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

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children from those countries," said David W. Teele, MD, professor of pediatrics at Boston University School of Medicine in Boston, Massachusetts.

To put it in perspective for those worried about the vertical transmission of hepatitis B to their patients, Teele offered a few numbers: "If you have a newborn who is born to a high risk or an infected mother, what's the likely outcome? If that mother is surface antigen-positive and E antigen-positive, between 70% and 90% of those babies are likely to become infected, about 85% to 90% of those infected babies will become chronically infected carriers, and of those who become carriers, approximately 25% are going to be expected to die of either cirrhosis or hepatocellular carcinoma."

"If the mother is surface antigen-positive but E antigen-negative, there is a somewhat lower rate of infection in the baby, but some more of these children may have acute symptomatic and sometimes fatal hepatitis, and some of them will become carriers and run the risk of dying of hepatocellular carcinoma or cirrhosis."

Teele discussed the cost of using the current vaccine for the 4 million or so children who would require immunization if the cost of the vaccine did not change.

'The Vaccine Compensation Act is going to keep the price up, but the economies of scale have to come into action. If you have 4 million live births, and in the best of all circumstances all 4 million get three doses, the market in the United States alone is 12 million doses of hepatitis B vaccine each year."

Although the cost per dose will depend on factors such as the contract with the supplier, HBV vaccine is high compared with other vaccines.

"One course of three injections is $65 to $130, and 4 million newborns would cost between $250 million and $500 million per year without accounting for inflation," he said.

However, Teele added, the cost is deceiving because treating the disease is more expensive. "The questions you have to ask are, how much is a life worth, what is the cost of the disease, how much do hospitalizations cost?"

In the United States each year, approximately 300,000 new cases of hepatitis B result in about 10,000 hospitalizations. Of these, about 250 die from acute hepatitis.

"If you just stopped right there, you'd be spending approximately $1 million to save one death from acute fulminant hepatitis," Teele said. Unfortunately, it does not stop at the 250 deaths from fulminant hepatitis. It is estimated that each year there are 4,000 deaths from cirrhosis induced by hepatitis B. In addition, another 800 to 1,000 deaths result from hepatocellular carcinoma from hepatitis B. Therefore, in the United States, there are approximately 5,000 deaths per year from either fulminant hepatitis, cirrhosis, or hepatocellular carcinoma. By dividing 5,000 into $250 million to $300 million, a more cost-effective intervention strategy emerges.

However, the reasons for not giving the vaccine remain. "If we give all babies vaccine, are we going to have a whole bunch of susceptible people who are 10 or 15 years old? Are we going to repeat the measles scenario?" Teele asked.

For now, the answer is unclear, although there are data that suggest that while the levels of antibody fall with time, immunity appears to be solid in children for at least nine years postimmunization, but longer studies are needed.

For those who are or will be immunizing children, it is recommended that the child's thigh or deltoid be the site of vaccination, depending on the size of the child. Vaccinations in the buttock are not recommended.

If the child is not producing antibodies after a full course of vaccine, one additional dose should pick up another 10% to 15%, said Teele. Two additional doses probably will cause immunity in 50% of the people who did not respond to primary vaccine. "After that it probably falls in the area of investigational strategies to catch nonresponders," Teele said.

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