö; Available from: https://www.finlex.fi/fi/laki/alkup/2022/20221243

14. Valtioneuvoston asetus seulonnoista annetun valtioneuvoston asetuksen 2 ja 5 §:n muuttamisesta 622/2023 [Internet]. Oikeusministeriö; Available from: https://www.finlex.fi/fi/laki/alkup/2023/20230622

15. Perry N, Broeders M, De Wolf C, Törnberg S, Holland R, Von Karsa L. European guidelines for quality assurance in breast cancer screening and diagnosis. 4th ed. Luxembourg: Office for official publications of the European Communities; 2006.

16. Suomen Syöpärekisteri: Syöpäseulontojen järjestäminen [Internet]. Suomen Syöpärekisteri; Available from: https://syoparekisteri.fi/seulonta/syopaseulontojen-jarjestaminen/

17. Säteilyturvallisuus mammografiatutkimuksissa, 25.1.2013 [Internet]. Säteilyturvakeskus; Available from: https://www.stuklex.fi/fi/ohje/ST3-8

18. Kalliomäki Hanna. Mammografian kuvausopas 2021. Suomen röntgenhoitajaliitto ry; 2021.

19. Sosiaali- ja terveysministeriön asetus säteilyn lääketieteellisestä käytöstä [Internet]. Oikeusministeriö; Available from: https://www.finlex.fi/fi/laki/alkup/2000/20000423

20. Sudah Mazen. Rintadiagnostiikan opas 4. painos [Internet]. 2019. Available from: https://1587667.167.directo.fi/@Bin/e8985edfe838c26d2ffacb8eedc8d8dd/1700043077/application/pdf/183959/Rintadiagnostiikan%20opas%204%20painos.pdf

21. American College of Radiology, D'Orsi CJ, Sickles EA, Mendelson EB, Morris EA, editors. ACR BI-RADS atlas: breast imaging reporting and data system. 5th edition. Reston, Va.: ACR, American College of Radiology; 2013.

22. Zonderland Harmien, Smithuis Robin. The Radiology Assistant: Bi-RADS for Mammography and Ultrasound 2013 [Internet]. Radiology department of the Academical Medical Centre in Amsterdam and the Rijnland hospital in Leiderdorp, the Netherlands; Available from: https://radiologyassistant.nl/breast/bi-rads/bi-rads-for-mammography-and-ultrasound-2013

23. Bärlund Maarit, Kellokumpu-Lehtinen Pirkko-Liisa. Syöpäpotilaan hoidon moniammatilliset suunnittelukokoukset - laadukkaan syövänhoidon kultastandardi. Duodecim. 2023;139(2):98–106.

24. Biganzoli L, Cardoso F, Beishon M, Cameron D, Cataliotti L, Coles CE, et al. The requirements of a specialist breast centre. The Breast. 2020 Jun;51:65–84.

25. Blaauwgeers Harriët, Burrion JB, De Paoli P. Accreditation and designation user manual V. 3.0. Brussel: Organisation of European Cancer Institutes; 2019.

26. Suomen Lääkäriliitto: Seulontamammografian erityispätevyys [Internet]. Suomen Lääkäriliitto; Available from: https://www.laakariliitto.fi/palvelut/koulutukset/erityispatevyydet/seulontamammografia/

27. European Commission Initiative on Breast Cancer. European guidelines on breast cancer screening and diagnosis. [Internet]. European Commission; 2022. Available from: https://healthcare-quality.jrc.ec.europa.eu/en/ecibc/european-breast-cancer-guidelines

28. Kovacs T, Rubio IT, Markopoulos C, Audisio RA, Knox S, Kühn T, et al. Theoretical and practical knowledge curriculum for European Breast Surgeons. European Journal of Surgical Oncology. 2020 Apr;46(4):717–36.

29. Finnish Cancer Register: Cancer information notification [Internet]. Available from: https://cancerregistry.fi/cancer-information-notification/

30. Laki sosiaali- ja terveydenhuollon asiakastietojen käsittelystä 703/2023 [Internet]. Oikeusministeriö; Available from: https://www.finlex.fi/fi/laki/alkup/2023/20230703

31. Finnish Cancer Register: Screening statistics [Internet]. Available from: https://cancerregistry.fi/statistics/screening-statistics/

32. Säteilylaki 859/2018 [Internet]. Oikeusministeriö; Available from: https://finlex.fi/fi/laki/alkup/2018/20180859

33. Virtanen A, Anttila A, Luostarinen T, Malila N, Nieminen P. Improving cervical cancer screening attendance in F inland. Intl Journal of Cancer [Internet]. 2015 Mar 15 [cited 2023 Nov 14];136(6). Available from: https://onlinelibrary.wiley.com/doi/10.1002/ijc.29176

34. Sarkeala Tytti, Lamminmäki Maarit. Miten houkuttelen syöpäseulontoihin? Duodecim. 2022;138(16):1369–71.

35. Terveyskylän Tutkimukseen tulijan talo: Mammografia ja muut rintarauhasen tutkimukset [Internet]. Terveyskylä; Available from: https://www.terveyskyla.fi/tutkimukseen/kuvantamistutkimuksia/mammografia-ja-muut-rintarauhasen-tutkimukset

36. Free form cncer: Breast cancer screening or mammography [Internet]. Available from: https://www.freefromcancer.fi/check-your-body/breast-cancer-screening-or-mammography/

37. Council Recommendation on strengthening prevention through early detection: A new EU approach on cancer screening replacing Council Recommendation 2003/878/EC [Internet]. Council of the European Union; Available from: https://data.consilium.europa.eu/doc/document/ST-14770-2022-INIT/en/pdf

38. Kregting LM, Sankatsing VDV, Heijnsdijk EAM, De Koning HJ, Van Ravesteyn NT. Finding the optimal mammography screening strategy: A cost-effectiveness analysis of 920 modelled strategies. Intl Journal of Cancer. 2022 Jul 15;151(2):287–96.

39. Shafik N, Ilmonen P, Viitasaari L, Sarkeala T, Heinävaara S. Flexible transition probability model for assessing cost-effectiveness of breast cancer screening extension to include women aged 45-49 and 70-74. Paci E, editor. PLoS ONE. 2023 Jun 23;18(6):e0287486.

40. Mann RM, Athanasiou A, Baltzer PAT, Camps-Herrero J, Clauser P, Fallenberg EM, et al. Breast cancer screening in women with extremely dense breasts recommendations of the European Society of Breast Imaging (EUSOBI). Eur Radiol. 2022 Jun;32(6):4036–45.

41. Houssami N, Zackrisson S, Blazek K, Hunter K, Bernardi D, Lång K, et al. Meta-analysis of prospective studies evaluating breast cancer detection and interval cancer rates for digital breast tomosynthesis versus mammography population screening. European Journal of Cancer. 2021 May;148:14–23.

42. Larsen M, Aglen CF, Lee CI, Hoff SR, Lund-Hanssen H, Lång K, et al. Artificial Intelligence Evaluation of 122 969 Mammography Examinations from a Population-based Screening Program. Radiology. 2022 Jun;303(3):502–11.

43. Lauritzen AD, Rodríguez-Ruiz A, Von Euler-Chelpin MC, Lynge E, Vejborg I, Nielsen M, et al. An Artificial Intelligence–based Mammography Screening Protocol for Breast Cancer: Outcome and Radiologist Workload. Radiology. 2022 Jul;304(1):41–9.

44. Lång K, Hofvind S, Rodríguez-Ruiz A, Andersson I. Can artificial intelligence reduce the interval cancer rate in mammography screening? Eur Radiol. 2021 Aug;31(8):5940–7.

45. Lång K, Josefsson V, Larsson AM, Larsson S, Högberg C, Sartor H, et al. Artificial intelligence-supported screen reading versus standard double reading in the Mammography Screening with Artificial Intelligence trial (MASAI): a clinical safety analysis of a randomised, controlled, non-inferiority, single-blinded, screening accuracy study. The Lancet Oncology. 2023 Aug;24(8):936–44.

# 17. ANNEXES

## 17.1 TEMPLATE FORM FOR QUALITY ASSESSMENT OF BREAST CANCER SCREENING IN WOMEN OF SCREENING AGE (ANNEX I)

The radiologist-in-charge of the wellbeing services county must be informed of all new cancers in screening age (up to 2 years after the end of screening).

The radiologist-in-charge must evaluate cancers in the context of quality control and training. The recommendation is to perform the assessment according to the breakdown below. Efforts should be made to review findings regularly with the screening radiologists, either at the MDT meeting or at separate meetings.

Findings/analyses are marked prominently in the questioned sections.

The form is stored according to the practice of the wellbeing services county for training and quality control purposes. Ideally, photos should also be attached to the form to allow review of findings at follow-up quality control meetings.

### 17.1.1 Mammography parameters

| | | | | | |
|---|---|---|---|---|---|
| **Breast density** | | a | b | c | d |
| **Mass/shape** | | | oval | round | irregular |
| **Mass/contour** | circumscribed | masked | microlobulated | indistinct | spiculated |
| **Deposition/density of glandular tissue** | | containing fat | low density | medium density | high density |
| **Microcalcifications** | | amorphous | coarse heterogeneous | fine pleomorphic | fine linear or branching |
| **Microcalcifications/ distribution** | diffuse | regional | grouped | linear | segmental |
| **Architectural distortion** | | | | yes | no |
| **Asymmetry** | | asymmetry | general | local | developing |
| **Other** | | skin puckering | inverted nipple | thickening of the skin | enlarged lymph node in the axilla |
| **Location** | upper outer quadrant | upper inner quadrant | lower outer quadrant | lower inner quadrant | central |

### 17.1.2 Implementation issues

| | | | |
|---|---|---|---|
| **Date of cancer diagnosis** | | | |
| **Symptoms** | lump | other | |
| **Date of last screening** | | | |
| **Date of any confirmations** | | | |
| **Side view taken** | yes | no | |
| **Target image/tomosynthesis** | yes | no | |
| **US** | yes | no | |
| **Core needle biopsy** | | | |
| **Lymph node biopsy** | yes | no | |
| **Size of lesion (largest, if multiple)** | x | y | z |

### 17.1.3 Post-diagnosis assessment, knowing where and how the cancer appears at the time of diagnosis

| | | | |
|---|---|---|---|
| **Sign of lesion in previous screening mammogram?** In retrospect, very common. | yes | no | did not participate |
| **Size of lesion seen earlier** | x | y | z |
| **How the cancer is detected** | | screening | interval |

### 17.1.4 Classification of interval cancers

| TERM | DEFINITION |
|---|---|
| **Genuine interval cancer** | no visible signs in previous screening images |
| **Minimal signs** | non-specific small abnormalities, very slow growth/calcification; Minimal-signs |
| **Invisible** | not visible on mammography; Occult |
| **Not noticed** | the lesion would have been diagnosable on an earlier mammogram; Missed |

### 17.1.5 Consideration of why cancer went undetected in previous investigations?

Were there any technical defects in the mammogram, e.g. layout error, poor projection, equipment failure? Human error due to, for example, a lesion that has remained relatively unchanged for a long time, but was initially interpreted as benign.

**Has the area been investigated before?**

No

If so, date _____ ; whether side view, tomosynthesis, target images, US, biopsy?

---

Why does the person who completed the form think that the wrong negative conclusion was made:

---

Name of the breast radiologist completing the form

---

Double reading

---

## 17.2. QUALITY CONTROL (ANNEX II)

The person responsible for screening in the wellbeing services county must be provided with the self-assessment results and the information necessary for quality control of the screening unit on an annual basis.

A self-assessment meeting is organised at least once a year in the screening unit under the leadership of the unit's radiology nurse in charge and chief radiologist to review the results of the self-assessment and the known interval cancers.

### 17.2.1 Self-assessment by the radiology nurse

Each year, the radiology nurse's self-assessment evaluates a random selection of at least 10 client images taken by the radiology nurse, for a total of 40 images. The evaluation is carried out by the radiology nurse with the nurse in charge, and at least every two years the images are also evaluated by the chief radiologist.

The aim of the self-assessment is that the images taken by the radiology nurse: (Kalliomäki Hanna. Mammography imaging guide 2021. Finnish Radiographers' Association)

| TERM | RECOMMENDATION | TARGET |
|---|---|---|
| Good photos | | ≥ 75 % |
| Diagnostic images | | ≤ 25 % |
| Non-diagnostic images | | 0 % |
| Technical re-mammograms | < 3 % | ≤ 2 % |

## 17.2.2 Information required for the radiologist's self-assessment

| TERM | DEFINITION | ABBREVIATION | RECOMMENDATION | TARGET |
|---|---|---|---|---|
| **Radiologist readings** | Total number of screenings read by a radiologist | RL | 1.Reader ≥ 2000<br>2.Reader<br>6 kk koulutus | 1.Reader ≥ 3500<br>2.Reader ≥ 3500 |
| **Positive result from a radiologist** | A radiologist referred to a double reading | RP | < 15 % | less for experienced, more for beginner, from double reading to follow-up examinations <3%, see screening targets |
| **Negative result from a radiologist** | Radiologist detects benign finding without double reading (i.e. RL-RP) | RN | ≥ 85 % | 90-95%, to avoid too much time spent on double reading |
| **Correct positive result from a radiologist** | Malignant finding from RP in screening follow-up examination | ROP | | 100 % |
| **Correct positive result** | All malignancies found from RL in follow-up examinations | OP | | |
| **Correct negative result** | From RL, all of which were found to be free of malignancy, ON = RL-OP | ON | | |
| **Radiologist's sensitivity** | sensitivity; the proportion of correct positives dete-cted by the radiologist out of all correct positives, i.e. the probability of illness | ROP / OP | ≥ 85 % | |
| **Radiologist's specificity** | the accuracy of the reding; the proportion of healthy subjects who are inter-preted as correct negatives in the reading, i.e. the probability of a healthy subject being found to be healthy | RN / ON | ≥ 85 % | |

### 17.2.3 Information required for quality control of the screening unit

The implementation of screening according to the recommended and/or target level describes a high-quality and effective screening. It also weighs the harms of screening against the benefits. Indicators should meet European quality criteria (Perry N, Broeders M, De Wolf C, et al. European guidelines for quality assurance in breast cancer screening and diagnosis. 4th ed. 2006).

These indicators must be calculated annually and changes over time must be monitored. In addition to the national results, regional figures must also be reported.

| QUALITY INDICATOR | DEFINITION | RECOMMENDED LEVEL | TARGET LEVEL |
|---|---|---|---|
| Coverage of invitations | invited to the screening/target population for screening | | 100 % |
| Participation rate | participants in the screening (=underwent mammography and read)/invited to the screening | > 70 % | > 75 % |
| Percentage of people sent for follow-up examinations | positive screening result / participants in the screening<br>-first round<br>-other rounds | < 7 %<br>< 5 % | < 5 %<br>< 3% |
| Follow-up examinations in specialised healthcare* | | | |
| Proportion of malignant tumours | Malignant tumours of the breast/ Those who have undergone surgery | | |
| DCIS as a proportion of all malignant tumours | DCIS/malignant tumours of the breast | 10 % | > 15 % |
| IN ADDITION TO THE WELL-BEING SERVICES COUNTY'S OWN QUALITY ASSESSMENT | | | |
| Sensitivity of the screening unit | The sensitivity of the screening unit can be roughly assessed by comparing the proportion of malignant findings among those screened with the national rate | | |
| Proportion of small cancers found in screening | Proportion of invasive cancers 10 mm or smaller | In the first round 20 %<br>In further rounds 25 % | First round ≥ 25 %<br>In further rounds ≥ 30 % |

***Increase the proportion of referrals to specialised healthcare if some of the examinations, such as stereotactic/ tomosynthesis-guided biopsy, are performed in specialised healthcare**

### 17.2.4 Evaluation of interval cancers

According to the European guidelines for quality assurance in cancer screening, the number of interval cancers should be kept to a minimum. Screening radiologists should review each interval cancer and the women's previous screening images should be re-read in relation to radiologists' self-assessment and continuing education (Perry N, Broeders M, De Wolf C, et al. European guidelines for quality assurance in breast cancer screening and diagnosis. 4th ed. 2006)

If an interval cancer is confirmed, it is reported to the wellbeing services county's chief radiologist, who analyses the finding in comparison with previous screening mammograms and records the data at the wellbeing services county in the agreed manner, and regularly reviews the data with the screening radiologists. Template form (Annex I).

The screening invitation should also include information on quality control for cancers found between screening rounds.

The proportion of interval cancers in the age group should be monitored and any increase should be addressed.

The radiological features of screen-detected cancers and interval cancers should (Annex I) be compared and the radiological features of false negative screening results in particular should be used for self-assessment and to improve the training of screening radiologists.

### 17.2.5 Pathology

If histopathological specimens from screening cases requiring treatment in specialised healthcare prove to be inconsistent with the final diagnosis, a feedback system between pathologists should be developed, for example by holding biannual joint meetings to discuss the cases. The recording of cases is done according to the practice of the wellbeing services county for training and quality control purposes.

### 17.2.6 Client experience of screening among screening participants

The screening unit is recommended to monitor the experience of screening participants with a Net Promoter Score (NPS) survey. This is an international measure of customer experience that includes a willingness to recommend and provides the customer's perspective on the issue. How likely would you be to recommend a screening service to your family and friends? Clients rate their willingness to recommend on a scale of 0 to 10, while they can also complete their rating verbally by answering the question "What influenced your experience?".