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

Submitted 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 greatly improve heart-lung machines and have devised an improved portable oxygen system that enables patients with chronic lung disease to live a more normal life. Actual treatment of patients with emphysema will also have been initiated.
As shown in Figure 1, there are three projects: A) Pumps, B) Portable Oxygen System, and C) Patient Evaluation and Testing.

Each of the three projects will contribute to the long term 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 we intend to develop a pump that will permit the pumping of blood in heart-lung machines for a prolonged time - at least 5-10 days. 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.
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 Ambulatory Abilities (1 year)

Clinical Applications of New Techniques (6 months)

Fig. 1
**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. It had 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 50-100 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. A paper describing these studies was presented at the Boston meeting of the Association for the Advancement of Medical Instrumentation in March, 1975.

**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 heavy.

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 more 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 improved heart-lung machine will contribute toward and lead to the achievement of the long term goal of an implantable artificial heart-lung system.

**Clinical Facilities**

The Clinical facilities of Jewish Hospital and the University of Cincinnati will be available to the research project. Such clinical evaluations will be done under the supervision of Dr. Heimlich and Dr. Patrick in accordance with the rules and regulations of each institution.

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

Salaries

Dr. Edward Patrick $24,000
Dr. David Dortch (Pulmonary medicine) 10,000
Professor Neil Armstrong No Salary
Dr. Henry Heimlich 12,000* 8,000
Dr. George Rieveschl, Jr. No Salary

Clinical and Laboratory Personnel

Nancy Palmer, R.N. 5,000
Michael McNeal 3,000 1770
Secretary 7,000 2,000
Graduate Students (2)
50% academic year and 100% summer 9,600

Total Salaries 70,600
Fringe Benefits (18.8%) 11,017
Total salaries including fringe benefits $81,617

Clinical Evaluation

Laboratory studies, drugs, in-patient care $15,000

Supplies and Research Equipment

(Including membrane oxygenator, oxygen sources and controls, bedside monitor for computer interface, sensors, blood flowmeter, pump modification materials, expendable supplies) 22,500

Consultant Services in Pulmonary Medicine 5,000
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*This amount is returned to the Surgical Fund, Jewish Hospital, to compensate for Dr. Heimlich's release time on this project. No fringe benefit applies.*