PROPOSAL FOR
DEVELOPMENT OF ARTIFICIAL OXYGENATORS FOR
RELIEF AND TREATMENT OF CHRONIC LUNG DISEASES

BY

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INTRODUCTION

"Currently, emphysema and chronic bronchitis are increasing causes of death in the U. S. accounting for over 30,000 fatalities a year. They are also a leading cause of disability, restricting the activity of hundreds of thousands of Americans, many of whom are confined to bed. The growing incidence of these diseases is likely to be sustained by the worsening of the air pollution problem. Of the estimated 1.3 million Americans who have emphysema, over half are under age 65. In terms of disability costs, emphysema ranks third among all diseases, exceeded only by heart and mental disorders. The total economic toll it causes is incalculable." (DHEW Publication No. (NIH) 74-614, Prepared by the Office of Information for Division of Lung Diseases, National Heart and Lung Institute).

"All primary physicians who provide ambulatory care encounter large and increasing numbers of patients with emphysema and chronic bronchitis that together are called chronic airway obstruction. Many have advanced disease and are disabled. Since significant hypoxemia is present in many of these patients, the value and practicality of outpatient oxygen therapy for both objective and subjective benefit has recently become of interest. Pertinent questions remain concerning indications, economic problems, safety, and the possibility of oxygen toxicity." (The Journal of the American Medical Association, June 17, 1974, Vol 228, No. 12).

The Cincinnati group has been concerned about this problem for over a period of two years, initiated research in this area, and formulated ideas and potential solutions. It now seems desirable to increase the pace and widen the scope of the work since initial successes indicate that the prognosis is favorable.
Our ultimate goal encompasses the development of an implantable artificial heart-lung system, which will achieve stabilization and reversal of the disease process.

It is anticipated that within one year we will have developed a pump that should revolutionize heart-lung machines and devised a portable oxygen system that enables patients with chronic lung disease to live a normal life. Treatment for patients with black lung disease and emphysema will also have been initiated.
PROPOSAL

As shown in Figure 1, there are three projects: A) Pumps, B) Portable Oxygen System, and C) Patient Evaluation and Testing. Funding for the first two projects is requested from the Benedum Foundation. Funding for the third project, with application to individuals with black lung disease, will be requested from another source unless the Benedum Foundation provides its financial support.

Each of the three projects will contribute to the goal of an implantable oxygenator that will carry out the function of an artificial heart-lung system. In addition, each project will have a very important short term application, accomplished in 6 months to 1 year (as shown in Figure 1). Each project will now be discussed in more detail.

A. PUMPS

Current Limitations

Heart-lung machines were initially developed to permit open heart surgery for periods up to several hours. More prolonged heart-lung support is needed for treatment of acute and chronic lung diseases, heart failure, complications following surgery, heart-lung disease, and carcinoma. Pumps now used to circulate blood in heart-lung machines lead to the eventual destruction of red blood cells, promote clotting and protein changes. This deficiency limits the length of time a patient can be treated using a heart-lung machine.

Desired Improvements

Although existing pumps (used in heart-lung machines) have been used for several days on patients, no long-term survival is reported. Initially
LONG TERM GOAL

ARTIFICIAL IMPLANTABLE
HEART-LUNG SYSTEM

A. PUMPS

B. PORTABLE OXYGEN SYSTEM

C. PATIENT EVALUATION AND TESTING

SHORT TERM APPLICATIONS

HEART-LUNG MACHINE (1 YEAR)

ASSIST RESPIRATORY FUNCTION. REVERSE DISEASE PROCESS (EMPHYSEMA, BLACK LUNG). IMPROVE AMBULATOR ABILITIES (1 YEAR)

CLINICAL APPLICATIONS OF NEW TECHNIQUES (6 MONTHS)

FIG. 1
we will develop a pump that will provide artificial oxygenation for a number of months. The long term goal will be to miniaturize such a pump so that it can be implanted within the body and function for indefinite periods of time.

Current Status
A high efficiency pump was developed for thermal control of the astronaut's space suit in the Apollo Lunar Program. This pump, which circulated water through the space suit, was designed for relatively low weight and low energy requirements. This pump has the added advantage of being powered either by a fixed power source or by battery. These characteristics are desirable for circulating blood in an artificial heart-lung system. We are fortunate to have obtained several of these pumps for study. Our tests with this pump indicate that it is 100 times less destructive to red blood cells than pumps now in use. These results already meet our short term goal and give promise of significant improvement for use in heart-lung machines and other blood pumping applications.

Remaining R & D
Develop the pump for use in present heart-lung machines.
Develop the pump for prolonged use in respiratory assistance.
Miniaturize the pump for implantation and portability.
B. PORTABLE OXYGEN SYSTEM

Current Limitations

Inefficient utilization of oxygen.
Cumbersome and not portable.
Poor control of blood oxygen and CO₂.
Poor delivery of oxygen to critical lung areas.
Inadequate duration of oxygen supply.

Current Status

A theoretical systems model has been conceived which indicates current technology, developed and advanced, would be sufficient to overcome the above limitations. This system includes the use of existing skin sensors, solid oxygen sources, and high pressure oxygen storage methods.

Remaining R & D

Improve delivery techniques of oxygen to lung.
Provide direct oxygenation of blood.
Construct and test prototypes for patient use.
C. PATIENT EVALUATION AND TESTING

Problem
Many individuals with lung disease (emphysema, chronic bronchitis, black lung disease, etc.) are disabled. Although otherwise well, their activities are limited due to respiratory insufficiency. Available equipment for delivery of oxygen is cumbersome and inefficient preventing them from leading a normal life. No current treatment is sufficient to stabilize or reverse chronic lung disease.

Rationale
A portable, cosmetically acceptable miniature oxygen supply will enable the patient with chronic lung disease to live a normal life. It will enable the patient to be ambulatory and, by providing adequate oxygen, there is evidence that the progress of the disease can be stabilized and perhaps reversed. A heart-lung machine that is improved by virtue of our pump will enable patients with chronic pulmonary disease to be carried through acute illnesses that would otherwise endanger them. The system, because the patient can be treated for a prolonged period, will be of value in the treatment of acute and chronic heart disease and postoperative complications, as well as lung problems.

Experience with and the development of the new heart-lung machine will contribute toward and lead to the achievement of the long term goal of an implantable artificial heart-lung system. This system will virtually be a replacement part for the patient with acute and chronic disease of the lung and/or heart.
Clinical Plans

Establishment of a relationship with a clinic in a coal mining region that is devoted to the primary concern of patients with black lung and emphysema will be established. A cooperative relationship will be developed with the doctors in this clinic where there will be joint evaluation of the patient and his needs. Patients will then be transferred to Cincinnati for treatment and utilization of the equipment we are developing.

In addition, the best available medical care will be furnished patients with these diseases. As the portable oxygen supply and heart-lung systems are developed and proven, they will be offered to patients requiring such treatment. Follow-up care will be provided in the associated clinic.

There will be a continuing education program to disseminate the new technical knowledge to doctors and other health personnel as progress is made.
## FIRST YEAR BUDGET

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<thead>
<tr>
<th>Co-Principal Investigators</th>
<th>Pump &amp; Oxygenation Projects</th>
<th>Clinical Project</th>
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<tbody>
<tr>
<td>Dr. Neil Armstrong</td>
<td>$50,000</td>
<td>$10,000</td>
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<td>Dr. Henry Heimlich</td>
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Fringe Benefits (18.8%)  
- 9,400 for Pump & Oxygenation Projects  
- 1,880 for Clinical Project

**Clinical and Lab Assistance**
- (1) Nurse: $5,000  
- (1) Lab Assistant: $3,000

**Secretary and Supplies (Cincinnati)**  
- $10,000

**West Virginia Black Lung Clinic**
- Nurse Clinician: $12,500  
- Clinic Space and Supplies: $13,000  
- M.D. Supervisor (Part-Time): $10,000

**Patient Transportation & Care, Lab Studies & Drugs**  
- $25,000

**Teaching (Dissemination of Clinical Results), Seminars, M.D. Fellowships**  
- $5,000 for Pump & Oxygenation Projects  
- $20,000 for Clinical Project

**Graduate (2) 50% Academic Year - 100% Summer**  
- $9,600

**Consultant Services**  
- $3,000 for Pump & Oxygenation Projects  
- $2,000 for Clinical Project

**Principal Investigator Travel**  
- $3,500 for Pump & Oxygenation Projects  
- $2,000 for Clinical Project

**Computer Usage**  
- $2,500 for Pump & Oxygenation Projects  
- $500 for Clinical Project

**Equipment**  
- $20,000 for Pump & Oxygenation Projects  
- $20,000 for Clinical Project

**Expendable Supplies**  
- $2,500 for Pump & Oxygenation Projects  
- $2,500 for Clinical Project

**TOTAL**  
- $123,500 for Pump & Oxygenation Projects  
- $127,380 for Clinical Project