A Patient's Story

Jenna Korb: Back from the Brink

Happy dreams of a promising future can vanish in an instant.

That's what Jenna Korb, then a bright, lively college student from Montana, learned when she went to the school nurse for a check-up.

It was 1993 and the 19-year-old had been feeling exhausted and lightheaded. She decided to drop by the college nurse for a spur-of-the-moment exam.

"I thought I'd get a quick slap on the hand for not getting more sleep and not eating better," says Jenna. But the nurse told her she looked terrible. "When she pricked my finger for a drop of blood, it didn't even look normal," recalls Jenna, now the executive director for the **Leukemia & Lymphoma Society San Diego/ Hawaii Chapter.**

Jenna was rushed to the local hospital and soon transferred to the Fred Hutchinson Cancer Research Center in Seattle. There she was diagnosed with myelodysplastic syndrome, a condition in which blood cells that develop in the bone marrow are defective and die off.

The prognosis was dire. Jenna underwent chemotherapy and lost her hair, but she needed a bone marrow transplant to survive. Prior to the transplant, Jenna's doctors approached her about taking part in clinical trials.

She decided to participate in two trials. "One was a medication for rejection that would allow me to take one pill after the transplant rather than 10 or 15," she says. "The other was a clinical trial for a drug I could take during treatment that would help relieve nausea."

The clinical trials at Fred Hutchinson were well-organized, Jenna recalls. "Everything they did was centralized. My responsibility was taking the pills and they recorded everything"

After the bone marrow transplant, Jenna spent 40 days in a Laminar air flow room, which keeps the air free of any impurities or pathogens that could lead to infection. At one point she became overwhelmed with the amount of medication she had to take.

"I started to skip taking the pills," Jenna says. "The researchers came in and said 'We can't effectively track your response to all these drugs because you're not taking everything we want you to take.' They monitored me very closely."

Jenna's body tried to reject the bone marrow: She wound up in intensive care several times and at one point had to be put into a drug-induced coma. Gradually, however, her condition improved. Seven years after the transplant, Jenna's doctors declared her disease free.

Today Jenna is "100% healthy" and her treatments and tests are in the past. Through her work with the Leukemia & Lymphoma Society she's met people who have received the drug she helped test and is gratified to know that "it's still out there working and helping with rejection to bone marrow transplants."

Who are the members of the clinical research team?

Research involves a lot people. Like members of a sports team, clinical trials have coaches, officials and players and each person has an important role to play.

The **Principal Investigator** (PI) is like the head coach of a team. He or she is responsible for organizing the study, recording and studying the data and directing the team. Like a head coach, the principal investigator follows a play book, which is called the study "protocol." The protocol is a set of instructions that everyone in the game must follow.

The research staff members are like assistant coaches who help the Principal Investigator. The **Clinical Research Coordinator** or CRC handles the day-to-day activity at the research site. He or she has easy access to the principle investigator and is the main contact for volunteers.

Referees help protect the safety of volunteers by making sure teams follow the rules. The number and type of referees involved in a trial depends on the research being conducted.

Every clinical trail is reviewed, approved and watched over by an independent local committee called an **Institutional Review Board** or IRB, which makes sure a trial is ethical and fair and that volunteers are not exposed to too much risk. An IRB can end a trial if it feels volunteers are not safe.

Some trials, especially ones studying serious or deadly conditions, are also overseen by a **Data Safety Monitoring Board** or DSMB. DSMBs are independent committees of community representatives and research experts who make sure the research is valuable and patients aren't exposed to unnecessary risk.

Referees from the federal government are also involved. The Office of Human Research Protections or "OHRP" helps protect volunteers participating in government sponsored research, while the Food and Drug Administration reviews studies, inspects research centers, monitors research groups and decides whether a treatment will be approved. Both the OHRP and the FDA can shut a study down if they feel it is too risky.

But by far the most important members of the team are the research volunteers. Volunteers are like the players on the field. Without them, research can't happen. Just like on a sports team which needs players with a range of talents, a clinical trial needs all sorts of volunteers. Demographics – things like gender, age, race and ethnic background – affect the way people respond to diseases and treatments. Because of these differences, scientists need to observe many different types of people – including healthy volunteers -- to understand how a treatment affects them.