



MODULE 3

TYPES OF RESEARCH STUDIES

Overview of Module 3: Types of Research Studies

This section will include:

- **Why Do We Do Research?**
- **Finding a Research Question**
- **Matching a Research Type to a Question**
- **Understanding Types of Research Studies**

Estimated Time Commitment: *45-60 minutes*



Instructions for Going through Module 3

You do not need to go through the module in one sitting. Feel free to take breaks and complete at your own pace!

We have broken the module up into 2 sections with suggested breaks:

Part 1 – Background on Research and Observational/Experimental Studies (Slides 5-21)

Part 2 – Quantitative, Qualitative and Patient-Centered Research (Slides 23-35)



Key Terms Used in this Module

- You will hear a lot of **new terms** during this module that you might not know
- We do **not expect you to know what these terms mean right away or memorize them** – just to familiarize yourself with the words
- Here is a **link to the key terms** used in this module that you can reference as you go through - click [here](#)

Part 1

**Background on Research and
Observational/Experimental Studies**

(Slides 5 to 21)

What is Research?

Research:

- is a **process**
- uses **scientific approach** rather than opinions to improve health
- **gathers and studies** information
- is focused on **increasing our understanding** of a topic
- is designed to **answer a question** through planned, **organized steps**



Why Do We Do Research?

Our **opinions and personal observations** are important but **vary from person to person** and from situation to situation.

Research helps us: **answer a question, make a decision or understand a topic systematically, by following a plan** and putting our opinion aside.



Before we (*individuals, hospitals, governmental agencies, insurers*) spend time, money and energy trying to fix a problem—**we need to have the best possible information about the problem, condition, question or topic.**



Why Do We Do Research continued...

An EXAMPLE of Why We Do Research: Stem Cell Therapy for COPD

Stem cells are immature cells found in the body that may be able to become many types of tissue...

A Hopeful Idea	The role of stem cells is not entirely understood but <i>there is some evidence that they may play a role in repairing injured tissue.</i>
Unproven Statements and Opinions	Many clinics in the United States and elsewhere offer stem cell therapy to COPD patients. These clinics claim that the stem cell therapy will help COPD patients. This therapy can be very expensive, yet these clinics can provide <i>no scientific evidence that it works.</i>
The Current Reality/The Facts	A well-designed <i>research study proved</i> that stem cells were <i>safe</i> for people with COPD, <i>but after two years</i> of follow-up there was <i>no evidence of any improvement</i> in lung function, shortness of breath, exercise capacity or quality of life of the COPD patients who received the stem cell treatment.
More Research Needed	We <i>do not yet know how to direct stem cells</i> to repair the lung. <i>Clinical trials</i> studying stem cells and COPD <i>continue today</i> —to better understand how stem cells affect the lungs and COPD. The Food and Drug Administration has <i>not approved stem cell therapy as a treatment for COPD due to lack of evidence.</i>

Patient-Focused or “Human Subjects” Research

Scientific and medical research is done in many steps

- ***Molecular***—What does the disease look like at the cellular level and can we impact the process?
- ***Animal research***—Is there any evidence that this works in animals with conditions similar to humans?
- ***Human Subjects***—Studying in humans for safety and then people with the disease for impact on people/patients



*****This “BRIDGE: Patient to Investigator” training will focus on types of research that involve patients, patient information or care given to patients*****

Research: Finding a Question and Study Type

Making decisions in medicine requires answering many questions. The following questions are often asked by physicians and patients:

- What is the **cause** of the condition or disease?
- What is the **natural progression** of the disease if it is **not treated**?
- What will happen next?
- How **many other people have this** same disease or condition?
- How does **the body deal with** this disease?
- How do **other people cope** with this disease?
- If a specific **treatment** is given, **what will change and is it safe**?
- Does the **treatment impact different groups (ethnic, gender, race)** of people in **different ways**?

Each of these questions can be answered by a ***different type of research study.***

Many are important in deciding whether or not to test a new treatment.

There are many types of research studies.

Types of Research

To properly answer specific questions, most health or medical research studies can be **separated into two broad categories:**

**Observational Research
or
Experimental Research**



Types of Research: Observational vs. Experimental

Observational Research	Experimental Research
<p>Researchers gather information or data about something that is already happening.</p> <p>Nothing is changed. There is no intervention other than usual treatment.</p> <p>The research team observes, gathers, measures, records and then analyzes the information gathered and makes a conclusion.</p>	<p>Researchers have a new treatment that they think may have a positive impact on the disease. To test this, they intervene or change something in the patient’s life—a drug is given, a procedure is done, etc.</p> <p>The research team makes a change with one group of patients and then observes how this change affected the patient.</p> <p>The “changed” or intervention group is often compared to a group that is not changed—a group that did not receive the intervention — called the usual care or control group (received a placebo)</p>

Types of Research: Observational vs. Experimental

Observational

“Studies that use existing information or new information by watching without interfering”

Observe, Measure, Record, Analyze

Here are the types of studies under this category (definitions in the following slides):

Cohort Study

Cross-sectional Study

Case-control Study

Epidemiology Study

Experimental

“Studies that require something new or include some type of action/change”

Change, Observe the Effects of the Change, Compare, Conclude

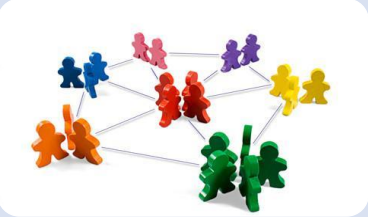
Here are the types of studies under this category (definitions in the following slides):

Randomized Controlled Trial

Pragmatic Clinical Trial

Comparative Effectiveness Study

Types of Observational Studies



Cohort Study:

Studies and compares a “cohort” of people (a group of people who share a defining characteristic)— over an extended period of time. For example, observes and may compare those who have one behavior (or exposure) like smoking to those who don’t have the behavior/exposure. Or those who have quit smoking to those who have not.



Cross-Sectional Study:

Uses a survey/interview to gather facts (and sometimes opinions) from a selected group of people for a specific topic and usually for a limited time period.



Case-Control Study:

Looks backwards to determine what might be associated with a certain result. Compares individuals with the result (or disease) to those without—looking for reasons, behaviors, situations that caused the one group to have the result or disease. May use interviews or a review of medical records to identify cases and controls.



Epidemiology Studies:

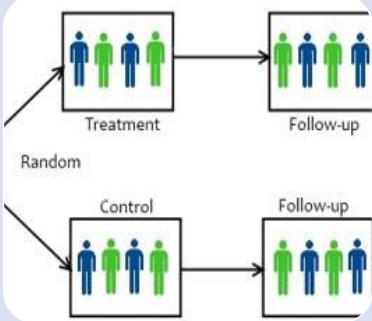
An epidemiology study uses new observations or existing information like what is in medical records to better define a condition and who is likely to have that condition in a population of people.

Don't worry, you do not need to memorize the specifics of these types of studies, but we did want you to be introduced to them. You can learn more about these studies by clicking [here](#).

Types of Research: Observational vs. Experimental

<u>Observational</u> “Studies that use existing information or new information by watching without interfering” Observe, Measure, Record, Analyze	<u>Experimental</u> “Studies that require something new or include some type of action/change” Change, Observe the Effects of the Change, Compare, Conclude
✓ Cohort Study	Randomized Controlled Trials
✓ Cross-sectional Study	Pragmatic Clinical Trials
✓ Case-control Study	Comparative Effectiveness Studies
✓ Epidemiology Study	

Types of Experimental Studies



Randomized-Controlled (Randomized-Clinical) Trial:

“Randomized” means **divided into two groups by chance**. Participants are assigned to **either the group getting the treatment** or drug—or the **group getting a “placebo”**—an inactive drug—a “fake” or “dummy” drug by a method like flipping a coin or by a computer program. Then the **two groups are compared** for the preselected results.



Pragmatic Clinical Trials:

Study in which participants are assigned to treatments in the settings where they live, work, or receive health care. Other types of studies test how treatments work in carefully controlled settings, but pragmatic studies look at how treatments work in everyday care.



Comparative Effectiveness Trials

These studies put **people randomly into two or more groups to compare newer medications with other medications**. They are usually done after both types of medications have been shown to work in a randomized clinical or control trial. They often have less intervention like fewer study visits and try to make the study similar to what happens in everyday practice.

Don't worry, you do not need to memorize the specifics of these types of studies, but we did want you to be introduced to them. You can learn more about these studies by clicking [here](#).

MODULE 3: REVIEW QUESTIONS (PART 1)

- The next few slides have some questions to help you review and remember what we have presented so far in this Module.
- This is not a graded test and is meant to only help you retain the information from this Module. There is an answer key at the end.
- Here are a couple documents to help you as you go through the review questions:
 - **Key Terms:** click [here](#)
 - **Types of Studies**
 - **Experimental:** click [here](#)
 - **Observational:** click [here](#)
- If you have any questions, please email BRIDGE@copdfoundation.org



MODULE 3: REVIEW QUESTIONS (PART 1)

1. Choose the answer below that best answers the question: “We do research to....”

- a) Answer a question
- b) Help make decisions
- c) Know more about a topic
- d) Get the best possible information about a topic, problem, disease or question
- e) All of the above

2. BRIDGE: Patient to Investigator Training is focused on which type of research (choose one answer below):

- a) Animal—studying how treatments work in animals
- b) Molecular—studying disease at the cellular level
- c) Human Subjects—research that deals with patients, patient information or care given to patients
- d) All of the above.

MODULE 3: REVIEW QUESTIONS (PART 1) CONTINUED...

Observational research studies vs. Experimental research studies:

3. Which of the following statements is NOT TRUE for Observational studies? (choose one)

- a) Researchers gather information about something that has already happened.
- b) Nothing is changed—there is no intervention.
- c) Researchers make a change with one group of patients and observe how the change affected the patients.
- d) The research team observes, gathers, measures, records and analyzes information and makes a conclusion.

4. Which of the following statements is NOT TRUE for Experimental studies (choose one)

- a) The research team makes a change with one group of patients and then observes how this change affected the patient.
- b) The “changed” or *intervention group* is often compared to a group that is not changed—a group that did not receive the intervention -- called the usual care or *control group*.
- c) Researchers gather information about something that has already happened.

MODULE 3: REVIEW QUESTIONS (PART 1) CONTINUED...

	"O" or "E"
5. Which of these "types of studies" are Observational and which are Experimental ?	
a) Cohort study —a group of people are studied over an extended period of time.	
b) Cross-sectional study —a selected group of people are interviewed/surveyed on a topic during a specific time frame	
c) Randomized Controlled (Clinical) Trial —People are assigned to either the group that gets the treatment or the group that gets the "fake" treatment. Groups are compared.	
d) Epidemiology Study —Uses new observations or existing information to better define a condition and who will get it.	
e) Comparative-effectiveness study —2 or more groups compare newer medications to other medications	
f) Case-control study —looks backwards to determine what reasons, behaviors, situations caused a certain result	
g) Pragmatic clinical trial —a change or "intervention" is delivered in a real-world setting	

MODULE 3: REVIEW QUESTIONS (PART 1) ANSWER KEY

1. **e** **Explanation:** All of the answers listed—to answer a question, to help make a decision, to know about a topic and to gather the best information—are ALL good reasons to do research.
2. **c** **Explanation:** We will only be focused on research studies that involve people, specifically: patients and patient caregivers like YOU.
3. **c** **Explanation:** Observational studies have no change or “intervention” that occurs. Observational studies use existing information or new information obtained from observing, interviewing, surveying, etc.
4. **c** **Explanation:** Experimental studies involve a new intervention or change to a group of people, often in comparison to others. So the answer “Researchers gather information about something that has already happened” is NOT TRUE for experimental studies—since this is not a new change or intervention.
5. **“O” for Observational=answers a, b, d, and f** (See slides 12-14 for more explanation)
 “E” for Experimental=answers c, e and g (See slides 12 and 15-16 for more explanation)

You completed Part 1 - Great job!
Feel free to take a break before going on to Part 2



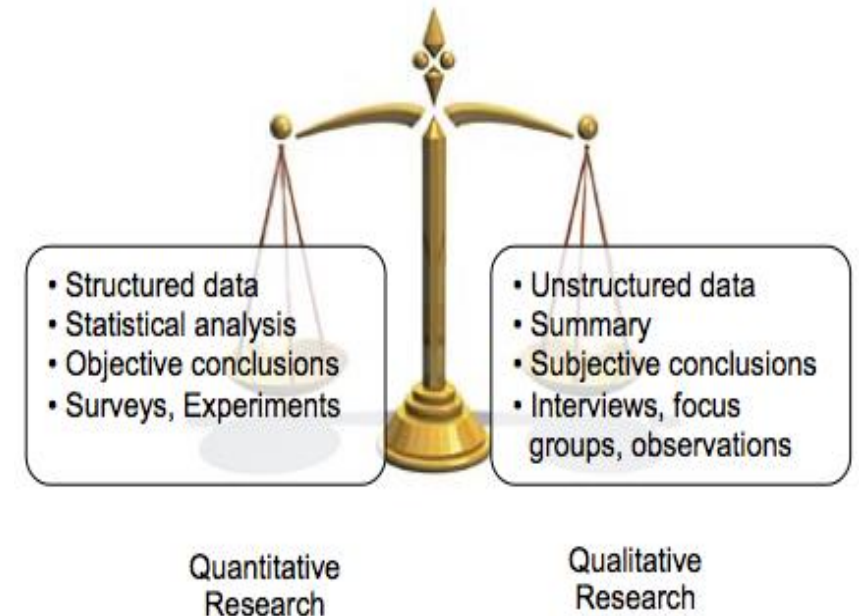
Part 2
Quantitative, Qualitative and
Patient-Centered Research
(Slides 23 to 35)

Types of Studies: Quantitative vs. Qualitative

In addition to organizing studies by Observational vs. Experimental, research studies can be divided into other categories.

Studies can also be categorized as either:

- **Quantitative** (*kwan ti tay tive*)
- **Qualitative** (*kwah li tay tive*) or
- **Mixed Methods**—*combining both quantitative and qualitative*



Types of Studies: Quantitative vs. Qualitative

Quantitative	Qualitative	Mixed Methods
The most common type of medical research	Information collected is often ideas, opinion, beliefs, attitudes, concerns (ideas)	Uses both qualitative and quantitative together
Uses tests or questionnaires or surveys to collect information	Can use focus groups or interviews or oral histories	Might use qualitative first to decide what type of surveys or other quantitative tests to use
The information or data is recorded as numbers	The information is recorded in words not translated to numbers	
Analysis of the data uses the numbers to give results	Analysis of the information tries to summarize the ideas into areas of thoughts often called domains	

Types of Studies: Quantitative vs. Qualitative—An Example

EXAMPLE: Quantitative

Research Question: *“What is the age or weight or lung function or COPD Assessment Test score of people newly diagnosed with COPD?”*

In group of people diagnosed with COPD in past 6 months—

- Ask **their age** and then find the **average age**, **find the range** (oldest and youngest)
- **Weigh people** or **find weight in medical records** and **find the average and range** (lowest and highest weights)
- **Test lung function** and then look at one part like their **forced expiratory volume in 1 second** (how much air they breathe out in one second) and **find the average and range** (highest and lowest number)
- **Ask people to fill out the COPD Assessment Test** using a **number to answer** each question; then add up each person’s score and **find the average score** and how many people had high scores (more than 10 or more than 20) **Use numbers to report people’s COPD status.**

Types of Studies: Quantitative vs. Qualitative—An Example

EXAMPLE: Qualitative

Research Question: *“What are the barriers to getting lung function testing (spirometry) or seeing a pulmonologist or going to pulmonary rehabilitation?”*

- **Ask questions of people** or caregivers of people with COPD from a certain city or from around the country
- Can **use focus groups to ask questions** so people can hear each other’s answer and add to comments of others—usually recorded so can be listened to later and again and again
- Can **use interview of people and ask them to “talk” about the issue**—can be recorded
- From focus groups or interviews—**read or listen to all responses**
- Use the responses of the whole group to **identify common concerns or ideas or barriers**

Types of Studies: Quantitative vs. Qualitative—An Example

EXAMPLE: Mixed Methods

Information from the *qualitative* work can help design a *quantitative* study

For example, in the *qualitative* study—15 people with COPD, there were common themes:

“Pulmonary rehabilitation is...”

- Hard to get---not available
- Costs a lot---not good insurance coverage
- Has not been recommended by doctor or nurse

Use this to determine what types of tests or surveys to do in a *quantitative* study

For example: Do a survey that can be translated into numbers to get information about the barriers

Ask 1000 people with COPD:

- Is there a pulmonary rehabilitation program within 20 miles of your home? (yes or no)
- How much does pulmonary rehabilitation program cost out of your pocket? (less than \$25, \$25 to \$100 or more than \$100)
- Who has recommended pulmonary rehabilitation to you? (No one = 0, Doctor = 1, Nurse =2, RT = 3, or other =4) Count and report how many of each.

Types of Research: Patient-Centered Research

**All the types of studies we have presented can become:
Patient-Centered Outcomes Research...**

<u>Observational</u> “Studies that use existing information or new information by watching without interfering” Observe, Measure, Record, Analyze	<u>Experimental</u> “Studies that require something new or include some type of action/change” Change, Observe the Effects of the Change, Compare, Conclude
✓ Cohort Study	✓ Randomized Controlled Trials
✓ Cross-sectional Study	✓ Pragmatic Clinical Trials
✓ Case-control Study	✓ Comparative Effectiveness Studies
✓ Epidemiology Study	

Types of Research: Patient-Centered Research

Patient-Centered Outcomes Research

- Research that asks questions and studies topics that are **of most interest to patients and their caregivers**
- Focused on **patients' unique perspectives**
- Done with the belief that considering **the patient perspective** will **improve** how **research questions** are developed and how research is done
- It is the **policy of the COPD Foundation** that the best way to get the patient/caregiver perspective is **to include patients/caregivers in the research process**



Types of Research Studies: Patient-Centered

Patient-Centered Research suggests that the **patient or caregiver perspective** is an **important part** of the study.

For example:

In Epidemiology Research...

The factors studied include issues that patients say are important and not just those that scientists or researchers think are important.

For example: People with COPD may want to know--Are COPD outcomes improved by having home health support or a caregiver who lives in the home?

In a Clinical Trial...

The question, the way the study is done, the outcomes and the results include input from patients or caregivers.

For example: Patients suggest that study visits be limited to 45 minutes or less and follow-up questions can be answered online, on the telephone or by mail, as is best for the patient. The final results are shared with all people in the study using language they understand.

MODULE 3: REVIEW QUESTIONS (PART 2)

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MODULE 3: REVIEW QUESTIONS (PART 2)

Match the type of research on the left with the correct description on the right

6. Qualitative Study	a) Uses tests, questionnaires or surveys to collect information which is recorded using numbers. Numbers are also used to report the results. This is the most common type of medical research.
7. Quantitative Study	b) Often uses ideas and opinions collected first to determine what tests to then do for collecting results expressed in numbers.
8. Mixed Methods Study	c) Information collected is often ideas, opinion, beliefs, attitudes, and concerns and can be gathered via focus groups or interviews or oral histories. Results are reported in words and summarized into areas of thoughts called domains.

MODULE 3: REVIEW QUESTIONS (PART 2) CONTINUED...

9. True or false: All of the types of studies discussed in this module and listed in the previous question can become Patient-Centered Outcomes Research?

- a) True
- b) False

10. Which of the following statements is NOT TRUE about Patient-Centered Outcomes Research?

- a) It is research that asks questions and studies topics that are of most interest to patients and their caregivers
- b) It is focused on patients' unique perspectives
- c) Can easily be done with mice in a laboratory setting as well.
- d) Done with the belief that considering the patient perspective will improve how research questions are developed and how research is done

MODULE 3: REVIEW QUESTIONS (PART 2) ANSWER KEY

6. c

7. a

8. b

Explanation: See slides 24-28 for more explanation

9. a-True

Explanation: All of the types of studies discussed in this training can be used with patients and can strive to include the unique patient perspective in their study planning, design and outcomes.

10. c

Explanation: Research done in a laboratory using mice would NOT be Patient-Centered Outcomes Research as it is not involving humans, the unique patient perspective or input from patients.

LINKS TO KEY RESOURCES FOR MODULE 3

Below is a table with links to key resources and information that you might find useful

Takeaway Documents	<ul style="list-style-type: none">• Module 3 Summary Document: click here• Module 3 Review Questions with Answer Key and Explanations: click here• Glossary of Key Terms: click here• Types of Observational Studies: click here• Types of Experimental Studies: click here• NIH: Why do Researchers do Different Kinds of Clinical Studies?: Click here
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**Congratulations! You have
completed Module 3!**

When you are ready, please go on to
***Module 4 – Designing, Doing and
Sharing a Research Study***

You don't have to do this right away –
you can do it when you have time

