



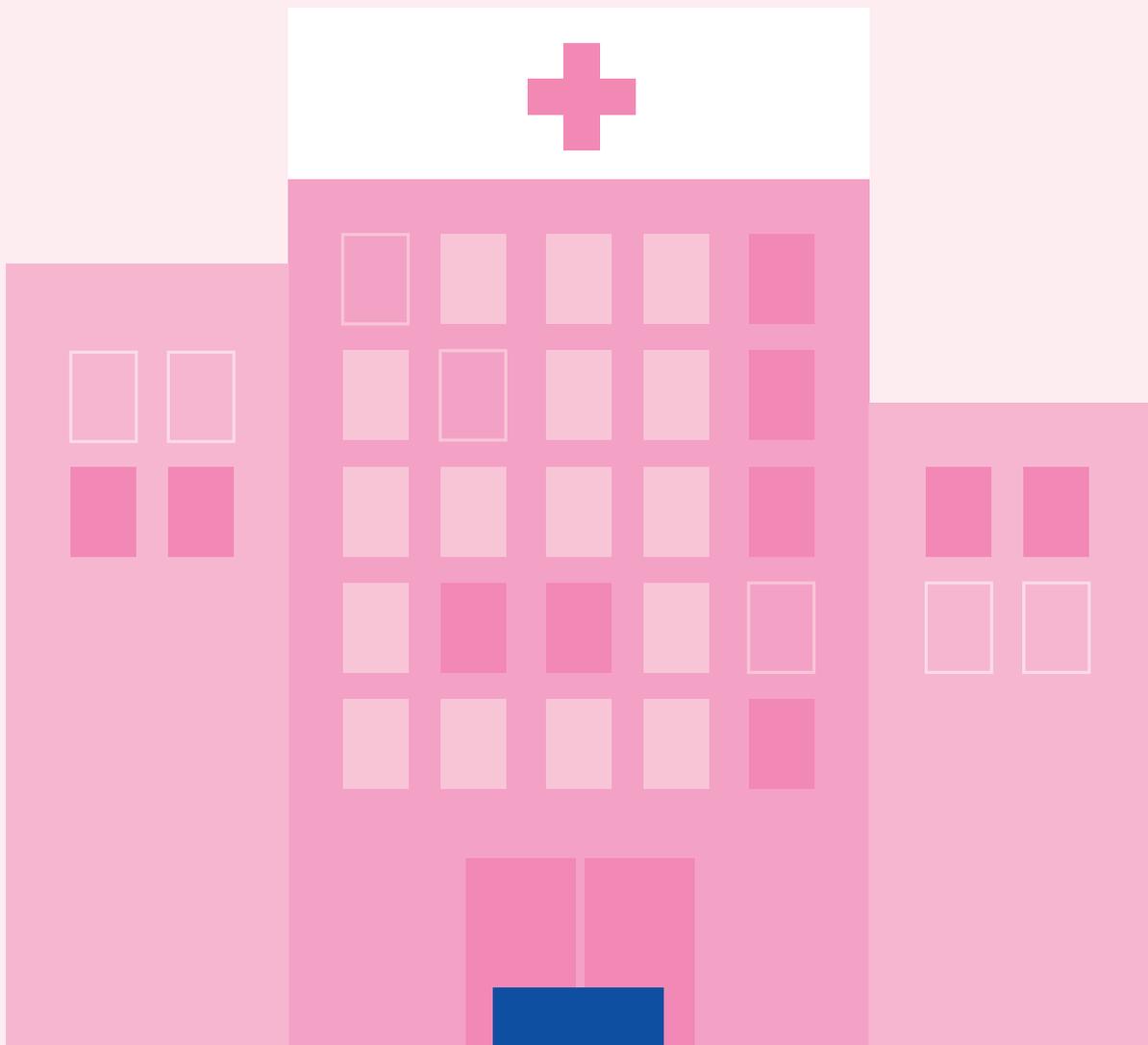
European
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EUROPEAN COMMISSION
INITIATIVE ON BREAST CANCER

Manual for Breast Cancer Services

European Quality Assurance Scheme
for Breast Cancer Services



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European Quality Assurance Scheme
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This manual is dedicated to the memory of ECIBC's patient representatives, Karen Benn and Sue Warman, whose strong will and dedication were invaluable in ensuring that these quality requirements respond to the real needs of women struggling with breast cancer in Europe.

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ACRONYMS

ALND	Axillary lymph node dissection
BCS	Breast cancer service
BI-RADS™	Breast Imaging Reporting and Data System
CB	Certification body
CEF	Clinical effectiveness
CIM	Complementary/integrative medicine
DCIS	Ductal carcinoma in situ
DGN	Diagnosis requirement
DGN-IMG	Imaging requirement
DGN-PTH	Pathology requirement
ECIBC	European Commission Initiative on Breast Cancer
ER	Oestrogen receptors
FFPE	Formalin-fixed paraffin-embedded
FLW	Follow-up requirement
FRW	Facilities, resources and workforce
GEN	General requirement
HER2	Human epidermal growth factor receptor 2
ICHOM	International Consortium for Health Outcomes Measurement
IHC	Immunohistochemistry
MDM	Multidisciplinary meeting
PAL	Palliative care requirement
PEX	Personal empowerment and experience
PR	Progesterone receptors
PROM	Patient-reported outcome measure
QA	Quality assurance
QASDG	Quality Assurance Scheme Development Group
RHB	Rehabilitation requirement
SAF	Safety
SCR	Screening requirement
SLNB	Sentinel lymph node biopsy
SOP	Standard operating procedures
TRT	Treatment requirement
TRT-RAD	Radiotherapy requirement
TRT-SUR	Surgery requirement
TRT-SYS	Systemic therapy requirement

FOREWORD

The *European Commission Initiative on Breast Cancer* is proud to publish the Manual of the European Quality Assurance Scheme for Breast Cancer Services.

This manual has been developed with the support of the Quality Assurance Scheme Development Group (QASDG), which includes professionals with a wide range of expertise, as well as patients. The experts were selected through a public open call, and QASDG members' conflicts of interest are assessed and managed accordingly.

The European Quality Assurance (QA) scheme is a collection of requirements, based on evidence, that can be followed by any breast cancer service (BCS) wishing to improve the quality of care offered to women.

The requirements are listed and described in this manual, which provides details on how the respective requirements must be met and describes the indicators to be used to verify quantitative requirements. The manual also provides guidance on how BCSs can demonstrate compliance with a given requirement.

The scheme is designed to be implemented on a voluntary basis. Auditors will check the requirements both remotely and during on-site visits to the physical premises of a BCS. Services demonstrating that they fulfil the requirements will be awarded a certificate.



INTRODUCTION

THE EUROPEAN COMMISSION INITIATIVE ON BREAST CANCER

Breast cancer is still the most common cancer among women in the European Union. Statistics from the [European Cancer Information System \(ECIS\)](#) indicate that more than 355 000 women are estimated to have been diagnosed with breast cancer in 2020 (13.3% of all cancer diagnoses).

Moreover, there are inconsistencies between incidence and mortality rates in some countries where mortality is higher than the European average despite a lower incidence. This may depend on many factors, including quality and access to care.

The [European Commission Initiative on Breast Cancer \(ECIBC\)](#) started its activities in 2015 with the objectives of improving the quality of breast cancer care and reducing inequalities in care access across Europe. The ECIBC project has been established by the European Commission's Directorate-General for Health and Food Safety, while the Commission's [Joint Research Centre](#) oversees the project.

Two main instruments have been created to achieve the ECIBC's aims:

1. The [European guidelines on breast cancer screening and diagnosis](#) are intended to provide up-to-date, evidence-based recommendations on breast cancer screening and diagnosis. Their development is reported transparently so that they can be implemented across Europe and beyond. They offer clear, objective and independent guidance on breast cancer screening and diagnosis to healthcare providers and women. They also guide healthcare managers and policymakers when planning, organising and monitoring the effectiveness of screening programmes.

To complement the European guidelines for screening and diagnosis by covering the entire breast cancer pathway, ECIBC also gathered guidelines developed by organisations worldwide. These guidelines are included in an [easy-to-search catalogue](#), and provide good practice for all breast cancer care processes after screening and diagnosis (treatment, rehabilitation, follow-up and survivorship care, and palliative care). The catalogue brings together guidelines that meet the ECIBC eligibility criteria for inclusion, and is updated periodically.

2. The [European quality assurance scheme for breast cancer services](#) (the European QA scheme) defines a set of requirements, with which breast cancer services (BCSs) providing services ranging from screening to follow-up, and even palliative care in some cases, must comply in order to be certified under the current scheme.

The European QA scheme encompasses a collection of requirements to support BCSs in improving their quality. The scheme focuses on enhancing the outcomes of care, while also taking into account patient experience and satisfaction. It is designed to be implemented on a voluntary basis. The European QA scheme will assess whether requirements are met using several tools (remote examination of documents, on-site visits, review of medical records, interviews with staff, etc.), including quantitative indicators.

This manual lists and describes these requirements.

SCOPE OF THE EUROPEAN QA SCHEME: BREAST CANCER CARE PATHWAY

The European QA scheme is applicable to all healthcare services covering the full extent of breast cancer management, from screening to follow-up, and palliative care in some cases (including where a BCS entity is outsourcing services).

Prevention of breast cancer is not treated as a separate service within the European QA scheme. However, requirements relating to prevention have been integrated into the overall scheme requirements for BCSs. In this context, prevention includes the following.

- Primary prevention in the average-risk female population when the intervention is specifically targeted at breast cancer (e.g. physical activity recommendations). However, primary prevention interventions in general may be included as 'service/process requirements' in one or more of the breast cancer procedures (e.g. smoking cessation, alcohol reduction or weight-loss counselling in early diagnosis or treatment settings).
- Secondary prevention in the average-risk female population (i.e. mammography screening).
- Primary and secondary prevention, surveillance, diagnosis (including genetic testing), treatment, rehabilitation and palliative care for breast cancer in women at increased risk of breast cancer.
- Diagnosis and, when indicated, surgical removal of lesions that are pathologically defined as being associated with 'uncertain malignant potential'.
- Other non-malignant breast diseases when implied in a differential diagnosis of cancer.

Male breast cancer and other male breast diseases, such as gynecomastia, do not fall under the scope of this scheme. However, the scheme may be adapted for breast cancer in men in the context of a future project, following the pilot run for female breast cancer.

To ensure that the European QA scheme follows a patient-centred approach, the quality and safety requirements are defined by taking into account the complete care pathway for breast cancer, including all related processes and sub-processes. The care pathway describes the healthcare chain, and relationships across healthcare sectors, by describing the outcomes of the relevant healthcare processes involved and considering quality targets. Specifically, the care pathway aims to:

- present the intervention/processes for which quality should be assured in a structured way;
- present the relevant healthcare sectors involved;
- assign responsibilities for healthcare processes to healthcare providers;
- identify starting points for quality assurance;
- identify quality potential within the breast cancer care pathway.

The care pathway that a patient follows can be described in a flow chart, including specific services, end points, quality targets and quality potentials that are relevant to breast cancer care, and considering the course of the disease and the various services involved.

Although individuals with breast cancer typically go through different processes of care, it is possible to identify a general care pathway that applies to ‘typical’ cases. These care pathways are intended as a guide in the definition of requirements, and are not an exhaustive definition of all possible variations of a general pathway. This is due to the differences in local organisational settings or specific cases of breast cancer that, for one reason or another, need to follow a different pathway. The simplified general care pathway proposed for the European QA scheme is represented in Figure 1.

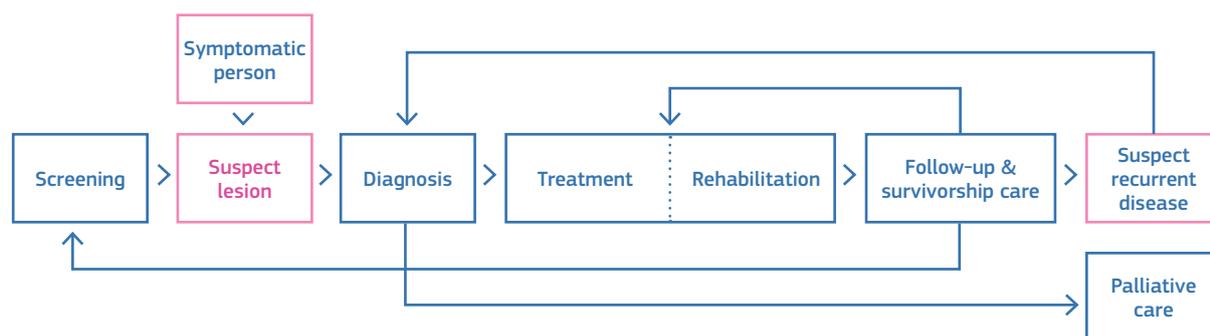


Figure 1. Breast cancer care pathway

The main processes of breast cancer care can be identified as: screening, diagnosis, treatment, rehabilitation, follow-up and survivorship care, and palliative care.

During investigation and treatment of the disease, the patient goes through various care processes and related sub-processes along the care pathway, provided by multiple professionals and services. The ‘treatment’ process itself comprises various sub-processes (e.g. surgery, radiotherapy, systemic therapy, psycho-oncological support, rehabilitation and palliative care), for both the primary treatment of breast cancer and the treatment of recurrent or metastatic disease. In this context, the concept of continuity of care becomes highly relevant. The patient must always be involved and empowered in all processes along the care pathway.

Particular emphasis should be placed on requirements that are at the boundaries of care processes and sub-processes, in order to address continuity of care. One important example of a service that crosses the boundaries of processes and sub-processes is psychosocial support resources, and their availability across all the different processes, as considered appropriate for each case.

The diversity of organisational settings for breast cancer care between countries and regions was highlighted in a survey published by the European Union in 2014 ⁽¹⁾. It is acknowledged that different processes such as screening and diagnosis, treatment, rehabilitation, follow-up and survivorship care, and palliative care in breast cancer care may be delivered by different entities, in both the public and/or private sectors. For these reasons, the European QA scheme has been developed as a modular scheme, enabling different legal entities or geographically separated services to participate according to the range of BCSs that they provide. However, it is essential to ensure that, wherever modules or processes and sub-processes within modules are delivered by different entities (even within the same overall organisation), all entities involved in the pathway take responsibility for meeting the requirements for, and coordinating the delivery of, continuity of care to individuals.

SELECTION CRITERIA FOR THE REQUIREMENTS IN THIS MANUAL

The methodology for selecting requirements is described in an ECIBC document ⁽²⁾. The requirements and indicators were selected by the QASDG members (including breast cancer professionals and patients) in a series of structured steps, set out in Figure 2.

The procedure consisted of the following essential steps.

- 1. Collection of requirements:** requirements for all breast cancer care processes were researched in existing literature, guidelines, indicator databases and quality assurance schemes, and were presented with reference to their evidence. In cases where the requirements retrieved did not address all the relevant quality potentials in the breast cancer care pathway, the QASDG developed new ones. Requirements that did not meet predefined inclusion criteria were excluded.
- 2. Panel process:** requirements were selected by a multi-disciplinary panel – the QASDG. In Delphi-style rounds, requirements were first rated for understandability and relevance, and then for feasibility. Relevance relates to the requirements' significance for a patient-centred care outcome, while feasibility relates to the requirements' ability to be implemented and provide meaningful data at service-provider level. Only requirements that were rated high for understandability, relevance and feasibility by the majority of the QASDG were included in the scheme.
- 3. Feasibility and pilot testing:** requirements were tested in a pilot run. They were amended according to the experiences gathered during the pilot run and then implemented within the scheme.

¹ Lerda D, Deandrea S, Freeman C, Lopez Alcalde J, Neamtiu L, Nicholl C, Nicholson N, Uluturk A, Villanueva Ferragud S. Report of a European survey on the organisation of breast cancer care services. Publications Office of the European Union, 2014, ISBN 978-92-79-37303-9.

² European Commission Initiative on Breast Cancer (ECIBC): Methods of the voluntary European Quality Assurance scheme for Breast Cancer Services. Selection of requirements and indicators. Available at: https://healthcare-quality.jrc.ec.europa.eu/sites/default/files/methodologies%20docs/ECIBC_Methods_QA_scheme.pdf.

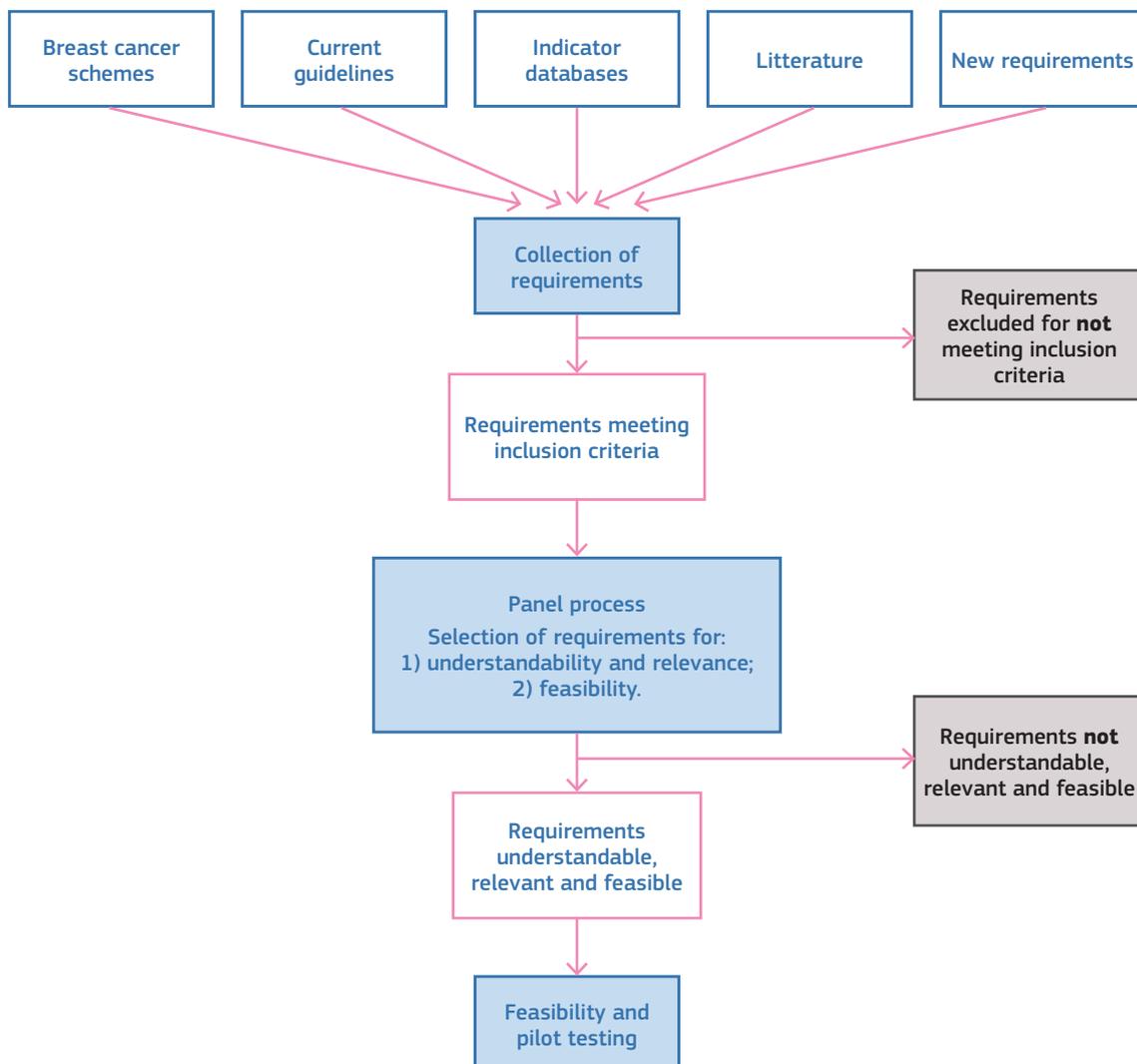


Figure 2. Requirement/indicator development procedure

The requirements of the QA scheme are described in this *Manual of the European Quality Assurance Scheme for Breast Cancer Services*, and the *European Quality Assurance Scheme Owner Manual*.

Additional resources are available to support implementation of the QA scheme:

- a **self-assessment tool** will help BCSs to determine their preparedness to comply with the QA scheme requirements, and identify what they need to do to achieve compliance;
- a **quality indicators (QIs) calculator** will help BCSs to calculate QIs in a standardised way in order to measure compliance with the QA scheme.

This version of the QA scheme will be used to assess its feasibility in real settings and to pilot the certification process. A final version of the QA scheme will be prepared based on the outcomes obtained during the feasibility checks and pilot run.

To test feasibility in real settings, selected services will use the self-assessment tool to assess their compliance with the requirements. The services will also explain their compliance in a dedicated section of the self-assessment tool, and will calculate the QIs by using the QI calculator. For the purpose of feasibility checks, the self-assessment tool includes a feedback section for each requirement, as well as a general feedback section. The feedback, as well as the data gathered through the self-assessment tool, will be analysed and will form the basis for updating the requirements.

The BCSs involved in the feasibility checks will test both the self-assessment tool and the QI tool, and will offer feedback in a structured way (using the self-assessment tool for the modules relevant to each participating BCS).

In addition, the certification process will be checked in a pilot run with the support of the European cooperation for Accreditation (EA).

CERTIFICATION OF BREAST CANCER SERVICES

SCOPE OF CERTIFICATION

Certification is the formal recognition by an independent, impartial organisation (certification body) that a BCS and its providers have been audited ⁽³⁾ and have demonstrated that they meet all the requirements of the European QA scheme.

The legal entity responsible for the BCS can apply for certification for meeting the requirements of the European QA scheme for one of the following modules:

- a. **Certification of the entire breast cancer care pathway:** BCS that provides all breast-care processes, including outsourced services (screening, breast centre including diagnosis, treatment, rehabilitation, follow-up and survivorship care, and palliative care).

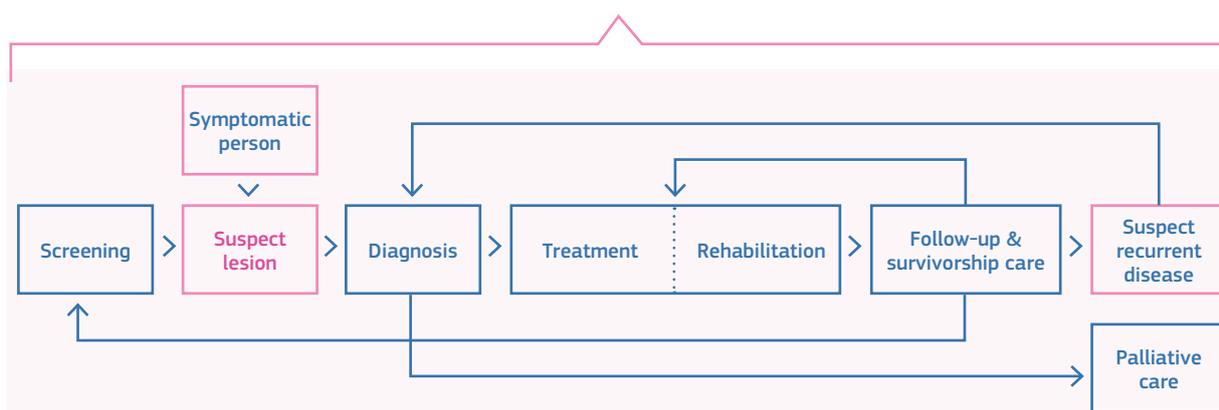


Figure 3. Certification of the entire breast cancer care pathway

- b. **Certification of screening programme, including outsourced services** (and, where applicable, diagnosis for referrals following screening).

A screening programme will need to have been operating a screening service for a minimum of two years before applying for certification, in order to provide sufficient evidence of compliance with the requirements for BCSs (e.g. one complete round of screening).

³ In relation to the European QA scheme, the terms 'audit', 'audited', 'auditing' and 'auditor' should be understood to include those activities that involve inspection, where 'inspection' is the examination of aspects of a BCS and determination of their conformity with the specific requirements or, on the basis of professional judgment, with the general requirements.

Screening programmes may involve one or more screening services (and, where applicable, diagnosis for referrals following screening) that are provided by outsourcing and/or by operating as a ‘network’ in different locations. In such circumstances, the legal entity that manages the overall screening programme would be the entity seeking certification.

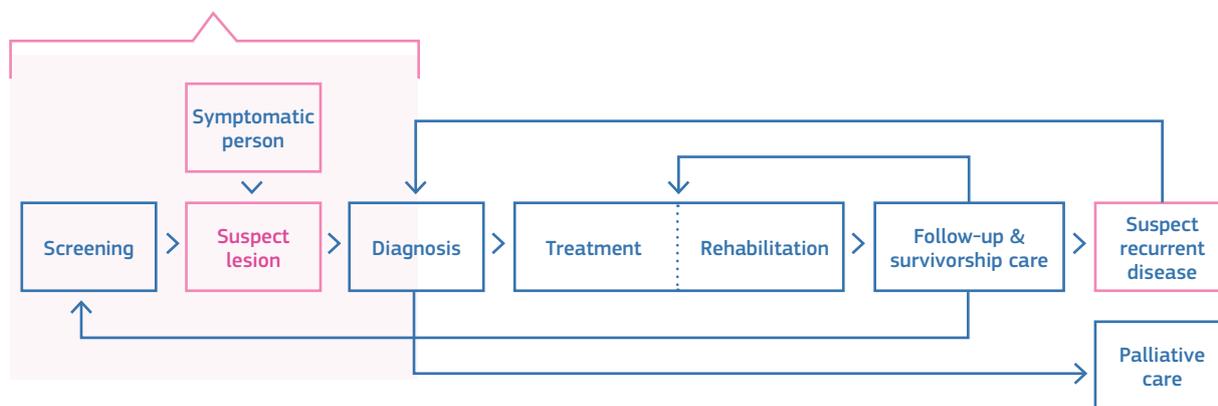


Figure 4. Certification of screening programme

Where a screening programme is also responsible for the diagnostic processes for referrals following screening, all the relevant European QA scheme requirements for diagnosis must also be met, irrespective of whether these processes are part of the same legal entity as the screening programme or outsourced services.

c. Certification of the breast cancer care pathway without screening, including outsourced services: breast centre, including diagnosis (including symptomatic women and referrals following screening), treatment, rehabilitation, follow-up and survivorship care, and palliative care.

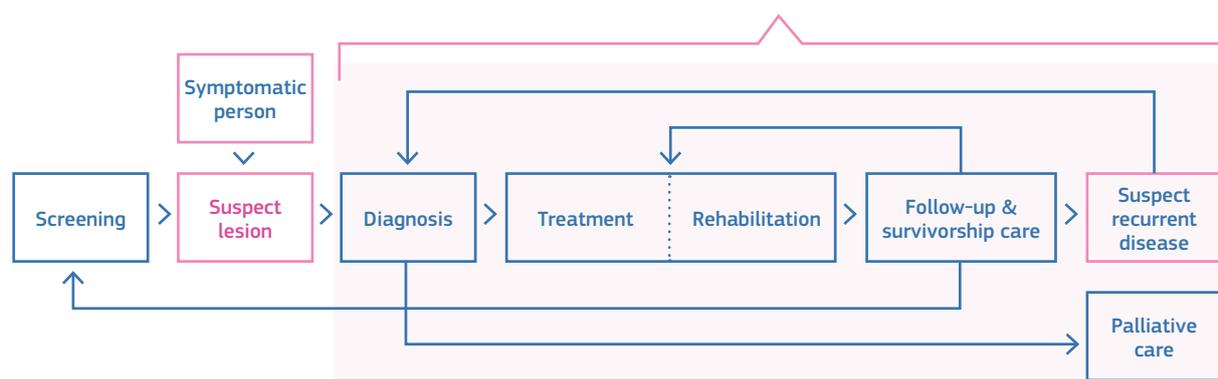


Figure 5. Certification of the breast cancer care pathway without screening

WHO CAN APPLY FOR CERTIFICATION?

In order to be eligible to apply for certification, the BCS must meet the following prerequisites.

1. The organisation responsible for providing the breast care services is a legal entity or a defined part of a legal entity.
2. The breast care services provided by this legal entity (in-house or partly outsourced with contracts/agreements) cover the processes described in the European QA scheme's modular approach (see 'Scope of certification' above).
3. The BCS entity has performed a self-assessment against the requirements of the European QA scheme for BCSs.
4. The BCS entity is willing to enter into an agreement/contract with an accredited certification body (CB) and comply with the terms and conditions of business.
5. The BCS entity has a database that can collect performance data on applicable quality indicators (QIs) and transfer the data (including QI data from external resources) successfully to its selected CB in the agreed format, at least every 12 months.
6. The BCS entity can submit calculated data for each applicable QI detailed in the requirements for BCSs (including QI data from external resources), for all care delivered in the 12 months prior to the certification audit.

The European QA scheme permits BCS entities to outsource processes or sub-processes of breast cancer care modules to external resources. Outsourced services that do not provide all of the processes within a module (see 'Scope of certification' above) are not eligible to apply for accredited certification to the European QA scheme as stand-alone activities or entities. However, the different sites at which outsourced services are delivered will be identified on certification documents, so that such services can be acknowledged as integral parts of the certified BCS, provided that they continue to demonstrate that they meet all of the relevant European QA scheme requirements.

Screening programmes may involve one or more screening services operating as a 'network' in different locations. In such circumstances, the legal entity that manages the overall screening programme would be the entity seeking certification. Formal agreements must be made with the different entities within the network that provide the screening services and, where these entities are legally differentiated, they are deemed to be outsourced services that must meet all of the relevant European QA scheme requirements.

'Networks' may also deliver other aspects of BCSs, such as treatment, for example, where oncology departments or centres in different hospitals provide chemotherapy services under the auspices of a national oncology institute. Where such networks are operating, the same principles and requirements apply as for networks within a screening programme.

More details on specific aspects of the certification process can be found in the *European Quality Assurance Scheme Owner Manual* and on the ECIBC website ⁽⁴⁾.

SUMMARY OF THE PROCESS FOR ACHIEVING AND MAINTAINING CERTIFICATION ⁽⁵⁾

1. Download the *Manual of the European Quality Assurance Scheme for Breast Cancer Services* from the European QA scheme website.
2. Carry out a self-assessment of compliance (including QIs) with applicable European QA scheme requirements using the web-based tools (self-assessment tool and QI calculator) provided on the European QA scheme website, and take action to address any non-conformity with the requirements.
3. Contact one of the approved CBs listed on the European QA scheme website and request access to the application documentation.
4. Submit the application for certification, including the application form and all specified information.
5. Sign the agreement/contract with the CB, including the agreement to pay all fees associated with the certification process.
6. Accept the proposed audit team and audit plan.
7. Participate in the certification audit, which includes visit(s) to the BCS facilities.
8. Address any non-conformity in order to demonstrate compliance with the European QA scheme requirements.
9. A certificate will be issued for the specified scope of certification and will be valid for three years.
10. Participate in annual surveillance activities.
11. Participate in recertification activities before the certificate expires.

⁴ <https://healthcare-quality.jrc.ec.europa.eu/ecibc/breast-quality-assurance-scheme>.

⁵ *European Quality Assurance Scheme Owner Manual, Annex 2.*

REQUIREMENTS

DEFINITIONS

The European QA scheme defines a set of **requirements** with which BCSs providing services from screening to follow-up, and in some cases until end-of-life care, will have to comply in order to be certified under the scheme.

- **Requirement** is the operational definition used within the ECIBC and encompasses the meaning of a 'standard' in the healthcare field: it is the **level of performance required by a quality assessment scheme with respect to a certain aspect that is meaningful for breast cancer screening, diagnosis and treatment.**

In the European QA scheme, each requirement comprises a **Statement**, associated with the corresponding supporting evidence and references, which is explained in several criteria. The **Statement** represents the overarching requirement and its general intent or principle. The criteria and/or indicators, and associated specifications, present measurable points by which achievement of the goal of the **Statement** may be objectively assessed. The criteria can specify different assessment approaches: structure, process or outcomes (see Glossary).

In the scheme, the requirements are classified according to the following **quality domains**:

- Clinical effectiveness (CEF)
- Safety (SAF)
- Facilities, resources and workforce (FRW)
- Personal empowerment and experience (PEX)

MEASUREMENT OF COMPLIANCE

The European QA scheme will assess whether the requirements are met using several tools (on-site visit, interview with staff, etc.), including quantitative indicators. Indicators describe the **fulfilment of a requirement by a clearly defined numerator and denominator**. Indicators are therefore always linked to a requirement, but not every requirement will have a quantitative indicator to be measured.

The quality assessment required may focus on two different levels of performance.

- a. **Patient level:** when the measurement is focused on the patient. In this case, compliance with the requirement will be measured with a **quantitative indicator**.
- b. **Breast service level:** the fulfilment of one or more criteria by the BCS will have to be assessed using different tools and methods during the audit.

HOW ARE THE REQUIREMENTS ORGANISED IN THE MANUAL?

The requirements have been assembled into three main chapters according to their scope.

Chapter I: General requirements (GEN) – cross-sectional requirements that can be applied to the entire pathway, regardless of the process involved.

Chapter II: Screening requirements (SCR) – requirements addressing specific aspects of screening programmes.

Chapter III: BCS requirements – requirements dealing with specific aspects within each care process.

- Diagnosis:
 - Diagnosis (DGN)
 - Imaging (DGN-IMG)
 - Pathology (DGN-PTH).
- Treatment:
 - Treatment (TRT)
 - Surgery (TRT-SUR)
 - Systemic therapy (TRT-SYS)
 - Radiotherapy (TRT-RAD).
- Rehabilitation (RHB).
- Follow-up and survivorship care (FLW).
- Palliative care (PAL).

The distribution of requirements and measurement elements (criteria and indicators), according to the different care pathway processes, is shown in this table:

PATHWAY PROCESS	NUMBER OF REQUIREMENTS
General	20
Screening	10
Diagnosis	25
Treatment	25
Rehabilitation	2
Follow-up	3
Palliative care	1
Total	86

WHAT DO THE REQUIREMENTS CONTAIN?

The requirements are compiled in the manual as a collection of worksheets. Each requirement has been divided into five sections with different coloured backgrounds (Figure 6):

- **Section 1:** Concept (black)
- **Section 2:** Measurement (pink)
- **Section 3:** Validity (blue)
- **Section 4:** Bibliography (blue)
- **Section 5:** Tools for implementation (blue).

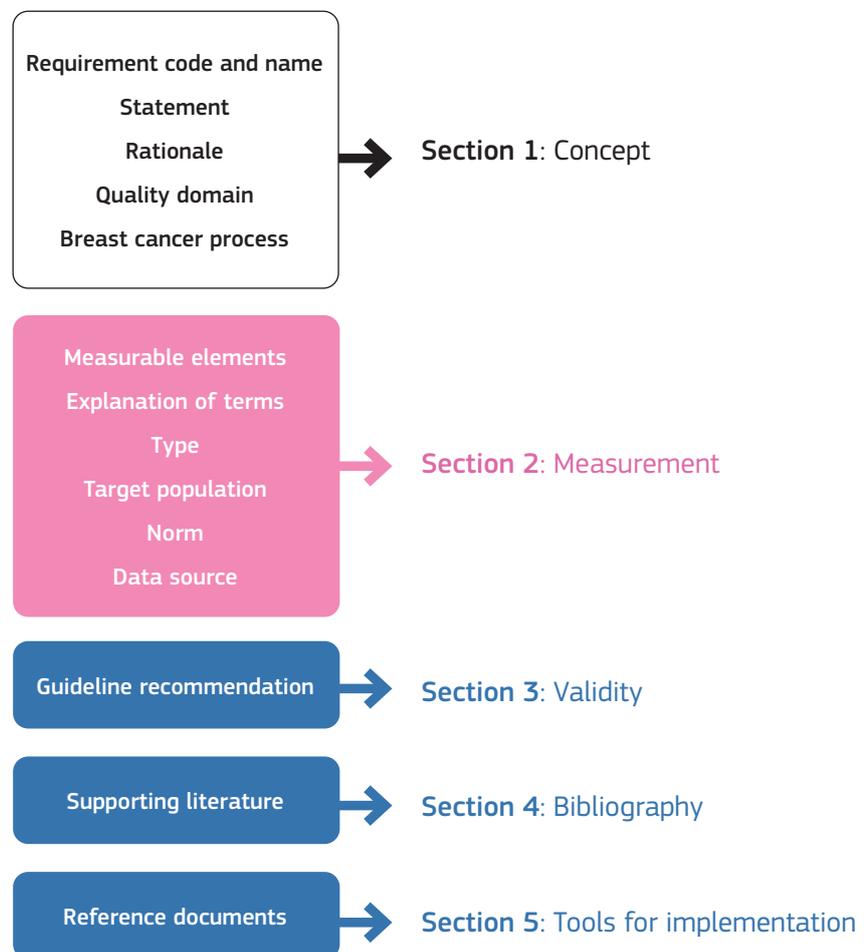


Figure 6. Requirement layout

The different sections are described below.

Section 1

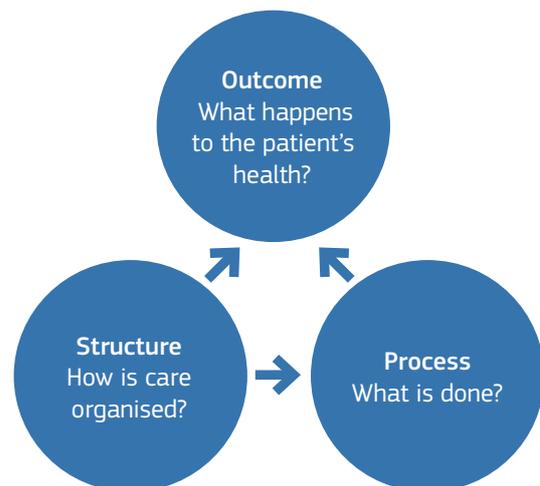
- **Name of the requirement**
- **Code:** alphanumeric sequence that identifies each requirement. It is made up of the acronym of its scope (the relevant process in the care pathway) and a number indicating its order in the specific process section.
- **Statement:** the requirement's general intent or principle.
- **Rationale:** the fundamental reason for the requirement.
- **Quality domain:** the dimension or issue of healthcare quality that the requirement pertains to (Clinical effectiveness; Safety; Facilities, resources and workforce; or Personal empowerment and experience).
- **Type of criteria:** structure/process/outcome. The Donabedian model is a three-component approach for **evaluating** the quality of healthcare. **Source:** Agency of Healthcare Research and Quality (AHRQ).

- **Definitions**

- **Structure:** structural measures give consumers a sense of a healthcare provider's **capacity, systems and processes** for providing high-quality care (i.e. availability of a protocol, procedure or guidelines, description of referral criteria, existence of a patient referral process, etc.).

- **Process:** process measures indicate **what a provider does** to maintain or improve health, either for healthy people or for those diagnosed with a health condition. These measures typically reflect generally accepted recommendations for clinical practice. The majority of healthcare quality measures used for public reporting are process measures (i.e. they verify whether the protocol or procedure is applied, the referral criteria met, or the planned process followed).

- **Outcome:** outcome measures reflect the **impact** of the healthcare service or intervention on a patient's health status. Outcome measures may seem to represent the 'gold standard' in measuring quality, but an outcome is the result of numerous factors, many beyond a provider's control (i.e. they verify whether applying the protocol or procedure improves health outcomes, or whether applying the referral criteria reduces the number of incorrect or unnecessary referrals).



- **Breast cancer process** : the scope of the requirement for the breast care pathway (Screening, Diagnosis, Treatment, Rehabilitation, Follow-up and Palliative care).

Section 2

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT [CODE]

Measurement element (code) (Indicator/criterion)	Each requirement may have 1 or several criteria to be met. Each criterion will be measured quantitatively (with an indicator) or as a categorical variable (a criterion with a dichotomous (yes/no) response). 1. Indicator: describes the fulfilment of a requirement through a clearly defined numerator and denominator. 2. Criterion: any measurement element for which the compliance is measured with a dichotomous response (yes/no).
Explanation of terms	Clarifies the meaning of any term included in the criterion/indicator, according to the manual.
Type	Specifies the assessment approach: structure, process or outcome.
Target population	Indicates the measurement target (patients, equipment, images, etc.) and, where necessary, the exclusion criteria to be applied.
Norm	Desired and achievable level of fulfilment.
Data source	The evidence and details/explanations of how the BCS must demonstrate compliance with a given requirement.

Section 3

GUIDELINE RECOMMENDATIONS [CODE]

Certainty of evidence	High, moderate, low or very low
Strength of recommendation	Strong, moderate, etc.
Guideline recommendations When available.	

Section 4

SUPPORTING LITERATURE [CODE]

List of literature references.

Section 5

REFERENCE DOCUMENTS [CODE]

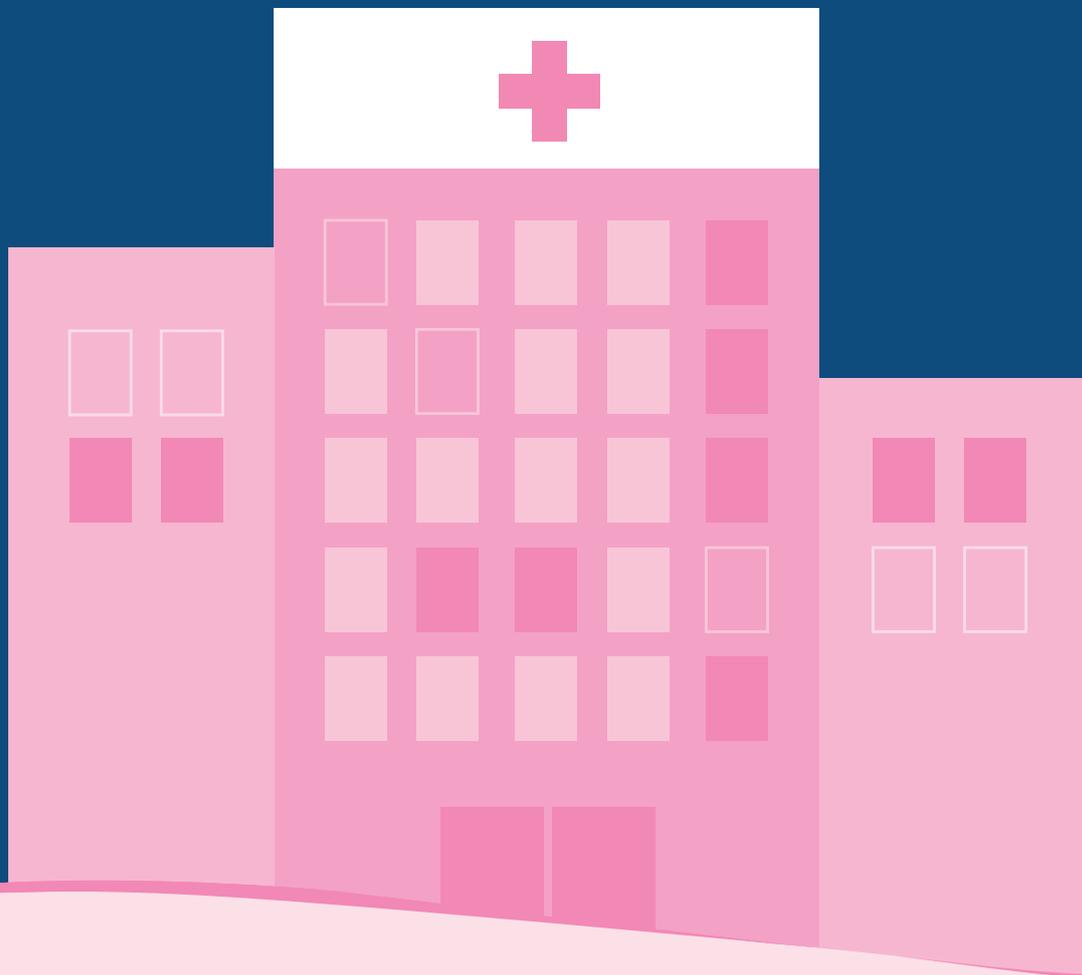
Technical documents and tools referred to in specific requirements and criteria that provide guidance both to services seeking to meet requirements and to auditors checking the fulfilment of requirements.

Some requirements are highlighted with this symbol for continuity of care: 

This symbol is an alert for the organisation to check possible issues related to continuity of care. For example, an exchange of information between in-house and outsourced services could be necessary to comply with the requirement.

CHAPTER 1

GENERAL REQUIREMENTS (GEN)



GENERAL REQUIREMENTS		
CODE	NAME	STATEMENT
GEN-1	Disciplines	The BCS must have a clinical director and the following professionals: radiologists, radiographers, oncoplastic breast surgeons (or both a breast surgeon and a plastic surgeon), pathologists, medical oncologists, radiation oncologists, breast care nurses, data managers, psycho-oncologists, clinical geneticists, clinical psychologists, nuclear medicine specialists, medical technical assistants, physiotherapists, nutrition specialists and lymphoedema specialists. Professionals can be in the same hospital or associated through a written agreement/contract.
GEN-2	Guidelines	The BCS must have adopted evidence-based protocols for the full pathway and all processes of care for patients with breast cancer, at all stages.
GEN-3	Quality improvement policy	The BCS must have a written quality improvement policy, including a quality management system, a patient safety system, and a clinical information system for monitoring the quality of breast cancer care.
GEN-4	Data management	The BCS must have a written policy defining the governance of data management.
GEN-5	Patient-reported outcome measures (PROMs) policy	The BCS must have a policy for routine measurement of patient-reported outcomes to monitor the well-being of women with breast cancer throughout the care pathway.
GEN-6	Patient relevance	The BCS must have implemented a policy to ensure relevant patient-centred care.
GEN-7	Patient information	The BCS must have a written policy about patient information. Women with breast cancer must be offered clear and understandable verbal and written information that describes the diagnostic process, treatment, follow-up and possible side effects.
GEN-8	Safety policy for medication	The BCS must have a written policy available for managing medications safely and appropriately.

GENERAL REQUIREMENTS

GEN-9	Pain management	The BCS must have a written policy for pain management in patients with breast cancer.
GEN-10	Physical activity and nutrition during treatment and follow-up	The BCS must have a written policy for providing lifestyle counselling (including on nutrition and physical activity) to their patients during treatment and follow-up.
GEN-11	 Lead time between pathology report with diagnosis and first treatment	The lead time between the pathology report with a diagnosis of cancer and the start of treatment must be no longer than 4 weeks.
GEN-12	Fertility preservation	The BCS must have a written policy on informing patients about the possibility of fertility preservation.
GEN-13	Complementary and integrative oncology	The BCS must have a written policy to ask the patient about and discuss the use of complementary and integrative medicine for breast cancer.
GEN-14	Research activities	The BCS must participate in research and must have a written policy on participation in research activities.
GEN-15	Staff competence	The BCS must have a policy to ensure that the professionals involved in patient care remain competent to deliver the service.
GEN-16	 Multidisciplinary meetings (MDMs)	The BCS must hold a multidisciplinary case management meeting at least once a week to discuss all patients before they start treatment (including patients with metastatic disease), after their primary treatment, and when there is any change in their treatment.
GEN-17	Time between the date of the multidisciplinary meeting (MDM) discussion and first treatment	The BCS must report the time between the date of the MDM discussion and the start of the first treatment.

GENERAL REQUIREMENTS

GEN-18	Nurse access	The BCS must have at least 2 breast care nurses available throughout the entire patient pathway to ensure continuity of care.
GEN-19	Nurse referral	All women diagnosed with breast cancer must be consulted by a breast care nurse at the time of diagnosis.
GEN-20	Training	The BCS must ensure that healthcare professionals are qualified and competent to deliver the service.

GEN-1: DISCIPLINES

Statement

The BCS must have a clinical director and the following professionals: radiologists, radiographers, oncoplastic breast surgeons (or both a breast surgeon and a plastic surgeon), pathologists, medical oncologists, radiation oncologists, breast care nurses, data managers, psycho-oncologists, clinical geneticists, clinical psychologists, nuclear medicine specialists, medical technical assistants, physiotherapists, nutrition specialists and lymphoedema specialists. Professionals can be in the same hospital or associated through a written agreement/contract.

Rationale

Sufficient staff and dedicated professionals are essential for providing high-quality BCSs. All BCSs should have a qualified team with the ability to provide high-quality multidisciplinary services.

Quality domain: Clinical effectiveness.

Breast cancer process: All processes.

Measurement: This requirement is measured by 1 criterion.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT GEN-1

GEN-1.1 criterion

The BCS has a clinical director and the following professionals: radiologists, radiographers, oncoplastic breast surgeons (or both a breast surgeon and a plastic surgeon), pathologists, medical oncologists, radiation oncologists, breast care nurses, data managers, psycho-oncologists, clinical geneticists, clinical psychologists, nuclear medicine specialists, medical technical assistants, physiotherapists, nutrition specialists and lymphoedema specialists. Professionals can be in the same hospital or associated through a written agreement/contract.

Type

Structure

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	GEN-1.1: List of BCS staff, including each professional's specialism. List of professionals directly employed by the BCS. If applicable: list of professionals from outsourced services who participate in breast cancer care, with a record or copy of their official agreement/contract. Auditors may check that at least 1 professional from each discipline, either employed or outsourced, is included in the list.

GUIDELINE RECOMMENDATIONS GEN-1

Certainty of evidence Not applicable

Strength of recommendation Not applicable

Guideline recommendations

No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE GEN-1

- DKG. Catalogue of requirements for Breast Cancer Centres of the German Cancer Society Version J2, 12 August 2019.
- NHS England. Manual for Cancer Services; Breast Cancer Measures. National Peer Review Programme. 2013.
- SIS/ISS. International Accreditation Program for Breast Centers/Units. 2013.
- Wilson ARM, Marotti L, Bianchi S, Biganzoli L, et al. The requirements of a specialist breast Centre (EUSOMA). European Journal of Cancer (2013) 49, 3579-3587.

REFERENCE DOCUMENTS GEN-1

GEN-2: GUIDELINES

Statement

The BCS must have adopted evidence-based protocols for the full pathway and all processes of care for patients with breast cancer, at all stages.

Rationale

Adherence to guidelines and protocols is associated with higher quality care.

Quality domain: Clinical effectiveness.

Breast cancer process: All processes.

Measurement: This requirement is measured by 7 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT GEN-2	
GEN-2.1 criterion	Protocols are consistent with current European guidelines for screening and diagnosis, and other (inter)national guidelines for the full care pathway as defined in the QA scheme, including guidelines on psychosocial care, rehabilitation and primary prevention of recurrence.
Type	Structure
GEN-2.2 criterion	The BCS pathway and processes are those defined in the European QA scheme.
Type	Structure
GEN-2.3 criterion	Protocols are adapted for local use, including local organisational aspects that define the centre's own requirements for the diagnosis and management of breast cancer at all stages.
Type	Structure
GEN-2.4 criterion	Tailoring of protocols to the local circumstances of the BCS is documented and up to date.
Type	Structure
GEN-2.5 criterion	The BCS has a policy for stimulating the adoption of protocols.
Type	Structure

GEN-2.6 criterion	The BCS reviews the documents and protocols regularly (at least annually). Minutes of the review meetings are available, including the date, and the names and signatures of attendees.
Type	Structure
GEN-2.7 criterion	Minutes of multidisciplinary meetings (MDMs) reflect the use of protocols and guidelines.
Type	Process

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	<p>GEN-2.1: List of current and approved care protocols. All care protocols include in their bibliography the European guidelines on breast cancer screening and diagnosis, or other reliable national or international guidelines related to the rest of the pathway (https://healthcare-quality.jrc.ec.europa.eu/international-guidelines).</p> <p>GEN-2.2 and GEN-2.3: List of all protocols from the pathway processes included in the requested certification. The protocols encompass:</p> <ol style="list-style-type: none"> 1. screening; or 2. BCS, including diagnosis, treatment, rehabilitation, follow-up, survivorship care, and palliative care; or 3. screening and BCS, including diagnosis, treatment, rehabilitation, follow-up and survivorship care, and palliative care. <p>GEN-2.4: Protocols address local organisational adaptations such as contracted services and their coordination with the BCS.</p> <p>GEN-2.5:</p> <ol style="list-style-type: none"> 1. Policy defining how to manage protocol implementation. 2. Auditors may ask professionals (from different disciplines) to locate the protocols (either electronic or print versions). 3. Auditors may ask professionals from different disciplines for specific examples of protocol implementation. <p>GEN-2.6: Care protocols and other agreed documents for care that are in force at the time of the audit, including the date of the last update (less than 12 months previously), authors and modifications.</p> <p>GEN-2.7: Minutes of MDMs from the last 12 months or a specific report assessing adherence to protocols.</p>

GUIDELINE RECOMMENDATIONS GEN-2

Certainty of evidence Not applicable

Strength of recommendation Not applicable

Guideline recommendations

No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE GEN-2

- DKG. Catalogue of requirements for Breast Cancer Centres of the German Cancer Society Version J2, 12 August 2019.
 - NHS England. Manual for Cancer Services; Breast Cancer Measures. National Peer Review Programme. 2013.
 - OECI Accreditation and Designation User Manual V. 3.0, 2019.
 - SIS/ISS. International Accreditation Program for Breast Centers/Units. 2013.
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REFERENCE DOCUMENTS GEN-2

GEN-3: QUALITY IMPROVEMENT POLICY

Statement

The BCS must have a written quality improvement policy, including a quality management system, a patient safety system, and a clinical information system for monitoring the quality of breast cancer care.

Rationale

Quality and risk management systems are assumed to be associated with better outcomes of care and fewer risks. All BCSs should have adopted a policy for quality improvement.

Quality domain: Clinical effectiveness; Safety.

Breast cancer process: All processes.

Measurement: This requirement is measured by 5 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT GEN-3

GEN-3.1 criterion	The BCS has a policy for quality improvement that is integrated into the organisation's overall quality policy and programme. A qualified individual is responsible for quality management of breast cancer care and the policy contains strategic objectives for at least the following quality domains: Clinical effectiveness; Facilities, resources and workforce; Personal empowerment and experience; and Safety.
Type	Structure
GEN-3.2 criterion	The BCS has a quality management system for monitoring quality and continuous quality improvement. Monitoring covers at least all the indicators included in the manual for each process (screening, diagnosis, treatment, rehabilitation, follow-up and survivorship care, and palliative care).
Type	Structure
GEN-3.3 criterion	The BCS has a database for monitoring the clinical quality of breast cancer care and research.
Type	Structure

GEN-3.4 criterion	The BCS has a data manager responsible for data collection and analysis.
Type	Structure
GEN-3.5 criterion	The BCS conducts an annual internal review resulting in a report that includes at least: the indicators monitored, a qualitative assessment of the results, and improvement actions for indicators that do not achieve the stated norm.
Type	Process

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	GEN-3.1: Quality policy and appointment of the individual responsible for breast cancer care quality management. GEN-3.2: Results of the monitoring of indicators. GEN-3.3: Auditors may access the database directly. GEN-3.4: Data manager's staff file, including job description. GEN-3.5: Report or minutes of the annual review session.

GUIDELINE RECOMMENDATIONS GEN-3

Certainty of evidence	Not applicable
Strength of recommendation	Not applicable
Guideline recommendations No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.	

SUPPORTING LITERATURE GEN-3

- DKG. Catalogue of requirements for Breast Cancer Centres of the German Cancer Society Version J2, 12 August 2019.
 - NAPBC (National Accreditation Program for Breast Centers) Standards Manual 2018.
 - NHS England. Manual for Cancer Services; Breast Cancer Measures. National Peer Review Programme. 2013.
 - OECI Accreditation and Designation User Manual V. 3.0, 2019.
 - SIS/ISS. International Accreditation Program for Breast Centers/Units. 2013.
 - Wilson ARM, Marotti L, Bianchi S, Biganzoli L, et al. The requirements of a specialist Breast Centre (EUSOMA). *European Journal of Cancer* (2013) 49, 3579-3587.
 - American College of Radiology. ACR-ASTRO practice parameter for radiation oncology. 2018.
-

REFERENCE DOCUMENTS GEN-3

GEN-4: DATA MANAGEMENT

Statement

The BCS must have a written policy defining the governance of data management.

Rationale

Adherence to guidelines and protocols for the governance of data management is associated with higher quality care. All BCSs must have adopted evidence-based protocols for data management. Data management should comply with current national regulations.

Quality domain: Clinical effectiveness.

Breast cancer process: All processes.

Measurement: This requirement is measured by 6 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT GEN-4

GEN-4.1 criterion	Policy is consistent with current European data protection and national legislation, and takes into account Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.
Type	Structure
GEN-4.2 criterion	The BCS has a written policy on data management, data protection and data privacy, and a secure procedure for the capture, storage, preservation, consultation and transmission of personal data according to the national and European regulations.
Type	Structure
GEN-4.3 criterion	The BCS documents how patients' rights with regard to the processing of their data are included in the policy (e.g. consent, the right to refuse processing, the right to be forgotten, etc.).
Type	Structure
GEN-4.4 criterion	The BCS ensures adequate protection for the data of patients involved in clinical trials.
Type	Structure

GEN-4.5 criterion	The BCS checks that any data sharing with outsourced services (collaborators and partners that process data) complies with the General Data Protection Regulation.
Type	Structure
GEN-4.6 criterion	The BCS reviews the documents and protocols regularly (at least annually). Minutes of the review meetings are available, including the date, and the names and signatures of attendees.
Type	Process

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	<p>GEN-4.1 and GEN-4.3: The BCS policy includes EU citizens' right to access healthcare in any EU country and to be reimbursed for care abroad by their home country. Directive 2011/24/EU on the application of patients' rights in cross-border healthcare sets out the conditions under which a patient may travel to another EU country to receive medical care and be subsequently reimbursed. It covers healthcare costs, as well as the prescription and delivery of medications and medical devices.</p> <p>GEN-4.2 Data management policy document including all elements mentioned in the criterion.</p> <p>GEN-4.4: Auditors may inspect the place where the clinical records of patients involved in clinical trials are stored and protected.</p> <p>GEN-4.5: Document of formal agreement with outsourced services.</p> <p>GEN-4.6: Protocols and other agreed documents for the governance of data management that are in force at the time of the audit, including the date of the last update (less than 12 months previously), authors and modifications.</p>

GUIDELINE RECOMMENDATIONS GEN-4

Certainty of evidence Not applicable

Strength of recommendation Not applicable

Guideline recommendations

No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE GEN-4

- OECI Accreditation and Designation User Manual V. 3.0, 2019.
 - Wilson (2013).
 - General Data Protection Regulation (GDPR) (Regulation (EU) 2016/679).
-

REFERENCE DOCUMENTS GEN-4

GEN-5: PATIENT-REPORTED OUTCOME MEASURES (PROMS) POLICY

Statement

The BCS must have a policy for routine measurement of patient-reported outcomes to monitor the well-being of women with breast cancer throughout the care pathway.

Rationale

Patient-reported outcomes are important for capturing patients' views on their health in terms of symptoms and physical, mental and social functioning, including overall health-related quality of life. Measuring such outcomes with PROMs is relevant for shared decision making and involving women in their care. Measuring outcomes with PROMs can also be used to evaluate treatment goals in long-term follow up.

Quality domain: Personal empowerment and experience.

Breast cancer process: All processes.

Measurement: This requirement is measured by 1 criterion.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT GEN-5

GEN-5.1 criterion	The BCS uses at least 1 patient PROM that is relevant to women with breast cancer. In choosing PROMs, the BCS may follow – but is not limited to – recommendations issued by the International Consortium for Health Outcomes Measurement (ICHOM) and/or the documents listed under reference documents
Type	Process
Target population	All women with breast cancer treated at the BCS.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	GEN-5.1: Information on which PROMs are used, how they are measured and how the BCS uses the results.

GUIDELINE RECOMMENDATIONS GEN-5

Certainty of evidence There are several reviews supporting the reliability and validity of PROMs in patients with breast cancer. The working group used the available evidence listed under supporting literature.

Strength of recommendation Not applicable

Guideline recommendations

No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE GEN-5

- OECI Quality standards V. 2015 Appendix II. OECI Accreditation and Designation.
- Ong WL, Schouwenburg MG, van Bommel ACM, Stowell C, Allison KH, Benn KE; Browne JP et al. A Standard Set of Value-Based Patient-Centered Outcomes for Breast Cancer: The International Consortium for Health Outcomes Measurement (ICHOM) Initiative. *JAMA Oncol.* 2017;3(5):677-685.
- Forde I, Nader C, Klazinga N, Slawomirski L, Van der Wees P. Recommendations to OECD Ministers of Health on the future of health statistics: Strengthening the international comparison of health system performance through patient-reported indicators. Paris: OECD, 2017.
- Kanatas A, Velikova G, Roe B, Horga K, Ghazali N, Shaw RJ, Rogers SN. Patient-reported outcomes in breast oncology: a review of validated outcome instruments. *Tumori*, 98: 678-688, 2012.
- Davies N, Gibbons E, Mackintosh A, Fitzpatrick R. A structured review of patient-reported outcome measures (PROMs) for breast cancer. Patient-reported Outcome Measurement Group. Oxford; University of Oxford, 2009.
- Howell D, Molloy S, Wilkinson K, Green E, Orchard K, Wang K, Liberty J. Patient-reported outcomes in routine cancer clinical practice: a scoping review of use, impact on health outcomes, and implementation factors. *Annals of Oncology* 26: 1846–1858, 2015.

REFERENCE DOCUMENTS GEN-5

- EDMONDTON system assessment scale.
- ICHOM has listed the following recommended instruments to measure PROMs:
 - Depression, pain, fatigue: recommended to track via the EORTC Quality of Life Questionnaire – Core Questionnaire (EORTC QLQ-C30).
 - Body image: recommended to track via the EORTC Quality of Life Questionnaire – Breast Cancer Specific Questionnaire (EORTC QLQ-BR23) and the BREAST-Q – Satisfaction with breasts.
 - Arm and breast symptoms: recommended to track via the EORTC Quality of Life Questionnaire – Breast Cancer Specific Questionnaire (EORTC QLQ-BR23).
 - Vasomotor symptoms: recommended to track via the EORTC Quality of Life Questionnaire – Breast Cancer Specific Questionnaire (EORTC QLQ-BR23).
 - Arthralgia: recommended to track via a subset of questions from the Functional Assessment of Cancer Therapy-Endocrine Symptoms (FACT-ES).
 - Sexual dysfunction: recommended to track via the EORTC Quality of Life Questionnaire – Breast Cancer Specific Questionnaire (EORTC QLQ-BR23) and a subset of questions from the Functional Assessment of Cancer Therapy-Endocrine.
 - Health-related quality of life: includes physical, emotional, cognitive and social functioning, ability to work and overall well-being. Recommended to track via the EORTC Quality of Life Questionnaire – Core Questionnaire (EORTC QLQ-C30).

Note:

Another international initiative has been launched by the Organization of Economic Collaboration and Development (OECD). The OECD initiated the Patient-Reported Indicators Survey (PaRIS) to develop internationally comparable patient-reported indicators, and a working group has been established to development, collect and report on patient-reported indicators for breast cancer care.

GEN-6: PATIENT RELEVANCE

Statement

The BCS must have implemented a policy to ensure relevant patient-centred care.

Rationale

Shared decision making is an important aspect of BCSs, requiring high-quality communication and tailored information that is relevant to the patient and takes into account their needs and values. The breast centre should have adopted such a policy to ensure patient-centred care.

Quality domain: Personal empowerment and experience.

Breast cancer process: All processes.

Measurement: This requirement is measured by 6 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT GEN-6

GEN-6.1 criterion	Members of the team are trained in communication skills and shared decision making periodically (at least every 5 years), to be demonstrated by certificates of attendance.
Type	Process
GEN-6.2 criterion	The training includes skills for providing appropriately tailored information that is relevant to the patient (including information about relevant treatment options, self-care, benefits and harms, patient safety and risks of complications).
Type	Process
GEN-6.3 criterion	The BCS has implemented a survey, conducted periodically, to measure patient experience/satisfaction, as well as patient communication.
Type	Process
GEN-6.4 criterion	The BCS has implemented improvements based on the results of the surveys.
Type	Process
GEN-6.5 criterion	The BCS has established a patient advisory/representative group to review the results of patient experience/satisfaction surveys, including patient communication.
Type	Structure

GEN-6.6 criterion	Patient-informed consent is obtained through a process defined by the centre and carried out by trained staff, and is registered in the clinical records.
Type	Process

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	<p>GEN-6.1: Training certificates for all professionals mentioned in requirement GEN-1.</p> <p>GEN-6.2: The training programme.</p> <p>GEN-6.3: Report analysing the results of patient experience/satisfaction surveys. The frequency of the surveys should be in line with national legislation, but at least every 12 months.</p> <p>GEN-6.4: Some examples of improvements made based on analysis of the results.</p> <p>GEN-6.5: An official document confirming the establishment and operation of the patient advisory group.</p> <p>GEN-6.6: Auditors may check a sample of procedures requiring the patient's informed consent and verify that the documentation is complete. They may also interview patients about what the informed consent process was like.</p>

GUIDELINE RECOMMENDATIONS GEN-6

Certainty of evidence	Not applicable
Strength of recommendation	Not applicable
Guideline recommendations	No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE GEN-6

- NAPBC (National Accreditation Program for Breast Centers) Standards Manual 2018.
 - SIS/ISS. International Accreditation Program for Breast Centers/Units. 2013.
-

REFERENCE DOCUMENTS GEN-6

GEN-7: PATIENT INFORMATION

Statement

The BCS must have a written policy about patient information. Women with breast cancer must be offered clear and understandable verbal and written information that describes the diagnostic process, treatment, follow-up and possible side effects.

Rationale

Clear and understandable information empowers the patient's self-management. It can support the patient in the shared decision-making process and make subjects easier to talk about (such as psychosocial problems and sexuality). It can help prevent and/or manage possible (late) side-effects and support the re-integration process. It also supports the patient to know where to find additional information and where to turn to if there is a problem.

Quality domain: Personal empowerment and experience.

Breast cancer process: All processes.

Measurement: This requirement is measured by 6 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT GEN-7

GEN-7.1 criterion	Leaflets and patient information documentation are adapted for local use.
Type	Structure
GEN-7.2 criterion	Documentation includes tailored, easy-to-understand verbal, written and online information that describes the diagnostic process, treatment, follow-up and possible (late) side effects.
Type	Structure
GEN-7.3 criterion	Documentation includes information about local outpatient support groups and advocacy organisations, a list of patients' rights (outlined in the European Parliament resolution on breast cancer), and information about where to go to find resources to improve self-management.
Type	Structure
GEN-7.4 criterion	The documents are up to date, and include the dates of issue and revision.
Type	Process

GEN-7.5 criterion	The centre has patient information materials available and they are easily accessible.
Type	Structure
GEN-7.6 criterion	Patients are involved in creating patient information materials.
Type	Process

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	<p>GEN-7.1: Patient information available in different languages according to the origins of the centre’s patient population; use of pictograms; availability of online materials or videos about the usual information processes (informed consent, admission to hospital, chart of patient rights, pre-surgical information, preparation for diagnostic tests, etc.).</p> <p>GEN-7.2: Printed and (if available) online documents specifically referring to the following.</p> <ol style="list-style-type: none"> 1. The diagnostic process. 2. The treatment process, with clear reference to the surgical process and medical treatment (systemic therapy and radiotherapy), including side effects and where to go to find resources to improve self-management. 3. Follow-up (i.e. nutrition, physical exercise, healthy habits, etc.). <p>GEN-7.3: Information leaflets or documents from local patient support groups or advocacy organisations.</p> <p>GEN-7.4: Auditors may check dates of issue and revisions of all documents and sources of information.</p> <p>GEN-7.5:</p> <ol style="list-style-type: none"> 1. List of authorised information materials that should be available in the hospital, including their location. 2. Check that information materials are available in situ (displayed or easily available). <p>The materials may have been produced by the centre or come from another source (public authorities, scientific associations, professional boards, patient associations, etc.).</p> <p>GEN-7.6 Auditors may ask for examples of patient participation (i.e. focus groups to review the text of the informed consent document, self-care materials, etc.).</p>

GUIDELINE RECOMMENDATIONS GEN-7

Certainty of evidence Moderate

Strength of recommendation Strong

Guideline recommendations

- The guideline development group recommends establishing the organisation of care around surgical procedures in such a way that:
 - information is repeatedly provided that is tailored to the specific phase of treatment;
 - this verbal information is supported with written information and/or a website (IKNL, 2012).
Evidence Quality: A1, A2, B (moderate); Strength of recommendation: strong.
- To ensure a patient-professional partnership, patients should be offered individually tailored information, including information about sources of support (including local and national organisations). Tailoring of information should take into account format (including whether written or taped), as well as the actual content and form that should be provided (NICE, 2013).

SUPPORTING LITERATURE GEN-7

- NAPBC (National Accreditation Program for Breast Centers) Standards Manual 2018.
- Wilson ARM, Marotti L, Bianchi S, Biganzoli L, et al. The requirements of a specialist Breast Centre (EUSOMA). *European Journal of Cancer* (2013) 49, 3579-3587.
- Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer. NICE, 2013.
- DKG. Catalogue of requirements for Breast Cancer Centres of the German Cancer Society Version J2, 12 August 2019.
- SIS/ISS. International Accreditation Program for Breast Centers/Units. 2013.
- OECI Accreditation and Designation User Manual V. 3.0, 2019.
- IKNL NABON. Breast Cancer Dutch Guideline, version 2.0 2012.

REFERENCE DOCUMENTS GEN-7

GEN-8: SAFETY POLICY FOR MEDICATION

Statement

The BCS must have a written policy available for managing medications safely and appropriately.

Rationale

Safety procedures are essential in preventing adverse events.

Quality domain: Clinical effectiveness; Safety.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 11 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT GEN-8

GEN-8.1 criterion	The BCS meets legal requirements and standards of practice when administering medications.
Type	Structure
GEN-8.2 criterion	The BCS identifies the team members who are qualified to prescribe, administer, store, handle and dispose of medications, and documents medication information in the patient record.
Type	Structure
GEN-8.3 criterion	The BCS has procedures in place to evaluate patients' requests to bring in or self-administer their own medication.
Type	Structure
GEN-8.4 criterion	The BCS has procedures in place to respond to requests for medication and medication information after business hours and in emergencies.
Type	Structure
GEN-8.5 criterion	The BCS has specific procedures in place for prescribing, preparing, storing, using and administering cytotoxic drug products.
Type	Structure

GEN-8.6 criterion	Before dispensing medication, a qualified staff member reviews each prescription for completeness and accuracy.
Type	Process
GEN-8.7 criterion	A qualified staff member regularly reviews each patient's prescriptions to assess the appropriateness of each medication, the use of multiple medications, and possible drug interaction.
Type	Process
GEN-8.8 criterion	A qualified staff member stores and disposes of medications safely and securely.
Type	Process
GEN-8.9 criterion	A qualified staff member fills the prescription and dispenses the medication in a timely and accurate way.
Type	Process
GEN-8.10 criterion	The BCS monitors and reports its use of medications through ongoing use reviews.
Type	Process
GEN-8.11 criterion	The team documents all incidents involving administering, using, storing and disposing of medications and uses this information to make improvements. This system is embedded in the BCS' general risk management programme.
Type	Process

FOR ALL CRITERIA

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT GEN-8

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	<p>GEN-8.1: Medication management plan or procedures from the pharmaceutical service, addressing all medication processes in the BCS, from selection to administration and monitoring. The bibliography should include the current national regulation.</p> <p>GEN-8.2: Ask professionals (compare answer with management plan).</p> <p>GEN-8.3: Medication management plan from the pharmaceutical service.</p> <p>GEN-8.4: Medication management plan from the pharmaceutical service.</p> <p>GEN-8.5: Medication management plan from the pharmaceutical service (management of cytotoxic drugs).</p> <p>GEN-8.6: Review of patients' medical records from the last 12 months (complete medical orders).</p> <p>GEN-8.7: Auditors may directly observe and ask professionals about the appropriateness of reviewing medication prescriptions in the context of the medication management plan from the pharmaceutical service.</p> <p>GEN-8.8: Auditors may inspect medication storage areas throughout the breast centre, while checking expiry dates and management of high-risk and lookalike/soundalike medications.</p> <p>GEN-8.9: Review of patients' medical records from the last 12 months (medication administration records).</p> <p>GEN-8.10: Assessment reports on medication use according to protocols (systemic treatment).</p> <p>GEN-8.11: Reports from the incident reporting and learning system (from the pharmaceutical service or from the hospital). Compare results with the implementation of improvement actions.</p>

GUIDELINE RECOMMENDATIONS GEN-8

Certainty of evidence Not applicable

Strength of recommendation Not applicable

Guideline recommendations

No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE GEN-8

- OECI Accreditation and Designation User Manual V. 3.0, 2019.
 - American College of Radiology, 2014.
 - Qmentum International. Cancer care Services. Standards. Accreditation Canada, 2013.
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REFERENCE DOCUMENTS GEN-8

GEN-9: Pain management

Statement

The BCS must have a written policy for pain management in patients with breast cancer.

Rationale

Pain can be a side effect of breast cancer treatment. Personalised pain management is important for the quality of life of patients with breast cancer.

Quality domain: Personal empowerment and experience; Clinical effectiveness.

Breast cancer process: Treatment; Follow-up; Rehabilitation; Palliative care.

Measurement: This requirement is measured by 4 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT GEN-9

GEN-9.1 criterion	The BCS has a policy stating that every patient has access to pain management and a pain specialist, and referral to palliative care.
Type	Structure
GEN-9.2 criterion	The BCS has protocols for pain management.
Type	Structure
GEN-9.3 criterion	The pain management service includes patient and family information, patient screening/assessment, and intervention.
Type	Process
GEN-9.4 criterion	The policy includes the description of a workforce equipped for pain management, including professional profiles, tasks, education requirements and supervision requirements.
Type	Structure

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	GEN-9.1: Policy for pain management or Statement of patient rights, including referral to palliative care. GEN-9.2: Protocol for acute and chronic pain management, including how to perform pain assessment in all circumstances (i.e. scales for different patient populations). GEN-9.3: Auditors may conduct patient interviews about how they have been informed, assessed, and whether any alternatives to pharmacological treatment have been offered. GEN-9.4: Standard operating procedures (SOP or similar) for the pain management service, including the workforce's: <ol style="list-style-type: none">1. professional profiles2. tasks3. education requirements4. supervision requirements.

GUIDELINE RECOMMENDATIONS GEN-9

Certainty of evidence	Not applicable
Strength of recommendation	Not applicable
Guideline recommendations	<ul style="list-style-type: none">• <i>The clinical service shall implement and maintain a procedure to assess, address and document clinical service user comfort, physical pain, discomfort or emotional distress (PAS 1616:2016).</i>

SUPPORTING LITERATURE GEN-9

- DKG 2017. Catalogue of requirements for Breast Cancer Centres of the German Cancer Society.
- OECl Accreditation and Designation User Manual V. 3.0, 2019.
- PAS 1616:2016. Healthcare. Provision of clinical services. Specification. 2016.

REFERENCE DOCUMENTS GEN-9

GEN-10: PHYSICAL ACTIVITY AND NUTRITION DURING TREATMENT AND FOLLOW-UP

Statement

The BCS must have a written policy for providing lifestyle counselling (including on nutrition and physical activity) to their patients during treatment and follow-up.

Rationale

Lifestyle factors are important in improving survival rates. There are indications of links between better survival after breast cancer and a healthy body weight, and being physically active. All BCSs should offer access to nutrition consulting. Physical exercise has a beneficial impact (measured by biomarkers and linked to better prognosis) on local recurrence for patients with breast cancer, and on physical functions, psychological outcomes and quality of life.

Quality domain: Clinical effectiveness; Personal empowerment and experience.

Breast cancer process: Treatment; Follow-up.

Measurement: This requirement is measured by 3 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT GEN-10

GEN-10.1 criterion	The BCS has a policy to offer (wherever possible) or recommend physical activity and nutrition programmes to their patients.
Type	Structure
GEN-10.2 criterion	Specialised professionals (e.g. a dietician and physical therapist) are available nearby.
Type	Structure
GEN-10.3 criterion	The BCS has implemented the policy during regular follow-up visits, and assessed compliance.
Type	Process

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	GEN-10.1: Breast cancer care protocol that includes specific information on nutrition and physical activity programmes. GEN-10.2: List of staff or outsourced services. GEN-10.3: Auditors may check the last assessment report on policy compliance.

GUIDELINE RECOMMENDATIONS GEN-10

Certainty of evidence Not applicable

Strength of recommendation Not applicable

Guideline recommendations

- Evidence shows that women who have a healthy diet after diagnosis have a lower rate of recurrence and a greater chance of surviving breast cancer (World Cancer Research Fund 2014; Hamer et al 2017; Dieli-Conwright CM, 2016).

The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE GEN-10

- World Health Organisation. Breast Cancer: prevention and control.2014; Available from: www.who.int/cancer/detection/breastcancer/en/index.html.
 - World Cancer Research Fund 2014. Diet, Nutrition and Physical Activity and Breast Cancer Survivors.
 - www.wcrf.org/sites/default/files/Breast-Cancer-Survivors-2014-Report.pdf
 - DKG. Catalogue of requirements for Breast Cancer Centres of the German Cancer Society Version J2, 12 August 2019.
 - OECI Quality standards V. 2015 Appendix II. OECI Accreditation and Designation.
 - Dieli-Conwright CM et al 2016. Reducing the Risk of Breast Cancer Recurrence: an Evaluation of the Effects and Mechanisms of Diet and Exercise. Breast Cancer Report 2016;8:139-150.
 - Hamer J et al. Lifestyle modifications for patients with breast cancer to improve prognosis and optimize overall health. CMAJ 2017;189(7): e268-e274.
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REFERENCE DOCUMENTS GEN-10

GEN-11: LEAD TIME BETWEEN PATHOLOGY REPORT WITH DIAGNOSIS AND FIRST TREATMENT

Statement

The lead time between the pathology report with a diagnosis of cancer and the start of treatment must be no longer than 4 weeks.

Rationale

Limiting the lead time between first consultation and primary treatment is considered important for high-quality services. This is relevant from a medical perspective and from the patient's perspective in terms of patient-centredness. The lead time between the consultation to discuss the pathology report with a diagnosis of cancer and primary treatment should not be longer than 4 weeks.

Quality domain: Clinical effectiveness; Personal empowerment and experience; Safety.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (GEN-11.1):** Proportion of women diagnosed in the BCS with lead time between pathology report with diagnosis of cancer and start of treatment no longer than 4 weeks.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT GEN-11

GEN-11.1 indicator	<p>Number of women with breast cancer diagnosed in the BCS who have no longer than 4 weeks' lead time between the pathology report with a diagnosis of breast cancer and primary treatment</p> <hr/> <p>Total number of women with breast cancer diagnosed and treated in the BCS</p> <p style="text-align: right;">x 100</p>
Type	Process
Target population	All women with breast cancer diagnosed and treated in the BCS.
Norm	90%
Data source	<p>Indicator to be calculated with the quality indicator calculator tool.</p> <p>The BCS provides documentation listing all patients treated in the previous calendar year, along with their lead time between the pathology report with a diagnosis of breast cancer and primary treatment. Data can potentially also be extracted from electronic or paper health records, either manually or via a batch report.</p>

GUIDELINE RECOMMENDATIONS GEN-11

Certainty of evidence Not applicable

Strength of recommendation Not applicable

Guideline recommendations

No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE GEN-11

- Anema HA, Kievit J, Fischer C, Steyerberg EW, Klazinga NS. Influences of hospital information systems, indicator data collection and computation on reported Dutch hospital performance indicator scores. *BMC Health Services Research* 2013, 13:212.
- DKG. Catalogue of requirements for Breast Cancer Centres of the German Cancer Society Version J2, 12 August 2019.
- Ferrua M, Couralet M, Nitenberg G, Morin S, Serin D, Minvielle E. Development and feasibility of a set of quality indicators relative to the timeliness and organization of care for new breast cancer patients undergoing surgery. *BMC Health Services Research* 2012, 12:167.
- Hoeve J van, Munck L de, Otter R, Vries J de, Siesling S. Quality improvement by implementing an integrated oncological care pathway for breast cancer patients. *The Breast* 23 (2014):364-370.
- Khare SR, Batist G, Bartlett G. Identification of performance indicators across a network of clinical cancer programs. *Curr Oncol.* 2016 Apr;23(2):81-90.
- Krzyzanowska MK, Barbera L, Elit L, Razzaq A, Saskin R, Nairayeritsyan, Bierman AS. Identifying population-level indicators to measure the quality of cancer care for women. *International Journal for Quality in Health Care* 2011; Volume 23, Number 5: pp. 554 – 564.
- NABON Breast Cancer Audit (NBCA) Factsheets Indicators 2016. DICA, IKNL, NBCA.
- Rosselli Del Turco M, Ponti A, Bick U, Biganzoli L, Cserni G, et al. Quality indicators in breast cancer care. *European Journal of Cancer* 46 (2010):2344-2356.
- Wilson ARM, Marotti L, Bianchi S, Biganzoli L, et al. The requirements of a specialist Breast Centre (EUSOMA). *European Journal of Cancer* (2013) 49, 3579-3587.

REFERENCE DOCUMENTS GEN-11

GEN-12: FERTILITY PRESERVATION

Statement

The BCS must have a written policy on informing patients about the possibility of fertility preservation.

Rationale

Some cancer treatments (e.g. chemotherapy and radiotherapy) can induce sterility. Fertility preservation is often possible, but to preserve the full range of options, fertility preservation approaches should be discussed as early as possible before treatment starts. The discussion can ultimately reduce distress and improve quality of life. Another discussion and/or referral may be necessary when the patient returns for follow-up and if pregnancy is being considered.

Quality domain: Personal empowerment and experience.

Breast cancer process: Diagnosis; Treatment.

Measurement: This requirement is measured by 2 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT GEN-12

GEN-12.1 criterion	Patients are informed about the possibility of fertility preservation as early as possible before treatment starts.
Type	Process
GEN-12.2 criterion	Patients with breast cancer who express an interest in fertility preservation are referred to reproductive specialists.
Type	Process

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	<p>GEN-12.1:</p> <ol style="list-style-type: none"> 1. Policy document/procedure protocol setting out when and how the patients are informed. 2. Auditors may ask patients who are present at the BCS during the audit, and undergoing treatments that can induce sterility, whether they have been informed about the possibility of fertility preservation in accordance with the policy. <p>GEN-12.2: Review of medical records. Random selection of at least 10 women in their fertile life phase who have undergone treatments that can induce sterility in the last 12 months.</p>

GUIDELINE RECOMMENDATIONS GEN-12

Certainty of evidence High

Strength of recommendation Strong

Guideline recommendations

- *Women desiring future fertility should be counselled on available fertility preserving options before starting anti-cancer treatment. Counselling should be implemented soon after diagnosis to allow prompt referral to fertility specialists* (ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up, 2013).
- *For women of childbearing age, fertility issues should always be discussed before the induction of breast cancer therapy. Strength of recommendation: strong. Quality of evidence: high* (KCE, 2013).
- *Chemotherapy during pregnancy is not contraindicated after 14 weeks of gestation. Strength of recommendation: weak. Quality of evidence: low* (KCE, 2013).

SUPPORTING LITERATURE GEN-12

- ESMO, 2013: Cancer, pregnancy and fertility: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up.
- Cancer Australia, 2010: Recommendations for follow-up of women with early breast cancer.
- NCCN, 2016: Breast Cancer.
- NAPBC (National Accreditation Program for Breast Centers) Standards Manual 2018.
- ASCO, 2016: Role of Patient and Disease Factors in Adjuvant Systemic Therapy Decision Making for Early-Stage, Operable Breast Cancer.
- KCE, 2013: BREAST CANCER IN WOMEN: DIAGNOSIS, TREATMENT AND FOLLOW-UP.
- ASCO, 2013: Fertility Preservation for Patients with Cancer.

REFERENCE DOCUMENTS GEN-12

GEN-13: COMPLEMENTARY AND INTEGRATIVE ONCOLOGY

Statement

The BCS must have a written policy to ask the patient about and discuss the use of complementary and integrative medicine for breast cancer.

Rationale

Complementary and integrative medicine (CIM) can be defined as a group of diverse medical healthcare systems, practices and products that are not generally considered to be part of conventional medicine. The use of complementary or integrative therapies among patients with cancer is constantly increasing in Western countries, although some therapies may increase risks and the benefits are unclear. Use of CIM can have an impact on treatment. Patients should be free to discuss this subject without any prejudice.

Quality domain: Clinical effectiveness; Safety; Personal empowerment and experience.

Breast cancer process: Treatment; Follow-up; Palliative care.

Measurement: This requirement is measured by 1 criterion.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT GEN-13

GEN-13.1 criterion	The BCS has implemented a policy to ensure discussion of the use of CIM. There is evidence from the auditors' site visit that this policy is implemented consistently.
Type	Process
Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	GEN-13.1: <ol style="list-style-type: none">1. The centre's standard operating procedure for assessing compliance, and the reports analysing that compliance.2. Auditors may ask patients about implementation of the policy.

GUIDELINE RECOMMENDATIONS GEN-13

Certainty of evidence Not applicable

Strength of recommendation Not applicable

Guideline recommendations

No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE GEN-13

- Baccetti S, Di Stefano M, Rossi E. *Le medicine complementari per il paziente oncologico*. Felici Edizioni, Pisa 2015.
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- Greenlee H, Balneaves LG, Carlson LE, Cohen M, Deng G, Hershman D, Mumber M, Perlmutter J, Seely D, Sen A et al. Clinical practice guidelines on the use of integrative therapies as supportive care in patients treated for breast cancer. *J. Natl. Cancer Inst. Monogr*. 2014, 2014, 346–358

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REFERENCE DOCUMENTS GEN-13

GEN-14: RESEARCH ACTIVITIES

Statement

The BCS must participate in research and must have a written policy on participation in research activities.

Rationale

Participation in research is considered important for bringing together cancer research and care institutions in Europe, in order to create a critical mass of expertise and competence. That includes research performed directly on patients in specific cases.

Quality domain: Clinical effectiveness.

Breast cancer process: All processes.

Measurement: This requirement is measured by 5 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT GEN-14

GEN-14.1 criterion	The research and clinical strategy plan is regularly updated with guidelines, trial procedures, quality procedures, etc.
Type	Structure
GEN-14.2 criterion	The organisation's responsibility within the research, innovation and development structures is clearly defined.
Type	Structure
GEN-14.3 criterion	The BCS is part of a clinical/research network.
Type	Structure
GEN-14.4 criterion	The clinical management unit and institutional review board are well defined.
Type	Structure
GEN-14.5 criterion	Structural cooperation between clinicians and researchers is well defined and organised.
Type	Structure

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	<p>GEN-14.1: The last update of the research strategy plan was less than 3 years ago.</p> <p>GEN-14.2: Document defining the organisational structure of the research area according to the country's regulation: governing entity, scientific director, internal scientific committee, external steering committee, etc.</p> <p>GEN-14.3: Signed document specifying that the BCS is part of a legally established research network or collaborative research consortium.</p> <p>GEN-14.4: Regulation/formal document describing the role of the clinical trials management unit and institutional review board.</p> <ol style="list-style-type: none">1. The clinical trials management unit reviews all proposals for clinical trials to ensure that they are of high quality and optimally designed, and that all the ethical, contractual and regulatory agreements are met.2. The institutional review board reviews research grant applications for quality. <p>GEN-14.5: Current collaboration agreement (document) between the BCS and the research institution(s).</p>

GUIDELINE RECOMMENDATIONS GEN-14

Certainty of evidence	Not applicable
Strength of recommendation	Not applicable
Guideline recommendations	No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE GEN-14

- CCIB systematic review on the impact of centres performing clinical research on clinical outcomes.
 - OECl Accreditation and Designation User Manual V. 3.0, 2019.
 - NAPBC (National Accreditation Program for Breast Centers) Standards Manual 2018.
 - NHS Scotland; Scottish Cancer Taskforce/National Cancer Quality Steering Group. Breast Cancer Clinical Quality Performance Indicators. May 2016.
 - Khare SR, Batist G, Bartlett G. Identification of performance indicators across a network of clinical cancer programs. *Curr Oncol.* 2016 Apr;23(2):81-90
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REFERENCE DOCUMENTS GEN-14

GEN-15: STAFF COMPETENCE

Statement

The BCS must have a policy to ensure that the professionals involved in patient care remain competent to deliver the service.

Rationale

Staff competence is assumed to be associated with high-quality care and better patient outcomes.

Quality domain: Clinical effectiveness; Facilities, resources and workforce.

Breast cancer process: All processes.

Measurement: This requirement is measured by 4 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT GEN-15

GEN-15.1 criterion	The BCS ensures that the professionals involved are qualified by acquiring verification of the validity of credentials required by law or regulation from the source that issued them.
Type	Process
GEN-15.2 criterion	All professionals involved in patient care participate annually in a minimum of 2 local, regional or national breast-specific continuing-education (CE, or equivalent) activities, appropriate to the discipline. Documentation of CE (or equivalent) units/credits is required.
Type	Process
GEN-15.3 criterion	The BCS ensures that all staff maintain their competency to undertake the role(s) to which they have been appointed.
Type	Process
GEN-15.4 criterion	The BCS ensures that the service maintains and adds competencies in line with the requirements of users and patients, including any individual special needs. These competencies are regularly assessed.
Type	Process

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	Sample review of staff files. GEN-15.1 Evidence of credential verification for professionals involved in patient care, in all staff files reviewed. GEN-15.2 Documentation of CE (or equivalent) units/credits from the 2 CE activities for professionals involved in patient care, in all staff files reviewed. GEN-15.3 Personal annual evaluation conducted by the head of unit or individual responsible, in all staff files reviewed. GEN-15.4 Documented evidence of privilege or competence assignment, maintenance or modification for professionals involved in patient care, conducted by the head of unit or individual responsible, in all staff files reviewed.

GUIDELINE RECOMMENDATIONS GEN-15

Certainty of evidence	Not applicable
Strength of recommendation	Not applicable

Guideline recommendations

No specific guideline recommendations available. Criteria derived from:

ISAS Standard 2017

- IAP Standard
- PAS 1616 standard
- SO 15189:2012
- ECIBC Working Groups (Competence and Training Subgroup inputs).

SUPPORTING LITERATURE GEN-15

- ISAS Standard 2017.
- IAP Standard.
- PAS 1616 standard.
- ISO 15189:2012.

REFERENCE DOCUMENTS GEN-15

GEN-16: MULTIDISCIPLINARY MEETINGS (MDMS)

Statement

The BCS must hold a multidisciplinary case management meeting at least once a week to discuss all patients before they start treatment (including patients with metastatic disease), after their primary treatment, and when there is any change in their treatment.

Rationale

Multidisciplinary teams are considered to optimise decision making in the diagnosis, treatment and support of patients. All patients with breast cancer who visit the BCS should be discussed by the multidisciplinary team.

Quality domain: Clinical effectiveness.

Breast cancer process: All processes.

Measurement: This requirement is measured by 2 criteria and 1 indicator.

- **Indicator to be monitored (GEN-16.3):** Proportion of women with breast cancer (absolute number of women counted) discussed by the multidisciplinary team before they start treatment, after their primary treatment, and when there is any change in their treatment.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT GEN-16

GEN-16.1 criterion 	There is a standard operating procedure describing how multidisciplinary meetings (MDMs) are managed, including team composition, meeting schedules, the team's role and responsibilities, how patients are referred to the MDM, and reports.
Type	Structure
GEN-16.2 criterion	Partipation of the following professionals in multidisciplinary meetings (MDMs) is mandatory: radiologists, oncoplastic breast surgeons (or both breast surgeons and plastic surgeons), pathologists, medical oncologists, radiation oncologists, breast care nurses, psycho-oncologists and data managers.
Type	Structure

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	GEN-16.1 and GEN-16.2: Ascertain that the standard operating procedure includes all the elements mentioned in the criteria.

GEN-16.3 indicator	<p>Number of women (absolute number of women counted) with breast cancer discussed by the multidisciplinary team before they start treatment (including patients with metastatic disease), after their primary treatment, and at any change in treatment</p> $\frac{\text{Number of women (absolute number of women counted) with breast cancer discussed by the multidisciplinary team before they start treatment (including patients with metastatic disease), after their primary treatment, and at any change in treatment}}{\text{Total number of women (absolute number of women counted) with breast cancer treated in the BCS}} \times 100$ <p>Total number of women (absolute number of women counted) with breast cancer treated in the BCS</p>
Type	Process
Target population	All women (absolute number of women counted) with breast cancer treated in the BCS.
Norm	≥ 90%
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool.

GUIDELINE RECOMMENDATIONS GEN-16

Certainty of evidence	Low to very low quality (risk of bias and imprecision)
Strength of recommendation	Conditional/provisional

Guideline recommendations

- IberoAmerican Cochrane Centre (Martinez, 2016):
We suggest that women with breast cancer are discussed in multidisciplinary meetings (provisional and conditional recommendation).
 - Five observational studies. Significant effects reported in favour of MDT for 5-year breast cancer mortality (RR 0.82, 95%CI 0.73 to 0.91), 5-year mortality (HR 0.83, 95%CI 0.78 to 0.89) and breast cancer specific 5-year survival (RR 1.04, 95%CI 1.02 to 1.07). Significantly more women satisfied with MDT than in the non-MDT group (RR 1.28, 95%CI: 1.06 to 1.54).

SUPPORTING LITERATURE GEN-16

- DKG. Catalogue of requirements for Breast Cancer Centres of the German Cancer Society Version J2, 12 August 2019.
 - OECI Quality standards V. 2015 Appendix II. OECI Accreditation and Designation.
 - Ferrua M, Couralet M, Nitenberg G, Morin S, Serin D, Minvielle E. Development and feasibility of a set of quality indicators relative to the timeliness and organization of care for new breast cancer patients undergoing surgery. *BMC Health Services Research* 2012, 12:16.
 - Martinez MJ, Posso M, Solà I, Alonso-Coello P. Should all breast cancer cases be discussed in multidisciplinary meetings? *Cochrane IberoAmerica*; 2016.
 - NABON Breast Cancer Audit (NBCA) Factsheets Indicators 2016. DICA, IKNL, NBCA.
 - NAPBC (National Accreditation Program for Breast Centers) Standards Manual 2018.
 - NHS England. Manual for Cancer Services; Breast Cancer Measures. National Peer Review Programme. 2013.
 - NHS Scotland; Scottish Cancer Taskforce/National Cancer Quality Steering Group. Breast Cancer Clinical Quality Performance Indicators. May 2016.
 - SIS/ISS. International Accreditation Program for Breast Centers/Units. 2013.
 - Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L (eds) (2006) European guidelines for quality assurance in breast cancer screening and diagnosis. 4th ed. European Commission; Office for Official Publications of the European Communities, Luxembourg.
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REFERENCE DOCUMENTS GEN-16

GEN-17: TIME BETWEEN THE DATE OF THE MULTIDISCIPLINARY MEETING (MDM) DISCUSSION AND FIRST TREATMENT

Statement

The BCS must report the time between the date of the MDM discussion and the start of the first treatment.

Rationale

It is important to monitor the time between the when the decision about treatment is made and when treatment actually starts.

Quality domain: Clinical effectiveness.

Breast cancer process: All processes.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (GEN-17.1):** Average number of days between the date of the multidisciplinary meeting (MDM) discussion and the start of the first treatment.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT GEN-17

GEN-17.1 indicator	The time between the date of the multidisciplinary meeting (MDM) discussion and the start of the first treatment. Measured as the number of days, calculated as an average.
Type	Process
Target population	All women (absolute number of women counted) with breast cancer treated in the BCS.
Norm	
Data source and additional information for auditing	Indicator to be calculated by the BCS To be measured at least annually and trends to be reported. The BCS should analyse data for trends in internal audits, which should include patients. Data can be used for benchmarking purposes.

GUIDELINE RECOMMENDATIONS GEN-17

Certainty of evidence Not applicable

Strength of recommendation Not applicable

Guideline recommendations

No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE GEN-17

- Ferrua M, Couralet M, Nitenberg G, Morin S, Serin D, Minvielle E. Development and feasibility of a set of quality indicators relative to the timeliness and organization of care for new breast cancer patients undergoing surgery. *BMC Health Services Research* 2012, 12:16.
- Martinez MJ, Posso M, Solà I, Alonso-Coello P. Should all breast cancer cases be discussed in multidisciplinary meetings? *Cochrane IberoAmerica*; 2016.
- NABON Breast Cancer Audit (NBCA) Factsheets Indicators 2016. DICA, IKNL, NBCA.
- NHS England. Manual for Cancer Services; Breast Cancer Measures. National Peer Review Programme. 2013.
- NHS Scotland; Scottish Cancer Taskforce/National Cancer Quality Steering Group. Breast Cancer Clinical Quality Performance Indicators. May 2016.
- SIS/ISS. International Accreditation Program for Breast Centers/Units. 2013.
- Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L (eds) (2006) European guidelines for quality assurance in breast cancer screening and diagnosis. 4th ed. European Commission; Office for Official Publications of the European Communities, Luxembourg.

REFERENCE DOCUMENTS GEN-17

GEN-18: NURSE ACCESS

Statement

The BCS must have at least 2 breast care nurses available throughout the entire patient pathway to ensure continuity of care.

Rationale

The breast care nurse is the patient's case manager throughout the entire care pathway and can act as a patient's advocate, offering an easily accessible route to address problems. By providing assessment, adequate information and psychosocial support to women at the diagnosis phase, during treatment, and during the follow-up and rehabilitation stage, breast care nurses can help women find more balance and better manage treatment-related symptoms and toxicity. Nurse-led follow-up can potentially result in better continuity of care and leave more time available for a patient's psychosocial and informational needs.

Quality domain: Personal empowerment and experience; Facilities, resources and workforce.

Breast cancer process: All processes.

Measurement: This requirement is measured by 4 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT GEN-18

GEN 18.1 criterion	The BCS has at least 2 breast care nurses to guarantee continuity of care.
Type	Structure
GEN 18.2 criterion	The breast care nurses are registered nurses with specialised training in breast care.
Type	Structure
GEN 18.3 criterion	A breast care nurse is available throughout the entire patient pathway (through diagnosis, treatment, follow-up and rehabilitation after initial treatment, and in case of recurrence and metastatic disease) to offer advice, support, further explanation of the treatment plan and educational information about side effects.
Type	Structure
GEN 18.4 criterion	The breast care nurse provides the clinical director with a report on all activities at least annually.
Type	Process

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	GEN-18.1: 1. The BCS' human resources list/document. 2. Direct observation. GEN-18.2: Staff files for the breast care nurses. GEN-18.3: Review of patients' medical records from the last 12 months to identify entries by breast care nurses. GEN-18.4: Breast care nurse's report (produced no longer than 12 months before the survey).

GUIDELINE RECOMMENDATIONS GEN-18

Certainty of evidence	Not applicable
Strength of recommendation	Not applicable
Guideline recommendations	No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE GEN-18

- DKG. Catalogue of requirements for Breast Cancer Centres of the German Cancer Society Version J2, 12 August 2019.
- Del Turco M, Ponti A, Bick U, Biganzoli L, Cserni G, et al. Quality indicators in breast cancer care. *European Journal of Cancer* 46(2010):2344-2356.
- Wilson ARM, Marotti L, Bianchi S, Biganzoli L, et al. The requirements of a specialist Breast Centre (EUSOMA). *European Journal of Cancer* (2013) 49, 3579-3587.
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- OECl Accreditation and Designation User Manual V. 3.0, 2019.

REFERENCE DOCUMENTS GEN-18

Dutch breast cancer guidelines, available at: www.oncoline.nl

GEN-19: NURSE REFERRAL

Statement

All women diagnosed with breast cancer must be consulted by a breast care nurse at the time of diagnosis.

Rationale

The breast care nurse is the patient's case manager throughout the entire care pathway and can act as a patient's advocate, offering an easily accessible route to address problems. Breast care nurses provide assessment and psychosocial support to women at the time of diagnosis or as soon as possible after, and before starting treatment. Adequate information can help women find more balance, control, information and support in making their choices.

Quality dimension: Clinical effectiveness, and Personal empowerment and experience.

Breast cancer process: Diagnosis; Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (GEN-19.1):** Proportion of women newly diagnosed with breast cancer who had a consultation with a breast care nurse at the time of diagnosis.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT GEN-19

GEN-19.1 indicator	Number of women with breast cancer who had a consultation with a breast care nurse at the time of the new diagnosis $\frac{\text{Number of women with breast cancer who had a consultation with a breast care nurse at the time of the new diagnosis}}{\text{Total number of women with newly diagnosed breast cancer}} \times 100$
Type	Process
Target population	Women aged ≥ 18 years newly diagnosed at the BCS. Exclusion: women diagnosed outside the BCS at another centre.
Norm	$\geq 95\%$
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool. The BCS needs to extract data from electronic or paper health records, either manually or via a batch report, to identify the indicator result.

GUIDELINE RECOMMENDATIONS GEN-19

Certainty of evidence Low

Strength of recommendation Unknown

Guideline recommendations

Oncoline: www.oncoline.nl/
(accessed on 20 November 2017).

SUPPORTING LITERATURE GEN-19

- Del Turco M, Ponti A, Bick U, Biganzoli L, Cserni G, et al. Quality indicators in breast cancer care. *European Journal of Cancer* 46(2010):2344-2356.
 - Wilson ARM, Marotti L, Bianchi S, Biganzoli L, et al. The requirements of a specialist BCS (EUSOMA). *European Journal of Cancer* (2013) 49, 3579-3587.
 - Biganzoli, Marotti, Hart et al. Quality indicators in breast cancer care: An update from the EUSOMA working group. *European Journal of Cancer* 86 (2017) 59e81.
 - OECI Accreditation and Designation User Manual V. 3.0, 2019.
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GEN-20: TRAINING

Statement

The BCS must ensure that healthcare professionals are qualified and competent to deliver the service ⁽⁶⁾.

Rationale

To provide high-quality care with better patient outcomes, healthcare professionals must have sufficient knowledge, expertise and skills to enable independent practice.

Quality domain: Facilities, resources and workforce.

Breast cancer process: All processes.

Measurement: This requirement is measured by 4 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT GEN-20

GEN-20.1 criterion	The radiographers, breast radiologists, medical physics experts, pathologists, breast care nurses, breast surgeons, oncoplastic breast surgeons, plastic surgeons, medical oncologists, radiation oncologists and psycho-oncologists working in the BCS meet all national requirements to be authorised to practise in their country.
Type	Structure
GEN-20.2 criterion	The abovementioned healthcare professionals working in the BCS are trained in communication skills and shared decision making periodically (at least every 5 years), to be demonstrated by attendance certificates.
Type	Structure
GEN-20.3 criterion	The abovementioned healthcare professionals working in the BCS have specific training and experience as detailed (see 'Additional information' below).
Type	Structure
GEN-20.4 criterion	Professionals who do not meet the abovementioned requirements are supervised by a professional with the corresponding qualifications and competences.
Type	Structure

⁶ See Glossary to check list and specifications of professions in breast cancer care.

Additional information (criterion GEN-20.3): specific training and experience required (see numbered notes below table)

Professionals	Attended a recognised (regional/national/international) ⁽⁷⁾ training course/activity/examination in	Volume of experience (number of cases during the previous calendar year)	Years of experience
Radiographers	Breast imaging ⁽⁸⁾	Performed at least 1 000 mammography examinations ⁽⁹⁾ (see requirement DGN-IMG-10)	
Breast radiologist	Breast imaging and diagnostic breast interventions ⁽⁸⁾	Read between 3 500 and 11 000 mammography examinations, within an organised screening programme ⁽¹⁰⁾	
Medical physics expert (MPE)	MPE in radiology (preferably MPE university training course and, if not available, EUTEMPE-RX)	Performed routine quality-assurance procedures on 5 mammography units	
Pathologist		Examined 100 breast specimens (see requirement DGN-PTH-2)	
Breast care nurse	Breast cancer care, including communicating breast cancer diagnosis, interventions offered in radiotherapy, and handling side effects		At least 1 year of post-registration experience in either a general or cancer setting

⁷ Recognised if:

- it was carried out in a certified/accredited training centre or breast centre;
- it is documented with continuing education (or equivalent) units or credits;
- the training content follows one of the included reference documents;
- it is recognised in the country of practice.

⁸ If not included in the general training for the medical specialism.

⁹ Retaken mammograms will not be considered.

¹⁰ See ECIBC recommendation on the number of readings for mammography readers in an organised screening programme.

Professionals	Attended a recognised (regional/national/international) ⁽⁷⁾ training course/activity/examination in	Volume of experience (number of cases during the previous calendar year)	Years of experience
Breast surgeon	Breast surgery	Performed primary surgeries on 50 newly diagnosed breast cancers (see requirement TRT-SUR-1)	At least 1 year of experience working in a breast surgery unit performing breast cancer surgery, after specialisation
Oncoplastic breast surgeon	Oncoplastic breast surgery	In charge of at least 50 breast cancer cases	At least 1 year of experience working in a breast surgery unit performing oncoplastic surgery, after specialisation
Plastic surgeon	Breast reconstruction ⁽⁸⁾		
Medical oncologist			At least 3 years of clinical experience in breast medical oncology, after specialisation
Radiation oncologist	Radiation protection ⁽⁸⁾		
Psycho-oncologist	Psycho-oncology	At least 1 year of experience working in psycho-oncology	

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	The BCS provides proof of compliance, such as: a list of names and licence confirmation for all listed professionals; certificates of attendance of specific training courses, continuing education credits, examinations, etc.; a case log for the past calendar year, confirming the number of cases; CV and working contracts confirming years of experience.

GUIDELINE RECOMMENDATIONS GEN-20

Certainty of evidence	Not applicable
Strength of recommendation	Not applicable
Guideline recommendations	
<ul style="list-style-type: none"> • <i>Only professionals with specialised training in their area of expertise should provide care to women participating in breast cancer screening programmes, breast cancer diagnostic services or screening assessment services</i> (ungraded good practice Statement) (ECIBC, 2021). <p>Criteria derived from available evidence listed under supporting literature used by ECIBC Working Groups (Competence and Training Subgroup inputs).</p>	

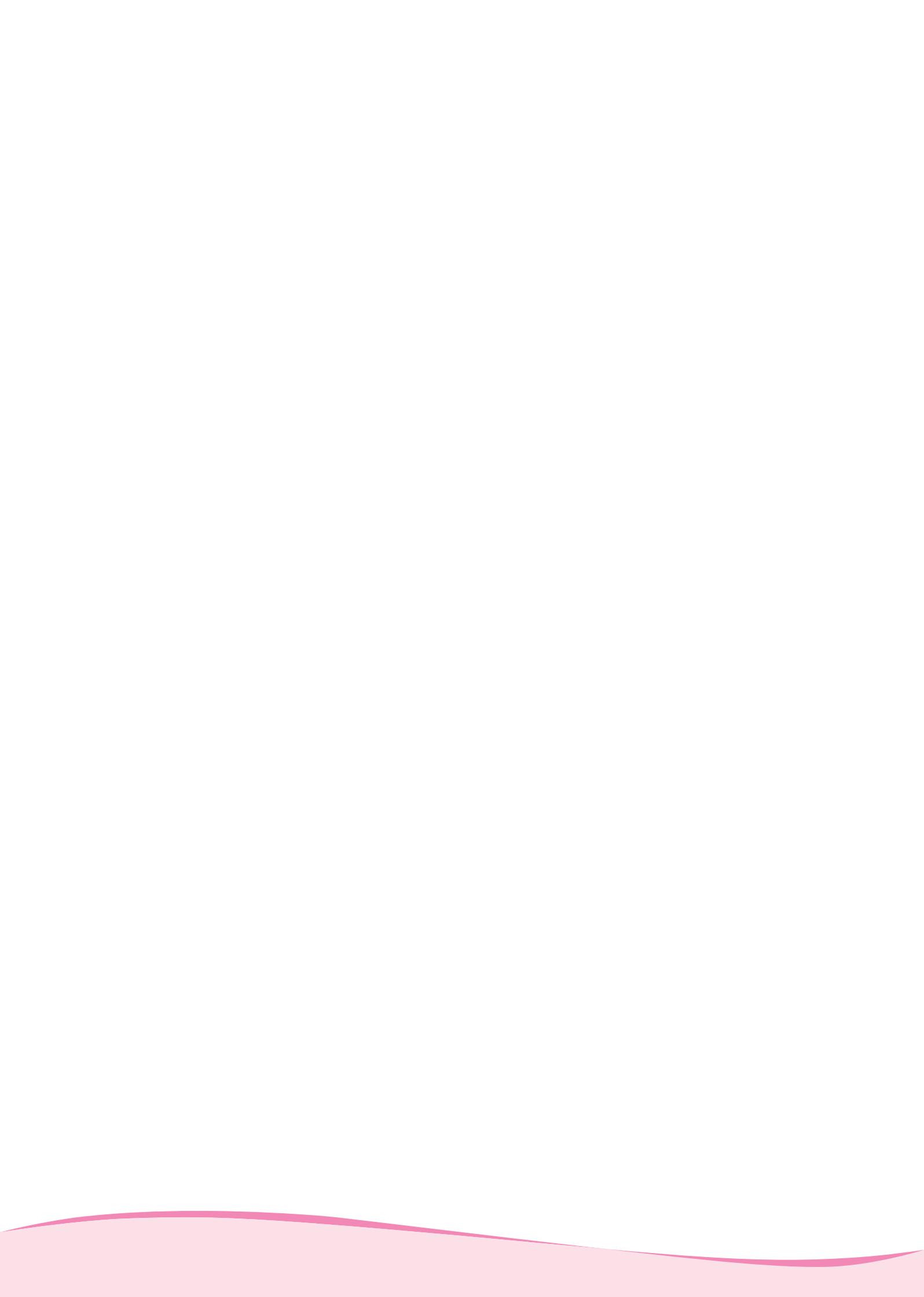
SUPPORTING LITERATURE GEN-20

- OEI Accreditation and Designation User Manual V. 3.0, 2019.
- NAPBC (National Accreditation Program for Breast Centers) Standards Manual 2018.
- Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L (eds) (2006) European guidelines for quality assurance in breast cancer screening and diagnosis. 4th ed. European Commission; Office for Official Publications of the European Communities, Luxembourg.
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- Wilson ARM, Marotti L, Bianchi S, Biganzoli L, et al. The requirements of a specialist Breast Centre (EUSOMA). *European Journal of Cancer* (2013) 49, 3579–3587.
- LRCB Dutch Reference Center for Screening. Accreditation Document, *The Radiographer*, 2012.
- ESR European Training Curriculum Level III (2018).
- DKG. Catalogue of requirements for Breast Cancer Centres of the German Cancer Society Version J2, 12 August 2019.
- European Commission, Radiation Protection No. 174, Guidelines on Medical Physics Expert, Directorate-General for Energy, Directorate D — Nuclear Safety & Fuel Cycle, Unit D.3 — Radiation Protection, 2014.

- Caruana CJ, Christofides S, Hartmann GH. European Federation of Organisations for Medical Physics (EFOMP) Policy **Statement** 12.1: Recommendations on Medical Physics Education and Training in Europe 2014. *PhysicaMedica*. 2014;30(6):598–603.
 - European Parliament and Council Recommendation 2008/C 111/01 on the establishment of the European Qualifications Framework for lifelong learning.
 - RP174 European guidelines on the Medical Physics Expert. EC. (2014).
 - EC. Council Directive 2013/59/EURATOM of 5 December 2013.
 - German Mammography Screening Program. Quality assurance in the mammography screening program: <https://fachservice.mammo-programm.de/fortbildungsangebote/fortbildungen> (accessed April 2019).
 - Geller et al. 2017 Characteristics associated with requests by pathologists for second opinions on breast biopsies. *J Clin Pathol*. 2017 November; 70(11): 947–953 NHS England. Quality Assurance Guidelines for Breast Pathology Services. 2011.
 - SIS/ISS. International Accreditation Program for Breast Centers/Units. 2013.
 - Guidelines for Quality Assurance in Mammography Screening – BreastCheck Ireland- 2015.
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 - Del Turco M, Ponti A, Bick U, Biganzoli L, Cserni G, et al. Quality indicators in breast cancer care. *European Journal of Cancer* 46(2010):2344-2356.
 - EONS Cancer Nursing Curriculum 2013.
 - Interim Quality Assurance Guidelines For Clinical Nurse Specialists In Breast Cancer Screening, NHS, 2012.
 - European Training Requirements for Breast Surgery. European Standards of Postgraduate Medical Specialist Training 2015.
 - NHS England. Quality Assurance Guidelines for Surgeons in Breast Cancer Screening 2009.
 - DKG. Catalogue of requirements for Breast Cancer Centres of the German Cancer Society 2019.
 - Pavlidis N, Alba E, Berardi R et al, The ESMO/ASCO global curriculum and evolution of medical oncology training in Europe. *ESMOopen* 2015.
 - Multidisciplinary training of cancer specialists in Europe. *Eur J Cancer*. 2017 Sep ;83 :1-8. Doi : 0.1016/j.ejca.2017.05.043. Epub 2017 Jul 10.
 - Dittrich C, Kosty M, Jezdic S, et al. ESMO/ASCO Recommendations for a Global Curriculum in Medical Oncology Edition 2016. *ESMO Open*. 2016;1(5):e000097. Published 2016 Sep 29. Doi:10.1136/esmooopen-2016-000097.
 - Eriksen et al., The updated ESTRO core curricula 2011 for clinicians, medical physicists and RTTs in radiotherapy/radiation oncology. *Radiother Oncol* 103, 103-108, 2012.
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 - Travado L, and Dalmas M. Psychosocial Oncology Care. (pp 35-39). In *European Guide for Quality National Cancer Control Programmes*. Albrecht Y, Martin-Moreno JM, Jelenc M, Gorgojo L, Harris M (Eds). National Institute of Public Health, Ljubljana, Slovenia, 2015.
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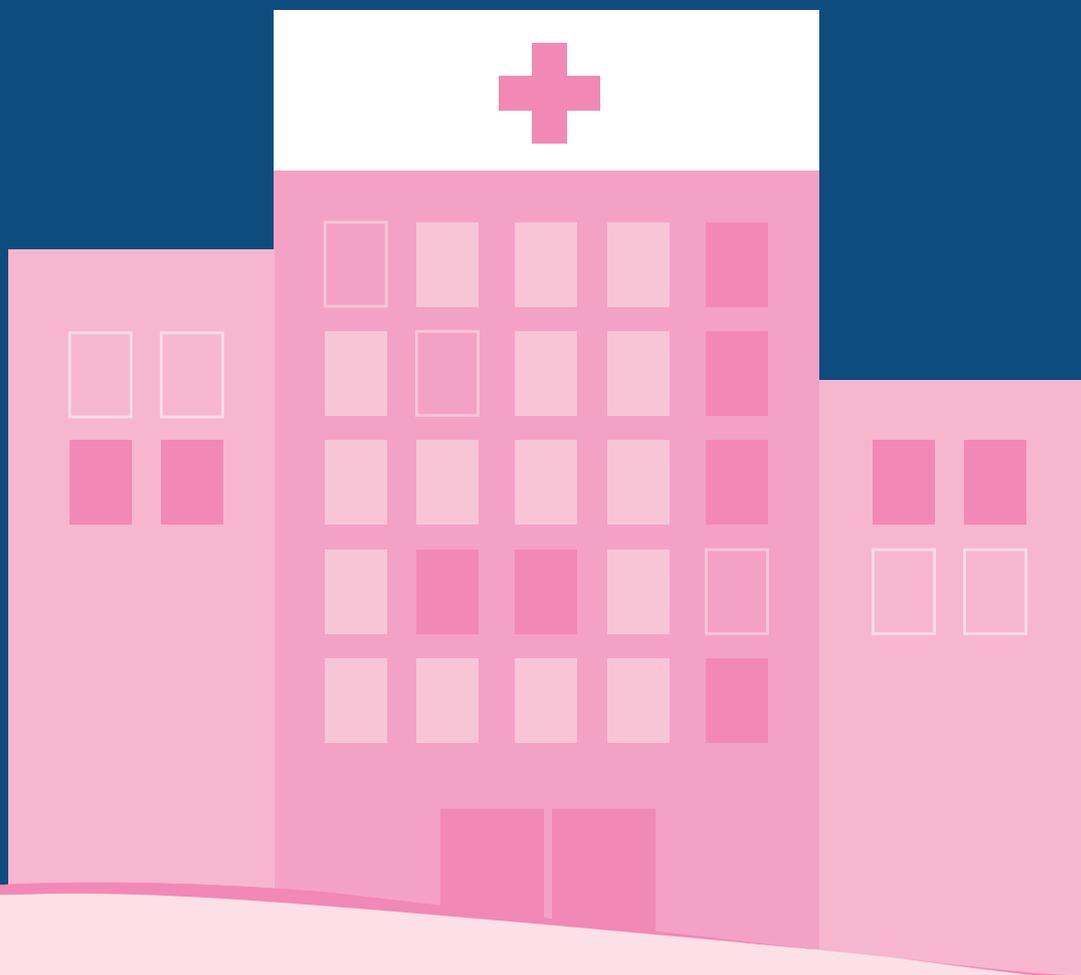
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- ESMO/ASCO Global Curriculum for training in medical oncology, Log Book, third edition, 2017.
- ESR European Training Curriculum Level III (2018).
- Cataliotti L, De Wolf C, Holland R. Guidelines on the standards for the training of specialised health professionals dealing with breast cancer. *Eur J Cancer* 2007; 43:660–75.
- Royal College of Pathologists, Curriculum for Specialty Training in Histopathology, 2015
- EUEMS European Training Requirements for Breast Surgery: https://uemssurg.org/__data/assets/pdf_file/0007/27637/ETR-Breast-Surgery-October-2015son.pdf (accessed on 16 October 2020).
- UEMS Breast Surgery Examination Syllabus: https://uemssurg.org/__data/assets/pdf_file/0003/57918/Breast-Surgery-syllabus-2018-final.pdf (accessed on 16 October 2020).
- ESSO Core Curriculum, 2013: <https://www.essoweb.org/media/documents/core-curriculum.pdf> (accessed on 16 October 2020).
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CHAPTER 2

SCREENING REQUIREMENTS (SCR)



SCREENING REQUIREMENTS

CODE	NAME	STATEMENT
SCR-1 	Screening programme	The organised screening programme must comply with the European guidelines for breast cancer screening and diagnosis (ECIBC).
SCR-2 	Reporting of screening programme indicators	The population screening programme should collect and periodically report data to monitor the results of the screening process.
SCR-3	Screening centre	The centre performing mammography screening must collect and periodically report data to monitor the results of the screening process.
SCR-4	Screening of women aged 50–69	Women aged 50–69 must be invited for mammography screening as part of a screening programme.
SCR-5	Lifestyle information	The centre providing breast screening must have a written policy for informing women about a healthy lifestyle (including nutrition and physical activity).
SCR-6	Women-reported outcome measures (PROMs) policy	The screening programme must have a policy for routine measurement of women-reported outcomes (satisfaction with screening) to monitor the well-being of women attending breast cancer screening.
SCR-7	Relevance to women	The screening programme must have implemented a policy to ensure relevant women-centred care.
SCR-8	Keeping women informed	The screening programme must have a written policy on how to keep women participating in the screening process informed.
SCR-9	Research activities	The screening programme must participate in research and must have a written policy for participation in research activities.
SCR-10	Multidisciplinary meetings (MDMs)	The screening programme must hold an MDM at least once a week to analyse the screening activity.
GEN-3*	Quality improvement policy	The BCS must have a written quality improvement policy, including a quality management system, a patient safety system, and a clinical information system for monitoring the quality of breast cancer care.
GEN-4*	Data management	The BCS must have a written policy defining the governance of data management.

CODE	NAME	STATEMENT
GEN-15*	Staff competence	The BCS must have a policy to ensure that the professionals involved in patient care remain competent to deliver the service.
GEN-20*	Training	The BCS must ensure that healthcare professionals are qualified and competent to deliver the service.
DGN-IMG-2*	Optimal mammographic image quality	The BCS must implement documented protocols to achieve optimal mammographic image quality and to check it periodically, including correct breast positioning, compression, immediate repeat imaging and recalls for technical reasons.
DGN-IMG-4*	Imaging equipment	The BCS must have a documented policy and protocols covering the selection, purchasing, installation, acceptance, calibration, operation, management, quality control, maintenance and, where relevant, replacement of all equipment that is used in breast imaging and intervention.
DGN-IMG-5*	Imaging facilities	The BCS must have all the necessary equipment to perform the specified imaging and image-guided diagnostic examinations.
DGN-IMG-6*	Mammogram labelling	The BCS must ensure that mammography image labelling identifies the woman correctly.
DGN-IMG-7*	Radiologist performance	The BCS must have a written policy to ensure that it reviews the performance of radiologists periodically.
DGN-IMG-8*	Policy on managing the throughput of women attending screening	The BCS must have a policy to separate women waiting for first-level screening from women waiting for diagnostic procedures or follow-up after therapy.
DGN-IMG-10*	Annual number of mammography examinations for radiographers	All mammograms completed in the BCS must be performed by radiographers who personally carry out a minimum of 1 000 mammography examinations per year.

*These requirements are also applicable to the screening programme. The full description for each of these can be found in Chapter I: General requirements (GEN) and Chapter III.a: Diagnosis (DGN), Pathology (DGN-PTH) and Imaging (DGN-IMG).

SCR-1: SCREENING PROGRAMME

Statement

The organised screening programme must comply with the European guidelines for breast cancer screening and diagnosis (ECIBC).

Rationale

Organised, population-based screening programmes for the early detection of breast cancer based on evidence-based recommendations are effective, and implementing these recommendations can improve and maintain the quality of the screening process. Shorter or longer screening intervals have the potential to increase harm.

Quality domain: Clinical effectiveness.

Breast cancer process: Screening.

Measurement: This requirement is measured by 9 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT SCR-1

SCR-1.1 criterion	The screening programme has a systematic call/recall system in place.
Type	Structure
SCR-1.2 criterion	The screening programme ensures the availability of appropriate, ECIBC-certified diagnostic, treatment and
Type	Structure
SCR-1.3 criterion	The screening programme has a screening policy specifying at least the target population, screening method and interval (see recommendations listed in the guideline recommendations section).
Type	Structure
SCR-1.4 criterion	The screening programme covers a defined target population.
Type	Structure
SCR-1.5 criterion	The screening programme ensures that the entire target population is actively invited and reached over time.
Type	Structure

SCR-1.6 criterion	The screening programme has a team responsible for overseeing screening centres.
Type	Structure
SCR-1.7 criterion	The screening programme has in place a structure for decision making and taking responsibility for healthcare management.
Type	Structure
SCR-1.8 criterion	The screening programme has a quality assurance system that uses the relevant data (see GEN-3 and GEN-4).
Type	Structure
SCR-1.9 criterion	The screening programme monitors cancer occurrence in the target population (including linking to relevant registries for programme monitoring and evaluation).
Type	Structure

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	BCS documentation, including policy and protocols for adopting the European guidelines for breast cancer screening and diagnosis. To be checked in the audit: Documents describing the governance, team (with defined roles and responsibilities) and structures involved; the call/recall process; cooperation to ensure diagnosis, treatment and aftercare; the screening policy and invitation process; transmission of the results; and reporting of indicators (see SCR-2: Reporting of screening programme indicators). The screening programme has put a quality management system in place to monitor quality and continuous quality improvement. Monitoring covers at least all the indicators included in the manual for the screening process.

GUIDELINE RECOMMENDATIONS SCR-1

Certainty of evidence Moderate

Strength of recommendation Strong

Guideline recommendations

The ECIBC's Guidelines Development Group recommends using an organised mammography screening programme for early detection of breast cancer in asymptomatic women (strong recommendation, moderate certainty of evidence). <https://healthcare-quality.jrc.ec.europa.eu/european-breast-cancer-guidelines/organisation-of-screening-programme> (last access: 06/04/2021)

Screening age:

- For asymptomatic women **aged 40 to 44** with an average risk of breast cancer, the ECIBC's Guidelines Development Group (GDG) suggests **not implementing mammography screening** (conditional recommendation, moderate certainty in the evidence).
- For asymptomatic women **aged 45 to 49** with an average risk of breast cancer, the ECIBC's Guidelines Development Group (GDG) suggests **against annual mammography screening over biennial or triennial mammography screening in the context of an organised screening programme** (conditional recommendation, very low certainty in the evidence).
- For asymptomatic women **aged 45 to 49** with an average risk of breast cancer, the ECIBC's Guidelines Development Group (GDG) suggests **either triennial or biennial mammography screening in the context of an organised screening programme** (conditional recommendation, very low certainty in the evidence).
- For asymptomatic women **aged 50 to 69** with an average risk of breast cancer, the ECIBC's Guidelines Development Group (GDG) recommends **against annual mammography screening in the context of an organised screening programme** (strong recommendation, very low certainty in the evidence).
- For asymptomatic women **aged 50 to 69** with an average risk of breast cancer, the ECIBC's Guidelines Development Group (GDG) suggests **biennial mammography screening over triennial mammography screening in the context of an organised screening programme** (conditional recommendation, very low certainty in the evidence).
- For asymptomatic women **aged 70 to 74** with an average risk of breast cancer, the ECIBC's Guidelines Development Group (GDG) recommends **against annual mammography screening in the context of an organised screening programme** (strong recommendation, very low certainty in the evidence).
- For asymptomatic women **aged 70 to 74** with an average risk of breast cancer, the ECIBC's Guidelines Development Group (GDG) suggests **triennial mammography screening over biennial mammography screening in the context of an organised screening programme** (conditional recommendation, very low certainty in the evidence).

Screening test:

- For asymptomatic women with an average risk of breast cancer, the ECIBC's Guidelines Development Group (GDG) **suggests against screening with digital breast tomosynthesis (DBT) over digital mammography (DM), in the context of an organised screening programme** (conditional recommendation, very low certainty in the evidence). Since the GDG made a strong recommendation for screening at **ages 50-69**, this applies specifically to this age group. In settings and where the increased costs are not a barrier to implementation, the GDG felt that the increased breast cancer detection rate associated with DBT may warrant its implementation.
- For asymptomatic women with an average risk of breast cancer, the ECIBC's Guidelines Development Group (GDG) **suggests against screening with DBT in addition to DM over DM alone, in the context of an organised screening programme** (conditional recommendation, very low certainty in the evidence).
- For asymptomatic women, **with high mammographic breast density and negative mammography**, in the context of an organised screening programme, the ECIBC's Guidelines Development Group **suggests not implementing tailored screening with automated breast ultrasound system (ABUS) over mammography screening alone** (conditional recommendation, very low certainty of the evidence).
- For asymptomatic women, **with high mammographic breast density and negative mammography**, in the context of an organised screening programme, the ECIBC's Guidelines Development Group **suggests additional screening with digital breast tomosynthesis or mammography screening alone** (conditional recommendation, low certainty in the evidence).
- For asymptomatic women, **with high mammographic breast density and a negative mammography**, in the context of an organised screening programme, the ECIBC's Guidelines Development Group **suggests not implementing tailored screening with hand-held ultrasound (HHUS) over mammography screening alone, where such is not already the practice** (conditional recommendation, low certainty of the evidence).
- For asymptomatic women, **with high mammographic breast density and a negative mammography**, in the context of an organised screening programme, the ECIBC's Guidelines Development Group **suggests not implementing tailored screening with magnetic resonance imaging (MRI) over mammography screening alone** (conditional recommendation, very low certainty of the evidence).
- The ECIBC's Guidelines Development Group suggests using double reading (with consensus or arbitration) over single reading to screen mammograms for early detection of breast cancer in mammography screening programmes (conditional recommendation, moderate certainty).

Invitation to screening:

- *The ECIBC's Guidelines Development Group recommends using a letter for inviting asymptomatic women aged 50 to 69 with an average risk of breast cancer (in whom screening is strongly recommended) to attend organised population-based screening programmes (Strong Recommendation, Moderate Certainty Evidence).*
- *The ECIBC's Guidelines Development Group suggests using either a letter with a General Practitioner's (GP) signature, a letter with a fixed appointment, a letter followed by a phone reminder or a letter followed by a written reminder over letters alone, for inviting asymptomatic women aged 50 to 69 with an average risk of breast cancer (in whom screening is strongly recommended) to attend organised population-based screening programmes (Conditional Recommendation, Moderate Certainty Evidence).*
- *The ECIBC's Guidelines Development Group suggests against using a letter accompanied by a face-to-face intervention, for inviting asymptomatic women aged 50 to 69 with an average risk of breast cancer (in whom screening is strongly recommended) to attend organised population-based screening programmes (Conditional Recommendation, Low Certainty Evidence).*
- *The ECIBC's Guidelines Development Group (GDG) suggests using a decision aid that explains the benefits and harms of screening over a 'regular' invitation letter for informing women about the benefits and harms of breast cancer screening (conditional recommendation, moderate certainty in the evidence).*

Communication strategy:

- *The ECIBC's Guidelines Development Group suggests in favour of using a targeted communication strategy instead of a general communication strategy to improve participation in screening programmes of socially disadvantaged women between the ages of 50 and 69 (conditional recommendation, low certainty in the evidence).*
- *The ECIBC's Guidelines Development Group suggests against using a tailored letter instead of a general communication strategy to improve participation in breast cancer screening programmes for socially disadvantaged women (conditional recommendation, moderate certainty in the evidence).*
- *The ECIBC's Guideline Development Group suggests using tailored or targeted communication strategies to improve participation in breast cancer screening programmes for socially disadvantaged women (conditional recommendation, very low certainty of the evidence).*
- *The ECIBC's Guidelines Development Group suggests in favour of using a targeted communication strategy instead of a general communication strategy to improve participation in screening programmes of women with intellectual disability between the ages of 50 and 69 (conditional recommendation, low certainty in the evidence).*
- *The ECIBC's Guidelines Development Group suggests in favour of using a targeted communication strategy instead of a general communication strategy to improve participation in non-native speaking women (conditional recommendation, low certainty in the evidence).*

(ECIBC guidelines)

SUPPORTING LITERATURE SCR-1

- European guidelines for breast cancer screening and diagnosis: <https://healthcare-quality.jrc.ec.europa.eu/european-breast-cancer-guidelines>
 - <https://healthcare-quality.jrc.ec.europa.eu/european-breast-cancer-guidelines> (accessed on 20 September 2020).
 - Madlensky L, Goel V Polzer J Ashbury FD. Assessing the evidence for organised cancer screening programmes. Eur J Cancer; 2003.
 - Ponti A, Anttila A, Ronco G, Senore C, Basu P, Segnan N et al. (IARC). Cancer screening in the European Union. Report on the implementation of the Council Recommendation on cancer screening (second report). Brussels: European Commission; 2017.
 - Eichholzer M, Richard A, Rohrmann S, Schmid SM, Leo C, Huang DJ, G uth U. Breast cancer screening attendance in two Swiss regions dominated by opportunistic or organized screening. BMC Health Serv Res; 2016.
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REFERENCE DOCUMENTS SCR-1

SCR-2: REPORTING OF SCREENING PROGRAMME INDICATORS



Statement

The population screening programme should collect and periodically report data to monitor the results of the screening process.

Rationale

Indicator monitoring can be used for quality improvement purposes. The screening programme should report the indicators listed below.

Quality domain: Clinical effectiveness.

Breast cancer process: Screening.

Measurement: This requirement is measured by 20 indicators.

1. Participation rate.
2. Invasive breast cancer detection rate.
3. Screening coverage.
4. Interval cancer rate.
5. Episode sensitivity.
6. Recall rate.
7. Breast cancer detection rate.
8. Invasive cancers \leq 10 mm rate.
9. Invasive cancers $>$ 20 mm rate.
10. Lymph node negative rate.
11. Time interval between screening and treatment.
12. Benign open surgery biopsy rate.
13. Advanced cancer (T2+), review errors.
14. Interval cancer, review errors.
15. Technical repeat examination.
16. Time between screening mammogram and issuing of results.
17. Proportion of screened women subject to early recall (see definition in the specification section) following diagnostic assessment.
18. Time between result of screening mammography and assessment offered.
19. Time between the assessment and issuing the result of the assessment when needle biopsy is not performed.
20. Time between the assessment and issuing the result of the assessment when needle biopsy is performed.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT SCR-2.1

SCR-2.1 indicator	Number of women screened _____ x 100
Participation rate	Total number of women invited
SCR-2.2 indicator	Number of invasive cancers screen-detected _____ x 100
Invasive breast cancer detection rate	Total number of women screened
SCR-2.3 indicator	Number of women screened _____ x 100
Screening coverage	Total number of eligible (or target) women within a given period
SCR-2.4 indicator	Number of interval cancers _____ x 100
Interval cancer rate	Total number of screened negative women at the last screening round
Interval cancer	Breast cancer that is diagnosed during the time between a regular screening mammogram that appears normal and the next screening mammogram. (National Cancer Institute: https://www.cancer.gov/publications/dictionaries/cancer-terms/def/interval-breast-cancer).
SCR-2.5 indicator	Number of screen-detected cancers _____ x 100
Episode sensitivity	Total number of all cancers detected (screen-detected and interval)
SCR-2.6 indicator	Number of women undergoing further assessment for clinical reasons based on a positive screening examination _____ x 100
Recall rate	Total number of women screened for breast cancer
SCR-2.7 indicator	Number of cancers screen-detected _____ x 100
Breast cancer detection rate	Number of women screened

SCR-2.8 indicator	Number of invasive cancers ≤10 mm screen-detected _____ x 100
Invasive cancers ≤ 10 mm rate	Total number of invasive cancers screen-detected
SCR-2.9 indicator	Number of invasive cancers > 20 mm screen-detected _____ x 100
Invasive cancers > 20 mm rate	Total number of women screened
SCR-2.10 indicator	Number of node-negative cancers screen-detected _____ x 100
Lymph node negative rate	Total number of invasive cancers screen-detected (pathologically determined)
SCR-2.11 indicator	Time interval between screening mammogram and treatment: median number of days
Time interval between screening and treatment	
SCR-2.13 indicator	Number of T2+ screen-detected cancers with previous mammogram (previous round) reviewed and defined as an incorrect reading (cancer was already present) _____ x 100
Advanced cancer (T2+), review errors	Total number of T2 cancers detected
SCR-2.14 indicator	Number of interval cancers with previous mammogram reviewed and defined as an incorrect reading _____ x 100
Interval cancer, review errors	Total number of interval cancers
SCR-2.15 indicator	Number of women with a repeat examination for technical reasons _____ x 100
Technical repeat examination	Total number of women screened

SCR-2.16 indicator	Time between screening mammogram and issuing of results	Time interval between screening mammogram and issuing of results: median number of days.
SCR-2.17 indicator	Proportion of screened women subject to early recall following diagnostic assessment	Number of women subjected to early recall following diagnostic assessment _____ x 100 Total number of women with negative (no cancer) diagnostic assessment
Explanation of terms		Early recall is defined as the recommendation for a woman to undergo short-term rescreening at an interval that is less than the programme's routine round length.
Norm		< 1%
SCR-2.18 indicator		Time between result of screening mammography and assessment offered
		Time between the screening mammography (date) and the first step of diagnostic assessment: median number of days.
SCR-2.19 indicator	Time between the assessment and issuing of the result when needle biopsy is not performed	Time between the date of diagnostic imaging and the date of the first step of further assessment: median number of days
SCR-2.20 indicator	Time between the assessment and issuing of the result when needle biopsy is performed	Time between the first step of the diagnostic assessment and issuing the final result of the needle biopsy, when performed: median number of days.

FOR ALL INDICATORS

Type	Process
Specifications	Indicators must be reported separately for first screening mammography and subsequent screening mammography. Indicators must be measured at least annually and trends reported. Screening programs should analyse data for trends in internal audits. Data can be used for benchmarking purposes.
Target population	Legal entity applying for certification.
Data source and additional information for auditing	<p>Indicator to be calculated by the screening programme.</p> <p>Documentation and data from the breast screening programme participating in population screening.</p> <p>The screening programme must describe how the indicators have been calculated, and provide the values for each indicator for the year(s) relevant to the certification process.</p> <p>Note: The programme will have to calculate these indicators. However, if that is not possible for all of them, certification can still be granted.</p>

GUIDELINE RECOMMENDATIONS SCR-2

Certainty of evidence	Not applicable
Strength of recommendation	Not applicable
<p>Guideline recommendations</p> <p>See key performance indicators summary table.</p> <ul style="list-style-type: none"> • Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L (eds) (2006). European guidelines for quality assurance in breast cancer screening and diagnosis. 4th ed. European Commission; Office for Official Publications of the European Communities, Luxembourg. 	

SUPPORTING LITERATURE SCR-2

- Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L (eds) (2006). European guidelines for quality assurance in breast cancer screening and diagnosis. 4th ed. European Commission; Office for Official Publications of the European Communities, Luxembourg.
 - <https://www.cancer.gov/types/breast/hp/breast-screening-pdq>
 - NHS Scotland; Scottish Cancer Taskforce/National Cancer Quality Steering Group. Breast Cancer Clinical Quality Performance Indicators. May 2016.
 - Bulliard JL, Variation in performance in low-volume mammography screening programmes: experience from Switzerland, 2011.
-

REFERENCE DOCUMENTS SCR-2

SCR-3: SCREENING CENTRE

Statement

The centre performing mammography screening must collect and periodically report data to monitor the results of the screening process.

Rationale

Indicator monitoring can be used for quality improvement purposes. The number of women identified with breast cancer in the screening programme is a surrogate indicator for the quality of care to be used in internal audits and for benchmarking. The centre performing mammography screening should report the indicators listed below.

Quality domain: Clinical effectiveness.

Breast cancer process: Screening.

Measurement: This requirement is measured by 3 indicators.

1. Recall rate.
2. Breast cancer detection rate.
3. Invasive cancers ≤ 10 mm rate.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT SCR-3.1

SCR-3.1 indicator	Number of women undergoing further assessment for clinical reasons based on a positive screening examination	_____ x 100
Recall rate	Total number of women screened for breast cancer	
Target population	Women screened for breast cancer.	
SCR-3.2 indicator	Number of cancers screen-detected	_____ x 100
Breast cancer detection rate	Total number of women screened	
Target population	Women screened for breast cancer.	
SCR-3.3 indicator	Number of invasive cancers ≤ 10 mm screen-detected	_____ x 100
Invasive cancers ≤ 10 mm rate	Total number of invasive cancers screen-detected	
Target population	Women with invasive cancers screen-detected.	

FOR ALL INDICATORS

Type	Structure
Norm	The acceptable and desirable levels of the rates to be achieved for each of the 3 components should be specified. These have not yet specified, and the indicator is therefore a monitoring tool.
Data source and additional information for auditing	Indicator to be calculated by the screening centres. <ul style="list-style-type: none">• To be measured at 6-month intervals and trends reported.• Centres should reflect on the trends identified in an annual internal audit.• Data can be used for benchmarking purposes.

GUIDELINE RECOMMENDATIONS SCR-3

Certainty of evidence	Not applicable
Strength of recommendation	Not applicable
Guideline recommendations	See key performance indicators summary table. Perry, 2006.

SUPPORTING LITERATURE SCR-3

- Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L (eds) (2006). European guidelines for quality assurance in breast cancer screening and diagnosis. 4th ed. European Commission; Office for Official Publications of the European Communities, Luxembourg.
- <https://www.cancer.gov/types/breast/hp/breast-screening-pdq>.

REFERENCE DOCUMENTS SCR-3

SCR-4: SCREENING OF WOMEN AGED 50–69

Statement

Women aged 50–69 must be invited for mammography screening as part of a screening programme.

Rationale

BCSs participating in a population breast cancer screening programme should adhere to guideline recommendations reflecting state-of-the-art evidence. The ECIBC Guideline Development Group has formulated a strong recommendation that women aged 50–69 with an average risk of breast cancer should undergo mammography screening.

Note: This only addresses this specific age group. There are conditional recommendations for other age groups (see guideline recommendations).

Quality domain: Clinical effectiveness.

Breast cancer process: Screening.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (SCR-4.1):** Proportion of asymptomatic women aged 50–69 who were invited for screening within a screening programme.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT SCR-4

SCR-4.1 indicator	Number of asymptomatic women aged 50–69, who were invited for screening within a screening programme. <hr style="width: 80%; margin-left: 0;"/> x 100 Total number of asymptomatic women aged 50–69
Type	Process
Target population	Asymptomatic women aged 50–69.
Norm	≥ 95%
Explanation of terms	This only addresses this specific age group. There are conditional recommendations for other age groups.
Data source and additional information for auditing	Indicator to be calculated by the screening programme. The BCS will need to extract data from electronic or paper health records, either manually or via a batch report, to identify: the total number of asymptomatic women aged 50–69 (denominator); the number of asymptomatic women aged 50–69 who were invited for screening within a screening programme (numerator); and the number of asymptomatic women aged 50–69 for whom it is unknown whether they were invited for screening within a screening programme (missing). The time frame should be specified, e.g. 1 or 2 calendar years.

GUIDELINE RECOMMENDATIONS SCR-4

Certainty of evidence Moderate (based on currently developed guideline recommendations).

Strength of recommendation Strong

Guideline recommendations

Current recommendations of the European guidelines on breast cancer screening and diagnosis (<https://healthcare-quality.jrc.ec.europa.eu/european-breast-cancer-guidelines>, last access 06/04/2021):

- *For asymptomatic women aged 40 to 44 with an average risk of breast cancer, the ECIBC's Guidelines Development Group (GDG) suggests not implementing mammography screening (conditional recommendation, moderate certainty of the evidence).*
- *For asymptomatic women aged 45 to 49 with an average risk of breast cancer, the ECIBC's Guideline Development Group (GDG) suggests mammography screening over no mammography screening, in the context of an organised screening programme (conditional recommendation, moderate certainty of the evidence).*
- *For asymptomatic women aged 50 to 69 with an average risk of breast cancer, the ECIBC's Guidelines Development Group (GDG) recommends mammography screening over no mammography screening, in the context of an organised screening programme (strong recommendation, moderate certainty of the evidence).*
- *For asymptomatic women aged 70 to 74 with an average risk of breast cancer, the ECIBC's Guideline Development Group (GDG) suggests mammography screening over no mammography screening, in the context of an organised screening programme (conditional recommendation, moderate certainty of the evidence).*

SUPPORTING LITERATURE SCR-4

- <https://healthcare-quality.jrc.ec.europa.eu/european-breast-cancer-guidelines>, last access 06/04/2021.

REFERENCE DOCUMENTS SCR-4

SCR-5: LIFESTYLE INFORMATION

Statement

The centre providing breast screening must have a written policy for informing women about a healthy lifestyle (including nutrition and physical activity).

Rationale

The role of nutrition and physical activity in cancer prevention has been extensively reviewed and shows that the incidence of the most common cancers could correlate with changes in these health behaviours. Screening can be used as an opportunity to give women some advice.

Quality domain: Personal empowerment and experience.

Breast cancer process: Screening.

Measurement: This requirement is measured by 2 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT SCR-5

SCR-5.1 criterion	The centre providing breast screening has a written policy for informing women about a healthy lifestyle (including nutrition and physical activity).
Type	Structure
SCR-5.2 criterion	Women are offered lifestyle counselling, including on nutrition and physical activity.
Type	Process

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	There is evidence from the auditors' site visit that the policy is implemented consistently.

GUIDELINE RECOMMENDATIONS SCR-5

Certainty of evidence Not applicable

Strength of recommendation Not applicable

Guideline recommendations

No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE SCR-5

- World Health Organisation. Breast Cancer: prevention and control. 2014. Available at: www.who.int/cancer/detection/breastcancer/en/index.html
 - World Cancer Research Fund, 2014. Diet, Nutrition and Physical Activity and Breast Cancer Survivors. www.wcrf.org/sites/default/files/Breast-Cancer-Survivors-2014-Report.pdf.
 - OECI Quality standards V. 2015 Appendix II. OECI Accreditation and Designation.
 - NAPBC (National Accreditation Program for Breast Centers) Standards Manual 2018.
 - Anderson AS, Mackison D, Boath C and Steele R. Promoting Changes in Diet and Physical Activity in Breast and Colorectal Cancer Screening Settings: An Unexplored Opportunity for Endorsing Healthy Behaviors, Cancer Prev. 2013.
 - Hamer J et al. Lifestyle modifications for patients with breast cancer to improve prognosis and optimize overall health. CMAJ 2017;189(7): e268-e274.
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REFERENCE DOCUMENTS SCR-5

SCR-6: WOMEN-REPORTED OUTCOME MEASURES (PROMS) POLICY

Statement

The screening programme must have a policy for routine measurement of women-reported outcomes (satisfaction with screening) to monitor the well-being of women attending breast cancer screening.

Rationale

Patient-reported outcomes are important for capturing women's views on their health, in terms of symptoms and physical, mental and social functioning, including overall health-related quality of life. Measuring such outcomes with PROMs is relevant for shared decision making and involving women in their care. Measuring outcomes with PROMs can also be used for evaluating treatment goals in long-term follow up.

Quality domain: Personal empowerment and experience.

Breast cancer process: Screening.

Measurement: This requirement is measured by 1 criterion.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT SCR-6

SCR-6.1 criterion	The screening programme uses at least 1 patient PROM that is relevant for women attending cancer screening.
Type	Process
Target population	All women attending screening.
Norm	Yes The criterion is met.
Data source and additional information for auditing	SCR-6.1: Information on which PROMs are used, how they are measured and how the results are used.

GUIDELINE RECOMMENDATIONS SCR-6

Certainty of evidence	Not applicable
Strength of recommendation	Not applicable
Guideline recommendations	No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE SCR-6

- Deandrea S, Salakari M, Neamtiu L, Ulutürk A, Lerda D, Pylkkanen L. Validated tools measuring women's satisfaction in breast cancer screening programmes: A systematic review. *The Breast*, 39 (2018).
-

REFERENCE DOCUMENTS SCR-6

- Breast Screening Satisfaction Scale (BSSS).
 - MammoGraphy Questionnaire (MGQ).
-

SCR-7: RELEVANCE TO WOMEN

Statement

The screening programme must have implemented a policy to ensure relevant women-centred care.

Rationale

Shared decision making is an important aspect of BCSs, requiring high-quality communication and tailored information that is relevant to each woman and takes into account their needs and values. The breast centre should have adopted such a policy to ensure women-centred care.

Quality domain: Personal empowerment and experience.

Breast cancer process: Screening.

Measurement: This requirement is measured by 6 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT SCR-7

SCR-7.1 criterion	Professionals working in screening are trained in communication skills and shared decision making periodically (at least every 5 years), to be demonstrated by certificates of attendance.
Type	Process
SCR-7.2 criterion	The training is aimed at developing skills for providing women with relevant and appropriately tailored information, including on safety and the relevant benefits and harms of screening.
Type	Process
SCR-7.4 criterion	The screening programme has implemented improvements based on the results of the surveys.
Type	Process
SCR-7.5 criterion	The screening programme has established a women's advisory/ representative group to review the results of the women's experience/ satisfaction surveys, including staff communication with women.
Type	Structure
SCR-7.6 criterion	Women's informed consent is obtained through a process defined by the centre and carried out by trained staff, and is registered in the screening records.
Type	Process

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	SCR-7.1: Training certificates for all professionals. SCR-7.2: Training programme. SCR-7.3: Report analysing the results of women's experience/satisfaction. The frequency of the surveys should be in line with national legislation, but at least every 12 months. SCR-7.4: Some examples of improvements made based on analysis of the results. SCR-7.5: An official document confirming the establishment and operation of the women's advisory group. SCR-7.6: Auditors may check a sample of procedures requiring the women's informed consent, and ask women their opinion on the process. They may also verify that the documentation is complete.

GUIDELINE RECOMMENDATIONS SCR-7

Certainty of evidence	Not applicable
Strength of recommendation	Not applicable
Guideline recommendations	No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE SCR-7

- SIS/ISS. International Accreditation Program for Breast Centers/Units. 2013.

REFERENCE DOCUMENTS SCR-7

SCR-8: KEEPING WOMEN INFORMED

Statement

The screening programme must have a written policy on how to keep women participating in the screening process informed.

Rationale

Women should be offered clear and current verbal and written information that describes the screening process, including possible harms. Information that is clear and easy to understand empowers women's self-management.

Quality domain: Personal empowerment and experience.

Breast cancer process: Screening.

Measurement: This requirement is measured by 5 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT SCR-8

SCR-8.1 criterion	Leaflets and information for women are adapted for local use.
Type	Structure
SCR-8.2 criterion	Documentation includes tailored, easy-to-understand verbal, printed and online information that describes the screening process.
Type	Structure
SCR-8.3 criterion	The documents are up to date, and include the dates of issue and revision.
Type	Process
SCR-8.4 criterion	The centre has information materials available for women and they are easily accessible.
Type	Structure
SCR-8.5 criterion	Women are involved in creating information materials for women.
Type	Process

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met
Data source and additional information for auditing	<p>SCR-8.1: Information for women available in different languages according to the origins of the centre’s female population; use of pictograms; availability of online materials or videos about the usual information processes (informed consent, preparation for diagnostic tests, etc.).</p> <p>SCR-8.2: Printed and (if available) online documents specifically referring to the screening process.</p> <p>SCR-8.3: Auditors may check the dates of issue and revision for all documents and sources of information.</p> <p>SCR-8.4:</p> <ol style="list-style-type: none"> 1. List of authorised information materials that should be available in the service, including their location. 2. Check that information materials are available in situ (displayed or easily available). <p>The materials may have been produced by the centre or come from another source (public authorities, scientific associations, professional boards, patient associations, etc.).</p> <p>SCR-8.5: Auditors may ask for examples of women’s participation (i.e. focus groups to review the text of the informed consent document, etc.).</p>

GUIDELINE RECOMMENDATIONS SCR-8

Certainty of evidence	Moderate
Strength of recommendation	Strong
Guideline recommendations	
<ul style="list-style-type: none"> • <i>To ensure a patient–professional partnership, patients should be offered individually tailored information, including information about sources of support (including local and national organizations). Tailoring of information should take into account format (including whether written or taped) as well as the actual content and form to be provided (NICE, 2013).</i> 	

SUPPORTING LITERATURE SCR-8

- Wilson ARM, Marotti L, Bianchi S, Biganzoli L, et al. The requirements of a specialist Breast Centre (EUSOMA). *European Journal of Cancer* (2013) 49, 3579-3587.
 - Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer. NICE, 2013.
-

REFERENCE DOCUMENTS SCR-8

SCR-9: RESEARCH ACTIVITIES

Statement

The screening programme must participate in research and must have a written policy for participation in research activities.

Rationale

Participation in research is considered important for bringing together cancer research and care institutions in Europe, in order to create a critical mass of expertise and competence. That includes research performed in specific cases directly on patients.

Quality domain: Clinical effectiveness.

Breast cancer process: Screening.

Measurement: This requirement is measured by 5 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT SCR-9

SCR-9.1 criterion	The research and clinical strategy plan is regularly updated with guidelines, trial procedures, quality procedures, etc.
Type	Structure
SCR-9.2 criterion	The organisation's responsibility within the research, innovation and development structures is clearly defined.
Type	Structure
SCR-9.3 criterion	The screening programme is part of a clinical/research network.
Type	Structure
SCR-9.4 criterion	The management team and institutional review board are well defined.
Type	Structure
SCR-9.5 criterion	Structural cooperation between clinicians and researchers is well defined and organised.
Type	Structure

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	<p>SCR-9.1 The last update of the research strategy plan is less than 3 years.</p> <p>SCR-9.2: Document defining the organisational structure of the research area according to the country's regulation: governing entity, scientific director, internal scientific committee, external steering committee, etc.</p> <p>SCR-9.3: Signed document specifying that the screening programme is part of a legally established research network or collaborative research consortium.</p> <p>SCR-9.4: Regulation/formal document describing the role of the clinical trials management unit and institutional review board.</p> <ol style="list-style-type: none"> 1. The clinical trials management unit reviews all proposals for clinical trials to ensure that they are of high quality and optimally designed, and that all the ethical, contractual and regulatory agreements are met. 2. The institutional review board reviews research grant applications for quality. <p>SCR-9.5: Current collaboration agreement (document) between the screening programme and the research institution(s).</p>

GUIDELINE RECOMMENDATIONS SCR-9

Certainty of evidence	Not applicable
Strength of recommendation	Not applicable
Guideline recommendations	
No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.	

SUPPORTING LITERATURE SCR-9

- CCIB systematic review on the impact of centres performing clinical research on clinical outcomes.
 - OECI Accreditation and Designation User Manual V. 3.0, 2019.
 - NAPBC (National Accreditation Program for Breast Centers) Standards Manual 2018.
 - NHS Scotland; Scottish Cancer Taskforce/National Cancer Quality Steering Group. Breast Cancer Clinical Quality Performance Indicators. May 2016.
 - Khare SR, Batist G, Bartlett G. Identification of performance indicators across a network of clinical cancer programs. *Curr Oncol.* 2016 Apr;23(2):81-90.
 - Stordeur S, Vrijens F, Devriese S, Beirens K, Van Eycken E, Vlayen J. Developing and measuring a set of process and outcome indicators for breast cancer. *The Breast*, 21(2012):253-260.
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REFERENCE DOCUMENTS SCR-9

SCR-10: MULTIDISCIPLINARY MEETINGS (MDMS)

Statement

The screening programme must hold an MDM at least once a week to analyse the screening activity.

Rationale

Multidisciplinary teams are considered to optimise decision making in the diagnosis, treatment and support of patients.

Quality domain: Clinical effectiveness.

Breast cancer process: Screening.

Measurement: This requirement is measured by 1 criterion.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT SCR-10

SCR-10.1 criterion	There is a standard operating procedure describing how multidisciplinary meetings (MDMs) are managed, including team composition, meeting schedules, the team's role and responsibilities, how cases are discussed in the MDM, and reports.
Type	Structure
Target population	Legal entity applying for certification.
Norm	Yes The criteria are met.
Data source and additional information for auditing	SCR-10.1: Ensure that the standard operating procedure includes all the elements mentioned in the criterion.

GUIDELINE RECOMMENDATIONS SCR-10

Certainty of evidence Not applicable.

Strength of recommendation Not applicable.

Guideline recommendations

No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE SCR-10

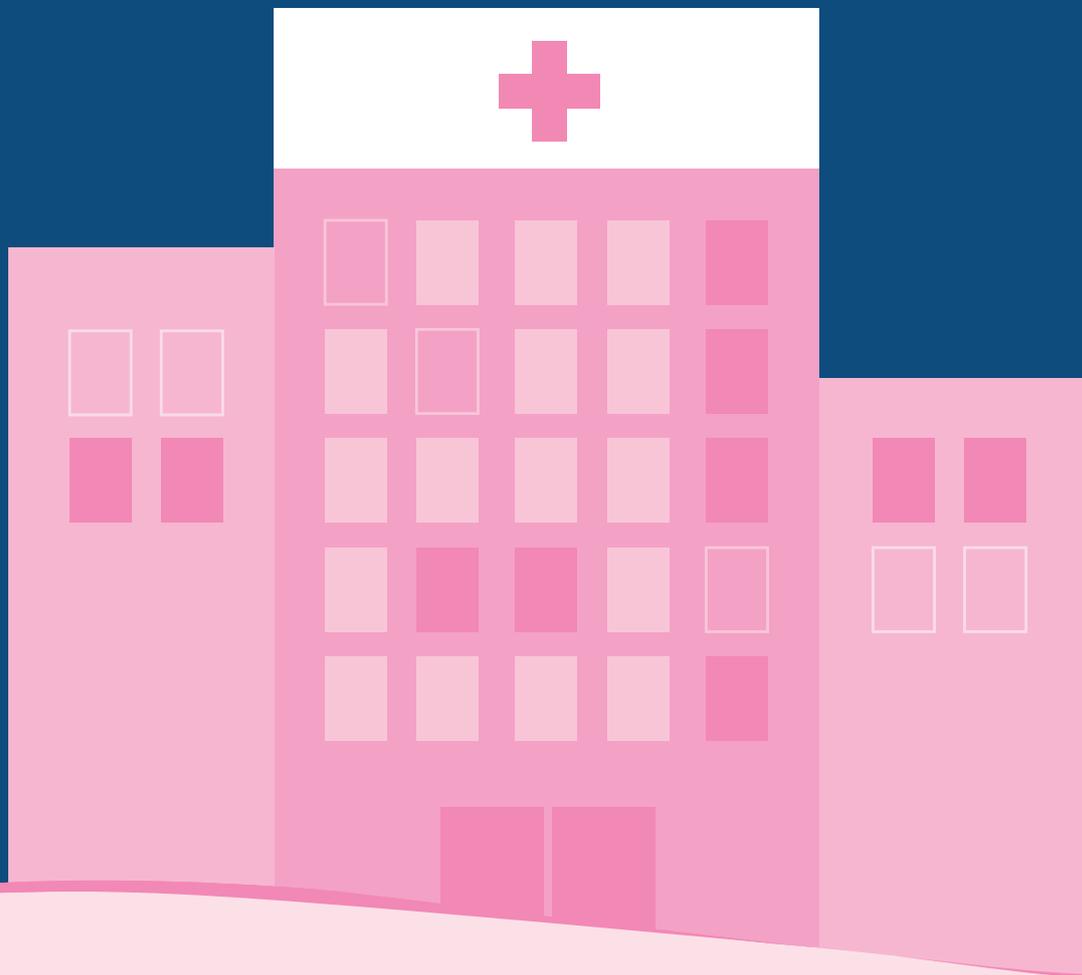
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- Martinez MJ, Posso M, Solà I, Alonso-Coello P. Should all breast cancer cases be discussed in multidisciplinary meetings? *Cochrane IberoAmerica*; 2016.
- NABON Breast Cancer Audit (NBCA) Factsheets Indicators 2016. DICA, IKNL, NBCA.
- NAPBC (National Accreditation Program for Breast Centers) Standards Manual 2018.
- NHS England. Manual for Cancer Services; Breast Cancer Measures. National Peer Review Programme. 2013.
- NHS Scotland; Scottish Cancer Taskforce/National Cancer Quality Steering Group. Breast Cancer Clinical Quality Performance Indicators. May 2016.
- SIS/ISS. International Accreditation Program for Breast Centers/Units. 2013.

REFERENCE DOCUMENTS SCR-10



CHAPTER 3

BREAST CENTRE REQUIREMENTS



CHAPTER 3 A:

DIAGNOSIS (DGN), PATHOLOGY (DGN-PTH) AND IMAGING (DGN-IMG)

DIAGNOSIS REQUIREMENTS		
CODE	NAME	STATEMENT
DGN-1	Diagnosis biopsy	Women with suspicious breast lesions (including mass lesions, asymmetric breast density, calcifications and/or architectural distortions) (BI-RADS™ ⁽¹¹⁾ 4 and 5) found by imaging must undergo minimally invasive biopsy for diagnosis. Fine needle aspiration cytology should not be used.
DGN-2	Diagnosis for suspected cancer in breast calcifications	To diagnose a breast cancer in women with suspicious breast calcifications found in mammography, stereotactic-guided needle core biopsy must be used. Note: the requirement does not assess the need for diagnosis, but refers to the biopsy technique to be used if diagnosis is planned.
DGN-3	Diagnosis service reporting	The diagnosis service must collect and periodically report data to monitor the performance of the service.
DGN-4	Genetic testing	All women diagnosed with breast cancer and with a high risk of genetic mutations must be offered genetic counselling, with unrestricted access to genetic testing.
DGN-5	Biomarkers collected before starting treatment	The oestrogen and progesterone receptor and HER2 status biomarkers must be collected and assessed before the start of treatment, for all women with invasive breast cancer.

¹¹ BI-RADS™: Breast Imaging Reporting and Data System. This system includes an assessment categorisation for mammography, ultrasound and MRI of the breast, enabling standardised reporting.

DGN-6	Excision diagnosis	The ratio of benign to malignant diagnoses must be monitored to minimise unnecessary operations for benign conditions.
DGN-7 	Pre-treatment diagnosis	All women treated for breast cancer (invasive or non-invasive) must have a histologically confirmed pre-treatment diagnosis of malignancy.
DGN-8	Staging	All BCSs must implement protocols for staging women with breast cancer in line with the European guidelines on breast cancer screening and diagnosis.
DGN-9	Pre-surgical localisation	The BCS must monitor the proportion of cases in which pre-surgical localisation fails.

DIAGNOSIS REQUIREMENTS: IMAGING

CODE	NAME	STATEMENT
DGN-IMG-1	Diagnostic mammography report	All reports for diagnostic mammograms must include a core set of essential information and be provided to the woman and/or primary healthcare provider, in line with the national regulations.
DGN-IMG-2	Optimal mammographic image quality	The BCS must implement documented protocols to achieve optimal mammographic image quality and to check it periodically, including correct breast positioning, compression, immediate repeat imaging and recalls for technical reasons.
DGN-IMG-3	Recall for technical reasons	The BCS must report on the percentage of recalls for technical reasons and have a policy to reduce their number.
DGN-IMG-4	Imaging equipment	The BCS must have a documented policy and protocols covering the selection, purchasing, installation, acceptance, calibration, operation, management, quality control, maintenance and, where relevant, replacement of all equipment that is used in breast imaging and intervention.

DIAGNOSIS REQUIREMENTS: IMAGING

CODE	NAME	STATEMENT
DGN-IMG-5	Imaging facilities	The BCS must have all the necessary equipment to perform the specified imaging and image-guided diagnostic examinations.
DGN-IMG-6	Mammogram labelling	The BCS must ensure that mammography image labelling identifies the woman correctly.
DGN-IMG-7	Radiologist performance	The BCS must have a written policy to ensure that it reviews the performance of radiologists periodically.
DGN-IMG-8	Policy on managing the throughput of women attending screening	The BCS must have a policy to separate women waiting for first-level screening from women waiting for diagnostic procedures or follow-up after therapy.
DGN-IMG-9	Specimen imaging	The BCS must have a policy in place to monitor the rate of intraoperative specimen imaging procedures.
DGN-IMG-10	Annual number of mammography examinations for radiographers	All mammograms completed in the BCS must be performed by radiographers who personally carry out a minimum of 1 000 mammography examinations per year.

DIAGNOSIS REQUIREMENTS: PATHOLOGY

CODE	NAME	STATEMENT
DGN-PTH-1	Time from receipt of specimen to issuing of result for non-surgical biopsies and surgical specimens	The maximum time from receipt of a breast specimen by the pathology service to the release of the pathology results, including immunohistochemistry (IHC), must be 5 working days for non-surgical biopsies and 10 working days for surgical specimens.
DGN-PTH-2	Diagnosis case numbers	Each pathologist working in a breast cancer centre must personally perform at least 100 routine assessments of breast specimens per year.
DGN-PTH-3	Diagnosis pathology service	Validated immunohistochemistry (IHC) and molecular pathology must be available.
DGN-PTH-4	Diagnosis pathology report for invasive and non-invasive breast cancer and specimens after neoadjuvant therapy	All pathology reports for breast cancer must contain a core set of prognostic and predictive parameters.
DGN-PTH-5	Diagnosis intraoperative assessment of sentinel lymph nodes	Frozen sections or other validated methods for the intraoperative assessment of sentinel lymph nodes must be available in the BCS.
DGN-PTH-6	Diagnosis pathology minimum storage time	The BCS must have a policy to ensure minimum storage time for formalin-fixed paraffin-embedded (FFPE) tissue samples and slides, as well as for formalin-fixed, not paraffin-embedded, fresh ('wet') material.

DGN-1: DIAGNOSIS BIOPSY

Statement

Women with suspicious breast lesions (including mass lesions, asymmetric breast density, calcifications and/or architectural distortions) (BI-RADS™ 4 and 5) found by imaging must undergo minimally invasive biopsy for diagnosis. Fine needle aspiration cytology should not be used.

Rationale

When assessing women with a screening mammography showing suspicious findings, the aim is to minimise the need for surgical removal of non-clinically relevant lesions while also minimising the risk of missing a clinically relevant lesion. The only way to reduce both risks significantly is to perform pre-surgical cytology or a histopathology assessment of suspicious lesions. Fine needle aspiration cytology should not be used.

Quality domain: Clinical effectiveness; Safety; Personal empowerment and experience.

Breast cancer process: Diagnosis.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (DGN-1.1):** Proportion of women with suspicious breast lesions in mammography (including mass lesions, asymmetric breast density, calcifications and/or architectural distortions), who undergo needle core biopsy.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-1

DGN-1.1 indicator	<p>Number of women with suspicious breast lesions found in mammography (including mass lesions, asymmetric breast density, calcifications and/or architectural distortions), who undergo needle core biopsy</p> <hr/> <p style="text-align: right;">x 100</p> <p>Total number of women with suspicious breast lesions found in mammography (including mass lesions, asymmetric breast density, calcifications and/or architectural distortions)</p>
Type	Process
Target population	Women with a screening mammography showing suspicious breast lesions.
Norm	≥ 85%
Data source and additional information for auditing	<p>Indicator to be calculated by the BCS.</p> <p>The BCS needs to extract data from electronic or paper health records, either manually or via a batch report, to identify: the number of women with suspicious breast lesions found in mammography at the BCS (denominator); the number of women with suspicious breast lesions found in mammography who undergo needle core biopsy (numerator); and the number of women diagnosed at the BCS for whom it is unknown if needle core biopsy was performed (missing).</p>

GUIDELINE RECOMMENDATIONS DGN-1

Certainty of evidence Moderate

Strength of recommendation Strong

Guideline recommendations

- *In individuals with suspicious breast lesions (including mass lesions, asymmetric breast density, calcifications and/or architectural distortions) in mammography, the ECIBC's Guidelines Development Group recommends needle core biopsy over fine needle aspiration cytology to diagnose breast cancer (strong recommendation, moderate certainty in the evidence).*
-

SUPPORTING LITERATURE DGN-1

- European guidelines for breast cancer screening and diagnosis:
<https://healthcare-quality.jrc.ec.europa.eu/european-breast-cancer-guidelines>
(accessed on 10 December 2019).
-

REFERENCE DOCUMENTS DGN-1

DGN-2: DIAGNOSIS FOR SUSPECTED CANCER IN BREAST CALCIFICATIONS

Statement

To diagnose a breast cancer in women with suspicious breast calcifications found in mammography, stereotactic-guided needle core biopsy must be used.

Note: the requirement does not assess the need for diagnosis, but refers to the biopsy technique to be used if diagnosis is planned.

Rationale

A woman with an abnormal screening test, such as a mammogram showing breast (micro) calcifications, which can be a sign of cancer, may wish to have the lesion tested for cancer. A tissue sample (biopsy) therefore needs to be taken from her breast.

Quality domain: Clinical effectiveness; Safety; Personal empowerment and experience.

Breast cancer process: Diagnosis.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (DGN-2.1):** Proportion of women (lesions counted) with suspicious breast calcifications found in mammography who undergo stereotactic-guided needle core biopsy.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-2

DGN-2.1 indicator	<p>Number of women (lesions counted) with suspicious breast calcifications in mammography who undergo stereotactic-guided needle core biopsy</p> $\frac{\text{Number of women (lesions counted) with suspicious breast calcifications in mammography who undergo stereotactic-guided needle core biopsy}}{\text{Total number of women (lesions counted) with suspicious breast calcifications in mammography}} \times 100$
Type	Outcome
Target population	Women with a screening mammography showing breast calcifications.
Norm	≥ 95%
Data source and additional information for auditing	<p>Indicator to be calculated by the BCS.</p> <p>During the audit, the BCS must describe how the indicator is monitored.</p>

GUIDELINE RECOMMENDATIONS DGN-2

Certainty of evidence Low

Strength of recommendation Strong

Guideline recommendations

- *In patients presenting breast calcifications, the ECIBC's Guidelines Development Group recommends the use of stereotactic-guided needle core biopsy over ultrasound-guided needle core biopsy to diagnose the presence of breast cancer (strong recommendation, low certainty evidence).*
-

SUPPORTING LITERATURE DGN-2

- European guidelines for breast cancer screening and diagnosis:
<https://healthcare-quality.jrc.ec.europa.eu/european-breast-cancer-guidelines>
(accessed on 10 December 2019).
-

REFERENCE DOCUMENTS DGN-2

DGN-3: DIAGNOSIS SERVICE REPORTING

Statement

The diagnosis service must collect and periodically report data to monitor the performance of the service.

Rationale

Indicator monitoring can improve service quality. The diagnosis service should collect data on the:

1. time between symptomatic imaging and communication of the final diagnosis to the woman when biopsy is not performed;
2. time between symptomatic imaging and communication of the final diagnosis to the woman when biopsy is performed;
3. number of assessment visits for definitive diagnosis.

Quality domain: Clinical effectiveness.

Breast cancer process: Diagnosis.

Measurement: This requirement is measured by 3 indicators and 1 criterion.

- **Indicator to be monitored (DGN-3.1):** Average number of days between symptomatic mammography and communication of diagnosis (when biopsy is not performed), measured as a number of days.
- **Indicator to be monitored (DGN-3.2):** Average number of days between symptomatic mammography and communication of diagnosis (when biopsy is performed), measured as a number of days.
- **Indicator to be monitored (DGN-3.3):** Number of assessment visits needed to obtain a definitive diagnosis.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-3

DGN-3.1 indicator	Time between symptomatic mammography and communication of diagnosis (when biopsy is not performed), measured as a number of days.
Type	Process
DGN-3.2 indicator	Time between symptomatic mammography and communication of diagnosis (when biopsy is performed), measured as a number of days.
Type	Process
DGN-3.3 indicator	Number of assessment visits to obtain a definitive diagnosis.
Type	Process

FOR THE INDICATORS

Target population	Women assessed in BCSs.
Norm	
Data source and additional information for auditing	Indicators to be calculated by the BCS. During the audit, the BCS must describe how these indicators are monitored.
DGN-3.4 criterion	Diagnostic services analyse data for trends in internal audits. Data can be used for benchmarking purposes.
Type	Process
Target population	Legal entity applying for certification.
Norm	Yes The criterion is met.
Data source and additional information for auditing	During the audit, the BCS must present the results of the analysis of trends.

GUIDELINE RECOMMENDATIONS DGN-3

Certainty of evidence	Not applicable
Strength of recommendation	Not applicable
Guideline recommendations	No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE DGN-3

- Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L (eds) (2006). European guidelines for quality assurance in breast cancer screening and diagnosis. 4th ed. European Commission; Office for Official Publications of the European Communities, Luxembourg.
 - <https://breastscreening.cancer.gov/>.
 - NHS Scotland; Scottish Cancer Taskforce/National Cancer Quality Steering Group. Breast Cancer Clinical Quality Performance Indicators. May 2016.
 - Bulliard JL, Variation in performance in low-volume mammography screening programmes: experience from Switzerland, 2011.
-

REFERENCE DOCUMENTS DGN-3

DGN-4: GENETIC TESTING

Statement

All women diagnosed with breast cancer and with a high risk of genetic mutations must be offered genetic counselling, with unrestricted access to genetic testing.

Rationale

The BCS may perform a risk assessment by reviewing the family history and identifying patients who have a high, medium or low risk of genetic mutations. Patients who are identified as high risk should be offered genetic counselling, along with written information about breast cancer mutations and the implications for them and their families.

Quality domain: Clinical effectiveness; Personal empowerment and experience.

Breast cancer process: Diagnosis.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (DGN-4.1):** Proportion of women aged 45 or under who are diagnosed with breast cancer, have a high risk of genetic mutations and have been tested for genetic mutations.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-4

DGN-4.1 indicator

Number of women aged 45 or under who are diagnosed with breast cancer, have a high risk of genetic mutations and have been tested for genetic mutations

_____ x 100

Total number of women aged 45 or under who are diagnosed with breast cancer and have a high risk of genetic mutations

Explanation of terms

A high-risk patient is defined as an individual with a cancer diagnosis that meets any of the following criteria.

1. A known mutation in a cancer susceptibility gene within the family.
2. Early-onset breast cancer.
3. Triple negative (ER-, PR-, HER2-) breast cancer ≤ age 60 y.
4. Two breast cancer primaries in a single individual.
5. Breast cancer at any age, and ≥ 1 close blood relative with breast cancer ≤ age 50 y; or ≥ 1 close blood relative with invasive ovarian cancer at any age; or ≥ 2 close blood relatives with breast cancer and/or pancreatic cancer at any age; or from a population at increased risk.
6. Personal and/or family history of 3 or more of the following (especially if early-onset): pancreatic cancer; prostate cancer (Gleason score ≥ 7); sarcoma; adrenocortical carcinoma; brain tumour; endometrial cancer; thyroid cancer; kidney cancer; dermatological manifestations and/or macrocephaly; hamartomatous polyps of the gastrointestinal tract; or diffuse gastric cancer (can include multiple primary cancers in the same individual).
7. Invasive ovarian cancer (source: NCCN Guidelines Version 2.2015).

Genetic counselling should include access to testing.

Type	Process
Target population	Women aged 45 or under who have breast cancer and a high risk of genetic mutations.
Norm	This is a monitoring indicator without a set norm.
Data source and additional information for auditing	<p>Indicator to be calculated by the BCS.</p> <p>The BCS will need to extract data from electronic or paper health records, either manually or via a batch report, to identify: the number of women aged 45 or under who are diagnosed with breast cancer and have a high risk of genetic mutations (denominator); the number of women aged 45 or under who are diagnosed with breast cancer, have a high risk of genetic mutations and have been tested for genetic mutations (numerator); and the number of women aged 45 or under who are diagnosed with breast cancer and have a high risk of genetic mutations, for whom it is unknown whether they were tested for genetic mutations (missing). The time frame should be specified, e.g. 1 or 2 calendar years.</p>

GUIDELINE RECOMMENDATIONS DGN-4

Certainty of evidence High

Strength of recommendation Strong

Guideline recommendations

- OECI Accreditation and Designation User Manual V.3.0 (OECI, 2015):
 - *An oncogenetic clinic is available and accessible to all appropriate patients.*
 - *Formal relationships exist between the cancer centre and reference genetic laboratories.*
 - *Oncogenetic counselling is offered to all appropriate patients.*
 - *Guidelines for referral to oncogenetic services are available.*
 - *Recommendations after a oncogenetic diagnosis are based on guidelines.*
 - *Psychologic support is offered in the oncogenetic service.*
- NICE guidelines (NICE, 2013):
 - *All eligible people should have access to information on genetic tests aimed at mutation finding.*
 - *Pre-test counselling (preferably two sessions) should be undertaken.*
 - *Discussion of genetic testing (predictive and mutation finding) should be undertaken by a healthcare professional with appropriate training.*
 - *Eligible people and their affected relatives should be informed about the likely informativeness of the test (the meaning of a positive and a negative test) and the likely timescale of being given the results.*

SUPPORTING LITERATURE DGN-4

- Del Turco MR, Pont A, Bick U, Bianzoli L et al. Quality indicators in breast cancer care. *European Journal of Cancer* 2010; 46:2344-2356.
- Biganzoli, Marotti, Hart et al. Quality indicators in breast cancer care: An update from the EUSOMA working group. *European Journal of Cancer* 86 (2017) 59e81.
- Khare S, Batist G, and Bartlett G. Identification of performance indicators across a network of clinical cancer programs. *Curr Oncol.* 2016 Apr;23(2):81-90.
- NAPBC (National Accreditation Program for Breast Centers) Standards Manual 2018.
- OECl Accreditation and Designation User Manual V. 3.0, 2019.
- NHS Scotland; Scottish Cancer Taskforce/National Cancer Quality Steering Group. Breast Cancer Clinical Quality Performance Indicators. May 2016.
- Gradishar WJ, Anderson BO, Balassanian R, Blair SL, Burstein HJ, Cyr A, Elias AD, Farrar WB, Forero A, Giordano SH, Goetz MP, Goldstein LJ, Isakoff SJ, Lyons J, Marcom PK, Mayer IA, McCormick B, Moran MS, O'Regan RM, Patel SA, Pierce LJ, Reed EC, Salerno KE, Schwartzberg LS, Sitapati A, Smith KL, Smith ML, Soliman H, Somlo G, Telli M, Ward JH, Shead DA, Kumar R. NCCN Guidelines Insights: Breast Cancer, Version 1.2017. *J Natl Compr Canc Netw.* 2017 Apr;15(4):433-451.
- NICE Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer. London: National Institute for Health and Care Excellence, 2013.
- NICE Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer. London: National Institute for Health and Care Excellence, 2013.

REFERENCE DOCUMENTS DGN-4

DGN-5: BIOMARKERS COLLECTED BEFORE STARTING TREATMENT



Statement

The oestrogen and progesterone receptor and HER2 status biomarkers must be collected and assessed before the start of treatment, for all women with invasive breast cancer.

Rationale

Before the start of any treatment (including neoadjuvant or metastatic treatment), it is important that the oestrogen and progesterone receptor (ER and PR) and HER2 status biomarkers are collected, to predict response rates to treatment and support decision making by the multidisciplinary team.

Quality domain: Clinical effectiveness.

Breast cancer process: Diagnosis.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (DGN-5.1):** Proportion of women with invasive breast cancer for whom the following biomarkers have been collected before starting treatment: oestrogen receptors (ER), progesterone receptors (PR) and HER2 status.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-5

DGN-5.1 indicator	Number of women diagnosed with invasive breast cancer for whom the following biomarkers have been collected before starting treatment: ER, PR and HER2 status. $\frac{\text{Number of women diagnosed with invasive breast cancer for whom the following biomarkers have been collected before starting treatment: ER, PR and HER2 status}}{\text{Total number of women diagnosed with invasive breast cancer}} \times 100$
Type	Process
Target population	Women aged 18 or older who are diagnosed with invasive breast cancer.
Norm	≥ 95%
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool.

GUIDELINE RECOMMENDATIONS DGN-5

Certainty of evidence High-moderate

Strength of recommendation Strong-moderate

Guideline recommendations

- *ER For predicting the response to endocrine therapy in patients with early or advanced breast cancer. Mandatory in all patients. (Duffy, 2017.)*
- *PR in combination with ER for predicting response to endocrine therapy in patients with early or advanced breast cancer. Mandatory in all patients. (Duffy, 2017.)*
- *HER2 for predicting response to anti-HER2 therapy in patients with early or advanced breast cancer. Mandatory in all patients. (Duffy, 2017.)*
- *Ki67 in combination with established clinical and pathological factors for determining prognosis in patients with newly diagnosed invasive breast cancer, especially if values are low or high. (Duffy, 2017.)*

SUPPORTING LITERATURE DGN-5

- Biganzoli, Marotti, Hart et al. Quality indicators in breast cancer care: An update from the EUSOMA working group. *European Journal of Cancer* 86 (2017) 59e81.
- Duffy MJ, Harbeck N, Nap M, Molina R, Nicolini A, Senkus E, Cardoso F. Clinical use of biomarkers in breast cancer: Updated guidelines from the European Group on Tumor Markers (EGTM). *European Journal of Cancer* 75 (2017) 284e298.

REFERENCE DOCUMENTS DGN-5

DGN-6: EXCISION DIAGNOSIS

Statement

The ratio of benign to malignant diagnoses must be monitored to minimise unnecessary operations for benign conditions.

Rationale

It is important to monitor the ratio of benign to malignant diagnoses. Benign lesions are not at risk of developing into cancer. Surgery for benign lesions should be limited to large lesions and be at the request of the patient, after informed consent that includes the patient's understanding that benign lesions normally do not progress to cancer. This indicator is important in order to minimise unnecessary operations for benign conditions.

Quality domain: Clinical effectiveness.

Breast cancer process: Diagnosis.

Measurement: This requirement is measured by 1 indicator (ratio).

- **Indicator to be monitored (DGN-6.1):** Relation between benign and malign diagnosis after open surgery.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-6

DGN-6.1 indicator (ratio)	$\frac{\text{Total number of women who have had open surgery (initial surgical procedure) and had a benign diagnosis}}{\text{Total number of women who have had open surgery (initial surgical procedure) and had a malignant diagnosis}} \times 100$
Type	Process
Target population	Women aged 18 or older who have open surgery in the BCS (initial surgical procedure).
Norm	1 benign: 4 malignant (25%).
Data source and additional information for auditing	<p>Indicator to be calculated by the BCS.</p> <p>The BCS needs to extract data from electronic or paper health records, either manually or via a batch report, to identify: the number of women who have open surgery (initial surgical procedure) (denominator); the number of women who have open surgery (initial surgical procedure) and are diagnosed with cancer (numerator); and the number of women for whom it is unknown whether they had open surgery (initial surgical procedure) (missing). The time frame should be specified, e.g. 1 or 2 calendar years.</p>

GUIDELINE RECOMMENDATIONS DGN-6

Certainty of evidence Low

Strength of recommendation Unknown

Guideline recommendations

No specific guideline recommendations available. The working group used available evidence listed under supporting literature.

SUPPORTING LITERATURE DGN-6

- Biganzoli, Marotti, Hart et al. Quality indicators in breast cancer care: An update from the EUSOMA working group. *European Journal of Cancer* 86 (2017) 59e81.
- Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L (eds) (2006) *European guidelines for quality assurance in breast cancer screening and diagnosis*. 4th ed. European Commission; Office for Official Publications of the European Communities, Luxembourg.
- Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L (eds.) (2013). *European guidelines for quality assurance in breast cancer screening and diagnosis*. Fourth edition, Supplements. European Commission; Office for Official Publications of the European Union, Luxembourg.

REFERENCE DOCUMENTS DGN-6

DGN-7: PRE-TREATMENT DIAGNOSIS



Statement

All women treated for breast cancer (invasive or non-invasive) must have a histologically confirmed pre-treatment diagnosis of malignancy.

Rationale

Before the start of any treatment, including surgery, it is important to have a confirmed diagnosis to support decision making by the multidisciplinary team, and to inform the patient.

Quality domain: Clinical effectiveness.

Breast cancer process: Diagnosis; Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (DGN-7.1):** Proportion of women (breasts counted) with breast cancer (invasive or non-invasive), who had a histologically confirmed malignant diagnosis before their first treatment.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-7

DGN-7.1 indicator	<p>Number of women (breasts counted) with breast cancer (invasive or non-invasive) who had a pre-treatment, histologically confirmed diagnosis of malignancy</p> <hr/> <p>Total number of women (breasts counted) with breast cancer (invasive or non-invasive) who were treated in the breast centre (first treatment)</p>	x 100
Type	Process	
Target population	Women aged 18 or older who were treated at the breast centre.	
Norm	≥ 95 %	
Data source and additional information for auditing	<p>Indicator to be calculated by the BCS.</p> <p>The BCS needs to extract data from electronic or paper health records, either manually or via a batch report, to identify: the number of women who had treatment for breast cancer (denominator); the number of women with breast cancer who had a pre-treatment diagnosis confirmed histologically (numerator); and the number of women with breast cancer for whom it is unknown whether they had a diagnosis confirmed histologically (missing).</p>	

GUIDELINE RECOMMENDATIONS DGN-7

Certainty of evidence Not applicable

Strength of recommendation Not applicable

Guideline recommendations

No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE DGN-7

- Biganzoli, Marotti, Hart et al. Quality indicators in breast cancer care: An update from the EUSOMA working group. *European Journal of Cancer* 86 (2017) 59e81.
 - Del Turco M, Ponti A, Bick U, Biganzoli L, Cserni G, et al. Quality indicators in breast cancer care. *European Journal of Cancer* 46(2010):2344-2356.
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REFERENCE DOCUMENTS DGN-7

DGN-8: STAGING

Statement

All BCSs must implement protocols for staging women with breast cancer in line with the European guidelines on breast cancer screening and diagnosis.

Rationale

The main cause of death from breast cancer is distant metastases. The detection of distant metastases in patients with breast cancer alters treatment and prognosis. The staging interventions aim to avoid overtreatment.

Quality domain: Clinical effectiveness.

Breast cancer process: Diagnosis; Treatment.

Measurement: This requirement is measured by 2 indicators.

- **Indicator to be monitored (DGN-8.1):** Proportion of women with breast cancer at clinical stage I not undergoing positron emission tomography-calculated tomography (PET-CT) or other whole-body staging examinations.
- **Indicator to be monitored (DGN-8.2):** Proportion of women with breast cancer at clinical stage III undergoing conventional staging examinations.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-8

DGN-8.1 indicator	Number of women with breast cancer at clinical stage I not undergoing positron emission tomography-calculated tomography (PET-CT) or other whole-body staging examinations	$\frac{\quad}{\quad} \times 100$
	Total number of women with breast cancer at clinical stage I diagnosed in the BCS	
DGN-8.2 indicator	Number of women with breast cancer at clinical stage III undergoing conventional staging examinations	$\frac{\quad}{\quad} \times 100$
	Total number of women with breast cancer at clinical stage III diagnosed in the BCS	

FOR ALL INDICATORS

Type	Process
Target population	Women aged 18 or older who are diagnosed with breast cancer in the BCS.
Norm	DGN-8.1: ≥ 95% DGN-8.2: ≥ 95%
Data source and additional information for auditing	<p>Indicators to be calculated by the BCS.</p> <p>The BCS will need to extract data from electronic or paper health records, either manually or via a batch report, to identify the following.</p> <ol style="list-style-type: none"> 1. The number of women who have breast cancer without symptoms suggestive of metastases at clinical stage I, diagnosed in the BCS (denominator); the number of women who have breast cancer without symptoms suggestive of metastases at clinical stage I, who are not undergoing positron emission tomography-calculated tomography (PET-CT) for staging (numerator); and the number of women who have breast cancer without symptoms suggestive of metastases at clinical stage I, diagnosed in the BCS and for whom it is unknown whether they had a staging examinations (missing). 2. The number of women who have breast cancer without symptoms suggestive of metastases at clinical stage III, diagnosed in the BCS (denominator); the number of women who have breast cancer without symptoms suggestive of metastases at clinical stage III, who are undergoing conventional staging examinations (numerator); and the number of women who have breast cancer without symptoms suggestive of metastases at clinical stage III, for whom it is unknown whether a staging examination was done (missing).

GUIDELINE RECOMMENDATIONS DGN-8

Certainty of evidence	DGN-8.1: very low DGN-8.2: moderate
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Strength of recommendation	DGN-8.1: strong DGN-8.2: strong
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Guideline recommendations

For breast cancer patients without symptoms suggestive of metastases at **clinical stage 1**, the ECIBC's Guidelines Development Group (GDG):

- **suggests against using conventional staging exams** (conditional recommendation, low certainty of the evidence);
- **recommends against using positron emission tomography-computed tomography (PET-CT)** (strong recommendation, very low certainty of the evidence).

For breast cancer patients without symptoms suggestive of metastases at **clinical stage 3**, the ECIBC's Guidelines Development Group (GDG):

- **recommends using conventional staging exams**, if positron emission tomography-computed tomography (PET-CT) is not readily available (strong recommendation, moderate certainty of the evidence);
- **suggests using positron emission tomography-computed tomography (PET-CT) alone** rather than conventional staging exams or the combination of conventional staging exams plus PET-CT (conditional recommendation, low certainty of the evidence).

European guidelines for breast cancer screening and diagnosis.

Available from: <https://healthcare-quality.jrc.ec.europa.eu/european-breast-cancer-guidelines> (accessed on 10 January 2020).

SUPPORTING LITERATURE DGN-8

- European guidelines for breast cancer screening and diagnosis.
Available from: <https://healthcare-quality.jrc.ec.europa.eu/european-breast-cancer-guidelines> (accessed on 10 January 2020).

REFERENCE DOCUMENTS DGN-8

DGN-9: PRE-SURGICAL LOCALISATION

Statement

The BCS must monitor the proportion of cases in which pre-surgical localisation fails.

Rationale

The BCS should collect and periodically report data to monitor the performance of the service. This information can be used for quality improvement purposes.

Quality domain: Clinical effectiveness.

Breast cancer process: Diagnosis; Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (DGN-9.1):** Proportion of women for whom pre-surgical localisation fails.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-9

DGN-9.1 indicator	$\frac{\text{Number of cases in which pre-surgical localisation fails}}{\text{Total number of cases in which pre-surgical localisation has been performed}} \times 100$
Type	Process
Target population	Women aged 18 or older who are diagnosed with breast cancer in the breast cancer centre.
Norm	
Data source and additional information for auditing	<p>Indicator to be calculated by the BCS.</p> <p>To be measured at least annually and the trends reported. The BCS should analyse data for trends in internal audits (patients should be included in the internal audit). Data can be used for benchmarking purposes.</p>

GUIDELINE RECOMMENDATIONS DGN-9

Certainty of evidence	Not applicable
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Strength of recommendation	Not applicable
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Guideline recommendations

No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE DGN-9

- Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L (eds) (2006). European guidelines for quality assurance in breast cancer screening and diagnosis. 4th ed. European Commission; Office for Official Publications of the European Communities, Luxembourg.
- Oberaigner, Introduction of organised mammography screening in Tyrol: results following first year of complete rollout, 2011.

REFERENCE DOCUMENTS DGN-9

DGN-IMG-1: DIAGNOSTIC MAMMOGRAPHY REPORT

Statement

All reports for diagnostic mammograms must include a core set of essential information and be provided to the woman and/or primary healthcare provider, in line with the national regulations.

Rationale

Interpretation of the mammogram and clarity of the information provided is important for high-quality care.

Quality domain: Facilities, resources and workforce.

Breast cancer process: Diagnosis.

Measurement: This requirement is measured by 3 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-IMG-1

DGN-IMG-1.1 criterion	The following criteria are included in the report: <ul style="list-style-type: none">a. relevant family and clinical history;b. comparison with previous studies (if available);c. mammographic breast density according to a validated classification (e.g. BI-RADS™ a, b, c, d class);d. type of abnormality detected, the number of clinically relevant abnormalities, their size and location, and the type of subsequent examinations to be performed to define the nature of the abnormality;e. diagnostic category and recommendation(s);f. single, formal diagnostic category system (e.g. BI-RADS™ or the classification reported in the 2006 European guidelines, preferably BI-RADS™).
Type	Process
DGN-IMG-1.2 criterion	All diagnostic mammography reports provided by the BCS include the same formal diagnostic category system.
Type	Process
DGN-IMG-1.3 criterion	The diagnostic mammography report is provided to the woman and/or to the primary healthcare provider in line with the national regulations.
Type	Process

FOR ALL CRITERIA

Target population	DGN-IMG-1.1 to DGN-IMG-1.3: Diagnostic mammography reports provided to the woman and/or to the primary healthcare provider.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	DGN-IMG-1.1 and DGN-IMG-1.2: Auditors may check a sample of diagnostic mammography reports. DGN-IMG-1.3: Auditors may ask professionals about the usual procedure or check the standard operating procedures.

GUIDELINE RECOMMENDATIONS DGN-IMG-1

Certainty of evidence	Not applicable
Strength of recommendation	Not applicable

Guideline recommendations

- *100% of the women should be informed by the radiographer on the method and time scale for receiving their results* (European guidelines, 2006).
- *The Breast Centre must use a single formal imaging risk classification (e.g. BIRADS™ or the European Classification)* (Wilson ARM, 2013).

SUPPORTING LITERATURE DGN-IMG-1

- Wilson ARM, Marotti L, Bianchi S, Biganzoli L, et al. The requirements of a specialist Breast Centre (EUSOMA). *European Journal of Cancer* (2013) 49, 3579-3587.
- Canadian Partnership Against Cancer. *Quality Determinants of Breast Cancer Screening with Mammography in Canada*. Toronto: Canadian Partnership Against Cancer; February, 2013.
- PAH Organisation (2016) *Mammography services quality assurance: baseline standards for Latin America and the Caribbean*. PAHO, Washington.
- *The Imaging Services Accrediation Scheme Standard: Statements, Rationale and criteria*. ISAS Standard, 2017.
- Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L (eds) (2006). *European guidelines for quality assurance in breast cancer screening and diagnosis*. 4th ed. European Commission; Office for Official Publications of the European Communities, Luxembourg.

REFERENCE DOCUMENTS DGN-IMG-1

- Wilson ARM, Marotti L, Bianchi S, Biganzoli L, et al. The requirements of a specialist Breast Centre (EUSOMA). *European Journal of Cancer* (2013) 49, 3579-3587.
 - Canadian Partnership Against Cancer. *Quality Determinants of Breast Cancer Screening with Mammography in Canada*. Toronto: Canadian Partnership Against Cancer; February, 2013.
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 - The Imaging Services Accrediation Scheme Standard: Statements, Rationale and criteria. ISAS Standard, 2017.
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DGN-IMG-2: OPTIMAL MAMMOGRAPHIC IMAGE QUALITY

Statement

The BCS must implement documented protocols to achieve optimal mammographic image quality and to check it periodically, including correct breast positioning, compression, immediate repeat imaging and recalls for technical reasons.

Rationale

Correct positioning and compression of the breast on the standard medio-lateral oblique and cranio-caudal views is necessary to allow maximum visualisation of the breast tissue, reduce recalls for inadequate positioning and maximise the cancer detection rate.

Quality domain: Clinical effectiveness.

Breast cancer process: Screening; Diagnosis.

Measurement: This requirement is measured by 4 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-IMG-2

DGN-IMG-2.1 criterion	The protocol includes the consultant radiographer checking 10 randomly chosen mammographic examinations for each radiographer every 2 months, against a defined protocol.
Type	Process
DGN-IMG-2.2 criterion	Policy and protocols are consistent with European and other (inter)national guidelines for breast positioning to achieve optimal mammographic image quality.
Type	Process
DGN-IMG-2.3 criterion	Documented protocols are made available by the BCS and used by trained radiographer.
Type	Process
DGN-IMG-2.4 criterion	The BCS provides evidence that it reviews documents and protocols for breast positioning for optimal mammographic image quality regularly (at least annually).
Type	Process

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	BCS documentation with protocols and policy for implementing the protocols on optimal image quality. Minutes of the meetings to review the documentation and protocols, including the date, and the names and signatures of attendees. DGM-IMG-2.1: Auditor may review the reports of consultant radiographers. DGM-IMG-2.4: Auditor may check the date of the last revision of the protocols.

GUIDELINE RECOMMENDATIONS DGN-IMG-2

Certainty of evidence	Not applicable
Strength of recommendation	Not applicable
Guideline recommendations	
<ul style="list-style-type: none"> • <i>Knowledge of adequate positioning techniques used by the radiographer is necessary (Perry, 2006).</i> • <i>It is the radiographer's responsibility within the team to produce an optimum image with regard to positioning and technical aspects and in a manner acceptable to women (Perry, 2006).</i> • <i>The compression of the breast tissue should be firm but tolerable. There is no optimal value known for the force, but attention should be given to the applied compression and the accuracy of the indication (Perry, 2006).</i> • <i>Compression force levels will depend on the compressibility of the breast and on levels of breast tenderness and acceptance of compression by the woman. Effective compression depends not only on the exertion of sufficient force but on the quality of positioning (NHS, 2017).</i> • <i>Less than 3% of the women should have a repeated examination, either a repeated mediolateral or cranio-caudal view. Audit must be carried out to monitor this (Perry, 2006).</i> • <i>Repeats and recall/call-back rates should be recorded and analysed periodically and at least every 3 months by the lead mammography QC technologist and the interpreting physician. The rates should not exceed 5% (Pan American Health Organization, 2016).</i> 	

SUPPORTING LITERATURE DGN-IMG-2

- LRCB Dutch Reference Center for Screening. Accreditation Document, The Radiographer (*kwaliteitsdocument mbb'er in de screening*), 2017.
- Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L (eds) (2006) European guidelines for quality assurance in breast cancer screening and diagnosis. 4th ed. European Commission; Office for Official Publications of the European Communities, Luxembourg.
- DKG. Catalogue of requirements for Breast Cancer Centres of the German Cancer Society Version J2, 12 August 2019.
- NHS England. Breast Screening Programme Guidance for breast screening mammographers. 2020 [online] <https://www.gov.uk/government/publications/breast-screening-quality-assurance-for-mammography-and-radiography> (last accessed 20 September 2020).
- NHS England. Manual for Cancer Services; Breast Cancer Measures. National Peer Review Programme. 2013.
- OEI Accreditation and Designation User Manual V. 3.0, 2019.
- SIS/ISS. International Accreditation Program for Breast Centers/Units. 2013.
- Wilson AR, Marotti L, Bianchi S, Biganzoli L, Claassen S, Decker T, et al., EUSOMA (European Society of Breast Cancer Specialists). The requirements of a specialist breast centre. *Eur J Cancer* 2013 Nov;49(17):3579e87.

REFERENCE DOCUMENTS DGN-IMG-2

DGN-IMG-3: RECALL FOR TECHNICAL REASONS

Statement

The BCS must report on the percentage of recalls for technical reasons and have a policy to reduce their number.

Rationale

The number of recalls for technical reasons is monitored to ensure good practice. A technical recall happens due to suboptimal positioning, suboptimal exposure or artefacts, such as blurring. The number of technical recalls should be as low as possible.

Quality domain: Clinical effectiveness.

Breast cancer process: Screening; Diagnosis.

Measurement: This requirement is measured by 2 criteria and 1 indicator.

- **Indicator to be monitored (DGN-IMG-3.3):** Proportion of women attending screening who require 1 or more technical recalls.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-IMG 3

DGN-IMG-3.1 criterion	Policy and protocols are consistent with European and other (inter)national guidelines for retakes.
Type	Structure
DGN-IMG-3.2 criterion	The BCS provides evidence that it reviews the documents and protocols for recalls for technical reasons regularly, at least once a year.
Type	Process

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	DGN-IMG-3.1: The BCS must provide a documented policy on minimising the number of technical recalls. DGN-IMG-3.2: BCS documentation with a policy and protocols for the periodical review of technical recall rates. Minutes of the meetings to review the documentation and protocols, including the date, and the names and signatures of attendees. To be checked in audit.

DGN-IMG-3.3 indicator	Number of women requiring 1 or more technical recalls _____ x 100 Total number of women attending screening
Explanation of terms	Recalls for technical reasons refer to recall reasons other than diagnostic recall.
Type	Process
Target population	Women screened for breast cancer.
Norm	≤ 2%
Data source and additional information for auditing	Indicator to be calculated by the BCS. The BCS needs to extract data from electronic or paper health records – either manually or via a batch report.

GUIDELINE RECOMMENDATIONS DGN-IMG-3

Certainty of evidence Not applicable

Strength of recommendation Not applicable

Guideline recommendations

- *Less than 3% of the women should have a repeated examination, either a repeated mediolateral or cranio-caudal view. Audit must be carried out to monitor this (Perry, 2006).*
- *Repeats and recall/call-back rates should be recorded and analysed periodically and at least every 3 months by the lead mammography QC technologist and the interpreting physician. The rates should not exceed 5% (Pan American Health Organization, 2016).*

SUPPORTING LITERATURE DGN-IMG-3

- Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L (eds) (2006). European guidelines for quality assurance in breast cancer screening and diagnosis. 4th ed. European Commission; Office for Official Publications of the European Communities, Luxembourg.
- NHS England. Manual for Cancer Services; Breast Cancer Measures. National Peer Review Programme. 2014.
- SIS/ISS. International Accreditation Program for Breast Centers/Units. 2013.

REFERENCE DOCUMENTS DGN-IMG-3

- NHS England. Manual for Cancer Services; Breast Cancer Measures. National Peer Review Programme. 2014.
 - NHS England. Breast Screening Programme Guidance for breast screening mammographers. 2020 [online] <https://www.gov.uk/government/publications/breast-screening-quality-assurance-for-mammography-and-radiography> , last access: 20/09/2020.
 - Wilson AR, Marotti L, Bianchi S, Biganzoli L, Claassen S, Decker T, et al., EUSOMA (European Society of Breast Cancer Specialists). The requirements of a specialist breast centre. Eur J Cancer 2013 Nov;49(17):3579e87.
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DGN-IMG-4: IMAGING EQUIPMENT

Statement

The BCS must have a documented policy and protocols covering the selection, purchasing, installation, acceptance, calibration, operation, management, quality control, maintenance and, where relevant, replacement of all equipment that is used in breast imaging and intervention.

Rationale

In order to produce reliable results, equipment must be suitable for the intended purpose and demonstrated to be continuously capable of achieving a specified level of performance.

Quality domain: Facilities, resources and workforce; Safety.

Breast cancer process: Screening; Diagnosis.

Measurement: This requirement is measured by 6 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-IMG-4

DGN-IMG-4.1 criterion	Policy and protocols explicitly refer to industry standards and European or other (inter)national guidelines for all equipment impacting the outcome of breast cancer care, for the entire care pathway defined in the European QA scheme (see reference documents for DGN-IMG-4).
Type	Structure
DGN-IMG-4.2 criterion	The BCS has documented instructions for the proper use of all equipment.
Type	Structure
DGN-IMG-4.3 criterion	The BCS documents that the equipment is only used by staff who are specifically trained and authorised.
Type	Structure
DGN-IMG-4.4 criterion	The BCS keeps records to demonstrate that equipment used for breast cancer care can achieve and maintain the required level of technical performance.
Type	Structure

DGN-IMG-4.5 criterion	The BCS reviews the documents and protocols regularly (at least annually). Minutes of the review meetings are available, including the date, and the names and signatures of attendees .
Type	Structure
DGN-IMG-4.6 criterion	Adverse events relating to patients or equipment malfunctions are recorded and analysed, and this is the responsibility of the head of the BCS.
Type	Process

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	<p>If the BCS is part of a larger institution, the documents for some of the functions listed above can be those of the larger institution. Evidence to support compliance with the requirement may be available in the BCS as:</p> <ul style="list-style-type: none"> • documented policies, Rationales and protocols; • purchase orders and equipment specifications; • manufacturers’ documented information and guidance; • records of validation, quality control and calibration (including external calibration certificates); • staff training and competence records; • records of maintenance and repair; • reference documents; • minutes of the meetings to review documents and policies, including the date, and the names and signatures of attendees.

GUIDELINE RECOMMENDATIONS DGN-IMG-4

Certainty of evidence Not applicable

Strength of recommendation Not applicable

Guideline recommendations

No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE DGN-IMG-4

- 2019. OECI Accreditation and Designation User Manual V. 3.0, 2019.
- 2018. American College of Radiology ACR, Digital Mammography, Quality Control Manual 2D and Digital Breast Tomosynthesis.
Available at: <https://www.acr.org/Media-Center/ACR-News-Releases/2018/2018-ACR-Digital-Mammography-Quality-Control-Manual-with-DBT-is-now-available>.
- 2018. The Royal Australian and New Zealand College of Radiologists, Mammography Quality Assurance Program. Available at: <http://www.ranzcr.edu.au/quality-a-safety/radiology/practice-quality-activities/mqap>.
- 2018. Gennaro G, Bernardi D, Houssami N. Radiation dose with digital breast tomosynthesis compared to digital mammography: per-view analysis, *Eur Radiol* (2018) 28:573–581.
- 2017. Corrections/Updates on: European protocol for the quality control of the physical and technical aspects of mammography screening chapter, 2b digital mammography, date 01-2017. Available from: www.euref.org.
- 2016. Mackenzie A, Warren LM, Wallis MG, Given-Wilson RM, Cooke J, Dance DR, Chakraborty DP, Halling-Brown MD, Looney PT, Young KC. The relationship between cancer detection in mammography and image quality measurements, *Phys Med*. 2016, Apr;32(4):568-74.
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Available at: <https://www.efomp.org/index.php?r=fc&id=protocols>.
- 2012. RADIATION PROTECTION N°162, Criteria for Acceptability of Medical Radiological Equipment used in Diagnostic Radiology, Nuclear Medicine and Radiotherapy, Luxembourg: Publications Office of the European Union.

SUPPORTING LITERATURE DGN-IMG-4

- 2012. Van Engen R, Bosmans H, Dance D, Heid P, Lazzari B, Marshall N, Schopphoven S, Thijssen M, Young K. Digital mammography update. European protocol for the quality control of the physical and technical aspects of mammography screening. S1, Part 1: Acceptance and constancy testing. In: European guidelines for quality assurance in breast cancer screening and diagnosis. Fourth edition, Supplements. Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L (eds.). European Commission, Office for Official Publications of the European Union, Luxembourg, pp. 1–54.
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- 2011. International Atomic Energy Agency, IAEA, Quality Assurance Program for Digital Mammography. Available at: http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1482_web.pdf.
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- 2006. Young KC, Cook JJH, Oduko JM, Bosmans H. Comparison of software and human observers in reading images of the CDMAM test object to assess digital mammography systems. In: Flynn MJ, Hsieh J (eds): *Proceedings of SPIE Medical Imaging 2006*, 614206 1-13.
- 2006. Van Engen RE, Swinkels MJ, Geertse TD, Oostveen LJ, Visser R. Using a homogeneity test as weekly quality control on digital mammography units, in: Astley S, Brady M, Rose C, Zwiggelaar R(ed), *Digital mammography*, Berlin, Heidelberg, 2006, 259-265.
- 2006. Van Engen R, Young K, Bosmans H, Thijssen M. European protocol for the quality control of the physical and technical aspects of mammography screening. Chapter 2b: Digital mammography. In: European guidelines for quality assurance in breast cancer screening and diagnosis. Fourth edition. Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L (eds.). European Commission, Office for Official Publications of the European Communities, Luxembourg, pp. 105–165.
- 2005. Young KC, Johnson B, Bosmans H, van Engen R. Development of Minimum Standards for Image Quality and Dose in Digital Mammography, E. Pisano (ed.). *Proceedings IWDM 2004*, Chapel Hill, 2005.
- 2000. Dance DR, Skinner CL, Young KC, Beckett JR, Kotre CJ. Additional factors for the estimation of mean glandular breast dose using the UK mammography dosimetry protocol. *Phys. Med. Biol.*, 45:3225–3240.
- 1990. Dance DR. Monte Carlo calculation of conversion factors for the estimation of mean glandular breast dose. *Phys. Med. Biol.*, 35:1211–1219.

REFERENCE DOCUMENTS DGN-IMG-4

- 2018. American College of Radiology ACR, Digital Mammography, Quality Control Manual 2D and Digital Breast Tomosynthesis. Available at: <https://www.acr.org/Media-Center/ACR-News-Releases/2018/2018-ACR-Digital-Mammography-Quality-Control-Manual-with-DBT-is-now-available>.
- 2018. The Royal Australian and New Zealand College of Radiologists, Mammography Quality Assurance Program. Available at: <http://www.ranzcr.edu.au/quality-a-safety/radiology/practice-quality-activities/mqap>.
- 2017. Corrections/Updates on: European protocol for the quality control of the physical and technical aspects of mammography screening chapter, 2b digital mammography, date 01-2017. Available from: www.euref.org.
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- AAPM report TG18 Assessment of Display Performance for Medical Imaging Systems. 2005.
- AAPM report Report No. 270, Display Quality Assurance. 2019.
- Protocol for the Quality Control of the Physical and Technical Aspects of Digital Breast Tomosynthesis Systems, version 1.03 March 2018. Available from: www.euref.org.

Additional information (DGN-IMG-4.1): measures and limiting values for mammography machines (film-screen, 2D digital, digital breast tomosynthesis)

1. Image quality

The protocol should include the threshold contrast visibility approach (e.g. using the model observer method) or follow other methods, approved by European or other national or international protocols, that can measure parameters related to image quality. As an example, the parameters in table a) below could be used in combination with those in table b):

a. Threshold contrast visibility

Diameter of detail (mm)	Radiation contrast using Mo/Mo 28 kV (%)
1	< 1.40
0.5	< 2.35
0.25	< 5.45
0.1	< 23.0

b. Signal-difference-to-noise-ratio

PMMA thickness (mm)	Limiting values Δ SDNR 45 mm
20	$\geq 0\%$
30	$\geq 0\%$
40	$\geq 0\%$
45	0 %
50	$\geq - 15\%$
60	$\geq - 30\%$

PMMA thickness (cm)	SDNR (relative to 5.0 cm PMMA) (%)
2.0	> 115
3.0	> 110
4.0	> 105
4.5	> 103
5.0	> 100
6.0	> 95
7.0	> 90

2. Average glandular dose

PMMA thickness (cm)	Equivalent compressed breast thickness (cm)	Limiting AGD (mGy)
2	2.1	≤ 1.2
3	3.2	≤ 1.5
4	4.5	≤ 2.0
4.5	5.3	≤ 2.5
5	6	≤ 3.0
6	7.5	≤ 4.5
7	9	≤ 6.5

3. Image homogeneity and system stability

- Visual image inspection for artefacts – no disturbing artefacts.
- System stability test according to the chosen protocol.

4. Monitors

- Primary display devices (reading monitors) should have a minimum size of 5 megapixels and a 10-bit graphic card.
- The measured contrast response should be within 10% of the greyscale standard display function contrast response for primary display devices.
- Luminance ratio should be at least 350 cd/m² for primary class displays following the DICOM (Digital Imaging and Communications in Medicine) calibration.
- Where high luminance monitors are used, it is advisable for breast silicone implants to be masked.

DGN-IMG-5: IMAGING FACILITIES

Statement

The BCS must have all the necessary equipment to perform the specified imaging and image-guided diagnostic examinations.

Rationale

All BCS should be able to perform examinations with the appropriate equipment, as that is key to providing high-quality BCSs. Mammography, ultrasound and percutaneous image-guided needle sampling facilities should ideally be located on the BCS premises.

Quality domain: Facilities, resources and workforce.

Breast cancer process: Screening; Diagnosis.

Measurement: This requirement is measured by 1 criterion.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-IMG-5

DGN-IMG-5.1 criterion	<p>DGN-IMG-5.1.A</p> <p>The BCS covering screening has the necessary equipment, or has an agreement with a local provider, to perform:</p> <ul style="list-style-type: none"> • mammography (preferably full-field digital, and possibly equipped with a tomosynthesis option).
	<p>DGN-IMG-5.1.B</p> <p>The BCS covering diagnosis (or screening and diagnosis) has the necessary equipment, or has an agreement with a local provider, to perform:</p> <ul style="list-style-type: none"> • mammography (preferably full-field digital, with tomosynthesis and contrast-enhanced options); • ultrasound of the breast and axilla (the ultrasound machine must have dedicated linear probes for breast and axilla ultrasound); • percutaneous image-guided needle sampling; • breast magnetic resonance imaging (MRI).
Type	Structure
Target population	Legal entity applying for certification.
Norm	<p>Yes</p> <p>All the criteria are met</p>
Data source and additional information for auditing	BCS documentation on the equipment in use. To be checked in the audit. Auditors may directly observe the equipment.

GUIDELINE RECOMMENDATIONS DGN-IMG-5

Certainty of evidence Not applicable

Strength of recommendation Not applicable

Guideline recommendations

No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE DGN-IMG-5

- Wilson ARM, Marotti L, Bianchi S, Biganzoli L, et al. The requirements of a specialist Breast Centre (EUSOMA). *European Journal of Cancer* (2013) 49, 3579-3587.
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REFERENCE DOCUMENTS DGN-IMG-5

DGN-IMG-6: MAMMOGRAM LABELLING

Statement

The BCS must ensure that mammography image labelling identifies the woman correctly.

Rationale

Stating the woman's identification on the mammogram ensures that the mammogram and the resulting diagnosis are attributed to the correct person and the specified breast. It also enables the mammogram to be traced and accessed in future.

Quality domain: Safety; Facilities, resources and workforce.

Breast cancer process: Screening; Diagnosis.

Measurement: This requirement is measured by 3 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-IMG-6

DGN-IMG-6.1 criterion	Labelling of the mammogram includes at least the patient's first name and surname, date of birth, and any other identification data; side and positioning views; the centre where the examination was performed; and the date of the examination.
Type	Process
DGN-IMG-6.2 criterion	The labels do not obscure or cover any part of the images.
Type	Process
DGN-IMG-6.3 criterion	Other data, including exposure parameters, compression force, breast thickness, radiation dose or parameters estimating the radiation dose, as well as the identification of the technician are available, even if not included on the label.
Type	Process

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	DGN-IMG-6.1 and DGN-IMG-6.2: Auditors may review a mammogram sample. DGN-IMG-6.3: Auditors may review a sample of clinical records.

GUIDELINE RECOMMENDATIONS DGN-IMG-6

Certainty of evidence Not applicable

Strength of recommendation Not applicable

Guideline recommendations

- *[The radiographer should] ensure correct identifications of the woman are in place* (Perry, 2006).
- *The following correct annotations should be clearly shown and must be correct: woman identification details, anatomical markers (L/R), positional markers (MLO, CC, etc.), mammographer identification, date and time of examination, organisation identifier* (NHS, 2017).

SUPPORTING LITERATURE DGN-IMG-6

- NHS England. Breast Screening Programme Guidance for breast screening mammographers, 2020. Available at: <https://www.cancer.gov/types/breast/hp/breast-screening-pdq> (last accessed 20 September 2020).
- PAH Organisation (2016). Mammography services quality assurance: baseline standards for Latin America and the Caribbean. PAHO, Washington.
- Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L (eds) (2006). European guidelines for quality assurance in breast cancer screening and diagnosis. 4th ed. European Commission; Office for Official Publications of the European Communities, Luxembourg.

REFERENCE DOCUMENTS DGN-IMG-6

DGN-IMG-7: RADIOLOGIST PERFORMANCE

Statement

The BCS must have a written policy to ensure that it reviews the performance of radiologists periodically.

Rationale

Radiologists must maintain adequate performance levels to provide high-quality care with better patient outcomes.

Quality domain: Facilities, resources and workforce.

Breast cancer process: Screening; Diagnosis.

Measurement: This requirement is measured by 3 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-IMG-7

DGN-IMG-7.1 criterion	The BCS reviews the performance of the radiologists periodically.
Type	Process
DGN-IMG-7.2 criterion	The BCS/screening programme provides performance metrics (e.g. detection rate, recall rate, false recall rate, further assessment rate, and interval cancer rate) for each reading radiologist at least annually.
Type	Process
DGN-IMG-7.3 criterion	The BCS reviews the documents and protocols regularly (at least annually). Minutes of the review meetings are available, including the date, and the names and signatures of attendees.
Type	Process

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	BCS documentation with a policy and protocols for the periodical review of the technical performance of radiologists. Minutes of the meetings to review the documentation and protocols, including the date, and the names and signatures of attendees. To be checked in audit.

GUIDELINE RECOMMENDATIONS DGN-IMG-7

Certainty of evidence Not applicable

Strength of recommendation Not applicable

Guideline recommendations

No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE DGN-IMG-7

- NHS England. Breast Screening Programme Guidance for breast screening mammographers, 2020. Available online: <https://www.cancer.gov/types/breast/hp/breast-screening-pdq> (last accessed 20 September 2020).
- The Imaging Services Accreditation Scheme Standard: Statements, Rationale and criteria. ISAS Standard, 2017.
- Public Health England, 2017. NHS Breast Screening Programme Consolidated standards. London: Public Health England.
- Canadian Partnership Against Cancer. Quality Determinants of Breast Cancer Screening with Mammography in Canada. Toronto: Canadian Partnership Against Cancer; February, 2013.
- Guidelines from the European Society of Breast Imaging for diagnostic interventional breast procedures., *Eur Radiol.* 2007 Feb;17(2):581-8.
- Wilson AR, Marotti L, Bianchi S, Biganzoli L, Claassen S, Decker T, et al., EUSOMA (European Society of Breast Cancer Specialists). The requirements of a specialist breast centre. *Eur J Cancer* 2013 Nov;49(17):3579e87.
- Guidelines for Quality Assurance in Mammography Screening. BreastCheck Ireland, 2015.

REFERENCE DOCUMENTS DGN-IMG-7

- The Imaging Services Accreditation Scheme Standard: Statements, **Rationale** and criteria. ISAS Standard, 2017.
- Public Health England (2017). NHS Breast Screening Programme Consolidated standards. London: Public Health England.
- Canadian Partnership Against Cancer. Quality Determinants of Breast Cancer Screening with Mammography in Canada. Toronto: Canadian Partnership Against Cancer; February, 2013.
- Guidelines from the European Society of Breast Imaging for diagnostic interventional breast procedures., *Eur Radiol.* 2007 Feb;17(2):581-8.
- Wilson AR, Marotti L, Bianchi S, Biganzoli L, Claassen S, Decker T, et al., EUSOMA (European Society of Breast Cancer Specialists). The requirements of a specialist breast centre. *Eur J Cancer* 2013 Nov;49(17):3579e87.
- Guidelines for Quality Assurance in Mammography Screening. BreastCheck Ireland, 2015.

DGN-IMG-8: POLICY ON MANAGING THE THROUGHPUT OF WOMEN ATTENDING SCREENING

Statement

The BCS must have a policy to separate women waiting for first-level screening from women waiting for diagnostic procedures or follow-up after therapy.

Rationale

During screening procedures, women attending screening should not encounter women attending a diagnostic procedure or follow-up mammography, in order to minimise additional anxiety about an already stressful procedure.

Quality domain: Personal empowerment and experience.

Breast cancer process: Screening; Diagnosis.

Measurement: This requirement is measured by 2 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-IMG-8

DGN-IMG-8.1 criterion	The policy includes the measures taken to ensure that women waiting for first-level screening are kept separate from women waiting for diagnostic procedures or follow-up after therapy.
Type	Structure
DGN-IMG-8.2 criterion	The BCS reviews the documents and protocols regularly (at least annually). Minutes of the review meetings are available, including the date, and the names and signatures of attendees.
Type	Process

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	BCS documentation, specifically protocols and policy. Minutes of the document and protocol review meetings, including the date, and the names and signatures of attendees. To be checked in audit.

GUIDELINE RECOMMENDATIONS DGN-IMG-8

Certainty of evidence Not applicable

Strength of recommendation Not applicable

Guideline recommendations

No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE DGN-IMG-8

- Cooperation Community, Mammography in the outpatient contract medical care KBV/ Spitzenverbände der Krankenkassen (Gbr/Spitzenverbände der Krankenkassen) (KOOP-MAMMO), Certification of future screening units in the framework of the legal programme for the early detection of breast cancer 2015.
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REFERENCE DOCUMENTS DGN-IMG-8

DGN-IMG-9: SPECIMEN IMAGING

Statement

The BCS must have a policy in place to monitor the rate of intraoperative specimen imaging procedures.

Rationale

Specimen imaging is important to ensure adequate resection of the image-detected lesion.

Quality domain: Facilities, resources and workforce.

Breast cancer process: Diagnosis.

Measurement: This requirement is measured by 2 indicators.

- **Indicator to be monitored (DGN-IMG-9.1):** Proportion of women (lesion counted) who had intraoperative specimen imaging following breast-conserving surgery for microcalcification with image-guided localisation.
- **Indicator to be monitored (DGN-IMG-9.2):** Proportion of women (lesion counted) who underwent surgical lesion removal with intraoperative specimen imaging.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-IMG-9

DGN-IMG-9.1 indicator	Number of women (lesion counted) who had intraoperative specimen imaging following breast-conserving surgery for microcalcification with image-guided localisation $\frac{\text{Number of women (lesion counted) who had intraoperative specimen imaging following breast-conserving surgery for microcalcification with image-guided localisation}}{\text{Total number of women (lesion counted) who had breast-conserving surgery for microcalcification with image-guided localisation}} \times 100$
Type	Process
Target population	Women aged 18 or older who had breast-conserving surgery for microcalcifications.
Norm	≥ 95%
DGN-IMG-9.2 indicator	Number of women (lesion counted) who had intraoperative specimen imaging $\frac{\text{Number of women (lesion counted) who had intraoperative specimen imaging}}{\text{Total number of women (lesion counted) who underwent lesion surgical removal}} \times 100$
Type	Process

FOR ALL INDICATORS

Target population	Women aged 18 or older who had lesion removal surgery.
Norm	This is a monitoring indicator without a set norm.
Specifications	Specimen imaging can be performed by mammography or ultrasonography depending on the preoperative imaging.
Data source and additional information for auditing	Indicators to be calculated by the BCS. BCS documentation listing: all patients who underwent breast-conserving surgery for microcalcifications with imaging-guided, preoperative wire marking before surgery; and patients who had intraoperative specimen imaging. Data can potentially also be extracted from electronic or paper health records – either manually or via a batch report.

GUIDELINE RECOMMENDATIONS DGN-IMG-9

Certainty of evidence	Not applicable
Strength of recommendation	Not applicable
Guideline recommendations	No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

- Wilson ARM, Marotti L, Bianchi S, Biganzoli L, et al. The requirements of a specialist Breast Centre (EUSOMA). *European Journal of Cancer* (2013) 49, 3579-3587.
- Canadian Partnership Against Cancer. *Quality Determinants of Breast Cancer Screening with Mammography in Canada*. Toronto: Canadian Partnership Against Cancer; February, 2013.
- Health Information and Quality Authority (HIQA). (2006) *National Quality Assurance Standards for Symptomatic Breast Disease Services* [Online]. Available from: <http://publichealthwell.ie/node/15597> (accessed on 29 November 2019).
- Interdisciplinary GoR level III Guidelines for the Diagnosis, Therapy and Follow-up Care of Breast Cancer, 2017.
- Interdisciplinary GoR level III Guidelines for the Diagnosis, Therapy and Follow-up Care of Breast Cancer, 2012.
- Guidelines for Quality Assurance in Mammography Screening. BreastCheck Ireland, 2015.

REFERENCE DOCUMENTS DGN-IMG-9

DGN-IMG-10: ANNUAL NUMBER OF MAMMOGRAPHY EXAMINATIONS FOR RADIOGRAPHERS

Statement

All mammograms completed in the BCS must be performed by radiographers who personally carry out a minimum of 1 000 mammography examinations per year.

Rationale

More experienced radiographers are likely to be more competent.

Quality domain: Clinical effectiveness.

Breast cancer process: Screening; Diagnosis.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (DGN-IMG-10.1):** Proportion of radiographers who have personally performed a minimum of 1 000 mammography examinations per year.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-IMG-10

DGN-IMG-10.1 indicator	Number of radiographers who have personally performed a minimum of 1 000 mammography examinations per year <hr style="width: 60%; margin-left: 0;"/> x 100 Total number of radiographers working at the BCS
Type	Process
Target population	All the mammograms performed at the BCS.
Norm	≥ 90%
Data source and additional information for auditing	The BCS will need to extract data from electronic or paper health records, either manually or via a batch report, to identify the total number of mammography examinations performed by each radiographer. The period must be specified (e.g. 1 or 2 calendar years).

GUIDELINE RECOMMENDATIONS DGN-IMG-10

Certainty of evidence Not applicable

Strength of recommendation Not applicable

Guideline recommendations

- *Diagnostic Breast Imaging Unit performs at least 1 000 mammograms per year* (European guidelines, 2006).
- *European reference centre for breast screening perform at least 10 000 mammograms a year* (European guidelines, 2006).

Related indicators:

- *100% of the radiographers have taken a minimum of 6 400 images annually or 19 200 images in 3 years* (LRCB, 2012).

SUPPORTING LITERATURE DGN-IMG-10

- Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L (eds) (2006). European guidelines for quality assurance in breast cancer screening and diagnosis. 4th ed. European Commission; Office for Official Publications of the European Communities, Luxembourg.
- LRCB Dutch Reference Center for Screening. Accreditation Document, The Radiographer (kwaliteitsdocument mbb'er in de screening), 2017. Available at: <https://www.lrcb.nl/resources/uploads/2017/02/Kwaliteitsdocument-MBB-ER-IN-DE-SCREENING-2017.pdf>.
- Guidelines for Quality Assurance in Mammography Screening. BreastCheck Ireland, 2015.

REFERENCE DOCUMENTS DGN-IMG-10

DGN-PTH-1: TIME FROM RECEIPT OF SPECIMEN TO ISSUING OF RESULT FOR NON-SURGICAL BIOPSIES AND SURGICAL SPECIMENS

Statement

The maximum time from receipt of a breast specimen by the pathology service to the release of the pathology results, including immunohistochemistry (IHC), must be 5 working days for non-surgical biopsies and 10 working days for surgical specimens.

Rationale

Timeliness in diagnostic procedures is an important dimension of quality assurance in breast cancer care, as it has an impact on how early treatment starts. It is also relevant from the patient's perspective, in terms of patient-centredness: delays at any stage of the diagnostic process may result in increased anxiety for the woman.

Quality domain: Clinical effectiveness; Personal empowerment and experience; Facilities, resources and workforce.

Breast cancer process: Diagnosis.

Measurement: This requirement is measured by 1 criterion and 2 indicators.

- **Indicator to be monitored (DGN-PTH-1.2):** Proportion of pathology results from non-surgical biopsies released from the pathology service within 5 working days (7 calendar days) after receipt of the breast specimen by the pathology service.
- **Indicator to be monitored (DGN-PTH-1.3):** Proportion of pathology results from surgical specimens released from the pathology service within 10 working days (14 calendar days) after receipt of the breast specimen by the pathology service.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-PTH-1

DGN-PTH-1.1 criterion	Each pathology service has a procedure for identifying cases that remain unreported for longer than anticipated, and has a documented system to manage and report those cases.
Type	Process
Target population	Legal entity applying for certification.
Norm	Yes The criterion is met.
Data source and additional information for auditing	Procedure for identifying and managing cases that are not reported within the anticipated time.

DGN-PTH-1.2 indicator	<p>Number of pathology results from non-surgical biopsies released from the pathology service within 5 working days (7 calendar days) after receipt of the breast specimen by the pathology service</p> <hr/> <p>Total number of pathology results from non-surgical biopsies released from the pathology service in any given time from receipt of the breast specimen by the pathology service</p>	x 100
DGN-PTH-1.3 indicator	<p>Number of pathology results from surgical specimens released from the pathology service within 10 working days (14 calendar days) from receipt of the breast specimen by the pathology service</p> <hr/> <p>Total number of pathology results from surgical specimens released from the pathology service in any given time from receipt of the breast specimen by the pathology service</p>	x 100
Type	Process	

FOR ALL INDICATORS

Explanation of terms	<ul style="list-style-type: none"> • The term 'breast specimen' refers both to needle core biopsies and surgical specimens. • Time should be measured in working/calendar days: 5 working days equals 7 calendar days, and 10 working days equals 14 calendar days. • Missing values for reasons such as a lack of sample identification, or damaged samples, should be measured and reported. Those values should be excluded.
Type	Process
Target population	All the breast specimens reported in the BCS. Cases that are diagnosed outside the BCS but have surgery conducted in the BCS must also be counted.
Norm	≥ 80%
Data source and additional information for auditing	<p>Indicators to be calculated by the BCS.</p> <ol style="list-style-type: none"> 1. Ideally, the BCS will extract the data from electronic or paper health records, either manually or via a batch report, to identify: the total number of pathology results released in the period considered for audit (denominator); and the number of pathology results released within the required time (numerator) during the same period. If this is not possible, the following will be required. 2. An annual report of how the BCS monitors the indicator, including the reporting of missing data. <p>A random review of pathology reports by the auditor (at least 10 for each type of breast specimen: non-surgical biopsies and surgical specimens), checking the time it took for reports to be released against the requirement (norm: minimum 80%, desirable 95%).</p>

SUPPORTING LITERATURE DGN-PTH-1

- OECD Accreditation and Designation User Manual V. 3.0, 2019.
- Royal College of Pathologists. Key performance indicators for pathology services. November 2019. Available at: <https://www.rcpath.org/uploads/assets/62de2970-42aa-4d73-9bf1122a1746331a/G181-Key-assurance-indicators-for-pathology-services.pdf>
- Landercasper J, Linebarger JH, Ellis RL, Mathiason MA, Johnson JM, Marcou KA, De Maiffe BM, Jago GS. A Quality Review of the Timeliness of Breast Cancer Diagnosis and Treatment in an Integrated Breast Center. *J Am Coll Surg.* 2010;210(4):449-55.
- *Protocolo Nacional de acreditación de las unidades de mama.* Sociedad Española de Senología y Patología Mamaria (SESPM). Available at: <http://www.sespm.es/archivos/PROTOCOLONACIONALACREDITACIONUNIDADES MAMA.pdf> (accessed April 2019).
- Quality Initiative of the National Consortium of Breast Centers. Available at: <http://www.breastcare.org/> (accessed April 2019)].
- Perry N, Broeders M, de Wolf C, Törnberg S, Holland R, von Karsa L (eds) (2006). European guidelines for quality assurance in breast cancer screening and diagnosis. 4th ed. European Commission; Office for Official Publications of the European Communities, Luxembourg.
- DKG. Catalogue of requirements for Breast Cancer Centres of the German Cancer Society. Catalogue of Requirements Pathology (24-01-2019). Available at: https://www.onkozert.de/wordpress/wp-content/uploads/2019/03/cr_pat-H2_ENG_190124.docx (accessed May 2019).
- SIS/ISS. International Accreditation Program for Breast Centers/Units. 2013.
- Wilson ARM, Marotti L, Bianchi S, Biganzoli L, et al. The requirements of a specialist Breast Centre (EUSOMA). *European Journal of Cancer* (2013) 49, 3579-3587.
- Tot T et al Optimal breast cancer pathology manifesto (*Eur J of Cancer* (2015) 51, 2285– 2288).

REFERENCE DOCUMENTS DGN-PTH-1

DGN-PTH-2: DIAGNOSIS CASE NUMBERS

Statement

Each pathologist working in a breast cancer centre must personally perform at least 100 routine assessments of breast specimens per year.

Rationale

More experienced pathologists perform better. All pathologists should have a minimum case-load, which is associated with higher quality care.

Quality domain: Clinical effectiveness; Safety; Facilities, resources and workforce.

Breast cancer process: Diagnosis.

Measurement: This requirement is measured by 1 criterion.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-PTH-2

DGN-PTH-2.1 criterion	All pathologists working in the BCS assess \geq 100 breast specimens per year.
Explanation of terms	Routine assessments are the analysis of histological specimens (core biopsies and surgical specimens) to provide a diagnosis, and prognostic and predictive parameters that guide the treatment of individual patients.
Type	Process
Target population	All pathologists working in the BCS. Exclusion: junior pathologists (residents/trainees). Pathologists who have started or ended their activity (e.g. retirement, maternity leave) in the period considered for the audit and have worked less than 12 months during that period.
Norm	Yes The criterion is met.
Data source and additional information for auditing	The BCS provides a list of the names of all pathologists performing breast cancer diagnosis, including the number of breast assessments they have conducted in the last calendar year.

GUIDELINE RECOMMENDATIONS DGN-PTH-2

Certainty of evidence Not applicable

Strength of recommendation Not applicable

Guideline recommendations

No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE DGN-PTH-2

- Royal College of Pathologists. Key performance indicators – for pathology services. November 2019. Available at: <https://www.rcpath.org/uploads/assets/62de2970-42aa-4d73-9bf1122a1746331a/G181-Key-assurance-indicators-for-pathology-services.pdf>
- Wilson ARM, Marotti L, Bianchi S, Biganzoli L, et al. The requirements of a specialist Breast Centre (EUSOMA). *European Journal of Cancer* (2013) 49, 3579-3587.
- Requirements for Pathologists in the German Mammography Screening Program. Available at: <http://fachservice.mammo-programm.de/fortbildungsangebote/qualitaetssicherung> (accessed April 2019).
- DKG. Catalogue of requirements for Breast Cancer Centres of the German Cancer Society. Catalogue of Requirements Pathology (24-01-2019). Available at: https://www.onkozert.de/wordpress/wp-content/uploads/2019/03/cr_pat-H2_ENG_190124.docx (accessed May 2019).
- Tot T et al Optimal breast cancer pathology manifesto (*EurJ of Cancer* (2015) 51, 2285– 2288).

REFERENCE DOCUMENTS DGN-PTH-2

DGN-PTH-3: DIAGNOSIS PATHOLOGY SERVICE

Statement

Validated immunohistochemistry (IHC) and molecular pathology must be available.

Rationale

Providing these techniques using validated procedures is essential in the pathological examination of breast cancer, to help guide decisions on optimal treatment and maximise disease management. Molecular testing of the specimen is identified as a quality potential by the QASDG.

Quality domain: Facilities, resources and workforce.

Breast cancer process: Diagnosis.

Measurement: This requirement is measured by 5 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-PTH-3

DGN-PTH-3.1 criterion	The pathology service has documented that IHC and molecular testing are available in-house or outsourced, and conducted according to European or international evidence-based guidelines.
Type	Structure
DGN-PTH-3.2 criterion	All tests used for breast cancer diagnosis in the pathology service are validated before introducing them into clinical service.
Type	Process
DGN-PTH-3.3 criterion	IHC tests for ER, PgR and HER2 are available and, wherever possible, are performed in-house.
Type	Structure
DGN-PTH-3.4 criterion	Internal and external quality assurance is required for the prognostic and predictive markers ER, PgR and HER2.
Type	Structure
DGN-PTH-3.5 criterion	Cooperation agreements are in place for outsourced testing to ensure that external laboratories also follow guidelines and are subject to quality control.
Type	Structure

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	<ul style="list-style-type: none">• The BCS (pathology service) provides a list of IHC/molecular pathology tests that are available in-house and those that are outsourced. For the latter, agreements/contracts with the providers must be made available, along with evidence that the tests are fulfilling the same specifications as described above.• Documentation showing that all tests used for clinical diagnosis are validated.• Documentation proving the BCS' participation in, and the results of, external quality-assurance processes for ER, PgR and HER2.

GUIDELINE RECOMMENDATIONS DGN-PTH-3

Certainty of evidence Criteria DGN-PTH-4.3 and DGN-PTH-4.4: high-moderate

Strength of recommendation Criteria DGN-PTH-4.3 and DGN-PTH-4.4: strong-moderate

Guideline recommendations

- ASCO/CAP Guideline update, Estrogen and Progesterone Receptor Testing in Breast Cancer (Allison, 2020):
 - Validated IHC is the recommended standard test for predicting benefit from endocrine therapy. No other assay types are recommended as the primary screening test for this purpose. Type: Evidence based; Evidence quality: High; Strength of recommendation: Strong.
 - There should be initial a test validation/verification prior to reporting any clinical samples. Prior to that, previously recommended principles apply, as described by Fitzgibbons et al¹² and more recently Torlakovic¹³ (Type: Evidence based; Evidence quality: High; Strength of recommendation: Strong).
 - The laboratory performing ER and PgR testing must participate in external proficiency testing or alternative performance assessment as required by its accrediting organization (Type: Evidence based; Evidence quality: High; Strength of recommendation: Strong).
- Interdisziplinäre S3-Leitlinie für die Früherkennung, Diagnostik, Therapie und Nachsorge des Mammakarzinoms. Langversion 4.2 – August 2019. AWMF-Registernummer: 032-0450L (Germany, 2019):
 - It must be ensured that the detection method used to determine the hormone receptor and HER2 status is reliable. This involves internal test validation, the use of standardized protocols and internal controls, and regular successful participation in external quality assurance measures (Good Quality Practice).
- Primary breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. (Senkus, 2015):
 - The pathological report should include the histological type, grade, immunohistochemical (IHC) evaluation of oestrogen receptor(ER) status (using a standardised assessment methodology, e.g.Allred or H-score) and, for invasive cancer, IHC evaluation ofprogesterone receptor (PgR) and human epidermal growthfactor 2 receptor (HER2) gene expression.
- Updated guidelines from the European Group on Tumor Markers (EGTM) (Duffy, 2017):
 - ER For predicting the response to endocrine therapy in patients with early or advanced breast cancer. Mandatory in all patients.
 - PR In combination with ER for predicting response to endocrine therapy in patients with early or advanced breast cancer. Mandatory in all patients.
 - HER2 For predicting response to anti-HER2 therapy in patients with early or advanced breast cancer. Mandatory in all patients.
 - Both ER and PR should be measured by IHC using an analytically and clinically validated assay.
 - The working group additionally used available evidence listed under supporting literature.

SUPPORTING LITERATURE DGN-PTH-3

- Kreienberg et al. Interdisciplinary GoR level III Guidelines for the Diagnosis, Therapy and Follow-up Care of Breast Cancer. *Geburtshilfe Frauenheilkd.* 2013 Jun; 73(6): 556–583.
- DKG. Catalogue of requirements for Breast Cancer Centres of the German Cancer Society. Catalogue of Requirements Pathology (24-01-2019). Available at: https://www.onkozert.de/wordpress/wp-content/uploads/2019/03/cr_pat-H2_ENG_190124.docx (accessed May 2019).
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- ISO 20166-1:2018, Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue – Part 1: Isolated RNA.
- ISO 20166-2:2018, Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue – Part 2: Isolated proteins.
- ISO 20166-3:2018, Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue – Part 3: Isolated DNA.
- ISO/AWI 20166-4, Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue – Part 4: In situ detection techniques.
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- CEN/TS 16826-1:2015, Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for snap frozen tissue – Part 1: Isolated RNA.
- CEN/TS 16835-2:2015, Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for snap frozen tissue – Part 2: Isolated proteins.
- CEN/TS 16826-3:2018, Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for snap frozen tissue – Part 3: Isolated DNA.

DGN-PTH-4: DIAGNOSIS PATHOLOGY REPORT FOR INVASIVE AND NON-INVASIVE BREAST CANCER AND SPECIMENS AFTER NEOADJUVANT THERAPY

Statement

All pathology reports for breast cancer must contain a core set of prognostic and predictive parameters.

Rationale

An accurate pathology report is necessary to assess the prognosis and predict the expected effect of systemic therapies. Standardised pathology reports will increase the consistency of diagnoses made by pathologists and the quality of prognostic information.

Quality domain: Clinical effectiveness; Safety.

Breast cancer process: Diagnosis; Treatment.

Measurement: This requirement is measured by 3 indicators.

- **Indicator to be monitored (DGN-PTH-4.1):** Proportion of pathology reports for invasive breast cancer with the core set reported.
- **Indicator to be monitored (DGN-PTH-4.2):** Proportion of pathology reports for non-invasive breast cancer with the core set reported.
- **Indicator to be monitored (DGN-PTH-4.3):** Proportion of pathology reports for specimens after neoadjuvant therapy with the core set reported.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-PTH-4

DGN-PTH-4.1 indicator	<p>Number of invasive breast cancer pathology reports containing all the core elements outlined under specifications</p> <hr/> <p style="text-align: right;">x 100</p> <p>Total number of pathology reports for invasive breast cancer</p>
Explanation of terms	<p>Minimum data set for invasive breast-cancer pathology report. This may not necessarily apply to re-excision specimens.</p> <p>For invasive breast cancer:</p> <ul style="list-style-type: none"> • Patient identification. • Specimen identification. • Date the specimen is received by the laboratory. • Laterality. • Histopathological type, according to the current WHO Classification of Breast Tumours (http://www.iccr-cancer.org/articles/new-who-classification-for-breast-tumours). • Histological grade, according to Elston and Ellis system. • Size* of invasive carcinoma, defined as the maximum dimension of the largest invasive focus. • Extent of the disease*, defined as the overall extent of disease (measured in 1 or 2 dimensions) to include all in situ and invasive disease. • Peritumoral lymphovascular invasion*. • Resection margins*, specifying the status of each margin and precise distance from each margin if less than 2 or 5 mm, depending on local practice (option to classify as focal, minimal/moderate or extensive for positive margins). • Confirmation of clip site (S), if present. • Lymph nodes*, including the total number examined, number of positive nodes, size of the largest deposit and presence/absence of extra nodal spread. • Pathologic staging*: pTN and pM (when applicable), according to the current <i>AJCC/UICC Cancer Staging Manual</i>. • Oestrogen receptor status, indicating % of positive cells (recommended pre-treatment). • Progesterone receptor status, indicating % of positive cells (recommended pre-treatment). • HER2/neu status (recommended pre-treatment). • Proliferation index Ki-67 (optional). • Identity and date of approval and identity of authorising pathologist. <p>(*for resection specimens only.)</p>
Type	Process

DGN-PTH-4.2 indicator	<p>Number of non-invasive breast cancer pathology reports containing all the core elements outlined under specifications</p> <hr/> <p style="text-align: right;">x 100</p> <p>Total number of pathology reports for non-invasive breast cancer</p>
Explanation of terms	<p>Minimum data set for non-invasive breast-cancer pathology report. This may not necessarily apply to re-excision specimens.</p> <p>For non-invasive breast cancer:</p> <ul style="list-style-type: none"> • Patient identification. • Specimen identification. • Date the specimen is received by the laboratory. • Laterality. • DCIS histological grade according to current WHO classification. • Presence of calcification. • Extent of the disease*. • Presence of (micro)invasion. • Peritumoral lymphovascular invasion*. • Resection margins*. • Confirmation of clip site (S), if present. • Pathologic staging* as pTis, according to current AJCC/UICC Cancer Staging Manual. • Identity and date of approval of authorising pathologist. <p>(*for resection specimens only.)</p>
Type	Process

DGN-PTH-4.3 indicator	<p>Number of pathology reports for specimens after neoadjuvant therapy containing all the core elements outlined under specifications</p> <hr/> <p>Total number of pathology reports for specimens after neoadjuvant therapy</p> <p style="text-align: right;">x 100</p>
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Explanation of terms	<p>Minimum data set for breast-cancer pathology report. This may not necessarily apply to re-excision specimens.</p> <p>For specimens after neoadjuvant therapy:</p> <ul style="list-style-type: none"> • Patient identification. • Specimen identification. • Date the specimen is received by the laboratory. • Laterality. • Histopathological type, according to the current WHO Classification of Tumours of the Breast. • Histological grade, according to Elston and Ellis system. • Presence/absence of DCIS. • Size* of (residual) invasive carcinoma (measured in 1 or 2 dimensions). • Extent* of the (residual) disease. • Peritumoral lymphovascular invasion*. • Resection margins*. • Confirmation of clip site (S), if placed pre-treatment. • Assessment of response to treatment and classification system used. • Lymph node status*, including presence of treatment effects, and presence and extent of residual tumour. • Pathologic staging: ypTM and ypN, according to current <i>AJCC/UICC Cancer Staging Manual</i>. • Identity and date of approval of authorising pathologist. <p>(*for resection specimens only.</p>
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Type	Process
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FOR ALL INDICATORS

Target population	All breast specimens diagnosed in the pathology service.
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Norm	≥ 90% of reports contain the minimum data set.
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Data source and additional information for auditing	<p>Indicators to be calculated by the BCS.</p> <p>Ideally, the BCS extracts data from electronic or paper health records, either manually or via a batch report, to identify the number of pathology reports. The time frame should be specified.</p> <p>If this is not possible, the following will be required.</p> <ol style="list-style-type: none"> 1. An annual report of how the BCS monitors the indicator, including the reporting of missing values. 2. A random review of pathology reports by the auditor (at least 10), checking the core data provided against the requirement (norm: 90%).
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GUIDELINE RECOMMENDATIONS DGN-PTH-4

Certainty of evidence Not applicable.

Strength of recommendation Not applicable.

Guideline recommendations

- ASCO/CAP Guideline update, Estrogen and Progesterone Receptor Testing in Breast Cancer (Allison 2020):
 - ER testing in cases of newly diagnosed DCIS (without associated invasion) is recommended to determine potential benefit of endocrine therapies to reduce risk of future breast cancer. PgR testing is considered optional (Type: Evidence based; Evidence quality: Intermediate; Strength of recommendation: Moderate).
- S-3 Guidelines of the DGGG and the DKG (Germany 2019):
 - The surgical material should be identified with unambiguous topographical markings and sent to the pathologist without the prior removal of any tissue by the clinician or surgeon (or others) (Good Clinical Practice).
 - pTNM status (Grade of recommendation A, level of evidence 1a).
 - Resection margin (R classification) and margin distances (Grade of recommendation A, level of evidence 1b).
 - Histological type (Grade of recommendation A, level of evidence 2b).
 - Histological grade (Grade of recommendation A, level of evidence 2a).
 - Peritumoral lymphovascular invasion (Grade of recommendation A, level of evidence 2b).
 - Age (Good Clinical Practice).
 - Estrogen/progesterone receptor status for hormone therapy (Grade of recommendation A, level of evidence 1a).
 - HER2/neu status for targeted anti-HER2 treatment (Grade of recommendation A, level of evidence 1b).
 - Ki-67 proliferation index in women with ER-/PgR-positive and HER2 negative invasive tumors for decision on chemotherapy (facultative; 2018 update of S3 guidelines).
- ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up, Senkus et al (2015):
 - Final pathological diagnosis should be made according to the WHO classification and the tumour–node–metastases (TNM) staging system. The pathological report should include the histological type, grade, IHC evaluation of ER status (using a standardised assessment methodology, e.g. Allred or H-score) and, for invasive cancer, IHC evaluation of PgR and HER2 gene expression. Disease stage should be assessed according to the TNM system.
- EUSOMA (Biganzoli, 2017): see below under supporting literature, level of evidence II.
- National guidelines on breast cancer. Belgian Health Care Knowledge Centre (KCE); 2010. Good Clinical Practice (GCP) 143C.
- Estrogen and progesterone receptors (ER/PgR) should be measured on all ductal carcinomas in situ (DCIS) and primary invasive breast cancers (1B evidence).

GUIDELINE RECOMMENDATIONS DGN-PTH-4

- European guidelines on breast cancer screening and diagnosis. Available at: <https://healthcare-quality.jrc.ec.europa.eu/european-breast-cancer-guidelines/towards-the-treatment-of-invasive-cancer>.
 - In women with invasive breast cancer, the ECIBC's Guidelines Development Group (GDG) suggests:
 - *administration of adjuvant endocrine therapy if 1% or greater of tumour cells show oestrogen receptor positivity rather than applying a threshold of 10% tumour cell oestrogen receptor positivity (conditional recommendation, very low certainty of the evidence)*
 - *administration of adjuvant endocrine therapy if 1% or greater of tumour cells show progesterone receptor positivity rather than applying a threshold of 10% tumour cell progesterone receptor positivity (conditional recommendation, very low certainty of the evidence)*
 - Updated Guidelines from the European Group on Tumor Markers, 2017:
 - *ER should be measured on all newly diagnosed primary invasive breast cancers (Level of evidence, LOE: 1A; Strength of recommendation, SOR: A).*
 - *PR should be measured on all newly diagnosed primary invasive breast cancers (LOE: 1B; SOR:A/B).*
 - *HER2 gene amplification or overexpression should be determined on all patients with primary invasive breast cancer (LOE, 1A; SOR, A).*
 - *Ki67 may be used in combination with established prognostic factors for determining prognosis (LOE: 1B; SOR, B)*
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- *Breast Cancer Clinical Pathway*. Spanish Society of Senology and Mammary Pathology (SESPM 2020). ISBN: 978-84-09-20296-6.

DGN-PTH-5: DIAGNOSIS INTRAOPERATIVE ASSESSMENT OF SENTINEL LYMPH NODES

Statement

Frozen sections or other validated methods for the intraoperative assessment of sentinel lymph nodes must be available in the BCS.

Rationale

In case of positive sentinel lymph nodes identified by frozen section or using other validated methods, the surgeon can proceed to axillary lymph node clearance without the need for a second operation.

Quality domain: Clinical effectiveness; Safety.

Breast cancer process: Diagnosis; Treatment.

Measurement: This requirement is measured by 1 criterion.

DGN-PTH-5.1 criterion	The BCS is able to conduct frozen section analysis or use other validated methods, such as one-step nucleic acid amplification (OSNA), for intraoperative assessment of sentinel lymph nodes.
Type	Structure
Target population	Legal entity applying for certification.
Norm	Yes The criterion is met.
Data source and additional information for auditing	The BCS (pathology service) provides a list of the methods available for conducting on-site, intraoperative assessment of sentinel lymph nodes (e.g. ability to perform frozen section, OSNA, etc). Documentation that all tests used for clinical diagnosis are validated.

GUIDELINE RECOMMENDATIONS DGN-PTH-5

Certainty of evidence Not applicable.

Strength of recommendation Not applicable.

Guideline recommendations

No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE DGN-PTH-5

- Liu LC, Lang JE, Lu Y, Roe D, Hwang SE, Ewing CA et al. Intraoperative frozen section analysis of sentinel lymph nodes in breast cancer patients: a meta-analysis and single institution experience. *Cancer* 2011;117:250–258.
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REFERENCE DOCUMENTS DGN-PTH-5

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- NICE, Intraoperative tests (RD-100i OSNA system and Metasin test) for detecting sentinel lymph node metastases in breast cancer, 2013.

DGN-PTH-6: DIAGNOSIS PATHOLOGY MINIMUM STORAGE TIME

Statement

The BCS must have a policy to ensure minimum storage time for formalin-fixed paraffin-embedded (FFPE) tissue samples and slides, as well as for formalin-fixed, not paraffin-embedded, fresh ('wet') material.

Rationale

It is important to establish minimum retention times for breast pathology tissues and semi-permanent or permanent pathological preparations, stored in appropriate conditions. This ensures that they are available for future clinical use for the patient's benefit, or for other purposes such as education, teaching, training, research, historical purposes, and audit or quality control.

Quality domain: Clinical effectiveness; Facilities, resources and workforce.

Breast cancer process: Diagnosis.

Measurement: This requirement is measured by 3 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT DGN-PTH-6

DGN-PTH-6.1 criterion	The BCS has a policy specifying the minimum storage times required for breast specimens: <ul style="list-style-type: none">- at least 10 years for paraffin blocks and slides;- at least 4 weeks for wet specimens (including fixed tissue samples of any size).
Type	Structure
DGN-PTH-6.2 criterion	The BCS ensures that specimens are safely stored in the appropriate conditions and at the correct temperature and humidity, in line with standard operating procedures based on national or international guidelines and good laboratory practices that are appropriate to the nature of the sample. Emergency arrangements are also in place in case of a power supply failure.
Type	Process
DGN-PTH-6.3 criterion	Breast specimens that are stored for shorter periods of time (such as small tissue samples used in their entirety for diagnostic or research purposes) are properly recorded and the reason documented.
Type	Process

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All criteria are met.
Data source and additional information for auditing	The BCS provides documentation of its policy on the correct storage conditions for breast samples, specifying the minimum storage time for each type of specimen, as well as evidence, such as records of the storage conditions for all breast specimens.

GUIDELINE RECOMMENDATIONS DGN-PTH-6

Certainty of evidence	Not applicable
Strength of recommendation	Not applicable
Guideline recommendations	No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE DGN-PTH-6

- Xie R, Chung J, Ylaya K et al. Factors Influencing the Degradation of Archival Formalin-Fixed Paraffin-Embedded Tissue Sections. *J Histochem Cytochem* 2011 59: 356.
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REFERENCE DOCUMENTS DGN-PTH-6

CHAPTER 3 B:

TREATMENT (TRT), SURGERY (TRT-SUR), SYSTEMIC THERAPY (TRT-SYS) AND RADIOTHERAPY (TRT-RAD)

TREATMENT REQUIREMENTS: SURGERY

Code	Name	Statement
TRT-SUR-1	Surgery	Each surgeon performing breast cancer surgery must personally carry out the primary surgery on a minimum of 50 newly diagnosed breast cancers per year.
TRT-SUR-2	Sentinel lymph node biopsy	All surgically treated women with clinically node-negative (cNO) invasive breast cancer must undergo sentinel lymph node biopsy (SLNB).
TRT-SUR-3	Axillary lymph node dissection with clinical node-negative	Most surgically treated women with pathologically node-negative (pNO) invasive breast cancer must not undergo axillary lymph node dissection (ALND) (staged by SLNB only).
TRT-SUR-4	Axillary lymph node dissection in ductal carcinoma in situ (DCIS)	Women with ductal carcinoma in situ (DCIS) who are surgically treated must not undergo axillary lymph node dissection (ALND).
TRT-SUR-5	Axillary lymph node dissection with 10 or more lymph nodes removed	All women treated with therapeutic axillary lymph node dissection (ALND) must have 10 or more lymph nodes (including sentinel nodes) removed.

TREATMENT REQUIREMENTS: SURGERY

CODE	NAME	STATEMENT
TRT-SUR-6	Breast-conserving surgery in ductal carcinoma in situ	Most women with ductal carcinoma in situ (DCIS) with a radiological tumour extent \leq 2 cm must not undergo mastectomy as the first choice of surgical treatment.
TRT-SUR-7	Breast-conserving surgery in invasive breast cancer with small tumour size	Most surgically treated women with invasive breast cancer with a pathological tumour size \leq 2 cm (pT1) must have breast-conserving treatment as the first choice of treatment.
TRT-SUR-8	Single breast operation for the primary tumour in ductal carcinoma in situ	Most surgically treated women with ductal carcinoma in situ (DCIS) must undergo only 1 operation for the primary tumour.
TRT-SUR-9	Invasive breast cancer with a single breast operation	Most surgically treated women with invasive breast cancer (T1, T2) must undergo only 1 operation for the primary tumour.
TRT-SUR-10	Immediate breast reconstruction after mastectomy	The preferred treatment option for women who have undergone mastectomy must be immediate breast reconstruction.
TRT-SUR-11	Delayed breast reconstruction	Women who have undergone mastectomy must be offered immediate breast reconstruction. When breast reconstruction is not immediate, women must undergo delayed breast reconstruction within 12 months after mastectomy.

TREATMENT REQUIREMENTS: SYSTEMIC THERAPY

CODE	NAME	STATEMENT
TRT-SYS-1	Lead time between last surgery and first adjuvant chemotherapy cycle	Lead time between last surgery and first adjuvant chemotherapy cycle in women with invasive M0 breast cancer must be no longer than 8 weeks.
TRT-SYS-2	Adjuvant chemotherapy in surgically treated women with invasive M0 breast cancer and ER-	All surgically treated women with ER- (T > 1 cm or Node+) invasive M0 breast cancer must undergo adjuvant chemotherapy.
TRT-SYS-3	Adjuvant anti-HER2 therapy in women with HER2+	All women with HER2+ invasive M0 breast cancer treated with adjuvant chemotherapy must undergo adjuvant anti-HER2 therapy.
TRT-SYS-4	Neoadjuvant anti-HER2 therapy in women with neoadjuvant chemotherapy	All women with HER2+ invasive M0 breast cancer treated with neoadjuvant chemotherapy must undergo neoadjuvant anti-HER2 therapy.
TRT-SYS-5	Monitored cardiac function in women with breast cancer treated with anti-HER2	All women with breast cancer treated with anti-HER2 therapy must undergo cardiac function monitoring every 3 months during treatment.
TRT-SYS-6	Prescription of endocrine therapy in surgically treated women ER+ and/or PR+	All surgically treated women with hormone sensitive (ER+ and/or PR+) invasive M0 breast cancer must be prescribed endocrine therapy.
TRT-SYS-7	Neoadjuvant chemotherapy in women with stage II and III triple negative breast cancer	Women with stage II and III triple negative breast cancer must be offered neoadjuvant chemotherapy.

TREATMENT REQUIREMENTS: SYSTEMIC THERAPY

CODE	NAME	STATEMENT
TRT-SYS-8	Women with stage II and III HER2+ breast cancer undergoing neoadjuvant systemic therapy	Women with stage II and III HER2+ breast cancer must be offered neoadjuvant systemic therapy.
TRT-SYS-9	Neoadjuvant systemic therapy in women with locally advanced breast cancer	All women with locally advanced breast cancer (tumour > 3 cm or T4 or nodal status ≥ N2) must undergo neoadjuvant systemic therapy.
TRT-SYS-10	Metastasis endocrine treatment	The preferred option for the first line of treatment in women with ER+ and HER2-metastatic breast cancer is endocrine-based treatment.
TRT-SYS-11	Bone-modifying agents in women with bone metastases from breast cancer	All women with bone metastases from breast cancer must receive bone-modifying agents.

TREATMENT REQUIREMENTS: RADIOTHERAPY

CODE	NAME	STATEMENT
TRT-RAD-1	Radiotherapy lead time	The lead time between completion of surgical therapy or the last cycle of adjuvant chemotherapy and first radiotherapy treatment for women with primary invasive M0 breast cancer must not exceed 8 weeks.
TRT-RAD-2	Invasive breast cancer with breast-conserving therapy	All women with M0 invasive breast cancer treated with breast-conserving therapy must be offered whole breast adjuvant radiotherapy or, when indicated, partial breast radiotherapy.
TRT-RAD-3	Mastectomy in invasive breast cancer	All women with invasive M0 breast cancer with ≥ 4 axillary lymph nodes involved must be offered local or regional radiotherapy after mastectomy.

TRT-SUR-1: SURGERY

Statement

Each surgeon performing breast cancer surgery must personally carry out the primary surgery on a minimum of 50 newly diagnosed breast cancers per year.

Rationale

More experienced surgeons perform better. All surgeons should have a minimum caseload.

Quality domain: Clinical effectiveness; Safety; Facilities, resources and workforce.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 criterion.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-SUR-1

TRT-SUR-1.1 criterion	All surgeons performing breast cancer surgery have a caseload of ≥ 50 primary breast cancer surgeries per year.
Type	Process
Target population	All surgeons performing breast cancer surgery. Exclusion: junior surgeons (residents/trainees).
Norm	Yes 100% of surgeons performing breast cancer surgery carry out ≥ 50 surgeries per year.
Data source and additional information for auditing	The BCS provides a list of the names of all surgeons performing breast cancer surgery, including a numbered list of their primary surgeries during the past calendar year. TRT-SUR-1.1: surgeons' staff files (professional experience).

GUIDELINE RECOMMENDATIONS TRT-SUR-1

Certainty of evidence Very low to moderate

Strength of recommendation Conditional/weak

Guideline recommendations

- Review IberoAmerican Cochrane Center (Posso, 2016):
 - *No significant effect of surgeon case load on 10-year mortality due to breast cancer (low-quality evidence).*
 - *No significant effect of surgeon case load on 10-year breast cancer recurrences (very low quality evidence), nor in 5-year breast cancer recurrences (low-quality evidence).*
 - *Better cosmetic results after surgery were found in patients treated by surgeons with a caseload of ≥ 13.5 patients/year (low-quality evidence).*
 - *A higher risk of re-operation after the first operation was found in women treated by surgeons with a caseload of < 35 surgeries/year (moderate-quality evidence).*
 - *A higher proportion of mastectomy was found in women being operated by surgeons with a caseload of < 15 patients/year (moderate-quality evidence).*

SUPPORTING LITERATURE TRT-SUR-1

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REFERENCE DOCUMENTS TRT-SUR-1

TRT-SUR-2: SENTINEL LYMPH NODE BIOPSY

Statement

All surgically treated women with clinically node-negative (cNO) invasive breast cancer must undergo sentinel lymph node biopsy (SLNB).

Rationale

Sentinel lymph node biopsy is accepted as the standard of care for axillary staging in early, clinically node-negative breast cancer, unless axillary node involvement is proven. All eligible women should undergo sentinel lymph node biopsy.

Quality domain: Clinical effectiveness.

Breast cancer process: Diagnosis; Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-SUR-2.1):** Proportion of surgically treated women with clinically node-negative (cNO) invasive breast cancer who underwent sentinel lymph node biopsy (SLNB).

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-SUR-2

TRT-SUR-2.1 indicator	<p>Number of surgically treated women (breasts counted) with cNO invasive breast cancer who underwent SLNB</p> <hr/> <p style="text-align: right;">x 100</p> <p>Total number of surgically treated women (breasts counted) with cNO invasive breast cancer</p>
Type	Process
Target population	<p>Women aged 18 years or older treated at the BCS who are diagnosed with primary invasive breast cancer.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> - locally advanced cancer; - neoadjuvant therapy; - prior ipsilateral breast cancer.
Norm	≥ 90%
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool.

GUIDELINE RECOMMENDATIONS TRT-SUR-2

Certainty of evidence High

Strength of recommendation Strong

Guideline recommendations

- Offer SLNB to all patients who are having a mastectomy for DCIS (NICE, 2009).
- Do not perform SLNB routinely in patients with a preoperative diagnosis of DCIS who are having breast-conserving surgery, unless they are considered to be at high risk for invasive disease (NICE, 2009).
- Minimal surgery, rather than lymph node clearance, should be performed to stage the axilla for patients with early invasive breast cancer and no evidence of lymph node on ultrasound or a negative ultrasound-guided needle biopsy. SLNB is the preferred technique (NICE, 2009).
- Perform SLNB using the dual technique with isotope and blue dye (NICE, 2009).
- All patients with invasive breast cancer who are operable should have axillary surgery. If there is no proven disease the optimal axillary procedure is SLNB. Quality of evidence: 1⁺. Strength of recommendation: strong (SIGN, 2013).
- SLNB, rather than full nodal clearance, is accepted as the standard of care for axillary staging in early, clinically node-negative breast cancer. Quality of evidence: II. Strength of recommendation: A.
- Women with primary breast cancer, tumors <3cm, and clinically and ultrasound negative nodes should receive SLNB. Quality of evidence: 1A. Strength of recommendation: Strong (KCE, 2013).
- SLNB is not recommended in women with tumors >3cm (T2) or T3-4 invasive breast cancer, inflammatory breast cancer, palpable nodes, multiple tumors, and potentially disturbed lymph flow due to prior surgery. Quality of evidence: 1A. Strength of recommendation: Strong (KCE, 2013).
- SLNB, rather than full nodal clearance, is now accepted as the standard of care for axillary staging in early, clinically node-negative breast cancer. Quality of evidence II; Strength of recommendation: A (Senkus, 2015).
- SLNB delivers less morbidity in terms of shoulder stiffness and arm swelling and allows for a reduced hospital stay. Quality of evidence: I; Strength of recommendation A (Senkus, 2015).
- SLNB is recommended for axillary staging of all patients with clinically node-negative early-stage breast cancer. Patients with pre-operative biopsy proven nodal metastases should undergo axillary lymph node dissection upfront. Quality of evidence: Good. Strength of recommendation: Acceptable (Alberta, 2012).
- Clinicians may offer SNB for women who have operable breast cancer who have the following circumstances: multicentric tumors. Evidence quality: intermediate. Strength of recommendation: moderate (Lyman, 2014).
- Clinicians may offer SNB for women who have operable breast cancer who have the following circumstances (Lyman, 2014):
 - Multicentric tumors. Evidence quality: intermediate. Strength of recommendation: moderate.
 - Ductal carcinoma in situ (DCIS) when mastectomy is performed. Evidence quality: insufficient. Strength of recommendation: weak.
 - Prior breast and/or axillary surgery. Evidence quality: intermediate. Strength of recommendation: strong.
 - Preoperative/neoadjuvant systemic therapy. Evidence quality: intermediate. Strength of recommendation: moderate.

GUIDELINE RECOMMENDATIONS TRT-SUR-2

- *Clinicians should not perform SNB for women who have early-stage breast cancer and are in the following circumstances (Lyman, 2014):*
 - Large or locally advanced invasive breast cancers (tumor size T3/T4). Evidence quality: insufficient. Strength of recommendation: weak.
 - Inflammatory breast cancer. Evidence quality: insufficient. Strength of recommendation: weak.
- DCIS when breast-conserving surgery is planned. Evidence quality: insufficient. Strength of recommendation: strong.
- *Pregnancy. Evidence quality: insufficient. Strength of recommendation: weak.*

SUPPORTING LITERATURE TRT-SUR-2

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SUPPORTING LITERATURE TRT-SUR-2

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REFERENCE DOCUMENTS TRT-SUR-2

TRT-SUR-3: AXILLARY LYMPH NODE DISSECTION WITH CLINICAL NODE-NEGATIVE

Statement

Most surgically treated women with pathologically node-negative (pNO) invasive breast cancer must not undergo axillary lymph node dissection (ALND) (staged by SLNB only).

Rationale

ALND is only indicated when axillary metastasis is evident. If axillary node disease is uncertain, other options are usually considered due to the serious side effects of ALND. Women with pathologically node-negative breast cancer, staged by SLNB, should not undergo ALND.

Quality domain: Clinical effectiveness.

Breast cancer process: Diagnosis; Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-SUR-3.1):** Proportion of surgically treated women with pathologically node-negative (pNO) invasive breast cancer who did not undergo ALND (staged by SLNB only).

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-SUR-3

TRT-SUR-3.1 indicator	$\frac{\text{Number of women (breasts counted) with pathologically node negative (pNO) invasive breast cancer who did not undergo ALND}}{\text{Total number of women (breasts counted) with pathologically node-negative (pNO) invasive breast cancer}} \times 100$
Type	Process
Target population	<p>Women aged 18 or older treated at the BCS with primary invasive breast cancer staged by SLNB.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> - lymph node involvement only verified by positive histology/cytology guided by ultrasound; - neoadjuvant therapy; - prior ipsilateral breast cancer.
Norm	≥ 80%
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool.

GUIDELINE RECOMMENDATIONS TRT-SUR-3

Certainty of evidence High

Strength of recommendation Strong

Guideline recommendations

- *If there is sonographically proven axillary lymph node disease preoperatively, axillary lymph node clearance should be undertaken; if there is no proven disease the optimal axillary procedure is a sentinel lymph node biopsy (SLNB) (or if not, available axillary node sample is an alternative) (SIGN, 2013).*
- *Patients undergoing breast conservation surgery and radiotherapy for T1 or T2 and clinically node-negative breast cancer and who have one or two positive nodes at sentinel lymph node biopsy may be considered for no further treatment to the axilla (SIGN 2013).*
- *Clinicians should not recommend axillary lymph node dissection (ALND) for women with early-stage breast cancer who do not have nodal metastases. Evidence quality: high. Strength of recommendation: strong (ASCO, Lyman, 2014).*
- *Clinicians should not recommend ALND for women with early-stage breast cancer who have one or two SNLB metastases and will receive breast-conserving surgery (BCS) with conventionally fractionated whole-breast radiotherapy. Evidence quality: high. Strength of recommendation: strong (ASCO, Lyman, 2014).*
- *Clinicians may offer ALND for women with early-stage breast cancer with nodal metastases found on SNLB who will receive mastectomy. Evidence quality: low. Strength of recommendation: weak (ASCO, Lyman, 2014).*
- *Minimal surgery, rather than lymph node clearance, should be performed to stage the axilla for patients with early invasive breast cancer and no evidence of lymph node involvement on ultrasound or a negative ultrasound-guided needle biopsy. Sentinel lymph node biopsy (SLNB) is the preferred technique (NICE, 2009).*
- *Offer ALND to patients with early invasive breast cancer who have macrometastases or micrometastases shown in a sentinel lymph node and have a preoperative ultrasound-guided needle biopsy with histologically proven metastatic cancer (NICE, 2009).*
- *Do not offer further axillary treatment to patients found to have only isolated tumour cells in their sentinel lymph nodes. These patients should be regarded as lymph node-negative (NICE, 2009).*
- *ALND is recommended for women with >3 positive SNLB nodes with micro- or macrometastases. Evidence quality: Very low; Strength of recommendation: strong (KCE, 2013).*

SUPPORTING LITERATURE TRT-SUR-3

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REFERENCE DOCUMENTS TRT-SUR-3

TRT-SUR-4: AXILLARY LYMPH NODE DISSECTION IN DUCTAL CARCINOMA IN SITU

Statement

Women with ductal carcinoma in situ (DCIS) who are surgically treated must not undergo axillary lymph node dissection (ALND).

Rationale

ALND should be avoided in women with DCIS who are surgically treated.

Quality domain: Clinical effectiveness.

Breast cancer process: Diagnosis; Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-SUR-4.1):** Proportion of surgically treated women with ductal carcinoma in situ (DCIS) who did not undergo axillary lymph node dissection (ALND).

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-SUR-4

TRT-SUR-4.1 indicator	Number of surgically treated women (breasts counted) with DCIS who did not undergo ALND _____ x 100 Total number of surgically treated women (breasts counted) with DCIS
Type	Process
Target population	Women aged 18 or older treated at the BCS who are diagnosed with DCIS primary breast cancer. Exclusions: DCIS treated with mastectomy; tumour size ≥ 5cm (≥T3).
Norm	≥ 95%
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool.

GUIDELINE RECOMMENDATIONS TRT-SUR-4

Certainty of evidence	High
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Strength of recommendation	Strong
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Guideline recommendations

- *If there is sonographically proven axillary lymph node disease preoperatively, axillary lymph node clearance should be undertaken; if there is no proven disease the optimal axillary procedure is a sentinel lymph node biopsy (SLNB) (or if not available axillary node sample is an alternative) (SIGN, 2013).*
- *Patients undergoing breast conservation surgery and radiotherapy for T1 or T2 and clinically node-negative breast cancer and who have one or two positive nodes at sentinel lymph node biopsy may be considered for no further treatment to the axilla (SIGN, 2013).*
- *Clinicians should not recommend axillary lymph node dissection (ALND) for women with early-stage breast cancer who do not have nodal metastases. Evidence quality: high. Strength of recommendation: strong (ASCO, Lyman 2014).*
- *Clinicians should not recommend ALND for women with early-stage breast cancer who have one or two SNLB metastases and will receive breast-conserving surgery (BCS) with conventionally fractionated whole-breast radiotherapy. Evidence quality: high. Strength of recommendation: strong (ASCO, Lyman 2014).*
- *Clinicians may offer ALND for women with early-stage breast cancer with nodal metastases found on SNLB who will receive mastectomy. Evidence quality: low. Strength of recommendation: weak (ASCO, Lyman 2014).*
- *Minimal surgery, rather than lymph node clearance, should be performed to stage the axilla for patients with early invasive breast cancer and no evidence of lymph node involvement on ultrasound or a negative ultrasound-guided needle biopsy. Sentinel lymph node biopsy (SLNB) is the preferred technique (NICE, 2009).*
- *Offer ALND to patients with early invasive breast cancer who have macrometastases or micrometastases shown in a sentinel lymph node and have a preoperative ultrasound-guided needle biopsy with histologically proven metastatic cancer (NICE, 2009).*
- *Do not offer further axillary treatment to patients found to have only isolated tumour cells in their sentinel lymph nodes. These patients should be regarded as lymph node-negative (NICE, 2009).*
- *ALND is recommended for women with >3 positive SNLB nodes with micro- or macrometastases. Evidence quality: Very low; Strength of recommendation: strong (KCE, 2013).*

SUPPORTING LITERATURE TRT-SUR-4

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REFERENCE DOCUMENTS TRT-SUR-4

TRT-SUR-5: AXILLARY LYMPH NODE DISSECTION WITH 10 OR MORE LYMPH NODES REMOVED

Statement

All women treated with therapeutic axillary lymph node dissection (ALND) must have 10 or more lymph nodes (including sentinel nodes) removed.

Rationale

Therapeutic ALND should only be conducted if lymph node metastasis is identified histologically. A high average lymph-node yield (≥ 10 nodes removed) reflects good surgery. Having 10 or more nodes removed is considered the standard.

Quality domain: Clinical effectiveness.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-SUR-5.1):** Proportion of surgically treated women who undergo axillary lymph node dissection (ALND) and have 10 or more lymph nodes (including sentinel nodes) removed.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-SUR-5

TRT-SUR-5.1 indicator	<p>Number of women (breasts counted) with pathologically positive nodes (pN1, 2, 3) who are treated with therapeutic ALND and have 10 or more lymph nodes (including sentinel nodes) removed</p> <hr/> <p style="text-align: right;">x 100</p> <p>Total number of women (breasts counted) with pathologically positive nodes (pN1, 2, 3) who are treated with therapeutic ALND</p>
Type	Process
Target population	<p>Women aged 18 or older treated at the BCS who are diagnosed with primary invasive breast cancer.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> - prior ipsilateral breast cancer; - neoadjuvant therapy.
Norm	$\geq 90\%$
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool.

GUIDELINE RECOMMENDATIONS TRT-SUR-5

Certainty of evidence (Very) low

Strength of recommendation Not applicable

Guideline recommendations

No specific guideline recommendations found.

SUPPORTING LITERATURE TRT-SUR-5

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- Stordeur S, Vrijens F, Beirens K, Vlayen J, DeVriese S, Van Eycken E. Quality indicators in oncology: breast cancer; KCE reports 150C. Belgian Health Care Knowledge Centre. Federaal Kenniscentrum voor de Gezondheidszorg Centre fédéral d'expertise des soins de santé, 2010.
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REFERENCE DOCUMENTS TRT-SUR-5

TRT-SUR-6: BREAST-CONSERVING SURGERY IN DUCTAL CARCINOMA IN SITU

Statement

Most women with ductal carcinoma in situ (DCIS) with a radiological tumour extent ≤ 2 cm must not undergo mastectomy as the first choice of surgical treatment.

Rationale

Breast-conserving surgery is considered the first choice of treatment in DCIS with small tumour size. However, the choice of surgery must be tailored to the individual patient. Most women with DCIS with a radiological tumour extent ≤ 2 cm should have breast-conserving surgery.

Quality domain: Clinical effectiveness.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-SUR-6.1):** Proportion of surgically treated women with DCIS with a radiological tumour extent ≤ 2 cm who did not undergo primary mastectomy.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-SUR-6

TRT-SUR-6.1 indicator	Number of surgically treated women (breasts counted) with DCIS with a radiological tumour extent ≤ 2 cm who did not undergo primary mastectomy _____ x 100 Total number of surgically treated women (breasts counted) with DCIS with a radiological tumour extent ≤ 2 cm
Type	Process
Population	Women aged 18–74 treated at the BCS who are diagnosed with primary DCIS. Exclusions: - invasive breast cancer; - prior ipsilateral breast cancer.
Norm	$\geq 80\%$
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool.

GUIDELINE RECOMMENDATIONS TRT-SUR-6

Certainty of evidence High

Strength of recommendation Strong

Guideline recommendations

- *Women with high grade and/or palpable and/or large size DCIS who are eligible for breast-conserving surgery should be offered the choice between local wide excision or mastectomy. Evidence quality: 1B; Recommendation: Strong) (Stordeur 2010).*
- *No RCTs comparing breast-conserving surgery with mastectomy in the treatment of patients with DCIS were identified. A meta-analysis of cohort studies of patients with DCIS who were treated by mastectomy or breast conservation surgery showed that local recurrence rates at five years were higher for patients treated by breast conservation surgery with or without radiotherapy. Evidence quality: 2** (SIGN, 2013).*

SUPPORTING LITERATURE TRT-SUR-6

- Andreano A, Anghinoni E, Autelitano M, Bellini A, Bersani M, Bizzoco S, et al. Indicators based on registers and administrative data for breast cancer: routine evaluation of oncologic care pathway can be implemented. *Journal of Evaluation in Clinical Practice* 22 (2016):62-70.
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REFERENCE DOCUMENTS TRT-SUR-6

TRT-SUR-7: BREAST-CONSERVING SURGERY IN INVASIVE BREAST CANCER WITH SMALL TUMOUR SIZE

Statement

Most surgically treated women with invasive breast cancer with a pathological tumour size ≤ 2 cm (pT1) must have breast-conserving treatment as the first choice of treatment.

Rationale

Breast-conserving surgery is considered the first choice of treatment in invasive breast cancer with a small tumour size. However, the choice of surgery must be tailored to the individual patient. Most women with invasive breast cancer with a pathological tumour size ≤ 2 cm should have breast-conserving surgery.

Quality domain: Clinical effectiveness.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-SUR-7.1):** Proportion of surgically treated women with invasive breast cancer with a tumour size ≤ 2 cm (pT1) who underwent breast-conserving surgery.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-SUR-7

TRT-SUR-7.1 indicator	<p>Number of surgically treated women (breasts counted) with invasive breast cancer with a pathological tumour size ≤ 2 cm (pT1) who underwent breast-conserving surgery</p> <hr/> <p>Total number of surgically treated women (breasts counted) with invasive breast cancer with a pathological tumour size ≤ 2 cm (pT1)</p> <p style="text-align: right;">x 100</p>
Type	Process
Target population	<p>Women aged 18 or older treated at the BCS who are diagnosed with primary invasive breast cancer.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> - locally advanced cancer; - prior ipsilateral breast cancer.
Norm	$\geq 70\%$
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool.

GUIDELINE RECOMMENDATIONS TRT-SUR-7

Certainty of evidence High

Strength of recommendation Strong

Guideline recommendations

- *Breast-conserving surgery followed by radiotherapy offers the same benefits regarding local tumour control, recurrence free survival and overall survival as modified radical mastectomy in women with stage I or II breast cancer who are candidates for breast-conserving surgery. Evidence quality: 1A (KCE, 2010).*
- *The choice for surgical treatment should be tailored to the individual patient with invasive stage I or II breast cancer. The patient should be fully informed of all treatment options. Evidence quality: 1A (KCE, 2010).*
- *Breast conserving surgery (wide local excision and radiation therapy) is the local treatment of choice in the majority of patients with invasive cancer. In some circumstances, mastectomy may still be carried out because of tumour size (relative to breast size), tumour multicentricity, prior radiation to the chest or breast, or patient choice (ESMO, Senkus 2015).*
- *Women with invasive breast cancer who are undergoing breast surgery should be offered the choice of either breast conservation surgery or mastectomy. Evidence quality: 1⁺; Recommendation: Strong (SIGN, 2013).*
- *Breast conservation therapy to the breast results in similar long-term mortality rates compared with mastectomy in patients with operable invasive breast cancer. Evidence quality: 1⁺ (SIGN, 2013).*

SUPPORTING LITERATURE TRT-SUR-7

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REFERENCE DOCUMENTS TRT-SUR-7

TRT-SUR-8: SINGLE BREAST OPERATION FOR THE PRIMARY TUMOUR IN DUCTAL CARCINOMA IN SITU

Statement

Most surgically treated women with ductal carcinoma in situ (DCIS) must undergo only 1 operation for the primary tumour.

Rationale

Achieving tumour-free resection margins in a single operation and thereby preventing reoperation is an important goal of breast surgery. Most women with DCIS should undergo only 1 operation.

Quality domain: Clinical effectiveness.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-SUR-8.1):** Proportion of surgically treated women with DCIS who underwent a single breast operation for the primary tumour (only 1 operation).

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-SUR-8

TRT-SUR-8.1 indicator	<p>Number of surgically treated women (breasts counted) with DCIS who underwent a single breast operation for the primary tumour</p> <hr/> <p>Total number of women (breast counted) with DCIS who underwent surgery for the primary tumour</p> <p style="text-align: right;">x 100</p>
Type	Process
Target population	<p>Women aged 18 or older treated at the BCS who are diagnosed with primary DCIS.</p> <p>Exclusions: invasive breast cancer; prior ipsilateral breast cancer.</p>
Norm	≥ 70%
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool.

GUIDELINE RECOMMENDATIONS TRT-SUR-8

Certainty of evidence High

Strength of recommendation Strong

Guideline recommendations

- *In women with DCIS or invasive breast cancer undergoing conservation surgery the radial margins must be clear (≥ 1 mm). Evidence quality: 2⁺; Recommendation: Strong (SIGN, 2013).*
- *Breast conserving surgery should aim at tumor free resection margins (IKNL, 2012).*
- *Negative margins of at least 2 mm are associated with a reduced risk of ipsilateral breast tumor recurrence in patients with DCIS (ASCO, 2016).*
- *No tumour at the inked margin is required and >2 mm (for in situ disease) is preferred (ESMO; Senkus, 2015).*
- *For all patients treated with breast-conserving surgery for DCIS, a minimum of 2 mm radial margin of excision is recommended. Re-excision should be considered if the margin is less than 2 mm, after discussion of the risks and benefits with the patient (NICE, 2009).*
- *When local wide excision is performed in women with DCIS, a tumor free resection margin of 2 mm is usually recommended. Evidence quality: 1C; Recommendation: Strong (KCE, 2010).*

SUPPORTING LITERATURE TRT-SUR-8

- ASCO-JCO-2014-Partridge AH, Rumble RB, Carey LA, Come SE, Davidson NE, Di Leo A, Gralow J, et al. Chemotherapy and Targeted Therapy for Women With Human Epidermal Growth Factor Receptor 2–Negative (or unknown) Advanced Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline.
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- NHS Scotland; Scottish Cancer Taskforce/National Cancer Quality Steering Group. Breast Cancer Clinical Quality Performance Indicators. May 2016.
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REFERENCE DOCUMENTS TRT-SUR-8

TRT-SUR-9: INVASIVE BREAST CANCER WITH A SINGLE BREAST OPERATION

Statement

Most surgically treated women with invasive breast cancer (T1, T2) must undergo only 1 operation for the primary tumour.

Rationale

Achieving tumour-free resection margins in a single operation, thereby preventing reoperation, is an important goal of breast surgery. Most women with invasive breast cancer should undergo only 1 operation.

Quality domain: Clinical effectiveness.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-SUR-9.1):** Proportion of surgically treated women with invasive breast cancer (T1, T2) who underwent a single breast operation for the primary tumour (only 1 operation).

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-SUR-9

TRT-SUR-9.1 indicator	<p>Number of surgically treated women with invasive breast cancer (T1, T2) who underwent a single breast operation for the primary tumour</p> <hr/> <p>Total number of women with invasive breast cancer (T1, T2) who underwent breast surgery for the primary tumour</p> <p style="text-align: right;">x 100</p>
Type	Process
Target population	<p>Women aged 18 or older who are treated at the BCS and diagnosed with primary invasive breast cancer.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> - DCIS; - locally advanced cancer; - prior ipsilateral breast cancer; - procedure solely for reconstructive purposes.
Norm	≥ 80%
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool.

GUIDELINE RECOMMENDATIONS TRT-SUR-9

Certainty of evidence High

Strength of recommendation Strong

Guideline recommendations

- *In women with DCIS or invasive breast cancer undergoing conservation surgery the radial margins must be clear ($\geq 1\text{mm}$). Evidence quality: 2*; Recommendation: Strong (SIGN, 2013).*
- *Breast conserving surgery should aim at tumor free resection margins (IKNL, 2012).*
- *Negative margins (no ink on tumor) minimize the risk of ipsilateral breast tumor recurrence in patients with stage I and II invasive breast cancer. Wider margins widths do not significantly lower this risk. The routine practice to obtain wider negative margins than no ink on tumor is not indicated (SSO-ASCO-ASRO; Moran, 2014).*

SUPPORTING LITERATURE TRT-SUR-9

- ASCO-JCO-2014-Partridge AH, Rumble RB, Carey LA, Come SE, Davidson NE, Di Leo A, Gralow J, et al. Chemotherapy and Targeted Therapy for Women With Human Epidermal Growth Factor Receptor 2–Negative (or unknown) Advanced Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline.
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REFERENCE DOCUMENTS TRT-SUR-9

TRT-SUR-10: IMMEDIATE BREAST RECONSTRUCTION AFTER MASTECTOMY

Statement

The preferred treatment option for women who have undergone mastectomy must be immediate breast reconstruction.

Rationale

Immediate breast reconstruction should be available for most women after mastectomy, as it can make the prospect of losing a breast easier to accept. However, not all women are ready for immediate reconstruction. Some of them may decline or defer reconstruction because of personal preference. Although no specific quality target is set for either immediate or delayed breast reconstruction, it is considered important to monitor the proportion of reconstructions.

Quality domain: Clinical effectiveness.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-SUR-10.1):** Proportion of women who underwent immediate breast reconstruction after mastectomy.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-SUR-10

TRT-SUR-10.1 indicator	<p>Number of women (breasts counted) who underwent immediate breast reconstruction after mastectomy</p> <hr/> <p>Total number of women (breasts counted) who underwent mastectomy</p> <p style="text-align: right;">x 100</p>
Type	Process
Target population	<p>Women aged 18 or older treated at the BCS who are diagnosed with primary DCIS or invasive breast cancer.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> - locally advanced cancer; - contra-indications due to important comorbidities; - prior ipsilateral breast cancer.
Norm	This is a monitoring indicator without a set norm
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool.

GUIDELINE RECOMMENDATIONS TRT-SUR-10

Certainty of evidence Moderate

Strength of recommendation Strong

Guideline recommendations

- *Systematic reviews of studies comparing immediate with delayed reconstruction found trials were of poor quality and had conflicting outcomes. Evidence quality: 2* (SIGN, 2013).*
- *A prospective longitudinal study reported that one year postoperatively, women undergoing either mastectomy alone, immediate or delayed reconstruction all showed similar levels of psychosocial morbidity and continuing support may be required in all patients Evidence quality: 2* (SIGN, 2013).*
- *A further cross-sectional study suggested that women seeking immediate breast reconstruction have higher levels of distress at presentation compared to those seeking delayed reconstruction. Evidence quality: 3 (SIGN, 2013).*
- *Offer immediate breast reconstruction to women who have been advised to have a mastectomy, including those who may need radiotherapy, unless they have significant comorbidities that rule out reconstructive surgery. [2018] (NICE, 2018)*
- *Discuss immediate breast reconstruction with all women who are being advised to have a mastectomy, and offer it except where significant comorbidities may preclude this option. Evidence quality: 1C (KCE, 2010).*
- *Immediate breast reconstruction following mastectomy results in similar survival rates as mastectomy without reconstruction. Evidence quality: 1C (Stordeur, 2010).*

SUPPORTING LITERATURE TRT-SUR10

- Andreano A, Anghinoni E, Autelitano M, Bellini A, Bersani M, Bizzoco S, et al. Indicators based on registers and administrative data for breast cancer: routine evaluation of oncologic care pathway can be implemented. *Journal of Evaluation in Clinical Practice* 22 (2016):62-70.
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REFERENCE DOCUMENTS TRT-SUR-10

TRT-SUR-11: DELAYED BREAST RECONSTRUCTION

Statement

Women who have undergone mastectomy must be offered immediate breast reconstruction. When breast reconstruction is not immediate, women must undergo delayed breast reconstruction within 12 months after mastectomy.

Rationale

Breast reconstruction should be available for women after mastectomy. Immediate reconstruction in most women can make the prospect of losing a breast easier to accept, but not all women will be suitable for immediate reconstruction. Some women may decline or defer reconstruction because of personal preference. Although no specific quality target is set for either immediate or delayed breast reconstruction, it is considered important to monitor the proportion of delayed breast reconstruction within 12 months after mastectomy.

Quality domain: Clinical effectiveness.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-SUR-11.1):** Proportion of women who underwent delayed breast reconstruction within 12 months after mastectomy.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-SUR-11

TRT-SUR-11.1 indicator	$\frac{\text{Number of women (breasts counted) who underwent delayed breast reconstruction within 12 months after mastectomy}}{\text{Total number of women (breasts counted) who underwent mastectomy}} \times 100$
Type	Process
Target population	<p>Women aged 18 or older treated at the BCS who are diagnosed with primary DCIS or invasive breast cancer and are eligible for surgery.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> - locally advanced cancer; - contra-indications due to important comorbidities; - prior ipsilateral breast cancer.
Norm	This is a monitoring indicator without a set norm.
Data source	<p>Indicator to be calculated with the quality indicator calculator tool. The BCS needs to extract data from electronic or paper health records, either manually or via a batch report, to identify: the number of women who underwent mastectomy (denominator); the number of women who underwent delayed breast reconstruction within 12 months after mastectomy (numerator); and the number of women who underwent mastectomy for whom it is unknown whether they underwent delayed breast reconstruction within 12 months after mastectomy (missing). The time frame should be specified, e.g. 1 or 2 calendar years.</p>

GUIDELINE RECOMMENDATIONS TRT-SUR-11

Certainty of evidence Moderate

Strength of recommendation Strong

Guideline recommendations

- *Systematic reviews of studies comparing immediate with delayed reconstruction found trials were of poor quality and had conflicting outcomes. Evidence quality: 2* (SIGN, 2013).*
- *A prospective longitudinal study reported that one year postoperatively, women undergoing either mastectomy alone, immediate or delayed reconstruction all showed similar levels of psychosocial morbidity and continuing support may be required in all patients. Evidence quality: 2* (SIGN, 2013).*
- *A further cross-sectional study suggested that women seeking immediate breast reconstruction have higher levels of distress at presentation compared to those seeking delayed reconstruction. Evidence quality: 3 (SIGN, 2013).*
 - *Offer immediate breast reconstruction to women who have been advised to have a mastectomy, including those who may need radiotherapy, unless they have significant comorbidities that rule out reconstructive surgery. [2018] (NICE, 2018)*
 - *Discuss immediate breast reconstruction with all women who are being advised to have a mastectomy, and offer it except where significant comorbidities may preclude this option. Evidence quality: 1C (KCE 2010).*
- *Evidence quality: 1C ().*
- *Immediate breast reconstruction following mastectomy results in similar survival rates as mastectomy without reconstruction. Evidence quality: 1C (KCE, 2010).*

SUPPORTING LITERATURE TRT-SUR-11

- Andreano A, Anghinoni E, Autelitano M, Bellini A, Bersani M, Bizzoco S, et al. Indicators based on registers and administrative data for breast cancer: routine evaluation of oncologic care pathway can be implemented. *Journal of Evaluation in Clinical Practice* 22 (2016):62-70.
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REFERENCE DOCUMENTS TRT-11

TRT-SYS-1: LEAD TIME BETWEEN LAST SURGERY AND FIRST ADJUVANT CHEMOTHERAPY CYCLE



Statement

Lead time between last surgery and first adjuvant chemotherapy cycle in women with invasive M0 breast cancer must be no longer than 8 weeks.

Rationale

Delaying chemotherapy for too long after surgery significantly increases the risk of local recurrence and might have an adverse impact on survival. Patients should undergo the first adjuvant chemotherapy cycle as soon as possible.

Quality domain: Clinical effectiveness; Safety; Personal empowerment and experience.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-SYS-1.1):** Proportion of surgically treated women with invasive M0 breast cancer, without radiotherapy between surgery and adjuvant chemotherapy, who underwent chemotherapy within ≤ 8 weeks after surgery.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-SYS-1

TRT-SYS-1.1 indicator	<p>Number of surgically treated woman with invasive M0 breast cancer, without radiotherapy between surgery and adjuvant chemotherapy, who started undergoing adjuvant chemotherapy within ≤ 8 weeks after surgery</p> <hr style="width: 100%;"/> <p style="text-align: right;">x 100</p> <p>Total number of surgically treated women with invasive M0 breast cancer, without radiotherapy between surgery and adjuvant chemotherapy, who underwent chemotherapy after surgery</p>
Type	Process
Target population	<p>Women aged 18 or older treated at the BCS who are diagnosed with primary invasive M0 breast cancer, and underwent surgery and adjuvant chemotherapy.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> - prior ipsilateral breast cancer; - DCIS; - M1 breast cancer; - radiotherapy before chemotherapy.
Norm	$\geq 80\%$
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool.

GUIDELINE RECOMMENDATIONS TRT-SYS-1

Certainty of evidence Low

Strength of recommendation Strong

Guideline recommendations

- *It is recommended to start adjuvant chemotherapy or radiotherapy within 8 weeks of completion of surgery. Level of evidence: 1c. Strength of recommendation: Strong.*
- (KCE, 2013).
- *Start adjuvant chemotherapy or radiotherapy as soon as clinically possible within 31 days of completion of surgery in patients with early breast cancer having these treatments (NICE, 2009).*
- *It is recommended that systemic treatment should start preferably within 2-6 weeks after surgery. The data show an important decrease in systemic therapy efficacy when it is administered more than 12 weeks after surgery (Senkus, 2015).*
- *Delaying chemotherapy beyond three months after surgery may have a detrimental outcome in older patients (>65 years) but the evidence for this association is weak. Level of evidence: 2+ (SIGN, 2013).*

SUPPORTING LITERATURE TRT-SYS-1

- Hoeve J van, Munck L de, Otter R, Vries J de, Siesling S. Quality improvement by implementing an integrated oncological care pathway for breast cancer patients. *The Breast* 23 (2014):364-370.
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- Kunker IH, Williams LJ, Jack WJL, Cameron DA, Dixon MD. Breast-conserving surgery with or without irradiation in women aged 65 years or older with early breast cancer (PRIME II): a randomized controlled trial. *Lancet Oncology* 2015; Volume 16;3.
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REFERENCE DOCUMENTS TRT-SYS-1

TRT-SYS-2: ADJUVANT CHEMOTHERAPY IN SURGICALLY TREATED WOMEN WITH INVASIVE M0 BREAST CANCER AND ER-

Statement

All surgically treated women with ER- (T > 1 cm or Node+) invasive M0 breast cancer must undergo adjuvant chemotherapy.

Rationale

Chemotherapy reduces the risk of the distant spread of breast cancer in the years after surgery, increasing the survival rate.

Quality domain: Clinical effectiveness.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-SYS-2.1):** Proportion of surgically treated women with ER- (T > 1 cm or Node+) invasive M0 breast cancer who underwent adjuvant chemotherapy.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-SYS-2

TRT-SYS-2.1 indicator	<p>Number of surgically treated women with ER- (T > 1 cm or Node+) invasive M0 breast cancer who underwent adjuvant chemotherapy</p> <hr/> <p>Total number of surgically treated women with ER- (T > 1 cm or Node+) invasive M0 breast cancer</p> <p style="text-align: right;">x 100</p>
Type	Process
Target population	<p>Women aged 18 or older treated at the BCS who are diagnosed with primary ER- (T > 1 cm or Node+) invasive M0 breast cancer, and surgically treated.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> - prior ipsilateral breast cancer; - DCIS; - ER+, T ≤ 1 cm; - NO, M1; - no surgery; - women who underwent neoadjuvant chemotherapy.
Norm	≥ 85%
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool.

GUIDELINE RECOMMENDATIONS TRT-SYS-2

Certainty of evidence	Not applicable.
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Strength of recommendation	Not applicable.
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Guideline recommendations

- *Chemotherapy is recommended in the vast majority of triple negative, HER2-positive breast cancers and in high risk luminal HER2-negative tumors. Level of evidence: I; Strength of recommendation: A (Senkus, 2015).*
- *The decision on systemic adjuvant therapy should be based on the predicted sensitivity to particular treatment types, the benefit from their use and an individual's risk of relapse. The final decision should also incorporate the predicted treatment sequelae, biological age, general health status, comorbidities and preferences (Senkus, 2015).*
- *The Early Breast Cancer Trialists' Collaborative overview (EBCTCG) overview (Peto 2012) states the relative benefit of chemotherapy is similar in all the subgroups independent of age, stage, histopathological grade and ER status. One needs to take into account that many trials included in the EBCTCG overview have incomplete data on ER expression (Senkus, 2015).*
- *Most Luminal A tumors, except those with the highest risk of relapse (extensive nodal involvement), require no chemotherapy. Level of evidence: I; Strength of recommendation: A (Senkus, 2015).*
- *Luminal B HER2-negative cancers constitute a population of highest uncertainty regarding chemotherapy indications. Level of evidence: I; Strength of recommendation: C (Senkus, 2015).*
- *Luminal B HER2-positive tumors are treated with chemotherapy, endocrine therapy and trastuzumab. Level of evidence: I; Strength of recommendation: A (Senkus, 2015).*
- *Adjuvant chemotherapy should be considered for all patients with breast cancer where benefits outweigh risk (SIGN, 2013).*
- *Chemotherapy should be offered to patients with ER-negative invasive breast cancer (T>1cm or Node+). Data from the EBCTCG and from several clinical trials offer evidence of benefit from chemotherapy vs. no treatment in terms of RFS and OS in patients with ER-negative tumors. Level of evidence: I (Del Turco, 2010).*
- *Decisions about adjuvant therapy should be made based on assessment of the prognostic and side effects of the treatment. Decisions should be made following discussion of these factors with the patient (NICE, 2009).*
- *The choice of the adjuvant systemic treatment for invasive breast cancer should be driven by the hormonal sensitivity, risk profile of the tumor, age, menopausal status, and comorbidities of the patient. Level of evidence: IA; Strength of recommendation: Strong (KCE, 2013).*

SUPPORTING LITERATURE TRT-SYS-2

- Bao H, Yang F, Xinyu Wang X, Su S, Liu D, Fu R, Zhang H, Liu M. Developing a set of quality indicators for breast cancer care in China. *International Journal for Quality in Health Care*, 2015, 27(4), 291–296.
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REFERENCE DOCUMENTS TRT-SYS-2

TRT-SYS-3: ADJUVANT ANTI-HER2 THERAPY IN WOMEN WITH HER2+

Statement

All women with HER2+ invasive M0 breast cancer treated with adjuvant chemotherapy must undergo adjuvant anti-HER2 therapy.

Rationale

The use of trastuzumab as immunotherapy/targeted therapy in the adjuvant therapy of HER2+ breast cancer reduces the risk of relapse by about 50%, and the risk of death by about 30%.

Quality domain: Clinical effectiveness.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-SYS-3.1):** Proportion of women with HER2+ breast cancer treated with adjuvant systemic therapy who underwent adjuvant anti-HER2 therapy.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-SYS-3

TRT-SYS-3.1 indicator	<p>Number of women with HER2+ (N+ or T > 1 cm) invasive M0 breast cancer treated with surgery and chemotherapy who underwent adjuvant anti-HER2 therapy</p> <hr/> <p>Total number of women with HER2+ (N+ or T > 1 cm) invasive M0 breast cancer treated with adjuvant chemotherapy</p>	x 100
Type	Process	
Target population	<p>Women aged 18 or older treated at the BCS who are diagnosed with primary invasive M0 breast cancer with HER2+ (N+ or N- T > 1 cm), and treated with adjuvant chemotherapy.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> - prior ipsilateral breast cancer; - DCIS; - M1; - T ≤ 1 cm; - HER2-. 	
Norm	≥ 85%	
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool.	

GUIDELINE RECOMMENDATIONS TRT-SYS-3

Certainty of evidence High

Strength of recommendation Strong

Guideline recommendations

- *Luminal B HER2-positive tumors are treated with chemotherapy, endocrine treatment and trastuzumab. Level of evidence: I; Strength of recommendation: A (Senkus, 2015).*
- *Trastuzumab combined with chemotherapy in patients with HER2 overexpression approximately halves the recurrence risk compared with chemotherapy alone, translating in a 10% increase in 10-year survival. Level of evidence: I, Strength of recommendation: A (Senkus, 2015).*
- *A one-year course of trastuzumab is indicated for women with HER2-positive, node-positive or high-risk node-negative breast cancer (tumor size >1cm) who received chemotherapy, and with a left ventricular ejection fraction of $\geq 55\%$ and no important cardiovascular risk factors. Level of evidence: Low; Strength of recommendation: Strong (KCE, 2013).*

SUPPORTING LITERATURE TRT-SYS-3

- Bao H, Yang F, Xinyu Wang X, Su S, Liu D, Fu R, Zhang H, Liu M. Developing a set of quality indicators for breast cancer care in China. *International Journal for Quality in Health Care*, 2015, 27(4), 291–296.
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- Senkus E, Kyriakides S, Ohno S, Penault-Llorca F, Poortmans P, Rutgers E, et al. on behalf of the ESMO Guidelines Committee. Primary breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Annals of Oncology* 26 (Suppl. 5) v8-v3.
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REFERENCE DOCUMENTS TRT-SYS-3

TRT-SYS-4: NEOADJUVANT ANTI-HER2 THERAPY IN WOMEN WITH NEOADJUVANT CHEMOTHERAPY

Statement

All women with HER2+ invasive M0 breast cancer treated with neoadjuvant chemotherapy must undergo neoadjuvant anti-HER2 therapy.

Rationale

The use of anti-HER2 therapy as neoadjuvant therapy in patients with invasive breast cancer increases pathologic complete response rates.

Quality domain: Clinical effectiveness.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-SYS-4.1):** Proportion of women with HER2+ (N+ or T > 1 cm) invasive M0 breast cancer treated with neoadjuvant chemotherapy who underwent neoadjuvant anti-HER2 therapy.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-SYS-4

TRT-SYS-4.1 indicator	<p>Number of women with HER2+ (N+ or T > 1 cm) invasive M0 breast cancer treated with neoadjuvant chemotherapy who underwent neoadjuvant anti-HER2 therapy</p> <hr style="width: 80%; margin-left: 0;"/> <p style="text-align: right;">x 100</p> <p>Total number of women with HER2+ (N+ or T > 1 cm) invasive M0 breast cancer treated with neoadjuvant chemotherapy</p>
Type	Process
Target population	<p>Women aged 18 or older treated at the BCS who are diagnosed with primary invasive M0 breast cancer with HER2+ (N+ or T > 1 cm), and treated with neoadjuvant chemotherapy.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> - prior ipsilateral breast cancer; - DCIS; - M1; - T ≤ 1 cm; - HER2-.
Norm	≥ 90%
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool.

GUIDELINE RECOMMENDATIONS TRT-SYS-4

Certainty of evidence High-low

Strength of recommendation Strong

Guideline recommendations

- *Luminal B HER2-positive tumours are treated with chemotherapy, endocrine treatment and trastuzumab. Level of evidence: I; Strength of recommendation: A (Senkus, 2015).*
- *Trastuzumab combined with chemotherapy in patients with HER2 overexpression approximately halves the recurrence risk compared with chemotherapy alone, translating in a 10% increase in 10-year survival. Level of evidence: I, Strength of recommendation: A. (Senkus, 2015).*
- *A one-year course of trastuzumab is indicated for women with HER2-positive, node-positive or high-risk node-negative breast cancer (tumour size >1cm) who received chemotherapy, and with a left ventricular ejection fraction of $\geq 55\%$ and no important cardiovascular risk factors. Level of evidence: Low; Strength of recommendation: Strong (KCE, 2013).*

SUPPORTING LITERATURE TRT-SYS-4

- Bao H, Yang F, Xinyu Wang X, Su S, Liu D, Fu R, Zhang H, Liu M. Developing a set of quality indicators for breast cancer care in China. *International Journal for Quality in Health Care*, 2015, 27(4), 291–296.
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- Iwamoto M, Nakamura F, Higashi T. Monitoring and evaluating the complexity of cancer care in Japan using administrative claims data. *Cancer Sci.* 2016 Jan;107(1):68-75.

REFERENCE DOCUMENTS TRT-SYS-4

TRT-SYS-5: MONITORED CARDIAC FUNCTION IN WOMEN WITH BREAST CANCER TREATED WITH ANTI-HER2

Statement

All women with breast cancer treated with anti-HER2 therapy must undergo cardiac function monitoring every 3 months during treatment.

Rationale

Treatment with anti-HER2 therapy is associated with an increased risk of congestive heart failure and ejection fraction reduction, warranting periodic monitoring.

Quality domain: Clinical effectiveness; Safety.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-SYS-5.1):** Proportion of women with breast cancer treated with anti-HER2 therapy, and whose cardiac function is monitored every 3 months.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-SYS-5

TRT-SYS-5.1 indicator	<p>Number of women with breast cancer treated with anti-HER2 therapy and whose cardiac function is monitored every 3 months</p> <hr/> <p>Total number of women with breast cancer treated with anti-HER2 therapy</p> <p style="text-align: right;">x 100</p>
Type	Process
Target population	<p>Women aged 18 or older treated at the BCS who are diagnosed with primary breast cancer and treated with anti-HER2 therapy.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> - prior ipsilateral breast cancer; - not treated with trastuzumab.
Norm	≥ 95%
Data source and additional information for auditing	Indicator to be calculated by the BCS.

GUIDELINE RECOMMENDATIONS TRT-SYS-5

Certainty of evidence Low

Strength of recommendation Strong

Guideline recommendations

- *In patients under trastuzumab, cardiac function should be monitored during treatment (every 3 months) and during follow-up. Level of evidence: Low; Strength of recommendations: Strong (KCE, 2013).*
- *Assess cardiac function before starting treatment with trastuzumab. Do not offer trastuzumab treatment to women who have any of the following: a left ventricular ejection fraction (LVEF) of 55% or less; a history of documented congestive heart failure; high-risk uncontrolled arrhythmias; angina pectoris requiring medication; clinically significant valvular disease; evidence of transmural infarction on electrocardiograph; poorly controlled hypertension (NICE, 2009).*
- *Repeat cardiac functional assessments every 3 months during trastuzumab treatment. If the LVEF drops by 10 percentage (ejection) points or more from baseline and to below 50% then trastuzumab treatment should be suspended. Restart trastuzumab therapy only after further cardiac assessment and a fully informed discussion with the patient on the treatment risks and benefits (NICE, 2018).*

SUPPORTING LITERATURE TRT-SYS-5

- Bao H, Yang F, Xinyu Wang X, Su S, Liu D, Fu R, Zhang H, Liu M. Developing a set of quality indicators for breast cancer care in China. *International Journal for Quality in Health Care*, 2015, 27(4), 291–296.
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TRT-SYS-6: PRESCRIPTION OF ENDOCRINE THERAPY IN SURGICALLY TREATED WOMEN ER+ AND/OR PR+

Statement

All surgically treated women with hormone sensitive (ER+ and/or PR+) invasive M0 breast cancer must be prescribed endocrine therapy.

Rationale

Endocrine therapy (such as tamoxifen) is used after surgery to reduce the risk of recurrence in women with hormone-sensitive breast cancer. This therapy should start as soon as possible, and no later than 1 year after diagnosis.

Quality domain: Clinical effectiveness.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-SYS-6.1):** Proportion of surgically treated women with hormone-sensitive (ER+ and/or PR+) invasive M0 breast cancer who were prescribed endocrine therapy.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-SYS-6

TRT-SYS-6.1 indicator	<p>Number of surgically treated women with hormone-sensitive (ER+ and/or PR+) invasive M0 breast cancer who were prescribed endocrine therapy</p> <hr/> <p>Total number of surgically treated women with hormone-sensitive (ER+ and/or PR+) invasive M0 breast cancer</p> <p style="text-align: right;">x 100</p>
Type	Process
Target population	<p>Women aged 18 or older treated at the BCS who are diagnosed with hormone-sensitive (ER+ and/or PR+) primary invasive M0 breast cancer, and surgically treated.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> - prior ipsilateral breast cancer; - DCIS; - M1; - without surgery; - not hormone-sensitive (ER-, PR-).
Norm	≥ 85%
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool.

GUIDELINE RECOMMENDATIONS TRT-SYS-6

Certainty of evidence High

Strength of recommendation Strong

Guideline recommendations

- *Premenopausal women with hormone-receptor positive breast cancer should receive adjuvant endocrine treatment with tamoxifen for 5 years, with or without an LHRH analogue. Level of evidence: 1A; Strength of recommendation: Strong. (KCE, 2013).*
- *Endocrine therapy is indicated in all patients with detectable ER expression irrespective of the use of chemotherapy and/or targeted therapy. Level of evidence: I, Strength of recommendation: A (Senkus, 2015).*
- *Pre-menopausal women with ER positive invasive breast cancer should be treated with tamoxifen for at least five years, to a total of 10 years, unless there are contraindications or side effects. Level of evidence: 1++, Strength of recommendation: Strong (SIGN, 2013).*
- *Adjuvant treatment with tamoxifen for five years has a positive effect on 5-10 year survival in ER positive women with invasive breast cancer. Level of evidence: A1; Strength of recommendation: 1 (IKNL, 2012).*
- *Consider adjuvant therapy for all patients with early invasive breast cancer after surgery at the multidisciplinary team meeting and ensure that decisions are recorded (NICE, 2018).*
- *Decisions about adjuvant therapy should be made based on assessment of the prognostic and predictive factors, the potential benefits and side effects of the treatment. Decisions should be made following discussion of these factors with the patient (NICE, 2018).*
- *Do not offer adjuvant tamoxifen after breast-conserving surgery to patients with DCIS (NICE, 2018).*

SUPPORTING LITERATURE TRT-SYS-6

- Bao H, Yang F, Xinyu Wang X, Su S, Liu D, Fu R, Zhang H, Liu M. Developing a set of quality indicators for breast cancer care in China. *International Journal for Quality in Health Care*, 2015, 27(4), 291–296.
- Barni S, Venturini M, Molino A, Donadio M, Rizzoli S, Maiello E, Gori S. Importance of adherence to guidelines in breast cancer clinical practice. The Italian experience (AIOM). *Tumori*, 97: 559-563, 2011.
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- KCE. Borstkanker bij vrouwen: Diagnose, behandeling en follow-up (synthese), 2013.
- NICE. Early and locally advanced breast cancer: diagnosis and treatment. Clinical guideline 2018.
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- IKNL NABON. Breast Cancer Dutch Guideline, version 2.0 2012.
- Khare SR, Batist G, Bartlett G. Identification of performance indicators across a network of clinical cancer programs. *Curr Oncol.* 2016 Apr;23(2):81-90.

REFERENCE DOCUMENTS TRT-SYS-6

TRT-SYS-7: NEOADJUVANT CHEMOTHERAPY IN WOMEN WITH STAGE II AND III TRIPLE NEGATIVE BREAST CANCER

Statement

Women with stage II and III triple negative breast cancer must be offered neoadjuvant chemotherapy.

Rationale

The current accepted standard of care is to use neoadjuvant chemotherapy in patients with stage II and III triple negative breast cancer, as it improves breast conservation and pathologic complete response. In this group of women, it is important to monitor the use of neoadjuvant chemotherapy.

Quality domain: Clinical effectiveness.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-SYS-7.1):** Proportion of women with stage II and III triple negative breast cancer who underwent neoadjuvant chemotherapy.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-SYS-7

TRT-SYS-7.1 indicator	<p>Number of women with stage II and III triple negative breast cancer who underwent neoadjuvant chemotherapy</p> <hr/> <p>Total number of women with stage II and III triple negative breast cancer</p> <p style="text-align: right;">x 100</p>
Type	Process
Target population	<p>Women aged 18 or older diagnosed with stage II and III triple negative breast cancer.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> - stage I; - M1 breast cancer; - stage II and III breast cancer ER+ or PR+ or HER2+.
Norm	Indicator without a set norm.
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool.

GUIDELINE RECOMMENDATIONS TRT-SYS-7

Certainty of evidence Moderate-high

Strength of recommendation Moderate-strong

Guideline recommendations

Neoadjuvant chemotherapy should be considered for all patients with breast cancer whose disease is inoperable (locally advanced or inflammatory) but localised to the breast/locoregional lymphnode groups (SIGN, 2013).

- *Neoadjuvant chemotherapy can be considered as part of a multimodal treatment approach for patients with stage IIa, IIb, and III breast cancer (SIGN, 2013).*
- *Preoperative systemic therapy for operable breast cancer: workup - Invasive Breast Cancer: Stage IIA T2, N0, M0, Stage IIB T2, N1, M0; T3, N0, M0 and Stage IIIA T3, N1, M0 (Gradishar, 2017).*

SUPPORTING LITERATURE TRT-SYS-7

- St Gallen consensus Meeting, 2017.
- Treatment of primary breast cancer. SIGN, 2013.
- Gradishar WJ, Anderson BO, Balassanian R, Blair SL, Burstein HJ, Cyr A, Elias AD, Farrar WB, Forero A, Giordano SH, Goetz MP, Goldstein LJ, Isakoff SJ, Lyons J, Marcom PK, Mayer IA, McCormick B, Moran MS, O'Regan RM, Patel SA, Pierce LJ, Reed EC, Salerno KE, Schwartzberg LS, Sitapati A, Smith KL, Smith ML, Soliman H, Somlo G, Telli M, Ward JH, Shead DA, Kumar R. NCCN Guidelines Insights: Breast Cancer, Version 1.2017. J Natl Compr Canc Netw. 2017 Apr;15(4):433-451.
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REFERENCE DOCUMENTS TRT-SYS-7

TRT-SYS-8: WOMEN WITH STAGE II AND III HER2+ BREAST CANCER UNDERGOING NEOADJUVANT SYSTEMIC THERAPY

Statement

Women with stage II and III HER2+ breast cancer must be offered neoadjuvant systemic therapy.

Rationale

The use of neoadjuvant systemic therapy in patients with stage II and III HER2+breast cancer improves breast conservation and pathologic complete response, and is the current accepted standard of care. It is important to monitor the use of neoadjuvant systemic therapy in this group of women.

Quality domain: Clinical effectiveness.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-SYS-8.1):** Proportion of women with stage II and III HER2+ breast cancer who underwent neoadjuvant systemic therapy.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-SYS-8

TRT-SYS-8.1 indicator	Number of women with stage II and III HER2+breast cancer who underwent neoadjuvant systemic therapy _____ x 100 Total number of women with stage II and III HER2+ breast cancer
Type	Process
Target population	Women aged 18 or older diagnosed with stage II and III HER2+breast cancer. Exclusions: - stage I; - M1 breast cancer; - breast cancer HER-.
Norm	Indicator without a set norm.
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool.

GUIDELINE RECOMMENDATIONS TRT-SYS-8

Certainty of evidence Moderate-high

Strength of recommendation Moderate-strong

Guideline recommendations

- Preoperative systemic therapy for operable breast cancer: workup - Invasive Breast Cancer: Stage IIA T2, N0, M0, Stage IIB T2, N1, M0; T3, N0, M0 and Stage IIIa T3, N1, M0 (Gradishar, 2017).

SUPPORTING LITERATURE TRT-SYS-8

- St Gallen consensus Meeting, 2017.
- Gianni L, Eiermann W, Semiglazov V, Manikhas A, Lluch A, Tjulandin S, Zambetti M, Vazquez F, Byakhov M, Lichinitser M, Climent MA, Ciruelos E, Ojeda B, Mansutti M, Bozhok A, Baronio R, Feyereislova A, Barton C, Valagussa P, Baselga J. Neoadjuvant chemotherapy with trastuzumab followed by adjuvant trastuzumab versus neoadjuvant chemotherapy alone, in patients with HER2-positive locally advanced breast cancer (the NOAH trial): a randomised controlled superiority trial with a parallel HER2-negative cohort. *The Lancet*, 2010; 375, p. 377-384.
- Kaufmann M, von Minckwitz G, Mamounas EP et al. Recommendations from an International Consensus Conference on the Current Status and Future of Neoadjuvant Systemic Therapy in Primary Breast Cancer. *Ann Surg Oncol* (2012) 19: 1508.
- Treatment of primary breast cancer. SIGN, 2013.
- Gradishar WJ, Anderson BO, Balassanian R, Blair SL, Burstein HJ, Cyr A, Elias AD, Farrar WB, Forero A, Giordano SH, Goetz MP, Goldstein LJ, Isakoff SJ, Lyons J, Marcom PK, Mayer IA, McCormick B, Moran MS, O'Regan RM, Patel SA, Pierce LJ, Reed EC, Salerno KE, Schwartzberg LS, Sitapati A, Smith KL, Smith ML, Soliman H, Somlo G, Telli M, Ward JH, Shead DA, Kumar R. NCCN Guidelines Insights: Breast Cancer, Version 1.2017. *J Natl Compr Canc Netw*. 2017 Apr;15(4):433-451.

REFERENCE DOCUMENTS TRT-SYS-8

TRT-SYS-9: NEOADJUVANT SYSTEMIC THERAPY IN WOMEN WITH LOCALLY ADVANCED BREAST CANCER

Statement

All women with locally advanced breast cancer (tumour > 3 cm or T4 or nodal status ≥ N2) must undergo neoadjuvant systemic therapy.

Rationale

The use of neoadjuvant systemic therapy in patients with locally advanced breast cancer reduces the risk of relapse and death.

Quality domain: Clinical effectiveness.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-SYS-9.1):** Proportion of women with locally advanced breast cancer (tumour > 3 cm or T4 or nodal status ≥ N2) who underwent neoadjuvant systemic therapy.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-SYS-9

TRT-SYS-9.1 indicator	<p>Number of women with locally advanced breast cancer (tumour > 3 cm or T4 or nodal status ≥ N2) who underwent neoadjuvant systemic therapy</p> <hr/> <p style="text-align: right;">x 100</p> <p>Total number of women with locally advanced breast cancer (tumour > 3 cm or T4 or nodal status ≥ N2)</p>
Explanation of terms	Neoadjuvant systematic therapy includes chemotherapy, endocrine therapy and/or targeted anti-HER2 therapy.
Type	Process
Target population	<p>Women aged 18 or older with locally advanced breast cancer (tumour > 3 cm or T4 or nodal status ≥ N2).</p> <p>Exclusion: M1 stage.</p>
Norm	≥ 90%
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool.

GUIDELINE RECOMMENDATIONS TRT-SYS-9

Certainty of evidence Moderate-high

Strength of recommendation Moderate

Guideline recommendations

- Neoadjuvant (primary, preoperative) systemic therapy is now deemed the standard treatment for patients with locally advanced, primarily inoperable or inflammatory breast carcinoma (SIGN, 2013).
- Patients with HER2-positive tumors should be treated with preoperative systemic therapy incorporating trastuzumab for at least 9 weeks of preoperative therapy. A pertuzumab-containing regimen may be administered preoperatively to patients with greater than or equal to T2 or greater than or equal to N1, HER2-positive early-stage breast cancer. (Gradishar, 2017).

SUPPORTING LITERATURE TRT-SYS-9

- Treatment of primary breast cancer. SIGN, 2013.
- Gradishar WJ, Anderson BO, Balassanian R, Blair SL, Burstein HJ, Cyr A, Elias AD, Farrar WB, Forero A, Giordano SH, Goetz MP, Goldstein LJ, Isakoff SJ, Lyons J, Marcom PK, Mayer IA, McCormick B, Moran MS, O'Regan RM, Patel SA, Pierce LJ, Reed EC, Salerno KE, Schwartzberg LS, Sitapati A, Smith KL, Smith ML, Soliman H, Somlo G, Telli M, Ward JH, Shead DA, Kumar R. NCCN Guidelines Insights: Breast Cancer, Version 1.2017. J Natl Compr Canc Netw. 2017 Apr;15(4):433-451.

REFERENCE DOCUMENTS TRT-SYS-9

TRT-SYS-10: METASTASIS ENDOCRINE TREATMENT

Statement

The preferred option for the first line of treatment in women with ER+ and HER2-metastatic breast cancer is endocrine-based treatment.

Rationale

Endocrine therapy is the preferred option for hormone receptor-positive disease, even in the presence of visceral disease, unless there is visceral crisis or proof of endocrine resistance. Chemotherapy is not the first choice for this group.

Quality domain: Clinical effectiveness.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-SYS-10.1):** Proportion of women with ER+ and HER2- metastatic (at diagnosis) breast cancer who underwent only endocrine-based therapy in the first line of treatment.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-SYS-10

TRT-SYS-10.1 indicator	Number of women with ER+ and HER2-metastatic (at diagnosis) breast cancer who underwent only endocrine-based therapy <hr style="width: 60%; margin-left: 0;"/> x 100 Total number of women with ER+ and HER2- metastatic breast cancer
Type	Process
Target population	Women aged 18 or older diagnosed with ER+ and HER2- breast cancer. Exclusion: women with ER- and/or HER2+ breast cancer.
Norm	≥ 50%
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool.

GUIDELINE RECOMMENDATIONS TRT-SYS-10

Certainty of evidence Not applicable

Strength of recommendation Not applicable

Guideline recommendations

No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE TRT-SYS-10

- Del Turco M, Ponti A, Bick U, Biganzoli L, Cserni G, et al. Quality indicators in breast cancer care. *European Journal of Cancer* 46(2010):2344-2356.
 - Biganzoli, Marotti, Hart et al. Quality indicators in breast cancer care: An update from the EUSOMA working group. *European Journal of Cancer* 86 (2017) 59e81.
 - Bao H, Yang F, Xinyu Wang X, Su S, Liu D, Fu R, Zhang H, Liu M. Developing a set of quality indicators for breast cancer care in China. *International Journal for Quality in Health Care*, 2015, 27(4), 291–296.
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REFERENCE DOCUMENTS TRT-SYS-10

TRT-SYS-11: BONE-MODIFYING AGENTS IN WOMEN WITH BONE METASTASES FROM BREAST CANCER.

Statement

All women with bone metastases from breast cancer must receive bone-modifying agents.

Rationale

Bone metastasis from breast cancer occurs frequently. Treatment of bone metastasis with bone-modifying agents reduces the risk of developing a skeletal event and bone pain, and could improve quality of life.

Quality domain: Clinical effectiveness.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-SYS-11.1):** Proportion of women diagnosed with breast cancer with bone metastasis who receive bone-modifying agents.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-SYS-11

TRT-SYS-11.1 indicator	<p>Number of women diagnosed with breast cancer with bone metastasis who receive bone-modifying agents</p> <hr/> <p>Total number of women diagnosed with breast cancer with bone metastasis</p> <p style="text-align: right;">x 100</p>
Type	Process
Target population	<p>Women aged 18 or older who are diagnosed with bone metastasis from breast cancer.</p> <p>Exclusion: breast cancer without bone metastasis</p>
Norm	90%
Data source and additional information for auditing	Indicator to be calculated by the BCS.

GUIDELINE RECOMMENDATIONS TRT-SYS-11

Certainty of evidence High

Strength of recommendation Not applicable

Guideline recommendations

- Recommendations for use of bisphosphonates for advanced breast cancer (Cancer Australia, 2011):
 - In women with advanced breast cancer and clinically evident bone metastases (who may or may not be having systemic therapy).
 - Bisphosphonates should be considered to reduce:
 - risk of developing a skeletal event
 - risk of hypercalcemia
 - rate (frequency) of skeletal events.
 - Bisphosphonates should be considered to delay time to a skeletal event.
 - Bisphosphonates should be considered to reduce bone pain.

SUPPORTING LITERATURE TRT-SYS-11

- Stordeur S, Vrijens F, Devriese S, Beirens K, Van Eycken E, Vlayen E. Developing and measuring a set of process and outcome indicators for breast cancer. *The Breast*, 21 (2012) 253e260.
- Pavlakis N, Stockler M. Bisphosphonates for breast cancer. *Cochrane Database Syst Rev*. 2002;(1):CD003474.
- Cancer Australia, 2011. Available at: <https://canceraustralia.gov.au/publications-and-resources/clinical-practice-guidelines/recommendations-use-bisphosphonates-advanced-breast-cancer>

REFERENCE DOCUMENTS TRT-SYS-11

TRT-RAD-1: RADIOTHERAPY LEAD TIME

Statement

The lead time between completion of surgical therapy or the last cycle of adjuvant chemotherapy and first radiotherapy treatment for women with primary invasive M0 breast cancer must not exceed 8 weeks.

Rationale

Delaying radiotherapy for too long after surgery significantly increases the risk of local recurrence and might have an adverse impact on survival. Women diagnosed with DCIS also have a higher risk of developing invasive disease in the same breast.

Quality domain: Clinical effectiveness.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-RAD-1.1):** Proportion of surgically treated women with primary M0 invasive breast cancer who underwent adjuvant radiotherapy, and who started undergoing radiotherapy ≤ 8 weeks after the date of surgery or the date of the last cycle of adjuvant chemotherapy.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-RAD-1

TRT-RAD-1.1 indicator	<p>Number of surgically treated women with primary M0 invasive breast cancer who underwent adjuvant radiotherapy, and who started undergoing radiotherapy ≤ 8 weeks after the date of surgery or the date of the last cycle of adjuvant chemotherapy</p> <hr style="width: 80%; margin-left: 0;"/> <p style="text-align: right;">x 100</p> <p>Total number of surgically treated women with primary M0 invasive breast cancer who underwent radiotherapy after surgery</p>
Type	Process
Target population	<p>Women aged 18 or older treated at the BCS who are diagnosed with primary invasive M0 breast cancer, are surgically treated for breast cancer (last surgery), and undergo adjuvant radiotherapy.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> - prior ipsilateral breast cancer; - DCIS; - M1 breast cancer - without surgery; - without radiotherapy.
Norm	≥ 80%
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool.

GUIDELINE RECOMMENDATIONS TRT-RAD-1

Certainty of evidence Low

Strength of recommendation Strong

Guideline recommendations

- *It is recommended to start adjuvant chemotherapy or radiotherapy within 8 weeks of completion of surgery. Quality of evidence: 1c. Strength of recommendation: Strong (KCE, 2013).*
- *Retrospective and observational studies indicate that delaying radiotherapy beyond eight weeks has a detrimental effect on local recurrence. Quality of evidence: 2+ (SIGN, 2013).*
- *Start adjuvant chemotherapy or radiotherapy as soon as clinically possible within 31 days of completion of surgery in patients with early breast cancer having these treatments (NICE, 2009).*

SUPPORTING LITERATURE TRT-RAD-1

- Barni S, Venturini M, Molino A, Donadio M, Rizzoli S, Maiello E, Gori S. Importance of adherence to guidelines in breast cancer clinical practice. The Italian experience (AIOM). *Tumori*, 97: 559-563, 2011.
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- Iwamoto M, Nakamura F, Higashi T. Monitoring and evaluating the complexity of cancer care in Japan using administrative claims data. *Cancer Sci.* 2016 Jan;107(1):68-75.
- Hoeve J van, Munck L de, Otter R, Vries J de, Siesling S. Quality improvement by implementing an integrated oncological care pathway for breast cancer patients. *The Breast* 23 (2014):364-370.
- Vujovic O, Yu E, Cherian A, Dar AR, Stitt L, Perera F. Time interval from breast-conserving surgery to breast irradiation in early stage node-negative breast cancer: 17-year follow-up results and patterns of recurrence. *International Journal of Radiation Oncology *Biology*Physics* 2015: 91 (2).
- Bao H, Yang F, Xinyu Wang X, Su S, Liu D, Fu R, Zhang H, Liu M. Developing a set of quality indicators for breast cancer care in China. *International Journal for Quality in Health Care*, 2015, 27(4), 291–296.
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- Stordeur S, Vrijens F, Devriese S, Beirens K, Van Eycken E, Vlayen J. Developing and measuring a set of process and outcome indicators for breast cancer. *The Breast* 21(2012):253-260.
- Treatment of primary breast cancer. SIGN. September 2013.
- Early diagnosis and locally advanced breast cancer: diagnosis and treatment. London. NICE, 2018.

REFERENCE DOCUMENTS TRT-RAD-1

TRT-RAD-2: INVASIVE BREAST CANCER WITH BREAST-CONSERVING THERAPY



Statement

All women with M0 invasive breast cancer treated with breast-conserving therapy must be offered whole breast adjuvant radiotherapy or, when indicated, partial breast radiotherapy.

Rationale

After breast-conserving surgery, radiotherapy substantially reduces the risk of cancer recurring in the breast and moderately reduces the risk of death. Radiotherapy may help prevent breast cancer from recurring or spreading to other parts of the body by eliminating microscopic lesions that remain in the breast after surgery.

Quality domain: Clinical effectiveness.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-RAD-2.1):** Proportion of women with M0 invasive breast cancer treated with breast-conserving therapy who underwent whole breast adjuvant radiotherapy.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-RAD-2	
TRT-RAD-2.1 indicator	<p>Number of women (breasts counted) diagnosed with M0 invasive breast cancer and treated with breast-conserving surgery who underwent whole breast adjuvant radiotherapy</p> <hr/> <p style="text-align: right;">x 100</p> <p>Total number of women (breasts counted) diagnosed with M0 invasive breast cancer and treated with breast-conserving surgery</p>
Target population	<p>Women aged 18 or older treated at the BCS who are diagnosed with primary invasive M0 breast cancer and treated with breast-conserving surgery.</p> <p>Exclusions:</p> <ul style="list-style-type: none"> - prior ipsilateral breast cancer; - DCIS; - M1 breast cancer; - without breast-conserving surgery; - partial breast radiotherapy.
Norm	≥ 90%
Type	Process
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool.

GUIDELINE RECOMMENDATIONS TRT-RAD-2

Certainty of evidence High

Strength of recommendation Strong

Guideline recommendations

- *Postoperative whole breast radiotherapy is strongly recommended after breast-conserving surgery. Quality of evidence: I, Strength of recommendation: A (Senkus, 2015).*
- *Postoperative external beam radiotherapy to the conserved breast should be considered for all patients undergoing conservation surgery for early breast cancer. Quality of evidence: 1++ (SIGN, 2013).*
- *In patients with early breast cancer adjuvant radiation therapy is indicated after breast-conserving surgery Quality of evidence: 1A. Strength of recommendation: Strong (KCE, 2013)*
- *Patients with early invasive breast cancer who have had breast-conserving surgery with clear margins should have breast radiotherapy (NICE, 2018).*
- *WBRT (whole breast radiation therapy) after BCS, with a boost to the tumour bed, should be considered in all elderly patients since it decreases risk of local relapse (Biganzoli, 2012).*

SUPPORTING LITERATURE TRT-RAD-2

- Andreano A, Anghinoni E, Autelitano M, Bellini A, Bersani M, Bizzoco S, et al. Indicators based on registers and administrative data for breast cancer: routine evaluation of oncologic care pathway can be implemented. *Journal of Evaluation in Clinical Practice* 22 (2016):62-70.
- Barni S, Venturini M, Molino A, Donadio M, Rizzoli S, Maiello E, Gori S. Importance of adherence to guidelines in breast cancer clinical practice. The Italian experience (AIOM). *Tumori*, 97: 559-563, 2011.
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- Caldarella A, Amunni G, Angiolini C, Crocetti E, Di Constanzo F, Di Leo A, et al. Feasibility of evaluating quality cancer care using registry data and electronic health records: a population-based study. *International Journal for Quality of Health Care* 2012; 24,4:411-418.
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- Falco G, Rocoo N, Procaccini E, Sommella MG, Bordoni D, Castagnetti F. et al. Breast conserving treatment for ductal carcinoma in situ in the elderly: can radiation therapy be avoided? Our experience. *International Journal of Surgery* 2014;12, supplement 2.

SUPPORTING LITERATURE TRT-RAD-2

- IKNL NABON. Breast Cancer Dutch Guideline, version 2.0 2012.
- Jacke CO, Albert US, Kalder M, The adherence paradox: guideline deviations contribute to the increased; 5 year survival of breast cancer patients. *BMC Cancer* 2015;15:734.
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- DKG. Catalogue of requirements for Breast Cancer Centres of the German Cancer Society Version J2, 12 August 2019.
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REFERENCE DOCUMENTS TRT-RAD-2

TRT-RAD-3: MASTECTOMY IN INVASIVE BREAST CANCER

Statement

All women with invasive M0 breast cancer with ≥ 4 axillary lymph nodes involved must be offered local or regional radiotherapy after mastectomy.

Rationale

Post-mastectomy radiotherapy significantly and substantially improves loco-regional control in all women with node-positive disease. Post-mastectomy radiotherapy significantly increases overall survival.

Quality domain: Clinical effectiveness.

Breast cancer process: Treatment.

Measurement: This requirement is measured by 1 indicator.

- **Indicator to be monitored (TRT-RAD-3.1):** Proportion of women with invasive M0 breast cancer with ≥ 4 axillary lymph nodes involved, who underwent local or regional radiotherapy after mastectomy.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT TRT-RAD-3

TRT-RAD-3.1 indicator	<p>Number of women (breasts counted) diagnosed with invasive M0 breast cancer with ≥ 4 axillary lymph nodes involved, who underwent local or regional radiotherapy after mastectomy</p> <hr style="width: 50%; margin-left: 0;"/> <p style="text-align: right;">x 100</p> <p>Total number of women (breasts counted) diagnosed with invasive M0 breast cancer with ≥ 4 axillary lymph nodes involved, who underwent mastectomy</p>
Target population	<p>Women aged 18 or older who are diagnosed with M0 breast cancer with ≥ 4 positive axillary lymph nodes.</p> <p>Exclusion: M1 breast cancer; without mastectomy</p>
Norm	$\geq 90\%$
Type	Process
Data source and additional information for auditing	Indicator to be calculated with the quality indicator calculator tool.

GUIDELINE RECOMMENDATIONS TRT-RAD-3

Certainty of evidence High

Strength of recommendation Strong

Guideline recommendations

- *Adjuvant chest wall radiotherapy after mastectomy should be offered to patients with early invasive breast cancer at high risk of local recurrence, i.e. with four or more positive axillary lymph nodes or involved resection margins. Quality of evidence: 1A. Strength of recommendation: Strong (KCE, 2013).*
- *Until data from a large ongoing randomized trial become available, radiotherapy after mastectomy should be offered to patients with 1-3 positive nodes. Quality of evidence: 1a. Strength of recommendation: Strong (KCE, 2013).*
- *Axillary radiotherapy should be discussed on a case-by-case basis in the multidisciplinary team meeting. Quality of evidence: 1A. Strength of recommendation: Strong (KCE, 2013).*
- *Post-mastectomy radiotherapy should be considered in patients with lymph node-positive breast cancer if they have high risk of recurrence (≥ 4 positive lymph nodes or T3/4 tumors) Quality of evidence: 1++ (SIGN, 2013).*
- *Post-mastectomy radiotherapy may be considered in patients with intermediate risk of recurrence (high-risk node-negative tumors or one to three positive axillary lymph nodes) Quality of evidence: 1++ (SIGN, 2013).*
- *All patients with node-positive disease benefited from post-mastectomy radiotherapy (PMRT), however the benefit was greater in those patients with ≥ 4 positive nodes compared to those with one to three positive nodes. Quality of evidence: 1++ (SIGN, 2013).*
- *Offer adjuvant chest wall radiotherapy to patients with early invasive breast cancer who have had a mastectomy and are at risk of local recurrence. Patients at a high risk of local recurrence include those with four or more positive axillary lymph nodes or involved resection margins (NICE, 2018).*
- *Do not offer radiotherapy following mastectomy to patients with early invasive breast cancer who are at low risk of local recurrence (for example, most patients who are lymph node-negative) (NICE, 2018).*

SUPPORTING LITERATURE TRT-RAD-3

- Andreano A, Anghinoni E, Autelitano M, Bellini A, Bersani M, Bizzoco S, et al. Indicators based on registers and administrative data for breast cancer: routine evaluation of oncologic care pathway can be implemented. *Journal of Evaluation in Clinical Practice* 22 (2016):62-70.
- Barni S, Venturini M, Molino A, Donadio M, Rizzoli S, Maiello E, Gori S. Importance of adherence to guidelines in breast cancer clinical practice. The Italian experience (AIOM). *Tumori*, 97: 559-563, 2011.
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REFERENCE DOCUMENTS TRT-RAD-3

CHAPTER 3 C:

REHABILITATION (RHB), FOLLOW-UP (FLW) AND PALLIATIVE CARE (PAL)

REHABILITATION REQUIREMENTS

CODE	NAME	STATEMENT
RHB-1	Lymphoedema service	The BCS must have a written policy in place for the prevention, diagnosis and treatment of lymphoedema.
RHB-2 	Psycho-oncology service	The BCS must have psycho-oncological care available (provided by specialists).

FOLLOW-UP REQUIREMENTS

CODE	NAME	STATEMENT
FLW-1 	Follow-up recurrence	The BCS must have a written policy on follow-up for women with breast cancer for the early detection of recurrence.
FLW-2 	Follow-up survivorship	The BCS must have a written policy for ensuring survivorship care for women treated for breast cancer.
FLW-3	Follow-up intensive surveillance	The BCS must have a written policy to avoid routine intensive surveillance in asymptomatic women after primary therapy for breast cancer.

PALLIATIVE CARE REQUIREMENTS

CODE	NAME	STATEMENT
PAL-1	Palliative care policy	The BCS must have a written policy on palliative care for women with breast cancer.

RHB-1: LYMPHOEDEMA SERVICE

Statement

The BCS must have a written policy in place for the prevention, diagnosis and treatment of lymphoedema.

Rationale

Lymphoedema is a common adverse effect after treatment for breast cancer. Treating lymphoedema may reduce it significantly.

Quality domain: Clinical effectiveness.

Breast cancer process: All processes.

Measurement: This requirement is measured by 5 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT RHB-1	
RHB-1.1 criterion	The BCS has a plan for the provision of advice to reduce the risk of lymphoedema, and for its diagnosis and treatment.
Type	Structure
RHB-1.2 criterion	Treatment includes, but is not limited to, complex decongestive physical therapy treatment.
Type	Structure
RHB-1.3 criterion	Treatment is conducted by a specialised lymphoedema service provider based on a multidisciplinary treatment plan.
Type	Structure
RHB-1.4 criterion	Treatment is conducted by the BCS or in coordination with another centre or provider.
Type	Structure
RHB-1.5 criterion	The BCS conducts an annual review of the BCS' policy, including (but not limited to) specifying the proportion of patients treated for lymphoedema.
Type	Process

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	RHB-1.1: Document (policy) regarding the management of lymphoedema. RHB-1.2: Protocol for the treatment of lymphoedema. RHB-1.3: Documented evidence of the professionals' authorisations, competences and assignment of professionals involved in lymphoedema rehabilitation, or their staff file. RHB-1.4: List of services provided by the BCS (in-house or outsourced). RHB-1.5: Report assessing implementation of the policy in the last year.

GUIDELINE RECOMMENDATIONS RHB-1

Certainty of evidence	High
Strength of recommendation	Strong

Guideline recommendations

- *Women with breast cancer should be informed about the risk of developing lymphoedema following surgery or radiotherapy and should be offered rapid access to a specialist lymphoedema service. Evidence quality: 1A (high); Strength of recommendation: Strong (KCE, 2013).*
- *Physical training, including specific exercises for cancer-related fatigue, can be considered after treatment for breast cancer. Evidence quality: 1A (high); Recommendation: Strong (KCE, 2013).*
- *Inform all patients with early breast cancer about the risk of developing lymphoedema and give them relevant written information before treatment with surgery and radiotherapy (NICE, 2018).*
- *Give advice on how to prevent infection or trauma that may cause or exacerbate lymphoedema to patients treated for early breast cancer (NICE, 2018).*
- *Ensure that all patients with early breast cancer who develop lymphoedema have rapid access to a specialist lymphoedema service (NICE, 2018).*
- *All breast units should have written local guidelines agreed with the physiotherapy department for postoperative physiotherapy regimens (NICE, 2018).*
- *Patients with lymphoedema should be referred to a physiotherapist with expertise in treatment of lymphoedema. Treatment should be aimed at manual lymph drainage, exercises and compression sleeve. Evidence quality: 1 (IKNL, 2010).*

SUPPORTING LITERATURE RHB-1

- DKG. Catalogue of requirements for Breast Cancer Centres of the German Cancer Society Version J2, 12 August 2019.
 - KCE. Breast cancer in women: diagnosis, treatment and follow-up. Brussels: KCE, 2013.
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REFERENCE DOCUMENTS RHB-1

- International consensus, Lymphoedema Framework. Best Practice for the Management of Lymphoedema, Published by Medical Education Partnership (MEP) Ltd., 2016.
 - Lymphoedema Framework. Template for Management: Developing a Lymphoedema Service. London: MEP Ltd., 2007.
 - National Institute for Health and Care Excellence (NICE). Complications of early or locally advanced breast cancer treatment, 2019. Available at: <https://pathways.nice.org.uk/pathways/early-and-locally-advanced-breast-cancer/complications-of-early-or-locally-advanced-breast-cancer-treatment#content=view-node:nodes-lymphoedema>
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RHB-2: PSYCHO-ONCOLOGY SERVICE

Statement

The BCS must have psycho-oncological care available (provided by specialists) ⁽¹²⁾.

Rationale

Psycho-oncological care is considered important in the treatment of women with breast cancer.

Quality domain: Personal empowerment and experience.

Breast cancer process: All processes.

Measurement: This requirement is measured by 4 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT RHB-2

RHB-2.1 criterion	Patients have timely access to psycho-oncological care throughout the patient journey.
Type	Process
RHB-2.2 criterion	The service is provided within the BCS or in coordination with other centres or providers. If services are provided outside the BCS, the psycho-oncologist interacts with the multidisciplinary team when necessary.
Type	Structure
RHB-2.3 criterion	The psycho-oncological service includes patient and family information, patient distress assessment, intervention and psychosocial care.
Type	Process
RHB-2.4 criterion	The BCS monitors the proportion of women who are assessed for psycho-oncological distress, at least after diagnosis, and who are referred for psycho-oncological care.
Type	Process

¹² The professional profiles involved, and their tasks, education and supervision needs are consistent with those recommended by the ECIBC (see Glossary).

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	<p>RHB-2.1:</p> <ol style="list-style-type: none">1. List of psycho-oncology professionals who are responsible for patients' psychosocial care (psychologists, psychiatrists, clinical social workers and counsellors). It should also include outsourced professionals and/or services.2. Document and procedures on:<ul style="list-style-type: none">- how to assess the need for psycho-oncology and referral, i.e. a list of screening questionnaires used, such as the Distress Thermometer;- how the process of referral is conducted: healthcare professional (e.g. nurse) or self-referral. <p>RHB-2.2: Minutes of multidisciplinary meetings showing the participation of the psycho-oncologist; or minutes documenting interaction with the psycho-oncologist if the psycho-oncologist services are provided outside the centre.</p> <p>RHB-2.3: Review the medical records of (at least 10) women referred to psycho-oncologist services in the last 12 months, and verify that the services provided include the issues mentioned in the criterion.</p> <p>RHB-2.4: Review the centre's standard operating procedure to see how it assesses compliance, as well as the reports analysing that compliance, i.e. monitoring how many patients were referred to psycho-oncological consultations.</p>

GUIDELINE RECOMMENDATIONS RHB-2

Certainty of evidence High

Strength of recommendation Strong

Guideline recommendations

Psychological support should be available to all patients diagnosed with breast cancer Quality evidence: 1A (high); Recommendation: Strong (KCE, 2013).

SUPPORTING LITERATURE RHB-2

- DKG. Catalogue of requirements for Breast Cancer Centres of the German Cancer Society Version J2, 12 August 2019.
- OECI Accreditation and Designation User Manual V. 3.0, 2019.
- KCE. Breast cancer in women: diagnosis, treatment and follow-up. Brussels: KCE, 2013.
- Neamtiu L, Deandrea S, Pylkkanen L, Freeman C, Lopez Alcalde J, Bramesfeld A, Saz-Parkinson Z, Ulutürk A, Lerda D. Psycho-oncological support for breast cancer patients: A brief overview of breast cancer services certification schemes and national health policies in Europe. *The Breast* 29 (2016) 178-180.

REFERENCE DOCUMENTS RHB-2

FLW-1: FOLLOW-UP RECURRENCE

Statement

The BCS must have a written policy on follow-up for women with breast cancer for the early detection of recurrence.

Rationale

Follow-up is an important element of quality of care for women with breast cancer, including surveillance of women for the early detection of recurrence. All BCSs should have a policy to ensure follow-up.

Quality domain: Clinical effectiveness; Safety.

Breast cancer process: Follow-up.

Measurement: This requirement is measured by 6 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT FLW-1

FLW-1.1 criterion	The BCS has a follow-up policy that includes a plan for collecting longitudinal data on relapse rate and vital status.
Type	Structure
FLW-1.2 criterion	Follow-up includes a plan for mammography in the BCS.
Type	Structure
FLW-1.3 criterion	Follow-up includes a plan for referral back to a regular screening programme.
Type	Structure
FLW-1.4 criterion	Follow-up is done within the BCS in the context of survivorship care and in coordination with other centres or providers.
Type	Process
FLW-1.5 criterion	The follow-up policy complies with current guidelines included on the ECIBC Guidelines Platform.
Type	Structure
FLW-1.6 criterion	The BCS conducts an annual internal review of, and meeting about, its policy.
Type	Process

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	FLW-1.1: Direct observation of the information system designed for the collection, storage and management of data on relapse rate and vital status. FLW-1.2: Follow-up protocol. FLW-1.3: Follow-up protocol. FLW-1.4: Auditors may check the medical records of some patients with over 5 years' survival to verify that the follow-up includes coordination with other specialists for early detection of recurrence. Auditors may check a sample (at least 10). FLW-1.5: The policy includes reliable national or international guidelines on follow-up in its bibliography (link to the Guidelines Platform). FLW-1.6: Auditors may check the report or minutes of the annual review session.

GUIDELINE RECOMMENDATIONS FLW-1

Certainty of evidence Not applicable

Strength of recommendation Not applicable

Guideline recommendations

No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE FLW-1

- Andreano A, Anghinoni E, Autelitano M, Bellini A, Bersani M, Bizzoco S, et al. Indicators based on registers and administrative data for breast cancer: routine evaluation of oncologic care pathway can be implemented. *Journal of Evaluation in Clinical Practice* 22 (2016):62-70.
- Barni S, Venturini M, Molino A, Donadio M, Rizzoli S, Maiello E, Gori S. Importance of adherence to guidelines in breast cancer clinical practice. The Italian experience (AIOM). *Tumori*, 97: 559-563, 2011.
- Del Turco MR, Pont A, Bick U, Bianzoli L et al. Quality indicators in breast cancer care. *European Journal of Cancer* 2010; 46:2344-2356.
- Krzyzanowska MK, Barbera L, Elit L, Razzaq A, Saskin R, Nairayeritsyan, Bierman AS. Identifying population-level indicators to measure the quality of cancer cared for women. *International Journal for Quality in Health Care* 2011; Volume 23, Number 5: pp. 554–564.
- KCE. Breast cancer in women: diagnosis, treatment and follow-up. Brussels: KCE, 2013.
- Stordeur S, Vrijens F, Devriese S, Beirens K, Van Eycken E, Vlayen J. Developing and measuring a set of process and outcome indicators for breast cancer. *The Breast*, 21(2012):253-260.
- Wilson ARM, Marotti L, Bianchi S, Biganzoli L, et al. The requirements of a specialist Breast Centre (EUSOMA). *European Journal of Cancer* (2013) 49, 3579-3587.

REFERENCE DOCUMENTS FLW-1

FLW-2: FOLLOW-UP SURVIVORSHIP

Statement

The BCS must have a written policy for ensuring survivorship care for women treated for breast cancer.

Rationale

Survivorship care is an important element of the quality of care for women with breast cancer. All BCSs should have a policy for survivorship care.

Quality domain: Clinical effectiveness; Safety.

Breast cancer process: Follow-up.

Measurement: This requirement is measured by 4 criteria.

FLW-2.1 criterion	The BCS has a comprehensive breast-cancer survivorship care process, including a personalised survivorship care plan with accompanying treatment summary. The survivorship care plan includes: <ol style="list-style-type: none">1. Information;2. advice and support to address early and late side effects of treatment, including (but not limited to) physiotherapy treatment for arm and shoulder mobility;3. counselling on nutrition, physical exercise, and psychosocial and sexual health.
Type	Structure
FLW-2.2 criterion	The survivorship care plan is in place as soon as possible after active treatment, but no later than 6 months after completing active treatment and no more than 1 year after the date of diagnosis.
Type	Process
FLW-2.3 criterion	Survivorship care is consistent with the policy for follow-up care.
Type	Process
FLW-2.4 criterion	Survivorship care is done within the BCS or in coordination with other centres or providers.
Type	Structure

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	FLW-2.1: Survivorship care protocol/policy. Must include the 3 elements mentioned in the criterion. FLW-2.2: <ol style="list-style-type: none">1. Auditors may review patients' medical records from the last 12 months and check a sample (at least 10).2. Auditors may review the outcomes report. FLW-2.3: Auditors may review patients' medical records from the last 12 months and check a sample (at least 10) to verify that they include a personalised survivorship care plan. FLW-2.4: Auditors may review the medical records of patients with over 5 years' survival to verify that follow-up includes coordination with other specialists such as primary care. Auditors may check a sample (at least 10).

GUIDELINE RECOMMENDATIONS FLW-2

Certainty of evidence	Not applicable
Strength of recommendation	Not applicable
Guideline recommendations	No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE FLW-2

- Andreano A, Anghinoni E, Autelitano M, Bellini A, Bersani M, Bizzoco S, et al. Indicators based on registers and administrative data for breast cancer: routine evaluation of oncologic care pathway can be implemented. *Journal of Evaluation in Clinical Practice*, 22 (2016):62-70.
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- Del Turco MR, Pont A, Bick U, Bianzoli L et al. Quality indicators in breast cancer care. *European Journal of Cancer* 2010; 46:2344-2356.
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- Stordeur S, Vrijens F, Devriese S, Beirens K, Van Eycken E, Vlayen J. Developing and measuring a set of process and outcome indicators for breast cancer. *The Breast*, 21(2012):253-260.
- Wilson ARM, Marotti L, Bianchi S, Biganzoli L, et al. The requirements of a specialist Breast Centre (EUSOMA). *European Journal of Cancer* (2013) 49, 3579-3587.
- OECI Accreditation and Designation User Manual V. 3.0, 2019.
- NAPBC (National Accreditation Program for Breast Centers) Standards Manual 2018.

REFERENCE DOCUMENTS FLW-2

FLW-3: FOLLOW-UP INTENSIVE SURVEILLANCE

Statement

The BCS must have a written policy to avoid routine intensive surveillance in asymptomatic women after primary therapy for breast cancer.

Rationale

Intensive surveillance (e.g. PET scan, bone scan, CBC testing, tumour markers, chest X-ray, liver ultrasound or computed tomography) is not recommended in asymptomatic women after primary therapy for breast cancer.

Quality domain: Clinical effectiveness; Safety.

Breast cancer process: Follow-up.

Measurement: This requirement is measured by 1 criterion.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT FLW-3

FLW-3.1 criterion	The BCS has protocols to avoid routine intensive surveillance for asymptomatic women after primary therapy for breast cancer. The protocol describes the tests/checks that are performed and the timeline (including, e.g. PET scan, bone scan, CBC testing, tumour markers, chest X-ray, liver ultrasound or calculated tomography).
Type	Structure
Target population	Legal entity applying for certification.
Norm	Yes All the criteria are met.
Data source and additional information for auditing	FLW-3.1: Documents/protocols on complementary tests to be used with asymptomatic women.

GUIDELINE RECOMMENDATIONS FLW-3

Certainty of evidence High-very low

Strength of recommendation Strong

Guideline recommendations

- *Intensive surveillance (CBC testing, tumour markers, chest X-ray, bone scans, liver ultrasound or calculated tomography) is NOT recommended for routine breast cancer surveillance. Evidence quality: 1A (high); strength of recommendation: strong (KCE, 2013).*
- *MRI should not be offered routinely as a post-treatment surveillance test in patients who have been treated for early invasive breast cancer or DCIS. Evidence quality: 1C (very low); strength of recommendation: strong (KCE, 2013).*
- *Do not offer ultrasound or MRI for routine post-treatment surveillance in patients who have been treated for early invasive breast cancer or DCIS (NICE, 2018).*
- *CBC testing, Chest X-rays, bone scans, liver ultrasound, CT scanning, FDG-PET scanning, breast MRI are NOT recommended for routine surveillance of patients with breast cancer after primary therapy (ASCO, 2012).*
- *Breast cancer tumor marker testing is NOT recommended for routine surveillance of patients with breast cancer after primary therapy (ASCO, 2012).*

SUPPORTING LITERATURE FLW-3

- Barni S, Venturini M, Molino A, Donadio M, Rizzoli S, Maiello E, Gori S. Importance of adherence to guidelines in breast cancer clinical practice. The Italian experience (AIOM). *Tumori*, 97: 559-563, 2011.
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- Wilson ARM, Marotti L, Bianchi S, Biganzoli L, et al. The requirements of a specialist Breast Centre (EUSOMA). *European Journal of Cancer* (2013) 49, 3579-3587.

REFERENCE DOCUMENTS FLW-3

PAL-1: PALLIATIVE CARE POLICY

Statement

The BCS must have a written policy on palliative care for women with breast cancer.

Rationale

Palliative care is an important element of quality of care for patients with breast cancer, and is aimed at symptom control and offering continuation of care until the end of life. Palliative care should be integrated early in the clinical pathway for patients with poor prognosis and progressive disease who have medical, surgical, radiation and other interventions. All BCSs should have a policy to ensure symptom control and palliative care.

Quality domain: Personal empowerment and experience.

Breast cancer process: All processes.

Measurement: This requirement is measured by 6 criteria.

MEASUREMENT OF COMPLIANCE WITH REQUIREMENT PAL-1

PAL-1.1 criterion	There is a palliative team, which includes a physician, nurse and other healthcare providers.
Type	Structure
PAL-1.2 criterion	There are documented procedures on the composition, roles and duties of the palliative care team.
Type	Structure
PAL-1.3 criterion	A physician with additional training in palliative medicine is available for consultation and, where necessary, for participation in the multidisciplinary meetings (MDMs). If the centre does not have 1 available, written procedures and agreements should be in place with outsourced services.
Type	Structure

PAL-1.4 criterion	There is a policy for integrating patient palliative care within the existing network of services, including (but not limited to) primary care, home care, hospice care and specialised care.
Type	Structure
PAL-1.5 criterion	<p>The following services are accessible to patients with advanced disease, according to their needs:</p> <ul style="list-style-type: none"> • inpatient consulting team; • outpatient palliative care clinic; • hospice/palliative care unit; • home care service. <p>If these services are not available at the centre or institution of which the breast cancer centre is part, written agreements should be established with external providers that offer these services.</p>
Type	Structure
PAL-1.6 criterion	There are documented procedures detailing how the patient can access the abovementioned services.
Type	Structure

FOR ALL CRITERIA

Target population	Legal entity applying for certification.
Norm	<p>Yes</p> <p>All the criteria are met.</p>
Data source and additional information for auditing	<p>PAL-1.1: Staffing of the palliative care centre.</p> <p>PAL-1.2: Document describing the roles of the staff within the palliative care centre.</p> <p>PAL-1.3: Staffing level of the palliative care centre (in-house or subcontracted). Evidence of credentials and privileges of at least 1 person trained in palliative medicine.</p> <p>PAL-1.4: Official document describing the palliative care centre's care coordination network.</p> <p>PAL-1.5: Portfolio of services (in-house or outsourced).</p> <p>PAL-1.6: Referral protocols when services are outsourced.</p>

GUIDELINE RECOMMENDATIONS PAL-1

Certainty of evidence Not applicable

Strength of recommendation Not applicable

Guideline recommendations

No specific guideline recommendations available. The working group used the available evidence listed under supporting literature.

SUPPORTING LITERATURE PAL-1

- OECI Accreditation and Designation User Manual V. 3.0, 2019.
- DKG. Catalogue of requirements for Breast Cancer Centres of the German Cancer Society Version J2, 12 August 2019.
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GLOSSARY

Accreditation

In the healthcare field: *accreditation is usually a voluntary programme, sponsored by a non-governmental agency, in which trained external peer reviewers evaluate a healthcare organisation's compliance with pre-established performance standards. Accreditation addresses organisational, rather than individual practitioner, capability or performance. Unlike licensing, accreditation focuses on continuous improvement strategies and achievement of optimal quality standards, rather than adherence to minimal standards intended to assure public safety.*

Source: Rooney AI, van Ostenberg PR, Licensure accreditation and certification: approaches to health services quality, Quality Assurance Project, 1999.

With specific regard to clinical services, accreditation is *a self-assessment and external peer assessment process used by [clinical services] to accurately assess their level of performance in relation to established standards and to implement ways to continuously improve.*

Source: Lelliott P, Young E, Burgess R, A core model for professionally led, clinical service accreditation, Health Quality Improvement Partnership (HQIP), 2009.

Act of granting credit or recognition by an external evaluation organisation of the achievement of accreditation standards, demonstrated through an independent external peer assessment of that organisation's level of performance in relation to the standards. See also ISQua accreditation.

Source: ISQua, *Guidelines and Principles for the Development of Health and Social Care Standards*. 4th Edition Version 1.2, September 2015.

Assessment approaches

Structure: includes all the factors that affect the context in which care is delivered. This includes the physical facility, equipment and human resources, as well as organisational characteristics such as staff training and payment methods. These factors control how providers and patients in a healthcare system act, and are measures of the average quality of care within a facility or system. Structure is often easy to observe and measure, and it may be the upstream cause of problems identified in process.

Process: is the sum of all actions that make up healthcare. These commonly include diagnosis, treatment, preventive care and patient education, but may be expanded to include actions taken by the patients or their families. Processes can be further classified as technical processes, how care is delivered, or interpersonal processes, which all encompass the way in which care is delivered. According to Donabedian, the measurement of process is nearly equivalent to the measurement of quality of care, because process contains all acts of healthcare delivery. Information about process can be obtained from medical records, interviews with patients and practitioners, or direct observations of healthcare visits.

Outcome: contains all the effects of healthcare on patients or populations, including changes to health status, behaviour or knowledge, as well as patient satisfaction and health-related quality of life. Outcomes are sometimes seen as the most important indicators of quality, because improving patient health status is the primary goal of healthcare. However, accurately measuring outcomes that can be attributed exclusively to healthcare is very difficult. Drawing connections between process and outcomes often requires large sample populations, adjustments by case mix, and long-term follow-ups as outcomes may take considerable time to become observable.

Source: adapted from Donabedian A, Evaluating the quality of medical care. 1966, The Milbank Quarterly, Vol. 83, No. 4, 2005.

Audit

Systematic, independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.

Source: Quality management systems – fundamentals and vocabulary (EN ISO 9000:2015).

In relation to the European QA scheme, the general terms ‘audit’, ‘audited’, ‘auditing’ and ‘auditor’ should be understood to include those activities that involve inspection, where ‘inspection’ is the examination of aspects of a BCS and determination of their conformity with the specific requirements or, on the basis of professional judgment, with the general requirements.

Breast cancer services

Comprises all healthcare services covering the full extent of breast cancer management, from screening to follow-up, and in some cases end-of-life care. These services may provide primary care, as well as a range of high-specialty services including, but not limited to, screening, diagnostic imaging, pathology, surgery, radiation and medical oncology.

Source: ECIBC, own definition, 2015. European Commission-Joint Research Centre, European Commission Initiative on Breast Cancer (ECIBC), European quality assurance scheme for breast cancer services. Available at: <https://healthcare-quality.jrc.ec.europa.eu/breast-quality-assurance-scheme> (last accessed 22 March 2021).

Care pathway

The healthcare pathway describes the healthcare chain, and cross-healthcare sector interfaces, by bundling and visualising the outcomes of the relevant healthcare processes involved and taking quality targets into consideration. In detail the care pathway aims to:

- present the intervention/processes for which quality should be assured in a structured way;
- present the relevant healthcare sectors involved;
- assign responsibilities for healthcare processes to healthcare providers;
- identify starting points for quality assurance;
- identify quality potentials within the care pathway.

The care pathway visualises the route a patient takes in a flow chart. This flow chart includes specific services, end points, quality targets and quality potentials relevant to the specific subject of the quality assurance scheme, taking into consideration the disease course and the various services involved.

Source: AQUA-Institute, *Allgemeine Methoden im Rahmen der sektorenübergreifenden Qualitätssicherung im Gesundheitswesen nach §137a SGB V*, Version 4.0. Göttingen, 2015.

Certification

The process by an independent body to provide a certificate that the product, service or system in question meets specific requirements.

Source: Accreditation legal framework (ISO/IEC 17000:2020).

Conformity assessment bodies

A body that performs conformity assessment activities, including calibration, testing, certification and inspection upon accreditation from the national accreditation body.

Source: Accreditation legal framework (ISO/IEC 17000:2020).

Dimensions (of quality in healthcare)

Dimensions of healthcare performance are those definable, preferably measurable and actionable, attributes of the system that are related to its function in maintaining, restoring or improving health.

- **Effectiveness:** the degree to which desirable outcomes are achieved, given the correct provision of evidence-based healthcare services to all who could benefit (but not to those who would not benefit). This may include related dimensions of appropriateness, competence and capability.
- **Safety:** the degree to which healthcare processes avoid, prevent and ameliorate adverse outcomes or injuries that stem from the healthcare processes themselves.
- **Responsiveness:** how a system treats people to meet their legitimate non-health expectations. This may include patient-centredness, acceptability, continuity and timeliness.
- **Accessibility:** the ease with which health services are reached. Access can be physical, financial or psychological, assuming that services are available.
- **Equity:** closely related to access, this is used as a metric to assess health-system financing and outcomes or health status.
- **Efficiency:** optimal use of available resources to yield maximum benefits or results.

Source: Kelley E, Hurst J, Health Care Quality Indicators Project Conceptual Framework Paper, OECD, 2006.

Indicator

Describes the fulfilment of a requirement by a clearly defined numerator and denominator.

Indicators are always linked to a requirement, but not every requirement will have a quantitative indicator to be measured.

Continuity of care

The degree to which a series of discrete healthcare events is experienced as being coherent, connected and consistent with the patient's medical needs and personal context.

National accreditation bodies

The sole body in a Member State that performs accreditation with authority derived from the State.

It is agreed that each Member State will appoint one national accreditation body (NAB) or address the NAB of another Member State. NABs operate on a non-profit basis and the Member State is expected to provide the appropriate financial and staff resources. They are in charge of evaluating, certifying and monitoring assessment bodies, and are able to restrict, suspend or withdraw the accreditation certificates awarded in case of a breach.

Source: Accreditation legal framework (ISO/IEC 17000:2020).

Outsourcing

Outsource (subcontract) means to *obtain goods or services from an outside supplier when considered as an alternative to carry out the associated process within the own organisation.*

Source: ISO 9000 Introduction and support package: guidance on some of the frequently used words found in the ISO 9000 family of standards.

A process or subprocess is defined as externalised (outsourced) when an entity that is responsible for the coordination of care provides a certain process or subprocess via an agreement with a different entity or healthcare professional. Responsibility for the coordination of care remains with the first entity.

Examples of processes or subprocesses that may be outsourced for a breast cancer service through an agreement are: magnetic resonance imaging, interventional radiology, medical oncology, radiotherapy, clinical genetics, nuclear medicine and rehabilitation.

Policy

Set of guidelines and rules declaring what the action protocol will be like, which resources will be allocated to it and how its performance will be assessed.

Quality potential

Quality potentials correspond to known or anticipated deficits in the quality of care for a specific disease, indication or intervention. They correspond with processes in the care pathway for which under-, over- or inadequate treatment has been reported, meaning treatment is not being provided at the required quality. Quality potentials are therefore starting points for measures to improve the quality of care.

Aligning quality assurance along quality potentials contributes to its effort-benefit balance. The identification of quality potentials is followed by the question of whether it is possible to reliably measure health service performance at these quality potentials in a systematic way that allows services to be compared. It must be noted that it may not be possible to assess quality-relevant data for every quality potential identified, either because the necessary information cannot be retrieved with data or because no adequate data source is available to the quality assurance scheme.

Source: AQUA-Institute, *Allgemeine Methoden im Rahmen der sektorenübergreifenden Qualitätssicherung im Gesundheitswesennach §137a SGB V*, Version 4.0. Göttingen, 2015.

Quality target

There is consensus that high-quality healthcare succeeds in reaching its set targets. These targets relate to healthcare being effective, safe, patient-centred and well coordinated, as well as to there being adequate access to care.

Quality targets take these dimensions into consideration. However, the targets are defined specifically for the diagnosis, indication or intervention that is subject to a quality assurance scheme, and according to the parameters that will demonstrate good quality.

Source: AQUA-Institute, *Allgemeine Methoden im Rahmen der sektorenübergreifenden Qualitätssicherung im Gesundheitswesennach §137a SGB V*, Version 4.0. Göttingen, 2015.

Requirement

A need or expectation that is stated, generally implied or obligatory.

Source: Quality management systems – fundamentals and vocabulary (EN ISO 9000:2005).

A 'requirement' is a general word used by the ECIBC that encompasses the meaning of a given standard in the healthcare field. It is the level of performance required by a certain quality assessment scheme with respect to a certain aspect that is meaningful for breast cancer care and diagnosis.

Professions in breast cancer care

- i. **Breast care nurse:** nurse (as recognised in EU directive 2005/36/EC) formally trained in breast cancer care.
- ii. **Breast radiologist:** medical doctor specialised in diagnosing and using medical imaging techniques (as recognised in EU Directive 2005/36/EC, referring to all of the titles that are achieved on completion of radiology or diagnostic radiology training courses) who is focused on breast imaging and breast imaging-guided interventions.
- iii. **Breast surgeon:** medical doctor specialised in gynaecology, general or plastic surgery (as recognised in EU Directive 2005/36/EC) and qualified to perform breast cancer surgery.
- iv. **Medical oncologist:** medical doctor specialised in medical oncology or internal medicine (as recognised in EU directive 2005/36/EC) and qualified to diagnose and treat oncological diseases.
- v. **Medical physicist expert:** professional with knowledge of physics and medicine, specialised in diagnostic and interventional radiology (as recognised in EQF level 8) and qualified to perform quality controls on imaging and oncological devices using radiation.
- vi. **Oncoplastic breast surgeon:** breast surgeon with knowledge of oncoplastic surgery (combining plastic surgery and oncology surgery to obtain a good aesthetic result and optimise oncological outcomes), and qualified to perform breast surgery and reconstructive surgery.
- vii. **Pathologist:** medical doctor specialised in pathology or anatomic pathology (as recognised in EU directive 2005/36/EC) who examines biopsy samples to provide a diagnosis, and prognostic and predictive parameters that guide the treatment of individual patients.
- viii. **Plastic surgeon:** medical doctor specialised in plastic surgery (as recognised in EU directive 2005/36/EC) and qualified to perform breast reconstruction surgery.
- ix. **Psycho-oncologist:** clinical psychologist formally trained in the psychological aspects of oncology.
- x. **Radiation oncologist:** medical doctor specialised in radiation oncology (as recognised in EU directive 2005/36/EC) and qualified to treat oncological diseases with radiotherapy.
- xi. **Radiographer:** healthcare professional trained to perform imaging examinations and post-processing (as recognised in EU directive 2005/36/EC and covered by the generic name 'radiographer/radiotherapist' in the European Commission's Regulated Professions Database).

ANNEX I. TABLES

Requirements, indicators and criteria for continuity of care

CODE	NAME	STATEMENT	CONTINUITY OF CARE BETWEEN
GEN-11	Lead time between pathology report with diagnosis and first treatment	The lead time between the pathology report with a diagnosis of cancer and the start of treatment must be no longer than 4 weeks.	Diagnosis-Treatment
GEN-17	Time between the date of the multidisciplinary meeting (MDM) discussion and first treatment	The BCS must report the time between the date of the MDM discussion and the start of the first treatment.	Diagnosis-Treatment
SCR-1.2	Screening programme criterion 1.2.	The screening programme ensures the availability of appropriate, ECIBC-certified diagnostic, treatment and aftercare services.	Screening-Diagnosis-Treatment
SCR-2.18	Screening programme indicator 2.18	Time between result of screening mammography and assessment offered	Screening-Diagnosis
DGN-5	Biomarkers collected before starting treatment	The oestrogen and progesterone receptor and HER2 status biomarkers must be collected and assessed before the start of treatment, for all women with invasive breast cancer.	Diagnosis-Treatment
DGN-7	Pre-treatment diagnosis	All women treated for breast cancer (invasive or non-invasive) must have a histologically confirmed pre-treatment diagnosis of malignity.	Diagnosis-Treatment

Requirements, indicators and criteria for continuity of care

CODE	NAME	STATEMENT	CONTINUITY OF CARE BETWEEN
TRT-RAD-2	Invasive breast cancer with breast-conserving therapy	All women with MO invasive breast cancer treated with breast-conserving therapy must be offered whole breast adjuvant radiotherapy or, when indicated, partial breast radiotherapy.	Surgery-Radiotherapy
TRT-RAD-3	Mastectomy in invasive breast cancer	All women with invasive MO breast cancer with ≥ 4 axillary lymph nodes involved must be offered local or regional radiotherapy after mastectomy.	Surgery-Radiotherapy
RHB-2	Psycho-oncology service	The BCS must have psycho-oncological care available (provided by specialists).	Treatment-Rehabilitation
FLW-1	Follow-up recurrence	The BCS must have a written policy on follow-up for women with breast cancer for the early detection of recurrence.	Several services-Follow up
FLW-2	Follow-up survivorship	The BCS must have a written policy for ensuring survivorship care for women treated for breast cancer.	Treatment-Follow up

Classification of the requirements according to pathway process and quality domain

QUALITY DOMAIN	BREAST CANCER CARE PATHWAY PROCESS						
	General	Screening	Diagnosis	Treatment	Rehabilitation	Follow-up	Palliative care
CEF	GEN-1	SCR-1	DGN-1*	TRT-SUR-1*	RHB-1	FLW-1*	
	GEN-2	SCR-2	DGN-2*	TRT-SUR-2		FLW-2*	
	GEN-3*	SCR-3	DGN-3	TRT-SUR-3		FLW-3*	
	GEN-4	SCR-4	DGN-4*	TRT-SUR-4			
	GEN-8*	SCR-9	DGN-5	TRT-SUR-5			
	GEN-9*	SCR-10	DGN-6	TRT-SUR-6			
	GEN-10*		DGN-7	TRT-SUR-7			
	GEN-11*		DGN-8	TRT-SUR-8			
	GEN-13*		DGN-9	TRT-SUR-9			
	GEN-14		DGN-IMG-2	TRT-SUR-10			
	GEN-15*		DGN-IMG-3	TRT-SUR-11			
	GEN-16		DGN-IMG-10	TRT-SYS-1*			
	GEN-17		DGN-PTH-1*	TRT-SYS-2			
	GEN-19*		DGN-PTH-2*	TRT-SYS-3			
			DGN-PTH-4*	TRT-SYS-4			
			DGN-PTH-5*	TRT-SYS-5*			
			DGN-PTH-6*	TRT-SYS-6			
				TRT-SYS-7			
				TRT-SYS-8			
			TRT-SYS-9				
			TRT-SYS-10				
			TRT-SYS-11				
			TRT-RAD-1				
			TRT-RAD-2				
			TRT-RAD-3				
SAF	GEN-3*		DGN-1*	TRT-SUR-1*			
	GEN-8*		DGN-2*	TRT-SYS-1*			
	GEN-11*		DGN-IMG-4*	TRT-SYS-5*			
	GEN-13*		DGN-IMG-6*				
			DGN-PTH-2*				
		DGN-PTH-4*					
		DGN-PTH-5*					
PEX	GEN-5	SCR-5	DGN-1*	TRT-SYS-1*	RHB-2	FLW-1*	
	GEN-6	SCR-6	DGN-2*			FLW-2*	
	GEN-7	SCR-7	DGN-4*			FLW-3*	
	GEN-9*	SCR-8	DGN-IMG-7				
	GEN-10*		DGN-PTH-1*				
	GEN-11*						
	GEN-12						
	GEN-13*						
	GEN-18*						
FRW	GEN-15*	DGN-IMG-1	DGN-IMG-4*	TRT-SUR-1*			PAL-1
	GEN-18*		DGN-IMG-5				
	GEN-19*		DGN-IMG-6*				
	GEN-20		DGN-IMG-7				
			DGN-IMG-9				
			DGN-PTH-1*				
			DGN-PTH-2*				
		DGN-PTH-3					
		DGN-PTH-6*					

CEF: Clinical effectiveness SAF: Safety PEX: Personal empowerment and experience FRW: Facilities, resources and workforce (*): identifies those requirements related to more than one quality domain.

List of indicators to be calculated with the quality indicator calculator tool or by the BCS

CODE	INDICATOR	TOOL	BCS
GEN-11.1	Proportion of women diagnosed in the BCS with lead time between pathology report with diagnosis of cancer and start of treatment no longer than 4 weeks.	X	
GEN-16.3	Proportion of women with breast cancer (absolute number of women counted) discussed by the multidisciplinary team before they start treatment, after their primary treatment, and when there is any change in their treatment.	X	
GEN-17.1	Average number of days between the date of the multidisciplinary meeting (MDM) discussion and the start of the first treatment.		X
GEN-19.1	Proportion of women newly diagnosed with breast cancer who had a consultation with a breast care nurse at the time of diagnosis.	X	
SCR-2.1	Participation rate.		X
SCR-2.2	Invasive breast cancer detection rate.		X
SCR-2.3	Screening coverage.		X
SCR-2.4	Interval cancer rate.		X
SCR-2.5	Episode sensitivity.		X
SCR-2.6	Recall rate.		X
SCR-2.7	Breast cancer detection rate.		X
SCR-2.8	Invasive cancers ≤ 10 mm rate.		X
SCR-2.9	Invasive cancers > 20 mm rate.		X
SCR-2.10	Lymph node negative rate.		X
SCR-2.11	Time interval between screening and treatment.		X
SCR-2.12	Benign open surgery biopsy rate.		X
SCR-2.13	Advanced cancer (T2+), review errors.		X
SCR-2.14	Interval cancer, review errors.		X
SCR-2.15	Technical repeat examination.		X
SCR-2.16	Time between screening mammogram and issuing of results.		X

List of indicators to be calculated with the quality indicator calculator tool or by the BCS

CODE	INDICATOR	TOOL	BCS
SCR-2.17	Proportion of screened women subject to early recall following diagnostic assessment.		X
SCR-2.18	Time between result of screening mammography and assessment offered.		X
SCR-2.19	Time between the assessment and issuing of the result when needle biopsy is not performed.		X
SCR-2.20	Time between the assessment and issuing of the result when needle biopsy is performed.		X
SCR-3.1	Recall rate (screening centres).		X
SCR-3.2	Breast cancer detection rate (screening centres).		X
SCR-3.3	Invasive cancers \leq 10 mm rate (screening centres).		X
SCR-4.1	Proportion of asymptomatic women aged 50–69 who were invited for screening within a screening programme.		X
DGN-1.1	Proportion of women with suspicious breast lesions in mammography (including mass lesions, asymmetric breast density, calcifications and/or architectural distortions), who undergo needle core biopsy.		X
DGN-2.1	Proportion of women (lesions counted) with suspicious breast calcifications found in mammography who undergo stereotactic-guided needle core biopsy.		X
DGN-3.1	Average number of days between symptomatic mammography and communication of diagnosis (when biopsy is not performed), measured as a number of days.		X
DGN-3.2	Average number of days between symptomatic mammography and communication of diagnosis (when biopsy is performed).		X
DGN-3.3	Number of assessment visits needed to obtain a definitive diagnosis.		X
DGN-4.1	Proportion of women aged 45 or under who are diagnosed with breast cancer, have a high risk of genetic mutations and have been tested for genetic mutations.		X
DGN-5.1	Proportion of women with invasive breast cancer for whom the following biomarkers have been collected before starting treatment: oestrogen receptors (ER), progesterone receptors (PR) and HER2 status.	X	

List of indicators to be calculated with the quality indicator calculator tool or by the BCS

CODE	INDICATOR	TOOL	BCS
DGN-6.1	Relation between benign and malign diagnosis after open surgery.		X
DGN-7.1	Proportion of women (breasts counted) with breast cancer (invasive or non-invasive), who had a histologically confirmed malignant diagnosis before their first treatment.		X
DGN-8.1	Proportion of women with breast cancer at clinical stage I not undergoing positron emission tomography-computed tomography (PET-CT) or other whole-body staging examinations.		X
DGN-8.2	Proportion of women with breast cancer at clinical stage III undergoing conventional staging examinations.		X
DGN-9.1	Proportion of women for whom pre-surgical localisation fails.		X
DGN-IMG-3.3	Proportion of women attending screening who require 1 or more technical recalls.		X
DGN-IMG-9.1	Proportion of women (lesion counted) who had intraoperative specimen imaging following breast-conserving surgery for microcalcification with image-guided localisation.		X
DGN-IMG-9.2	Proportion of women (lesion counted) who underwent surgical lesion removal with intraoperative specimen imaging.		X
DGN-IMG-10.1	Proportion of radiographers who have personally performed a minimum of 1 000 mammography examinations per year.		X
DGN-PTH-1.2	Proportion of pathology results from non-surgical biopsies released from the pathology service within 5 working days (7 calendar days) after receipt of the breast specimen by the pathology service.		X
DGN-PTH-1.3	Proportion of pathology results from surgical specimens released from the pathology service within 10 working days (14 calendar days) after receipt of the breast specimen by the pathology service.		X
DGN-PTH-4.1	Proportion of pathology reports for invasive breast cancer with the core set reported.		X
DGN-PTH-4.2	Proportion of pathology reports for non-invasive breast cancer with the core set reported.		X
DGN-PTH-4.3	Proportion of pathology reports for specimens after neoadjuvant therapy with the core set reported.		X

List of indicators to be calculated with the quality indicator calculator tool or by the BCS

CODE	INDICATOR	TOOL	BCS
TRT-SUR-2.1	Proportion of surgically treated women with clinically node-negative (cNO) invasive breast cancer who underwent sentinel lymph node biopsy (SLNB).	X	
TRT-SUR-3.1	Proportion of surgically treated women with pathologically node-negative (pNO) invasive breast cancer who did not undergo ALND (staged by SLNB only).	X	
TRT-SUR-4.1	Proportion of surgically treated women with ductal carcinoma in situ (DCIS) who did not undergo axillary lymph node dissection (ALND).	X	
TRT-SUR-5.1	Proportion of surgically treated women who undergo axillary lymph node dissection (ALND) and have 10 or more lymph nodes (including sentinel nodes) removed.	X	
TRT-SUR-6.1	Proportion of surgically treated women with DCIS with a radiological tumour extent \leq 2cm who did not undergo primary mastectomy.	X	
TRT-SUR-7.1	Proportion of surgically treated women with invasive breast cancer with a tumour size \leq 2 cm (pT1) who underwent breast-conserving surgery.	X	
TRT-SUR-8.1	Proportion of surgically treated women with DCIS who underwent a single breast operation for the primary tumour (only 1 operation).	X	
TRT-SUR-9.1	Proportion of surgically treated women with invasive breast cancer (T1, T2) who underwent a single breast operation for the primary tumour (only 1 operation).	X	
TRT-SUR-10.1	Proportion of women who underwent immediate breast reconstruction after mastectomy.	X	
TRT-SUR-11.1	Proportion of women who underwent delayed breast reconstruction within 12 months after mastectomy.	X	
TRT-SYS-1.1	Proportion of surgically treated women with invasive M0 breast cancer, without radiotherapy between surgery and adjuvant chemotherapy, who underwent chemotherapy within \leq 8 weeks after surgery.	X	
TRT-SYS-2.1	Proportion of surgically treated women with ER- (T > 1 cm or Node+) invasive M0 breast cancer who underwent adjuvant chemotherapy.	X	

List of indicators to be calculated with the quality indicator calculator tool or by the BCS

CODE	INDICATOR	TOOL	BCS
TRT-SYS-3.1	Proportion of women with HER2+ breast cancer treated with adjuvant systemic therapy who underwent adjuvant anti-HER2 therapy.	X	
TRT-SYS-4.1	Proportion of women with HER2+ (N+ or T > 1 cm) invasive M0 breast cancer treated with neoadjuvant chemotherapy who underwent neoadjuvant anti-HER2 therapy.	X	
TRT-SYS-5.1	Proportion of women with breast cancer treated with anti-HER2 therapy, and whose cardiac function is monitored every 3 months.		X
TRT-SYS-6.1	Proportion of surgically treated women with hormone-sensitive (ER+ and/or PR+) invasive M0 breast cancer who were prescribed endocrine therapy.	X	
TRT-SYS-7.1	Proportion of women with stage II and III triple negative breast cancer who underwent neoadjuvant chemotherapy.	X	
TRT-SYS-8.1	Proportion of women with stage II and III HER2+ breast cancer who underwent neoadjuvant systemic therapy.	X	
TRT-SYS-9.1	Proportion of women with locally advanced breast cancer (tumour > 3 cm or T4 or nodal status ≥ N2) who underwent neoadjuvant systemic therapy.	X	
TRT-SYS-10.1	Proportion of women with ER+ and HER2- metastatic (at diagnosis) breast cancer who undergo only endocrine-based therapy in the first line of treatment.	X	
TRT-SYS-11.1	Proportion of women diagnosed with breast cancer with bone metastasis who receive bone-modifying agents.		X
TRT-RAD-1.1	Proportion of surgically treated women with primary M0 invasive breast cancer who underwent adjuvant radiotherapy, and who started undergoing radiotherapy ≤ 8 weeks after the date of surgery or the date of the last cycle of adjuvant chemotherapy.	X	
TRT-RAD-2.1	Proportion of women with M0 invasive breast cancer treated with breast-conserving therapy who underwent whole breast adjuvant radiotherapy.	X	
TRT-RAD-3.1	Proportion of women with invasive M0 breast cancer with ≥ 4 axillary lymph nodes involved, who underwent local or regional radiotherapy after mastectomy.	X	
Total number	73	26	47

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