

Study Buddies

By Meredith Matthews

Teens talk about being part of medical trials—or not.

The next time you pop a pill for a backache or a cold, check out the label. It may say the drug is safe and effective for ages 12 to adult. But how does the drug's manufacturer know whether it's good for you? Have scientists ever studied it in teens?

In some cases, the answer is no. Many treatments—drugs, devices, and techniques such as surgeries—have been well tested in adults but not in teens. That's changing, though, as health officials encourage more research in young people.

More Info, Please

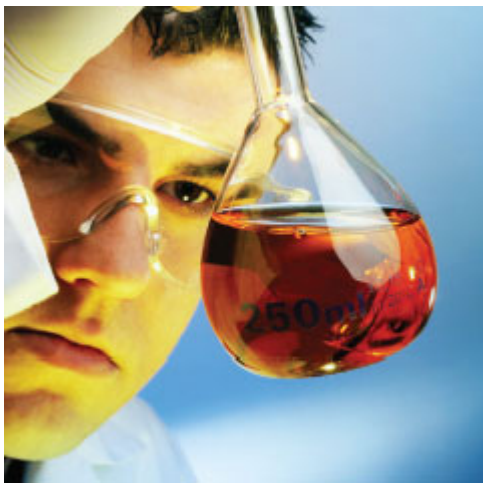
Health providers need to know the best way to help teens with problems. And that information has been hard to find. Most products aren't developed for or tested in this age-group, according to the U.S. Food and Drug Administration. The Best Pharmaceuticals for Children Act, renewed in 2007, seeks more research of health products in kids and teens.

Researchers aren't wasting any time getting young people involved. Perhaps half the patients in Seattle Children's Hospital's Adolescent and Young Adult Cancer Program take part in trials, according to Dr. Rebecca Johnson, the program's medical director. Some studies aim to help teens beat an illness; others test treatments that might have fewer toxic side effects than current treatments.

Why bother? There's a common saying among scientists who study teens: "Children are not little adults." Teens' bodies differ from those of both older and younger people. Their organs work like kids' organs, but their hormone levels are closer to those of adults, so treatments can cause more side effects, says Johnson. That's not the only reason more research is needed. Many cancer treatments affect future fertility—the ability to have children—which is a "huge consideration in adolescents," Johnson notes.

Problems such as high blood pressure that used to affect mainly adults are occurring in a growing number of teens. "We don't have the option of *not* treating the disease, but we don't know the best way *to* treat it," says Dr.

Michael Spigarelli, medical director of clinical trials in Cincinnati Children's Hospital's adolescent medicine division.



iStock

So researchers create studies, many of which are helping teens. Between 1975 and 1995, cancer deaths in kids and teens dropped nearly 40 percent. That change is “really the result of clinical trials,” says Dr. Yoram Unguru, a childhood cancer specialist at Johns Hopkins University in Baltimore.

Tough Decisions

Those successes don't mean a trial is a shortcut to a cure. A participating teen might be in the control group that doesn't get the treatment being studied. (Control groups help researchers see how something new stacks up against the current best treatment.) Or the treatment may not work well. Teens participating in clinical trials are taking “a huge leap of faith,” admits Unguru.

No one can force people to join studies. Those younger than 18 can't decide on their own to take part—parents or guardians have to sign a consent form. But researchers want teens to have a say and exclude those who don't want to participate. Unguru and his colleagues asked kids and teens who took part in studies about their experiences; pressure from parents and doctors to participate was common. However, when teens have a role in the choice—they provide assent, as opposed to legal consent—it's “empowering ... because so many [other] decisions are taken out of their hands,” Unguru says.

The chance to speak up meant a lot to Valery Y., 17, who learned in 2009 that she had leukemia, a blood cancer. Her doctors asked her to participate in a study of differing medication doses. “I didn't hesitate to say yes,” the

Baltimore teen remembers; her parents agreed. "I knew there was a chance that the treatment I would get would not work or even make me worse," Valery reflects. What helped her decide? She learned that any children she might have could develop the same disease. By taking part in the trial, explains Valery, "I would feel like I have already done what I could ... to either prevent or help save my kids from cancer."

Some teens make the opposite choice, such as Trey H., also a 17-year-old from Baltimore. After surgery and chemotherapy wiped out most of his osteosarcoma (a cancerous bone tumor), he could have joined a study for a therapy called interferon. "My family and I talked about it a lot, and ... I decided not to do it," says Trey. That's because for the 72-week study, he'd have weekly interferon injections and face side effects. "I wanted to help others with this type of cancer," explains Trey, "but I had had enough of feeling sick, losing my hair, and being stuck with needles to last a lifetime!"

The Bigger Picture

Whether to participate in a clinical trial is a personal choice. People consider potential side effects and health risks, as Trey did. In many drug studies, participants are randomly put in either the treatment group or the control group, which receives the standard treatment or a placebo (a harmless substitute). People in the control group are usually no worse off than people not participating in the study. Those people receiving the new treatment may encounter unexpected problems, but they may also gain benefits they wouldn't otherwise have had.

Morgan H. is already seeing positive results from being in a trial. The 16-year-old from Washington could have had chemotherapy and radiation for Hodgkin's disease, another form of blood cancer, "because I know that works." The study she joined was about skipping high doses of radiation that can have unwanted long-term effects, and in the end, Morgan thinks she made the right choice. "I was nervous about it, but now I'm really glad I've done it," she says. "I feel not having radiation is going to be beneficial. I have a lot of life in me and want to have a good quality of life when I'm older."

Many teens hope for similar outcomes and also opt to join studies for the greater good. (It's certainly not to get rich; people in trials generally are paid only for the expenses of participating, with sometimes a token amount added for their time.) Even if a study has disappointing results, "it goes into [medical journals] and helps us to continually improve" research, says Johnson. "It's something sort of good to come out of a bad situation."

Trey agrees that clinical trials are “a good thing.” In fact, thinking about others influenced his decision to stay out of the study. Trey says he had toyed with the idea of trying it for a bit but not long term. “One of my doctors explained that if I did the trial but didn’t do the complete 72 weeks, the information they gathered wouldn’t be useful,” he points out, “and that did help me decide not to do it.”

For those who do participate, the social rewards are just as important as the personal ones. Being involved in research “gives teens a voice,” reflects Valery. If the study she was a part of does go on to benefit other teens staring down cancer, adds Valery, “it all may have been worthwhile.”

Testing, Testing, 1, 2, 3

Are people in clinical trials treated like guinea pigs? No. By the time a drug, a device, or a medical technique is cleared for human testing, it’s already been tried out in test tubes *and* on guinea pigs, mice, and other lab animals. Then, to make sure the item tested is safe and works in people, the U.S. Food and Drug Administration (FDA) groups clinical trials into the following phases.

Phase 1: Testing in small groups of people (sometimes as few as 10) helps scientists learn how the therapy is used by the body, what side effects it causes, and what doses may be safe. Often, study participants are healthy people.

Phase 2: The treatment is studied in 20 to 300 patients with the health condition, mainly to see how well it fights the illness or injury and whether any safety issues pop up. In phase 2 and phase 3 studies, the product or technique is usually tested against a control group.

Phase 3: Huge studies of 300 to 3,000 people put the study item up against the usual therapy. In most cases, neither patients nor researchers know who’s getting the experimental treatment (a process called blind testing), and some patients (the control group) get just the standard treatment instead.

Phase 4: Once the FDA clears the treatment so that anyone can use it, “post-marketing” studies by manufacturers reveal any problems that might have been invisible in small study groups.

Healthy People Help Too

You don't have to be sick to be in a study. Some clinical trials involve healthy people, either to test a therapy's effects or to serve in a control group that doesn't receive it. Some experiments track healthy people to see who develops problems. Cincinnati Children's Hospital studies everything from skin-care products to the relationships of teens and parents, says Dr. Michael Spigarelli, who directs the research.



iStock

Some studies track how healthy teens are.

For instance, Brandi G., 15, from Kentucky, was in a study that looked at the circulatory systems of obese preteens and teens with type 2 diabetes. She isn't obese and doesn't have diabetes. Brandi was in the control group. Being in the study wasn't hard, she says. In addition to having blood drawn, body measurements taken, and heart and blood tests run, she filled in a food diary and wore an activity monitor. Brandi thinks her contribution will help "so there's more knowledge about teens."

Reasons for Rules

You won't find mad scientists running Frankenstein-like clinical trials. Many rules protect participants. For instance, trials have to be approved by an institutional review board—experts who ensure the study minimizes risk to participants.

Another requirement, informed consent, has been getting a lot of attention because of a recent book—*The Immortal Life of Henrietta Lacks*, written by Rebecca Skloot. It tells the story of Lacks, a young mother who died of cancer in 1951. In the hospital, samples of her tumors were taken without her knowledge or consent.

Scientists discovered that those cells stayed alive in the laboratory. Since the 1950s, cells that came from Lacks have become a mainstay of research. Scientists have used them for everything from developing the vaccine for polio to studying radiation poisoning.

Sounds terrific, right? But doctors did not ask Lacks or her family for consent to take or use her tissue. Her family members weren't compensated for the cells, which have made millions of dollars for private companies. Today, research protections make such a scenario far less likely.

Name: _____ Date: _____

1. Which of the following is not a reason teens opt to participate in trials?
 - A to improve their own health conditions
 - B to make money
 - C to contribute to the greater good
 - D to have a voice and have a say in things

2. The author presents evidence in this article for which of the following arguments?
 - A All teens should participate in medical trials.
 - B Teens should rarely participate in medical trials; they're too risky.
 - C It's a personal choice whether a teen should participate in a medical trial.
 - D Before a teen participates in a medical trial, he or she should talk to his or her parents and consider all the risks, benefits, and potential side effects.

3. Which of the following conclusions about children's and teens' involvement in medical trials is supported by the passage?
 - A Studies with younger people improve what we know about products and treatments.
 - B Involving children in the medical trials makes them feel better, even if the impact on our medical knowledge isn't large.
 - C There are too many risks involved in conducting studies with youth, so we should abolish these types of studies altogether.
 - D Children's and teens' involvement in medical trials is only helpful some of the time.

4. Read the following sentence: "However, when teens have a role in the choice—they provide assent, as opposed to legal consent—it's 'empowering ... because so many [other] decisions are taken out of their hands,' Unguru says."

The word **assent** means

 - A reach the peak of
 - B agreement
 - C difference
 - D data

5. This passage is mostly about
 - A whether or not parents should sign their kids up to participate in medical trials
 - B the challenges of recruiting young people to participate in medical trials
 - C the impact of younger people's involvement, or lack thereof, in medical trials
 - D the risks involved in participating in medical trials, especially for children and teenagers

6. What are some of the things a teen might consider in determining whether to participate in a medical trial or not?

7. What does Unguru mean when he says that children participating in the trials take “a huge leap of faith”?

8. The question below is an incomplete sentence. Choose the word that best completes the sentence.

Some teens choose *not* to participate in a trial _____ they're already exhausted from treatment after treatment and don't want to go through more.

- A also
- B because
- C although
- D however

9. Answer the following questions based on the sentence below.

Deciding whether or not to participate in a medical study is a personal choice for teens and children.

What? deciding whether or not to participate in a medical study

(is) What? _____

(for) Who? _____

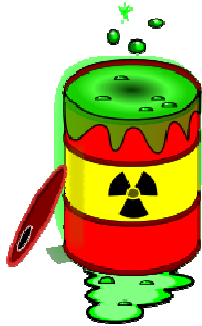
Directions: Read the vocabulary word and definition below to complete questions 10a, 10b, and 11.

Vocabulary Word: **toxic** (tox · ic): poisonous.

10a. Read the sentences below and underline all forms of the word **toxic**.

1. "Don't drink that! It's toxic!"
2. Some things that are safe for animals to eat can be toxic if ingested by humans.
3. It's a toxic environment and harmful to your health to be there.
4. There are toxic substances in that that can cause cancer if you inhale too much of it.
5. You have to dispose of toxic waste in a special way.

10b. Where would you expect to find toxic substances?



11. If someone showed you a toxic piece of food, would you eat it?

Teacher Guide & Answers

Passage Reading Level: Lexile 1080

Featured Text Structure: Argumentative – the writer presents evidence for both sides of an argument

Passage Summary: In the article “Study Buddies,” the author provides context about teens’ participation in medical trials. She then highlights multiple perspectives related to the pros and cons of participating in a medical research trial.

1. Which of the following is not a reason teens opt to participate in trials?
 - A to improve their own health conditions
 - B to make money**
 - C to contribute to the greater good
 - D to have a voice and have a say in things

2. The author presents evidence in this article for which of the following arguments?
 - A All teens should participate in medical trials.
 - B Teens should rarely participate in medical trials; they’re too risky.
 - C It’s a personal choice whether a teen should participate in a medical trial.**
 - D Before a teen participates in a medical trial, he or she should talk to his or her parents and consider all the risks, benefits, and potential side effects.

3. Which of the following conclusions about children’s and teens’ involvement in medical trials is supported by the passage?
 - A Studies with younger people improve what we know about products and treatments.**
 - B Involving children in the medical trials makes them feel better, even if the impact on our medical knowledge isn’t large.
 - C There are too many risks involved in conducting studies with youth, so we should abolish these types of studies altogether.
 - D Children’s and teens’ involvement in medical trials is only helpful some of the time.

4. Read the following sentence: “However, when teens have a role in the choice—they provide assent, as opposed to legal consent—it’s ‘empowering ... because so many [other] decisions are taken out of their hands,’ Unguru says.”

The word **assent** means

- A reach the peak of
 - B agreement**
 - C difference
 - D data

5. This passage is mostly about
 - A whether or not parents should sign their kids up to participate in medical trials
 - B the challenges of recruiting young people to participate in medical trials
 - C the impact of younger people’s involvement, or lack thereof, in medical trials**
 - D the risks involved in participating in medical trials, especially for children and teenagers

6. What are some of the things a teen might consider in determining whether to participate in a medical trial or not?

Suggested answer: Potential side effects and health risks

7. What does Unguru mean when he says that children participating in the trials take “a huge leap of faith”?

Suggested answer: Because signing up for a trial doesn't necessarily mean you'll get the new treatment; you could be placed in a control group. Also, the new treatment isn't guaranteed to work.

8. The question below is an incomplete sentence. Choose the word that best completes the sentence.

Some teens choose *not* to participate in a trial _____ they're already exhausted from treatment after treatment and don't want to go through more.

- A also
- B because**
- C although
- D however

9. Answer the following questions based on the sentence below.

Deciding whether or not to participate in a medical study is a personal choice for teens and children.

What? deciding whether or not to participate in a medical study

(is) What? **is a personal choice**

(for) Who? **teens and children**

To the Teacher: ReadWorks recommends that you teach this vocabulary word to the whole class out loud using the four steps listed below.

Vocabulary Word: **toxic** (tox · ic): poisonous.

Step 1: Introduce the word

- a. Teacher writes the word on the board and divides it into syllables: (tox · ic)
- b. Teacher says: “This word is toxic. What is the word?” [All students reply together out loud: “toxic.”]

Step 2: Provide a child-friendly definition

- a. Teacher says: “Toxic means poisonous.”
- b. Teacher says: “In the passage, it is explained that certain studies are aimed at finding treatments with less toxic, or less poisonous, side-effects.”
- c. Teacher says: “What is the word?” [All students reply together out loud: “toxic.”]

Step 3: Practice the word

Teacher provides examples and additional opportunities to repeat the word. Read the first sentence out loud to your students. Begin reading it again and when you come to the vocabulary word prompt students to say the vocabulary word out loud. Then, finish reading the sentence out loud to your students.

Directions: Read the vocabulary word and definition below to complete questions 10a, 10b, and 11.

Vocabulary Word: **toxic** (tox · ic): poisonous.

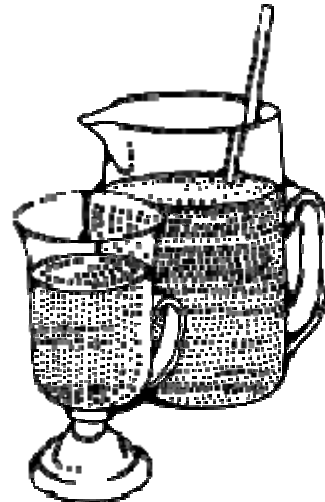
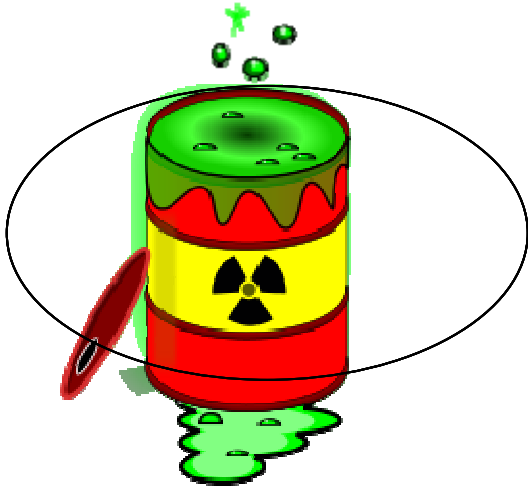
10a. Read the sentences below and underline all forms of the word **toxic**.

1. "Don't drink that! It's toxic!"
2. Some things that are safe for animals to eat can be toxic if ingested by humans.
3. It's a toxic environment and harmful to your health to be there.
4. There are toxic substances in that that can cause cancer if you inhale too much of it.
5. You have to dispose of toxic waste in a special way.

Step 4: Check for student understanding

To the Teacher: This step can be completed as a whole class activity or as an independent practice.

10b. Where would you expect to find toxic substances?



11. If someone showed you a toxic piece of food, would you eat it?

Suggested answer: No, because it is poisonous and would be very harmful to my body if I ate it.

Suggested Additional Vocabulary: manufacturer, fertility, empowering, consent, mainstay