


How to Evaluate



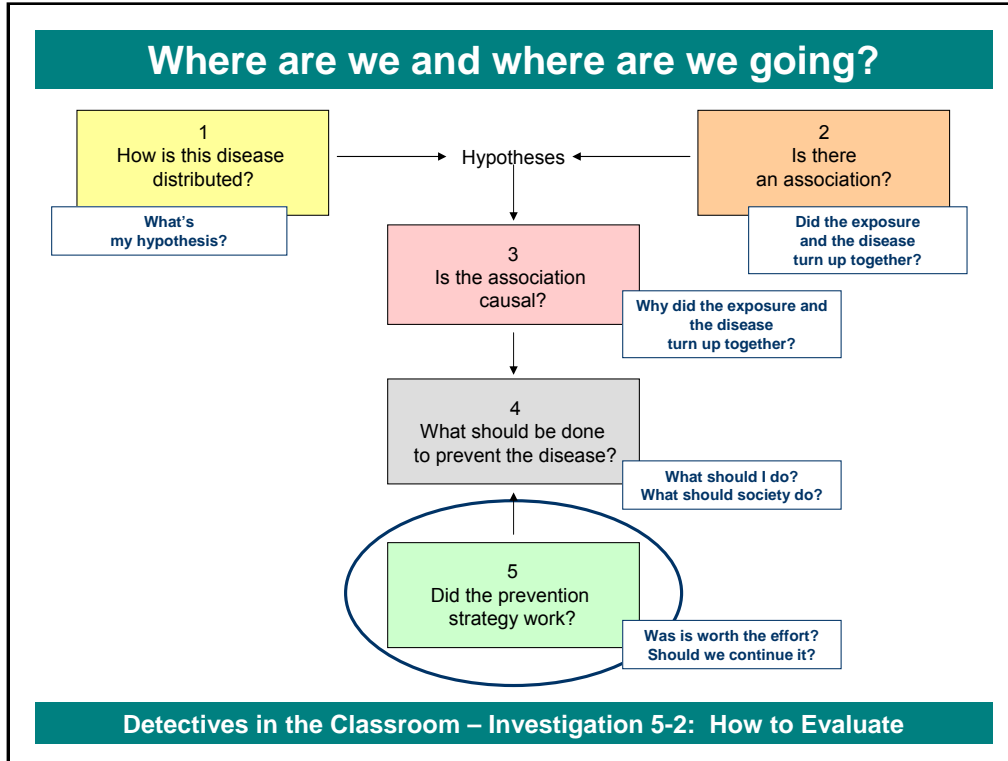
Did the prevention strategy work?

Detectives in the Classroom – Investigation 5-2: How to Evaluate

The illustration shows a person with dark skin and curly hair, wearing a yellow shirt with the letters 'CML' on it. They are sitting at a desk, looking down at a document with a grid of 'x' marks. A thought bubble above their head contains the text 'Did the prevention strategy work?'.

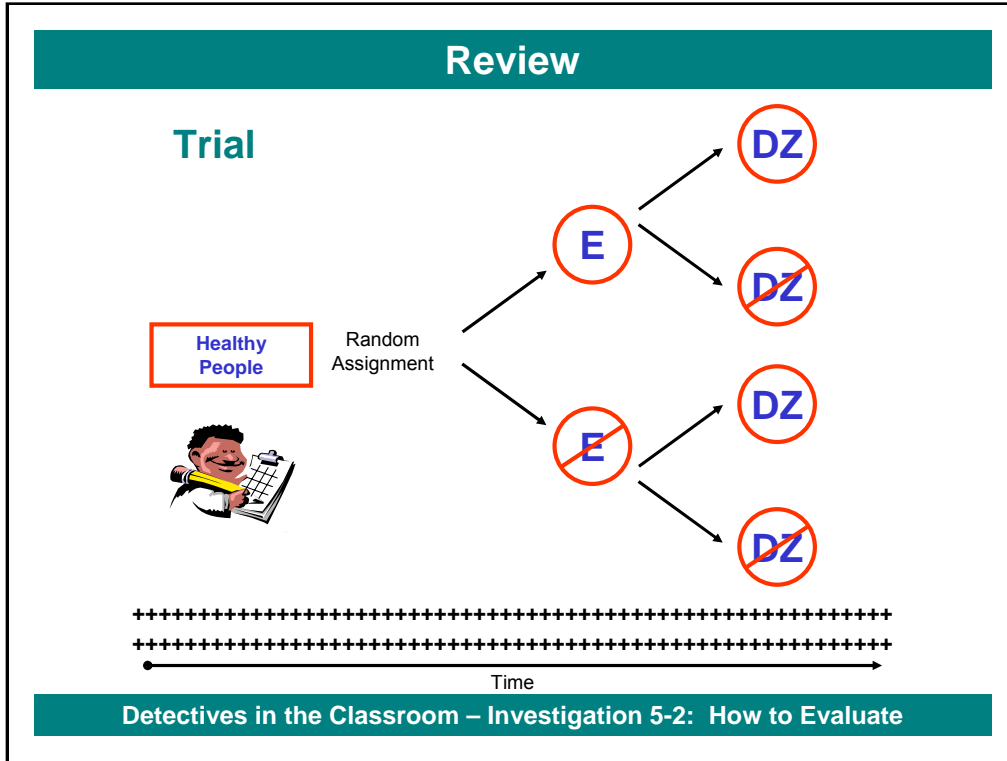
In **Investigation 5-2: How to Evaluate**, students will learn that the same epidemiologic study designs used for studying causality can also be used to evaluate the effectiveness of a risk management strategy.

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Remind students again that in the Module 5 investigations, they are learning how to answer the question “Did the prevention strategy work?”

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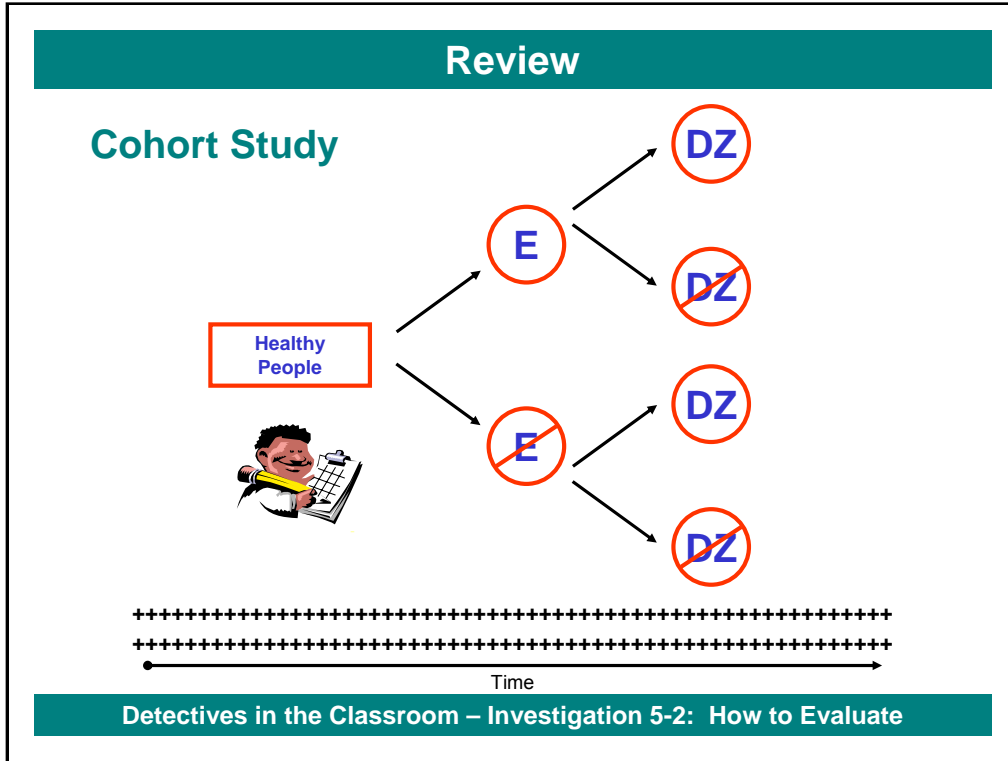


Prepare for this investigation by reviewing the four study designs that were presented in Investigation 2-6.

Ask students:

- Can you identify this study design? (Trial)

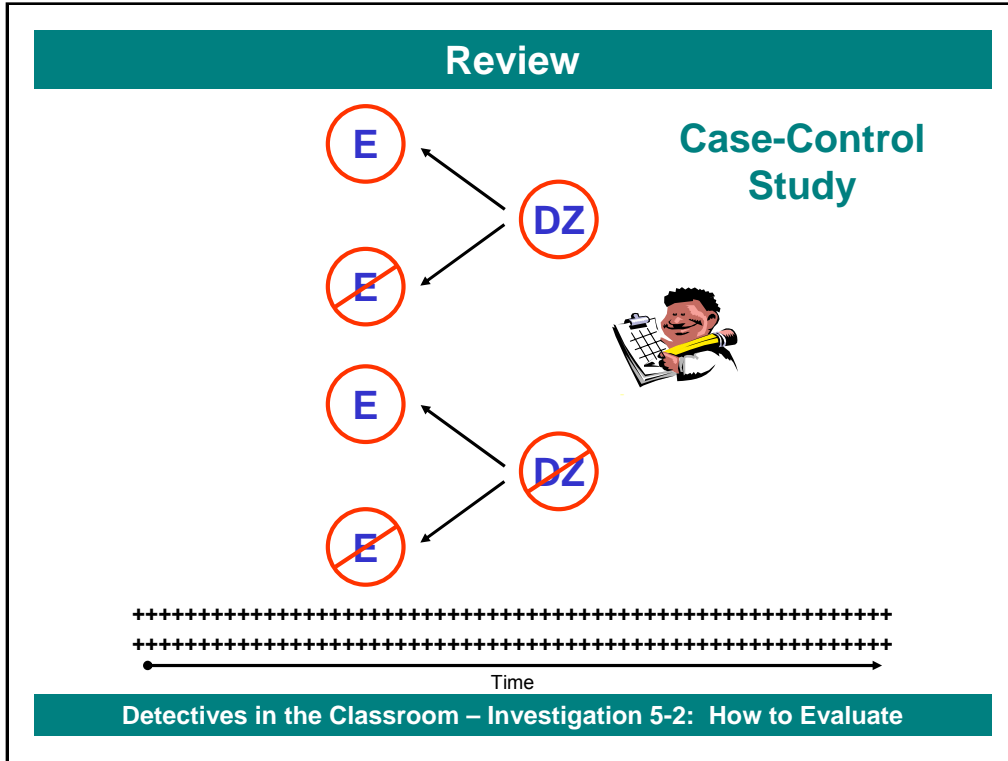
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Ask students:

- Can you identify this study design? (Cohort study)

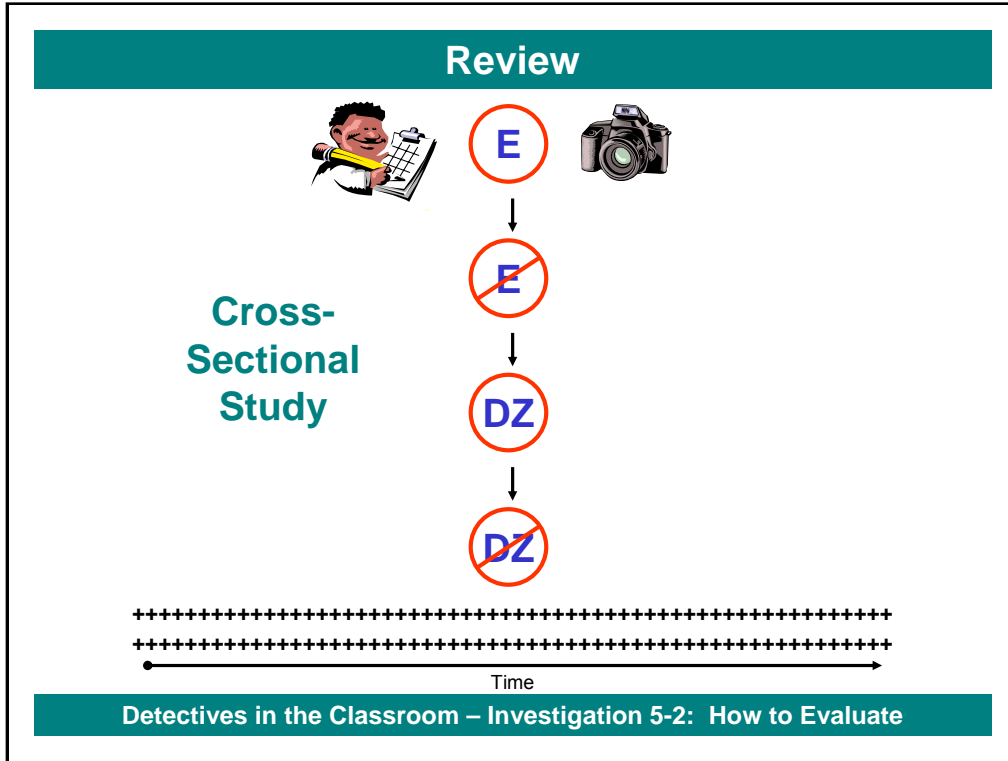
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Ask students:

- Can you identify this study design? (Case-control study)

Next Slide



Ask students:

- Can you identify this study design? (Cross-sectional study)

Next Slide

Review

Risk Management
Steps taken to reduce the levels of risk to which an individual or a population is exposed.

Detectives in the Classroom – Investigation 5-2: How to Evaluate

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

Next Slide

“Diet and Exercise Dramatically Delay Type 2 Diabetes”

The following was adapted from National Institute of Diabetes and Digestive and Kidney Diseases, August 8, 2007 press release. http://www.nidDK.nih.gov/press/releases/8_8_07.htm, viewed on 2/28/08.

Diet and Exercise Dramatically Delay Type 2 Diabetes

People can develop type 2 diabetes at any age. In type 2 diabetes, the pancreas does not make enough insulin, and the fat, muscle, or liver cells do not use it properly. At least 10 million Americans at high risk for type 2 diabetes which can have serious health consequences if untreated.

Most common in adults, type 2 diabetes can develop at any age, even childhood. It is strongly associated with obesity (more than 80% with type 2 diabetes are overweight), inactivity, family history of diabetes, and racial or ethnic background. Compared to whites, black adults have a 60% higher rate of type 2 diabetes and Hispanic adults have a 90% higher rate. The prevalence of type 2 diabetes has tripled in the last 30 years, and much of the increase is due to the dramatic upsurge in obesity.

Results from a major study bring good news about type 2 diabetes. As announced by HHS Secretary, Tommy G. Thompson, at the National Institutes of Health, Americans at high risk for type 2 diabetes can sharply lower their chances of getting the disease with diet and exercise. “In view of the rapidly rising rates of obesity and diabetes in America, this good news couldn’t come at a better time,” said Secretary Thompson. “So many of our health problems can be avoided through diet, exercise and making sure we take care of ourselves.

The findings came from the Diabetes Prevention Program (DPP). This is a major study that compared diet and exercise to drug treatment among 3,234 people with impaired glucose tolerance, a condition that often precedes diabetes. On the advice of the DPP’s external data monitoring board, the study ended a year early.

Participants were randomly assigned to one of three groups, as shown below.

Group	Intervention	Description	% Developed Diabetes
1	Lifestyle intervention	Participants received intensive training in diet, exercise (most chose walking), and behavior modification skills aimed at reducing weight by 7% through a low-fat diet and exercising for 150 minutes a week.	14%
2	Metformin & information	Participants received treatment with the drug metformin (850 mg twice a day) and received information on diet and exercise.	22%
3	Placebo & information	Participants received placebo pills, in place of metformin, and received information on diet and exercise.	29%

Those randomly assigned to the lifestyle intervention (Group 1) maintained their physical activity for 30 minutes per day, usually with walking or other moderate intensity exercise, and lost 5.7% of their body weight. Group 1 had the fewest participants (14%) develop diabetes during the three-year study period. The study also found that fewer participants who were treated with the oral diabetes drug Metformin (Group 2) developed diabetes (22%) compared to the placebo group (29%).

Detectives in the Classroom – Investigation 5-2: How to Evaluate

Students should now take out the article assigned for homework, “Diet and Exercise Dramatically Delay Type 2 Diabetes.”

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“Diet and Exercise Dramatically Delay Type 2 Diabetes”

Group	Intervention	Description	% Developed Diabetes
1	Lifestyle Intervention	Participants received intensive training in diet, exercise, and behavior modification skills aimed at reducing weight by 7% through a low-fat diet and exercising for 150 minutes a week.	14%
2	Metformin & Information	Participants received treatment with the drug metformin (850 mg twice a day) and received information on diet and exercise.	22%
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Detectives in the Classroom – Investigation 5-2: How to Evaluate

Review the results of the study with the class.

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Epi Teams



Detectives in the Classroom – Investigation 5-2: How to Evaluate

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

Next Slide

“Diet and Exercise Dramatically Delay Type 2 Diabetes”

Detectives in the Classroom Name: _____

Investigation 5-2: Epi Log Worksheet Date: ____/____/____

How To Evaluate

1. What study design was used to evaluate this risk management strategy?
2. Draw a flow diagram of the study design with numbers whenever possible.
3. Why do you think Groups 2 and 3 received information on diet and exercise? Why were they not given just Metformin or the placebo?
4. The authors reported that type 2 diabetes "... is strongly associated with obesity (more than 80% of people with type 2 diabetes are overweight), inactivity, family history of diabetes, and racial or ethnic background." What does "strongly associated" mean?

Detectives in the Classroom – Investigation 5-2: How to Evaluate

Give each student an **Investigation 5-2: Epi Log Worksheet**.

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“Diet and Exercise Dramatically Delay Type 2 Diabetes” 1

Trial

Diet and Exercise Dramatically Delay Type 2 Diabetes

Develop type 2 diabetes at any age. In type 2 diabetes, the pancreas produces insulin, and the fat, muscle, or liver cells do not use it properly. People at high risk for type 2 diabetes which can have serious health complications if untreated.

In adults, type 2 diabetes can develop at any age, even childhood. Obesity (more than 80% with type 2 diabetes are obese) is a condition that often precedes diabetes. On the advice of a health care provider, people with a family history of diabetes, and racial or ethnic background. Complications of type 2 diabetes include heart disease, kidney disease, and nerve damage. The prevalence of type 2 diabetes has tripled in the last 30 years, and is due to the dramatic upsurge in obesity.

A major study bring good news about type 2 diabetes. As announced by Tommy G. Thompson, at the National Institutes of Health, type 2 diabetes can sharply lower their chances of getting the disease. “In view of the rapidly rising rates of obesity and diabetes, this couldn’t come at a better time,” said Secretary Thompson. “Diabetes complications can be avoided through diet, exercise and making sure you get regular checkups.”

Case-Control Study

The findings came from the Diabetes Prevention Program (DPP). This is a major study that compared diet and exercise to drug treatment among 3,234 people who were at high risk for type 2 diabetes. On the advice of a health care provider, people with a family history of diabetes, and racial or ethnic background. Complications of type 2 diabetes include heart disease, kidney disease, and nerve damage. The prevalence of type 2 diabetes has tripled in the last 30 years, and is due to the dramatic upsurge in obesity.

Intervention	Description
Lifestyle intervention	Participants received intensive training in diet, exercise (30 minutes of walking), and behavior modification skills aimed at reducing weight by 7% through a low-fat diet and exercising for 150 minutes a week.
Oral medication	Participants received treatment with the drug metformin (850 mg twice a day) and received information on diet and exercise.
Placebo & information	Participants received placebo pills, in place of metformin, and received information on diet and exercise.

Participants assigned to the lifestyle intervention (Group 1) maintained an average of 7.5% weight loss, usually with walking or other moderate intensity of their body weight. Group 1 had the fewest participants developing type 2 diabetes during the three-year study period. The study also found that fewer participants assigned to the lifestyle intervention (Group 1) developed type 2 diabetes (22.7%) compared to the placebo group (29%).

Cohort Study

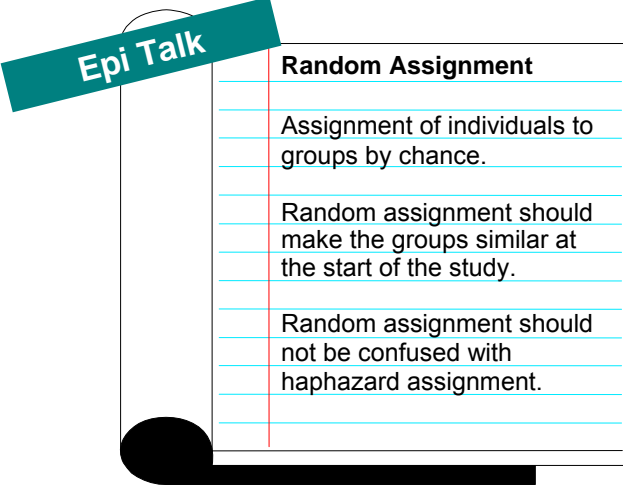
Cross-Sectional Study

Detectives in the Classroom – Investigation 5-2: How to Evaluate

Students should answer Question 1 on their **Investigation 5-2: Epi Log Worksheets** by identifying which study design was used to evaluate this risk management strategy. (Trial) Keep showing this slide as students answer Question 1.

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Epi Talk



Random Assignment

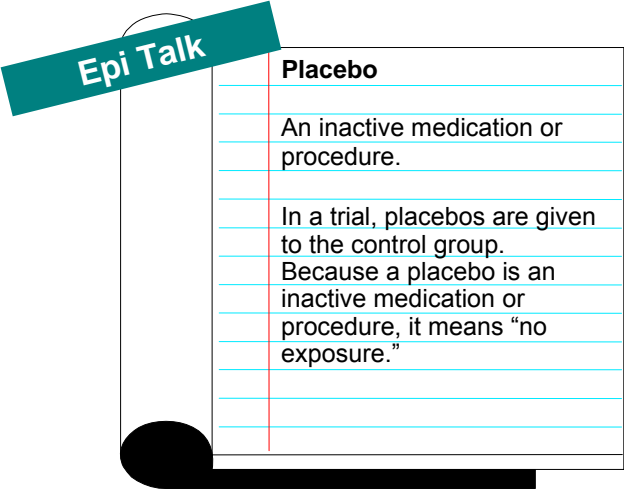
- Assignment of individuals to groups by chance.
- Random assignment should make the groups similar at the start of the study.
- Random assignment should not be confused with haphazard assignment.

Detectives in the Classroom – Investigation 5-2: How to Evaluate

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

Next Slide

Epi Talk



Epi Talk

Placebo

An inactive medication or procedure.

In a trial, placebos are given to the control group. Because a placebo is an inactive medication or procedure, it means “no exposure.”

Detectives in the Classroom – Investigation 5-2: How to Evaluate

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

Next Slide

“Diet and Exercise Dramatically Delay Type 2 Diabetes”

2

Detectives in the Classroom Name: _____

Investigation 5-2: Epi Log Worksheet Date: ____/____/____

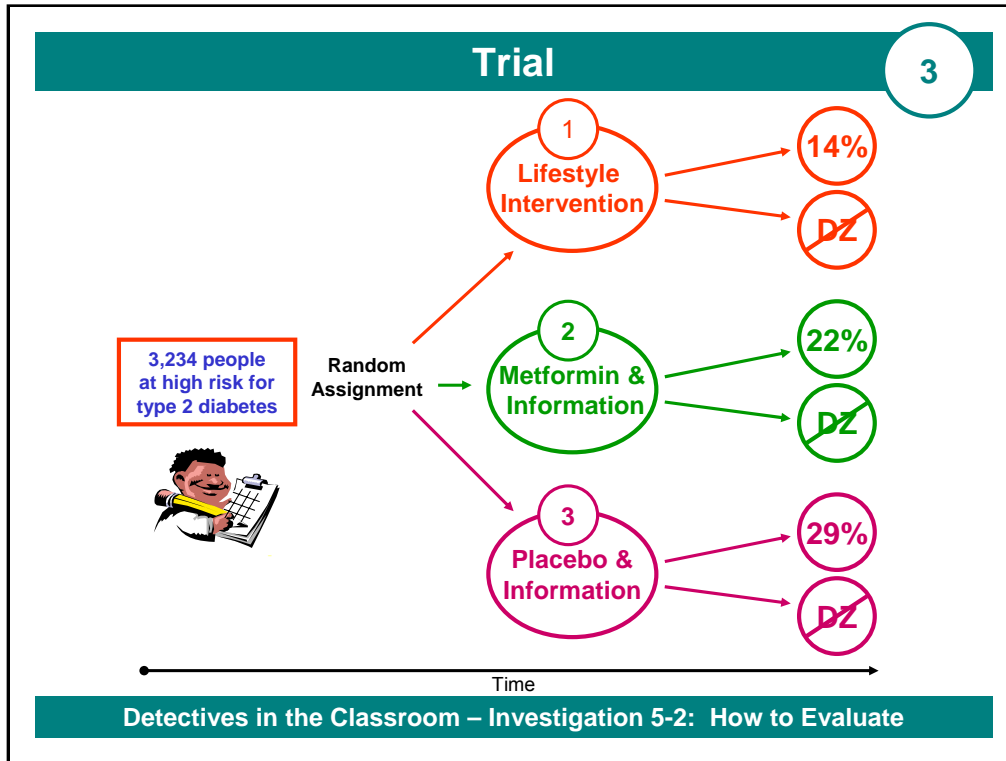
How To Evaluate

1. What study design was used to evaluate this risk management strategy?
2. Draw a flow diagram of the study design with numbers whenever possible.
3. Why do you think Groups 2 and 3 received information on diet and exercise? Why were they not given just Metformin or the placebo?
4. The authors reported that type 2 diabetes "... is strongly associated with obesity (more than 80% of people with type 2 diabetes are overweight), inactivity, family history of diabetes, and racial or ethnic background." What does "strongly associated" mean?

Detectives in the Classroom – Investigation 5-2: How to Evaluate

Students should answer Question 2 on their **Investigation 5-2: Epi Log Worksheets** by drawing a flow diagram of the study design, putting in numbers whenever possible. Compare students' answers with the following slide.

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Address misconceptions.

☀ Teacher Alert: Students may be confused by the fact that this diagram is slightly different from the “trial” diagram seen before. This is simply because three different strategies (instead of two) were tested and compared.

- Group 1 received lifestyle intervention.
- Group 2 received metformin and information.
- Group 3 received placebo and information.

Students should answer Question 3 on their **Investigation 5-2: Epi Log Worksheets** by explaining why Groups 2 and 3 received information on diet and exercise. Why were they not given just metformin or the placebo? (Information on diet and exercise is given to Groups 2 and 3 because that is the ethical thing to do. In other words, if information that may help people protect themselves from diabetes is available, participants have a right to receive that information.)

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“Diet and Exercise Dramatically Delay Type 2 Diabetes”

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Type 2 diabetes “... is strongly associated with obesity (more than 80% of people with type 2 diabetes are overweight), inactivity, family history of diabetes, and racial or ethnic background.”

Detectives in the Classroom – Investigation 5-2: How to Evaluate

Students should answer Question 4 on their **Investigation 5-2: Epi Log Worksheets** by explaining the meaning of “strongly associated” in the statement “Type 2 diabetes ... is strongly associated with obesity (more than 80% of people with type 2 diabetes are overweight), inactivity, family history of diabetes, and racial or ethnic background.”

(The “strength of association” means the number of times more likely that type 2 diabetes will develop in an exposed group of people than in an unexposed group. In this study, the exposure could be obesity, inactivity, family history of diabetes, or racial or ethnic background.)

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“Diet and Exercise Dramatically Delay Type 2 Diabetes”



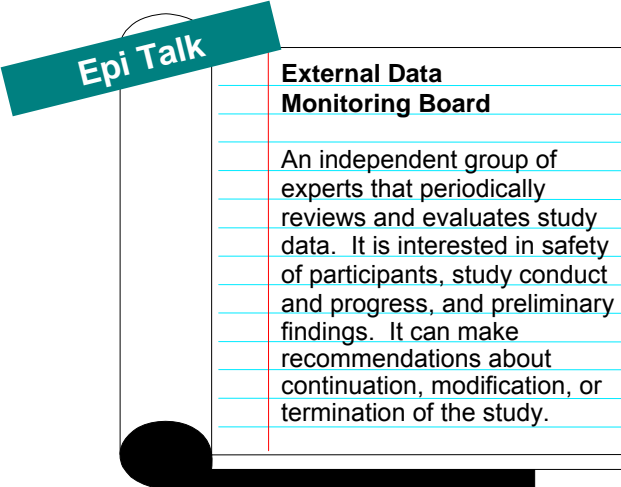
	Type 2 Diabetes	No Type 2 Diabetes	Total	Type 2 Diabetes Risks	Relative Risk
Obesity	40 a	60 b	100	$\frac{40}{100}$ 40 %	4 times as likely
No Obesity	10 c	90 d	100	$\frac{10}{100}$ 10 %	
	Count			Divide	Compare

Detectives in the Classroom – Investigation 5-2: How to Evaluate

The strength of the association is determined by counting, dividing, and comparing. Address misconceptions.

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Epi Talk



External Data Monitoring Board
An independent group of experts that periodically reviews and evaluates study data. It is interested in safety of participants, study conduct and progress, and preliminary findings. It can make recommendations about continuation, modification, or termination of the study.

Detectives in the Classroom – Investigation 5-2: How to Evaluate

Ask students to find “External data monitoring board” in the **Epi Talk** list. Review its definition.

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External Data Monitoring Board

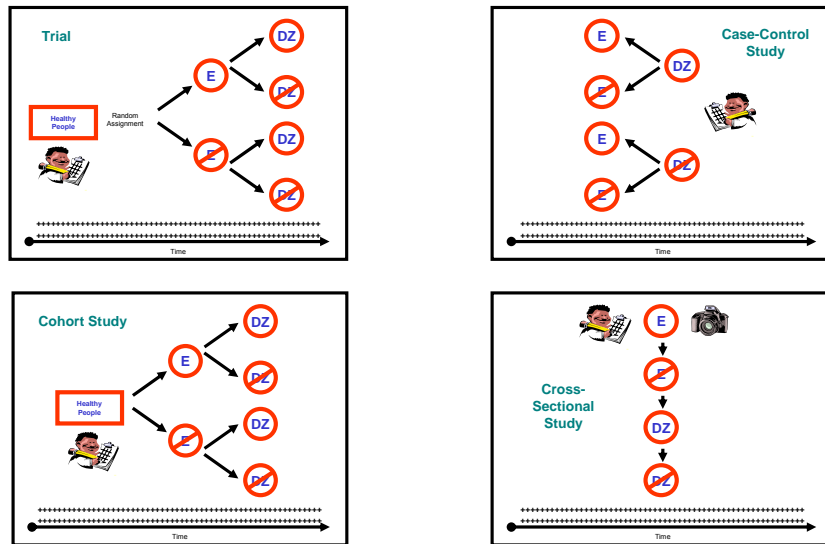
Students should answer Question 5 on their **Investigation 5-2: Epi Log Worksheets** by explaining what would justify a decision by an external data monitoring board to end the study. (The data had clearly answered the research questions and showed that Group 1 [Lifestyle Intervention] and Group 2 [Metformin & Information] had lower rates of type 2 diabetes.)

Ask students:

- Do you think the study should be ended based on the results seen in the diagram for Question 2?

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Ideal Conditions? / Everyday Conditions?



Detectives in the Classroom – Investigation 5-2: How to Evaluate

The effectiveness of a risk management strategy can be evaluated under *ideal conditions* or under *everyday conditions*.

Ask students:

- Which of the four study designs would determine the extent to which an intervention produces a beneficial result under *ideal conditions*? (Trial)


A risk management strategy's effectiveness means the extent to which the intervention produces a beneficial result under *everyday conditions*.

Ask students:

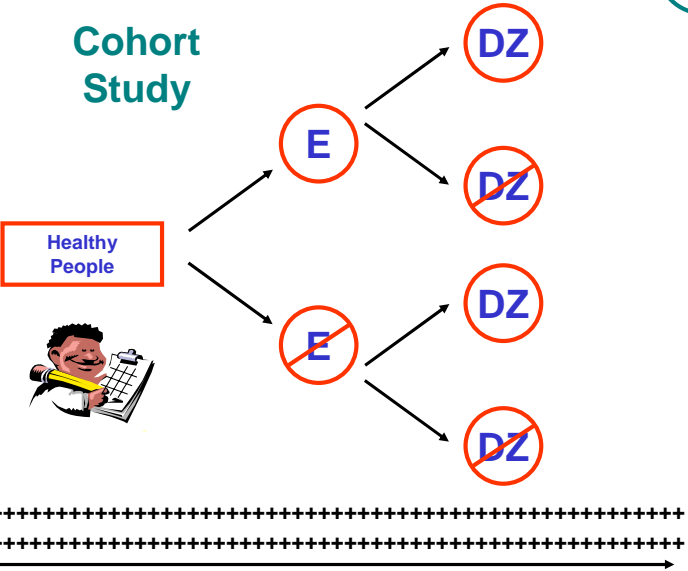
- Which of the four study designs would determine the extent to which an intervention produces a beneficial result under *everyday conditions*? (Cohort, case-control, and cross-sectional study)

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Lifestyle Intervention Effectiveness 6



Cohort Study

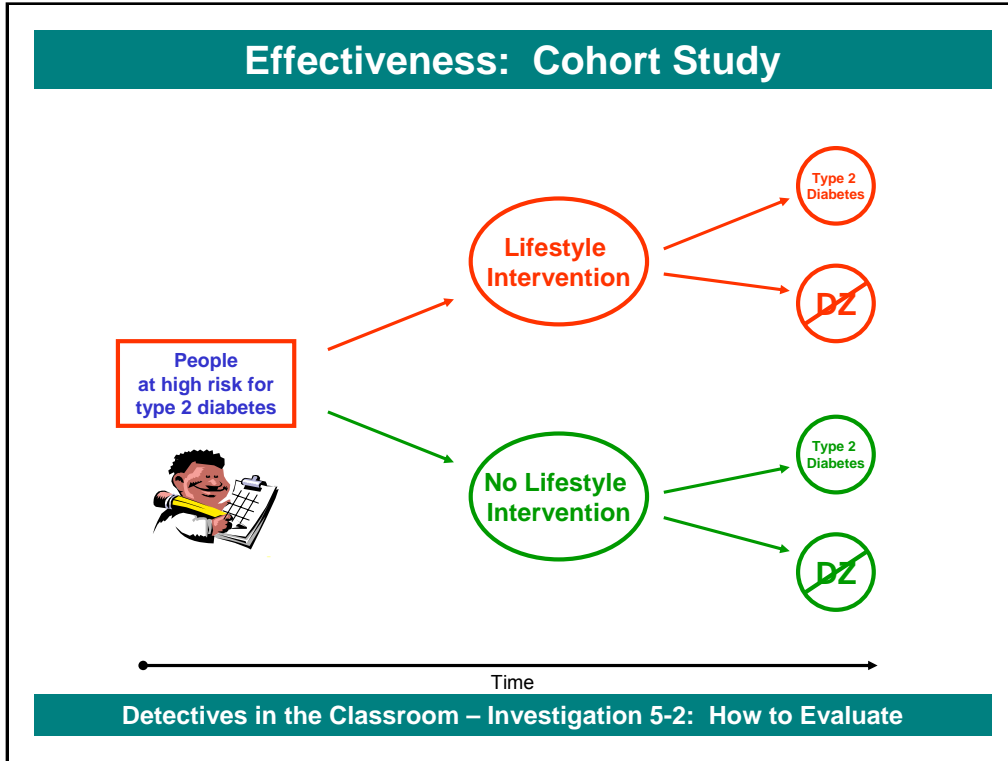


Detectives in the Classroom – Investigation 5-2: How to Evaluate

Students should answer Question 6 on their **Investigation 5-2: Epi Log Worksheets** by drawing a flow diagram of a cohort study to determine the effectiveness of the lifestyle intervention in preventing type 2 diabetes under everyday conditions.

Compare students' answers with the following slide.

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Address misconceptions.

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Investigation 5-2: Epi Log Worksheets

Question 7: Lifestyle Intervention Effectiveness

The following table shows the results of a case-control study that investigated the effectiveness of a lifestyle intervention in preventing type 2 diabetes under everyday conditions. The study included 100 cases of type 2 diabetes (DZ) and 100 controls (E) who had never had type 2 diabetes. The cases were selected from a local hospital and the controls were selected from a local community center. The study was conducted over a period of 10 years. The results are shown in the table below.

Case/Control	Intervention	Number
Cases (DZ)	Yes	30
	No	70
Controls (E)	Yes	40
	No	60

Lifestyle Intervention Effectiveness

7

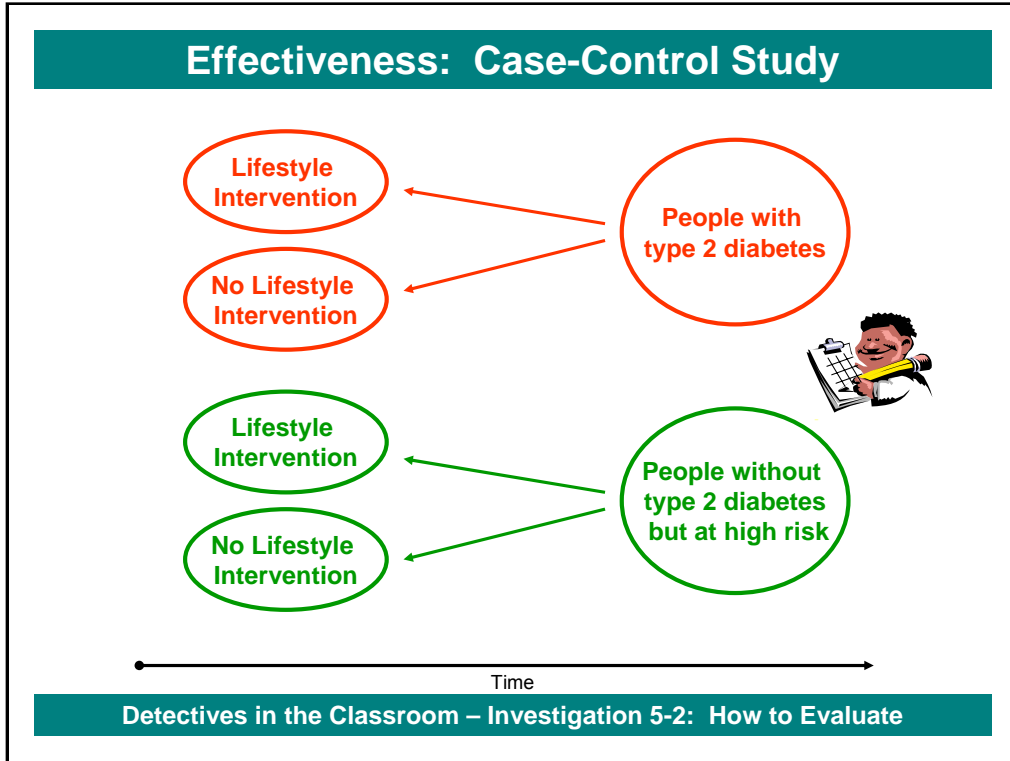
Case-Control Study

Detectives in the Classroom – Investigation 5-2: How to Evaluate

Students should answer Question 7 on their **Investigation 5-2: Epi Log Worksheets** by drawing a flow diagram of a case-control study to determine the effectiveness of the lifestyle intervention in preventing type 2 diabetes under everyday conditions.

Compare students' answers with the following slide.


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Address misconceptions.

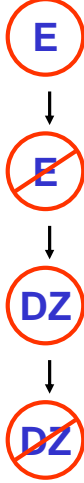
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Lifestyle Intervention Effectiveness 8



**Cross-
Sectional
Study**



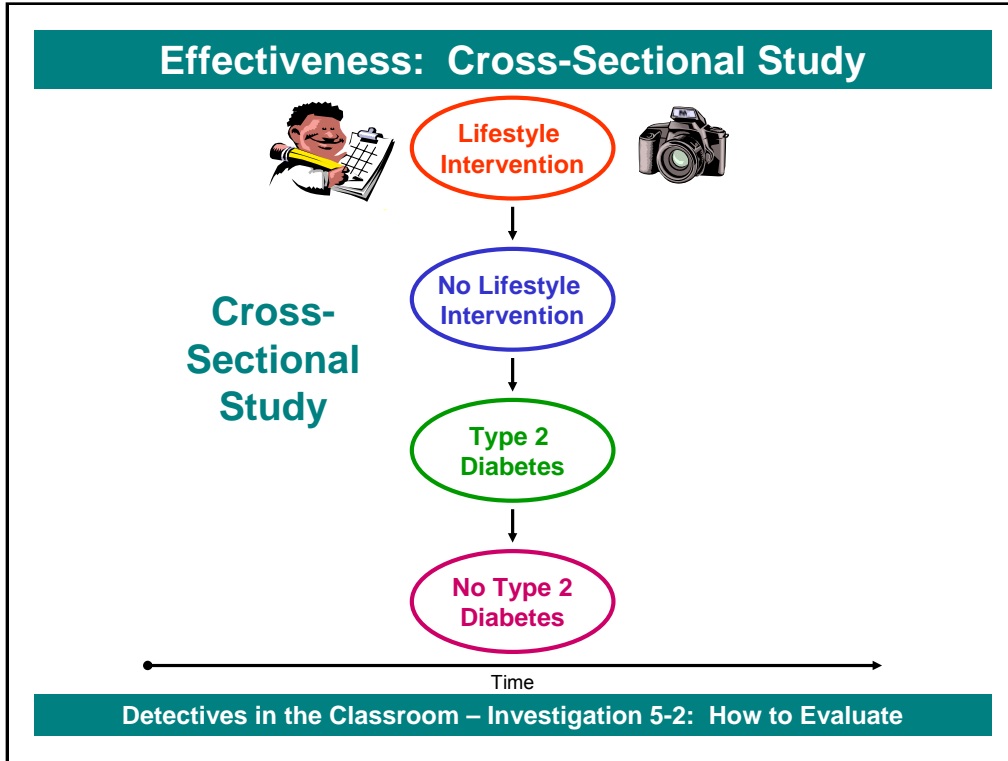




Detectives in the Classroom – Investigation 5-2: How to Evaluate

Students should answer Question 8 on their **Investigation 5-2: Epi Log Worksheets** by drawing a flow diagram of a cross-sectional study to determine the effectiveness of the lifestyle intervention in preventing type 2 diabetes under everyday conditions. Compare students' answers with the following slide.

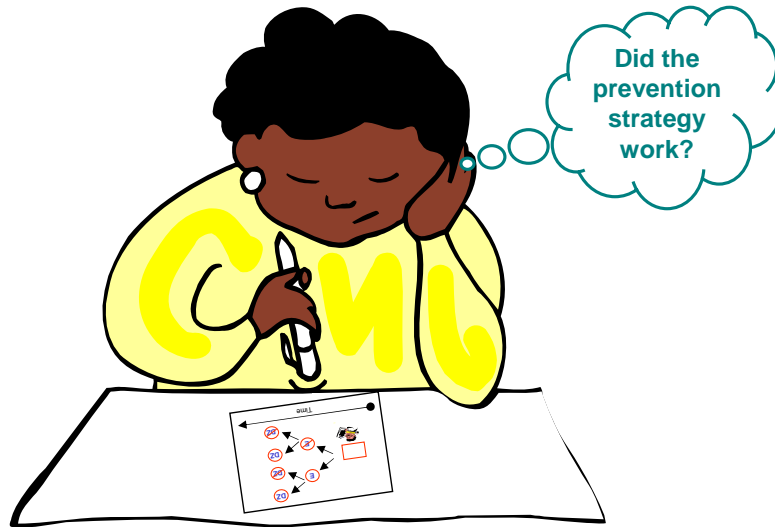
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Address misconceptions.

Next Slide

Essential Question 5



Detectives in the Classroom – Investigation 5-2: How to Evaluate

Remind students that to answer Essential Question 5—“Did the prevention strategy work?”—they must evaluate the strategy.

In this investigation they discovered that the same epidemiologic study designs presented in Investigation 2-6 can be used to assess risk management strategies. This is done by calculating risks and comparing risks of disease in populations of people who were and were not exposed to the strategy.

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How to Evaluate



Detectives in the Classroom – Investigation 5-2: How to Evaluate

This concludes **Investigation 5-2: How to Evaluate** and students can now put away their **Epi Logs**.