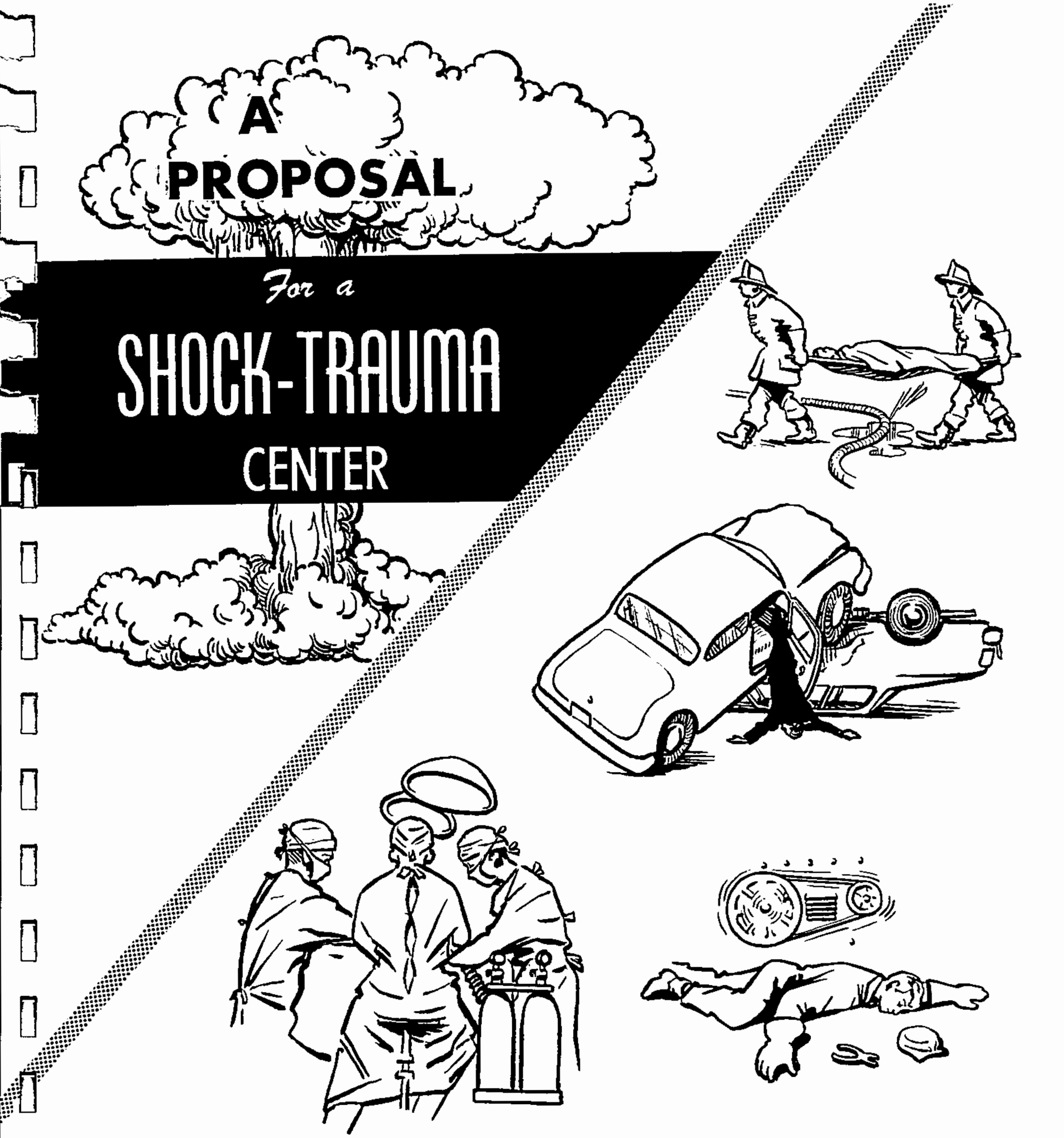
A PROPOSAL For a SHOCK-TRAUMA CENTER

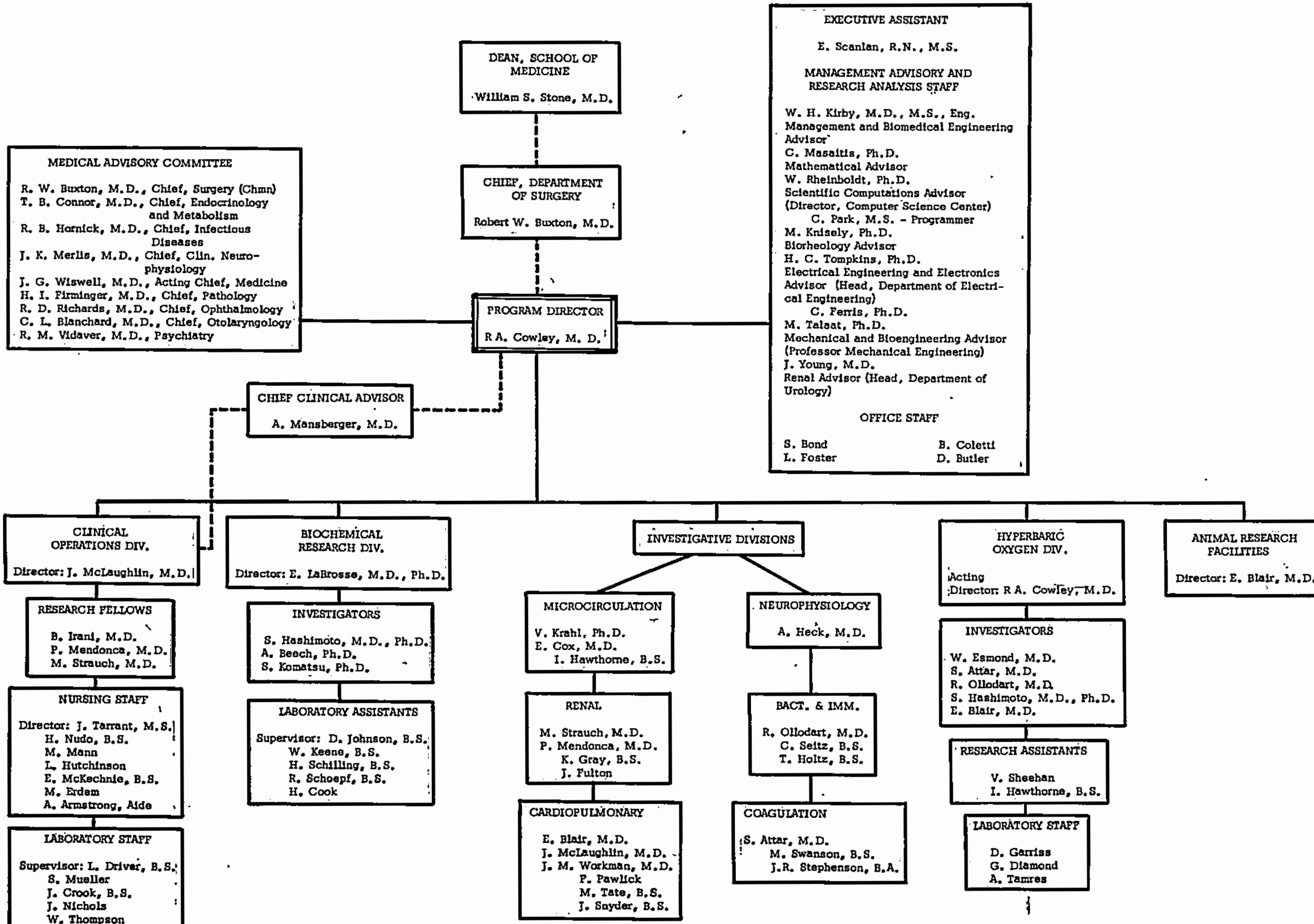


UNIVERSITY of MARYLAND
SCHOOL of MEDICINE

L 2379

CONTENTS

SHOCK PROGRAM



ORGANIZATION CHART

L 2398

INTRODUCTION

Shock is generally associated with severe injury, but sepsis, myocardial failure and many other conditions are also manifested by this syndrome. It is characterized principally by the inability of the injured individual to maintain an adequate circulation. Because of this striking situation, most studies of shock have been directed primarily to circulatory factors, their cause, and correction. Most studies have not been aimed at the total problem involved, namely, the reaction of the body to injury, the maintenance of life and repair of injury.

In the shock state, the use of the body's biochemical reserves, particularly the critical areas of reserve, determines to a large extent whether or not the patient survives. The studies currently in progress at the University of Maryland are aimed primarily at understanding the biochemical responses to injury in man. This requires careful metabolic studies which have not hitherto been considered possible because of the urgency of obvious life-saving measures that must be employed immediately by the attending physician.

Our own experience in physiological and biochemical monitoring of severely ill patients on the cardiac surgery service convinced us that we could organize a clinical shock program that would perhaps better elucidate the mechanism of shock and improve methods of resuscitation without jeopardy to the patient.

With the approval of the Chairman of the Department of Surgery, R.W. Buxton and Dean of University Medical School, William S. Stone, the principle investigator conferred with Col. J. Moncrief[1] regarding the development of a central specialized area for the study of patients in shock.

The proposal presented to Col. Moncrief suggested that if provisions were made for the formation of a metabolic study group as well as necessary technical personnel, supplies, and equipment; planned metabolic studies could be carried out concurrently with the resuscitation. A contract proposal was submitted to the Army entitled: "Clinical Shock: A Study of the Biochemical Response to Injury in Man".

The granting of the contract has resulted in 1) the institution of the present Army pilot clinical shock program, enabling a clinical shock team to make primary investigations into the mechanisms of shock, and 2) provided a background which has assisted the University in achieving an $800,000 National Institute of Health Research Facility Grant for a Shock Trauma Center. This Center will allow expansion of the above objectives and present mechanisms of operation by the creation of a complete self-contained integrated study unit for shock patients. The Research Facility grant award has won the support of President Elkins and the Board of Reagents of the University of Maryland. Matching funds are asked from the State Legislature now in session for financing the University's portion of the 1.6 million dollar Shock Trauma Center.

[1] Former chief of the Surgical Research Branch, U.S. Army Medical Research and Development Command Headquarters at present Commander and Director of U.S. Army Surgical Research Unit, Brooke Army Medical Center.

These projects could neither have been initiated or accomplished without the complete support of William S. Stone, M.D., Dean of the Medical School, Robert W. Buxton, M.D., Chairman of the Department of Surgery and the staff members in the Department of Surgery. Acknowledgement is made to Dr. Theodore Woodward and Dr. Arthur Haskins and their respective departments of Medicine and Obstetrics and Gynecology for their cooperation in referring patients and allowing the Unit autonamy in resuscitation. Liaison with Col. Donald Glew, the present Chief of the Surgical Research Branch, O.S.G., has been of great value. His support, time, and advice has assisted the Unit in carrying out its mission within the administrative framework of the Surgeon General's Office. Particular mention is afforded to the investigators in the program for their support, time and effort in this endeavor.

This brochure outlines the purpose of the present Clinical Shock Unit in order that the reviewer may better evaluate our proposal for a Clinical Center To Study Shock and Trauma.

PURPOSE OF THE UNIT

The Unit was instituted for the purpose of studying shock in man. The goal of this study is twofold: 1) to seek an understanding of the mechanism of shock and of the changes produced in different types of tissues at the cellular level, and 2) to evaluate various methods of resuscitation and attempt to develop more efficient plans of therapy. The facilities available in the Unit provide an unusual opportunity to study patients directly, to perform controlled observations and to collect data on the physiological and biochemical processes occuring at the time of shock. Laboratory facilities within the Unit are also available for use in animal experiments. The scheme on page 10 diagramatically demonstrates this concept.

HISTORY OF THE UNIT

An Army research contract application was submitted June 23, 1961 and was awarded in January the following year. The Clinical Shock Unit laboratories in the hospital were not completed and made active until March of 1963. During the first year research conducted was basically experimental, however, ward metabolic studies were initiated on the critically ill.

In the beginning, teamwork and organization of the research plan was difficult to obtain. Almost all experimental problems relevant to the program evolved from two major factors: 1) the original nature of the study (scientific study of shock in man), and 2) the unprecedented design of the study. These factors which allow freedom for creative research also creates problems of organization and programming. Guidelines appropriate for resolution of these problems were unavailable since none had been established previously. Resolution of these problems by frequent conferences, scientific presentations and constructive reviews soon stimulated individual coordinated research. Our program was further strengthened by the acquisition of Drs. Kirby and Masaitis who improved the methods of management and assisted in developing bettor methods and techniques of research analysis and data handling. The APPENDIX contains pertinent information such as organization of the research plan, statistics of the Unit, and illustrative sketches of the future facility.

ACCOMPLISHMENTS OF THE UNIT

In the process of organizing the Unit and in the period immediately following the opening of the Unit, it became apparent that the problems to be studied needed to be more clearly defined. Since many arising questions, methods of data collection and even some measuring devices were entirely new in this field of research, the formulation of different tasks of the Unit had to be revised as work progressed. Each subsequent revision lead to a more specific outline of the problems and to greater coordination of efforts by different staff members.

The first major phase of the research has been completed and is summarized as follows:

a) Various methods of collecting clinical, physiological, and biochemical data were tested and uniform procedures for data collection and their recording were established. Page 25 describes Information Handling procedures.

b) Modern equipment for studying physiologic, clinical, and especially, biochemical processes was acquired and installed.

c) The procedures and the tasks for the animal experiments were clearly outlined.

d) A large volume of data on patients and experimental animals were collected.

e) Certain hypotheses concerning physiological and biochemical processes were formulated.

Abstracts typifying the units progress during this phase of the research are included in the APPENDIX on pages 12 - 17. These abstracts illustrate the various aspects of the research conducted by the Unit. The first abstract (Beech) illustrates biochemical data collection, their classification and correlations as well as some conclusions based on these correlations. The second abstract (Attar) illustrates the development of a hypothesis from the data of human patients and from the findings of other researchers. The third abstract (Cowley) shows a formulation of a far reaching conjecture based on limited data from animal experiments. This conjecture calls for modification of experimental procedure to obtain additional data to test and to improve the conjecture. The fourth abstract (Hashimoto) describes preliminary results obtained from testing experimental therapy. It indicates which of three substances tested on animals deserves further investigation. The fifth abstract (Mansberger and McLaughlin) describes the clinical results of our present methods of therapy.

FUTURE PLANS OF THE UNIT

These achievements constitute a solid basis for the second even more fruitful phase of research. Formulated hypotheses will permit more efficient and more purposeful collection of data. Further analysis of already available and new data will yield additional tests of the formulated hypotheses and will lead to new conjectures that will make the future research more challenging and better planned. Established procedures for data collection is need to test various hypotheses and to modify them according to new experiences.

During the first phase of operation of the Unit, of necessity, there was relatively limited interdependence of various researchers in the Unit and only a little coordination of their efforts. It appears that early in the second phase of research, more basic and complex hypotheses will emerge. This will require more coordination of individual research efforts and will impose some restrictions on freedom of the research. However, this coordination will lead to a more tightly consorted effort toward the unification of acquired knowledge into a theory of shock.

DESCRIPTION OF PRESENT AND FUTURE FACILITIES

The research facilities for the shock program at the present time include four areas with a net floor space of 12,842 feet: 1) an animal research laboratory, 2) clinical shock trauma unit, 3) a special studies research laboratory, and 4) data information center. The animal surgical research facilities include the surgical research laboratory located in the Bressler Research Building, floor 6 across the street from University Hospital. This contains complete animal operating room facilities, x-ray-isotope area, histology and medical electronics laboratories. An animal farm housing large and small animals supervised by a full time DVM contains a facility for 100 dogs.

The Clinical Shock Trauma Unit facilities include a 2 bed clinical shock unit with attached biochemical, physiology and cardiopulmonary physiology laboratories. The special studies research laboratories are located on 3rd floor of the Bressler Research Building which are in the process of renovation, and include small OHP chambers as well as a large 8' x 22' walk in chamber.

The special Data Information Center is located on Ward 4B of the Hospital and contains shock patient charts, flow sheets, duplicating equipment, etc. as described on page 26. This area alrady makes use of the Computer Science Center of the University of Maryland established in February, 1962. This Center provides an all-university research and service facility for the faculty, the research staff, and the studients of the University.

In March, 1963, an IBM 7090/1401 computer system was installed in the Computer Science Center. The IBM 7090 was converted to the faster 7094 system this past September. The system is a two-channel, fourteen tape 7094 configuration with a 32,768 word memory and an on-line card reader, card punch, and printer. The 1401 has an 8000 position memory and shares four magnetic tape drives with the 7094 via a switching device. With its card read-punch unit, high speed printer, paper tape reader, and paper tape punch, the 1401 serves as the input-output unit for the 7094.

A second 1401 and two additional tape drives units were installed in November, 1964, thus increasing the overall flexibility of the system. The second 1401 has a 4000 position memory and will share two magnetic tape drives with the 7094 via a switching device. This 1401 will serve as the second input-output unit for the 7094.

The Computer Science Center system is compatable with the monitoring and computation systems contemplated for the Shock Trauma Center as described in the proposal. This will be of great assistance in achieving a more sophisticated type of research program.

The new Shock Trauma Center will be a part of the University of Maryland Medical School - Hospital complex, and will be constructed over the present hospital E wing. This wing connects the general hospital to the Psychiatric Hospital and will include three floors with an area of 13,566 square feet. This multidisciplinary complex will provide for the first time the resources necessary for simultaneous resuscitation and study of a large group of patients. Professional, nursing and laboratory support will be available on a 24 hour basis.

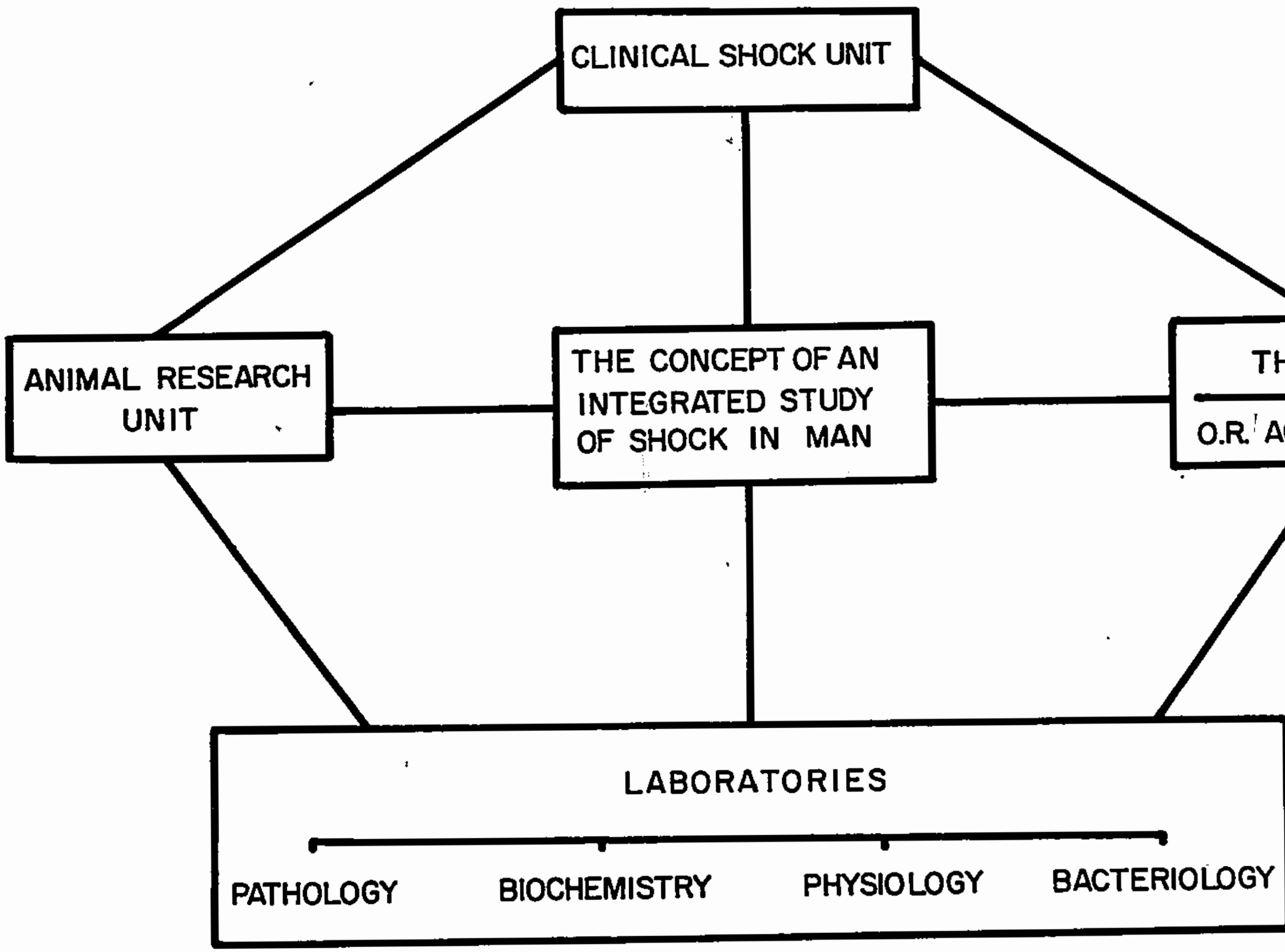
It will include a data information center, operation rooms, an isotope catheterization laboratory, a hyperbaric oxygen facility, support and research laboratories. The patient area will consist of a shock ward of 6 beds (2 of which will be isolation beds), and 6 shock convalescent beds for post-shock and control studies. The protocols are so designed that the patient in shock is his own control.

This will be the first clinical center specifically designed to study shock and trauma. Sketches and drawings on the last 4 pages of the APPENDIX identify the component parts as well as the physical proximity of the center to the University Hospital.

SHOCK TRAUMA CENTER

COMPONENT FACILITIES – TRAUMA SHOCK UNIT

THE SHOCK PATIENT IS THE CORE AROUND WHOM REVOLVES A DYNAMIC RESEARCH STRUCTURE



APPENDIX

ABSTRACTS TYPIFYING UNIT PROGRESS

PLASMA AMINO ACID CHANGES IN CLINICAL SHOCK

J. A. Beech

Plasma was obtained from venous blood in 10 healthy volunteers, 8 patients prior to surgery, 28 during surgery involving occlusion of the aorta, 30 on admission to the Shock Trauma Unit and 10 terminal shock patients.

After preparation, the plasma was analyzed for free amino acids and related compounds by the method of Moore & Stein; it was found that out of the 37 compounds analyzed for each patient, an apparently high degree of inter-correlation between 17 amino acids existed in many of the analyses. The samples showing this correlation to the greatest extent were selected from the mixed group originally taken. On this basis, it was found that none of the terminal patients and only 18% of the shock patients had high correlation between amino acids, compared with 89% of the non-shock patients. The correlation data has been submitted to detailed mathematical and statistical analysis with the aid of an IBM 7094 computer.

Regression analysis by pairing amino acids has revealed that a number of pairs are highly correlated. There are three possible explanations for these high correlations:

(1) The amino acids may be interconvertable, such as is the case with serine and glycine.
(2) The amino acids may be produced by the same biochemical process, as alanine and aspartic acid; or
(3) Because of structural similarities, amino acids may be converted into the same metabolites, as serine and threonine.

The present investigation is attempting to analyze further the interrelationships of the plasma amino acids and to set up testable hypothesis. For example, phenylalanine and tyrosine are more highly correlated in surgical patients than in normal subjects. Since phenylalanine is converted to tyrosine in the liver, it is possible that this correlation has occurred because in patients undergoing surgery the liver is relatively depressed in regard to this conversion. This hypothesis is testable by giving a phenylalanine load and by doing other liver function tests.

ALTERATIONS IN COAGULATION IN SHOCK - CLINICAL STUDY

S. Attar

The thesis of intravascular coagulation has been advanced by Hardaway to account for altered hemostasis and hypercoagulability in shock, which ultimately leads to irreversible changes and death.

Seventy-four patients were studied in the clinical shock unit: thirty-three were in hemorrhagic shock and forty-one in septic shock. Blood samples were obtained at six hour intervals for silicone clotting times, prothrombin times and fibrinogen. These tests were selected to reflect changes in the four stages of coagulation. The complexity of coagulation mechanisms, and the interplay of various factors at the time of bleeding or sepsis, including therapy, rendered interpretation of the data impossible without resorting to the "scientific method" of analysis. A continuous phase-stage relationship was found to exist in human shock patients. The changes in coagulation were demonstrated to follow a definite oscillatory behavioral pattern, controlled by the onset of shock, its severity and final outcome. In surviving patients, the oscillatory pattern representing alternating phases of accelerated and decelerated coagulation gradually returned to its pre-shock state. In the non-survivors, an oscillatory pattern of increasing amplitude and frequency was obtained that exceeded the safe maximum, and finally destroyed itself. While therapy was found to modify the oscillatory behavior, there was no indication in this series that it changed its basic pattern.

These overall changes in coagulability were also demonstrated in the changes in fibrinogen and to a lesser degree, in prothrombin activity.

From the above data, one would conclude that the processes of coagulation and anticoagulation are activated after hemorrhagic and septic shock. Survival is dependent on the dynamic equilibrium of these two opposing phenomena. This forms the basis of future work in this field, in studying the mechanisms underlying these coagulation changes as well as investigating therapeutic means to keep the dynamic equilibrium of blood in states of shock.

HEMORRHAGIC SHOCK MODEL

R.A. Cowley and C. Masaitis

An empirical law that expresses probability of death of a dog in hemorrhagic shock was obtained. This probability is expressed as a function of relative defficiency of systolic blood pressure (x) and duration (t) of this defficiency. The following relation was obtained:

(1) $p = -\frac{2x^3}{s^3} + \frac{3x^2}{s^2}$, $x_o \quad x \quad s$, where p is the probability of death, and s is given by

(2) $s = \frac{1}{1 + at^{\beta}}$, $t \quad t \quad t_1$, where α and β are constants that depend on the type of animals. These constants are computed by fitting experimentally obtained mortality rates and the corresponding values of x and s in formula (1). The quantity s can be interpreted as a measure of irreversible shock, i.e. irreversible by simple reinfusion of the animals own blood. As it is seen by (1), s depends on duration t and it is equal to the smallest defficiency of systolic blood pressure that produced 100% mortality if allowed to last for duration equal to t. The values x, t, and t_1, above are the bounds of the ranges of x and t that were used in experiments from which the parameters (constants) a and β were computed. These are the ranges for which the present model is valid.

Probability of death can be interpreted as a measure of overall deterioration of the body. One of the principal causes of this deterioration is the hypoxia induced by hypovolemia. Hypoxia (h) can be defined in terms of oxygen pressure in blood and the cardiac output. Then h represents the instantaneous effect of the shock and, therefore, the rate of deterioration is some function of h, i.e.

(3) $\frac{dp}{dt} = f(h)$

Further experiments with dogs are planned that would provide the measurements necessary to compute the values of h. The formulas (1) and (3) relate the defficiency of blood pressure to hypoxia. Therefore, a simultaneous observation of mortality rate and evidence of hypoxia in hemorrhagic shock will provide the necessary data for determination of the function (f) in (3) and for obtaining a relation between degree of hypoxia and defficiency of blood pressure at different stages of shock.

In the next step of the study the relation between hypoxia and anaerobic metabolism will be investigated. It is expected that this will permit determination of the relation between metabolites in blood and tissues and the overall deterioration of the body, i.e. the severity of the shock. The activities of various compensatory mechanisms in the body, such as blood coagulants and anticoagulants, vasoconstriction and relaxation etc. will be correlated and employed to explain certain phases of the dynamics of the shock.

A large variety of standard hemorrhagic shocked dog preparations will be obtained, as a byproduct of this investigation. These preparations will be useful in the study of various shock phenomena and in the evaluation of therapeutic procedures. It should be noted that within certain regions of deficiency of blood pressure and its duration the present model gives rather accurate predictions of mortality rate. The study that is already completed shows that a more uniform preparation of hemorrhagic shock in dogs is obtained by reducing the blood pressure in each dog by a certain fixed percentage of the initial systolic pressure instead of lowering it to a constant pressure as for example in the Fine preparation.

EXPERIMENTAL HEMORRHAGIC SHOCK IN DOGS TREATED WITH MITOCHONDRIA

S. Hashimoto and S. Kumatsu

Recent studies by a number of investigators have suggested that the enzyme system in the mitochondria are considerably impaired in shock. Landahn and Lueders introduced the use of mitochondrial therapy for experimental liver damage induced by CCl_4, and these workers have also used mitochondria for the treatment of liver diseases in man.

We have administered intravenously, fresh dog liver mitochondria, (DLM) lyophilized beef liver mitochrondia (BLM) and lyophilized beef heart electron transport particles (ETP) to dogs for the treatment of experimental hemorrhagic shock. The DLM group had a 59% survival rate, the BLM group, 80%, and ETP group, 36% survival rate as compared to 17% for controls. The BLM and ETP groups showed lower uptake volumes than the control group, even though in these groups maximum bleed-out volumes were higher as compared with the controls. When we compared the lactate level of the ETP group one hour after the onset of shock with the level one hour after beginning of reinfusion, we see a significant decrease in the lactate level, while in the control group, the lactate level is significantly increased. A possible explanation for this effect on plasma lactate may be the retention of the high "NADH oxidase" activity by the infused ETP preparation.

The relationship between "NAPH oxidase" activity and therapeutic action in hemorrhagic shock has been studied in more detail by the use of an inhibitor. ETP and ETP + rotenone have been administered in ETP equivalent doses to rats subjected to hemorrhagic shock. When rotenone is incubated with ETP it binds firmly and completely abolishes the "NAPH oxidase" activity of the ETP; the osmotic effect of the ETP is not altered, of course. As in the studies with dogs, the BH-ETP significantly increased the survival time of the shocked rate. This beneficial effect of ETP was abolished by preincubation with rotenone. However, rotenone in saline was not significantly different from saline alone.

This further study provides confirmatory evidence that it is the enzymatic activity of ETP (NAPH oxidase activity) which is essential in regard to its beneficial effect on survival when used as a treatment for hemorrhagic shock.

THE TREATMENT OF SHOCK-TRAUMA IN A RESEARCH UNIT

A. Mansberger and J. McLaughlin

The goal of the Shock-Trauma Unit at the University of Maryland Hospital is to study in depth numerous physiologic and biochemical processes simultaneously and in conjunction with the treatment of critically ill patients. To accomplish this goal a team of scientists with diverse medical and paramedical backgrounds has been assembled and a well equipped clinical treatment area supported by round the clock clinical and research laboratories has been established. A clinically trained, research oriented fellow is constantly in attendance and he is supported by the Clinical Director and by consultants from the various specialty services. Nursing care is supplied by specially trained graduate nurses versed in acute care techniques and research methods. By utilization of the team approach, treatment of the patient is never interrupted, but rather, is supported by the research activity in progress.

Therapy is based on clinical evaluation and is guided by the physiologic and biochemical patterns of change in the shock state. From our experience a therapeutic triad has evolved consisting of 1)correction, if possible, of the basic disease process, and the shock induced illness, 2) correction of volume deficits and 3) correction of acid base and electrolyte abnormalities.

A clinical evaluation is made at the time the patient is first seen and therapeutic guidelines are established. Initial samples of blood and urine are obtained and treatment is begun on a clinical basis, Central venous or right atrial pressure is obtained by percutaneous cannulation of the subclavian vein and arterial pressure is monitored by means of a cannula placed in the radial artery. These measurements serve as continuous gudies to volume therapy and supply vital information concerning cardiac status. Urinary output is monitored by bladder catheterization. Within 20 minutes arterial blood pH, pCO_2, pO_2 and base deficit are available by the Astrup method and within one hour measurement of blood electrolytes is completed. During this initial period study protocols are carried out if not contradicted by the patient's condition: Cardiac output and blood volume is determined and if a tracheostomy is present pulmonary status is evaluated. Blood samples for immunologic assay, amino acid analyses, coagulation studies and other examinations are obtained according to the protocols

Increased tissue perfusion is the key to effective therapy. In most circumstances this can be accomplished by correcting volume abnormalities and acid base and electrolyte imbalances. Correction of these abnormalities then allows the buffering systems and other compensatory mechanisms to react effectively. Vasoconstriction is eleviated and tissue perfusion becomes effective as indicated by laboratory examinations which reveal a fall in blood lactic acid levels.

In addition to volume and acid-base therapy, specific measures are indicated under certain circumstances. For example, tracheostomy and respiratory assistance are utilized in cases of ventilatory insufficiency, digitalis and hydrocortisone in pharmacologic doses is given to patients with septic shock for both the antiendo and exotoxic effect and to promote vasodilation. In all instances therapy is tailored for the individual patient and it is this individualization of therapy that has produced our clinical results. Basic principles of good medical and surgical practice are not excluded.

Of a series of thirty-five patients in "refractory shock", twenty-four were discharged from the Unit recovered from their hypotensive episode. In all of these patients study protocols were carried out without interferring with clinical resuscitation. Methods of resuscitation and therapy undergo constant re-evaluation in order to seek better means of patient care.

ACTIVITIES AND PROCEDURES OF THE CLINICAL SHOCK UNIT

Admission Procedures:

Patients admitted to the Clinical Shock Unit are referred by the hospital staff from two sources, the accident room and the hosptal, ,rivate and ward, patient areas. Shock patients can be admitted directly to the Unit without consultation. Potential shock patients are admitted only with approval by the Clinical Director.

The referring physician contacts the Unit by telephone, dialing 300. The nurse receiving the call requests certain pertinent information. If the patient is in shock, she finds out the expected time of arrival. She then contacts in the following order the research fellow on call, the clinical laboratory, the Clinical Director and investigators who have requested notification. If the patient is diagnosed as being in a potential shock state, the referring physician is requested to contact the Clinical Director who notifies the Unit of his decision to admit.

Upon admission of the patient, initial blood samples are drawn, therapy is instituted and cannulations are performed for the monitoring of central venous pressure and arterial pressure. EKG leads are attached for continuous monitoring Prior to cannulations, a nurse takes measurements of the vital signs at frequent intervals.

Cannulation of the bladder is performed as soon as possible for the evaluation of renal function. The patient is weighed and measured to calculate body surface area. A blood volume and cardiac output is performed.

Monitored parameters are recorded on the machine at specified intervals and whenever there is a sudden change during the admission phase. A permanent EKG and pulse contour are recorded. The clinical picture of the patient, research procedures performed and resuscitative therapy instituted are all recorded by the nurse on the Master flow sheet. Urine tests and measurements performed and intravenous therapy started, are recorded on the Urinary Function flow sheet. Other records kept by the nurse include, nurses notes, vital signs, and medication and treatment records. The research fellow is responsible for writing a history and physical and progress notes.

As long as the patient remains in Category II, blood samples are drawn every six hours, hourly urinary output is measured, tested, recorded, and saved. Six hour urine samples are sent to the lab for testing. The patient is weighed every twelve hours. Cardiac outputs and blood volumes are done at frequent intervals.

Monitored parameters are recorded on the machine at least every hour. Pulse contours are run every eight hours and data recorded on the two flow sheets are kept current. Other routine records are also dept current.

When the jpatient is placed in Category III, blood samples are taken eaily and the collected urine specimens are sent to the lab for testing every twenty-four hours. Other data is recorded as prescribed.

STUDY CATEGORIES

1. Study Categories: Upon admission to the Unit, all patients will automatically be in Category I.

If the patient is in shock or had been in shock prior to admission, he will be automatically assigned to Category II and remain in this category until changed by the Clinical Director.

If the patient is in "potential shock", he will go from Category I to Category III. If, after admission, he goes into shock, he will automatically go to Category I, and hence Category II as per shock patients, and remain in that category until changed by the Clinical Director.

In case sudden deterioration is observed in a stable patient, he will automatically go into Category I and hence Category II until changed by the Director.

In case of demise, terminal samples, which are the same as Category I will be taken.

The following is an outline of the routine blood and urine studies performed according to patient categories.

Category I - On admission to Unit or just prior to admission

Blood Studies	Blood Drawn
pH, pCO_2, pO_2, O_2 Sat, Base Excess, Buffer Base, Stand, Bicarb., Hb, Hct., L/P ratio, Glucose, Urea, Creatinine	Arterial - 10 cc heparinized
Clinical Enzymes	10cc heparinized
Amino Acids	35cc heparinized
Bacteriology	10cc clotted

Electrolytes, Osmometry, Refractometry	10cc clotted
Clotting time, Fibrinogen, Pro-time, Serum Complement	7.5cc clotted
Thrombo-elastography, Platelet counts	

Urine Studies

Admission - Foley inserted. Initial Foley sample measured and tested (pH, protein, sugar, acetone, specific gravity) then discarded.

Category II - Every six hours while the patient is acute

Blood Studies	Blood Drawn
pH, pCO_2, pO_2, O_2 sat., Base Excess, Buffer Base, Stand. Bicarb., Hb., Hct., L/P ratio, Glucose, Urea, Creatinine	10cc heparinized
Clinical Enzymes	10cc heparinized (daily)
Amino Acids	35cc heparinized
Bacteriology	10cc clotted (daily)
Electrolytes, Osmometry, Refractometry	10cc clotted
Clotting, Fibrinogen, Pro-time, Serum Complement	7.5cc clotted
Thrombo-elastography, Platelet counts	

Urine Studies

After initial bladder emptying per Foley, hourly urine is measured and tested as in Category I, then saved for every six hour evaluation of electrolytes, creatinine, urea nitrogen, and microscopy.

Category III - Daily as per Clinical Director

Blood Studies	Blood Drawn
pH, pCO_2, pO_2, O_2 sat., Base Excess, Buffer Base, Stand. Bicarb., Hb., Hct., L/P ratio, Glucose, Urea, Creatinine	10cc heparinized
Clinical Enzymes	10cc heparinized
Amino Acids	35cc heparinized
Bacteriology	10cc clotted
Electrolytes, Osmometry, Refractometry	10cc clotted
Clotting, Fibrinogen, Pro-time, Serum Complement	7.5cc clotted
Thrombo-elastography, Platelet counts	

Urine Studies

Hourly urine measured, tested, then saved for 24 hour evaluation of electrolytes, creatinine, urea nitrogen and microscopy.

Category IV - Weekly as per Clinical Director - Same as III - Following transfer from Unit (urine studies discontinued)

STASTICAL SUMMARY OF PATIENTS STUDIED BY SHOCK UNIT

I. TOTAL NUMBER OF PATIENTS STUDIED BY UNIT — 220

Before Unit Opened (March 1962-March 1963)		66	
After Unit Opened		154	
Admitted	150		
Studied, not admitted	4		

II. SUMMARY OF PATIENTS ADMITTED TO UNIT (March 1963-Feb 1965)

Number of Admissions		150
Number Recovered		90
Number Expired		60
Within 1 hour after admission	4	
Within 3 hours after admission	5	
Within 6 hours after admission	4	
In operating room	2	
Recovery Rate of All Admissions	60.7%	
Mortality Rate of All Admissions	39.3%	
Number of Patients Admitted in Shock		122
Recovery Rate of Patients in Shock	53.3%	
Mortality Rate of Patients in Shock	39.3%	
Number of Patients Admitted in Potential Shock		20
Recovery Rate	o5%	
Mortality Rate	15%	
Number of Control Patients Admitted		8
Recovery Rate	100%	

III. CATEGORIES AND DISPOSITION OF PATIENTS ADMITTED

	Number Patients	Number Recovered	Number Expired	Recovery Rate	Mortality Rate	Percent Patients Admitted
SHOCK PATIENTS						
Septic	52	23	29	44.2%	55.8%	34.7%
Hemorrhagic	25	17	8	68.0%	32.0%	16.7%
Cardiogenic	20	10	10	50.0%	50.0%	13.3%
Undiagnosed	5	1	4	20.0%	80.0%	3.3%
Trauma	6	5	1	83.3%	16.7%	4.0%
Trauma-Hem.	4	4	0	100.0%		2.7%
Hem.-Septic	4	0	4		100.0%	2.7%
Chemical	4	3	1	75.0%	25.0%	2.7%
Hypovolemic	2	0	0	100.0%		1.3%
Sub-Total	122	65	57	53.3%	46.7%	81.4%
POTENTIAL SHOCK PATIENTS						
Trauma	8	8	0	100.0%		5.3%
Other	8	5	3*	62.5%	37.5%	4.7%
Hemorrhagic	2	2	0	100.0%		1.3%
Chemical Burn	2	2	0	100.0%		1.3%
Sub-Total	20	17	3	85.0%	15.0%	13.3%
CONTROL PATIENTS						
Sub-Total	8	8	0	100.0%		5.3%
TOTAL	150	90	60	60.7%	39.3%	100.0%

*Terminal Cancer - 2
Anesthesia Death - 1

IV. SUMMARY OF UNFULFILLED REQUESTS FOR ADMISSION

Expired Before Arriving at STU	19
Decision Not to Admit Due to Protocol	4
No Bed Available	9
Infectious Patient Already in Unit	8
	40

V. SUMMARY OF ADMISSIONS AND DEATHS ACCORDING TO TIME OF DAY

Time Intervals	No. Admitted	% Admitted	No. of Deaths	% Deaths
7 - 3	69	46.0%	25	41.7%
3 - 11	61	40.7%	17	28.3%
11 - 7	20	13.3%	18	30.0%

NURSING CARE PROVIDED IN THE SHOCK UNIT

To assure the highest standard of nursing care required by patients in shock and to perform consistant and accurate research functions assigned to the nurse, a minimum of 24 nursing hours per patient per day are required. An estimated 10-16 nursing hours per day is required for most patients who have stabilized yet remain critically ill. The above stated nursing requirements have evolved from the past two years experience in the Shock Trauma Unit.

At the present time, based on an anticipated 65% occupancy of the two beds in the Unit, the nursing staff consisting of a supervisor, six professional nurses and one nursing assistant is able to provide an average of 16.9 professional nursing hours and 3.0 nursing assistant hours, making a total of 19.9 nursing hours per patient per day. This number of nursing hours can only provide the 24 hours of nursing care needed for one patient in shock and one convalescing patient who does not require extensive care. An increase in the number of staff nurses would be necessary to provide adequate care for 2 patients in shock and also assure the performance of assigned research functions.

THE NURSING ROLE AND NURSING KNOWLEDGE REQUIRED IN THE SHOCK TRAUMA UNIT

To meet the nursing needs for the type of patients admitted to the Unit and also perform the research functions assigned to the nurse, the following is basic knowledge the nurse must know and understand:

1) Theories of shock
2) Clinical signs and symptoms of shock
3) Action and toxic effects of medications
4) Significance of arterial and central venous pressure
5) Significance of renal, respiratory and circulatory distress
6) Significance of patient activity and behavioral patterns to shock phases
7) Significance of weight, fluid and electrolyte balance
8) Diagnostic measures
9) Disease processes in various illnesses
10) Basic nursing principles and techniques
11) Current methods of resuscitation
12) Electronic monitoring
13) Research protocols and procedures
14) Methods of recording data
15) Use of specialized equipment

Based on this knowledge the nurse performs the following activities:

A. Patient Care

1) Observes the patients and makes critical judgments based on the above knowledge
2) Performs emergency measures based on her critical judgment
3) Assist in the resuscitation procedures and measures
4) Provides for continuity of therapy and research
5) Provides emotional support to the patient
6) Performs comfort measures
7) Records observations, therapy and special laboratory studies
8) Maintains supplies and equipment necessary for patient therapy

B. Research Functions

1) Collects blood and other laboratory samples as prescribed
2) Collects measures and tests hourly urine output
3) Operates electronic monitoring systems
4) Performs electrocardiography
5) Assists investigators with special research procedures
6) Assists in writing nursing procedures
7) Records pertinent data on special formats and assists in summarizing data for analysis

Because of the degree of responsibility and type of knowledge expected of the nurse working in the Unit it is essential that she have a sound basic science background as well as special nursing skills. Therefore, the staff nurses employed should have a B.S. degree in nursing with the exception of special circumstance. To inform the nurses of current developments, there is continuous in-service education of the staff through conferences, special classes and utilization of current literature. With the institution of hyperbaric oxygen therapy further demands and educational requirements will be required of the staff.

THE LABORATORY SERVICE PROVIDED IN THE SHOCK UNIT

The clinical laboratory is an integral part of the patient care and study facility. This laboratory functions 24 hours a day and performs a variety of tests useful in the evaluation of the critically ill patient. These laboratory examinations serve both as quide to therapy and for evaluation of the shock patient. The highly trained technician performs all of the examinations listed in the study protocol. Such constant coverage is of vital necessity if simultaneous therapy and study is to be carried out.

INFORMATION HANDLING

Patient information may be classed into two general groups, namely, (a) routine studies and (b) special studies. Under routine studies are listed the more standard blood and urine laboratory analyses as well as the electronic monitored data usually recorded by brush recorders. During the initial phase of the shock research program, clinical patient data gathering had been primarily the function of the shock unit nursing staff. Special patient studies were initiated by the research investigators. The data from these studies were usually kept by the respective investigators. During the present phase of the research program, all raw data, whether routine or special, is filed in the information center.

Animal research data related to the shock research effort are logged at the various subtask laboratories. It is planned to have these raw data made available at the information center as soon after experimentation as possible.

Even with the present volume of shock patients, raw data collection has occupied considerable time of the nursing staff, technicians, and interested investigators. Preliminary investigations have been made in relation to automated information storage techniques. These are intended to be restudied with the assistance acquired in the recent past. The director of the Computer Center has invited the shock unit to consider its possible application.

Problems associated with the integration of physiological analog data derived from electronic devices have been considered, but deferred until phase II of the research for two reasons. First, problems and initial hypotheses are only beginning to place demands on these observed data. Second, the requirement for the advanced technology for analog to digital conversion has only recently been met through the interest and active participation of the chairman and senior staff of the Department of Electrical Engineering at College Park.

In order to meet the needs of the investigators associated with clinical patient research, it was necessary to overcome a common, but very formidable obstacle, namely, patient's medical records. It is not always sufficient to do research with data restricted to observations commencing with the time of admission. This need was met by having the medical record of every shock unit patient photocopied and placed in the information center.

A CENTRAL INFORMATION CENTER FOR SHOCK RESEARCH

It is believed that the establishment of this information center will yield long term benefits to present and future shock research investigators. It should also serve as a significant adjunct to the teaching programs in the medical and nursing schools. The easy access to specific patient records, special research data, completed definitive studies, and the availability of the associated published papers in a single research unit constitute a by-product of this research effort not previously anticipated. <u>With appropriate support, this unusual set of teaching and research information could be centralized and made available to military and civilian research investigators throughout the country</u>.

For this, the utilization of the combined physiological monitoring systems, analog data conversion facility and associated computing unit is being considered from the (patient) control and analysis points of view. The need for real-time patient data via the monitoring systems is, of course, determined by the clinical specialists. Having important patient data in a digital form compatible with a large scientific computing unit such as the IBM 7094 located at College Park has certain obvious advantages. The precise computations to be made will naturally depend on those models or equations formulated, revised, and/or refined as the research proceeds.

BUDGET ANALYSIS

TOTAL OPERATING COST OF THE CLINICAL SHOCK PILOT STUDY
DEMONSTRATING SOURCES OF SUPPORT

ARMY RESEARCH CONTRACT #DA-49-193-MD-2229

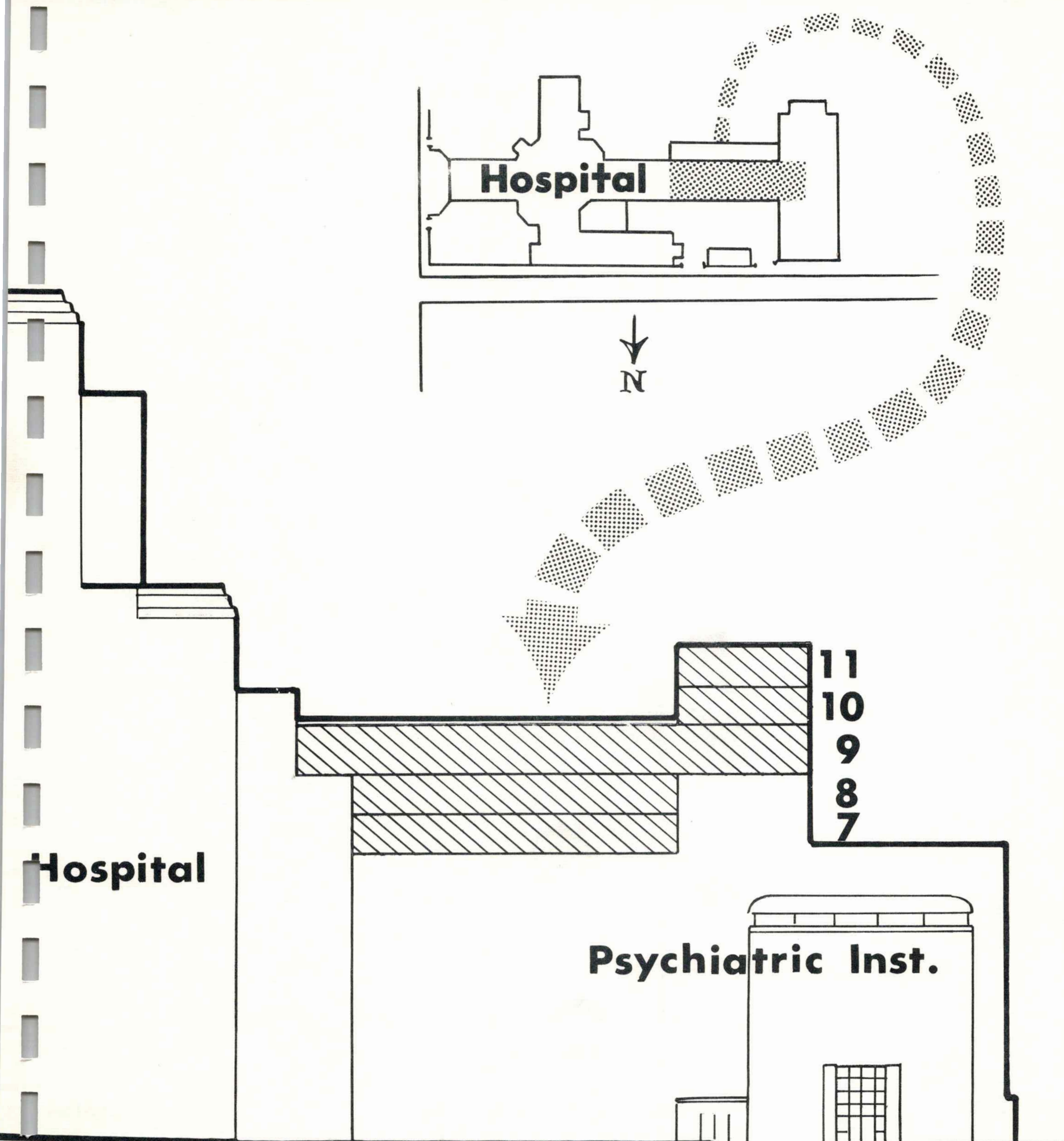
JANUARY 1962 TO DECEMBER 1964

	Army Budget	University Contribution	
Salaries	334,973	300,370*	
Travel	5,777	4,100	
Equipment	107,053	182,600	
Supplies	104,778	78,210	
Other (Fringe Expenses)	26,827	25,602	
Hospitalization	29,331	------	
Overhead	100,491	------	
Installation & Renovations	------	110,900	
	700,233	701,782	
			1,410,015

Operating room size OHP chamber donated on Hercules Poster Corp for installation as University funds become available $250,000

$34,500 of the equipment item, in the Column OTHER, was a contribution from the Dixie Manufacturing Co.

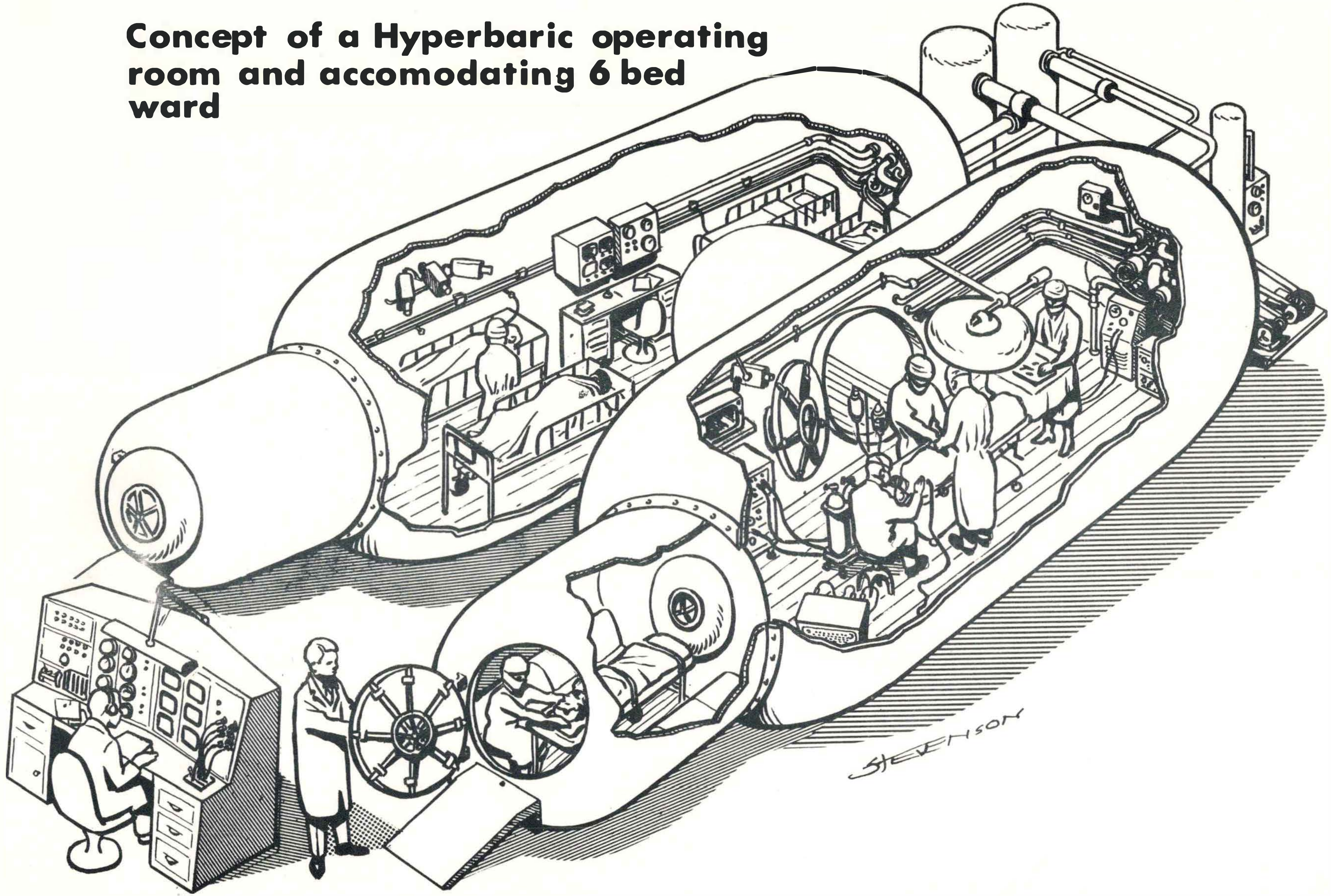
* Salaries calculated on the percent of time spent on shock research



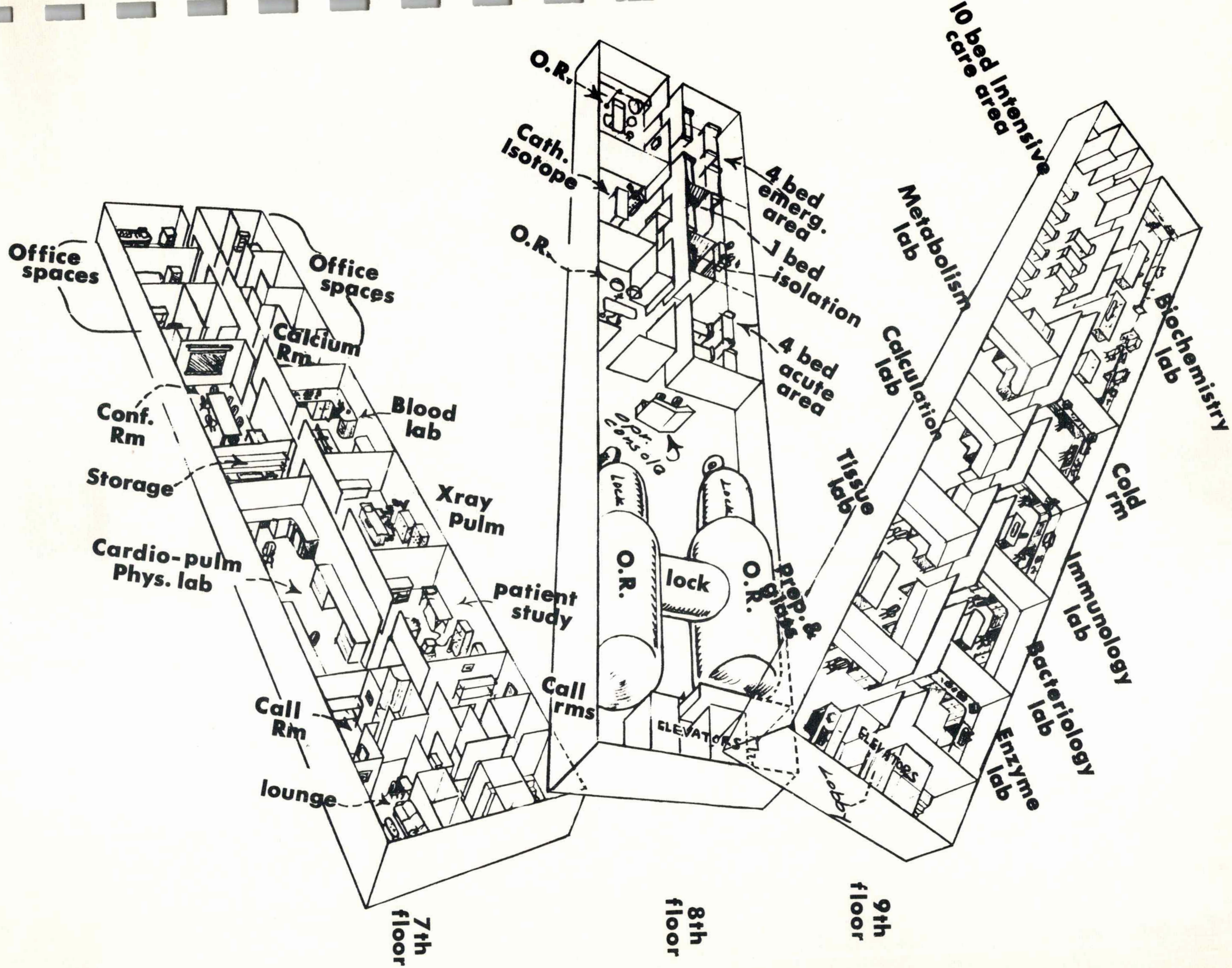
SITE OF SHOCK-TRAUMA CENTER
University of Maryland Hospital
floors 7,8 and 9

L ..55

Concept of a Hyperbaric operating room and accomodating 6 bed ward



L 2355


Office spaces
Office spaces
Calcium Rm
Conf. Rm
Blood lab
Storage
Xray pulm
Cardio-pulm Phys. lab
patient study
Call Rm
lounge
7th floor
O.R.
Cath. Isotope
O.R.
4 bed emerg. area
1 bed isolation
4 bed acute area
Opr. console
lock
lock
O.R.
lock
O.R.
Prep. & plans
Call rms
ELEVATORS
8th floor
10 bed Intensive care area
Metabolism lab
Calculation lab
Tissue lab
Biochemistry lab
Cold rm
Immunology lab
Bacteriology lab
Enzyme lab
ELEVATORS
Lobby
9th floor

COMPUTER CENTER, COLLEGE PARK