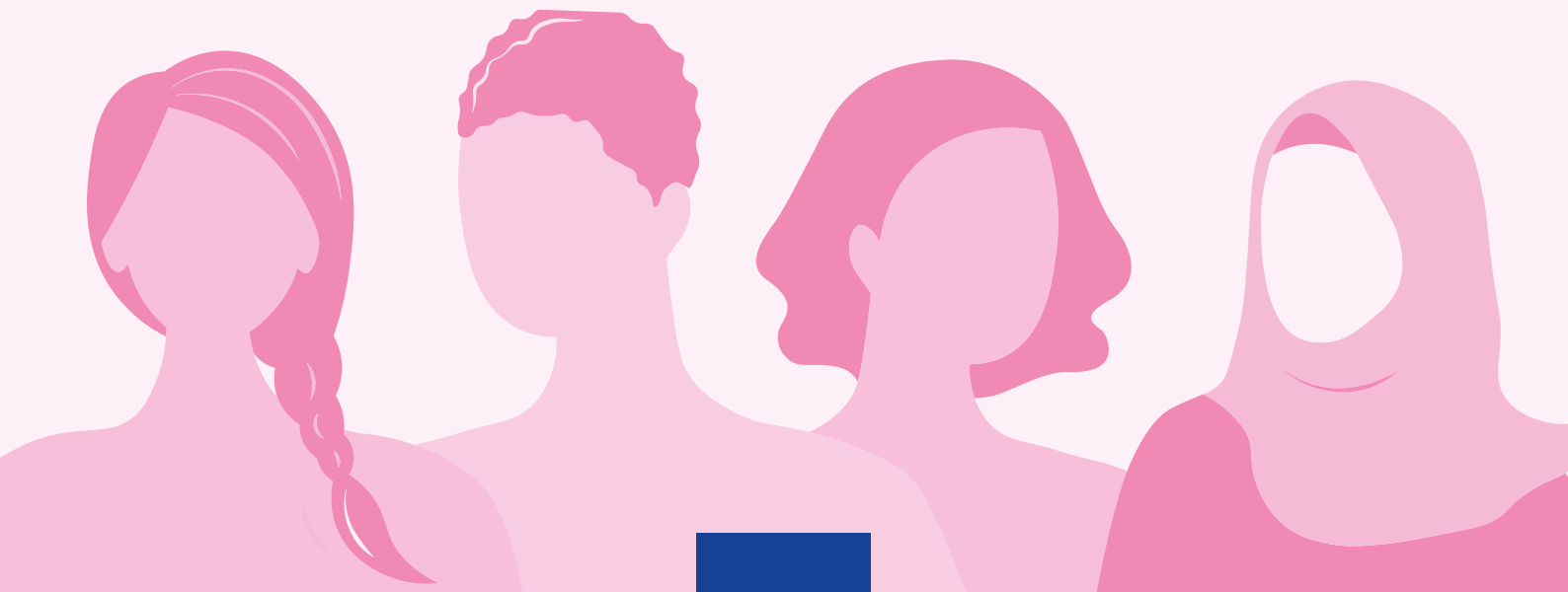
European Commission

ECIBC

EUROPEAN COMMISSION
INITIATIVE ON BREAST CANCER

European Quality Assurance Scheme for Breast Cancer Services



Contact information
European Commission, Joint Research Centre (JRC), Ispra, Italy
JRC-CANCER-POLICY-SUPPORT@ec.europa.eu
https://cancer-screening-and-care.jrc.ec.europa.eu/en

EU Science Hub
https://joint-research-centre.ec.europa.eu

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European Quality Assurance Scheme for Breast Cancer Services

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AUTHORS AND CONTRIBUTORS

THE JRC TEAM COORDINATING THE PROJECT:

Annett JANUSCH-ROI, Shawn BALDACCHINO, Marta GARCIA ESCRIBANO, Aliki STATHOPOULOU, Luciana STĂNICĂ, Gian Paolo MORGANO, Agnes MÄNNIK, Agnieszka KINSNER-OVASKAINEN, Tony O'GRADY, Sandra CALDEIRA and Ciarán NICHOLL.

Former JRC staff: Luciana NEAMȚIU, Donata LERDA, Jesús López ALCALDE, Massimo AMBROSIO, Giulia BOCCHI, Anke BRAMESFELD, Silvia DEANDREA, Nadya DIMITROVA, Grazia FEDERICO, Crystal FREEMAN, Sazan PAKALIN, Elena PARMELLI, Liisa PYLKKÄNEN, Emilia RIGGI, Zuleika SAZ-PARKINSON, Beatriz TORIGHELLI, Asli ULUTÜRK TEKIN and Nadia VILAHUR CHIARAVIGLIO.

THE EUROPEAN COMMISSION INITIATIVE ON BREAST CANCER QUALITY ASSURANCE DEVELOPMENT GROUP (QASDG):

Robert MANSEL, Francesco SARDANELLI, Kathi APOSTOLIDIS, Bettina BORISCH, Hilde BOSMANS, Jennifer-Jane BRIDGES, Sara BRUCKER, Augusto CARACENI, Luigi CATALIOTTI, Saskia CLAASSEN, Alexandru ENIU, Andre GRIVEGNEE, Cary KAUFMAN, Kraja FATJONA, Thanos KOSMIDIS, Jasna MESARIĆ, Ruben ORDA, Niall PHELAN, Piera POLETTI, Antonio PONTI, David RITCHIE, Vitor RODRIGUES, Elio Giovanni ROSSI, Sabine SIESLING, Giorgio STANTA, Luzia TRAVADO, Francisco TRESSERRA, Chantal VAN ONGEVAL, Mary WOODS and Marzia ZAMBON.

Former members of the QASDG: Karen BENN († 2020), Jacques BERNIER, Marie CANTWELL, Nadya DIMITROVA, Daniele GENERALI, Vanessa KAAB-SANYAL, Mechthild KRAUSE, Saghatchian MAHASTI, Zoltán MÁTRAI, Philip POORTMANS, Charles SHAW, Aliki STATHOPOULOU, Tibor TOT, Cary VAN LANDSVELD-VERHOEVEN, Simone WESSELMANN and Maggie WILCOX († 2021).

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Bettina BORISCH, Mireille BROEDERS, Xavier CASTELLS, Jan DANEŠ, Stephen DUFFY, Patricia FITZPATRICK, Markus FOLLMANN, Livia GIORDANO, Paolo GIORGI ROSSI, Axel GRÄWINGHOLT, Solveig HOFVIND, Lydia IOANNIDOU-MOUZAKA, Susan KNOX, Annette LEBEAU, Lorenzo MEMEO, Nancy SANTESSO, Holger SCHÜNEMANN and Alberto TORRESIN.

Former members of the GDG: Mariangela AUTELITANO, Edoardo COLZANI, Roberto D'AMICO, Chris DE WOLF, Miranda LANGENDAM, Helen MCGARRIGLE, Lennarth NYSTRÖM, Elsa PEREZ GÓMEZ, Cecily QUINN, Peter RABE, Ruben VAN ENGEN, Sue WARMAN († 2021), Yvonne WENGSTRÖM and Kenneth YOUNG

[1] Testing the European quality assurance scheme: https://cancer-screening-and-care.jrc.ec.europa.eu/en/ecibc/breast-quality-assurance-scheme/testing-the-scheme

The European quality assurance scheme for breast cancer services is dedicated to the memory of ECIBC's cancer advocates and patient representatives, Karen Benn, Sue Warman and Maggie Wilcox, whose unwavering determination and dedication were invaluable in shaping these quality requirements to address the needs of women affected by breast cancer.

TABLE OF CONTENTS

ABBREVIATIONS

ALND	axillary lymph node dissection
BCS	breast cancer service
BI-RADS™	Breast Imaging Reporting and Data System
CE	continuing education
CoC	continuity of care
DCIS	ductal carcinoma in situ
DGN	diagnosis requirement
DGN-IMG	imaging requirement
DGN-PTH	pathology requirement
DGN-TRT	diagnosis and treatment
EA	European co-operation for Accreditation
EC	European Commission
ECIBC	European Commission Initiative on Breast Cancer
ER	oestrogen receptor
FFPE	formalin-fixed paraffin-embedded
FLW	follow-up & survivorship
GEN	general requirement
GDG	Guidelines Development Group
HER2	human epidermal growth factor receptor 2
IAF	International Accreditation Forum
ICHOM	International Consortium for Health Outcomes Measurement
IHC	immunohistochemistry
ISO	International Organisation for Standardisation
ISO/IEC	International Organisation for Standardisation / International Electrotechnical Commission
IT	information technology
JRC	Joint Research Centre
MDM	multidisciplinary meeting
MLA	Multilateral Agreement
NAB	National Accreditation Body
MRI	magnetic resonance imaging
PAL	palliative care requirement
PR	progesterone receptor
PROM	patient-reported outcome measure
QA	quality assurance
QASDG	Quality Assurance Scheme Development Group
RHB	rehabilitation
SCR	screening requirement
SLNB	sentinel lymph node biopsy
TRT	treatment requirement
TRT-RAD	radiotherapy requirement
TRT-SUR	surgery requirement
TRT-SYS	systemic therapy requirement

FOREWORD

The **European Quality Assurance (QA) Scheme for Breast Cancer Services** is a voluntary certification scheme delivered by the European Commission Initiative on Breast Cancer (ECIBC). It covers the entire care pathway, from breast cancer screening to palliative care, and has been developed to support quality improvement in breast cancer services across Europe, within the context of organised, population-based cancer screening programmes.

As a result of the **European Council Recommendation** from 2003[1], the European Union (EU) has been focusing on improving cancer prevention, screening and care for breast, colorectal and cervical cancer. In 2008, the European Parliament and Council further reinforced the request to support Members States in their efforts to fight cancer and in December 2022[2] the Council Recommendation was updated to include lung, prostate and gastric cancer.

The **European Commission's Joint Research Centre (JRC)** has been mandated to coordinate the ECIBC in collaboration with the Directorate-General for Health and Food Safety (DG SANTE) as an activity under the European Commission Knowledge Centre on Cancer (KCC)[3], one of the flagship initiatives of the Europe's Beating Cancer Plan[4].

ECIBC represents the first in a forthcoming series of **European guidelines**, which provide evidence-based recommendations, and **European QA schemes** aimed at addressing the most prevalent cancers in Europe. The Commission is currently evaluating how to formally implement and operationalise the schemes for cancer care services across Europe wishing to apply for certification. The availability of the scheme for implementation and certification will be duly communicated and published on the JRC web-hub[5] and newsletter.

[1] Council Recommendation on cancer screening (2003/878/EC): https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:327:0034:0038:EN:PDF
[2] Council Recommendation on strengthening prevention through early detection 2022/C 473/01: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022H1213%2801%29
[3] Knowledge Centre on Cancer: https://knowledge4policy.ec.europa.eu/cancer_en
[4] Europe's Beating Cancer Plan – Improving early detection of cancer: https://ec.europa.eu/info/strategy/priorities-2019-2024/promoting-our-european-way-life/european-health-union/cancer-plan-europe_en#improving-early-detection-of-cancer
[5] JRC web-hub for the European cancer guidelines and quality assurance schemes: https://cancer-screening-and-care.jrc.ec.europa.eu/en

The development of the European QA scheme for breast cancer services is steered by the JRC with the scientific involvement of the **Quality Assurance Scheme Development Group (QASDG)** and the support of selected experts from the Guideline Development Group (GDG). Both multi-disciplinary groups are composed of experts representing different subject areas, such as breast cancer epidemiology, diagnostic radiology, pathology, breast surgery, oncology, and patient representation and advocacy. The scheme was **tested** within real healthcare settings by 20 entities, including breast cancer services, certification bodies and national accreditation bodies from 9 EU countries[6]. This first implementable version of the scheme incorporates the feedback and outcomes from the testing phase and has been **validated by the European co-operation for Accreditation (EA)** to ensure harmonised applicability of the accredited certification approach across Europe and beyond.

The European Commission will ensure the **timely update** of the scheme contents in the light of scientific/technical advances and/or technological evolution, and the experiences gained from practical applications.

The information contained in this document has been checked very carefully. The Commission would be grateful to users that point out any errors, inaccuracies or omissions in this document.

[6] Testing the European quality assurance scheme – https://cancer-screening-and-care.jrc.ec.europa.eu/en/ecibc/breast-quality-assurance-scheme/testing-the-scheme.

EXECUTIVE SUMMARY

ABOUT THE EUROPEAN QA SCHEME FOR BREAST CANCER SERVICES

The **European Commission Initiative on Breast Cancer** offers a person-centred quality assurance scheme (the European QA scheme) alongside the European evidence-based guidelines. This initiative aims to support healthcare providers and screening programme organisers, as well as policymakers and other stakeholders, with the instruments necessary to implement high-quality breast cancer screening, diagnosis, treatment and follow-up care that is equally accessible across Europe.

The European QA scheme defines a common set of quality and safety requirements for breast cancer services across diverse healthcare settings. These requirements will be revised periodically to reflect updates of the European guidelines and to take into account continuing advances in healthcare.

Breast cancer services that comply with these requirements are eligible to apply for the European QA scheme certification, underpinned by the European legislative framework on accreditation (defined in Regulation (EC) No 765/2008[7]), equally recognised in all Member States. This accredited certification framework ensures that services are evaluated in a harmonised manner across Europe and provides assurance that, regardless of where patients are treated, they can expect a consistently high standard of care. The objective of the certification is to increase confidence in the quality of care that the services provide to women and to ensure the continuity of care where services are delivered within different structures.

Specific provisions are included in the scheme for those breast cancer services that already hold certification for other well-established quality assurance schemes, in order to avoid duplication of efforts and to facilitate transition to accredited certification for the European QA scheme.

IMPLEMENTATION AND CERTIFICATION BODIES

The scheme is available to all breast cancer services and certification bodies. The implementation of the scheme is *voluntary*, and organised according to a *modular* approach, which enables cancer care services to seek certification for specific parts or the entire cancer care pathway in different structures (hospitals, clinics, cancer centres, breast units, cancer care networks, etc.). Additionally, the scheme provides a time-limited *stepwise* approach to certification, facilitating the preparation of cancer care services and a gradual achievement of a complete module certification. Accredited certification is granted by those certification bodies that have achieved accreditation according to the standard ISO/IEC 17065. Accreditation of the certification process is granted by National Accreditation Bodies that are signatories to the European co-operation for Accreditation multilateral recognition agreement for ISO/IEC 17065[7].

[7] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93: eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R0765

STRUCTURE OF THE EUROPEAN QA SCHEME MANUAL

This manual provides all the necessary information for the breast cancer services, certification bodies and National Accreditation Bodies participating in the scheme, with regard to the organisation, management and maintenance of the scheme, and the certification process.

It consists of two main parts and three annexes, which are either *normative* or *informative*. Parts and annexes marked as *normative* indicate the mandatory elements, prerequisites and conditions that the respective participants must fulfil to comply with the scheme, while the *informative* glossary and annex provide a list of terms and supplementary context, guidance or examples supporting the implementation of the scheme respectively.

I. **Part I Operation and certification** (normative): sets out the full details of how the European QA schemes are implemented, managed and maintained with specificities for the European QA scheme for breast cancer services. Prerequisites and conditions for breast cancer services, National Accreditation Bodies and certification bodies to participate in the scheme are outlined.

II. **Part II Breast cancer service requirements** (normative): includes a collection of quality and safety requirements for breast cancer services and provides examples of the type of evidence that may be presented to demonstrate compliance with each requirement.

III. **Glossary** (informative): includes definitions of terms as used in the context of the scheme.

IV. **Annex 1 Quality Indicators** (normative): includes instructions for calculating all the quality indicators defined within the service requirements.

V. **Annex 2 Competence specifications for auditing** (normative): outlines the competence specifications for the certification body's auditors and audit team.

IV. **Annex 3 Supporting materials** (informative): includes the reference documents related to the requirements of the scheme.

ADDITIONAL TOOLS SUPPORTING IMPLEMENTATION

Additional resources have been developed to support the implementation of the scheme.

These include:

- *a self-assessment tool* to help services to assess and improve their current performance and, for those interested in the European QA scheme certification, to evaluate their readiness and identify steps towards compliance;
- *a training template* for radiologists and radiographers working in breast cancer screening services.

ACCESS AND UPDATES TO THE EUROPEAN QA SCHEME

The current version of the European QA scheme for breast cancer services and supporting material can be accessed and downloaded freely from the JRC web-hub for the European cancer guidelines and quality assurance schemes[8]. All the original documents are published in English and are identified with a unique document code, date and version number. Only the published versions can be used for certification purposes.

Any updates to documents will be provided to all certification bodies registered with the European QA scheme owner as official communications, and published on the web-hub[8], as well as advertised through the web-hub's newsletter[9]. The web-hub and newsletter serve as essential tools for participants and other interested parties to stay informed about the latest changes and developments, and to ensure compliance with updated standards. Certification bodies will be responsible for informing applicant and certified cancer care services of any changes.

A summary of changes will be included in each updated document. Draft documents will be made available through the web-hub for public consultation for 30 days before they are formally published. If no objections are received in that period of time, the documents will be considered accepted. Following the publication of the updated scheme, there will be a 3-year transition period to enable breast cancer services and certification bodies to implement any necessary changes to their processes or systems.

[8] JRC web-hub for the European cancer guidelines and quality assurance schemes https://cancer-screening-and-care.jrc.ec.europa.eu/en

[9] Subscription page to the latest news on cancer screening, diagnosis and care https://cancer-screening-and-care.jrc.ec.europa.eu/en/Subscribe

PART I
OPERATION AND CERTIFICATION

CHAPTER 1

INTRODUCTION

- This chapter describes the structure and content organisation of the European quality assurance (QA) scheme for breast cancer services.
- The scope of the European QA scheme encompasses the entire breast cancer care pathway, from screening to palliative care, with a person-centred approach and is applicable to all healthcare settings across Europe.
- A modular certification approach allows diverse organisational structures of breast cancer services to participate in the scheme.
- Continuity of care is a core feature of the scheme and aims to ensure that discrete breast cancer services are experienced as coherent, connected and consistent with the individual or patient's medical needs and personal context.

Part I of the European QA scheme manual aims to set out the full details of how the European quality assurance (QA) scheme is organised, managed and maintained, including the European QA scheme owner's conditions and responsibilities for breast cancer services (BCS) and certification bodies[10] participating in the scheme. An accredited certification approach, which is delivered through an internationally recognised framework[11], has been adopted as the foundation for the European QA schemes. Through this approach, BCS that have implemented the specific European QA scheme requirements can be audited by certification bodies that have demonstrated their competence, impartiality and integrity by achieving accreditation from a National Accreditation Body (NAB). These certification bodies can grant accredited certification to BCS that have successfully demonstrated their conformity with the European QA scheme requirements. In addition, Part I provides information about how BCS and certification bodies, that are already participating in quality assessments within the cancer care sector, can also participate in the European QA scheme, without the need to duplicate audits or assessments respectively.

As part of the forthcoming series of the European QA schemes, such as the schemes for colorectal and cervical cancer services, operation and certification will be common to these schemes. Thus, references to *cancer care services* within Part I specifically refer to BCS for the purposes of this scheme manual.

Part I consists of six chapters:
Chapter 1 serves as the introduction describing the scope of the European QA scheme for BCS, the processes of care that are encompassed by the scheme, a modular approach to accredited certification, and continuity of care.

Chapter 2 explains the European framework on which accredited certification is based, including the European Commission (EC) Regulation that initially established the framework, the internationally agreed requirements for NABs and certification bodies, and the role that these bodies play in delivering accredited certification to cancer care services.

Chapter 3 describes the role and responsibilities of the European QA scheme owner in the European QA scheme, including: the confidentiality, use and release of information relating to participating cancer care services and certification bodies; how interested parties can access information and documents about the European QA scheme; the way in which documents are controlled; and how participating cancer care services and certification bodies can use the certificate and statement of conformity of the European QA scheme.

Chapter 4 sets out the conditions and responsibilities of cancer care services and certification bodies, for participating in the European QA scheme.

Chapter 5 provides a description of the evaluation and certification process, detailing the different stages of the process for attaining certification, namely application for certification, audit, certification, surveillance audit and re-certification audit.

[10] Certification bodies perform the conformity assessment activities of auditing and certification. Please refer to the Glossary for further details.

[11] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93: eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R0765

Chapter 6 details the different types of existing quality assessments within cancer care operating in Europe and sets out how these can be utilised by cancer care services and certification bodies that wish to participate in the European QA scheme, whilst avoiding duplication of audits.

SCOPE OF THE EUROPEAN QA SCHEME FOR BREAST CANCER SERVICES (BCS)

The European QA scheme covers the full extent of breast cancer management, from screening to follow-up & survivorship, and palliative care and is applicable to all healthcare services, including where breast cancer services are provided by different sites/legal entities.

Prevention of cancer is not treated as a separate service within the European QA scheme for BCS. However, requirements relating to prevention have been integrated into the overall scheme requirements for BCS (Part II: Breast cancer service requirements). In this context, prevention includes the following:

- primary prevention in the average-risk population when the intervention is targeted at a specific cancer. However, primary prevention interventions in general may be included as 'service/process requirements' in one or more of the BCS procedures (e.g. smoking cessation, alcohol reduction or weight-loss counselling in early diagnosis or treatment settings);
- secondary prevention in the average-risk population (i.e. screening);
- primary and secondary prevention, surveillance, diagnosis, treatment, rehabilitation and palliative care for individuals at increased risk of cancer;
- diagnosis and, when indicated, surgical removal of lesions that are pathologically defined as being associated with 'uncertain malignant potential';
- other non-malignant diseases when implied in a differential diagnosis of cancer.

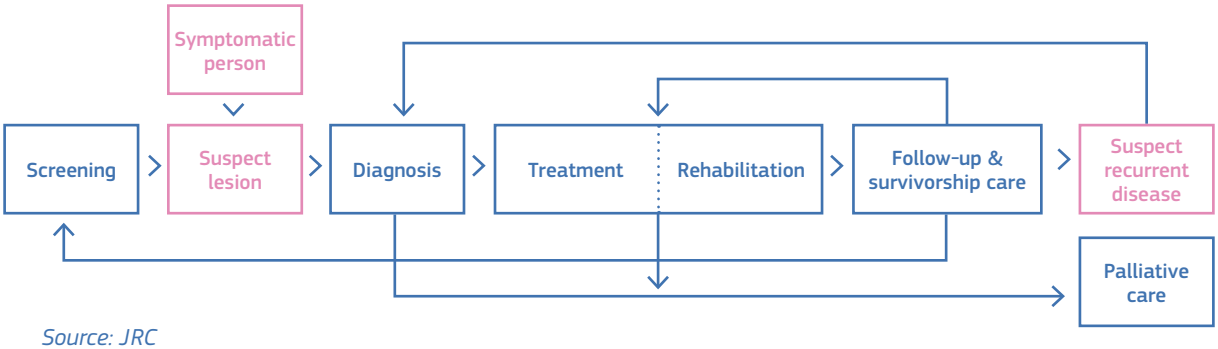
Male breast cancer and other male breast diseases, such as gynecomastia, do not fall under the scope of this scheme. However, the scheme may be adapted to breast cancer in men in the context of a future project, following the implementation of the scheme for female breast cancer.

To ensure that the European QA scheme follows a person-centred approach, the quality and safety requirements are defined by taking into account the entire care pathway for breast cancer, including all related processes and sub-processes. Ultimately, the scheme 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 improvement;
- identify quality potential within the breast cancer care pathway.

A simplified typical breast cancer care pathway used for the European QA scheme is represented in Figure 1.

Figure 1. The breast cancer care pathway covered by the European QA scheme.



Source: JRC

The main processes of breast cancer care can be identified as: screening, diagnosis, treatment, rehabilitation, follow-up & survivorship care, and palliative care. Each of these care processes may have related sub-processes that are provided by multiple professionals and services. For example, treatment may comprise various sub-processes, such as surgery, radiotherapy and systemic therapy, for both primary and recurrent or metastatic disease. The patient must always be involved and empowered in all processes along the care pathway.

REQUIREMENTS FOR BCS

Requirements are an important tool to assist cancer care services in measuring, monitoring and improving their performance. These have been developed for specific cancer types using a rigorous and extensive process; the methods used to select and develop the requirements for breast cancer are fully described in a EC publication[12] and summarised in Part II, Introduction, Section: Development of requirements. All BCS must meet the requirements that are applicable to their chosen module of certification, as indicated in Part II: Breast cancer service requirements, which also sets out the requirements for BCS in full.

CERTIFICATION MODULES

The diversity of organisational settings for breast cancer services between countries and regions has been highlighted in both published[13] and unpublished surveys by the Joint Research Centre (JRC), the European Commission's science and knowledge service. It is acknowledged that different processes or sub-processes in the breast cancer care pathway 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 certification scheme, enabling different legal entities or geographically separated services to participate according to the range of breast cancer services

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

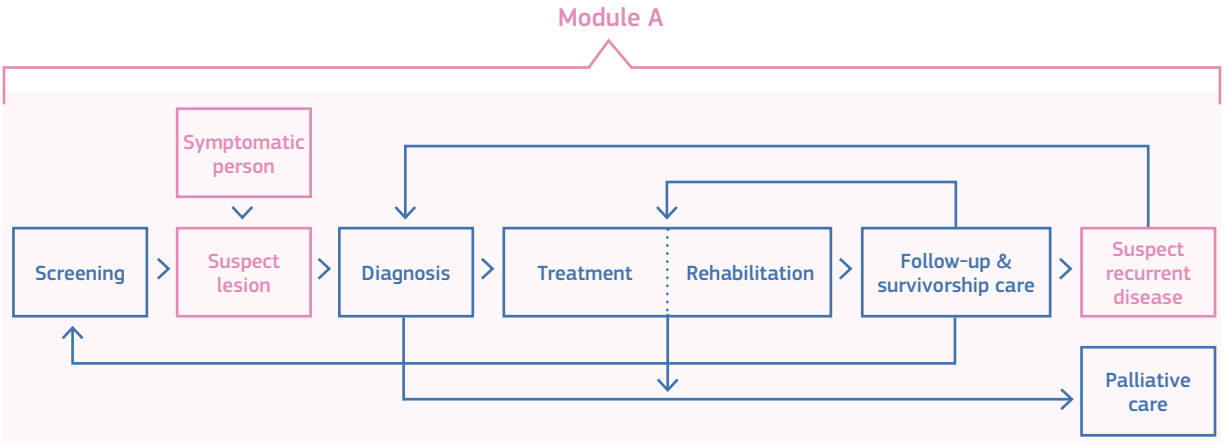
[13] Lerda D, Deandrea S, Freeman C, Lopez Alcalde J, Neamtiu L, Nicholl C, Nicholson N, Uluturk A and Villanueva Ferragud S. *Report of a European survey on the organisation of breast cancer care services*. Publications Office of the European Union, 2014, ISBN 978-92-79-37303-9.

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 (see Part I, Chapter 4, Section: Cancer care services).

Any eligible entity that provides breast cancer services may apply for certification according to the European QA scheme requirements for one of the following modules.

Module A: Certification of the entire breast cancer care pathway, including breast cancer screening, diagnosis, treatment, rehabilitation, follow-up & survivorship care, and palliative care processes (Figure 2).

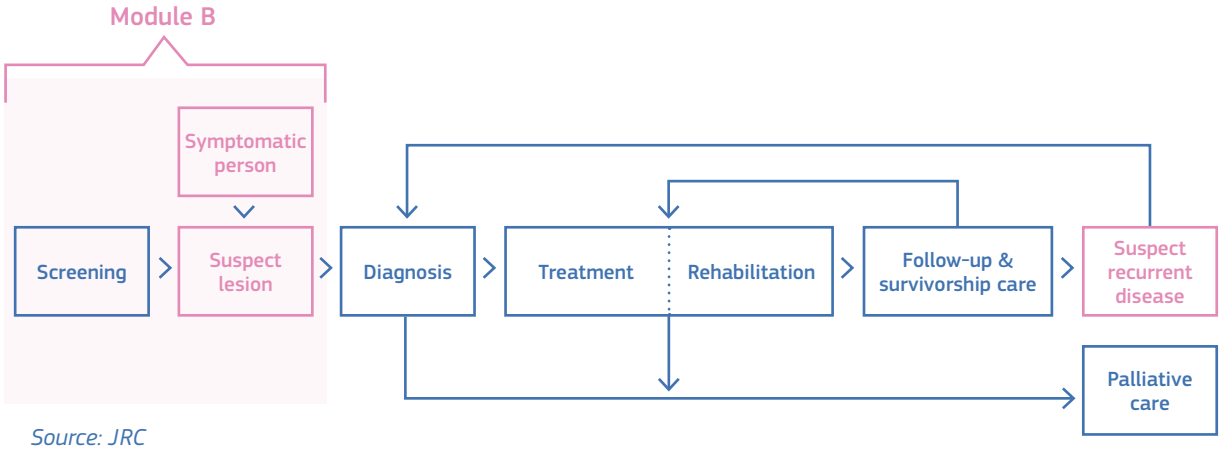
Figure 2. Certification of the entire breast cancer care pathway.



Source: JRC

Module B: Certification of breast cancer screening, covering the breast cancer screening process (Figure 3).

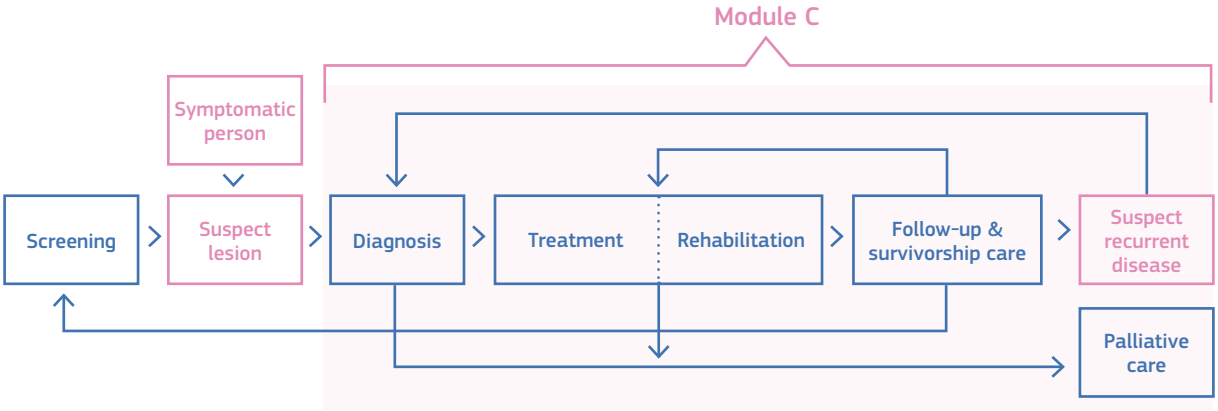
Figure 3. Certification of breast cancer screening.



Source: JRC

Module C: Certification of the breast cancer care pathway from diagnosis to palliative care, including breast cancer diagnosis (of symptomatic patients or referrals following screening), treatment, rehabilitation, follow-up & survivorship care, and palliative care processes (Figure 4).

Figure 4. Certification of the breast cancer care pathway from diagnosis to palliative care.



Source: JRC

Additionally, the scheme provides a time-limited, stepwise approach to certification, allowing BCS entities to initially apply for certification for: specific care processes within Module A or Module C and/or for a subset of sites/legal entities within a network delivering any of the modules (Part I, Chapter 5, Section: Time-limited, stepwise approach to certification).

By following this approach, BCS entities can progressively apply for and gradually achieve accredited certification for all processes within Module A or Module C, and for all sites/legal entities in a network delivering breast cancer services within a module, over a period of five (5) years, until all have been included in the accredited certification.

CONTINUITY OF CARE

Continuity of care is essential for a person-centred cancer care pathway, particularly where modules, processes and/or sub-processes are delivered by different entities (such as departments or units) or services (e.g. gynaecology, oncology, radiology) within the same overall organisation.

A BCS seeking certification is responsible for coordinating with other BCS entities to ensure continuity of individual patient care between modules and between processes and sub-processes. The specific requirements for managing continuity of care at all points in the breast cancer care pathway are clearly highlighted in Part II: Breast cancer service requirements.

Examples of situations in which each BCS entity should coordinate with other BCS entities to ensure that the requirements for continuity of care are met for all patients include the following:

- a screening programme that is delivered through a network of screening services (continuity of care **within a module**);

- a screening service that refers individuals to one or more breast cancer centre for diagnosis (continuity of care **between modules**);
- breast cancer centres that accept referrals from one or more breast cancer screening services (continuity of care **between modules**);
- breast cancer centres that provide diagnosis, treatment, rehabilitation, follow-up & survivorship care, and/or palliative care services, through different collaborating sites/legal entities (continuity of care **between processes/sub-processes within a module**);
- breast cancer services that are delivered through an organisational system of services such as oncology (continuity of care **between processes/sub-processes within and between modules**);
- referral centres that receive patients diagnosed with breast cancer from different entities (such as hospitals) (continuity of care **between modules**);
- any part of the BCS that is delivered through a network of service providers (continuity of care **between processes/sub-processes within a module**);
- a BCS that initially applies for only part of the breast cancer services that it provides (e.g. only screening or only breast cancer centre, when it provides both) (continuity of care **between modules**).

CHAPTER 2

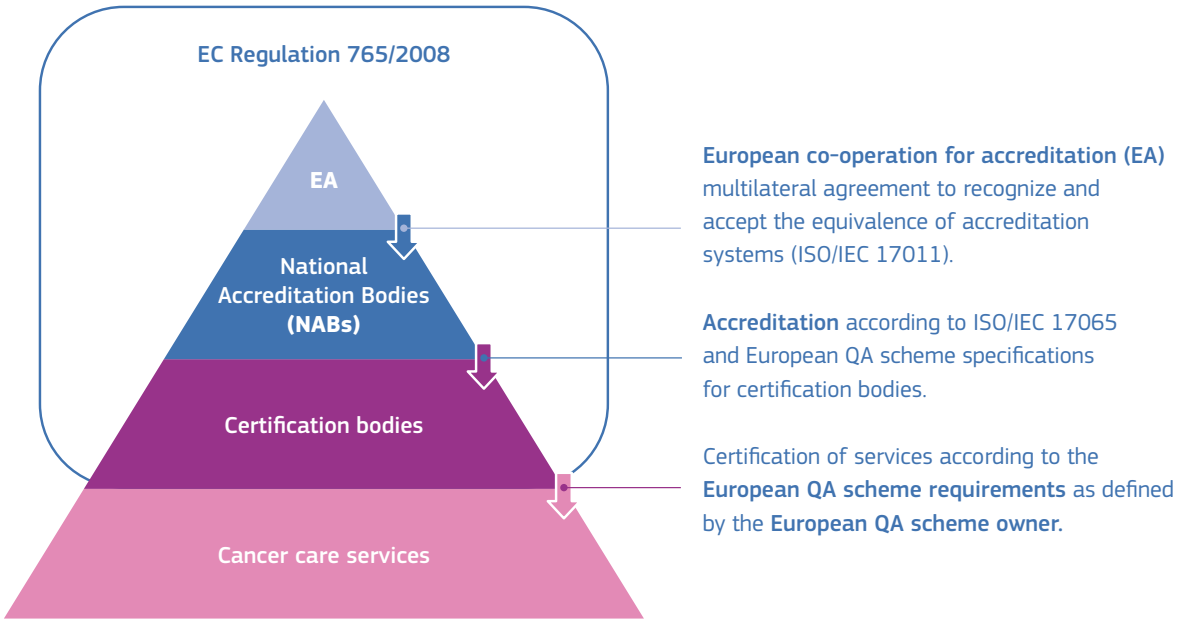
ACCREDITED CERTIFICATION

- The European QA scheme is established on the accredited certification framework set out in European legislation.
- Through this framework, the scheme relies on international standards for certification, operating within a free market and supporting equal access to the scheme for certification bodies and cancer care services.
- Cancer care services which voluntarily participate and comply with the scheme requirements achieve a certification, an attestation of compliance, that is recognised and accepted across the European Member States.

The European QA scheme adopts the accredited certification approach set out in Regulation (EC) 765/2008[14] as the foundation for recognising cancer care services[15] that comply with specified requirements. This offers significant advantages, including:

- providing an internationally recognised framework (Figure 5);
- being well-established within Member States;
- using international and harmonised standards;
- delivering a consistent approach to audits of QA scheme requirements enabling comparability of certified services;
- operating using nationally appointed accreditation bodies;
- involving local and/or regional certification bodies and auditors, thus reducing the need for interpreters and translation during the audit process;
- supporting equal opportunity in a free market of certification and cancer care services.

Figure 5. Illustration of the building blocks of the accredited certification scheme.



Source: JRC

This framework ensures:

- the compliance of NABs with harmonised standards (ISO/IEC 17011);
- the competence and compliance of certification bodies with harmonised standards (ISO/IEC 17065 plus European QA scheme specifications for certification bodies);
- the harmonisation of auditing across regions and Member States;
- the compliance of cancer care services with the European QA scheme requirements (European QA scheme certification).

[14] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93: eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32008R0765 For the purposes of this European QA scheme for breast cancer services, 'cancer care services' specifically refer to breast cancer services, or the BCS entity as applicable

[15] For the purposes of this European QA scheme for breast cancer services, 'cancer care services' specifically refer to breast cancer services, or the BCS entity as applicable.

*(Source: JRC)*REQUIREMENTS FOR ACCREDITATION BODIES ACCREDITING CERTIFICATION BODIES[16] (ISO/IEC 17011)

The European co-operation for Accreditation (EA) has an evaluation process to ensure that NABs comply with the relevant standard for accreditation activities, ISO/IEC 17011: *Conformity assessment — General requirements for accreditation bodies accrediting conformity assessment bodies*. NABs that have demonstrated their compliance with ISO/IEC 17011 through the EA's peer-evaluation process become signatories of the EA Multilateral Agreement (EA MLA). This is a signed agreement between the EA members, whereby the signatories recognise and accept the equivalence of the accreditation systems operated by the signing members, and also the reliability of the conformity assessment results provided by conformity assessment bodies (including certification bodies), which are accredited by the signing members.

REQUIREMENTS FOR BODIES CERTIFYING PRODUCTS, PROCESSES AND SERVICES (ISO/IEC 17065)

Certification bodies that wish to certify cancer care services for compliance with any of the modules of the European QA scheme shall demonstrate their competence and compliance with ISO/IEC 17065: *Conformity assessment – Requirements for bodies certifying products, processes and services* by undergoing a process of accreditation against this standard and the conditions and specifications for certification bodies set out in Part I, Chapter 4: Participating in the European QA scheme and Annex 2: Competence specifications for auditing.

Within the context of the European accreditation framework, this accreditation is carried out by a NAB that is a signatory to the multilateral mutual recognition agreement operated by the EA. For the purpose of this scheme, a NAB-accredited certification body is defined as a certification body that is compliant with ISO/IEC 17065 and accredited by a NAB to certify for the European QA scheme for BCS.

COMPLIANCE OF CANCER CARE SERVICES WITH THE EUROPEAN QA SCHEME REQUIREMENTS

A cancer care service that implements the requirements of the European QA scheme and wishes to receive an attestation of compliance with the European QA scheme requirements should seek NAB-accredited certification. Thus, the auditing and certification processes are carried out by, or in collaboration with, accredited certification bodies.

[16] Certification bodies perform the conformity assessment activities of auditing and certification and thus are included in the broader term of conformity assessment bodies. Please refer to the Glossary for further details.

There are defined certification modules (sets of requirements) to which a cancer care service can be certified (see Part I, Chapter 1, Section: Certification modules).
Cancer care services must comply with the conditions specified in Part I, Chapter 4, Section: Cancer care services and the requirements for the processes and sub-processes of the relevant module of the cancer care pathway specified in Part II: Breast cancer service requirements and Annex 1: Quality indicators.

Certification is awarded after a successful demonstration that the cancer care service complies with the European QA scheme requirements for a specified module.

CHAPTER 3

THE EUROPEAN QA SCHEME OWNER

- The European Commission, represented by the Joint Research Centre, is the owner of the European QA scheme and is responsible for its maintenance, updates, and overall integrity.
- The scheme owner's responsibilities include ensuring the quality and confidentiality of information, providing training and guidance, maintaining lists of certified cancer care services and accredited certification bodies, and regularly reviewing and updating the scheme.
- Availability of resources, changes and updates for the scheme are communicated in a timely manner to all users, including cancer care services, certification bodies, and national accreditation bodies.

The European Commission (EC), represented by the Joint Research Centre (JRC), is the owner of the scheme. The JRC, acting as the Scientific Competence Office through the Commission's Directorate-Generals for Health and Food Safety (DG SANTE), is responsible for maintaining and updating the European QA schemes.

The European QA scheme owner takes full responsibility for:

- the objectives, content and integrity of the European QA scheme;
- maintenance of the European QA scheme and the provision of guidance when required;
- the structure for operating and managing the European QA scheme (which may include, for example, facilitating the exchange of experiences between cancer care services[17] and between certification bodies);
- documenting, maintaining and publishing the content of the European QA scheme and ensuring relevant parties, such as certification bodies that are registered with the European QA scheme owner and cancer care services, are advised of any updates through official communications;
- ensuring access to up-to-date listings of certified cancer care services and accredited certification bodies;
- maintaining the registration process for cancer care services and accredited certification bodies;
- ensuring that the European QA scheme is developed and updated by individuals who are competent in both technical and conformity assessment aspects of cancer care;
- providing access for cancer care services, certification bodies and other involved parties to training materials and information related to the implementation of the European QA scheme, the requirements for cancer care services and certification bodies, and the certification process;
- making and maintaining arrangements to protect the confidentiality of information provided to the scheme owner by certification bodies involved in the European QA scheme;
- evaluating and managing the risks and liabilities arising from its activities;
- ensuring adequate arrangements (e.g. insurance or reserves) to cover liabilities arising from its activities;
- ensuring that it has the financial stability and resources required for it to fulfil its role in operating the European QA scheme;
- maintaining a relationship with all relevant national authorities by keeping them updated on the European QA scheme's current status and any developments;
- maintaining a relationship with the EA by keeping it updated on the European QA scheme's current status and any developments, in order to ensure that any relevant EA publications remain current.

The scheme owner will periodically review the scheme to confirm its validity and to update requirements as necessary according to an established review and updating strategy. In particular, the scheme owner will ensure that provisions are made to review Part I: Scheme operation and certification, as a consequence of feedback received from the operation of the scheme and/or of any modification to ISO or EN standards and relevant EA documents. The European QA scheme will be updated on a regular basis and within a time frame that aligns with any

[17] For the purposes of this European QA scheme for breast cancer services, 'cancer care services' specifically refer to breast cancer services, or the BCS entity as applicable.

associated published transition arrangements and at most every 3 years. Provisions will also be made to review any sections in Part II: Breast cancer service requirements on an ad hoc basis whenever there are significant developments in cancer care (for example, the introduction of new approaches to treatment) and/or there is additional evidence to support the guidelines on which the requirements are based. Amendment of the requirements will be considered and, if appropriate, will be adopted before any scheduled review date. The revised scheme will be evaluated by EA before publication. The new version of the scheme, and associated transition arrangements, will be published and communicated to all relevant stakeholders, including cancer care services, certification bodies and NABs. The transition period would typically be over 3 years, during which both the previous and updated versions of the scheme are valid. Following the transition period, certifications to the previous version would no longer be valid.

CONFIDENTIALITY, INFORMATION USE AND INFORMATION RELEASE

The **cancer care service**, by applying for certification, gives permission for the European QA scheme owner and respective certification body to use any information it has provided for internal processes and sanction procedures and for publication of information about the cancer care service (see below). All information held by the European QA scheme owner is available to itself as the scheme owner and the certification body that the cancer care service is working with. Information held by the European QA scheme owner will never include patient-specific information or raw data used for calculating quality indicators. The European QA scheme owner and/or certification body may release and/or publish the following information about the cancer care service to third parties or into the public domain: name; site addresses (as applicable); unique European QA scheme identifier; status (registered/applicant, certification status and history of certification status); and scope of certification. No other information, particularly in relation to compliance to specific requirements and/or indicators, may be released without the written consent of the cancer care service entity.

The **certification body**, by registering with the European QA scheme owner, gives permission for the European QA scheme owner to use information for internal processes, sanction procedures and for publication of information about the certification body. All information held by the European QA scheme owner about a certification body is available only to the European QA scheme owner. The European QA scheme owner may release the following information about the certification body to third parties or into the public domain: name; address; contact details; accreditation identifier and the NAB with which accreditation is held. No other information may be released without the written consent of the certification body.

ACCESS TO THE EUROPEAN QA SCHEME AND DOCUMENT CONTROL

Cancer care services and certification bodies can access and download all relevant information and documents relating to the European QA scheme from the JRC web-hub for European cancer

guidelines and quality assurance schemes[18], including the European QA scheme, supporting materials, a list of certified cancer care services or services in the process of certification, and a list of accredited certification bodies for the European QA scheme. Access to the self-assessment tool for cancer care services is provided by the European QA scheme owner.

[18] JRC web-hub for European cancer guidelines and quality assurance schemes: https://cancer-screening-and-care.jrc.ec.europa.eu/en

CHAPTER 4

PARTICIPATING IN THE EUROPEAN QA SCHEME

- This chapter outlines the eligibility conditions and responsibilities that cancer care services and certification bodies must meet and accept to participate in the European QA scheme.
- Certification bodies must register with the scheme owner, be accredited to ISO/IEC 17065 and comply with the scheme's specifications to certify for the European QA scheme.
- Cancer care services[19] are responsible for demonstrating compliance with the European QA scheme requirements, maintaining records, and providing information to the certification body, while certification bodies are responsible for conducting audits, maintaining impartiality, and reporting incidents of misuse.

[19] For the purposes of this European QA scheme for breast cancer services, 'cancer care services' specifically refer to breast cancer services, or the BCS entity as applicable.

CANCER CARE SERVICES[20]

All aspects of cancer care management, from screening to palliative care, are regarded as services, irrespective of the definition of the entity that is providing the particular aspect of cancer care management. Entities can be legally and/or geographically separate and can be referred to in different ways. For example: a 'unit' (such as a screening unit that is providing a cancer care screening service); a 'department' (such as a department that is providing an endoscopy service); a 'centre' (such as a cancer centre that is providing diagnostic and treatment services); or differently described entities providing cancer care services.

CANCER CARE SERVICES PROVIDED BY NETWORKS

Networking and formalised collaboration between healthcare providers is increasingly recognised as an option for delivering cancer care services[21]. Cancer care services may be provided by a network of organisations and specialists to enable close multidisciplinary working and/or ensure easy access to all necessary services; for example, across a geographical region. Networks may consist of multiple entities (e.g. entire institutions, parts of institutions, oncology departments, screening facilities, etc.) belonging to different institutions that are dedicated to screening, diagnosis, treatment, rehabilitation, follow-up & survivorship care, and palliative care. The entities, or collaborators, must have formal arrangements to work together in a structured way under the common governance[22] (with respect to the European QA scheme) of a single, responsible legal entity, and to adopt harmonised standards of care across the network. Coordinating patient care is the responsibility of multidisciplinary, inter-professional teams.

All entities collaborating in the provision of cancer care services within the specified certification module are considered within the scope of certification and for the purpose of this scheme they are referred to collectively as the cancer care service or specifically, the BCS.

Where cancer care services are provided by a network of entities, a **responsible entity** that represents the network (for example, one of the legal entities within the network) can apply for one of the European QA scheme certification modules and may initially apply using a time-limited, stepwise approach (see Part I, Chapter 4, Section: Time-limited, stepwise approach to certification). A single screening service is not eligible to apply for accredited certification unless it is part of a screening programme's application.

The following are examples of networks:

- screening programmes may involve one or more screening services operating as a network in different locations;

[20] For the purposes of this European QA scheme for breast cancer services, 'cancer care services' specifically refer to breast cancer services, or the BCS entity as applicable.

[21] Albreht, Tit, Kiasuwa, Régine and Van den Bulcke, Marc (Eds.). *European Guide on Quality Improvement in Comprehensive Cancer Control*, 2017, ISBN: 978-961-7002-28-7.

[22] Different entities within the network are not obliged to have the same management structure or to collaborate with the single, responsible entity for aspects other than the scope of the European QA scheme.

- chemotherapy services provided by oncology departments or centres in different hospitals under the auspices of a national or regional oncology institute;
- palliative care services delivered through hospices, hospitals, day-care facilities and home care.

ELIGIBILITY CONDITIONS AND RESPONSIBILITIES OF CANCER CARE SERVICES

Any cancer care service entity is eligible to voluntarily participate in the scheme subject to the following conditions and responsibilities:

Conditions

1. The organisation or entity (the cancer care service) responsible for providing the cancer care services, the **responsible entity**, must be a legal entity or a defined part of a legal entity (e.g. a cancer centre that is a department within a legal entity such as a hospital). A single legal entity must be responsible for any cancer care services that are provided by a network of different entities.

2. The cancer care service entity must be willing to enter into an agreement/contract with an applicant/accredited certification body that defines the rights, responsibilities and liabilities of the parties to that agreement. A cancer care service may enter into an agreement/contract with an accredited certification body from any country, provided that the certification body meets the European QA scheme requirements. This is particularly relevant where there is no such certification body within the cancer care service's country. Certification bodies that are authorised to certify cancer care services for the European QA scheme are listed on the European QA scheme website.

3. The cancer care services provided by a legal entity must cover one of the modules described in Part I, Chapter 1, Section: Certification modules.

   A screening programme will need to have been operating breast cancer screening services for a minimum of two (2) years before applying for certification, in order to provide sufficient evidence of compliance with the requirements for cancer care services (e.g. one complete round of screening).

   Screening programmes may involve breast cancer screening services that are provided by one or more entities 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. For example, screening services are not eligible for stand-alone accredited certification for the European QA scheme but shall be eligible for accredited certification as part of an application from an organised screening programme. Pathology and Imaging services are not eligible for stand-alone accredited certification for the European QA scheme but are only eligible for accredited certification as part of an application from a cancer care centre. Pathology and Imaging services may however already hold, and are eligible to apply for, NAB accreditation for their services (see Part I, Chapter 6: Existing quality assessments within cancer care services).

Whichever module a cancer care service entity chooses, all processes and sub-processes within that module must be included in the certification, even where some of those are provided by other sites/legal entities (see also Part I, Chapter 5, Section: Time-limited stepwise approach to certification). The different sites/legal entities at which services are delivered will be identified on certification documents (see Part I, Chapter 5, Section: Certification), so that they can be acknowledged as integral parts of the certified services, provided that they continue to demonstrate that they meet all of the relevant European QA scheme requirements. After achieving accredited certification, cancer care services are required to maintain up-to-date records of all services delivered at different sites and/or by different entities within the network.

4. Cancer care services participating in the European QA scheme are required to comply with all relevant national and European legislation. However, in the event of a perceived conflict between the European QA scheme requirements and any national or European legal requirements, the latter take precedence. Additionally, where a cancer care service is required by law to fulfil a criterion or indicator that overlaps with the QA scheme requirements, the data and records for this do not need to be checked during a certification audit. For example, if the law requires that all patients receiving chemotherapy must be given cardiac function tests and a cancer care service would lose its licence to operate if it does not comply. In this instance, the cancer care service must demonstrate that it has a procedure for ensuring that it meets this legal requirement.

5. Cancer care services that voluntarily seek certification for the European QA scheme will need to undergo an independent third-party audit by an applicant/accredited certification body to confirm that they meet the applicable European QA scheme requirements, in order to obtain a certificate and be eligible to use the European QA scheme's statement of conformity. Cancer care services that apply for certification to a non-accredited certification body that is an applicant for accreditation, accept the risk of delayed or not being granted accredited certification if the certification body does not achieve accreditation.

6. By applying for certification, cancer care services commit to providing the information specified by the certification body at the time of application (see Part I, Chapter 5, Section: Applicaa tion for certification). Application to a certification body is also taken as agreement that the certification body shares the application status and specified information with the European QA scheme owner for the purposes of monitoring and developing the scheme's operation (see Part I, Chapter 3, Section: Confidentiality, information use and information release).

7. A cancer care service must have a database that is capable of collecting performance data on applicable indicators. The calculated quality indicator data (including data from external resources) must be provided to its selected certification body in the agreed format, at least every 12 months for all care delivered in the 12 months prior to the certification audit. Access to a suitable database and calculation of quality indicator data can be organised by the BCS, for example, through formal arrangements with a cancer registry.

Responsibilities

1. It is the responsibility of the cancer care service to demonstrate that its cancer care services comply with all of the European QA scheme requirements as applicable to the scope of its activities as detailed in Part II: Breast cancer service requirements. For on-site visits, it is the cancer care service entity's responsibility to ensure that all members of the audit team are given access to all of the activities, areas and staff indicated in the audit plan.

2. The European QA scheme permits processes or sub-processes of cancer care modules to be provided by one or more cancer care service entities under a common responsible entity. In such cases, all the involved cancer care services must meet the respective European QA scheme requirements, including the applicable Part II, Chapter 2: General requirements and Annex 1: Quality indicators. In particular, the responsible cancer care service must ensure that all the entities within the service collect any performance data required and transfer the data at least every 12 months for work carried out in the previous 12 months.

3. The European QA scheme permits cancer care services to opt for a time-limited, stepwise approach for initial application for NAB-accredited certification. Cancer care services opting for a time-limited, stepwise approach must have plans in place to demonstrate how they intend to achieve certification within a 5-year period for a complete module and for all sites/legal entities delivering the module as applicable.

4. Prior to certification, if there is any evidence of deliberate misuse by the cancer care service of the relationship between the cancer care service entity and the European QA scheme owner, the relationship between the cancer care service and the certification body, and/or any aspect of the European QA scheme, the cancer care service will be excluded from certification for a minimum of 12 months. Any case of misuse will be publicised on the European QA scheme and certification body websites.

CERTIFICATION BODIES

ELIGIBILITY CONDITIONS AND RESPONSIBILITIES OF CERTIFICATION BODIES

Any certification body is eligible to participate in the scheme subject to the following conditions and responsibilities. By voluntarily applying and establishing an agreement with the scheme owner to certify services to the European QA scheme, certification bodies agree to these conditions and accept the responsibilities of the scheme. Certification bodies are permitted to seek accreditation for one or more modules within the European QA scheme.

Conditions

1. Certification bodies must be a legal entity or part of a legal entity (a governmental certification body is considered to be a legal entity on the basis of its governmental status).

2. Certification bodies must be accredited to ISO/IEC 17065[23] by a NAB for certifying to the European QA scheme. The NAB must be a signatory to the EA multilateral recognition agreement[24] for accreditation to ISO/IEC 17065. Non-accredited certification bodies that have applied and are in the process of accreditation, may only accept applications and conduct audits of cancer care services solely for the purposes of their accreditation process. However, for granting certification to any cancer care service certification bodies must have demonstrated that they comply with these conditions and have achieved accreditation. Non-accredited certification bodies that do not seek accreditation may participate in the scheme by collaborating with a willing accredited certification body through an agreement/contract that specifies the role of the non-accredited certification body in the scheme according to the provisions of ISO/IEC 17065 (see Part I, Chapter 6: Existing quality assessments within cancer care services).

3. Certification bodies must register with and enter into an agreement/contract with the European QA scheme owner before accepting applications and carrying out audits of cancer care services for certification to the European QA scheme. Registration with the European QA scheme owner (contact details can be found on the European QA scheme owner's website) is initiated by making a formal written request to enter into an agreement/contract. As part of the agreement/contract, the scheme owner retains the right to share information on the certification body's current application and accreditation status, scope of accreditation and locations covered by its accreditation with cancer care services interested in applying for certification.

Responsibilities

1. By registering with the European QA scheme owner, a certification body commits to meet all applicable European QA scheme specifications (e.g. applying any changes to the European QA scheme requirements within a specified time-frame), including complying with the terms and conditions for the use of the European QA scheme certificate and statement of conformity. A certification body becomes eligible to provide certification for the European QA scheme only while it has a valid agreement from the European QA scheme owner to do so.

2. The certification body must provide details of how its current accreditation status, scope of accreditation and locations covered by its accreditation can be verified (e.g. on the website of the NAB with which it is accredited). Where a certification body's scope of accreditation does not cover the full range of cancer care services (e.g. screening services only), the certification body must ensure that the limits and scope of the accreditation are clear and publicly available, and that certification services outside the scope of the accreditation are distinguished from those that are accredited.

3. A certification body must inform the European QA scheme owner in writing about changes in its accreditation status (e.g. suspension, withdrawal or termination) within three (3) working days of the change in status, detailing its action plans and the circumstances leading to this

[23] ISO/IEC 17065: Conformity assessment – requirements for bodies certifying products, processes and services.
[24] EA multilateral recognition agreement: https://european-accreditation.org/mutual-recognition/the-ea-mla/

4. A certification body is responsible for:
   - informing the European QA scheme owner of all applicant cancer care service entities;
   - providing updated information on participating cancer care services to the European QA scheme owner;
   - updating the European QA scheme owner on the certification status of cancer care services;
   - publishing or providing, on request, the names and scope of certified cancer care services, and the validity of certifications. A certification body must inform the European QA scheme owner within three (3) working days when it suspends or withdraws a certification held by a cancer care service entity, and when it reinstates a suspended or withdrawn certification;
   - reporting incidents of misuse of the European QA scheme certificate and statement of conformity to the European QA schemes owner;
   - making available and maintaining information about the certification processes, rules and procedures;
   - informing applicant and certified cancer care services of any changes to European QA scheme documents.

5. Certification bodies must enter into a legally enforceable agreement/contract with client cancer care service entities that includes the content shown in Part I, Chapter 5, Section: Application for certification, and that takes account of the responsibilities of both the certification body and the client.

6. Certification bodies and any collaborating organisation (see Part I, Chapter 4: Participating in the European QA scheme) must carry out their certification activities independently and impartially. In the context of the European QA scheme, a certification body and its staff cannot provide consultancy services to a cancer care service entity, and must identify and manage any risks to its impartiality that arise from its activities and relationships (including those of its staff). The European QA scheme permits outsourcing of auditing activities by a certification body.

7. Where a certification body is working with a collaborating organisation (see Part I, Chapter 6: Existing quality assessment within cancer care services) as an external resource, the certification body is responsible for:
   - informing the European QA scheme owner, in writing, of the agreements it has in place for outsourcing any auditing activities;
   - demonstrating that the external resource has been assessed and subsequently monitored, and meets the applicable requirements for the outsourced activities;
   - obtaining the cancer care service's agreement to use external resources before those external resources are deployed.

8. Certification bodies must appoint a contact person who has technical knowledge and understanding of the European QA scheme and any IT platform that the scheme uses. This person will be responsible for representing a certification body, being the key user of the scheme's IT platform, and maintaining contact with the European QA scheme owner.

9. Certification bodies and any collaborating organisation must carry out audits and certification activities in accordance with the audit and certification process described in Part I,

Chapter 5: Certification process, and must have documented procedures covering all aspects of the certification process.'

10. Although certification is not a legal compliance audit, certification bodies must be aware of the applicable legal requirements. Cancer care services must be required to provide information during audits, on any arrangements relevant to the European QA scheme requirements, to ensure that:
    - management and employees of the cancer care service understand and comply with all legal requirements relevant to their responsibilities;
    - all cancer care service documentation, including procedures, work instructions, contracts and agreements meet legal requirements and are respected;
    - any issues of legal non-compliance raised by regulatory authorities or other interested parties are addressed and resolved by the cancer care service in a timely manner.

11. Certification bodies must keep all records relating to activities carried out for the European QA scheme for a period of time that is compliant with national legal requirements and, where relevant, NAB requirements.

12. Where certification bodies offer certification services outside the country or region in which they are established, they must ensure that the language in which the certification audits are to be conducted is agreed at the beginning of the application process. It must be made clear if there will be a need for the translation of any documents, records, etc. In addition, certification body auditors must be aware of any legislation (national or regional) that is applicable to cancer care services in the specific country or region.

13. Certification bodies are required to manage the competence of personnel involved in the certification process in accordance with the requirements of ISO/IEC 17065, clause 6.1.2.

14. Certification bodies must determine the composition of the overall audit team (including both on- and off-site auditors), and the required competences, according to the module for which the cancer care service entity is seeking certification, in accordance with the specifications below.

15. Certification bodies are encouraged to use the European QA scheme certificate template provided by the scheme owner upon request. The scheme's certificate template must be used in accordance with the scheme owner's instructions and guidelines, and must not be altered or modified in any way. If a certification body chooses not to use the scheme's certificate template, it must submit to the scheme owner for approval, the certificate template it intends to use. Such template must include the minimum information required in the certificate, the EU emblem and must be approved before issuing any certificates using their own template (See Part I, Chapter 5, Section: Certification).

AUDIT TEAM AND AUDITORS FOR THE EUROPEAN QA SCHEME FOR CANCER CARE SERVICES

All auditors (and technical experts, as necessary) must receive training on the European QA scheme for cancer care services and have a good understanding of the aims, objectives and requirements. Audit team members must be aware of any legislation (national or regional) related to cancer care services that is applicable to an applicant cancer care service.

It is essential that certification body audit teams have the collective competence to audit cancer care services for the specific processes within the modules and for the specific cancer types addressed by the European QA scheme. Details of the certification body audit team competences required for each different cancer type covered by the European QA schemes are published in the respective manual's Annex 2: Competence specifications for auditing.

Certification bodies must record the rationale and process for appointing the audit team for each audit undertaken and inform cancer care service entities of the proposed audit team in advance of the commencement of an audit. Cancer care services will be given the opportunity to put forward any valid objections they may have with regard to individual team members. During the certification cycle, the certification body may decide to vary the composition of the on-site team of auditors by appointing individuals from the overall audit team in rotation.

LEAD AUDITOR

In all cases, certification bodies must appoint a lead auditor to coordinate the audit process. A lead auditor is expected to:

- coordinate the audit process, including both on- and off-site activities;
- lead and manage the team of auditors to ensure that relevant activities are audited within the agreed time frame for the audit(s), and to provide support and advice as necessary;
- direct the audit team in both on- and off-site activities, including preparation and reporting;
- take the lead in the development of audit plans and audit schedules;
- undertake desk-based reviews of organisations' policies, procedures, guidance and training material, and assess their effectiveness in facilitating compliance with the European QA scheme;
- conduct interviews, facilitate discussion and carry out reviews of records and facilities at the cancer care services' premises to gather evidence to support compliance to the service requirements;
- participate in audits, if required, as an auditor with competence in one of the cancer care processes or sub-processes;
- conduct an opening meeting at on-site visits to:
  - introduce the audit team and explain their roles in the audit,
  - explain the purpose and process of the audit(s),
  - clarify and confirm the scope of the audit(s) and the particular requirements that are being audited,
  - confirm the details of the audit plan, logistics, guides and facilities required by the team,
  - confirm reporting arrangements and determine who is authorised by the cancer care service to agree corrective actions resulting from the audit visit,
  - confirm confidentiality undertaking;
- during the on-site visit(s) and at the completion of the audit, ensure that the audit team members have seen sufficient evidence to provide assurance that the cancer care service is meeting the requirements of the European QA scheme for the agreed scope of activities;
- chair an audit team meeting at the on-site visit(s) to:
  - analyse all relevant information and evidence gathered during the document and record review and the on-site audit activity(ies),
  - discuss the outcome of the audit including any non-conformities identified, and agree

the recommendation on certification,
  - identify processes, situations, etc., where the cancer care service is meeting requirements, as well as identify opportunities for improvement,
  - coordinate inputs from the audit team for the audit report;
- produce the audit records and report which will document non-conformity findings and provide comments on the processes and procedures implemented by the cancer care service to deliver compliance with the European QA scheme;
- chair a closing meeting with the cancer care service prior to leaving the site(s) to present the findings and outcome of the audit and, where possible, the audit report;
- be responsible for making the overall recommendation on certification;
- conduct and lead follow-up activities, where necessary.

A LEAD AUDITOR IS ALSO EXPECTED TO:

- have strong intellectual, analytical and problem solving abilities in order to be able to apply the requirements of the European QA scheme to a variety of practical circumstances and to differentiate between good and poor practice;
- be well organised and presented;
- manage a team of auditors (and technical experts, as necessary);
- be able to communicate verbally with staff and management at all levels in the cancer care service;
- possess excellent interpersonal and good communication skills;
- possess good written communication skills;
- demonstrate excellent time management;
- demonstrate good auditing techniques, including demonstrating acceptable behaviour during audits;
- be able to report accurately and concisely, both verbally and in writing;
- be able to provide empathic feedback where required;
- have a good knowledge and understanding of:
  - the aims, objectives and requirements of the European QA scheme,
  - the processes and sub-processes of the cancer care pathway,
  - healthcare indicators and methods for measuring and reporting,
  - the underlying principles of quality assurance and quality management,
  - evidence- and risk-based approaches,
  - IT and its use in the management and confidentiality and security of data;
- possess the following qualities:
  - integrity,
  - independence,
  - fairness,
  - due professional care,
  - confidentiality.

A lead auditor may be a non-health professional, however, they must:

- have a university degree;
- be competent to carry out audits in accordance with the requirements of ISO/IEC 17065 and the European QA scheme.

CHAPTER 5

CERTIFICATION PROCESS

- The BCS may systematically evaluate their compliance with the European QA scheme through a self-assessment. The certification process includes application, evaluation, issue of certificate, and maintenance of certification.
- Certified cancer care services may use the European QA scheme's statement of conformity to promote their certification status. This must be done in accordance with specified guidelines to avoid misuse or misrepresentation.
- A stepwise approach allows BCS to progressively achieve certification for all the breast cancer care processes within a full module and to include all the sites where services are delivered.

STEPS TOWARDS CERTIFICATION OF CANCER CARE SERVICES[25]

The overall certification process comprises a number of different stages, namely application for certification, evaluation (including auditing), award of certification, surveillance audit and re-certification audit.

The following is a summary of the steps that a cancer care service should take to prepare, apply for, achieve and maintain accredited certification. A representation of this summary is given in Figures 6 and 7.

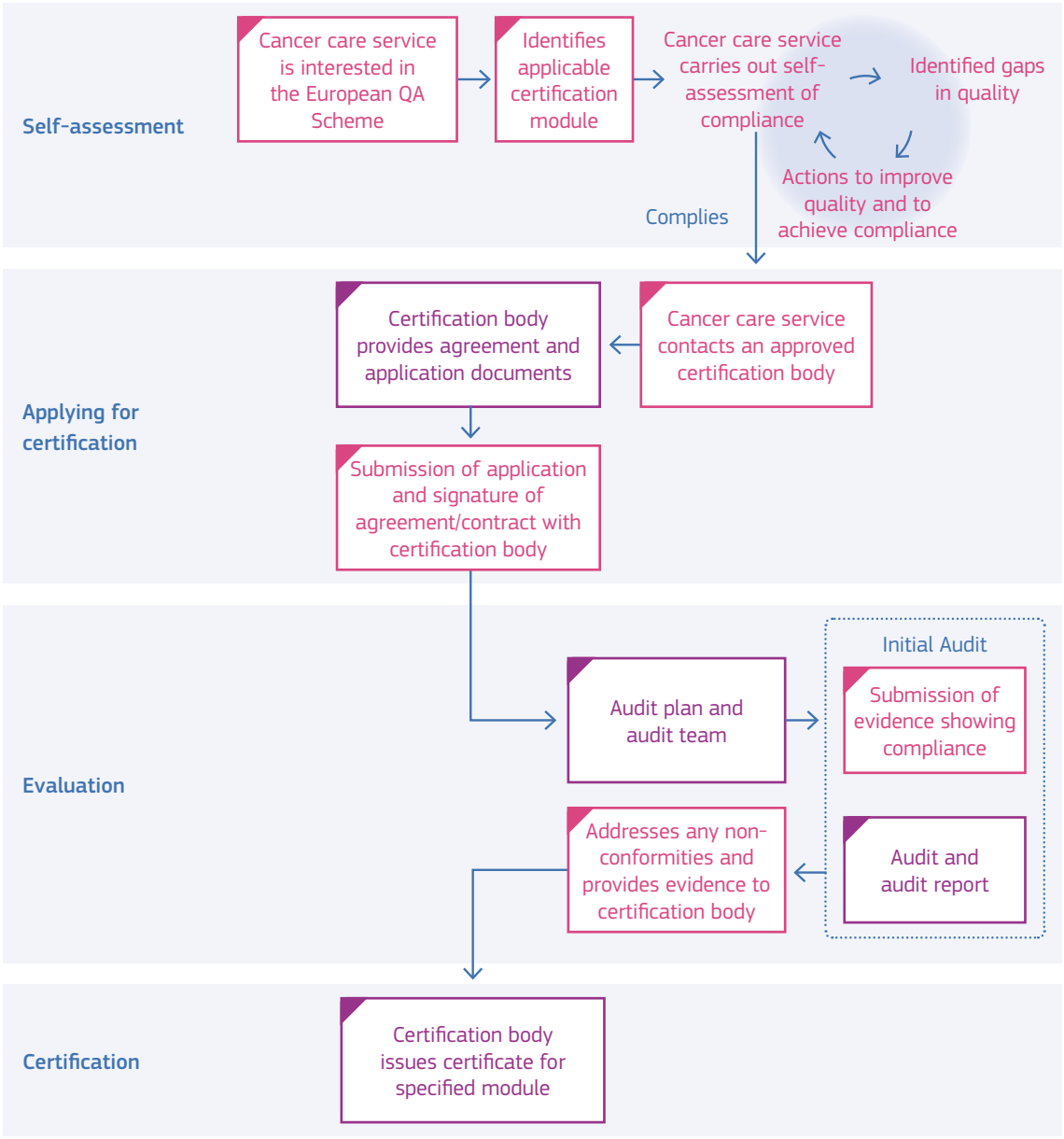
1. Download the respective European QA scheme manual from the European QA scheme website[26].
2. Carry out a self-assessment[27] of compliance with applicable eligibility conditions of Part I, Chapter 4: Participating in the European QA scheme and the requirements of Part II: Breast cancer service requirements and Annex 1: Quality indicators, identify gaps and areas where improvements may be needed, and take action to address any non-compliances.
3. Select one of the registered certification bodies listed on the European QA scheme website and contact it to obtain the application documentation.
4. Submit an application for certification for a specific module (see Part I, Chapter 1, Section: Certification modules and Part II, Introduction), including the application form and all specified information.
5. Sign an agreement/contract with the certification body, including an agreement to pay all fees associated with the certification process.
6. Accept the proposed audit team and plan for the initial certification audit.
7. Participate in the certification audit, including remote (off-site) activities and on-site visit(s) to the cancer care service facilities.
8. Address any non-conformities to demonstrate compliance with the European QA scheme requirements.
9. Receive a certificate from the certification body, which is valid for three (3) years and for a specified certification module.
10. Undergo annual surveillance audits.
11. Undergo re-certification audits before the certificate expires.

[25] For the purposes of this European QA scheme for breast cancer services, 'cancer care services' specifically refer to breast cancer services, or the BCS entity as applicable.

[26] European QA scheme website can be found on the JRC web-hub for European cancer guidelines and quality assurance schemes: https://cancer-screening-and-care.jrc.ec.europa.eu/en.

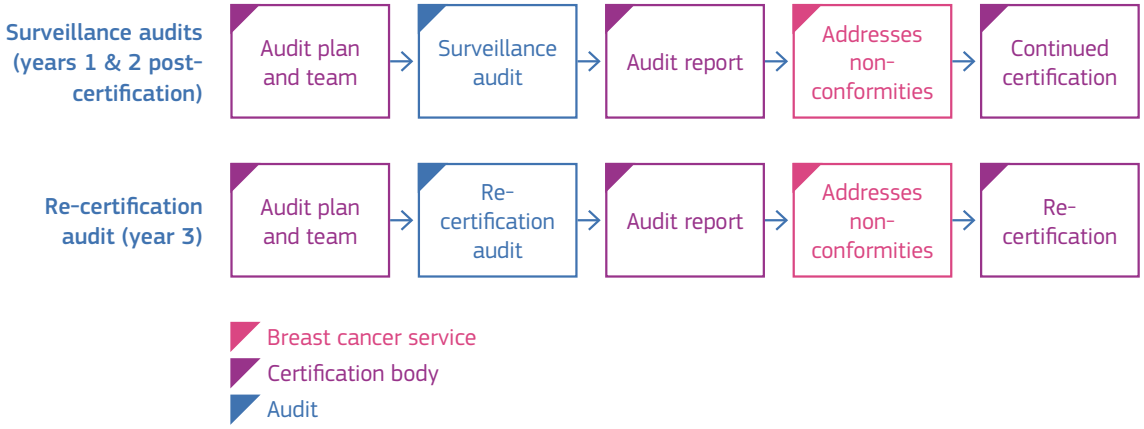
[27] Use the self-assessment software tool provided on the European QA scheme website, if desired.

Figure 6. Steps for cancer care services to apply and achieve initial certification.



Source: JRC

Figure 7. Steps for cancer care services to maintain certification.



Source: JRC

APPLICATION FOR CERTIFICATION

Detailed application information is required in order for certification bodies to prepare for and plan the next stage of the certification process. This information will be requested by certification bodies (e.g. using application forms, on-line facilities) and must include:

- date of application;
- legal name and full postal address of registered office of the applicant BCS entity;
- contact details:
  - name of legal representative who is authorised to sign on the organisation's behalf,
  - name of the BCS's clinical director,
  - name of representative to whom all administrative enquiries should be addressed,
  - business addresses, telephone numbers and email addresses of the above individuals;
- details of any collaborating organisations providing breast cancer services, including names of schemes and standards of any current quality assurance recognition, certification or accreditation held by each collaborating organisation;
- services provided by the applicant and the collaborating organisations:
  - breast cancer screening;
  - breast cancer centre, including:
    - diagnosis (including symptomatic patients and referrals following screening),
    - treatment,
    - rehabilitation,
    - follow-up & survivorship care,
    - palliative care;
- sites at which services are provided:
  - places (where services are managed and delivered),
  - name and title of person responsible for managing service at each site,
  - business address and contact details for each site;
- description of services provided at each site, that are to be included in the certification, e.g.:
  - breast cancer screening;

  - breast cancer centre, including:
    - diagnosis (including symptomatic patients and referrals following screening),
    - treatment,
    - rehabilitation,
    - follow-up & survivorship care,
    - palliative care;
- description of sub-processes provided at each site, e.g.:
  - screening provision,
  - imaging and guided imaging interventions,
  - nuclear medicine,
  - pathology (cytology, histology, prognostics and genomics),
  - genetic evaluation (risk assessment) and testing,
  - laboratory testing,
  - surgery,
  - reconstructive surgery,
  - medical oncology,
  - radiation oncology,
  - other medical treatments,
  - fertility preservation,
  - complementary and integrative medicine,
  - nursing care (including community-based nursing and district nursing),
  - rehabilitation modules and interventions (physiotherapy, psychotherapy, sexual counselling, neurocognitive therapy, physical exercise, nutrition and, where relevant, management of lymphoedema),
  - symptom control,
  - supportive care,
  - psycho-oncology (including screening for distress),
  - social service counselling,
  - reintegration (e.g. going back to work),
  - patient/person involvement and empowerment (e.g. communication of diagnosis and treatment plan, patient information, patient navigation provided by a health professional, shared decision-making and self-management),
  - primary prevention and health promotion,
  - research,
  - continuity of care,
  - data management,
  - patient safety,
  - quality improvement;
- European QA scheme and module(s) to which the BCS is to be certified;
- if the BCS has opted for a time-limited, stepwise approach to certification, a plan for achieving certification for all processes in a module and all sites/legal entities (see Part I, Chapter 5, Section: Time-limited stepwise approach to certification);
- organisational structure, including numbers of breast cancer-specific surgeons, radiologists, medical oncologists, radiation oncologists, pathologists, nurses and other professionals;
- names, qualifications and background of personnel assigned to providing breast cancer services;
- details of any current quality-assurance recognition, certification or accreditation held,

including name of scheme(s) and standard(s);
- any relevant outsourced[28] cancer care or other externally provided related services with the legal names of the providers;
- declaration of willingness to abide by the requirements of the certification agreement/contract:
  - signature;
  - name of authorised person;
  - date.

AGREEMENTS/CONTRACTS

Certification agreements/contracts must contain, as a minimum, all of the requirements of ISO/IEC 17065 clause 4.1.2.2, and must include the responsibilities of both the certification bodies and cancer care services, as well as the terms and conditions of the agreement/contract in accordance with the following details:

- background circumstances of the agreement/contract;
- names, addresses and authorised representatives of the parties (certification body and cancer care service entity) to the agreement/contract;
- definitions of terms;
- services to be provided;
- language in which the audit activities will be conducted, particularly where auditors and auditees normally use different languages. If there will be a need for translation of documents, records, etc., this must be made clear at the beginning of the application process;
- rights, responsibilities and liabilities of the parties to the agreement/contract (e.g. requirement for cancer care service to inform the certification body of any significant changes to its personnel, workforce, facilities, network of services, etc.);
- rules governing the use of certificates and statements of conformity;
- surveillance of certification;
- suspension, withdrawal and termination of certification;
- complaints;
- appeals;
- use of subcontractors;
- changes by the cancer care service;
- changes to the scheme and specified requirements;
- transfer of certification;
- fees and charges;
- ownership of information/data;
- intellectual property:
  - owned by the certification body,
  - ownership of pre-existing material,
  - third-party material,
  - moral rights,
  - ownership of certification documentation and statement of conformity;
- insurance and liability;
- termination;

[28] Refer to the Glossary. In the context of the European QA scheme, outsourced care services are generally services that are within the scope of the certification module but provided by an external organisation through formal arrangements with the BCS.

- force majeure;
- survival and severability;
- dispute resolution;
- alteration of the agreement/contract;
- serving notice under the agreement/contract;
- governing law and jurisdiction.

In preparation for the audit stage of the certification process, an initial review of the application details will be undertaken by the certification body, along with a contract review and a document review. The module for which the application is made will be confirmed and where a cancer care service has opted for a time-limited, stepwise approach to certification, the certification body will discuss the cancer care service plan and assess its potential for achieving the full scope of certification for the specified module.

Information provided by the applicant cancer care service will be used to determine the extent of the audit and will usually be done following discussion with the cancer care service.

EVALUATION OF CANCER CARE SERVICES

The purpose of the evaluation (by means of an audit[26] in the context of this scheme) is for the certification body to examine and review sufficient evidence in order to verify the cancer care service's compliance with **all** of the applicable European QA scheme requirements. It is the responsibility of the cancer care service to ensure that it meets all of the applicable requirements and conditions for certification before it undergoes certification audits.

In advance of any audit activity being undertaken, an audit team will be appointed and the following information will be provided to a cancer care service about:

- the number of auditor days that will be needed;
- the proposed plan for carrying out the audit, including both on-site visits and remote (off-site) activities;
- the agenda for any on-site visits and remote (off-site) activities;
- any key members of staff needed during on-site visits;
- any processes, services, meetings, documents, results and reports that the cancer care service will need to make available to the audit team, including information from different sites and different locations (where applicable), and other collaborators where relevant.

An initial certification audit must always include on-site visits to the cancer care service. Remote (off-site) audit activities (e.g. examination of written and/or electronic information, telephone discussions/interviews) may be used to evaluate the cancer care service; certification bodies must record their rationale for the approach to initial certification audits. Where certification bodies and any collaborating organisation use ICT for off-site audit activities, they must ensure that they comply with the International Accreditation Forum (IAF) publication IAF MD4[29].
The cancer care service will be advised of the dates by which it must provide any information

[29] IAF MD, 4:2023. *IAF Mandatory Document for the Use of Information and Communication Technology (ICT) for Auditing/Assessment Purposes.*

or evidence of compliance that is needed for remote (off-site) auditing and/or prior to on-site visits. The information or evidence may be provided in the format (e.g. paper documentation such as records and notebooks, digital documentation) normally used by the cancer care service. A certification body may request all the relevant calculated indicators for the cancer care services provided for all sites.

AUDIT DAYS AND AUDIT PLAN

The number of audit days required to audit a cancer care service depends on:

- the certification module;
- the size and complexity of the cancer care service. For example, a screening programme that involves a network of screening services will require more audit days than a screening programme that involves only one screening service;
- the number and geographical location of sites where the cancer care services are provided. For example, a regional screening programme with a small number of geographical locations will require fewer audit days than a national screening programme with a large number of geographical locations;
- the number of entities or collaborating organisations involved in delivering cancer care services;
- the extent of compliance with the European QA scheme requirements. For example, if during the audit, a certification body records multiple, systemic non-conformities, more audit days will be required to determine compliance;
- any other aspect of the cancer care service that is relevant to the provision of the specific cancer care.

The extent of the audit, including the strategy for sampling the evidence of compliance, will be determined using the information provided by the applicant cancer care service in its application. The applicable requirements to be audited will be confirmed to the cancer care service in advance and before commencement of the audit.

AUDIT SAMPLING

The **sampling strategy** adopted by a certification body for sampling the cancer care service's evidence of compliance must take the following factors into consideration:

- the scope of activities;
- the size and complexity of the cancer care service (including numbers of staff and patients;
- the number and geographical location of sites where the cancer care services are provided;

The sampling strategy must be based on the particular circumstances of a cancer care service in order to be confident that a cancer care service complies with the applicable requirements. For example, some evidence from all sites/services within a network should be examined by the auditors either remotely (off-site) and/or at on-site visits in accordance with the certification body's sampling strategy as determined in discussion with the coordinating cancer care service entity.

The following will be included in the audit team's sampling strategy:

- examination of the key management and monitoring controls implemented by the cancer care service;
- examination of the evidence that key controls are effective in ensuring compliance with the

QA scheme requirements;
- audits of systems and processes, such as data management, quality management and improvement systems;
- examination of a sample of records showing different patients' progress through the processes and sub-processes of cancer care, commencing at 'first contact point' to 'completion of care';
- examination of indicators' raw data, missing data and calculation approach;
- examination of representative samples for applicable requirements.

It is acceptable for a certification body to identify and examine evidence that is representative of a number of different criteria and/or indicators. For example, criteria that require regular reviews of documents may be collectively evaluated by examining the cancer care service's policy and procedure for document review and by randomly selecting some documents to verify that the stated review procedure is followed. Another example would be for auditors to select several quantitative indicators and examine the raw data, percentage missing variables and calculations associated with these to give confidence in the way a cancer care service collects and manages raw data. Auditors shall assess the percentage missing data for variables that are needed to assess general data eligibility (age and topography), to assess indicator-specific data eligibility, and to compute the indicators (numerator, denominator and/or indicator variables).

A team of auditors would normally attend the on-site audit at the same time, but, depending on circumstances, it may be necessary for different audit team members to attend on separate dates or at different times.

In order to avoid duplication of efforts as far as possible, different auditors will be assigned to audit different aspects of the cancer care service's activities both remotely (off-site) and through on-site visits, each auditor having been made aware of the extent and limit of their assigned role.

AUDIT TECHNIQUES

The following audit techniques will be used to sample sufficient evidence to determine whether a cancer care service meets **all** of the applicable European QA scheme requirements:
- examining documents, records and reports;
- on-site visits, including different sites and different locations (where applicable);
- observing service delivery;
- interviewing staff;
- interacting with patient representatives, where applicable;
- observing multidisciplinary meetings.

Other auditing techniques may also be used.

During the audit process the following aspects of the cancer care service will be examined:
- the design of the cancer care service, including risk assessment, patient safety, preventative planning and contingency arrangements;
- functions, processes, sites and outputs;
- the management system;
- existing quality assessments, i.e. accredited or certified services;
- arrangements with external providers of related cancer care or other services;

- documentation, processes, procedures, records and reports;
- arrangements for measuring performance against European QA scheme indicators;
- arrangements for submitting and updating calculated indicator data to the certification body;
- resources (personnel, facilities, equipment and technology);
- patient experience, including any feedback from patients;
- other information as necessary.

Many of the European QA scheme requirements detailed in Part II: Breast cancer service requirements include examples of the types of evidence of compliance that might be examined. However, other types of evidence may also be acceptable.

Where feasible, auditors may carry out some audit activities remotely (off-site) before conducting an on-site audit, including the following:

- examining documents, records and reports relating to:
  - the design of the cancer care service, including risk assessment, preventive planning and contingency arrangements,
  - functions, processes, sites and outputs,
  - the management system,
  - patient safety measures,
  - existing quality assessments, such as accredited or certified services,
  - arrangements for measuring performance against the European QA scheme indicators,
  - arrangements for submitting and updating calculated indicator data to the certification body,
  - resources (personnel, facilities, equipment and technology),
  - patient involvement processes;
- conducting telephone interviews with staff.

During an on-site audit, the certification body's on-site audit team will:

- verify the validity, accessibility and implementation of the procedures, processes and systems, as described in the documents, records and reports, provided by the cancer care service;
- follow up on any queries arising from the remote (off-site) audit activities carried out before the on-site visit;
- observe delivery of the service by management and staff;
- explore the patient experience, by agreement and where appropriate and acceptable;
- provide the cancer care service with feedback on the audit findings before leaving the site.

During certification audits, evidence from all sites/services within a network will be examined by the auditors remotely and/or at on-site visits in accordance with the certification body's sampling strategy and determined based on the particular circumstances of the cancer care service.

A written report on the findings of the audit process shall be provided within a timescale agreed between the cancer care service and the certification body. The report must address all of the applicable European QA scheme requirements and any contractual requirements specified by the European QA scheme owner or certification body. The minimum content of an audit report shall include:

- name of certification body;

- names of certification body auditors;
- name of European QA scheme;
- date(s) of audit;
- name(s) of the cancer care service(s) audited;
- scope of certification audit (Module and care processes covered);
- list of all applicable requirements;
- information about the extent of the audit (e.g. sites visited, networks of cancer care services);
- description of any exceptional, excellent and exemplary practices identified, as well as any improvements to the processes and sub-processes that have been introduced;
- details of any minor, major or contractual non-conformities identified;
- details of any opportunity for improvement actions identified;
- action plan due date;
- due date for completion of actions;
- conclusions regarding compliance with **all** of the applicable QA scheme requirements;
- recommendation with regard to the decision on certification.

Certification bodies may use their own reporting format provided that the above minimum content is included.

NON-CONFORMITIES

Non-conformities will be raised where the audit team identifies that the cancer care service is not conforming to all of the European QA scheme requirements. These must be raised in reference to the specific requirement and categorised according to the nature of the non-conformity (see below). Where a non-conformity arises due to regional or national legislation, the regional or national legislation will normally take precedence. For example, if national or regional legislation mandates inviting individuals aged 40-75 for cancer screening, this takes precedence over the European QA scheme lower age range requirement of screening individuals aged 50-69 and would be considered compliant.

However, in cases where regional or national legislation specifies a lower acceptable limit than the European QA scheme requirement, the European QA scheme takes precedence. For example, if national or regional legislation specifies that only patients aged 55-65 should be invited for screening, this would be a non-conformity if the European QA scheme requires inviting individuals aged 50-69 for screening.
An action plan describing the actions that the cancer care service will take to address non-conformities and a time frame for the actions to be completed will be agreed between the certification body and the cancer care service.

Non-conformities must be categorised as follows:

- **Minor:** any non-conformity that does not in itself put patients at risk or adversely affect the performance of the overall service. The cancer care service will need to provide documentary evidence of the actions taken to resolve the minor non-conformities. Examples of minor non-conformities include:
  - a BCS does not have a formal written policy for pain management. This would be resolved by provision of evidence by the BCS to the certification body that it had documented and

implemented a policy for pain management;
  - a BCS does not have documented instructions for the proper use of all equipment (where applicable). This would be resolved by provision of evidence by the BCS to the certification body that it had documented and implemented instructions for the proper use of all equipment;
  - an algorithm for calculating an indicator contains an error, which results in incorrect results. This would be resolved by provision of evidence by the BCS to the certification body that it had reviewed the algorithms for **all** indicators calculated by the BCS, and implemented and tested revised algorithms to ensure that all calculated indicator results were correct.

- **Major:** any non-conformity that could result in failure or reduced operability of the service, and that could put patients at risk. Depending on the specific nature of the non-conformities, these must be resolved within a reasonable timescale from the audit and according to the certification body's rules and procedures. The cancer care service will need to provide documentary evidence of the actions taken and where necessary, these actions will be verified through an additional visit to the cancer care service. Moreover, in critical circumstances, it may be necessary to require additional immediate actions to be taken, or to suspend in whole or in part, the certification, until the non-conformities have been adequately addressed. Examples of major non-conformities include:
  - One or more professionals working in the BCS do not meet the experience requirements specified and carry out their work unsupervised (GEN-1).
  - The BCS cannot demonstrate that the imaging equipment used for breast cancer screening and/or diagnosis is capable of achieving and maintaining the required level of technical performance (DGN-IMG-2).
  - The BCS does not monitor cardiac function in women with breast cancer treated with anti-HER2 therapy before, during or after treatment (TRT-SYS-7).
  - The proportion of women with invasive breast cancer for whom the biomarkers are collected and assessed before treatment is at 85%, which is significantly below the defined norm and there is no valid justification for the underperformance (DGN-TRT-5).

- **Contractual:** Any non-conformity relating to contractual requirements of the European QA scheme owner and/or the certification body.

EXCEPTIONAL PRACTICES AND OPPORTUNITIES FOR IMPROVEMENT ACTIONS

Exceptional practices identified by auditors may include examples from any of the care processes where the cancer care service is delivering; for example, outstanding care to patients, excellent training and support for staff, first-class facilities or any other outstanding aspect of the service. Improvements to processes and sub-processes are also included in this reporting category.

In addition, a certification body may identify opportunities for improvement actions for the cancer care service that do not in themselves constitute non-conformity with the European QA scheme requirements, but that could lead to improvements in the cancer care service if implemented.

CERTIFICATION

Upon completion of the evaluation, the certification body will review all of the information and results related to the evaluation of the cancer care service and will decide on the certification.

REVIEW

The certification body will assign an individual(s) to review the audit report and any other information related to the certification process. The assigned individual(s), must be authorised, competent and independent of the evaluation process. The reviewer(s) must be satisfied that there is sufficient evidence that:

- the cancer care service has been audited by a competent audit team;
- the audit was comprehensive enough to be confident that the cancer care service complies with **all** of the applicable European QA scheme requirements and any certification requirements;
- **all identified non-conformities are confirmed to have been addressed and resolved** before the certification body grants certification to the cancer care service for a defined module of activities.

CERTIFICATION DECISION

Following the review, assigned individual(s) makes the decision whether or not to grant certification to the cancer care service.

CERTIFICATION DOCUMENTATION

A certificate will be issued identifying the certified cancer care service, the certification module (as described in Part I, Chapter 1, Section: Certification modules) and the sites/legal entities included in the certification (where applicable). Where different sites and/or legal entities are collaborating (for example within a network, see Part I, Chapter 1, Section: Continuity of care and Part I, Chapter 4, Section: Cancer care services), these may be:

- multiple sites that deliver distinct care processes or sub-processes within the cancer care pathway; or
- multiple regional sites that are performing the same care processes or sub-processes; or
- a combination of these.

Where a cancer care service has applied for a specific module but has chosen to exclude certain care processes by opting for a time-limited, stepwise approach, the certificate will detail the specific module and the care processes that are currently included in that module and, where applicable, the sites/legal entities where these processes are delivered.

At a minimum, the following information must be included on the certificate for the European QA scheme:

- the EU emblem;
- a unique certificate identifier, established by the certification body issuing the certificate;
- name and address of the cancer care service responsible entity, to which the certification is granted;

- statement of conformity;
- name, address and logo (where applicable) of the certification body issuing the certificate;
- name and version of the European QA scheme under which the certificate is issued;
- scope of certification (the module and care processes covered);
- description of the service (for example, where services are provided at physical sites or online). When the certified activities are performed by different sites/legal entities, the certificate will include the names and addresses of the sites/legal entities' and any temporary sites which are identified as such, with their respective sub-scopes;
- date of when certification is granted;
- certificate's period of validity or date of expiry;
- certificate's date of issue;
- means by which the certificate's authenticity can be verified (e.g. status published on certification body website);
- name, role and signature (or defined authorisation) of individual at certification body who is responsible for the certificate;
- accreditation symbol of the certification body granting the certification.

A template for the certificate is provided by the scheme owner and will be made available to certification bodies upon request. Certification bodies are encouraged to use this template when certifying services, unless an alternative template that includes the minimum required information, has been approved by the scheme owner.

The certified cancer care service may use the statement of conformity as described later on in the sub-section 'Use of the European QA scheme certificate and statement of conformity' of this chapter and may also request from the European QA scheme owner to use the graphic of the European Commission Initiative on Breast Cancer (ECIBC) under which the scheme has been developed.

Within four (4) weeks after the certification decision, a copy of the certificate will be provided to the European QA scheme owner by the certification body, along with the cancer care service's calculated indicator data in the agreed format, the data for which must be updated at the agreed frequency.

Every site covered by the certification must be mentioned on the main certificate, and every site is entitled to get its own sub-certificate. Where sub-certificates are issued for different sites, the certification body must make clear:

- that the cancer care service certification is for the organisation as a whole;
- which specific activities performed by that specific site/legal entity are covered by the certification;
- that there is a traceable link to the main certificate (e.g. a code);
- that the validity of the sub-certificate depends on the validity of the main certificate.

Under no circumstances will certification documents be issued solely in the name of one of the sites or legal entities working in collaboration with the 'lead' entity that has been granted certification, or suggest that the service delivered by a collaborating site/legal entity is certified in its own right.

COMPLAINTS AND APPEALS AGAINST CERTIFICATION DECISION

Where a cancer care service is dissatisfied with any aspect of a certification body's service (except a decision on certification), a certification body's documented process must be made available to the cancer care service for submitting complaints. If a cancer care service is not satisfied that its complaint has been satisfactorily investigated and that the requirements of ISO/IEC 17065 may not have been met, it can escalate its complaint to the appropriate NAB.

A documented process for investigating appeals must also be made available by the certification body where a cancer care service is dissatisfied with a certification body's decision on certification. A cancer care service can only make an appeal in relation to a certification decision that affects it directly. If a cancer care service is not satisfied that its appeal has been satisfactorily investigated and that the requirements of ISO/IEC 17065 may not have been met, it can escalate its appeal to the appropriate NAB. It should be noted that NABs cannot overturn certification decisions.

MAINTAINING CERTIFICATION

A certificate is valid for a period of three (3) years subject to a cancer care service continuing to meet the European QA scheme requirements and conditions for certification. Cancer care services can maintain certification by undergoing surveillance and re-certification audit visits, and by continuing to meet the European QA scheme requirements and conditions for certification. In addition, a cancer care service entity must maintain up-to-date records of key personnel and workforce, services provided, and different sites and premises at different locations (where applicable), and must inform the certification body within four (4) weeks of any significant changes. Significant changes are any alterations that have the potential to have an adverse effect on the provision of cancer care or compliance with the European QA scheme requirements. This includes, but is not limited to, changes to services provided, replacement of key personnel, reduction in workforce numbers and structural changes to facilities.

SURVEILLANCE AUDIT AND RE-CERTIFICATION FREQUENCY AND PROCEDURES

Surveillance audits of certified cancer care services must be undertaken in accordance with a certification body's documented procedures at least once every 12 months. Cancer care service entities will need to provide:

- information on any changes that have occurred, including changes to the organisational structure, management, management system, staff, facilities, equipment, processes, services provided, outcome of internal or external audits, complaints investigated and patient satisfaction;
- details of indicator performance measures over the preceding 12 months.

The surveillance may not necessarily cover all of the elements examined in the initial audit, but auditors must sample selected elements of the service to confirm continuing compliance with the European QA scheme requirements. All relevant indicators must be reviewed annually. The surveillance plan must take into account:

- improvements and exceptional practices that have been identified;
- the nature of any non-conformities raised during previous audits;
- any changes that have taken place in the cancer care service since the previous audit;

- compliance with the indicator norms;
- any complaints received about the cancer care service.

Certification will only be valid if the cancer care service continues to meet the specified European QA scheme requirements and conditions for certification.

The first surveillance activity must take place within 12 months of the initial audit (not the certification decision), and re-certification activities must take place within a time frame that ensures that the audit process is completed before the certificate expires, in accordance with the certification body's procedures.

All of the European QA scheme requirements must be re-evaluated at least once in the 3-year certification period. Following successful demonstration that the cancer care service meets all of the relevant European QA scheme requirements, a further certificate will be issued that is valid for a period of three (3) years, subject to the cancer care service continuing to meet the European QA scheme requirements and conditions for certification during that period.

EXTENSION OF CERTIFICATION SCOPE

Cancer care services can apply to extend the scope of their certified activities, where a cancer care service has previously been certified for a particular module. The process for extending the scope is normally similar to the initial process of applying for certification, with the audit focusing on the additional scope of activities. Scope extension audits may also be conducted in conjunction with surveillance or re-certification audits.

REDUCTION OF CERTIFICATION SCOPE

A cancer care service may reduce its certification if, for example, circumstances change and a cancer care service entity no longer provides certain elements of the service (e.g. where a certified screening service and cancer centre have separated into independent legal entities), provided that the certification is still in accordance with the European QA schemes' modular approach, as described in Part I, Chapter 1, Section 3: Certification modules.

TERMINATION OF CERTIFICATION

A cancer care service may request to terminate the certification to the European QA scheme by giving the relevant certification body formal written notice of its intention. The certification body will inform the European QA scheme owner of a cancer care service's certification termination.

USE OF THE EUROPEAN QA SCHEME CERTIFICATE AND STATEMENT OF CONFORMITY

The European QA scheme owner defines a statement of conformity that can be used by cancer care service entities that achieve and maintain accredited certification for their services. Certified cancer care service entities will be eligible to use the European QA scheme's statement and refer to the European QA scheme in marketing and publicity material. Full details on the use of the statement of conformity, and specific requirements for the format, content and use of the certificate and statement of conformity are given below.

Certificate

A cancer care service entity may display the certificate issued by a certification body only on internal walls and surfaces of buildings belonging to the cancer care service.

Statement of conformity (reference to accredited certification)

Breast cancer services (BCS) certified for the European QA scheme, may make reference to their accredited certification by using only the following wording:

'[Name of the responsible BCS entity] ([unique certificate identifier]) is certified by [certification body name], for the **European Quality Assurance Scheme for Breast Cancer Services [version number]** for [**Module A**, covering breast cancer screening, diagnosis, treatment, rehabilitation, follow-up & survivorship, and palliative care, **Module B**, covering breast cancer screening or **Module C**, covering breast cancer diagnosis, treatment, rehabilitation, follow-up & survivorship, and palliative care]'.

In cases where a BCS entity has applied for and achieved accredited certification following the time-limited, stepwise approach for specific care processes, only the respective certified processes should be specified alongside Module A or Module C (i.e., Module A, covering breast cancer screening and/or diagnosis and/or treatment and/or rehabilitation, follow-up & survivorship, and palliative care OR Module C, covering breast cancer diagnosis, and/or treatment, and/or rehabilitation, follow-up & survivorship, and palliative care).

Individual sites certified under a BCS certification, should always refer to the responsible entity of the BCS and the unique identifier whenever they use the statement of conformity. This statement must be used only by BCS who hold the European QA scheme accredited certification.

Use of the European QA scheme's statement of conformity by cancer care services

A cancer care service entity is not obliged to use the European QA scheme's statement of conformity, but, if it does, its use must be consistent with the following.

The statement of conformity:

- must always be associated with the unique identifier issued to the cancer care service entity by the European QA scheme owner, and the name or symbol of the certified cancer care service;
- may be used on stationery, marketing and publicity materials, pricing quotes, reports, certificates, exhibition stands and brochures;
- may be used on websites, provided that the extent and limitations of the cancer care service's certification are clearly described;
- must be displayed using the wording specified by the European QA scheme owner in the appropriate format and size;
- must not be used in any way that might be misleading about the status of a certified cancer care service (e.g. the statement of conformity may not be used on any stationery, marketing and publicity materials, pricing quotes, reports, certificates, exhibition stands, websites and brochures relating solely to activities that are not included in the scope of certification);
- must not be used on reports or certificates issued by external providers which provide services that are not within the scope of the respective certification module;

- must not be used on stationery, marketing and publicity materials, pricing quotes, reports, certificates, exhibition stands, websites and brochures by a cancer care service whose certification has been suspended or withdrawn;
- must not be used by a cancer care service that has requested to terminate the certification;
- must not be displayed on the exterior of any buildings, on flags or on vehicles.

Certification bodies may suspend certification if a cancer care service deliberately misuses the certificate and/or statement of conformity. If deliberate and persistent misuse of the certificate and/or statement of conformity occurs after this has been raised as an issue with either a certification body or a cancer care service, the European QA scheme owner may take whatever action is required against a certification body or a cancer care service entity to protect its reputation and integrity. In extreme cases this may include legal action.

The European Commission, represented by the JRC, as the European QA scheme owner, does not assume any liability for any damages arising from the misuse or improper usage of any certificates provided. Users are solely responsible for the proper use and security of their certificates, and should always follow the guidelines and instructions provided by the issuing authorities. The European Commission shall not be held responsible for any losses, damages, or consequences resulting from the misuse or improper handling of certificates.

SANCTIONS

The following sanctions may be imposed by a certification body on a cancer care service that is found not to be complying with the European QA scheme requirements (for example, where non-conformities are so significant that patient health or safety is being compromised):

- suspension of certification scope;
- withdrawal of certification.

These sanctions may also be applied if a cancer care service fails to meet its contractual obligations. The reasons for imposing sanctions may be published by the certification body.

In extreme situations (e.g. in cases where persistent fraudulent claims regarding certification could undermine the reputation and integrity of the scheme owner or the schemes), the European QA scheme owner may impose the following sanctions where a cancer care service or certification body is found not to be complying with the European QA scheme, including contractual requirements. For example:

- legal action,
- publication of the details of misuse of the certificate or statement of conformity.

The scheme owner may also publish its reasons for imposing sanctions.

SUSPENSION OF CERTIFICATION

If a cancer care service is unable to demonstrate that it meets the European QA scheme requirements and conditions for certification within the specified time frames or shows sustained non-conformity (e.g., unable to achieve indicator norms), certification bodies may suspend certification for a specified period of time, normally not exceeding six (6) months. A cancer care service will be informed that, during a period of suspension, the cancer care service must discontinue the use of marketing and promotional materials that refer to certification and the European QA scheme, or that include the scheme's statement of conformity.

Certification may also be suspended if deliberate misuse of the certificate or the statement of conformity by a cancer care service is detected and confirmed.

Where different sites/legal entities are included in the certification (e.g. networks), certification documentation may either be suspended or withdrawn in its entirety or the individual site/legal entity may be removed from the certification documentation if any of the sites does not meet the necessary requirements for maintaining certification. In the case that certification is suspended or withdrawn for an individual site/legal entity, the cancer care service must make arrangements to continue to provide such services in compliance with the European QA scheme (i.e., by using another site/legal entity within the certified network of services). Should compliant services not be immediately available, the cancer care service shall make these arrangements over a reasonable timeline to retain accredited certification for the respective certification module. In the meantime, the scope of certification should be updated as applicable.

WITHDRAWAL OF CERTIFICATION

If a cancer care service entity continues to be unable to demonstrate that it meets the European QA scheme requirements and conditions for certification beyond the 6-month suspension period, a decision will be taken by the certification body on whether to withdraw certification. A certification body may also withdraw a cancer care service's certification if the entity is found to be operating illegally or without integrity.

Cancer care services will be informed that, upon withdrawal of certification, the cancer care service entity must:

- discontinue the use of marketing and promotional materials that refer to certification and the European QA scheme, or that include the scheme's statement of conformity;
- return all certification documents to the certification body;
- inform the European QA scheme owner of the withdrawal of its certificate.

In addition, the certification body will inform the scheme owner if it withdraws a certification.

TIME-LIMITED, STEPWISE APPROACH TO CERTIFICATION

The delivery of cancer care services throughout Europe is very diverse, and different parts of a cancer care service (screening, diagnosis, treatment, rehabilitation, follow-up & survivorship care, and palliative care) may have particular quality assurance arrangements in place according to the ways in which cancer care services are organised in different Member States across Europe. Cancer care may be delivered by different legal or geographically separated entities. A transitional approach is therefore proposed in recognition of the fact that, in the early stages of the European QA scheme's implementation, there will be a need to accommodate this diversity of healthcare infrastructures in Europe in an inclusive way, allowing for different starting points in different countries.

It is proposed that, for a limited period of time, cancer care services may seek accredited certification for their services in a stepwise approach. This recognises the progression from discreet and specific cancer care processes within diverse infrastructures to a more coherent position with fewer variances in the delivery of cancer care services in different regions and countries. It is anticipated that this may encourage national authorities and organisations delivering cancer care services to participate in this European QA scheme, irrespective of the extent and coherence of their current provisions. However, cancer care services are required to achieve accredited certification for the full range of services included in the cancer care service module (as described in Part I, Chapter 1, Section: Certification modules) within five (5) years of initial certification.

Cancer care services may apply for either or both: i) a care process-specific stepwise approach, or ii) a site-specific stepwise approach, to accredited certification. Extensions to their scope of accredited certification can be applied for over a period of five (5) years, until all care processes within the module, and all sites/legal entities in a network of services are included in the accredited certification. If this is not achieved by the cancer care services, within the specified time period of five (5) years, after communication with the scheme owner, accredited certification will be withdrawn from the cancer care service.

The requirements for the BCS are detailed in Part II: Breast cancer service requirements and Annex 1: Quality indicators. Irrespective of whether a site-specific or a care process-specific (see below) stepwise approach is followed, all BCS entities must meet all the relevant requirements in order to achieve accredited certification for the specified, limited scope. The audit and certification process described in Part I, Chapter 5: Certification process will also apply to both approaches.

Cancer care services opting for a time-limited, stepwise approach will be expected to have plans in place to demonstrate how they intend to achieve certification for a complete module and for all sites/legal entities delivering the module. During the application process, certification bodies will discuss this plan with the cancer care service and assess its potential to achieve the full scope of certification for the specified module. Certification bodies shall keep the scheme owner informed of such applications.

PROCESS-SPECIFIC STEPWISE APPROACH TO CERTIFICATION

Where a legal entity is responsible for all of the processes in its chosen certification module, for example a breast cancer centre, the entire service must normally be included in the certification. However, if the legal entity initially wishes to seek certification for a specific care process within Module A or Module C, it may do so on a transitional basis, provided that accredited certification of all the processes for the chosen module is achieved within five (5) years. See Figure 8, Example A. Process-specific stepwise approach to certification is applicable to Modules A and C. A BCS can initially apply for, and be granted, accredited certification for the following breast cancer care processes within **Module A**:

- screening;
- diagnosis (including imaging and pathology) services. Imaging and pathology services are not eligible for stand-alone accredited certification, neither separately nor together;
- treatment services;
- rehabilitation, follow-up & survivorship, and palliative services;
- any combination of care processes as mentioned above.

BCS can initially apply for, and be granted, accredited certification for the following breast cancer care processes within **Module C**:

- diagnosis (including imaging and pathology) services. Imaging and pathology services are not eligible for stand-alone accredited certification, neither separately nor together;
- treatment services;
- rehabilitation, follow-up & survivorship, and palliative services;
- any combination of care processes as mentioned above.

If a BCS entity does not initially apply for accredited certification for all of the cancer care processes in Modules A or C, the criteria for managing continuity of care between the different processes must be clear, robust and documented in order to explain how this will be implemented. This especially applies when one or more processes of Modules A or C, are provided by different entities.

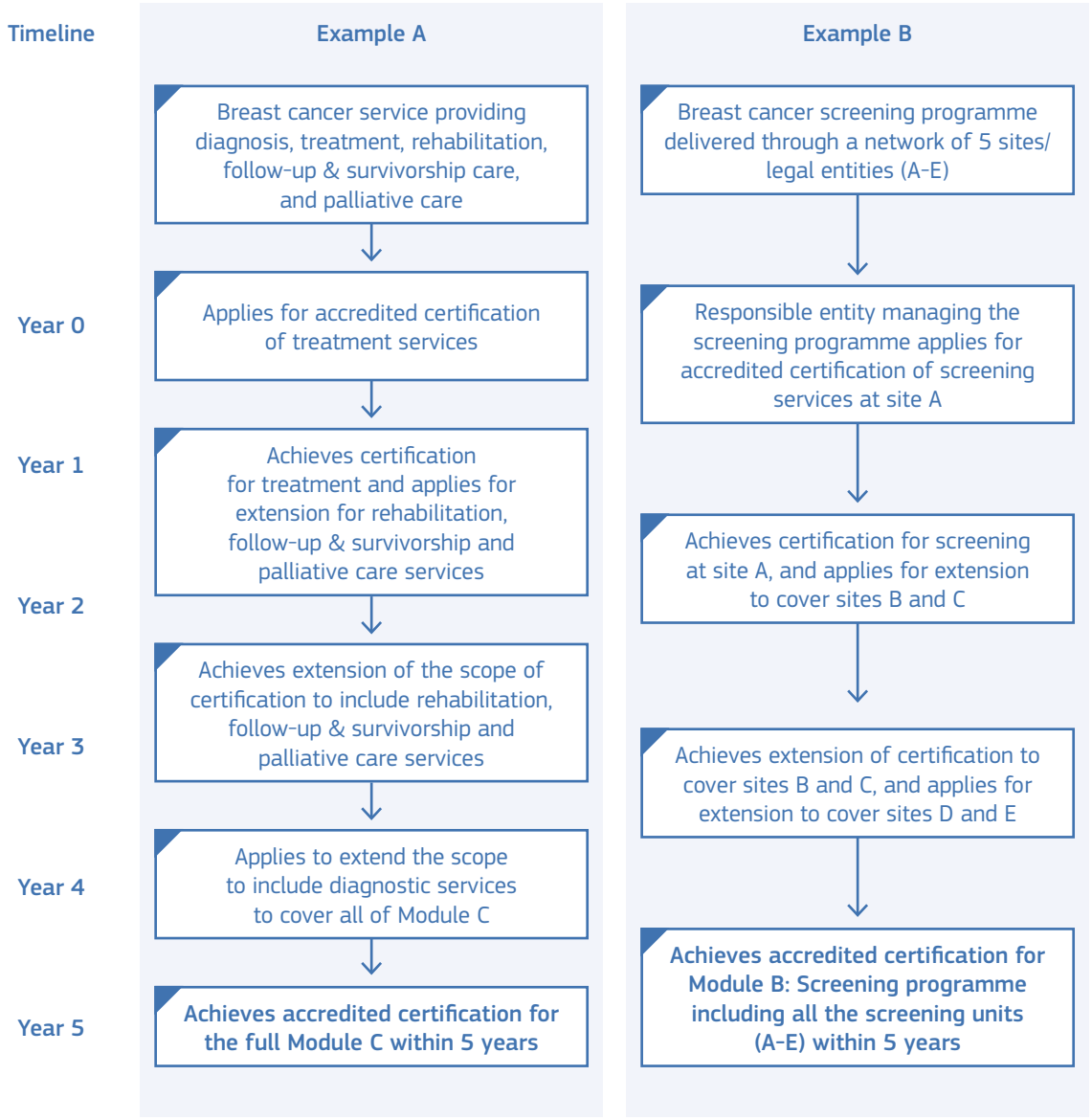
SITE-SPECIFIC STEPWISE APPROACH TO CERTIFICATION

Where a legal entity is responsible for a network of sites/legal entities, for example several different hospital sites, the whole network must normally be included in the certification. However, if the legal entity initially wishes to seek certification for one or more of the collaborating sites/legal entities within the network, it may do so on a transitional basis, provided that accredited certification of all sites/legal entities for the chosen module is achieved within five (5) years. See Figure 8, Example B.

If a cancer care service entity does not initially apply for accredited certification for all of the cancer care sites/legal entities delivering the certification module (Module A, B or C) that it has chosen, the criteria for managing continuity of care between the different sites/legal entities must be clear, robust and documented in order to explain how this will be implemented.

Figure 8 provides further details of two examples of a time-limited, stepwise approach to accredited certification.

Figure 8. Examples of a time-limited, stepwise approach to accredited certification.



Source: JRC

MANAGEMENT OF EXTRAORDINARY EVENTS AND CIRCUMSTANCES

There may be situations that prevent a certification body from carrying out on-site audits of cancer care services, or that affect the ability of a certified cancer care service to demonstrate that it meets all of the European QA scheme requirements. Events or circumstances that are beyond the control of the certification body or the cancer care service are deemed 'extraordinary events or circumstances'. Examples include: war, strikes, riots, political instability, geopolitical tension, terrorism, crime, pandemics, flooding, earthquakes, malicious computer hacking, and other natural or man-made disasters.

Alternative approaches to auditing cancer care services and the delivery of cancer care may need to be adopted. Guidance for NABs, certification bodies and cancer care service entities on managing extraordinary events or circumstances with regard to their impact on accreditation, certification, auditing and the delivery of services can be found in the IAF publication IAF ID3: *Informative Document for Management of Extraordinary Events and Circumstances Affecting ABs, certification bodies and Certified Organizations*[30].

There may be occasions when extraordinary events or circumstances (such as a pandemic) affect the delivery or operation of the **entire** European QA scheme. To ensure a consistent approach across all cancer care services and certification bodies under such circumstances, it may be necessary for the European QA scheme owner to modify some of the European QA scheme requirements for a specified period of time for all participating cancer care service entities affected by the extraordinary event. Where it is deemed necessary for the European QA scheme owner to modify any of the requirements, guidance will be published on the European QA scheme owner's website.

[30] IAF ID3: *Informative Document for Management of Extraordinary Events and Circumstances Affecting ABs, certification bodies and Certified Organizations*: https://www.iaf.nu/upFiles/IAFID32011_Management_of_Extraordinary_Events_or_Circumstances.pdf

CHAPTER 6

EXISTING QUALITY ASSESSMENTS WITHIN CANCER CARE SERVICES

- Third-party cancer care certification schemes are encouraged to participate in the European QA scheme, enabling breast cancer services to implement both schemes simultaneously while avoiding duplication of audits.
- Procedures for adopting the European QA scheme requirements and transitioning to accredited certification are provided for third-party scheme owners and associated certification bodies.
- Cancer care services that already hold quality assessments may request to have these recognised in fulfilment of the applicable European QA scheme requirements.

The European QA scheme includes a set of essential requirements that cancer care services can implement to increase confidence in the quality of care they provide throughout Europe. The requirements are applicable to healthcare services covering either the full extent or parts of cancer care (as described in Part I, Chapter 1, Section: Certification Modules), from the screening programme to follow-up and palliative care.

Cancer care services may already be participating in other quality assessments through:

- Third-party[31] cancer care certification schemes (i.e. schemes other than the European QA scheme), which certify the entire cancer care pathway or are limited to specific parts of the pathway, such as the cancer screening programme or the cancer centre that delivers diagnosis, treatment, rehabilitation, follow-up, survivorship and palliative care (see Part I, Chapter 1, Section: Certification Modules);
- NAB-accreditation and NAB-accredited certifications to ISO standards on specific systems and/or sub-processes of the cancer care processes, such as management systems or imaging and pathology.

The following sections describe how these quality assessment activities can be utilised or recognised to facilitate participation in the European QA scheme and, at the same time, avoid duplication of audits of the BCS and/or assessments of the certification bodies.

THIRD-PARTY SCHEME PARTICIPATION IN THE EUROPEAN QA SCHEME

Third-party scheme owners of existing cancer care certification schemes operating in Europe may wish to offer cancer care services the opportunity to participate in the European QA scheme instead of, or in addition to, having certification to the third-party scheme.

In such cases, third-party scheme owners can adopt the requirements of the European QA scheme and accredited certification for one or more modules of the European QA scheme. The cancer care services certified to the third-party scheme will be able to participate in the European QA scheme, avoiding duplication of audits.

There are two paths for third-party scheme owners and associated certification bodies to participate in the accredited certification for the European QA schemes (Figure 9). Each path consists of two main prerequisites that third-party scheme owners and any associated certification bodies, they may collaborate with, must address:

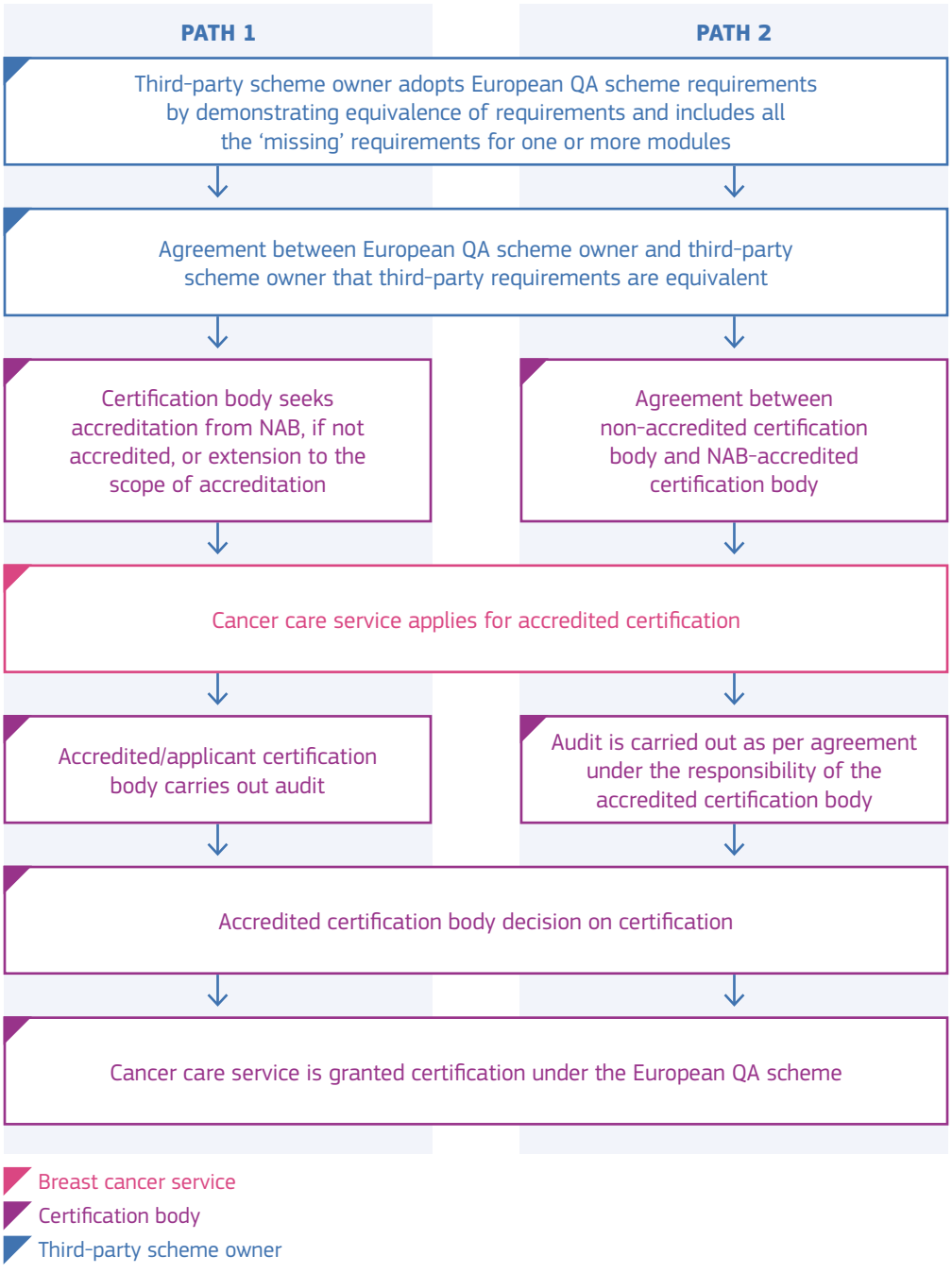
i) **adoption of the European QA scheme requirements**, which is common for both Path 1 and Path 2. The third-party scheme owner adopts the European QA scheme requirements by demonstrating the equivalence of the third-party scheme requirements (incorporating any European QA scheme requirements not previously included) and establishing agreement with the European QA scheme owner.

[31] In the context of the European QA scheme, the use of the term `third-party' scheme owners refers to scheme owners of existing QA schemes other than the European QA scheme.

ii) **accredited certification, that requires either**

- the certification body to seek accreditation or extension of the scope of the ISO/IEC 17065 accreditation to include the European QA scheme (Path 1),
  OR
- the non-accredited certification body to collaborate with an accredited certification body (Path 2).

Figure 9. Participation in the European QA scheme by third-party cancer care certification schemes operating in Europe.



Source: JRC

ADOPTION OF THE EUROPEAN QA SCHEME REQUIREMENTS BY THE THIRD-PARTY CANCER CARE SCHEME

Third-party scheme owners who wish to participate in the European QA scheme can adopt its requirements by firstly demonstrating the equivalence of the third-party scheme requirements with the specified requirements of one or more of the European QA scheme's modules, and secondly by incorporating any European QA scheme requirements that were not previously included in the third-party scheme.

Third-party scheme owners seeking to demonstrate the equivalence of their requirements must in the first instance contact the European QA scheme owner to discuss their intentions. The first step for the owners of third-party cancer care certification schemes is to demonstrate the formal status of their scheme by satisfying all of the following pre-conditions.

- They have established and implemented a regional, national, European or international scheme **prior to** the formal adoption of the European QA scheme.
- They have been appointed, nominated or approved at a regional, national, European or international level, to provide a cancer care service certification scheme.
- They have evidence of the efficacy of the third-party scheme requirements in delivering improvements in cancer care and have published their requirements for quality assurance and certification.
- They ensure the confidentiality of cancer care service information.
- They have procedures for dealing with complaints and appeals.

Third-party scheme owners that meet all of these pre-conditions must also carry out an equivalence analysis of the requirements of their scheme for cancer care services to the requirements of one or more of the modules of the European QA scheme for cancer care services.

In order to demonstrate the equivalence of their requirements for cancer care services, third-party scheme owners will need to have compared the requirements of both schemes and, where necessary, identified and incorporated any 'missing' European QA scheme requirements into their own scheme. Evidence that the third-party scheme meets all of the European QA scheme requirements, such as the detailed equivalence or 'gap' analysis carried out to identify and incorporate the 'missing' requirements, must be provided to the European QA scheme owner.

When the European QA scheme owner has confirmed the equivalence of the requirements, the respective scheme owners can then enter into an agreement setting out the responsibilities and liabilities for updates and changes to the third-party scheme and the European QA scheme, and for communications about the schemes. Third-party scheme owners must comply with the European QA scheme owner's requirements, as set out in the agreement, including the specific terminology, which may be used when making reference to the equivalence of the third-party scheme requirements for cancer care services with those of the European QA scheme.

THIRD-PARTY SCHEMES AND ACCREDITED CERTIFICATION FOR THE EUROPEAN QA SCHEME

There are two ways in which third-party scheme owners can adopt accredited certification to one or more modules of the European QA scheme for their certified cancer care services. They

can request the certification bodies, which carry out audits and provide certification on their behalf (herein referred to as certification bodies of the third-party scheme), to (see Figure 9):

- Path 1) seek extension of the scope of ISO/IEC 17065 accreditation or seek accreditation (see Part I, Chapter 2, Section: Requirements for bodies certifying products, processes and services (ISO/IEC 17065)) to certify cancer care services for one or more modules of the European QA scheme, or
- Path 2) collaborate with an accredited certification body to certify cancer care services for one or more modules of the European QA scheme.

Path 1) Extension of scope of the ISO/IEC 17065 accreditation or seek accreditation to certify one or more modules of the European QA scheme

A certification body of a third-party scheme that already holds accreditation according to ISO/IEC 17065 for certifying cancer care services for the third-party scheme can apply for an extension to its scope of accreditation to include the European QA scheme.

Before extending the scope of accreditation, the NAB will need to assess the additional arrangements that the certification body of a third-party scheme has put in place to incorporate any European QA scheme requirements that were not previously included in the third-party scheme, including the processes for determining the competence of auditors, for performing audits and certification, and for transitioning cancer care services to accredited certification for the European QA scheme.

If the certification body of a third-party scheme is not already accredited for ISO/IEC 17065, it will be assessed by the NAB against the applicable requirements of ISO/IEC 17065, as well as the specifications and conditions of the European QA scheme, including the processes for determining the competence of auditors and for performing audits and certification. During the accreditation process, the NAB witnesses the necessary number of audits to confirm that the accreditation requirements and the European QA scheme specifications and conditions are fulfilled. In order to avoid duplication, the witnessed audit(s) will ideally be an initial certification audit of an uncertified cancer care service that is seeking certification for the European QA scheme. In the absence of any uncertified cancer care services applying to a certification body for certification for the European QA scheme, with the agreement of the NAB, the witnessed audit can be the re-certification audit that is required by the certification body of any cancer care service that is seeking re-certification for the third-party scheme and has also applied to include the European QA scheme for cancer care services.

In the case where the NAB assessment confirms that the certification body fulfils the applicable ISO/IEC 17065 requirements and the European QA scheme specifications and conditions, the previous audits performed can be accepted in fulfilment of the equivalent European QA scheme requirements. Equivalence is established following a gap-analysis that is approved by the European QA scheme owner. All previous audits conducted after the date from which the certification body can provide evidence of its compliance with the respective ISO/IEC 17065 requirements can be accepted.

If there are any non-conformities raised during the NAB assessment of the certification body, that would cast doubt on the competence of the certification body, previous cancer care service audits cannot be accepted towards the fulfilment of the European QA scheme requirements and new audits need to be performed to evaluate compliance to the European QA scheme cancer care service requirements.

In any case, where non-accredited certification bodies seek to have previous audits be recognised and accepted, examples of these audits need to be assessed to confirm that they have been conducted in accordance with the accreditation requirements and the European QA scheme specifications.

After attaining accreditation for the European QA scheme, a certification body may continue to provide certification for a third-party scheme alongside the European QA scheme certification, provided that, where relevant, the certification body ensures that it and the cancer care services distinguish clearly between accredited and non-accredited certifications.

Once accredited for ISO/IEC 17065, certification bodies can apply to extend their scope of accreditation to include other European QA schemes as these are developed.

Path 2) Collaboration with an accredited certification body

Certification bodies of third-party schemes that are not NAB-accredited (herein referred to as non-accredited certification bodies) can enter into legally enforceable agreements with accredited certification bodies to offer auditing services for the European QA scheme requirements in collaboration with the respective accredited certification body. Before entering into any agreement, the accredited certification body must carry out a risk assessment of the non-accredited certification body. The risk assessment will be based on ISO/IEC 17065 and the European QA scheme requirements, and will cover impartiality, competence, consistency and independence in auditing activities. The accredited certification body will also consider the countries in which it intends to collaborate with the non-accredited certification body.

When taking into account audits carried out by non-accredited certification bodies, accredited certification bodies must comply with the relevant requirements of ISO/IEC 17065 and in particular, ensure that the non-accredited certification body meets the applicable requirements described in Clause 6.2.2 on 'External resources (outsourcing)'. Accredited certification bodies must also ensure that there is sufficient evidence to ascertain that audits undertaken by the certification body for the third-party scheme have been, and continue to be, carried out by competent auditors in accordance with the European QA scheme specifications and conditions, and that they are confident that the cancer care services audited by these certification bodies meet the European QA scheme requirements. Where this kind of collaboration occurs, the accredited certification bodies must not contract out the accredited certification review and decision process.

When the accredited certification body risk assessment of the non-accredited certification body confirms that the applicable ISO/IEC 17065 requirements are fulfilled, audits of the existing scheme that have previously been conducted by the certification body, may be accepted in fulfilment of the equivalent European QA scheme requirements. Equivalence is established

following a gap-analysis that is approved by the European QA scheme owner. All previous audits conducted after the date from which the non-accredited certification body can provide evidence of its compliance with the ISO/IEC 17065 applicable requirements can be accepted.

If there are any non-conformities raised during the risk assessment of the non-accredited certification body, that would cast doubt on the competence of the non-accredited certification body, previous cancer care service audits cannot be accepted towards the fulfilment of the European QA scheme requirements and new audits need to be performed to evaluate compliance to the European QA scheme cancer care service requirements.

Accredited certification for the European QA scheme outside the region or country of establishment

Accredited certification bodies may provide certification services for the European QA scheme to cancer care services outside the country or region in which they are established. Accredited certification bodies may enter into arrangements with a number of different 'external resources', including certification bodies associated with third-party schemes that are not accredited, provided that a risk assessment has been carried out and all of the relevant conditions are met. Non-accredited certification bodies may enter into arrangements with one or more accredited certification bodies to be involved in the certification services for the European QA scheme for cancer care services in different countries.

Where certification bodies provide certification for the European QA scheme for cancer care services outside the country or region in which they are established, they must ensure that the language in which the certification audits are to be conducted is agreed at the beginning of the application process. It must be made clear if there will be a need for translating any documents, records etc. In addition, certification body auditors must be aware of any legislation (national or regional) that is applicable to cancer care services in the specific region or country.

TRANSITION OF CANCER CARE SERVICES FROM THIRD-PARTY SCHEMES TO THE EUROPEAN QA SCHEME

Where a third-party scheme owner chooses to adopt accredited certification for the European QA scheme, participating cancer care services holding certification for the third-party scheme can apply for the European QA scheme accredited certification. The cancer care services shall request acceptance of the third-party scheme certification towards the fulfilment of equivalent requirements of the European QA scheme. Examples of the previous third-party audits may need to be assessed to confirm that they have been conducted in accordance with the accreditation requirements and the European QA scheme specifications.

Before a transition from non-accredited or accredited certification for a third-party scheme to accredited certification for the European QA scheme could occur, cancer care services would:

- adopt and provide evidence of compliance with any European QA scheme requirements not previously included in the third-party scheme;
- apply for accredited certification for the European QA scheme;
- request acceptance of the third-party scheme certification towards the fulfilment of equiv-

alent requirements of the European QA scheme
- be audited by the certification body for any European QA scheme requirements not previously included in the third-party scheme.

This transition can take place without the need for duplication of third-party audits depending on:
- the absence of non-conformities raised during the NAB assessment of a certification body for the European QA scheme which, if present, would cast doubt on the competence of the certification body, and
- the cancer care services adopting and providing evidence of compliance with any European QA scheme requirements not previously included in the third-party scheme.

Accredited certification bodies are required by the European QA scheme owner to take into account any certifications held by a cancer care service, provided that the conditions described previously are met, in order to avoid the duplication of audits and facilitate the transition to accredited certification. Accredited certification bodies must put in place transition arrangements that describe how the transition from non-accredited or accredited certification for the third-party scheme to accredited certification for the European QA scheme will be managed.

ACCEPTANCE OF EXISTING ACCREDITED CERTIFICATION AND NAB ACCREDITATIONS

Cancer care services, including where these are part of a larger organisation (such as a hospital or institute), may already hold NAB accreditation or accredited certification for some aspects of their services. Where this is the case, these NAB accreditations or accredited certifications can be accepted as meeting specific applicable European QA scheme requirements. The following are examples of accredited certifications or NAB accreditations, which could be used to provide evidence of compliance with specific European QA scheme requirements.

ACCREDITED MANAGEMENT SYSTEM CERTIFICATIONS[32] AND NAB ACCREDITATIONS FOR ISO 15189, ISO/IEC 17025 AND ISO/IEC 17020[33]

Any part of a cancer care service that is certified under a specific management system standard (e.g., ISO 9001 or EN 15224) from a certification body that is accredited for ISO/IEC 17021-1 by a NAB that is part of a mutual recognition agreement between NABs, can provide this as evidence that it meets the applicable European QA scheme management system requirement (Part II, Chapter 2: General requirements, GEN-3) and any other applicable requirements, following a gap analysis.

Any parts of a cancer care that hold NAB accreditation for ISO 15189, ISO/IEC 17025 and ISO/IEC 17020 for sub-processes that form part of the cancer care pathway (such as pathology or imaging services) of a European QA scheme can provide their scope of NAB accreditation as evidence that they meet applicable European QA scheme requirements (e.g. GEN-3), or any other

[32] See Glossary.

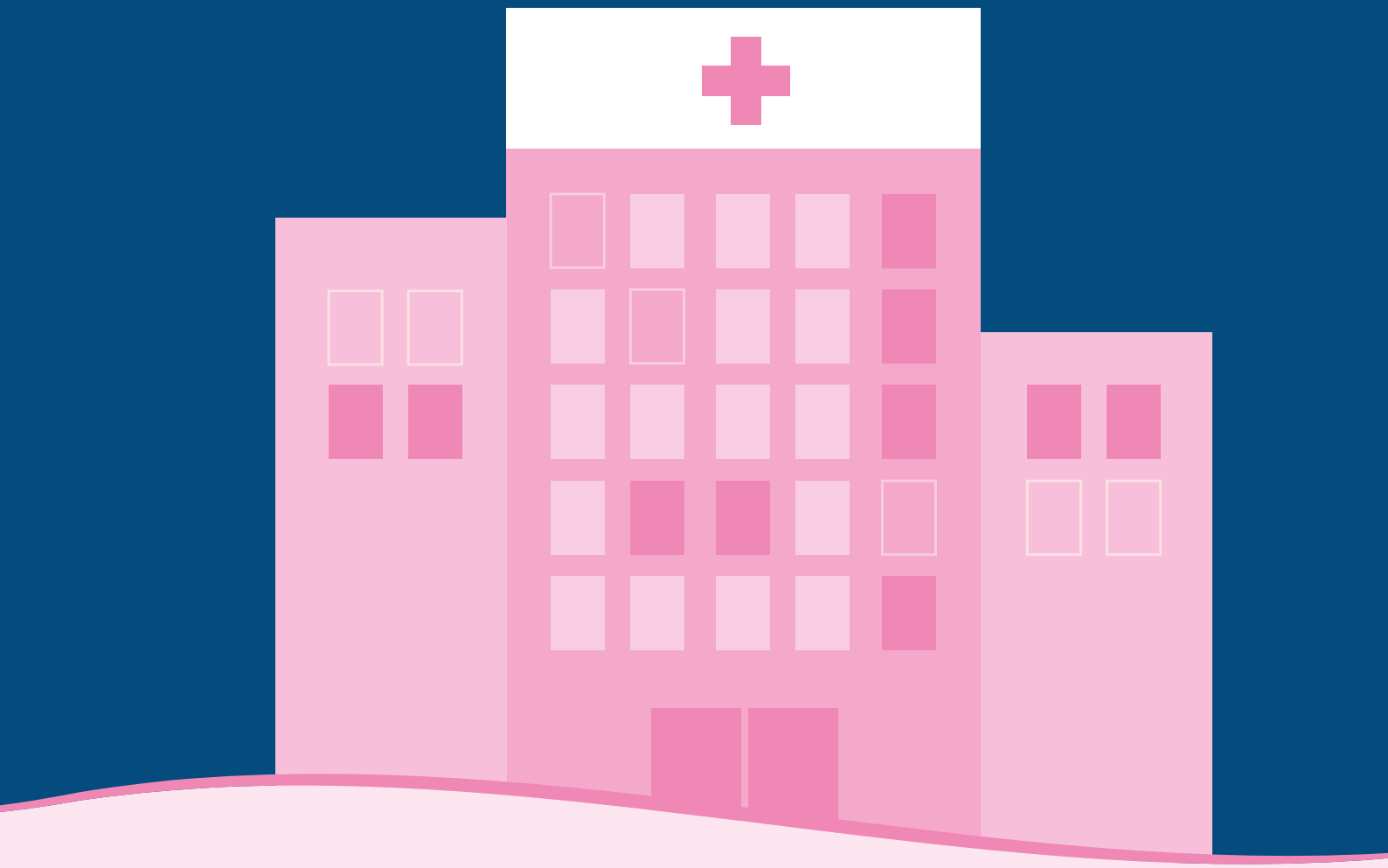
[33] Accreditations which involve the assessment of the competence and impartiality of an organisation and the compliance of their work to nationally and internationally recognised standards or schemes, such as the ISO 15189 standard for medical laboratories.

applicable requirements following a gap analysis. The accreditation must have been awarded by a NAB that is part of a mutual recognition agreement between accreditation bodies[34]. If any applicable European QA scheme requirements for relevant sub-processes are not entirely covered by a cancer care service's NAB accreditation, the cancer care service can apply to their NAB to extend the scope of their accreditation to include the 'missing' European QA scheme requirements. Certification bodies must adopt a 'presumption of conformity'[35] for cancer care services that have such accredited certification or NAB accreditation. Where such services provide evidence of accredited certification, or NAB accreditation (such as an up-to-date certificate and scope of certification/accreditation), 'presumption of conformity' by the certification body means that no duplicate audit of the management system or applicable sub-processes of the service will be carried out by the certification body.

[34] The EA mutual recognition agreement: https://european-accreditation.org/mutual-recognition/the-ea-mla/

[35] Presumption of conformity means that where cancer care services already hold NAB-accredited certification or NAB accreditation for a scope of activities relevant to specified processes or sub-processes of modules of the European QA scheme, these activities can be accepted as conforming to the relevant requirements of the QA scheme (see also Regulation EC 765/2008 Article 11 and Europa.eu: https://europa.eu/youreurope/business/product-requirements/compliance/conformity-assessment/index_en.htm).

PART II
BREAST CANCER SERVICE REQUIREMENTS



CHAPTER 1

INTRODUCTION

The European QA scheme defines a set of requirements for breast cancer services from screening to end-of-life care. BCS can voluntarily apply for certification of a respective certification module or care process in the context of the time-limited, stepwise approach to certification (refer to Part I, Chapter 5: Certification process). BCS must be found compliant with the respective requirements in order to be certified under the scheme (refer to Part II, Introduction, Table of requirements).

DEFINITIONS

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

  In the European quality assurance (QA) scheme, each requirement comprises a **statement**, associated with the corresponding supporting evidence and references (found in Annex 3: Supporting materials), which is explained in several criteria and/or indicators.

  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 statement goals may be objectively audited. The criteria can specify different auditing approaches: structure, process or outcomes.

  The European QA scheme considers requirements in the following quality domains:
  - Clinical effectiveness,
  - Safety,
  - Facilities, resources and workforce,
  - Personal empowerment and experience.

- **General requirements** apply to all care processes within the European QA scheme. They often relate to system-level processes that are relevant to all care processes and all BCS and which are also applicable to general cancer care.

- **General cancer care requirements** refer to services that are not specific to the cancer-site or are cancer-site agnostic. These requirements may apply to system-level processes but also to more specific care processes across the various European QA schemes. Such requirements are represented with this symbol throughout this manual:

- **Continuity of care requirements** aim to connect discrete healthcare events to be experienced as coherent and consistent with patients' medical needs. The continuity of care symbol highlights requirements that ensure continuity of care for patients within and across care processes. Such requirements may require exchange of information between discrete services and alert the organisation to ensure continuity of care at these critical points in the care process. These requirements are represented with this symbol throughout the manual:

- **Cancer-site-specific requirements** aim to improve the quality of the services within specific care processes throughout the breast cancer care pathway.

MEASUREMENT OF COMPLIANCE

The European QA scheme will evaluate whether the requirements are met using several tools such as on-site visit/s, review of documentation and interviews with staff. Requirements include two types of measurable elements: criteria and indicators.

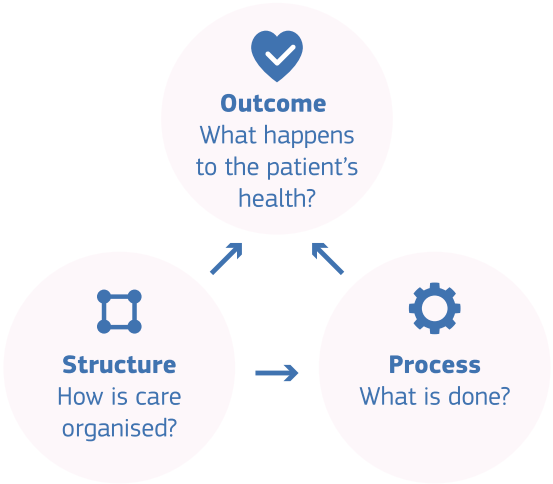
- **Criteria** describe records, documents and resources that must be present within the service, and the care services that must be provided or activities that the service must do to fulfil the requirement. Criteria must be present within the service to show compliance to the requirement. Generic examples of evidence that can be provided by the services or requested by the auditor to evaluate compliance are detailed in the **Evidence for Compliance** section.

- **Indicators** are quantitative quality indicators that describe the fulfilment of a requirement by a clearly defined numerator and denominator. Indicators are always linked to a requirement and rely on patient clinical data, but not every requirement will have a quantitative indicator to be measured. All indicators within the respective certification module or process must be calculated to show compliance with the European QA scheme for breast cancer services. The percentage of missing data must be measured and reported in addition to details of the calculations, the raw data and the computed indicator for the respective time period. Further details on how to compute the indicators can be found in Annex 1: Quality indicators.

TYPE OF MEASUREMENT ELEMENT

The types of measurement elements are based on the Donabedian model for evaluating the quality of healthcare[36] and are:

Figure 10. Donabedian model for evaluating quality in healthcare.



Source: JRC

[36] Donabedian, A., The Definition of Quality and Approaches to Its Assessment, Vol. 1: Explorations in Quality Assessment and Monitoring. Health Administration Press, Ann Arbor, Michigan, 1980.

- **Structure** measures give consumers a sense of a healthcare provider's **capacity, systems and resources**, for providing high quality care (e.g. availability of a protocol, policy or facilities, human resources, organisational structure, description of referral criteria, existence of a patient referral process).

- **Process** measures refer to what is done in giving and receiving care and how: **what care services do** 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 (e.g. they verify whether the protocol or procedure is applied, the referral criteria met or the planned process followed).

- **Outcome** measures reflect the **impact** of the healthcare service or intervention on the health status of patients and populations. Outcome measures often represent the goal for measuring quality, nonetheless an outcome is the result of numerous factors (e.g. quality of life, patient's satisfaction with care, improved patient's knowledge or behaviour).

DEVELOPMENT OF REQUIREMENTS

The European QA scheme requirements are underpinned by the European Breast Cancer Guidelines[37], as well as the collection of guidelines on breast cancer care[38]. The methodology for selecting requirements is described in the methods publication of ECIBC[39]. 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 11.

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[40]:** requirements were tested in a pilot run. Based on the experiences gathered during the pilot run, they were amended and subsequently implemented within the scheme.

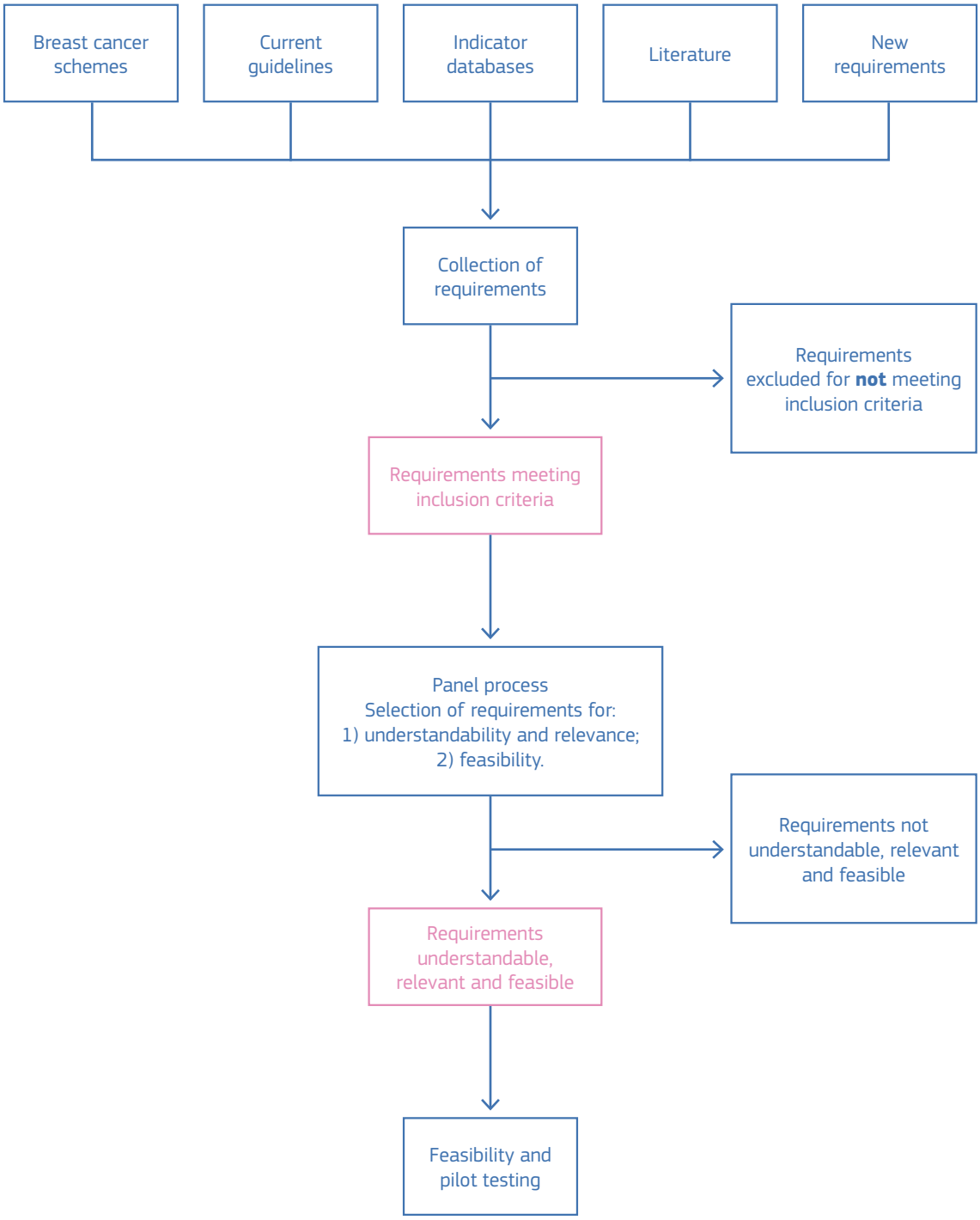
[37] European guidelines on breast cancer screening and diagnosis - https://cancer-screening-and-care.jrc.ec.europa.eu/en/ecibc/european-breast-cancer-guidelines

[38] International guidelines on breast cancer care - https://cancer-screening-and-care.jrc.ec.europa.eu/en/ecibc/international-guidelines

[39] 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://cancer-screening-and-care.jrc.ec.europa.eu/en/ecibc/methodologies/quality-assurance

[40] Testing the European quality assurance scheme - https://cancer-screening-and-care.jrc.ec.europa.eu/en/ecibc/breast-quality-assurance-scheme/testing-the-scheme.

Figure 11. Requirement/indicator development procedure.



Source: JRC

REQUIREMENTS ORGANISATION

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

Chapter 2: General requirements (GEN) – requirements applicable to all processes of care (system level).

Chapter 3: Screening requirements (SCR)

Chapter 4: Diagnosis requirements
- Imaging requirements (DGN-IMG),
- Diagnosis requirements (DGN),
- Pathology requirements (DGN-PTH),
- Diagnosis to treatment continuity of care requirements (DGN-TRT);

Chapter 5: Treatment requirements
- Treatment requirements (TRT),
- Surgery requirements (TRT-SUR),
- Systemic therapy requirements (TRT-SYS),
- Radiotherapy requirements (TRT-RAD);

Chapter 6: Rehabilitation (RHB), follow-up and survivorship, (FLW) and palliative care (PAL)

Table 1. The distribution of requirements according to the care pathway processes.

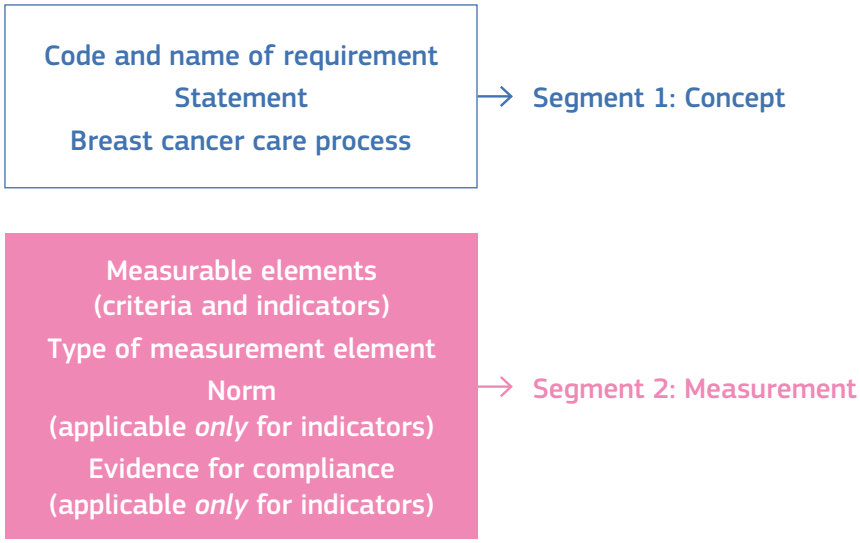
PATHWAY PROCESS	NUMBER OF REQUIREMENTS
General	7
Screening	3
Diagnosis	23
Treatment	26
Rehabilitation, follow-up & survivorship, and palliative care	5
Total	**64**

Source: JRC

FORMAT OF REQUIREMENTS

The requirements in the manual are presented in the order of care and per care process. The requirement format includes the statement of the requirement, the measurable elements and the expected evidence needed to audit each measurable element. This information is divided into two segments:

Figure 12. Requirement format.



Source: JRC

SEGMENT 1

- **Code:** alphanumeric sequence that identifies each requirement. It is made up of the acronym of its scope (the relevant process in the care pathway), the sub-process where applicable and a number indicating the order in the specific process section.
- **Name of the requirement.**
- **Statement:** the requirement's objective, intent or principle.
- **Breast cancer care process:** the scope of the requirement for the breast care pathway (screening, diagnosis, treatment, rehabilitation, follow-up and survivorship care, and palliative care).

SEGMENT 2

MEASUREMENT OF COMPLIANCE	
Measurement element code (criterion or indicator)	Each requirement may have one or several criteria to be met and/or indicators to be measured: 1. **Criterion:** any measurement element for which the compliance is measured with a dichotomous response (yes/no); 2. **Indicator:** describes the fulfilment of a requirement through a quantitative measure, which is often defined by a numerator and a denominator. **Norm:** Target level of quality for the respective indicator.
EVIDENCE OF COMPLIANCE	
Evidence of compliance	The evidence and details/explanations of how the BCS may demonstrate compliance with a given criterion. This is not applicable for indicators for which details for computation are provided in Annex 1: Quality indicators.

Additional information for each requirement is provided in Annex 3: Supporting materials, namely to provide guidance for BCS to implement the requirements but also to provide the background information supporting the requirement.

Annex 3: Supporting materials describes the **rationale** behind each requirement, explaining its significance in the context of quality care as well as the **quality domain** it is associated to. **Guideline recommendations** are also provided, including the recommendation statement, source guideline, certainty of evidence, and strength of recommendation. Furthermore, technical **reference documents** and a list of **supporting literature**, consisting of sources of evidence considered during requirement development, are included to guide care services in implementing requirements and improving quality of care.

TABLE OF REQUIREMENTS

The table of requirements provides a list of all the requirements within the European QA scheme for breast cancer services and applicability to each respective module. The care processes to which the requirements apply are also indicated, which should serve as a blueprint for the time-limited step-wise approach. This may also provide guidance to the services about which requirements may be applicable to the respective departments of care. Finally, the requirements that are cancer-site agnostic and can be applicable to cancer care in general are also highlighted, as well as the requirements that are associated with the continuity of care.

The modules referred to in the table are the following:
Module A: Certification of the entire breast cancer care pathway;
Module B: Certification of breast cancer screening;
Module C: Certification of the breast cancer care pathway from diagnosis to palliative care.

Table 2: Table of requirements and applicability to the module or care process

CODE	TITLE	Module			Care process					
		A	B	C	Screening	Diagnosis	Treatment	Rehabilitation to palliative care*		
GEN-1	Professional staff and training	✔	✔	✔	✔	✔	✔	✔	✔	
GEN-2	Guidelines and protocols	✔	✔	✔	✔	✔	✔	✔	✔	
GEN-3	Quality management	✔	✔	✔	✔	✔	✔	✔	✔	
GEN-4	Data governance	✔	✔	✔	✔	✔	✔	✔	✔	
GEN-5	Patient-reported outcome measures (PROMs)	✔	✔	✔	✔	✔	✔	✔	✔	
GEN-6	Patient centredness and information	✔	✔	✔	✔	✔	✔	✔	✔	
GEN-7	Research activities	✔	✔	✔	✔	✔	✔	✔	✔	
SCR-1	Screening programme	✔	✔		✔					
SCR-2	Reporting of screening indicators	✔	✔		✔					✔
SCR-3	Healthy lifestyle information	✔	✔		✔				✔	
DGN-IMG-1	Optimal mammographic image quality	✔	✔	✔	✔	✔				
DGN-IMG-2	Imaging equipment policy	✔	✔	✔	✔	✔			✔	
DGN-IMG-3	Imaging equipment facilities	✔	✔	✔	✔	✔				

* Rehabilitation, follow-up and survivorship care, and palliative care.

CODE	TITLE	Module			Care process					
		A	B	C	Screening	Diagnosis	Treatment	Rehabilitation to palliative care*		
DGN-IMG-4	Radiologists' performance	✔	✔	✔	✔	✔				
DGN-IMG-5	Separate women attending screening and women attending diagnostic procedures	✔	✔	✔	✔	✔				
DGN-IMG-6	Diagnostic mammography report	✔		✔		✔				
DGN-IMG-7	Intraoperative specimen imaging	✔		✔		✔				
DGN-1	Reporting the performance of the diagnostic service	✔		✔		✔			✔	
DGN-2	Biopsy technique for suspicious breast calcifications	✔		✔		✔				
DGN-3	Diagnostic biopsy technique	✔		✔		✔				
DGN-4	Proportion of benign diagnoses after open surgery	✔		✔		✔				
DGN-5	Genetic testing	✔		✔		✔			✔	

* Rehabilitation, follow-up and survivorship care, and palliative care.

CODE	TITLE	Module			Care process					
		A	B	C	Screening	Diagnosis	Treatment	Rehabilitation to palliative care*		
DGN-PTH-1	Diagnostic intraoperative assessment of sentinel lymph nodes	✔		✔		✔	✔			
DGN-PTH-2	Diagnostic pathology service	✔		✔		✔			✔	
DGN-PTH-3	Diagnostic pathology report	✔		✔		✔				
DGN-PTH-4	Pathology specimen minimum storage time	✔		✔		✔			✔	
DGN-PTH-5	Time from receipt of specimen to issuing of results for non-surgical and surgical specimens	✔		✔		✔				
DGN-TRT-1	Nurse access and referral	✔		✔		✔	✔	✔	✔	✔
DGN-TRT-2	Multidisciplinary meetings	✔		✔		✔	✔	✔	✔	✔
DGN-TRT-3	Psycho-oncology care	✔		✔		✔	✔	✔	✔	✔
DGN-TRT-4	Pre-treatment diagnosis	✔		✔		✔	✔		✔	✔
DGN-TRT-5	Assessment of biomarkers before starting treatment	✔		✔		✔	✔			✔
DGN-TRT-6	Lead time between pathology report and first treatment	✔		✔		✔	✔			✔

* Rehabilitation, follow-up and survivorship care, and palliative care.

CODE	TITLE	Module			Care process					
		A	B	C	Screening	Diagnosis	Treatment	Rehabilitation to palliative care*		
TRT-1	Medication safety	✔		✔			✔		✔	
TRT-2	Fertility preservation	✔		✔			✔		✔	
TRT-3	Physical activity and nutrition during treatment and follow-up	✔		✔			✔	✔	✔	
TRT-4	Pain management	✔		✔			✔	✔	✔	
TRT-5	Complimentary and integrative medicine	✔		✔			✔	✔	✔	
TRT-6	Lead time between last surgery and first adjuvant chemotherapy cycle	✔		✔			✔			✔
TRT-7	Lead time to first radiotherapy treatment	✔		✔			✔			✔
TRT-SUR-1	Sentinel lymph node biopsy	✔		✔			✔			
TRT-SUR-2	Avoid axillary lymph node dissection for pathological node-negative invasive breast cancer	✔		✔			✔			

* Rehabilitation, follow-up and survivorship care, and palliative care.

CODE	TITLE	Module			Care process					
		A	B	C	Screening	Diagnosis	Treatment	Rehabilitation to palliative care*		
TRT-SUR-3	Avoid axillary lymph node dissection for ductal carcinoma in situ (DCIS)	✔		✔			✔			
TRT-SUR-4	Breast-conserving surgery for DCIS	✔		✔			✔			
TRT-SUR-5	Breast-conserving surgery for invasive breast cancer with small tumour size	✔		✔			✔			
TRT-SUR-6	Single breast operation for primary DCIS	✔		✔			✔			
TRT-SUR-7	Single breast operation for the primary invasive breast cancer	✔		✔			✔			
TRT-SUR-8	Breast reconstruction after mastectomy	✔		✔			✔			
TRT-SYS-1	Neoadjuvant chemotherapy for stages II and III triple negative breast cancer	✔		✔			✔			

* Rehabilitation, follow-up and survivorship care, and palliative care.

CODE	TITLE	Module			Care process					
		A	B	C	Screening	Diagnosis	Treatment	Rehabilitation to palliative care*		
TRT-SYS-2	Neoadjuvant systemic therapy for stages II and III human epidermal growth factor receptor 2 (HER2)-positive breast cancer	✔		✔			✔			
TRT-SYS-3	Neoadjuvant systemic therapy for locally advanced breast cancer	✔		✔			✔			
TRT-SYS-4	Endocrine therapy for surgically treated, oestrogen receptor (ER)-positive and/or progesterone receptor (PR)-positive, invasive breast cancer	✔		✔			✔			✔
TRT-SYS-5	Adjuvant chemotherapy for surgically treated, ER-negative invasive breast cancer	✔		✔			✔			
TRT-SYS-6	Anti-HER2 therapy in women with HER2-positive breast cancer receiving chemotherapy	✔		✔			✔			

* Rehabilitation, follow-up and survivorship care, and palliative care.

CODE	TITLE	Module			Care process					
		A	B	C	Screening	Diagnosis	Treatment	Rehabilitation to palliative care*		
TRT-SYS-7	Monitored cardiac function for breast cancer treated with anti-HER2	✔		✔			✔			
TRT-SYS-8	Endocrine-based therapy as first line treatment for metastatic ER-positive and HER2-negative breast cancer	✔		✔			✔			
TRT-SYS-9	Bone-modifying agents for bone metastasis from breast cancer	✔		✔			✔			
TRT-RAD-1	Adjuvant radiotherapy for M0 invasive breast cancer treated with breast-conserving therapy	✔		✔			✔			✔
TRT-RAD-2	Radiotherapy for invasive breast cancer after mastectomy	✔		✔			✔			✔
RHB-1	Lymphoedema service	✔		✔			✔	✔	✔	
FLW-1	Follow-up of asymptomatic women after primary therapy	✔		✔				✔	✔	

* Rehabilitation, follow-up and survivorship care, and palliative care.

CODE	TITLE	Module			Care process					
		A	B	C	Screening	Diagnosis	Treatment	Rehabilitation to palliative care*		
FLW-2	Early detection of recurrence	✔		✔				✔	✔	✔
FLW-3	Survivorship policy	✔		✔				✔	✔	✔
PAL-1	Palliative care policy	✔		✔		✔	✔	✔	✔	✔

* Rehabilitation, follow-up and survivorship care, and palliative care.

Source: JRC

CHAPTER 2

GENERAL REQUIREMENTS (GEN)

GEN-1: PROFESSIONAL STAFF AND TRAINING

STATEMENT

The BCS must have access to a sufficient number of persons necessary for the continuous operation of its processes, including a clinical director and the following professionals[41]: 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, nuclear medicine specialists, physiotherapists, nutritionists and lymphoedema specialists. Professionals can be internal to the BCS or external and associated through a written agreement/contract.

The BCS must ensure that healthcare professionals (internal and external) are qualified and competent to perform their activities and deliver the service.

BREAST CANCER CARE PROCESS: All processes.

MEASUREMENT OF COMPLIANCE	
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, physiotherapists, nutrition specialists and lymphoedema specialists. Professionals can be internal to the BCS or external and associated through a written agreement/contract.
GEN-1.2 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.
GEN-1.3 criterion	The BCS ensures that the professionals involved are qualified by education, training and licensure or regulation. For the professions listed below, specific training and experience is required:

[41] The specific job titles listed for professionals may not be the same throughout Europe. See Glossary – Professions in breast cancer care for the terms used for this European QA scheme.

Professionals	Attended a recognised (regional/national/international)[42] training course/activity/examination in	Volume of experience (number of cases during the previous calendar year)	Years of experience
Radiographers	Breast imaging[43]	Performed at least 1 000 mammography examinations[44]	
Breast radiologist	Breast imaging and diagnostic breast interventions[43]	Read between 3 500 and 11 000 mammography examinations, including mammograms read outside the centre[45]	
Medical physics expert	Medical physics expert in radiology (preferably a university training course and, if not available, European Training and Education for Medical Physics Experts in Radiology (EUTEMPE-RX))	Performed routine quality-assurance procedures on 5 mammography units	
Pathologist		Examined at least 100 breast specimens[46]	

[42] Recognised if:
- it was carried out in a certified/accredited training centre or breast centre, or
- it is documented with continuing education (or equivalent) units or credits, or
- the training content follows one of the documents included in the relevant reference documents section, or
- it is recognised in the country of practice.

[43] If not included in the general training for the medical specialism.

[44] Retaken mammograms will not be considered.

[45] See ECIBC recommendation on the number of readings for mammography readers in an organised, population-based screening programme.

[46] Routine assessments are the analysis of histological specimens (core needle biopsies and surgical specimens) to provide a diagnosis, and prognostic and predictive parameters that guide the treatment of individual patients.

Professionals	Attended a recognised (regional/national/ international)[42] training course/ activity/examination in	Volume of experience (number of cases during the previous calendar year)	Years of experience
Breast care nurse	Breast cancer care, including communicating breast cancer diagnoses, interventions offered in radiotherapy and handling side effects		At least 1 year of post- registration experience in either a general or cancer setting
Breast surgeon	Breast surgery	Performed primary surgeries on at least 50 newly diagnosed breast cancers	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[43]		
Medical oncologist			At least 3 years of clinical experience in breast medical oncology, after specialisation
Radiation oncologist	Radiation protection[43]		
Psycho-oncologist	Psycho-oncology		At least 1 year of experience working in psycho-oncology

MEASUREMENT OF COMPLIANCE	
GEN-1.4 criterion	The BCS ensures that all staff maintain their competence to undertake the role(s) to which they have been appointed.
GEN-1.5 criterion	All professionals involved in cancer care are trained periodically (at least every 5 years) in communication skills and shared decision-making. 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).
GEN-1.6 criterion	All professionals involved in cancer care (refer to the list specified in GEN-1.3) participate annually in a minimum of 2 local, regional or national breast-specific continuing education (CE) (or equivalent) activities, appropriate to the discipline.
GEN-1.7 criterion	Professionals who do not meet the abovementioned requirements are supervised by a professional with the corresponding qualifications and competences.
EVIDENCE OF COMPLIANCE	
GEN-1.1	List of BCS staff, including each professional's specialism. List of professionals directly employed by the BCS and where applicable, the list of professionals from outsourced services that participate in breast cancer care, with a record or copy of their legally binding, written agreement/contract.
GEN-1.2	Documented evidence of competence assignment, maintenance or modification for professionals involved in patient care, conducted by the nominated responsible individual, in all staff records reviewed.
GEN-1.3	Staff records: • Evidence of the nationally required credentials for professionals involved in patient care, in all staff records reviewed. • Additionally, evidence of credential verification for professionals involved in patient care should be included in all staff records reviewed. • Documentation of CE (or equivalent) units/credits and/or certificates of attendance to specific training courses, case records for professionals involved in patient care, in all staff records reviewed. • The BCS provides a list of the names of all professionals from each discipline currently involved in patient care and describing the compliance with the training and experience mentioned in GEN-1.3 table. Exclusions: junior professionals (residents/trainees).
GEN-1.4	Personal annual evaluation conducted by the nominated responsible individual, in all staff records reviewed.

EVIDENCE OF COMPLIANCE	
GEN-1.5	Contents of the training delivered in communication skills and shared decision-making.
GEN-1.6	Documentation of CE (or equivalent) units/credits from the 2 CE activities for professionals involved in patient care, in all staff records reviewed.
GEN-1.7	Supervision policy or similar document describing which procedures have to be supervised, the individual responsible for this supervision in each case and records of supervision.

GEN-2: GUIDELINES AND PROTOCOLS

STATEMENT
The BCS must have adopted and implemented evidence-based protocols for all processes of the entire care pathway for women attending screening and patients with breast cancer.

BREAST CANCER CARE PROCESS: All processes.

MEASUREMENT OF COMPLIANCE	
GEN-2.1 criterion	Protocols are consistent with current European guidelines for breast cancer screening and diagnosis, and other (inter)national guidelines for the entire cancer care pathway as defined in the QA scheme, including guidelines on psychosocial care, rehabilitation and primary prevention of recurrence.
GEN-2.2 criterion	The BCS pathway and processes are those defined in the European QA scheme.
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.
GEN-2.4 criterion	Tailoring of protocols to the local circumstances of the BCS is documented and kept up to date.
GEN-2.5 criterion	The BCS has a policy for stimulating the adoption of protocols.
GEN-2.6 criterion	The BCS reviews the documents and protocols regularly (at least annually). Records of the reviews are available, including the date, and the names and signatures of the reviewers.
GEN-2.7 criterion	Records of multidisciplinary meetings (MDMs) reflect the use of protocols and guidelines.
GEN-2.8 criterion	Protocols for staging women with breast cancer using diagnostic imaging are consistent with the European guidelines on breast cancer screening and diagnosis.

EVIDENCE OF COMPLIANCE	
GEN-2.1	List of current and approved cancer care protocols. All cancer 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[47].
GEN-2.2	List of all protocols from the pathway processes included in the certification module (refer to Part I, Chapter 1, Section: Certification modules).
GEN-2.3 and GEN-2.4	Protocols address local organisational adaptations, such as contracted services and their coordination with the BCS; adaptations to local circumstances, if any, are documented.
GEN-2.5	Policy defining how to manage protocol adoption and implementation in the BCS.
GEN-2.6	Cancer care protocols and documents that are in force at the time of the audit, including the date of the last update, authors and modifications.
GEN-2.7	Records of MDMs from the last 12 months, or a specific report evidencing adherence to protocols and guidelines.
GEN-2.8	Records demonstrating evidence of the centre's internal checks to ensure compliance with the protocols for staging women with breast cancer, including any measures taken to address non-compliance.

[47] International guidelines on breast cancer care https://healthcare-quality.jrc.ec.europa.eu/en/ecibc/international-guidelines

GEN-3: QUALITY MANAGEMENT

STATEMENT

The BCS must have a written quality improvement policy, and must have implemented a quality management system that is capable of meeting the European QA scheme requirements consistently, including a patient safety system and a clinical information system for monitoring the quality of breast cancer care.

BREAST CANCER CARE PROCESS: All processes.

MEASUREMENT OF COMPLIANCE	
GEN-3.1 criterion	The BCS has a quality management system for monitoring quality and continuous quality improvement. The quality management system must include policies and/or procedures for: • quality improvement, containing strategic objectives for at least the following quality domains: clinical effectiveness; patient safety; personal empowerment and experience; and facilities, resources and workforce; • documentation and document control; • administrative, medical and management records, and control of those records; • staff impartiality and integrity; • facility infrastructure and equipment; • reporting on quality indicator results; • management review; • risk management; • corrective and preventive actions; • internal and external audits; • patient safety; • confidentiality and privacy; • handling of complaints; • patient involvement, including patients' and users' feedback; • staff feedback; • staff safety; • outsourcing (if applicable).
GEN-3.2 criterion	The BCS has an appointed, qualified individual(s) who is responsible for quality management of breast cancer care.
GEN-3.3 criterion	Quality monitoring covers the applicable indicators included in this European quality assurance scheme for breast cancer services.
GEN-3.4 criterion	The BCS has an appointed individual, who is responsible for data management. Data collection and analysis are carried out by individual(s) trained in data management.

MEASUREMENT OF COMPLIANCE	
GEN-3.5 criterion	The BCS has an indicator database for monitoring the clinical quality of breast cancer care.
GEN-3.6 criterion	The BCS conducts an annual internal review, resulting in a record that includes, at a minimum, the indicators monitored, an assessment of the results and improvement actions for indicators that do not achieve the stated norm.
EVIDENCE OF COMPLIANCE	
GEN-3.1	Documented management system policies and procedures including (but not limited to): • quality improvement policy and activities; • standard operating procedures; • staff qualifications and staff training records; • communications and meetings; • equipment maintenance records, including internal and external calibration records; • records of internal and external audits and identified non-conformities; • incident records and action taken; • accident records and action taken; • risk management records; • records of corrective and preventative actions; • feedback from patients and other service users, including complaints and actions taken to resolve these; • staff recommendations; • service agreements/contracts with external providers. A BCS entity that provides evidence that it has established and maintains a management system that meets the requirements of ISO 9001, EN 15224 or other relevant standard shall be considered towards the fulfilment of this requirement (refer to Part I, Chapter 6: Existing quality assessments within cancer care services). This includes entities providing outsourced services to the BCS. A BCS may be included within a broader management system, for example within a broader hospital management system.
GEN-3.2	Record of the appointment of the individual(s) responsible for breast cancer care quality management.
GEN-3.3	Results of the monitoring of indicators.
GEN-3.4	Access to the database may be provided.
GEN-3.5	Staff record of the individual(s) responsible for data management, collection and analysis, including job description.
GEN-3.6	Record of the annual review session.

GEN-4: DATA GOVERNANCE

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

BREAST CANCER CARE PROCESS: All processes.

MEASUREMENT OF COMPLIANCE	
GEN-4.1 criterion	The policy governing data management is consistent with current European and national data protection legislation, and considers Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.
GEN-4.2 criterion	The BCS has a written policy on data management, data protection and data privacy, and a written procedure for the collection, processing, recording, reporting, storage, retrieval, preservation, consultation and transmission of personal data, according to European and national legislation.
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.).
GEN-4.4 criterion	The BCS ensures adequate protection for the data of patients involved in clinical trials.
GEN-4.5 criterion	The BCS ensures that any data sharing among collaborators, partners or outsourced services that process data complies with the General Data Protection Regulation.
GEN-4.6 criterion	The BCS reviews the data management documents and procedures regularly (at least annually). Records of the review are available, including the date, and the names and signatures of the reviewers.
EVIDENCE OF COMPLIANCE	
GEN-4.1 and GEN-4.3	Policy governing data management considers and makes reference to the European and national legislation as well as the Directive 2011/24/EU on the application of patients' rights in cross-border healthcare.
GEN-4.2	Data management policy document including all elements mentioned in the criterion.
GEN-4.4	Evidence of how and where the clinical records of patients involved in clinical trials are stored and protected.
GEN-4.5	Requirements for data sharing are documented in formal agreement.
GEN-4.6	Data management documents and procedures that are in force at the time of the audit, including the date of the last update, authors and modifications.

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

STATEMENT
The BCS must have a written policy for routine measurement of patient-reported outcome measures (PROMs) throughout the entire breast cancer care pathway.

BREAST CANCER CARE PROCESS: All processes.

MEASUREMENT OF COMPLIANCE	
GEN-5.1 criterion	The BCS has a written policy for the measurement of patient-reported outcomes measuring women's satisfaction after attending screening and/or throughout the breast cancer care pathway.
GEN-5.2 criterion	The BCS uses at least 1 PROM that is relevant to women attending breast cancer screening and/or 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.
EVIDENCE OF COMPLIANCE	
GEN-5.1	Policy for collecting PROMs.
GEN-5.2	Information on which PROMs are used, how they are measured and how the BCS uses the results.

GEN-6: PATIENT CENTREDNESS AND INFORMATION

STATEMENT

The BCS must have a written policy to ensure relevant patient-centred care, including patient information. Clear and understandable verbal and written information describing the screening process must be offered to women attending screening. Similarly, information that describes diagnostic process, treatment, follow-up and possible side effects must be offered to women with breast cancer.

BREAST CANCER CARE PROCESS: All processes.

MEASUREMENT OF COMPLIANCE	
GEN-6.1 criterion	Up-to-date (including dates of issue and revision) leaflets and patient information, developed with and involving patients and adapted for local use, are available and easily accessible at the BCS.
GEN-6.2 criterion	Documentation includes: • tailored, easy-to-understand verbal, written and online information that describes the screening process, diagnostic process, treatment, follow-up and possible (late) side effects. • 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.
GEN-6.3 criterion	The BCS has implemented a survey, conducted periodically, to measure patient experience and/or satisfaction, as well as communication with patients. The BCS has established a patient advisory/representative group to review the results of patient experience and/or satisfaction surveys, including communication. The BCS implements improvements based on the results of these surveys.
GEN-6.4 criterion	Informed consent is obtained through a process defined by the BCS and carried out by trained staff, and is registered in the screening or clinical records, respectively.
EVIDENCE OF COMPLIANCE	
GEN-6.1	Any material that is provided for information to women attending screening and patients.

EVIDENCE OF COMPLIANCE	
GEN-6.2	Documents or materials specifically referring to the following: • The screening process. • The diagnostic process. • The treatment process, with a clear reference to the surgical process and medical treatment (systemic therapy and radiotherapy), including information about possible side effects and guidance on where to find resources to enhance self-management. • Rehabilitation process (i.e. psychological care, physical/functional, cognitive, sexual, etc.). • Follow-up and survivorship care (i.e. nutrition, physical exercise, healthy habits, stress-management, sleep, sexuality, etc.). • Information from local patient support groups or advocacy organisations.
GEN-6.3	Records of analysis of the results of patient experience and/or satisfaction surveys which are conducted showing participation of the patient advisory group. Documented examples of improvements that have been made based on the analysis of the results.
GEN-6.4	Procedure in place at the BCS for informed consent and records of informed consent.

GEN-7: RESEARCH ACTIVITIES

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

BREAST CANCER CARE PROCESS: All processes.

MEASUREMENT OF COMPLIANCE	
GEN-7.1 criterion	The research and clinical strategy plan is regularly updated with guidelines, trial procedures, quality procedures, etc.
GEN-7.2 criterion	The organisation's responsibility within the research, innovation and development structures is clearly defined.
GEN-7.3 criterion	The BCS is part of a clinical/research network.
GEN-7.4 criterion	The clinical management unit / management team and institutional review board are well defined.
GEN-7.5 criterion	Structural cooperation between clinicians and researchers is well defined and organised.
EVIDENCE OF COMPLIANCE	
GEN-7.1	Up-to-date research and clinical strategy plan.
GEN-7.2	Document defining the organisation's responsibility within the research, innovation and development structures.
GEN-7.3	Documented agreement between the BCS and a clinical/research network.
GEN-7.4	Documented information describing the role of the clinical management unit and institutional review board.
GEN-7.5	Current collaboration document between the BCS and the research institution(s).

CHAPTER 3

SCREENING REQUIREMENTS (SCR)

SCR-1: SCREENING PROGRAMME

STATEMENT
The screening programme must comply with the European guidelines for breast cancer screening and diagnosis (ECIBC) on the implementation of an organised, population-based screening programme.

BREAST CANCER CARE PROCESS: Screening.

MEASUREMENT OF COMPLIANCE	
SCR-1.1 criterion	The screening programme has a screening policy specifying at least the target population, screening method and interval (see recommendations listed in Annex 3, Section: Guideline recommendations).
SCR-1.2 criterion	The screening programme must invite and reach over time the entire target population that includes at least women aged 50-69.
SCR-1.3 criterion	The screening programme has a systematic call/recall system in place.
SCR-1.4 criterion	The screening programme ensures the availability of appropriate, diagnostic, treatment and aftercare services.
SCR-1.5 criterion	The screening programme monitors cancer occurrence in the target population (including linking to relevant registries for programme monitoring and evaluation).
SCR-1.6 criterion	The screening programme has in place a structure for decision-making and taking responsibility for healthcare management.
SCR-1.7 criterion	The screening programme has a team responsible for overseeing screening centres that must meet at least once a week to analyse the screening activity and data trends.
SCR-1.8 criterion	The screening programme centres have the necessary equipment, or have an agreement with a local provider, to perform mammography (full-field digital, and preferably equipped with a tomosynthesis option).
SCR-1.9 criterion	The screening programme centres have a policy for retakes[48] consistent with European and other (inter)national guidelines, and reviews the documents and protocols for recalls for technical reasons regularly, at least once a year.
SCR-1.10 indicator	Proportion of eligible women aged 50-69 who were invited for screening within a screening programme. **Norm ≥ 95 %**

[48] A retake refers to a repeat mammogram taken during the same screening session because of technical reasons.

EVIDENCE OF COMPLIANCE	
SCR-1.1 and SCR-1.8	Documentation, including policy and protocols, for adopting the European guidelines for breast cancer screening and diagnosis, and documentation on the equipment in use.
SCR-1.2, SCR-1.3, SCR-1.4, SCR-1.6 and SCR-1.9	Documentation or records 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; and the regular review of recalls for technical reasons.
SCR-1.5	Records of monitoring activities undertaken as detailed in a documented protocol. The latter should include frequency and type of monitoring. Records of links with other relevant registries.
SCR-1.7	Procedure describing how the screening programme meetings are managed, the team composition, meeting schedules, the team's roles and responsibilities, how cases are discussed and reported.

SCR-2: REPORTING OF SCREENING INDICATORS

STATEMENT

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

BREAST CANCER CARE PROCESS: Screening.

MEASUREMENT OF COMPLIANCE

The following screening indicators must be calculated for monitoring purposes. In cases where any indicators are not calculated, the justification must be documented. The justified absence of some calculated indicators does not preclude the grant of certification.

The programme should use the indicators initially to establish baseline performance and to monitor trends with the objective of facilitating improvements in performance as necessary. No norms are specified except for SCR-2.15 (see below). Indicators should be:

a) reported separately for first screening mammography and subsequent screening mammography, and
b) calculated for the screening programme and, where indicated, stratified according to each centre or radiographer performing mammography screening.

MEASUREMENT OF COMPLIANCE		
SCR-2.1 indicator	Screening coverage.	
SCR-2.2 indicator	Participation rate.	
SCR-2.3 indicator	Recall rate[49].	
SCR-2.4 indicator	Breast cancer detection rate[49].	
SCR-2.5 indicator	Invasive breast cancer detection rate.	
SCR-2.6 indicator	Invasive cancers > 20 mm rate.	
SCR-2.7 indicator	Invasive cancers ≤ 10 mm rate[49].	
SCR-2.8 indicator	Lymph node negative rate.	
SCR-2.9 indicator	Interval cancer rate[50].	
SCR-2.10 indicator	Episode sensitivity.	
SCR-2.11 indicator	Benign open surgery biopsy rate.	
SCR-2.12 indicator	Interval cancer, review errors.	
SCR-2.13 indicator	Advanced cancer (≥T2[51]), review errors.	
SCR-2.14 indicator	Technical repeat examination[52].	
SCR-2.15 indicator	Proportion of screened women subject to early recall following diagnostic assessment. **Norm < 1 %**	
SCR-2.16 indicator	Time between screening mammogram and issuing of results.	
SCR-2.17 indicator	Time between result of screening mammography and assessment offered.	
SCR-2.18 indicator	Time between the assessment and issuing the result of the assessment when needle biopsy is performed.	
SCR-2.19 indicator	Time between the assessment and issuing the result of the assessment when needle biopsy is not performed.	
SCR-2.20 indicator	Time interval between screening and treatment.	

[49] Indicator should be reported for the overall screening programme AND stratified by each centre performing mammography screening, where applicable.
[50] See Glossary.
[51] According to Union for International Cancer Control's (UICC) TNM classification of malignant tumours (TNM), 8th edition.
[52] Indicator must be reported separately for each radiographer.

SCR-3: HEALTHY LIFESTYLE INFORMATION

STATEMENT

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

BREAST CANCER CARE PROCESS: Screening.

MEASUREMENT OF COMPLIANCE	
SCR-3.1 criterion	The centre providing breast screening has a written policy for informing women about a healthy lifestyle (including nutrition and physical activity).
SCR-3.2 criterion	Women are offered counselling on a healthy lifestyle (including on nutrition and physical activity).
EVIDENCE OF COMPLIANCE	
SCR-3.1	Policy for informing women about a healthy lifestyle.
SCR-3.2	Evidence that the policy is consistently implemented.

CHAPTER 4

DIAGNOSIS REQUIREMENTS (DGN)

Imaging (DGN-IMG)

Diagnosis (DGN)

Pathology (DGN-PTH)

Diagnosis to treatment (DGN-TRT)

DGN-IMG-1: 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.
For the screening programme, this requirement is applicable to each screening centre.

BREAST CANCER CARE PROCESS: Screening; diagnosis.

MEASUREMENT OF COMPLIANCE	
DGN-IMG-1.1 criterion	The protocol includes the consultant radiographer/radiologist checking 10 randomly chosen mammographic examinations for each radiographer every 2 months, against a defined protocol.
DGN-IMG-1.2 criterion	Policy and protocols are consistent with European and other (inter) national guidelines for breast positioning to achieve optimal mammographic image quality.
DGN-IMG-1.3 criterion	Documented protocols are made available by the BCS and used by trained radiographers.
DGN-IMG-1.4 criterion	The BCS reviews documents and protocols for breast positioning for optimal mammographic image quality regularly (at least annually).

EVIDENCE OF COMPLIANCE

BCS records show the implementation of protocols on optimal image quality. Records include the documentation and protocol review, the date, and the names and signatures of reviewers.

DGM-IMG-1.1	Records of consultant radiographer checks.
DGM-IMG-1.2	Policy and protocols.
DGM-IMG-1.3	Evidence of the availability of the protocols.
DGM-IMG-1.4	Records of the last revision of the protocols.

DGN-IMG-2: IMAGING EQUIPMENT POLICY

STATEMENT

The BCS providing breast cancer screening and/or diagnosis must have a written 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.

BREAST CANCER CARE PROCESS: Screening; diagnosis.

MEASUREMENT OF COMPLIANCE	
DGN-IMG-2.1 criterion	Policy and protocols explicitly refer to industry standards and European or other (inter)national guidelines for imaging equipment impacting the outcome of breast cancer care, for the entire care pathway defined in the European QA scheme (see additional information within the reference documents section of DGN-IMG-2).
DGN-IMG-2.2 criterion	The BCS has documented instructions for the proper use of all imaging equipment.
DGN-IMG-2.3 criterion	The BCS documents that the imaging equipment is only used by staff members who are specifically trained and authorised.
DGN-IMG-2.4 criterion	The BCS keeps records to demonstrate that imaging equipment used for breast cancer care can achieve and maintain the required level of technical performance.
DGN-IMG-2.5 criterion	The BCS reviews the documents and protocols regularly (at least annually). Records of the reviews are available, including the date, and the reviewers' names and signatures.
DGN-IMG-2.6 criterion	Adverse events relating to patients or imaging equipment malfunctions are recorded and analysed, and this is the responsibility of the head of the BCS or the nominated responsible individual.

EVIDENCE OF COMPLIANCE

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, such as:

- documented policies, rationales and protocols;
- purchase orders and equipment specifications;
- documentation on the equipment in use
- 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;
- document and policy reviews, including the date, and the reviewers' names and signatures.

DGN-IMG-3: IMAGING EQUIPMENT FACILITIES

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

BREAST CANCER CARE PROCESS: Screening; diagnosis.

MEASUREMENT OF COMPLIANCE

DGN-IMG-3.1 criterion

The BCS covering imaging and image-guided diagnostics has the necessary equipment, or has an agreement with a local provider, to perform:

- mammography (full-field digital, preferably with tomosynthesis and contrast-enhanced options);
- ultrasound of the breast and axilla (the ultrasound machine must have dedicated high-frequency linear probes for breast and axilla ultrasound);
- percutaneous image-guided needle sampling;
- at least 1.5-T breast magnetic resonance imaging (MRI) with a dedicated bilateral breast coil.

EVIDENCE OF COMPLIANCE

BCS documentation on the equipment in use. Agreements with local providers, where applicable.

DGN-IMG-4: RADIOLOGISTS' PERFORMANCE

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

BREAST CANCER CARE PROCESS: Screening; diagnosis.

MEASUREMENT OF COMPLIANCE	
DGN-IMG-4.1 criterion	The BCS reviews the performance of the radiologists periodically.
DGN-IMG-4.2 criterion	The BCS provides performance metrics for each reading radiologist at least annually.
DGN-IMG-4.3 criterion	The BCS reviews the documents and protocols regularly (at least annually). Records of the reviews are available, including the date, and the reviewers' names and signatures.
EVIDENCE OF COMPLIANCE	
DGM-IMG-4.1	Records of radiologists' performance review.
DGM-IMG-4.2	Examples of screening programme performance metrics: detection rate, recall rate, false recall rate, further assessment rate and interval cancer rate. Example of a diagnostic setting performance metric: the average number of mammograms read every year.
DGM-IMG-4.3	Records of the document or protocol reviews.

DGN-IMG-5: SEPARATION OF WOMEN ATTENDING SCREENING AND WOMEN ATTENDING DIAGNOSTIC PROCEDURES

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.

BREAST CANCER CARE PROCESS: Screening; diagnosis.

MEASUREMENT OF COMPLIANCE	
DGN-IMG-5.1 criterion	The BCS has a policy that 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.
DGN-IMG-5.2 criterion	The BCS reviews the documents and protocols regularly (at least annually). Records of the reviews are available, including the date, and the reviewers' names and signatures.
EVIDENCE OF COMPLIANCE	
DGM-IMG-5.1	Policy and protocols.
DGM-IMG-5.2	Records of the document and protocol reviews.

DGN-IMG-6: DIAGNOSTIC MAMMOGRAPHY REPORT

STATEMENT
All reports for diagnostic mammograms must include a core set of essential information and be provided to the primary healthcare provider and the women are informed of the result, in line with national regulations.

BREAST CANCER CARE PROCESS: Diagnosis.

MEASUREMENT OF COMPLIANCE	
DGN-IMG-6.1 criterion	The following criteria are included in the report: a. Relevant family and clinical history; b. Comparison with previous studies (if available); c. Mammographic breast density according to a validated classification, e.g. Breast Imaging Reporting and Data System (BI-RADS™) a, b, c, d class); d. Type of abnormality detected, the number of clinically relevant abnormalities, their size and location; 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™).
DGN-IMG-6.2 criterion	All diagnostic mammography reports provided by the BCS include the same formal diagnostic category system.
DGN-IMG-6.3 criterion	The diagnostic mammography report is provided to the primary healthcare provider and the woman is informed of the result, in line with national regulations.
EVIDENCE OF COMPLIANCE	
DGN-IMG-6.1 and DGN-IMG-6.2	Medical records, such as diagnostic mammography reports.
DGM-IMG-6.3	Information verifying the implementation of the procedures.

DGN-IMG-7: INTRAOPERATIVE SPECIMEN IMAGING

STATEMENT
The BCS must have a policy in place to monitor the rate of intraoperative specimen imaging procedures. Specimen imaging can be performed by mammography or ultrasonography, depending on the preoperative imaging.

BREAST CANCER CARE PROCESS: Diagnosis.

MEASUREMENT OF COMPLIANCE	
DGN-IMG-7.1 indicator	Proportion of women who had intraoperative specimen imaging following breast-conserving surgery for microcalcifications with image-guided localisation. **Norm ≥ 95 %**
DGN-IMG-7.2 indicator	Proportion of women who underwent surgical lesion removal with intraoperative specimen imaging. **Indicator for monitoring purposes.**

DGN-1: REPORTING THE PERFORMANCE OF THE DIAGNOSTIC SERVICE

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

BREAST CANCER CARE PROCESS: Diagnosis.

MEASUREMENT OF COMPLIANCE	
DGN-1.1 criterion	Diagnostic services analyse data for trends in performance during internal audits. Data can be used for benchmarking purposes.
DGN-1.2 indicator	Median number of working days between symptomatic mammography and communication of diagnosis (when biopsy is performed), measured as a number of working days. **Indicator for monitoring purposes.**
DGN-1.3 indicator	Median number of working days between symptomatic mammography and communication of diagnosis (when biopsy is not performed), measured as a number of working days **Indicator for monitoring purposes.**
EVIDENCE OF COMPLIANCE	
DGN-1.1	Records of the trends analysis.

DGN-2: DIAGNOSTIC BIOPSY TECHNIQUE

STATEMENT
If a breast lesion is identified as requiring tissue sampling, a minimally invasive core needle biopsy for diagnosis prior to surgery must be performed. Fine needle aspiration cytology should not be performed.

BREAST CANCER CARE PROCESS: Diagnosis.

MEASUREMENT OF COMPLIANCE	
DGN-2.1 indicator	Proportion of women with suspicious breast lesions at mammography, ultrasound and/or MRI stages who undergo core needle biopsy. **Norm ≥ 90%**

DGN-3: BIOPSY TECHNIQUE FOR SUSPICIOUS BREAST CALCIFICATIONS

STATEMENT
Stereotactic-guided or tomosynthesis-guided core needle biopsy must be used to diagnose women with suspicious breast calcifications found in mammography.

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

BREAST CANCER CARE PROCESS: Diagnosis.

MEASUREMENT OF COMPLIANCE	
DGN-3.1 indicator	Proportion of women (lesions counted) with suspicious breast calcifications found in mammography who undergo stereotactic-guided or tomosynthesis-guided core needle biopsy. **Norm ≥ 95 %**

DGN-4: PROPORTION OF BENIGN DIAGNOSES AFTER OPEN SURGERY

STATEMENT
The proportion of women diagnosed with benign lesions after open surgery who must be monitored to minimise unnecessary operations for benign conditions.

BREAST CANCER CARE PROCESS: Diagnosis.

MEASUREMENT OF COMPLIANCE	
DGN-4.1 indicator	Proportion of women diagnosed with a benign lesion after open surgery. **Norm < 20 %**

DGN-5: GENETIC TESTING

STATEMENT

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

BREAST CANCER CARE PROCESS: Diagnosis.

MEASUREMENT OF COMPLIANCE	
DGN-5.1 indicator	Proportion of women diagnosed with breast cancer and with a high risk of genetic mutations who have been offered genetic counselling and have access to genetic testing. **Indicator for monitoring purposes.**
Explanation of terms	A high-risk patient is defined as an individual with a cancer diagnosis that meets any of the following criteria: • A known mutation in a cancer susceptibility gene within the family; • Early-onset breast cancer; • Triple negative (ER-negative, PR-negative and HER2-negative) breast cancer ≤ age 60 years; • Two breast cancer primaries in a single individual; • Breast cancer at any age, and ≥ 1 close blood relative with breast cancer ≤ age 50 years; 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; • 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); • Invasive ovarian cancer. (Source: National Comprehensive Cancer Network (NCCN) Guidelines, Genetic/Familial High-Risk Assessment: Breast and Ovarian, version 2.2015.)

DGN-PTH-1: DIAGNOSTIC 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.

BREAST CANCER CARE PROCESS: Diagnosis; treatment.

MEASUREMENT OF COMPLIANCE	
DGN-PTH-1.1 criterion	The BCS is able to conduct frozen section analysis or use other validated methods, such as one-step nucleic acid amplification, for intraoperative assessment of sentinel lymph nodes.

EVIDENCE OF COMPLIANCE

- A list of the methods available for conducting on-site, intraoperative assessments of sentinel lymph nodes (e.g. ability to perform frozen section, one-step nucleic acid amplification, etc.).
- Documentation demonstrating that all tests used for clinical diagnosis are validated.

DGN-PTH-2: DIAGNOSTIC PATHOLOGY SERVICE

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

BREAST CANCER CARE PROCESS: Diagnosis.

MEASUREMENT OF COMPLIANCE	
DGN-PTH-2.1 criterion	The pathology service has documented that IHC and molecular testing are available and conducted according to European or international evidence-based guidelines (within the BCS or outsourced).
DGN-PTH-2.2 criterion	All tests used for breast cancer diagnosis in the pathology service are verified (for CE-IVD) or validated (for an in-house or laboratory-developed test) before introducing them into clinical service.
DGN-PTH-2.3 criterion	IHC tests for ER, PR and HER2 are available and, wherever possible, are performed within the BCS facility.
DGN-PTH-2.4 criterion	Internal quality control and external quality assessment is in place for the prognostic and predictive markers ER, PR and HER2.
DGN-PTH-2.5 criterion	Cooperation agreements are in place for outsourced testing to ensure that external laboratories also follow guidelines and are subject to quality control.
EVIDENCE OF COMPLIANCE	
DGN-PTH-2.1, DGN-PTH-2.3	A list of IHC/molecular pathology tests that are available within the BCS facility 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.
DGN-PTH-2.2	Documentation showing that all tests used for clinical diagnosis are validated.
DGN-PTH-2.4	Documentation proving the BCS' participation in, and the results of external quality assessment processes for, ER, PR and HER2.
DGN-PTH-2.5	Agreements.

DGN-PTH-3: DIAGNOSTIC PATHOLOGY REPORT

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

BREAST CANCER CARE PROCESS: Diagnosis.

MEASUREMENT OF COMPLIANCE	
DGN-PTH-3.1 criteria	Pathology reports for invasive breast cancer (excluding re-excision specimens) must include the following minimum set of parameters: • 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 the Elston and Ellis system; • Confirmation of clip site (S), if present; • ER status, indicating % of positive cells (recommended pre-treatment); • PR status, indicating % of positive cells (recommended pre-treatment); • HER2 receptor status (recommended pre-treatment); • Proliferation index Ki-67 (optional); • Identity and date of approval and identity of authorising pathologist. **Additional parameters for resection specimens only:** • 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 diseases; • 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); • 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 AJCC/UICC Cancer Staging Manual.

MEASUREMENT OF COMPLIANCE	
DGN-PTH-3.2 criteria	Pathology reports for non-invasive breast cancer (excluding re-excision specimens) must include the following minimum set of parameters: • Patient identification; • Specimen identification; • Date the specimen is received by the laboratory; • Laterality; • DCIS histological grade according to current WHO classification; • Presence of (micro)invasion; • Presence of calcification; • Confirmation of clip site (S), if present; • Identity and date of approval of authorising pathologist. **Additional parameters for resection specimens only:** • Extent of the disease; • Peritumoral lymphovascular invasion; • Resection margins; • Pathologic staging as pTis, according to the current AJCC/UICC Cancer Staging Manual.
DGN-PTH-3.3 criterion	Pathology reports for specimens after neoadjuvant therapy (excluding re-excision specimens) must include the following minimum set of parameters: • 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 the Elston and Ellis system; • Presence/absence of DCIS; • Confirmation of clip site (S), if placed pre-treatment; • Assessment of response to treatment and classification system used; • Pathologic staging: ypTM and ypN, according to current AJCC/UICC Cancer Staging Manual; • Identity and date of approval of authorising pathologist. **Additional parameters for resection specimens only:** • Size of (residual) invasive carcinoma (measured in 1 or 2 dimensions); • Extent of the (residual) disease; • Peritumoral lymphovascular invasion; • Resection margins; • Lymph node status, including presence of treatment effects, and presence and extent of residual tumour;

EVIDENCE OF COMPLIANCE

- Relevant pathology reporting templates.
- A random sample of electronic or paper health records within a specified time frame and that are extracted, either manually or via a batch report, and reviewed. At least 90 % of the reports must contain the minimum set of parameters.
- Records of how the BCS monitors the compliance to the requirement and corrective actions, such as annual reports.

DGN-PTH-4: PATHOLOGY SPECIMEN MINIMUM STORAGE TIME

STATEMENT

The BCS must have a written 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.

BREAST CANCER CARE PROCESS: Diagnosis.

MEASUREMENT OF COMPLIANCE	
DGN-PTH-4.1 criterion	The BCS has a written policy specifying the minimum storage times required for breast specimens: • At least 10 years for paraffin blocks and slides; • At least 4 weeks for wet specimens (including fixed tissue samples of any size).
DGN-PTH-4.2 criterion	The BCS ensures that specimens are safely stored in the appropriate conditions (e.g. temperature and humidity), in line with SOPs 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 failure.
DGN-PTH-4.3 criterion	Breast specimens that are stored for shorter periods of time (such as small tissue samples used entirely for diagnostic or research purposes) are properly recorded and the reason documented.

EVIDENCE OF COMPLIANCE

Policy on the appropriate storage conditions for breast specimens, specifying the minimum storage time for each type of specimen as well as evidence, such as records of the storage time and conditions for all breast specimens.

DGN-PTH-5: TIME FROM RECEIPT OF SPECIMEN TO ISSUING OF RESULTS 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 IHC, must be 5 working days for non-surgical biopsies and 10 working days for surgical specimens.

BREAST CANCER CARE PROCESS: Diagnosis.

MEASUREMENT OF COMPLIANCE	
DGN-PTH-5.1 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.
DGN-PTH-5.2 indicator	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. **Norm ≥ 80 %**
DGN-PTH-5.3 indicator	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. **Norm ≥ 80 %**
EVIDENCE OF COMPLIANCE	
DGN-PTH-5.1	Documented procedure.

DGN-TRT-1: NURSE ACCESS AND REFERRAL

STATEMENT

The BCS must have at least 2 breast care nurses available throughout the entire patient care pathway to ensure continuity of care. All women diagnosed with breast cancer must be consulted by a breast care nurse at the time of diagnosis.

BREAST CANCER CARE PROCESS: Diagnosis; treatment; rehabilitation, follow-up & survivorship care, and palliative care.

MEASUREMENT OF COMPLIANCE	
DGN-TRT-1.1 criterion	The BCS has at least 2 breast care nurses[53] available throughout the entire patient care pathway (through diagnosis, treatment, rehabilitation and follow-up, and in case of recurrence and metastatic disease) to guarantee continuity of care; offer advice, support and further explanation of the treatment plan; and educational information about side effects.
DGN-TRT-1.2 criterion	The breast care nurse provides the clinical director with a report on all activities at least annually.
DGN-TRT-1.3 indicator	Proportion of women newly diagnosed with breast cancer who had a consultation with a breast care nurse at the time of diagnosis. **Norm ≥ 95 %**
EVIDENCE OF COMPLIANCE	
DGN-TRT-1.1	• The human resources list/document. • Direct observation by the auditors. • Patients' medical records from the last 12 months showing entries by breast care nurses.
DGN-TRT-1.2	Breast care nurses' reports.

[53] The professional profiles involved, and their tasks, education and supervision needs are consistent with those described in requirement GEN-1 (see also Glossary).

DGN-TRT-2: 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) and after their primary treatment. The BCS must report the time between the date of the MDM discussion and the start of the first treatment.

BREAST CANCER CARE PROCESS: Diagnosis; treatment.

MEASUREMENT OF COMPLIANCE	
DGN-TRT-2.1 criterion	There is a standard operating procedure describing how MDMs are managed, including team composition, meeting schedules, the team's role and responsibilities, how patients are referred to the MDM, and reports.
DGN-TRT-2.2 criterion	Participation of the following professionals in MDMs is mandatory: breast radiologists, oncoplastic breast surgeons (or both breast surgeons and plastic surgeons), pathologists, medical oncologists, radiation oncologists and breast care nurses. Psycho-oncologists, physicians with additional training in palliative medicine and data managers also attend MDMs when necessary.
DGN-TRT-2.3 indicator	Proportion of women with breast cancer (absolute number of women counted) discussed by the multidisciplinary team at least once before they start treatment or after their primary treatment. **Norm ≥ 90 %**
DGN-TRT-2.4 indicator	Median number of working days between the date of the MDM discussion and the start of the first treatment. **Indicator for monitoring purposes.**
EVIDENCE OF COMPLIANCE	
DGN-TRT-2.1 and DGN-TRT-2.2	Procedures and/or records that include all the elements mentioned in the criteria.

DGN-TRT-3: PSYCHO-ONCOLOGY CARE

STATEMENT
The BCS must have psycho-oncological care available (provided by specialists)[54].

BREAST CANCER CARE PROCESS: Diagnosis; treatment; rehabilitation, follow-up & survivorship care, and palliative care.

MEASUREMENT OF COMPLIANCE	
DGN-TRT-3.1 criterion	Patients have timely access to distress screening and psycho-oncological care throughout the patient journey.
DGN-TRT-3.2 criterion	Psycho-oncology care is provided within the BCS or in coordination with other centres or providers. If such care is provided outside the BCS, the psycho-oncologist interacts with the multidisciplinary team when necessary.
DGN-TRT-3.3 criterion	The psycho-oncological care includes patient, partner and family information, patient distress assessment, intervention and psychosocial care.
DGN-TRT-3.4 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.
EVIDENCE OF COMPLIANCE	
DGN-TRT-3.1	• 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. • Documents and procedures on: - 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.
DGN-TRT-3.2	Records of multidisciplinary meetings showing the participation of the psycho-oncologist; or records documenting interaction with the psycho-oncologist if the psycho-oncologist services are provided outside the centre.
DGN-TRT-3.3	Evidence that the psycho-oncological care received includes patient, partner and family information, patient distress assessment, intervention and psychosocial care.
DGN-TRT-3.4	Documented procedure outlining how the BCS monitors the proportion of women who are assessed for psycho-oncological distress and referred for psycho-oncological care.

[54] The professional profiles involved, and their tasks, education and supervision needs are consistent with those described in requirement GEN-1 (see also Glossary).

DGN-TRT-4: PRE-TREATMENT DIAGNOSIS

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

BREAST CANCER CARE PROCESS: Diagnosis; treatment.

MEASUREMENT OF COMPLIANCE	
DGN-TRT-4.1 indicator	Proportion of women (breasts counted) with breast cancer (invasive or non-invasive), who had a histologically confirmed malignant diagnosis before their first treatment. **Norm ≥ 95 %**

DGN-TRT-5: ASSESSMENT OF BIOMARKERS BEFORE STARTING TREATMENT

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

BREAST CANCER CARE PROCESS: Diagnosis; treatment.

MEASUREMENT OF COMPLIANCE	
DGN-TRT-5.1 indicator	Proportion of women with invasive breast cancer for whom the following biomarkers have been collected and assessed before starting treatment: ER, PR and HER2 status. **Norm ≥ 95 %**

DGN-TRT-6: LEAD TIME BETWEEN PATHOLOGY REPORT WITH DIAGNOSIS AND FIRST TREATMENT

STATEMENT

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

BREAST CANCER CARE PROCESS: Diagnosis; treatment.

MEASUREMENT OF COMPLIANCE	
DGN-TRT-6.1 indicator	Proportion of women diagnosed in the BCS with a lead time of no longer than 4 weeks between the date of issue of the pathology report with a diagnosis of breast cancer and the start of the first treatment. **Norm ≥ 90 %**

CHAPTER 5

TREATMENT REQUIREMENTS (TRT)

Treatment (TRT)

Surgery (TRT-SUR)

Systemic therapy (TRT-SYS)

Radiotherapy (TRT-RAD)

TRT-1: MEDICATION SAFETY

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

BREAST CANCER CARE PROCESS: Treatment.

MEASUREMENT OF COMPLIANCE	
TRT-1.1 criterion	The BCS meets legal requirements and standards of practice when administering medications.
TRT-1.2 criterion	The BCS monitors and reports its use of medications through ongoing use reviews, 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.
TRT-1.3 criterion	The BCS has procedures in place: • to evaluate patients' requests to bring in and/or self-administer their own medication; • to respond to requests for medication and medication information after business hours and in emergencies; • for prescribing, preparing, storing, using and administering cytotoxic drug products.
TRT-1.4 criterion	The BCS identifies the team members who are qualified to prescribe, administer, store, handle and dispose of medications, and document medication information in the patient record. Qualified staff must: • review each prescription for completeness and accuracy, before dispensing medication; • regularly review each patient's prescriptions to assess the appropriateness of each medication, the use of multiple medications, and possible drug interactions; • store and dispose of medications safely and securely; • complete prescriptions and dispense medication in a timely and accurate manner.

EVIDENCE OF COMPLIANCE	
TRT-1.1	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.
TRT-1.2	• Assessment reports on medication use according to protocols. • Reports from the incident reporting and learning system (from the pharmaceutical service or from the hospital).

EVIDENCE OF COMPLIANCE	
TRT-1.3	Evidence of the procedures that are in place and the professionals' awareness of them.
TRT-1.4	• List of responsible, qualified team members. • Patients' medical records from the last 12 months (including complete medical orders and medication administration). • Process of dispensing medication and by whom and how the appropriateness review of medication prescriptions is performed. • Medication storage areas throughout the BCS.

TRT-2: FERTILITY PRESERVATION

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

BREAST CANCER CARE PROCESS: Treatment.

MEASUREMENT OF COMPLIANCE	
TRT-2.1 criterion	Patients are informed about the possibility of fertility preservation as early as possible before treatment starts.
TRT-2.2 criterion	Patients with breast cancer who express an interest in fertility preservation are referred to reproductive specialists.

EVIDENCE OF COMPLIANCE	
TRT-2.1	• Policy setting out when and how the patients are informed. • Evidence of implementation of the policy.
TRT-2.2	Medical records of patients who have undergone treatments that can induce sterility.

TRT-3: PHYSICAL ACTIVITY AND NUTRITION DURING TREATMENT AND FOLLOW-UP

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

BREAST CANCER CARE PROCESS: Treatment; rehabilitation, follow-up & survivorship care, and palliative care.

MEASUREMENT OF COMPLIANCE	
TRT-3.1 criterion	The BCS has a policy to offer (wherever possible) or recommend nutritional care and physical activity programmes to their patients.
TRT-3.2 criterion	Professionals specialised in nutrition and physical therapy are available nearby.
TRT-3.3 criterion	The BCS has implemented the policy during regular follow-up visits and assessed compliance.
EVIDENCE OF COMPLIANCE	
TRT-3.1	Protocol that includes specific information on nutrition and physical activity programmes.
TRT-3.2	List of staff or outsourced services.
TRT-3.3	Evidence of assessments on policy compliance.

TRT-4: PAIN MANAGEMENT

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

BREAST CANCER CARE PROCESS: Treatment; rehabilitation, follow-up & survivorship care, and palliative care.

MEASUREMENT OF COMPLIANCE	
TRT-4.1 criterion	The BCS has a written policy stating that every patient has access to pain management (including screening, assessment and interventions), a pain and palliative care specialist and referral to palliative care.
TRT-4.2 criterion	The BCS has protocols for pain management.
TRT-4.3 criterion	The pain management service includes patient and family information.
TRT-4.4 criterion	The policy includes the description of a workforce equipped for pain management, including professional profiles, tasks, education requirements and supervision requirements.
EVIDENCE OF COMPLIANCE	
TRT-4.1	Policy for pain management or 'Statement of patient rights', including referral to palliative care.
TRT-4.2	Protocol for acute and chronic pain management, including procedures for pain assessment in all circumstances (i.e. scales for different patient populations).
TRT-4.3	Records showing that patients have been informed, assessed, and whether any alternatives to pharmacological treatment have been offered.
TRT-4.4	Policy for the pain management service, including the workforce's: • professional profiles, • tasks, • education requirements, • supervision requirements.

TRT-5: COMPLEMENTARY AND INTEGRATIVE MEDICINE

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.

BREAST CANCER CARE PROCESS: Treatment; rehabilitation, follow-up & survivorship care, and palliative care.

MEASUREMENT OF COMPLIANCE	
TRT-5.1 criterion	The BCS has implemented a written policy to ensure discussion of the use of complementary and integrative medicine.
EVIDENCE OF COMPLIANCE	
TRT-5.1	• Policy on the use of complimentary and integrative medicine. • Evidence of implementation of the policy.

TRT-6: LEAD TIME BETWEEN LAST SURGERY AND FIRST ADJUVANT CHEMOTHERAPY CYCLE

STATEMENT

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

BREAST CANCER CARE PROCESS: Treatment.

MEASUREMENT OF COMPLIANCE	
TRT-6.1 indicator	Proportion of surgically treated women with M0, invasive breast cancer, without radiotherapy between surgery and adjuvant chemotherapy, who started chemotherapy within ≤ 8 weeks after surgery. **Norm ≥ 80 %**

TRT-7: LEAD TIME TO FIRST RADIOTHERAPY TREATMENT

STATEMENT

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

BREAST CANCER CARE PROCESS: Treatment.

MEASUREMENT OF COMPLIANCE	
TRT-7.1 indicator	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 after the date of the last cycle of adjuvant chemotherapy. **Norm ≥ 80 %**

TRT-SUR-1: SENTINEL LYMPH NODE BIOPSY

STATEMENT

All surgically treated women with clinically node-negative (cN0) invasive breast cancer must undergo a sentinel lymph node biopsy (SLNB).

BREAST CANCER CARE PROCESS: Diagnosis; treatment.

MEASUREMENT OF COMPLIANCE	
TRT-SUR-1.1 indicator	Proportion of surgically treated women with cN0 invasive breast cancer who underwent SLNB. **Norm ≥ 90 %**

TRT-SUR-2: AVOID AXILLARY LYMPH NODE DISSECTION FOR PATHOLOGICAL NODE-NEGATIVE INVASIVE BREAST CANCER

STATEMENT

Most surgically treated women with pathological node-negative (pN0) invasive breast cancer must not undergo axillary lymph node dissection (ALND) (staged by SLNB only).

BREAST CANCER CARE PROCESS: Treatment.

MEASUREMENT OF COMPLIANCE	
TRT-SUR-2.1 indicator	Proportion of surgically treated women with pN0 invasive breast cancer who did not undergo ALND (staged by SLNB only). **Norm ≥ 80 %**

TRT-SUR-3: AVOID AXILLARY LYMPH NODE DISSECTION FOR DCIS

STATEMENT

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

BREAST CANCER CARE PROCESS: Treatment.

MEASUREMENT OF COMPLIANCE	
TRT-SUR-3.1 indicator	Proportion of surgically treated women with DCIS who did not undergo ALND. **Norm ≥ 95 %**

TRT-SUR-4: BREAST-CONSERVING SURGERY FOR DCIS

STATEMENT

Most women with DCIS with a radiological tumour extent ≤ 2 cm must not undergo mastectomy as the first choice of surgical treatment.

BREAST CANCER CARE PROCESS: Treatment.

MEASUREMENT OF COMPLIANCE	
TRT-SUR-4.1 indicator	Proportion of surgically treated women with DCIS with a radiological tumour extent ≤ 2 cm who did not undergo primary mastectomy. **Norm ≥ 80 %**

TRT-SUR-5: BREAST-CONSERVING SURGERY FOR INVASIVE BREAST CANCER WITH SMALL TUMOUR SIZE

STATEMENT

Most surgically treated women with invasive breast cancer with a pathological tumour size pT1[55] (≤ 2 cm) must be offered breast-conserving treatment as the first choice of treatment.

BREAST CANCER CARE PROCESS: Treatment.

MEASUREMENT OF COMPLIANCE	
TRT-SUR-5.1 indicator	Proportion of surgically treated women with invasive breast cancer with a tumour size pT1 (≤ 2 cm) who underwent breast-conserving surgery. **Norm ≥ 70 %**

[55] According to UICC TNM classification of malignant tumours, 8th edition. See Glossary.

TRT-SUR-6: SINGLE BREAST OPERATION FOR PRIMARY DCIS

STATEMENT

Most surgically treated women with DCIS must undergo only 1 operation for the primary tumour.

BREAST CANCER CARE PROCESS: Treatment.

MEASUREMENT OF COMPLIANCE	
TRT-SUR-6.1 indicator	Proportion of surgically treated women with DCIS who underwent only 1 breast operation for the primary tumour. **Norm ≥ 70 %**

TRT-SUR-7: SINGLE BREAST OPERATION FOR PRIMARY INVASIVE BREAST CANCER

STATEMENT

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

BREAST CANCER CARE PROCESS: Treatment.

MEASUREMENT OF COMPLIANCE	
TRT-SUR-7.1 indicator	Proportion of surgically treated women with invasive breast cancer (T1, T2) who underwent only 1 breast operation for the primary tumour. **Norm ≥ 80 %**

TRT-SUR-8: BREAST RECONSTRUCTION AFTER MASTECTOMY

STATEMENT

Women who have undergone a mastectomy must be offered immediate breast reconstruction, unless otherwise clinically indicated and considering the patient's preference. When breast reconstruction is not immediate, women must be offered delayed breast reconstruction within 2 years following a mastectomy.

BREAST CANCER CARE PROCESS: Treatment.

MEASUREMENT OF COMPLIANCE	
TRT-SUR-8.1 criterion	The BCS has a policy in place to ensure that women who have undergone a mastectomy are offered breast reconstruction immediately, unless otherwise clinically indicated and considering the patient's preference. When breast reconstruction is not immediate, women must be offered delayed breast reconstruction within 2 years following a mastectomy.

EVIDENCE OF COMPLIANCE

Policy regarding breast reconstruction following a mastectomy. Records demonstrating compliance with the policy.

TRT-SYS-1: NEOADJUVANT CHEMOTHERAPY FOR STAGE II AND STAGE III TRIPLE NEGATIVE BREAST CANCER

STATEMENT

Women with stage II and stage III[56] triple negative breast cancer must be offered neoadjuvant chemotherapy.

BREAST CANCER CARE PROCESS: Treatment.

MEASUREMENT OF COMPLIANCE	
TRT-SYS-1.1 indicator	Proportion of women with stage II and stage III triple negative breast cancer who underwent neoadjuvant chemotherapy. **Indicator for monitoring purposes.**

[49] According to UICC TNM classification of malignant tumours, 8th edition. See Glossary.

TRT-SYS-2: NEOADJUVANT SYSTEMIC THERAPY FOR STAGE II AND STAGE III HER2-POSITIVE BREAST CANCER

STATEMENT

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

BREAST CANCER CARE PROCESS: Treatment.

MEASUREMENT OF COMPLIANCE	
TRT-SYS-2.1 indicator	Proportion of women with stage II and stage III HER2-positive breast cancer who underwent neoadjuvant systemic therapy. **Indicator for monitoring purposes.**

TRT-SYS-3: NEOADJUVANT SYSTEMIC THERAPY FOR LOCALLY ADVANCED BREAST CANCER

STATEMENT

All women with locally advanced breast cancer (at least those with tumour T4 or nodal status ≥ N2) must undergo neoadjuvant systemic therapy.

BREAST CANCER CARE PROCESS: Treatment.

MEASUREMENT OF COMPLIANCE	
TRT-SYS-3.1 indicator	Proportion of women with locally advanced breast cancer (at least those with tumour T4 or nodal status ≥ N2) who underwent neoadjuvant systemic therapy. **Norm ≥ 90 %**

TRT-SYS-4: ENDOCRINE THERAPY FOR SURGICALLY TREATED, ER-POSITIVE AND/OR PR-POSITIVE, INVASIVE BREAST CANCER

STATEMENT
All surgically treated women with hormone sensitive (ER-positive and/or PR-positive), M0, invasive breast cancer must be recommended endocrine therapy according to their treatment plan (e.g. recommended by the MDM).

BREAST CANCER CARE PROCESS: Treatment.

MEASUREMENT OF COMPLIANCE	
TRT-SYS-4.1 indicator	Proportion of surgically treated women with ER-positive and/or PR-positive, M0, invasive breast cancer who were recommended endocrine therapy. **Norm ≥ 85 %**

TRT-SYS-5: ADJUVANT CHEMOTHERAPY FOR SURGICALLY TREATED, ER-NEGATIVE, INVASIVE BREAST CANCER

STATEMENT
All surgically treated women with ER-negative, ≥T1c or node-positive (N+), M0, invasive breast cancer must undergo adjuvant chemotherapy.

BREAST CANCER CARE PROCESS: Treatment.

MEASUREMENT OF COMPLIANCE	
TRT-SYS-5.1 indicator	Proportion of surgically treated women with ER-negative, ≥T1c or N+, M0, invasive breast cancer who underwent adjuvant chemotherapy. **Norm ≥ 85 %**

TRT-SYS-6: ANTI-HER2 THERAPY FOR HER2-POSITIVE BREAST CANCER RECEIVING CHEMOTHERAPY

STATEMENT
All women with HER2-positive, M0, invasive breast cancer receiving neoadjuvant and/or adjuvant chemotherapy must also receive anti-HER2 therapy.

BREAST CANCER CARE PROCESS: Treatment.

MEASUREMENT OF COMPLIANCE	
TRT-SYS-6.1 indicator	Proportion of women with HER2-positive, M0, invasive breast cancer receiving neoadjuvant chemotherapy who also received neoadjuvant anti-HER2 therapy. **Norm ≥ 90 %**
TRT-SYS-6.2 indicator	Proportion of women with HER2-positive, M0, invasive breast cancer receiving adjuvant chemotherapy who also received adjuvant anti-HER2 therapy. **Norm ≥ 90 %**

TRT-SYS-7: MONITORED CARDIAC FUNCTION FOR BREAST CANCER TREATED WITH ANTI-HER2

STATEMENT
All women with breast cancer treated with anti-HER2 therapy must undergo cardiac function monitoring before, at the end of the treatment and regularly during the treatment (at least once during the treatment).

BREAST CANCER CARE PROCESS: Treatment.

MEASUREMENT OF COMPLIANCE	
TRT-SYS-7.1 indicator	Proportion of women with breast cancer treated with anti-HER2 therapy and whose cardiac function is monitored before, at the end of the treatment and regularly during the treatment (at least once during the treatment). **Norm ≥ 95 %**

TRT-SYS-8: ENDOCRINE-BASED THERAPY AS FIRST-LINE TREATMENT FOR METASTATIC, ER-POSITIVE AND HER2-NEGATIVE BREAST CANCER

STATEMENT

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

BREAST CANCER CARE PROCESS: Treatment.

MEASUREMENT OF COMPLIANCE	
TRT-SYS-8.1 indicator	Proportion of women with ER-positive and HER2-negative metastatic (at diagnosis) breast cancer who underwent only endocrine-based therapy as the first-line of treatment for their metastatic disease. **Norm ≥ 75 %**
TRT-SYS-8.2 indicator	Proportion of women with ER-positive and HER2-negative metachronous metastatic breast cancer who underwent only endocrine-based therapy in the first-line of treatment for their metastatic disease. **Norm ≥ 75 %**

TRT-SYS-9: BONE-MODIFYING AGENTS FOR BONE METASTASES FROM BREAST CANCER

STATEMENT

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

BREAST CANCER CARE PROCESS: Treatment.

MEASUREMENT OF COMPLIANCE	
TRT-SYS-9.1 indicator	Proportion of women diagnosed with breast cancer with bone metastasis who receive bone-modifying agents. **Norm ≥ 90 %**

TRT-RAD-1: ADJUVANT RADIOTHERAPY FOR M0, INVASIVE BREAST CANCER TREATED 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.

BREAST CANCER CARE PROCESS: Treatment.

MEASUREMENT OF COMPLIANCE	
TRT-RAD-1.1 indicator	Proportion of women with M0, invasive breast cancer treated with breast-conserving therapy who underwent whole breast adjuvant radiotherapy or, when indicated, partial breast radiotherapy. **Norm ≥ 90 %**

TRT-RAD-2: RADIOTHERAPY FOR INVASIVE BREAST CANCER AFTER MASTECTOMY

STATEMENT

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

BREAST CANCER CARE PROCESS: Treatment.

MEASUREMENT OF COMPLIANCE	
TRT-RAD-2.1 indicator	Proportion of women with M0, invasive breast cancer with ≥ 4 axillary lymph nodes involved, who underwent local or regional radiotherapy after mastectomy. **Norm ≥ 90 %**

CHAPTER 6:

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

RHB-1: LYMPHOEDEMA SERVICE

STATEMENT

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

BREAST CANCER CARE PROCESS: Treatment; rehabilitation, follow-up & survivorship care, and palliative care.

MEASUREMENT OF COMPLIANCE	
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.
RHB-1.2 criterion	Treatment includes, but is not limited to, complex decongestive physical therapy treatment.
RHB-1.3 criterion	Treatment is conducted by a specialised lymphoedema service provider based on a multidisciplinary treatment plan.
RHB-1.4 criterion	Treatment is conducted by the BCS or in coordination with another centre or provider.
RHB-1.5 criterion	The BCS conducts an annual review of the implementation of the BCS' policy, including (but not limited to) reporting on the proportion of patients treated for lymphoedema.
EVIDENCE OF COMPLIANCE	
RHB-1.1	Policy regarding the management of lymphoedema.
RHB-1.2	Protocol for the treatment of lymphoedema.
RHB-1.3	• Staff record of the team members responsible for the lymphoedema service. • Medical or treatment records.
RHB-1.4	Records of lymphoedema services provided by the BCS (internally or outsourced).
RHB-1.5	Reports assessing the implementation of the policy in the previous year.

FLW-1: FOLLOW-UP OF ASYMPTOMATIC WOMEN AFTER PRIMARY THERAPY

STATEMENT

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

BREAST CANCER CARE PROCESS: Rehabilitation, follow-up and survivorship care.

MEASUREMENT OF COMPLIANCE		
	FLW-1.1 criterion	The BCS has protocols to avoid routine intensive follow-up for asymptomatic women after primary therapy for breast cancer. The protocol describes the specific tests/checks that are performed (this may include PET scan, bone scan, complete blood count testing, tumour markers, chest X-ray, liver ultrasound or calculated tomography) and the timeline.
EVIDENCE OF COMPLIANCE		
	FLW-1.1	Documents/protocols on tests that should performed on asymptomatic women after primary therapy for breast cancer.

FLW-2: EARLY DETECTION OF RECURRENCE

STATEMENT

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

BREAST CANCER CARE PROCESS: Rehabilitation, follow-up & survivorship care, and palliative care.

MEASUREMENT OF COMPLIANCE	
FLW-2.1 criterion	The BCS has a follow-up policy that includes a plan for collecting longitudinal data on recurrence rate and vital status.
FLW-2.2 criterion	Follow-up includes a plan for a mammography in the BCS.
FLW-2.3 criterion	Follow-up includes a plan for referral back to a regular screening programme.
FLW-2.4 criterion	Follow-up is done within the BCS in coordination with other centres and providers.
FLW-2.5 criterion	The follow-up policy complies with current (inter)national guidelines.
FLW-2.6 criterion	The BCS conducts an annual review of the follow-up policy.
EVIDENCE OF COMPLIANCE	
FLW-2.1	Information system designed for the collection, storage and management of data on recurrence rate and vital status.
FLW-2.2 and FLW-2.3	Follow-up policy.
FLW-2.4	Medical records of patients with over 5 years' survival to verify that the follow-up includes coordination with other specialists for early detection of recurrence.
FLW-2.5	The policy references (inter)national guidelines.
FLW-2.6	Records of the annual review.

FLW-3: SURVIVORSHIP POLICY

STATEMENT

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

BREAST CANCER CARE PROCESS: Rehabilitation, follow-up & survivorship care, and palliative care.

MEASUREMENT OF COMPLIANCE	
FLW-3.1 criterion	The BCS has a comprehensive breast cancer survivorship care process, including an assessment of the survivor's needs and a personalised survivorship care plan with accompanying treatment summary. The survivorship care plan includes: • information; • advice and support to address acute, late and long-term side effects of treatment, including (but not limited to) physiotherapy treatment for arm and shoulder mobility; • counselling on nutrition, physical exercise, and psychosocial and sexual health.
FLW-3.2 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.
FLW-3.3 criterion	Survivorship care is consistent with the policy for follow-up care.
FLW-3.4 criterion	Survivorship care is done within the BCS or in coordination with other centres or providers.
EVIDENCE OF COMPLIANCE	
FLW-3.1	Survivorship care protocol/policy.
FLW-3.2	Medical records.
FLW-3.3	Evidence that the survivorship policy is consistent with the follow-up care policy.
FLW-3.4	Records of survivorship care services provided by the BCS (internally or outsourced).

PAL-1: PALLIATIVE CARE POLICY

STATEMENT

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

BREAST CANCER CARE PROCESS: Diagnosis; treatment; rehabilitation, follow-up & survivorship care, and palliative care.

MEASUREMENT OF COMPLIANCE	
PAL-1.1 criterion	There is a team providing palliative care, which includes a physician, nurse and other healthcare providers.
PAL-1.2 criterion	There are documented procedures on the composition, roles and duties of the team providing palliative care.
PAL-1.3 criterion	A physician with additional training in palliative medicine is available for consultation and, where necessary attends MDMs. If the centre does not have one available, written procedures and agreements should be in place with outsourced services.
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.
PAL-1.5 criterion	The following services are accessible to patients with advanced disease, according to their needs: • Inpatient consulting team; • Outpatient palliative care clinic; • Hospice/palliative care unit; • Home care service. If these services are not available at the centre or institution of which the breast cancer centre is part, arrangements should be established with external providers that offer these services.
PAL-1.6 criterion	There are documented procedures detailing how the patient can access the abovementioned services.

EVIDENCE OF COMPLIANCE	
PAL-1.1, PAL-1.2 and PAL-1.3	• Staff records of the team for palliative care and evidence of credentials of at least one person trained in palliative care medicine. • Records describing the roles of staff providing palliative care.
PAL-1.4	Official document describing the coordination network for the provision of palliative care.
PAL-1.5	Records of palliative care services provided by the BCS (internally or outsourced).
PAL-1.6	Procedures and/or records of patient referral to palliative care services.

GLOSSARY

Accreditation
Formal recognition by an independent body, of organisational competence and compliance with specific requirements that are typically published as national or ISO standards. Accreditation involves the assessment of the competence and impartiality of an organisation and the compliance of their work to nationally and internationally recognised standards or schemes, such as the ISO/IEC 17065 service certification standard.

In the context of the European legal framework on accreditation, Regulation (EC) No 765/2008 states that 'accreditation shall mean an attestation by a national accreditation body that a conformity assessment body meets the requirements set by harmonised standards and, where applicable, any additional requirements including those set out in relevant sectoral schemes, to carry out a specific conformity assessment activity.' (Regulation (EC) No 765/2008; ISO/IEC 17000:2020(E)).

The term 'accreditation' can have other meanings in different contexts. A description of some of these different contexts is given in the 2015 European Commission publication:
Joint Research Centre, Institute for Health and Consumer Protection, Lerda, D., Neamtiu, L., Ulutürk, A. et al., *Review and analysis of external quality assessment of breast cancer services in Europe – Supporting information for the development of a European quality assurance scheme for breast cancer services,* Publications Office, 2015. https://data.europa.eu/doi/10.2788/446515.

Accreditation certificate
In the context of the European legal framework on accreditation, a formal document or set of documents stating that accreditation has been granted to a conformity assessment body for the defined scope.

Accreditation symbol
In the context of the European legal framework on accreditation: a symbol issued by an accreditation body to be used by accredited certification bodies to indicate they are accredited (adapted from ISO/IEC 17011).

Accredited certification
It is the confirmation that an organisation, product or service complies with the criteria laid out in a recognised standard, i.e. ISO 9001, or a scheme, i.e. European QA Scheme, where certification is carried out by a certification body that is accredited to ISO/IEC 17065.

Agreement
A document describing the processes and procedures that discreet entities (such as geographically separate locations of the same legal entity or different legal entities cooperating in breast cancer care) agree to implement.

Appeal
Request for reconsideration of a decision made by a certification body with regard to a cancer care service (adapted from ISO/IEC 17000).

Audit
Systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which specified requirements are fulfilled (ISO 19011, ISO 9000, ISO/IEC 17000).

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

Audit team
All personnel who are involved in auditing a cancer care service, whether in an on-site visit to the cancer care service or by carrying out other off-site auditing activities (e.g. individuals with specialist expertise who may be consulted on limited aspects of a cancer care service's activities) (ISO 19011).

Auditor
A person qualified to carry out audits for or on behalf of a certification body (ISO/IEC 17021-1).

Breast cancer centre
An entity that is responsible for providing breast cancer diagnosis, treatment, rehabilitation, follow-up and survivorship, and palliative care. Some of these activities may be provided by different entities, but the breast cancer care must be coordinated by the BCS responsible entity to ensure continuity of care.

Breast cancer services
Comprises all healthcare services or entities covering the full extent of breast cancer management, from screening to 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.

The term '**cancer care services**' is used when the context is not specific to the European QA scheme for breast cancer services but also applicable to forthcoming European QA schemes for other cancers.

(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).

Breast cancer service entity or entities (or BCS)
The body that has legal responsibility for any part of the breast cancer service. A cancer care service entity is used when the context is not specific to the European QA scheme for breast cancer services but also applicable to forthcoming European QA schemes.

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.

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

Certification

A formal attestation by an independent, impartial organisation (certification body) that a cancer care service and their providers have been audited and have demonstrated that they meet all the European QA scheme requirements.

(Adapted from ISO definition (https://www.iso.org/certification.html): 'the provision by an independent body of written assurance (a certificate) that the product, service or system in question meets specific requirements'.)

For *accredited certification* see respective glossary term above.

Certification body

An organisation that is a legal entity or part of a legal entity that provides audit and certification services. For clarity, within this manual the specific term 'certification body' is used to refer to a body performing auditing and/or certification. The certification body activities are incorporated in the broader term of conformity assessment, thus a certification body may also be referred to as a conformity assessment body (see ISO/IEC 17065 'certification body: third-party conformity assessment body operating certification schemes').

Certification decision

Granting, continuing, expanding or reducing the scope of, or suspending, restoring, withdrawing or refusing certification by a certification body (ISO/IEC 17000).

Certification module

A certification module is a defined set of requirements for which certification can be granted. The certification modules include distinct or an aggregation of processes (e.g. screening, diagnosis, treatment, follow-up, rehabilitation, palliative care and the complete care pathway) that fall under the responsibility of a single entity.

Competence
Demonstrated ability to apply knowledge and skills to achieve intended results (ISO 19011).

Complaint
Expression of dissatisfaction, other than appeal, by any person or organisation to a conformity assessment body or an accreditation body, relating to the activities of that body, where a response is expected (ISO/IEC 17000).

Complementary and integrative medicine
A group of diverse medical healthcare services, practices and products that are not generally considered to be part of conventional medicine but are used alongside conventional medicine. The goal is to provide comprehensive care that considers all aspects of wellbeing.

Conformity assessment body
Body that performs conformity assessment activities and that can be the object of accreditation (ISO/IEC 17011). Conformity assessment activities include calibration, testing, certification and inspection (Regulation EC 765/2008) (ISO/IEC 17000). Inspection bodies and certification bodies are types of conformity assessment bodies that perform specific conformity assessment activities. For clarity, within this manual the specific term 'certification body' is used to refer to a body performing auditing and/or certification.

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. It involves maintaining an ongoing relationship between a patient and health care provider(s) across various settings, such as different facilities, hospitals, clinics and home care.

Contract
A legally binding agreement that sets out terms and conditions, including financial remuneration, between different entities (see also ISO 9000:2015 'Contract: binding agreement').

Early recall
The recommendation for a woman to undergo short-term re-screening at a time interval that is less than the programme's routine interval or screening round length.

Evaluation
A combination of selection and determination functions of conformity assessment activities (ISO/IEC 17065). These functions include sampling, testing, inspection, audit, validation, verification and peer assessment (ISO/IEC 17000). Specifically for the European QA scheme, evaluation includes the process of selecting and or collecting the material or data related to the requirements as well as the process of determining the extent to which the specified requirements are fulfilled.

Exceptional practice
Exceptional practices are where the cancer care service is delivering outstanding care to patients, excellent training and support for staff, first-class facilities and environment, or any other outstanding aspect of the service. It also includes any improvements made to cancer care service processes and sub-processes.

External provider
In the context of the European QA scheme, an external provider is an organisation that, through formal arrangements with the responsible legal entity, provides services related to cancer care that are processes or sub-processes that do not fall within the scope of a certification module and/or are not normally performed by the responsible legal entity for the BCS.
'External provider: Provider that is not part of the organisation' (ISO 9000).
Examples of services that may be externally provided for a BCS through an agreement are: magnetic resonance imaging, contrast-enhanced mammography, interventional radiology, genetic testing and nuclear medicine.

External resources
Different entities or healthcare professionals used by a certification body to audit processes or sub-processes (ISO/IEC 17065).

Extraordinary event or circumstance
An event or circumstance that is beyond the control of the certification body or entity providing a cancer care service, such as: war, strikes, riots, political instability, geopolitical tension, terrorism, crime, pandemics, flooding, earthquakes, malicious computer hacking, and other natural or man-made disasters (IAF ID3 2011).

Formal assurance
An assurance that exists when cancer care service entities achieve accredited certification from certification bodies that have been accredited to the international standard ISO/IEC 17065 by a national accreditation body that is a signatory to a multilateral agreement of the European co-operation for Accreditation (EA).

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).

Lead auditor
An individual that leads and coordinates the audit team's activity. They may also be known as audit team leader (ISO 9000).

Management system
A set of interrelated or interacting elements to establish policies, objectives and processes to achieve those objectives (ISO 9000). It is used to direct and control an organisation with regard to quality and safety management.

Minimum certifiable set of requirements
The set of requirements for a cancer care process within a module, along with associated continuity of care requirements, which is accepted for certification for a limited period of time (Refer to Part I, Chapter 6: Time-limited stepwise approach to certification and to Part II, Chapter 1: Table of Requirements).

National accreditation body
The sole body in a Member State that performs accreditation with authority derived from the State (Regulation EC 765/2008, ISO/IEC 17011).
Accreditation bodies do not develop or publish the standards that are used for accreditation or certification.

Networks
Arrangement whereby different legal entities or geographical locations of the same legal entity work together in cooperation to deliver the entire cancer care service, or discreet processes (such as treatment, surgery or diagnosis) within the cancer care service. Please note that where networks involve different legal entities, each legal entity takes individual responsibility (e.g. for financial arrangements), but all entities cooperate through the terms of an agreement/contract to ensure continuity of patient care.

Non-conformity
Deviation from specified requirements related to the cancer care service or to certification requirements defined by the certification body (ISO/IEC 17021-1).

Non-conformity – contractual
This is any non-conformity relating to contractual requirements of the European QA scheme owner and/or the certification body.

Non-conformity – major
A non-conformity that could result in a failure of the service or a reduced operability of the service that could put patients at risk (ISO/IEC 17021-1).

Non-conformity – minor
A non-conformity that does not in itself adversely affect the performance of the overall service. A number of minor non-conformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major non-conformity (ISO/IEC 17021-1).

Off-site audit activities
Activities such as document examination, telephone interviews, examination of electronic records and other activities that may be carried out remotely by one or more auditors during the audit process before, during and/or after an on-site visit.

On-site audit team
Auditors who attend the premises of a cancer care service entity with the aim of auditing and verifying the compliance of that cancer care service with the European QA scheme requirements.

On-site visits
Attendance by an auditor or team of auditors at the cancer care service entity's site(s) to carry out audit activities to verify the BCS's compliance with the requirements of the European QA scheme.

Opportunity for improvement action
An action that the certification body identifies that the cancer care service entity could take, but which constitutes neither a major nor a minor non-conformity with the European QA scheme requirements and is regarded as an improvement in practices.

Outsourcing
An outsourced service is where an external organisation performs part of a responsible organisation's function or process by means of a supply agreement or contract. The responsibility for the outsourced service remains with the organisation that is procuring the service. 'Outsource: Make an arrangement whereby an external organisation performs part of an organisation's function or process.' (ISO 9000).

In the context of the European QA scheme, outsourced services are generally cancer care services that are within the scope of the certification module but outside of the responsible entity and its collaborators.

Patient safety
Pursuit of the reduction and mitigation of unsafe acts within the healthcare system, as well as the use of best practices shown to lead to optimal patient outcomes.

Policy
A 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. 'Policy: Intentions and direction of an organisation as expressed by its top management.' (ISO 9000).

Primary case
A primary cancer case is defined as a newly diagnosed in situ or invasive breast cancer.

Process
Set of interrelated or interacting activities that result in an outcome. 'Process: set of interrelated or interacting activities which transforms inputs into outputs.' (ISO/IEC 17065).

PROFESSIONS IN BREAST CANCER CARE

i. **Breast care nurse:** a 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. **Clinical geneticist, or medical geneticist:** healthcare professional qualified and trained in medical genetics and genomics, covering the full breadth of clinical diagnosis, familiarity with laboratory techniques, interpretation of data, and genetic counselling.

v. **Data manager:** Responsible for registering, developing, overseeing, organizing, storing, and analysing data, data systems and indicators. A data manager ensures that all of this is always done with the utmost security and confidentiality, and in a timely manner.

vi. **Lymphoedema specialist:** health care professionals with specialised training and expertise in the diagnosis, assessment, and management of (oncology-related) lymphoedema. Recognised professions in Europe that can provide lymphoedema care include: physiotherapists, nurses, occupational therapists, manual lymphatic drainage therapists, and medical doctors/surgeons.

vii. **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.

viii. **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.

ix. **Nuclear medicine specialist:** medical doctor specialised in nuclear medicine (as recognised in EU Directive 2005/36/EC) and qualified to use radiopharmaceuticals to diagnose and treat disease.

x. **Nutritionist:** a healthcare professional trained to perform a variety of dietary related techniques to improve diets of groups or individuals in different settings (as recognised in EU Directive 2005/36/EC and covered by the generic name 'nutritionist/clinical nutritionist' in the European Commission's Regulated Professions Database).

xi. **Oncoplastic breast surgeon:** breast surgeon with knowledge of oncoplastic surgery (combining plastic surgery and oncology surgery to obtain a good aesthetic result and optimum oncological outcomes), and qualified to perform breast surgery and reconstructive surgery.

xii. **Pathologist:** medical doctor specialised in pathology or anatomic pathology (as recognised in EU directive 2005/36/EC) who examines biopsy and surgical specimens to provide a diagnosis, and prognostic and predictive parameters that guide the treatment of individual patients.

xiii. **Physiotherapist:** healthcare professional trained to perform a diagnosis on the basis of physiotherapist assessment and on the safe and effective application of physiotherapy interventions (as recognised in EU Directive 2005/36/EC).

xiv. **Plastic surgeon:** medical doctor specialised in plastic surgery (as recognised in EU Directive 2005/36/EC) and qualified to perform breast reconstruction surgery.

xv. **Psycho-oncologist:** clinical psychologist (as recognised in EU Directive 2005/36/EC) formally trained in the psychosocial aspects of cancer care, or a mental health professional specialised in psycho-oncology.

xvi. **Radiation oncologist:** medical doctor specialised in radiation oncology (as recognised in EU Directive 2005/36/EC) and qualified to treat oncological diseases with radiotherapy.

xvii. **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).

Quality
Degree to which a set of inherent characteristics of a service meets requirements (ISO 9000).

Quality assurance
The systematic monitoring and evaluation of the various aspects of a service to ensure that standards of quality are being met (ISO 9000).

Quality domains
Definable aspects or characteristics of a service, preferably measurable and actionable, which contribute to its overall quality. Also referred to as dimensions of quality. Quality domains can help organisations to assess and improve the quality of their service. This QA scheme focuses on the four domains:

- clinical effectiveness;
- safety;
- facilities, resources and workforce; and
- personal empowerment and experience.

Quality improvement
Implementation of changes to deliver person-centred care that is better, safer, more effective and more efficient, using a range of specific tools and methods (ISO 9000).

Quality indicator
A means of demonstrating that a requirement is being met. Indicators are always linked to a requirement, but not every requirement will have a quantitative indicator to be measured. A quantitative indicator is expressed using a clearly defined numerator and denominator.

Quality potential
Quality potentials correspond to known or anticipated deficits in the quality of care for a specific disease, indication or intervention. They correspond to processes in the care pathway for which under-, over- or inadequate treatment has been reported, meaning that treatment is not being provided at the required quality. Quality potentials are therefore starting points for implementing measures to improve the quality of care (AQUA-Institute, *Allgemeine Methoden im Rahmen der sektorenübergreifenden Qualitätssicherung im Gesundheitswesennach* §137a SGB V, Version 4.0. Göttingen, 2015).

Quality target
A defined parameter within the context of a quality assurance scheme that signifies high-quality healthcare and relate to healthcare being effective, safe and patient-centred (AQUA-Institute, *Allgemeine Methoden im Rahmen der sektorenübergreifenden Qualitätssicherung im Gesundheitswesennach* §137a SGB V, Version 4.0. Göttingen, 2015).

Recall for technical reasons
Calling back an individual to repeat one or multiple mammograms because an image of sufficient quality has not been obtained.

Records
Records contain information from a particular point in time, stating results achieved or providing evidence of activities performed. Records can be in any format or medium, providing they are readily accessible and protected from unauthorised alteration.

'Record: Document stating results achieved or providing evidence of activities performed.' (ISO 9000).

Requirement
In the European QA scheme, a requirement refers to the target level of performance or a standard required with respect to a certain aspect of the cancer screening and care service. 'A need or expectation that is stated, generally implied or obligatory.' (ISO 9000).

Scope
Extent and boundaries of the audit, certification, accreditation or scheme activity. (ISO 19011). 'Scope of certification: identification of the product(s), process(es) or service(s) for which the certification is granted, the applicable certification scheme, and the standard(s) and other normative document(s), including their date of publication, to which it is judged that the product(s), process(es) or service(s) comply.' (ISO/IEC 17065).

Screening programme (organised, population-based)
Legal entity managing a screening process in which the procedures are specified (e.g. standard operating procedures) and a team at national, regional or local level is responsible for implementing the policy (i.e. for coordinating the delivery of screening services, maintaining the required quality, and reporting on performance and results).

Screening service
Entity performing screening procedures/tests and working under an agreement/contract for an organised, population-based screening programme.

Service
Provision of an aspect or aspects of cancer care to a patient by an entity, which may be a legal entity or a clearly defined part of a legal entity, such as a unit, department or centre. 'Service: output of an organisation with at least one activity necessarily performed at the interface between the organisation and the customer.' (ISO 9000).

Shared decision-making
An approach where clinicians and patients make decisions together using the best available evidence. Patients are encouraged to think about the available screening, treatment or management options and the likely benefits and harms of each so that they can communicate their preferences and help select the best course of action for themselves. Shared decision-making respects patient autonomy and promotes patient engagement (Elwyn, G., Laitner, S., Coulter, A., Walker, E., Watson, P., Thomson, R. et al. *Implementing shared decision making in the NHS*. BMJ 2010; 341: c5146; doi:10.1136/bmj.c5146).

Staging
Reference to staging within the European QA scheme for breast cancer care, follows the Union for International Cancer Control (UICC) TNM classification of malignant tumours, 8th edition as illustrated in the table below.

Table 3. Breast Tumours Stage Classification.

Stage		Primary tumour – **T**	Regional lymph nodes – **N**	Distant metastasis – **M**
Stage 0		Tis	N0	M0
Stage I	Stage IA	T1*	N0	M0
	Stage IB	T0, T1	N1mi	M0
Stage II	Stage IIA	T0, T1	N1	M0
		T2	N0	M0
	Stage IIB	T2	N1	M0
		T3	N0	M0

Stage		Primary tumour – **T**	Regional lymph nodes – **N**	Distant metastasis – **M**
Stage III	Stage IIIA	T0, T1, T2	N2	M0
		T3	N1, N2	M0
	Stage IIIB	T4	N0, N1, N2	M0
	Stage IIIC	Any T	N3	M0
Stage IV		Any T	Any N	M1

*T1 includes T1mi

Source: UICC TNM Classification of Malignant Tumours, 8th edition.

Standards making body
An organisation such as the International Organisation for Standardisation (ISO) that develops and publishes technical standard documents.

Survivorship
Survivorship focuses on health and the physical, psychological, social and economic issues affecting people after the end of the primary treatment for cancer. Post-treatment cancer survivors range from people having no disease after finishing treatment, people who continue to receive treatment to reduce the risk of the cancer coming back, and people with well-controlled disease and few, symptoms, who receive treatment to manage cancer as a chronic disease.

Survivorship care includes issues related to follow-up care, the management of late side effects of treatment, the improvement of quality of life, and psychological and emotional health (ESMO Patient Guide on Survivorship, based on the ESMO Clinical Practice Guideline, 2017).

Technical standard
Normative document containing a set of requirements against which something can be measured, judged or evaluated.

TNM classification
References to the TNM clinical classification, pathological classification and staging of breast cancer within this European QA scheme follow the UICC TNM classification of malignant tumours, 8th edition.

ANNEX 1
QUALITY INDICATORS

The European quality assurance (QA) scheme for breast cancer services is a collection of evidence-based requirements (described in the manual of the European Quality Assurance Scheme for Breast Cancer Services) that can be followed by any breast cancer service (BCS) wishing to improve the quality of care offered to women.

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

The breast cancer service will be able to compute the quality indicators from their own data by using this guide, which details criteria for data inclusion, data quality and considerations about missing data. This guide includes all the quality indicators in the ECIBC QA scheme. The list of quality indicators will be needed during the auditing activities but also serves as a quality monitoring tool in the process of quality improvement.

TIME FRAME AND MONITORING

The time frame used for all indicators is the previous calendar year of the site visit.

Indicators for monitoring purposes must be measured at least annually and trends are to be reported. The BCS should analyse data for trends and quality improvement activities. Data can be used for benchmarking purposes.

DATA ELIGIBILITY CRITERIA

Applies to all indicators specified in this Annex in addition to the specific data eligibility:

- Women aged 18 or older;
- Topography in the range C50.0 to C50.9*;
- Patients with prior ipsilateral breast cancer (invasive or in situ) are excluded*.

DATA QUALITY CHECK

VARIABLE VALIDATION

Please refer to the data dictionary for the variable names, format values and the specified references (such as the TNM Classification of Malignant Tumors (TNM) and the International classification of diseases (ICD)).

For each variable, all the values must respect the correct definition, i.e. dates must be valid and integers should not have decimals.

*Applies for the indicators where the diagnosis of invasive or in situ breast cancer is an eligibility criterion.

MISSING DATA CHECKS AND REPORTING

This section defines the general rule on how to deal with missing data for each indicator. Additional considerations for missing values are defined for specific indicators, where applicable. Where missing values imply the absence of an intervention (e.g. dates not reported for events not performed), these should not be considered as missing values but as negative values and be included in the indicator as applicable. For the purpose of this document, the term 'missing values' refers exclusively to the lack of data or information.

The percentage of missing data must be measured and reported for variables needed to:

- assess general data eligibility (age and topography),
- assess indicator-specific eligibility, and
- compute the indicator (numerator, denominator and/or indicator variables).

The percentage of missing data must be calculated before calculating the main indicators. When the percentage of missing data of a variable is higher than an indicative cut-off of 20 %, the indicators using that variable should be interpreted carefully.

Proportion quality indicator: Missing values should not be included in the denominator for the calculation of the indicator and the percentage of missing values documented.

Example: There are 100 eligible women: 10 records have missing data,
50 records fulfil the norm and 40 records do not.
Indicator = 56 % (50/90)
Percentage of missing data = 10 % (10/100)

Time interval quality indicator: Records with missing values in **any** of the date variables used to calculate the indicator should not be included in the indicator calculation. This includes indicators measuring median time and proportion indicators measuring compliance to time intervals (e.g. DGN-1.2, DGN-PTH-4.2, DGN-PTH-4.3, etc.).

COHERENCE CHECKS

This section provides a list of data coherence rules to identify and correct illogical data points. Records that violate any of these checks must be assessed for coherence and corrected. Coherence rules must be implemented to ensure the adherence to the data eligibility criteria or the internal consistency of the data variables in each record.

Age

The age variable must be in a reasonable range above 18 years old to rule out data entry errors.

Date range

For date variables, dates must not be in the future, i.e. beyond the current date.

Date chronology

- Date of symptomatic mammography must precede the date of communication of diagnosis.
- Date of screening mammogram must precede the date of issuing the results.

- Date of result of the screening mammography must precede the date of the assessment offered.
- Date of assessment must precede the date of issuing the result of the assessment.
- Date of screening mammogram must precede the date of the treatment.
- Date of receipt of the breast specimen by the pathology service must precede the date of biopsy released from the pathology service.
- Date of receipt of the breast specimen by the pathology service must precede the date of pathology result from surgical specimen released from the pathology service.
- Date of issue of the pathology report with a diagnosis of cancer must precede the date of the start of the treatment.
- First breast surgery must precede second breast surgery.
- Second breast surgery must precede third breast surgery.
- Date of breast reconstruction cannot precede first breast surgery.
- Neoadjuvant chemotherapy must precede (by definition) first breast surgery.
- Neoadjuvant endocrine therapy must precede (by definition) first breast surgery.
- Neoadjuvant anti HER2-therapy must precede (by definition) first breast surgery.
- Neoadjuvant radiotherapy must precede (by definition) first breast surgery.
- Adjuvant chemotherapy must follow (by definition) first breast surgery.
- Adjuvant radiotherapy must follow (by definition) first breast surgery.
- Neoadjuvant chemotherapy must precede start of adjuvant chemotherapy.
- Neoadjuvant chemotherapy must precede end of adjuvant chemotherapy.
- Start of adjuvant chemotherapy must precede end of adjuvant chemotherapy.
- Neoadjuvant radiotherapy must precede adjuvant radiotherapy.

Surgical data

- Second surgery cannot be a breast conserving surgery after a mastectomy at first intervention.
- Third surgery cannot be a breast conserving surgery after a mastectomy at first intervention.
- Third surgery cannot be a breast conserving surgery after a mastectomy at second intervention.
- Second surgery cannot be a mastectomy after a mastectomy at first intervention.
- Third surgery cannot be a mastectomy after a mastectomy at first intervention.
- Third surgery cannot be a mastectomy after a mastectomy at second intervention.
- Reconstruction can be performed only when a mastectomy has been performed.

Dates not reported for events not performed

- Date of first intervention must not be reported if not performed.
- Date of second intervention must not be reported if not performed.
- Date of third intervention must not be reported if not performed.
- Date of breast reconstruction must not be reported if not performed.
- Date of SLNB must not be reported if not performed.
- Date of axillary lymph node (LN) dissection must not be reported if not performed.
- Date of neoadjuvant chemotherapy must not be reported if not performed.
- Date of neoadjuvant endocrine therapy must not be reported if not performed.
- Date of neoadjuvant anti-hormone therapy must not be reported if not performed.
- Date of neoadjuvant radiotherapy must not be reported if not performed.
- Starting date of neoadjuvant chemotherapy must not be reported if not performed.
- Ending date of neoadjuvant chemotherapy must not be reported if not performed.
- Date of neoadjuvant radiotherapy must not be reported if not performed.

For the relevant indicators within this scheme, the number of LNs should only be considered when sampled during sentinel lymph node biopsy (SLNB) or axillary lymph node dissection (ALND)

- Examined lymph nodes must be reported only when SLNB or ALND is/are performed.
- Metastatic lymph nodes must be reported only when SLNB or ALND is/are performed.
- Number metastatic lymph nodes cannot be greater than the number of examined lymph nodes.

Further checks

There should be no duplicate records.

SCREENING

Indicators should be reported for the first screening round and subsequent screening rounds.

For the screening indicators within this scheme, 'screen-detected' cancer (invasive or in situ) refers to pathologically confirmed breast cancer following a positive screening test.

SCR-1: SCREENING PROGRAMME

SCR-1.10: Proportion of eligible women aged 50-69 who were invited for screening within a screening programme	
Numerator	Number of eligible women aged 50-69, who were invited for screening within a screening programme
Denominator	Total number of eligible women aged 50-69
Data eligibility	• Please refer to the eligibility criteria of the breast cancer screening programme in place in the country from which the BCS originates • Women aged 50-69
Norm	≥ 95 %

SCR-2: REPORTING OF SCREENING INDICATORS

SCR-2.1: Screening coverage	
Numerator	Number of women screened
Denominator	Total number of eligible (or target) women within a given period
Data eligibility	• Please refer to the specific target population and eligibility criteria of the breast cancer screening programme in place in the country from which the BCS originates
Indicator for monitoring purposes	

SCR-2.2: Participation rate	
Numerator	Number of women screened
Denominator	Total number of women invited
Data eligibility	• Please refer to the eligibility criteria of the breast cancer screening programme in place in the country from which the BCS originates
Indicator for monitoring purposes	

SCR-2.3: Recall rate	
Indicator must be reported for the overall screening programme and stratified by each centre performing mammography screening, where applicable	
Numerator	Number of women undergoing further assessment for clinical reasons based on a positive screening examination
Denominator	Total number of women screened for breast cancer
Data eligibility	• Please refer to the eligibility criteria of the breast cancer screening programme in place in the country from which the BCS originates • Women screened for breast cancer
Indicator for monitoring purposes	

SCR-2.4: Breast cancer detection rate	
Indicator must be reported for the overall screening programme and stratified by each centre performing mammography screening, where applicable	
Numerator	Number of cancer cases (invasive and in situ) screen-detected
Denominator	Total number of women screened
Data eligibility	• Please refer to the eligibility criteria of the breast cancer screening programme in place in the country from which the BCS originates • Women screened for breast cancer
Indicator for monitoring purposes	

SCR-2.5: Invasive breast cancer detection rate	
Numerator	Number of invasive cancer cases screen-detected
Denominator	Total number of women screened
Data eligibility	• Please refer to the eligibility criteria of the breast cancer screening programme in place in the country from which the BCS originates • Women screened for breast cancer
Indicator for monitoring purposes	

SCR-2.6: Invasive cancers ≥ 20 mm rate	
Numerator	Number of invasive cancers ≥ 20 mm screen-detected
Denominator	Total number of women screened
Data eligibility	• Please refer to the eligibility criteria of the breast cancer screening programme in place in the country from which the BCS originates • Women screened for breast cancer
Indicator for monitoring purposes	

SCR-2.7: Invasive cancers ≤ 10 mm rate	
Indicator must be reported for the overall screening programme and stratified by each centre performing mammography screening, where applicable	
Numerator	Number of invasive cancers ≤ 10 mm screen-detected
Denominator	Total number of invasive cancers screen-detected
Data eligibility	• Please refer to the specific eligibility criteria of the breast cancer screening programme in place in the country from which the BCS originates • Primary invasive breast cancer cases • Screen-detected breast cancer cases
Indicator for monitoring purposes	

SCR-2.8: Lymph node negative rate	
Numerator	Number of node-negative cancers screen-detected
Denominator	Total number of invasive cancers screen-detected
Data eligibility	• Please refer to the specific eligibility criteria of the breast cancer screening programme in place in the country from which the BCS originates • Primary invasive breast cancer cases • Screen-detected breast cancer cases
Indicator for monitoring purposes	

SCR-2.9: Interval cancer[57] rate	
Numerator	Number of interval cancers
Denominator	Total number of women with a negative screening result at the screening round
Data eligibility	• Please refer to the specific eligibility criteria of the breast cancer screening programme in place in the country from which the BCS originates • Women with a negative breast cancer screening result
Indicator for monitoring purposes	

SCR-2.10: Episode sensitivity	
Numerator	Number of screen-detected cancers
Denominator	Total number of all cancers detected (screen-detected and interval)
Data eligibility	• Please refer to the specific eligibility criteria of the breast cancer screening programme in place in the country from which the BCS originates • Primary invasive and in situ breast cancer cases • All screen-detected and interval breast cancer cases
Indicator for monitoring purposes	

[57] See Glossary

SCR-2.11: Benign open surgery biopsy rate	
Numerator	Number of women found not to have invasive cancer or DCIS after an open surgical biopsy
Denominator	Total number of women screened
Data eligibility	• Please refer to the specific eligibility criteria of the breast cancer screening programme in place in the country from which the BCS originates
Indicator for monitoring purposes	

SCR-2.12: Interval cancer, review errors	
Numerator	Number of interval cancers with previous mammogram reviewed and defined as an incorrect reading (cancer was already visible and detectable)
Denominator	Total number of interval cancers
Data eligibility	• Please refer to the specific target population and eligibility criteria of the breast cancer screening programme in place in the country from which the BCS originates • Primary invasive and in-situ breast cancer cases • Women screened for breast cancer • Interval breast cancer cases
Indicator for monitoring purposes	

SCR-2.13: Advanced cancer (≥ T2[58]), review errors	
Numerator	Number of ≥ T2 screen-detected cancers with previous mammogram (previous round) reviewed and defined as an incorrect reading (cancer was already visible and detectable)
Denominator	Total number of ≥ T2 cancers detected
Data eligibility	• Please refer to the specific eligibility criteria of the breast cancer screening programme in place in the country from which the BCS originates • Primary invasive ≥ T2 breast cancer cases • Screen-detected breast cancer cases
Indicator for monitoring purposes	

[58] According to UICC TNM classification of malignant tumours, 8th edition. See Glossary.

SCR-2.14: Technical repeat examination	
Indicator must be reported separately for each radiographer	
Numerator	Number of women requiring one or more recalls for technical reasons
Denominator	Total number of women screened
Data eligibility	• Please refer to the specific target population and eligibility criteria of the breast cancer screening programme in place in the country from which the BCS originates • Women screened for breast cancer
Indicator for monitoring purposes	

SCR-2.15: Proportion of screened women subject to early recall[59] following diagnostic assessment	
Numerator	Number of women subjected to early recall following diagnostic assessment
Denominator	Total number of women with negative (no cancer) diagnostic assessment
Data eligibility	• Please refer to the specific target population and eligibility criteria of the breast cancer screening programme in place in the country from which the BCS originates • Women with a negative breast cancer screening result
Norm	< 1 %

SCR-2.16: Time between screening mammogram and issuing of results	
Indicator	Time interval between screening mammogram and issuing of first-level screening results: median number of working days
Data eligibility	• Please refer to the specific eligibility criteria of the breast cancer screening programme in place in the country from which the BCS originates • Breast cancer screening result is available
Indicator for monitoring purposes	

[59] A woman is recommended to undergo rescreening at a time interval that is shorter than the programme's routine screening interval. See Glossary.

SCR-2.17: Time between the result of screening mammography and assessment offered	
Indicator	Time between the result of screening mammography and assessment offered: median number of working days
Data eligibility	• Please refer to the specific eligibility criteria of the breast cancer screening programme in place in the country from which the BCS originates • Breast cancer screening result is available • First step of diagnostic assessment took place
Indicator for monitoring purposes	

SCR-2.18: Time between the assessment and issuing the result of the assessment when needle biopsy is performed	
Indicator	Time between the assessment and issuing the result of the assessment when needle biopsy is performed: median number of working days
Data eligibility	• Please refer to the specific eligibility criteria of the breast cancer screening programme in place in the country from which the BCS originates • Diagnostic assessment result is available • Women who underwent a needle biopsy
Indicator for monitoring purposes	

SCR-2.19: Time between the assessment and issuing the result of the assessment when needle biopsy is not performed	
Indicator	Time between the assessment and issuing the result of the assessment when needle biopsy is not performed: median number of working days
Data eligibility	• Please refer to the specific eligibility criteria of the breast cancer screening programme in place in the country from which the BCS originates • Diagnostic assessment result is available • Women who underwent a needle biopsy are excluded
Indicator for monitoring purposes	

SCR-2.20: Time interval between screening and treatment	
Indicator	Time interval between first-level screening mammogram and treatment: median number of working days
Data eligibility	• Please refer to the specific target population and eligibility criteria of the breast cancer screening programme in place in the country from which the BCS originates • Primary invasive and in situ breast cancer cases • Screen-detected breast cancer cases • Patients started breast cancer treatment
Indicator for monitoring purposes	

DIAGNOSIS

DGN-IMG-7: INTRAOPERATIVE SPECIMEN IMAGING

DGN-IMG-7.1: Proportion of women who had intraoperative specimen imaging during breast-conserving surgery for calcifications with image-guided localisation	
Numerator	Number of women who had intraoperative specimen imaging during breast-conserving surgery for calcifications with image-guided localisation
Denominator	Total number of women who had breast-conserving surgery for calcifications with image-guided localisation
Data eligibility	• Women who underwent breast-conserving surgery for breast calcifications in the BCS • Women who underwent image-guided localisation
Norm	≥ 95 %

DGN-IMG-7.2: Proportion of women who underwent surgical lesion removal with intraoperative specimen imaging	
Numerator	Number of women who had intraoperative specimen imaging
Denominator	Total number of women who underwent lesion surgical removal
Data eligibility	• Women who underwent surgical lesion removal in the BCS
Indicator for monitoring purposes	

DGN-1: REPORTING THE PERFORMANCE OF THE DIAGNOSTIC SERVICE

DGN-1.2: Median number of working days between symptomatic mammography and communication of diagnosis (when core needle biopsy is performed), measured as a number of working days	
Indicator	Time between symptomatic mammography and communication of diagnosis (when core needle biopsy is performed), measured as a number of working days
Data eligibility	• Women who underwent a symptomatic mammography in the diagnosis service • Diagnostic assessment result is available • Women who underwent a core needle biopsy
Indicator for monitoring purposes	

DGN-1.3: Median number of working days between symptomatic mammography and communication of diagnosis (when core needle biopsy is not performed), measured as a number of working days	
Indicator	Time between symptomatic mammography and communication of diagnosis (when core needle biopsy is not performed), measured as a number of working days.
Data eligibility	• Women who underwent a symptomatic mammography in the diagnosis service • Diagnostic assessment result is available • Women who underwent a core needle biopsy are excluded
Indicator for monitoring purposes	

DGN-2: DIAGNOSTIC BIOPSY TECHNIQUE

DGN-2.1: Proportion of women with suspicious breast lesions at mammography, ultrasound and/or MRI, who undergo core needle biopsy	
Numerator	Number of women with suspicious breast lesions found at mammography, ultrasound and/or MRI, who undergo core needle biopsy
Denominator	Total number of women with suspicious breast lesions found in mammography (including mass lesions, asymmetric breast density, calcifications and/or architectural distortions)
Data eligibility	• Women with a mammography, ultrasound and/or MRI showing suspicious breast lesions
Norm	≥ 90 %

DGN-3: BIOPSY TECHNIQUE FOR SUSPICIOUS BREAST CALCIFICATIONS

DGN-3.1: Proportion of women (lesions counted) with suspicious breast calcifications found at mammography who undergo stereotactic-guided or tomosynthesis-guided core needle biopsy	
Numerator	Number of women (lesions counted) with suspicious breast calcifications at mammography who undergo stereotactic-guided or tomosynthesis-guided core needle biopsy
Denominator	Total number of women (lesions counted) with suspicious breast calcifications in mammography
Data eligibility	• Please refer to the specific target population and eligibility criteria of the breast cancer screening programme in place in the country from which the BCS originates • Women with a screening mammography showing breast calcifications
Norm	≥ 95 %

DGN-4: PROPORTION OF BENIGN DIAGNOSES AFTER OPEN SURGERY

DGN-4.1: Proportion of women diagnosed with a benign lesion after open surgery	
Numerator	Total number of women who had a benign diagnosis and have had open surgery (initial surgical procedure)
Denominator	Total number of women with a benign or malignant diagnosis who have had open surgery (initial surgical procedure)
Data eligibility	• Women diagnosed with a benign or malignant breast lesion • Diagnosed in the BCS • Women who have had open surgery
Norm	< 20 %

DGN-5: GENETIC TESTING

DGN-5: Proportion of women diagnosed with breast cancer and with a high-risk* of genetic mutations, who have been offered genetic counselling and have access to genetic testing	
Numerator	Number of women diagnosed with breast cancer and with a high-risk* of genetic mutations, who have been offered genetic counselling and access to genetic testing
Denominator	Total number of women diagnosed with breast cancer and with a high-risk* of genetic mutations
Data eligibility	• Primary invasive and *in-situ* breast cancer cases • Diagnosed in the BCS • Patients with a high-risk* of genetic mutation *Explanation of terms* * A high-risk patient is defined as an individual with a cancer diagnosis that meets any of the following criteria: • A known mutation in a cancer susceptibility gene within the family; • Early-onset breast cancer; • Triple negative (ER-negative, PR-negative, HER2-negative) breast cancer ≤ age 60 years; • Two breast cancer primaries in a single individual; • Breast cancer at any age, and ≥ 1 close blood relative with breast cancer ≤ age 50 years; 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; • 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). (Source: National Comprehensive Cancer Network Guidelines, Genetic/Familial High-Risk Assessment: Breast and Ovarian, version 2.2015.)
Indicator for monitoring purposes	

DGN-PTH-5: TIME FROM RECEIPT OF SPECIMEN TO ISSUING OF RESULTS FOR NON-SURGICAL BIOPSIES AND SURGICAL SPECIMENS

DGN-PTH-5.2: Proportion of pathology results from non-surgical biopsies released from the pathology service within 5 working days (or 7 calendar days) after receipt of the breast specimen by the pathology service	
Numerator	Number of pathology results from non-surgical biopsies released from the pathology service within 5 working days (or 7 calendar days) after receipt of the breast specimen by the pathology service
Denominator	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
Data eligibility	• All non-surgical 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 %

DGN-PTH-5.3: Proportion of pathology results from surgical specimens released from the pathology service within 10 working days (or 14 calendar days) after receipt of the breast specimen by the pathology service	
Numerator	Number of pathology results from surgical specimens released from the pathology service within 10 working days (or 14 calendar days) from receipt of the breast specimen by the pathology service
Denominator	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
Data eligibility	• All surgical 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 %

DGN-TRT-1: NURSE ACCESS AND REFERRAL

DGN-TRT-1.3: Proportion of women newly diagnosed with breast cancer who had a consultation with a breast care nurse at the time of diagnosis	
Numerator	Number of women with breast cancer who had a consultation with a breast care nurse at the time of the new diagnosis
Denominator	Total number of women with newly diagnosed breast cancer
Data eligibility	• All primary invasive and in situ breast cancer cases • Diagnosed in the BCS
Norm	≥ 95 %

DGN-TRT-2: MULTIDISCIPLINARY MEETINGS (MDMs)

DGN-TRT-2.3: Proportion of women with breast cancer (absolute number of women counted) discussed by the multidisciplinary team at least once before they start treatment or after their primary treatment	
Numerator	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) or after their primary treatment
Denominator	Total number of women (absolute number of women counted) with breast cancer treated in the BCS
Data eligibility	• All primary invasive and in situ breast cancer cases (absolute number of women counted) • Diagnosed and treated in the BCS
Norm	≥ 90 %

DGN-TRT-2.4: Median number of working days between the date of the MDM discussion and the start of the first treatment	
Indicator	The time between the date of the MDM discussion and the start of the first treatment. Measured as the number of working days, calculated as an average
Data eligibility	• All primary invasive and in situ breast cancer cases • Treated in the BCS • Patients discussed in a MDM • Patients started breast cancer treatment
Indicator for monitoring purposes	

DGN-TRT-4: PRE-TREATMENT DIAGNOSIS

DGN-TRT-4.1: Proportion of women (breasts counted) with breast cancer (invasive or non-invasive), who had a histologically confirmed malignant diagnosis before their first treatment	
Numerator	Number of women (breasts counted) with breast cancer (invasive or non-invasive) who had a pre-treatment, histologically confirmed diagnosis of malignancy
Denominator	Total number of women (breasts counted) with breast cancer (invasive or non-invasive) who were treated in the BCS (first treatment)
Data eligibility	• All primary invasive and in situ breast cancer cases • Treated in the BCS
Norm	≥ 95 %

DGN-TRT-5: ASSESSMENT OF BIOMARKERS BEFORE STARTING TREATMENT

DGN-TRT-5.1: Proportion of women with invasive breast cancer for whom the following biomarkers have been collected and assessed before starting treatment: ER, PR and HER2 status	
Numerator	Number of women diagnosed with invasive breast cancer for whom the following biomarkers have been collected and assessed before starting treatment: ER, PR and HER2 status
Denominator	Total number of women diagnosed with invasive breast cancer
Data eligibility	• All primary invasive breast cancer cases • Diagnosed in the BCS
Norm	≥ 95 %

DGN-TRT-6: LEAD TIME BETWEEN PATHOLOGY REPORT WITH DIAGNOSIS AND FIRST TREATMENT

DGN-TRT-6.1: Proportion of women diagnosed in the BCS with a lead time of no longer than 4 weeks between the date of issue of the pathology report with a diagnosis of breast cancer and the start of the first treatment	
Numerator	Number of women with breast cancer diagnosed in the BCS who have no longer than 4 weeks' lead time between the date of issue of the pathology report with a diagnosis of breast cancer and the start of the first treatment
Denominator	Total number of women with breast cancer diagnosed and treated in the BCS
Data eligibility	• All primary invasive and in situ breast cancer cases • Diagnosed and treated in the BCS
Norm	≥ 90 %

TREATMENT

TRT-6: LEAD TIME BETWEEN LAST SURGERY AND FIRST ADJUVANT CHEMOTHERAPY CYCLE

TRT-6.1: Proportion of surgically treated women with non-metastatic (M0), invasive breast cancer, without radiotherapy between surgery and adjuvant chemotherapy, who started chemotherapy within ≤ 8 weeks after surgery	
Numerator	Number of surgically treated woman with M0, invasive breast cancer, without radiotherapy between surgery and adjuvant chemotherapy, who started adjuvant chemotherapy within ≤ 8 weeks after surgery
Denominator	Total number of surgically treated women with M0, invasive breast cancer, without radiotherapy between surgery and adjuvant chemotherapy, who started chemotherapy after surgery
Data eligibility	• All primary invasive breast cancer cases • Treated in the BCS • Patients who underwent surgery • Patients who underwent adjuvant chemotherapy • M0 breast cancer • Patients who underwent radiotherapy before adjuvant chemotherapy excluded
Norm	≥ 80 %

TRT-7: LEAD TIME TO FIRST RADIOTHERAPY TREATMENT

TRT- 7.1: Proportion of surgically treated women with primary, M0, invasive breast cancer who underwent adjuvant radiotherapy, and who started radiotherapy ≤ 8 weeks after the date of surgery or after the date of the last cycle of adjuvant chemotherapy	
Numerator	Number of surgically treated women with primary, M0, invasive breast cancer who underwent adjuvant radiotherapy, and who started radiotherapy ≤ 8 weeks after the date of surgery or after the date of the last cycle of adjuvant chemotherapy
Denominator	Total number of surgically treated women with primary, M0, invasive breast cancer who underwent radiotherapy after surgery
Data eligibility	• All primary invasive breast cancer cases • Treated in the BCS • M0 breast cancer • Patients who underwent surgery • Patients who underwent radiotherapy after surgery
Norm	≥ 80 %

TRT-SUR-1: SENTINEL LYMPH NODE BIOPSY

TRT-SUR-1.1: Proportion of surgically treated women with clinically node-negative (cN0) invasive breast cancer who underwent SLNB	
Numerator	Number of surgically treated women (breasts counted) with cN0 invasive breast cancer who underwent SLNB
Denominator	Total number of surgically treated women (breasts counted) with cN0 invasive breast cancer
Data eligibility	• All primary invasive breast cancer cases • Surgically treated in the BCS • cN0 cases • Patients with locally advanced cancer are excluded • Patients who underwent neoadjuvant therapy are excluded
Norm	≥ 90 %

TRT-SUR-2: AVOID AXILLARY LYMPH NODE DISSECTION FOR PATHOLOGICAL NODE-NEGATIVE INVASIVE BREAST CANCER

TRT-SUR-2.1: Proportion of surgically treated women with pathological node-negative (pN0) invasive breast cancer who did not undergo ALND (staged by SLNB only)	
Numerator	Number of women (breasts counted) with pN0 invasive breast cancer who did not undergo ALND
Denominator	Total number of women (breasts counted) with pN0 invasive breast cancer
Data eligibility	• All primary invasive breast cancer cases • Surgically treated in the BCS • Staged by SLNB • pN0 cases • Patients with lymph node involvement only verified by positive histology/cytology guided by ultrasound are excluded • Patients who underwent neoadjuvant therapy are excluded
Norm	≥ 80 %

TRT-SUR-3: AVOID AXILLARY LYMPH NODE DISSECTION FOR DCIS

TRT-SUR-3.1: Proportion of surgically treated women with DCIS who did not undergo ALND	
Numerator	Number of surgically treated women (breasts counted) with DCIS who did not undergo ALND
Denominator	Total number of surgically treated women (breasts counted) with DCIS
Data eligibility	• All primary in-situ breast cancer cases • Treated in the BCS • Patients who underwent surgery • Patients treated with mastectomy are excluded • Tumour size > 5 cm (T3) are excluded
Norm	≥ 95 %

TRT-SUR-4: BREAST-CONSERVING SURGERY FOR DCIS

TRT-SUR-4.1: Proportion of surgically treated women with DCIS with a radiological tumour extent ≤ 2 cm who did not undergo primary mastectomy	
Numerator	Number of surgically treated women (breasts counted) with DCIS with a radiological tumour extent ≤ 2 cm who did not undergo primary mastectomy
Denominator	Total number of surgically treated women (breasts counted) with DCIS with a radiological tumour extent ≤ 2 cm
Data eligibility	• All primary in-situ breast cancer cases • Surgically treated in the BCS • Patients who underwent surgery • Radiological tumour extent ≤ 2 cm
Norm	≥ 80 %

TRT-SUR-5: BREAST-CONSERVING SURGERY FOR INVASIVE BREAST CANCER WITH SMALL TUMOUR SIZE

TRT-SUR-5.1: Proportion of surgically treated women with invasive breast cancer with a tumour size pT1 (≤ 2 cm) who underwent breast-conserving surgery	
Numerator	Number of surgically treated women (breasts counted) with invasive breast cancer with a pathological tumour size ≤ 2 cm (pT1) who underwent breast-conserving surgery
Denominator	Total number of surgically treated women (breasts counted) with invasive breast cancer with a pathological tumour size ≤ 2 cm (pT1)
Data eligibility	• All primary invasive breast cancer cases • Surgically treated in the BCS • Pathological tumour size ≤ 2 cm (pT1) • Patients with locally advanced cancer are excluded
Norm	≥ 70 %

TRT-SUR-6: SINGLE BREAST OPERATION FOR PRIMARY DCIS

TRT-SUR-6.1: Proportion of surgically treated women with DCIS who underwent only 1 breast operation for the primary tumour	
Numerator	Number of surgically treated women (breasts counted) with DCIS who underwent only 1 breast operation for the primary tumour
Denominator	Total number of women (breast counted) with DCIS who underwent surgery for the primary tumour
Data eligibility	• All primary in-situ breast cancer cases • Surgically treated in the BCS • Patients who underwent surgery
Norm	≥ 70 %

TRT-SUR-7: SINGLE BREAST OPERATION FOR THE PRIMARY INVASIVE BREAST CANCER

TRT-SUR-7.1: Proportion of surgically treated women with invasive breast cancer (T1, T2) who underwent only 1 breast operation for the primary tumour	
Numerator	Number of surgically treated women with invasive breast cancer (T1, T2) who underwent only 1 breast operation for the primary tumour
Denominator	Total number of women with invasive breast cancer (T1, T2) who underwent breast surgery for the primary tumour
Data eligibility	• All primary invasive breast cancer cases • Surgically treated in the BCS • Patients who underwent surgery • T1 or T2 tumours • Patients with locally advanced cancer are excluded
Norm	≥ 80 %

TRT-SYS-1: NEOADJUVANT CHEMOTHERAPY FOR STAGE II AND STAGE III TRIPLE NEGATIVE BREAST CANCER

TRT-SYS-1.1: Proportion of women with stage II and stage III triple negative breast cancer who underwent neoadjuvant chemotherapy	
Numerator	Number of women with stage II and stage III triple negative breast cancer who underwent neoadjuvant chemotherapy
Denominator	Total number of women with stage II and stage III triple negative breast cancer
Data eligibility	• All primary invasive breast cancer cases • Treated in the BCS • Stage II or stage III breast cancer • ER-negative, PR-negative and HER2-negative • M1 breast cancer excluded
Indicator for monitoring purposes	

TRT-SYS-2: NEOADJUVANT SYSTEMIC THERAPY FOR STAGE II AND STAGE III HER2-POSITIVE BREAST CANCER

TRT-SYS-2.1: Proportion of women with stage II and stage III HER2-positive breast cancer who underwent neoadjuvant systemic therapy	
Numerator	Number of women with stage II and stage III HER2-positive breast cancer who underwent neoadjuvant systemic therapy
Denominator	Total number of women with stage II and stage III HER2-positive breast cancer
Data eligibility	• All primary invasive breast cancer cases • Treated in the BCS • Stage II or stage III breast cancer • HER2-positive • M1 breast cancer excluded
Indicator for monitoring purposes	

TRT-SYS-3: NEOADJUVANT SYSTEMIC THERAPY FOR LOCALLY ADVANCED BREAST CANCER

TRT-SYS-3.1: Proportion of women with locally advanced breast cancer (at least those with tumour T4 or nodal status ≥ N2) who underwent neoadjuvant systemic therapy	
Numerator	Number of women with locally advanced breast cancer (at least those with tumour T4 or nodal status ≥ N2) who underwent neoadjuvant systemic therapy
Denominator	Total number of women with locally advanced breast cancer (at least those with tumour T4 or nodal status ≥ N2)
Data eligibility	• All primary invasive breast cancer cases • Treated in the BCS • Locally advanced breast cancer (T4 or nodal status ≥ N2) • M1 breast cancer excluded
Norm	≥ 90 %

TRT-SYS-4: ENDOCRINE THERAPY FOR SURGICALLY TREATED, ER-POSITIVE AND/OR PR-POSITIVE, INVASIVE BREAST CANCER

TRT-SYS-4.1: Proportion of surgically treated women with ER-positive and/or PR-positive, M0, invasive breast cancer who were recommended endocrine therapy	
Numerator	Number of surgically treated women with ER-positive and/or PR-positive, M0, invasive breast cancer who were recommended endocrine therapy
Denominator	Total number of surgically treated women with ER-positive and/or PR-positive, M0, invasive breast cancer
Data eligibility	• All primary invasive breast cancer cases • Treated in the BCS • M0 breast cancer • Patients who underwent surgery • ER-positive and/or PR-positive
Norm	≥ 85 %

TRT-SYS-5: ADJUVANT CHEMOTHERAPY FOR SURGICALLY TREATED, ER-NEGATIVE, INVASIVE BREAST CANCER

TRT-SYS-5.1: Proportion of surgically treated women with ER-negative, ≥ T1c or node-positive (N+), M0, invasive breast cancer who underwent adjuvant chemotherapy	
Numerator	Number of surgically treated women with, ER-negative, ≥ T1c or N+, M0, invasive breast cancer who underwent adjuvant chemotherapy
Denominator	Total number of surgically treated women with ER-negative, ≥ T1c or N+, M0, invasive breast cancer
Data eligibility	• All primary invasive breast cancer cases • Surgically treated in the BCS • ER-negative • Pathological tumour size > 1cm or N+ cases • M0 breast cancer • Patients who underwent neoadjuvant therapy are excluded
Norm	≥ 85 %

TRT-SYS-6: ANTI-HER2 THERAPY FOR HER2-POSITIVE BREAST CANCER RECEIVING CHEMOTHERAPY

TRT-SYS-6.1: Proportion of women with HER2-positive, M0, invasive breast cancer receiving neoadjuvant chemotherapy who also received neoadjuvant anti-HER2 therapy	
Numerator	Number of women with HER2-positive, M0, invasive breast cancer receiving neoadjuvant chemotherapy who also received neoadjuvant anti-HER2 therapy
Denominator	Total number of women with HER2-positive, M0, invasive breast cancer receiving neoadjuvant chemotherapy
Data eligibility	• All primary invasive breast cancer cases • Surgically treated in the BCS • M0 breast cancer • HER2-positive • Patients who underwent neoadjuvant chemotherapy
Norm	≥ 90 %

TRT-SYS-6.2: Proportion of women with HER2-positive, M0, invasive breast cancer receiving adjuvant chemotherapy who also received adjuvant anti-HER2 therapy	
Numerator	Number of women withHER2-positive, M0, invasive breast cancer treated with surgery and chemotherapy who also received adjuvant anti-HER2 therapy
Denominator	Total number of women with, HER2-positive, M0, invasive breast cancer receiving adjuvant chemotherapy
Data eligibility	• All primary invasive breast cancer cases • M0 breast cancer • Treated in the BCS • HER2-positive • Patients who underwent adjuvant chemotherapy • M1 breast cancer excluded
Norm	≥ 90 %

TRT-SYS-7: MONITORED CARDIAC FUNCTION FOR BREAST CANCER TREATED WITH ANTI-HER2

TRT-SYS-7.1: Proportion of women with breast cancer treated with anti-HER2 therapy, and whose cardiac function is monitored before, at the end of the treatment and regularly during the treatment (at least once during the treatment)	
Numerator	Number of women with breast cancer treated with anti-HER2 therapy and whose cardiac function is monitored before, at the end of the treatment and regularly during the treatment (at least once during the treatment)
Denominator	Total number of women with breast cancer treated with anti-HER2 therapy
Data eligibility	• All primary invasive and in-situ breast cancer cases • Treated in the BCS • HER2-positive • Patients who underwent and completed anti-HER2 therapy
Norm	≥ 95 %
Missing values	Records with missing values for cardiac function testing before or after treatment should not be included in the indicator. Additionally, there should be at least 1 non-missing value for cardiac function tests performed during treatment for the record to be included

TRT-SYS-8: ENDOCRINE-BASED THERAPY AS FIRST-LINE TREATMENT FOR METASTATIC, ER-POSITIVE AND HER2-NEGATIVE BREAST CANCER

TRT-SYS-8.1: Proportion of women with ER-positive and HER2-negative metastatic (at diagnosis) breast cancer who underwent only endocrine-based therapy in the first-line of treatment for their metastatic disease	
Numerator	Number of women with ER-positive and HER2-negative metastatic (at diagnosis) breast cancer who underwent endocrine-based therapy as the first-line of treatment for their metastatic disease
Denominator	Total number of women with ER-positive and HER2-negative metastatic breast cancer who received first-line systemic treatment for their metastatic disease
Data eligibility	• All primary invasive metastatic breast cancer cases • Treated in the BCS • Patients who underwent first-line systemic treatment • ER-positive and HER2-negative
Norm	≥ 75 %

TRT-SYS-8.2: Proportion of women with ER-positive and HER2-negative metachronous metastatic breast cancer who underwent only endocrine-based therapy in the first-line of treatment for their metastatic disease	
Numerator	Number of women with ER-positive and HER2-negative metachronous metastatic breast cancer who underwent endocrine-based therapy as the first-line of treatment for their metastatic disease
Denominator	Total number of women with ER-positive and HER2-negative metachronous metastatic breast cancer who received first-line systemic treatment for their metastatic disease
Data eligibility	• All invasive breast cancer cases that presented with metachronous metastasis • Treated in the BCS • Patients who underwent first-line systemic treatment • ER-positive and HER2-negative
Norm	≥ 75 %

TRT-SYS-9: BONE-MODIFYING AGENTS FOR BONE METASTASES FROM BREAST CANCER

TRT-SYS-9.1: Proportion of women diagnosed with breast cancer with bone metastasis who receive bone-modifying agents	
Numerator	Number of women diagnosed with breast cancer with bone metastasis who receive bone-modifying agents
Denominator	Total number of women diagnosed with breast cancer with bone metastasis
Data eligibility	• All primary invasive breast cancer cases • Treated in the BCS • With bone metastasis
Norm	≥ 90 %

TRT-RAD-1: ADJUVANT RADIOTHERAPY FOR M0, INVASIVE BREAST CANCER TREATED WITH BREAST-CONSERVING THERAPY

TRT-RAD-1.1: Proportion of women with M0, invasive breast cancer treated with breast-conserving therapy who underwent whole breast adjuvant radiotherapy or, when indicated, partial breast radiotherapy	
Numerator	Number of women (breasts counted) diagnosed with M0, invasive breast cancer and treated with breast-conserving surgery who underwent whole breast adjuvant radiotherapy or, when indicated, partial breast radiotherapy
Denominator	Total number of women (breasts counted) diagnosed with M0, invasive breast cancer and treated with breast-conserving surgery
Data eligibility	• All primary invasive breast cancer cases • Treated in the BCS • M0 breast cancer • Patients who underwent breast-conserving surgery
Norm	≥ 90 %

TRT-RAD-2: RADIOTHERAPY FOR INVASIVE BREAST CANCER AFTER MASTECTOMY

TRT-RAD-2.1: Proportion of women with M0, invasive breast cancer with ≥ 4 axillary lymph nodes involved, who underwent local or regional radiotherapy after mastectomy	
Numerator	Number of women (breasts counted) diagnosed with M0, invasive breast cancer with ≥ 4 axillary lymph nodes involved, who underwent local or regional radiotherapy after mastectomy
Denominator	Total number of women (breasts counted) diagnosed with M0, invasive breast cancer with ≥ 4 axillary lymph nodes involved, who underwent mastectomy
Data eligibility	• All primary invasive breast cancer cases • Treated in the BCS • M0 breast cancer • ≥ 4 positive axillary lymph nodes • Patients who underwent mastectomy
Norm	≥ 90 %

ANNEX 2
COMPETENCE SPECIFICATIONS FOR AUDITING

The certification body must define the competence requirements for its personnel involved in the auditing and certification of the breast cancer services according to the European QA scheme. When determining these competency requirements, the certification body must consider all the relevant requirements referenced in ISO/IEC 17065, in addition to those specified in this document.

Competence requirements for auditors and audit teams

An audit team must be composed of auditors (and technical experts where necessary) having the collective competence to undertake the audit. This must include the generic competence described in ISO/IEC 17065 and the following competences for each of the applicable cancer care processes.

For system level processes, knowledge, understanding and experience of:

- quality management;
- quality improvement;
- data management;
- statutory and regulatory requirements, where applicable;
- patient safety;
- patient experience;
- ethics;
- privacy.

For all pathway processes, knowledge, understanding and experience of:

- patient safety;
- the patient experience of the process;
- patient reported outcomes;
- cancer nursing care;
- psycho-oncological and social care;
- the European QA scheme requirements;
- the relationships between the specific process and other cancer care processes;
- healthcare indicators, measuring and reporting.

For breast cancer screening processes, knowledge, understanding and experience of:

- providing a screening programme;
- screening performance evaluation;
- imaging modalities used to assess suspicious findings in first-level screening mammography (additional mammographic views or tomosynthesis, ultrasound, etc.);
- percutaneous breast biopsy.

For breast cancer diagnosis processes, knowledge, understanding and experience of:

- diagnostic imaging;
- percutaneous breast biopsy;
- cytology and histopathology of lesions.

For breast cancer treatment processes, knowledge, understanding and experience of:

- image-guided pre-surgical localisation of breast lesions;
- cancer surgery;
- radiation therapy;
- medical oncology;
- clinical genetics;
- nuclear medicine.

For breast cancer rehabilitation processes, knowledge, understanding and experience of:

- physiotherapy;
- cancer nursing care.

For breast cancer follow-up and survivorship care processes, knowledge, understanding and experience of:

- follow-up, including periodical surveillance (including imaging and laboratory surveillance) or re-inclusion in a screening programme;
- survivorship care, including recovering from side effects of treatment: physical, psychological, sexual, cognitive and other.

For breast cancer palliative care processes, knowledge and understanding of:

- palliative care and/or end-of-life care.

Certification bodies must ensure that, where a cancer care service entity provides integrated or overlapping cancer care processes (e.g. both screening and diagnostic processes), the audit team includes the knowledge, understanding and experience requirements for each process.

Certification bodies must define the criteria for determining competence initially and on a continuing basis, and these must be based on the criteria for cancer care service practitioners specified in Part II: Breast cancer service requirements. When deciding on the composition of an audit team for a cancer care service audit, a certification body is expected to consider including qualified and practising specialists (however named) (see Part II: Breast cancer service requirements) with relevant experience in breast cancer:

- screening (e.g. radiologist, radiographer),
- diagnosis (e.g. pathologist),
- care nursing,
- patient views, empowerment and experience,
- treatment (e.g. physician, surgeon, oncologist),
- medical physics,
- epidemiology,
- patient safety.

Certification bodies must ensure that, as a minimum, proof of professional competence, such as a revalidation certificate or similar, is available for each auditor. In addition to their professional competence, certification bodies must provide evidence that auditors demonstrate:

- integrity and independence;
- fairness;
- due professional care;
- confidentiality;
- an evidence- and risk-based approach;
- acceptable behaviour during audits;
- good auditing techniques;
- appropriate technical knowledge.

ANNEX 3
SUPPORTING MATERIALS

The European QA scheme is based on evidence coming from recommendations from the **European guidelines on breast cancer screening and diagnosis**, as well as the **collection of guidelines on breast cancer care**. As part of the scheme development, requirements for all breast cancer care processes were researched in existing literature, guidelines, indicator databases and quality assurance schemes. The bibliography is now presented herein within as supporting materials aiming to provide guidance for BCS to implement the requirements but also to provide the background information supporting the requirement. This additional information for each requirement is provided herein in the following structure:

Rationale: The fundamental reason for the requirement in the context of the quality of care;
Quality domain: The dimension or issue of healthcare quality that the requirement pertains to (clinical effectiveness; safety; facilities, resources and workforce; and personal empowerment and experience).

GUIDELINE RECOMMENDATIONS

Guideline recommendations related to the requirement expressed as the recommendation statement, source guideline, the reported certainty of evidence and strength of recommendation, where available.

REFERENCE DOCUMENTS

Reference documents: Technical documents and tools aimed to provide guidance to care services to support the implementation of the respective requirement and quality improvement in the respective care process. The documents may also support auditors when auditing compliance to the requirement.

SUPPORTING LITERATURE

Supporting literature: List of references considered during the requirement development, as a source of the requirement or a source of evidence supporting the requirement and its impact on quality improvement.

GENERAL

GEN-1: PROFESSIONAL STAFF AND TRAINING

RATIONALE

Sufficient staff and dedicated professionals are essential for providing high quality BCS. All BCS should have a qualified team with the ability to provide high quality multidisciplinary services. Staff competence is assumed to be associated with high quality care and better patient outcomes. Thus, 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; Clinical effectiveness; Safety.

GUIDELINE RECOMMENDATIONS

- European Commission, 2024, European Guidelines on Breast Cancer Screening and Diagnosis:
  - Only professionals with specialised training in the area they practice should provide care to women participating in breast cancer screening programmes, breast cancer diagnostic services or screening assessment services (*ungraded good practice statement*).
  - The ECIBC's Guidelines Development Group (GDG) suggests that mammography readers read between 3 500 and 11 000 mammograms annually in organised population-based screening programmes (*conditional recommendation, very low certainty of the evidence*).
  - The ECIBC's GDG suggests communication skills training for healthcare professionals working with women who undergo mammography screening, in the context of an organised population-based screening programme (*conditional recommendation, very low certainty of the evidence*).

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GEN-2: GUIDELINES AND PROTOCOLS

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

QUALITY DOMAIN: Clinical effectiveness.

GUIDELINE RECOMMENDATIONS

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

SUPPORTING LITERATURE

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GEN-3: QUALITY MANAGEMENT

RATIONALE

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

QUALITY DOMAIN: Clinical effectiveness; Safety.

GUIDELINE RECOMMENDATIONS

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

REFERENCE DOCUMENTS

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GEN-4: DATA GOVERNANCE

RATIONALE

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

QUALITY DOMAIN: Clinical effectiveness.

GUIDELINE RECOMMENDATIONS

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

SUPPORTING LITERATURE

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GEN-5: PATIENT-REPORTED OUTCOME MEASURES (PROMs)

RATIONALE

Patient-reported outcomes are important for capturing patients' views on their health in terms of symptoms and physical, mental and social functioning, including their 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.

GUIDELINE RECOMMENDATIONS

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

REFERENCE DOCUMENTS

- EDMONDTON system assessment scale.
- ICHOM has listed the following recommended instruments to measure PROMs:
  - Arm and breast 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).
  - 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.
  - Depression, pain, fatigue: recommended to track via the EORTC Quality of Life Questionnaire – Core Questionnaire (EORTC QLQ-C30).
  - 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).
  - 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.
  - Vasomotor symptoms: recommended to track via the EORTC Quality of Life Questionnaire – Breast Cancer Specific Questionnaire (EORTC QLQ-BR23).

Note: Another international initiative has been launched by the Organisation 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.

SUPPORTING LITERATURE

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GEN-6: PATIENT CENTEREDNESS AND INFORMATION

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 reintegration 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.

GUIDELINE RECOMMENDATIONS

- IKNL NABON, Breast Cancer Dutch Guideline, 2012. 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 (*based on evidence quality ranging from A1 - B*).
- NICE Clinical Guideline, Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer, 2013:
  - To ensure a patient-professional partnership, patients should be offered individually tailored information, including information about sources of support (including local and national organisations) (*certainty of evidence not reported*);
  - 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 (*certainty of evidence not reported*).

SUPPORTING LITERATURE

- Biganzoli, L., Cardoso, F., Beishon, M., et al., 'The Requirements of a Specialist Breast Centre', *Breast*, Vol. 51, 2020, pp. 65–84.
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- SIS/ISS, 'International Accreditation Program for Breast Centers/Units', 2020.

GEN-7: 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, including research performed directly on patients in specific cases.

QUALITY DOMAIN: Clinical effectiveness.

GUIDELINE RECOMMENDATIONS

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

REFERENCE DOCUMENTS

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SUPPORTING LITERATURE

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SCREENING

SCR-1: SCREENING PROGRAMME

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.

GUIDELINE RECOMMENDATIONS

- European Commission (2024). European Guidelines on Breast Cancer Screening and Diagnosis:
  - The ECIBC's GDG recommends using an organised mammography screening programme for early detection of breast cancer in asymptomatic women (strong recommendation, moderate certainty of the evidence).

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

Screening test:

- For asymptomatic women with an average risk of breast cancer, the ECIBC's GDG suggests using digital breast tomosynthesis (DBT) over digital mammography (DM), in the context of an organised population-based screening programme (*conditional recommendation, very low certainty of the evidence*).
- For asymptomatic women with an average risk of breast cancer, the ECIBC's GDG suggests not using both digital breast tomosynthesis (DBT) and digital mammography (DM), in the context of an organised population-based screening programme (*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 population-based screening programme, the ECIBC's GDG suggests not implementing tailored screening with automated breast ultrasound system (ABUS) (*conditional recommendation, very low certainty of the evidence*).
- For asymptomatic women, with high mammographic breast density and a negative mammography, in the context of an organised population-based screening programme, the ECIBC's GDG suggests not implementing tailored screening with hand-held ultrasound (HHUS), where such is not already the practice (*conditional recommendation, low certainty of the evidence*).
- For asymptomatic women with high mammographic breast density detected for the first time with digital mammography (DM), the ECIBC's GDG suggests implementing tailored screening with additional digital breast tomosynthesis (DBT) in the context of an organised population-based screening programme (*conditional recommendation, very low certainty of the evidence*).
- For asymptomatic women, with high mammographic breast density detected in a previous screening exam, the ECIBC's GDG suggests using digital breast tomosynthesis (DBT) over digital mammography (DM) in the context of an organised population-based screening programme (*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 population-based screening programme, the ECIBC's GDG suggests not implementing tailored screening with magnetic resonance imaging (MRI) (*conditional recommendation, very low certainty of the evidence*).
- The ECIBC's GDG suggests using double reading (with consensus or arbitration) over single reading to screen mammograms for early detection of breast cancer in organised population-based screening programmes (*conditional recommendation, moderate certainty of the evidence*).

Invitation to screening:

- The ECIBC's GDG 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 of the evidence*).
- The ECIBC's GDG 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 of the evidence*).
- The ECIBC's GDG suggests not 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 of the evidence*).
- The ECIBC's 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 of the evidence*).

Communication strategy:

- The ECIBC's GDG suggests using a targeted communication strategy over a general communication strategy to improve participation in organised population-based screening programmes of socially disadvantaged women between the ages of 50 and 69 (*conditional recommendation, low certainty of the evidence*).
- The ECIBC's GDG suggests not using a tailored communication strategy to improve participation in breast cancer screening programmes of socially disadvantaged women between the ages of 50 and 69 (*conditional recommendation, moderate certainty of the evidence*).
- The ECIBC's Guideline Development Group (GDG) suggests using tailored or targeted communication strategies to improve participation in organised population-based screening programmes of socially disadvantaged women between the ages of 50 and 69 (*conditional recommendation, very low certainty of the evidence*).
- The ECIBC's GDG suggests in favour of using a targeted communication strategy over a general communication strategy to improve participation in organised population-based screening programmes of women with intellectual disability between the ages of 50 and 69 (*conditional recommendation, low certainty of the evidence*).
- The ECIBC's GDG suggests using a targeted communication strategy over a general communication strategy to improve participation in organised population-based screening programmes of non-native speaking women between the ages of 50 and 69 (*conditional recommendation, low certainty of the evidence*).

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SCR-2: REPORTING OF SCREENING INDICATORS

RATIONALE
Indicator monitoring can be used for quality improvement purposes.

QUALITY DOMAIN: Clinical effectiveness.

Note: In the presence of breast imaging examinations in-between organised screening rounds, the interval cancer rate is increased by asymptomatic cancers that could have been diagnosed at the next round.

GUIDELINE RECOMMENDATIONS

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

REFERENCE DOCUMENTS

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SUPPORTING LITERATURE

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SCR-3: HEALTHY LIFESTYLE INFORMATION

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.

GUIDELINE RECOMMENDATIONS

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

SUPPORTING LITERATURE

- Anderson, A. S., 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.
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- OECI, 'Accreditation and Designation User Manual', V. 3.2, 2019.
- World Cancer Research Fund, 'Diet, Nutrition and Physical Activity and Breast Cancer Survivors', 2014, www.wcrf.org/sites/default/files/Breast-Cancer-Survivors-2014-Report.pdf.
- World Health Organisation, 'Breast Cancer: prevention and control', 2014, www.who.int/cancer/detection/breastcancer/en/index.html.

DIAGNOSIS

DGN-IMG-1: OPTIMAL MAMMOGRAPHIC IMAGE QUALITY

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.

GUIDELINE RECOMMENDATIONS

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

REFERENCE DOCUMENTS

- European Commission, Directorate-General for Health and Consumers, Broeders M, Wolf C, Perry N. European guidelines for quality assurance in breast cancer screening and diagnosis, Publications Office, 2006.
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SUPPORTING LITERATURE

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- SIS/ISS, 'International Accreditation Program for Breast Centers/Units', 2020.

DGN-IMG-2: IMAGING EQUIPMENT POLICY

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.

GUIDELINE RECOMMENDATIONS

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

REFERENCE DOCUMENTS

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- European Commission, Directorate-General for Energy and Transport, 'European guidance on estimating population doses from medical x-ray procedures', Publications Office, 2008, https://data.europa.eu/doi/10.2768/38190.
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- European Commission, Directorate-General for Environment, 'Guidance on diagnostic reference levels (DRLs) for medical exposures', Publications Office, 1999.
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Assurance Program', 2018, http://www.ranzcr.edu.au/quality-a-safety/radiology/practice-quality-activities/mqap.

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DGN-IMG-2.1 Additional information for breast cancer services: 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):

Table 1A. 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

Source: Adapted from European guidelines for quality assurance in breast cancer screening and diagnosis – Fourth edition, supplements, 2013.

Table 1B. Signal-difference-to-noise-ratio (SDNR).

PMMA[60] thickness (mm)	Limiting values ΔSDNR 45 mm
20	≥ 0%
30	≥ 0%
40	≥ 0%
45	0 %
50	≥ - 15%
60	≥ - 30%

[60] PMMA: polymethyl methacrylate.

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

Source: Adapted from Quality Controls in Digital Mammography protocol of the EFOMP Mammo Working group, 2018 and from European guidelines for quality assurance in breast cancer screening and diagnosis – Fourth edition, supplements, 2013.

2. Average glandular dose

Table 2. Limiting 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

Source: Adapted from European guidelines for quality assurance in breast cancer screening and diagnosis – Fourth edition, supplements, 2013.

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 grey-scale 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.

SUPPORTING LITERATURE

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DGN-IMG-3: IMAGING EQUIPMENT FACILITIES

RATIONALE

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

QUALITY DOMAIN: Facilities, resources and workforce.

GUIDELINE RECOMMENDATIONS

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

REFERENCE DOCUMENTS

- European Commission, Directorate-General for Energy, Chateil, J., Cavanagh, P., Ashford, N. et al. Referral guidelines for medical imaging – Availability and use in the European Union. Publications Office, 2024. https://data.europa.eu/doi/10.2833/18118.

SUPPORTING LITERATURE

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DGN-IMG-4: RADIOLOGISTS' PERFORMANCE

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

QUALITY DOMAIN: Facilities, resources and workforce.

GUIDELINE RECOMMENDATIONS

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

REFERENCE DOCUMENTS

- Biganzoli, L., Cardoso, F., Beishon, M., et al., 'The Requirements of a Specialist Breast Centre', *Breast*, Vol. 51, 2020, pp. 65–84.
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- Public Health England, 'NHS Breast Screening Programme Consolidated standards', London, 2017.

SUPPORTING LITERATURE

- Biganzoli, L., Cardoso, F., Beishon, M., et al., 'The Requirements of a Specialist Breast Centre', *Breast*, Vol. 51, 2020, pp. 65–84.
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- Public Health England, 'NHS Breast Screening Programme Consolidated standards', London, 2017.

DGN-IMG-5: SEPARATION OF WOMEN ATTENDING SCREENING AND WOMEN ATTENDING DIAGNOSTIC PROCEDURES

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.

GUIDELINE RECOMMENDATIONS

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

SUPPORTING LITERATURE

- 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.

DGN-IMG-6: DIAGNOSTIC MAMMOGRAPHY REPORT

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

QUALITY DOMAIN: Facilities, resources and workforce.

GUIDELINE RECOMMENDATIONS

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

REFERENCE DOCUMENTS

- Biganzoli, L., Cardoso, F., Beishon, M., et al., 'The Requirements of a Specialist Breast Centre', *Breast*, Vol. 51, 2020, pp. 65–84.
- Canadian Partnership Against Cancer, 'Quality Determinants of Breast Cancer Screening with Mammography in Canada', Canadian Partnership Against Cancer, Toronto 2013.
- ISAS Standard, 'The Imaging Services Accreditation Scheme Standard: Statements, Rationale and criteria', 2017.
- PAH Organisation, 'Mammography services quality assurance: baseline standards for Latin America and the Caribbean', PAHO, Washington, 2016.
- Perry, N., Broeders, M., de Wolf, C., et al., European guidelines for quality assurance in breast cancer screening and diagnosis, Fourth edition, European Commission, *Office for Official Publications of the European Communities*, Luxembourg, 2006.

SUPPORTING LITERATURE

- Biganzoli, L., Cardoso, F., Beishon, M., et al., 'The Requirements of a Specialist Breast Centre', *Breast*, Vol. 51, 2020, pp. 65–84.
- Canadian Partnership Against Cancer, 'Quality Determinants of Breast Cancer Screening with Mammography in Canada', Canadian Partnership Against Cancer, Toronto 2013.
- ISAS Standard, 'The Imaging Services Accreditation Scheme Standard: Statements, Rationale and criteria', 2017.
- PAH Organisation, 'Mammography services quality assurance: baseline standards for Latin America and the Caribbean', PAHO, Washington, 2016.
- Perry, N., Broeders, M., de Wolf, C., et al., European guidelines for quality assurance in breast cancer screening and diagnosis, Fourth edition, European Commission, *Office for Official Publications of the European Communities*, Luxembourg, 2006.

DGN-IMG-7: INTRAOPERATIVE SPECIMEN IMAGING

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

QUALITY DOMAIN: Facilities, resources and workforce.

GUIDELINE RECOMMENDATIONS

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

SUPPORTING LITERATURE

- Biganzoli, L., Cardoso, F., Beishon, M., et al., 'The Requirements of a Specialist Breast Centre', *Breast*, Vol. 51, 2020, pp. 65–84.
- BreastCheck, 'Guidelines for Quality Assurance in Mammography Screening', Ireland, 2015.
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DGN-1: REPORTING THE PERFORMANCE OF THE DIAGNOSTIC SERVICE

RATIONALE
Indicator monitoring can improve service quality.

QUALITY DOMAIN: Clinical effectiveness.

GUIDELINE RECOMMENDATIONS

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

SUPPORTING LITERATURE

- Bulliard, J. L., 'Variation in performance in low-volume mammography screening programmes: experience from Switzerland', 2011.
- NHS Scotland, Scottish Cancer Taskforce / National Cancer Quality Steering Group, 'Breast Cancer Clinical Quality Performance Indicators', 2016.
- Perry, N., Broeders, M., de Wolf, C., et al., European guidelines for quality assurance in breast cancer screening and diagnosis, Fourth edition, European Commission, *Office for Official Publications of the European Communities*, Luxembourg, 2006, https://breastscreening.cancer.gov/.

DGN-2: DIAGNOSTIC BIOPSY TECHNIQUE

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 a histopathology assessment of suspicious lesions. Fine needle aspiration cytology should not be used.

QUALITY DOMAIN: Clinical effectiveness; Safety; Personal empowerment and experience.

GUIDELINE RECOMMENDATIONS

- European Commission, European Guidelines on Breast Cancer Screening and Diagnosis, 2024: In individuals with suspicious breast lesions (including mass lesions, asymmetric breast density, calcifications and/or architectural distortions) in mammography, the ECIBC's GDG recommends needle core biopsy over fine needle aspiration cytology to diagnose breast cancer (*strong recommendation, moderate certainty of the evidence*).

SUPPORTING LITERATURE

- European Commission, European Guidelines on Breast Cancer Screening and Diagnosis, 2024, https://cancer-screening-and-care.jrc.ec.europa.eu/en/ecibc/european-breast-cancer-guidelines.

DGN-3: BIOPSY TECHNIQUE FOR SUSPICIOUS BREAST CALCIFICATIONS

RATIONALE

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

QUALITY DOMAIN: Clinical effectiveness; Safety; Personal empowerment and experience.

GUIDELINE RECOMMENDATIONS

- European Commission, European Guidelines on Breast Cancer Screening and Diagnosis, 2024: In individuals presenting with breast calcifications, the ECIBC's GDG 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 of the evidence*).

SUPPORTING LITERATURE

- European Commission, 'European Guidelines on Breast Cancer Screening and Diagnosis', 2024, https://cancer-screening-and-care.jrc.ec.europa.eu/en/ecibc/european-breast-cancer-guidelines.
- Nguyen, D. L., Boron, A., Oluyemi, E. T., et al., 'Comparison of Diagnostic Mammography-Guided Biopsy and Digital Breast Tomosynthesis-Guided Biopsy of Suspicious Breast Calcifications: Results in 1354 Biopsies', *AJR Am J Roentgenol*, Vol. 220, Issue 2, February 2023, pp. 212–223, DOI: 10.2214/AJR.22.28320, Epub: 14 September 2022, PMID: 36102725.

DGN-4: PROPORTION OF BENIGN DIAGNOSES AFTER OPEN SURGERY

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.

GUIDELINE RECOMMENDATIONS

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

SUPPORTING LITERATURE

- Biganzoli, L., Marotti, L., Hart, C. D. et al., 'Quality indicators in breast cancer care: An update from the EUSOMA working group', *European Journal of Cancer*, Vol. 86,2017, 59e81.
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DGN-5: 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.

GUIDELINE RECOMMENDATIONS

- NICE, Clinical Guideline: Familial breast cancer, 2013: classification, care and managing breast cancer and related risks in people with a family history of breast cancer:
  - All eligible people should have access to information on genetic tests aimed at mutation finding (*certainty of evidence not reported*).
  - Pre-test counselling (preferably two sessions) should be undertaken (*certainty of evidence not reported*).
  - Discussion of genetic testing (predictive and mutation finding) should be undertaken by a healthcare professional with appropriate training (*certainty of evidence not reported*).
  - 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 (*certainty of evidence not reported*).

REFERENCE DOCUMENTS

- OECI, 'Accreditation and Designation User Manual', V. 3.2, 2019.

SUPPORTING LITERATURE

- Biganzoli, L., Marotti, L., Hart, C. D., et al., 'Quality indicators in breast cancer care: An update from the EUSOMA working group', *European Journal of Cancer*, Vol. 86, 2017, 59e81.
- Del Turco, M. R, Ponti, A., Bick, U., et al., 'Quality indicators in breast cancer care', *European Journal of Cancer*, Vol. 46, 2010, pp. 2344–2356.
- Gradishar, W. J., Anderson, B. O., Balassanian, R. et al., 'NCCN Guidelines Insights: Breast Cancer', Version 1, *J Natl Compr Canc Netw.,* Vol. 15, Issue 4, April2017, pp. 433–451.
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- NAPBC, 'Optimal Resources for Breast Care 2024 Standards', 2024.
- NHS Scotland, Scottish Cancer Taskforce/National Cancer Quality Steering Group, 'Breast Cancer Clinical Quality Performance Indicators', 2016.
- NICE, 'Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer', National Institute for Health and Care Excellence, London, 2013.
- OECI, 'Accreditation and Designation User Manual', V. 3.2, 2019.

DGN-PTH-1: DIAGNOSTIC INTRAOPERATIVE ASSESSMENT OF SENTINEL LYMPH NODES

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.

GUIDELINE RECOMMENDATIONS

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

REFERENCE DOCUMENTS

- Bernet, L., Cano, R., Martinez, M., et al., 'Diagnosis of the sentinel lymph node in breast cancer: a reproducible molecular method: a multicentric Spanish study', *Histopathology*, Vol. 58, 2011, pp. 863–869.
- NICE, 'Intraoperative tests (RD-100i OSNA system and Metasin test) for detecting sentinel lymph node metastases in breast cancer', 2013.

SUPPORTING LITERATURE

- Bernet, L., Pinero, A., Vidal-SIcart et al., 'Consenso sobre la biopsia selectiva del ganglio centinela en el cáncer de mama', Revisión 2013 de la Sociedad Española de Senología y Patología Mamaria, Rev Esp Patol., Vol. 47, Issue 1, 2014, pp. 22–32.
- DKG, 'Catalogue of requirements for Breast Cancer Centres of the German Cancer Society', Catalogue of Requirements Pathology, 2023, https://www.onkozert.de/en/practices-cooperation-partners/ (accessed January 2024).
- European Breast Cancer Council Working Group, 'Optimal breast cancer pathology manifesto', *European Journal of Cancer*, Vol. 51, 2015, pp. 2285–2288.
- Espinosa-Bravo, M., Navarro-Cecilia, J., Ramos Boyero, M., et al., 'Intraoperative assessment of sentinel lymph node by one-step nucleic acid amplification in breast cancer patients after neoadjuvant treatment reduces the need for a second surgery for axillary lymph node dissection' *Breast*, Vol. 31, 2017, pp. 40–45.
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- Perry, N., Broeders, M., de Wolf, C., et al., 'European guidelines for quality assurance in breast cancer screening and diagnosis, Fourth ed.' European Commission, *Office for Official Publications of the European Communities*, Luxembourg, 2006.
- Spanish Society of Senology and Mammary Pathology, Breast Cancer Clinical Pathway, 2020.
- UK Royal College of Pathologists, 'Guidelines for non-operative diagnostic procedures and reporting in breast cancer screening', 2016.
- UK Royal College of Pathologists, 'Pathology reporting of breast disease in surgical excision specimens incorporating the dataset for histological reporting of breast cancer', 2016.

DGN-PTH-2: DIAGNOSTIC PATHOLOGY SERVICE

RATIONALE

Providing these techniques using validated procedures are 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.

GUIDELINE RECOMMENDATIONS

- ASCO-CAP, Guideline update: Estrogen and Progesterone Receptor Testing in Breast Cancer, 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 (*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 al. and more recently Torlakovic (*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 organisation (*Evidence quality: High; Strength of recommendation: Strong*).
- AWMF-DKG-German Cancer Aid, updated S3 Clinical Practice Guideline: Evidence-based Guideline for the Early Detection, Diagnosis, Treatment and Follow-up of Breast Cancer, 2019. When determining the hormone receptor and HER2 status and the Ki-67 proliferation index, the reliability of the detection methods used shall be ensured. This includes internal test validation, the use of standardised protocols, on slide and internal controls as well as regular successful participation in external quality assurance measures (*Good quality practice*).
- Updated guidelines from the European Group on Tumour Markers (EGTM), Duffy, M. J. et al., 2017:
  - ER For predicting the response to endocrine therapy in patients with early or advanced breast cancer. Mandatory in all patients (*Level of Evidence: IA, Strength of Recommendation: A*).
  - PR In combination with ER for predicting response to endocrine therapy in patients with early or advanced breast cancer. Mandatory in all patients (*Level of Evidence: IB, Strength of Recommendation: A/B*).
  - HER2 For predicting response to anti-HER2 therapy in patients with early or advanced breast cancer. Mandatory in all patients (*Level of Evidence: IA, Strength of Recommendation: A*).
  - Both ER and PR should be measured by IHC using an analytically and clinically validated assay (*Level of Evidence and Strength of Recommendation not applicable*).
  - The Working Group additionally used available evidence listed under supporting literature.

SUPPORTING LITERATURE

- Allison, K., Hammond, M. E., Dowsett, M. et al., 'Estrogen and Progesterone Receptor Testing in Breast Cancer: AASCO/CAP Guideline Update', *Journal of Clinical Oncology*, 2020, DOI: 10.1200 / JCO.19.02309.
- Biganzoli, L., Marotti, L., Hart, C., et al., 'Quality indicators in breast cancer care: An update from the EUSOMA working group', *European Journal of Cancer*, Vol. 86, 2017.
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- CEN/TS 16826-3:2018. Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for snap frozen tissue – Part 3: Isolated DNA.
- CEN/TS 16835-2:2015. Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for snap frozen tissue – Part 2: Isolated proteins.
- Cree, I.A., Deans, Z., Ligtenberg, M.J., et al., 'Guidance for laboratories performing molecular pathology for cancer patients', *J Clin Pathol*, Vol. 67, 2014, pp. 923–931.
- Deutsche Krebsgesellschaft (DKG) und Deutsche Gesellschaft für Gynäkologie und Geburtshilfe (DGGG), ‚Interdisziplinäre S3-Leitlinie für die Früherkennung, Diagnostik, Therapie und Nachsorge des Mammakarzinoms', Langversion 4.4, 2021, AWMF-Registernummer: 032-045OL, https://www.leitlinienprogramm-onkologie.de/fileadmin/user_upload/S3_Guideline_Breast_Cancer.pdf.
- DKG, 'Catalogue of requirements for Breast Cancer Centres of the German Cancer Society', Catalogue of Requirements Pathology, 2023, https://www.onkozert.de/en/practices-cooperation-partners/ (accessed January 2024).
- Duffy, M. J., Harbeck, N., Nap, M., et al., 'Clinical use of biomarkers in breast cancer: Updated guidelines from the European Group on Tumour Markers (EGTM)', *European Journal of Cancer,* Vol. 75, 2017, 284e298.
- ESMO, 'Primary breast cancer: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up', *Annals of Oncology*, Volume 26, Issue suppl_5, 1, 2015, v8-v30.
- Fitzgibbons, P. L., Bradley, L. A., Fatheree, L. A. et al., 'Principles of Analytic Validation of Immunohistochemical Assays: Guideline From the College of American Pathologists Pathology and Laboratory Quality Center', *Archives of Pathology & Laboratory Medicine*, Vol. 138, November 2014, No 11:1432-1443.
- Fitzgibbons, P. L., Murphy, D. A., Hammond, M. E. et al., (2010). Recommendations for validating estrogen and progesterone receptor immunohistochemistry assays', *Arch Pathol Lab Med,* Vol. 134, 2010, pp. 930–935.
- Hammond, M.E., Hayes, D.F., Dowsett, M., et al., 'American Society of Clinical Oncology/ College of American Pathologists guideline recommendations for immunohistochemical testing of estrogen and progesterone receptors in breast cancer (unabridged version)'. *Arch Pathol Lab Med*, Vol. 134, 2010.
- 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 20184-1:2018. Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for frozen tissue – Part 1: Isolated RNA.
- ISO 20184-2:2018. Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for frozen tissue – Part 2: Isolated proteins.
- 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.
- ISO/TS 20658:2017. Requirements for collection, transport, receipt and handling of samples.
- Kreienberg, R., Albert, U.S., Follmann, M., et al., 'Interdisciplinary GoR level III Guidelines for the Diagnosis, Therapy and Follow-up Care of Breast Cancer: Short version - AWMF Registry No.: 032-045OL AWMF-Register-Nummer: 032-045OL - Kurzversion 3.0', Geburtshilfe Frauenheilkd, 2013, Vol. 73, Issue 6, pp. 556-583.
- OECI, 'Accreditation and Designation User Manual', V. 3.2, 2019.
- Royal College of Pathologists, 'Pathology reporting of breast disease in surgical excision specimens incorporating the dataset for histological reporting of breast cancer', 2016.
- Rakha, E. A., Pinder, S. E., Bartlett, et al., National Coordinating Committee for Breast Pathology. 'Updated UK recommendations for HER2 assessment in breast cancer', *J Clin Pathol*, Vol. 68, 2015.
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- Stordeur, S., Vrijens, F., Beirens, K., et al., '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.
- Stordeur, S., Vrijens, F., Devriese, S., et al., 'Developing and measuring a set of process and outcome indicators for breast cancer', *The Breast*, Vol. 21, 2012, pp.253–260.
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- Wolff, A. C., Hammond, M. E., Hicks, D. G. et al., 'Reply to Rakha EA et al.', *J Clin Oncol*, Vol. 33, 2015, pp. 1302–1304.
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DGN-PTH-3: DIAGNOSTIC PATHOLOGY REPORT

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.

GUIDELINE RECOMMENDATIONS

- ASCO-CAP, Guideline update: Estrogen and Progesterone Receptor Testing in Breast Cancer, 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*).
- AWMF-DKG-German Cancer Aid, updated S3 Clinical Practice Guideline, 2021. Evidence-based Guideline for the Early Detection, Diagnosis, Treatment and Follow-up of Breast Cancer:
  - The surgical material shall be clearly marked topographically and sent to the pathologist without incision on the tissue material obtained (*Good Clinical Practice*).
  - The surgical material shall be marked clearly topographically with details of the problem and the clinical-radiological findings and sent in full to the pathologist (*Good Clinical Practice*).
  - To assess the course of the disease (prognosis), the pTNM status (locoregional tumour spread, locoregional lymph node involvement, distant metastasis) shall be assessed according to the current TNM classification (currently 8th edition (*Grade of recommendation: A, Level of evidence: 1a*).
  - To assess the course of the disease (prognosis), the resection margin status (R classification, according to current TNM-classification, currently 8th edition) as well as safety margins shall be assessed (*Grade of recommendation: A, Level of evidence: 1b*).
  - To assess the course of the disease (prognosis), the histological type (according to current WHO classification) shall be determined (*Grade of recommendation: A, Level of evidence: 2b*).
  - To assess the course of the disease (prognosis) the histological grading according to Elston and Ellis shall be determined (*Grade of recommendation: A, Level of evidence: 2a*).
  - To assess the course of the disease (prognosis) the peritumoral lymph vessel invasion (according to the current TNM classification, currently 8th edition) shall be assessed (*Grade of recommendation: A, Level of evidence: 2b*).
  - To assess the probable effect of adjuvant systemic therapies (prediction), the estrogen/progesterone receptor status for endocrine systemic therapy shall be assessed (*Grade of recommendation: A, Level of evidence: 1a*).
  - To assess the probable effect of adjuvant systemic therapies (prediction), the HER2 status for a targeted anti-HER2 therapy shall be determined (*Grade of recommendation: A, Level of evidence: 1b*).
  - Ki-67 proliferation index in women with ER-/PgR-positive and HER2 negative invasive tumours for decision on chemotherapy (*facultative; 2018 update of S3 guidelines*).

- ESMO, Senkus, E. et al. Clinical Practice Guidelines for diagnosis, treatment and follow-up: Primary breast cancer, 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 and 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 (*Grade of recommendation and Level of evidence not applicable*).
- KCE, Good Clinical Practice Guidelines, Breast cancer in women: Diagnosis, Treatment and Follow-up, 2010. Estrogen receptors and progesterone receptors (ER/PgR) should be measured on all ductal carcinomas in situ (DCIS) and primary invasive breast cancers (*Strong recommendation, moderate level of evidence*).
- European Commission, European Guidelines on Breast Cancer Screening and Diagnosis, 2024: In women with invasive breast cancer, the ECIBC's 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 Tumour Markers, Duffy, M. J. et al., 2017. Clinical use of biomarkers in breast cancer:
  - ER should be measured on all newly diagnosed primary invasive breast cancers (*Level of evidence: IA, Strength of recommendation: A*).
  - PR should be measured on all newly diagnosed primary invasive breast cancers (*Level of evidence: 1B, Strength of recommendation: A/B*).
  - HER2 gene amplification or overexpression should be determined on all patients with primary invasive breast cancer (*Level of evidence: IA, Strength of recommendation: A*).
  - Ki67 may be used in combination with established prognostic factors for determining prognosis (*Level of evidence: IB, Strength of recommendation: B*).

SUPPORTING LITERATURE

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- Gonzalez, M. A., and Pinder, S. E., 'Invasive carcinoma: other histologic prognostic factors – size, vascular invasion and prognostic index', in: O'Malley, F. P., Pinder, S. E. (eds), *Breast Pathology*, Elsevier, Philadelphia, PA, 2006, pp. 235–240.
- Kreienberg, R., Albert, U.S., Follmann, M., et al., 'Interdisciplinary GoR level III Guidelines for the Diagnosis, Therapy and Follow-up Care of Breast Cancer: Short version - AWMF Registry No.: 032-045OL AWMF-Register-Nummer: 032-045OL - Kurzversion 3.0', Geburtshilfe Frauenheilkd, 2013, Vol. 73, Issue 6, pp. 556-583.
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- Stordeur, S., Vrijens, F., Beirens, K., et al., '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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DGN-PTH-4: PATHOLOGY SPECIMEN MINIMUM STORAGE TIME

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.

GUIDELINE RECOMMENDATIONS

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

SUPPORTING LITERATURE

- Biganzoli, L., Cardoso, F., Beishon, M., et al., 'The Requirements of a Specialist Breast Centre', *Breast*, Vol. 51, 2020, pp. 65–84.
- Cree, I. A., Deans, Z., Ligtenberg, M. J. L. et al., 'Guidance for laboratories performing molecular pathology for cancer patients', *J Clin Pathol* Vol. 67, 2014, pp. 923–931.
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DGN-PTH-5: TIME FROM RECEIPT OF SPECIMEN TO ISSUING OF RESULTS FOR NON-SURGICAL BIOPSIES AND 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.

GUIDELINE RECOMMENDATIONS

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

SUPPORTING LITERATURE

- Biganzoli, L., Cardoso, F., Beishon, M., et al., 'The Requirements of a Specialist Breast Centre', *Breast*, Vol. 51, 2020, pp. 65–84.
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- Royal College of Pathologists, 'Key performance indicators for pathology services', 2019, https://www.rcpath.org/uploads/assets/62de2970-42aa-4d73- 9bf1122a1746331a/G181-Key-assurance-indicators-for-pathology-services.pdf.
- SIS/ISS, International Accreditation Program for Breast Centers/Units, 2020.
- Sociedad Española de Senología y Patología Mamaria, 'Protocolo Nacional de acreditación de las unidades de mama', https://sespm.es/wp-content/uploads/2023/03/PROTOCOLO-DE-ACREDITACION-DE-UNIDADES-DE-MAMA.pdf (accessed April 2019).
- Tot, T., Viale, G., Rutgers, E., et al., 'Optimal breast cancer pathology manifesto', *EurJ of Cancer* Vol. 51, 2015, pp. 2285–2288).

DGN-TRT-1: NURSE ACCESS AND REFERRAL

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; clinical effectiveness.

GUIDELINE RECOMMENDATIONS

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

REFERENCE DOCUMENTS

- Dutch breast cancer guidelines, www.oncoline.nl.

SUPPORTING LITERATURE

- Biganzoli, L., Cardoso, F., Beishon, M., et al., 'The Requirements of a Specialist Breast Centre', *Breast*, Vol. 51, 2020, pp. 65–84.
- Biganzoli, L., Marotti, L., Hart, C., et al., 'Quality indicators in breast cancer care: An update from the EUSOMA working group', *European Journal of Cancer* Vol. 86, 2017.
- Del Turco, M., Ponti, A., Bick, U., et al., 'Quality indicators in breast cancer care', *European Journal of Cancer* Vol. 46, 2010, pp. 2344–2356.
- DKG, 'Catalogue of requirements for Breast Cancer Centres of the German Cancer Society', Version L1, 2023.
- OECI, 'Accreditation and Designation User Manual', V. 3.2, 2019.

DGN-TRT-2: MULTIDISCIPLINARY MEETINGS (MDMs)

RATIONALE

Multidisciplinary teams are considered to optimise decision-making in the diagnosis, treatment and support of patients. All patients with breast cancer who visit BCS should be discussed by the multidisciplinary team. It is important to monitor the time between when the decision about treatment is made and when treatment actually starts.

QUALITY DOMAIN: Clinical effectiveness.

GUIDELINE RECOMMENDATIONS

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

SUPPORTING LITERATURE

- DKG, 'Catalogue of requirements for Breast Cancer Centres of the German Cancer Society', Version L1, 2023.
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- NABON, Breast Cancer Audit (NBCA), 'Factsheets Indicators 2016'.
- NAPBC, 'Optimal Resources for Breast Care 2024 Standards', 2024.
- NHS England, 'Manual for Cancer Services; Breast Cancer Measures', National Peer Review Programme, 2013.
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- SIS/ISS, International Accreditation Program for Breast Centers/Units, 2020.

DGN-TRT-3: PSYCHO-ONCOLOGY CARE

RATIONALE

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

QUALITY DOMAIN: Personal empowerment and experience.

GUIDELINE RECOMMENDATIONS

- ESMO, 'Clinical Practice Guidelines: Care of the adult cancer patient at the end of life', 2021:
  - Early detection and treatment of psychological distress leads to better adherence to treatment, better communication, reduced patient anxiety and reduced depression (*Level of Evidence: II, Grade of Recommendation: A*).
  - Assessment and treatment of anxiety and existential distress should be undertaken early in the disease as these are highly prevalent in cancer patients at end of life (*Level of Evidence: I, Grade of Recommendation: A*).
- ESMO, 'Clinical Practice Guidelines for diagnosis, treatment and follow-up: Early breast cancer', 2019. The breast unit/centre should have or be able to refer patients to plastic/reconstructive surgeons, psychologists, physiotherapists and geneticists when appropriate (*Level of Evidence: II, Grade of Recommendation: A*).
- NCCN, 'Clinical Practice Guidelines in Oncology: Distress Management', 2023:
  - Distress should be recognised, monitored, documented and treated promptly at all stages of disease and in all settings (*category 2A*).
  - Interdisciplinary institutional committees should be formed to implement standards for distress management (*category 2A*).
  - Licensed mental health professionals and certified chaplains experienced in the psychosocial aspects of cancer should be readily available as staff members or by referral (*category 2A*).
- AWMF-DKG-German Cancer Aid, updated S3 Clinical Practice Guideline, 'Evidence-based Guideline for the Early Detection, Diagnosis, Treatment and Follow-up of Breast Cancer', 2021. The psycho-oncological interventions listed below shall be offered to patients after the individual needs have been determined using validated measuring instruments: a) relaxation method; b) psychoeducational interventions; c) individual psychotherapeutic interventions; d) psychotherapeutic group interventions, and e) psychotherapeutic couple interventions (*Grade of Recommendation: A, Level of Evidence: 1a*).
- AWMF-DKG-German Cancer Aid, extended S3 Clinical Practice Guideline, 'Palliative care for patients with incurable cancer', 2020. In cases of non-pharmacological treatment of depression, behavioural-therapy interventions (e.g. cognitive behavioural therapy interventions or problem-solving approaches), interpersonal psychotherapy interventions, mindfulness-based stress reduction or acceptance and commitment therapy should be delivered (*Grade of Recommendation: B; Level of Evidence: 1-*).

SUPPORTING LITERATURE

- Albreht, T., Martin-Moreno, J. M., Jelenc, M., Gorgojo, L. and Harris, M. (eds), 'European Guide for Quality National Cancer Control Programs', National Institute of Public Health, Ljubljana, Slovenia, 2015.
- Biganzoli, L., Cardoso, F., Beishon, M. et al., 'The Requirements of a Specialist Breast Centre', *Breast*, Vol. 51, 2020, pp. 65–84.
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- Crawford, G. B., Dzierżanowski, T., Hauser, K. et al., 'Care of the adult cancer patient at the end of life: ESMO Clinical Practice Guidelines', ESMO open, Vol. 6, Issue 4, 2021.
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- 'Evidence-based Guideline for the Early Detection, Diagnosis, Treatment and Follow-up of Breast Cancer', German Guideline Program in Oncology (German Cancer Society, German Cancer Aid, AWMF): 'Interdisciplinary Evidenced-based Practice Guideline for the Early Detection, Diagnosis, Treatment and Follow-up of Breast Cancer', Long version 4.4, May 2021, AWMF Registration Number: 032/045OL,
- http://www.leitlinienprogramm-onkologie.de/leitlinien/mammakarzinom/.
- 'Extended S3 Guideline Palliative care for patients with incurable cancer. German Guideline Program in Oncology (German Cancer Society, German Cancer Aid, AWMF): 'Palliative care for patients with incurable cancer', Extended version. Short version 2.2, 2020 AWMF-registration number 128/001OL.
- https://www.leitlinienprogramm-onkologie.de/leitlinien/palliativmedizin.
- KCE, 'Breast cancer in women: diagnosis, treatment and follow-up', KCE, Brussels, 2013.
- NCCN, 'Clinical Practice Guidelines in Oncology: Distress Management' – Version 2.2023.
- Neamtiu, L., Deandrea, S., Pylkkanen, L. et al., 'Psycho-oncological support for breast cancer patients: A brief overview of breast cancer services certification schemes and national health policies in Europe', *The Breast* Vol. 29, 2016, pp. 178–180.
- OECI, 'Accreditation and Designation User Manual', V. 3.2, 2019.
- Paluch-Shimon, S., Cardoso, F., Partridge, A. H. et al., 'ESO-ESMO fifth international consensus guidelines for breast cancer in young women (BCY5)', *Annals of Oncology*, Vol. 11, 2022, pp. 1097–1118, DOI: 10.1016 / j.annonc.2022.07.007.
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DGN-TRT-4: PRE-TREATMENT DIAGNOSIS

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; safety.

GUIDELINE RECOMMENDATIONS

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

SUPPORTING LITERATURE

- Biganzoli, L., Marotti, L., Hart, C. D., et al., 'Quality indicators in breast cancer care: An update from the EUSOMA working group', *European Journal of Cancer*, Vol. 86, 2017, 59e81.
- Del Turco, M., Ponti, A., Bick, U. et al., 'Quality indicators in breast cancer care', *European Journal of Cancer* Vol. 46, 2010, pp. 2344–2356.

DGN-TRT-5: ASSESSMENT OF BIOMARKERS BEFORE STARTING TREATMENT

RATIONALE

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

QUALITY DOMAIN: Clinical effectiveness.

GUIDELINE RECOMMENDATIONS

- Updated guidelines from the European Group on Tumor Markers (EGTM), Duffy, M. J. et al., 'Clinical use of biomarkers in breast cancer', 2017:
  - ER For predicting the response to endocrine therapy in patients with early or advanced breast cancer. Mandatory in all patients (*Level of evidence: IA, Strength of recommendation: A*).
  - PR in combination with ER for predicting response to endocrine therapy in patients with early or advanced breast cancer. Mandatory in all patients (*Level of evidence: IB, Strength of recommendation: A/B*).
  - HER2 for predicting response to anti-HER2 therapy in patients with early or advanced breast cancer. Mandatory in all patients. (*Level of evidence: IA, Strength of recommendation: A*).
  - 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 (*Level of evidence: IB, Strength of recommendation: A/B*).

SUPPORTING LITERATURE

- Biganzoli, L., Marotti, L., Hart, C. D., et al., 'Quality indicators in breast cancer care: An update from the EUSOMA working group', *European Journal of Cancer*, Vol. 86, 2017, 59e81.
- Duffy, M. J., Harbeck, N., Nap, M. et al., 'Clinical use of biomarkers in breast cancer: Updated guidelines from the European Group on Tumour Markers (EGTM)', *European Journal of Cancer* Vol. 75, 2017, 284e298.

DGN-TRT-6: LEAD TIME BETWEEN PATHOLOGY REPORT WITH DIAGNOSIS AND FIRST TREATMENT

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.

GUIDELINE RECOMMENDATIONS

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

SUPPORTING LITERATURE

- Anema, H. A., Kievit, J., Fischer, C. et al., 'Influences of hospital information systems, indicator data collection and computation on reported Dutch hospital performance indicator scores', *BMC Health Services Research* Vol. 13, 2013, p. 212.
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- Ferrua, M., Couralet, M., Nitenberg, G. et al., '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* Vol. 12, 2012, p. 167.
- Hoeve, J. van, Munck, L. de, Otter, R. et al., 'Quality improvement by implementing an integrated oncological care pathway for breast cancer patients', *The Breast* Vol. 23, 2014, pp. 364–370.
- Khare, S. R., Batist, G., Bartlett, G., 'Identification of performance indicators across a network of clinical cancer programs', *Curr Oncol*. Vol. 23, Issue 2, April 2016, pp. 81–90.
- Krzyzanowska, M. K., Barbera, L., Elit, L. et al., 'Identifying population-level indicators to measure the quality of cancer care for women; *International Journal for Quality in Health Care*, Vol. 23, Issue 5, 2011, pp. 554–564.
- NABON Breast Cancer Audit (NBCA), 'Factsheets Indicators 2016' DICA, IKNL, NBCA.
- Rosselli Del Turco, M., Ponti, A., Bick, U. et al., 'Quality indicators in breast cancer care', *European Journal of Cancer* Vol. 46, 2010, pp. 2344–2356.

TREATMENT

TRT-1: MEDICATION SAFETY

RATIONALE
Safety procedures are essential in preventing adverse events.

QUALITY DOMAIN: Clinical effectiveness; safety.

GUIDELINE RECOMMENDATIONS

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

SUPPORTING LITERATURE

- OECI, 'Accreditation and Designation User Manual', V. 3.2, 2019.
- Qmentum International, 'Cancer care Services', Standards, Accreditation Canada, 2013.

TRT-2: 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.

GUIDELINE RECOMMENDATIONS

- ESMO, 'ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up: Cancer, pregnancy and fertility', 2013. 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 (*Level of Evidence: IV, Grade of Recommendation: B*).
- KCE, 'Good Clinical Practice Guidelines, Breast cancer in women: 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*).
  - Chemotherapy during pregnancy is not contraindicated after 14 weeks of gestation (*Strength of recommendation: weak. Quality of evidence: low*).

SUPPORTING LITERATURE

- ASCO, 'Fertility Preservation for Patients with Cancer', 2013.
- ASCO, 'Role of Patient and Disease Factors in Adjuvant Systemic Therapy Decision Making for Early-Stage, Operable Breast Cancer', 2016.
- Belgian Health Care Knowledge Centre (KCE), 'Breast cancer in women: diagnosis, treatment and follow-up', Good Clinical Practice (GCP), Brussels, KCE Reports 143, 2013.
- Cancer Australia, 'Recommendations for follow-up of women with early breast cancer', 2010.
- ESMO, 'Cancer, pregnancy and fertility: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up', 2013.
- NAPBC, 'Optimal Resources for Breast Care 2024 Standards', 2024.
- NCCN, 'Breast Cancer', 2016.

TRT-3: PHYSICAL ACTIVITY AND NUTRITION 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 BCS 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.

GUIDELINE RECOMMENDATIONS

- NCCN, 'Clinical Practice Guidelines in Oncology: Survivorship', 2022. Cancer survivors should be assessed for dietary patterns and timing of meals (i.e. intake of different types of foods, frequency, portions). All survivors should be encouraged to make informed choices about food to ensure variety and adequate nutrient intake, limit red meat, processed foods and sugars, eat a predominantly plant-based diet and drink alcohol sparingly if at all (*category 2A*).
- NCCN, 'Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue', 2023. Cancer-related fatigue interventions for patients on active treatment: maintain optimal level of physical activity. Consider initiation and/or encourage maintenance of a physical activity/exercise programme, as appropriate per health care provider, consisting of cardiovascular endurance (walking, jogging, or swimming) and resistance (weights) training. Consider referral to rehabilitation: physical therapy, occupational therapy, and physical medicine (*category 1*).
- AWMF-DKG-German Cancer Aid, updated 'S3 Clinical Practice Guideline', 2021. Evidence-based Guideline for the Early Detection, Diagnosis, Treatment and Follow-up of Breast Cancer:
  - Patients shall be advised to be physically active during oncological therapy, as this has a positive effect on the physical fitness of the patient and thus facilitates the performance of daily activities (ADL) (*Grade of Recommendation: A, Level of Evidence: 1a*).
  - Exercise programmes with strength and endurance training shall be offered with the aim of reducing therapy-related limitations in physical performance, reducing fatigue and improving the quality of life of breast cancer patients (*Grade of Recommendation: A, Level of Evidence: 1a*).
- AGO, 'AGO Recommendations for the Diagnosis and Treatment of Patients with Early Breast Cancer: Update 2022', 2022. Physical exercise (endurance training three times a week in combination with workout exercises two times a week) show beneficial effects on quality of life, cardio-respiratory fitness, physical performance, sleep, pain, depression, lymphedema and fatigue (*LoE1a/A/AGO++*).
- ASCO guideline: 'Exercise, Diet, and Weight Management During Cancer Treatment', 2022. Oncology providers should recommend aerobic and resistance exercise during active treatment with curative intent to mitigate side effects of cancer treatment (*Type: evidence based, benefits outweigh harms; Evidence quality: moderate to low; Strength of recommendation: strong*).

- ESMO, 'ESMO Clinical Practice Guidelines for diagnosis and treatment: Cancer-related fatigue', 2020. Physical exercise of moderate intensity and aerobic and functional resistance exercise are recommended in patients with cancer-related fatigue for controlling it (*Quality of evidence: I, Strength of recommendation: B*).
- ESMO, 'ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up: Early breast cancer', 2019. Patients should be encouraged towards adopting a healthy and active lifestyle, including diet modification (healthy diet and limited alcohol intake) and achieving and maintaining an ideal body weight, which may lead to optimal cancer outcomes (*Quality of evidence: II, Strength of recommendation: A*).

SUPPORTING LITERATURE

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- NCCN, 'Clinical Practice Guidelines in Oncology: Survivorship', Version 1, 2022.
- NCCN, 'Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue', Version 2.2023.
- OECI, 'Accreditation and Designation User Manual', V. 3.2, 2019.
- World Cancer Research Fund, 'Diet, Nutrition and Physical Activity and Breast Cancer Survivors', 2014, www.wcrf.org/sites/default/files/Breast-Cancer-Survivors-2014-Report.pdf.
- World Health Organisation, 'Breast Cancer: prevention and control', 2014, www.who.int/cancer/detection/breastcancer/en/index.html.

TRT-4: PAIN MANAGEMENT

RATIONALE

Pain can be due to advanced breast cancer or 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.

GUIDELINE RECOMMENDATIONS

- NCCN, 'Clinical Practice Guidelines in Oncology: Adult Cancer Pain', 2022:
  - For pain management, an interdisciplinary team is optimal; consider early referral to a palliative care provider (*category 2A*).
  - Provide accessible educational material to improve pain assessment, pain management, and the safe use of opioid medications based on the patient's identified needs. Involve patients in developing treatment plans and setting meaningful, realistic expectations and measurable goals (*category 2A*).
  - The experience of pain has been associated with suffering. The multidimensional impact of 'suffering' on patients and their families must be considered, and these concerns must addressed in a culturally respectful manner (*category 2A*).

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TRT-5: COMPLEMENTARY AND INTEGRATIVE MEDICINE

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.

GUIDELINE RECOMMENDATIONS

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

SUPPORTING LITERATURE

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TRT-6: LEAD TIME BETWEEN LAST SURGERY AND FIRST ADJUVANT CHEMOTHERAPY CYCLE

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.

GUIDELINE RECOMMENDATIONS

- KCE, 'Good Clinical Practice Guidelines. Breast cancer in women: Diagnosis, Treatment and Follow-up', 2013. It is recommended to start adjuvant chemotherapy or radiotherapy within 8 weeks of completion of surgery (*Level of evidence: 1c, Strength of recommendation: Strong*).
- NICE, 'Early and locally advanced breast cancer: diagnosis and treatment', 2018. Clinical guideline. 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 (*certainty of evidence not reported*).
- ESMO, 'ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up: Primary breast cancer', 2015. Neoadjuvant therapy should start as soon as diagnosis and staging are completed (ideally within 2-4 weeks). 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 (*certainty of evidence not reported*).
- SIGN, 'Treatment of primary breast cancer: A national clinical guideline', 2013. 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+*).

SUPPORTING LITERATURE

- Andreano, A., Anghinoni, E., Autelitano, M. 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*, Vol. 22, 2016, pp. 62–70.
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TRT-7: LEAD TIME TO FIRST RADIOTHERAPY TREATMENT

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.

GUIDELINE RECOMMENDATIONS

- KCE, 'Good Clinical Practice Guidelines, Breast cancer in women: Diagnosis, Treatment and Follow-up', 2013. It is recommended to start adjuvant chemotherapy or radiotherapy within 8 weeks of completion of surgery (Recommendations 2010) (*Grade: 1C; Strong recommendation based on low or very low level of evidence*).
- SIGN, 'Treatment of primary breast cancer: A national clinical guideline', 2013. Retrospective and observational studies indicate that delaying radiotherapy beyond eight weeks has a detrimental effect on local recurrence (*Quality of evidence: 2+*).
- NICE, 'Early and locally advanced breast cancer: diagnosis and treatment', Clinical guideline, 2018. 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 (*certainty of evidence not reported*).

SUPPORTING LITERATURE

- Bao, H., Yang, F., Xinyu Wang, X. et al., 'Developing a set of quality indicators for breast cancer care in China', *International Journal for Quality in Health Care*, Vol. 27, Issue 4, 2015, pp. 291–296.
- Barni, S., Venturini, M., Molino, A. et al., 'Importance of adherence to guidelines in breast cancer clinical practice. The Italian experience (AIOM)', *Tumori*, Vol. 97, 2011, pp. 559–563.
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TRT-SUR-1: SENTINEL LYMPH NODE BIOPSY

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.

GUIDELINE RECOMMENDATIONS

- NICE, 'Early and locally advanced breast cancer: diagnosis and management', 2018:
  - Offer SLNB to all patients who are having a mastectomy for DCIS (*certainty of evidence not reported*).
  - Do not routinely perform SLNB for women with a preoperative diagnosis of DCIS who are having breast-conserving surgery, unless they are considered to be at high risk for invasive disease (*certainty of evidence not reported*).
  - 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 (*certainty of evidence not reported*).
  - Perform SLNB using the dual technique with isotope and blue dye (*certainty of evidence not reported*).
- SIGN, 'Treatment of primary breast cancer: A national clinical guideline', 2013. 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*).
- KCE, 'Good Clinical Practice Guidelines, Breast cancer in women: Diagnosis, Treatment and Follow-up', 2013:
  - In women with primary breast cancer of less than 3 cm and with clinically and ultrasonographically negative nodes, a sentinel lymph node biopsy should be performed (*Grade: 1A; Strong recommendation based on high level of evidence*).
  - Sentinel lymph node biopsy is not recommended for large T2 (i.e. > 3 cm) or T3-4 invasive breast cancers; inflammatory breast cancer; patients with suspicious palpable axillary lymph nodes; multiple tumours; and possibly disturbed lymph drainage after recent axillary surgery or a large biopsy cavity after tumour excision (*Grade: 1A; Strong recommendation based on high level of evidence*).
- ESMO, 'ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up: Primary breast cancer', 2015*:*
  - 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*).
  - 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*).
- Alberta Health Services, 'Clinical Practice Guideline: Sentinel lymph node biopsy and axillary node dissection in early stage breast cancer', 2012. 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*).

- ASCO, 'Clinical Practice Guideline Update: Sentinel Lymph Node Biopsy for Patients With Early-Stage Breast Cancer', 2014:
  - Clinicians may offer SNB for women who have operable breast cancer who have the following circumstances: multicentric tumours (*Evidence quality: intermediate, Strength of recommendation: moderate*).
  - 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*).
    - 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*).
  - Clinicians should not perform SNB for women who have early-stage breast cancer and are in the following circumstances:
    - 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

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using registry data and electronic health records: a population- based study', *International Journal for Quality of Health Care*, Vol. 24, Issue 4, 2012, pp. 411–418.
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- NAPBC, 'Optimal Resources for Breast Care 2024 Standards', 2024.
- NHS England, 'Manual for Cancer Services; Breast Cancer Measures', National Peer Review Programme, 2013.
- NICE, 'Early and locally advanced breast cancer: diagnosis and treatment', Clinical guideline, 2018.
- Rosselli Del Turco, M., Ponti, A., Bick, U. et al., 'Quality indicators in breast cancer care', *European Journal of Cancer*, Vol. 46, 2010, pp. 2344–2356.
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TRT-SUR-2: AVOID AXILLARY LYMPH NODE DISSECTION FOR PATHOLOGICAL NODE-NEGATIVE INVASIVE BREAST CANCER

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.

GUIDELINE RECOMMENDATIONS

- SIGN, 'Treatment of primary breast cancer: A national clinical guideline', 2013:
  - If there is 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 (or if not available, axillary node sample is an alternative) (*key clinical recommendation*).
  - 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 (*Quality of evidence: 1^{-} - 1^{++}*).
- ASCO, 'Clinical Practice Guideline Update: Sentinel Lymph Node Biopsy for Patients With Early-Stage Breast Cancer', 2014:
  - 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*).
  - 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 with conventionally fractionated whole-breast radiotherapy (*Evidence quality: high. Strength of recommendation: strong*).
  - Clinicians may offer ALND for women with early-stage breast cancer with nodal metastases found on SNLB who will receive a mastectomy (*Evidence quality: low. Strength of recommendation: weak*).
- NICE, 'Early and locally advanced breast cancer: diagnosis and management', 2018:
  - 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 (*certainty of evidence not reported*).
  - 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 (*certainty of evidence not reported*).
  - 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 (*certainty of evidence not reported*).

- KCE, 'Good Clinical Practice Guidelines, Breast cancer in women: Diagnosis, Treatment and Follow-up', 2013. For women with three or more positive sentinel lymph nodes with micro- or macrometastases, we recommend ALND (*Evidence quality: Very low; Strength of recommendation: strong*).

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TRT-SUR-3: AVOID AXILLARY LYMPH NODE DISSECTION FOR DCIS

RATIONALE
Axillary lymph node dissection (ALND) should be avoided in women with DCIS who are surgically treated.

QUALITY DOMAIN: Clinical effectiveness.

GUIDELINE RECOMMENDATIONS

- SIGN, 'Treatment of primary breast cancer: A national clinical guideline', 2013:
  - If there is 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 (or if not available axillary node sample is an alternative) (*certainty of evidence not reported*).
  - 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 (*Quality of evidence: 1^{-} – 1^{++}*).
- ASCO, 'Clinical Practice Guideline Update: Sentinel Lymph Node Biopsy for Patients With Early-Stage Breast Cancer', 2014:
  - 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*).
  - 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 with conventionally fractionated whole-breast radiotherapy (*Evidence quality: high, Strength of recommendation: strong*).
  - Clinicians may offer ALND for women with early-stage breast cancer with nodal metastases found on SNLB who will receive a mastectomy (*Evidence quality: low. Strength of recommendation: weak*).
- NICE, 'Early and locally advanced breast cancer: diagnosis and management', 2018:
  - 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 (certainty of evidence not reported).
  - 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 (*certainty of evidence not reported*).
  - 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 (*certainty of evidence not reported*).

- KCE, 'Good Clinical Practice Guidelines, Breast cancer in women: Diagnosis, Treatment and Follow-up', 2013. ALND is recommended for women with > 3 positive SNLB nodes with micro- or macrometastases (*Evidence quality: very low; Strength of recommendation: strong*).

SUPPORTING LITERATURE

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- Stordeur, S., Vrijens, F., Devriese, S. et al., 'Developing and measuring a set of process and outcome indicators for breast cancer', *The Breast*, Vol. 21, 2012, pp. 253–260.
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TRT-SUR-4: BREAST-CONSERVING SURGERY IN DCIS

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 ≤ 2cm should have breast-conserving surgery.

QUALITY DOMAIN: Clinical effectiveness.

GUIDELINE RECOMMENDATIONS

- Stordeur, S. et al., 'Developing and measuring a set of process and outcome indicators for breast cancer', 2012. 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*).
- SIGN, 'Treatment of primary breast cancer: A national clinical guideline', 2013. 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^{++}*).

SUPPORTING LITERATURE

- Andreano, A., Anghinoni, E., Autelitano, M. 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*, Vol. 22, 2016, pp. 62–70.
- Barni, S., Venturini, M., Molino, A. et al., 'Importance of adherence to guidelines in breast cancer clinical practice. The Italian experience (AIOM)', *Tumori*, Vol. 97, 2011, pp. 559–563.
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- NAPBC, 'Optimal Resources for Breast Care 2024 Standards', 2024.

- 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.
- Rosselli Del Turco, M., Ponti, A., Bick, U. et al., 'Quality indicators in breast cancer care', *European Journal of Cancer*, Vol. 46, 2010, pp. 2344–2356.
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- SIGN, 'Treatment of primary breast cancer', September 2013.
- SIS/ISS, International Accreditation Program for Breast Centers/Units, 2020.
- Stordeur, S., Vrijens, F., Devriese, S. et al., 'Developing and measuring a set of process and outcome indicators for breast cancer', *The Breast*, Vol. 21, 2012, pp. 253–260.

TRT-SUR-5: BREAST-CONSERVING SURGERY FOR INVASIVE BREAST CANCER WITH SMALL TUMOUR SIZE

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.

GUIDELINE RECOMMENDATIONS

- KCE, 'Good Clinical Practice Guidelines, Breast cancer in women: Diagnosis, Treatment and Follow-up', 2010:
  - 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*).
  - The choice of surgery must be tailored to the individual patient with stage I or II breast cancer, who should be fully informed of the surgical options (*Evidence quality: 1A*).
- ESMO, 'ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up', 2015: Primary breast cancer. Breast conservation (wide local excision and RT) 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 (*certainty of evidence not reported*).
- SIGN, 'Treatment of primary breast cancer: A national clinical guideline', 2013:
  - 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*).
  - 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^+*).

SUPPORTING LITERATURE

- Andreano, A., Anghinoni, E., Autelitano, M. 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*, Vol. 22, 2016, pp. 62–70.
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- Stordeur, S., Vrijens, F., Devriese, S. et al., 'Developing and measuring a set of process and outcome indicators for breast cancer', *The Breast*, Vol. 21, 2012, pp. 253–260.

TRT-SUR-6: SINGLE BREAST OPERATION FOR THE PRIMARY DCIS

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.

GUIDELINE RECOMMENDATIONS

- SIGN, 'Treatment of primary breast cancer: A national clinical guideline', 2013. In women with DCIS or invasive breast cancer undergoing conservation surgery the radial margins must be clear (≥ 1mm) (*Evidence quality: 2^+; Recommendation: strong*).
- IKNL NABON, 'Breast Cancer Dutch Guideline', 2012. Breast conserving surgery should aim at tumor-free resection margins (*certainty of evidence not reported*).
- SSO-ASTRO-ASCO, 'Consensus Guideline on Margins for Breast-Conserving Surgery With Whole-Breast Irradiation in Ductal Carcinoma In Situ', 2016. Margins of at least 2 mm are associated with a reduced risk of IBTR relative to narrower negative margin widths in patients receiving WBRT (*Strength of recommendation: moderate, Strength of evidence: moderate*).
- ESMO, 'ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up: Primary breast cancer', 2015. No tumour at the inked margin is required and > 2 mm (for in situ disease) is preferred (*certainty of evidence not reported*).
- NICE, 'Early and locally advanced breast cancer: diagnosis and management', 2018. 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 (*certainty of evidence not reported*).
- KCE, 'Good Clinical Practice Guidelines, Breast cancer in women: Diagnosis, Treatment and Follow-up', 2010. When local wide excision is performed in women with DCIS, a minimum radial excision margin of 2 mm is usually recommended, with pathological examination of the specimen (*Evidence quality: 1C; Recommendation: strong*).

SUPPORTING LITERATURE

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Stages I and II Invasive Breast Cancer', *Ann Surg Oncol*, Vol. 21, 2014, pp. 704–716.
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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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- Rosselli Del Turco, M., Ponti, A., Bick, U. et al., 'Quality indicators in breast cancer care', *European Journal of Cancer*, Vol. 46, 2010, pp. 2344–2356.
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- Stordeur, S., Vrijens, F., Devriese, S. et al., 'Developing and measuring a set of process and outcome indicators for breast cancer', *The Breast*, Vol. 21, 2012, pp. 253–260.

TRT-SUR-7: SINGLE BREAST OPERATION FOR PRIMARY INVASIVE BREAST CANCER

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.

GUIDELINE RECOMMENDATIONS

- SIGN, 'Treatment of primary breast cancer: A national clinical guideline', 2013. In women with DCIS or invasive breast cancer undergoing conservation surgery the radial margins must be clear (≥ 1mm) (*Evidence quality: 2^+; Recommendation: strong*).
- IKNL NABON, 'Breast Cancer Dutch Guideline', 2012. Breast conserving surgery should aim at tumor free resection margins (*certainty of evidence not reported*).
- SSO-ASCO-ASRO, 'Consensus guideline on margins for breast-conserving surgery with whole-breast irradiation in stages I and II invasive breast cancer', 2014. 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 (*certainty of evidence not reported*).

SUPPORTING LITERATURE

- ASCO-JCO, Partridge, A. H., Rumble, R. B., Carey, L. A. 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', 2014.
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- Stordeur, S., Vrijens, F., Devriese, S. et al., 'Developing and measuring a set of process and outcome indicators for breast cancer', *The Breast*, Vol. 21, 2012, pp. 253–260.

TRT-SUR-8: BREAST RECONSTRUCTION AFTER MASTECTOMY

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.

GUIDELINE RECOMMENDATIONS

- SIGN, 'Treatment of primary breast cancer: A national clinical guideline', 2013:
  - Systematic reviews of studies comparing immediate with delayed reconstruction found trials were of poor quality and had conflicting outcomes (*Evidence quality: 2^+*).
  - 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^+-3*).
  - 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: 2^+-3*).
- NICE, 'Early and locally advanced breast cancer: diagnosis and management', 2018. 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 (*certainty of evidence not reported*).
- KCE , 'Good Clinical Practice Guidelines. Breast cancer in women: Diagnosis, Treatment and Follow-up', 2010. Immediate breast reconstruction should be discussed with all patients being advised to have a mastectomy, except when significant comorbidities preclude this option (*Evidence quality: 1C*).
- KCE, 'Quality indicators in oncology: breast cancer', 2010. Immediate breast reconstruction after mastectomy offers the same survival benefits as mastectomy without reconstruction (*Evidence quality: 1C*).

SUPPORTING LITERATURE

- Andreano, A., Anghinoni, E., Autelitano, M. 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*, Vol. 22, 2016, pp. 62–70.
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TRT-SYS-1: NEOADJUVANT CHEMOTHERAPY FOR STAGE II AND STAGE III TRIPLE NEGATIVE BREAST CANCER

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.

GUIDELINE RECOMMENDATIONS

- SIGN, 'Treatment of primary breast cancer: A national clinical guideline', 2013. 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 lymph node groups (*Evidence quality: 1*$^{++}$).
- NCCN, 'Clinical Practice Guidelines in Oncology: Breast Cancer', 2017. In patients with operable tumors, preoperative systemic therapy is the preferred approach for the following scenarios: for patients with TNBC and HER2+ breast cancer that is clinical stage T2N0 and higher or is clinically node positive (*certainty of the evidence not reported*).

SUPPORTING LITERATURE

- Andreano, A., Anghinoni, E., Autelitano, M. 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*, Vol. 22, 2016, pp. 62–70.
- Gradishar, W. J., Anderson, B. O., Balassanian, R. et al., 'NCCN Guidelines Insights: Breast Cancer, Version 1.2017', *J Natl Compr Canc Netw*, Vol. 15, Issue 4, ' 2017, pp. 433–451.
- SIGN, 'Treatment of primary breast cancer', 2013.
- St Gallen consensus meeting, 2017.

TRT-SYS-2: NEOADJUVANT SYSTEMIC THERAPY FOR STAGE II AND STAGE III HER2-POSITIVE BREAST CANCER

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.

GUIDELINE RECOMMENDATIONS

- NCCN, 'Clinical Practice Guidelines in Oncology: Breast Cancer', 2017. In patients with operable tumors, preoperative systemic therapy is the preferred approach for the following scenarios: for patients with TNBC and HER2+ breast cancer that is clinical stage T2N0 and higher or is clinically node positive (*certainty of the evidence not reported*).

SUPPORTING LITERATURE

- Gianni, L., Eiermann, W., Semiglazov, V. et al., '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*, Vol. 375, 2010, pp. 377–384.
- Gradishar, W. J., Anderson, B. O., Balassanian, R. et al., 'NCCN Guidelines Insights: Breast Cancer, Version 1.2017', *J Natl Compr Canc Netw*, Vol. 15, Issue 4, April 2017, pp. 433–451.
- Kaufmann, M., von Minckwitz, G., Mamounas, E. P. 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*, Vol. 19, 2012, p. 1508.
- SIGN, 'Treatment of primary breast cancer', 2013.
- St Gallen consensus meeting, 2017.

TRT-SYS-3: NEOADJUVANT SYSTEMIC THERAPY FOR LOCALLY ADVANCED BREAST CANCER

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.

GUIDELINE RECOMMENDATIONS

- SIGN, 'Treatment of primary breast cancer: A national clinical guideline', 2013. 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 lymph node groups (*Level of evidence: 1++*).
- NCCN, 'Clinical Practice Guidelines in Oncology: Breast Cancer', 2017. Not all patients are appropriate candidates for preoperative systemic therapy. According to the NCCN Panel, among those with inoperable breast tumors, preoperative systemic therapy is indicated in patients with locally advanced or inoperable breast cancer, including those with inflammatory breast cancer. (*certainty of the evidence not reported*).

SUPPORTING LITERATURE

- Gradishar, W. J., Anderson, B. O., Balassanian, R. et al., 'NCCN Guidelines Insights: Breast Cancer, Version 1.2017', *J Natl Compr Canc Netw,* Vol. 15, Issue 4, April 2017, pp. 433–451.
- SIGN, 'Treatment of primary breast cancer', 2013.

TRT-SYS-4: ENDOCRINE THERAPY FOR SURGICALLY TREATED, ER-POSITIVE AND/OR PR-POSITIVE, INVASIVE BREAST CANCER

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.

GUIDELINE RECOMMENDATIONS

- KCE, 'Good Clinical Practice Guidelines, Breast cancer in women: Diagnosis, Treatment and Follow-up', 2013. 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*).
- ESMO, 'ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up: Primary breast cancer', 2015. 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*).
- SIGN, 'Treatment of primary breast cancer: A national clinical guideline', 2013. Pre-menopausal women with ER-positive invasive breast cancer should be treated with tamoxifen for at least 5 years, to a total of 10 years, unless there are contraindications or side effects (*Level of evidence: 1++, Strength of recommendation: strong*).
- IKNL NABON, 'Breast Cancer Dutch Guideline', 2012. Adjuvant treatment with tamoxifen for 5 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*).
- NICE, 'Early and locally advanced breast cancer: diagnosis and management', 2018:
  - Consider adjuvant therapy for all patients with early invasive breast cancer after surgery at the multidisciplinary team meeting and ensure that decisions are recorded (*certainty of evidence not reported*).
  - 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 (*certainty of evidence not reported*).

SUPPORTING LITERATURE

- Bao, H., Yang, F., Xinyu Wang, X. et al., 'Developing a set of quality indicators for breast cancer care in China', *International Journal for Quality in Health Care*, Vol. 27, Issue 4, 2015, pp. 291–296.
- Barni, S., Venturini, M., Molino, A. et al., 'Importance of adherence to guidelines in breast cancer clinical practice. The Italian experience (AIOM)', *Tumori*, Vol. 97, 2011, pp. 559–563.
- Biganzoli, L., Marotti, L., Hart, C. D., et al., 'Quality indicators in breast cancer care: An update from the EUSOMA working group', *European Journal of Cancer*, Vol. 86, 2017, 59e81.

- Caldarella, A., Amunni, G., Angiolini, C. 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*. Vol. 24, Issue 4, 2012, pp. 411–418.
- Chin-Lenn, L., Craighead, P., Bryant, H. E. et al., 'Quality Indicators for Ductal Carcinoma In Situ (DCIS) of the Breast: Development Using a Multidisciplinary Delphi Process and Its Use in Monitoring Population-Based Treatment', *J. Surg. Oncol.*, Vol. 108, 2013, pp. 348–351.
- Del Turco, M., Ponti, A., Bick, U. et al., 'Quality indicators in breast cancer care', *European Journal of Cancer*, Vol. 46, 2010, pp. 2344–2356.
- IKNL NABON, 'Breast Cancer Dutch Guideline', version 2.0, 2012.
- Jacke, C. O., Albert, U. S., Kalder, M., 'The adherence paradox: guideline deviations contribute to the increased 5-year survival of breast cancer patients', *BMC Cancer*, Vol. 15, 2015, p. 734.
- KCE, 'Borstkanker bij vrouwen: Diagnose, behandeling en follow-up (synthese)', 2013.
- Khare, S. R., Batist, G., Bartlett, G., 'Identification of performance indicators across a network of clinical cancer programs', *Curr Oncol*, Vol. 23, Issue 2, April 2016, pp. 81–90.
- NICE, 'Early and locally advanced breast cancer: diagnosis and treatment. Clinical guideline', 2018.
- Senkus, E., Kyriakides, S., Ohno, S. 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,* Vol. 26, Suppl. 5, 2015, v8-v30.
- SIGN, 'Treatment of primary breast cancer', September 2013.
- Stordeur, S., Vrijens, F., Devriese, S. et al., 'Developing and measuring a set of process and outcome indicators for breast cancer', *The Breast*, Vol. 21, 2012, pp. 253–260.

TRT-SYS-5: ADJUVANT CHEMOTHERAPY FOR SURGICALLY TREATED, ER-NEGATIVE, INVASIVE BREAST CANCER

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.

GUIDELINE RECOMMENDATIONS

- ESMO, 'ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up', 2015: Primary breast cancer:
  - 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*).
  - 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 (*certainty of evidence not reported*).
  - 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 (*certainty of evidence not reported*).
  - 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*).
  - Luminal B HER2-negative cancers constitute a population of highest uncertainty regarding chemotherapy indications (*Level of evidence: I; Strength of recommendation: C*).
  - Luminal B HER2-positive tumors are treated with chemotherapy, endocrine therapy and trastuzumab (*Level of evidence: I; Strength of recommendation: A*).
- SIGN, 'Treatment of primary breast cancer: A national clinical guideline', 2013. Adjuvant chemotherapy should be considered for all patients with breast cancer where benefits outweigh risk (*certainty of evidence not reported*).
- Del Turco, M. et al., 'Quality indicators in breast cancer care', 2010. 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*).
- NICE, 'Clinical guideline. Early and locally advanced breast cancer: diagnosis and management', 2018. 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 (*certainty of evidence not reported*).

- KCE, 'Good Clinical Practice Guidelines. Breast cancer in women: Diagnosis, Treatment and Follow-up', 2013. 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*).

SUPPORTING LITERATURE

- Bao, H., Yang, F., Xinyu Wang, X. et al., 'Developing a set of quality indicators for breast cancer care in China', *International Journal for Quality in Health Care*, Vol. 27, Issue 4, 2015, pp. 291–296.
- Biganzoli, L., Marotti, L., Hart, C. D., et al., 'Quality indicators in breast cancer care: An update from the EUSOMA working group', *European Journal of Cancer*, Vol. 86, 2017, 59e81.
- Caldarella, A., Amunni, G., Angiolini, C. 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*. Vol. 24, Issue 4, 2012, pp. 411–418.
- Del Turco, M., Ponti, A., Bick, U. et al., 'Quality indicators in breast cancer care', *European Journal of Cancer*, Vol. 46, 2010, pp. 2344–2356.
- DKG, 'Catalogue of requirements for Breast Cancer Centres of the German Cancer Society', Version L1, 24 October 2023.
- Jacke, C. O., Albert, U. S., Kalder, M., 'The adherence paradox: guideline deviations contribute to the increased 5-year survival of breast cancer patients', *BMC Cancer*, Vol. 15, 2015, p. 734.
- NICE, 'Early and locally advanced breast cancer: diagnosis and treatment. Clinical guideline', 2018.
- Senkus, E., Kyriakides, S., Ohno, S. 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,* Vol. 26, Suppl. 5, 2015, v8-v30.
- SIGN, 'Treatment of primary breast cancer, September 2013.
- Stordeur, S., Vrijens, F., Devriese, S. et al., 'Developing and measuring a set of process and outcome indicators for breast cancer', *The Breast*, Vol. 21, 2012, pp. 253–260.

TRT-SYS-6: ANTI-HER2 THERAPY FOR HER2-POSITIVE BREAST CANCER RECEIVING CHEMOTHERAPY

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.

GUIDELINE RECOMMENDATIONS

- ESMO, 'ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up: Primary breast cancer', 2015:
  - Luminal B HER2-positive tumors are treated with chemotherapy, endocrine treatment and trastuzumab (*Level of evidence: I; Strength of recommendation: A*).
  - Trastuzumab combined with chemotherapy in patients with HER2 overexpression approximately halves the recurrence risk compared with chemotherapy alone, translating into a 10 % increase in 10-year survival (*Level of evidence: I, Strength of recommendation: A*).
- KCE, 'Good Clinical Practice Guidelines, Breast cancer in women: Diagnosis, Treatment and Follow-up', 2013. A one-year course of trastuzumab is indicated for women with HER2-positve, node-positive or high-risk node-negative breast cancer (tumor size > 1cm) who received chemotherapy, and with a left ventricular ejection fraction of ≥ 55 % and no important cardiovascular risk factors (*Level of evidence: low; Strength of recommendation: strong*).

SUPPORTING LITERATURE

- Bao, H., Yang, F., Xinyu Wang, X. et al., 'Developing a set of quality indicators for breast cancer care in China', *International Journal for Quality in Health Care*, Vol. 27, Issue 4, 2015, pp. 291–296.
- Biganzoli, L., Marotti, L., Hart, C. D., et al., 'Quality indicators in breast cancer care: An update from the EUSOMA working group', *European Journal of Cancer*, Vol. 86, 2017, 59e81.
- Del Turco, M., Ponti, A., Bick, U. et al., 'Quality indicators in breast cancer care', *European Journal of Cancer*, Vol. 46, 2010, pp. 2344–2356.
- DKG, 'Catalogue of requirements for Breast Cancer Centres of the German Cancer Society', Version L1, 24 October 2023.
- Iwamoto, M., Nakamura, F., Higashi, T., 'Monitoring and evaluating the complexity of cancer care in Japan using administrative claims data', *Cancer Sci.*, Vol. 107, Issue 1, January 2016, pp. 68–75.
- Jacke, C. O., Albert, U. S., Kalder, M., 'The adherence paradox: guideline deviations contribute to the increased 5-year survival of breast cancer patients', *BMC Cancer*, Vol. 15, 2015, p. 734.
- Senkus, E., Kyriakides, S., Ohno, S. 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,* Vol. 26, Suppl. 5, 2015, v8-v30.
- SIGN, 'Treatment of primary breast cancer', September 2013.
- Stordeur, S., Vrijens, F., Devriese, S. et al., 'Developing and measuring a set of process and outcome indicators for breast cancer', *The Breast*, Vol. 21, 2012, pp. 253–260.

TRT-SYS-7: MONITORED CARDIAC FUNCTION FOR BREAST CANCER TREATED WITH ANTI-HER2

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.

GUIDELINE RECOMMENDATIONS

- KCE, 'Good Clinical Practice Guidelines, Breast cancer in women: Diagnosis, Treatment and Follow-up', 2013. 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*).
- NICE, 'Early and locally advanced breast cancer: diagnosis and treatment', 2018:
  - 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 arhythmias; angina pectoris requiring medication; clinically significant valvular disease; evidence of transmural infection on electrocardiograph; poorly controlled hypertension (*certainty of evidence not reported*).
  - 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 (*certainty of evidence not reported*).

SUPPORTING LITERATURE

- Bao, H., Yang, F., Xinyu Wang, X. et al., 'Developing a set of quality indicators for breast cancer care in China', *International Journal for Quality in Health Care*, Vol. 27, Issue 4, 2015, pp. 291–296.
- KCE, 'Borstkanker bij vrouwen: Diagnose, behandeling en follow-up (synthese)', 2013.
- NICE, 'Early and locally advanced breast cancer: diagnosis and treatment. Clinical guideline', 2018.
- Stordeur, S., Vrijens, F., Devriese, S. et al., 'Developing and measuring a set of process and outcome indicators for breast cancer', *The Breast*, Vol. 21, 2012, pp. 253–260.
- Visser, A., Van de Ven, N., Ruczynski, L. I. A. et al., 'Cardiac monitoring during adjuvant trastuzumab therapy: Guideline adherence in clinical practice', Acta oncologica, Vol. 55, Issue 4, 2016, pp. 423–429.

TRT-SYS-8: ENDOCRINE-BASED THERAPY AS FIRST-LINE TREATMENT FOR METASTATIC, ER-POSITIVE AND HER2-NEGATIVE BREAST CANCER

RATIONALE

Endocrine therapy is the preferred option for ER-positive metastatic 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.

GUIDELINE RECOMMENDATIONS

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

SUPPORTING LITERATURE

- Bao, H., Yang, F., Xinyu Wang, X. et al., 'Developing a set of quality indicators for breast cancer care in China', *International Journal for Quality in Health Care*, Vol. 27, Issue 4, 2015, pp. 291–296.
- Biganzoli, L., Marotti, L., Hart, C. D., et al., 'Quality indicators in breast cancer care: An update from the EUSOMA working group', *European Journal of Cancer*, Vol. 86, 2017, 59e81.
- Del Turco, M., Ponti, A., Bick, U. et al., 'Quality indicators in breast cancer care', *European Journal of Cancer*, Vol. 46, 2010, pp. 2344–2356.

TRT-SYS-9: BONE-MODIFYING AGENTS FOR BONE METASTASES FROM BREAST CANCER

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.

GUIDELINE RECOMMENDATIONS

- NBBC, Cancer Australia, 'Recommendations for use of bisphosphonates for advanced breast cancer', 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.

    (*Level of evidence: I*).
  - Bisphosphonates should be considered to delay time to a skeletal event (*Level of evidence: I*).
  - Bisphosphonates should be considered to reduce bone pain (*Level of evidence: I*).

SUPPORTING LITERATURE

- Cancer Australia, 2011, https://canceraustralia.gov.au/publications-and-resources/clinical-practice-guidelines/recommendations-use-bisphosphonates-advanced-breast-cancer.
- Pavlakis, N.,Stockler, M., 'Bisphosphonates for breast cancer', Cochrane Database Syst Rev. 2002, (1), CD003474.
- Stordeur, S., Vrijens, F., Devriese, S. et al., 'Developing and measuring a set of process and outcome indicators for breast cancer', *The Breast*, Vol. 21, 2012, pp. 253–260.

TRT-RAD-1: ADJUVANT RADIOTHERAPY FOR M0, INVASIVE BREAST CANCER TREATED WITH BREAST-CONSERVING THERAPY

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.

GUIDELINE RECOMMENDATIONS

- ESMO, 'ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up': Primary breast cancer, 2015. Postoperative whole breast radiotherapy is strongly recommended after breast-conserving surgery (*Quality of evidence: I, Strength of recommendation: A*).
- SIGN, 'Treatment of primary breast cancer: A national clinical guideline', 2013. 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++*).
- KCE, 'Breast cancer in women: Diagnosis, Treatment and Follow-up', 2013. In patients with early breast cancer, adjuvant radiotherapy is indicated after breast-conserving surgery. (*Quality of evidence: 1A. Strength of recommendation: strong*).
- NICE, 'Early and locally advanced breast cancer: diagnosis and management', 2018. *Patients with early invasive breast cancer who have had breast-conserving surgery with clear margins should have breast radiotherapy* (*certainty of evidence not reported*).
- SIOG-EUSOMA, 'Management of elderly patients with breast cancer: updated recommendations', 2012. WBRT (whole breast radiation therapy) after breast-conserving surgery, with a boost to the tumour bed, should be considered in all elderly patients since it decreases risk of local relapse (*Level of evidence: 1*).

SUPPORTING LITERATURE

- Andreano, A., Anghinoni, E., Autelitano, M. 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*, Vol. 22, 2016, pp. 62–70.
- Bao, H., Yang, F., Xinyu Wang, X. et al., 'Developing a set of quality indicators for breast cancer care in China', *International Journal for Quality in Health Care*, Vol. 27, Issue 4, 2015, pp. 291–296.
- Barni, S., Venturini, M., Molino, A. et al., 'Importance of adherence to guidelines in breast cancer clinical practice. The Italian experience (AIOM)', *Tumori*, Vol. 97, 2011, pp. 559–563.
- Biganzoli, l., Wiliers, H., Oakman, C. et al., 'Management of elderly patients with breast cancer: updated recommendations of the International Society of Geriatric Oncology (SIOG) and European Society of Breast Cancer Specialists (EUSOMA)', *Lancet Oncol*, Vol. 13, 2012, pp. 3148–3160.

- Biganzoli, L., Marotti, L., Hart, C. D., et al., 'Quality indicators in breast cancer care: An update from the EUSOMA working group', *European Journal of Cancer*, Vol. 86, 2017, 59e81.
- Caldarella, A., Amunni, G., Angiolini, C. 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*. Vol. 24, Issue 4, 2012, pp. 411–418.
- Chin-Lenn, L., Craighead, P., Bryant, H. I. et al., 'Quality Indicators for Ductal Carcinoma In Situ (DCIS) of the Breast Development Using a Multidisciplinary Delphi Process and Its Use in Monitoring Population-Based Treatment', *Journal of Surgical Oncology*, Vol. 108, 2013, pp. 348–351.
- Del Turco, M., Ponti, A., Bick, U. et al., 'Quality indicators in breast cancer care', *European Journal of Cancer*, Vol. 46, 2010, pp. 2344–2356.
- DKG, 'Catalogue of requirements for Breast Cancer Centres of the German Cancer Society, Version L1, 24 October 2023.
- EBCTCG (Early Breast Cancer Trialist Collaborative Group), 'Effect of radiotherapy after breast-conserving surgery on 10-year recurrence and 15-year breast cancer death: meta-analysis of individual patient data for 10 801 women in 17 randomised trials', *The Lancet*, Vol. 378, 2011, p. 9804.
- Falco, G., Rocoo, N., Procaccini, E. et al., 'Breast conserving treatment for ductal carcinoma in situ in the elderly: can radiation therapy be avoided? Our experience', *International Journal of Surgery*, Vol. 12, Suppl. 2, 2014.
- IKNL NABON, 'Breast Cancer Dutch Guideline', version 2.0, 2012.
- Jacke, C. O., Albert, U. S., Kalder, M., 'The adherence paradox: guideline deviations contribute to the increased 5-year survival of breast cancer patients', *BMC Cancer*, Vol. 15, 2015, p. 734.
- Senkus, E., Kyriakides, S., Ohno, S. 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,* Vol. 26, Suppl. 5, 2015, v8-v30.

TRT-RAD-2: RADIOTHERAPY FOR INVASIVE BREAST CANCER 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.

GUIDELINE RECOMMENDATIONS

- KCE, 'Good Clinical Practice Guidelines, Breast cancer in women: Diagnosis, Treatment and Follow-up', 2013:
  - 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*).
  - 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*).
  - Axillary radiotherapy should be discussed on a case-by-case basis in the multidisciplinary team meeting (*Quality of evidence: 1A. Strength of recommendation: strong*).
- SIGN, 'Treatment of primary breast cancer: A national clinical guideline', 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^{++}*).
  - Post-mastectomy radiotherapy may be considered in patients with intermediate risk of recurrence (high-risk node-negative tumors or 1-3 positive axillary lymph nodes (*Quality of evidence: 1^{++}*).
  - 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 1-3 positive nodes (*Quality of evidence: 1^{++}*).
- NICE, 'Early and locally advanced breast cancer: diagnosis and management', 2018:
  - 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 4 or more positive axillary lymph nodes or involved resection margins (*certainty of evidence not reported*).
  - 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) (*certainty of evidence not reported*).

SUPPORTING LITERATURE

- Andreano, A., Anghinoni, E., Autelitano, M. 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*, Vol. 22, 2016, pp. 62–70.
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- Barni, S., Venturini, M., Molino, A. et al., 'Importance of adherence to guidelines in breast cancer clinical practice. The Italian experience (AIOM)', *Tumori*, Vol. 97, 2011, pp. 559–563.
- IKNL NABON, 'Breast Cancer Dutch Guideline', version 2.0, 2012.
- Jacke, C. O., Albert, U. S., Kalder, M., 'The adherence paradox: guideline deviations contribute to the increased 5-year survival of breast cancer patients, *BMC Cancer,* Vol. 15, 2015, p. 734.
- Khare, S. R., Batist, G., Bartlett, G., 'Identification of performance indicators across a network of clinical cancer programs', *Curr Oncol*, Vol. 23, Issue 2, April 2016, pp. 81–90.
- SIGN, 'Treatment of primary breast cancer', September 2013.
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REHABILITATION, FOLLOW-UP AND PALLIATIVE CARE

RHB-1: LYMPHOEDEMA SERVICE

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

QUALITY DOMAIN: Clinical effectiveness.

GUIDELINE RECOMMENDATIONS

- Academy of Oncologic Physical Therapy of APTA, 'Interventions for Breast Cancer-Related Lymphedema: Clinical Practice Guideline', 2020:
  - Early identification of subclinical lymphedema in high-risk groups through prospective surveillance may improve outcomes (*Grade C*).
  - Intervention for subclinical lymphedema may include education, self-massage and use of compression garments (*Grade C*).
  - If early subclinical lymphedema persists or progresses after initial conservative intervention, individuals may benefit from more intensive interventions, such as complete decongestive therapy (CDT) (*Grade C*).
  - Postoperative exercise and resumption of activity should be coordinated with the interprofessional team and an individualised exercise programme should be gradually increased while monitoring for adverse events (*Best practice*).
- NCCN, 'Clinical Practice Guidelines in Oncology: Breast Cancer', 2023. Lymphedema is a potential side effect after the treatment of axillary lymph node surgery resulting from damage to the lymphatic system. Early detection/diagnosis of lymphedema is key for optimal management. Consider a pre-treatment measurement of both arms as a baseline for patients with risk factors for lymphedema (*category 2A*).
- AWMF-DKG-German Cancer Aid, updated S3 Clinical Practice Guideline, 'Evidence-based Guideline for the Early Detection, Diagnosis, Treatment and Follow-up of Breast Cancer', 2021:
  - All patients with axillary lymphadenectomy shall be informed about the options for detection, prophylaxis and treatment of postoperative lymphedema (*Grade of Recommendation: A; Level of Evidence: 1b*).
  - Patients after surgical treatment of breast cancer and the occurrence of lymphedema should be introduced to supervised, slowly progressive strength training for lymphedema treatment (*Grade of Recommendation: B; Level of Evidence: 1b*).

REFERENCE DOCUMENTS

- Davies, C., Levenhagen, K., Ryans, K. et al., 'Interventions for breast cancer-related lymphedema: clinical practice guideline from the Academy of Oncologic Physical Therapy of APTA', *Physical therapy*, Vol. 100, Issue 7, 2020, pp. 1163–1179.
- 'Evidence-based Guideline for the Early Detection, Diagnosis, Treatment and Follow-up of Breast Cancer', German Guideline Program in Oncology (German Cancer Society, German Cancer Aid, AWMF): 'Interdisciplinary Evidenced-based Practice Guideline for the Early Detection, Diagnosis, Treatment and Follow-up of Breast Cancer', Long version 4.4, May 2021, AWMF Registration Number: 032/045OL, http://www.leitlinienprogramm-onkologie.de/leitlinien/mammakarzinom/.
- International consensus, Lymphoedema Framework, *Best Practice for the Management of Lymphoedema*, Published by Medical Education Partnership (MEP) Ltd, London, 2016.
- Lymphoedema Framework, *Template for Management: Developing a Lymphoedema Service*, MEP Ltd, London, 2007.
- National Institute for Health and Care Excellence (NICE), 'Complications of early or locally advanced breast cancer treatment', 2019, 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.
- NCCN, 'Clinical Practice Guidelines in Oncology: Breast Cancer', Version 2, 2023.

SUPPORTING LITERATURE

- DKG, 'Catalogue of requirements for Breast Cancer Centres of the German Cancer Society', Version L1, 24 October 2023.
- KCE, 'Breast cancer in women: diagnosis, treatment and follow-up', KCE, Brussels, 2013.

FLW-1: FOLLOW-UP OF ASYMPTOMATIC WOMEN AFTER PRIMARY THERAPY

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.

GUIDELINE RECOMMENDATIONS

- KCE, 'Good Clinical Practice Guidelines, Breast cancer in women: Diagnosis, Treatment and Follow-up', 2013:
  - 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*).
  - 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 except in the following situations: Lobular invasive cancer; very young patients (< 35 years); BRCA-associated cancers; if initial tumour was not seen at mammography/ultrasound; in specific clinical situations where other imaging modalities are not reliable, or have been inconclusive (*Evidence quality: 1C (very low); Strength of recommendation: strong*).
- NICE guideline, 'Early and locally advanced breast cancer: diagnosis and management', 2018. Do not offer ultrasound or MRI for routine post-treatment surveillance in patients who have been treated for early invasive breast cancer or DCIS (*certainty of evidence not reported*).
- ASCO clinical practice guideline update, 'Breast Cancer Follow-Up and Management After Primary Treatment', 2012:
  - CBC testing, chest X-rays, bone scans, liver ultrasound, CT scanning, FDG-PET scanning and breast MRI are NOT recommended for routine surveillance of patients with breast cancer after primary therapy (*certainty of evidence not reported*).
  - Breast cancer tumour marker testing (CA 15-3 or CA 27.29) is not recommended for routine surveillance of patients with breast cancer after primary therapy (*certainty of evidence not reported*).

SUPPORTING LITERATURE

- Barni, S., Venturini, M., Molino, A. et al., 'Importance of adherence to guidelines in breast cancer clinical practice. The Italian experience (AIOM)', *Tumori*, Vol. 97, 2011, pp. 559–563.
- Biganzoli, L., Cardoso, F., Beishon, M. et al., 'The Requirements of a Specialist Breast Centre', *Breast*, Vol. 51, 2020, pp. 65–84.
- Del Turco, M. R., Pont, A., Bick, U., L. et al., 'Quality indicators in breast cancer care', *European Journal of Cancer*, Vol. 46, 2010, pp. 2344–2356.
- KCE, 'Breast cancer in women: diagnosis, treatment and follow-up', KCE, Brussels, 2013.
- Stordeur, S., Vrijens, F., Devriese, S. et al., 'Developing and measuring a set of process and outcome indicators for breast cancer', *The Breast*, Vol. 21, 2012, pp. 253–260.

FLW-2: 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 BCS should have a policy to ensure follow-up.

QUALITY DOMAIN: Clinical effectiveness; safety.

GUIDELINE RECOMMENDATIONS

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

SUPPORTING LITERATURE

- Andreano, A., Anghinoni, E., Autelitano, M. 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*, Vol. 22, 2016, pp. 62–70.
- Barni, S., Venturini, M., Molino, A. et al., 'Importance of adherence to guidelines in breast cancer clinical practice. The Italian experience (AIOM)', *Tumori*, Vol. 97, 2011, pp. 559–563.
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- European Commission, Collection of Guidelines on Breast Cancer Care, https://healthcare-quality.jrc.ec.europa.eu/en/ecibc/international-guidelines.
- KCE, 'Breast cancer in women: diagnosis, treatment and follow-up', KCE, Brussels, 2013.
- Krzyzanowska, M. K., Barbera, L., Elit, L. et al., 'Identifying population-level indicators to measure the quality of cancer care for women', *International Journal for Quality in Health Care*, Vol. 23, Issue 5, 2011, pp. 554 – 564.
- Stordeur, S., Vrijens, F., Devriese, S. et al., 'Developing and measuring a set of process and outcome indicators for breast cancer', *The Breast*, Vol. 21, 2012, pp. 253–260.

FLW-3: SURVIVORSHIP POLICY

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

QUALITY DOMAIN: Clinical effectiveness; safety.

Note: Attention should be paid to the length of the survivorship after the end of any treatment to avoid any discrimination to women with a previous history of breast cancer (https://ending-discrimination-cancersurvivors.eu/about/#:~:text=Cancer%20survivors%20are%20indeed%20the%20object%20of%20several,access%20financial%20services%20such%20as%20mortgages%20and%20insurance).

GUIDELINE RECOMMENDATIONS

- NCCN, 'Clinical Practice Guidelines in Oncology: Survivorship', 2022:
  - Care of the cancer survivor should include (*category 2A*):
  1. Surveillance for cancer spread or recurrence, and screening for subsequent primary cancers.
  2. Monitoring long-term effects of cancer, including psychosocial, physical and immunologic effects.
  3. Prevention and detection of late effects of cancer and therapy.
  4. Evaluation and management of cancer-related syndromes, with appropriate referrals for targeted intervention.
  5. Coordination of care between primary care providers and specialists to ensure that all of the survivor's health needs are met.
  6. Planning for ongoing survivorship care:
     - Information on treatment received, including all surgeries, radiation therapy (RT), and systemic therapies.
     - Information regarding follow-up care, surveillance, and screening recommendations.
     - Information on post-treatment needs, including information on acute, late and long-term treatment-related side effects and health risks when possible.
     - Delineation of roles of all health care providers (including oncologists, primary care physicians – PCPs, and subspecialists) in long-term survivorship care with coordinated timing of care and transfer of care as appropriate.
     - Promotion of adherence to healthy behaviour recommendations.
     - Periodic assessment of ongoing needs and identification of appropriate resources.
  - Screening should be a shared responsibility between primary and oncology care physicians. For survivors living with metastatic disease, recommendations for screening should be tailored to the survivor's individualised risk and disease status (*category 2A*).
  - A periodic assessment at least annually is recommended for all survivors to determine any needs and necessary interventions (*category 2A*).
  - Care providers are also encouraged to assess the following at regular intervals: a) current disease status; b) functional/performance status; c) medication use (including over-the-counter medications and supplements); d) comorbidities; e) prior cancer treatment history and modalities used; f) family history; g) psychosocial factors; h)

assess weight and health behaviours that can modify cancer and comorbidity risk (including tobacco/alcohol use) (*category 2A*).

- NCCN, 'Clinical Practice Guidelines in Oncology: Breast Cancer', 2023. Coordination of care between the primary care provider and specialists is encouraged. Additionally, a personalised survivorship treatment plan including a personalised treatment summary of possible long-term toxicity and clear follow-up recommendations is recommended (*category 2A*).
- ESMO, 'Clinical Practice Guideline for the diagnosis, staging and treatment of patients with metastatic breast cancer', 2021:
  - Proactive symptom management and education helps to alleviate side effects and improves quality of life (*Quality of evidence: I; Strength of recommendation: A*).
  - All treatments should include formal patient education regarding side-effect management (*Quality of evidence: I; Strength of recommendation: A*).

REFERENCE DOCUMENTS

- Gennari, A., André, F., Barrios, C. H. et al., 'ESMO Clinical Practice Guideline for the diagnosis, staging and treatment of patients with metastatic breast cancer', *Annals of oncology*, Vol. 32, Issue 12, 2021, pp. 1475–1495.
- NCCN, 'Clinical Practice Guidelines in Oncology: Breast Cancer', Version 2.2023.
- NCCN, 'Clinical Practice Guidelines in Oncology: Survivorship', Version 1.2022.

SUPPORTING LITERATURE

- Andreano, A., Anghinoni, E., Autelitano, M. 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*, Vol. 22, 2016, pp. 62–70.
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- NAPBC, 'Optimal Resources for Breast Care 2024 Standards', 2024.
- OECI, 'Accreditation and Designation User Manual', V. 3.2, 2019.
- Stordeur, S., Vrijens, F., Devriese, S. et al., 'Developing and measuring a set of process and outcome indicators for breast cancer', *The Breast*, Vol. 21, 2012, pp. 253–260.

PAL-1: PALLIATIVE CARE POLICY

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 BCS should have a policy to ensure symptom control and palliative care.

QUALITY DOMAIN: Personal empowerment and experience.

GUIDELINE RECOMMENDATIONS

- AWMF-DKG-German Cancer Aid, extended S3 Clinical Practice Guideline: 'Palliative care for patients with incurable cancer', 2020:
  - Patients with incurable cancer and a highly complex situation shall receive specialist palliative care (SPC) (*Grade or Recommendation: A; Level of Evidence: 3*).
  - Patients should be offered a needs assessment by a specialist palliative care team after the diagnosis of incurable advanced cancer (*Grade or Recommendation: A; Level of Evidence: 3*).
  - A specialist palliative care core team shall consist of members from at least three professional groups (physician, nursing profession and other professional groups). Of these at least the physician and nurse shall possess a specialist palliative care qualification (*Grade or Recommendation: A; Level of Evidence: 1-*).
  - A palliative outpatient clinic should be offered to outpatients with incurable cancer as an addition to already existing healthcare services. Consultation and shared treatment in the palliative outpatient clinic shall take place in close coordination with the main healthcare provider or the main care team (*Grade or Recommendation: B; Level of Evidence: 1+*).
  - Patients with incurable cancer shall be offered a contact to a palliative care support team during a hospital stay (*Grade or Recommendation: A; Level of Evidence: 1+*).
  - A specialist palliative homecare team shall work as an independent and multi-professional team consisting of a physician, nurse and another professional group. (*Grade or Recommendation: A; Level of Evidence: 1-*).
  - Specialist palliative homecare and palliative outpatient clinics shall provide the following components when caring for patients with incurable cancer to improve quality of life: a) assessing symptoms and needs of patients and family carers in all four dimensions (physical, psychological, social and spiritual); b) treatment of symptoms and problems in all four dimensions; c) resource-based support of patients and their family carers, particularly when establishing goals of care and discussing the illness; d) advance care planning; e) coordination and organisation of palliative care; f) care for the patient during the dying phase; g) rituals of saying goodbye and remembering; h) arranging grief counselling, and i) supporting members of the main care team/ healthcare provider (*Grade or Recommendation: A; Level of Evidence: 1-*).
- NCCN, 'Clinical Practice Guidelines in Oncology: Palliative Care', 2023. Interprofessional palliative care teams, including but not limited to board-certified palliative care physicians,

advanced practice providers, nurses, social workers, chaplains and pharmacists, should be readily available to provide consultative or direct care to patients / families / caregivers and/or healthcare professionals who request or require their expertise (*category 2A*).

REFERENCE DOCUMENTS

- Kaasa, S., Loge, J. H., Aapro, M. et al., 'Integration of oncology and palliative care: a Lancet Oncology Commission', *Lancet Oncol.*, Vol. 19, Issue 11, November 2018, e588-e653.

SUPPORTING LITERATURE

- Andreano, A., Anghinoni, E., Autelitano, M. 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*, Vol. 22, 2016, pp. 62–70.
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- German Guideline Program in Oncology (German Cancer Society, German Cancer Aid, AWMF): 'Palliative care for patients with incurable cancer', Extended version – Short version 2.2, 2020, AWMF-registration number 128/001OL, http://leitlinienprogramm-onkologie.de/Leitlinien.7.0.html.
- Krzyzanowska, M. K., Barbera, L., Elit, L. et al., 'Identifying population-level indicators to measure the quality of cancer care for women', *International Journal for Quality in Health Care*, Vol. 23, Issue 5, 2011, pp. 554–564.
- Levy, M., Smith, T., Alvarez-Perez, A. et al., 'Palliative Care Clinical Practice Guidelines', in *Oncology*, Version 1, National Comprehensive Cancer Networks (NCCN), 2016.
- NCCN, 'Clinical Practice Guidelines in Oncology: Palliative Care', Version 1.2023.
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