

Review Cycle: October 1972 #RM000 AB

RMPS STAFF BRIEFING DOCUMENT 910 APPLICATION

Title: New York - New Jersey Transplant Program

Applicant: The Community Blood Council Director of

of Greater New York, Inc. Project: Louis N. Baker, Ph.D.

Funding Requested:		Direct	Indirect	Total	
	01:	339,920	39,294	379,214	
	02:	288,038	38,155	326,193	
	03:	177,725	27,270	204,995	

Summary:

Applicant proposes a cadaver kidney organ procurement program to be developed in the Greater New York Metropolitan area, with full participation of NYM/RMP, New Jersey RMP, and Nassau-Suffolk RMP. The program is an outgrowth of several years' planning by NYM/RMP and with institutions and a developmental grant given to the New York Blood Center for the period July 1, 1971 - December 31, 1972.

Program objectives are: (1) to increase the supply of organs from the present 50/year to 400/year by the end of the third year; (2) provide a coordinating network for organ procurement, preservation, and distribution among 14 transplant hospitals, 5 organ preservation laboratories, 6 tissue-typing laboratiories, and other hospitals; (3) establish professional and public educational programs, (4) develop third-party payment sources and, (5) develop complementary research programs to be supported by other than RMP sources.

The basic proposal complied with the review provisions of the Kidney Disease Guidelines, but was not fully responsive with regard to funding and cost elements, development of third-party support, and specification of committed cooperation. A program assistance visit was arranged and conducted on September 20 to discuss these factors. A supplement to the proposal was received on October 5, which proposed a funding period reduced from 5 years to 3 years, less total program grant cost, and a sharper decrement of RMPS support. The Supplement also provides a response to other issues raised by the staff visitors.

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE

HEALTH SERVICES AND MENTAL HEALTH ADMINISTRATION

TO : Deputy Director, DOD

DATE: October 12, 1972

FROM : Senior Health Consultant, DPTD

SUBJECT: Staff Comments on the 910 Application, New York - New Jersey Transplant Program

Staff review of the original proposal elicited a number of significant discrepancies with the Kidney Disease Guidelines. While the review processes were complied with, we observed conflicts with policy stated and implied in RMPS guidelines. A program assistance visit was arranged on September 20, and on October 5 a Supplement to the application was received as a response to matters discussed at the meeting with staff. Participants in the meeting are listed in the Supplement.

Major points of discussion at the program assistance meeting included:

1. The proposed 5-year funding period and overall high cost.

2. Failure to reflect early development of support from third parties.

3. The strength of the commitments to the program by existing organ procurement groups.

4. Specific budget items such as the cost of organ procurement, the size of the educational program, and the inclusion of costs items normally included in overhead.

5. Possible involvement with other organ procurement networks.

6. Involvement of other renal transplant and dialysis activities in these regions.

The RMP participants generally accepted the criticisms with good grace, and expressed willingness to provide more specific information requested, including a reduction to 3-year RMPS support.

Two items were not resolved to the full satisfaction of all:

a) the cost of donor-organ recovery, which is double the amount recommended elsewhere; and,

b) the efficacy of substituting educational efforts for direct Surgeon involvement in developing organ donation and recovery sources.

Statements made in the meeting were in direct opposition to previous experience and expertrenal advice heretofore obtained. As a part of the discussion of these factors, staff were troubled by the fact that neither dates nor minutes could be produced regarding meetings of the Transplant Advisory Committee.

The Supplemental document represents a significant realignment by the applicant, but is not entirely satisfactory to staff in the following ways:

- 1. The decrement of RMPS support is not as sharp as it should be, being only 14% in Year 02 and 46% in Year 03. The statements in the application may not accurately reflect the early potential for third-party support. Another New York Region has reported that Medicaid has already agreed to reimburse for donor organs, and only the amount of such payments is to be established. Another eastern RMP has influenced the Hospital Insurance Council to advise its constituents of its agreement with the concept of reimbursement for organ donations. The Blood Center appears unnecessarily cautious with regard to the need for immediate intensive efforts to obtain third-party program support.
- 2. The program sponsors appear to be relying too heavily on educational activities to increase the supply of organs. Their affirmation at the site visit, that the outside renal Consultants favored educational activities in preference to dedicated surgeon efforts in organ procurement, is in contradiction to advice given heretofore.
- 3. The Blood Center's interest in ultimately becoming a multi-organ source is not reflected in its refusal to accept developmental costs, such as renovations. At the same time, the Center is apparently asking full first-year support of its tissue-typing laboratory while it converts from research grants support to a service facility.
- 4. The Supplemental proposal has not clarified the intention, stated at the site visit, to reduce the number of service tissue-typing laboratories once the Blood Center's laboratory is converted to a service operation. We are asked to support a 6th tissue-typing laboratory which has not yet performed service activities, and with regard to which there is question regarding ultimate acceptance as a major center by transplanters.

As you know, in later seeking to clarify some of the purported Consultant advice which appears to contradict previous tranplanter posture, we encountered potential problems which could affect successful implementation of this proposal. Perhaps there will be opportunity to discuss this further in Council toward clarifications acceptable to all involved parties.