competence irrespective of board status. We believe board eligibility is required to assure high quality care.

The facility's commitment should also be evident by the following:

• The component teams must be integrated into a comprehensive team with clearly defined leadership and corresponding responsibility.

• The anesthesia service must identify a team for transplantation that must be available at all times.

• The infectious disease service must have both the professional skills and laboratory resources needed to discover, identify, and manage the complications from a whole range of organisms, may of which are uncommonly encountered.

• The nursing service must identify a team or teams trained not only in hemodynamic support of the patient, but also in the special problems of managing immunosuppressed patients.

• Pathology resources must be available for studying and reporting promptly the pathological responses to transplantation.

• Adequate social service resources must be available.

• Mechanisms must be in place for managing the lung transplant program that assure that patient selection criteria are consistent with those set forth in the facility's written patient selection criteria and that the facility is responsible for the ethical and medical considerations involved in the patient selection process and application of patient selection criteria.

• Adequate plans exist for organ procurement meeting legal and ethical criteria, as well as yielding viable transplantable organs in reasonable numbers.

## 4. Facility Plans

The facility must have overall facility plans, commitments, and resources for a program that will ensure a reasonable concentration of experience; specifically, 10 or more lung transplantation cases per year in patients who have end-state pulmonary or cardiopulmonary disease. The facility must show that this level of activity is feasible and likely to continue on the basis of plans, commitments, and resources.

## 5. Experience and Survival Rates

The facility must demonstrate experience and success with a clinical organ transplantation program involving immunosuppressive technique. The facility must have an established lung transplantation program with documented evidence of 10 or more patients, who have end-stage pulmonary or cardiopulmonary disease, in each of the two preceding 12-month periods. The facility can use single lung, double lung and heart-lung transplant patients in meeting this criterion. The Medicare cardiac and liver transplant criteria require a minimum volume of 12 transplants annually. However, based on the recommendation of the National Heart, Lung, and Blood Institute, we have established 10 cases per year as the basic standard for a lung transplant program.

We are establishing a minimum volume criterion because we believe a significant number of transplants is generally needed to maintain the entire transplant team commitment and skills to assure that procedures are of appropriate quality and safety. Our own research in heart transplantation has documented improved survival associated with Medicare approved facilities over those that do not meet the Medicare criteria, which includes minimum volume thresholds. In addition, Jeffrey Hosenpud, M.D. et al., reported in the Journal of the American Medical Association (volume 271, No. 23, June 15, 1994, page 1844) on the effect of transplant center volume on cardiac transplant outcome. These researchers found increased risk of mortality in centers performing fewer than 9 cardiac transplants per year. Further, research conducted by Erick B. Edward, et al and presented in the Fifteenth world Congress of the Transplantation Society demonstrated that, after correcting for patient mix covariates, patients mortality following liver transplantation in the United States is a function of center transplant volume. Such articles confirm our view that volume generally is a strong factor in predicting survival. Although we are not aware of published studies such as those with heart and liver transplants, empirically demonstrating that volume is associated with successful outcome and team proficiency in lung transplantion, we believe it is reasonable to assume a similar relationship would exist for lung transplants.

We have established the minimum volume of 10 transplants per year for lungs based on the fact that there are fewer lungs than hearts and livers available for transplanation. The NHLBI recommended 10 transplants as an appropriate number.

We have contacted a large sample of active lung transplant programs to gather data regarding the volume of transplants performed over the past three years. In arraying the results of these data, we found that the vast majority of centers that are designated as lung transplant centers perform a very small number of procedures. In fact, a significant number of these centers performed less than two transplants annually. Over 80 percent of the total transplants in the data were performed in those centers that exceeded the volume thereshold recommended by NHLBI. Thus, although a relatively small number of the total facilities designated to perform lung transplants by the organ Procurement and Transplanation Network are expected to qualify initially (approximately 15 of 77), we expect the facilities that are approved initially to perform over 80 percent of the lung transplants. Thus, we do not anticipate adverse impact on beneficiary access as a result of this criterion.

Based on the results of this analysis, we believe that 10 is a reasonable threshold for volume criteria. However, we welcome comments during the comment period as to the appropriateness of the number. Further, as we discuss later, exceptions to the facility criteria, including the number of persons who received transplants, may be warranted if there is justification. However, as a general matter, we believe less than 10 transplants a year is not sufficient to maintain the standard of performance needed for approval.

Survival rates may be influenced by many factors including random chance and patient selection. However, most authorities agree that a patient who is not free of adverse prognostic factors warrants lung transplantation only if he or she has a reasonable prognosis and the donor lung cannot be used in a patient who is a good candidate with at least a moderately urgent need and who is in reasonable geographic proximity. Based on data from the NHLBI report for the 996 patients receiving lung transplants in the United States prior to January 1, 1993, Kaplan-Meier actuarial survivals at 1, 2, and 3 years are 72 percent, 66 percent, and 63 percent, respectively. For patients receiving a single lung transplant (669 patients), and sequential bilateral transplantation of two lungs (161 patients), survival data are similar-73 percent, and 75 percent, respectively, at 1 year, and 67 percent and 71 percent at 2 years. With the two lungs transplanted while joined ("en bloc"), results seem less favorable, with 63 percent and 57 percent 1 and 2year survivals. When all lung and heartlung data are aggregated, the U.S. experience for 1,287 patients (1987 through 1992) is 69 percent, 62 percent and 59 percent actuarial survival at 1, 2, and 3 years, respectively.