



INFORMATION

Getting and using the right information can make all the difference. It can really affect the results of your care. Here's how to be well informed and make wise health care choices.

Quality Breast Cancer Care Means:

Understanding Your Diagnosis

Using Evidence-Based Information

Understanding Your Diagnosis

There are many different types of breast cancer. The doctor who determines what type of breast cancer you have is called a “**pathologist**.” The type of cancer you have is called your “**diagnosis**.” It is very important that the pathologist gives you an accurate diagnosis. It is also important that you understand your diagnosis. Your treatment will be different depending on your diagnosis.

Here’s how doctors make a breast cancer diagnosis. A doctor takes a sample of your breast tissue. (This is called a “**biopsy**.”) Then, the pathologist looks at the tissue sample. (The tissue samples that pathologists look at are also called “breast tissue **slides**.”) The pathologist describes your cancer in a report. The report tells your “**specific disease characteristics**.” Your disease characteristics tell what type of breast cancer you have. The disease characteristics help your doctors decide what treatment to recommend.

Learning about your diagnosis helps you make informed care choices. The bad news is that your diagnosis can be hard to understand. The good news is that your doctors should have all this information. Important information about your disease may be gathered from a number of places. These may include:

- your **pathology report**, also called a “biopsy report,”
- X rays,
- bone scans,
- blood tests,
- surgical reports, and

- special tests—for example, for **HER2/neu** status.

Read on for advice on how to understand your pathology report.

What You Can Do:

Learn exactly what your diagnosis is.

Ask if there is more than one name for it. For example, “breast cancer,” “**invasive ductal carcinoma**,” and “**infiltrating ductal carcinoma**” can all mean the same thing.

Is this the first time you have ever had breast cancer? If so, here are some important questions to ask your doctor:

1. Is my breast cancer invasive or noninvasive?
2. What stage is my breast cancer? (for example, Stage 0, Stage I, Stage IIA, Stage IIB, etc.)
3. How large is my tumor?
4. Has the cancer spread to my **lymph nodes**?
If so, to how many lymph nodes?
5. Is my breast cancer **estrogen receptor-negative** or **estrogen receptor-positive**?
6. Is my breast cancer **progesterone receptor-negative** or **progesterone receptor-positive**?
7. Is my breast cancer HER2/neu-negative or HER2/neu-positive?

The answers to these questions will help you understand some of your disease characteristics. Be sure to ask what each disease characteristic means for you. You need this information to make informed treatment choices. See page 30 to learn why these questions are important.

What are the stages of breast cancer and what do they mean? ¹¹

After breast cancer has been diagnosed, many tests are done. Some of these tests find out if cancer cells have spread within the breast or to other parts of the body.

There are three important terms used to describe breast cancer:

- **In situ breast cancer**—This means that the cancer has not spread outside the **duct** or **lobule** where it started.
- **Invasive breast cancer**—This means that the cancer has spread outside the duct or lobule to surrounding tissue.
- **Metastatic breast cancer**—This means the cancer has spread outside the duct or lobule and has spread to another organ.

The process used to find out whether the cancer has spread is called “staging.” It is important to know the stage of the disease in order to plan the best treatment.

The following stages are used for breast cancer:

Stage 0 (noninvasive or in situ)

There are two types of stage 0 (**carcinoma in situ**) breast disease:

- **Ductal carcinoma in situ (DCIS)** is sometimes called “**precancer**” or a very early breast cancer. It may or may not develop into an invasive type of breast cancer.
- **Lobular carcinoma in situ (LCIS)** is not actually cancer. It is a marker showing that the woman has an increased risk of getting invasive breast cancer in either breast. LCIS often affects both breasts.

Stage I (invasive)

In stage I, the cancer:

- is not larger than 2 centimeters (about 1 inch) *and*
- has not spread outside the breast.

Stage IIA (invasive)

In stage IIA, the cancer is either:

- not larger than 2 centimeters (about 1 inch) but has spread to the lymph nodes under the arm, *or*
- between 2 and 5 centimeters (1 to 2 inches) but has not spread to the lymph nodes under the arm.

Stage IIB (invasive)

In stage IIB, the cancer is either:

- between 2 and 5 centimeters (1 to 2 inches) and has spread to the lymph nodes under the arm, *or*
- larger than 5 centimeters (about 2 inches) but has not spread to the lymph nodes under the arm.

Stage IIIA (invasive)

In stage IIIA, the cancer is either:

- smaller than 5 centimeters (about 2 inches) and has spread to the lymph nodes under the arm, and the lymph nodes are attached to each other or to other structures, *or*
- larger than 5 centimeters and has spread to the lymph nodes under the arm, and the lymph nodes may be attached to each other or to other structures.

Stage IIIB (invasive)

In stage IIIB, the cancer has either:

- spread to tissues near the breast, such as the skin or chest wall, including the ribs and muscles in the chest, *or*
- spread to lymph nodes inside the chest wall along the breastbone.

Stage IV (metastatic)

In stage IV, the cancer has either:

- spread to other organs of the body, most often the bones, liver, or lungs, *or*
- spread to the lymph nodes in the neck, near the collarbone.

¹¹ The information presented in this box is adapted from the National Cancer Institute's (NCI) Physician Data Query (PDQ) database.

The more information you have about your specific diagnosis, the more informed your treatment choice will be.

Have you been diagnosed with breast cancer a second time? If so, you may want to ask your doctor these questions:

1. Is this new tumor a new **primary tumor**? Or is it a local **recurrence**? Or does it mean that I have metastatic breast cancer?
2. Is this tumor different in any way from my previous tumor? If so, how will the differences affect my treatment?
3. What were the results of my bone scan, liver function tests, chest X ray, and any other tests?
4. What are my treatment options?
5. How will I know if the treatment is working?

Once again, the answers to these questions will help you figure out your treatment choices. The more information you have about your specific diagnosis, the more informed your treatment choice will be.

Why are these questions important? They are important because doctors decide which treatments to recommend based on your diagnosis. Each woman with breast cancer has a different set of disease characteristics. These characteristics help doctors predict which women will most likely benefit from each treatment. And there are some drugs that only help women with one specific characteristic. Several different disease characteristics will be listed on your pathology report. The following four characteristics are the ones used most often by doctors to recommend treatment.

You can learn more about these and other disease characteristics by reading *Dr. Susan Love's Breast Book* or visiting her web site (page 106). The Y-ME National Breast Cancer Organization (page 106) also has a helpful brochure. It's called, "Understanding Your Breast Cancer Pathology Report: A Guide for Breast Cancer Patients." Call Y-ME to request a copy. Or you can print a copy from the group's **web site**.

1. Lymph Node Status—Lymph nodes are small oval glands that help your body fight infection. They also help carry liquid throughout the body. If a woman's breast cancer has spread to any of the lymph nodes near her breast or under her arm, her breast cancer is considered **node-positive**. If a woman's breast cancer has not spread to the lymph nodes, her breast cancer is considered **node-negative**.

Women with node-negative breast cancer have a better chance of survival than women with node-positive breast cancer. So doctors often offer more aggressive treatments to women with node-positive breast cancer. For example, some doctors recommend stronger types of **chemotherapy** drugs to women with node-positive breast cancer than to women with node-negative breast cancer.

Sometimes treatment recommendations are based on the number of lymph nodes that have been invaded by the cancer. For example, many doctors recommend that women

with four or more affected lymph nodes get **radiation** therapy after having a mastectomy.

2. Tumor Size—In general, women with smaller breast cancer tumors have a better chance of survival than women with larger breast cancer tumors. So doctors often offer more aggressive treatments to women with larger tumors.

3. Estrogen and Progesterone Receptor Status—**Estrogen** and **progesterone** are normal hormones in every woman's body. Breast cells have some **receptors** for estrogen and some receptors for progesterone.

Receptors are molecules on cells that bind other molecules. When estrogen and progesterone come in contact with these receptors, the breast cells grow and reproduce.

In some breast cancers, the cancer cells have many more estrogen and progesterone receptors than normal. These breast cancers are called estrogen receptor-positive and progesterone receptor-positive. Breast cancers with low amounts of estrogen and progesterone receptors or no receptors at all are called estrogen receptor-negative and progesterone receptor-negative.

Tamoxifen is a drug that can block the estrogen receptors in breast cells. Tamoxifen is an effective treatment in women with estrogen receptor-positive breast cancer. However, the drug has little effect on a woman's breast cancer when it is estrogen receptor-negative.

A few breast cancers are estrogen receptor-negative and progesterone receptor-positive. Tamoxifen may help women with this type of breast cancer for reasons we do not completely understand.

4. HER2/neu Status—HER2/neu is another type of receptor that affects the growth of breast cancer cells. In some breast cancers, the cancer cells have many more of these receptors than normal. These breast cancers are called HER2/neu-positive. Breast cancers with low amounts of the receptor or none at all are called HER2/neu-negative.

It is important to remember that there is a large range of possible HER2/neu levels. Determining each woman's HER2/neu status is not a black-and-white issue. For example, it is sometimes unclear whether women with low levels of the receptor should be considered HER2/neu-positive or HER2/neu-negative.

Herceptin is a drug that can block HER2/neu. It is an effective treatment in many women with metastatic, HER2/neu-positive breast cancer. But the drug has little effect on women with HER2/neu-negative breast cancer.

There are two types of laboratory tests that measure HER2/neu status—the IHC test and the FISH test. Some evidence suggests that the FISH test is better at showing which women will benefit from Herceptin and which will not. However, neither test is perfect.

Have you been diagnosed with DCIS or LCIS?

DCIS and LCIS are often classified as stage 0 breast cancer. But not everyone agrees that this is how they should be classified. DCIS is short for “ductal carcinoma in situ.” LCIS is short for “lobular carcinoma in situ.” There are a few important things to know about DCIS and LCIS:

- Researchers and doctors disagree about whether DCIS is even cancer. Some of them view DCIS as a **precancerous condition**.
- LCIS is *not* cancer. It is a marker showing that a woman has an increased risk of getting invasive breast cancer. LCIS often affects both breasts.
- Some cases of DCIS grow very slowly and never develop into invasive breast cancers. That means that some cases of DCIS would never invade surrounding tissue and become life-threatening forms of breast cancer. The problem is that no one knows how to tell which cases of DCIS will develop into dangerous forms of breast cancer and which won't.
- As more and more women get mammograms each year, more and more cases of DCIS are diagnosed. Some people think this is a good thing. That's because

the public has been told again and again that “early detection saves lives.” But it's more complicated than that. It is not helpful to treat a woman for breast cancer if that breast cancer is not life-threatening. Since we don't know which cases of DCIS will become life-threatening, we may be giving breast cancer treatment to women who don't need to be treated. This is called “overtreatment.”

- As with DCIS, the problem with LCIS is that no one knows which women with LCIS will develop invasive breast cancer and which won't.
- You should know that doctors disagree on the best way to treat women with DCIS and LCIS. And many **advocates**, researchers, and doctors are concerned that we overtreat women with DCIS and LCIS. If you have been diagnosed with DCIS or LCIS, consider joining a clinical trial to help us learn more about DCIS and LCIS and how best to treat them. To learn more about clinical trials, see pages 23-25.

You can learn more about DCIS and LCIS by reading *Dr. Susan Love's Breast Book* or visiting her web site (page 106).

So far, Herceptin is only approved for use in women with metastatic breast cancer. There are some **clinical trials** underway that are testing the drug in women with HER2/neu-positive, early breast cancer. We won't know if Herceptin helps women with early breast cancer until the clinical trials are complete.

Remember—Sometimes the more specific your diagnosis is, the more specific your treatment can be. It is important to use drugs that have been shown to help your type of breast cancer. And it is important not to use drugs that have not been shown to help your type of breast cancer, unless you are taking part in a clinical trial

about the drug. That's because all cancer drugs have side effects, so you may be hurting your body more than helping it. It's important to learn about the risks and benefits of each treatment before making any decision about your care.

Ask for a copy of your pathology report.

Your pathology report has important information about your cancer. A pathologist writes this report after looking at a sample of your breast tissue under a microscope. Ask your doctor if a *breast* pathologist wrote your pathology report. If not, you might want to ask if a breast pathologist is available to look at your breast tissue.

What is the difference between “metastatic” and “end-stage” breast cancer?

Sometimes the terms “metastatic” breast cancer and “end-stage” breast cancer can be confusing. Here's how we define them in the guide.

When a woman has metastatic breast cancer, that means that her cancer has spread to another organ. Breast cancer most often spreads to the bones, liver, or lungs. Some women with metastatic breast cancer live comfortably with their disease for many years.

When a woman has end-stage breast cancer, that means she is nearing the end of her life. At this point, treatments have

stopped working to control the cancer growth. Now, the goal usually shifts from controlling or stopping cancer growth to **palliative care**.

If you have been diagnosed with metastatic breast cancer, you may want to read Musa Mayer's book, *Advanced Breast Cancer: A Guide to Living with Metastatic Disease*. (See Patient-Centered Guides on page 105.) It is the only in-depth book on the subject right now. *Dr. Susan Love's Breast Book* (page 106) has a chapter called “Metastatic Disease: Treatments.”

If your pathology report is wrong, you might get the wrong care.

Your pathology report describes your specific disease characteristics (for example, the tumor size, number of lymph nodes involved, estrogen and progesterone receptor status, etc.). This information helps your **oncologist** and others understand what type of cancer you have. It also helps them predict what the cancer tumor will do. And it helps your doctors and you understand what treatments may help you. Ask your doctor to explain your specific disease characteristics to you.

The Y-ME National Breast Cancer Organization (page 106) has a good brochure called “Understanding Your Breast Cancer Pathology Report: A Guide for Breast Cancer Patients.” Visit the group’s web site to print a copy. Or call and ask for a copy to be mailed to you.

Dr. Susan Love’s Breast Book (page 106) has a helpful section called “How to Interpret a Biopsy Report.” She also has this information on her web site.

Get a second opinion about your diagnosis and pathology.

There are two kinds of **second opinions** that can help you. You should get both kinds of second opinions.

1. You should have a second pathologist determine your specific diagnosis. This is called a “pathology second opinion.”
2. You should visit more than one doctor to talk about your treatment choices. This is called a “treatment second opinion.”

Get a pathology second opinion *before* getting a treatment second opinion. A pathology second opinion can help you be sure that your diagnosis and disease characteristics are correct. This is very important, because doctors base their treatment advice on your pathology report. If your pathology report is wrong, you might get the wrong care. Every so often, it’s difficult for pathologists to give a clear-cut diagnosis. So you may get conflicting pathology reports. In this case, it’s especially important to learn as much as you can about your specific diagnosis.

To get a pathology second opinion you must have your breast tissue slides sent to a second breast pathologist. You can arrange to have this done on your own. You do not need your doctor’s OK to have a pathology second opinion. But you may have to pay for it yourself. This is what you need to do:

1. Find a breast pathologist at a different hospital or cancer center to give the second opinion. One way is to call the pathology department at another hospital. The hospital doesn’t have to be near you. You can call hospitals anywhere in the country. Ask them if they have a breast pathologist who could review your breast tissue slides.
You may want to contact the group, FindCancerExperts.com (page 101). They help patients all over the country get pathology second opinions.
2. Have you found a breast pathologist to review your slides? If so, call the path-

ology department at the hospital where your biopsy was done. Ask them to send your breast tissue slides to the breast pathologist who will give the second opinion.

Ask your doctors if they will keep your breast tissue.

Right now, researchers are looking for specific ways to identify different subtypes of breast cancer. They are also trying to find more targeted ways to treat specific types of breast cancer. This is a promising area of research. It holds the future of breast cancer treatment.

Your breast tumor gives important information about your disease. This information may be important to your future care. It might help you later as new treatments and drugs come out. Your tissue also contains information that can help breast cancer researchers. This is why we think it is important that you ask that your breast tissue be stored properly and that you have access to it in the future. Ask your doctors these questions:

- How will my breast tissue be preserved?
- Can it be flash-frozen and stored?
- How can I access my tissue in the future?

The Future of Breast Cancer Research and Treatment

Until recently, most breast cancers have been treated the same way—with surgery, radiation therapy, and/or chemotherapy. Doctors have decided how much and what kind of treatment to recommend based on:

- the size of the tumor,
- other characteristics of the patient's tumor, and
- whether there is cancer in the patient's lymph nodes.

This is not a very precise way to understand how an individual woman's breast cancer will act or how to treat it. Most scientists believe that a more precise way is to learn how specific breast cancer genes

work. They hope to find ways to repair or counter the work of these genes.

Genes are pieces of DNA, the molecules inside cells that carry genetic information and pass it from one generation to the next. Most genes are responsible for making specific proteins. Proteins are needed for the body to function properly. By studying genes and the proteins they make, scientists are learning a lot about breast cancer.

Scientists look at breast cancer **cells** from the tumors of breast cancer patients. With new tools that have been developed, scientists can now look at all of the genes in breast cancer cells. They try to see how

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The Future of Breast Cancer Research and Treatment

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genes act in each woman's breast cancer. If there are genes that act the same way in several women's breast cancers, this is called a "pattern." Then scientists try to figure out if the pattern has meaning. For example, did this genetic pattern cause the breast cancer? Are breast cancers with this genetic pattern less aggressive or more aggressive than other breast cancers? These patterns are also called "molecular profiles." This just means it is a description of how genes behave in certain breast cancer cells. These patterns, or molecular profiles, are allowing breast cancers to be grouped in new ways. Some day this type of

"molecular profiling" will replace the current way doctors describe breast cancer stages. Researchers hope that they will be able to develop different treatments that are targeted to the different subtypes of breast cancer.

This is where breast cancer research and treatment is headed. So it will be more and more important to understand your specific disease characteristics. Your breast tumor contains very important information. And it is important that your breast tissue is preserved and that you have access to it in the future. You should discuss this with your doctor.

Using Evidence-Based Information

Evidence-based information is very important to getting quality care. Doctors shouldn't just tell you about your breast cancer care choices. They should give clear, timely, correct information. And they should tell you the research **evidence** that backs up each choice. They should also tell you when there is not much evidence available. Some patients want a lot of information. Others don't. But all patients need doctors who practice **evidence-based medicine**.

There is still a lot we don't know about breast cancer. But there is a lot we do know, too. You just have to know where to look for trustworthy information.

What You Can Do:

Take the time you need.

Breast cancer is terrifying and feels urgent. But most breast cancer patients (regardless of the stage of their breast cancer) can safely take a few weeks to:

- find the right doctors,
- learn about the good points and bad points of each care choice, and
- make informed choices.

This is time well spent. Are you worried that waiting a little will harm your health? Ask your doctor if you can spend a few weeks thinking about your choices. Ask if that would be bad for someone with your **diagnosis**. You need some time to make informed choices.

Ask questions.

Keep asking until you understand. First, ask your doctor *which* choices you need to make *when*. You don't need to decide everything at once. But one choice may affect other choices for your care. For example, some **clinical trials** may not take patients who have already taken a certain drug. If you take this drug before finding out about the clinical trial, you won't be able to enter the trial. To learn more about clinical trials, see pages 23-25.

When your doctor tells you your care choices, ask if they are your *only* choices. For example, you may choose to have your **reconstructive surgery** at the same time as your **mastectomy**. But, some breast surgeons may not want you to have reconstructive surgery right away. They may want you to wait until after **chemotherapy** or **radiation**. This may be just because your surgeon isn't used to working with a **plastic surgeon**.

Get more than one opinion about your treatment choices.

Getting **second opinions** is important. After you get a pathology second opinion (see page 34), you should get second opinions about your treatment options. They will give you more information and help you choose a course of care. Your **health plan** and doctor should *want* you to get a second opinion. Usually, you can get a second opinion if you ask for it.

Get the second opinion *outside* the first doctor's medical practice or cancer center.

You have every right to tell your doctor, “Thank you for your time and advice. This is a big decision, so I need a second opinion.” If you feel uneasy, you can blame it on a relative. (You could say, “My sister insists I get another opinion.”) Or you can probably work directly with your health plan to get another opinion. That way, you don't have to talk about it with your doctor at all. Sometimes your **primary care doctor** can help you get a second opinion.

Get the second opinion *outside* the first doctor's **medical practice** or cancer center. Often doctors who work together don't like to disagree with each other. Some doctor's offices prefer certain treatments for breast cancer. That usually means that a second opinion from the same medical practice or center will be the same as the first. You are more likely to get an independent second opinion if the second doctor does *not* work with the first.

Some hospitals have a panel of doctors who discuss how best to treat difficult breast cancer cases. You might want to ask your doctor if this approach makes sense for your situation.

Think about talking to a range of doctors, including a surgeon, **medical oncologist**, **radiation oncologist**, and others. Each has a treatment they offer (surgery, chemotherapy, radiation, etc.). And each will have their own view of the whole range of treatments. For example, some patients can't get **breast-conserving surgery** because their tumors are too large. But sometimes chemotherapy can shrink the tumor so that breast-conserving

surgery is a choice. You are more likely to hear about different options if doctors from a variety of specialties contribute to your decision making.

You should also think about getting a second opinion on each major aspect of your care. For example, let's say a patient must choose:

- between a mastectomy or breast-conserving surgery with radiation,
- a set of chemotherapy drugs to take, and
- whether or not to have reconstructive surgery (if she chooses a mastectomy).

To make these choices, the patient should consider visiting:

- more than one **surgical oncologist** to learn about and choose a surgery,
- more than one medical oncologist to learn about and choose a set of chemotherapy drugs, and
- more than one plastic surgeon to learn about and choose a type of reconstructive surgery.

Learn about evidence-based medicine.

You need doctors that practice evidence-based medicine. This means their advice is based on the best medical research. It means they have a system for reviewing old and new medical studies. Your doctor needs to understand what the evidence means and how it relates to your breast cancer. This is a very important part of your doctor's job. New medical research is always giving us new information. So keeping up with the evidence is an ongoing job.

While a doctor's experience is an important part of decision making, it is no substitute for information we've learned from well-designed research. Not all doctors are experts on evidence. Some rely more on **anecdotal evidence**, old information, or their personal experiences. Listen carefully to your doctors. Are they talking about evidence that comes from two or more well-designed research studies? Or are they telling stories? Their stories could be about what worked once for one of their patients. If you can't tell if their advice is based on tradition, opinion, or evidence, ask.

You may hear the term "community standards." That is simply the treatment most people are getting in a certain region. It may or may not

be based on evidence. For example, in some parts of the country, doctors routinely advise mastectomy for some patients. Somewhere else, doctors might advise a **lumpectomy** with radiation for those same patients. So it is important to learn about the scientific evidence in support of treatments, and not just whether it is commonly done.

Learn about breast cancer clinical practice guidelines.

There are many guidelines for how to treat breast cancer. These are called "breast cancer clinical practice guidelines."

Some guidelines are much better than others. Some are created by a diverse team of experts who really study all the evidence. Other

Keep in mind that...

Any medical advice you get is someone's opinion of

- which evidence relates to you,
- what that evidence means, and
- how that evidence stacks up against the evidence for other choices.

Remember that the most reliable evidence comes from scientific studies of large groups of people. This kind of evidence is most likely to tell us whether some patients will benefit from a particular treatment.

Even the best breast cancer treatments do not work in every patient because not everyone responds to treatment in the

same way. A good study can tell us how likely it is, or the "probability," that an individual patient will be helped by a treatment. It cannot tell us what will happen for sure. For example, a study may show that breast cancer patients have a 50% probability of responding to a particular treatment. That means that about half of the breast cancer patients who take the treatment will benefit from it.

It is important for you to know the evidence for each treatment choice. Using evidence to make medical decisions will greatly improve your chances of getting the best possible treatment.

guidelines are created by companies or organizations that will profit from recommending one treatment over another. Good national breast cancer guidelines are based on scientific evidence. Panels of experts from across the country write the guidelines. They rely on and identify the research studies that support their recommendations.

Keep in mind that clinical practice guidelines are just that—guidelines. Guidelines will *not* tell you exactly what your care should be. But

they will give you a good idea of your choices. They are written for large groups of people. You may have other health issues that affect your doctor’s advice or your choice. But you should understand what the **standard of care** is.

Doctors do not always follow breast cancer treatment guidelines. This may be because your doctor is unaware of them or disagrees with them. Or it may be because there are conflicting guidelines. If your doctor recommends care that doesn’t follow national guidelines, ask why.

Where can I find breast cancer guidelines?

There are many guidelines for breast cancer treatment. We recommend guidelines from three groups:

- Contact the National Cancer Institute (NCI) (page 103) to get a copy of their breast cancer guidelines. These guidelines are part of NCI’s Physician Data Query (PDQ) database. Also, in November 2000, the National Institutes of Health (NIH) and NCI published a paper called, “Consensus Statement on Adjuvant Therapy for Breast Cancer.” (**Adjuvant therapy** is treatment breast cancer patients get after surgery.) This paper tells what NIH/NCI recommends for treating non-metastatic breast cancer. Contact NCI (page 103) for a copy of this paper.
- You can also contact the National Comprehensive Cancer Network (NCCN) (page 104) to get a copy of their breast cancer guidelines. NCCN

is made up of many of the leading cancer centers in the country.

- The Blue Cross and Blue Shield Association (BCBS) creates evidence-based technology assessments. Technology assessments are similar to guidelines. They summarize what is known about whether a specific technology helps a specific health condition. Sometimes new technologies are used in breast cancer care before they have been studied for effectiveness. **Sentinel lymph node biopsy** is one example. Other times technologies that help patients with other health conditions are applied to breast cancer care before they have been shown to help breast cancer patients. BCBS has a research program to judge the effectiveness of such technologies. They summarize the evidence and their recommendations in reports for consumers. Contact BCBS (page 100) to learn more about their breast cancer technology assessments.

If your doctor recommends care that doesn't follow national guidelines, ask why.

Not all studies are created equal.¹²

There are many kinds of scientific studies. Some give more reliable evidence than others. That means you can trust the evidence. Most scientists agree on the following system for ranking studies. The studies are listed here from *most* reliable (1) to *least* reliable (6).

1. Systematic reviews of **randomized controlled clinical trials**
2. Randomized controlled clinical trial—**Blind**
3. Randomized controlled clinical trial—Non-blind
4. **Controlled clinical trial**—non-randomized
5. **Observational studies** (cohort and case-control studies)
6. **Uncontrolled studies (case series)**
7. Opinion of doctor based on his or her experience with past patients

But even the best types of studies can be designed and carried out poorly. And even if two studies are designed the same, one may still be better than the other. How do you know if a study was well done? Here are some things to look for.

In a good study, the following things are all true:

- The patients in the **control group** and

the patients in the **investigational group** are similar to each other. (For example, they are the same ages and races, they have the same types and stages of illness, and they live in the same area.)

- The researchers can follow the progress of all patients reliably and consistently.
- The researchers always use the same definitions and measurements of illness.
- Most of the patients in the study stay in the study the whole time.
- Most of the patients do what they are asked to do.
- The researchers use **statistical methods** to understand the information.
- The results are reviewed by researchers and/or experts who did not design or run the study. (This is called a “**peer review**.”)

NBCCF believes that breast cancer patients should have the best possible information when making choices about their care. That is why we want every breast cancer therapy and prevention therapy to be tested. The same goes for every screening technique and diagnostic tool. And we want them tested in at least one, well-done, blind, randomized controlled clinical trial. That way, breast cancer patients will have the most reliable evidence.

¹² The information presented in this box is adapted from the National Cancer Institute's Web site (www.cancer.gov) and Harris RP, et al. Current methods of the U.S. preventive services task force. *American Journal of Public Health* 2001;20(3S):21-35.

Medical research is not all the same.

Some studies are better than others. A good study gives results you can trust. “**Validity**” and “**reliability**” refer to how much you can trust a study’s results. A study’s validity and reliability depend on:

- how well the study was designed,
- what questions were asked,
- how big the study was, and
- if the same results were found more than once, or are backed up by other research.

Also, different types of studies offer different levels (strengths) of evidence. For example,

controlled studies give stronger evidence than uncontrolled studies or case series.

In a controlled study, one group of patients gets the new treatment. This group is called the investigational group. Another group of patients does not get the new treatment. This second group gets a standard treatment for the same disease. This group is called the control group. The investigational group and the control group are then compared.

There are different types of uncontrolled studies. One type looks at the effects of a new treatment by looking at the same patients before and after they get the treatment. These

Get informed when you are asked for informed consent.

You will have to sign forms giving your “**informed consent**” before you can get some treatments or before you participate in a clinical trial. They should tell you the expected benefits and possible risks from the treatment you are going to get. The forms you sign are also written to protect doctors and hospitals against lawsuits.

The most important part of the informed consent process is to learn about the treatment’s risks and benefits. For breast cancer treatment and clinical trials, you should ask:

- What benefits can I expect?
- What are the side effects of the treatment? (Ask about all side effects: common and rare, short-term and long-term,

temporary and permanent.)

- Who will take care of me and pay if something goes wrong?
- What could happen if I decide against this treatment or clinical trial?

Once you schedule your surgery and treatment, ask for copies of the informed consent forms you will be asked to sign. Ask to take them home with you and review them with your family or friends. That way you will not be rushed into reading and signing them. You should not have to read and sign informed consent forms right before surgery or beginning a treatment.

If there is little or no evidence . . . try to join a clinical trial.

studies don't use a separate comparison group of patients.

The randomized controlled clinical trial gives the highest level of evidence. This type of trial is the "gold standard" of medical research. In it, the patients are assigned by chance to get the new treatment or not. (This makes the study "randomized.")

What if there is little or no evidence?

There are many questions about breast cancer care that have *no* right answers. And sometimes doctors can't agree if one treatment is better than another. For example, there may be two different treatments, but no one knows if one of them works better.

What if there is little or no evidence to support a treatment for you? What if the evidence conflicts? Try to join a clinical trial. This is the only way we'll get the answers we so badly need. To learn more about clinical trials, see pages 23-25.

Remember, we all hope that new and better care will be found. New treatments that are being tested are called **investigational**

treatments. These treatments have not been proven. So a new investigational therapy *may not work as well* as the standard therapy. Or the new therapy *may work the same or better* than the standard therapy. We don't know the answers to these questions until we conduct a well-designed clinical trial.

With advanced breast cancer, most patients get more than one type of treatment. They may get many different treatments over a long time. So doctors may not be sure which drug works better when it is given first, second, third, and so on. Sometimes, past research guides this decision. Other times there is no research to guide us.

Good doctors combine up-to-date evidence with their best judgment. They base their advice on your treatment history and **pathology report.** And, of course, they look at how you are feeling and what you want. Doctors should share their reasons for advising certain treatments.

Different doctors have different approaches to their breast cancer patients. This is especially true with advanced breast cancer. The guidelines for treatment are less clear than they are

Do you want to see where medical evidence comes from?

A good place to start is the database called "Medline." It is run by the National Library of Medicine (page 105). Go to www.ncbi.nlm.nih.gov/PubMed. You'll find a huge database that lists titles and

abstracts of research studies published in peer-reviewed, scientific journals. After getting the **citations** on-line, look for the complete journal articles on-line or at a university library.

with early breast cancer. So different doctors will recommend different choices when it's a "judgment call."

- Some doctors propose strong combinations of drugs for **metastatic breast cancer** patients. Their goal is to try to get a **remission**.
- Other doctors believe in giving fewer or less powerful drugs to their metastatic breast cancer patients. Their goal is to keep the disease under control without using up treatment options too quickly. (Some treatments shouldn't be given to breast cancer patients more than once.) And they want to pay attention to your **quality of life**.

Remember, no matter what stage or type of breast cancer you have, the decision is always in your hands. A good **oncologist** should have a real sense of what you need and want.

Gather your own information.

The **Internet** offers a lot of information. But be careful, because you can't trust a lot of it.

Remember to always weigh the information you gather. Compare sources and think about the evidence carefully. By comparing different sources, you'll see where they all agree. Differences may tell you where doctors disagree or where there is a current lack of evidence.

Learn the difference between risk reduction and prevention.

In medicine, the goal is to reduce the risk of, prevent, or cure illness or disease. The amount of risk reduction can be measured in terms of **absolute risk reduction** or in terms of **relative risk reduction**.

If these concepts are confusing to you, don't worry. Just ask the following questions when your doctor offers you a treatment:

Understanding Absolute Risk Reduction Versus Relative Risk Reduction

Let's say the risk of your cancer coming back is 4%. If you take treatment X, the risk of your cancer coming back is 3%. The difference between 4% and 3% is 1% ($4\% - 3\% = 1\%$). The 1% decrease in risk is called "absolute risk reduction."

However, your doctor might talk about relative risk reduction instead. He or she might say that your risk will be reduced

by 25% if you take treatment X. This is because 1% is 25% of 4% ($1\% \div 4\% = 25\%$). The 25% decrease in risk is called "relative risk reduction."

Ask your doctor to explain which kind of risk reduction she or he is talking about. Sometimes the numbers can be very misleading.

Keep asking your doctors to explain what they are saying until you understand it.

1. What is my risk of getting breast cancer again if I do take the treatment? And what is the risk if I do *not* take the treatment?
2. What is my risk of dying from breast cancer in the next five years or 10 years if I do take the treatment? And what is the risk if I do *not* take the treatment?
3. What are the risks of bad side effects if I take the treatment?

These questions will help you decide if you think the treatment is worthwhile.

Also, know the difference between “prevention” and “risk reduction.” For most of us, “prevention” means something that will stop us from ever getting a disease. But the word “prevention” is often used to describe what is really “risk reduction.” Whenever you see the word “prevention,” be sure to ask these questions:

- Is it really prevention or is it risk reduction?
- And if it is risk reduction, is it absolute or relative risk reduction?

It is helpful to know both.

You can still ask questions, even if you don't feel like you know these terms. Keep asking your doctors to explain what they are saying until you understand it.

Keep track of your health care information.

Keeping track of all the professional care, advice, and information you get is a big and important job. Here are some ideas to help you stay organized:

- It is always good to have a family member or friend go to appointments with you. They can help you ask questions and take notes.
- Before your appointment, write down your questions. Leave space for filling in the answers you get from your doctors and nurses.
- If you track your own care, buy a notebook and be your own best secretary. Write down the dates of meetings, advice, and treatments.
- Ask to tape-record meetings with your doctor so that you can listen to them at home. Some doctors now tell patients to do this. They know it's hard for patients to understand all the information they get in a short time.
- Ask for copies of your medical records and reports.
- Ask for written instructions about your breast cancer care and medicines.

Are you having trouble getting your medical records? If so, learn about the health laws in your state by contacting Georgetown University's Health Privacy Project (page 102).

