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CNE: Breast cancer care gets personal

Molecular subtyping and gene sequencing have paved the way to treatment advances customized to individual patients.

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Continuing Nursing Education

Learning objectives

1. State how breast cancer is diagnosed and evaluated.
2. Identify the implications of genetics for patients with breast cancer.
3. Discuss targeted therapy for breast cancer.
4. Describe novel therapies for breast cancer.

Purpose/goal: To provide nurses with information on how to better care for patients with breast cancer.

Marriott and the planners of this CNE activity have disclosed no relevant financial relationships with any commercial companies pertaining to this activity. See the end of this article to learn how to earn 1.51 CNE credit.

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Breast cancer is the most common cancer in women in the United States. In 2014, an estimated 235,030 new cases will be diagnosed. Although incidence has been rising, mortality has been declining thanks to earlier detection and treatment advances. Breast cancer care is becoming more personalized, with treatment options tailored to the individual patient. This article describes the steps involved in developing a treatment plan for a breast cancer patient, explains genetic considerations based on a patient's genetic makeup, and discusses related nursing implications.

Breast cancer diagnosis

The American Cancer Society recommends that all women have a screening mammogram starting at age 40 to identify early-stage cancer and provide a baseline for annual evaluation of breast changes that may suggest cancer. Diagnostic mammograms, in contrast, are done when a patient has a palpable lump or mass. The radiologist evaluates the mammogram based on a standard protocol and makes recommendations for next steps, if needed, to reach a diagnosis. (See the box below)

BI-RADS® assessment categories for breast imaging

The Breast Imaging and Reporting and Data System, known as BI-RADS®, is a standardized system for describing mammography results. As shown below, BI-RADS categories are numbered 0 through 6. A patient whose mammograms fall into category 4 or 5 should be considered for a needle-core biopsy for definitive diagnosis. A biopsy may be obtained by a surgeon or radiologist using ultrasound, mammography, or magnetic resonance imaging (MRI).

CATEGORY	DESCRIPTION
0	Additional imaging needed, such as targeted ultrasound or spot compression views
1	Negative
2	Benign finding
3	Probably benign finding; initial short-interval follow-up may be suggested
4	Suspicious abnormality; biopsy should be considered
5	Highly suggestive of cancer; appropriate action should be taken
6	Known biopsy-proven cancer; appropriate action should be taken.

Breast cancer staging

Once a cancer diagnosis is confirmed, a multistep treatment plan is developed. The first step is cancer staging to determine disease extent. Staging is based on three criteria from the American Joint Committee on Cancer Staging. (See the box below.)

Staging criteria of the American Joint Committee on Cancer

T	Tumor size
N	Number of involved lymph nodes
M	Presence of distant metastasis

A number is added to each category to indicate the size or extent of the primary tumor and degree of spread. A stage is generated from this information. For example, T2 refers to a tumor greater than 20 mm but less than or equal to 50 mm in the greatest dimension; N0 denotes no regional lymph node metastasis; and M0 means no distant metastasis. Together, these criteria—T2N0M0—indicate stage 2A breast cancer.

The earliest-stage breast cancer is classified as in situ because it's confined to the milk ducts (called ductal carcinoma in situ). On the other hand, carcinoma in situ in the breast lobules (lobular carcinoma in situ) is not necessarily considered a true cancer but rather a high risk marker for developing invasive cancer.

About 80% of invasive cancers are ductal; about 10% to 15% are lobular. Invasive ductal cancer has four subtypes—medullary, tubular, metaplastic, and colloid. Less common types of breast cancer include Paget's disease of the breast, malignant phyllodes tumors, and inflammatory breast cancer.

In patients with invasive cancer, axillary lymph nodes may be evaluated through an ultrasound-guided biopsy, fine-needle aspirate, or sentinel lymph node biopsy. The latter targets a particular lymph node to determine the likelihood that cancer has spread to the lymphatic tissue. Additional studies may include computed tomography (CT), MRI, bone scan, or positron emission tomography/CT, depending on history and clinical presentation. Once diagnostic testing is completed, the patient's breast cancer is assigned a stage.

Pathology assessment

The next step in developing a treatment plan is to review the information in the pathology report. The report includes the histology (cell type) of the patient's cancer, staging information, important prognostic information on how aggressive the tumor might be, and other information the oncologist should consider in developing a treatment plan.

For invasive cancers, the pathology review indicates the tumor's hormone-receptor status and HER2 status. (HER2 stands for human epidermal growth factor receptor 2, a protein that promotes cancer cell growth if overexpressed.) Hormone-receptor information includes the degree to which estrogen and progesterone receptors in the tumor have the potential to respond to hormone treatment, expressed as a percentage. About 70% of breast cancers are estrogen-receptor positive (ER+) or progesterone-receptor positive (PR+).

The pathologist also identifies if HER2 is overexpressed by assigning a number from 0 to 3, with 0 indicating HER2 isn't overexpressed and 3 denoting it's overexpressed in more than 30% of cancer cells. In general, tumors that overexpress HER2 tend to be more aggressive.

Molecular subtyping and gene sequencing

Since completion of the human genome project, many advances have been made in cancer treatment. Whole genomic profiling has spawned the development of DNA sequencing technology, in turn leading to tests that help guide treatment of breast and certain other cancers. Among the newest tools for breast cancer are those that estimate the likelihood of benefiting from chemotherapy. Many tests are in development; this article discusses the two tests approved by the Food and Drug Administration for estimating recurrence risk in patients with early-stage breast cancer—Oncotype DX® and MammaPrint. These tests may be indicated for women with early-stage breast cancer to help guide treatment after surgery. (See the box below.)

Genomic tests that help guide treatment

Test name	Genetic basis	Indications	Clinical utility	Population studied
Oncotype DX	21 genes	• Stage 1 or 2 breast cancer • Hormone-receptor positive breast cancer	• Predicts benefit of chemotherapy • Predicts risk of cancer recurrence within next 10 years • Generates recurrence risk score (low risk, lower than 18; intermediate risk, 18 to 31; high risk, over 31)	Patients who completed 5 years of tamoxifen therapy
MammaPrint	70 genes	Node-negative breast cancer	Predicts high or low risk of distant metastasis at 5 years	Patients with untreated breast cancer

Oncotype Dx and MammaPrint were developed by different methods. Oncotype DX was based on research in women who'd completed 5 years of tamoxifen therapy; MammaPrint, on research in untreated patients. Some clinicians believe this is an important difference. Although the two tests overlap in terms of their use in predicting recurrence, only Oncotype DX is useful in helping to predict chemotherapy benefits.

Clinical practice guidelines from the National Comprehensive Cancer Network (NCCN) and other reference organizations recommend genomic profiling testing as a standard of care for treatment planning in early-stage breast cancer. Genomic testing of tumor tissue offers the most advanced care available and can help to avoid under- or overtreatment. When considering where to get treatment, patients should consider whether a particular facility has established such testing as routine care.

Oncotype Dx and MammaPrint exemplify how research is transforming breast cancer treatment based on the molecular characteristics of the patient's tumor instead of solely on tumor stage and size. Knowing in advance that a particular treatment wouldn't benefit a patient spares the patient the potential side effects of treatment. .

Developing a personalized treatment plan

One size *doesn't* fit all when it comes to treatment. Standard treatments for breast cancer may include surgery of varying types, with or without radiation and with or without chemotherapy, hormonal therapy, and targeted therapies. Chemotherapy may be given as a neoadjuvant (presurgical) or adjuvant (post-surgical) treatment.

Multiple chemotherapy drug regimens exists. Many factors must be considered in determining the appropriate regimen, including cancer stage, results of molecular studies, the patient's performance status, toxicity of therapy, comorbid conditions, cancer recurrence risk, genetic considerations, and potential benefit of chemotherapy.

Many of the drug treatments used to treat breast cancer are targeted to specific types of breast cancer. Treatment decisions are based on whether the breast cancer is:

- hormone-receptor positive
- HER2 positive
- triple negative (negative for estrogen and progesterone receptors and negative for HER2)
- positive for estrogen, progesterone, and HER2 receptors.

Various forms of radiation may be given as an adjuvant treatment, including daily external whole-breast irradiation, chest-wall irradiation, nodal irradiation, and accelerated partial-breast irradiation. Specific indications exist for each of these options; appropriate therapy should be customized to each patient.

Changing the treatment landscape: Newer targeted therapies

Targeted therapies hold the promise of more individualized cancer treatment. Targeted therapies are drugs or other substances that interfere with cancer growth and spread by inhibiting specific molecules involved in tumor growth and progression. (In contrast, chemotherapy directly kills rapidly proliferating cells without differentiating cancer cells from normal cells.)

Each tumor has its own genetic signature, and therapies can be developed to target unique proteins on cancer cells. Targeted therapies help clinicians customize treatment based on a particular set of molecular targets produced by the patient's tumor. The goals are to decrease harm to normal cells, reduce side effects, and improve quality of life. Also, testing for certain genes in cancer cells may indicate whether a patient's tumor will respond to treatment.

Many targeted therapies are available only through a clinical trial. Most people think of clinical trials as a last-resort option. In reality, a clinical trial can be an option for first-line therapy. The more patients who participate in clinical trials, the sooner scientists can identify new molecular targets, develop new breast-cancer therapies, and create customized drug "cocktails" specific to each patient's tumor characteristics.

The first personalized breast cancer treatments focused on estrogen and progesterone receptors, found in many breast cancer cells. Cancers with such receptors grow in response to these hormones. Several drugs can be used to block the effects of these hormones on breast cancer cells. Tamoxifen was the first drug approved to target the estrogen receptor. Today, several other hormone-receptor blocking drugs are available to treat breast cancer.

Treatments that target HER2 receptors

Several therapies are available for patients with HER2-positive or HER2-negative breast cancer. (See the box below.)

Therapies targeted to HER2-positive breast cancer
The drugs summarized below are used specifically to treat HER2-positive breast cancer.

DRUG	ACTIONS	FDA-APPROVED USES
ado-trastuzumab emtansine (Kadcyla®; also known as TDM-1)	• Contains trastuzumab linked to a toxin (a drug-antibody conjugate); delivers toxin directly to targeted cancer cells	HER2/neu-overexpressing, metastatic breast cancer in patients who previously received trastuzumab and a taxane chemotherapy agent
lapatinib (Tykerb®)	• Small-molecule drug that passes through cell membranes and targets tyrosine kinases inside cell • Prevents HER2 signals from activating cell growth	• Certain types of advanced or metastatic breast cancer
pertuzumab (Perjeta®)	• Targets different area of HER2 receptor than trastuzumab • Works in complimentary fashion with trastuzumab to prevent HER2 signals from promoting cell growth	• Early-stage breast cancer as neoadjuvant treatment in combination with certain chemotherapy drugs and herceptin • Metastatic breast cancer in combination with herceptin and chemotherapy
trastuzumab (Herceptin®)	• Prevents HER2 protein from sending growth-promoting signals • May induce immune system to attack cells that express high HER2 levels	• Early-stage, HER2-overexpressing breast cancer, given after surgery • HER2-overexpressing metastatic breast cancer

Drugs used to treat HER2-negative breast cancer
Everolimus is approved for treating postmenopausal women with advanced hormone-receptor positive, HER2-negative breast cancer, in combination with exemestane (a hormonal therapy) after failure of previous hormonal therapy. A common molecular abnormality in breast cancer is the PI3kinase/AKT/mTOR pathway. Everolimus inhibits mTOR (mammalian target of rapamycin), an enzyme within the cell that helps regulate cancer-cell proliferation. This drug also reduces angiogenesis (new blood-vessel development) in cancer cells. It's under investigation as a treatment for early-stage breast cancer in combination with the usual hormonal therapy. Other drugs that target the PI3kinase/AKT/mTOR and angiogenesis pathways are currently in clinical trials.

Other novel treatment strategies under investigation

- *Metformin.* This drug has been used to treat diabetes for many years. Research shows diabetic patients taking it were less likely to develop cancer or to die from the disease compared to those not taking the drug. In other studies, patients with early-stage breast cancer who were taking metformin had higher surgical response rates to neoadjuvant (presurgical) therapies compared to those not taking metformin and to other patients without diabetes. Presumably, metformin slows tumor-cell growth by affecting the pathways that regulate tumor-cell division and survival. Clinical trials are underway to evaluate metformin's potential for reducing breast-cancer recurrence after standard breast cancer treatment is completed.
- *PARP inhibitors.* Poly(ADP-ribose) polymerase (PARP) is a nuclear enzyme involved in repairing DNA damage, mediating cell death, and regulating immune response. PARP activation occurs when cells are damaged. Targeting PARP may prevent tumor cells from repairing DNA and developing drug resistance, which may make these cells more sensitive to cancer therapies. PARP inhibitors have shown some activity in patients with BRCA gene mutations.
- *Insulin-like growth factor (IGF) targets.* IGF-signaling pathways play a role in regulating cell growth, proliferation, and differentiation. Research shows changes in this signaling pathway promote breast-cancer growth. Therapies that target this pathway are being studied in clinical trials.
- *Cyclin D kinase 4/6 targets.* Drugs intended to block proteins called cyclin-dependent kinases (required for cell division) also are in clinical trials. These proteins may control the ability of breast cancer to grow.

Hereditary breast cancer: More than just BRCA

Mutations in the BRCA 1 and BRCA 2 genes increase breast cancer and ovarian cancer risk. In a recent high-profile case, Angelina Jolie underwent prophylactic mastectomy after tests showed she had inherited a damaged BRCA gene. Several susceptibility genes can affect the lifetime risk for breast cancer in men as well as women. (See the box below.)

Understanding genetic mutations

Although all cancers result from a change, or mutation, in the gene of a chromosome, *somatic* (acquired) mutations are caused by exposure to cancer-causing agents or carcinogens. Such mutations aren't inherited.

On the other hand, inherited cancers occur when a mutation in the parent germ cell is passed onto offspring. Each cell that develops from that egg and sperm has this genetic abnormality. However, even if someone has an inherited mutation, the disease won't necessarily be expressed. Whether it does depends in part on Mendelian laws of inheritance, which describe the principles of dominant and recessive genes. With a dominant gene, having just one copy of the gene allows a particular trait to be expressed; with a recessive gene, a person must have a pair of genes to allow expression.

However, some traits don't follow this inheritance pattern because of penetrance and expressivity. *Penetrance* refers to how frequently the gene is expressed in a given population; *expressivity* is the extent to which a trait is expressed in an individual. Low penetrance and expressivity explain why an individual with a genetic mutation may not develop the disease.

Hereditary breast cancer was first identified about 20 years ago with discovery of the BRCA genes. Both BRCA1 and BRCA2 produce tumor-suppressor proteins. All human beings carry these "caretaker" genes, which are responsible for DNA repair and help ensure stability of the genome. A damaged or mutated BRCA gene can't repair DNA; therefore, the genetic material may be changed in a way that allows genetic alterations, leading to cancers of the breast, ovaries, and even the fallopian tube, pancreas, prostate, and peritoneal region. These BRCA1 and BRCA2 mutations account for about 20% to 25% of hereditary breast cancers and 5% to 10% of breast cancers, as well as 15% of ovarian cancers. Other inherited conditions, such as Cowden disease and Peutz-Jeghers syndrome, also may increase breast cancer risk.

Screening for hereditary breast cancer risk

Persons with the following should be evaluated to screen for hereditary breast cancer risk:

- personal or family history of a known cancer gene mutation
- personal or family history of early-onset breast cancer (younger than age 50)
- personal or family history of triple-negative (estrogen-, progesterone-, and HER2 negative) breast cancer
- personal or family history of two primary breast cancers in a single individual
- two or more family members on the same side of the family with the same cancer
- personal or family history of ovarian cancer
- personal or family history of male breast cancer.

Genetic counseling

Before testing, patients with risk factors for a hereditary cancer syndrome should be evaluated by a qualified genetics professional, who will complete a comprehensive genetics assessment. (See the box below.)

Qualified genetics professionals include:

- board-certified licensed genetics counselors
- physicians board-certified in medical genetics
- genetics clinical nurses (GCN)
- advanced practice nurses in genetics (APNG)
- advanced practice oncology nurses with specialized education in genetics
- board-certified physicians with experience in cancer genetics

Licensing boards for these professionals include the American Board of Genetic Counseling, American Board of Medical Genetics, and Genetics Nursing Credentialing Commission.

A comprehensive genetics assessment includes:

- family health history, including at least a three-generation pedigree
- family cancer history
- patient health history
- female reproductive history

- cancer screenings
- risk-reduction interventions
- physical examination as appropriate
- lifestyle factors
- exposure to environmental toxins
- race and ethnicity
- psychosocial assessment
- reason for seeking genetic counseling
- pretest counseling, including the patient's willingness to undergo testing and how she will use the information provided. For example, if tests show she has a mutation, will she consider interventions to decrease risk? Will she inform other family members of the results?

Risk-reduction measures

If genetic tests identify a mutation, the patient should receive counseling on the relative risk of developing cancer, as well as measures to lower the risk. Risk-reduction measures may involve prophylactic surgery, such as mastectomy or oophorectomy; drug therapy, such as an anti-estrogen drug; and lifestyle interventions, such as smoking cessation or avoidance, weight management, improved nutrition, exercise, and stress management. Risk-reduction measures apply to patients with breast cancer as well as those identified as high risk. In addition, more vigilant screening (as with mammography or colonoscopy) may identify cancer sooner and allow earlier intervention.

Accredited breast centers

How do patients decide where to seek breast cancer care? Such care is becoming more specialized and more likely to involve many practitioners from various disciplines. A multidisciplinary team can provide the highest quality of care.

The National Accreditation Program for Breast Centers is a consortium of national professional organizations dedicated to improving the quality of care and patient outcomes. It sets evidence-based standards for quality care and outcomes, including patient and professional education requirements.

Breast center accreditation is a voluntary application process. To become accredited, breast centers are evaluated thoroughly and must complete a successful onsite survey. Accreditation assures patients, clinicians, and insurance providers that the facility meets or exceeds standards for excellence in breast care. A commitment to meeting high standards is maintained through recertification every 3 years. For a list of accredited breast programs, visit http://napbc-breast.org/resources/find.html.

Nursing implications

Breast cancer patients can experience emotional and physical distress related to the cancer diagnosis itself, treatment, and survivorship-related issues. Nurses can provide support for women at several stages.

Breast cancer screening

Despite controversy over the age at which mammography screening should begin, major organizations, such as the American Cancer Society, American Society of Clinical Oncology, and NCCN still recommend annual screening mammography starting at age 40. Encourage women to get annual mammograms and provide education on how to perform a breast self-exam.

For women who lack insurance coverage for mammograms, the National Breast and Cervical Cancer Early Detection program (NBCCEDP) provides breast and cervical cancer early-detection testing to low-income, underserved, underinsured, and uninsured women. Usually, uninsured women who are diagnosed with cancer through the NBCCEDP can receive treatment through Medicaid. This program is administered by the Centers for Disease Control and Prevention through local charitable organizations. Also identify any local agencies that can provide mammography and other screening services.

Supporting patients during cancer staging work-up

A breast cancer diagnosis causes considerable anxiety. Patients have many concerns, such as how cancer treatment will affect their lives, ability to care for children, relationships with spouses or partners, body image, sexuality, and fertility (for women of childbearing age). Some patients may be facing advanced disease for which only control, not cure, is possible.

Besides providing emotional support, help patients get timely medical appointments to promote treatment planning, and help them connect with resources to provide information. Many cancer treatment facilities have dedicated breast cancer nurse navigators, who can help decrease patients' anxiety. Many nurse navigators are oncology certified and serve as both educational and support resources.

Help patients identify their concerns and develop a list of questions to ask their physician. As needed, explain how they can obtain a second opinion. Provide education on the various aspects of developing a treatment plan. Identify patients who may be at increased risk for a genetic or familial-related breast cancer, and encourage them to consult a genetics professional. If possible, encourage patients to connect with an accredited breast center and to consider clinical trials when choosing treatment.

Supporting patients during treatment

Many cancer patients receive care primarily from a medical, surgical, or radiation oncologist and their staff. However, they may need to be followed concurrently by their primary care or specialist care physician for comorbid issues. If you're an office nurse who sees cancer patients, network with the treating physician's office to ensure timely communication on treatment-related side effects the patient may be experiencing. Urge patients to communicate their concerns so they can receive appropriate management. Point out they may need to be treated over an extended time with several clinicians involved in their care, including the treating physician, oncology nurse or advanced practice clinician, physical or occupational therapist, registered dietitian, social worker, psychologist, and case manager.

Supporting patients after treatment

After completing treatment for breast cancer, patients may have long-term side effects that should be addressed in a multidisciplinary manner. Nurses can be vital in coordinating post-treatment care to help ensure the patient's ongoing health and rehabilitation needs are addressed. Some patients who've undergone lumpectomy, mastectomy, and axillary radiation are at risk for lymphedema; if this condition occurs, they should have continued follow-up with referral to a lymphedema-trained physical therapist. Some patients may be on hormonal therapy that can reduce bone density; they should undergo bone density screening and receive education on bone health.

In some cases, cancer treatment causes sudden menopause and side effects that decrease quality of life. Nurses can be instrumental in providing education on managing side effects, such as hot flashes and sleep problems.

Finally, screen patients for long-term psychological problems related to body image and sexuality. Refer them to www.cancer.net (the patient website of the American Society of Clinical Oncology [ASCO]) for information on managing long-term side effects. George Washington University provides an educational program for primary care providers on cancer survivorship at https://www.cancersurvivorshipcentereducation.org/Home_Page.html. (See the box below for more patient-oriented websites.)

Resources for cancer patients
As appropriate, refer patients to the websites below.

American Cancer Society: www.cancer.org
American Society of Clinical Oncology: www.cancer.net
Fertile Hope: www.fertilehope.org/dev/index.cfm (information, support, and hope for cancer patients whose medical treatments pose infertility risks)
National Accreditation Program for Breast Centers: http://napbc-breast.org/resources/find.html
National Breast and Cervical Cancer Early Detection Program: www.cdc.gov/cancer/nbccedp or 1-800-232-4636 (provides access to breast and cervical cancer screening services for low-income, uninsured, and underserved women)
National Comprehensive Cancer Network: www.nccn.com

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