



Memorandum

Date . February 3, 1982

From Surgeon General

Subject Liver Transplantation

To The Assistant Secretary for Health

The time has come to evaluate liver transplantation as a therapeutic procedure in the light of recent advances in immuno-suppressive therapy.

Background Information

Liver transplantation, which has had a very spectacular failure rate in days gone by, has clearly reached the stage of genuine patient service, although there are still major derivative scientific observations that can and must be made.

In 1980, his last year in Denver, Tom Starzl, currently at the University of Pittsburgh, entered 14 patients into what was the first cyclosporin A trial. Two of these recipients died during operation and could not be treated with any immuno-suppression. Of the other 12, 11 lived out the full first post-operative year. At the University of Pittsburgh Health Sciences Center, 26 patients were treated with liver transplantation in 1981. Unfortunately the first four of these recipients died because of poorly preserved livers, a mechanical and technical problem which was promptly rectified. Twenty-one of the next 23 recipients are surviving and this survival figure of better than 90 percent is probably representative of what can be offered to patients today.

The liver transplant unit at the University of Pittsburgh is the only one engaged in large scale efforts in the United States today. In England, the major center is at the University of Cambridge where Professors Calne and Williams have reported a remarkable increase in survival after the introduction of the new drug cyclosporin A. There is no doubt that the great progress made in the transplantation in the last two years is directly attributable to the introduction of cyclosporin A.

There needs to be at least one prototype liver transplantation center, or perhaps more generally speaking, a center for hepatic surgery in this country. Starzl has such a center in Pittsburgh now, but the problems of funding have been difficult. Third party insurance carriers have a tendency to make the allegation that the procedure is still experimental and thus not fundable. Yet, it is unfair and improper to expect the Government research agencies to provide full hospitalization for such patients of whom an increasing number are being returned to society in good health.

Projection for the Future

Within the next five to ten years it seems certain that 10 to 20 liver transplantations centers will be required in the United States. The training for the Surgeons who will man these centers will be a very large responsibility and at the moment will fall only on the Center at the University of Pittsburgh. With the history of 26 liver transplantations in 1981, the projected figure for 1982 is to perform between 60 and 70 such procedures. This tremendous increase in numbers is directly tied to the expectation of success from the new treatment program with cyclosporin A and low doses of steroids..

While we are awaiting the best statistics that we can turn up for the United States, it has been estimated that there are between 20,000 and 25,000 deaths a year in the United States from various types of liver disease. Because many of these patients have alcoholic cirrhosis certainly only a minority of those who die of liver disease would be bonafide candidates for liver transplantation.

It would be poor stewardship of resources to fund liver transplantation unless cyclosporin A and low dose steroids were used post operatively. To fund liver transplantation for all ages would open Pandora's box in reference to accurate diagnosis in reference to alcoholic cirrhosis and the propriety of performing liver transplantation even on a reformed alcoholic.

On the other hand, funding by Medicaid of liver transplantation in children would put a procedure no longer experimental in the service category, would encourage other third party payers to fund the procedure, would encourage other transplantation teams to move forward in training, and would provide us with experience in funding liver transplantations should we expand the categories eligible for transplantation in the future.

It is not known how many children suffer from liver disease amenable to transplantation but there are probably between 200 and 500 children born annually with biliary atresia here in the United States. If transplantation were limited at the start to children under the age of six the operative burden would probably be manageable and we would not get into other categories of diagnosis because of the age limitation.

Recommendation 1

Find a way to fund the University of Pittsburgh Health Sciences Centers Transplantation Unit as they gear up to train other teams.

Recommendation 2

Declare liver transplantation in children, when accompanied by treatment for immuno-suppression with cyclosporin A and steroids to be no longer an experimental procedure but one which should be paid for as a service by Medicaid up to the age of six years.