

## The Journey

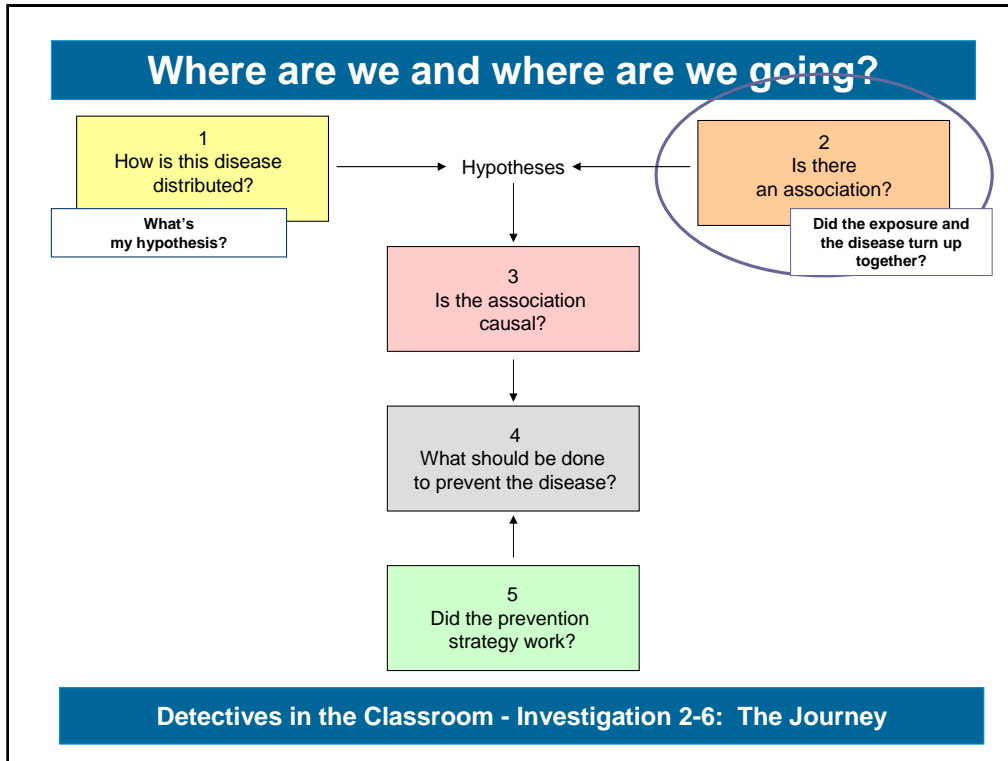
# The Journey



Detectives in the Classroom - Investigation 2-6: The Journey

In **Investigation 2-6: The Journey**, students will learn to describe the four basic epidemiologic study designs and begin to appreciate the advantages and disadvantages of each.

**Next Slide**



Remind students again that in the Module 2 investigations, they are learning how to answer the second Essential Question: “Is there an association between the hypothesized cause and the disease?”

**Next Slide**

## Review



	Disease	No Disease	Total
Exposed			
Not Exposed			



What is a natural experiment?

What is an observational study?

Why do we need to do observational studies?

How is the 2x2 table used to test hypotheses?

Detectives in the Classroom - Investigation 2-6: The Journey

To review, ask students:

- What is a natural experiment? (A natural experiment occurs as people come or do not come in contact with various exposures as they go about their daily lives. Exposure may be a result of lifestyle decisions, such as smoking or diet, or of simply living in a certain location, such as residing near a chemical plant or in an air-polluted city. Everyone is performing natural experiments on herself or himself.)
- What is an observational study? (This is a study in which the investigator looks at the natural experiments that a group of people performed on themselves and determines who was and was not exposed and who did and did not become sick.)
- Why do we need observational studies? (We are limited to observational studies of natural experiments when we want to study something that may be harmful. In such a case, it is not ethical to conduct a real experiment on humans. In other words, we cannot intentionally expose study subjects to something that may cause harm.)
- How is the 2 x 2 table used to test hypotheses? [The 2 x 2 table is an efficient way to show how people are distributed in epidemiologic studies for each combination of exposure and disease (in cells a, b, c, and d). The table makes it easier to calculate and compare risks.]

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## The Journey from Exposure to Disease



Detectives in the Classroom - Investigation 2-6: The Journey

Today students are going to consider several ways to collect and study information from a natural experiment. To help them understand this process, describe the scenario of what an epidemiologist is really trying to understand, that is, *the journey from exposure to disease*.

Explain that for any disease there is a period of time, a *journey*, between the exposure to the cause or causes of the disease and the discovery of the disease.

The length of this journey between exposure and disease can be a matter of hours or days (e.g., food poisoning—12 to 36 hours; the common cold—a few days) or can be many years (e.g., cancer—10 to 30 years). To test hypotheses, epidemiologists study people's natural experiments and observe what happened during this journey.

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## Analogy



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Using a train analogy, describe this journey between exposure and disease. Imagine passengers riding on a train and performing many natural experiments on themselves as they travel. During the train ride, some passengers may or may not come in contact with particular exposures and may or may not develop various diseases.

Discuss the idea of a study design and point out that there are several ways to test hypothesized exposure/disease associations.

Explain that students are already familiar with one study design, the controlled trial, which is the fundamental *experimental* design.

First, they will review the controlled trial study design and then learn about three others used to assess natural experiments.

**Next Slide**

**Epi Talk**

**Epi Talk**

**Study Design**

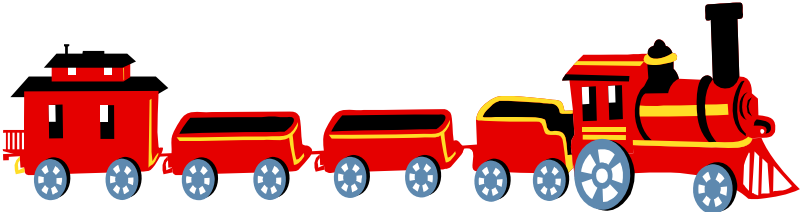
Procedures and methods, established beforehand, that are followed by the investigator conducting the study.

**Detectives in the Classroom - Investigation 2-6: The Journey**

Ask students to find “Study design” in the **Epi Talk** list.  
Review its definition.


**Next Slide**

**Timing**



{

Timing



**E**

**DZ**

When does the epidemiologist start to observe the journey?

When are the passengers identified as exposed or unexposed?

When are the passengers identified as sick or not sick?

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Students should picture different ways the epidemiologist can be involved in studying the journey between exposure and disease.

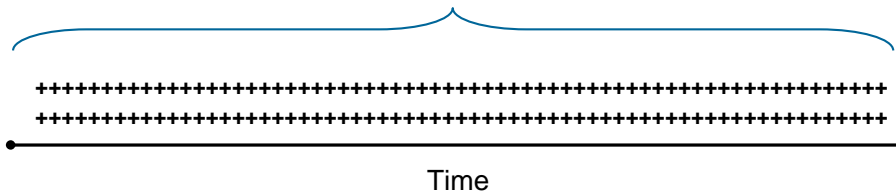
They should think of various ways that information about the exposure and disease can be collected.

In terms of the train ride analogy, the answers to the following three questions distinguish the different study designs:

- When and for how long does the epidemiologist observe the journey?
- When and how often are passengers identified as exposed or unexposed?
- When and how often are passengers identified as sick or not sick?

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## Label the Train Tracks




Detectives in the Classroom - Investigation 2-6: The Journey

For this investigation students will be asked to label four sets of train tracks by placing an “epidemiologist icon” on the tracks at the point where the researcher first starts to be involved in the study, an “E” where passengers are first identified as exposed or unexposed, and a “DZ” where passengers are first identified as sick or not sick.

**Next Slide**

**Label the Train Tracks**

Study Design: **Controlled Trial**



**E** **DZ**

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+++++

Time →

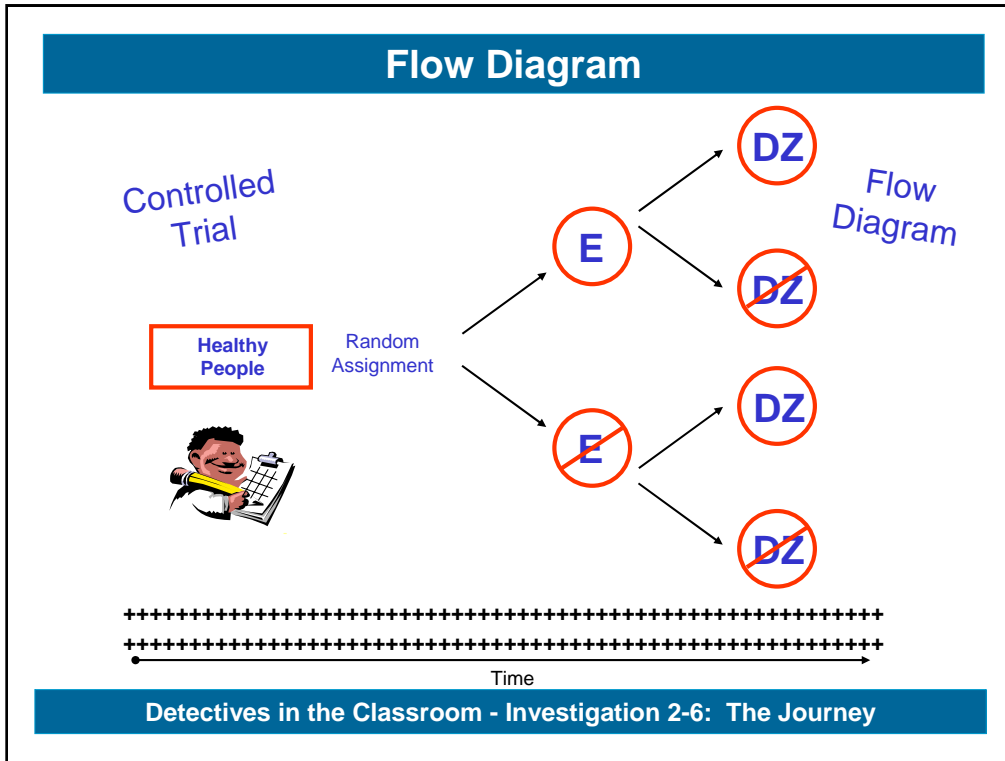
**Detectives in the Classroom - Investigation 2-6: The Journey**

Give each student an **Investigation 2-6: Epi Log Worksheet—Study Design Sheet**. Have students label the first set of train tracks as “Controlled Trial.”

Then ask students to mark the tracks for a controlled trial study design by putting the “epidemiologist icon” at the place on the train track where the researcher *first* starts to be involved in the study, an “E” where passengers are *first* identified as exposed or unexposed, and a “DZ” where passengers are *first* identified as sick or not sick.

Using class discussion, help students realize that in a controlled trial study design, the epidemiologist starts the journey by randomly dividing the passengers into two groups. Before and perhaps during the train ride, the treatment group will be given an exposure and the control group will not be given the exposure. The investigator rides on the train for the entire journey and keeps checking that all passengers are exposing themselves as assigned; the investigator then observes who does and does not develop the disease. For example, in a vaccine trial, the epidemiologist would check how many passengers developed the disease in the vaccine group compared with the control group.

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Explain that a way to show how the study unfolds during the journey is by creating a flow diagram. Specific steps are followed in a certain order. As you present each step, ask students to draw the flow diagram on the **Study Design Sheet**.

Step 1: Select a sample for the controlled trial. All participants are either sick or healthy, depending on what kind of trial it is.

⚙ Teacher Alert: Controlled trials can be used to test the hypothesis that an exposure will prevent a disease from occurring or treat a disease that has already occurred. In a prevention trial (depicted on this slide), the study sample is free of the disease. In a treatment trial, the study sample has the disease.

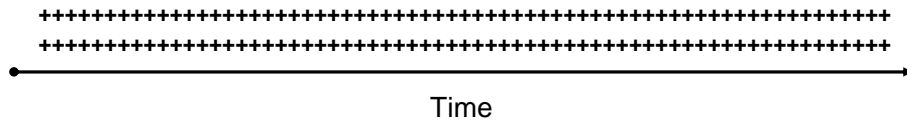
Step 2: Randomly assign the people to treatment and control groups, and give the exposure to the treatment group and not to the control group.

Step 3: At the end of the journey, the risk of disease in the treatment group is calculated and compared with that in the control group.

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## Label the Train Tracks

Study Design: Cohort Study



Detectives in the Classroom - Investigation 2-6: The Journey

Explain that students will learn about three other study designs, one at a time, and figure out how to label a set of train tracks to depict each. In each case, they will put the “epidemiologist icon” at the place on the train track where the researcher first starts to be involved in the study, an “E” where passengers are first identified as exposed or unexposed, and a “DZ” where passengers are first identified as sick or not sick.

Students should label the next set of train tracks as “Cohort Study.”

Then after listening to the description of a cohort study (next slide), each student should mark the tracks for a cohort study with the “epidemiologist icon,” “E,” and “DZ.”

**Next Slide**

## Label the Train Tracks

### Cohort Study

Just as in the controlled trial, the epidemiologist is also on the train during the entire journey. But there is an important difference. The epidemiologist is not telling passengers what to do. Rather, the epidemiologist is just observing them and counting. Passengers are not being told to have or not have an exposure, they are just living their normal lives. The epidemiologist, on the ride for the whole journey, just keeps observing everyone's exposures and whether or not they develop the disease during the journey.

Detectives in the Classroom - Investigation 2-6: The Journey

Read the following to the class:

***Just as in the controlled trial, the epidemiologist is also on the train during the entire journey. But there is an important difference. The epidemiologist is not telling passengers what to do. Rather, the epidemiologist is just observing them and counting. Passengers are not being told to have or not have an exposure; they are simply living their normal lives. The epidemiologist, on the ride for the whole journey, keeps observing everyone's exposures and whether or not they develop the disease during the journey.***

Give students time to label the train tracks.

**Next Slide**

## Label the Train Tracks

Study Design: Cohort Study



E

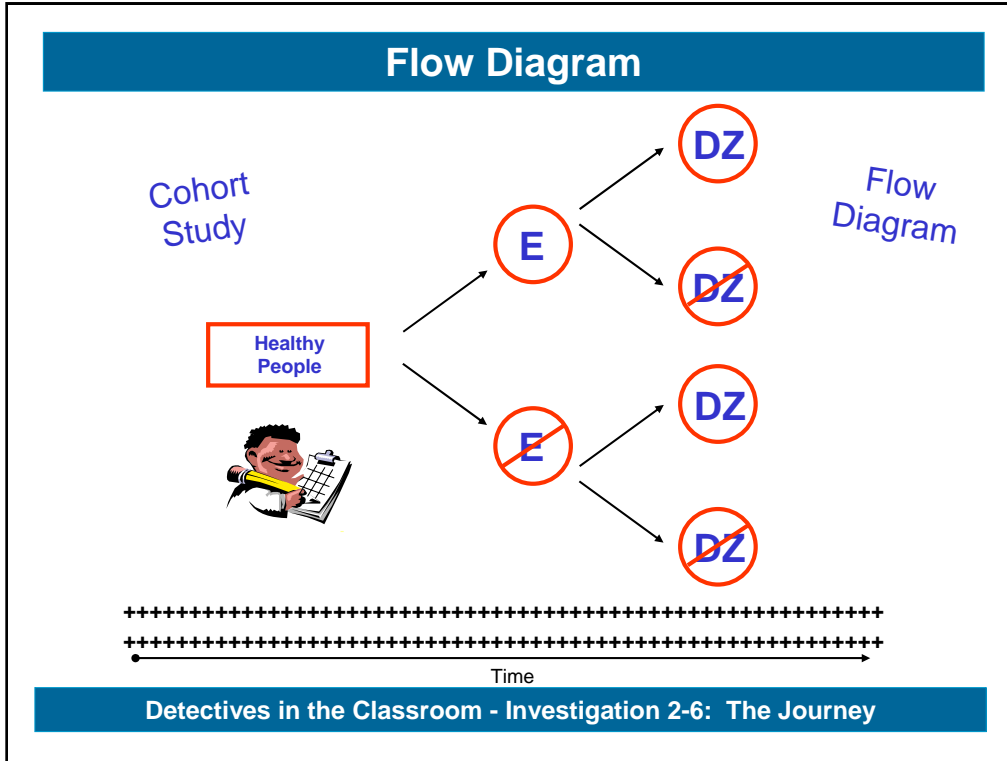
DZ



Detectives in the Classroom - Investigation 2-6: The Journey

Using class discussion, help students realize that in a cohort study, the epidemiologist starts out with a group of people who do not have the disease. The epidemiologist assesses whether each passenger is exposed or not exposed and then rides on the train for the entire journey, continuing to observe who is and is not in contact with the exposure. At the end of the journey, the epidemiologist determines who does and does not develop the disease.

**Next Slide**



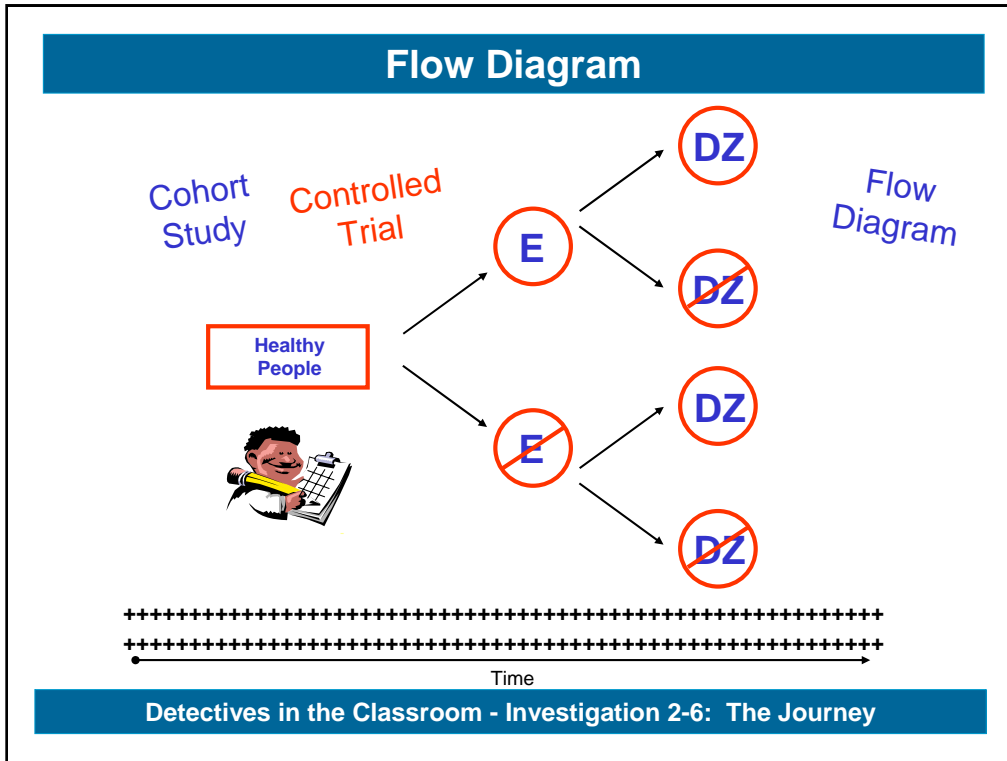
As with the controlled trial, a flow diagram can show how the cohort study unfolds during the journey. Again, specific steps are followed in a certain order. As you present each step, ask students to draw the flow diagram on the **Study Design Sheet**.

Step 1: Find a study population of healthy people.

Step 2: Identify who is and is not exposed.

Step 3: Follow the people through time; calculate the risk of disease in the exposed group and compare it with that in the unexposed group.

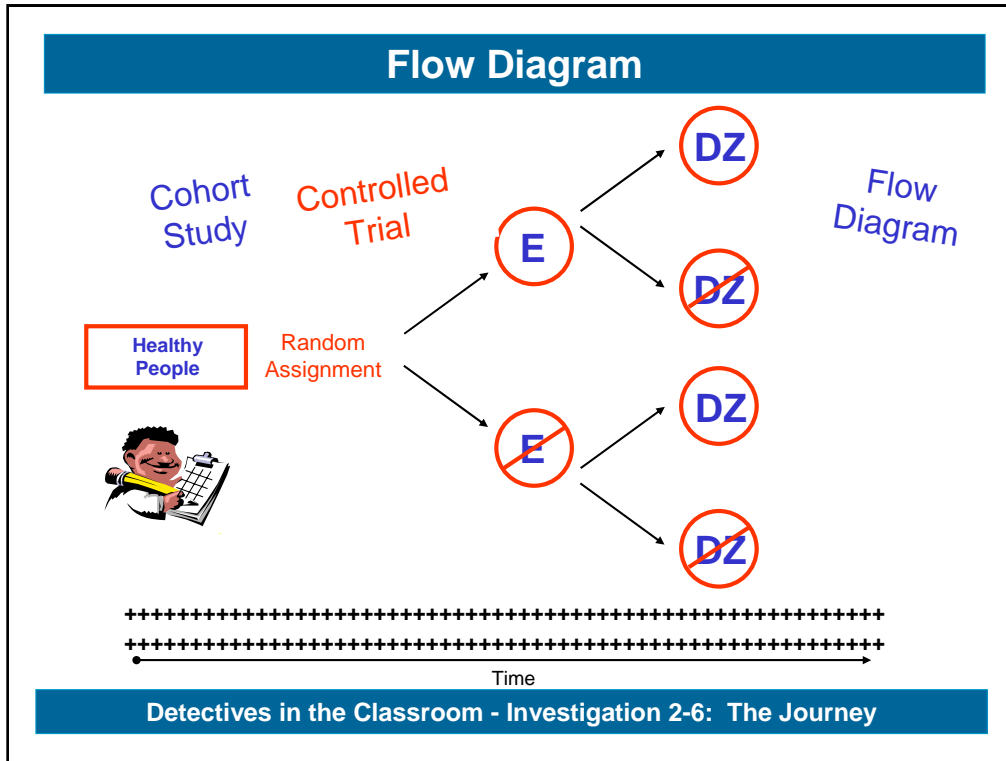
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Ask students:

- How is the design of the cohort study similar to that of the controlled trial? (Diagrams are similar. Epidemiologist is on the train for the entire journey.)

**Next Slide**



Ask students:

- How are the designs of the cohort study and the controlled trial different? (In a controlled trial, the epidemiologist randomly assigns the passengers to an exposed or unexposed group. In other words, the controlled trial is a real experiment.)
- What else is different? (In a cohort study, the epidemiologist merely *observes* what the passengers are exposing themselves to rather than telling the passengers whether or not to have the exposure. In other words, the cohort study is an observational study of a natural experiment. It is not a real experiment. The epidemiologist observes rather than intervenes. All of the epidemiology designs, except the controlled trial, are observational studies.)

⚙ Teacher Alert: In the controlled trial, the exposure is hypothesized to be beneficial. In the cohort study, the exposure can be hypothesized to be beneficial or harmful.

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**Review**

**Epi Talk**

<b>Observational Studies</b>
Epidemiologic studies of natural experiments in which the investigator is not involved in the intervention other than to record, classify, count, and statistically analyze results.

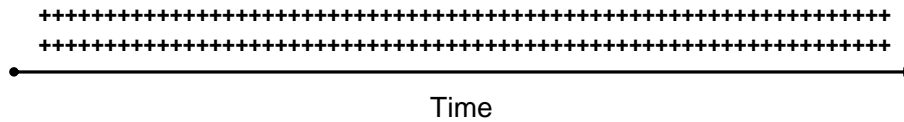
**Detectives in the Classroom - Investigation 2-6: The Journey**

Ask students to find “Observational studies” in the **Epi Talk** list.  
Review its definition.

**Next Slide**

## Label the Train Tracks

Study Design: Case-Control Study



Detectives in the Classroom - Investigation 2-6: The Journey

Students should label the next set of train tracks as “Case-Control Study.”

Then after listening to the description of a case-control study (next slide), each student should mark the tracks for a case-control study with the “epidemiologist icon,” “E,” and “DZ.”

**Next Slide**

## Label the Train Tracks

### Case-Control Study

The epidemiologist is not on the journey. Rather, the epidemiologist is waiting at the train station at the end of the journey. As passengers get off the train, the epidemiologist selects sick passengers for the case group and selects passengers who are similar but not sick for the control group. The epidemiologist then asks each person in the case group and control group questions about their exposures during the train ride. The epidemiologist relies on passengers' memories of their exposures that occurred during the train ride.

Detectives in the Classroom - Investigation 2-6: The Journey

Read the following to the class:

**The epidemiologist is *not* on the journey. Rather, the epidemiologist is waiting at the train station at the end of the journey. As passengers exit the train, the epidemiologist selects sick passengers for the case group and passengers who are similar but not sick for the control group. The epidemiologist then asks each person in the case group and control group questions about her or his exposures during the train ride. The epidemiologist relies on passengers' memories of the exposures that occurred during the train ride.**

Give students time to label the train tracks.

**Next Slide**

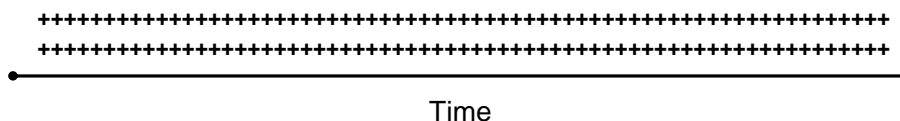
## Label the Train Tracks

Study Design: Case-Control Study



DZ

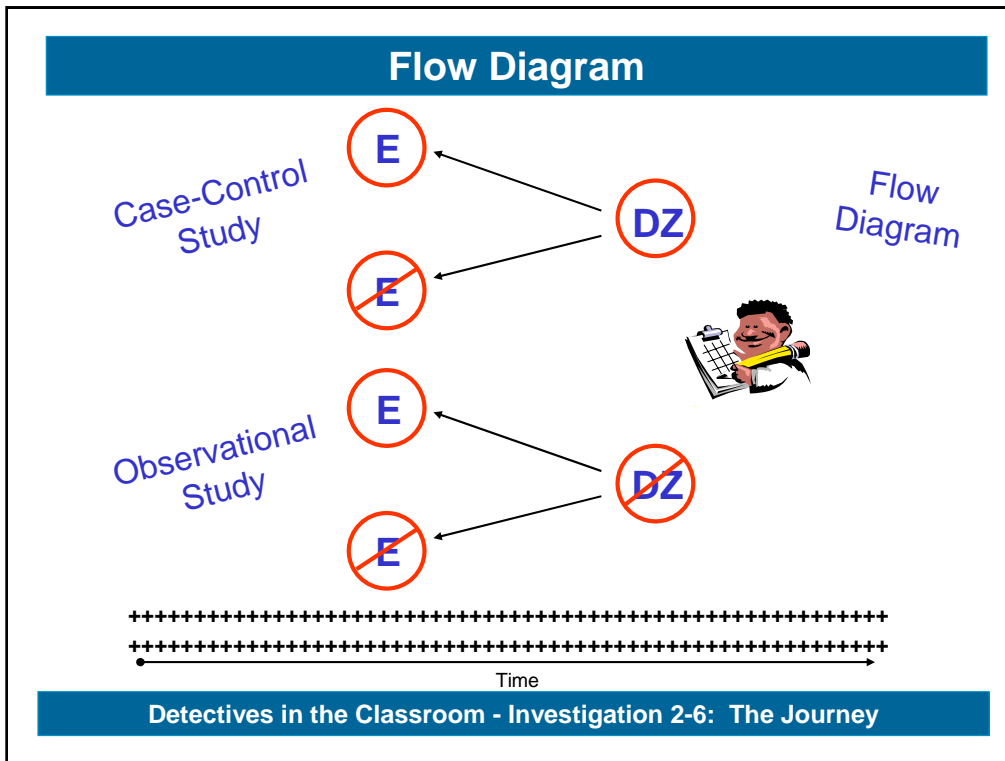
E



Detectives in the Classroom - Investigation 2-6: The Journey

Using class discussion, help students realize that in a case-control study, the epidemiologist waits until the end of the train ride to identify people with and without the disease and then asks about their previous exposures during the trip.

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Explain that the way a case-control study unfolds is different. As you present each step, ask students to draw the flow diagram on the **Study Design Sheet**.

Step 1: Select a group of people with the disease and a control group without the disease.

Step 2: Ask people with the disease whether or not they have been exposed in the past. Ask control subjects whether or not they have been exposed in the past.

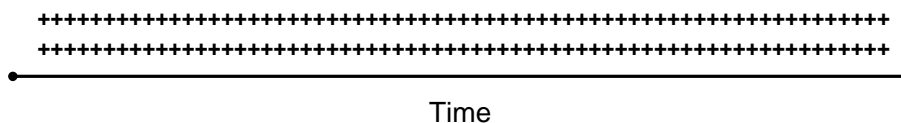
Ask students:

- What are the differences between the cohort and case-control study designs? (The case-control study design is sort of backwards compared with the cohort design. The cohort design started with measurement of exposure and followed up with assessment of disease. The case-control study starts with determination of disease and looks backwards to determine exposure. Note that the case-control study takes less time and effort because the epidemiologist does not have to wait for the outcome.)

**Next Slide**

## Label the Train Tracks

Study Design: Cross-Sectional Study



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Students should label the next set of train tracks as “Cross-Sectional Study.”

Then after listening to the description of a cross-sectional study (next slide), each student should mark the tracks for a cross-sectional study with the “epidemiologist icon,” “E,” and “DZ.”

**Next Slide**

## Label the Train Tracks

### Cross-Sectional Study

The epidemiologist, who has not been on the journey, stops the train somewhere during the trip (kind of like a train robbery) and takes a “snapshot” of all the passengers by asking them whether or not they have the exposure and whether or not they have the disease. Then the epidemiologist leaves the train and goes home to analyze the data from that particular day. The journey continues without the epidemiologist.

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Read the following to the class:

**The epidemiologist, who has not been on the journey, stops the train somewhere during the trip (rather like a train robbery) and takes a “snapshot” of all the passengers by asking them whether or not they have the exposure and whether or not they have the disease. Then the epidemiologist leaves the train and goes home to analyze the data from that particular day. The journey continues without the epidemiologist.**

Give students time to label the train tracks.

**Next Slide**

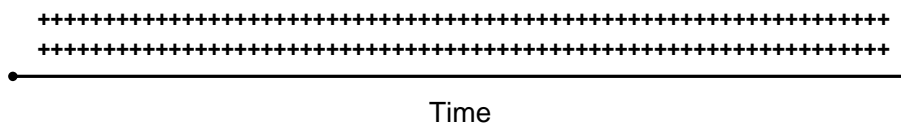
## Label the Train Tracks

Study Design: Cross-Sectional Study



E

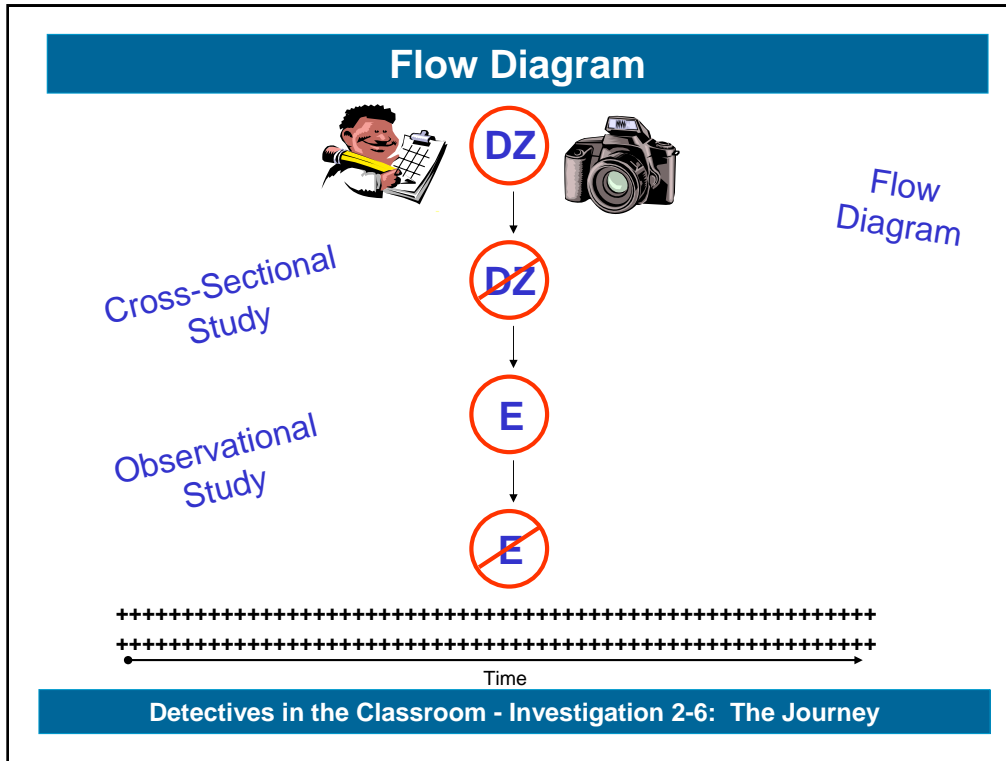
DZ



Detectives in the Classroom - Investigation 2-6: The Journey

Using class discussion, help students realize that in a cross-sectional study, the epidemiologist, who has not been on the journey, stops the train somewhere during the trip. The epidemiologist takes a “snapshot” of the passengers by asking them, at the same time, whether or not they have the exposure and whether or not they have the disease. Then the epidemiologist leaves the train and goes home to analyze the data from that particular day and the train ride continues without the epidemiologist.

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Explain that the cross-sectional study has only one step because all the information is collected at one point in time. As you present each step, ask students to draw the flow diagram on the **Study Design Sheet**.

Step 1: The epidemiologist asks each person at this point in time whether or not she or he has the disease and whether or not she or he has the exposure.

Ask students:

- How is this study design different from the others? (This is just a snapshot. It does not identify the time order of the exposure and the disease.)
- What are the advantages of this study design compared with the others? (Faster; less time and effort for the epidemiologist)

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**Epi Talk**

**Epi Talk**

**Controlled Trial**

An epidemiologic experiment in which subjects are assigned into groups to receive or not receive a hypothesized beneficial intervention.

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Ask students to find “Controlled trial” in the **Epi Talk** list.  
Review its definition.

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**Epi Talk**

**Epi Talk**

**Cohort Study**

An analytical epidemiological study design in which the investigator selects a group of exposed individuals and a group of unexposed individuals and follows both groups to compare the frequency with which the disease occurs in each group.

**Detectives in the Classroom - Investigation 2-6: The Journey**

Ask students to find “Cohort study” in the **Epi Talk** list.  
Review its definition.

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**Epi Talk**

**Epi Talk**

**Case-Control Study**

An analytical epidemiological study design in which the investigator selects a group of individuals with a disease (cases) and a group of similar individuals without the disease (controls) and compares the frequency with which an exposure occurred in the cases versus the controls.

**Detectives in the Classroom - Investigation 2-6: The Journey**

Ask students to find “Case-control study” in the **Epi Talk** list.  
Review its definition.

**Next Slide**

**Epi Talk**

**Epi Talk**

**Cross-Sectional Study**

An analytical epidemiological study design in which the investigator selects a group of individuals and determines the presence or absence of a disease and the presence or absence of an exposure at the same time.

**Detectives in the Classroom - Investigation 2-6: The Journey**

Ask students to find “Cross-sectional study” in the **Epi Talk** list.  
Review its definition.

**Next Slide**

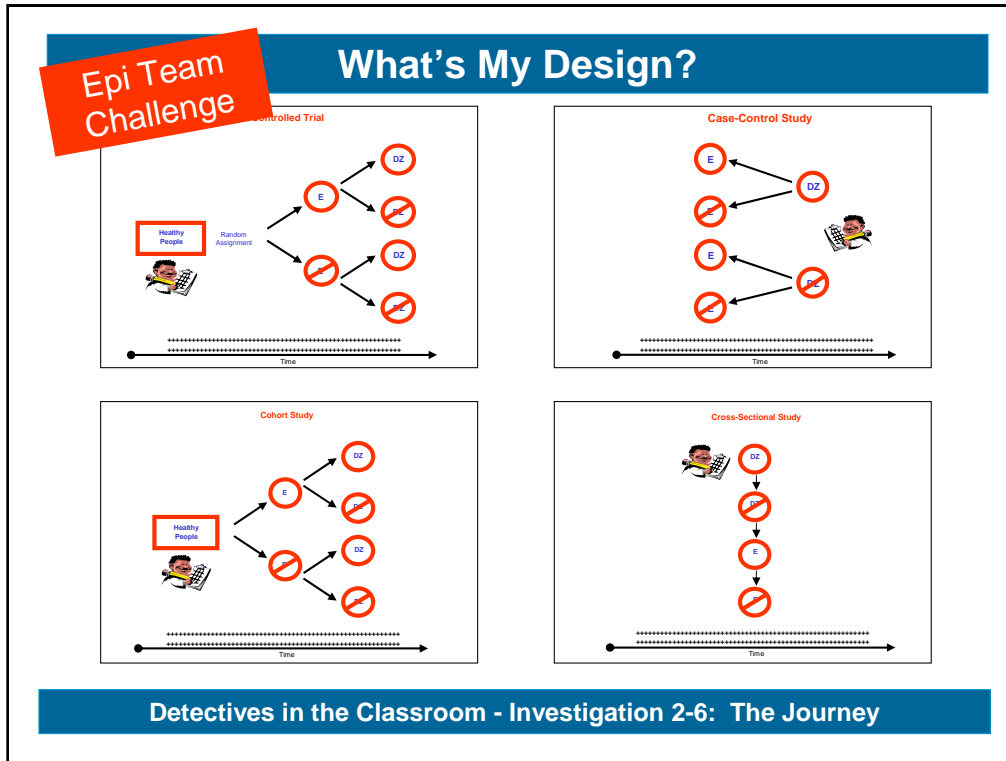
## Epi Teams



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Divide the class into Epi Teams of four or five students per team.

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Tell students they are now to practice for an Epi Team Challenge that will be held during the next class.

Give each Epi Team a set of **Study Design Cards**, which have the four study designs written on them.

You are going to show them a clue for a study design. Members of each Epi Team should decide among themselves what study design or designs the clue describes and, when you call for “Cards,” should hold up the appropriate **Study Design Card** or **Cards**.

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## What's My Design?

Assign treatment and control groups.

Give exposure to treatment group, but not control group.

Follow through time and compare risk of disease in treatment group with risk of disease in control group.

Epidemiologist is involved during the entire time from exposure and disease.

Controlled Trial

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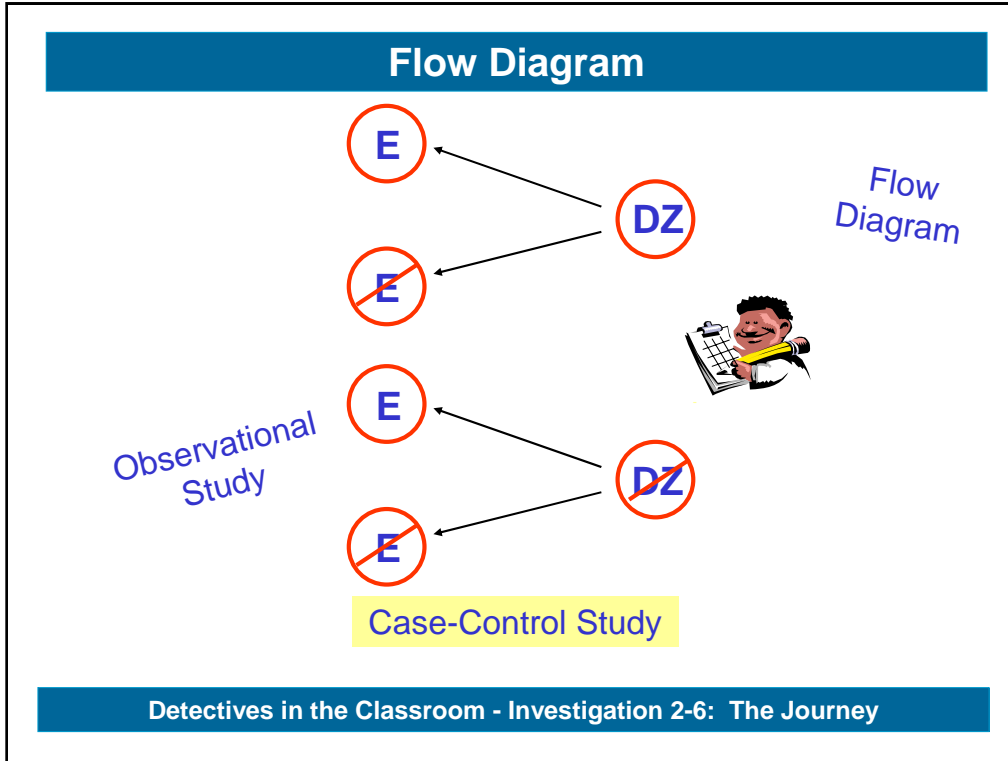
Give Epi Teams time to discuss.

Ask for "Cards."

Show students the correct answer.

Discuss as needed.

**Next Slide**



Give Epi Teams time to discuss.  
Ask for "Cards."  
Show students the correct answer.  
Discuss as needed.

**Next Slide**

**What's My Design?**

Observational  
Study

Cohort, Case-Control, and Cross-Sectional Study

**Detectives in the Classroom - Investigation 2-6: The Journey**

Give Epi Teams time to discuss.  
Ask for "Cards."  
Show students the correct answer.  
Discuss as needed.

**Next Slide**

## The Journey



Detectives in the Classroom - Investigation 2-6: The Journey

Just as detectives use various methods to consider or eliminate suspects, epidemiologists select one of four study designs to gather evidence and test their hypotheses. As students develop their understanding of the controlled trial, cohort study, case-control study, and cross-sectional study designs, they are broadening their hypothesis testing skills and becoming Detectives in the Classroom.

This concludes **Investigation 2-6: The Journey** and students can now put away their **Epi Logs**.