



Lesson 4: Pathology and Treatment Options

Lesson Summary:

Students are introduced to pathology reports and learn how to interpret them and draw conclusions about possible treatment approaches based on evidence. They are first introduced to pathology through lesson characters Steve and Nikki. Students begin the lesson by discussing what they currently know about pathology reports and why they are important. The class then learns how to interpret pathology reports through fictional but realistic examples before going more in-depth into the stages and types of breast cancer. Once students have an understanding of pathology, they begin discussing treatment approaches.

Lesson Duration: Two 45–60-minute class periods

How to Use This Guide

This lesson plan was created to aid instructors in planning their lesson. It provides slide-by-slide details so educators will be prepared to engage, explain, discuss, and analyze every part of the lesson. The lesson is designed to be two 45–60-minute class periods, but it is flexible, depending on the students' needs and time available. All handouts are included in this guide, as well as additional resources for more learning activity ideas.

Objectives

Upon completion of this lesson, students will be able to:

- Discuss the purpose of pathology reports and the roles of pathologists
- Distinguish among different types of breast cancer
- Understand how cancers are staged
- Read and interpret a pathology report
- Identify common misconceptions about cancer treatment and clinical trials
- Graphically organize their accumulated knowledge about cancer
- Differentiate between cancer treatment options
- Predict treatment plans for patients
- Understand the criteria for evaluating the effectiveness of a new treatment
- Design a cancer treatment clinical trial

Materials:

- Handout: [Pathology Primer](#) (page 16)
- Handout: [A Guide to Interpreting a Pathology Report](#) (pages 17-18)
- Handout: [Thelma Jackson Pathology Report](#) (page 19)
- Handout: [Cancer Stages](#) (pages 20-21)
- Handouts: [Sample Pathology Reports](#) (Sally Jones, Pamela Hunter, Luisa Santiago, Brittany Featherston, Claire Addington, Velma Belt, Marguerite Carrell, Jonathan Woolsey, Naomi Lohman, Rose Haygood) (pages 22-31)
- Handout: [Tumor Grade](#) (pages 32-33)
- Handout: [Sarah Williams Pathology Report](#) (page 34)
- Handouts: [Cancer Treatment Factsheets](#) (Biological Therapy, Chemotherapy, Hormone Therapy, Radiation Therapy, Surgery) (pages 35-40)
- Handout: [Cancer Treatments Summary](#) (pages 41-42)



- Clinical Trials: [Facts and Myths Cards](#) (pages 43-46)
- Handout: [Treatment Choices by Stage](#) (pages 47-49)
- Handout: [Clinical Trials Factsheet](#) (pages 50-55)
- Handout: [Design a Clinical Trial](#)
- Lesson 4 Quiz
- Answer Keys
- Interactive whiteboard (optional)
- Flip chart paper and markers
- Computer with Internet access/LCD projector

Subjects:

- Health
- Language Arts and Literacy
- Science

Vocabulary:

adjuvant therapy, aromatase inhibitor, autopsy pathologist, axillary lymph nodes, benign, bias, biological therapy, blinding, body fluid, breast reconstruction, breast-sparing surgery, carcinoma, carcinoma in situ, cell, chemotherapy, clinical trial, control group, cyclophosphamide, cyst, cytologist, cytopathologist, Data and Safety Monitoring Boards, diagnostic trials, doxorubicin, duct, ductal carcinoma in situ (DCIS), eligibility criteria, endocrine system, endpoint, estradiol, estrogen, external radiation, fluorescent in situ hybridization (FISH), forensic pathologist, HER2/neu gene, histologic grade, hormone, hormone therapy, incision, infertile, inflammatory breast cancer, informed consent, infusion, inoperable, institutional review board, internal radiation, intraductal carcinoma, intravenously, investigational group, lobe, lobular carcinoma in situ (LCIS), local therapy, lumpectomy, lymph node, lymphatic system, lymphedema, lymphovascular invasion, macroscopic, malignant, mastectomy, menopause, metastasis, microscope, monoclonal antibody, mutation, neoadjuvant therapy, nodule, oncologist, oncology, ovary, paclitaxel, pathologist, pathology, pathology report, placebo, prevention, principal investigator, progesterone, proliferate, prophylactic mastectomy, protocol, quality of life trials, radiation, radiation therapy, radiology, randomization, receptor, recurrent cancer, screening trials, side effect, specimen, stage, staining, supportive care, surgeon, surgery, systemic therapy, target, targeted therapy, tissue, trastuzumab, treatment trials, trials, tumor

Advance Preparation:

Day 1: Pathology

Pre-Lesson Prep Assignment

- Make one copy per student of [Pathology Primer](#) (page 16). This should be assigned one session in advance as a homework assignment and will be discussed during the lesson.

Real-World Scenario – Steve and Nikki

- Review Steve and Nikki's real-world scenarios throughout the lesson so that you can effectively use their story in the classroom.
- Review the learning activity Small Group Brainstorm.

Reading a Pathology Report

- Make one copy per student of [A Guide to Interpreting a Pathology Report](#) (pages 17–18) and [Thelma Jackson Pathology Report](#) (page 19).
- Review the learning activity Reading Pathology Reports.



- Make one copy per group of [Sample Pathology Reports](#) (pages 22–31). (There are likely more samples than groups; instructors can choose a sampling that shows a range.)

Breast Cancer Stages

- Review the learning activity Breast Cancer Stages.
- Make one copy per student of [Cancer Stages](#) (pages 20–21).

Interpreting Pathology Reports

- Review the learning activity Interpreting Pathology Reports.
- Make one copy per student of [Tumor Grade](#) (pages 32–33).
- Prepare flip chart paper and markers for each group.

Homework Assignment

- Review the homework assignment Sarah Williams Pathology Report.
- Make one copy per student of [Sarah Williams Pathology Report](#) (page 34).

Day 2: Treatment Options

Talk About It!

- Review the Talk About It discussion question and activity.

KWL Chart

- Review the learning activity KWL Chart.
- Prepare flip chart paper and markers for each group.

Differentiating Treatment Options

- Review the learning activity Treatment Options Jigsaw and determine how to execute.
- Make one copy per student of [Cancer Treatment Factsheets](#) (pages 35–40) and [Cancer Treatments Summary](#) (pages 41–42).
- Distribute poster board (optional).
- Review the learning activity Drag-and-Drop Cancer Treatments Summary.

Clinical Trial Misconceptions

- Review the learning activity Clinical Trials—Facts and Myths.
- Make one set of [Clinical Trials: Facts and Myths Cards](#) per group (pages 43–46). (Optional: set up online survey tool.)
- Review the discussion question.

Predicting a Treatment Plan

- Review the learning activity Predicting a Treatment Plan.
- Make one copy per group of [Treatment Choices by Stage](#) (pages 47–49).

Homework Assignment

- Review the homework assignment.

Designing a Clinical Trial

- Review the learning activity Designing a Clinical Trial.
- Make one copy per group of [Clinical Trials Factsheet](#) (pages 50–55) and [Design a Clinical Trial](#) (page 56–62).
- Review the writing activity.

Career Connection

- Pathologist
- Laboratory Technician
- Oncologist
- Pharmacist
- Physician's Assistant



- Plastic Surgeon
- Radiation Oncologist
- Surgeon
- Treatment Nurse

A Note about Cancer

Cancer is a disease that unfortunately touches many people. You may have students with a parent, guardian, or loved one affected by cancer. Adolescents affected by cancer cope in their own ways, depending on their stage of life. Some students may want to share their personal experiences, while others may not. Reassure students that you want them to be comfortable in the classroom and will not ask them to share experiences unless they want to.

You may learn a student is personally affected prior to or while implementing the curriculum. If you discover a student is affected by cancer, talk with him privately and make sure he is comfortable with participating in the learning activities, discussions, and explorations.

If you know a student is affected by cancer prior to starting the curriculum:

- Give the student a brief summary of the lessons, and ask how he feels about it. Tell the student it may not bother him now, but he should let you know if it does.

If you learn a student is affected by cancer while implementing the curriculum:

- Ask who he has spoken to about the cancer. If the answer is no one, ask if he would like to talk to someone, such as a guidance counselor or other trusted adult.

Connect students with support. Possible sources include the following:

- guidance counselors
- family friends
- family doctors or pediatricians
- faith-based counselors

Look for warning signs. Keep an eye out for signs of distress, such as

- changes in academic performance,
- changes in behavior with other students,
- evidence of alcohol or drug use, or
- evidence of anxiety or depression.



Lesson 4 Plan – Day 1: Pathology

Pre-Lesson Prep Assignment

- [Slide 1] Distribute the pre-lesson prep assignment, [Pathology Primer](#), one session before Lesson 4. Students should complete this assignment as homework; it will be reviewed during Day 1 of this lesson.

ENGAGE

Real-World Scenario – Steve and Nikki

- [Slide 4] Re-introduce Steve and Nikki, who are learning more about their mother's cancer. They are interested in learning more of the details and want to understand what the pathology report is and how it's used.
- [Slide 5] **Optional Learning Activity: Small Group Brainstorm.** Tell the class they will develop a response to Steve's first question, What is a pathology report used for?, through the learning activity. Divide students into small groups and have them brainstorm what they know about pathology reports, including what information is usually included in them. Then ask students to share any questions they have about pathology reports and make a list for the class. Use the SMART Board and write the student responses to this question in the box provided. You can then save the notes the students make to each question by saving via one of the following methods:
 - Press the Print Screen button on the keyboard, and paste the screen image into a Word document.
 - Use the screen capture feature of the Notebook software that comes with the SMART Board to add the screen to a set of class notes to be shared with the class later.
 - Use PowerPoint's annotate pen and save the notes to the slide.

What Is Pathology?

- [Slide 6] Ask students if they have ever watched CSI (Crime Scene Investigation) or another television show that highlights the work of pathologists. Pathologists are doctors who identify diseases by studying cells and tissues under a microscope. Ask students why pathologists might be important in diagnosing breast cancer. (Pathologists can evaluate whether there is cancer present, what type of cancer it is, and how far it has spread in the tissue.)
- [Slide 7] Tell students that the class will begin this portion of the lesson by discussing the [Pathology Primer](#) they reviewed for homework prior to the lesson. Ask students to put their handouts and homework away for the time being, and encourage discussion.
- [Slides 8–12] Discuss who pathologists are.
 - [Slide 9] Explain that forensics is the use of scientific tests to study crime.
 - [Slides 10–11] Anatomical pathologists study the organs, tissues, and cells of patients. Discuss what these types of pathologists do. Autopsy pathologists and surgical pathologists perform autopsies and study the organs, tissues, and cells. Forensic pathologists work to determine the cause of death. Cytologists are technicians, and cytopathologists are the physicians who review and interpret the specimens.
 - [Slide 12] Clinical pathologists study the body fluids of patients, including blood, serum, plasma, urine, respiratory mucous, and cerebrospinal fluid.
- [Slide 13] Discuss what pathology reports are.



- Pathology reports are written medical documents that describe specimens that were collected by a doctor and sent to a pathologist for analysis. These reports help doctors diagnose a condition so they can prescribe the best course of action to treat a particular disease.
- [Slide 14] Group discussion. Ask students to provide three reasons why pathology reports are important.
- [Slide 15] Homework review. Tell students to pull out their homework from the night before. Ask for volunteers to share their answers to the homework questions.

EXPLORE

Breast Anatomy

- [Slide 16] Explain that lobular carcinoma occurs in the lobes of the breast, while ductal carcinoma occurs in the ducts of the breast.

Reading a Pathology Report

- [Slides 17] Slides 17 and 18 accompany [A Guide to Interpreting a Pathology Report](#) and [Thelma Jackson Pathology Report](#). Distribute the handouts for students to reference as you go through these slides. Review the top portion:
 - Patient Information. The first information you should look for is the patient's name, age, and gender.
 - Specimen(s) Received. This section is a description of what specimen was submitted to the pathologist from the surgeon and what procedure was done to obtain it. These are the tissues that will be examined by a pathologist to establish a diagnosis.
 - Clinical History. This section refers to the patient's breast cancer history, such as any procedures that have been done and/or a diagnosis.
 - Gross Description. In this section, you will find macroscopic descriptions of the samples, such as size.
 - Description. This section describes characteristics of a patient's cancer, including the stage.
 - Procedures/Addenda. Test results often come back at different times and their results are added to a pathology report here. You will see test results for the estrogen receptor, progesterone receptor, and HER2/neu. Results will be expressed with a number and an interpretation. These tests have important implications for treatment.
- [Slide 18] This is the lower half of [Thelma Jackson Pathology Report](#). Spend time discussing each of the categories. TEACHER NOTE: The handout includes additional information about the Description and Procedures/Addenda sections.
 - **Optional Learning Activity: Reading Pathology Reports.** Tell the class they will develop a response to Steve's second question, How do I read a pathology report?, through the learning activity.
 - Divide the class into five groups, and distribute the [Sample Pathology Reports](#) to each one. Let students know the reports are from actual patients but that their names have been changed to protect their privacy. Assign each of the five groups just one section of the report to review:
 - Specimen(s) Received
 - Clinical History
 - Gross Description
 - Description
 - Procedures/Addenda
 - After each group has a chance to review their section in each report, ask students to explain what they have learned about the patients from the pathology reports, highlighting some differences and similarities.



EXPLAIN

Reading Pathology Reports

- [Slide 19] Distribute one pathology report from [Sample Pathology Reports](#) to each group from the previous exercise. Let students know the reports are from actual patients but that their names have been changed to protect their privacy. The following slide should be used by each group as they perform the activity.

ELABORATE

Breast Cancer Stages

- [Slide 20] Explain to students that to plan treatment, doctors need to know the extent (stage) of the disease. The stage is based on the size of the tumor and whether the cancer has spread. Staging may involve X-rays and lab tests. These tests can show whether the cancer has spread and, if so, to what parts of the body. When breast cancer spreads, cancer cells are often found in lymph nodes under the arm (axillary lymph nodes). The stage often is not known until after surgery to remove the tumor in the breast and the lymph nodes under the arm.
- Next, tell students that they will be dividing into small groups to discuss the differences among the stages. Emphasize that this is just an exercise to see what they know before learning about the stages. Ultimately, you will be discussing how these stages relate to pathology reports.
 - **Learning Activity: Breast Cancer Stages**
 - Divide the class into three to six groups, and have students brainstorm what they know about the stages of breast cancer and what happens in each stage. Then ask students to share any questions they have about the stages of breast cancer and make a list for the class. Use the SMART Board and write the student responses to this question in the box provided. You can then save the notes the students make to each question by saving via one of the following methods:
 - Press the Print Screen button on the keyboard and paste the screen image into a Word document.
 - Use the screen capture feature of the Notebook software that comes with the SMART Board to add the screen to a set of class notes to be shared with the class later.
 - Use PowerPoint's annotate pen and save the notes to the slide.
- [Slide 21] Stage 0 is carcinoma in situ; this means that the cancer is confined to where it originally developed and has not invaded surrounding tissue.
 - Keeping students in their groups, distribute [Cancer Stages](#) and share information about breast cancer stages on the following five slides. Explain that there are two kinds of Stage 0 breast disease: lobular carcinoma in situ (LCIS), which is defined by abnormal cells lining a lobe, and ductal carcinoma in situ (DCIS), which is defined by abnormal cells lining the duct. LCIS is technically not a cancer but rather a precancerous condition. DCIS can sometimes become invasive.
- [Slide 22] Stage I is an early stage of invasive cancer. The tumor size is 2 cm or less, and no cancer cells are outside of the breast.
 - Discuss Stage I cancer and refer to the handout as needed. Ask for a volunteer to explain the difference between Stage 0 and Stage I cancer.
- [Slide 23] Stage II cancer meets one of the following criteria:
 - Tumor size is 2 cm or less and cancer has spread to underarm lymph nodes
 - Tumor size is between 2 cm and 5 cm and there is no cancer outside the breast



- Tumor size is between 2 cm and 5 cm and cancer has spread to underarm lymph nodes
- Tumor size is greater than 5 cm and there is no cancer outside the breast
- [Slide 24] Stage III is locally advanced cancer. This stage is divided into three categories: Stage IIIA; Stage IIIB; and Stage IIIC. Discuss the three categories of Stage III cancer on this slide and the three following slides. Discuss how these categories differ from previous stages and each other.
 - [Slide 25] Stage IIIA:
 - Tumor size is 5 cm or less. The cancer has spread to lymph nodes under the arm that are attached to each other or to other structures. The cancer may have spread to lymph nodes behind the breastbone.
 - Tumor size is greater than 5 cm. The cancer has spread to underarm lymph nodes that are either alone, attached to each other, or attached to other structures. The cancer may have spread to lymph nodes behind the breastbone.
 - [Slide 26] Stage IIIB:
 - Tumor of any size that has grown into the chest wall or the skin of the breast. It may be associated with swelling of the breast or with nodules (lumps) in the breast skin.
 - The cancer may have spread to underarm lymph nodes, lymph nodes that are attached to each other or to other structures, or lymph nodes behind the breastbone.
 - [Slide 27] Stage IIIC:
 - Tumor of any size that has spread to either lymph nodes behind the breastbone and under the arm or to lymph nodes above or below the collarbone.
 - [Slide 28] Stage IV is distant metastatic cancer. The cancer has spread to other parts of the body. Discuss how this stage differs from the others.

Interpreting Pathology reports

- [Slide 29] Distribute [Tumor Grade](#) handout to each group to use with the other handouts they have for the following learning activity.
 - **Learning Activity: Interpreting Pathology Reports**
 - Ask each group to create a chart or presentation highlighting information for their patient indicated on the slide. Make sure students are able to locate the relevant information and remind them to refer to [A Guide to Interpreting a Pathology Report](#), [Cancer Stages](#), and [Tumor Grade](#) for assistance. When the groups have completed their charts, display them in the room and have each group present their patient's report.

EVALUATE

- [Slide 30] **Homework Assignment: Sarah Williams Pathology Report.** Ask students to demonstrate their understanding of a pathology report with this writing assignment. Distribute [Sarah Williams Pathology Report](#) to students.
 - Review the pathology report for Sarah Williams and write an answer to Steve's questions: What is a pathology report used for? How do I read a pathology report? Include details about what each section of the pathology report means and how it will be used by doctors.



Lesson 4 Plan – Day 2: Treatment Options

ENGAGE

Talk About It!

- [Slide 32] Ask one or two students to share their experiences with an injury or illness that led to choosing a method of recovery. This could include taking a certain type of medication that had side effects versus another or doing physical therapy instead of having surgery. Or share an example from your life in which you had a choice to make, and ask for students to share what their decision would have been and why. Through this discussion, address the question, Why could it be important for people with cancer (and their families) to learn about all treatment options, even if they only need one type? This activity should get students talking about choices; the pros and cons of decisions; and how an individual's lifestyle, age, or general preference can come into play when making health decisions.

Nikki's Question/Review of Lesson 1

- [Slide 33] Remind students of Steve and Nikki's mom and some of the questions she is facing. Pose Nikki's question to the class: "I never knew there were so many different cancer treatments. Does anybody know about the different treatments? We don't know what Mom should do and what's going to happen to her. Is she going to lose her hair?" Tell students to think back to what they've learned so far to address these questions.
 - Begin by reviewing the learning activity from Lesson 1, What Do You Believe? Focus on the following statements and review the answers:
 - Treating cancer with surgery can cause it to spread throughout the body.
 - Cancer is something that can be effectively treated. There is currently a cure for cancer, but the medical industry won't tell the public about it because they make too much money treating cancer patients.
 - Next, review any relevant cancer treatment questions generated in Lesson 1, if applicable. If you feel comfortable, students also could share any experiences of their family members or friends who have gone through cancer treatment.

EXPLORE

KWL Chart

- [Slide 34] To further explore what students have learned so far, tell them they will be creating a KWL chart.
 - **Learning Activity: KWL Chart.** Divide the class into five-person groups and distribute flip chart paper and markers to each group. Ask the groups to create a KWL chart. Allow groups time to complete their KWL charts. Post each group's chart and discuss them as a class.
 - Optional: Students can also do this using an online shared Google Drive document and project their work onto the SMART Board.

EXPLAIN

Differentiating Treatment Options

- [Slide 35] Introduce five treatment options, and explain that the following learning activity will help students understand these options.
 - Biological therapy
 - Chemotherapy
 - Hormone therapy
 - Radiation therapy



- Surgery
- **Learning Activity: Treatment Options Jigsaw.** Emphasize that during this jigsaw, each individual student is responsible for his or her own work and the success of the group depends on the work of every person. Use the same groups that were created for the KWL Chart activity.
 - Assign or ask groups to select a leader, recorder, typist, etc.
 - Assign one of the five cancer treatments to each student in the KWL./jigsaw group.
 - You can combine the treatments together if you prefer to work with fewer groups.
 - Tell the class that each student in the group will become an expert on one treatment (or treatments, if you combine treatments together).
 - Have each treatment expert group gather separately. Provide each treatment expert group with the appropriate [Cancer Treatment Factsheets](#) and [Cancer Treatments Summary](#).
 - Allow the treatment expert groups to read their specific treatment factsheet. As an expert group, they should seek to answer the questions generated in Lesson 2 or from the KWL charts and complete the appropriate row for their treatment on the [Cancer Treatments Summary](#). Students do not need to memorize the information, but they should have a firm understanding of the treatment. They may need to do additional research if the factsheet does not answer all of their questions.
 - After each treatment expert group has discussed their treatment, have students regroup into their original KWL/jigsaw groups.
 - Each expert then presents the information on their assigned treatment to their KWL/jigsaw group and states what the treatment expert group consensus was on the characteristics of the treatment. While the information is discussed, students complete their charts on the [Cancer Treatment Summary](#).
 - Be mindful of each group's progress by moving around the room and asking the group leaders to describe how the lesson is going. If problems arise with students who are not participating, work with that specific group to draw the information out of the student.
 - Have each KWL/jigsaw group complete their KWL chart by filling in the L column (what they learned). Review the updated KWL charts as a class.
 - Collect the KWL charts from each group at the end of the lesson. The KWL charts could be used to create an assessment for students.
 - Optional: You can also do this as a Safari activity. Have each group research their treatment option online and create a poster. Display the completed posters, and allow students time to examine all of the posters. Have each group present their poster to the rest of the class.

Drag-and-Drop Activity

- [Slide 36-37] **Learning Activity: Drag-and-Drop Cancer Treatments Summary.** Choose 5–10 volunteers to come up one at a time and drag-and-drop the descriptions into the correct treatment option rows.

ELABORATE

Clinical Trial Misconceptions

- [Slide 38] **Learning Activity: Clinical Trials—Facts and Myths.** [Ask](#) students to complete the first part of this activity before moving on to the following slides, which provide answers on the “facts” versus the “myths.”



- Divide the class into groups of four to six students. Give each group one set of [Clinical Trials: Facts and Myths Cards](#). Tell the groups to divide the cards into two piles: Facts and Myths.
- Once the cards have been placed in the two piles, go through the statements on the following slides to learn the correct answers.
- Optional: Instead of using small groups and the cards, you can use an online survey tool in conjunction with students' smartphones

Following is all of the detail from slides [X-X] and this activity.

- [Slide 39] Statement 1: People who join clinical trials are just “guinea pigs” for research. (Myth) People who decide to take part in a clinical trial are called participants, and strict guidelines are in place to ensure that these volunteers are treated humanely. A participant has the right to withdraw from a trial at any time. The participant may also discuss further treatment options with the study physician or be referred back to a primary care provider for standard care. Survey results show that 97 percent of people were treated with dignity and respect and that the quality of care they received was “excellent” or “good.”
- [Slide 40] Statement 2: A person can leave a clinical trial whenever they want. (Fact) People who decide to take part in a clinical trial can leave the study at any time.
- [Slide 41] Statement 3: Cancer treatment clinical trials only provide “last resort” treatment. (Myth) Cancer treatment clinical trials are not only for patients in the end stages of their disease but also for many newly diagnosed cancer patients. If only the sickest patients participated in treatment trials, researchers would not know how to treat patients with earlier stages of cancer. Phase III cancer treatment clinical trials cover all stages of cancer, from the most advanced to the most localized.
- [Slide 42] Statement 4: You do not have to have cancer to participate in a cancer clinical trial. (Fact) Three types of trials are available to people without cancer: (1) prevention, (2) early detection/screening, and (3) diagnostic.
 - Prevention trials study ways to prevent cancer.
 - Early detection/screening trials look at ways to improve the early detection of cancer.
 - Diagnostic trials focus on ways to test for cancer or to identify it better.

Each type of trial has its own guidelines about who can participate. Generally, participants are alike in key ways, such as the type and stage of cancer they have, age, gender, and other factors.
- [Slide 43] Statement 5: Many people who join cancer treatment clinical trials get a sugar pill (placebo) instead of being treated. (Myth) Placebos are rarely used in cancer treatment trials. No one is ever given a placebo when an effective treatment is available. However, in rare cases, a placebo may be used when testing a new drug if there is no known effective treatment.
- [Slide 44] Statement 6: Positive results from studies conducted on mice may not translate into positive outcomes for humans. (Fact) A clinical trial is one of the steps in a long and careful cancer research process. Getting promising results from testing a new drug on mice, for example, is a preliminary step to human research studies. Treatments that work well in mice do not always work well in people.



- [Slide 45] Statement 7: Clinical trials are only held in large cities. (Myth) Clinical trials are underway all over the country—in cancer centers, major medical centers, community hospitals and clinics, physicians' offices, and veterans and military hospitals in numerous cities and towns across the United States.
- [Slide 46] Statement 8: New treatments may not always be better than standard treatments. (Fact) New treatments under study are not always better than, or even as good as, standard treatments—and they may have unexpected side effects. Through a process called informed consent, participants learn about a trial's treatments and tests, as well as their possible benefits and risks, before deciding whether or not to participate.
- [Slide 47] Statement 9: There are no real benefits to participating in a clinical trial. (Myth) People can benefit from clinical trials. In cancer treatment trials, for example, participants receive high-quality cancer care and would be among the first to benefit if a new approach is proven to work.
- [Slide 48] Statement 10: A person can only sign up for a clinical trial if they agree to it. (Fact) Researchers running the clinical trial are required by law to present and explain the study as part of the informed consent process. This process includes signing an informed consent document, discussing what the trial entails with the research team, and understanding the potential risks and benefits of participating. Although reputable researchers do not fool people or sign them up against their will, sometimes people have difficulty understanding the information they need to know about a trial before agreeing to join. For many people, it is important to ask a friend or family member to come with them to be sure that all important questions are raised. Taking notes or using a tape recorder can also help.
- [Slide 48] Discussion Question: Ask the group what they learned about clinical trials and what they would still like to learn.

Predicting a Treatment Plan

- [Slide 49] Tell students they will apply their knowledge of cancer treatments to suggest treatment options. Have students work in the same groups from yesterday when they were interpreting and reading a sample pathology report. However, you can also mix students so that the groups are made up of students who reviewed different pathology reports in Day 1. You may also wish to have a jigsaw group review the reports so that each group contains an expert on each treatment type.
 - **Learning Activity: Predicting a Treatment Plan.** Distribute the [Sample Pathology Reports](#) to each group and provide copies of [Treatment Choices by Stage](#).
 - Depending on how much time you have, you may want each group to work with one pathology report or multiple reports. If you are able to have students work with multiple reports, you will be able to compare treatment options across groups.
 - Have students get their copy of [A Guide to Interpreting a Pathology Report](#) from yesterday. Tell each team to create a chart highlighting the following information for all of the pathology reports:
 - Patient's name and age
 - Clinical history
 - Staging and what the overall stage of the cancer is
 - Estrogen and progesterone receptors test results
 - HER2/neu test results
 - Treatment recommendations



- Walk around the room to make sure students are able to locate these items, and remind them to refer to [A Guide to Interpreting a Pathology Report](#) and related handouts for assistance.
- When the groups have completed their charts, display them in the room and have students present their recommendations for treatment options. Have groups justify their treatment recommendations. If groups do not come to the same recommendation, have the groups discuss their differences and come to a consensus.

EVALUATE

- [Slide 50] **Homework Assignment.** Distribute [Treatment Choices by Stage](#) to students. For homework, have each student review [Sarah Williams Pathology Report](#) and make a recommendation for treatment options based on her breast cancer. Students should justify their treatment recommendation.
- [Slide 51] **Learning Activity: Designing a Clinical Trial**
 - If necessary for your students, review the requirements for a scientific experiment.
 - Divide the class into groups of three to five students (have an even number of groups). Distribute [Clinical Trials Factsheet](#) and have students read it. Tell the groups they will be designing a clinical trial.
 - Distribute [Design a Clinical Trial](#) and allow enough time for students to answer the questions. Once groups have finished, have each group present their protocol to a partner group. After all groups have shared their clinical trial, allow time for groups to revise their protocols, if necessary. Ask students if they think Sarah Williams would be a good candidate for their clinical trials. You can also have each group present their trial to the whole class. Then create a class-wide clinical trial by taking elements from each group's protocol.
- [Slide 52] **Writing Activity:** Ask the class to write a letter to a fictional patient who would be an ideal candidate for the trial. The letter should describe the study and summarize the risks and benefits.
 - Use the SMART Board and write the student responses to this question in the box provided. You can then save the notes the students make to each question by saving via one of the following methods:
 - Press the Print Screen button on the keyboard and paste the screen image into a Word document.
 - Use the screen capture feature of the Notebook software that comes with the SMART Board to add the screen to a set of class notes to be shared with the class later.
 - Use PowerPoint's annotate pen and save the notes to the slide.
- [Slide 53] **Lesson 4 Quiz**



Additional Resources

- College of American Pathologists, MyBiopsy.org
<http://www.cap.org/apps/docs/reference/myBiopsy/index2.html>
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Next Generation Science Standards

Performance Indicators

HS-LS1: From Molecules to Organisms: Structures and Processes

- HS-LS1-2: Develop and use a model to illustrate the hierarchical organization of interacting systems that provide specific functions within multicellular organisms.

Science and Engineering Practices

Developing and Using Models

- Use a model based on evidence to illustrate the relationships between systems or between components of a system. (HS-LS1-4), (HS-LS1-5), (HS-LS1-7)

Constructing Explanations and Designing Solutions

- Construct an explanation based on valid and reliable evidence obtained from a variety of sources (including students' own investigations, models, theories, simulations, peer review) and the assumption that theories and laws that describe the natural world operate today as they did in the past and will continue to do so in the future. (HS-LS1-1)

Disciplinary Core Ideas

LS1.A: Structure and Function

- Multicellular organisms have a hierarchical structural organization, in which any one system is made up of numerous parts and is itself a component of the next level. (HS-LS1-2)

LS1.B: Growth and Development of Organisms

- In multicellular organisms individual cells grow and then divide via a process called mitosis, thereby allowing the organism to grow. The organism begins as a single cell (fertilized egg) that divides successively to produce many cells, with each parent cell passing identical genetic material (two variants of each chromosome pair) to both daughter cells. Cellular division and differentiation produce and maintain a complex organism, composed of systems of tissues and organs that work together to meet the needs of the whole organism. (HS-LS1-4)

Crosscutting Concepts

Structure and Function

- Investigating or designing new systems or structures requires a detailed examination of the properties of different materials, the structures of different components, and connections of components to reveal its function.



Pathology Primer

What is pathology?

Pathology is the study and diagnosis of diseases in living things by examining tissues, organs, cells, and fluids.

Who are pathologists?

Pathologists are doctors who study and diagnose diseases or conditions present in tissues, organs, cells and fluids. To become a pathologist, a person goes to college for 4 years, medical school for 4 years, and then completes a 4-5 year residency. Additional years of study are added if the person wants to specialize in a particular branch of pathology, such as forensics. They generally work in hospitals or medical centers with extensive laboratory equipment. There are two main types of pathologists: anatomical and clinical.

Anatomical pathologists study the organs, tissues, and cells of patients. Examples include:

- Autopsy pathologist
- Forensic pathologist
- Surgical pathologist
- Cytologists

Clinical pathologists study the body fluids of patients, including blood plasma, urine, respiratory mucous and cerebrospinal fluid.

What are pathology reports?

Pathology reports are written medical documents that describe specimens that were collected by a doctor and sent to a pathologist for analysis. These reports help doctors diagnose a condition so a doctor can prescribe the best course of action to treat a particular disease.

Homework Questions: (complete on a separate sheet of paper)

1. Describe the role of a pathologist in your own words.
2. How many years does it take to become a pathologist?
3. A forensic pathologist belongs to which subdivision of pathology?
4. What types of fluids are studied by clinical pathologists?
5. Would you be interested in becoming a pathologist? Why or why not?



A Guide to Interpreting a Pathology Report

The first information you should look for is the patient's name, age and gender.

Specimen(s) received

This section lists where the tissues were taken from.

Clinical History

This section refers to the patient's breast cancer history, such as any procedures that have been done and/or a diagnosis.

Gross Description

In this section, you will find macroscopic descriptions of the samples, such as size.



Description

This section describes characteristics of a patient's cancer.

Specimen Type:	Identifies where the sample was taken from.
Specimen Size:	The largest piece of tissue the pathologist looks at.
Laterality:	Identifies the side of the body the tissue sample came from.
Tumor Size:	The size of the tumor present in the sample. Size is measured in centimeters. Size is important for diagnosis.
Final Diagnosis:	Type of cancer present in the sample.
Histologic Grade:	Indicates how different the cancer cells are from healthy cells. There are three grades: <ul style="list-style-type: none"> • Grade 1: Cancer cells are similar to healthy cells and grow slowly. • Grade 2: Cancer cells do not look like healthy cells and grow more quickly. • Grade 3: Cancer cells look very different from healthy cells and grow very fast.
Stage:	Stage describes the extent of the cancer. Stage ranges from 0-IV.
Number of nodes examined:	When breast cancer spreads, cancer cells are often found in the lymph nodes under the arm. This number tells how many lymph nodes were examined by the pathologist.
Number of positive nodes:	This number tells how many lymph nodes in the sample contain cancer cells. A large number of positive lymph nodes may indicate the cancer is more serious.
Lymphovascular invasion:	If cancer cells have invaded the blood or lymphatic tissue, there



is a risk that cancer may return after the tumor is removed.
Lymphovascular invasion will be either present or absent.

Procedures/Addenda

Test results often come back at different times and their results are added to a report here. You will see test results for the hormones estrogen and progesterone and the protein HER2/neu. Results will be expressed with a number and an interpretation. These tests have important implications for treatment.

Estrogen (ER) and progesterone (PR) are hormones that stimulate the development and maintenance of female characteristics. These hormones bind to cells that have ER and PR receptors. Cells with ER and PR receptors are located in the breast, uterus, brain, heart, liver and bone. In the tissues of the breast and uterus, ER and PR cause cells to grow and divide, or proliferate. For example, estrogen triggers cell proliferation in milk glands to prepare the breast to produce milk if a woman becomes pregnant. While ER and PR have many beneficial effects, they can also be harmful due to their ability to trigger cell proliferation in the breast and uterus.

Some breast cancer cells have hormone receptors while others do not. A cell is hormone positive if it has many ER or PR receptors and hormone negative if it has no receptors. Typically, the hormone receptor test results are a number between 0-3:

Result Interpretation

0	No receptors
1+	Small number of receptors
2+	Medium number of receptors
3+	Large number of receptors

ER and PR positive cancers respond well to hormone therapies that block the interaction between the hormone and the hormone receptor.

HER-2/neu is a protein involved in normal cell growth. Some cancer cells have too many copies of the gene that makes the HER2/neu protein. Cancers that have too many copies of HER2 tend to grow very fast. The HER2/neu test uses a staining technique. A sample that has little to no staining is negative. Typically, the HER2/neu test results are a number between 0-3, and refer to the level of staining intensity:

Result Interpretation

0	Negative
1+	Negative
2+	Borderline
3+	Positive

Cancers that are HER2/neu positive respond well to biological therapy, which uses antibodies.



CONFIDENTIAL

University Hospital 1 University Place SURGICAL PATHOLOGY REPORT

Patient	
Name:	Jackson, Thelma
Age:	68
Patient ID:	3456789
Gender:	Female

Specimen(s) Received

Left breast re-excision and axillary node dissection

Clinical History

Left breast cancer

Gross Description

Received is a specimen consisting of a piece of skin measuring 8 x 7.5 cm. The skin surface is smooth. Multiple sections reveal fibrofatty breast tissue. No other lesions are identified. Multiple tan-pink lymph nodes present.

Description

Specimen Type:	Left breast biopsy, axillary lymph nodes
Specimen Size:	Greatest dimension: 8 cm
Laterality:	Left
Tumor Size:	Greatest dimension: 2.5 cm
Final Diagnosis:	Invasive ductal carcinoma
Histologic grade:	3
Stage:	IIIA
Number of nodes examined:	4
Number of positive nodes:	2
Lymphovascular invasion:	Present

Procedures/Addenda

Prognostic Markers by Chromavision ACIS Assisted Quantitative Image Analysis		
Test	Results	Interpretation
ER	1+	Positive
PR	3+	Positive
HER2/neu	3+	Positive



Cancer Stages

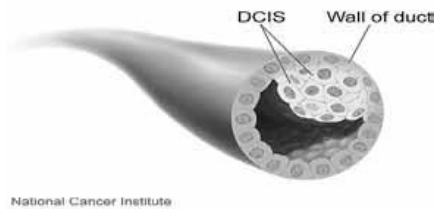
Page 1 of 2

To plan treatment, doctors need to know the extent (stage) of the disease. The stage is based on the size of the tumor and whether the cancer has spread. Staging may involve x-rays and lab tests. These tests can show whether the cancer has spread and, if so, to what parts of the body. When breast cancer spreads, cancer cells are often found in lymph nodes under the arm (axillary lymph nodes). The stage often is not known until after surgery to remove the tumor in the breast and the lymph nodes under the arm.

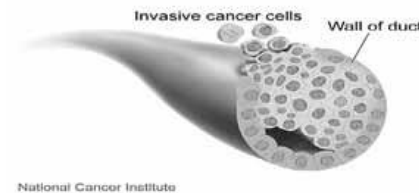
These are the stages of breast cancer:

Stage 0 is carcinoma in situ.

- Lobular carcinoma in situ (LCIS): Abnormal cells are in the lining of a lobule. LCIS seldom becomes invasive cancer. However, having LCIS in one breast increases the risk of cancer in the other breast.
- Ductal carcinoma in situ (DCIS): Abnormal cells are in the lining of a duct. DCIS is also called intraductal carcinoma. The abnormal cells have not spread outside the duct. They have not invaded the nearby breast tissue. DCIS sometimes becomes invasive cancer if not treated.



Stage I is an early stage of invasive breast cancer. The tumor is no more than 2 centimeters ($\frac{3}{4}$ of an inch) across. Cancer cells have not spread beyond the breast.



Stage II is one of the following:

- The tumor is no more than 2 centimeters ($\frac{3}{4}$ of an inch) across. The cancer has spread to the lymph nodes under the arm.
- The tumor is between 2 - 5 centimeters ($\frac{3}{4}$ of an inch to 2 inches). The cancer has not spread to the lymph nodes under the arm.
- The tumor is between 2 - 5 centimeters ($\frac{3}{4}$ of an inch to 2 inches). The cancer has spread to the lymph nodes under the arm.
- The tumor is larger than 5 centimeters (2 inches). The cancer has not spread to the lymph nodes under the arm.



Cancer Stages

Page 2 of 2

Stage III is locally advanced cancer. It is divided into Stage IIIA, IIIB, and IIIC.

Stage IIIA is one of the following:

- The tumor is no more than 5 centimeters (2 inches) across. The cancer has spread to lymph nodes under the arm that are attached to each other or to other structures. Or the cancer may have spread to lymph nodes behind the breastbone.
- The tumor is more than 5 centimeters across. The cancer has spread to underarm lymph nodes that are either alone or attached to each other or to other structures. Or the cancer may have spread to lymph nodes behind the breastbone.

Stage IIIB is a tumor of any size that has grown into the chest wall or the skin of the breast. It may be associated with swelling of the breast or with nodules (lumps) in the breast skin.

- The cancer may have spread to lymph nodes under the arm.
- The cancer may have spread to underarm lymph nodes that are attached to each other or other structures. Or the cancer may have spread to lymph nodes behind the breastbone.
- Inflammatory breast cancer is a rare type of breast cancer. The breast looks red and swollen because cancer cells block the lymph vessels in the skin of the breast. When a doctor diagnoses inflammatory breast cancer, it is at least Stage IIIB, but it could be more advanced.

Stage IIIC is a tumor of any size. It has spread in one of the following ways:

- The cancer has spread to the lymph nodes behind the breastbone and under the arm.
- The cancer has spread to the lymph nodes above or below the collarbone.

Stage IV is distant metastatic cancer. The cancer has spread to other parts of the body.

Recurrent cancer is cancer that has come back (recurred) after a period of time when it could not be detected. It may recur locally in the breast or chest wall. Or it may recur in any other part of the body, such as the bone, liver, or lungs.

Source: U.S. Department of Health and Senior Services, National Institutes of Health, National Cancer Institute. What You Need To Know About™ Breast Cancer



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University Hospital 1 University Place SURGICAL PATHOLOGY REPORT

Patient	
Name:	Jones, Sally
Age:	56
Patient ID:	1234567
Gender:	Female

Specimen(s) Received

Left breast, needle biopsy/core biopsy

Clinical History

Left breast core biopsy

Gross Description

Received are multiple yellow-white-tan core needle biopsies of fibrofatty breast tissue measuring from less than 0.1 cm to 1.1 cm in length.

Description

Specimen Type: Left breast biopsy
 Specimen Size: Greatest dimension: 1.1 cm
 Laterality: Left
 Tumor Size: Greatest dimension: 0.2 mm
 Final Diagnosis: Infiltrating ductal carcinoma
 Histologic grade: 3
 Stage: I
 Number of nodes examined: 0
 Number of positive nodes: 0
 Lymphovascular invasion: Absent

Procedures/Addenda

Prognostic Markers by Chromavision ACIS Assisted Quantitative Image Analysis		
Test	Results	Interpretation
ER	1+	Positive
PR	1+	Positive
HER2/neu	3+	Positive



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**University Hospital
1 University Place
SURGICAL PATHOLOGY REPORT**

Patient	
Name:	Hunter, Pamela
Age:	65
Patient ID:	2345678
Gender:	Female

Specimen(s) Received

Right breast, needle biopsy/core biopsy

Clinical History

Right breast excisional biopsy and sentinel node dissection

Gross Description

Received are pieces of soft tissue measuring 6 x 4 x 8 cm. A grey-tannish nodule is identified.

Description

Specimen Type:	Right breast biopsy
Specimen Size:	Greatest dimension: 8 cm
Laterality:	Right
Tumor Size:	Greatest dimension: 2.5 cm
Final Diagnosis:	Infiltrating ductal carcinoma
Histologic grade:	1
Stage:	II
Number of nodes examined:	3
Number of positive nodes:	0
Lymphovascular invasion:	Absent

Procedures/Addenda

Prognostic Markers by Chromavision ACIS Assisted Quantitative Image Analysis		
Test	Results	Interpretation
ER	2+	Positive
PR	2+	Positive
HER2/neu	1+	Negative



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University Hospital
1 University Place
SURGICAL PATHOLOGY REPORT

Patient	
Name:	Santiago, Luisa
Age:	71
Patient ID:	9876543
Gender:	Female

Specimen(s) Received

Right breast radical mastectomy (including lymph nodes)

Clinical History

Right mastectomy, right breast cancer

Gross Description

Received is an ellipse of tan-white skin, measuring 20 x 9.5 cm. Also received are multiple tan-pink lymph nodes. Multiple sections of fibrofatty tissue are present.

Description

Specimen Type: Right Breast mastectomy
Specimen Size: Greatest dimension: 20 cm
Laterality: Right
Tumor Size: 6.5 x 4 x 2.2 cm
Final Diagnosis: Infiltrating ductal carcinoma
Histologic grade: 2
Stage: IIIA
Number of nodes examined: 3
Number of positive nodes: 1
Lymphovascular invasion: Present

Procedures/Addenda

Prognostic Markers by Chromavision ACIS Assisted Quantitative Image Analysis		
Test	Results	Interpretation
ER	3+	Positive
PR	3+	Positive
HER2/neu	3+	Positive



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University Hospital 1 University Place SURGICAL PATHOLOGY REPORT

Patient	
Name:	Featherston, Brittany
Age:	39
Patient ID:	1144956
Gender:	Female

Specimen(s) Received

Left breast, sentinel node dissection

Clinical History

Biopsy, total mastectomy, left breast cancer

Gross Description

Received is a left total mastectomy specimen measuring 21.5 x 16.0 x 5.0 cm. A mass is felt in the upper inner quadrant of the breast.

Description

Specimen Type:	Left breast, lymph nodes
Specimen Size:	Greatest dimension: 21.5 cm
Laterality:	Left
Tumor Size:	3.4 cm
Final Diagnosis:	Intraductal carcinoma
Histologic grade:	3
Stage:	II
Number of nodes examined:	10
Number of positive nodes:	0
Lymphovascular invasion:	Absent

Procedures/Addenda

Prognostic Markers by Chromavision ACIS Assisted Quantitative Image Analysis		
Test	Results	Interpretation
ER	2+	Positive
PR	3+	Positive
HER2/neu	0	Negative



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University Hospital
1 University Place
SURGICAL PATHOLOGY REPORT

Patient	
Name:	Addington, Claire
Age:	43
Patient ID:	31012117
Gender:	Female

Specimen(s) Received

Right breast sentinel node, right breast lumpectomy

Clinical History

Right breast cancer

Gross Description

Received is a specimen of adipose tissue measuring 2.5 x 1.5 x 1 cm. Lymph nodes are also received.

Description

Specimen Type:	Right breast lumpectomy, lymph nodes
Specimen Size:	Greatest dimension: 20 cm
Laterality:	Right
Tumor Size:	3.5 cm
Final Diagnosis:	Ductal carcinoma in situ
Histological grade:	1
Stage:	0
Number of nodes examined:	2
Number of positive nodes:	0
Lymphovascular invasion:	Absent

Procedures/Addenda

Prognostic Markers by Chromavision ACIS Assisted Quantitative Image Analysis		
Test	Results	Interpretation
ER	3+	Positive
PR	3+	Positive
HER2/neu	0	Negative



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University Hospital
1 University Place
SURGICAL PATHOLOGY REPORT

Patient	
Name:	Belt, Velma
Age:	44
Patient ID:	9613321
Gender:	Female

Specimen(s) Received

Right breast, sentinel lymph node biopsy, right breast lumpectomy

Clinical History

Right breast lumpectomy, stereotactic core biopsy, sentinel lymph node biopsy

Gross Description

Received is a portion of tissue measuring 5 cm.

Description

Specimen Type:	Right breast lumpectomy, lymph nodes
Specimen Size:	Greatest dimension: 5 cm
Laterality:	Right
Tumor Size:	3.5 cm
Final Diagnosis:	Infiltrating ductal carcinoma
Histologic grade:	1
Stage:	II
Number of nodes examined:	2
Number of positive nodes:	0
Lymphovascular invasion:	Absent

Procedures/Addenda

Prognostic Markers by Chromavision ACIS Assisted Quantitative Image Analysis		
Test	Results	Interpretation
ER	3+	Positive
PR	3+	Positive
HER2/neu	0	Negative



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University Hospital 1 University Place SURGICAL PATHOLOGY REPORT

Patient	
Name:	Carrell, Marguerite
Age:	39
Patient ID:	1144956
Gender:	Female

Specimen(s) Received

Left breast, left sentinel lymph node biopsy

Clinical History

Left breast cancer, bilateral mastectomy

Gross Description

Received is a portion of adipose tissue that measures 2 x 1.5 x 0.5 cm and contains several lymph nodes. Also received is the left breast which measures 17.5 x 17 x 2 cm. The largest tumor measures 1.9 cm and is tan-white in color.

Description

Specimen Type: Left breast biopsy, Lymph nodes
 Specimen Size: Greatest dimension: 17.5 cm
 Laterality: Left
 Tumor Size: 1.9 cm
 Final Diagnosis: Infiltrating ductal carcinoma
 Histologic grade: 3
 Stage: II
 Number of nodes examined: 9
 Number of positive nodes: 2
 Lymphovascular invasion: Absent

Procedures/Addenda

Prognostic Markers by Chromavision ACIS Assisted Quantitative Image Analysis		
Test	Results	Interpretation
ER	1+	Positive
PR	1+	Positive
HER2/neu	3+	Positive



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University Hospital 1 University Place SURGICAL PATHOLOGY REPORT

Patient	
Name:	Woolsey, Jonathan
Age:	58
Patient ID:	117349
Gender:	Male

Specimen(s) Received

Left breast, left sentinel lymph node biopsy

Clinical History

Left breast cancer, Left radical mastectomy

Gross Description

Received is a left radical mastectomy specimen that measures 14.5 x 12 x 3 cm and contains several lymph nodes. The largest tumor measures 2.3 x 2.2 x 2.0 cm and is tan-gray to tan-yellow in color.

Description

Specimen Type: Left mastectomy, Lymph nodes
 Specimen Size: Greatest dimension: 14.5 cm
 Laterality: Left
 Tumor Size: 2.3 cm
 Final Diagnosis: Invasive ductal carcinoma
 Histologic grade: 3
 Stage: III
 Number of nodes examined: 20
 Number of positive nodes: 6
 Lymphovascular invasion: Absent

Procedures/Addenda

Prognostic Markers by Chromavision ACIS Assisted Quantitative Image Analysis		
Test	Results	Interpretation
ER	1+	Positive
PR	3+	Positive
HER2/neu	0	Negative



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University Hospital 1 University Place SURGICAL PATHOLOGY REPORT

Patient	
Name:	Lohman, Naomi
Age:	60
Patient ID:	2194230
Gender:	Female

Specimen(s) Received

Sentinel lymph node left axilla, left breast tissue

Clinical History

Left breast lumpectomy, left breast cancer

Gross Description

Received is a specimen of yellow-pink-tan adipose tissue measuring 1.2 x 1 x 0.5 cm. Also received is a portion of breast tissue with attached ellipse of skin. The specimen measures 6.5 x 5.5 x 3 cm.

Description

Specimen Type:	Left breast lumpectomy, lymph nodes
Specimen Size:	Greatest dimension: 6.5 cm
Laterality:	Left
Tumor Size:	1.7 cm
Final Diagnosis:	Invasive ductal carcinoma
Histologic grade:	2
Stage:	I
Number of nodes examined:	3
Number of positive nodes:	0
Lymphovascular invasion:	Absent

Procedures/Addenda

Prognostic Markers by Chromavision ACIS Assisted Quantitative Image Analysis		
Test	Results	Interpretation
ER	2+	Positive
PR	0	Negative
HER2/neu	0	Negative



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University Hospital 1 University Place SURGICAL PATHOLOGY REPORT

Patient	
Name:	Haygood, Rose
Age:	48
Patient ID:	5703536
Gender:	Female

Specimen(s) Received

Sentinel node breast, sentinel node right axillary tissue, right breast mass

Clinical History

Right breast carcinoma

Gross Description

Received is a specimen measuring 9.5 x 7 x 3.5 cm. Two samples containing lymph nodes were also received. The specimen contained a tumor measuring 1 cm.

Description

Specimen Type:	Right breast biopsy, lymph nodes
Specimen Size:	Greatest dimension: 9.5 cm
Laterality:	Right
Tumor Size:	1 cm
Final Diagnosis:	Infiltrating ductal carcinoma
Histologic grade:	1
Stage:	I
Number of nodes examined:	2
Number of positive nodes:	0
Lymphovascular invasion:	Absent

Procedures/Addenda

Prognostic Markers by Chromavision ACIS Assisted Quantitative Image Analysis		
Test	Results	Interpretation
ER	3+	Positive
PR	3+	Positive
HER2/neu	0	Negative



Tumor Grade

Page 1 of 2

What is a tumor?

To understand tumor grade, it is helpful to know how tumors form. The body is made up of many types of cells. Normally, cells grow and divide to produce new cells in a controlled and orderly manner. Sometimes, however, new cells continue to be produced when they are not needed. As a result, a mass of extra tissue called a tumor may develop. A tumor can be benign or malignant. Cells in malignant tumors are abnormal and divide without control or order. These cancerous cells can invade and damage nearby tissue, and spread to other parts of the body .

What is tumor grade?

Tumor grade is a system used to classify cancer cells in terms of how abnormal they look under a microscope and how quickly the tumor is likely to grow and spread. Many factors are considered when determining tumor grade, including the structure and growth pattern of the cells. The specific factors used to determine tumor grade vary with each type of cancer.

Histologic grade, also called differentiation, refers to how much the tumor cells resemble normal cells of the same tissue type. Nuclear grade refers to the size and shape of the nucleus in tumor cells and the percentage of tumor cells that are dividing.

Tumor grade should not be confused with the stage of a cancer. Cancer stage refers to the extent or severity of the cancer, based on factors, such as the location of the primary tumor, tumor size, number of tumors, and lymph node involvement (spread of cancer into lymph nodes).

How is tumor grade determined?

If a tumor is suspected to be malignant, a doctor removes a sample of tissue or the entire tumor during a biopsy. A pathologist examines the tissue to determine whether the tumor is benign or malignant. The pathologist can also determine the tumor grade and identify other characteristics of the tumor cells.

What do the different tumor grades signify?

Based on the microscopic appearance of cancer cells, pathologists commonly describe tumor grade by four degrees of severity: Grades 1, 2, 3, and 4. The cells of Grade 1 tumors resemble normal cells, and tend to grow and multiply slowly. Grade 1 tumors are generally considered the least aggressive in behavior. Grade 2 tumors are more aggressive than Grade 1 tumors. Conversely, the cells of Grade 3 or Grade 4 tumors do not look like normal cells of the same type. Grade 3 and 4 tumors tend to grow rapidly and spread faster than tumors with a lower grade.



Tumor Grade

Page 2 of 2

Does tumor grade affect a patient's treatment options?

Doctors use tumor grade and many other factors, such as cancer stage, to develop an individual treatment plan for a patient and to predict a patient's prognosis. Generally, a lower grade indicates a better prognosis (the likely outcome or course of a disease; the chance of recovery or recurrence). However, the importance of tumor grade in planning treatment and estimating a patient's prognosis is greater for certain types of cancers, such as soft tissue sarcoma, primary brain tumors, lymphomas, and breast and prostate cancer. Patients should speak with their doctor about tumor grade and how it relates to their diagnosis and treatment.

Source: U.S. Department of Health and Senior Services, National Institutes of Health, National Cancer Institute. Tumor Markers: Questions and Answers.



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University Hospital 1 University Place Surgical Pathology Report

Patient	
Name:	Williams, Sarah
Age:	53
Patient ID:	A1136KB
Gender:	Female

Specimen(s) Received

Right breast biopsy

Clinical History

Stereotactic mammotome biopsy

Gross Description

Received are multiple, tan/yellow, cylindrical pieces of soft tissue the largest measuring 1.5 x 0.3 cm.

Description

Specimen Type: Right breast biopsy
 Specimen Size: Greatest dimension: 1.5 cm
 Laterality: Right
 Tumor Size: Greatest dimension: 0.5 cm
 Final Diagnosis: Infiltrating ductal carcinoma
 Histologic grade: 1
 Stage: I
 Number of nodes examined: 0
 Number of positive nodes: 0
 Lymphovascular invasion: Absent

Procedures/Addenda

Prognostic Markers by Chromavision ACIS Assisted Quantitative Image Analysis		
Test	Results	Interpretation
ER	3+	Positive
PR	3+	Positive
HER2/neu	0	Negative



Cancer Treatment Factsheet: Biological Therapy

Biological therapy helps the immune system fight cancer. The immune system is the body's natural defense against disease. Part of the immune system's response to disease is the production of antibodies; proteins which bind to foreign substances. Monoclonal antibodies are substances produced in the laboratory which immitate natural antibodies. Monoclonal antibodies are designed to locate and bind to cancer cells wherever they are in the body. They can be used in cancer detection or therapy as each one recognizes and binds to a different protein. Monoclonal antibodies can also be used to deliver drugs, toxins, or radioactive material directly to a tumor.

Trastuzumab ("tras-TU-zoo-mab") or Herceptin® is a monoclonal antibody which targets cancer cells that overexpress a specific protein called HER-2/neu. HER-2/neu is a protein involved in normal cell growth, and it is overexpressed in some fast-growing cancers. By binding to HER-2/neu positive cells, trastuzumab can slow or stop the growth of the cancer cells. Trastuzumab can be used in the treatment of HER-2/neu positive breast cancer patients whose cancer has metastasized.

Trastuzumab is given intravenously. It may be given alone or with chemotherapy. Trastuzumab is a form of systemic therapy because it travels through the bloodstream to reach cells all over the body.

The first time a patient receives Trastuzumab, the most common side effects are fever and chills. Some patients also have pain, weakness, nausea, vomiting, diarrhea, headaches, difficulty breathing or rashes. Side effects usually become milder after the first treatment.

Trastuzumab may also cause heart damage. This may lead to heart failure. Trastuzumab can also affect the lungs. It can cause breathing problems that require a doctor at once. Before a patient receives Trastuzumab, their doctor will check for the heart and lungs. During treatment, the doctor will watch for signs of lung problems.

Sources: U.S. Department of Health and Senior Services, National Institutes of Health, National Cancer Institute. What You Need To Know About™ Breast Cancer and "Herceptin (Trastuzumab): Questions and Answers."



Cancer Treatment Factsheet: Chemotherapy

Chemotherapy uses powerful drugs to attack rapidly dividing cancer cells. Chemotherapy is a form of systemic treatment because the drugs travel in the bloodstream and target cells throughout the body. Chemotherapy for breast cancer is usually a combination of drugs. The drugs may be given as a pill or by injection into a vein. Once in the bloodstream, the drugs circulate through the body attacking the original tumor as well as cancer cells that may have spread to other parts of the body.

Patients with breast cancer can have chemotherapy in an outpatient part of the hospital, at the doctor's office or at home. Some patients need to stay in the hospital during treatment.

Side effects depend mainly on the specific drugs and the dose. Since chemotherapy drugs target all rapidly dividing cells in the body, not just cancer cells, the following cell types may be affected:

- **Blood cells:** These cells fight infection, help blood to clot, and carry oxygen to all parts of the body. When drugs affect blood cells, patients are more likely to get infections, bruise or bleed easily, and feel very weak and tired. Years after chemotherapy, some patients can develop leukemia (cancer of the blood cells).
- **Cells in hair roots:** Chemotherapy can cause hair loss. Their hair will grow back, but it may be somewhat different in color and texture.
- **Cells that line the digestive tract:** These are also rapidly dividing cells affected by chemotherapy drugs. Therefore, chemotherapy can cause poor appetite, nausea and vomiting, diarrhea, or mouth and lip sores.

Doctors can suggest ways to control many of these side effects.

Some drugs used for breast cancer can cause tingling or numbness in the hands or feet. This problem usually goes away after treatment is over. Other problems may not go away. In some patients, the drugs used for breast cancer may weaken the heart.

Some anticancer drugs can damage the ovaries. The ovaries may stop making hormones. Some women may have symptoms of menopause. The symptoms include hot flashes and vaginal dryness. Menstrual periods may no longer be regular or may stop altogether. Some women become infertile (unable to become pregnant). For women over the age of 35, infertility is likely to be permanent.

Source: U.S. Department of Health and Senior Services, National Institutes of Health, National Cancer Institute. What You Need To Know About™ Breast Cancer



Cancer Treatment Factsheet: Hormone Therapy

Some breast tumors need hormones to grow. Hormone therapy is a systemic treatment that keeps cancer cells throughout the body from getting or using the natural hormones they need. Lab tests can determine whether a tumor is hormone sensitive; has receptors for the hormones estrogen or progesterone. If someone has this kind of tumor, they may receive hormone therapy.

This treatment uses drugs or surgery:

- **Drugs:** The doctor may suggest a drug that can block the natural hormone from reaching the tumor. One such drug is Tamoxifen, which blocks estrogen. Another type of drug prevents the body from producing hormones. An aromatase inhibitor is a drug that prevents the formation of estradiol, a female hormone, by interfering with an aromatase enzyme. If the patient has not gone through menopause, their doctor may give them a drug that stops the ovaries from making estrogen.
- **Surgery:** If the patient has not gone through menopause, they may have surgery to remove the ovaries. The ovaries are the main source of the body's estrogen. A woman who has gone through menopause does not need surgery. (The ovaries produce less estrogen after menopause.)

The side effects of hormone therapy depend largely on the specific drug or type of treatment. Tamoxifen is the most common hormone treatment. In general, the side effects of Tamoxifen are similar to some of the symptoms of menopause. The most common are hot flashes and vaginal discharge. Other side effects are irregular menstrual periods, headaches, fatigue, nausea, vomiting, vaginal dryness or itching, irritation of the skin around the vagina, and skin rash. Not all women who take Tamoxifen have side effects.

It is possible to become pregnant when taking Tamoxifen, however this drug may harm the unborn baby. If the patient is still menstruating, they should discuss birth control methods with their doctor. Serious side effects of Tamoxifen are rare. However, it can cause blood clots in the veins. Blood clots form most often in the legs and in the lungs. Women may also have a slight increase in their risk of stroke. Tamoxifen can cause cancer of the uterus. Patients should get regular pelvic exams from their doctor. Patients should tell their doctor about any unusual vaginal bleeding between exams. When the ovaries are removed, menopause occurs at once. The side effects are often more severe than those caused by natural menopause. Health care providers can suggest ways to cope with these side effects.

Source: U.S. Department of Health and Senior Services, National Institutes of Health, National Cancer Institute. What You Need To Know About™ Breast Cancer



Cancer Treatment Factsheet: Radiation Therapy

Radiation therapy is a local therapy using high-energy rays to kill cancer cells in the breast and surrounding lymph node area. Most patients receive radiation therapy after breast-sparing surgery (removes the cancer but not the breast). Some patients receive radiation therapy after a mastectomy. Studies have found equal survival rates for breast-sparing surgery (with radiation therapy) and mastectomy for Stage I and Stage II breast cancer. Treatment depends on the size of the tumor and other factors. The radiation destroys breast cancer cells that may remain in the area after surgery.

Some patients have radiation therapy before surgery to destroy cancer cells and shrink the tumor. Doctors use this approach when the tumor is large or may be hard to remove. Some patients also have chemotherapy or hormone therapy before surgery.

Doctors use two types of radiation therapy to treat breast cancer. Some women receive both types:

- External radiation: The radiation comes from a large machine outside the body. Most patients go to a hospital or clinic for treatment. Treatments are usually five days a week for several weeks.
- Internal radiation: Thin plastic tubes that hold a radioactive substance are put directly in the breast. The implants stay in place for several days. A patient stays in the hospital while they have implants. Doctors remove the implants before going home.

Side effects depend mainly on the dose and type of radiation and the part of the body treated. It is common for the skin in the treated area to become red, dry, tender and itchy. The breast may feel heavy and tight. These problems will go away over time. Toward the end of treatment, the skin may become moist and “weepy.” Exposing this area to air as much as possible can help the skin heal. Bras and some other types of clothing may rub the skin and cause soreness. Patients may want to wear loose-fitting cotton clothes during this time. Gentle skin care is also important. Patients should check with their doctor before using any deodorants, lotions or creams on the treated area. These effects of radiation therapy on the skin will go away and the area gradually heals once treatment is over. However, there may be a lasting change in skin color. Although the side effects of radiation therapy can be distressing, doctors can usually relieve them.

Patients are likely to become very tired during radiation therapy, especially in the later weeks of treatment. Resting is important, but doctors usually advise patients to try to stay as active as they can.

Source: U.S. Department of Health and Senior Services, National Institutes of Health, National Cancer Institute. What You Need To Know About™ Breast Cancer



Cancer Treatment Factsheet: Surgery

Page 1 of 2

Surgery is the most common treatment for breast cancer. It is a form of local therapy, because it targets the cancer in the breast tumor. There are several types of surgery. Your doctor can explain each type, discuss and compare the benefits and risks, and describe how each will change the way a patient looks:

- **Breast-sparing surgery:** (Remove the cancer but not the breast.) Also called breast-conserving surgery, lumpectomy, segmental mastectomy, and partial mastectomy. Sometimes an excisional biopsy serves as a lumpectomy because the surgeon removes the whole lump. After breast-sparing surgery, most women receive radiation therapy to the breast. This treatment destroys cancer cells that may remain in the breast.
- **Mastectomy:** Remove the breast, or as much of the breast tissue as possible. Some women have radiation therapy after surgery.
- **Lymph Node Biopsy:** When a patient undergoes surgery to remove a breast tumor, a sentinel lymph node biopsy or an axillary lymph node dissection is often performed. During a sentinel lymph node biopsy, the surgeon removes a few of the lymph nodes closest to the tumor in order to determine if the cancer has spread there. If the doctor finds cancer cells in the sentinel lymph nodes, more nodes may be removed. In an axillary lymph node dissection, the surgeon removes the underarm lymph nodes.
- **Breast reconstruction:** Plastic surgery to rebuild the shape of the breast following a mastectomy. This may be done at the same time as a mastectomy or later.

Studies have found equal survival rates for breast-sparing surgery (with radiation therapy) and mastectomy for Stage I and Stage II breast cancer.

The time it takes to heal after surgery is different for everyone. Surgery causes pain and tenderness. Medicine can help control the pain. Before surgery, patients should discuss the plan for pain relief with their doctor or nurse. After surgery, doctors can adjust the plan if more relief is needed. Any kind of surgery also carries a risk of infection, bleeding or other problems. Patients should tell their health care provider right away if they develop any problems.

Patients may feel off balance if they've had one or both breasts removed, especially if they have large breasts. This imbalance can cause discomfort in the neck and back. Also, the skin where the breast was removed may feel tight. Arm and shoulder muscles may feel stiff and weak. These problems usually go away. The doctor, nurse, or physical therapist can suggest exercises to help regain movement and strength. Exercise can also reduce stiffness and pain. Some patients may be able to begin gentle exercises within days of surgery.



Cancer Treatment Factsheet: Surgery

Page 2 of 2

Because nerves may be injured or cut during surgery, patients may have numbness and tingling in their chest, underarm, shoulder, and upper arm. These feelings usually go away within a few weeks or months, but for some patients, numbness does not go away.

Removing the lymph nodes under the arm slows the flow of lymph fluid. The fluid may build up in the arm and/or hand and cause swelling. This swelling is called lymphedema. Lymphedema can develop right after surgery or months to years later.

Patients will need to protect their arm and hand on the side that was treated for the rest of their life:

- Avoid wearing tight clothing or jewelry on the affected arm
- Carry a purse or luggage with the other arm
- Use an electric razor to avoid cuts when shaving underarms
- Have shots, blood tests, and blood pressure measurements on the other arm
- Wear gloves to protect the hands when gardening and when using strong detergents
- Have careful manicures and avoid cutting the cuticles
- Avoid burns or sunburns to the affected arm and hand

Patients should ask their doctor how to handle any cuts, insect bites, sunburn, or other injuries to their arm or hand. Also, patients should contact their doctor if their arm or hand is injured, swells, or becomes red and warm.

If lymphedema occurs, the doctor may suggest a patient raise their arm above their heart whenever they can. The doctor may show patients hand and arm exercises. Some women with lymphedema wear an elastic sleeve to improve lymph circulation. Medication, manual lymph drainage (massage), or use of a machine that gently compresses the arm may also help. Patients with lymphedema may be referred to a physical therapist or another specialist.

Source: U.S. Department of Health and Senior Services, National Institutes of Health, National Cancer Institute. What You Need To Know About™ Breast Cancer and “Sentinal Lymph Node Biopsy: Questions and Answers”



Cancer Treatments Summary

Name: _____

Date: _____

Complete the following table:

Treatment	Impact on cell activity	Materials & Equipment	Side effects	Used when ...
Surgery	Removes some or all cancer cells/tissues			
Radiation Therapy		Source of radiation		
Chemotherapy			Hair loss, bruising, more susceptible to infections, fatigue, nausea, diarrhea	
Hormone Therapy				Patient tests positive for estrogen and progesterone receptors
Biological Therapy			Can affect the heart's ability to pump blood	



Cancer Treatments Summary Answers

Complete the following table :

Treatment	Impact on cell activity	Materials & Equipment	Side effects	Used when ...
Surgery	Removes some or all cancer cells/ tissues	Anesthesia, Scalpel, etc	Wound infections, pain, tenderness	Patient is recommended to remove part or all of the breast
Radiation Therapy	Destroys cells with internal or external radiation	Source of radiation	Redness, swelling, fatigue	A lumpectomy is performed, or after a mastectomy when the tumor is larger
Chemotherapy	Destroys cells with anticancer drugs	Drugs: IVs and/ or pills	Hair loss, bruising, more susceptible to infections, fatigue, nausea, diarrhea	A tumor is large and needs to be shrunk before surgery or as part of therapy after surgery has removed part or all of the breast
Hormone Therapy	Prevents cancer cells from getting or using the hormones they need	Drugs and possible surgery to remove ovaries	Symptoms of menopause	Patient tests positive for estrogen and progesterone receptors
Biological Therapy	Binds to sites on cells and blocks proteins allowing cancer cells to grow	Drugs	Can affect the heart's ability to pump blood	Patient tests HER2/neu positive



Clinical Trials: Facts and Myths

People who join clinical trials are just “guinea pigs” for research.

A person can leave a clinical trial whenever they want.

Cancer treatment clinical trials only provide “last resort” treatment.

You do not have to have cancer to participate in a cancer clinical trial.

Many people who join cancer treatment clinical trials get a sugar pill (placebo) instead of being treated.



Clinical Trials: Facts and Myths

Positive results from studies conducted on mice may not translate into positive outcomes for humans.

Clinical trials are only held in large cities.

New treatments may not always be better than standard treatments.

There are no real benefits to participating in a clinical trial.

A person can only sign up for a clinical trial if they agree to it.



Clinical Trials: Facts and Myths

Name: _____

Date: _____

TRUE

FALSE

- | | | |
|-------|-------|--|
| _____ | _____ | People who join clinical trials are just “guinea pigs” for research. |
| _____ | _____ | A person can leave a clinical trial whenever they want. |
| _____ | _____ | Cancer treatment clinical trials only provide “last resort” treatment. |
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| _____ | _____ | There are no real benefits to participating in clinical trials. |
| _____ | _____ | A person can only sign up for a clinical trial if they agree to it. |



Clinical Trials: Facts and Myths

TRUE	FALSE	Answers
<input type="checkbox"/>	<input checked="" type="checkbox"/>	People who join clinical trials are just “guinea pigs” for research.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	A person can leave a clinical trial whenever they want.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Cancer treatment clinical trials only provide “last resort” treatment.
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<input type="checkbox"/>	<input checked="" type="checkbox"/>	There are no real benefits to participating in clinical trials.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	A person can only sign up for a clinical trial if they agree to it.



Treatment Choices by Stage

Page 1 of 3

Treatment options depend on the stage of disease and these factors:

- The size of the tumor in relation to the size of the breast;
- The results of lab tests (such as whether the breast cancer cells need hormones to grow);
- Whether the patient has gone through menopause; and
- The patient's general health.

Below are brief descriptions of common treatments for each stage. Other treatments may be appropriate for some women. Clinical trials can be an option at all stages of breast cancer.

Stage 0

Stage 0 breast cancer refers to lobular carcinoma in situ (LCIS) or ductal carcinoma in situ (DCIS).

LCIS: Most women with LCIS do not have treatment. Instead, the doctor may suggest regular checkups to watch for signs of breast cancer. Some women take Tamoxifen to reduce the risk of developing breast cancer. Others may take part in studies of promising new preventive treatments. Having LCIS in one breast increases the risk of cancer for both breasts. A very small number of women with LCIS try to prevent cancer with surgery to remove both breasts. This is a bilateral prophylactic mastectomy. The surgeon usually does not remove the underarm lymph nodes.

DCIS: Most women with DCIS have breast-sparing surgery followed by radiation therapy. Some women choose to have a total mastectomy. Underarm lymph nodes are not usually removed. Women with DCIS may receive Tamoxifen to reduce the risk of developing invasive breast cancer.

Stages I, II, IIIA, and Operable IIIC

Patients with Stage I, II, IIIA, and operable (can treat with surgery) IIIC breast cancer may have a combination of treatments. Some may have breast-sparing surgery followed by radiation therapy to the breast. This choice is common for patients with Stage I or II breast cancer. Others may decide to have a mastectomy.

With either approach, patients (especially those with Stage II or IIIA breast cancer) often have lymph nodes under the arm removed. The doctor may suggest radiation therapy after mastectomy if cancer cells are found in one to three lymph nodes under the arm, or if the tumor in the breast is large. If cancer cells are found in more than three lymph nodes under the arm, the doctor usually will suggest radiation therapy after mastectomy.



Treatment Choices by Stage

Page 2 of 3

The choice between breast-sparing surgery (followed by radiation therapy) and mastectomy depends on many factors:

- The size, location, and stage of the tumor;
- The size of the breast;
- Certain features of the cancer;
- How the woman feels about saving her breast;
- How the woman feels about radiation therapy; and
- The woman's ability to travel to a radiation treatment center.

Some patients may have chemotherapy before surgery. This is called neoadjuvant therapy (treatment before the main treatment). Chemotherapy before surgery may shrink a large tumor so that breast-sparing surgery is possible. Women with large Stage II or IIIA breast tumors often choose this treatment.

After surgery, many patients receive adjuvant therapy. Adjuvant therapy is treatment given after the main treatment to increase the chances of a cure. Radiation treatment can kill cancer cells in and near the breast. Women may also have systemic treatment (uses substances that travel through the bloodstream, reaching and affecting cells all over the body) such as chemotherapy, hormone therapy, or both. This treatment can destroy cancer cells that remain anywhere in the body. It can prevent the cancer from coming back in the breast or elsewhere.

Stages IIIB and Inoperable IIIC

Women with Stage IIIB (including inflammatory breast cancer) or inoperable Stage IIIC breast cancer usually have chemotherapy.

If the chemotherapy shrinks the tumor, the doctor then may suggest further treatment.

- **Mastectomy:** The surgeon removes the breast. In most cases, the lymph nodes under the arm are removed. After surgery, a woman may receive radiation therapy to the chest and underarm area.
- **Breast-sparing surgery:** The surgeon removes the cancer but not the breast. In most cases, the lymph nodes under the arm are removed. After surgery, the patient may receive radiation therapy to the breast and underarm area.
- **Radiation therapy instead of surgery:** Some patients have radiation therapy but no surgery. The doctor also may recommend more chemotherapy, hormone therapy or both. This therapy may help prevent the disease from coming back in the breast or elsewhere.



Treatment Choices by Stage

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Stage IV

In most cases, people with Stage IV breast cancer have hormone therapy, chemotherapy or both. Some also may have biological therapy. Radiation may be used to control tumors in certain parts of the body. These treatments are not likely to cure the disease, but they may help someone live longer.

Many patients have supportive care along with anticancer treatments. Anticancer treatments are given to slow the progress of the disease. Supportive care helps manage pain, other symptoms or side effects (such as nausea). It does not aim to extend a woman's life. Supportive care can help people feel better physically and emotionally. Some patients with advanced cancer decide to have only supportive care.

Recurrent Breast Cancer

Recurrent cancer is cancer that has come back, usually after a period of time during which it could not be detected. The cancer may come back to the same place as the original (primary) tumor or to another place in the body. Treatment for the recurrent disease depends mainly on the location and extent of the cancer. Another main factor is the type of treatment the patient had before.

If breast cancer comes back only in the breast after breast-sparing surgery, the patient may have a mastectomy. Chances are good that the disease will not come back again.

If breast cancer recurs in other parts of the body, treatment may involve chemotherapy, hormone therapy or biological therapy. Radiation therapy may help control cancer that recurs in the chest muscles or in certain other areas of the body.

Treatment can seldom cure cancer that recurs outside the breast. Supportive care is often an important part of the treatment plan. Many patients have supportive care to ease their symptoms and anticancer treatments to slow the progress of the disease. Some receive only supportive care to improve their quality of life.

Source: U.S. Department of Health and Senior Services, National Institutes of Health, National Cancer Institute. What You Need To Know About™ Breast Cancer



Clinical Trials Factsheet

Page 1 of 6

Clinical trials are research studies involving people. They are the final step in a long process that begins with preliminary laboratory research and animal testing. Clinical trials try to answer specific scientific questions to find better ways to prevent, detect or treat diseases or to improve care for people with diseases.

In cancer research, a clinical trial is designed to show how a certain anticancer approach - for instance, a promising drug, a new surgical procedure, a new diagnostic test, or a possible way to prevent cancer - affects the people who receive it.

Types of Clinical Trials

- **Treatment trials** test new treatments.
- **Prevention trials** look for the best way to prevent cancer in people who have never had cancer, or to prevent cancer from coming back or a new cancer occurring in people who have already had cancer.
- **Screening trials** test the best way to find cancer, especially in its early stages.
- **Diagnostic trials** examine new tests or procedures that can better identify whether people have cancer.
- **Quality of Life trials** explore ways to improve comfort and quality of life for cancer patients.

For a treatment to become part of standard treatment, it must first go through 3 or 4 clinical trial phases. The early phases make sure the treatment is safe. Later phases show if it works better than the standard treatment.

Purpose	Number of people
Phase I	
To find a safe dose To decide how the new treatment should be given To see how the new treatment affects the human body	15-30
Phase II	
To determine if the new treatment has an effect on a certain cancer To see how the new treatment affects the human body	Less than 100
Phase III	
To compare the new treatment (or new use of a treatment) with the current standard treatment	From 100 to thousands
Phase IV	
To further assess the long-term safety and effectiveness of a new treatment	Several hundred to several thousand



Clinical Trials Factsheet

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The guidelines that clinical trials follow clearly state who will be able to join the study and the treatment plan. Every trial has a person in charge, usually a doctor, who is called the principal investigator. The principal investigator prepares a plan for the study, called a protocol, which is like a recipe for conducting a clinical trial.

The protocol explains what the trial will do, how the study will be carried out, and why each part of the study is necessary. It includes information on:

- The reason for doing the study
- Who can join the study
- How many people are needed for the study
- Any drugs they will take, the dose, and how often
- What medical tests they will have and how often
- What information will be gathered about them

Who Can Join a Clinical Trial?

Based on the questions the research is trying to answer, each clinical trial protocol clearly states who can or cannot join the trial. Eligibility criteria can be general (age, sex, type of cancer) to specific (cancer stage, tumor characteristics). Common criteria for entering a trial include the following:

- Having a certain type or stage of cancer
- Having received a certain kind of therapy in the past
- Being in a certain age group

Criteria such as these help ensure that people in the trial are as alike as possible. This way doctors can be sure that the results are due to the treatment being studied and not other factors. These criteria also help ensure:

- Safety
Some people have health problems besides cancer that could be made worse by the treatments in a study. People interested in joining a trial will receive medical tests to be sure they are not put at increased risk.
- Accurate and meaningful study results
A patient may not be able to join some clinical trials if they already had another kind of treatment for their cancer. Otherwise, doctors could not be sure whether results were due to the treatment being studied or the earlier treatment.



Clinical Trials Factsheet

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Researchers use many different techniques to reduce bias in clinical trials, including blinding and randomization. Bias occurs when a trial's results are affected by human choices or other factors not related to the treatments being tested.

Blinding

Trials set so that participants do not know which intervention they are receiving are known as single-blinded trials. Those in which neither researchers nor participants know who is in the investigational or control group are called double-blinded trials. Double-blinded trials ensure that people assessing the outcome will not be influenced by knowing which intervention a participant is receiving and also that follow-up treatment will be the same.

Randomization

Randomization is a process used in some clinical trials to prevent bias. Randomization helps ensure that unknown factors do not affect trial results.

Randomization is used in all phase III and some phase II trials. These trials are called randomized clinical trials. Participants will be assigned by chance to either an investigational group or a control group. Group assignment will be determined with a computer program or table of random numbers.

- The control group is made up of people who will get the most widely accepted treatment (standard treatment) for their cancer.
- The investigational group is made up of people who will get the new agent or intervention being tested.

Comparing these groups to each other often clearly shows which treatment is more effective or has fewer side effects. People thinking about joining a randomized clinical trial need to understand they have an equal chance to be assigned to either one of the groups. The doctor does not choose the group.

Placebos

A placebo is designed to look like the medicine being tested, but it is not active. Placebos are almost never used in cancer treatment trials. Placebos may only be used in treatment trials when



Clinical Trials Factsheet

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there is no standard treatment. In some cases, a study may compare standard treatment plus a new treatment, to standard treatment plus a placebo. Participants will be told if the study uses a placebo.

Endpoints

An endpoint is a measurable outcome that indicates an intervention's effectiveness. Endpoints differ depending on the phase and type of trial. For instance, a treatment trial endpoint could be tumor response or participant survival. Quality-of-life or supportive care trial endpoints could include participants' welfare and control of symptoms.

Examples of endpoints include:

- Tumor response rate - the proportion of trial participants whose tumor was reduced in size by a specific amount, usually described as a percentage. If 7 of 10 patients responded, the response rate is 70%.
- Disease-free survival - the amount of time a participant survives without cancer occurring or recurring, usually measured in months.
- Overall survival - the amount of time a participant lives, typically measured from the beginning of the clinical trial until the time of death.

Ending Trials Early

There can be compelling reasons for halting a trial early. If participants experience severe side effects, or if there is clear evidence that risks outweigh benefits, the Institutional Review Board (IRB) and Data and Safety Monitoring Boards (DSMB) will recommend that the trial be stopped early. A trial might also be stopped if there is clear evidence that the new intervention is effective - in order to make it widely available.

Patient Protection

Federal rules help ensure that clinical trials are run in an ethical manner. Participants rights and safety are protected through:

- Informed consent;
- Careful review and approval of the clinical trial protocol by a scientific review panel and an IRB; and
- Ongoing monitoring provided during the trial by the IRB, DSMBs for phase III trials and the research team.



Clinical Trials Factsheet

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Informed Consent

Informed consent is a process through which people learn the purpose, risks and benefits of a clinical trial before deciding whether to join. It is a critical part of ensuring patient safety in research. During the informed consent process people learn important information about a clinical trial. This information may help them decide whether to join.

The research team, which is made up of doctors and nurses, explains the trial's purpose, procedures and risks and benefits.

They will also discuss participant's rights, including the right to:

- Make a decision about participating
- Leave the study at any time.
- Learn about all treatment options
- Learn all that is involved in the trial - including all details about treatment, tests, and possible risks and benefits
- Discuss the trial with the principal investigator and other members of the research team
- Both hear and read the information in a language they can understand

After discussing all aspects of the study, the team gives the candidate an informed consent form to read. The form includes written details about the information that was discussed and also describes the privacy of personal records. If the candidate agrees to take part in the study, they sign the form. But even after someone signs the consent form, they can leave the study at any time.

Most clinical trials have to go through different types of review that are designed to protect all people who take part. These reviews are conducted by scientific review panels, IRBs, and DSMBs.

Deciding to Take Part in Clinical Trials

Whenever someone needs treatment for cancer, clinical trials may be an option. Choosing to join a clinical trial is something only an individual, those close to them and doctors and nurses can decide together.

Weighing the Pros and Cons

As a treatment option, a clinical trial has possible benefits as well as drawbacks. People considering participating should discuss the following issues with their doctor and the people close to them.



Clinical Trials Factsheet

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Possible Benefits

- Clinical trials offer high-quality cancer care. If someone is in a randomized study and does not receive the new treatment being tested, they will receive the best known standard treatment. This may be as good as, or better than, the new approach.
- If a new treatment is proven to work, the participant may be among the first to benefit.
- By looking at the pros and cons of clinical trials and other treatment choices, participants take an active role in a decision that affects their life.
- The chance to help others and improve cancer treatment.

Possible Drawbacks

- New treatments under study are not always better than, or even as good as, standard care.
- If patients receive standard care instead of the new treatment being tested, it may not be as effective as the new approach.
- New treatments may have side effects that doctors do not expect or that are worse than those of standard treatment.
- Even if a new treatment has benefits, it may not work for some individuals. Even standard treatments, proven effective for many people, do not help everyone.
- Health insurance and managed care providers do not always cover all patient care costs in a study. What they cover varies by plan and by study. To find out in advance what costs are likely to be paid in your case, participants should check with their insurance company and talk to a doctor, nurse or social worker from the study.

Source: U.S. Department of Health and Senior Services, National Institutes of Health, National Cancer Institute. Taking Part in Cancer Treatment Research Studies.



Design a Clinical Trial

Page 1 of 3

Name: _____

Date: _____

The standard treatment for women with Stage I, II or IIIA breast cancer that has spread to lymph nodes in the armpit is chemotherapy. Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die.

During chemotherapy, patients receive infusions, or the slow injection of a fluid into a vein or tissue, of drugs. For this trial, patients will get 1 course of the chemotherapy drugs doxorubicin and cyclophosphamide every 3 weeks. Patients will receive four courses of treatment. About 3 weeks after the last course, these patients receive an infusion of paclitaxel every 3 weeks for four courses.

Findings from a new clinical trial suggest adding a new monoclonal antibody, Drug X, to standard chemotherapy treatment may be more effective for treating breast cancer. Monoclonal antibodies (MOABs) are a form of biological therapy now being studied in the laboratory and in clinical trials. The dosage for Drug X includes an infusion once a week for 51 weeks. Design a clinical trial to test the efficacy of Drug X.

1. In your own words, describe the research question.
2. Explain what type of clinical trial you will design.
3. What is your hypothesis?
4. Explain your independent and dependent variables.
5. Describe what medical and health professionals will be on the research team.



Design a Clinical Trial

Page 2 of 3

6. Describe the clinical trial protocol. Include a diagram that outlines the study design. Be sure to include the following:
 - The number of people who will be in the study
 - Describe eligibility criteria
 - Describe the control and investigational groups
 - What materials will be needed (agents, dosage, and timing of dosage)
 - Explain what your endpoints (outcomes) will be and how they will be measured
 - What medical tests participants will have and how often
 - What information will be collected about participants
 - How will you tell if Drug X is working
 - Outline the timeline



Design a Clinical Trial

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7. How will you address randomization?
8. Describe who would be interested in participating. Explain the benefits and barriers someone might face in this clinical trial. How will you recruit patients to your study?
9. Describe three possible outcomes and explain the implications of each.
10. How will you address any unexpected outcomes?
11. Explain how you will protect patient rights.



Design a Clinical Trial

Answers

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The standard treatment for women with stage I, II or IIIA breast cancer that has spread to lymph nodes in the armpit is chemotherapy. Drugs used in chemotherapy use different ways to stop tumor cells from dividing so they stop growing or die.

During chemotherapy, patients receive infusions of the chemotherapy drugs doxorubicin and cyclophosphamide every 3 weeks for four courses. About 3 weeks after the last course, these patients will receive an infusion of paclitaxel every 3 weeks for four courses.

Findings from a new clinical trial suggest adding a new monoclonal antibody, Drug X, to standard chemotherapy treatment may be more effective for treating breast cancer. Monoclonal antibodies (MOABs) are a form of biological therapy now being studied in the laboratory and in clinical trials. The dosage for Drug X includes an infusion once a week for 51 weeks. You will design a clinical trial to test the efficacy of Drug X.

1. In your own words, describe the research question.

Answers will vary. Sample response: Does taking a new drug, Drug X, during standard chemotherapy lead to better outcomes for breast cancer patients whose disease has spread to their under-arm lymph nodes?

2. Explain what type of clinical trial you will design.

A treatment trial. A Phase II study to determine if new treatment is effective or a Phase III study to see if the new treatment is better than standard care.

3. What is your hypothesis?

Answers will vary. Sample response: If Drug X is better than the standard treatment, then patients taking Drug X will have better outcomes.

4. Explain your independent and dependent variables.

*Independent variable - receipt of Drug X by members of the investigational group.
Dependent variable - response to Drug X*

5. Describe what medical and health professionals will be on the research team.

*Primary investigator, usually a doctor, who designs the study and prepares the protocol;
doctors and nurses*



Design a Clinical Trial

Answers

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6. Describe the clinical trial protocol. Include a diagram that outlines the study design. Be sure to include the following:

Answers will vary, but responses may include the following:

- The number of people who will be in the study

Phase II trials range from 100 to thousands; Phase III trials from 100 to thousands of people.

- Describe eligibility criteria

Age, sex, geographic location, cancer type and stage.

- Describe the control and investigational groups

Control group will receive standard chemo; investigational group will receive the new treatment being tested (standard chemo plus Drug X).

- What materials will be needed (agents, dosage, and timing of dosage)

Standard chemo includes infusions of doxorubicin and cyclophosphamide every 2 weeks for 4 courses. Investigational group will also receive one infusion of Drug X per week for 51 weeks.

- Explain what your endpoints (outcomes) will be and how they will be measured

Tumor response rate, overall survival, quality of life.

- What medical tests participants will have and how often

Test to measure tumor response rate may include clinical breast exams, MRI, mammograms at regular intervals to determine changes in tumor size; questions to determine patient quality of life and side effects of the drug.

- What information will be collected about participants

Age, sex, race, medical history, family history, cancer pathology, etc...

- How will you tell if Drug X is working

Compare outcomes of investigational group to those of control group. If Drug X is effective, we would expect to see better outcomes in the investigational group compared to the control group; ie greater tumor response, better survival rate.



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- Outline the timeline

	Week(s)	Infusion
Course 1	1	doxorubicin and cyclophosphamide
	2-3	
Course 2	4	doxorubicin and cyclophosphamide
	5-6	
Course 3	7	doxorubicin and cyclophosphamide
	8-9	
Course 4	10	doxorubicin and cyclophosphamide
	11-12	

Investigational group will also receive infusion of Drug X weeks 1 through 51.

- How will you address randomization?

Answers may vary. Sample responses: Use a random number generator to assign each patient to either the investigational or control group. The trial may be blinded, either single (participant does not know if they are in the investigational or control group) or double (neither the participant nor the provider knows). Students may also note limiting bias by ensuring that investigators do not have a financial interest in the outcome.

- Describe who would be interested in participating. Explain the benefits and barriers someone might face in this clinical trial. How will you recruit patients to your study?

Answers will vary. Sample responses: Patients who are interested might be eager to try new treatments or interested in helping to advance cancer research. Potential benefits might include better quality of life, tumor response, and survival. Barriers to participation might include misinformation regarding clinical trials, mistrust of doctors, fear of possible side effects or worse outcomes, and concern about cost.

Recruitment answers will vary - look for creative responses.



Design a Clinical Trial

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9. Describe 3 possible outcomes and explain the implications of each.

Answers will vary. Sample response: There are three possible outcomes for patients taking Drug X; they may do better than patients taking the standard treatment, they may do worse, or they may fare the same. If there is convincing evidence that patients on Drug X are doing much better than patients receiving standard care, the trial may be ended early to make the drug widely available. If there is evidence that the risks outweigh the benefits of Drug X, the trial could end early.

10. How will you address any unexpected outcomes?

Answers should include making a report to IRB. The study may end early if risks of the trial outweigh benefits, or if there is evidence that the experimental treatment is more effective than standard care.

11. Explain how you will protect patient rights.

Gain approval before starting study, continuous monitoring by IRB, DSMB, and research team. Must obtain informed consent before new patients are started on the trial. Patients are told about potential risks of the study and that they can leave the trial at any time.

Lesson 4 Quiz



1. Pathology is the study and diagnosis of diseases in living things by examining:
 - a. Tissues
 - b. Organs
 - c. Cells
 - d. Fluids
 - e. All of the above

2. Match the description of a pathology report on the left with the section name on the right.

____ Has descriptions of the samples themselves (i.e. color, size).	a. Specimen(s) Received
____ Refers to the patient's breast cancer history, such as procedures that have been done and the diagnosis.	b. Clinical History
____ Shows test results, such as ER & PR receptor tests.	c. Gross Description
____ Lists exactly where the tissues were taken from.	d. Final Pathologic Diagnosis
Procedures/Addenda	e.
____ Has the pathologist's diagnosis based on the findings of tissue samples.	

3. Explain three characteristics of a patient's cancer that is located in the description section of a pathology report.

4. Explain why pathology reports are important.

5. An anatomical pathologist studies body fluids of patients including blood, plasma, urine, respiratory mucous and cerebrospinal fluid.
 - a. True
 - b. False

6. What is biological therapy? Explain who can benefit from using Trastuzumab and how it fights cancer.

7. Why does chemotherapy make many patients lose their hair?

8. Hormone therapy drugs kill cancer cells by:
 - a. Starving them
 - b. Feeding them hormones
 - c. Outnumbering them
 - d. Fighting them

9. Approximately how many of all breast cancer diagnoses are estrogen receptor positive?
 - a. 3/4
 - b. 1/2
 - c. 1/4
 - d. 2/3

10. Compare and contrast a mastectomy and a lumpectomy.



11. What are some of the potential benefits to participating in a clinical treatment trial?



Lesson 4 Quiz Answers

1. Pathology is the study and diagnosis of diseases in living things by examining:

e. All of the above

2. Match the description of a pathology report on the left with the section name on the right.

c. Gross Description	Has descriptions of the samples themselves (i.e. color, size)
b. Clinical History	Refers to the patient's breast cancer history, such as procedures that have been done and the diagnosis
e. Procedures/Addenda	Shows test results such as ER & PR receptor tests
a. Specimen(s) Received	Lists exactly where the tissues were taken from
d. Final Pathologic Diagnosis	Has the pathologist's diagnosis based on the findings of tissue samples

3. Explain three characteristics of a patient's cancer that is located in the description section of a pathology report.

Answers will vary, but can include specimen type, size, laterality, diagnosis, histological grade, stage, number of lymph nodes and lymphovascular invasion.

4. Explain why pathology reports are important.

Pathology reports are written medical documents that describe specimens that were collected by a doctor and sent to a pathologist for analysis.

5. An anatomical pathologist studies body fluids of patients including blood, plasma, urine, respiratory mucous and cerebrospinal fluid.

b. False. Anatomical pathologists study the organs, tissues, and cells of patients. third checkpoint occurs at the point in metaphase where all the chromosomes should have aligned at the mitotic plate. This checkpoint is responsible for starting anaphase.

6. What is biological therapy? Explain who can benefit from using Trastuzumab and how it fights cancer.

Biological therapy fights cancer by aiding the patients immune system. Patient's whose cancer cells overexpress the protein HER-2/neu can use a monoclonal antibody called Trastuzumab. Trastuzumab recognizes and binds to cells with HER-2/neu. This slows or halts the growth of cancer cells.

7. Why does chemotherapy make many patients lose their hair?

Chemotherapy is not selective to only cancer cells. Other healthy cells in the body may be affected, such as those in the skin, hair or bone marrow.

8. Hormone therapy drugs kill cancer cells by:



a. Starving them

9. Approximately how many of all breast cancer diagnoses are estrogen receptor positive?

a. 3/4

10. Compare and contrast a mastectomy and a lumpectomy

A mastectomy removes the whole breast while a lumpectomy removes only the tumor and surrounding tissue. Both are surgical procedures used to treat and cure cancer.

11. What are some of the potential benefits to participating in a clinical treatment trial?

Answers will vary. Participants receive high-quality care. Participants in a randomized trial will either receive the new treatment being tested (which may be better than current treatments) or the best known standard treatment. Participants improve cancer treatments and help future patients.