Fourth Evaluation Report on the Austrian Breast Cancer Screening Programme

Evaluation report for the period 2014 to 2021

On behalf of the Federal Ministry of Social Affairs, Health, Care and Consumer Protection

Gesundheit Österreich
GmbH

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This report contributes to the implementation of the 2030 agenda, in particular, Sustainable Development Goal (SDG) 3, "Health and Well-being" and sub-goal 3.4 "By 2030, reduce premature mortality from non-communicable diseases by one third through prevention and treatment and promote mental health and well-being".

Executive summary

Background

Since January 2014, Austria has had a population-based and quality-assured breast cancer screening programme (BKFP) for 45- to 69-year-old women and, since June 2023, for 45- to 74-year-old women, who are invited to participate every two years. Women aged 40 to 44 and 75 and over can also register to take part by opting in. The focus of this evaluation report lies on the data of the fourth screening round in 2020 and 2021, which is analysed in terms of programme participation, tumour detection and quality of findings and compared with the data of the past screening rounds as well as international performance parameters. The most important findings regarding the technical quality assurance of the devices used are also described. In this way, the benefits of the programme should be demonstrated and any problematic areas identified in time to derive appropriate recommendations for the continuation of the programme.

Method

The focus is on analysing the fourth screening round 2020/2021. All case histories that began with a radiological breast cancer screening examination between January 2014 and December 2021 are included.

The evaluations of programme quality are based on pseudonymised data transmitted by extra- and intramural service providers via the Austrian e-card system in accordance with a data set definition agreed between the programme partners. The quality indicators are largely based on the "European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis" (Perry et al. 2006).

Results

In 2020/2021, 614.835 women, or 40 per cent of women in the core target group (45 to 69 years old), participated in the Austrian Breast Cancer Screening Programme (BKFP). The participation rate has fallen by one percentage compared to 2018/2019. The proportion of women with a breast cancer screening examination (BKFU) or a diagnostic mammography is 53 per cent. At district level, participation varies between 12 and 51 per cent. Due to the COVID-19 pandemic, there was a 12.5 per cent decline in participation in 2020 compared to 2019. In 2021, on the other hand, participation increased by 22 per cent compared to 2020 due to a catch-up effect. Of the participants in 2018/2019, 59 per cent took part in the BKFP again two years later as planned. The range of participation at district level is 37 to 72 per cent.

Compared to the hospital billing data, around 92 per cent of women treated for breast cancer in 2020 and around 79 per cent in 2021 were documented as part of the BKFP. Around 25 per cent

of the tumour-specific information, such as size or stage, is missing from the data records submitted.

Of the participants, just under two per cent were called back for an assessment after the screening mammography (around half of them for a biopsy). Subsequently, 2,584 invasive carcinomas were detected, which corresponds to 421 carcinomas per 100,000 examinations or twice the background incidence (the number of new cases per year before the introduction of the screening programme). In addition, 403 DCIS (ductal carcinomas in situ) were detected (66 per 100,000 screenings). Of the invasive carcinomas detected 78 per cent had a diameter of 15 millimetres or less, and over 30 per cent of the carcinomas were smaller than ten millimetres at the time of detection. In 79 per cent of invasive carcinomas, a tumour stage of 0 or 1 with a favourable prognosis was detected during BKFU. The time between the BKFU and the preparation of the written report was 1.6 working days on average.

Interval carcinomas are (invasive) carcinomas that are discovered up to two years after an inconspicuous BKFU. According to BKFU conducted in 2018/2019, 263 invasive interval cancers (20.5 % of the background incidence) were documented in the first year and 581 (45.4 % of the background incidence) were documented in the second year. An estimated 60 percent of the interval carcinomas (mainly from the second year after an inconspicuous BKF U) were presumably asymptomatic according to their tumour characteristics. As in 2016/2017, the majority of interval carcinomas have similar characteristics in terms of size, involvement of lymph nodes or metastasis to the invasive carcinomas detected in the screening.

The programme sensitivity during this period was 0.75, i. e. out of 100 women who actually had invasive breast cancer (incl. interval carcinomas), 75 were detected in the BKFP. The programme specificity was 0.985, i.e. for every 100 women without invasive breast cancer, almost 99 were identified as healthy, whereas around one in every 100 women without invasive breast cancer received an assessment.

For the period 2020/2021, the positive predictive value of the screening was 0.23, i.e. for every 100 women with a conspicuous BKFU, 23 actually had breast cancer.

During this monitoring period, an ultrasound was used in 74 per cent of the BKF screenings. More than four per cent of the BKFU were found to be BI-RADS 3, after which the participant was invited for an interim breast examination after a shortened interval of six or twelve months.

In the BKFP, the combined readings and documentation based on the first mammography reading and the ultrasound examination performed by the first reader give the first reader a benefit of information. The final reading is therefore usually prepared on the basis of this combined reading in consensus with the second reader. For this reason, an isolated evaluation of the reading modalities is difficult. Based on the data available, the sensitivity of the first reading is around 80 per cent. The ultrasound examination increases the sensitivity of the reading by around four percentage points with almost the same specificity. The second reading increases the sensitivity of the reading by around 0.2 percentage points compared to the first reading and ultrasound.

Discussion

The population-based and quality-assured Austrian breast cancer screening programme is decentralised and thus organised at neighbouring locations, which makes it easier for individual women to participate. Furthermore, fully digital mammography systems with an optimal dose-image quality ratio are used throughout the country.

However, the participation rate as well as the re-participation rate remained below expectations in 2020/2021, partly due to the COVID-19 pandemic, and also below the European targets and comparative values of other European countries. To increase participation, in addition to the invitation and reminder system, the communication level of the trusted physicians should also be further promoted and expanded. Additionally, the variations in participation rate at the district level should be analysed and appropriate regional measures implemented to increase participation.

In 2020/2021, as in the previous screening cycle, the BKFP met or exceeded the recommendations of European experts in terms of breast cancer detection and tumour characteristics (size, stage, metastasis) of the detected carcinomas and is comparable to the German mammography screening programme. The low rate of follow-up visits for assessments of abnormal mammograms and the short time between the screening and the preparation of the written report are to be emphasised as beneficial for the women, since part of the diagnostic imaging is already carried out by ultrasound at the time of the BKFU. This fact also has a positive impact on the beneficial predictive value of the BKFP; in Austria, for example, 23 out of 100 women with conspicuous BKFU actually had breast cancer. In the German mammography screening programme, where ultrasound is only used at a follow-up visit, this was the case for 15 out of 100 women in 2020. Both the biopsy rate and the ratio of benign to malignant biopsies in the BKFP are in line with expectations.

The relatively high ultrasound rate in international comparison can be explained by the programme structure of the BKFP, as ultrasound is used as part of the screening examination (especially in the case of high breast density and to assess abnormalities). The increase in sensitivity of the ultrasound examination is to be expected due to the limited significance of the data, but there is surprisingly no decrease in specificity. An evaluation of the effect of ultrasound alone or of the double readings does not seem to serve the purpose under the given conditions of reporting, and the combination of the two imaging procedures mammography and ultrasound should generally be assessed with regard to their effectiveness.

Both the number of interval carcinomas and their number in relation to the carcinomas detected by BKFU remained encouragingly stable compared to the previous screening cycle. Especially in the first year after an inconspicuous BKFU, the interval cancer rate stayed well below the expert's recommendation of 30% of the background incidence. For the second year the recommended rate of 50% of the background incidence as well was undercut.

As already described in the third evaluation report, a large proportion of the invasive interval carcinomas occurring in the core target group of 45- to 69-year-old women do not differ from

the tumours detected in the screening in terms of size, metastasis or lymph node involvement, although the opposite would have been expected, especially for the second year after a negative BKFU. Due to the high proportion of presumably asymptomatic or non-palpable interval carcinomas, it can again be confirmed that, especially in the second year after the BKFU, some of them are true interval carcinomas (i.e. growing faster than the screening interval), which are detected outside the specified screening interval due to BKFU as part of a diagnostic mammography. Thus, by means of this risk-adjusted form of screening within the diagnostic setting, the detection of asymptomatic carcinomas can be increased within the current list of indications for diagnostic (referred) mammography. The available data only allow a rough estimate of the number of carcinomas detected in this way. For more accurate quantification and particularly for an estimate of the possible effects on the detection rate, programme sensitivity, and interval carcinoma rate, it would be necessary, as already recommended in the third evaluation report, to check (on a random basis) whether the cases in question are genuine interval carcinomas by analysing the mammography images of the BKFU. Similarly, an analysis of possible impact of the approach on the rate of false-positive findings appears to be important.

Due to the identified data gaps in the areas of tumour and pathology, the validity of the data with regard to screening detection, interval carcinomas and tumour characteristics for the screening cycle is limited. Since it is not known and cannot be traced how many tumours from the screening and how many from the diagnostic area are missing from the documentation, the effect of the data gap on individual programme parameters cannot be traced in detail.

Keywords

Evaluation, Breast cancer, Screening, Early detection of breast cancer, Mammography, Ultrasound, Interval cancers

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Abbreviations

ABD	Data sheet for Assessment of Diagnostic Imaging
ACR	American College of Radiology
AGD	average glandular dose
AGES	Austrian Agency for Health and Food Safety
AI	artificial intelligence
aOR	adjusted odds ratio
ATHIS	Austrian Health Interview Survey
BIQG	Federal Institute for Quality in Health Care
BI-RADS	Breast Imaging Reporting and Data System
BC	Breast cancer
BGK	Federal Health Commission
BKF	Breast cancer screening
BKFP	Breast Cancer Screening Programme
BKFU	Breast cancer screening examination (BKFU)
CDMAM	contrast detail mammography
CDR	cancer detection rate
CI	Confidence interval
CNN	convolutional neural network(s)
CR-System	Digital imaging plate system
DCIS	Ductal carcinoma in situ
DICOM	Digital Imaging and Communications in Medicine
DLD	Diagnosis and service documentation within the framework of performance-oriented hospital financing
DR	Double-Reading
DR-System	Digital full-field system
e. g.	for example
EBSCO	Elton B. Stephens Company
ECIBC	European Commission Initiative on Breast Cancer
EFOMP	European Federation of Organisations for Medical Physics
EN	European standard
EU	European Union
EUREF-Ö	Recommendations of the European Reference Organisation for Quality Assured Breast Screening and Diagnostic Services, adapted for Austria
fbPK-AS	External (coded and not belonging to own area) area-specific personal identifier "Official Statistics" (§ 13 Master Data Register Ordinance)
FFDM	full-field digital mammography
FOM	figure of merit
GDA	Healthcare providers
GmbH	Limited liability company
GÖG	Gesundheit Österreich GmbH
GÖGG	Federal Law on the Gesundheit Österreich GmbH
HER2	human epidermal growth factor receptor 2

ICD	international statistical classification of diseases and related health problems
IET	Institute for Clinical Epidemiology of the hospitals in Tyrol GmbH
IQWiG	Institute for Quality and Efficiency in Health Care
IR	incidence rate
KA	Hospital
KFA	Health Care Institution
Ki-67	Antigen Kiel 67
KUL	Data sheet for referred (diagnostic) blank notification without patient data
KUM	Data sheet for referred (diagnostic) mammography
KUS	Data sheet for referred (diagnostic) breast examination by ultrasound only
LKF	Performance-oriented hospital financing
MEL	Individual medical services in accordance with performance-oriented hospital financing
mGy	Milligray
mm	Millimetre
MRI	Magnetic resonance imaging
MUG	Medical University of Graz
n	Sample size
ÖGUM	Austrian Society for Ultrasound in Medicine
ÖNORM	Austrian standard(s)
ÖQMED	Austrian Society for Quality Assurance and Quality Management in Medicine GmbH
OR	Odds-Ratio
OVE	Austrian Electrotechnical Association
PAT	Data sheet for pathological findings of surgically removed tumours
PMMA	Polymethyl methacrylate
pN	Clinical stage of regional lymph nodes
PPV	Positive predictive value
pT	Clinical stage primary tumour
RefZQS	Reference Centre for Technical Quality Assurance
SCR	Data sheet for breast cancer screening by mammography
SR	Single-Reading
SUS	Data sheet for breast cancer screening by ultrasound only
SV	National insurance
SVC	Sozialversicherungs-Chipkarten Betriebs- und Errichtungsgesellschaft m. b. H.
SZL	Data sheet for blank notification of a privately paid breast cancer screening examination (self-payer) without patient data
SZM	Data sheet for privately paid breast cancer screening (self-payer)
TQS	Technical quality assurance
Tsd.	Thousand
TTH	threshold thickness
TUM	Datasheet for tumour and therapeutic measures
UICC	Union contre le cancer
US	Ultrasound
VU-GV	Comprehensive screening contract
WT	working days

1 Introduction

In Austria, 5,443 women and 87 men were diagnosed with breast cancer in 2020. This corresponds to an age-standardised rate of 111.4 per 100,000 women and 2.1 per 100.000 men (Statistik Austria 2023a). In the same period, 1,646 women and 17 men died of breast cancer (age-standardised rates: 31.6/100,000 women and 0.5/100,000 men; Statistik Austria 2023b). Breast cancer is the most common cancer and, along with lung cancer, the most common cause of cancer death among women (Statistik Austria 2023a und 2023b)

As early as 2003, the Council of the European Union recommended the introduction of organised population-based cancer screening programmes with quality assurance at all levels of care. In addition, the European Parliament called for making the fight against breast cancer a public health objective and developing effective strategies for better prevention, screening, diagnosis, treatment and after-care of breast cancer. The European Guidelines for Quality Assurance in Breast Cancer Screening and Diagnosis (Directorate-General 2006) provide concrete recommendations for the introduction of structured screening programmes. In Austria, breast cancer screening had already been offered as part of preventive medical check-ups since 1988, and was also carried out by referral outside of preventive medical check-ups. On 25 November 2011, the Federal Health Commission (BGK) decided to replace the previously prevailing opportunistic breast cancer screening with a structured Austria-wide screening programme The programme started in January 2014.

Screening programmes are basically aimed at a population that does not show any signs of the respective "targeted" disease and thus place special demands on the quality, safety and benefit of the measures taken. The benefit of early detection of a disease and the improved chances of cure that can be expected are offset by possible harm, for example due to radiation exposure, false-positive findings, overdiagnosis and overtreatment. It is therefore essential that the BKFP is periodically evaluated and the achievement of its objectives is reviewed in accordance with the quality standard for breast cancer screening and the Second Additional Protocol to the General Agreement on Preventive Medical Screenings. The primary goal of the breast cancer screening programme, as with any screening measure, is to reduce mortality, which is therefore one of the most important endpoints in the assessment of a screening programme, along with improving quality of life. Equally relevant is the analysis of whether the participants can make an informed decision to participate.

The evaluation is oriented towards the dimensions of effectiveness, acceptance, appropriateness and efficiency and is carried out through a programme-specific analysis of the following areas (Gollmer et al. 2011):

» Implementation of the programme and compliance with the underlying quality specifications according to the quality standard
» Development of breast cancer mortality
» Structure/process/outcome quality of the programme
» Other areas relevant to the programme (focus modules such as communication).

The evaluation includes the programme evaluation (carried out by Gesundheit Österreich GmbH) and the preparation of feedback reports for the BKFP facilities as well as for the regionally responsible radiologists in terms of an ongoing quality assurance. These feedback reports are prepared by the Institute of Medical Informatics at the Medical University of Graz and are not included in this evaluation report.

The fourth evaluation report comprises data from BKFU from the first eight programme years 2014 to 2021, including any associated documented assessments and tumour operations; the focus of the data analyses is on the fourth screening round in 2020 and 2021.

In addition, the current results of the technical quality assurance by the responsible reference centre at AGES are described.

The final chapter is dedicated to the conclusions that can be drawn and recommendations for the continuation of the programme.

2 Programme Performance

2.1 Background

This evaluation report presents the results of various quality indicators of the Austrian Breast Cancer Screening Programme (BKFP). The quality indicators named by Perry et al. (2006), which are referred to as "EU indicators" (see Table 6.10appendix), form a central component here. Some of these indicators are regularly collected and compiled by the EU member states as part of the European Commission Initiative on [1]Breast Cancer[1].

An important feature for assessing the quality of a screening programme is the number and stage of carcinomas detected during screening or interval carcinomas (carcinomas detected after a negative BKFU within the routine screening interval of two years), which are also a basis for the measure of programme sensitivity. The calculation of the number of interval carcinomas is based on the assumption that the further course of action can be derived directly from the BI-RADS findings of the mammography and/or ultrasound (see also Chapter 2.9 or Table2: 1):

Table2: 1
BI-RADS findings and further course of action

BKF-finding	Further course of action
BI-RADS 0	Diagnostic Imaging
BI-RADS 1, 2	Follow-up visit at the regular 24-month interval
BI-RADS 3	Intermediate BKF screening after six or twelve months
BI-RADS 4, 5	Invasive assessment
BI-RADS 6	Histologically confirmed carcinoma (this value is not possible as a part of BKFP and is evaluated as an incorrect entry).

Source: GÖG

A defined goal of a screening programme is to reduce mortality through early diagnosis of cancer. This impact is assessed contradictorily in the literature. Potential changes in disease-specific and general mortality are essential components of programme evaluation. Other relevant endpoints, such as the increase in life expectancy with good health or quality of life, have yet not been considered in the evaluation, as the necessary data have not been collected so far.

[1] see also: https://ecibc.jrc.ec.europa.eu

2.2 Database

The data base for the evaluations presented with regard to programme quality is formed by the data reported by the participating extramural and intramural healthcare providers (GDA) in accordance with the standardised data set definition with regard to the BKFU carried out (see Gollmer et al. 2017). These GDAs include radiological institutes and hospitals participating in the programme. All case histories that began with a radiological breast examination between January 2014 and December 2021 are included.

The evaluations presented here focus on the core target group of the BKFP (45- to 69-year-old women) for the reporting period. The two opt-in groups of women aged 40 to 44 and women aged 70 and over are only marginally examined in selected evaluations.

Most of the evaluations in the report are presented at the overall Austrian level due to the high volume of data and evaluations. In addition, the participation rates are also shown per federal state and district of residence.

The documentation of the BKFP is carried out with the following data sheets, which are subsequently named in the text and in tables or figures using their abbreviations:

Table 2.2:
Data sheets for documentation in the BKFP

SCR	BKFU with mammography and, if necessary, ultrasound
SUS	BKFU only with ultrasound
SZM	Self-payer BKFU with mammography and, if necessary, ultrasound
SZL	Self-payer blank notification for BKFU (without patient data)
KUM	Referred diagnostic breast imaging with mammography and, if necessary, ultrasound
KUS	Referred diagnostic breast imaging only with ultrasound
KUL	Referred diagnostic breast imaging blank notification (without patient data)
ABD	Diagnostic Imaging
AID	Invasive assessment
TUM	Tumour therapy documentation
PAT	Pathology therapy documentation

Source: GÖG

On the part of the data-holding agency (GÖG), the data are held in a relational database (Microsoft SQL Server) and read out and analysed using Ripley/Lapsley (2017) and Wickham et al. (2018).

2.3 Data flow

All documented data are encrypted on site when it is entered before they are transmitted via the e-card system to the pseudonymisation agency and the data-holding agency (GÖG). The data to be transmitted are already separated into different data packages in the physician's software and specially encrypted depending on the further processing:

» The medical data are encrypted for data storage before transmission. They also contain a GDA-internal patient ID that is encrypted once again and can only be meaningfully used by the original treating organisation.
» The national insurance number of the woman examined is encrypted before transmission for the pseudonymisation agency of the Austrian national insurance. The pseudonymisation agency calculates a project-specific pseudonym from this and therefore cannot be linked to any other pseudonym.
» The site and physician identifiers are encrypted for medical quality assurance prior to transmission for the purpose of generating the feedback reports.

The pseudonymisation agency is operated by the Austrian National Insurance Agency. The transmission of the files between the system partners (SVC, pseudonymisation agency, GÖG, MUG) takes place via a service ("data turntable") of the SV. Encryption ensures that only the intended recipient can read the data. The pseudonymisation in connection with the encryption of the various data packages ensures that it is impossible for the organisations involved, especially the programme evaluation (GÖG) and the medical quality assurance (Medical University of Graz), to draw conclusions about individual programme participants from the data.

2.4 Data completeness

The completeness of the documentation of mammography and sonography screenings in the areas of screening and diagnostics is ensured and can be classified as complete insofar as the billing of the services is linked to the documentation within the framework of the BKFP. Additional documentation of all breast carcinomas occurring within the screening cycles that is as complete as possible is of the utmost importance for a valid data analysis of breast cancer detection, tumour characteristics and the number of interval carcinomas. The information required for this is mainly extracted from the two therapy documentation sections "Tumour" and "Pathology", which are to be documented by the treating hospitals. Since, in contrast to mammograms, there is no connection between documentation in the BKFP and billing for services in the case of pathological findings or tumour operations, there are occasional data gaps that can only be identified with a time lag.

2.4.1 Method

Routine data for billing purposes from Austrian hospitals can be used as one possibility for data synchronisation. Women from the core target group (45 to 69 years) with an ICD-10 main diagnosis of C50 (malignant neoplasm of the mammary gland) or D05 (carcinoma in situ of the mammary gland) and a breast surgery procedure are compared with women with a transmitted documentation sheet "tumour" or "pathology" from the so-called DLD (Diagnosis and Service Documentation of Performance-Oriented Hospital Financing [LKF]). GÖG has information on the federal state of residence of the women from the screening programme; the billing data from the hospitals can be used to show both the federal state of residence and the federal state in which the medical service was provided (service federal state). Subsequently, a total comparison of women expected to be included in the BKFP documentation can be carried out per federal state and year.

The following breast surgery services (MEL - individual medical services) are combined with the two breast cancer diagnoses mentioned for the analysis of the billing data:

1. Partial breast resection with or without axillary lymphadenectomy (MEL: QE040 and QE050)
2. Subcutaneous mastectomy with or without axillary lymphadenectomy (MEL: QE060 and QE070)
3. Total mastectomy with or without axillary lymphadenectomy (MEL: QE080 und QE090)

2.4.2 Results

In 2020, 3,745 women with breast cancer (invasive or DCIS) were treated with breast surgery in the core target group (45- to 69-year-old women) in Austrian hospitals and documented as part of service billing. This compares with 3,450 women for whom tumour-specific information, i. e. at least the answer as to whether breast cancer was present or not, was documented as part of the BKFP. The **documentation rate** as part of the screening programme for **2020** can therefore be assumed to be around **92 percent** (see Table 23). The lowest rate is calculated for women living in Vienna at 77.5 per cent.

In 2021, the assumed number of breast cancer patients in the core target group was 4,134 women, with 3,281 women having a pathology or tumour sheet from the BKFP documentation. The Austria-wide **documentation rate** for **2021** therefore falls to around **79 per cent**, with the lowest documentation rates for women living in Vienna (55.4 per cent) and Lower Austria (64.5 per cent) (see Table 23). Overall, tumour-specific data from the **2020/2021 screening cycle** was transmitted from around **85 per cent** of women in the core target group.

If, in contrast to the federal states of residence, breast cancer patients are considered at the level of the federal states of performance, i.e. at the level of the federal states in which the women were treated, the number of patients (including those living abroad) in the core target

group is 3,803 women in 2020 and 4,189 women in 2021 (see Table 2.4). It can also be seen that significantly more women (1,155 women in 2020 and 1,260 women in 2021) were treated in Viennese hospitals than women living in Vienna (815 women in 2020 and 866 women in 2021). A more detailed analysis at hospital level indicates that from the core target group in Vienna, around 350 women with breast cancer from Lower Austria and around 40 women from Burgenland are treated each year.

Table 23:
Women with ICD-10 main diagnosis C50 or D05 and a MEL QE040-QE090 according to DLD and women documented in the BKFP, core target group for 2020 and 2021 per federal state of residence

	2020			2021		
	Women in hospitals according to DLD	Documented women in the BKFP	Proportion of documented women	Women in hospitals according to DLD	Documented women in the BKFP	Proportion of documented women
Burgenland	138	139	100.0	158	129	81.6
Carinthia	277	288	100.0	306	365	100.0
Lower Austria	781	787	100.0	840	542	64.5
Upper Austria	602	516	85.7	705	670	95.0
Salzburg	210	211	100.0	238	179	75.2
Styria	484	447	92.4	524	438	83.6
Tyrol	303	302	100.0	326	302	92.6
Vorarlberg	135	128	94.8	171	176	100.0
Vienna	815	632	77.5	866	480	55.4
Total	3,745	3,450	92.1	4,134	3,281	79.4

Source: GÖG

Table 2.4:
Women with ICD-10 main diagnosis C50 or D05 and a MEL QE040-QE090 according to DLD, core target group for 2020 and 2021 per federal state including women living abroad

	2020	2021
Burgenland	88	99
Carinthia	298	316
Lower Austria	497	498
Upper Austria	600	713
Salzburg	263	281
Styria	454	498
Tyrol	318	353
Vorarlberg	130	171
Vienna	1,155	1,260
Total	3,803	4,189

Source: GÖG

2.4.3 Discussion

The focus of this evaluation report is on the analysis of the fourth screening round of the Austrian Breast Cancer Screening Programme in 2020 and 2021. For 2020, the proportion of documented tumours is satisfactory at over 90 per cent. However, due to the decrease in the rate to below 80 percent in 2021, the validity of the data with regard to screening, interval carcinomas and tumour characteristics for the screening cycle is limited. As a rough estimate, after deducting the recurrences from the billing data, a data gap in the BKFP of around 1,000 carcinomas can be assumed for the two years. If the detection of invasive tumours and DCIS in the programme in recent years is used for a distribution of missing invasive tumours, the number of missing invasive tumours can be estimated at around 850 and the number of missing DCIS at around 150. Since it is not known and cannot be traced how many tumours from the screening and how many from the diagnostic area are missing from the documentation, the effect of the data gap on individual programme parameters cannot be traced in detail.

The data gap in Viennese hospitals is also striking. This shows a lower documentation rate not only for women living in Vienna, but above all for around 350 patients per year from Lower Austria who were treated in Vienna but inadequately documented as part of the BKFP.

2.5 Participation and re-participation

2.5.1 Method

As a two-year interval is defined for regular participation in the BKFP, the general performance of the programme is described in two-year cycles. Even though the Austrian BKFP, unlike in Germany, has not had an invitation system with appointment scheduling in the actual sense since July 2014, the letters sent out fulfil a reminder function and the women eligible for participation can arrange for BKFU on their own initiative.

All women who had at least one BKFU by mammography and/or ultrasound (data sheets SCR, SUS) during the observation period are counted as participants. Also formally counted (according to the data sheet) are diagnostic examinations after an early recall (i. e. after BKFU with the result BI-RADS 3) within ten or 15 months (corresponding to the two early recall intervals of six or twelve months). This ensures that a breast cancer detected as a result of an intermediate mammography following screening (BKFU) is attributed to the BKFP (Perry et al. 2006, p. 52). The rates do not directly take into account blank notifications for self-payer screenings or diagnostic examinations (without medical data, age or pseudonym; this applies to the SZL and KUL data sheets). The number of cases within the core target group is calculated aliquot to the other data sheets and an approximate measure of the rate increase is given separately.

Since a woman may have been examined several times during the respective observation period, only the most critical finding per examined woman is counted. According to the two-year

eligibility, the data are presented in two-year cycles. By focusing on the number of participants (as opposed to the number of examinations), comparability and interpretability are facilitated.

The official population statistics of Statistik Austria for 2014 (for the two-year interval 2014/2015), 2016 (for the two-year interval 2016/2017) and 2018 (for the two-year interval 2018/2019) and 2020 (for the two-year interval 2020/2021) are used as a reference point for the calculation of the participation rate.

2.5.2 Participation result

In the **2020/2021** two-year cycle, **614,835 women from the core target group** of women aged 45-69 (**40 per cent** of eligible women in the age group) took up a BKFU. This proportion increased by around 76,000 women compared to 2014/2015 and is comparable to that of 2016/2017. Compared to 2018/2019, however, around 7,400 fewer women took part in the programme. The number of women from the core target group participating in the BKFP thus remains stable at around 40 per cent across all screening cycles (see Table 2.5).

If the estimated proportion is supplemented by an additional 15,000 or so blank notifications for self-payer examinations within the core target group, the participation rate for 2020/2021 increases to a maximum of 41 per cent. However, this rate cannot be validated exactly, as both, the number of examinations of self-paying women is estimated and the same woman could be counted more than once.

In 2020/2021, the range of state-specific participation rates in the core target group was 13 percentage points (see Table 2.5); in particular, the participation rate in the states of Lower Austria, Salzburg, Styria and Vienna was comparatively higher than in the other states at 41 to 45 per cent). In the western federal states of Tyrol and Vorarlberg, the participation rate at the start of the programme was comparatively low, which could be partly explained by the system changeover, as in Tyrol in particular there had already been a mammography screening programme before the introduction of the BKFP. The participation rate could subsequently be increased in both federal states (see Table 2.5.)

The proportion of women in the core target group of 45- to 69-year-olds who had a mammography performed - regardless of whether for the purpose of screening or for diagnostic reasons (**mammography coverage rate**) - also remained stable compared to previous years at **53 per cent** (see Table 2.5). Based on the federal provinces, the coverage rate is between 43 per cent in Vorarlberg and 56 per cent in Burgenland and Lower Austria. The proportion of diagnostic mammograms in the coverage rate also varies between the federal states. The difference between the BKF participation rate and the coverage rate is around six to eight percentage points in Salzburg, Upper Austria and Vorarlberg and 22 percentage points in Carinthia, where diagnostic mammography is carried out comparatively more frequently. The coverage rate does not include blank notifications (notifications of mammograms carried out without further information, see also chapter 2.14) because the missing age data does not allow correct

allocation. An aliquot distribution would mean an increase of this general mammography rate or coverage rate within the core target group from an estimated two percentage points to a maximum of about 55 percentage points. This figure is three percentage points lower than in 2018/2019 due to fewer documented blank notifications and represents the upper limit, as women could also be counted twice here due to the lack of assignment of the pseudonym.

In the opt-in group of 40- to 44-year-old women, the proportion of those who had a screening mammography or diagnostic mammography decreased by one percentage point from 34 to 33 percent, and in the opt-in group of women over 70, the proportion increased by one percentage point from 26 to 27 per cent (see also Table 2.7).

Table 2.5:
Proportion of women in the core target group (45- to 69-year-old women) who participated in the BKFP, per two-year cycle and federal state of residence

	2014/2015	2016/2017	2018/2019	2020/2021			
	Participa-tion rate	Participa-tion rate	Participa-tion rate	Target population	Women in BKFP	Participation rate BKFP	Mammography coverage rate[2]
Burgenland	41 %	43 %	41%	56,559	22,198	39%	56 %
Carinthia	34 %	35 %	33%	105,949	33,522	32%	54 %
Lower Austria	42 %	45 %	44 %	305,362	129,064	42%	56 %
Upper Austria	34 %	37 %	39%	256,783	96,838	38 %	45%
Salzburg	45 %	46 %	45%	97,796	44,197	45%	51 %
Styria	38 %	42 %	43%	219,827	92,115	42%	53 %
Tyrol	31 %	38 %	38 %	129,503	49,886	39%	53 %
Vorarlberg	32 %	36 %	36%	66,474	23,556	35%	43%
Vienna	38 %	43 %	42%	300,344	122,796	41%	51 %
Total	37 %	41 %	41%	1,538.597	614,835	40 %	53 %
Total incl. blank notifications						max. ca. 41 %	max. ca. 55 %

Source: GÖG

A breakdown of the individual participating age groups (see Table 2.6) shows that the proportion of 45- to 49-year-old women with a screening examination fell from 40 per cent to 38 per cent, the proportion of 50- to 59-year-old women from 41 per cent to 40 per cent and the proportion of 60- to 69-year-old women from 42 per cent to 41 per cent. An additional look at the opt-in groups shows that the proportion of women aged 40 to 44 participating in the BKFP fell from 21 per cent to 20 per cent, while the proportion of women aged 70 and over rose slightly from 15 per cent to 16 per cent.

2
Mammography, regardless of whether screening or diagnostic; without blank notifications

Table 2.6:
Number and proportion of women who participated in the BKFP per age group and per two-year cycle

	2014/2015		2016/2017		2018/2019		2020/2021	
40 to 44 years (opt-in)	42,100	13%	60,440	20%	58,935	21%	55,143	20%
45 to 49 years	114,908	33%	136,259	39%	132,145	40%	119,630	38 %
50 to 59 years	237,648	38 %	271,523	41%	279,001	41%	279,939	40%
60 to 69 years	185,697	40%	207,237	43%	211,068	42%	215,266	41%
from 70 years (opt-in)	62,552	9%	82,322	12%	104,554	15%	113,575	16 %

Source: GÖG

A look at the two opt-in groups at federal state level (see Table 2.7) shows that between eight per cent (Carinthia) and 28 per cent (Salzburg) of women aged 40 to 44 and between seven per cent (Carinthia) and 20 per cent (Vienna) of women aged 70 and over took part in the screening programme in 2020/2021. The mammography coverage rate (i.e. regardless of whether for the purpose of screening or for diagnostic reasons) in the younger opt-in group is between 21 per cent (Vorarlberg) and 38 per cent (Carinthia), whereby the high proportion both in Carinthia and in the core target group can be explained by an above-average number of diagnostic mammograms. The coverage rate for the older opt-in group is between 18 per cent (Vorarlberg) and 31 per cent (Vienna).

Table 2.7:
Number and proportion of women in the opt-in groups per federal state of residence who took part in the BKFP in 2020/2021

	40–44 years				over 70 years			
	Target population	Women in BKFP	Participation rate BKFP	Coverage rate	Target population	Women in BKFP	Participation rate BKFP	Coverage rate
Burgenland	9,847	1,791	18 %	37%	26,653	3,032	11%	27 %
Carinthia	16,722	1,370	8%	38 %	52,690	3,544	7%	27 %
Lower Austria	52,813	11,665	22 %	37%	143,956	25,389	18 %	30 %
Upper Austria	44,909	8,472	19%	28%	116,749	17,023	15%	21%
Salzburg	17,488	4,854	28%	34%	44,380	8,258	19%	25 %
Styria	38,469	7,882	20%	33%	109,949	17,005	15%	25 %
Tyrol	23,996	4,658	19%	36%	57,777	7,350	13%	27 %
Vorarlberg	12,894	1,708	13%	21%	28,745	3,692	13%	18 %
Vienna	64,136	12,743	20%	33%	139,631	28,282	20%	31%
Total	281,274	55,143	20%	33%	720,530	113,575	16 %	27 %

Source: GÖG

A look at the participation rate in 2020/2021 at the level of women's residential districts shows that the range is between twelve per cent and 51 per cent (seeTable 6. 1). Comparably large

differences between the residential districts are also evident in the analysis of BKFP participation since the start of the programme in 2014. Depending on the residential district, between 44% and 92% of the core target group took part in the screening programme at least once.

In 2020/2021, just under 73 per cent of women in the core target group who had a mammography were examined exclusively in the screening setting, around 23 per cent only had diagnostic mammograms according to one indication, and just under four per cent of women had both a screening examination and a diagnostic mammography in the two years (see Table 2.8).

Table 2.8:
Number and proportion of women in the core target group with a screening or diagnostic mammography per two-year cycle

	2016/2017		2018/2019		2020/2021	
Diagnostic only	166.094	21.3%	179,750	22.4%	188,028	23.3%
Screening only	584,535	74.9%	594,133	74.0%	585,086	72.6%
Diagnostic and screening	29,650	3.8%	27,358	3.4%	28,785	3.6%
Unknown	0	0%	1,365	0.2%	3,752	0.5 %

Source: GÖG

2.5.3 Result Re-participation

Of the approximately 590,000 participants from the core target group in 2018/2019 whose test result was clearly negative (BI-RADS 1 or 2) and who were consequently invited for a further routine examination after two years, 349,282 women had another BKF examination in 2020/2021. The **re-participation rate** for **2020/2021** is therefore around **59 per cent**. This figure is comparable with the re-participation rate from the 2016/2017 screening cycle (around 58 per cent) (see Table 2.9). In 2018/2019, 17.3 per cent of participants caught up on their BKFU late in 2022 and up to the reporting date of 2023, while a further 17 per cent had not had a screening examination since their last BKFP participation.

Comparing all age groups (57 per cent of women aged 40 to 44 and 52 per cent of women aged 70 and over), there are no significant differences in re-participation, but there are differences between the federal states in the most common reason for postponing a BKF examination - an intermediate diagnostic examination. This diagnostic mammography was the reason why almost 20 per cent of Carinthian women and only five per cent of Salzburg women were unable to participate again (see Table 2.9).

Equally large differences in re-participation can be seen when comparing the residential districts. On the one hand, more than 70 percent of women in the districts of Tamsweg, Neunkirchen and St. Johann im Pongau took part in the screening programme again at the scheduled interval, while on the other hand the re-participation rate in some districts of Carinthia and in Lienz is only around 40 percent (seeTable 6. 1). The relatively high number of

diagnostic mammograms is particularly striking in the districts with low re-participation, but there is no significant difference in re-participation between urban and rural residential districts.

The average time to re-participation within the core target group shortened from around 34 months between the first and second screening rounds and around 31 months between the second and third rounds to around 26 months, bringing it even closer to the planned screening interval of two years.

Table 2.9:
Women in the core target group (45- to 69-year-old women) with an inconspicuous (BI-RADS 1, 2) BKF examination in 2018/2019 who participated again in 2020/2021, by federal state of residence (line by line in per cent)

	Re-participation 2018/2019 after 2016/2017	Re-participation 2020/2021 after 2018/2019	Diagnostic examination	Deceased without re-participation	No examination at the scheduled interval	Total
Burgenland	58.27	58.21	14.08	0.48	27.23	100.00
Carinthia	50.10	49.69	19.63	0.58	30.10	100.00
Lower Austria	59.36	59.80	10.28	0.58	29.34	100.00
Upper Austria	60.13	59.80	6.64	0.47	33.08	100.00
Salzburg	61.55	65.11	4.66	0.36	29.87	100.00
Styria	60.36	60.19	10.27	0.51	29.03	100.00
Tyrol	55.67	57.09	10.69	0.41	31.81	100.00
Vorarlberg	56.04	56.42	6.51	0.40	36.67	100.00
Vienna	56.84	57.89	9.48	0.65	31.98	100.00
Total	58.26	58.88	9.70	0.53	30.90	100.00

Source: GÖG

2.5.4 Discussion

The participation rate of 70 per cent per two-year cycle recommended by Perry et al. (2006) is still not achieved at 40 per cent (or a maximum of 41 per cent including blank notifications), even taking into account the fact that it is not always possible to draw a clear distinction between the diagnostic area from which an (unknown) proportion of screening is attributable. The continued low level of participation can also be explained by the temporary slump in test numbers during the COVID-19 pandemic. This applies in particular to 2020, in which around 12.5 per cent fewer women took part in the BKFP than in 2019 (see Table 2.10).

In an international comparison, higher participation rates can be observed, albeit subject to significantly longer programme durations. For example, Scandinavian countries with decades of screening tradition or Spain report participation rates of around 80 per cent, the UK around 75 per cent, France around 65 per cent and Italy around 60 per cent. In Germany, the most recent

participation rate was around 49 per cent in 2020 (Kooperationsgemeinschaft Mammografie 2022).

The rate of women participating again in the current reporting period also shows potential for improvement in the invitation system and, in this context, in communication within the BKFP. In addition, it can be assumed that this low rate or delayed re-participation could also have a negative impact on the number and status of carcinomas detected 24 to 36 months after a BKFP examination. As is known from representative surveys of the core target group conducted by GÖG in recent years as part of the evaluation, trusted doctors (usually general practitioners or gynaecologists) are by far the most important source of information and communication in the context of screening programmes (Gollmer et al. 2019). The recommendation is once again made to further emphasise and expand this level of communication in addition to the invitation and reminder system. Additionally, the variations in participation rate at the district level should be analysed and appropriate regional measures implemented to increase participation.

2.5.5 BKFP participation in view of COVID-19 in the period 2020 to 2022

Due to the postponements and cancellations of BKFU caused by the COVID-19 pandemic, the pandemic had a negative impact on the number of participants in the breast cancer screening programme in 2020, but not in 2021. A comparison of the number of BKFP participants in the core target group (45 to 69 years) from **2020** with those from 2019 shows a **decrease of around 40,000 participations** (from around 320,000 to 280,000 participants), which corresponds to a share of around **12.5 per cent** for Austria as a whole (see Table 2.10). Comparing the decrease in the individual federal states, a heterogeneous picture emerges – from 1.3 per cent in Tyrol to 18.7 per cent in Salzburg.

In **2021**, there was a catch-up effect in the examinations, with more than 341,000 women in the core target group, around **61,000 more women (plus 22 per cent)** took part in the BKFP than in 2020, but the overall participation rate within the 2020/2021 screening cycle of 40 per cent of eligible women could no longer be significantly improved (see chapter 2.5.2). The effect varies from state to state, with participation increasing by 13.5 per cent in Tyrol in 2021 compared to 2020 and by 32.4 per cent in Salzburg. This can be explained by the fact that the pandemic-related decline in BKFU in 2020 was relatively low in Tyrol and relatively high in Salzburg (see Table 2.10).

In 2022, participation across Austria fell again to around 300,000 women from the core target group. This decline can be explained by the regularity of a two-year participation interval implemented in the programme and the associated eligibility to participate. Women are sent reminders two years after their last BKF examination and their e-card is activated for participation. It can therefore be assumed that the lockdown-related slump in participation in the second quarter of 2020 will continue over several screening cycles in the second quarter of every two years and that the quarters will slowly level out. If one compares the two years 2020 and 2022,

which are related according to the described participation interval, around seven per cent more women took part in the BKFP throughout Austria in 2022 than in 2020 (see Table 2.10).

Similar effects in terms of participation can be seen in the opt-in groups. The number of women aged 40 to 44 participating in the programme fell by 17 per cent between 2019 and 2020, increased again by 25 per cent in 2021 and remained stable in 2022. Among women over 70, participation fell by four per cent in 2020 and increased by 19 per cent in 2021, stabilising at this level in 2022.

Table 2.10:
Participants (TN) in the core target group 2019 to 2022 per federal state of residence

	TN 2019	TN 2020	Decrease in per cent 2020 vs. 2019	TN 2021	Increase in per cent 2021 vs. 2019	Increase in per cent 2021 vs. 2020	TN 2022	Change in per cent 2022 vs. 2020
Burgenland	11,871	9,996	15,8	12,436	4,8	24,4	11,102	11,1
Carinthia	18,415	15,278	17.1	18,831	2.3	23.3	15,120	- 1.0
Lower Austria	67,479	58,980	12.6	72,024	6.7	22.1	63,454	7.6
Upper Austria	50,376	44,089	12.5	53,976	7.1	22.4	47,646	8.1
Salzburg	23,623	19,216	18,7	25,434	7.7	32.4	21,314	10.9
Styria	48,935	42,631	12.9	50,601	3.4	18,7	43,866	2.9
Tyrol	23,790	23,483	1.3	26,659	12.1	13.5	24,382	3.8
Vorarlberg	11,927	11,009	7.7	12,657	6.1	15.0	11,677	6.1
Vienna	63,759	55,380	13.2	68,605	7.6	23.9	60,941	10.0
Total	320,175	280,062	12.5	341,605	6.7	22.0	299,965	7.1

Source: GÖG

As mentioned, the decline in BKFU in 2020 can be attributed to the second quarter which saw the first lockdown in the wake of the coronavirus pandemic and a 40 per cent decrease compared to the previous year's level. Although a relatively large number of BKFU were subsequently held in the summer of 2020, the level of 2019 could not be reached (see Table 2.11). In the annual analysis of participation figures, more women are shown in the total per screening cycle than in the analysis of the participation rate in chapter 2.5.2 (each woman is counted once per cycle), as women can have a screening in both years and are therefore counted twice in the annual analysis.

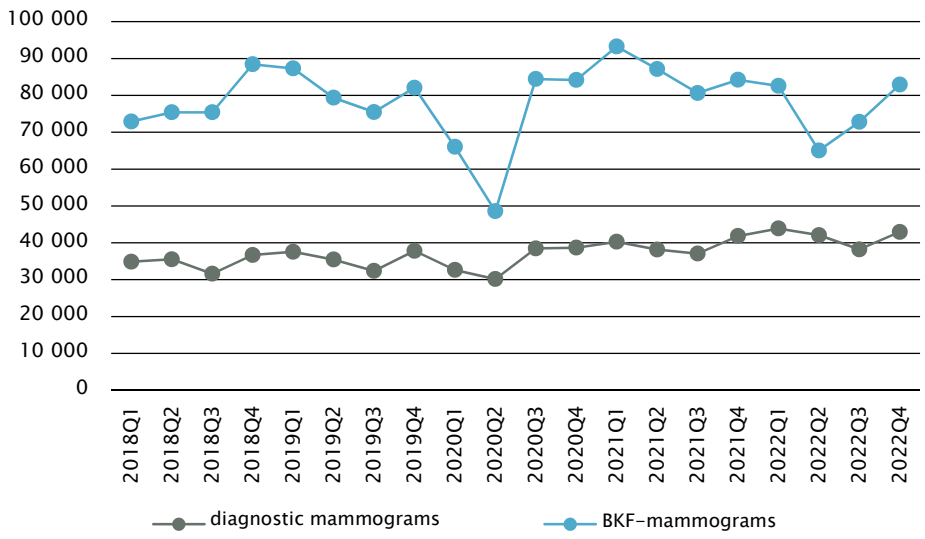
Table 2.11:
Participants in the core target group in 2019 and 2020 per quarter

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter	Total
2019	86,310	78,214	74,583	81,068	320,175
2020	65,025	47,579	84,430	83,028	280,062
2021	92,585	86,154	79,645	83,221	341,605
2022	81,505	63,032	72,507	82,921	299,965

Source: GÖG

In contrast to BKFU, the area of diagnostic mammograms following an indication was less affected by the fluctuations caused by the pandemic. Although there was also a slight decline in the number of BKFU in the second quarter of 2020, these remained relatively stable over the period from 2018 to 2022 with a frequency of between 30,000 and 43,000 BKFUs approximately. Similarly, there is no evidence that the diagnostic area is compensating for the lack of BKFU (Figure 2.1).

Figure 2.1:
Number of diagnostic mammograms and BKF mammograms 2018 to 2022 in the core target group per quarter



Source: GÖG

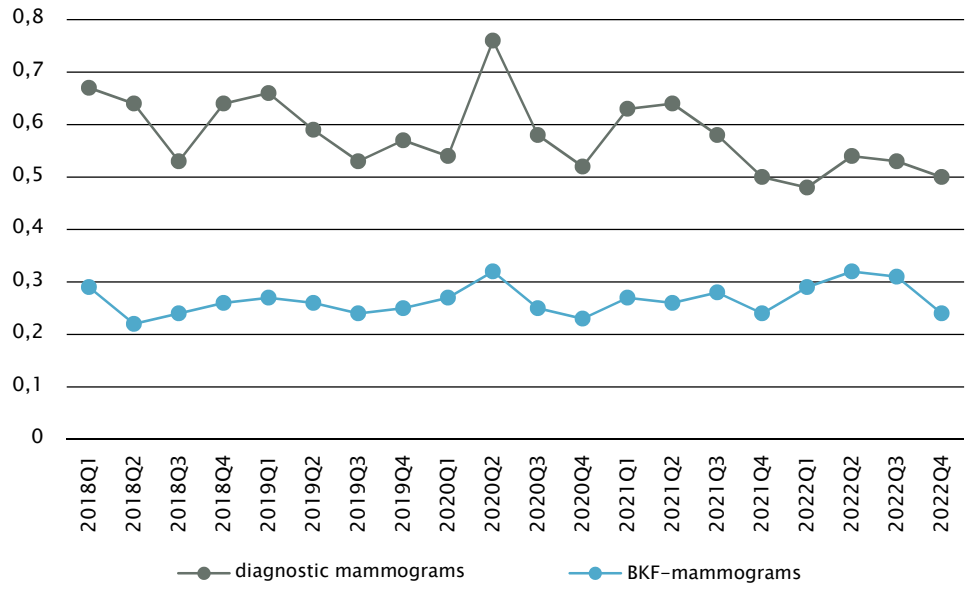
In addition to a quantitative analysis of the participation figures, an evaluation of the possible temporal shift of BI-RADS-5 findings (high probability of a malignant carcinoma) as part of the BKFU can be used to assess the possible effects of the lockdowns. For example, around 800 BI-RADS-5 findings were documented in 2017 and 2018 and 827 in 2019; this figure fell by around ten percent to 744 BI-RADS-5 findings in 2020. In 2021, the number of findings rose again by 18 percent to 905, and in the following year 2022, 881 BI-RADS-5 findings were documented within the core target group.

The changes in the frequency of BI-RADS-5 findings run parallel to the decrease and increase in BKFP participation figures and show no significant or above-average shifts in the time of diagnosis or the frequency of diagnosis.

A look at the development of the proportion of BI-RADS-5 findings in all examinations over time shows that the proportion of BKFUs remain stable in the long term at between 0.22 per cent and 0.32 per cent (average 0.26 per cent). For diagnostic mammograms, on the other hand, there was a significant increase in the proportion of BI-RADS 5 findings among all findings from 0.54

per cent in the first quarter of 2020 to 0.76 per cent in the second quarter of 2020, which corresponds to an increase of over 30 per cent (see Figure 2.2). Thereafter, the proportion falls back to an average level and subsequently indicates neither an increased frequency of diagnosis nor increased delays in diagnosis. This short-term increase in the proportion is due to the constant number of BI-RADS-5 findings with a simultaneous reduction in the number of examinations. It is also possible that more urgent mammograms were brought forward in cases of suspected disease during the first lockdown caused by the coronavirus pandemic, which could also explain the short-term increase in malignant findings.

Figure 2.2:
Percentage of BI-RADS 5 findings in diagnostic mammograms and BKF mammograms 2018 to 2022 in the core target group per quarter



Source: GÖG

2.6 Excursus: Identification of factors influencing participation

The results of the BKFP evaluation to date show a relatively low programme participation and re-participation rate compared to other countries (see also chapter2.5) and fall short of expectations. On the one hand, this fact points to a potential for improvement in terms of user-friendliness/accessibility of the BKFP and, on the other hand, raises the question of why women do not participate in the programme again or do so with a long delay. Apart from the noticeable regional differences, little is known about the different participation behaviour of the various user groups. The 2016 Health Report used ATHIS data to determine that although household income has an impact on the utilisation of mammography, neither education nor migration

background were found to be influencing factors here (no differentiation was made as to whether the mammograms were performed for screening purposes or not, although the question is introduced with a screening context; Griebler et al. 2017).

The participation rates to date and, above all, the re-participation rates raise the question of what reasons women have for deciding in favour of or against participation and what influencing factors hinder participation. There are some districts with conspicuously high and some with conspicuously low participation rates that can form a good starting point for such an analysis. What is particularly interesting here is why many women who have already participated do not participate again, or only after a long delay. It should be noted that the BKFP, like all measures, has both benefits and risks, such as overdiagnosis or false-positive/negative diagnoses. It is therefore crucial that women can decide whether to participate on the basis of neutral, evidence-based information. Under no circumstances should women be coerced. However, it is just as important that participation is not hindered by systemic barriers or other obstacles.

The first step was therefore to identify factors that can influence participation in screening programmes based on a comprehensive literature review. This work provides a basis for planning a study that analyses the reasons for the conspicuous participation patterns described above.

2.6.1 Method

Suitable literature was identified by means of a structured database search in Medline via EBSCOhost (medical subject headings) and a supplementary hand search (Google, Google Scholar, existing literature in our collection). The "subject headings" and the keywords were selected from an orienting search with identification of suitable key publications. The following restrictions were applied:

» English/German
» Systematic reviews, reviews and meta-analyses in research
» Research period: from 2015

The hits from the literature search were screened by title and abstract. From a total of eight hits in the manual search, one was included; from the database search with 123 hits, 18 were initially identified on the basis of the title. Due to the large number of recent systematic reviews with meta-analyses, the evaluation period was limited to 2020 to 2022 and twelve articles were used to identify influencing factors. The following section describes those aspects that can influence participation or represent a barrier to participation in breast cancer screening.

2.6.2 Results

Possible factors influencing participation

The identified systematic reviews and meta-analyses mainly comprised studies from countries with high income levels and therefore well-developed healthcare systems. Some of the studies focussed on factors influencing screening participation across all diseases, although only studies that included breast cancer screening were included. Others specifically analysed the factors influencing participation in breast cancer screening.

A number of recent studies have investigated factors influencing participation in screening programmes that could potentially have a positive or negative impact on participation (Bongaerts et al. 2020; Grimley et al. 2020; Le Bonniec et al. 2022; Mandrik et al. 2021). In a broad-based screening and partly cross-disease "umbrella review" from 2022, these influencing factors were also assigned to five domains (Le Bonniec et al. 2022):

» Individual domain: e.g. knowledge, beliefs, emotions, behaviour, motivation, awareness and perceived control
» Social domain, e.g. stigma, influence of family and peers
» Healthcare system domain, e.g. accessibility of screening services (e.g. distance to screening centre, access to appointments and health information)
» Healthcare provider domain, e.g. interaction between patients and professionals, characteristics of the doctor such as age and gender
» Domain Screening procedure, e.g. characteristics of the screening such as pain or validity of the test, procedure, invitation method - including multiple reminders

It was also found that both the recommendations of healthcare providers and the quality of communication have a particularly strong influence on screening participation for most diseases (Le Bonniec et al. 2022). However, previous participation also tends to have a positive influence on future participation (Mandrik et al. 2021). Baccolini et al. (2022) were able to show in an equally recent systematic review with meta-analysis that an adequate health literacy level also has a demonstrable influence on participation/adherence in cancer screening programmes. For breast cancer screening, seven included studies showed a significantly higher screening participation rate among people with adequate health literacy (3; 95-%-CI: 1.27-2.36).

A study of differences between women living in rural and urban areas did not reveal any significant differences in screening participation. However, the studies included in the meta-analysis showed contradictory results, which in turn affects the validity of the meta-analysis (Walji et al. 2021). Rollet et al. (2021) also identified a region-related socioeconomic status as an influencing factor of screening participation in their systematic review in addition to the aspects already mentioned. However, this is fraught with implementation problems in measurement and interpretation difficulties. For example, it is unclear whether the region-specific status measured says more about the individuals living in the region or about the regional conditions (Rollet et al. 2021).

Ethnicity is an aspect that is fraught with many difficulties in the study and summarises many underlying aspects such as belief (Rollet et al. 2021). However, there are indications from a review by Racine / Isik Andsoy (2022) that the aspects listed below, which may be associated with migration, are relevant influencing factors:

» Language barriers or a lack of education can make participation more difficult.
» There are time constraints due to other commitments (childcare, job search).
» A health belief or ideas about breast cancer that determine the disease as an uncontrollable fate.
» There is discrimination in the healthcare system or a lack of support from service providers.
» Cultural aspects such as a sense of shame prevent access. (Racine / Isik Andsoy 2022)

Determinants of (non)participation

Several systematic reviews and meta-analyses investigated the determinants of non-participation in population-based structured breast cancer screening programmes. The following determinants were associated with higher non-participation (Ding et al. 2022; Mottram et al. 2021):

» Low income (OR: 1.20; 95-%-CI: 1.10–1.30)
» Lower age of the woman (OR: 1.09; 95-%-CI: 1.01–1.18)
» Low education (OR: 1.18; 95-%-CI: 1.05–1.32)
» A designated screening centre that is far away from your place of residence (OR: 1.15; 95-%-CI: 1.07–1.24)
» Being unmarried (OR: 1.68; 95-%-CI: 1.32–2.14)
» Migration status (being a migrant) (OR: 2.64; 95-%-CI: 2.48–2.82)
» General practitioner provided by a man (OR: 1.43; 95-%-CI: 1.20–1.61)

Women with previous false-positive findings were less likely to return for screening (OR 0.77; 95-%-CI: 0.68–0.88; Mottram et al. 2021).

Ding et al. (2022) affirmed that their study confirmed already known determinants of non-participation, but also emphasised that some of the influences in the meta-analysis were less pronounced than in the original studies. According to recent reviews and meta-analyses, illness or disability also reduces the likelihood of participation in breast cancer screening programmes, especially in the case of neurological and psychiatric illnesses and disability (Andiwijaya et al. 2022; McWilliams et al. 2022). While the study by Ding et al. (2022) did not focus on disability and hardly any studies on persons with disabilities were considered, the authors of the other two studies each analysed almost 30 studies on disability and screening participation (Andiwijaya et al. 2022; McWilliams et al. 2022).

In contrast, increased participation in breast cancer screening programmes can be demonstrated for people with the following characteristics (Mottram et al. 2021):

» Higher socio-economic status (n = 11 studies; OR: 1.45; 95-%-CI: 1.20 to 1.75)
» Higher income (n = 5 studies; OR: 1.96; 95-%-CI: 1.68 to 2.29)

» Ownership of a home (n = 3 studies; OR: 2.16; 95-%-CI: 2.08 to 2.23)
» Having no immigration status (n = 7 studies; OR: 2.23; 95-%-CI: 2.00 to 2.48)
» Being married or living together (n = 7 studies; OR: 1.86; 95-%-CI: 1.58 to 2.19)
» Having a medium rather than a low level of education (n = 6 studies; OR: 1.24; 95-%-CI: 1.09 to 1.41)

Mottram et al. (2021) found no difference in age groups or rural vs. urban residence.

2.6.3 Summary

There are a number of factors that can influence participation in a breast cancer screening programme at the individual level, but also at the contextual level. The influencing factors researched provide a comprehensive starting point for investigating the questions of low participation rates, low re-participation rates and, in particular, the large differences in participation between individual districts. The next step was to plan and implement an analysis of the phenomena on this basis. In regions with particularly low and in those with particularly high participation rates, contextual factors beyond the individual domain, such as the distance to the nearest screening centre and characteristics of the healthcare providers involved, should also be investigated.

2.7 Assessments

2.7.1 Results

A BI-RADS-0 finding in screening is usually followed by diagnostic (non-invasive) imaging with mammography, ultrasound or MRI. However, assessment with diagnostic (non-invasive) imaging is also performed after BKFU with BI-RADS 4 and 5, the proportion of which is unknown. In **2020/2021**, **6,942 women** from the **core target group** received a BKFU with **BI-RADS 0** (the number of women differs slightly from the number of findings). An assessment with diagnostic (non-invasive) imaging was documented for 5,503 women (see Table 2.12). Compared to previous years, this is a significant increase in the number of BI-RADS-0 findings, with the documentation rate falling slightly.

An invasive assessment is to be expected after a BI-RADS-4 or BI-RADS-5 finding in a BKFU or a diagnostic (non-invasive) imaging. In 2020/2021, **5,171 women** with **BI-RADS 4 or 5** were diagnosed by BKFU. Based on the documented examinations, it can also be assumed that around one third of the diagnostic (non-invasive) assessments following a BI-RADS-0 finding in BKFU lead to the recommendation of an invasive assessment (2,424 women). It can therefore be estimated that, as in previous years, a maximum of **1.2 per cent** of participants (around **7,600 women**) received a **biopsy** in 2020/2021 as a result of radiological findings requiring an assessment. The biopsy rate is therefore comparable to the German programme, in which a

biopsy was indicated in 1.1 percent of the women examined in 2020. Since not all BI-RADS-4 or BI-RADS-5 findings were actually followed by an invasive assessment – reasons for this could be a refusal on the part of the patient or undocumented biopsies – it can be assumed that the true value is slightly lower. In 2020/2021, an invasive assessment was documented for 4,064 women. The documentation rate for invasive assessments therefore remains stable compared to 2018/2019.

Since the documentation of the diagnostic (non-invasive) imaging and invasive assessment is nevertheless incomplete, the biopsy rate cannot be determined exactly. However, it would be important to know the exact rates of assessments and, in particular, those of biopsies, as these provide information about unnecessary burdens on healthy participants (Perry et al. 2006). More than half (about 62 per cent) of the participants in the core target group with documented minimally invasive biopsy had a malignant finding (B5) in 2020/2021 (see Table 2.12). According to the available data, the **ratio of malignant to non-malignant biopsy findings** is **at least 1:1**, as in previous years, which corresponds to the expected value in the BKFP. However, it is possible that benign results were not or not fully documented in individual hospitals and that the documentation is therefore systematically biased towards malignant findings, which is why the true value may be somewhat lower.

Table 2.12:
Overview of BKFP participants in the core target group of 45- to 69-year-old women per BKFP cycle (absolute, in per cent, per 100,000 BKFP participants)

	2016/ 2017	in %	Per 100,000	2018/ 2019	in %	per 100,000	2020/ 2021	in %	Per 100,000
BKFP participants	613,954	100.00	100,000	621,049	100.00	100,000	614,835	100.00	100,000
Expected diagnostic (non-invasive) imaging (after BI- RADS 0)	5,158	0.84	840	6,123	0.99	986	6,942	1.13	1,131
Expected invasive assessment (after BI- RADS 4,5)	5,952	0,97	969	5,560	0.90	895	5,171	0.84	843
BKFP participants with documented diagnostic (non-invasive) imaging	4,998	100.00	814	5,313	100.00	855	5,503	100.00	896
Expected invasive assessment (BI- RADS 4,5)	2,427	48,56	395	2,372	44.65	382	2,424	44.05	395
BKFP participants with documented invasive assessment	4,576	100.00	745	4,366	100.00	703	4,064	100.00	662
• Normal, benign (B1, B2)	1,600	34,97	261	1,445	33,10	233	1,210	29.77	197
• Uncertain malignant potential (B3)	355	7.76	58	293	6.71	47	298	7.33	49
• Suspicion of malignancy (B4)	21	0.46	3	20	0.46	3	16	0.39	3
• Malignancy (B5)	2,569	56,14	418	2,604	59.64	419	2,540	62.50	414
• Open biopsy	31	0.68	5	4	0.09	1	0	0.00	0
BKFP participants with documented therapy/open biopsy	3,635	100.00	592	3,367	100.00	542	3,245	100.00	529
• invasive	2,890	79.50	471	2,858	84.88	460	2,627	80.96	428
• DCIS	487	13.40	79	431	12.80	69	413	12.73	67
• other, non-specific malignancy	4	0.11	1	2	0.06	0	10	0.31	2
BKFP participants with a malignant finding (excluding recurrences) after a BKFU requiring assessment (BI-RADS 0, 4, 5)	3,318	100.00	540	3,243	100.00	522	2,997	100.00	488
• Invasive	2,837	85.50	462	2,819	86.93	454	2,584	86.22	421
• DCIS	478	14.41	78	422	13.01	68	403	13.45	66
• Other, non-specific malignancy	3	0.09	0	2	0.06	0	10	0.33	2

Source: GÖG

Considering the results of the BKFU at the level of BI-RADS findings, it can be seen that in 2020/2021, a finding requiring **assessments** (i.e. BI-RADS 0, 4 or 5) was documented in **13,014 BKFU or in 2.07 per cent** of all BKFU (1.97 per cent of women) (see Table 2.13andTable 2.14), 93.34 per cent of the findings were inconspicuous (BI-RADS 1 or 2). These women are or were invited back for a BKFU after two years. About **4.6 per cent** of the women were diagnosed with **BI-RADS 3**, which is why they are or were invited to an intermediate BKFU in the sense of an early recall after a shortened interval of six or twelve months. The number of BKFU differs somewhat from the number of participants, as in exceptional cases several screenings were documented for one participant. The results of the BKFU are used to calculate the positive predictive value of the BKFP (i. e. the proportion of women with conspicuous result requiring assessment who had breast cancer).

Table 2.13:
Distribution of BI-RADS findings in the core target group per two-year cycle

BI-RADS findings	2014/2015	2016/2017	2018/2019	2020/2021	Total
0	4,506	5,651	6,717	7,511	24,385
1	145,532	162,843	156,162	149,170	613,718
2	370,194	425,385	437,246	437,145	1,669,977
3	21,400	28,486	30,061	28,826	108,773
4	4,310	4,681	4,307	3,854	17,151
5	1,383	1,643	1,619	1,649	6,292
Total	547,325	628,689	636,113	628,155	2,440,297

Source: GÖG

Table 2.14:
Distribution of BI-RADS findings in the core target group per two-year cycle (column by column in per cent)

BI-RADS findings	2014/2015	2016/2017	2018/2019	2020/2021	Total
0	0.82	0.90	1.06	1.20	1.00
1	26.59	25.90	24.55	23.75	25.15
2	67.64	67.66	68.74	69.59	68.43
3	3.91	4.53	4.73	4.59	4.46
4	0.79	0.74	0.68	0.61	0.70
5	0.25	0.26	0.25	0.26	0.26
Total	100.00	100.00	100.00	100.00	100.00

Source: GÖG

If the BI-RADS findings are analysed at the level of the federal states of residence, see (Table 2.15), there are minor differences in the proportion of findings requiring assessment (BI-RADS 0, 4 or 5). In 2020/2021, the rate fluctuated between approximately 1.4 per cent for Salzburg and 2.7 per cent for Vienna. In Carinthia and Vienna, BI-RADS-3 findings (early recall) were

documented in over six per cent of cases, while in Tyrol and Vorarlberg the corresponding figure was less than two per cent.

Table 2.15:
Distribution of BI-RADS findings in the core target group per two-year cycle (column-wise in per cent)

BI-RADS findings	Burgen-land	Carinthia	Lower Austria	Upper Austria	Salz-burg	Styria	Tyrol	Vorarl-berg	Vienna	Total
0	0.88	1.62	1.30	0.75	0.61	1.33	0.81	0.85	1.70	1.20
1	27.41	12.14	21.94	24.00	33.53	24.91	27.85	36.52	19.57	23.75
2	67.35	79.27	70.85	70.15	61.41	68.98	68.63	60.32	71.11	69.59
3	3.70	6.08	5.14	3.96	3.70	3.99	1.86	1.68	6.63	4.59
4	0.47	0.68	0.53	0.81	0.52	0.55	0.59	0.22	0.72	0.61
5	0.19	0.21	0.24	0.32	0.24	0.24	0.26	0.42	0.27	0.26
Total	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00

Source: GÖG

2.7.2 Discussion

Perry et al. (2006) define target values for the rate of additional imaging (1 to 5 per cent according to the EU-11 indicator) and further assessments (below 3 to 7 per cent according to the EU-12 indicator). However, they assume a fundamentally different programme sequence (the ultrasound examination is part of the assessment after a conspicuous BKFU) than the Austrian BKFP owing to the early use of ultrasound at the time of the BKFU adopted in Austria.

It is therefore fundamentally understandable that additional imaging is used more frequently in the Austrian BKFP than by recommended by Perry et al. (2006). At the same time, the rate of recalls has fortunately fallen significantly since the start of the programme to around two per cent, which considerably reduces the frequency of women being charged for a finding requiring assessments.

The biopsy rate can only be estimated approximately due to incomplete documentation. In order to validate the estimate of a maximum of 1.2 per cent, the evaluation of the Tyrolean mammography screening by the IET offers a relevant point of comparison here. The IET has an almost complete register, which is why its values can be considered valid. The IET calculates a biopsy rate of around one per cent of screening examinations in Tyrol. In 50 per cent of these invasive assessments, an invasive carcinoma or ductal in situ carcinoma was discovered (Buchberger et al. 2021). Similar values of 1.1 per cent are reported from the German mammography screening programme for 2020 (Kooperationsgemeinschaft Mammografie 2020) and largely correspond to the results of the Austrian BKFP. The same applies to the ratio of malignant to benign biopsy findings of at least 1:1, which corresponds to the expected value in the BKFP.

2.8 Breast cancer detection

2.8.1 Method

The detection of breast cancer is calculated based on the data sheets in the TUM and PAT tables, which are clearly documented as DCIS (ductal in situ carcinoma that has not broken through the natural tissue boundaries yet, but is nevertheless treated due to the unresolved probability of developing into an invasive carcinoma) or as invasive carcinoma For example, cases with a total remission after neoadjuvant therapy are not included here. In addition, cases with a minimally invasive biopsy found to be breast carcinoma (Finding is B5a, B5b) are also included.

The breast cancer detection rate is calculated from the number of BKFU requiring assessments (BI-RADS 0, 4 or 5) that subsequently result in a breast cancer diagnosis. The detection rate also includes cases with documented neoadjuvant therapy. These cases (599 invasive carcinomas or 23 percent) are not included in the analysis of tumour characteristics due to possible distortions (e.g. as a result of reduced tumour size). Therefore, the data from a maximum of 77 percent of the detected invasive carcinomas (without neoadjuvant therapy) in the core target group are included in the tumour biology presentations.

BKFU with BI-RADS 6 finding (histologically confirmed breast cancer prior to the screening) as well as recurrences are not included in the calculation of the detection rate. Similarly, breast cancer cases after an inconspicuous BKFU (BI-RADS 1, 2) are not included in the detection rate, but are assigned to the interval carcinomas (see Chapter 2.9). This also applies to interval carcinomas that were supposedly asymptomatic at the time of diagnosis and were discovered after an early or risk-adjusted examination via referred diagnostic breast imaging. The possible effects of these mammograms on programme parameters are shown in the chapter2.9.3.

In addition, the detection rate within the core target group of 45- to 69-year-old women is related to the background incidence (C50, invasive breast cancer) according to the EU-14 indicator (Perry et al. 2006, p. 28 f, 45 f, 50). The background incidence rate is the number of new cases per year without a screening programme (breast cancer incidence rate in the absence of screening [IR]). The calculated incidence for the years 2000 to 2010 was used for the evaluation, as it can be assumed that the cancer statistics are largely complete: C50-IR for 2000 to 2010 = 216 per 100,000 women in the core target group.

As screening mammograms were already performed in various settings in the form of opportunistic or "grey" screening before the start of the BKFP in Austria in 2014, the BKFP is considered follow-up screening according to the European guidelines and the aim is for the detection rate of the BKFP to be at least 1.5 times the background incidence.

Contrary to the recommendation of Perry et al. (2006), recurrences (carcinomas after breast cancer findings up to ten years ago) are not included in the detection rate because the women

concerned should not participate in the BKFU and are monitored more closely as a part of specific post cancer care.

According to the recommendations of Gigerenzer et al. (2008), the risk of a breast cancer diagnosis per 100,000 BKFP participants is given in the report. This should allow lay people, in particular, to better assess the risk of disease and the benefits of participation in the BKFP.

2.8.2 Results

In **2020/2021**, **2,584** BKFU of women in the **core target group** requiring assessment resulted in a diagnosis of **invasive breast cancer** (C50 according to ICD-10 coding). This corresponds to a **breast cancer detection rate** of **421 invasive carcinomas per 100,000 women examined** in the core target group (see Table 2.16). **403** BKFU (66 per 100,000) led to a **DCIS diagnosis** (ductal in situ carcinoma, D05 according to ICD-10 coding). This means that **breast cancer** was detected in **a total** of **2,987 women** from the core target group of 45- to 69-year-olds, and the overall breast cancer detection rate in the 2020/2021 cycle is **487 cases per 100,000 women examined** (see Table 2.16). Compared to 2018/2019, the detection rate has therefore fallen by around 20 cases per 100,000 or around five per cent.

Around 85 per cent of the carcinomas detected in the BKFP are invasive, as in the previous cycles, with the proportion of invasive carcinomas increasing with the age of the participant. Around 80 per cent of women aged 45 to 49 and around 90 per cent of women aged 60 to 69 have an invasive carcinoma.

Breast cancer detection within the federal states of residence appears to be homogeneous; in federal states with organised and complete tumour documentation within the framework of cancer registries, such as Upper Austria, Tyrol and Vorarlberg, the documented detection rate is naturally somewhat higher. Comparatively lower breast cancer detection rates are found for those federal states of residence that also have lower documentation rates compared to the expected cases from the billing data (see also chapter 2.4).

Table 2.16:
Number of women in the core target group per breast cancer status (breast cancer detected after a BKFU requiring assessment, excluding recurrences) per two-year cycle

	2014/2015	Per 100,000	2016/2017	Per 100,000	2018/2019	Per 100,000	2020/2021	Per 100,000
normal/ benign	544,264	99,512	624,895	99,462	632,539	99,483	610,805	99,512
Breast cancer	2,626	480	3,315	528	3,241	509	2,987	487
- of which invasive	2,263	414	2,837	452	2,819	443	2,584	421
- of which DCIS	363	66	478	76	422	66	403	66
Total	546,890	100,000	628,210	100,000	635,780	100,000	613,792	100,000

Source: GÖG

In addition, in 2020/2021, 116 invasive carcinomas (210 per 100,000) and 30 DCIS (54 per 100,000) were detected in the opt-in group of 40 to 44-year-old women and 995 invasive carcinomas (854 per 100,000) and 126 DCIS (108 per 100,000) in the group of women aged 70 and over - i.e. a total of 3,695 invasive carcinomas and 560 DCIS (see Table 2.17). Considering individual age groups within the core target group for 2020/2021, there is an approximately 85 per cent increase in the incidence of invasive carcinoma within the 60-69 year old women group (555 per 100,000) compared to the 45-49 year old women group (302 per 100,000). In principle, an - expected - increase in detection rates can be recognised with increasing age of the participants.

Table 2.17:
Number of women (after a BKFU requiring assessment) per breast cancer status and per age group for 2020/2021 (excl. recurrences)

Age group	Invasive carcinoma	Per 100,000	DCIS	Per 100,000
40 to 44 years (opt-in)	116	210	30	54
45 to 49 years	359	302	79	66
50 to 59 years	1,033	370	178	64
60 to 69 years	1,192	555	147	68
70 to 74 years (opt-in)	387	731	49	93
from 75 years (opt-in)	608	1,006	77	127
Total	3,695	473	560	72

Source: GÖG

As already mentioned in the chapter 2.8.1, it is important to know the number of carcinomas with neoadjuvant therapy, as these are not used for the analysis of tumour characteristics due to possible distortions. In 2020/2021, **599** of the 2,584 **invasive carcinomas** (around 23 per cent or 95 per 100,000) in the core target group were accompanied by **neoadjuvant therapy** (Table

2.18). At the level of the federal states of residence, the proportion of neoadjuvant therapies for invasive carcinomas ranges from 13 per cent in Upper Austria to 36 per cent in Salzburg.

Table 2.18:
Number of women in the core target group per malignancy with neoadjuvant therapy 2020/2021 excl. recurrences per 100,000

	Women	Per 100,000
invasive after BI-RADS 0, 4, 5	1,985	316
invasive after BI-RADS 0, 4, 5 with neoadjuvant therapy	599	95
DCIS after BI-RADS 0, 4, 5	375	60
DCIS after BI-RADS 0, 4, 5 with neoadjuvant therapy	28	4

Source: GÖG

Of the 1,985 invasive carcinomas without neoadjuvant therapy, **complete tumour data is only available for 1,337 cases (67 percent)** due to documentation gaps, which is necessary, for example, for the presentation of the tumour stage according to the International Union Against Cancer (UICC) or for the analysis of the frequency of distant metastases. In turn, data on hormone status or tumour size is available for 1,527 carcinomas (77 percent). In about a quarter of the cases, the tumour categorisation was documented under the variable "unknown" (see Table 6.2appendix).

A comparison of the stage distribution of detected carcinomas between the two-year intervals shows a reduction - albeit only slight - in the proportion of advanced **tumour stages III and IV** from 4.9 percent (2014/2015) and 3.5 percent (2016/2017) to 2.4 percent **in 2020/2021**. In over 75 percent of women, a small tumour without lymph node involvement and without distant metastases was detected as part of the BKFP (see Table 2.19).

Table 2.19:
Tumour stage in BKFU-detected breast cancer in participants in the core target group (excl. cases with neoadjuvant therapy, only cases with complete pathological documentation) per two-year cycle

	2014/2015	in %	2016/2017	in %	2018/2019	in %	2020/2021	in %
0 (in situ)	62	4.16	42	2.60	47	2.90	46	3.40
I	1,051	70.58	1,208	74.66	1,193	73.51	1,008	75.40
II	303	20.35	312	19.28	335	20.64	251	18.80
III	58	3.90	44	2.72	42	2.59	18	1.30
IV	15	1.01	12	0.74	6	0.37	14	1.10
Total	1,489	100.00	1,618	100.00	1,623	100.00	1,337	100.00

Source: GÖG

The proportion of women aged between 60 and 69 is highest in stage I at just under 78 per cent, and lowest in the opt-in group of 40 to 44-year-old women at 61.5 per cent (see Table 2.20).

Table 2.20:
Tumour stage distribution per age group for 2020/2021 (excl. cases with neoadjuvant therapy, only cases with complete pathological documentation)

	40 to 44 years	45 to 49 years	50 to 59 years	60 to 69 years	70 years and older	Total
0 (in situ)	11.54	4.11	4.54	2.35	1.43	3.15
I	61.54	70.00	74.29	77.74	72.12	73.39
II	25.00	21.18	19.09	17.87	24.52	20.83
III	1.92	4.12	0.76	1.10	1.92	1.65
IV	0.00	0.59	1.32	0.94	0.01	0.98
Total	100.00	100.00	100.00	100.00	100.00	100.00

Source: GÖG

In 2020/2021, the proportion of documented invasive tumours **ten millimetres or smaller** within the core target group improved from 31 per cent to just under **43 per cent**. The proportion of tumours **less than 15 millimetres** in size also increased from 55 to almost **78 percent** (excluding cases with the expression "unknown").

Around **75 per cent** of the carcinomas detected were found to be **without lymph node involvement** (excluding cases with the expression "unknown"). The lymph nodes were also affected in around 17 per cent of carcinomas, and in 27 per cent of cases the status of the lymph nodes was unknown (see Table 6.3appendix).

In around **88 per cent** of the invasive carcinomas detected in the BKFP within the core target group, **no distant metastasis** was detected, in around ten per cent no statement could be made and in one per cent metastases were already present (excluding "unknown"; see Table 6.4appendix).

2.8.3 Discussion

The incompleteness of the tumour-specific data does not allow any conclusions to be drawn about the tumour stage, the presence of metastases or other important parameters for around a third of the carcinomas detected, which makes it difficult to evaluate the programme and assess its benefits. For this reason, an improvement in the degree of completeness (were all carcinomas documented?) and completeness of the tumour data (were all tumour-specific data documented for reported carcinomas?) appears essential in the future. The decrease in the number of detected carcinomas in 2020/2021 compared to the 2018/2019 cycle is attributable on the one hand to the decline in the participation rate due to the COVID-19 pandemic and on the other hand to documentation gaps in individual federal states (see chapter 2.4).

In **relation to the background incidence** (i.e. the **incidence calculated without screening**), the **breast cancer detection rate** of invasive carcinomas in the core target group in 2020/2021 was

twice the background incidence (cf. 2018/2019: 2.1 times). Despite a slight decrease in detection, this value again exceeds the target value of 1.5 for follow-up screening defined by Perry et al. (2006). Due to the widespread "grey" or opportunistic screening in Austria prior to the introduction of the BKFP, it can be argued that this target value for organised and systematic follow-up screening is entirely suitable as a reference, even if the participation rate can be increased in the planned two-year interval.

The detection rate achieved within a programme setting close to the participant's home as in Austria can certainly be seen as a success in international comparison; for example, the German mammography screening programme (implemented nationwide since 2009 as part of specialised screening units) has also been detecting 2.1 times the regional background incidence for several years (Kooperationsgemeinschaft Mammographie 2022). In particular, it should be emphasised that this increase in detection should be seen in relation to opportunistic screening already carried out before the BKFP.

At first glance, the detection rate of 421 cases of invasive breast cancer per 100,000 examinations for 2020/2021 (see Table 2.16) is below the estimate of 492 or 536 cases in the first evaluation report (Gollmer et al. 2017), which at that time still had to be carried out on the basis of SV billing data, whereby this value also included interval carcinomas within one year and recurrences. If these are included (around 80 per 100,000), the two values converge.

The fact that the ratio of invasive breast cancer to DCIS (see Table 2.16) has remained more or less the same in the previous two-year intervals contradicts the assumption of a prevalence round in 2014/2015 (first screening round in which tumours that have already been present in the target group for some time are detected), as a decrease in this value would have been expected in this case. Only the distribution of tumour stages shows that in the two-year interval 2014/2015, more advanced carcinomas were detected to a small extent and that the proportion of these carcinomas continued to decrease slightly until 2020/2021 in the sense of incidence rounds (follow-up screening in which mainly new tumours are detected), although the figures here are not clear and the differences are small.

Further tumour-specific benchmarks from Perry et al. (2006) for the evaluation of a successful screening programme are also met for 2020/2021, as they were in 2018/2019. For example, the proportion of invasive carcinomas in the total number of carcinomas detected in the BKFP (85 per cent) corresponds to the international target (80 to 90 per cent). The detection of DCIS as part of screening programmes has been the subject of controversial debate for many years, as there is a risk of overdiagnosis and overtreatment on the one hand, and the potential for the development of invasive carcinomas is unclear on the other. The advantages of early detection of DCIS in terms of improving the prognosis or avoiding invasive carcinomas have been shown by Weigel et al. (2016) and Duffy et al. (2015). Perry et al. (2006, p. 185) also assume that surgical removal of "high-grade type" DCIS in particular reduces mortality. On the other hand, DCIS findings in particular are often considered an indication of overdiagnosis or overtreatment, as they could also regress spontaneously or, to a certain extent, never become clinically noticeable or irrelevant in terms of mortality (Esserman/Yau 2015). Narod et al. (2015), for example,

estimate in this context that the cancer-specific 20-year mortality rate after a DCIS finding is only three per cent.

The targets for the proportion of invasive carcinomas that should be smaller than or equal to ten millimetres (target: more than 25 per cent) or smaller than 15 millimetres (target: more than 50 per cent) at the time of detection are also far exceeded at 43 per cent and 78 per cent respectively. The palpability of a breast carcinoma depends on a number of factors, but it is generally assumed to be palpable from a tumour size of about 20 to 25 millimetres (Mathis et al. 2010 or Tabar et al. 2011). For classification into tumour stage I, the tumour may have a maximum size of 20 millimetres. The fact that more than three quarters of the carcinomas detected in the screening are smaller than 15 millimetres can be emphasised as positive. The information on size distribution also exceeds the results of the German mammography screening programme, which reports 35 percent of carcinomas with a size of less than or equal to ten millimetres and 57 percent of carcinomas smaller than 15 millimetres for 2020 (Kooperationsgemeinschaft Mammographie 2022).

The proportion of carcinomas with a stage II or higher, i.e. stages with a less favourable prognosis (target: below 25 percent), is also in a pleasing range at around 21.2 percent and has improved by 2.4 percentage points compared to 2018/2019. At 75 per cent, the proportion of carcinomas without lymph node involvement is exactly the same as the European guidelines (Perry et al. 2006).

2.9 Interval carcinomas

2.9.1 Method

Interval carcinomas are defined as carcinomas that are detected after a negative BKFU within the routine screening interval of two years. This procedure is based on the process logic described in the chapter 2.1 and the associated assumption that the BI-RADS classification also corresponds to the radiological intention at the initial examination.

Interval carcinomas are basically unavoidable and arise in the context of every cancer screening programme, since some of these carcinomas do not exist at the time of the screening and the screening is only provides a snapshot.

In general, a distinction can be made between the following types of interval carcinoma (Perry et al. 2006, 182; Renart-Vicens et al. 2014, p. 2):

» True interval carcinomas with inconspicuous or negative screening mammography
» Occult, tumours that are not visible with mammography
» Carcinomas with minimal, non-specific signs in the screening mammography

» Diagnostically detected carcinomas after false-negative results (due to technical errors), where the screening mammography would appear to be conspicuous in a retrospective review
» Unclassifiable carcinomas

The estimated number of interval carcinomas can be compared with the background incidence (new cases without screening) defined in the chapter2.8, just like breast cancer detection in screening. Perry et al. (2006) recommend that the rate of interval carcinomas detected in the first year after a screening examination should not exceed 30 per cent of the background incidence. For the second year, they give a benchmark of 50 per cent.

In addition, the number of interval carcinomas can be considered in relation to the number of carcinomas detected in screening and compared over time. Interval cancers are also classified according to the tumour stages pT and pN (Perry et al. 2006; Sobin et al. 2011) and other tumour characteristics in order to be able to quantify the difference to carcinomas detected in screening.

Perry et al. 2006) also recommend differentiating between carcinomas diagnosed 0 to 12, 13 to 24 or more than 24 months after a negative screening when analysing interval carcinomas. For this reason, the interval cancers are grouped in the presentation according to the years since the BKFU. An increased interval carcinoma rate in the first year after a BKFU in conjunction with corresponding tumour characteristics such as size or tumour stage could be interpreted as an indication of increased false-negative findings. Another option is the early detection of true interval carcinomas by means of an early or risk-adjusted screening via referred diagnostic breast imaging (see chapter2.9.3). An increased interval cancer rate in the second year could indicate possible optimisation potential in the programme modality, for example with regard to the participation interval.

Only carcinomas detected by the end of 2021 are included in the calculations, as at the current time only these can be reliably determined as not being those detected within the scope of the BKFP. This means that BKFU from 2018/2019 can be included in the calculation of the interval carcinoma rate. In addition, the restriction of the screening period inevitably underestimates the number of carcinomas detected more than two years after a BKFU.

Due to the increasing incidence of breast cancer with age, only women within the core target group are included for reasons of better comparability, unless the evaluation is carried out by age group.

2.9.2 Results

Due to the limitations described in chapter 2.14, the number of interval carcinomas (IC) cannot be determined exactly, but only estimated approximately.

Assuming the process logic specified by the BKFP (see chapter2.1), 844 invasive interval cancers (C50 only) or **917 invasive or ductal interval carcinomas** (C50 or D05) are recorded in the **core target group** of 45- to 69-year-old women for the years 2018/2019. This corresponds to a reduction of 128 invasive or ductal interval cancers compared to 2014/2015 and 19 compared to 2016/2017 (see Table 2.21).

Of the invasive interval carcinomas, 263 (44 per 100,000 participants) were documented in the first year and 581 (98 per 100,000 participants) in the second year after the BKFU; the distribution remains almost unchanged compared to 2016/2017. Of the invasive or ductal interval carcinomas (C50 or D05), **290 (49 per 100,000) were detected in the first year** and **627 (106 per 100,000) in the second year** after the BKFP (see Table 2.21). For 2018/2019, this corresponds to a further decrease in the number of ICs per 100,000 examinations in the second year compared to the 2016/2017 period; the number in the first year is almost identical or comparatively high. It can be assumed that the referred diagnostic breast imaging described in Chapter 2.9.3about one year after the BKFU is responsible for the increased number of documented interval carcinomas in the second year, as they do not appear as BKFU-detected carcinomas due to the data available.

If one compares the number of interval carcinomas with the number of total breast cancer cases, the proportion stabilises at 22 per cent from the second screening round onwards (see Table 2.21).

Table 2.21:
Women with carcinoma detection (invasive and ductal) after a BKFU in 2014/2015, 2016/2017 and 2018/2019 in the core target group of

	BKF-detected breast cancer	Per 100,000 TN	0-11 months (IC first year)	Per 100,000 TN	12-23 months (IC second year)	Per 100,000 TN	IC total	Proportion of IC in all breast cancer cases
2014/ 2015	2,626	480	428	79	617	113	1,045	28.5 %
2016/ 2017	3,315	528	281	48	655	114	936	22.0 %
2018/ 2019	3,241	509	290	49	627	106	917	22.1%

TN: Participants
IC: Interval carcinoma
BC: Breast cancer

Source: GÖG

Comparing the groups of 45- to 49-year-old, 50- to 59-year-old and 60- to 69-year-old women, there are no clearly interpretable differences in the relative proportions of interval carcinomas detected in the first or second year (see Table 2.22). Among 45 to 49-year-olds, the proportion of invasive or ductal interval cancers detected in the first or second year remained almost unchanged per 100,000 compared to 2016/2017. In the age group of 50 to 59-year-old women, the proportion of interval carcinomas decreased compared to 2016/2017, while it increased slightly in women aged between 60 and 69.

Table 2.22:
Interval carcinomas (invasive and ductal) after an inconspicuous BKFU per age group in 2018/2019

	IC in first year	Per 100,000 TN	IC in second year	Per 100,000 TN
40 to 44 years (opt-in)	27	50	24	44
45 to 49 years	73	59	131	106
50 to 59 years	110	41	261	98
60 to 69 years	107	53	235	116
from 70 years (opt-in)	60	60	165	165
Total	377	50	816	109

TN: Participants
IC: Interval carcinoma

Source: GÖG

Within the core target group, there are a further 117 documented invasive carcinomas (C50) and 31 DCIS (D05) following an abnormal BKFU with BI-RADS 0, 4 or 5, which, however, cannot be clearly attributed to a BKF case history or a BKF episode due to the large time intervals between the examination steps or the incomplete documentation. It is unclear whether these are delayed treatments or cases separated from the BKFU. It is also unclear why timely data on assessment examinations or pathology/tumour are missing after the conspicuous BKFU (not performed or not documented) and only follow at a later date. However, these are probably not interval carcinomas in the classical sense, and there is probably no incorrect finding in the screening. However, they are listed for the sake of completeness.

The number of invasive interval carcinomas (C50 only), like the number of invasive carcinomas detected in the BKFP, can be related to the background incidence to assess their volume size. The **ratio** of **invasive interval carcinomas diagnosed** in the **first year** after a negative BKFU (based on a **background incidence** of 216 per 100,000) is **20.5 per cent** for 2018/2019 (target value: less than 30 per cent, cf. 2016/2017: 19 per cent) and **45.4 per cent** for invasive interval carcinomas diagnosed in the **second year** (target value: less than 50 per cent, cf. 2016/2017: 46 per cent).

To date, 261 carcinomas (235 of which were invasive) have also been diagnosed three or four years after a negative screening examination within the core target group in 2018/2019, after the woman concerned had not attended the BKFP again at the regular interval of two years. Due

to the short observation period for this research question, the data is underestimated and the number will still increase.

A look at the distribution of breast density of interval cancers in 2018/2019 compared to the general breast density distribution of women in the BKFP across all age groups shows a trend towards increased density (see Table 2.23). Around half as many interval carcinomas were documented compared to all mammography findings with density grade 1, while density grade 2 occurs around 20 per cent less frequently. Instead, the density grade 3 of the interval carcinomas is about 20 per cent higher than all findings, and the density grade 4 is even twice as high (see Table 2.23andTable 2.29).

Table 2.23:
Breast density for interval carcinomas (invasive and ductal) after an inconspicuous BKFU per age group in 2018/2019 and by row in per cent

	Breast density unknown		ACR 1		ACR 2		ACR 3		ACR 4	
40 to 44 years (opt-in)	3	5.9%	0	0.0%	13	25.5%	27	52.9%	8	15.7 %
45 to 49 years	13	6.4 %	4	2.0 %	34	16.7%	112	54.9%	41	20.1 %
50 to 59 years	5	1.4 %	10	2.7%	124	33.4%	186	50.1%	46	12.4%
60 to 69 years	8	2.3 %	30	8.8%	144	42.1%	138	40.4%	22	6.4 %
from 70 years (opt-in)	3	1.3%	37	16.4%	112	49.8 %	63	28.0 %	10	4.4%
Total	32	2.7%	81	6.8%	427	35.8%	526	44.1%	127	10.7%

ACR 1-4: Density grade of the breast according to the American College of Radiology

Source: GÖG

In 75 per cent of the 917 invasive or ductal interval carcinomas within the core target group, subsequent tumour-specific documentation can be used for further data analysis. In 25 percent of these interval carcinomas, further information such as tumour stage, size, metastases or hormone status is sometimes missing.

Just over 50 per cent of the carcinomas diagnosed in the core target group after a negative BKFU in 2018/2019, of which the documentation can be used for analysis purposes, have tumour stage I. Around eight per cent were diagnosed with tumour stage III or IV in the first year and around seven per cent in the second year after the inconspicuous screening examination (see Table 6.8appendix). The proportion of **interval carcinomas with stage II+** increases from **34 per cent** within the **first year to just** under **41 per cent in the second year** (see Table 2.24). The interval carcinomas have a higher proportion of tumour stage II or III or IV carcinomas than carcinomas detected during a BKFU in the comparison period (23.6 percent in 2018/2019).

In almost **79 per cent** of interval carcinomas, **no metastases** are detected within the **first year**; this value increases to about **88 per cent** in the **second year** of occurrence (without "unknown"). In 18 per cent of cases in the first year and 11 per cent of cases in the second year, no assessment of metastasis can be made (see Table 6.7appendix). Compared to invasive carcinomas

detected in the BKFP in the core target group, there is no relevant difference in the frequency of distant metastases (around 83 per cent in 2018/2019) – see Table 2.24.

As in 2016/2017, the interval carcinomas in 2018/2019 hardly differ from the carcinomas detected in screening in terms of tumour size. In the **first year**, **37 per cent** of the ICs are **ten millimetres or less** in size (comparison screening: just under 31 per cent), **62 per cent** are **smaller than 15 millimetres**, compared to around 78 per cent in the screening of the comparison period (see also Table 2.24).

In about **70 per cent** of invasive interval carcinomas in 2018/2019, the **lymph nodes are not yet affected** (excluding cases with the expression "unknown", comparison screening: 73 per cent) (see Table 2.24).

Compared to screening, oestrogen-negative breast cancer occurs more frequently with interval carcinomas. Particularly in the first year after the inconspicuous BKFU, the proportion is comparatively high at around 48 per cent (screening around 30 per cent). The same applies to negative progesterone status, where the proportion of interval carcinomas in the first year is 55 per cent (compared to screening: around 39 per cent; see Table 6.5 and Table 6.9 in the appendix).

Table 2.24:
Tumour characteristics of invasive interval carcinomas compared to invasive carcinomas detected in the BKFP in the core target group in 2018/2019 (each without "unknown")

	IC in first year	IC in second year	BKF-detected BC
Tumour stage II+	34.1 %	40.8 %	23.6 %
Free of metastases	78.7 %	77.6 %	83.0 %
without lymph node involvement	68.8 %	73.3 %	73.0 %
Tumour size ≤ 10 mm	37.1 %	33.6 %	30.6 %
Tumour size < 15 mm	62.2 %	71.8 %	77.9 %

IC: Interval carcinoma
BC: Breast cancer

Source: GÖG

2.9.3 Discussion

Interval carcinomas are defined as carcinomas that are discovered during a diagnostic examination after a negative BKFU within the routine screening interval of two years. Some of these carcinomas are unavoidable in screening, as fast-growing, aggressive breast cancers can become clinically evident within a short time. However, these fast-growing tumours are comparatively rarer, with their proportion of the total number of breast carcinomas decreasing with age (Mandelblatt et al. 2009, p. 744).

On the other hand, false-negative screening results or occult (not visible with mammography) carcinomas can also lead to interval carcinomas. Renart-Vicens et al. (2014) state that in an international comparison the false negative rate can be 12 to 41 per cent of interval carcinomas, although such a comparison is problematic because of the different programme procedures and the different ways in which the interval carcinoma rate is calculated (Bennett et al. 2011). Blanch et al. (2014) show for the Spanish breast cancer screening programme that about 20 per cent of the carcinomas diagnosed in the first year were true, i.e. interval carcinomas that developed after the screening. In this study, the other interval carcinomas (i. e. carcinomas detected in the interval) were occult tumours in 42 per cent, false-negative findings in 32 per cent and carcinomas with minimal signs at the time of the BKFU in 31 per cent.

As in 2016/2017, comparatively few interval carcinomas occurred in the Austrian Breast Cancer Screening Programme in the 2018/2019 screening cycle. The European guidelines (Perry et al. 2006) stipulate that the proportion of invasive interval carcinomas in the first year after a negative BKFU compared to the background incidence (i. e. the incidence without screening) should be a maximum of 30 per cent and in the second year a maximum of 50 per cent. At 20.5 per cent, the first year in particular is once again well below this benchmark, and a ratio of 45.4 per cent for the second year can also be regarded as positive. In terms of the incidence of interval carcinomas, the Austrian BKFP can be compared with the German screening programme, which reports a ratio of 21.4 per cent for the first year and a ratio of 37.7 per cent for the second year of the regional background incidence of the federal states included in the analysis (Kooperationsgemeinschaft Mammographie 2020). A positive trend is also consolidating with regard to a reduced proportion of interval carcinomas in the number of total breast cancer cases, as was already the case in 2016/2017 and now also in 2018/2019 (22 per cent) compared to 2014/2015 (28.5 per cent).

As in 2016/2017, the number of interval carcinomas within the first year remains comparatively low. Nevertheless, particularly in cases where breast cancer was detected immediately after a BKFU with an inconspicuous result, the question arises as to what motivated an assessment examination and thus the breast cancer diagnosis. Input errors or processes that deviate from the intended process logic are also conceivable here. It should be examined whether the documentation could be improved in such a way that the currently undocumented decisions are also recorded, so that the range of possible ways of counting interval carcinomas and thus also their number (especially in the first year) would be reduced.

It is remarkable that a large proportion of the invasive interval carcinomas occurring in the core target group of 45- to 69-year-old women do not differ from the tumours detected in the screening in terms of size, metastases or lymph node involvement, although the opposite would rather be expected, especially for the second year after a negative BKFU. Only the proportion of tumour stage II+ is higher in comparison, especially in the second year after the inconspicuous BKFU. However, as no information on size, lymph node involvement or distant metastases is available for around 25 percent of the documented interval carcinomas, the positive trend in the tumour characteristics of interval carcinomas could be somewhat overestimated. This is also reflected in the relatively high proportion of cases with tumour stage II, III or IV (40.8 percent of interval carcinomas in the second year) compared to the carcinomas detected in screening.

However, false-negative screening results or occult breast carcinomas at the time of screening would tend to increase the proportion of symptomatic or advanced interval carcinomas to a far greater extent. Since this was also not the case in 2018/2019, as was the case in 2016/2017, the hypothesis already put forward in the third evaluation report (Gollmer et. al 2021) can be repeated that some of the interval carcinomas are true interval carcinomas (i.e. growing faster than the screening interval) that are due to a referred diagnostic breast imaging outside the specified screening interval. This thesis is supported by the fact that due to the tumour biology or size of the interval carcinomas, it can be assumed that about 60 per cent of the cases were asymptomatic or non-palpable tumours at the time of diagnosis. Since both the number of interval carcinomas increases significantly in the second year compared to the first year after the negative BKFU (especially after 12 to 14 months) and the data on tumour characteristics (tumour stage, metastases, lymph node involvement, tumour size) further approximate the data of the screening-detected tumours in the second year (see Table 2.24), it can be assumed that this referred diagnostic imaging takes place around the beginning of the second year after the BKFU. As in 2016/2017, there is no significant difference in the individual age groups within the core target group for 2018/2019 (see Table 2.22).

Summarising the results of the data on interval carcinomas from 2016/2017 and 2018/2019, it appears that this is already an established risk-adjusted form of screening within the diagnostic setting as part of the list of indications for diagnostic (referred) mammograms applicable to the BKFP after around one year. The extent of the carcinomas detected in this way can only be very roughly estimated on the basis of the available data; between 200 and 400 carcinomas could be involved per screening cycle. These would increase the detection rate and reduce the interval carcinoma rate due to their asymptomatic nature outside the diagnostic and screening setting. For more accurate quantification and particularly for an estimate of the possible effects on the detection rate, programme sensitivity, and interval carcinoma rate, it would be necessary, as already recommended in the third evaluation report, to check (on a random basis) whether the cases in question are genuine interval carcinomas by analysing the mammography images of the BKFU. A retrospective consideration of the given indications for the referred diagnostic breast imaging -these are not part of the available data set- could also assist in the correct classification of these carcinomas. A further expected improvement in sensitivity or shorter screening intervals could possibly lead to an increase in false-positive findings. Tests in this regard should also be considered in the context of further analyses.

Any resulting discussion about a possible shortening of the invitation interval in the BKFP should be seen in the context of the general participation discipline in the regular interval, as it does not seem to make much sense to shorten the invitation interval until the current two-year interval has become established. A comparison of the age groups also shows no clear trend that would speak for an age-specific adjustment of the screening invitation interval.

A more accurate interpretation of interval carcinomas would also benefit from indicators of aggressiveness or an estimate of the growth rate of a carcinoma. Although variables such as progesterone receptor status, oestrogen receptor status, HER2 status or the Ki-67 proliferation index are also recorded as part of the BKFP, the status "unknown" is often documented for these

variables, which is why the documentation quality is very heterogeneous between the hospitals and hospital authorities.

2.10 Positive predictive value, sensitivity and specificity of the BKFP

2.10.1 Method

Another important measure of the performance of a screening programme is the positive predictive value (PPV – proportion of women with conspicuous findings requiring assessment who had breast cancer) as well as the sensitivity (proportion of women with documented breast cancer who previously had conspicuous findings in the BKFP requiring assessment) and the specificity (proportion of women with inconspicuous findings who did not have breast cancer) of the BKFU. The advantage of the PPV is that no information about so-called false-negative (FN) findings is required for the calculation – in this specific case, these are BKFU results that do not result in a further recommendation for diagnostic (non-invasive) or invasive assessment, whereby a carcinoma already existed at the time of the BKFU and ideally could have already been detected. To calculate the sensitivity and specificity, knowledge of the number of FN findings is necessary, but this is not given.

Perry et al. (2006) recommend using the number of all interval carcinomas (see chapter 2.9) to calculate the sensitivity of the programme. As this data must be available, sensitivity and specificity can only be calculated for the screening cycles 2014/2015, 2016/2017 and 2018/2019 (for 2020/2021 the definitive number of interval carcinomas is not available yet).

An assessment of the sensitivity and specificity of the partial results of the BKFU (first mammography reading, second mammography reading, ultrasound) can be found in Chapter 2.11.5.

2.10.2 Results

In a total of, 13,014 BKFU within the core target group of 45- to 69-year-old women in 2020/2021 a BKF finding requiring assessment (BI-RADS 0, 4 or 5) was documented, which actually resulted in a breast carcinoma diagnosis in 2,987 cases (according to Perry et al. DCIS or invasive carcinoma) (see Table 2.25). This results in a **positive predictive value** (PPV) of the BKFU of **0.22** (**C50** invasive BC only) or of **0.23 (C50 or D05 DCIS)**. This means that 23 percent of the women with conspicuous finding requiring assessment were also diagnosed with breast cancer (incl. DCIS). The PPV fell by three percentage points compared to 2018/2019 (PPV 0.26).

In 2018/2019, 917 interval carcinomas were recorded or 3.241 carcinomas were detected in the BKFP. Taking into account the other 148 carcinomas already mentioned in the chapter2.9, which

cannot be clearly assigned due to the large time intervals between the diagnosis and treatment steps, this results in a general programme sensitivity of the BKFU of 0.75 and a general **programme specificity of 0.985** for 2018/2019. This means that 75 percent of women with documented breast cancer had previously had a finding requiring assessment as part of the BKFP. The sensitivity therefore remains unchanged compared to 2016/2017. In almost 99 per cent of the women without a breast cancer diagnosis, an inconspicuous finding was documented in the BKFU. If only the cases with invasive breast cancer are considered, the same values for programme sensitivity and specificity are obtained.

Table 2.25:
BKF screening results vs. Breast cancer diagnoses (DCIS or invasive carcinoma) for women in the core target group in the years 2016 to 2021

	2016/2017			2018/2019			2020/2021		
	BC	no BC	Total	BC	no BC	Total	BC	no BC	Total
requiring assessment (BI-RADS 0, 4, 5)	3,315	8,660	11,975	3,241	9,402	12,643	2,987	10,027	13,014
No assessment required (IC)	936	615,778	616,714	917	622,072	623,137	—	—	—
Not clearly classifiable	155	—	—	148	—	—	—	—	—
Total	4,406	624,438	628,689	4,306	631,474	635,780	—	—	—

BC: Breast cancer
IC: Interval carcinoma

Source: GÖG

2.10.3 Discussion

The positive predictive value (PPV) as well as the values for sensitivity and specificity of the BKFP can only be compared to a limited extent with data from the literature – mostly data on the sole use of mammography, double reading or ultrasound – due to the early comprehensive use of ultrasound. In any case, a comparison with the German mammography screening programme, in which a PPV of 0.15 is reported for 2020 (Kooperationsgemeinschaft Mammografie 2022), appears interesting. Compared to Austria (23 per cent), only 15 per cent of the women called in for an assessment actually had a breast carcinoma The significantly higher PPV in the Austrian BKFP can be explained by the use of ultrasound examination already during the screening, whereas in Germany ultrasound is only used as part of the diagnostic imaging It can also be assumed that the identified data gaps in intramural documentation (see chapter2.4) and the associated reduction in the number of carcinomas documented as "screening-detected" are partly responsible for the slightly lower PPV in 2020/2021.

When evaluating programme sensitivity, it should be noted that this is based on the number of all interval carcinomas – and not the actual false-negative findings. When evaluating programme

sensitivity, it should be noted that this is based on the number of all interval carcinomas - and not the actual false-negative findings.

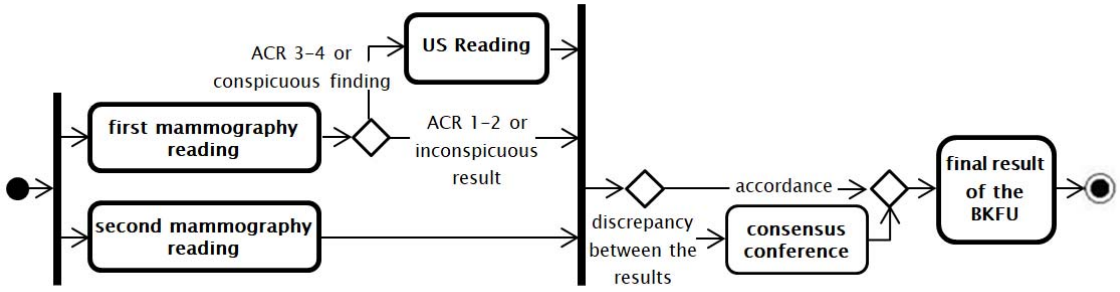
2.11 Individual findings

2.11.1 Method

In the Austrian BKFP, a double reading of mammograms on the one hand and the conditional use of ultrasound in screening on the other hand were agreed upon as quality assurance measures. In the event of a discrepancy between the readings of the two experts, a consensus conference is held (see Figure 2.3). The standardised documentation of the BKFP contains information on the first mammography reading, the ultrasound reading prepared by the first reader, the second mammography reading and the final reading.

The effect of both measures with regard to sensitivity and specificity of the screening examinations and thus their benefit for a screening programme are discussed contradictorily in the literature. Since this is an observational study, it can only be described to what extent the final finding of the BKFU corresponds to the documented individual findings and in this sense can be explained by the individual findings, assuming the diagnostic process described in Figure 2.3.

Figure 2.3:
Sequence of individual reading in the BKFP



Source: GÖG

2.11.2 First mammography reading

As in the previous screening cycles, there is a high degree of agreement between the first mammography reading and the final reading of the BKFU in 2020/2021. For example, of the approximately 800,000 screening examinations carried out (all age groups), there is an

agreement of around 99 per cent regarding the effective consequence of an invasive assessment or an mammographically inconspicuous classification (see Table 2.26). Overall, the **agreement between the first mammography reading and the final BKF reading is around 96 per cent**. In around 40 per cent of the examinations, an inconspicuous final reading was documented after an initial recommendation for diagnostic imaging based on the first reading, followed by a sonography examination and a second reading.

Table 2.26:
Proportion of examinations for each effective result of the first reading and effective final reading of the BKFU in 2020/2021 (given as a percentage)

First reading/Final reading	Normal	Early recall	Diagnostic Imaging	Invasive assessment	Total
Normal	98.90	0.91	0.13	0.06	100.00
Early recall	1.78	97.66	0.32	0.24	100.00
Diagnostic Imaging	40.78	7.98	49.08	2.16	100.00
Invasive assessment	0.11	0.15	0.57	99.18	100.00
Total final readings	93.91	4.01	1.15	0.93	100.00

Source: GÖG

Subsequently, in 1,954 (75.5 per cent) of the confirmed invasive carcinomas in the core target group, an invasive assessment (BI-RADS 4 or 5) was recommended by the first reader. In the case of 1,644 BI-RADS 4 or 5 readings by the first reader, the suspected carcinoma was again not confirmed (0.27 per cent). In a further 375 (14.5 per cent) confirmed invasive breast cancer cases, the first readings was decisive for further diagnostic imaging (e.g. MRI examination). In 228 invasive carcinomas (8.8 per cent), the first and second readings or ultrasound reading had divergent results (Table 2.27).

Table 2.27:
Mammography-first reading vs. First mammography reading vs. invasive malignancy diagnoses for 2020/2021 in the core target group

First reading	Invasive carcinoma		No carcinoma	
	Number	In percent	Number	In percent
Normal	3	0.12	575,842	93.90
Early recall	24	0.93	17,315	2.82
Diagnostic Imaging	375	14.55	5,573	0.91
Invasive assessment	1,954	75.56	1,644	0.27
divergent with second reading or ultrasound	228	8.84	12,845	2.09
Total	2,584	100.00	613,219	100.00

Source: GÖG

2.11.3 Ultrasound

An **ultrasound examination was performed** in around **74 per cent** of the complete BKFU in 2020 and 2021. In principle, ultrasound can be carried out as a supplementary screening examination in cases of high breast density (ACR density 3 and 4), as the scope for mammography is often limited in these cases. In 36 per cent of examinations (around 221,700), dense breast tissue (and no suspicious findings) was cited as the reason for using ultrasound. Moreover, ultrasound can be used for the immediate assessment of conspicuous or focal findings (approx. 4 percent). In the documentation there is also the option to state other reasons (34 per cent) as an indication for the ultrasound (see Table 2.28).

Of 3,133 suspicious first mammography readings (0.51 per cent of all BKFUs), 2,357 cases were recommended for an invasive assessment after the ultrasound. Of around 21,200 focal findings made by the first reader (around 3.4 per cent of all BKFUs), 14,250 cases resulted in an inconspicuous ultrasound reading and 5,243 cases in an early recall recommendation after six or twelve months.

In around 97 per cent of the examinations in which ultrasound was used due to increased breast density combined with no suspicious first reading, the ultrasound reading was also inconspicuous. A similar value is shown for the variable "other reasons for ultrasound", according to which the ultrasound reading was classified as inconspicuous in 94 per cent of cases (see Table 2.28)

Table 2.28:
Number of BKFU per ultrasound indication and result of ultrasound examination for the 2020/2021 core target group

	Diagnostic Imaging	Early recall	Invasive assessment	Normal	Total	In per cent
Dense breast with no suspicious findings by the first reader	509	4,283	225	216,674	221,691	35.91
Suspicious findings by first reader (density of breast insignificant)	45	51	2,357	680	3,133	0.51
Focal findings by the first reader	1,116	5,243	573	14,250	21,182	3.43
Other by first reader	3,775	7,999	874	197,794	210,442	34.08
Dense breast with no suspicious findings by the second reader	3	6	1	442	452	0.07
Focal findings by the second reader	1	1	1	148	151	0.02
Other by second reader	7	13	4	374	398	0.06
No ultrasound	0	0	0	0	159,983	25.91
Total	5,456	17,596	4,053	430,363	617,432	100.00

Source: GÖG

This Table 2.29shows the distribution of breast density among the BKF findings in the individual age groups. The density categorisation introduced by the American College of Radiology (ACR) describes the proportion of glandular tissue in mammographic images and provides information

about the sensitivity of mammography, which is considerably reduced at density grades three and four.

There is an age-dependent frequency with regard to increased breast density. For example, a high breast density of ACR 3 or 4 was found in around 63 per cent of examinations of 40 to 44-year-old women, but only in around 27 per cent of examinations of 60 to 69-year-old women. Overall, this was the case in just over 40 per cent of the examinations across all age groups (Table 2.29).

Table 2.29:
Breast density per age group according to ACR classification for 2020/2021 in per cent

Age group	ACR 1	ACR 2	ACR 3	ACR 4	Total
40 to 44 years (opt-in)	6.09	30.39	49.86	13.66	100.00
45 to 49 years	7.62	34.36	47.51	10.51	100.00
50 to 59 years	14.11	44.10	36.61	5.18	100.00
60 to 69 years	22.72	49.79	25.30	2.20	100.00
70 to 74 years (opt-in)	24.51	51.11	22.65	1.73	100.00
from 75 years (opt-in)	24.51	52.02	21.85	1.62	100.00
Total	15.79	43.62	34,97	5.62	100.00

Source: GÖG

Similar to the first mammography reading, a high degree of agreement between the effective ultrasound reading and the effective final BKF reading can also be seen in the additive ultrasound examination (see Table 2.30). In the 2020/2021 cycle, over 99 per cent of all examinations in the core target group with ultrasound reading and an indication for invasive assessment were also documented as part of the BKF final reading.

Table 2.30:
Proportion of examinations for each effective ultrasound reading and effective final reading of the BKFU for the core target group in 2020/2021 (given as a percentage)

Ultrasound reading/Final reading	Normal	Early recall	Diagnostic Imaging	Invasive assessment	Total
Normal	98.10	1.31	0.35	0.23	100.00
Early recall	1.64	97.01	0.83	0.52	100.00
Diagnostic Imaging	3.15	0.40	95.40	1.04	100.00
Invasive assessment	0.40	0.07	0.40	99.13	100.00
Total	94.18	3.81	1.16	0.85	100.00

Source: GÖG

2.11.4 Second mammography reading

Assuming that the second reading is supplementary to the combined mammography and ultrasound examination carried out by the first reader, in 2020 and 2021, 142 final readings of the BKFU (0.02 per cent) in the core target group of women between the ages of 45 and 59 effectively only correspond to the second mammography reading and cannot be explained by the first mammography reading or ultrasound reading. This low proportion of effective influence of the second reading on the final reading of the BKFU is also reflected in the low increase in breast cancer detection sensitivity. In 2020/2021, nine more invasive carcinomas were identified in the core target group following analysis of the combined first reading/ultrasound/second reading than in the combination of first reading and ultrasound alone. This correlates to a sensitivity increase in the BKFU of approx. 0.24 percentage points (see Chapter 2.11.5).

The Table 2.31shows the setting in which the double reading took place in 2020/2021. In almost 87 per cent of cases, the double reading was carried out within a group practice in the private practice sector, in 1.6 per cent of cases by remote data transmission of the mammography images. The remainder (11.5 per cent) of double readings were done in a hospital.

Table 2.31:
Setting of double reading 2020/2021

	Readings	In percent
within a group practice (private practice)	536,499	86.9
in a hospital	70.789	11.5
by remote data transmission	10,144	1.6
Total	617,432	100.0

Source: GÖG

2.11.5 Sensitivity and specificity of the findings

The use of ultrasound and double reading leads to more carcinomas being identified, i.e., the sensitivity of the BKFU (proportion of women with documented breast cancer who previously had a finding requiring assessment in the BKFP) is increased as a result. On the basis of the available data, which was not generated during a controlled study, the influence of the use of ultrasound and double reading on sensitivity cannot be accurately determined, and, at best, only estimated. The main reason for the analytical difficulty is the fact that the combination of first mammography reading and ultrasound reading represents an advantage in terms of information over the second reader, who reviews the mammography alone. The individual readings are therefore often summarised by consensus to form a final BKF reading. This generally consists of a combination of the first mammography reading and ultrasound. A prerequisite for analysing the individual readings is that they can be clearly classified in the documentation.

During **2020/2021**, **2,422 invasive carcinomas were identified in the core target group** following the **first mammography reading** requiring assessment, an additional **106 invasive carcinomas** were detected following **ultrasound reading** requiring assessment (insofar as the consequences of the final reading of the BKFU had not already been effectively explained by the first mammography reading), and **19 invasive carcinomas** were detected following the **second mammography reading** requiring assessment (insofar as the consequences of the final result of the BKFU had not already been effectively explained by the first mammography reading) (see Table 2.32). Because these figures do not represent disjoint sets, they cannot be added together to obtain the total amount of identified carcinomas.

Due to the limitations of the available data, and taking into account interval carcinomas, it is only possible to approximately estimate the **sensitivity** of the **first mammography reading**. According to this estimate, it is around 69 per cent for the 2016/2017 screening cycle and around 81 per cent for 2018/2019. Not all data on the subsequent interval carcinomas are yet available for the screening years 2020/2021, so the sensitivity for this period based on the first reading is higher, as expected, and is over **83 per cent** (see Table 2.32).

Based on this value, **sensitivity increases** by approx. **4 per cent points** with the use of **ultrasound**, with a simultaneous **specificity reduction** (for the proportion of women with inconspicuous findings who did not have breast cancer) of approx. **0.2 per cent points.**

The second **mammography reading** in turn **increases** the **sensitivity** by almost one percentage point compared to the first mammography reading, and by 0.2 percentage points **compared to the combination of first reading and ultrasound** (see Table).

In these estimates, a reduction in specificity appears negligible due to the fact that the majority of the BKFU are inconspicuous.

Table 2.32:
Sensitivity and specificity of the combination readings per cycle in the core target group (only invasive carcinomas, assuming clear classification of the findings)

	2016/2017			2018/2019			2020/2021[3]		
	detected carcinomas	Sensitivity	Specificity	detected carcinomas	Sensitivity	Specificity	detected carcinomas	Sensitivity	Specificity
First MA reading	2,662	68.5%	98.8%	2,604	81.3%	98.7%	2,422	83.3 %	98.6%
First MA reading and US (vs. First MA reading)	2,795 (+133)	71.9%	98.6%	2,759 (+155)	86.1%	98.5%	2,528 (+106)	87.0%	98.4%
First MA reading (without US) and Second MA reading (vs. First MA reading)	2,687 (+25)	69.2%	98.8%	2,637 (+33)	82.3%	98.7%	2,441 (+19)	84.0 %	98.6%
First MA reading and US and Second MA reading (vs. First MA reading and US)	2,802 (+7)	72.1%	98.6%	2,768 (+9)	86.4%	98.5%	2,535 (+7)	87.2%	98.4%

MA: Mammography
US: Ultrasound

Source: GÖG

2.11.6 Discussion

At the time of screening, Perry et al. (2006) recommend that further diagnostic imaging, e.g., ultrasound, should be performed in addition to mammography in no more than one to five per cent of cases. The Austrian BKFP (Gollmer et al. 2011), in contrast to most other countries, and similar to the French Breast Cancer Screening Programme (Ancelle-Park et al. 2012), provides for the option of ultrasound at the screening stage in cases of dense breast tissue or conspicuous mammography findings as sensitivity of mammography is reduced in cases of dense breast tissue. Remuneration for the ultrasound from the Austrian National Insurance is subject to a cap in the Austrian BKFP. This means there is no pecuniary incentive for increased ultrasound use.

The benefit of ultrasound as a screening method has still not been definitively determined in existing literature (Gartlehner et al. 2013). In a randomised study on 40 to 49-year-old women, Ohuchi et al. (2016) showed that the use of ultrasound in this age group can increase the sensitivity of breast cancer screening at the expense of specificity.

[3] Sensitivity without complete inclusion of all interval carcinomas within two years due to missing data at the time of reporting

At present, ultrasound is primarily performed in the Austrian BKFP in the case of dense breast tissue and conspicuous mammography; as in the previous screening cycle, this led to an increase in sensitivity of around four per cent in 2020/2021 compared to first mammography reading, with surprisingly unchanged specificity, i.e. hardly any additional false-positive findings have been generated by the ultrasound examination since the start of the programme.

In general, ultrasound was used in around 74 per cent of examinations in the 2020/2021 cycle. This proportion of ultrasound examinations appears elevated compared to the benchmark values for the EU-11 and EU-12 indicators (see Table 2.33), but this is due to Austria's previously mentioned programme structure.

A possible point of comparison for validation is provided by Buchberger et al. (2018), who determined a sensitivity increase of approx. twelve percentage points for the Tyrol Breast Cancer Screening Programme from 2008 to 2010. Hereby, the following limitations apply: due to the one-year invitation interval in the programme, Buchberger et al. (2018) only included interval carcinomas detected in the first year after the BKFU, which explains the more significant increase in sensitivity compared to the results in this report. Furthermore, they limited their analysis to cases in which an ultrasound was carried out. In contrast, this report analyses the influence on the overall performance of the BKFP, generating a lower value.

Also, the Austrian BKFP includes an obligatory, independent, and decentralised double reading and consensus conferences for cases with contradictory individual reading. Within the framework of the quality standards for breast cancer screening (Gollmer et al. 2011), separate, standardised documentation of individual readings was determined.

Perry et al. (2006) expect that a second reading increases BKFP sensitivity by five to fifteen percent, however only when mammography is used alone at the time of the BKF examination. Based on the available figures, in the case of Austria, this assumption is not confirmed. In Austria, the first reader has the benefit of information due to the combined reading and documentation using mammography (first reading) and ultrasound. The final reading of the BKFU is compiled in consensus with the second reader, usually based on the combination of these readings. Against this background, the evaluation of the effects of the ultrasound or the double reading alone does not appear to be effective. Instead, the combination of the two imaging procedures mammography and ultrasound should generally be assessed for their efficacy.

However, to collectively assess the effects of double reading and the ultrasound reading, it should be determined how many cases there are in which the final result of the BKFU deviate from the first mammography reading and can be explained solely by the second reading or the ultrasound reading. Subsequently, it can be checked how many of the cases referred for assessment due to the second or ultrasound reading result in a breast cancer diagnosis (see 2.11.5).

In summary, based on the available data, more than 98 per cent of final readings of the BKFU (effectively in terms of their consequences) correspond to the first mammography reading. Both

the use of ultrasound during the BKFU and, to a lesser extent, the double reading, result in more carcinomas being identified, i.e., the sensitivity is somewhat increased.

2.12 Overview of the quality indicators

A screening programme aims to reduce mortality and increase quality of life through early detection of cancer. This potential benefit is offset by the potential harm stemming from possible overdiagnosis (IQWiG 2015; Sauerland/Rummer 2017) or the increased psychological burden placed on healthy participants. To enable a more accurate estimate of the benefit-to-harm ratio in a screening, programme evaluation tailored to the respective implementation, as presented here, is required.

Perry et al. (2006) recommend that the proportion of invasive carcinomas discovered during a screening programme should not exceed 90 per cent (EU-16 indicator), of which at least 25 to 30 per cent should be smaller than 10 mm (EU-19 indicator) or 50% should be smaller than 15 mm (EU-20 indicator). Depending on the setting, less than 25 or 30 percent of the carcinomas should be stage II or higher (EU-17). More than 70 or 75 percent of the carcinomas should show no lymph node involvement (EU-18).

Harm resulting from false-positive results can include, for example, psychological stress and increased radiation exposure from radiological examinations or complications relating to invasive assessment, which were in retrospect found to be unjustified. Harm resulting from overdiagnosis or overtreatment can stem from the treatment of a tumour that would never have become clinically conspicuous or relevant to the health of the patient if it had not been diagnosed and subsequently treated.

Table 2.33 Table provides an overview of the EU indicators mentioned in the report and the minimum or target values defined by Perry et al. (2006) for each indicator. The values will be compared with the evaluation results of the Austrian BKFP for 2020/2021 and the interval carcinoma data from the 2018/2019 screening cycle. The legend contains notes on the indicators explaining their respective correlation or limitations (see also Chapter 2.14) compared to the Austrian BKFP. Values highlighted in green fulfil EU requirements, but those highlighted in pink do not fulfil EU requirements. Values highlighted in white are only partially comparable with EU requirements (refer to the comment in the table).

Table 2.33:
Quality indicators for the evaluation of a breast cancer screening programme in accordance with EU guidelines and BKFP results for 2020/2021

ID	Indicator	Acceptable	Target	BKFP 2020/2021
EU-5	Participation rate	> 70 %	> 75 %	40 %
EU-8	Proportion of examinations that are radiologically acceptable	97 %	> 97 %	99.88 %[1]
EU-10	Proportion of examinations that were repeated due to technical reasons	< 3 %	< 1 %	0.02 %[1]
EU-11	Proportion of screening examinations with additional diagnostic imaging examination	< 5 %	< 1 %	74 % (ultrasound)[2]
EU-12	Assessment rate/recall rate for further assessment (follow-up screening)	< 5 %	< 3 %	2.0 %
EU-13	Early recall rate after assessment	< 1 %	0 %	4.6 % (after screening)[3]
EU-14	Breast cancer detection rate in relation to the assumed background incidence (breast cancer incidence without screening, IR) for follow-up screening	1.5 × IR	> 1.5 × IR	2.0 × IR
EU-15	Interval carcinoma rate in relation to assumed background incidence rate			
	Months 0–11 (first year)	30 %	< 30 %	20.5 % (2018/2019)
	Months 12–23 (second year)	50 %	< 50 %	45.4 % (2018/2019)
EU-16	Proportion of invasive carcinomas	90 %	80–90 %	85 %
EU-17	Proportion of carcinomas with tumour stage II+ (II, III or IV) for follow-up screening	25 %	< 25 %	21.2 %
EU-18	Proportion of invasive carcinomas without lymph node involvement for follow-up screening	75 %	> 75%	75 %[4]
EU-19	Proportion of invasive carcinomas with a size ≤ 10 millimetres (for follow-up screening)	≥ 25 %	≥ 30 %	42.6 %[4]
EU-20	Proportion of invasive carcinomas with a size < 15 millimetres	50 %	> 50 %	77.9 %[4]
EU-38.1	Duration (in working days (WD)) between mammography screening and findings	15 WD	10 WD	1.60 WD[5]

Comments:
[1]The figures are based on self-reported data from the radiologists. It is known from the initial phase of the BKFP that the radiological software often uses default settings that are not changed by the readers.
[2] US is an integral component of BFKU in the Austrian BKFP for screenings of dense breast tissue or conspicuous mammography result. Dense breast tissue or conspicuous mammography finding. This results in a high rate of additional imaging and a low recall rate.
[3] The value for early recalls after screening is shown here. Due to the early use of the US in the BKFU, the line between screening and assessment cannot be clearly drawn in the BKFP.
[4] Possible limitations of the data due to data gaps
[5] It is not clear from the EU guidelines exactly which point in time is meant (completion of the findings, possible dispatch of a finding by letter, receipt of the report). For the BKFP, the moment is defined as the completion of the findings.

Source: Perry et al. (2006); Calculations BKFP: GÖG

2.13 Mortality

2.13.1 Method

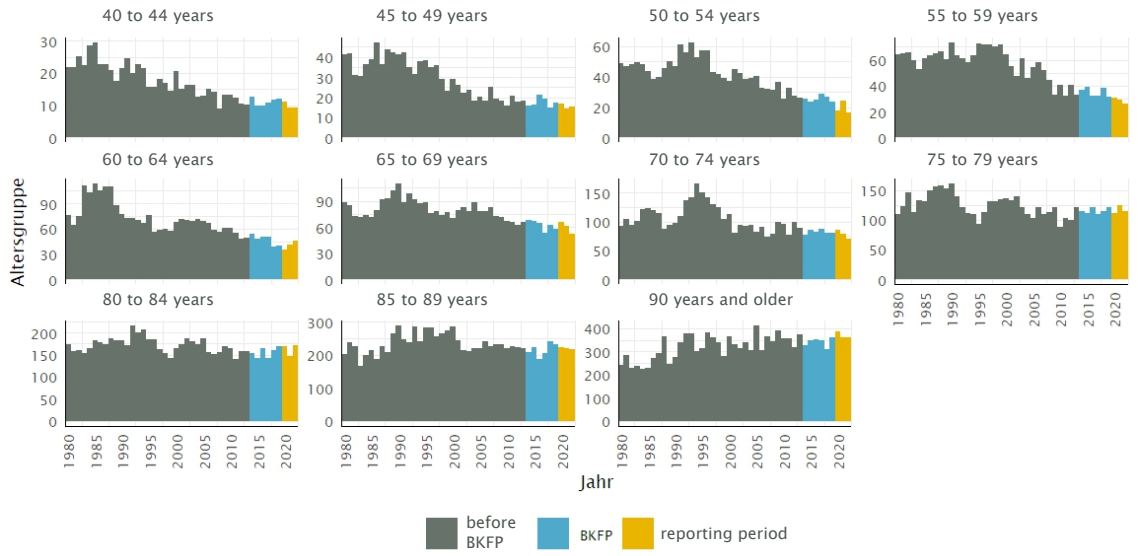
The causes of death were taken from the official cause of death statistics from Statistik Austria for 2014 until 2022. In accordance with Section 15c (5) GÖGG, it is possible to classify the cause of death of women who have undergone a radiological breast examination directly to the pseudonymised data of the BKFP using the coded area-specific personal identification number "Official Statistics" (fbPK-AS). For the subpopulation of women who never underwent any type of breast examination, the cause of death cannot be ascertained using the aforementioned data matching. In principle, the cause of death for this group can be determined using the difference between the causes of death retrieved from the FbPK-AS and the official cause of death statistics. By visualising the mortality rates per age group, the aim is to examine whether the trends of previous years will continue in the 2020/2021 and 2022 observation period.

2.13.2 Results

For the entire observation period from 1980 to 2022 (see Figure 2.4), a noticeable decrease in mortality due to breast cancer (according to ICD-10 coding C50 invasive breast cancer or D05 ductal in situ carcinomas) can be observed, especially in the age groups of 40- to 75-year-old women since the late 1980s. This trend has weakened since the 2010s and has essentially continued since the introduction of the breast cancer screening programme in 2014.

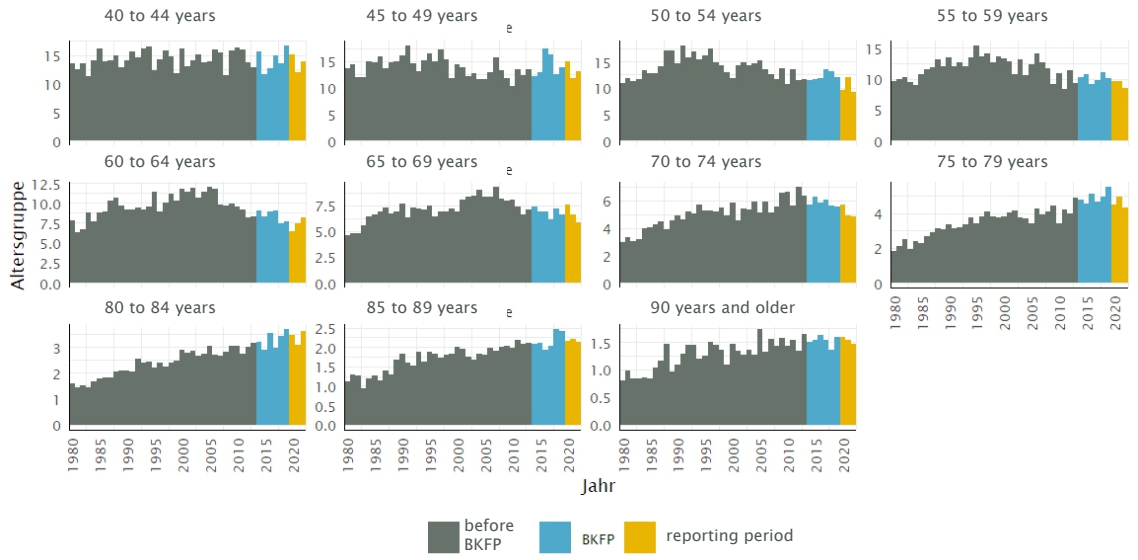
If breast cancer mortality is compared with general mortality (see Figure 2.5) in order to take account of changes in demographics or life expectancy, it can be seen that the proportion of deaths from breast cancer in the 50 to 65 age group has fallen slightly since around the mid-2000s. No change in the proportion of the mortality rate resulting from breast cancer is identifiable since the introduction of the BKFP in 2014. In the 40 to 59 age group, breast cancer is cited as the cause of death in ten to 15 per cent of deaths. Among women aged 75 or older, the proportion is less than five per cent.

Figure 2.4:
Breast cancer mortality rate (C50, D05) per 100,000 women per year and age group



Source: Statistik Austria; Image: GÖG

Figure 2.5:
Proportion of mortality from breast cancer (C50, D05) in total mortality per year and age group



Source: Statistik Austria; Image: GÖG

2.13.3 Discussion

The breast cancer mortality rate sank in the decades before the introduction of an organised BKFP, which can be explained by various influencing factors, such as extensive so-called "grey" screening and improvements in treatment (Tabar et al. 2018) or changes in hormone replacement therapy, for example. The respective contribution of each influencing factor remains unclear. At the same time, the proportion of breast cancer as a cause of death in overall mortality increased slightly in line with the long-term trend, particularly in the 75 to 89 age groups. An interpretation of these two trends would require a multi-decade analysis of microdata, such as those now being collected as part of the BKFP evaluation, to better understand the interaction of breast cancer with other diseases or causes of death and to assess the extent to which these are shifts due to earlier diagnosis and better therapies for breast cancer or other potentially lethal diseases.

Due to the comparatively short programme, duration, no effect can yet be expected from the organised screening.

Mortality is naturally lower among younger women in the core target group, which is why random fluctuations may appear as larger swings in the short term in a longitudinal analysis (see Figure 2.5). Overall, the trend of the previous year continued into 2020/2021 and 2022 with no identifiable breaks.

However, it should be noted that any changes to the official cause of death statistics e.g., the determination or coding of cause of death, during the selected observational period of more than 20 years would influence the aforementioned analysis but this would not be evident when reading the data.

2.14 Limitations

The data platform mentioned in chapter 2.2 is subject to several limitations, which must be considered in the interpretation. Some of the limitations are due to the decentralized nature of the data collection resulting from the decentralized structure of the BKFP. The participating health care service providers (GDA) have no knowledge of the data registered by other offices, which makes comprehensive documentation difficult, especially for intramural facilities, as they do not always know whether the affected woman is a BKFP participant or not. The GÖG carries out retrospective classification based on the programme pseudonym.

The documentation schema for therapeutic measures (datasheets TUM, PAT) was compiled long before the programme's initiation in 2014 and slightly revised in 2017 to reduce the number of obligatory data to be entered and simplify the data entry process. Since a card system is used for documentation and transmission, amendments to the data set of the BKFP needs to be coordinated with the release planning of the e-card time plan. Changes of the e-card data set are carried out during only two annual data interface releases, resulting in protracted lead times.

The productive implementation of the next dataset revision with further dataset simplification and clarification will begin in early 2021. For this reason, data from the new scheme could already be analysed for this report.

2.14.1 Data quality

Since the datasets do not have case history ID numbers, the individual datasets are grouped into case histories using heuristic rules. Because the documentation is incomplete – in particular, data relating to assessments is often missing – this classification is subject to a degree of imprecision. This relates primarily to determining whether a carcinoma was detected during a BKFU ("screening-detected cancer") or during a referred diagnostic breast imaging. This is especially relevant for determining the number of interval carcinomas. In individual cases associated with unusual case histories, screening-detected cancer may be wrongly counted as an interval carcinoma or an interval carcinoma wrongly counted as screening-detected cancer.

Decentralized documentation means that data are recorded at different sites using different methods. Although it is ensured that the data comply with the formal data set specification and are complete in this sense, there are minor differences in the interpretation of individual data fields. Particularly in the intramural setting, data are often entered after extended periods by auxiliary staff using medical documentations, which means that individual pathological findings, for example, are sometimes incompletely reproduced. Also, the ideal-typical diagnosis process is not adhered to in individual cases. For example, the BKFP intends that a BKFU with BI-RADS 1 or 2 should be followed by a routine examination in two years, BI-RADS 3 by an intermediate examination after six or twelve months, BI-RADS 0 by a diagnostic imaging and BI-RADS 4 or 5 by an invasive assessment. These assumptions suggested during the inception of the programme are not always fulfilled. In practice, in individual cases, women with BI-RADS 1, 2, or 3 are also referred for further assessment, for example, due to dense breast tissue. This complicates the compilation of case histories and their interpretation.

An additional limitation is the partially insufficient data integrity and data completeness. As described in the chapters 2.4and 2.8, both undocumented carcinomas and incompletely documented data sets have a negative impact on essential programme parameters such as detection, interval carcinomas, positive predictive values and programme sensitivity and specificity, and analysis results may be underestimated or overestimated.

2.14.2 Blank notification

BKFP data collection takes place based on several standardized datasheets. A pseudonym for the treated women is documented on most datasheets. This pseudonym, generated by SVC, does not allow conclusions to be drawn about the identity of any individual person. For extramural data sheets containing a pseudonym, it is guaranteed that a service has been billed by the doctors to the social insurance. Since the beginning of the programme, there has also been a

"referred diagnostic mammography blank notification" datasheet, which does not contain a pseudonym. This enables radiologists to disclose information on mammography or breast ultrasound examinations to allow for frequency calculation, even in cases where the woman did not consent to the transmission of her data, e.g., during elective medical services. Between 2018 and 2021, the "Self-Payer Blank Notification" option has also been available. This option enables the documentation of special elective screening mammograms when no disease was suspected in cases where the women did not consent to the transmission of her data.

From a database perspective, the advantage of pseudonymised data is that duplicate data, i.e., records that have been transmitted more than once, can be removed from datasets on the basis of the pseudonym. This is not possible using blank notifications. Particularly in the initial phase of the programme, duplicate data was transmitted, for example, as a result of software errors. From an evaluation perspective, the pseudonymised datasets from the registered physician sector have the advantage that they are linked to medical service billing, meaning that it can be assumed the service was actually performed. This cannot be guaranteed when using the blank notification option. Nevertheless, the blank notifications are factored into the frequencies for each radiological institute or physician. Fulfilment of the pre-defined minimum frequency is a requirement for participation in the programme. Neither the coordination centre nor the certification commission of the Academy of Medicine, which confirms attainment of the minimum frequency using the medical evaluations used to calculate mammography frequency, can validate the number of blank notifications.

2.14.3 Participation

In the first half of 2014, the BKFP used an invitation system. During this time, the younger and older women in the 45 to 69-year-old core target group were primarily invited and participation and eligibility developed accordingly. This fact led to periodic fluctuations being observed in the annual review, which is why it was deemed more appropriate to review the programme every two years. It can also be assumed that an unknown proportion of the mammograms documented as diagnostic are actually attributable to screening and that this proportion is therefore underestimated.

In association with the calculation of the participation rate, the corresponding official population statistics from Statistik Austria serve as an auxiliary figure. These statistics do not precisely correspond to the number of women eligible for participation, which includes all of the women insured by the participating national health insurance providers, i.e., also women who reside abroad, but not, for example, women insured with national health insurance providers (KFA´s) not participating in the programme. Due to data processing constraints, the number of women eligible for participation cannot be exactly defined. However, internal analyses show that the population statistics provide a sufficient approximation of the women eligible for participation.

2.14.4 Background incidence rate

The calculated breast cancer detection rate is related to the background incidence - which is a problematic concept because it assumes a condition without any screening. In Austria, based on the rate of mammograms, it can be presumed that, before the introduction of the BKFP, "grey" and unorganised screening had been practised for many years. Also, a type of opportunistic screening existed in the form of preventative check-ups. The concept of background incidence is also inaccurate as it is possible that the quality of official cancer statistics has improved in the subsequently stated period, meaning the background incidence for a time in the more distant past may have been set too low. For this reason, the calculated background incidence rates for the years 2000 to 2010 were used as a comparative value.

2.14.5 Interval carcinomas

Because the BKFP collects data on all breast cancer cases (insofar as patients do not object to the transmission of their data), it also contains information on carcinomas identified outside the BKFP programme via referred diagnostic breast imaging. In principle, this makes it possible to calculate the number of interval carcinomas. Due to the decentralised nature of documentation in the Austrian BKFP and lack of documentation of the physician's intention for further assessment or therapy, the number of interval carcinomas can only be estimated with some assumptions made regarding regular examination procedures and the corresponding time intervals.

It is conceivable that a delayed diagnosis is mistakenly classified as an interval carcinoma in individual cases. In principle, this type of misclassification is also possible when the treating physicians deviate from programme-related procedures and immediately order an assessment despite inconspicuous BKFU findings (BI-RADS 1 or 2). Another example would be an early-recall examination being documented as a diagnostic imaging. In this context, classification as an interval carcinoma can occur due to deviation from the diagnosis and treatment pathways defined by the programme (Gollmer et al. 2011; Gollmer et al. 2018). It can be assumed that this problem affects a negligibly small number of women in the core target group.

2.14.6 Mortality

The question of whether it is possible to reduce the mortality rate by means of a screening programme cannot, in principle, be answered on the basis of observational data such as those presented here. This is because the examined women are not randomly assigned to the BKFP participant group or non-participant group, which makes inferring causal links extremely difficult or impossible. Therefore, in the sense of self-selection bias, it is possible that the BKFP participant group systematically differs from the non-participant group, for example, in their health-related behaviour and subsequent mortality rate (in general or specific to the cause of death) In principle, in this situation, a case-control study would be conceivable in this situation.

However, except for age and approximate place of residence, there are few background variables without a direct connection to the BKFP, making the construction of suitable control groups impossible.

A general methodological difficulty exists in the exact definition of the desired target value. The BKFU is likely to bring forward the time of diagnosis by an unknown period of time, so that, for example, five- or ten-year survival rates from observational studies cannot be meaningfully interpreted. Furthermore, the study period was not sufficiently long ago to be able to meaningfully calculate survival rates. It can be assumed that a woman identified as having breast cancer in 2018 would have already died, especially in the case of a more aggressive or metastatic cancer Many other women diagnosed with breast cancer during the breast cancer screening examination were still undergoing treatment as this report was being prepared.

3 Technical quality assurance of the devices

In the Austrian breast cancer screening programme, a standardised periodic inspection of the technical devices involved in the programme is mandatory – with the aim of ensuring that as many tumours as possible can be diagnosed in the mammograms carried out as part of the screening. In particular, the finest microcalcifications with a size of approx. 100–180 µm, which are often early signs of ductal in situ carcinomas, should be depicted with the highest possible contrast and high sharpness with low noise. A test protocol – the EUREF-Ö guidelines – was developed by Austrian medical physics experts based on international guidelines for the technical testing of the devices.

The Reference Centre for Technical QA in the Austrian Breast Cancer Screening Programme (RefZQS) was established at the Austrian Agency for Health and Food Safety (AGES), which is responsible for practical device testing and the continued development of test protocols. An important aspect of the BKFP was the continuous use of digital devices from the very start of the programme (digital imaging plates and fully digital systems).

3.1 Method

As part of the periodic testing of the devices used, the image quality of the mammography systems is checked under standardised conditions depending on the radiation exposure. The radiation exposure during the mammography is given as the average glandular dose (AGD). The extent of the radiation exposure depends, among other things, on the thickness of the examined breast tissue, which is simulated using various test specimens (PMMA phanto[4]m). The aim is to ensure adequate diagnostic imaging quality with the lowest possible level of radiation exposure. For the Austrian programme, additional test protocols were specified for peripheral devices and ultrasound systems, which must also be applied.

Every quarter, the qualifications relating to technical quality assurance of each site are reported to ÖQMed, the Austrian Medical Association, and the BKFP coordination centre. If deviations or defects are identified during testing, the obligatory measures stated in the test report must be implemented within the specified time frame.

At the time of initial approval of FFDM systems used in the programme, associated peripheral systems or ultrasound devices used, an acceptance test must be carried out by trained employees of the reference centre or by freelance medical physicists trained and approved by the RefZQS or employees of a technical office, the manufacturer or the testing institute. The stipulated test protocol must also be followed after conducting necessary repairs or during the annual test. During routine use, daily, weekly, monthly, and half-yearly tests are scheduled for

[4] PMMA phantoms are test specimens made of a transparent thermoplastic called Poly(methyl methacrylate).

the various systems. Diagnostic monitors must be tested daily by the radiologist or the radiographers. The other tests on mammography systems are based on the performance of defined PMMA test specimen images, which are created by the radiologist and transmitted to AGES as uncompressed DICOM files in "for processing" format and assessed by RefZQS. To check the ultrasound devices, two images are taken monthly for each transducer used and also sent to the RefZQS.

Four categories were introduced to assess the TQS analysis findings, which then determine further procedures:

» Category 1 - OK: The system was found to be fully functional at the relevant test point.
» Category 2 - OK: A specific deviation from OK-1 criteria was identified, however, the system can continue to be used. Rectification of the identified deviation is recommended. The further progress will be monitored.
» Category 3 -NOK: A deviation requiring correction was identified. The service technician must be informed and the defect must be rectified within a period to be determined in each individual case.
» Category 4 - NOK: The device must be immediately withdrawn from service after report from the RefZQS.

3.2 Results

3.2.1 Number of screenings and mammography system types

By the end of the first quarter of 2023, 180 mammography systems had been inspected by the Reference Centre for Technical Quality Assurance. There are categorized into four system types (see Table 3.1)

The largest proportion, which has steadily increased since the beginning of the BKFP, is made up of full-field digital systems (DR systems). Correspondingly, the proportion of digital imaging plate systems (CR systems) has continually decreased. The last imaging plate systems in the BKFP were dismantled in the third quarter of 2023, meaning that only digital full-field systems are still in use.

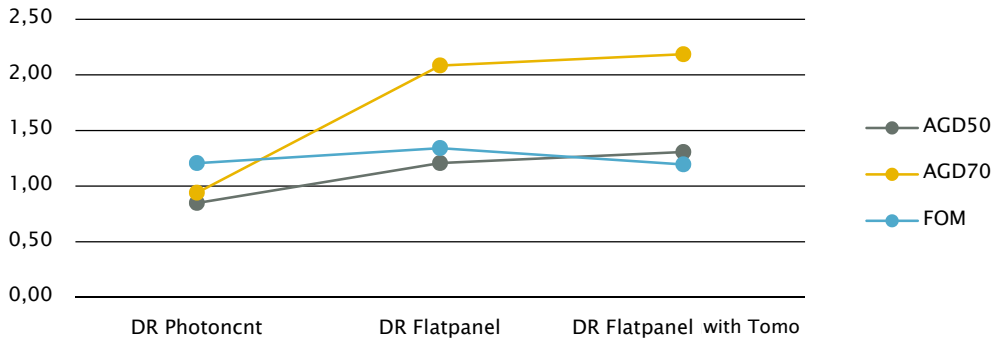
Table 3.1:
Distribution of mammography system types over time

Technology/period	Q1 2023		Q3 2022		Q3 2021		Q3 2020		Q3 2019	
DR flat panel	177	98.3%	176	97.3%	175	96.6 %	174	94.1%	167	91.8%
• of which tomosynthesis-capable	127	70.6%	121	66.9%	117	64.6 %	86	49.4%	63	37.7%
DR photon counting	3	1.7%	3	1.7%	4	2.2%	6	3.2%	8	4.4%
CR (powder-coated)	0	0.0%	2	1.1%	2	1.1%	5	2.7%	7	3.8%
CR (needle technology)	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Total	180	100.0%	181	100.0%	181	100.0%	185	100.0%	182	100.0%

Source: Reference Centre for Technical QA in the Austrian Breast Cancer Screening Programme, GÖG

Figure 3.1 shows the average mean parenchymal doses (in mGy) and the Figure of Merit (FOM), a measure of the image quality-dose ratio, of the three device types approved for use in the BKFP. All the systems used have a very similar image quality/dose ratio, which corresponds to the current state of the art.

Figure 3.1:
Dose requirements (AGD) of the X-ray systems used in the BKFP (as of Q3/2023).



AGD50 = average parenchyma dose in mGy for 50 mm PMMA (corresponds to 60 mm breast)
AGD70 = average parenchyma dose in mGy for 70 mm PMMA (corresponds to 90 mm breast)
FOM = Figure of Merit, indicator for displaying image quality and dose, the smaller the FOM, the higher the image quality of the FFDM system.

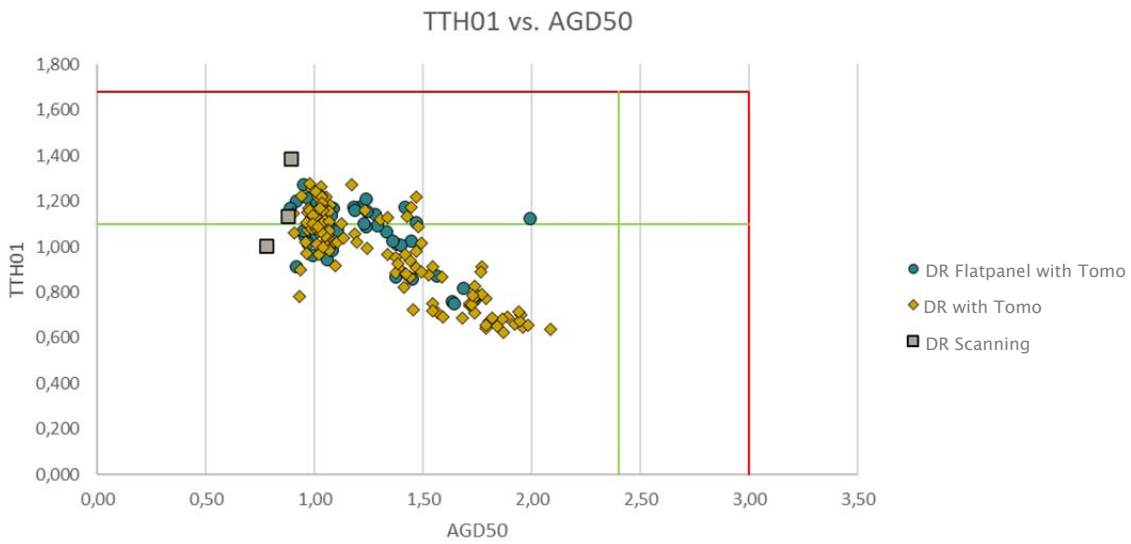
Image and source: Reference Centre for Technical QA in the BKFP

Figure 3.2 is a more detailed list of all mammography systems in Austria reviewed as part of the BKFP (as of Q3 2023). The average dose requirement for a breast thickness of 50 mm is plotted on the horizontal axis. The vertical axis shows the CDMAM image quality at a gold plate

diameter of 0.1 mm, which is a measure of the contrast resolution (and thus the image quality). For both values, smaller values correspond to a better system. The limit values to be complied with are marked in red, the limit values for the optimum setting are marked in green.

All mammography systems used in the BKFP comply with the optimal dose requirement limits. Around two thirds of the devices are within the limit values for the optimum settings in terms of contrast resolution, but all systems are well below the target values and therefore fulfil the required quality guidelines.

Figure 3.2:
Dose requirement (AGD) of the X-ray systems used in the BKFP compared to the contrast resolution achieved (TTH01; as of Q3 2023)



AGD50 = average parenchymal dose in mGy at 50 mm PMMA (corresponds to 60 mm breast)
TTH01 = CDMAM image quality for a diameter of 0.1 mm
The smaller the two values are, the better the FFDM system is.

Image and source: Reference Centre for Technical QA in the BKFP

3.2.2 BKFP ultrasound equipment

At the end of the first quarter of 2023, 235 ultrasound devices were inspected by the Reference Centre for Technical Quality Assurance as part of the BKFP.

According to the Austrian Society for Ultrasound in Medicine (ÖGUM), the average service life of an ultrasound device is eight to ten years, after which the device is no longer considered to be state of the art. As of the third quarter of 2023, there were 22 appliances in the BKFP (around 9 per cent) that are more than ten years old. By replacing components (especially new transducers) and updating software, even these older devices can produce images that comply with EUREF-Ö guidelines.

Devices with automatic focus have been in use in the BKFP since 2018. At the end of the third quarter of 2023, 37 devices (around 15 per cent) were equipped with autofocus, 17 of which also offer the option of manual focus depth.

Devices from 13 different manufacturers are tested in the BKFP, whereby five of the manufacturers have fewer than five devices in use for the BKFP. The variety of ultrasound devices is therefore significantly greater than in the case of mammography systems, where four manufacturers (from a total of seven different manufacturers) are responsible for over 90 per cent of the devices used.

3.2.3 Adjustment requirements and measures

Mammography devices

At the beginning of the BKFP, 45 percent of the inspected mammography systems required adjustments to comply with EUREF-Ö criteria. The most common adjustments were image parameter optimization, including dose increases (54 devices), more thorough imaging plate cleaning (30 devices), further radiation field collimation (22 devices), and imaging plate replacement (21 devices). Despite the efforts of technicians from the manufacturers, three devices were no longer able to comply with imaging quality requirements. In these cases, the devices had to be replaced. Within the period considered in this evaluation report, far fewer adjustments were necessary, although deviations were often identified. Deviations or defects identified during the reinstallation of flat-panel detectors were mainly related to radiation field collimation but, in individual cases, also due to imaging quality and dose. Most deviations were identified during the weekly mammography device tests (primarily artifacts or inhomogeneities). This demonstrated the higher QA standards for EUREF-Ö compared to the currently applicable Austrian standards.

Peripheral devices

In the first year of the BKFP, deviations from diagnostic monitor threshold values requiring adjustment or, in the case of four workstations, device replacement, were identified at 32 sites.

At the end of 2020, the last BKFP site switched from diagnostics with laser imagers and film showcases to diagnostics with diagnostic monitors. In the first quarter of 2021, 248 diagnostic monitors were in use at the BKFP, around a quarter of which were wide-screen monitors with eight, ten or twelve megapixels. Although significantly fewer defects and deviations were found in the diagnostic monitors than in the first year of the BKFP, adjustments still have to be made on an ongoing basis. This primarily concerns those test points where deviations can be rectified by recalibration, e.g. the deviation in luminance between two related image display devices.

Ultrasound devices

At the beginning of the BKFP, approx. 23 per cent of all transducers had defects, most frequently element failures and intensity losses in the sound elements as well as damage to the transducer membrane. The number of defects requiring repair has fallen significantly thanks to regular quality checks and has stabilised at a level of around eight per cent since the end of 2019. Most of these defects are rectified by replacing the transducer; it has never been necessary to purchase a new ultrasound device.

3.3 Discussion

As expected, all imaging plate systems were replaced by digital full-field systems in 2023. The trend towards tomosynthesis-capable full-field systems in Austrian radiological institutes is also continuing. These devices allow the breast tissue to be visualised in slice images. By the end of the first quarter of 2023, the proportion of systems capable of tomosynthesis maintained by the Reference Centre amounted to 70 per cent of the fully digital systems. All new mammography systems installed since January 2022 are tomosynthesis-capable.

International studies indicate that the use of tomosynthesis (virtual 3D) allows significantly improved tumour detection compared to traditional mammography (2D), particularly in dense breasts. Numerous studies have shown that a combination of tomosynthesis planes and 2D images can achieve significantly improved findings compared to traditional 2D findings. This has a particular impact on improved sensitivity, specificity and recall rate. At the beginning of 2023, the BKFP decided to authorise tomosynthesis as part of screening, making Austria an international pioneer in this field. A technical quality assurance system required for the use of tomosynthesis was developed based on the relevant standard of the Austrian Association for Electrical Engineering (OVE EN IEC 61223-3-6) and a newly created protocol of the European Federation of Medical Physics (EFOMP) for technical quality assurance for tomosynthesis and has been introduced throughout Austria since the second quarter of 2023. In the new quality assurance protocol, the reconstructed slices, the synthetically generated 2D image and the individual projection images are analysed in order to cover as many technical aspects of tomosynthesis as possible.

4 Conclusions and recommendations

4.1 Participation and re-participation

As is known from representative surveys of the core target group conducted by GÖG as part of the evaluation (Gollmer et. al 2019), trusted doctors (usually general practitioners or gynaecologists) are by far the most important source of information and communication in the context of screening programmes. In addition to the invitation and reminder system, this level of communication should also be further emphasised and expanded. In addition, the different participation rates at district level should be analysed and appropriate regional measures implemented to increase participation and regular re-participation. In addition, it is recommended that the analysis of the two questions of why women decide for or against participation and which influencing factors hinder participation should be continued as part of the programme evaluation.

4.2 Detection and interval carcinomas

As described in the chapter2.9, data again indicate that some of the diagnosed interval carcinomas are apparently a risk-adjusted form of screening now established in Austria within the diagnostic setting as part of the list of indications for diagnostic (referred) mammograms after about one year that applies to the BKFP. The available data only allow a rough estimate of the number of carcinomas detected in this way. For more accurate quantification and an estimate of the possible effects on the detection rate, programme sensitivity, and interval carcinoma rate, relevant cases should (randomly) be assessed using the mammograms of the BFKU to determine if they are genuinely interval carcinomas. A retrospective consideration of the given indications for the referred diagnostic breast imaging -these are not part of the available data set- could also assist in the correct classification of these carcinomas. Additionally, it should be analysed whether the shortened interval times lead to an increase in false-positive findings.

For a more accurate interpretation of interval carcinomas, indicators of aggressiveness and an estimation of the growth rate of a carcinoma should be integrated into the analyses to an even greater extent in future. However, this requires complete data sets on the tumour characteristics.

4.3 Double reading and ultrasound

Due the combined reading and documentation using mammography (first reading) and ultrasound, in the Austrian BKFP, there is benefit of information for the first reader. The final readings of the BKFU are compiled in consensus with the second reader, usually based on the

combination of these readings. Against this background, the evaluation of the effects of the ultrasound or the double reading alone does not appear to be effective. Instead, the efficacy of the diagnostic imaging combination of mammography and ultrasound should be assessed.

In the Austrian programme, the number of readings per reader is compiled using all first and second readings. Eliminating double readings would also reduce the number of mammography screening findings per person and year. This means that, for many, the applicable quality criteria in Austria for participation in the programme would be more challenging to fulfil.

Artificial intelligence (AI) systems are advancing rapidly and have shown promising results. However, their effectiveness and safety of use in population-related breast cancer screening programmes require further study.

Against this backdrop, it appears appropriate to continue with Austria's well-established double reading system and to pursue newer developments, particularly with regard to promising AI technology and their scientific evaluation. Any decision to switch to a system without double reading, which would naturally drastically reduce the reading volume of radiologists participating in the Austrian BKFP, must be weighed up carefully and should only be made when systems are in place that provide significant advantages compared to double reading.

4.4 Mortality

Overall, an evaluation of the influence of the BKFP on disease-specific or general mortality rates is exceptionally challenging. The extent of this challenge was highlighted by the German Mammography Screening Programme's decision to analyse the feasibility of this influence from 2012 and 2016 in two feasibility studies (Hense et al. 2017). This type of feasibility study based on the German model would also appear to be useful to evaluate the influence of the Austrian BKFP on mortality rates in the long term. This would help more accurately determine the data requirements and possible need for cooperation within the scope of the upcoming evaluation periods.

Furthermore, it should be questioned whether the mortality rate should remain the primary endpoint in determining the effectiveness of the BKFP, also due to the related methodological difficulties. Alternatively, the effects of early breast cancer detection on quality of life and the negative consequences of possible overdiagnosis could be evaluated.

4.5 Documentation

For a valid assessment of important programme parameters such as the number and type of carcinomas detected by the screening or the number and type of carcinomas detected after an inconspicuous screening examination (interval carcinomas), the data gaps identified in the chapter2.4 should be closed. This concerns both the absolute number of documented carcino-

mas in the hospitals and the avoidance of the indication "unknown" when submitting tumour-specific data using the "Pathology" and "Tumour" data sheets.

For a more valid classification of "screening-detected" carcinomas and interval carcinomas, a possibility should be created or used to be able to correctly classify any carcinomas detected by a referred diagnostic breast imaging (see also chapter 2.9.3).

It is also recommended that documenting service providers be informed of unclear data processes that do not correspond to process logic in order to support a possible data check.

4.6 Technical quality assurance

The technical quality assurance according to EUREF-Ö, which is currently only prescribed for the institutes listed as screening locations in the BKFP, is of a higher quality than the currently applicable ÖNORM or OVE EN in several points due to the involvement of the reference centre. This applies in particular to the weekly test, in the course of which artefacts, homogeneity and long-term stability of imaging parameters in mammography systems are examined by experts at the RefZQS using specially developed analysis software. For those institutes that are listed as assessment centres and not screening sites, ÖNORM, not EUREF-Ö, applies. Therefore, most of these institutes conduct technical quality assurance in compliance with ÖNORM, with few assessment centres voluntarily complying with EUREF-Ö. The future ÖNORM, which is currently being drawn up, addresses previous experiences with the EUREF-Ö and includes manufacturer-specified aspects of technical assurance. In contrast to EUREF-Ö, no reference centre is involved in these examinations and therefore, no weekly testing is carried out. For this reason, and because of previous experiences related to switching device inspection from ÖNORM to EUREF-Ö standards, the Reference Centre recommends that the higher EUREF-Ö standards be implemented in the assessment centres.

The new quality assurance for tomosynthesis also exceeds the requirements of the OVE EN IEC 61223-3-6 standard, which has been in force since August 2022. In contrast to the EN, the reference centre also takes into account the synthetically generated 2D image frequently used by radiologists in quality assurance. The evaluation of the recorded data takes place in the reference centre and is therefore more extensive than specified by the EN. Over the next few years, data from quality assurance for tomosynthesis-capable mammography systems will be collected. It is planned to make further recommendations and, if necessary, adjustments to the quality assurance procedures based on this data.

With regard to ultrasound devices, the reference centre has no data to indicate the extent to which the ÖNORM published in January 2021 has been adopted by the non-screening locations. As stipulated in the BKFP, regular technical quality assurance is a unique aspect that has led to significant improvements to the ultrasound devices in service. The increased quality awareness of radiologists as a result of the regular checks is reflected in more regular transducer replacements by the institutes, so that the number of defective transducers has remained roughly

constant in recent years. The Reference Centre is therefore strongly in favour of regular technical quality assurance being carried out for BKFP assessment centre ultrasound devices and also devices not used by the BKFP.

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6 Annex

6.1 Supplementary tables and figures on programme performance

Table 6. 1:
Women in the core target group (45- to 69-year-old women) with a screening examination in 2020/2021 as well as re-participation rate and rate of diagnostic mammograms per residential district, sorted in ascending order by participation rate

Residential district	Target population	Women in BKFP	Participation rate	Re-participation rate	No re-participation due to diagnostic MA
203 - Hermagor	3,349	401	12%	40%	28%
707 - Lienz	8,723	2,151	25 %	38 %	13%
311 - Horn	5,756	1,625	28%	53 %	17%
803 - Dornbirn	14,484	4,097	28%	48%	7%
201 - Klagenfurt (Stadt)	19,142	5,788	30 %	49%	19%
202 - Villach (Stadt)	11,889	3,604	30 %	54 %	18 %
417 - Vöcklabruck	23,698	7,023	30 %	49%	15%
207 - Villach Land	12,530	3,905	31%	55%	17%
204 - Klagenfurt Land	11,521	3,643	32%	51 %	18 %
206 - Spittal an der Drau	14,317	4,538	32%	53 %	13%
209 - Wolfsberg	9,633	3,081	32%	37%	34%
408 - Grieskirchen	11,229	3,579	32%	58 %	3%
414 - Schärding	10,007	3,194	32%	60 %	1%
314 - Lilienfeld	4,604	1,538	33%	57 %	11%
612 - Liezen	14,727	4,819	33%	58 %	6%
104 - Güssing	5,183	1,774	34%	59 %	13%
208 - Völkermarkt	7,787	2,631	34%	43%	23 %
409 - Kirchdorf an der Krems	9,829	3,343	34%	59 %	7%
802 - Bregenz	22,789	7,636	34%	54 %	6%
210 - Feldkirchen	5,644	1,976	35%	50%	16 %
404 - Braunau am Inn	18,306	6,346	35%	59 %	2%
616 - Voitsberg	9,798	3,401	35%	58 %	12%
904 - Vienna-Wieden	5,220	1,833	35%	52 %	12%
905 - Vienna-Margareten	8,087	2,844	35%	57 %	9%
305 - Amstetten	19,784	7,206	36%	50%	16 %
407 - Gmunden	18,531	6,695	36%	61 %	7%
701 - Innsbruck (Stadt)	19,935	7,139	36%	56 %	13%

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Continuation of Table 6.1

Residential district	Target population	Women in BKFP	Participation rate	Re-participation rate	No re-participation due to diagnostic MA
901 – Vienna city centre	2,832	1,016	36%	57 %	12%
908 – Vienna-Josefstadt	3,729	1,361	36%	55%	12%
912 – Vienna-Meidling	14,996	5,340	36%	56 %	10%
915 – Vienna-Rudolfsh.-Fünf.	11,136	4,064	36%	53 %	8%
406 – Freistadt	11,518	4,245	37%	57 %	5%
418 – Wels-Land	12,722	4,705	37%	61 %	6%
906 – Vienna Mariahilf	4,842	1,784	37%	54 %	12%
101 – Eisenstadt (City)	2,702	1,039	38 %	56 %	16 %
105 – Jennersdorf	3,448	1,306	38 %	55%	16 %
107 – Neusiedl am See	11,307	4,337	38 %	59 %	12%
405 – Eferding	5,810	2,213	38 %	62 %	6%
411 – Perg	11,818	4,480	38 %	61 %	6%
416 – Urfahr-Umgebung	15,434	5,860	38 %	63 %	5%
606 – Graz-Umgebung	28,495	10,844	38 %	61 %	10%
703 – Innsbruck (Land)	31,540	12,031	38 %	58 %	11%
709 – Schwaz	14,479	5,440	38 %	52 %	14%
804 – Feldkirch	18,215	6,995	38 %	57 %	6%
907 – Vienna-Neubau	4,940	1,858	38 %	58 %	9%
919 – Vienna-Döbling	11,857	4473	38 %	55%	10%
205 – St. Veit an der Glan	10,137	3,955	39%	52 %	21%
316 – Mistelbach	14,328	5,612	39%	60 %	10%
412 – Ried im Innkreis	10,718	4,178	39%	60 %	6%
415 – Steyr-Land	10,794	4,219	39%	57 %	11%
620 – Murtal	13,286	5,233	39%	55%	12%
702 – Imst	10,362	4,071	39%	55%	10%
708 – Reutte	5,978	2,349	39%	63 %	5%
913 – Vienna-Hietzing	9,154	3,599	39%	60 %	10%
103 – Eisenstadt-Umg.	8,234	3,301	40%	58 %	15%
106 – Mattersburg	7,498	2,973	40%	58 %	16 %
109 – Oberwart	10,543	4,194	40%	59 %	14%
306 – Baden	26,988	10,796	40%	59 %	12%
317 – Mödling	22,401	8,889	40%	59 %	13%
325 – Zwettl	7,455	3,016	40%	62 %	2%
617 – Weiz	16,058	6,488	40%	60 %	9%
903 – Vienna-Landstraße	14,574	5,799	40%	59 %	11%
909 – Vienna-Alsergrund	6,076	2,405	40%	56 %	11%

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Continuation of Table 6.1

Residential district	Target population	Women in BKFP	Participation rate	Re-participation rate	No re-participation due to diagnostic MA
916 – Vienna-Ottakring	16,061	6,402	40%	57 %	9%
917 – Vienna-Hernals	8,655	3,472	40%	62 %	9%
918 – Vienna-Währing	8,131	3,235	40%	58 %	10%
302 – St. Pölten (Stadt)	9,690	4,003	41%	60 %	9%
303 – Waidhofen/Ybbs (Stadt)	1,932	784	41%	52 %	12%
308 – Gänserndorf	19,029	7,762	41%	57 %	11%
309 – Gmünd	6,744	2,752	41%	63 %	7%
704 – Kitzbühel	12,194	4,994	41%	62 %	7%
910 – Vienna-Favoriten	31,020	12,673	41%	59 %	8%
914 – Vienna-Penzing	15,720	6,471	41%	58 %	10%
923 – Vienna-Liesing	18,417	7,554	41%	61 %	11%
310 – Hollabrunn	9,599	4,008	42%	62 %	7%
402 – Steyr (Stadt)	6,552	2,739	42%	56 %	13%
410 – Linz-Land	26,523	11,078	42%	63 %	8%
413 – Rohrbach	9,729	4,073	42%	66 %	1%
601 – Graz (Stadt)	42,985	17,990	42%	58 %	11%
902 – Vienna-Leopoldstadt	15,288	6,381	42%	55%	10%
911 – Vienna-Simmering	15,996	6,786	42%	60 %	8%
108 – Oberpullendorf	7,276	3,100	43%	59 %	13%
319 – St. Pölten (Land)	23,947	10,253	43%	61 %	9%
320 – Scheibbs	6978	2,990	43%	55%	13%
322 – Waidhofen an der Thaya	4,756	2,044	43%	63 %	6%
401 – Linz (Stadt)	33,162	14,107	43%	63 %	7%
610 – Leibnitz	15,334	6,568	43%	59 %	9%
706 – Landeck	7,458	3,228	43%	58 %	11%
920 – Wien-Brigittenau	12,898	5,482	43%	53 %	9%
921 – Vienna-Floridsdorf	27,611	11,900	43%	57 %	10%
301 – Krems/Donau (Stadt)	4,515	1,982	44 %	55%	11%
501 – Salzburg (Stadt)	26,451	11,605	44 %	63 %	4%
622 – Hartberg-Fürstenfeld	16,755	7,371	44 %	59 %	13%
801 – Bludenz	10,986	4,828	44 %	68 %	8%
304 – Wr. Neustadt (Stadt)	7,619	3,424	45%	62 %	8%
307 – Bruck an der Leitha	18,464	8,317	45%	58 %	12%
312 – Korneuburg	17,309	7,794	45%	59 %	10%
313 – Krems (Land)	10,611	4,792	45%	58 %	12%
323 – Wr. Neustadt (Land)	14,149	6,298	45%	63 %	8%

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Continuation of Table 6.1

Residential district	Target population	Women in BKFP	Participation rate	Re-participation rate	No re-participation due to diagnostic MA
313 – Krems (Land)	10,611	4,792	45%	58 %	12%
323 – Wr. Neustadt (Land)	14,149	6,298	45%	63 %	8%
503 – Salzburg-Umgebung	27,174	12,187	45%	64 %	4%
505 – Tamsweg	3,686	1,672	45%	72 %	2%
705 – Kufstein	18,834	8,483	45%	63 %	10%
315 – Melk	13,555	6,279	46%	62 %	13%
403 – Wels (Stadt)	10,403	4,761	46%	58 %	6%
504 – St. Johann im Pongau	14,172	6,526	46%	70%	3%
506 – Zell am See	15,896	7,346	46%	66 %	8%
611 – Leoben	10,961	4,991	46%	63 %	11%
621 – Bruck-Mürzzuschlag	18,654	8,650	46%	66 %	9%
922 – Vienna-Donaustadt	33,104	15,064	46%	61 %	9%
102 – Rust (Stadt)	368	174	47 %	70%	11%
321 – Tulln	19,322	9,165	47 %	64 %	8%
502 – Hallein	10,417	4,861	47 %	63 %	6%
603 – Deutschlandsberg	11,570	5,390	47 %	61 %	8%
318 – Neunkirchen	15,827	7,614	48%	71%	7%
623 – Südoststeiermark	16,060	7,754	48%	60 %	13%
614 – Murau	5,144	2,616	51 %	69%	8%

Source: GÖG

Table 6.2:
Extent and behaviour per two-year cycle related to invasive breast cancer detected in BKFP in women in the core target group (excluding neoadjuvant therapy)

	2014/2015	Per cent	2016/2017	Per cent	2018/2019	Per cent	2020/2021	Per cent
In-situ carcinoma								
pTis, DCIS or. LCIS	69	4.63	80	4.94	76	4.68	55	2.73
Invasive carcinoma								
pT1mic	17	1.14	9	0.56	31	1.91	11	0.55
pT1a	89	5.98	84	5.19	71	4.37	93	4.62
pT1b	361	24.24	419	25.90	311	19.16	405	20.11
pT1c	572	38.42	607	37.52	597	36.78	629	31.28
pT2	246	16.52	219	13.54	220	13.56	247	12.26
pT3	20	1.34	13	0.80	25	1.54	21	1.04
pT4a	1	0.07	0	0.00	0	0.00	1	0.05
pT4b	2	0.13	5	0.31	3	0.18	2	0.10
No tumour, unknown								
pT0	0	0.00	3	0.19	10	0.62	0	0.00
pT0, unknown*	4	0.27	74	4.57	0	0.00	42	2.09
pTX	4	0.27	4	0.25	2	0.12	21	1.04
Unknown	104	6.98	101	6.24	277	17.07	487	24.18
Total	1,489	100.00	1,618	100.00	1,623	100.00	2,014	100.00

*The value was recorded on a simplified scale. The value can mean pT0 or "not available".

Source: GÖG

Table 6.3:
Lymph node involvement per two-year cycle related to invasive breast cancer detected in the BKFP in women in the core target group (excluding neoadjuvant therapy)

	2014/2015	Per cent	2016/2017	Per cent	2018/2019	Per cent	2020/2021	Per cent
Negative	**978**	**65.68**	**1,077**	**66.57**	**925**	**57.00**	**1,091**	**54.18**
pN negative*	799	53.66	935	57.79	104	6.41	0	0.00
pN0	99	6.65	82	5.07	255	15.71	383	19.02
pN0 (ITC)	3	0.20	1	0.06	5	0.31	10	0.50
pN0 (sn)	77	5.17	59	3.65	561	34.57	698	34.66
Positive	**301**	**20.23**	**303**	**18.71**	**309**	**19.04**	**338**	**16.79**
pN positive*	183	12.29	223	13.78	32	1.97	0	0.00
pN1mi	8	0.54	8	0.49	49	3.02	63	3.13
pN1a	32	2.15	18	1.11	159	9.80	228	11.32
pN1b	1	0.07	0	0.00	5	0.31	7	0.35
pN2a	46	3.09	41	2.53	42	2.59	32	1.59
pN2b	1	0.07	0	0.00	0	0.00	1	0.05
pN3a	28	1.88	13	0.80	21	1.29	7	0.35
pN3b	1	0.07	0	0.00	1	0.06	0	0.00
pN3c	1	0.07	0	0.00	0	0.00	0	0.00
pNX	**38**	**2.55**	**45**	**2.78**	**25**	**1.54**	**41**	**2.04**
Unknown	**172**	**11.55**	**193**	**11.93**	**364**	**22.43**	**544**	**27.01**
Total	**1,489**	**100.00**	**1,618**	**100.00**	**1,623**	**100.00**	**2,014**	**100.00**

*The value was recorded on a simplified scale and can no longer be assigned to the detailed scale.

Source: GÖG

Table 6.4:
Metastases per two-year cycle related to invasive breast cancer detected in the BKFP in women in the core target group (excluding neoadjuvant therapy without "unknown")

	2014/2015	Per cent	2016/2017	Per cent	2018/2019	Per cent	2020/2021	Per cent
M0	1,127	75.69	1,209	74.72	1,347	82.99	1,183	88.48
M1	32	2.15	41	2.53	15	0.92	15	1.12
MX	330	22.16	368	22.74	261	16.08	139	10.40
Total	1,489	100.00	1,618	100.00	1,623	100.00	1,337	100.00

Source: GÖG

Table 6.5:
Biomarker statuses as a percentage of invasive breast cancer detected in the BKFP in women in the core target group (excluding neoadjuvant therapy) in 2020/2021

	Oestrogen status	Progesterone status	HER2 status	Ki-67 proliferation index
Negative	30.64	38.73	55.21	-
Positive	45.18	37.09	3.38	-
Unknown	24.18	24.18	41.41	78.80
Low	-	-	-	10.18
Intermediate	-	-	-	8.59
High	-	-	-	2.43
Total	100.00	100.00	100.00	100.00

Source: GÖG

Table 6.6:
Histopathological grading of invasive breast cancer detected as part of the BKFP in women in the core target group (excluding neoadjuvant therapies) in 2020/2021

	Number	Per cent
G1	324	16.09
G2	687	34.11
G3	185	9.18
GX	11	0.55
Unknown	807	40.07
Total	2,014	100.00

Source: GÖG

Table 6.7:
Distribution of metastasis status associated with invasive carcinomas among the core target group in per cent during 2018/2019 (without unknown)

	IC first year	IC second year
M0	78.65	87.64
M1	2.62	1.69
MX	18.73	10.67
Total	100.00	100.00

IC: Interval carcinoma

Source: GÖG

Table 6.8:
Distribution of tumour stages in invasive carcinomas among the core target group in per cent during 2018/2019 (without unknown)

	IC first year	IC second year
0 (in-situ)	13.48	7.87
I	52.43	51.31
II	25.84	33.71
III	5.24	5.43
IV	3.00	1.69
Total	100.00	100.00

IC: Interval carcinoma

Source: GÖG

Table 6.9:
Biomarker status in per cent for interval cancers in the core target group in 2018/2019

	Oestrogen status		Progesterone status		HER2 status		Ki-67 proliferation index	
	IC first year	IC second year	IC first year	IC second year	IC first year	IC second year	IC first year	IC second year
Negative	48.27	39.25	54.91	46.74	34.68	29.40	—	—
Positive	28.90	35.92	22.25	28.43	4.91	3.19	—	—
Unknown	22.83	24.83	22.83	24.83	60.40	67.41	63.58	69.21
Low	—	—	—	—	—	—	10.40	11.65
Intermediate	—	—	—	—	—	—	15.32	10.82
High	—	—	—	—	—	—	10.69	8.32
Total	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00

Source: GÖG

Table 6.10:
Quality indicators for breast cancer screening programmes based on Perry et al. (2006)

ID	Indicator
EU-5	Proportion of women invited that attend for screening
EU-6	Proportion of eligible women reinvited within the specified screening interval
EU-7	Proportion of eligible women reinvited within the specified screening interval + 6 months
EU-8	Proportion of women with a radiographically acceptable screening examination
EU-10	Proportion of women undergoing a technical repeat screening examination
EU-11	Proportion of women undergoing additional imaging at the time of the screening examination in order to further clarify the mammographic appearances
EU-12	Proportion of women recalled for further assessment
EU-13	Proportion of screened women subjected to early recall following diagnostic assessment
EU-14	Breast cancer detection rate, expressed as a multiple of the underlying, expected, breast cancer incidence rate in the absence of screening (IR)
EU-15	Interval cancer rate as a proportion of the underlying breast cancer incidence rate in the absence of screening
EU-16	Proportion of screen-detected cancers that are invasive
EU-17	Proportion of screen-detected cancers that are stage II+
EU-18	Proportion of invasive screen-detected cancers that are node-negative
EU-19	Proportion of invasive screen-detected cancers that are ≤ 10 mm in size
EU-20	Proportion of invasive screen-detected cancers that are < 15 mm in size
EU-25	Absolute sensitivity of core biopsy
EU-26	Complete sensitivity of core biopsy
EU-27	Specificity of core biopsy
EU-28	Proportion of localised impalpable lesions successfully excised at the first operation
EU-29	Proportion of image-guided FNAC procedures with insufficient result
EU-30	Proportion of image-guided FNAC procedures from malignant lesions with an insufficient result
EU-31	Proportion of patients subsequently proven to have breast cancer with a pre-operative FNAC or core biopsy at the diagnosis of cancer
EU-32	Proportion of patients subsequently proven to have clinically occult breast cancer with a pre-operative FNAC or core biopsy that is diagnostic for cancer
EU-33	Proportion of image-guided core/vacuum procedures with an insufficient result
EU-34	Benign to malignant open surgical biopsy ratio in women at initial and subsequent examinations
EU-37	Proportion of patients where a repeat operation is needed after incomplete excision
EU-38.1	Time (in working days) between screening mammography and result
EU-38.5	Time (in working days) between assessment and issuing of results
EU-38.6	Time (in working days) between decision to operate and date offered for surgery
EU-39.1	Time (in working days) between screening mammography and result ≤ 15 wd
EU-39.2	Time (in working days) between screening mammography and result ≤ 10 wd
EU-39.3	Time (in working days) between symptomatic mammography and result ≤ 5 wd
EU-39.8	Time (in working days) between decision to operate and date offered for surgery ≤ 15 wd
EU-39.9	Time (in working days) between decision to operate and date offered for surgery ≤ 10 wd

Source: Perry et al. (2006)