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National Accreditation Program for Breast Centers
American College of Surgeons

Optimal Resources for **Breast Care**

2024 Standards

Released February 2023

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Important Information

These standards are intended solely as qualification criteria for National Accreditation Program for Breast Centers (NAPBC) accreditation. They do not constitute a standard of care and are not intended to replace the medical judgment of any physician or health care professional in individual or general circumstances.

"Standard" as used in *Optimal Resources for Breast Care* is defined as a "qualification for accreditation," not standard of care.

In order for a program to be found compliant with the NAPBC Standards, the program must be able to demonstrate compliance with the entire standard as outlined in the **Definition and Requirements, Documentation**, and **Measure of Compliance** sections under each standard. The **Documentation** and **Measure of Compliance** sections under each standard are intended to provide summary guidance on how compliance must be demonstrated but are not intended to stand alone or supersede the **Definition and Requirements**.

In addition to verifying compliance with the standards as written and outlined in *Optimal Resources for Breast Care*, the NAPBC may also consider additional administrative factors when reviewing a program for accreditation. The NAPBC reserves the right to withhold accreditation based on such factors. Examples include, but are not limited to: non-payment of accreditation invoices and outstanding fees, failure to schedule or complete an accreditation site visit in a timely manner, failure to properly remit any or all contracts and contractual obligations related to NAPBC accreditation.

Confidentiality Requirements

The American College of Surgeons (ACoS) and the National Accreditation Program for Breast Centers (NAPBC) expect NAPBC-accredited programs to follow local, state, and federal requirements related to patient privacy, risk management, and peer review in complying with or providing information to demonstrate compliance with standards of accreditation. These requirements vary from state-to-state.

Acknowledgments

The National Accreditation Program for Breast Centers (NAPBC) is thankful to its Board, the representatives of the national professional organizations dedicated to breast health, and the members of the NAPBC Standards Revision Project who were vital to the completion of *Optimal Resources for Breast Care*. The NAPBC is further grateful to all those who provided thoughtful and essential comments during the public feedback period. The NAPBC acknowledges the extensive contributions of the following people who participated in the creation of *Optimal Resources for Breast Care*.

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About the NAPBC

The National Accreditation Program for Breast Centers (NAPBC) is a quality program of the American College of Surgeons, assisted by representatives from other national professional organizations focused on breast health. The NAPBC is dedicated to the improvement of quality outcomes for patients with breast disease and breast cancer through the implementation of multidisciplinary care guided by evidence-based accreditation standards, and comprehensive professional and patient education.

The NAPBC: Background and the Value of Accreditation
The evaluation and management of patients with diseases of the breast historically occurred in a fragmented and disorganized clinical setting. In a complex clinical environment involving a multitude of health care professionals and clinicians, patients are best served by utilizing multidisciplinary coordination. This team-based approach to patient care resulted in the birth of the "breast center" concept in the United States in the 1970s. In recent decades, there has been a proliferation of breast centers providing care to the thousands of patients diagnosed with breast cancer, as well as addressing the equally compelling needs of the many patients presenting with non-malignant breast diseases.

Evidence-based and consensus-developed standards have garnered widespread recognition and ever-increasing importance. The United States health care system is undergoing a dramatic transformation centered on data-driven quality improvement, and documentation of adherence to widely accepted standards of care for all diseases, including those of the breast.

In order to improve the quality of patient evaluation and management of patient care, NAPBC accreditation is granted to breast programs that demonstrate compliance with the standards established herein. NAPBC accreditation is awarded to hospitals, academic medical centers, teaching hospitals, freestanding cancer centers, and private medical practices that demonstrate compliance with the NAPBC standards.

NAPBC-accredited centers must provide the following services:

- A multidisciplinary team approach to coordinate the best possible patient care and available treatment options
- Access to breast-specific information, education, and support
- Ongoing monitoring and improvement of patient care
- Information about participation in clinical trials and new treatment options

Benefits of Becoming a NAPBC-Accredited Program
Accreditation by the NAPBC provides notable benefits that will enhance a breast program and its quality of patient care.

NAPBC-accredited programs receive the following:

- A model for organizing and managing a breast program to ensure multidisciplinary, integrated, and comprehensive breast care services
- Internal and external assessment of breast program performance based on recognized standards, demonstrating a commitment to quality care
- Accreditation for having met performance measures for high-quality breast care
- National recognition as a NAPBC-accredited program

Standards Interpretation
NAPBC-accredited programs must understand, implement, and demonstrate compliance with the accreditation standards outlined in *Optimal Resources for Breast Care* as written and defined by the NAPBC. While a full glossary of terms is provided at the end of this manual, it is important to establish definitions for several of these key terms prior to reading the accreditation standards.

> **Accredited Program(s):** A single or multiple-location medical institution providing diagnostic services, treatment services, and comprehensive multidisciplinary care for patients with breast disease or breast cancer, which has achieved accreditation by the National Accreditation Program for Breast Centers (NAPBC). This also refers to initial applicant programs that are actively pursuing accreditation with the NAPBC.

Calendar year review: Compliance criteria requiring annual review must be completed at least once for each full calendar year, from January 1 – December 31.

Triennial review: Compliance criteria requiring triennial review must be completed at least once every three years, during the NAPBC-accredited program's triennial accreditation cycle.

Culturally appropriate decision making: Culturally appropriate decision making may involve offering resources for patients that are written or provided in the language(s) spoken by the patient, using patient-friendly terms that are sensitive to the ethnic, cultural, sexual, or gender-based aspects of their lives, and providing discussions or consultations with patients regarding aspects of their care that may affect or be affected by such aspects of the patient's life.

For example: Discussing flat closure with LGBTQ patients.

Protocol: Previously referred to as "policies and procedures" in past versions of the NAPBC Standards, a protocol is a structured and consistent process crafted by the NAPBC-accredited program to help implement the required compliance criteria for specific NAPBC standards. Protocols must be written and documented in a manner that demonstrates compliance with whichever NAPBC standard the protocol is designed to address. Additionally, all protocols must be formally approved by the Breast Program Leadership Committee (BPLC). Identical protocols that apply to several affiliated NAPBC-accredited programs are acceptable. Such protocols must be specifically stylized for each affiliated program, **and** be formally approved by each BPLC, as applicable. Protocols do not need to be officially recognized hospital or institutional policies.

It is the responsibility of all NAPBC-accredited programs to read *Optimal Resources for Breast Care* in its entirety, and demonstrate compliance with all applicable requirements for all applicable standards.

In order for a program to be found compliant with the NAPBC Standards, the program must be able to demonstrate compliance with the entire standard as outlined in the **Definition and Requirements, Documentation**, and **Measure of Compliance** sections under each standard. The **Documentation** and **Measure of Compliance** sections under each standard are intended to provide summary guidance on how compliance must be demonstrated, but are not intended to stand alone or supersede the **Definition and Requirement**s.

Accreditation Process
Processes for accreditation are detailed and updated on the National Accreditation Program for Breast Centers (NAPBC) website. The NAPBC reserves the right to revise accreditation processes as needed.

Accreditation Awards
Compliance ratings for each standard are decided based on consensus by the assigned NAPBC Site Reviewer and the NAPBC staff. When required, the NAPBC Executive Reviewers will also contribute to the compliance rating decision as the final adjudicators.

Each standard is rated as "Compliant," "Non-compliant," or "Not Applicable.

Accreditation Status	Definition
Accredited	Awarded when a program has completed the site visit process, and demonstrated full compliance with **all** applicable standards. **Accredited** outcomes: • Program appears on the "Find an Accredited Program" website • Program has full access to the accreditation Quality Portal and its related resources • Certificate of accreditation is awarded
Accredited – Corrective Action Required ***Renewal Applicants Only***	Awarded when a **renewal** program receives a non-compliant rating on fewer than 20% of applicable standards rated during the site visit process. **Corrective Action** outcomes: • Program has twelve (12) months from the date of the site visit to resolve all non-compliant standards ratings • Program appears on the "Find an Accredited Program" website • Program has full access to the accreditation Quality Portal and its related resources • Certificate of accreditation is awarded **after** all non-compliant standards ratings have been resolved and **Accredited** status has been achieved
Not Accredited – Corrective Action Required ***Initial Applicants Only***	Awarded when an **initial** applicant receives a non-compliant rating on 1-2 applicable standards rated during the site visit process. **Not Accredited Corrective Action** outcomes: • Program has twelve (12) months from the date of the site visit to resolve all non-compliant standards ratings • Program does **not** appear on the "Find an Accredited Program" website • Program has full access to the accreditation Quality Portal and its related resources • Certificate of accreditation is awarded **after** all non-compliant standards ratings have been resolved and **Accredited** status has been achieved
Not Accredited	Awarded when a **renewal program** receives a non-compliant rating on more than 20% of applicable standards rated during the site visit process. Awarded when an **initial applicant** receives a non-compliant rating on three (3) or more applicable standards. Awarded when **any** program does not resolve non-compliant standards within the established timeframe for corrective action. **Not Accredited** outcomes: • Program does **not** appear on the "Find an Accredited Program" website • Program does **not** have access to the accreditation Quality Portal • Program may re-apply as an initial applicant after one calendar year of compliance with all applicable standards

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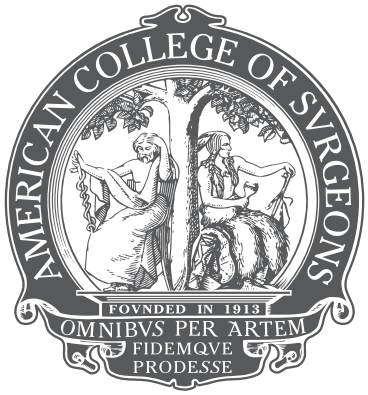

AMERICAN COLLEGE OF SURGEONS
NATIONAL ACCREDITATION PROGRAM FOR BREAST CENTERS

1 Institutional Administrative Commitment

Rationale

This chapter is designed to help NAPBC-accredited programs utilize their available resources, services, and administrative support to provide the best possible care to all patients with breast disease or breast cancer. Institutional administration must support the NAPBC-accredited program with aligned goals for patient experience, service, and high-quality care.

1.1 Administrative Commitment

Definition and Requirements

NAPBC-accredited programs must provide a letter of authority from facility leadership (CEO or equivalent) demonstrating commitment to the NAPBC-accredited program. The letter of authority must include, but is not limited to:

- A high-level description of the NAPBC-accredited program
- Any initiatives involving the NAPBC-accredited program during the accreditation cycle that were initiated for the purposes of ensuring quality of care and patient safety
- Facility leadership's involvement in the NAPBC-accredited program
- Examples of current and future financial investment in the NAPBC-accredited program
- For example: plans for equipment purchases or expanded services

Documentation

Submitted with Pre-Review Questionnaire

- Letter of authority from facility leadership that includes all required elements

Measure of Compliance

Once each accreditation cycle, the NAPBC-accredited program fulfills all compliance criteria:

- NAPBC-accredited program authority is established and documented through a letter from facility leadership that addresses all required elements

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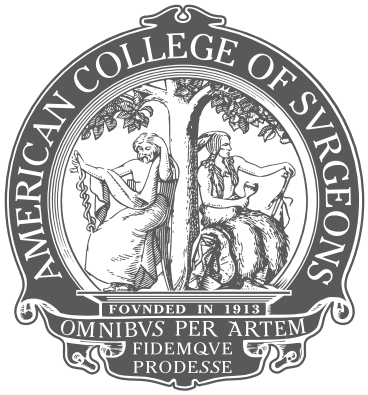

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NATIONAL ACCREDITATION PROGRAM FOR BREAST CENTERS

2 Program Scope and Governance

Rationale

The NAPBC Standards are designed to provide multidisciplinary care to all patients with breast disease or breast cancer. The leadership structure outlined in Chapter 2 promotes multidisciplinary oversight for the entire NAPBC-accredited program, and accountability for fulfilling the measures of compliance for each standard.

2.1 Breast Program Leadership Committee

Definition and Requirements

The Breast Program Leadership Committee (BPLC) is the governing body of a NAPBC-accredited program and is chaired by the Breast Program Director (BPD). Each NAPBC-accredited program must have its own BPLC.

At minimum, the BPLC must consist of at least three physician members, representing three different medical disciplines. One of these physicians must be the BPD. The BPLC is responsible for establishing the core group of health care professionals who contribute to the various patient care protocols developed by the NAPBC-accredited program.

Examples of BPLC member disciplines include, **but are not limited to:**

- Pathology
- Radiology
- Surgery
- Medical oncology
- Radiation oncology
- Reconstructive surgery
- Physical medicine
- Genetic professionals
- Certified Tumor Registrars (CTRs)
- Research
- Nursing
- Social work
- Hospital administration

As the minimum membership requirement for the BPLC consists of three physicians from different medical disciplines, it is not required for all of the disciplines listed above to be represented on the BPLC.

It is recommended, but not required, that a community representative and/or patient representative be a full member of the BPLC.

Membership appointments to the BPLC must occur at least once during each accreditation cycle. These appointments must occur at the first meeting of the accreditation cycle. All appointments must be documented in the BPLC meeting minutes. If a required member cannot continue to serve on the BPLC, a new member must be appointed at the next BPLC meeting, with documentation of the new appointment included in the BPLC meeting minutes.

Requirements for BPLC membership:

- Physician committee members must be compliant with Standard 4.1
- Physician committee members must possess current medical licensure and active medical staff appointment
- Non-physician committee members must have appropriate qualifications/certifications in their field

The BPLC must plan, implement, evaluate, and improve all breast-related activities provided by the NAPBC-accredited program.

Each calendar year, the BPLC must:

- Meet a minimum of four times per year
- Ensure each BPLC member attends at least **75 percent** of the BPLC meetings held each calendar year
- Plan, implement, evaluate, and improve all breast-related activities of the NAPBC-accredited program
- Ensure program compliance with all NAPBC Standards

Documentation

Submitted with Pre-Review Questionnaire

- BPLC meeting minutes, including documentation of member attendance
- Breast Program Leadership Committee (BPLC) Template

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- The BPLC must maintain multidisciplinary membership, including a minimum of three physicians from different medical disciplines, one of which must be the BPD
- BPLC membership must be documented in the BPLC meeting minutes at the first meeting of the calendar year, at least once each accreditation cycle
- The BPLC must meet a minimum of four times each calendar year
- All BPLC members must attend at least 75 percent of BPLC meetings held each calendar year

2.2 Breast Program Director

Definition and Requirements

A physician must be appointed as the Breast Program Director (BPD), who maintains the authority and accountability for the operations of the NAPBC-accredited program. Appointment of co-BPDs is permissible. If co-BPDs are appointed, at least one must be a physician.

The appointment of the BPD must be documented in the Breast Program Leadership Committee (BPLC) meeting minutes during the first BPLC meeting of the calendar year, at least once during each accreditation cycle.

The responsibilities of the BPD include:

- Familiarity with the NAPBC Standards, and NAPBC site visit processes
- Ensuring the NAPBC-accredited program maintains compliance with the NAPBC Standards
- Designating an individual(s) to prepare and submit all information required and requested by the NAPBC, and confirming that the information submitted is accurate and complete. This information includes, but is not limited to:
  - Program application forms
  - Annual program updates
  - Updates/changes to the program name, ownership, and Federal Employer Identification Number (FEIN)
  - Change of the BPD(s)
  - Corrective action documentation
  - Appeals documentation
- Overseeing the selection of Breast Care Team (BCT) members
- Overseeing the development and maintenance of protocols for the BCT, and other NAPBC-accredited program personnel
- Overseeing the distribution of protocols to the BPLC and the BCT

Documentation

Submitted with Pre-Review Questionnaire

- BPLC meeting minutes documenting the appointment of the BPD

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- A physician with authority and accountability for the operations of the NAPBC-accredited program is appointed as the Breast Program Director
- The Breast Program Director maintains compliance with all the responsibilities of the position

2.3 Breast Care Team

Definition and Requirements

The NAPBC-accredited program must have a defined, multidisciplinary, Breast Care Team (BCT) with a minimum of one appointed physician member from **each** of the following specialties:

- Surgery
- Pathology
- Radiology
- Medical oncology
- Radiation oncology

Any surgeon, pathologist, radiologist, medical oncologist, radiation oncologist, or reconstructive surgeon granted privileges to treat patients with breast disease or breast cancer in the NAPBC-accredited program after January 1, 2024, must be a member of the BCT, and maintain compliance with all NAPBC Standards. Physician providers granted privileges to treat patients with breast disease or breast cancer at multiple NAPBC-accredited programs are only required to participate as a member of the BCT at one of the NAPBC-accredited programs where they hold privileges. Such physicians must provide a letter of attestation documenting BCT membership at the facility of participation. The letter of attestation must be issued by the Breast Program Leadership Committee (BPLC) at the facility of participation.

The Breast Program Director (BPD) and the Breast Program Leadership Committee (BPLC) have discretion to include additional health care professionals as members of the BCT. These health care professionals include, **but are not limited to:** advanced practice providers, licensed/registered nurses, Certified Tumor Registrars (CTRs), physical medicine providers, genetic professionals, researchers, supportive care team professionals, radiology technologists, patient navigators, social workers, Registered Dietitian Nutritionists, exercise professionals, ordained clergy or religious leaders, financial advisors, certified lymphedema therapists, plastic or reconstructive surgeons, and clinical psychologists.

Requirements for BCT membership:

- Members must have appropriate qualifications/certifications/registrations in their field (see Chapter 4)
- Collaboration and development of treatment plans, including transition of care, which will lead to the best possible outcomes for patients (see Chapter 5)
- Members must provide patient care in compliance with the NAPBC Standards, and in accordance with institutional policies
- Surgery, pathology, radiology, medical oncology, and radiation oncology BCT members must participate in Multidisciplinary Breast Care Conferences (MBCC), as necessary to demonstrate compliance with Standard 2.4
  - At least one surgeon, pathologist, radiologist, medical oncologist, and radiation oncologist must attend each MBCC
  - Other specialties are encouraged, but not required, to attend the MBCC
- Compliance with continuing education, as required by Standard 8.2

Documentation

Submitted with Pre-Review Questionnaire

- Breast Care Team (BCT) Template

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- The Breast Care Team must have a minimum of one appointed physician member from each of the following specialties: surgery, pathology, radiology, medical oncology, and radiation oncology
- All surgeons, pathologists, radiologists, medical oncologists, radiation oncologists, and reconstructive surgeons granted privileges to treat patients with breast disease or breast cancer in the accredited program after January 1, 2024, are members of the Breast Care Team and maintain compliance with the NAPBC Standards
- The Breast Care Team members meet all the membership requirements

2.4 Multidisciplinary Breast Care Conference

Definition and Requirements

Multidisciplinary Breast Care Conferences (MBCC) are integral to improving the care of patients with breast disease or breast cancer by reviewing and contributing to patient management and patient outcomes, while providing education to physicians and other staff in attendance. Attendance and active participation are encouraged from all members of the Breast Care Team (BCT). All participants attending the MBCC must maintain complete confidentiality for all information disclosed during each conference.

The Breast Program Leadership Committee (BPLC) is responsible for monitoring individual and specialty attendance on an annual basis. **At least one surgeon, radiologist, pathologist, radiation oncologist, and medical oncologist must attend each MBCC.** The BPLC must also set attendance requirements for all specialties attending the MBCC, which is applied at the individual level. For example, if the BPLC sets a 75 percent attendance requirement for pathologists, then each pathologist member of the BCT must attend 75 percent of MBCC meetings.

On-site supportive care team professionals, and reconstructive or plastic surgeons are strongly encouraged to attend each MBCC.

Treating physicians are strongly encouraged to attend the MBCC when their patients are being presented.

Attending the MBCC via videoconference is acceptable, but the virtual attendee(s) must have access to all meeting materials required for full participation and input, such as imaging studies, specimen photographs, and pathology reports and/or slides.

The MBCC discussion must address the following elements for each case presented:

- Clinical and/or pathological stage
- Treatment planning using evidence-based guidelines
- Options and eligibility for genetic testing (where applicable)
- Options and eligibility for clinical research studies (where applicable)
- Options and eligibility for supportive care services (where applicable)
- Visual display of pathology slides and imaging studies

If a MBCC is shared between NAPBC-accredited programs, each participating NAPBC-accredited program must maintain their own separate MBCC records, which document full compliance with this standard.

Requirements for MBCC Frequency and Case Presentation

Analytic Case Load (excluding class of case 00)	Required MBCC Frequency	Case Presentation
1-250 cases	Twice a month, or more frequently at the discretion of the BPLC Accredited programs with fewer than 100 analytic breast cancer cases per year have the option of including these cases as part of a general cancer conference	A minimum of 50% of all analytic cases must be prospectively presented each calendar year
251+ cases	Weekly Weekly meetings of the MBCC are defined as an average of four meetings each month, and a total of **at least 48 meetings each calendar year**	A minimum of 30% of all analytic cases must be prospectively presented each calendar year

Prospective cases include, but are not limited to:

- Newly-diagnosed cases with treatment not yet initiated, or treatment initiated, and discussion of additional treatment is required
- Cases previously diagnosed, initial treatment completed, and discussion of adjuvant treatment or treatment for recurrence or progression is needed
- Cases previously diagnosed, and discussion of supportive or palliative care is needed
- Cases in consideration for clinical trials/research

Each calendar year, the BPLC must discuss and evaluate the following:

- MBCC meeting frequency
- MBCC attendance by multidisciplinary physicians, and BCT members
- Number of cases presented, and percentage of prospective cases
- Elements of discussion for each case, including, but not limited to, whether the following were discussed:
  - Clinical and/or pathological stage
  - Treatment planning using evidence-based guidelines
  - Appropriateness and availability for genetic testing, clinical research studies, and supportive care services, (where applicable)

The BPLC discussion and evaluation must be documented in the BPLC meeting minutes each calendar year.

Documentation

Reviewed On-Site

- The site reviewer must attend a Multidisciplinary Breast Care Conference

Submitted with Pre-Review Questionnaire

- Multidisciplinary Breast Care Conference (MBCC) Template
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- The Breast Program Leadership Committee (BPLC) must establish and oversee the following:
  - MBCC frequency requirements
  - MBCC attendance requirements
  - MBCC attendance records
  - Prospective and annual case presentations, including the required discussion elements
- The MBCC evaluation is completed by the BPLC, and documented in the BPLC meeting minutes

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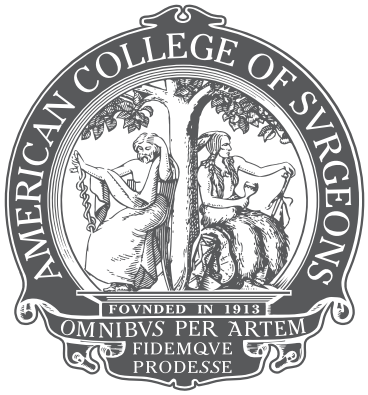

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NATIONAL ACCREDITATION PROGRAM FOR BREAST CENTERS

3 Facilities and Equipment Resources

Rationale

Chapter 3 of the NAPBC Standards is designed to help NAPBC-accredited programs emphasize safety and continuity of care for patients with breast disease or breast cancer. While delivering the high-quality breast care associated with all NAPBC-accredited programs, maintaining the appropriate certifications and/or accreditations for the medical facility ensures high reliability and consistency across all service lines.

3.1 Facility Accreditation

Definition and Requirements

The NAPBC-accredited program must deliver breast care in an appropriate health care facility.

If required by state law, the facility must be licensed by the appropriate state licensing authority. If state licensure is not required, the facility must be accredited or licensed by a recognized federal, state, or local authority, appropriate to facility type.

Documentation

Submitted with Pre-Review Questionnaire

- Documentation of health care facility accreditation or licensure
- If applicable, a CoC Accreditation Report from the most recent CoC site visit demonstrating compliance with CoC Standard 3.1

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- The facility is accredited or licensed by a recognized federal, state, or local authority, appropriate to the facility type

3.2 Radiation Oncology Quality Assurance

Definition and Requirements

The NAPBC-accredited program must follow recognized quality assurance practices for the safe delivery of radiation oncology treatment. To demonstrate compliance with this standard, the facility must be accredited by one of the NAPBC-approved radiation oncology organizations outlined below, or the facility must implement a radiation oncology quality assurance (QA) program.

Accreditation from one of the following organizations is approved by the NAPBC to demonstrate compliance with this standard:

- The American College of Radiation Oncology (ACRO)
- The American Society for Radiation Oncology Accreditation Program for Excellence (ASTRO-APEx)
- The American College of Radiology Radiation Oncology Practice Accreditation (ACR- ROPA)

If the facility is not accredited by one of the organizations listed above, a radiation oncology quality assurance (QA) program must be in place, and a Radiation Quality Assurance report must confirm adherence with the following quality assurance practices:

- Patient identity must be verified by two independent methods before each encounter
- Daily, monthly, and annual quality assurance procedures must be completed on radiation treatment machines, following the guidelines of the American Association of Physicists in Medicine (AAPM)
- Dosage calculations must be independently verified for every new or changed treatment before starting treatment
- Patient-specific quality assurance must be completed prior to initiating Intensity-Modulated Radiation Therapy (IMRT)

If radiation oncology is referred to an outside facility, the NAPBC-accredited program must provide the required documentation as outlined above from the referred facility.

Documentation

Submitted with Pre-Review Questionnaire

- Documentation of facility accreditation for radiation oncology, or the self-administered Radiation Quality Assurance report, which includes all the required elements

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- The facility is accredited by ACRO, ASTRO-APEx, or ACR-ROPA, or a self-administered quality assurance program is in place
- If the NAPBC-accredited program has a locally developed quality assurance program in place, a Radiation Quality Assurance report must confirm adherence to the required quality assurance practices

3.3 Image Guided Biopsy Quality Assurance

Definition and Requirements

Stereotactic Core Needle Biopsy
Stereotactic core needle biopsy must be performed at an American College of Radiology (ACR)-accredited facility, or by an American Society of Breast Surgeons (ASBrS) Breast Procedure Program-certified surgeon.

The ACR designation of Breast Imaging Center of Excellence (BICOE) does meet the measure of compliance for radiology accreditation for ultrasound and MRI. However, BICOE designation does not meet the measure of compliance for surgeons providing image guided biopsy.

Ultrasound-Guided Needle Biopsy
Diagnostic ultrasound and/or ultrasound-guided needle biopsy must be performed at an ACR ultrasound-accredited facility, or by an ASBrS breast ultrasound-certified surgeon.

Surgeons who perform breast diagnostic ultrasound and/or ultrasound-guided breast biopsy must be certified to perform these procedures by the ASBrS Breast Ultrasound Certification Program. Surgeons performing breast diagnostic ultrasound and/or ultrasound-guided breast biopsy must provide documentation of ASBrS certification (or proof of application) at the time of the NAPBC site visit. This requirement does not apply to surgeons using ultrasound as an extension of the clinical diagnosis or localization.

An ACR BICOE designation does meet the measure of compliance for radiologists, but not for surgeons.

MRI Biopsies
The NAPBC-accredited facility must be accredited in breast MRI by the ACR if MRI biopsies are performed by the NAPBC-accredited program.

Documentation

Submitted with Pre-Review Questionnaire

- Documentation of all required accreditations and certifications, based on the procedures performed at the NAPBC-accredited program

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Radiology facilities and physicians performing stereotactic core needle biopsy are accredited/certified by the ACR and/or ASBrS
- Diagnostic ultrasound and/or ultrasound-guided needle biopsy are performed at an ACR ultrasound-accredited facility by accredited radiologists
- Surgeons performing diagnostic ultrasound and/or ultrasound-guided needle biopsy are certified through the ASBrS Breast Ultrasound Certification Program
- MRI biopsies are performed at a facility accredited in breast MRI by the ACR

3.4 Breast Imaging Quality Assurance

Definition and Requirements

The NAPBC-accredited program must follow recognized quality assurance practices for performing breast MRI. All mammography services must be provided in accordance with federal guidelines established by the Mammography Quality Standards Act (MQSA). To demonstrate compliance with this standard, the facility must meet one of the following criteria:

- Breast Imaging Center of Excellence (BICOE) accreditation
- American College of Radiology (ACR) accreditation for breast MRI
- Have an established referral relationship with a local facility to provide the breast MRI services outlined below

NAPBC-accredited programs performing breast MRI on-site must have the capacity to provide all of the following services:

- Mammographic correlation
- Directed breast ultrasound
- MRI-guided intervention

If the NAPBC-accredited program does not have the capacity to perform all of the services outlined above, it must establish a referral relationship with a local facility with the capacity to provide these required services. The referred facility must be accredited by the American College of Radiology (ACR) for breast MRI.

Documentation

Reviewed On-Site

- If breast MRI services are referred to a local facility, the site reviewer will evaluate and confirm the referral relationship

Submitted with Pre-Review Questionnaire

- Documentation of BICOE accreditation or ACR accreditation for breast MRI

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- NAPBC-accredited programs performing breast MRI on-site must be accredited by BICOE or accredited by the ACR for breast MRI
- NAPBC-accredited programs not performing breast MRI on-site must have an established referral relationship with a local facility to provide these breast MRI services
- The referred facility must be accredited by the ACR for breast MRI
- NAPBC-accredited programs must provide all mammography services in accordance with federal guidelines established by the Mammography Quality Standards Act (MQSA)

3.5 Pathology Quality Assurance

Definition and Requirements

The NAPBC-accredited program must utilize recognized breast cancer surgical specimen pathology reporting templates, and those templates must contain the required core data elements outlined by the College of American Pathologists (CAP). The breast cancer surgical specimen pathology reports must utilize synoptic formatting.

To demonstrate compliance with this standard, the facility must document accreditation for anatomic pathology from one of the following organizations:

- College of American Pathologists (CAP)
- American Association for Laboratory Accreditation (A2LA)
- Accreditation Commission for Health Care (ACHC)
- The Joint Commission (TJC)
- COLA Laboratory Accreditation

NAPBC-accredited programs located in New York State (NY) or Washington State (WA) may provide documentation of clinical laboratory quality assurance for anatomic pathology from the New York State Department of Health or the Washington State Department of Health, respectively, in lieu of documentation of anatomic pathology accreditation from one of the organizations listed above.

Documentation

Submitted with Pre-Review Questionnaire

- Documentation of approved anatomic pathology accreditation

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- The facility is accredited for anatomic pathology by an approved laboratory accreditation organization or qualifying state Department of Health

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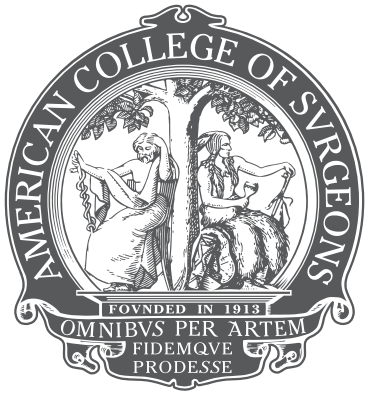

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NATIONAL ACCREDITATION PROGRAM FOR BREAST CENTERS

4 Personnel and Services Resources

Rationale

Health care providers and staff take patients' lives in their hands every day. Each specialist must maintain appropriate credentials and complete continuing education in the treatment and/or management of breast disease and breast cancer to help ensure the delivery of high-quality care consistent with currently established best practices.

4.1 Physician Credentials

Definition and Requirements

The management of patients with breast disease or breast cancer must be conducted by a multidisciplinary team, including surgeons, radiologists, pathologists, radiation oncologists, and medical oncologists. All physicians involved in the evaluation and management of patients with breast disease or breast cancer must meet **one** of the following requirements:

- Board certification from the American Board of Medical Specialties (ABMS), the American Osteopathic Association (AOA), or equivalent

OR

- Demonstrate ongoing cancer education by earning 12 cancer-related Continuing Medical Education (CME) hours each calendar year, six of which must be related to breast disease or breast cancer

Scope of Standard
This standard applies to physician members of the Breast Care Team (BCT) who are involved in the evaluation and management of patients with breast disease or breast cancer at the accredited program for at least one calendar year. This standard does not apply to physicians who are in fellowship, residency, or physicians within the five years immediately following graduation from fellowship or residency.

Documentation

Submitted with Pre-Review Questionnaire

- Physician Certification Credentials Template
- Documentation of CME credit hours for all BCT physicians who are not board certified and are involved in the evaluation and management of patients with breast disease or breast cancer
- If applicable, CoC Accreditation Report from the most recent CoC site visit documenting compliance with CoC Standard 4.1
- If applicable, CoC Physician Certification Credentials Template

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- All physicians on the Breast Care Team (BCT) involved in the evaluation and management of patients with breast disease or breast cancer must be board certified (or equivalent)
- Physicians who are not board certified must demonstrate ongoing cancer-related education by earning 12 cancer-related CME credit hours each calendar year, six of which must be related to breast disease or breast cancer

4.2 Oncology Nursing Credentials

Definition and Requirements

Oncology nursing care must be provided by nurses with specialized knowledge and skill in breast disease or breast cancer as demonstrated by a cancer-specific certification, or continuing education in oncology nursing. Oncology nursing competency must be reviewed each calendar year, per hospital policy.

All registered nurse and advanced practice nurse members of the Breast Care Team (BCT) who provide direct breast oncology care must demonstrate compliance with **one** of the following requirements:

- Current cancer-specific certification in the nurse's specialty from an accredited certification program

OR

- Continuing education by completing 36 cancer-related Nursing Continuing Professional Development (NCPD) hours each accreditation cycle, with emphasis on hours that are applicable to patients with breast disease or breast cancer

Nurses in the process of obtaining a cancer-specific certification do not need to submit documentation of cancer-related continuing education, but must provide documentation of progress toward certification.

Oncology Nursing Certifications
Oncology nursing certifications that qualify for this standard include, but are not limited to:

- Advanced Oncology Certified Nurse Practitioner (AOCNP®)
- Advanced Oncology Certified Clinical Nurse Specialist (AOCNS®)
- Advanced Oncology Certified Nurse (AOCN®)
- Certified Breast Care Nurse (CBCN®)
- Oncology Certified Nurse (OCN®)
- Oncology Nurse Navigator-Certified Generalist (ONN-CG™)

Continuing Education
Oncology nursing certification is strongly preferred. If a nurse providing direct breast oncology care is not certified, then the nurse must complete 36 cancer-related NCPD hours each accreditation cycle, with emphasis on hours that are applicable to patients with breast disease or breast cancer.

Scope of Standard
This standard applies to registered nurses and advanced practice nurses who are members of the BCT and provide direct breast care in the NAPBC-accredited program for at least one calendar year. Specifically, the standard applies to BCT nurses in medical oncology who give chemotherapy, BCT nurses in radiation oncology, BCT nurse navigators, and BCT nurses in the cancer center or breast clinic(s) within the NAPBC-accredited program. This standard does not apply to nurses in the hospital who have occasional contact with cancer patients, it does not apply to operating room or recovery room nurses, and it does not apply to nurses who are not members of the BCT.

Documentation

Submitted with Pre-Review Questionnaire

- Oncology Nursing Credentials Template
- Documentation of NCPD hours for all BCT nurses providing direct breast oncology care who do not hold a cancer-specific certification
- If applicable, CoC Accreditation Report from the most recent CoC site visit, documenting compliance with CoC Standard 4.2
- If applicable, CoC Oncology Nursing Credentials Template
- A protocol that states oncology nursing competency must be evaluated each year per hospital or facility policy

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- All BCT nurses providing direct breast oncology care hold a cancer-specific certification or demonstrate continuing education by completing 36 cancer-related Nursing Continuing Professional Development (NCPD) hours each accreditation cycle, with emphasis on hours that are applicable to patients with breast disease or breast cancer
- Programs have in place a protocol that ensures oncology nursing competency is reviewed each year per hospital policy

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4.3 Physician Assistant Credentials

Definition and Requirements

Oncology care must be provided by Physician Assistants (PAs) with specialized knowledge and skill in breast disease or breast cancer as demonstrated by continuing education in oncology.

All PAs who provide direct breast oncology care must demonstrate ongoing education by earning 36 cancer-related continuing education hours each accreditation cycle, with emphasis on hours that are applicable to patients with breast disease or breast cancer.

Scope of Standard
This standard applies to PAs who provide direct breast care in the NAPBC-accredited program for at least one calendar year. Specifically, the standard applies to PAs in medical oncology clinics, PAs in radiation oncology, PAs in infusion sites, and PAs in the breast center, cancer center, or breast clinics within the NAPBC-accredited program. This standard does not apply to PAs in the hospital who have occasional contact with cancer patients, and it does not apply to operating room or recovery room PAs. If the NAPBC-accredited program does not have PAs, this standard will be rated "not applicable."

Documentation

Submitted with Pre-Review Questionnaire
- Physician Assistant Education Template

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:
- All PAs providing direct breast oncology care earn 36 cancer-related continuing education hours each accreditation cycle, with emphasis on hours that are applicable to patients with breast disease or breast cancer

4.4 Genetic Professional Credentials

Definition and Requirements

Genetic testing and counseling for patients with breast disease or breast cancer must be performed by genetic professionals with an educational background in cancer genetics and hereditary cancer syndromes.

Genetic professionals must meet one of the following qualifications to demonstrate compliance with this standard, including, but not limited to:

- Board certification or board eligibility by the American Board of Genetic Counseling (ABGC)
- Board certification or board eligibility by the American Board of Medical Genetics and Genomics (ABMGG)
- Advanced Genetics Nursing Certification (AGN-BC) from the American Nurses Credentialing Center (ANCC)
- Advanced Clinical Genomics Nurse (ACGN) credentials from the Nurse Portfolio Credentialing Commission (NPCC)
- Clinical Genomics Nurse (CGN) credentials from the Nurse Portfolio Credentialing Commission (NPCC)
- Completion of City of Hope Intensive Course in Genomic Cancer Risk Assessment
- Qualified, licensed, health care professional with Cancer Genetic Risk Assessment (CGRA) certification from the National Consortium of Breast Centers (NCBC)
- Qualified, licensed, health care professional with Advanced Oncology Certified Nurse Practitioner (AOCNP) credentials, or equivalent certification from the Oncology Nursing Certification Corporation (ONCC)
- Board certified or board eligible physician with experience in cancer genetics
  - This qualification requires providing cancer risk assessment to patients on a regular basis

The continuing education requirements for genetic professionals are discussed in Standard 8.2.

If genetic counseling is provided by a telegenetics company or a facility outside the NAPBC-accredited program, the referred company or facility must utilize board certified genetic counselors.

NAPBC-accredited programs must consider conflict of interest when choosing professionals to provide cancer risk assessment and genetic counseling.

Due to variability in access to genetic counseling and testing, it may be necessary for some NAPBC-accredited programs to utilize an alternative service delivery model to meet compliance with this standard. Please refer to the *Optimal Resources for Breast Care* Appendix for more information on alternative service delivery models.

Documentation

Submitted with Pre-Review Questionnaire

- Certification/credentialing information for the cancer genetic professionals performing genetic counseling
- If applicable, documentation that board certified genetic counselors are utilized by the outside telegenetics company

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Genetic counseling and testing are performed by qualified genetic professionals

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4.5 Patient Navigation Credentials

Definition and Requirements

A patient navigation protocol must be developed and implemented to guide patients with possible breast disease or breast cancer through all patient services, whether such services are provided on-site or by referral.

Patient navigation must be provided by professionals, such as nurses and social workers, who have documented training, experience, or education in providing individualized assistance to patients with breast disease or breast cancer, their families, and their caregivers.

If a certification includes patient navigation within its exam, the certification qualifies as documented patient navigation training. Examples of such certifications with documented patient navigation training include, but are not limited to:

- Oncology Certified Nurse (OCN®)
- Certified Breast Care Nurse (CBCN®)
- Oncology Nurse Navigator-Certified Generalist (ONN-CG™)
- Oncology Patient Navigator-Certified Generalist (OPN-CG™)
- Advanced Oncology Certified Nurse Practitioner (AOCNP®)
- Advanced Oncology Certified Clinical Nurse Specialist (AOCNS®)
- Advanced Oncology Certified Nurse (AOCN®)

Lay navigators may also be utilized to provide patient navigation services, but such lay navigators must have documented proof of training in patient navigation for patients with breast disease or breast cancer. Examples include, but are not limited to, the National Consortium of Breast Centers (NCBC) Certified Navigator Breast Advocate (CN-BA) program, and the George Washington University School of Medicine and Health Sciences education program: Oncology Patient Navigator Training.

Documentation

Submitted with Pre-Review Questionnaire

- Protocol for patient navigation through all provided and referred patient services
- Documentation of training for all patient navigators

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- A patient navigation protocol is developed and implemented to guide patients with possible breast disease or breast cancer through all patient services, whether such services are provided on-site or by referral
- Patient navigators have required training, experience, and/or education

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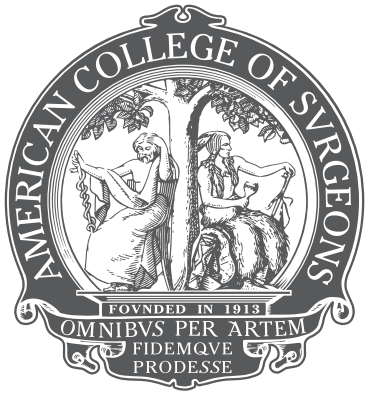

AMERICAN COLLEGE OF SURGEONS
NATIONAL ACCREDITATION PROGRAM FOR BREAST CENTERS

5 Patient Care: Expectations and Protocols

Rationale

The Chapter 5 standards support care that focuses on the patient journey from the patient's perspective. Each standard is accompanied by rationale that describes the accreditation standard in the context of the patient journey.

5.1 Screening for Breast Cancer

Rationale

Most people will never be diagnosed with breast cancer. But for those asymptomatic persons who are ultimately diagnosed, their journey begins with the screening process. The NAPBC-accredited program must view screening from that perspective.

Definition and Requirements

This standard evaluates asymptomatic patients.

The NAPBC-accredited program must adopt nationally recognized guidelines for breast cancer screening. Sources for nationally recognized guidelines include, but are not limited to:

- American College of Radiology
- American Cancer Society
- American Association for Cancer Research Cancer Progress Report
- Siteman Cancer Center: Your Disease Risk™

The NAPBC-accredited program must develop and implement protocols to address the following:

- Notification, education, and provision of additional screening for patients with increased breast density
- Appropriate use of screening MRI and ultrasounds, including the determination of which patients need to receive screening MRIs and/or ultrasounds

The NAPBC-accredited program must utilize risk assessment screening strategies based on the needs of their patient population. The NAPBC-accredited program has full discretion regarding when this risk assessment occurs within their programmatic workflow. Patients who receive a screening mammogram at the NAPBC-accredited program must also be provided with evidence-based risk reduction strategies for breast cancer. The risk reduction strategies must either be discussed with the patient, or provided to them in a written or electronic format. It is not required that an individualized discussion occur with each patient, as long as the written or electronic resources for risk reduction are provided to the patient.

The NAPBC-accredited program must also provide patients who are identified as high-risk for breast cancer with referral to the appropriate health care providers. The management of patients at increased risk for breast cancer is discussed in Standard 5.4.

Evaluation by the BPLC

Each accreditation cycle, the BPLC must review and assess:

- The protocol for notifying and educating patients about increased density
- Additional post-mammography screening, such as tomography, breast ultrasound and/or MRI, for patients with increased density on mammography
- The risk reduction strategies provided to patients

As barriers to compliance with this standard are identified, they must be addressed by the NAPBC-accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

Documentation

Reviewed On-Site

- The site reviewer will evaluate preselected medical records for patients who do not have cancer to confirm compliance with this standard, including:
  - Appropriate additional imaging (density and MRI use)
  - Risk assessment, with referral to appropriate health care providers for patients at increased risk of breast cancer, as outlined in Standard 5.4

Submitted with Pre-Review Questionnaire

- Required protocols
- Example of education on additional screening provided to patients with increased density
- Examples of risk reduction materials
- Example resources/referrals provided to patients addressing risk reduction
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Adoption of nationally recognized guidelines for screening
- Protocols are developed and implemented for:
  - Notifying, educating, and providing additional screening for patients with increased density
  - Risk assessment and provision of appropriate referrals
  - Appropriate use of screening MRI and ultrasounds, including which patients must receive screening MRIs or ultrasounds
- Patients who receive a screening mammogram also receive evidence-based risk reduction strategies for breast cancer
- The BPLC evaluation is completed and documented in the BPLC meeting minutes once each accreditation cycle

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5.2 Diagnostic Imaging of the Breast and Axilla

Rationale

Abnormal imaging or clinical findings trigger a cascade of events that may be enormously stressful for the patient and the patient's support system. There are a variety of clinical and non-clinical issues that must be considered. Steps to minimize anxiety, avoid confusion, and facilitate a timely approach to the imaging abnormality must be considered.

Definition and Requirements

This standard evaluates patients with a clinical finding or an abnormal mammogram. Requirements for patients without an abnormal finding are outlined in Standard 5.1.

A protocol must be developed and implemented to address the following:

- Confirmation that during the diagnostic process the patient has been evaluated to determine their risk for the development of breast cancer
  - When the risk evaluation occurs is left to the discretion of the NAPBC-accredited program, as long as it occurs during the diagnostic process
- Access to biopsy services for patients that have an abnormal mammogram or MRI
- Performance of a recommended biopsy, or the notification of a recommended biopsy to the patient

Imaging and Pathology Concordance
A process must be developed and implemented for radiology and pathology to evaluate the concordance between imaging and biopsy pathology. For example: the radiologist comments on concordance in the biopsy report; or through a radiology/pathology conference. Imaging and biopsy pathology slides or report must be reviewed. A process must be in place addressing the management of any discordant reviews.

The results of the concordance decision must be documented in the medical record with a recommended action.
For example, clinical follow-up, surgical consultation recommendation, excision recommendation, or imaging follow-up. The NAPBC-accredited program must have a process in place for follow-up on any recommended actions.

Communication of Results
Biopsy pathology results and any follow-up recommendations must be communicated directly to the patient, or the referring physician. A written or electronic copy of the biopsy pathology results must be provided to the patient.

Evaluation by the BPLC
Each accreditation cycle, the BPLC must review and assess:

- The barriers to efficient diagnosis for abnormal imaging
  - For example: turnaround time for core biopsy results
- The process for discordant biopsies is reviewed and any barriers are assessed
- The processes for patient follow-up, biopsy recommendations, and biopsy results are reviewed, and any barriers assessed

As barriers to compliance with this standard are identified, they must be addressed by the NAPBC-accredited program.

The BPLC evaluations and discussions must be documented in the BPLC meeting minutes.

Documentation

Submitted with Pre-Review Questionnaire

- Required protocol
- Documentation of the process for evaluating, documenting, and follow-up on radiology and pathology concordance
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- A protocol is developed and implemented for:
  - Risk evaluation at the time of diagnostic breast imaging if not performed during screening
  - Referral and access to biopsy for patients with abnormal mammogram or MRI
  - Performance of a recommended biopsy or communication to the patient regarding the recommendation for biopsy
- A process is in place for:
  - Evaluating, communicating, and documenting concordance between imaging and biopsy pathology
  - Management of discordant reviews
  - Follow-up of recommended action
- Biopsy pathology results are communicated to the patient or the referring physician
- The BPLC evaluation is completed and documented in the BPLC meeting minutes once each accreditation cycle

5.3 Evaluation and Management of Benign Breast Disease

Rationale

Anxiety, concern, and worry often accompany the evaluation, testing, and treatment recommendation processes for patients with non-malignant abnormalities. These patients must receive advice about the meaning of the abnormality and treatment or non-treatment options available to them.

Definition and Requirements

This standard evaluates patients with benign breast disease. For example: nipple discharge, cysts, infections of the breast, and benign lesions (such as radial scar, fibroadenoma, and papilloma).

A protocol must be developed and implemented to manage and follow patients with benign breast disease according to nationally recognized guidelines. For example:

- Appropriate additional imaging for patients without cancer (density and MRI use)
- Concordance between physical exam, imaging, and pathology
- Establishment of a follow-up plan

Communication of Results
Patients with a benign biopsy or surgery must have their pathology reviewed with them, either by the NAPBC-accredited program or the referring physician. This review must be documented in the patient medical record.

If the NAPBC-accredited program is not the provider communicating the results, a documented protocol must be in place to contact the patient and confirm they have received the results. The method of contact is at the discretion of the NAPBC-accredited program. The patient must also be provided with a contact number in case they wish to further discuss the biopsy results.

Evaluation by the BPLC
Each accreditation cycle, the BPLC must review and assess:

- The barriers to efficient evaluation and diagnosis of patients with benign breast disease
  - If the BPLC identifies non-compliance or barriers to compliance, an intervention or new protocol must be proposed and documented in the BPLC meeting minutes with plans for interval monitoring
- The protocol for assessing and documenting concordance and any related barriers
- The protocol for the follow-up plan and any related barriers

As barriers to compliance with this standard are identified, they must be addressed by the NAPBC-accredited program.

The BPLC evaluations and discussions must be documented in the BPLC meeting minutes.

Documentation

Reviewed On-Site

- The site reviewer will evaluate preselected medical records to confirm compliance with this standard, if not confirmed during the review of Standard 5.1, including:
  - Medical records for patients who do not have cancer are evaluated for appropriate additional imaging (density and MRI use)
  - Documentation of the process for evaluation, documentation, and follow-up of radiology and pathology concordance
  - Documentation of communication of follow-up plans and pathology results

Submitted with Pre-Review Questionnaire

- The required protocol to manage and follow patients with benign breast disease
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- A protocol is in place for managing and following patients with benign breast disease according to nationally recognized guidelines
- Patients with a benign biopsy or surgery must have their pathology reviewed with them, with documentation in the medical record
- The BPLC evaluation is completed and documented in the BPLC meeting minutes once each accreditation cycle

5.4 Management of Patients at Increased Risk for Breast Cancer

Rationale

People at increased risk for the development of an index breast cancer or a recurrence may suffer considerable anxiety about their own future and the implications for their loved ones. Decisions regarding employment, insurability, prophylactic options, and future family-related choices can be overwhelming. Patients benefit from comprehensive, accurate, risk assessment, which facilitates an appropriate understanding of their cancer risks, and shared decision making with their health care providers.

Definition and Requirements

The NAPBC-accredited program must develop and implement a protocol for the management of patients who are at an increased risk for breast cancer. Examples include patients with dense breast tissue, lifestyle risk factors, family history of cancer, and a history of high-risk lesions.

The established protocol must address the following requirements:

- Consideration for risk reduction strategies, including lifestyle modification, as outlined in Standard 5.1
  - When appropriate, high-risk patients must be offered pharmacologic or surgical intervention
- Imaging surveillance following evidence-based guidelines
- Referral to appropriate health care providers for patients with high-risk lesions discovered on a breast biopsy, with appropriate management according to nationally recognized guidelines
  - Examples of high-risk lesions: atypical ductal hyperplasia (ADH), atypical lobular hyperplasia (ALH), and lobular carcinoma in situ (LCIS)
- Referral to genetic professionals for patients with possible genetic risk based on family history, or other factors for genetic evaluation and testing as outlined in Standard 5.5
- Consideration for referral to genetic professionals for patients with abnormal test results (such as pathogenic, likely pathogenic, or variant of uncertain significance) performed by non-genetic professionals, or with test results performed at outside institutions

Risk reduction strategies must be discussed with the patient and documented in the medical record.

Evaluation by the BPLC

Each calendar year, the BPLC must review and assess:

- The protocol for managing patients at increased risk for breast cancer not due to a hereditary cancer syndrome

As barriers to compliance with this standard are identified, they must be addressed by the accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

Documentation

Reviewed On-Site

- The site reviewer will evaluate preselected medical records for patients at increased risk for breast cancer to confirm compliance with the standard, including:
  - Discussion of risk reduction strategies and pertinent family history, with documentation in the patient medical record
  - Consideration for genetic counseling and testing in accordance with nationally recognized guidelines for high-risk patients with breast disease or breast cancer

Submitted with Pre-Review Questionnaire

- Required protocol
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- The protocol is developed and implemented for the management of patients at increased risk for breast cancer
- The BPLC evaluation is completed and documented in the BPLC meeting minutes

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5.5 Genetic Evaluation and Management

Rationale

Accurate genetic evaluation and testing has a major impact on all aspects of cancer care, from primary cancer screenings to guiding management and treatment decisions, and ongoing cancer surveillance. Genetic evaluation and management must consider the impact that the identification of pathogenic and likely pathogenic genetic variants have, or may have, on the patient and family unit.

Definition and Requirements

The NAPBC-accredited program must, at a minimum, **consider** genetic counseling and testing for the following patients:

- All newly diagnosed patients with breast disease or breast cancer
- Patients determined to be at high risk for genetic cancer predisposition
  - These patients are determined based on screening as outlined in Standards 5.1 and 5.4

This consideration for genetic counseling and testing must be in accordance with nationally recognized guidelines, and documented in the patient medical record.

The NAPBC-accredited program must develop and implement a protocol addressing the following requirements for managing patients for genetic evaluation:

- Evidence-based process for genetic evaluation, counseling, and testing
- Provision of a written/electronic copy of the genetic evaluation and testing discussed with the patient, reported to the treatment team, and documented in the medical record
- Documentation of effort to help patients inform at-risk family members and/or provide cascade testing
- Consideration for referral to genetic professionals for patients with abnormal test results (such as pathogenic, likely pathogenic, or variant of uncertain significance) performed by non-genetic professionals, or with test results performed at outside institutions

Professionals approved to provide genetic testing and counseling are outlined in Standard 4.4.

Any genetics services not provided on-site by the NAPBC-accredited program must be provided through a referral relationship with other facilities and/or local agencies, or via telegenetics services. Alternative service delivery models may be utilized by NAPBC-accredited programs to maximize delivery of optimal genetics services to all eligible patients. Please refer to the *Optimal Resources for Breast Care* Appendix for alternative service delivery models approved by the NAPBC for genetic testing and counseling.

Evaluation by the BPLC

Each accreditation cycle, the BPLC must review and assess:

- Considerations for genetic evaluation and management, as outlined above

As barriers to compliance with this standard are identified, they must be addressed by the NAPBC-accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

Documentation

Reviewed On-Site

- The site reviewer will evaluate preselected medical records for patients who have had a genetic evaluation. Specifically, the site reviewer will evaluate at least one positive case (pathogenic/likely pathogenic (P/LP) variant in a breast cancer predisposition gene) and one negative case (no P/LP variant identified, but patient may be identified and managed as high risk based on family/personal history and/or breast cancer risk calculations). These medical records will be assessed for:
  - Consideration of patients for genetic counseling and/or testing
  - Documentation of personalized genetic risk assessment and evaluation
  - Documentation of pertinent family history
  - Genetic evaluation and testing results are provided to and discussed with the patient and available in time for treatment decisions
  - Appropriate management for individuals with both pathogenic or likely pathogenic genetic variants and variants of uncertain significance (VUS) or negative results with residual high risk based on family history
  - Discussion of family members appropriate for cascade testing

Submitted with Pre-Review Questionnaire

- Required protocol
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Newly diagnosed and high-risk patients with breast disease or breast cancer are considered for genetic counseling and testing according to nationally recognized guidelines, with documentation in the patient medical record
- A protocol is developed and implemented for managing patients for genetic evaluation
- Genetic testing is offered to appropriate patients by the genetic professional, discussed with and provided to patients, and available for treatment decisions when applicable
- The BPLC evaluation is completed and documented in the BPLC meeting minutes

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5.6 Evaluation and Treatment Planning for the Newly Diagnosed Cancer Patient

Rationale

The diagnosis of breast cancer starts a cascade of events for which the patient is likely unprepared. Few people are familiar with the set of risks and decisions that must be made. This is naturally a time of great fear and apprehension. Timely and compassionate care will help mitigate the tremendous emotional swings that are associated with this new phase of the patient's life, and the lives of their support system.

Definition and Requirements

The NAPBC-accredited program must complete the following workups for all newly diagnosed patients with breast cancer:

- Staging
- Biopsy
- Imaging
- Metastatic workup
- Laboratory workup
- Evaluation of barriers to care

Staging
In this context, staging requires assignment of the proper cancer stage using the American Joint Committee on Cancer (AJCC) system. The core biopsy, imaging, and physical exam determine the clinical prognostic stage, which must be reported according to the most recent AJCC system. The clinical prognostic stage must be determined based on the information available at the time of staging. The clinical prognostic stage must be discussed with the patient prior to treatment, and the stage must be documented in the patient medical record.

Over the course of ongoing patient evaluation and treatment, the stage assignment must be appropriately determined and documented in the patient medical record. The later stage assignments must be discussed with the patient, and used during any Multidisciplinary Breast Care Conference (MBCC). Recurrence, and post-neoadjuvant stage, are examples of later stage assignment.

Biopsy
The NAPBC-accredited program must review clinically relevant outside biopsy/surgical pathology slides before providing treatment. This is required for all patients, including those with recurrence or previous treatment.

If the outside slides cannot be retrieved for review, this must be discussed with the patient and documented in the patient medical record. In the absence of the outside slides, the outside pathology report must be reviewed. This review may be conducted as an official consultation, or at the Multidisciplinary Breast Care Conference (MBCC).

Imaging
A member of the patient care team must review all imaging studies. The NAPBC-accredited program must review outside breast imaging studies before providing treatment. If review of the outside breast imaging is not possible, the NAPBC-accredited program must complete any necessary imaging studies before providing treatment.

This review may be conducted as an official consultation, or at the Multidisciplinary Breast Care Conference (MBCC). If the review is conducted at the MBCC, the images must be shown.

Metastatic Workup
The NAPBC-accredited program must complete a metastatic workup, as indicated by evidence-based national guidelines. The workup must be documented in the patient medical record.

Laboratory Workup
The NAPBC-accredited program must complete a laboratory workup, as indicated by evidence-based national guidelines. The workup must be documented in the patient medical record.

Barriers to Care
The NAPBC-accredited program must evaluate and address any barriers to effective and efficient care.
Examples of such barriers include, but are not limited to:

- Timely acquisition of outside imaging and pathology
- Insurance pre-approvals
- Financial impact on the patient and family
- Limited resources such as PET scanner, CT etc.

Culturally appropriate shared decision making must be used to determine the risks versus benefits of pretreatment testing.

Evaluation by the BPLC
Each calendar year, the BPLC must review and assess:

- The process of, and obstacles between, diagnosis and treatment time
  - For example: turnaround time for core biomarkers and genomic ancillary testing results, additional imaging, access and availability of specialists, and pre-authorizations
- Whether outside slides are being retrieved and reviewed before treatment at the NAPBC-accredited program

As barriers to compliance with this standard are identified, they must be addressed by the accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

Documentation

Reviewed On-Site

- The site reviewer will evaluate preselected medical records to confirm compliance with the standard, including:
  - Staging
  - Review of outside biopsy/surgical pathology slides
  - Review of outside imaging studies
  - Appropriate metastatic and laboratory workup
  - Evaluating and addressing barriers to effective and efficient care
  - Culturally appropriate shared decision making

Submitted with Pre-Review Questionnaire

- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Clinical staging is documented in the patient medical record and discussed with the patient before treatment at the NAPBC-accredited program
- Biopsy/surgery pathology slides from outside facilities are reviewed by the NAPBC-accredited program before providing treatment
- Breast images from outside facilities are reviewed at the NAPBC-accredited program before providing treatment
- Appropriate workups (metastatic workup, laboratory) are documented in the patient medical record
- Culturally appropriate shared decision making is utilized
- Barriers to effective and efficient care are evaluated and addressed
- The BPLC evaluation is completed and documented in the BPLC meeting minutes each calendar year

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5.7 Comprehensive Evaluation of Patient Factors Before Treatment

Rationale

Patients must be viewed in the context of their entire personhood. Decisions made purely based on clinical care guidelines run the risk of failure if they don't consider all of the factors that affect the patient. Unless these factors are considered during the evaluation period, there is a risk that treatments will either not be accepted or will not produce the results that are expected.

Definition and Requirements

Evaluation by the BPLC
Each calendar year, the BPLC must review and assess one of the following categories of patient pre-treatment evaluation:

- Functional assessments
  - For example: frailty, range of motion, surgical risk factor, baseline lymphedema
- Evaluation for referrals to oncofertility, cardiooncology, exercise program, nutrition counseling, genetics, or physical therapy
- Social well-being assessments
  - For example: psychosocial distress, social and behavioral determinants of health (for example, does the patient live alone, does the patient work more than one job, does the patient have income)

As barriers to compliance with this standard are identified, they must be addressed by the accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

Documentation

Submitted with Pre-Review Questionnaire

- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- The BPLC evaluation is complete and documented in the BPLC meeting minutes

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5.8 Patient Navigation

Rationale

Individuals undergoing treatment for breast disease or breast cancer are generally unfamiliar with the numerous phases of care, and the associated decision-making related to each that must be made as they traverse the patient journey. Patient navigators serve as a resource and ally in this stressful time.

Definition and Requirements

Patient navigation begins at the time of patient presentation to the NAPBC-accredited program and continues beyond treatment. Patient navigation is an integral role in the patient journey as it assists with transitions of care, continuity, and communication between the treatment team members.

A protocol must be developed and implemented to address patient navigation throughout the patient journey. Examples include:

- The patient has a point of contact (the navigator(s)) from the moment of diagnosis onward
- Facilitation of timely transitions between surgery and medical oncology treatment
- Assistance with addressing survivorship and surveillance throughout treatment
- Alerting the radiation oncology team if a patient cannot complete chemotherapy, and finishes treatment early

Evaluation by the BPLC
Each accreditation cycle, the BPLC must review and assess:

- The protocol for patient navigation

As barriers to compliance with this standard are identified, they must be addressed by the accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

Documentation

Submitted with Pre-Review Questionnaire

- Required protocol
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- A protocol is developed and implemented to address patient navigation throughout the patient journey
- The BPLC reviews the protocol at least once each accreditation cycle
- The protocol review is documented in the BPLC meeting minutes

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5.9 Surgical Care

Rationale

Many patients will require surgical treatment for their cancer. The concept of undergoing anesthesia and having part of their body altered or removed is extraordinarily stressful. While this is something the breast care team is familiar with, getting the patient to a level of comfort requires thoughtful consideration, education, and inclusion of the patient in the decision-making process.

Definition and Requirements

Patients undergoing surgery for breast cancer must receive the following care with documentation in the patient medical record:

- Guideline/evidence-based care
  - Examples:
    - The NAPBC-accredited program follows national guidelines provided by ASCO for the management of locally advanced inflammatory and T2 triple negative and HER2 positive breast cancer, and patients are referred for neoadjuvant systemic therapy
    - The NAPBC-accredited program establishes a process for axillary management, including up front sentinel node biopsy, up front axillary dissection, and completion axillary dissection based on current literature
- Culturally appropriate shared decision making
  - Examples that the NAPBC-accredited program is promoting shared decision-making: education of surgical staff, brochures, use of Patient Reported Outcomes (PRO)/patient satisfaction surveys asking shared decision-making questions
- Preoperative and postoperative patient education, to help prepare for surgery and recovery
- Preoperative and postoperative functional assessment and appropriate referrals
- Enhanced Recovery after Surgery (ERAS) protocols and/or opioid-sparing multimodal pain management strategies to facilitate same-day discharge

Protocols must be developed and implemented for:

- Preoperative and postoperative functional assessment and appropriate referrals to exercise, physical therapy, and/or lymphedema management
  - All patients must be considered for preoperative and postoperative functional assessment
- Enhanced Recovery after Surgery (ERAS) and/or opioid-sparing multimodal pain management strategies to facilitate same-day discharge

The patient must receive a copy of the definitive surgery pathology report. Providing the patient with either a written or electronic copy of the report in any format meets the measure of compliance for this standard. The report must be discussed with the patient.

CoC Operative Standards
NAPBC-accredited programs must demonstrate compliance with the Commission on Cancer Standard 5.3 Sentinel Node Biopsy for Breast Cancer, and Standard 5.4 Axillary Lymph Node Dissection for Breast Cancer. If the NAPBC-accredited program is part of a hospital that is Commission on Cancer accredited, demonstration of a compliant rating for Standards 5.3 and 5.4 in the CoC Accreditation Report meets the measure of compliance for this requirement of this standard.

Evaluation by the BPLC
Each calendar year, the BPLC must review and assess:

- Surgical outcomes and processes and ways to improve outcomes and processes. For example, re-excision rate, infection rate, and/or patient satisfaction

As barriers to compliance with this standard are identified, they must be addressed by the accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

Documentation

Reviewed On-Site

- The site reviewer will evaluate preselected medical records to confirm compliance with the standard, including:
  - Guideline/evidence-based care
  - Culturally appropriate shared decision making
  - Preoperative and postoperative patient education
  - Preoperative and postoperative functional assessment and appropriate referrals
  - Utilization of ERAS protocols and/or multimodal pain management
  - Compliance with Commission on Cancer Standards 5.3 and 5.4

Submitted with Pre-Review Questionnaire

- Examples of preoperative and postoperative patient education
- Required protocol for preoperative and postoperative functional assessment and appropriate referrals
- Required protocol for Enhanced Recovery after Surgery (ERAS) and/or multimodal pain management

- If applicable, CoC Accreditation Report documenting a compliant rating for Standards 5.3 and 5.4
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Patients undergoing surgery for breast cancer receive the following care with documentation in the patient medical record:
  - Care provided according to evidence-based guidelines
  - Culturally appropriate shared decision making
  - Assessment of barriers to care
  - Preoperative and postoperative patient education
  - Preoperative and postoperative functional assessment and appropriate referrals
  - Utilization of ERAS protocols and/or multimodal pain management
- Protocol is developed and implemented for preoperative and postoperative functional assessment and appropriate referrals
- Protocol is developed and implemented for Enhanced Recovery after Surgery (ERAS) and/or multimodal pain management
- A copy of the definitive surgery pathology report is provided to and discussed with the patient
- Compliance with Commission on Cancer Standards 5.3 and 5.4 are met
- The BPLC evaluation is completed and documented in the BPLC meeting minutes each calendar year

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5.10 Reconstructive Surgery

Rationale

Some patients who require surgical treatment for their cancer may not be focused on postoperative cosmetic outcomes due to fears of cancer recurrence, while others are too focused on potential disfigurement to make sound oncologic decisions. The surgical team must collaborate with the patient to understand and address concerns, and consider physical, social, cultural, and emotional factors that may impact treatment decisions while striving to restore the patient's sense of well-being safely and efficiently.

Definition and Requirements

Patients with breast cancer must receive the following care with documentation in the patient medical record:

- Appropriate patients undergoing mastectomy are offered a preoperative referral to a reconstructive/plastic surgeon
  - Reconstruction may also include assistance with oncoplastic reconstructions/reductions, symmetry procedures, and other related procedures/assistance
  - Breast reconstruction referrals are documented in the patient medical record. If the patient is deemed inappropriate and/or the patient declines the referral offer, it must be documented in the patient medical record
- Culturally appropriate shared decision making
  - Examples that the NAPBC-accredited program is promoting shared decision making: Documentation of discussion in the medical record, use of surveys to measure patient understanding of surgical decision making and cosmetic outcomes, preoperative multidisciplinary consultation where appropriate, and the collection of information on gender identity and gender minority status (LGBTQ and gender or sexual minority status) and how the patient's gender identity may affect their decision making process regarding reconstruction
- Multidisciplinary input of the impact of reconstruction on other treatment modalities is obtained preoperatively

Protocols must be developed and implemented for:

- Preoperative and postoperative functional assessment and appropriate referrals to exercise, physical therapy, and/or lymphedema management
  - All patients must be considered for preoperative and postoperative functional assessment
- Education about the risks and benefits of reconstructive surgery
  - For example: postoperative appearance, the use of a prosthesis, delayed reconstruction, timing of reconstruction relative to radiation and systemic therapy

Surgeons must seek to maximize satisfaction of cosmesis within the limits of cancer care and patient factors.

Evaluation by the BPLC

Each calendar year, the BPLC must review and assess:

- How the program evaluates outcomes of reconstructive surgery. For example: cosmesis/quality of life/function
  - The BPLC evaluates patient satisfaction, and documents an action plan based on identified opportunities for improvement. For example, oncoplastic Continuing Medical Education for surgeons, or increased referral for oncoplastic cases with plastic surgeon

Each accreditation cycle, the BPLC must review and assess:

- The availability of reconstructive options available to all patients and the impact on multidisciplinary care on the patient

As barriers to compliance with this standard are identified, they are addressed by the accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

Documentation

Reviewed On-Site

- The site reviewer will evaluate preselected medical records to confirm compliance with the standard, including:
  - Patient referral or documentation of discussion
  - Culturally appropriate shared decision making
  - Discussion of the risks and benefits of reconstruction
  - Multidisciplinary input on the impact of reconstruction
  - Preoperative and postoperative functional assessment and appropriate referrals
  - Education about the risks and benefits of reconstructive surgery

Submitted with Pre-Review Questionnaire

- Required protocol for preoperative and postoperative functional assessment and appropriate referrals
- Required protocol for education about the risks and benefits of reconstructive surgery
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Patients with breast cancer receive the following care with documentation in the patient medical record:
  - Appropriate patients undergoing mastectomy are offered a preoperative referral to a reconstructive/plastic surgeon
  - Culturally appropriate shared decision making
  - Multidisciplinary input on the impact of reconstruction on other treatment modalities
- Protocol is developed and implemented for preoperative and postoperative functional assessment and appropriate referrals
- Protocol is developed and implemented for education about the risks and benefits of reconstructive surgery
- The BPLC evaluation of outcomes is completed and documented in the BPLC meeting minutes each calendar year
- The BPLC evaluation of the availability of reconstructive options to all patients and its impact on multidisciplinary care of the patient is completed and documented in the BPLC meeting minutes once each accreditation cycle

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5.11 Medical Oncology

Rationale

Patients with breast cancer are often prescribed oral or intravenous medications that are costly and can cause significant short- or long-term side effects. At times, these toxicities are tolerated for only modest improvements in survival. Programs should discuss treatment side effects and toxicities with patients and their support system while elaborating on the benefits of such treatments. Care must be taken to prevent or alleviate the side effects of treatment medications.

Definition and Requirements

Patients with breast cancer must receive the following care with documentation in the patient medical record:

- Guideline/evidence-based care (for example: NCCN, ASCO, QOPI). Patients falling outside of evidence-based guidelines are discussed at the Multidisciplinary Breast Care Conference (MCBB), or with multidisciplinary input
  - Examples of guideline/evidence-based guidelines include, but are not limited to:
    - Genomic testing is considered in patients with endocrine responsive disease with 0-3 positive nodes
    - Appropriate patients with endocrine responsive disease are considered for endocrine therapy
    - Consideration of HER2 targeted therapy in HER2 positive. If this is not administered, then documentation why it was not administered
    - Patients with triple negative disease are considered for chemotherapy (neoadjuvant, when appropriate)
- Culturally appropriate shared decision making
  - Examples that the NAPBC-accredited program is promoting shared decision making:
    - Discussing and documenting the benefits and risks of systemic treatment with the patient, including toxicities
    - Providing patients information on clinical trials
- Exercise therapy recommendations for pain control, fatigue, anxiety, depression, sleep, loss of function and improved survival

A protocol must be developed and implemented for the assessment of side effects of systemic therapy and appropriate referral and interventions. For example:

- Nutrition support is offered for patients to maintain a healthy diet while experiencing the side effects of chemotherapy
- Acupuncture is offered for control of chemotherapy induced neuropathy
- Pharmacological interventions are available to address symptoms. For example: pain, nausea, hot flashes, vaginal dryness, sexual dysfunction
- Cold caps are offered to avoid chemotherapy induced alopecia

Evaluation by the BPLC

Each calendar year, the BPLC must review and assess:

- Medical oncology outcomes and processes, and ways to improve outcomes and processes. For example, hospitalizations, febrile neutropenia, dose reduction

As barriers to compliance with this standard are identified, they must be addressed by the accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

Documentation

Reviewed On-Site

- The site reviewer will evaluate preselected medical records to confirm compliance with the standard, including:
  - Care provided according to evidence-based guidelines
  - Culturally appropriate shared decision making
  - Exercise therapy recommendations

Submitted with Pre-Review Questionnaire

- Required protocol
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Patients with breast cancer receive the following care with documentation in the patient medical record:
  - Guideline/evidence-based care
  - Culturally appropriate shared decision making
  - Exercise therapy recommendations
- A protocol is developed and implemented for the assessment of side effects of systemic therapy and appropriate referral and interventions
- The BPLC evaluation of outcomes is completed and documented in the BPLC meeting minutes each calendar year

5.12 Radiation Oncology

Rationale

Radiation therapy added to local surgical therapy can decrease cancer recurrence and sometimes alleviate symptoms. NAPBC-accredited programs should discuss the risk of treatment-related complications and side effects with the potential benefits and provide the safest, most effective treatment with the lowest number of fractions considering all patient factors.

Definition and Requirements

Patients with breast cancer must receive the following care with documentation in the patient medical record:

- Guideline/evidence-based care (for example: NCCN, ASTRO). Patients falling outside of evidence-based guidelines are discussed at the Multidisciplinary Breast Care Conference (MBCC), or with multidisciplinary input
  - Examples of guidelines/evidence-based guidelines include, but are not limited to:
    - All lymph node positive patients with breast cancer are evaluated by radiation oncology or discussed at the MBCC
    - Patients who are candidates for breast conservation and postoperative radiation are discussed at MBCC or referred to a radiation oncologist
    - The majority of early-stage patients with breast cancer having breast conservation surgery are treated with a form of hypo-fractionation
    - Offering observation when appropriate
    - Offering regional nodal radiation when appropriate
- Culturally appropriate shared decision making is routinely incorporated
  - Examples that the NAPBC-accredited program is promoting shared decision making:
    - Implementation of "choosing wisely" recommendations
      - Limiting radiation in hormonally sensitive patients over 70
      - Validated shared decision-making surveys
      - Multidisciplinary input prior to reconstruction, including oncoplastics or initiation of hormonal therapy

A protocol must be developed and implemented for assessment of side effects of radiation therapy and appropriate referral and interventions. For example:

- Evaluation and referral for lymphedema or mobility complications
- Evaluation and treatment of radiation related dermatitis
- Post treatment instructions on what to expect and how to manage post treatment effects are provided to each patient at the conclusion of treatment

Evaluation by the BPLC

Each calendar year, the BPLC must review and assess:

- Radiation oncology outcomes and processes, and ways to improve outcomes and processes

As barriers to compliance with this standard are identified, they must be addressed by the accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

Documentation

Reviewed On-Site

- The site reviewer will evaluate preselected medical records to confirm compliance with the standard, including:
  - Care provided according to evidence-based guidelines
  - Culturally appropriate shared decision making

Submitted with Pre-Review Questionnaire

- Required protocol
- The BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Patients with breast cancer receive the following care with documentation in the patient medical record:
  - Guideline/evidence-based care
  - Culturally appropriate shared decision making
- A protocol is developed and implemented for assessment of side effects of radiation therapy and appropriate referral and interventions
- The BPLC evaluation is completed and documented in the BPLC meeting minutes each calendar year

5.13 Surgical Pathology

Rationale

Surgical pathology can provide prognostic information, particularly in cases of neoadjuvant therapy. Pathology reports must be timely, accurate, self-standing documents containing the necessary data to guide treating clinicians, including information on initial receptors, margins, and complete nodal evaluation.

Definition and Requirements

The NAPBC-accredited program must review clinically relevant outside biopsy/surgical pathology slides before providing treatment to the patient (see Standard 5.6).

Estrogen and progesterone receptors, and HER2 studies only need to be performed on one specimen (for example: the core biopsy), but the results must be included in the synoptic report for the definitive surgery, even if performed on the core biopsy or at an outside facility. Referring to prior pathology reports **does not** meet the measure of compliance for this standard.

Evaluation by the BPLC
Each calendar year, the BPLC must review and assess:

- Pathology outcomes and processes, and ways to improve outcomes and processes. For example, the time between the definitive surgery and definitive surgery pathology results

As barriers to compliance with this standard are identified, they must be addressed by the accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

Documentation

Reviewed On-Site

- The site reviewer will evaluate preselected medical records to confirm compliance with the standard, including:
  - The pathology report for the definitive surgery

Submitted with Pre-Review Questionnaire

- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Estrogen and progesterone receptors and HER2 studies are included in the definitive surgery pathology report
- The BPLC evaluation is completed and documented in the BPLC meeting minutes each calendar year

5.14 Breast Cancer Staging Using the AJCC System

Rationale

Once a Stage grouping is assigned, patients carry that for the rest of their treatment and for all future visits. Staging is also critical for gathering data that allows researchers to conduct studies to help improve care. It is therefore critical that Stage grouping using both anatomic and non-anatomic features is gathered. Documentation of pathological (postoperative) staging or posttherapy pathological (post-neoadjuvant and surgery) staging using genomic and pathologic data helps guide oncologists to make appropriate choices for systemic therapies, and help eliminate over- and under-treatment.

Definition and Requirements

Pathological staging (after surgical treatment) or posttherapy pathological staging (after neoadjuvant therapy followed by surgical resection) must be reported by the managing physician according to the most recent American Joint Committee on Cancer (AJCC) system, which includes appropriate genomic testing to determine prognostic stage. AJCC staging must be documented in the medical record, and discussed with the patient.

Evaluation by the BPLC
Each accreditation cycle, the BPLC must review and assess:

- Documentation of clinical, pathological, and, if available, prognostic staging

As barriers to compliance with this standard are identified, they must be addressed by the NAPBC-accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

Documentation

Reviewed On-Site

- The site reviewer will evaluate preselected medical records to confirm compliance with this standard, including:
  - Documentation of pathological or posttherapy pathological stage and related discussion

Submitted with Pre-Review Questionnaire

- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Pathological or posttherapy pathological staging must be reported by the managing physician and discussed with the patient, with documentation of both in the medical record
- The BPLC evaluation is completed and documented in the BPLC meeting minutes once each accreditation cycle

Bibliography

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Survivorship and surveillance begin at the point of diagnosis. The placement of these standards at the end of Chapter 5 should not be construed as an indication that they should only apply post-treatment.

5.15 Survivorship

Rationale

Patients with breast disease or breast cancer are at risk for complications and symptoms that can delay other treatments and interfere with recovery. Identification and control of these symptoms is essential to promote compliance with continued therapies and restore the patient's sense of normalcy. After treatment, some patients need assistance and guidance to help them return to their "new normal." Other patients may see their diagnosis as a "wake up call" to improve their overall health. NAPBC-accredited programs promoting a healthy lifestyle will not only decrease patient risk for disease recurrence, but will also improve the patient's post-cancer well-being.

Definition and Requirements

The NAPBC-accredited program must use evidence-based guidelines to develop and implement a protocol addressing persistent symptoms, functional issues, and social and behavioral determinants of health for maximizing symptom management, physical function, and social well-being among patients with breast disease or breast cancer. Examples of such evidence-based guidelines include those provided by the ACSM, APTA, ONS, ACS, NCCN, and ASCO.

Examples of evidence-based guidelines include, but are not limited to, the following:

- Referral to local or online exercise programs
- Referral to a social worker if psychosocial distress remains elevated post-treatment
- Referral to outpatient rehabilitation if specific functional complaints arise
- Referral to outpatient rehabilitation for evaluation and treatment for lymphedema, as needed

The protocol must also address how patients with breast disease or breast cancer are connected to evidence-based elements of breast cancer recovery.

- For example, ensuring that breast cancer survivors receive referrals to exercise programming at follow-up appointments
- For services that are not available on-site, the treatment team must help facilitate patient access to needed resources

It is recommended, but not required, that a written summary of treatment and associated survivorship recommendations is provided to the patient and the patient's primary care provider.

Patients must be encouraged to maintain a relationship with their primary care provider, who is informed about the care the patient received, and potential side effects the patient may encounter.

Evaluation by the BPLC

Each accreditation cycle, the BPLC must review and assess:

- The protocol for following evidence-based guidelines to address persistent symptoms, functional issues, and social and behavioral determinants of health, for maximizing symptom management, physical function, and social well-being among patients with breast disease or breast cancer
- Barriers to maximizing wellness of patients with breast disease or breast cancer after treatment

As barriers to compliance with this standard are identified, they must be addressed by the NAPBC-accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

Documentation

Reviewed On-Site

- The site reviewer will evaluate preselected medical records to confirm compliance with this standard, including:
  - Persistent symptoms are queried and addressed according to evidence-based guidelines
  - Functional status is addressed according to evidence-based guidelines
  - Social and behavioral health is assessed regularly and addressed according to evidence-based guidelines

Submitted with Pre-Review Questionnaire

- Required protocol
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- A protocol is developed and implemented for following evidence-based guidelines for addressing persistent symptoms and maximizing physical function and social and behavioral health
- Symptom status, functional status, and social well-being are tracked in the patient medical record
- The BPLC evaluation must be completed and documented in the BPLC meeting minutes

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5.16 Surveillance

Rationale

As patients finish treatment, they may require education regarding the potential for long-term effects and disease recurrence. Communicating the post-treatment plan for surveillance of long-term effects and disease recurrence helps minimize patient anxiety and increase the likelihood of their full participation in surveillance plans.

Definition and Requirements

The NAPBC-accredited program must use evidence-based guidelines to develop and implement a protocol addressing the following:

- Appropriate clinical and imaging surveillance for disease progression or recurrence
- Surveillance for long-term and late effects of disease and treatment
  - For example: Assessing patients for depression, cardiotoxicity, lymphedema, sexual well-being, and sleep disturbance
- Surveillance for disease, surveillance for long-term and late effects, and requirements for documenting in the patient medical record
  - For example: Patients who receive axillary dissections are automatically referred to rehabilitation for ongoing assessments and, if necessary, lymphedema treatment

For services that are not available on-site, the NAPBC-accredited program must facilitate access to the necessary resources and services.

Evaluation by the BPLC
Each accreditation cycle, the BPLC must review and assess:

- The protocol for following evidence-based guidelines for disease surveillance and long-term and late effects of disease and treatment

As barriers to compliance with this standard are identified, they must be addressed by the NAPBC-accredited program.

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

Documentation

Reviewed On-Site

- The site reviewer will evaluate preselected medical records to confirm compliance with this standard, including:
  - Disease surveillance is addressed according to evidence-based guidelines
  - Treatment of long-term and late effects is addressed according to evidence-based guidelines and/or disease site team recommendations

Submitted with Pre-Review Questionnaire

- Required protocol
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- A protocol is developed and implemented for following evidence-based guidelines for disease surveillance and long-term and late effects of treatment
- Surveillance for disease and long-term and late effects is documented in the patient medical record
- The BPLC evaluation is completed and documented in the BPLC meeting minutes

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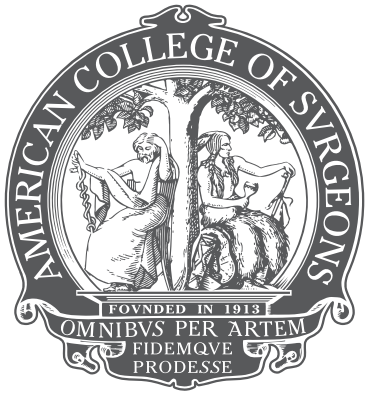
ACS NAPBC

National Accreditation Program for Breast Centers
American College of Surgeons



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6 Data Surveillance and Systems

Submission to a NAPBC-specific database is not required by *Optimal Resources for Breast Care*, therefore, there are no Chapter 6 standards.

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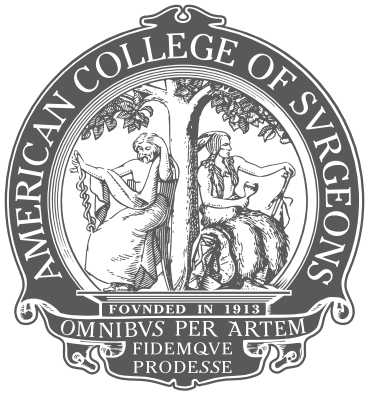

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7 Quality Improvement

Rationale

The Institute of Medicine outlines the following factors as contributory to high-quality care: safe, timely, effective, efficient, equitable, and patient-centric. NAPBC-accredited programs must embark on quality improvement initiatives that address these factors in order to continuously improve the quality of the care they deliver to patients with breast disease or breast cancer.

In Development

7.1 Quality Measures

Definition and Requirements

The National Accreditation Program for Breast Centers (NAPBC) requires accredited programs to treat patients with breast disease or breast cancer in accordance with all nationally accepted quality measures. The NAPBC approves such nationally accepted quality measures based on a determination of need for quality or accountability regarding a specific aspect of breast care. All approved quality measures must be reviewed and implemented by the NAPBC-accredited program. The timeline for implementation and the expected compliance rate for all new quality measures is determined by the NAPBC. The Breast Program Leadership Committee (BPLC) must monitor the accredited program's adherence with all required quality measures.

If adherence to any required quality measure falls below its expected rate of compliance, a corrective action plan must be developed and implemented to improve performance. The corrective action plan must document how the NAPBC-accredited program will investigate and resolve all barriers affecting a required quality measure which falls below its expected rate of compliance.

Programs with no cases eligible for assessment in an approved quality measure are exempt from demonstrating compliance with the requirements for that individual quality measure.

Evaluation by the BPLC
Each calendar year, the BPLC must review and assess:

- Compliance with all required quality measures
- Development and implementation of corrective action plans for all quality measures that fall below the expected rate of compliance

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

Documentation

Submitted with Pre-Review Questionnaire

- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- The BPLC monitors the program's compliance with quality measures approved by the NAPBC
- The BPLC develops and implements a corrective action plan for any quality measure that falls below its expected rate of compliance
- The BPLC evaluation is completed and documented in the BPLC meeting minutes

7.2 Quality Improvement Initiatives

Definition and Requirements

Under the guidance of the Breast Program Director (BPD) and the Breast Program Leadership Committee (BPLC), the NAPBC-accredited program must measure, evaluate, and improve its performance through at least one breast cancer-specific quality improvement (QI) initiative each year.

This QI initiative requires the NAPBC-accredited program to identify a problem, understand the root cause of the identified problem through use of a recognized performance improvement methodology, and implement a planned solution to the problem. Reports on the status of the QI initiative must be given to the BPLC at least twice each calendar year, and documented in the BPLC meeting minutes.

Required Components for Quality Improvement Initiatives

1. **Review Data to Identify the Problem**
   The QI initiative must be focused on an already-identified, quality-related problem specific to the NAPBC-accredited program.

   The following may be used to identify the focus of the QI initiative:
   - Barriers, supported by data, identified during the BPLC evaluations required by Chapter 5 of *Optimal Resources for Breast Care*
   - Data-focused quality programs identified through a chart review of a specific cohort of patients in order to assess an area of specific concern, or to assess an area of care specified in nationally recognized guidelines
   - Data-focused quality programs identified through a physician, specialty-specific quality improvement program; examples include, but are not limited to, the American Society of Breast Surgeons' Mastery of Surgery program, the American Society for Radiation Oncology's Radiation Oncology Incident Learning System (RO-ILS), or the American Society of Plastic Surgeons' Tracking Operations and Outcomes for Plastic Surgeons (TOPS) program
   - Data-focused quality program identified through a specialty-based facility-specific quality improvement program; examples include, but are not limited to, the American College of Radiology's National Mammography Database (NMD), or the National Consortium of Breast Centers' National Quality Measures for Breast Centers program (NQMBC)
   - Data-focused quality programs identified through an internal institution-specific or health-system-specific database, which may include the entire cancer registry or a smaller established clinical database
   - Data-focused problems identified in a Standard 7.1 quality measure
   - Problems identified through review of National Cancer Database data, including Cancer Quality Improvement Program (CQIP) or Rapid Cancer Reporting System (RCRS) data
   - Any other data-focused breast cancer-specific, quality-related problem determined by the BPLC

2. **Write the Problem Statement**
   The QI initiative must have a problem statement. The problem statement must outline:
   - A specific, already identified, quality-related problem that is specific to the NAPBC-accredited program to solve through the QI initiative
   - The baseline and goal metrics (must be numerical)
   - The anticipated timeline for completing the QI initiative, and achieving the expected outcome

   The problem statement for the QI initiative cannot state that a study is being done to see if a problem exists. The problem must already be known to exist.

3. **Choose and Implement Performance Improvement Methodology and Metrics**
   The BPD and BPLC must identify the subject matter experts needed to execute the QI initiative. For example, if the QI initiative is focused on the time between pre-surgery chemotherapy and surgery, then at least one breast surgeon and one medical oncologist must be included on the QI initiative team.

   A recognized, standardized performance improvement methodology must be selected and implemented to conduct the QI initiative (for example, Lean, DMAIC, or PDCA/PDSA).

   In line with the quality improvement methodology selected, the team must conduct analysis to identify all possible factors contributing to the problem. This may involve literature review and/or root-cause analyses. Based on the results of this analysis, an intervention is developed that aims to fix the cause of the problem being studied.

   It is recommended to establish a project calendar, which includes the launch date of the QI initiative, when status updates will be given at BPLC meetings, and a project end date.

QI initiatives are expected to last approximately one year. If additional time is required, the initiative may be extended for a second year (for a total of two years). However, a new QI initiative must be started at the beginning of each calendar year, even if a previous QI initiative is still in progress. The last BPLC meeting of the calendar year must include a status update for any ongoing QI initiative that will be extended into a second calendar year.

4. **Implement Intervention and Monitor Data**
   The intervention chosen in step three must be implemented. If oversight of the implementation suggests the intervention is not working, then the intervention must be modified.

5. **Present Quality Improvement Initiative Summary**
   Once the QI initiative has been completed, a document summarizing the initiative and the results must be presented and discussed with the BPLC and the BCT, and documented in the BPLC meeting minutes. The results of the QI initiative must be quantifiable, using outcomes data compared to the baseline data and the numerical goal metrics established in step two. The results of the QI initiative must also be compared with national benchmark data, whenever possible.

   The summary presentation must include:
   - Summary of the data reviewed to identify the problem
   - The problem statement
   - The QI initiative team members
   - Performance improvement methodology utilized
   - The implemented intervention
   - If applicable, any adjustments made to the intervention
   - Results of the implemented intervention

BPLC Reports
Updates to the BPLC on the QI initiative's status at least twice each calendar year must be provided. Status updates, at a minimum, indicate the current status of the QI initiative and the planned next steps. The final summary and results report may qualify as one of the required reports.

Documentation

Reviewed On-Site
- Documentation of QI initiative team's work from throughout the initiative (for example, meeting minutes, literature review, etc.)

Submitted with Pre-Review Questionnaire
- Quality Improvement Initiative Template
- BPLC meeting minutes documenting required status updates and presentation of the QI initiative summary

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that NAPBC-accredited programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:
- One quality improvement initiative based on an identified quality-related problem is initiated each year. The QI initiative documentation includes how it measured, evaluated, and improved performance through implementation of a recognized, standardized performance improvement methodology
- Status updates are provided to the BPLC two times. Reports are documented in the BPLC meeting minutes
- A final presentation of a summary of the quality improvement initiative is presented after the QI initiative is complete. The summary presentation includes all required elements

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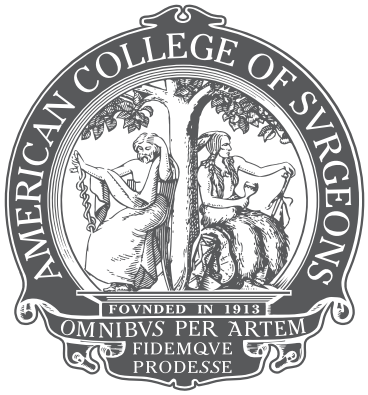

AMERICAN COLLEGE OF SURGEONS
NATIONAL ACCREDITATION PROGRAM FOR BREAST CENTERS

8 Education: Professional and Community Outreach

Rationale

NAPBC-accredited programs must strive to focus efforts on education about breast cancer prevention, healthy lifestyles, and screening awareness. Such education helps lessen the physical, emotional, and financial burdens of a possible cancer diagnosis by improving the odds of faster detection, and faster treatment. Lifestyle modifications, such as achieving and maintaining a healthy body mass index, and reducing alcohol intake can reduce the risk for breast cancer. Continuing education for health care professionals providing care to patients with breast disease or breast cancer ensures that providers remain current on new options for neoadjuvant, primary, and adjuvant treatment to help deliver the best possible outcomes for their patients.

8.1 Education, Prevention, and Early Detection Programs

Definition and Requirements

Each calendar year, the NAPBC-accredited program must provide or coordinate a minimum of two education programs targeted to the local community. These programs must focus on breast disease or breast cancer education, prevention, and/or early detection. Coordinating these programs with other facilities or local agencies does meet the measure of compliance for this standard.

Prevention programs identify risk factors and use strategies to modify attitudes and behaviors to reduce the chance of developing breast cancer. Early detection programs apply screening guidelines to detect cancers at an early stage, which improves the likelihood of increased survival and decreased morbidity. For early detection programs, a follow-up process must be defined and implemented for patients with positive findings.

Education, prevention, and/or early detection programs include, but are not limited to:

- Risk reduction through lifestyle modification or chemoprevention
- Breast cancer awareness
- Breast care education
- Genetic counseling for high-risk populations
- Screening mammography and clinical examination

An education or prevention program may address multiple cancer sites, but at least one component of the program must be dedicated to breast disease or breast cancer.

Education and prevention programs may be held virtually, but there must be real-time interaction with participants. Pre-recorded programs or resources with no option for participant interaction or participation **do not** meet the measure of compliance for this standard.

Documentation

Submitted with Pre-Review Questionnaire

- Education, Prevention, and Early Detection Program Template
- The process used to follow up with patients found to have positive findings as a result of participation in early detection programs

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- Each calendar year, two or more breast disease or breast cancer education, prevention, and/or early detection programs are provided
- For early detection programs, follow-up must be provided to patients with positive findings

8.2 Continuing Education

Definition and Requirements

The Breast Care Team (BCT)
Physicians and Advanced Practice Registered Nurses (APRNs) who are members of the BCT must complete a minimum of **two total hours** of **breast-specific** Continuing Medical Education (CME) or Nursing Continuing Professional Development (NCPD), each calendar year. Documentation must be available for each breast-specific educational activity contributing toward the two credit hours. Local, state, regional, and national educational activities are all acceptable. Any combination of credits (0.25, 0.5, 1.0, 2.0) earned from breast-specific educational activities is acceptable. For example: eight 0.25 CME credits; two 1.0 NCPD credits; two 0.5 and one 1.0 CME credits.

- Industry-sponsored educational activities that promote specific products or therapies **do not** count toward meeting the measure of compliance for this standard
- CME and NCPD credits earned for attending a Multidisciplinary Breast Cancer Conference (MBCC) **do not** count toward meeting the measure of compliance for this standard

CME and NCPD credits earned for compliance with Standards 4.1 or 4.2 (excluding credits earned from MBCC attendance) may be utilized to meet the measure of compliance for this standard, as long as those credits are breast-specific.

The requirements outlined above apply only to physician and APRN members of the BCT.

Other members of the BCT are encouraged to complete annual, breast-specific, continuing education; however, that is not a requirement to meet the measure of compliance for this standard.

Genetic Professionals and Counselors
Genetic professionals and counselors (as defined in Standard 4.4) at the NAPBC-accredited program who provide care to patients with breast disease or breast cancer must complete a minimum of **two total hours** of genetics-related Continuing Medical Education (CME) or Nursing Continuing Professional Development (NCPD) each calendar year. The two credit hours must focus on cancer genetics and hereditary cancer predisposition syndromes. Documentation must be available for each cancer-specific genetic educational activity contributing toward the two credit hours. Local, state, regional, and national educational activities are all acceptable.

Any combination of credits (0.25, 0.5, 1.0, 2.0) earned from cancer-specific educational activities is acceptable. For example: eight 0.25 CME credits; two 1.0 NCPD credits; two 0.5 and one 1.0 CME credits.

- Educational activities provided by commercial genetic testing laboratories regarding how to perform genetic testing **do not** count toward meeting the measure of compliance for this standard
- CME and NCPD credits earned for attending a Multidisciplinary Breast Cancer Conference (MBCC) **do not** count toward meeting the measure of compliance for this standard

CME and NCPD credits earned for compliance with Standards 4.1 or 4.2 (excluding credits earned from MBCC attendance) may be utilized to meet the measure of compliance for this standard, as long as those credits focus on cancer genetics and hereditary cancer predisposition syndromes.

Continuing Education Units
Continuing Education Units (CEUs) are acceptable to demonstrate compliance with this standard for appropriate genetic professionals. Documentation of **0.2 CEUs** must be available to demonstrate compliance with this standard. All requirements and restrictions outlined above also apply to personnel documenting CEUs instead of CME or NCPD.

Documentation

Submitted with Pre-Review Questionnaire
- Continuing Education Template

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:
- Physician and Advanced Practice Registered Nurse members of the BCT must complete a minimum of two hours of breast-specific CME or NCPD each calendar year
- Genetic professionals at the NAPBC-accredited program who provide care to patients with breast disease or breast cancer must complete a minimum of two hours of CME, NCPD, or 0.2 CEUs each calendar year, focusing on cancer genetics and hereditary cancer predisposition syndromes

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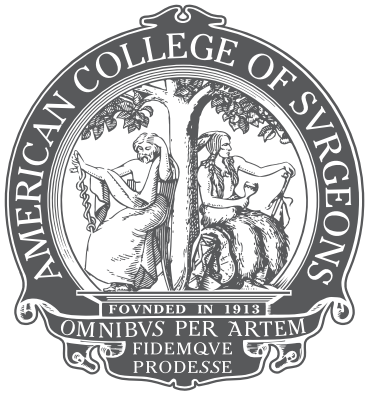

AMERICAN COLLEGE OF SURGEONS
NATIONAL ACCREDITATION PROGRAM FOR BREAST CENTERS

9 Research

Rationale

In order to advance medical science in service to patient care in every sense, it is important to learn as much as possible from patients who receive treatment. Accordingly, NAPBC-accredited programs must endeavor to enroll patients into scientific studies that may broaden the overall understanding of breast diseases.

9.1 Clinical Research Accrual

Definition and Requirements

The NAPBC-accredited program must enroll a minimum of two percent (2%) of its analytic breast cancer cases in clinical research studies. The clinical research studies must be related to breast disease or breast cancer. This requirement must be met each calendar year.

Cancer-Related Research Studies Eligible for Accrual
Clinical research studies eligible to count for accrual must meet the following requirements:

1. Related to breast disease or breast cancer
2. Approved by an internal or external Institutional Review Board (IRB) that is responsible for the review and oversight of the research study
3. Have informed, written, subject consent (unless consent is waived by the IRB)

Categories of breast disease or breast cancer-related clinical research studies eligible for accrual:

- Basic Science
- Device Feasibility
- Diagnostic
- Health Services Research
- Prevention
- Screening
- Supportive Care
- Treatment

Definitions for these categories may be found on the National Cancer Institute Clinical Trial Reporting Program User Guide (see Primary Purpose Value Definitions).

Additional categories of breast disease or breast cancer-related clinical research studies for accrual:

- Cancer-specific biorepositories or tissue banks
  - Such biobanks must collect samples for use in clinical trials and/or clinical research
- Economics of cancer care
  - Studies that assess the costs and effectiveness of cancer interventions and/or analyze the financial impact of cancer care on patients
- Genetic studies
  - Studies that examine contributing genes or how different exposures modify the effect of a gene mutation that may be at risk for cancer development
  - Studies that examine genetic polymorphisms and mutations for early risk assessment
- Patient registries with an underlying breast disease or breast cancer research focus
  - Such registries must be used in clinical trials and/or clinical research
- Epidemiological studies with an underlying breast disease or breast cancer research focus

Humanitarian Use Devices studies cannot be counted as an accrual under this standard.

Calculating Compliance
Compliance with this standard is calculated using the number of subjects with breast disease or breast cancer enrolled in eligible clinical research studies (numerator), and the total number of annual analytic breast cancer cases (denominator).

To count for accrual, subjects enrolled in eligible clinical research studies must fall into at least one of the following categories:

- Diagnosed and/or treated at your program and enrolled in a breast disease or breast cancer-related clinical research study within your program
- Diagnosed and/or treated at your program and enrolled in a breast disease or breast cancer-related clinical research study within a staff physician's office of your program
- Diagnosed and/or treated at the program, then referred by your program for enrollment onto a breast disease or breast cancer-related clinical research study through another program or facility
- Referred to your program for enrollment onto a breast disease or breast cancer-related clinical research study through another program or facility

Researchers and clinical trial investigators who accept referral of subjects from other programs for the purpose of participation in a breast disease or breast cancer-related clinical research study must cooperate with the data management team of the cancer program from which the patient was referred.

If one subject is enrolled in two different trials or studies, that subject may be counted **twice** for accrual. However, if one subject is enrolled in two arms of a protocol, or enrolled in a sub-study of a protocol, that subject only counts **once** for accrual.

If the clinical research is cancer-related, but it is not specific to breast disease or breast cancer, subject accruals are allowed to count provided the **study** relates to breast disease or breast cancer. The subjects enrolled must still be patients with breast disease or breast cancer.

Evaluation by the BPLC
Each calendar year, the BPLC must review and assess:

- The yearly accrual to breast disease or breast cancer-related clinical research studies
- If the required accrual percentage is not met, the BPLC identifies contributing factors and identifies an action plan to address those factors

The BPLC evaluation and discussion must be documented in the BPLC meeting minutes.

Documentation

Reviewed On-Site

- Tracking documents that detail the number of subjects accrued to specific clinical research studies

Submitted with Pre-Review Questionnaire

- Clinical Research Accrual Template
- BPLC meeting minutes documenting the required evaluation

Documentation uploaded into the Pre-Review Questionnaire must have all protected health information removed.

It is expected that NAPBC-accredited programs follow local, state, and federal requirements related to patient privacy, risk management, and peer review for all standards of accreditation. These requirements vary state-to-state.

Measure of Compliance

The NAPBC-accredited program fulfills all compliance criteria:

- The annual number of breast disease or breast cancer subjects accrued to breast disease or breast cancer-related clinical research studies meets or exceeds two percent (2%)
- The BPLC evaluation is completed and documented in the BPLC meeting minutes

Appendix

Alternative Service Delivery Models

Quality genetic counseling is dependent on services provided by healthcare professionals with genetic training and continuing education, such as a NAPBC-approved genetic professionals (see Standard 4.4). It is therefore vital to utilize collaborative alternative service delivery models within NAPBC-accredited programs that promote the delivery of high-value genetics services by all clinicians. Alternative service delivery models provided by genetic professionals may include any of the following:

Alternative Service Delivery Models	
Telegenetics	Genetic counseling may be provided remotely by live videoconferencing. This approach may involve the genetic professional to be present at a healthcare facility with access to the required telegenetics equipment. Increasingly, telegenetics may be facilitated through various software or applications that allow either or both the patient and/or provider to participate in telegenetics appointments outside of a healthcare facility setting. Telegenetics services are also increasingly provided by commercial companies that provide support for all aspects of genetic counseling and testing, while working in conjunction with referring physicians.
Group Genetic Counseling	In this model, different patients have pre-test counseling together provided by the genetic professional, typically for the same clinical indication (such as a family history of breast cancer). This model may allow for break-out sessions for individual discussions between patients and genetic professional after the group session.
Mainstreaming	Several different forms of this delivery model currently exist: • Genetic professionals assisting and partnering with non-genetic clinicians for risk assessment and/or pre-test or post-test counseling • Genetic professionals educating a community of clinicians (such as providing in-services or educational presentations) to facilitate management of routine cases with post-test referral to genetic professionals
Tumor-First Testing Models	In this model, genetic screening is first performed on tumor tissue, often as part of the pathology workflow, with genetic counseling by the genetic professional offered based on the tumor results. Considerable care must be taken when using this model to ensure proper informed consent. Clinicians must also be aware that, depending on the type of tumor testing employed, the chance of missing a germline genetic variant is high, and the clinicians must also be sure to perform proper risk assessment and genetic testing based on other personal and family risk factors present in the patient.
Direct Genetic Testing	In the direct model, patients are offered genetic testing with little to no pre-test discussion. Written documents, recorded video, or other resources may be provided instead of genetic counseling. Considerable care must be taken to ensure appropriate informed consent is completed with each patient. Clinicians must also be wary to avoid the potential negative outcomes of this model, including unnecessary prophylactic surgeries, unnecessary testing, psychosocial distress, and false reassurance from results leading to inappropriate medical management. Post-test genetic counseling by a genetic professional is crucial in this model to ensure proper understanding of the test results, and optimal medical management of the patient.
Direct Access/ Direct-to-Consumer-Testing*	This model is not currently appropriate for all patients and may only be most suitable for curious patients, and those without access to counseling due to financial limitations. This testing is prone to false-negatives and false-positives as it is not designed as a clinical test. Any variants found on a direct-to-consumer test must be confirmed in a CLIA-certified laboratory. Direct-to-consumer testing results should be reviewed by a healthcare provider experienced in genomics, and interpreting such test results.* ***This delivery model does not currently meet the measure of compliance for genetic services as required by Standard 5.5.**

It is important to note that these models all have numerous benefits and limitations, and that NAPBC-accredited programs may need to utilize several different models to accommodate the unique needs of their different clinics and patient populations. Regardless of the service delivery model used, the genetic professional must meet the defined requirements specified in the measures of compliance for Standard 4.4, and all aspects of appropriate genetic risk assessment and testing that must be complete as described in the measures of compliance for Standard 5.5.

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Glossary, Acronyms, and Key Terms

A2LA: American Association for Laboratory Accreditation

AAPM: American Association of Physicists in Medicine

ABGC: American Board of Genetic Counseling

ABMGG: American Board of Medical Genetics and Genomics

ABMS: American Board of Medical Specialties

Accession number: A unique patient identifier assigned when the patient is abstracted in the cancer registry. The accession number consists of the year in which the patient was first seen at the reporting facility and the consecutive order in which the patient was abstracted.

Accreditation Report: Document released to NAPBC programs at the conclusion of their initial or reaccreditation site visit. The accreditation report includes compliance ratings for each applicable standard and may include specific comments regarding the program's performance. The accreditation report also states the assigned accreditation award and, if applicable, the corrective action due date.

Accredited Program(s): A single or multiple-location medical institution providing diagnostic services, treatment services, and comprehensive multidisciplinary care for patients with breast disease or breast cancer, which has achieved accreditation by the National Accreditation Program for Breast Centers (NAPBC). This also refers to initial applicant programs that are actively pursuing accreditation with the NAPBC.

ACHC: Accreditation Commission for Health Care

ACoS: The American College of Surgeons

ACoS Cancer Programs: American College of Surgeons' programs focused on improving care and treatment for patients with cancer, including Commission on Cancer, National Accreditation Program for Breast Centers, National Accreditation Program for Rectal Cancer, the National Cancer Database, American Joint Committee on Cancer, and the Clinical Research Program.

ACR: American College of Radiology

ACRO: American College of Radiation Oncology

ACR-ROPA: American College of Radiology Radiation Oncology Practice Accreditation

ACS: The American Cancer Society

ACGN: Advanced Clinical Genomics Nurse

ACSM: American College of Sports Medicine; ACSM Guidelines for Exercise and Cancer.

ADH: Atypical Ductal Hyperplasia; a type of high-risk breast lesion.

Adjuvant therapy: Additional treatment given after primary treatment (typically surgery) to reduce the risk of recurrence, e.g., systemic therapy or radiation therapy.

AGN-BC: Advanced Genetics Nursing Certification

AICR: American Institute for Cancer Research

AJCC: American Joint Committee on Cancer

ALH: Atypical Lobular Hyperplasia; a type of high-risk breast lesion.

Analytic breast cancer case: Cases for which the hospital provided the initial diagnosis of cancer and/or for which the hospital contributed to first course treatment.

ANCC: American Nurses Credentialing Center

Annually: Once each calendar year.

AOA: American Osteopathic Association

AOCN: Advanced Oncology Certified Nurse

AOCNP: Advanced Oncology Certified Nurse Practitioner

AOCNS: Advanced Oncology Certified Clinical Nurse Specialist

Appeal: A part of the site visit process where the applicant program contests one or more of the findings of the site visit.

APRN: Advanced Practice Registered Nurses

APTA: American Physical Therapy Association

ASBrS: American Society of Breast Surgeons

ASCO: American Society of Clinical Oncology

ASTRO: American Society for Radiation Oncology

ASTRO-APEx: The American Society for Radiation Oncology Accreditation Program for Excellence

BICOE: Breast Imaging Center of Excellence

Breast Care Team (BCT): See definition and requirements in Standard 2.3.

Breast Program Director (BPD): See definition and requirements in Standard 2.2.

Breast Program Leadership Committee (BPLC): See definition and requirements in Standard 2.1.

Calendar year: January 1 - December 31.

Calendar year review: Compliance criteria requiring annual review must be completed at least once for each full calendar year, from January 1 – December 31.

CAP: College of American Pathologists

CBCN: Certified Breast Care Nurse

CE: Continuing Education

CEU: Continuing Education Unit

CEO or equivalent: A high-ranking member of hospital/institutional administration with the authority for high level decision making and resource allocation.

CGN: Clinical Genomics Nurse

CGRA: Cancer Genetic Risk Assessment certification

Class of Case: Class of Case divides cases into two groups that reflects the program's primary responsibility in managing the cancer, analytic and non-analytic cases. More information Class of Case is available in the Facility Oncology Registry Data Standards.

CME: Continuing Medical Education

CoC: The Commission on Cancer

Community representative: An individual who resides within the accredited program's service area.

Compliance: The accredited program meets all the compliance criteria required for a specific standard.

CQIP: Cancer Quality Improvement Program, a report provided to accredited programs by the National Cancer Database that includes short-term quality and outcome data and long-term data, including five-year survival rates for commonly treated malignancies.

Corrective action: The process by which a cancer program shows they have met a standard(s) that was noncompliant at the time of the site visit.

CTR(s): Certified Tumor Registrar

Culturally appropriate decision making: Culturally appropriate decision making may involve offering resources for patients that are written or provided in the language(s) spoken by the patient, using patient-friendly terms that are sensitive to the ethnic, cultural, sexual, or gender-based aspects of their lives, and providing discussions or consultations with patients regarding aspects of their care that may affect or be affected by such aspects of the patient's life. For example: Discussing flat closure with LGBTQ patients.

For example: Discussing flat closure with LGBTQ patients.

Definitive treatment: Neoadjuvant therapy, surgical resection, initiation of non-operative care, or initiation of palliative care.

DMAIC: Acronym for Define, Measure, Analyze, Improve, and Control; DMAIC is a structured quality improvement methodology.

ERAS: Enhanced Recovery After Surgery

Evaluation of barriers: "As barriers to compliance with this standard are identified, they are addressed by the accredited program." This is a common requirement in in Chapter 5 *Optimal Resources for Breast Care*. The requirement here is that any conflicts or obstacles that prevent, prohibit, limit, or deter compliance with the given standard must be specifically discussed and managed by the accredited program to prevent such issues from obstructing compliance with the NAPBC standards.

Genetic Professional: The NAPBC defines genetic professionals as health care professionals who meet one of the required qualifications listed in Standard 4.4.

HER2: Human epidermal growth factor receptor 2

IMRT: Intensity-Modulated Radiation Therapy

IRB: Internal Review Board

LCIS: Lobular Carcinoma in situ

LGBTQ: Lesbian, gay, bisexual, transgender, questioning/queer

MBCC: Multidisciplinary Breast Care Conference

Medical Records Review: The evaluation of patient medical records to determine compliance with specific standards.

Monitor: Closely and consistently observe and evaluate a function or process.

MQSA: Mammography Quality Standards Act

MRI: Magnetic Resonance Imaging

NAPBC: National Accreditation Program for Breast Centers

NAPBC-accredited program(s): A single or multiple-location medical institution providing diagnostic services, treatment services, and comprehensive multidisciplinary care for patients with breast disease or breast cancer, which has achieved accreditation by the National Accreditation Program for Breast Centers (NAPBC).

NAPRC: National Accreditation Program for Rectal Cancer

NCCN: National Comprehensive Cancer Network

NCDB: National Cancer Database

NCI: National Cancer Institute

NCPD: Nursing Continuing Professional Development (formerly CNE- Continuing Nursing Education)

Neoadjuvant therapy: Treatment provided to initiate further treatment and/or reduce the size of the primary breast cancer before definitive treatment.

Newly diagnosed: Patients who have received a breast cancer diagnosis at the NAPBC-accredited program, or have received a diagnosis elsewhere and present for evaluation and/or treatment at the NAPBC-accredited program before receiving any treatment elsewhere.

NMD: National Mammography Database

Non-compliance: The NAPBC-accredited program does not meet one or more of the compliance criteria required for a specific standard.

NQMBC: National Consortium of Breast Centers' National Quality Measures for Breast Centers Program

OCN: Oncology Certified Nurse

ONCC: Oncology Nursing Certification Corporation

ONN-CG: Oncology Nurse Navigator-Certified Generalist

ONS: Oncology Nursing Society

Outside provider/outside facility: Any individual or entity that is not part of the NAPBC-accredited program at a specific medical institution. These outside providers/facilities may, or may not, be involved in the treatment, testing, or evaluation of patients receiving care at the NAPBC-accredited program.

PA: Physician Assistant

Patient representative: A current or former patient of a NAPBC-accredited program.

PCP: Primary Care Physician

PDCA: Plan, Do, Check, Act; PDCA is a structured quality improvement methodology.

PDSA: Plan, Do, Study, Act; PDSA is a structured quality improvement methodology.

Policy and procedure: See Protocol

Pre-Review Questionnaire (PRQ): An online reporting tool that is utilized to demonstrate compliance with NAPBC standards. Formerly known as "Survey Application Record (SAR)".

PRO: Patient Reported Outcomes

Protocol: Previously referred to as "policies and procedures" in past versions of the NAPBC Standards, a protocol is a structured and consistent process crafted by the NAPBC-accredited program to help implement the required compliance criteria for specific NAPBC standards. Protocols must be written and documented in a manner that demonstrates compliance with whichever NAPBC standard the protocol is designed to address. Additionally, all protocols must be formally approved by the Breast Program Leadership Committee (BPLC). Identical protocols that apply to several affiliated NAPBC-accredited programs are acceptable. Such protocols must be specifically stylized for each affiliated program, **and** be formally approved by each BPLC, as applicable. Protocols do **not** need to be officially recognized hospital or institutional policies.

PRQ: See Pre-Review Questionnaire

QOPI: Quality Oncology Practice Initiative

RCRS: Rapid Cancer Reporting System

RDN: Registered Dietitian Nutritionist

Referred Services: Diagnostic services, treatment services, and comprehensive care that are provided at another facility.

RO-ILS: American Society for Radiation Oncology's Radiation Oncology Incident Learning System

Site Reviewer: NAPBC-trained health care professional who conducts site visits, and reviews the compliance documentation of a NAPBC-accredited program. The site reviewer assists in verifying whether the accredited program is in compliance with the NAPBC Standards.

Site Visit: A virtual or in-person review of the NAPBC-accredited program by a NAPBC site reviewer to verify compliance with the NAPBC standards, and recommend an accreditation award. After initial accreditation, site visits occur once every three years.

Standard: Qualification criteria for NAPBC accreditation (not standard of care).

Survey/Surveyor: Retired terminology. See "Site Visit" and "Site Reviewer".

Synoptic format: A structured format that includes all of the following:

- All core elements must be reported (whether applicable or not)
- All core elements must be reported in a "diagnostic parameter pair" format, in other words, data element followed by its response (answer)
- Each diagnostic parameter pair must be listed on a separate line or in a tabular format to achieve visual separation
- All core elements must be listed together in one location in the pathology or operative report

TJC: The Joint Commission

TOPS: American Society of Plastic Surgeons' Tracking Operations and Outcomes for Plastic Surgeons (TOPS) Program

Triennial review: Compliance criteria requiring triennial review must be completed at least once every three years, during the NAPBC-accredited program's triennial accreditation cycle.

VUS: Variants of uncertain significance

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