News

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Decoy May Block Key AIDS Protein

Because it is not known what causes the human immunodeficiency virus (HIV) to reproduce, many researchers are concentrating on developing therapies that will prevent HIV from entering T cells.

HIV finds its way inside T cells by binding to CD4 protein. The protein gp120 makes contact with CD4, and it is this interaction that scientists hope to interrupt.

Several laboratories are working on "CD4 decoys": synthetic mimics that would bind gp120 and prevent it from reaching CD4. However, most decoys of this sort are seen by the immune system as "foreign" and are destroyed in the bloodstream. Also, the decoys can interfere with CD4's function in the normal immune system: binding to the MHC class II protein.

Stuart L. Schreiber, PhD, and his colleagues at Harvard University in Cambridge, Massachusetts, have developed small synthetic protein fragments that successfully block the binding of HIV to T cells. Called CPFs, these fragments appear to work without affecting normal T cell function.

Because CD4 binds both gp120 and the MHC protein, Dr. Schreiber reasoned that these molecules must have an attachment site in common on CD4. The researchers found a tiny site and discovered that one component of this site, the amino acid phenylalanine, is particularly crucial to the binding of both molecules. Using chemical synthesis techniques developed in earlier studies, Dr. Schreiber made several protein fragments containing phenylalanine altered by the addition of the CPF structure. When gp120 binds to one of these fragments, it is unable to attach to CD4. While CPFs do not stop the reproduction of HIV once it is inside the cell, they appear to stop the spread of infection to healthy cells in test tube experiments.

CPFs may be developed into anti-acquired immunodeficiency syndrome (AIDS) agents for use alone or in combination with other therapies. Alternatively, these CD4 decoys may provide a toxin "delivery vehicle" system in which drugs attached to CPFs are brought directly to HIV An advantage of small protein fragments like CPFs is that they can be administered orally. Larger proteins generally must be injected.

Drugs based on CPFs are still in the early phase of development. In vivo studies have yet to be conducted.

Red Cross Launches Transformation of Blood Program

If crisis is the cutting edge for change and growth, the acquired immunodeficiency syndrome (AIDS) epidemic has awakened the transformation of the American Red Cross blood program.

In a statement issued recently by Red Cross President Elizabeth H. Dole, the plans were unveiled for what she called "the total transformation of how we collect, process, and deliver one-half of the nations blood supply."

"Instead of continuing to patch and bandage a system that evolved in the 1940s," Dole said, "we will move to the next generation. Drawing heavily on our people and our finances, we intend to expand the world of the possible. Rather than just meeting standards, we will raise them. Instead of just fixing problems, we will spend our time preventing them...because of the AIDS epidemic, nothing short of a transformation is needed. The world has changed, and we must change with it if we are to live up to the expectations of the American public."

Assuring safe blood is the goal from the top down. The board of directors already has launched rigorous structural reforms this past year. In August, the Red Cross established a centralized structure for blood services, took aggressive action to address its regulatory compliance problems, formed a new department of education, recruitment, and training for all staff, and increased its own internal inspections with a rededication to quality assurance.

Dole detailed a five-point plan that will be implemented in the next two and one-half years at a cost of $120 million. 'We will revolutionize blood banking," said Dole.

The following is the five-step plan that the board approved.

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1. Every Red Cross blood center will be closed temporarily. This will be done in stages, region by region, for eight weeks at a time. During the closure, the facility will be reequipped, new standard operating procedures will be instituted, and staff will be trained to carry them out. Blood will be provided from other operating Red Cross centers through the blood transport system so that no patient will go without a needed transfusion. At the end of each transformation, donor recruitment, blood collections, and the production of the blood components will resume.

2. The testing of all blood collected by the 53 Red Cross blood centers throughout the country will be consolidated and placed in fewer than 10 regional laboratories. In addition, the number of inspectors will be increased. One of the greatest concerns of the Congress, the Food and Drug Administration (FDA), the public, and the Red Cross has ensured the quality control of testing procedures that are difficult to maintain with absolute integrity when 53 different laboratories are involved.

Fifty years ago, blood banks performed two tests on blood to ensure its safety. Today, they perform seven. Red Cross blood banks performed 100 million more tests from 1985 through 1990 than they did in the previous five years.

More than one-third of the FDA citations of the Red Cross blood bank in the past year stem from errors reported or the lack of proper procedures in the blood testing process. Fewer testing labs will give greater control over quality at this stage. Each lab will be operated identically, providing more efficiency and higher effectiveness in the provision of safe blood products. In addition, the updated technology in these regional labs will enable the Red Cross to adapt to the quickly changing world of blood banking to ensure the safest possible blood supply.

3. One standard, national computer system throughout all Red Cross blood operations will be adopted. At present, there are ten diverse computer systems that were responsible for 25% of the citations made by the FDA in the last year. Additionally, development is underway of a new state-of-the-art donor referral registry, through which one national computer system will record and store any donor history data and test results that categorize the donor as unsuitable. One registry of ineligible blood donors will guarantee that only the healthiest blood donors contribute to the system.

4. The availability of customized patient services, such as specialized blood typing, tissue services, or the return of a patient's own blood during surgery will be expanded. Currently, these are provided only by some of the blood centers. The goal is that all blood services the Red Cross provides will be available to all Red Cross customers. With this change, smaller hospitals will be able to take advantage of technological advances in blood banking as easily as larger hospitals.

5. The separation of the oversight of all Red Cross regional services from that of the local chapter and the formation of a new biomedical board of directors at the local level working with blood services staff should ensure the adequacy and safety of the blood supply in each community.

"Some of the most learned minds in pharmaceutical manufacturing will join us and provide their advice in the critical planning phase, and again at the points of implementation," said Dole. "By October we will select the first of five to ten transformation teams of specialized staff."

Those team members will design the new regional laboratories and will be chosen from existing regional and national staff and other members of the blood banking community.

This transformation of the blood bank operations is the most dramatic and far-reaching public safety step the Red Cross has taken.

"But it is what Americans expect, and it is what Americans will get," Dole said. "And, as I have indicated, it will be expensive. But, as I said the day I took this job, there can be no higher trust than the blood of life we distribute. All our blood facilities will meet exacting standards of quality, or they will not collect blood."

From *Infectious Disease News*, July 1991;4:8.

Some Concern Over Instituting Hepatitis B Vaccine Into Babies' Routine Vaccination Schedules

The recent recommendation of the Immunization Practices Advisory Committee (ACIP) that hepatitis B vaccine be included in routine immunization for all US infants has raised questions about the cost and problems of instituting the policy.

"It seems to me that the customary issues in [pediatric] practice until now for hepatitis B have been either selected practices that have a lot of persons who are immigrants from countries where hepatitis B vertical transmission or horizontal transmission in infancy is a major problem, or the practices that have parents who have been willing and anxious to adopt