A Patient's Story

A Painful Loss and "Unbearable" Images Inspire Healthy Volunteer

Kymone Freeman, a poet and playwright from Washington, DC, has seen first hand the devastating impact of AIDS on families and communities.

When Kymone's favorite uncle died from AIDS his family reacted with denial.

"They tried to pretend that he just got sick and passed away from anything but AIDS," says Kymone. "My family would not visit my uncle in his final days in the hospital because they feared they would contract the disease."

But it wasn't just his family that was impacted. On a youth leadership trip to Kenya in 2004 Kymone visited AIDS clinics and orphanages set up for children who had lost their parents to AIDS.

"Seeing people who were dying without comfort and beyond help was unbearable," he says. "That opened my eyes to the worldwide AIDS pandemic."

So in 2007, when Kymone learned about an upcoming AIDS vaccine trial sponsored by the National Institutes for Health (NIH), Kymone wanted to participate as a healthy volunteer.

His long-term girlfriend, however, was adamantly opposed.

"When I told my girlfriend I was thinking about doing the trial, it caused a lot of problems," he said. "We didn't break up, but it came at a high cost at home."

Despite his eagerness to help find a vaccine for AIDS, Kymone admits he had some initial reservations himself. He was nervous when the NIH site staff described the treatment's potential side effects, but he says the NIH staff took the time to explain the potential effects and the likelihood that they would occur and their patience and willingness to answer his questions calmed his fears.

"The only side effect I had during the trial was that I caught a cold the two times the vaccine was introduced. But it was winter, so possibly it was just a common cold I would have gotten anyway," he says.

Kymone's participation lasted about nine months. "I went to the site about once a month and would get a shot or give a blood sample to see how my body was responding," he says. Although Kymone and other volunteers weren't exposed to the AIDS virus, researchers wanted to see whether the vaccine stimulated an antibody response.

Kymone says his experience with the vaccine trial was a learning experience. He's glad that he participated, and encourages others to consider taking part.

"What I'd say to anyone who is thinking about it is, 'Educate yourself and involve your family and friends in the decision.'"

How can I make sure a clinical trial is safe?

When deciding whether or not to participate in a clinical trial, safety is a key consideration.

CenterWatch estimates that the chances of dying due to an investigational drug during a clinical trial are about 1 in 10,000. Those odds need to be considered in light of the possible benefits of participation, such as helping future generations who have the same condition.

While the risk of dying as a result of a trial is low, the odds of experiencing a serious adverse event are significantly higher: about 1 in 30. Most serious adverse events happen in trials for people with cancer, heart disease and immunology/infectious diseases like AIDS. For these volunteers, trial participation often represents their best hope of survival.

Researchers work hard to keep participants safe. Before human trials can begin, investigational treatments are tested for safety in the lab or in animals and every clinical trial must follow a study plan or "protocol" to help ensure safety.

Regulators overseeing trials likewise work to keep participants safe. Every trial is overseen by a local independent review board (IRBs) that is in charge of making sure the trial is fair and ethical. Some trials are also overseen by a Data Safety Monitoring Board, which makes sure the research is valuable and patients aren't exposed to unnecessary risk. Federal regulators, such as the Office of Human Research Protections and the Food and Drug Administration which has the final say in whether or not a treatment is approved, also play a role. These regulators can shut down a trial if they consider it too risky.

While regulators safeguard volunteers, clinical research participants should take steps to protect themselves as well. As a research participant you should:

- **Educate yourself.** Learn everything you can about the study treatment. Ask questions of study staff and outside healthcare professionals and do your own independent research about the study drug.
- **Check an organization's certification.** A number of organizations, such as the Association for the Accreditation of Human Research Protection Programs, the Association of Clinical Research Professionals, the Drug Information Association and the Academy of Pharmaceutical Physicians and Investigators, offer certification programs that provide a level of quality assurance for would-be participants.
- **Speak up.** If you ever sense that researchers are evading your questions, feel that you are not getting complete answers or do not feel comfortable in a trial, you need to raise your concerns. Talk to study staff, your doctor or the IRB monitoring your trial.
- **Put your own interests first.** Remember, you are a volunteer and are free to drop out of a trial at any time for any reason.

Ultimately, the decision to participate in a trial is subjective: what may seem too risky to one person may be very promising to another. Researchers and watchdogs work hard to keep volunteers safe, but every investigation involves risks. As a participant you owe it to yourself to learn as much as you can about a trial and understand your rights as a volunteer.