UCSF
UC San Francisco Electronic Theses and Dissertations

Title
Enhanced management of cardiac catheterization data through increased resource utilization

Permalink
https://escholarship.org/uc/item/8kt6f6r2

Author
Pfeil, Catherine Nina

Publication Date
1981

Peer reviewed|Thesis/dissertation

eScholarship.org Powered by the California Digital Library
University of California

ENHANCED MANAGEMENT OF CARDIAC CATHETERIZATION DATA THROUGH INCREASED RESOURCE UTILIZATION

by

Catherine Nina Pfeil

DISSERTATION

Submitted in partial satisfaction of the requirements for the degree of

DOCTOR OF PHILOSOPHY

in

Medical Information Science

in the

GRADUATE DIVISION

of the

UNIVERSITY OF CALIFORNIA

San Francisco

[redacted]

Date

University Librarian

Degree Conferred: JUN 2 8 1981

© 1981

CATHERINE NINA PFEIL

All Rights Reserved

ABSTRACT

It is frequently recognized that the data management needs of clinical services transcend the capabilities of single computers. It is, therefore, common for computer-based information systems to manage only subsets of essential clinical data. This situation is epitomized by the computer-based management of clinical cardiac catheterization data.

This dissertation describes a model information system for the catheterization laboratory which promotes comprehensive data management through a multi-computer approach. This model focuses on the timeliness, stability, accessibility, clinical utility and the forms of data which define the catheterization environment. Thus the model system centers on meeting clinical information management goals, while providing a flexible interface to various users. Furthermore, the model proposes innovative uses of computer science to support data collection, coordination and reporting.

New methods of data collection are defined for the creation of a timed record (log) of the catheterization and for the translation of that log into a textual description of the procedure. Interactive techniques are developed for the specification of the results of selective coronary angiography and for the recording of pre-catheterization test results.

The coordination of data is accomplished through a machine independent computer network which facilitates shared access to computers and resources. Data are stored on one computer, thereby providing a research data base.

Methods for defining and generating reports are oriented toward clinician control. Multiple reports for distinct user populations are easily defined and automatically formatted. The textual style of the reports reflects natural language.

A prototype of the model was implemented at the San Francisco Veterans

Administration Medical Center for the Cardiac Catheterization Laboratory. This prototype employs three different computers with distinct operating systems and varying peripherals. Thus the information system is not constrained by the resources of one computer. Rather, the data management tasks utilize the resources of several computers to enchance the clinician's ability to manage patient data.

Acknowledgements

I would like to extend my sincere thanks to Dr. Edward W. Gertz for his encouragement, guidance and support throughout this research effort. I also want to thank Dr. Judith A. Wisneski who was always available to answer questions and review the results of this work. I am grateful to Dr. Azad Bolour for his extensive efforts in reviewing this dissertation.

I owe special thanks to Paul D. Keltz for his technical expertise and for his opinions of my ideas. Thanks also to Melanie H. Okawachi for her editorial comments.

I am especially grateful for the patience and understanding of my friends and family. Without their support, this work would never have been accomplished.

This research was conducted in the Cardiac Catheterization Laboratory at the San Francisco Veterans Administration Medical Center in conjunction with the Section on Medical Information Science at the University of California at San Francisco. Financial support was provided by a National Library of Medicine Traineeship.

Table of Contents

Abstract

Acknowledgements

1. Introduction 1

Significance of this Work 2

Layout of this Dissertation 3

2. Medical Background 5

Basic Anatomy of the Heart 6

Basic Physiology of the Heart 10

Basic Pathology of the Heart 13

Catheterization of the Heart 17

3. Information Framework 22

Timeliness 26

Stability 30

Accessibility and Clinical Utility 32

Forms of Data 33

4. Prior Work 40

Manual Methods 40

Introduction of Computer-based Methods 41

Commercial Systems 44

Use of Computers to Log Clinical Events 46

Recording Coronary Artery Data 48

Data Completeness 51

Computer Generation of Clinical Reports 52

Use of Multiple Computers and Networks 55

User Acceptance 59

5. Model System 61

Collection of Data Arising During Catheterization 63

Verification of the Log 65

Generation of the Procedure Description 65

Ventricular Analysis 68

Analysis of the Coronary Artery Data 69

Collection of the Pre-Catheterization Data 71

Highlighting Data for Inclusion in Reports 73

Generation of Reports 73

Other Functions 74

Considerations for Implementing the Model 76

Construction and Format of the Data Base 76

Essential Computer Hardware and Software 77

6. Networking 81

User View of the Network 83

Communication Protocol 83

Use of the Network 87

Evaluation of the Network 90

General Utility of the Network 93

7. Implementation of the Prototype System 95

Clinical Perspective 95

Computer Science Perspective 133

Resources and Basic Groundwork 133

Data Base 138

Division of Tasks Among Computers 142

Innovative Applications of Computer Science 144

8. Summary, Future Work and Conclusions 154

Future Work 155

Conclusions 158

References 159

Glossary 167

Appendix A: Data Base Structure

Appendix B: Software Tasks

List of Figures

1. Structure of the Heart 7
2. Coronary Arteries 8
3. Schematic of Circulation 9
4. Pressure Waveforms 11
5. Left Ventricular Silhouettes 20
6. Left Ventriculogram for Sample Patient 23
7. Information Flow in the Catheterization Laboratory 25
8. Dynamic Nature of the Catheterization Laboratory 28
9. Coronary Artery Templates 49
10. Example Menu for use During Catheterization 64
11. Relationship between Maneuvers, Codes and Phrases 67
12. Recording of Coronary Artery Data 71
13. State Diagram of Network Communications Protocol 87
14. Sample Communication Between Computers 88
15. Main Menu of Prototype System 97
16. Menu of Pre-Catheterization Data Collection 98
17. Collection of Clinical Laboratory Data 98
18. Collection of Chest X-ray Data 99
19. Detection of Conflicting Results 100
20. Clinician Verification of Conflict 100
21. Main Menu of Dedicated Laboratory Computer 101
22. Menu of Maneuvers for Femoral Approach 101
23. Menu of Drugs Commonly Administered 102
24. Catheterization Log 103
25. Catheterization Summary Report 106

26. Editting of Catheterization Log 107

27. Adjustment of time of a Maneuver in the Log 108

28. Insertion of Maneuver into Log 108

29. Insertion of an Event into the Log 109

30. Menu for Editting 109

31. Menu for Femoral Approach used in Editting 110

32. Specification of Maneuver Details using Menus 111

33. Specification of Maneuver Details using Numeric Ranges 111

34. Menu of Ventricular Analysis Methods 112

35. Display of Ventricular Analysis Results 112

36. Display of Ventricular Analysis Results #2 113

37. Specification of Occlusions in an Artery 113

38. Specification of Distal Flow in an Artery 114

39. Summary of Right Coronary Artery 114

40. Summary of Left Anterior Descending Artery 114

41. Summary of Circumflex Artery 115

42. Selection of Hemodynamics for Formal Report 115

43. Verification and Labelling of Hemodynamics 116

44. Request for Report Generation 117

45. Memo to Inform Secretary a Report is Ready 117

46. Formal Catheterization Report 118

47. Conference Report 129

48. Anesthesiology Report 130

49. Referral Report 131

50. Status Report 132

51. Configuration and Interconnection of Computers 137

52. Primary Data Base 140

53. Parallel Data Base 141

54. Division of Tasks Among the Computers 143

55. Textual Templates 145

56. Report Descriptors 148

57. Definition of Referral Report 148

58. Menu Form #1 149

59. Menu Form #2 151

60. Menu Form #2 with Sub-menus 151

61. Menu Form #3 152

62. Menu Form #4 152

63. "Working" Patient Table 153

64. Adjustment of Artery Template 156

List of Tables

1. Hemodynamics for Cardiac Chambers and Great Vessels 12

2. Catheterization Data Categories 38

3. Software Needs for Prototype System 77

4. Network Keyword Commands 85

Chapter 1: Introduction

Computers were first introduced into medical information management over fifteen years ago (16). Since that time, they have been primarily applied to research tasks. When applied to clinical tasks, computers have usually produced disappointing results (26). The primary cause of this is a failure to idenfity and meet clinical information management needs. In many cases, the output has been incomplete, delinquent or clinically useless. In other cases, the process of inputting the data has forced clinicians to change their perception of the data to conform to the idiosyncrasies of the computer.

There are, of course, notable exceptions to this general state of affairs (8, 16, 28, 29, 109). But most of these exceptions are based on large, expensive and highly customized single-computer systems. Few medical institutions can justify the acquisition of such computer systems. Instead, each department within a hospital must justify its specific need and purchase equipment from its own limited funds. As a result, standard commercially available mini-computers with minimal peripherals and software dominate in the clinical environment.

Consequently, there are usually multiple computers in any one medical center, each dedicated to a single task. Over the full set, there may be a plethora of resources. Many operating systems, languages, data base systems and peripherals may be at hand. Isolated, each machine is bound by its own limited resources and provides, at best, a subset of the resources necessary for comprehensive management of clinical data. Combined, such computer systems can provide the flexibility which is essential to accommodate the variety of data and tasks of the clinical environment.

The interconnection of multiple computer systems for the purpose of sharing data management tools, then, becomes an important goal of a clinical

information system. These tools are the operating systems, languages, data base management systems and peripherals of each computer. When they are available to any data management task which demands them, the result is a flexible and useful system. Thus the need to force data into computer-convenient forms is reduced. The system can then meet the requirements of clinician-convenience, a key to successful clinical information management.

A prototype system reflecting this goal was implemented at the San Francisco Veterans' Administration Medical Center. The cardiac catheterization laboratory in that center presented clinical data management problems which parallel those of hospitals in general. Several computer systems were available. Each computer supported unique peripherals. And each computer was assisting in the management of isolated clinical data. Naturally, the clinicians in the catheterization laboratory wanted to manage all their catheterization data with computer support. Yet no single computer supported all the necessary tools. Combined, the computers do provide the necessary tools. Consequently, this laboratory is ideal for the implementation of a prototype system to yield enhanced management of cardiac catheterization data through increased resource utilization.

Significance of this Work

Three benefits arise from this work. First, it is demonstrated that divergent medical computer systems can be interconnected to provide shared access to resources. The interconnection is independent of specialized hardware or software.

Second, this work reveals that when computers are interconnected, the task of managing clinical data can be centered about clinical goals. Specifically, the properties which are inherent in data can be matched to capabilities supported by the computers. At no time is data management constrained by the

limitations of one isolated machine.

Finally, and most importantly, this work represents a significant improvement in the management of cardiac catheterization data. In the past, several partial solutions to data management have been proposed for this clinical specialty. Most of these solutions only considered a subset of the potential data. Many solutions were inconsiderate of the user's needs, presenting awkward interfaces and/or confusing reports. None of these partial solutions fully meet clinical goals. In contrast, this work demonstrates a multi-computer approach which considers the full set of catheterization data, is centered about the clinical goals of cardiac catheterization and presents an interface suitable and responsive to clinical goals.

Layout of this Dissertation

Chapter 2 presents the general medical background. It discusses the anatomy, physiology and pathology of the heart. The goals and techniques of cardiac catheterization are then presented.

Chapter 3 assesses the problem areas in the management of cardiac catheterization data. This discussion is presented in terms of the timeliness, stability, accessability and clinical utility of the data. The forms of the data arising from catheterizaion are also considered. This assessment then serves as a template for discussing previous research efforts and for presenting the results of this dissertation.

Chapter 4 considers relevant prior work which impacts this research. Attention is given to the use of computer techniques in the catheterization laboratory, in medical services for reporting purposes, in the assurance of data completeness and in the use and development of computer networking.

Chapter 5 proposes a model information management system for the catheterization laboratory. The model describes a system which collects all data

and generates concise, clinically useful reports. Furthermore, the collection, maintenance and reporting of the data are coordinated with the clinician's needs and goals. This model is dependent on a multi-computer, or distributed, approach.

Chapter 6 considers the design of a machine independent computer network. The implementation and consequences of this network are reviewed.

Chapter 7 describes an implementation of the prototype information management system for a catheterization laboratory. This presentation centers about the clinician's view of the system. The resources and methods employed to implement the system are then discussed.

Chapter 8 summarizes the research. Consideration is given to areas for future work relating to systems for the catheterization laboratory and also to systems for clinical services in general. Finally, to conclude the thesis, the significance of this work to Medical Information Science in general is discussed.

Chapter 2: Medical Background

The primary function of the heart is to pump the blood. This action provides transportation of vital nutrients to all parts of the body and of waste products to specialized organs for removal from the body. A diseased heart will produce inadequate blood flow, eventually resulting in damage and possibly death to the deprived body tissues. In fact, heart disease is the primary cause of morbidity and mortality in the United States. In 1974, 707,833 people in the United States died of heart disease and 394,000 suffered heart attacks (71).

Directly associated with heart disease is an enormous financial impact. The costs related to heart disease in 1974 totaled over $20 billion (Physicians / Nurses: $2.7 billion, Hospitals: $6.9 billion, Lost wages: $8.6 billion, Research / CCU's: $1.1 billion) (71). The number of deaths due to heart disease has increased steadily over the years. In 1978, 37.5% of all deaths in the United States were the result of heart disease (110). Costs continue to rise at an even more startling rate (54, 110). With such overwhelming statistics, it is expected that quick, accurate diagnosis and successful treatment of heart disease could serve to reduce morbidity and mortality rates and therefore also reduce costs.

Patients suspected to be suffering from heart disease are initially evaluated through the use of non-invasive methods. After the clinician has reviewed the medical history and physical exam, a series of routine tests may be conducted. The most prevalent of the non-invasive tests are:

Electrocardiogram: to analyze the "electrical" behavior of the heart for arrhythmias or abnormal patterns which disrupt coordinated, effective contraction of the heart

Echocardiogram: to determine the size and structure of chambers, valvular structure and motion.

Exercise Tolerance Test: to analyze the "electrical" behavior of the heart while the patient is exercised until: 1) either a pre-defined time has elapsed or a pre-defined heart rate has developed, or 2) cardiac symptoms develop. The electrocardiogram is monitored continuously to detect changes which indicate the patient's heart is not receiving sufficient oxygen (i.e., myocardial ischemia). This test is the most accurate non-invasive indicator of coronary artery disease.

Each of these tests, combined with a history, physical examination, clinical laboratory tests and chest X-ray can contribute to a clinician's assessment of a patient's cardiac function. Not only is the nature of the heart disease highlighted, but the need for additional tests to refute or justify treatment is obtained.

However, the major cause of heart disease, coronary artery disease (CAD), cannot be precisely defined by any of the non-invasive tests. Many other diseases of the heart also cannot be confirmed or quantitated solely through the use of non-invasive tests. The ultimate test for many diseases of the heart is an invasive procedure called cardiac catheterization. This sophisticated and complex procedure allows a clinician to measure, view and analyze the heart's function with great accuracy (39, 71, 97).

To gain a proper perspective of the clinical information which cardiac catheterization can expose, knowledge of the anatomy, physiology and pathology of the heart is essential. Therefore, a brief overview of the clinical properties of the heart is presented.

Basic Anatomy of the Heart

The heart consists of two sides: the right heart and the left heart. Separating the two sides is a wall of tissue called the septum. Each side of the heart has two chambers. The receiving chamber is called the atrium; the pumping or muscular chamber is the ventricle. Each atrium serves as a "holding tank" or reservoir where blood collects prior to passage into the associated

ventricle. The ventricle serves as the primary pumping portion of the heart to propel the blood to the rest of the body. Separating each ventricle from the atrium (the entry to the ventricle) and a large artery (the exit from the ventricle) is a pair of valves. These valves are opened and closed in a rhythm coordinated with the contraction and relaxation (i.e., the pumping) of the atria and ventricles, thereby facilitating the propulsion of blood to the other body tissues.

The blood is carried to the other body tissues through the arteries and returned to the heart through the veins. The arteries and veins directly adjoining the heart are called the great vessels: vena cava, pulmonary artery, pulmonary veins, aorta. The cavernous veins (or Vena Cava) deliver blood from the body (the systemic circulation) to the heart where they empty into the right atrium. The pulmonary artery carries blood from the right ventricle to the lungs where the blood picks up oxygen. The pulmonary veins then deliver the blood from the lungs to the left atrium. Finally, the aorta carries the oxygenated blood from the left ventricle to the body (the systemic circulation). Figure 1 shows the anatomical relationship of the heart's chambers, its valves and the great vessels.

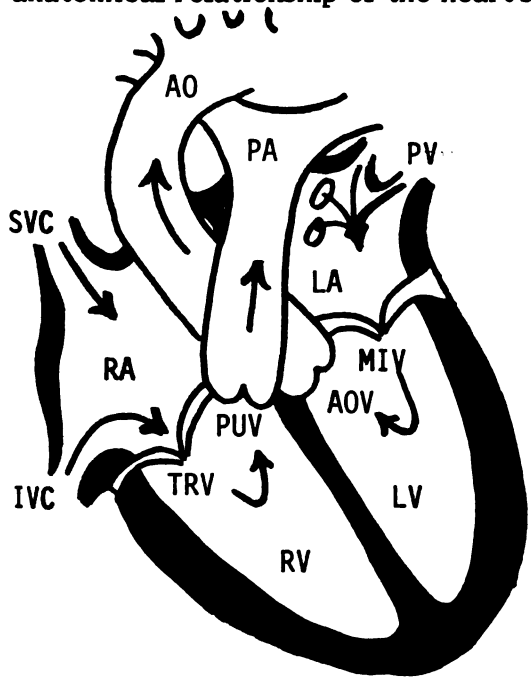


FIGURE 1: STRUCTURE OF THE HEART. *Blood flow through the heart.* SVC = *superior vena cava;* IVC = *inferior vena cava;* RA = *right atrium;* RV = *right ventricle;* PA = *pulmonary artery;* PV = *pulmonary veins;* LA = *left atrium;* LV = *left ventricle;* AO = *aorta. Valves are* TRV = *tricuspid valve;* PUV = *pulmonic valve;* MIV = *mitral valve;* AOV = *aortic valve (52).*

To maintain the pumping action, the heart tissue must be continuously and generously nourished. Although it comprises less than 1% of the total body weight of an adult, the heart requires 20% of the blood flow to provide its nourishment (24). This blood flow is carried to the heart tissue by the coronary arteries. These arteries arise from the aorta at the point where it contacts the left ventricle. So, as the freshly oxygenated blood is pumped into the aorta, a portion is diverted into the coronary arteries.

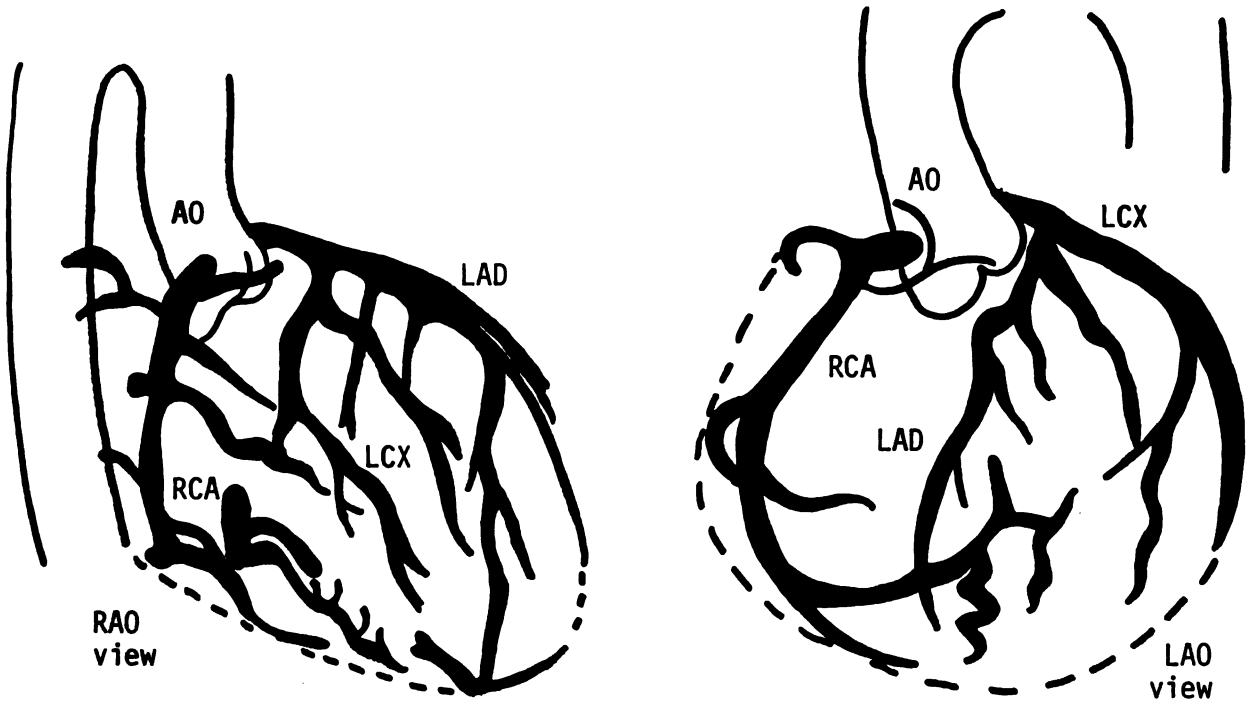


FIGURE 2: CORONARY ARTERIES. *Angiographic views of coronary arteries from right anterior oblique view (RAO) and left anterior oblique view (LAO).* RCA = *right coronary artery;* LAD = *left anterior descending branch of the left coronary artery;* LCX = *left circumflex branch;* AO = *aorta (30).*

Whereas the other body tissues may be perfused by parallel vessels providing collateral flow, the heart is not equipped with such a back-up system. The coronary arteries are the sole source by which the heart is nourished. Each of the two coronary arteries supplies flow for specific and exclusive areas of the heart's anatomy. The right coronary artery (RCA) carries blood primarily to the

right heart and to the inferior or posterior walls of the left ventricle. The left coronary artery divides into two major branches: the anterior descending (LAD) and the circumflex (LCX), which together carry blood to the main pumping portion (the left ventricle) of the heart (see Figure 2). The LAD carries blood to the septum and the anterior wall of the left ventricle; the LCX supplies the lateral wall of the left ventricle (57). After the blood has passed through the heart tissue, it returns directly to the right atrium through the coronary veins. The systemic circulation is bypassed. The coronary arteries are, therefore, a separate circulatory system which supplies only the heart.

The heart then, propels blood for three distinct circulatory systems (see Figure 3). The right heart propels the blood through the pulmonary circulation. Here the oxygen depleted blood is re-oxygenated. The left heart then propels the freshly oxygenated blood through the systemic circulation to provide nourishment for the body. At the same time the left heart propels blood into the systemic circulation a portion is diverted into the coronary circulation to carry nourishment to the heart itself.

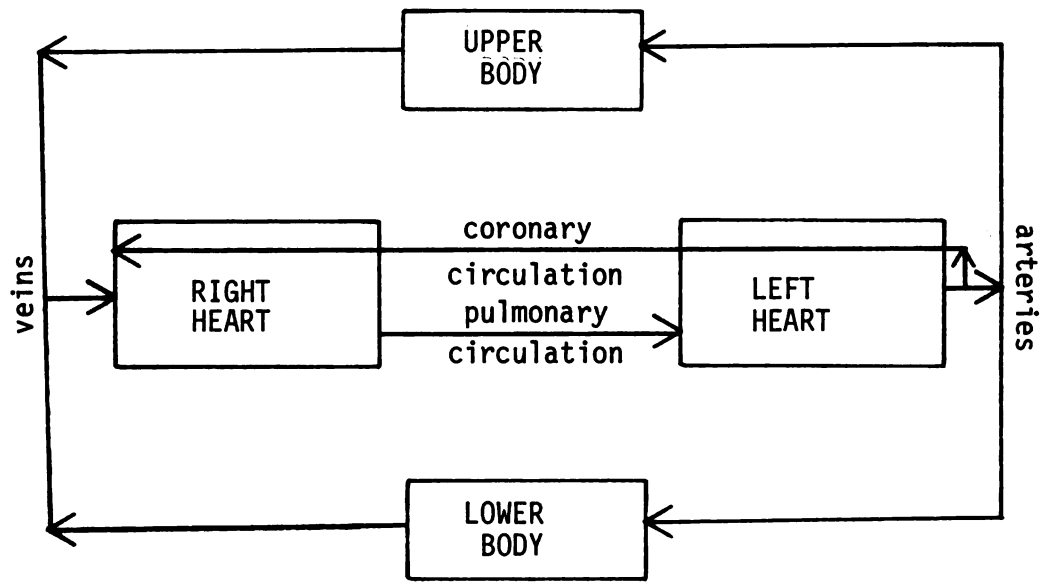


FIGURE 3: SCHEMATIC BLOCK DIAGRAM OF BLOOD CIRCULATION. *Note the separate circulatory systems for the body, lungs and heart.*

Basic Physiology of the Heart

The two sides of the heart function in parallel. The atria contract in unison while both ventricles relax. Then the ventricles contract and the atria relax. The period during which the chambers are relaxed and filling with blood is known as diastole. After the chamber has filled, it contracts and expels the blood. This period of contraction is called systole. Coordinated with the diastolic and systolic periods, the valves open to permit forward flow of the blood and close to prevent backflow of the blood. Specifically, during ventricular diastole, the valves between the atria and ventricles open. These are the mitral and tricuspid valves. At the same time, the valves between the ventricles and arteries are closed. These are the pulmonic and aortic valves. In contrast, during ventricular systole, the pulmonic and aortic valves open as the mitral and tricuspid valves close.

The contractions of the heart generate pressures throughout the cardiovascular system. The fluctuation and gradients in the pressure of adjacent chambers and vessels cause the blood to flow through the heart and body. These fundamental aspects of blood flow are called hemodynamics.

To illustrate the significance of hemodynamics, consider the left heart. During ventricular systole, the blood collects in the left atrium and the pressure in that chamber increases. At the end of systole, the pressure in the left ventricle falls. The mitral valve opens and then the atrium begins to contract. The blood flows into the left ventricle because the pressure in that chamber is less than that of the atrium. As the ventricle is filled, its pressure rises and the mitral valve closes. The left ventricle then begins to contract. Pressure in the left ventricle rises. When the left ventricular pressure exceeds that in the aorta, the aortic valve opens. The left ventricle continues to contract, rising in pressure as the blood is forcibly expelled into the aorta. The left ventricle then

begins to relax and its pressure falls. As soon as that pressure drops below that of the aorta, the aortic valve closes. The left ventricular pressure continues to fall. When that pressure is less than the pressure in the atrium, then the mitral valve opens again and the cycle repeats. This process is graphically represented in Figure 4. Note that the left atrial pressure ranges from 0 mmHg to 20 mmHg, while the left ventricular pressure may rise above 120 mmHg. The pressure within the aorta varies from 120 mmHg during ventricular systole to 80 mmHg during ventricular diastole. This baseline arterial pressure provides the necessary systemic pressure for the blood to perfuse the other organs (e.g., the kidney, the liver, the brain).

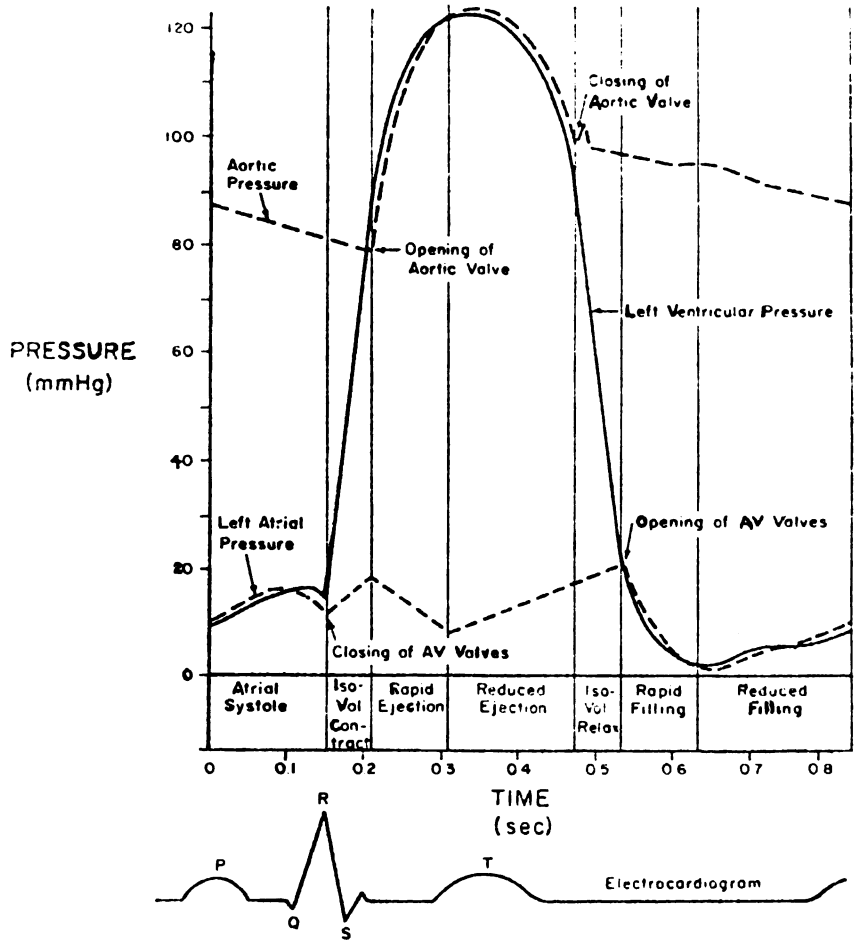


FIGURE 4: REPRESENTATIVE PRESSURE WAVEFORMS. *Waveforms are represented from the aorta, left ventricle and left atrium for one full contraction of the heart.*

The electrocardiogram is also shown. AV valves refer to the mitral and tricuspid valves. (57)

The hemodynamics of the right heart are essentially the same as those for the left heart, although the maximal pressures achieved are considerably lower.

In contrast to the normal systemic circulatory needs for a minimum pressure of 80 mmHg, the pulmonary circulatory pressure rarely rises above 30 mmHg and is generally about 12 mmHg. This pressure is optimal for the transport of the blood through the lungs.

The pressures generated by the heart's contraction comprise the bulk of hemodynamic parameters (see Table 1). There are however, other hemodynamic parameters which also reflect blood flow.

Table 1: Normal Hemodynamic Values (39)

A. Pressures (mmHg)	
1. Systemic arterial:	
peak systolic / end diastolic	100-140 / 60-90
mean	70-105
systolic mean	80-130
2. Left ventricle	
peak systolic / end diastolic	100-140 / 3-12
systolic mean / diastolic mean	80-130 / 1-10
3. Left atrium (or pulmonary wedge)	
mean	1-10
"a" wave	3-15
"v" wave	3-15
diastolic mean	1-10
4. Pulmonary artery	
peak systolic / end diastolic	15-30 /4-12
mean	9-16
systolic mean	10-20
5. Right ventricle	
peak systolic / end diastolic	15-30 / 0-8
systolic mean / diastolic mean	10-20 / 0-4
6. Right atrium	
mean	0-8
"a" wave	2-10
"v" wave	2-10
B. Resistances (dynes-sec-cm^2)	
1. total systemic resistance	770-1500
2. total pulmonary resistance	100-300
3. pulmonary arteriolar (vascular) resistance	20-120
C. Flows	
1. cardiac output	Varies with patient's size
2. cardiac index (L/min/M^2)	2.8-4.2
3. stroke index (ml/beat/M^2)	30-65
D. Oxygen consumption (L/min/M^2)	110-150

Prominent among these is the cardiac output. Reflecting the amount of blood pumped by the heart each minute, the cardiac output must be maintained within strict limits for the blood to perfuse the body tissues. However, actual cardiac output is dependent on the patient's physical size and so varies dramatically among patients. To normalize this hemodynamic parameter, the cardiac index is calculated by dividing the cardiac output by the patient's body surface area.

Resistance to blood flow is generated by the blood vessels to accommodate variations in cardiac output and pressures. The vessels dilate and constrict in an effort to maintain optimal pressures for tissue perfusion (in the systemic circulation) and gas exchange (in the pulmonary circulation). Variations in the cardiac output also affects oxygen consumption. These two hemodynamic parameters tend to rise and fall together as a reflection of exercise or stress.

Thus, the heart propels blood by generating cyclic pressures and maintaining uni-directional flow. This, in turn, provides optimal conditions for nourishment of the heart and other body tissues.

Basic Pathology of the Heart

Not all hearts are capable of generating appropriate pressures or of maintaining uni-directional flow. Under such circumstances, blood flows abnormally through the chambers and blood vessels. This abnormal flow may be caused by a structural (usually congenital) defect, by a diseased valve or by a failure of the heart muscle to contract efficiently.

The most common structural defect of the heart is a shunt. Presence of a shunt permits abnormal blood flow between the two sides of the heart or between the systemic and pulmonary circulations. A shunt between the left and right hearts generally implies a hole or defect in the septum. As the pressures of the left heart are normally greater than those of the right heart, some blood

flows to the right heart instead of flowing toward the systemic circulation. Consequently, the output of oxygen rich blood into the systemic circulation is reduced. If, on the other hand, the right heart pressures are higher than those of the left heart, blood flows from the right heart directly to the left heart. The volume of blood then pumped by the left heart consists of oxygen rich blood from the pulmonary circulation plus oxygen depleted blood which was shunted from the right heart. In either case, the presence of a shunt results in deficient flow of oxygenated blood to body tissues.

A shunt may also be present between a vessel of the systemic circulation and a vessel of the pulmonary circulation. Similar to a shunt between the two sides of the heart, a circulatory shunt either diverts oxygenated blood back to the pulmonary circulation or allows oxygen depleted blood into the systemic circulation.

Mis-positioning or malformation of the great vessels also produces abnormal blood flow. The root of the aorta may be switched with the root of the pulmonary artery. This structural defect fully isolates the systemic circulation from the pulmonary circulation. Therefore, the right heart pumps to the systemic circulation, the left heart pumps to the pulmonary circulation and the blood in the pulmonary circulation is fully oxygenated, the blood in the systemic circulation is never oxygenated. This situation is not compatible with life and generally this transposition of the great vessels is accompanied by a shunt between the atria or between the great vessels, thereby providing connection between the pulmonary and systemic circulations. Other structural defects of the great vessels may involve an anomolous position of the root of a single vessel or constriction of part of a vessel. In the case of anomolous positioning of the vessel's root, the result is similar to that produced by shunts. Constriction of a vessel does not interfere with the direction of blood flow, but impedes the

flow. To produce normal flow through the constricted area, the heart must work harder, contracting with greater pressure. This method of compensation places excessive strain on the heart. So, if the constriction is not removed, the heart may be damaged over time and eventually fail to contract.

Stenosis of the aortic or pulmonic valve poses conditions equivalent to that of a constricted vessel; it impedes the blood flow. The heart, however, attempts to force a normal amount of blood through the valve. As a consequence, the heart overworks and eventually fails. Stenosis of the mitral or tricuspid valve prevents blood from flowing into a ventricle. Thus the blood backs up in the pulmonary or systemic venous circulation respectively and the arterial circulation is reduced.

Unfortunately, normal formation of the heart does not preclude heart disease. In fact, the majority of heart disease is acquired disease (24, 39, 58). This does not imply that the majority of heart disease is a consequence of infection. Basic wear-and-tear of the heart's structures and adherence of materials such as calcium or atheromas (fat masses) to the heart structures also serve as major contributors to disease.

The valves of the heart are susceptible to disease, calcium deposits and wear-and-tear on those with uncorrected congenital deformities. In the event of certain diseases or calcium deposits, a valve may become stenosed. Similar to a congenitally stenosed valve, a valve which becomes stenosed impedes forward blood flow. The chamber attempting to propel blood through such a valve generates abnormally high pressures to force the blood through the narrowed orifice. However, the flow through the stenosed valve is still below normal. The blood then backs up in the circulatory system, congestion develops and the heart fails.

Wear-and-tear on deformed valves as well as infections can render a valve

incompetent. In contrast to a stenosed valve, an incompetent valve opens fully, but does not fully close. When the blood leaks back into the chamber it has just left it is called regurgitation. The chamber not only fills from "upstream" flow but also from regurgitated "downstream" flow. The normal flow from "upstream" fills the chamber. Yet the chamber must expand even further to contain the regurgitated blood. So, the total volume of blood in the chamber rises, the heart works harder to maintain forward flow. As this condition worsens, the heart may eventually fail to generate sufficient forward flow to nourish the body. This situation will eventually lead to heart failure and possibly death.

Failure of the heart to contract is not strictly a consequence of malformed or diseased valves. The heart muscle is also vulnerable. Areas of weakness, scarring or death may result. The muscle is then unable to contract evenly. The rhythm of the contractions may become disrupted. Each contraction is therefore reduced in efficiency. The circulation becomes inadequate and other organs are not properly perfused by the blood. As the contractions decrease in force and efficiency, congestion develops. The heart tries to work harder to propel the blood. The delicate balance of pressures is disrupted and eventually the heart fails to contract.

However, neither structural defects nor infection are the primary catalysts for disabling the heart muscle. The most prevalent form of heart disease, coronary artery disease is the main contributor to heart failure. This disease is the primary cause of mortality and morbidity in western civilization (39, 58).

Coronary artery disease is a condition which impedes the flow of blood through the coronary arteries. As was stated earlier, the coronary arteries carry the blood to the heart tissues without benefit of collateral flow. As a consequence of this unique circulatory system, any reduction in flow through these vessels will deprive an area of the heart from receiving nourishment. As

the blockage increases, the heart tissue suffers ischemia, a lack of oxygen. The patient feels associated pain called angina. If the blockage fully isolates a branch of an artery, a myocardial infarction or "heart attack", may result where a portion of the heart dies due to the blocked artery. Weakness and scarring develop in the area of infarction. The heart muscle is then able to contract normally. In many cases, the patient's heart fails and death ensues.

Catheterization of the Heart

Virtually every disorder of the heart can be successfully treated if it is accurately diagnosed in its early stages. Unfortunately, diagnosis is complicated because different diseases may produce similar symptoms. However, selection of appropriate therapy depends on precise definition and quantitation of the disease.

As a first step in diagnosing a specific disease, the clinician generally performs a physical examination, takes chest X-rays, arranges for blood tests and orders an electrocardiogram. Additional non-invasive tests may be performed to measure the movement and size of the heart (echocardiogram) and to evaluate the amount of stress the heart can safely endure (exercise, stress or treadmill test). While these tests complement one another to provide the clinician with a very good assessment of the patient's cardiac condition, they do not provide the full picture. Non-invasive tests are not sensitive to all types of cardiac disease. Where an abnormality is detected, the non-invasive tests may not be specific. Where specificity is attained, the extent of a disease is generally difficult to estimate. Yet optimal treatment is contingent on precise diagnosis of both the disease and its severity.

Cardiac catheterization provides the specific and definitive information for accurate diagnosis of most heart disease. In this invasive procedure the clinician positions catheters which allow him to measure the cardiac

hemodynamics and to determine the flow of blood. Being long, narrow and flexible, these catheters are threaded through the vessels and chambers without disrupting the "normal" behavior of the heart (39, 71, 97). Catheters are introduced via the systemic circulation. To thread a catheter to the right heart, a vein is selected; to thread a catheter to the left heart an artery is selected. Selected vessels are usually in the arm or groin and of sufficient size to accommodate a catheter. Introduction of a catheter through the arm is said to be a brachial approach to the heart, whereas introduction through the groin is a femoral approach to the heart.

After the catheter tip has been positioned in the heart or its proximal vessels, the anatomy, physiology and pathology of the heart can be evaluated. The anatomy of the heart and vessels is examined via angiography. This process involves injection of a radio-opaque agent through a catheter to silhouette the anatomy. Enhanced X-ray images of these silhouettes outline the size, shape and motion of a cardiac structure. Furthermore, the injected agent flows with the blood. Thus the clinician can view the direction and force of blood flow.

However, visual impressions of the force of blood flow do not reveal sufficient information for evaluation of cardiac physiology. Recordings of pressure waveforms and measurement of blood gases are essential for accurate diagnosis. It is the subsequent calculation of hemodynamic parameters which reflect the extent to which the disease has impaired the heart as a pump. Moreover, these parameters are the crux for ensuing treatment and prognosis. Accordingly, cardiac catheterization is performed to measure hemodynamic parameters and to obtain angiographic studies. As such, this procedure provides the most accurate account of the anatomy and physiology of the cardiovascular system.

Nevertheless, cardiac catheterization is not a casual process of random

measurements or studies. The objective is to perform maneuvers in an orderly and efficient manner to yield maximally informative events. So, prior to the actual performance of the catheterization, the cardiologist will develop a plan (protocol) specifying the maneuvers which provide data to confirm or reject a provisional, pre-catheterization diagnosis. This protocol is a carefully reasoned plan which is developed for each patient. All measurements, blood samples and angiographic studies can be considered to be events resulting from the maneuvers of the protocol.

In fact, most of the maneuvers concern the means for measurement of hemodynamic parameters. Routinely performed, these maneuvers not only obtain results, but also provide data to ensure that the condition of the heart is sufficient to allow or to require additional measurement and study. As the catheter is advanced, pressures are continually monitored. At appropriate sites, hemodynamic parameters are determined. Excessively high pressures may indicate a diseased valve or vessel "downstream" where pressures were previously determined to be unusually low. Simultaneous measurements at both the "upstream" and "downstream" sites yield parameters which precisely define the degree of disease. Measurement of the pressures in the right or left ventricle reveals pumping capacity while disclosing any congestion in the associated circulatory system. Thus the manuevers to obtain hemodynamic parameters are important in that they provide the cardiologist with the first impression of the location and severity of the heart disease.

Suspicion or detection of a shunt necessitates special maneuvers. Oximetry, the measurement of the oxygen content of the blood, may be performed. Reduced oxygen levels in the left ventricle suggest a shunting of oxygen depleted blood from the right heart to the left heart. Conversely, detection of oxygen rich blood in the right ventricle suggests a shunting of

oxygenated blood from the left heart or from the systemic circulation. In addition to oximetry, another method to detect a shunt involves the introduction of an indicator into the circulation. The indicator is a substance which can be measured (e.g., hydrogen gas) or viewed (e.g., a radio-opaque agent). Once in a circulatory system, the indicator will flow with the blood. Any detours from normal flow are thereby visually detected.

The injection of radio-opaque agents as a visual indicator of blood flow is not only employed to illuminate shunts. This maneuver, known as angiography, is routinely performed to silhouette cardiac anatomy. A specialized version of this maneuver, ventriculography, introduces a bolus of radio-opaque agent into a ventricle (most commonly the left ventricle) producing an outline of the pumping chamber. The size, shape and contractility of the ventricle are then clearly discernable. Abnormalities reflecting increased volume, uneven wall motion and inefficient contraction are readily visible (see Figure 5).

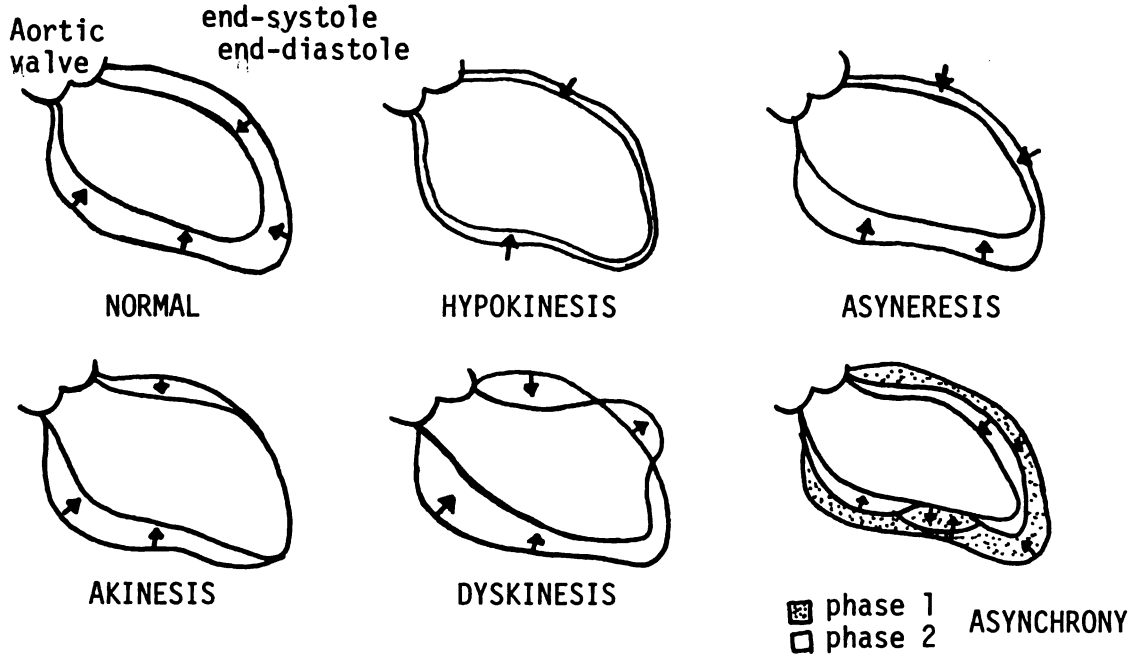


FIGURE 5: LEFT VENTRICULAR IMAGES. *Patterns of left ventricular contraction in the right anterior oblique (RAO) projection. Arrows denote wall motion (30).*

Yet the most elaborate angiographic maneuver is employed to silhouette the coronary arteries. Selective coronary angiography is the sole means by which the site and extent of coronary artery obstruction can be determined. Likewise with other forms of angiography, selective coronary angiography introduces a radio-opaque agent into a coronary artery. As the agent flows through the artery, it can be seen to flow around atheromas, lesions and obstructions. Where the obstruction is complete, the artery image ends abruptly. In view of the prevalence and consequences of coronary artery disease, this angiographic manuever has developed into a highly refined and specialized process.

Indeed, the data obtained through the various maneuvers has made cardiac catheterization a touchstone in the specification and evaluation of heart disease. No patient is subjected to cardiac surgery without the benefit of the anatomical and physiological information which catheterization provides. Obscure or confusing problems in heart disease are systematically elucidated when catheterization is performed. But cardiac catheterization is not only the most accurate means for diagnosis of heart disease. It is also a key for research. Virtually all advances in cardiac surgery give credit to the information gained through cardiac catheterization (71). The effects of drugs on cardiac physiology and metabolism is delimited through the precise measurement techniques afforded by cardiac catheterization. All in all, cardiac catheterization is, and will continue to be, the most specific and definitive tool for determining the status of the heart.

Chapter 3: Problem Areas of Interest

An information system for the cardiac catheterization laboratory must be useful to the clinician in meeting his goals. Specifically, it must integrate the management of data with the clinical tasks. Yet to effectively manage catheterization data the nature of the catheterization environment and the problem areas of managing data within that environment must be considered. Within this environment, perhaps the most prominent factor is that no two catheterization cases are the same. Even where the patients are suffering from the same disease with apparently similar symptoms, the maneuvers, the quantity and the types of results obtained may be very disparent. Thus the incidence and frequency of events occurring in the catheterization laboratory is highly variable and somewhat unpredictable.

In order to gain an understanding of this environment, it is useful to review a sample catheterization case. This case represents a typical catheterization for a patient with a provisional diagnosis of mitral stenosis (i.e., a mitral valve which has narrowed and impedes forward blood flow).

> A 47-year-old woman had had acute rheumatic fever at eight years of age and a murmur ever since. She did well thereafter until five years ago, when she noticed exertional dyspnea and paroxysmal nocturnal dyspnea. Four years ago, these symptoms worsened. Her symptoms then improved for nearly two years, only to return about two months prior to admission. She has also complained of chest pain following mild exertion.
>
> Physical examination gave evidence of mitral stenosis with indications of poor pulmonary function. The ECG showed atrial fibrillation, right axis deviation and right ventricular hypertrophy. X-rays showed a large heart with prominent left atrium, right ventricle, pulmonary arteries and pulmonary vasculature.

Cardiac catheterization revealed the resting heart rate to be irregular at 60-65 BPM. The right ventricular pressure was 45/7 mmHg, the pulmonary artery pressure was 45/23 mmHg, pulmonary wedge pressure was 19 mmHg with simultaneous left ventricular pressure at 120/7 mmHg and cardiac output was 2.0 L/min. Following exercise, the heart rate increased to 110 BPM, the pulmonary wedge pressure increased to 30 mmHg and the left ventricular end-diastolic pressure remained at 7 mmHg. The calculated mitral valve area was .8 cm^2 during exercise. Inferior wall hypokinesis was present on the left ventriculogram and the ejection fraction was 0.50 (see Figure 6). No significant lesions were present in the coronary arteries.

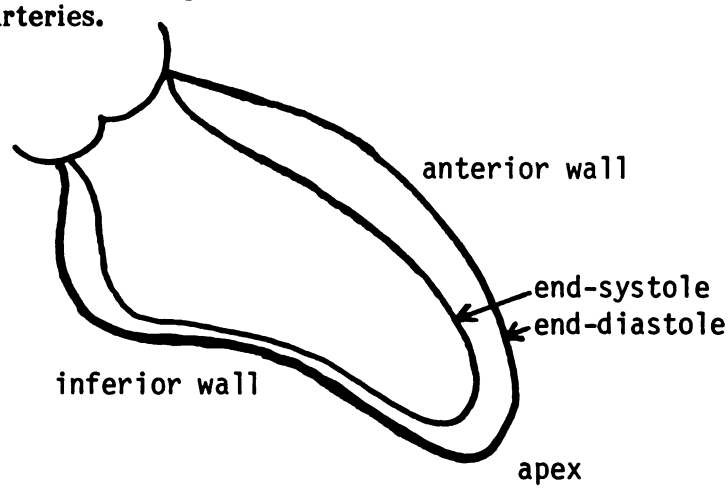


FIGURE 6: LEFT VENTRICULOGRAM FOR SAMPLE PATIENT FROM RAO (right anterior oblique) VIEW. *The left ventriculogram shows inferior wall hypokinesis. That is, the inferior wall does not move as much as it should.*

To begin with, consider the emphasis of the various aspects of this case. The patient's history (exertional dyspnea and paroxysmal nocturnal dyspnea) and the pre-catheterization test results (ECG and X-ray) together indicate that stress testing (i.e., exercise) should be included in the catheterization protocol. The patient's condition also indicates a need to obtain pressure waveforms and calculate hemodynamic parameters for the right ventricle, pulmonary artery and pulmonary wedge. In order to assess left ventricular function, a left ventriculogram is essential. The presence of chest pain necessitates visualization of the coronary arteries via selective coronary angiography.

In this case, it is important to note that the pulmonary wedge pressure is related to the state of the patient. Resting wedge pressure is 19 mmHg, which is at the upper limit of the normal range. However, after exercising, the wedge pressure rises to 30 mmHg (which is definitely abnormal) and the left ventricular end-diastolic pressure (LVEDP) remains at 7 mmHg. These results are a definite indication of significant mitral stenosis. The decrease in cardiac output following exercise additionally confirms the provisional diagnosis. Had the resting pulmonary wedge pressure been 30 mmHg, the patient would not have been exercised and the stenosis would have been considered significantly more serious.

The inter-relationships of the data obtained during catheterization are well illustrated in this case. The primary problem for this patient is mitral stenosis. The stage of this condition is demonstrated by the differences in the measurements obtained while the patient was resting as opposed to those obtained during exercise. The left ventriculogram reveals inferior wall hypokinesis which probably developed as a result of the rheumatic involvement of the heart muscle. The visualization of the coronary arteries does not show significant lesions and therefore the chest pain experienced by the patient is unlikely due to insufficient blood flow to the heart tissues.

In view of the foregoing example, a model of information flow in the catheterization lab can be formulated as that in Figure 7. It is important to note that the final diagnosis does not depend solely on data obtained during the catheterization. Rather, the full set of catheterization data includes the pre-catheterization data (i.e., the history and current state), the procedure protocol and the data obtained during the actual procedure. So, only after all the data has been collected, coordinated and reported can the goal of a definite and quantitated diagnosis be achieved.

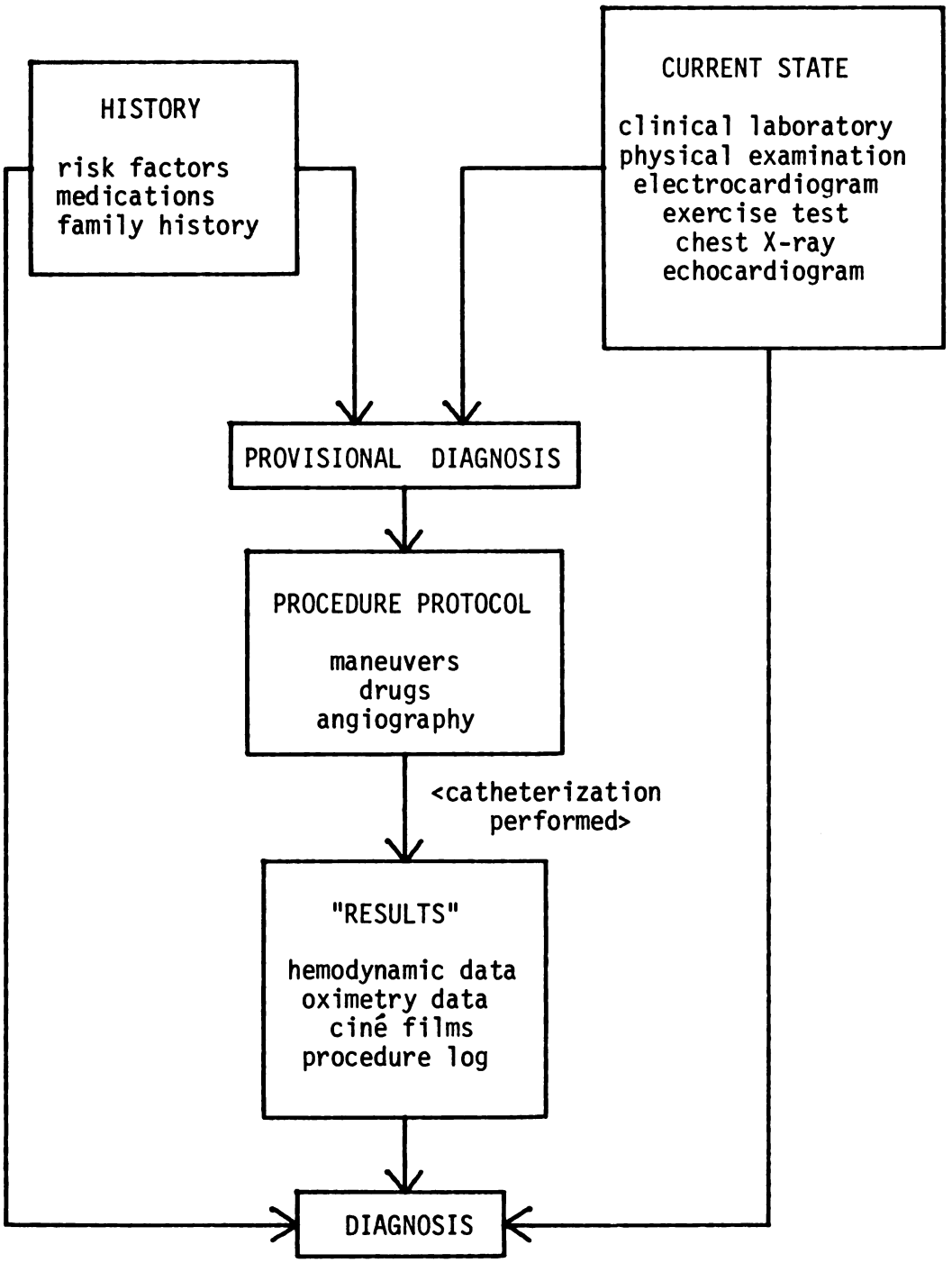


FIGURE 7: INFORMATION FLOW IN THE CATHETERIZATION LABORATORY. *Note the volume of data which must be collected and evaluated prior to the catheterization. This data constitutes the pre-catheterization data and serves as justification for performing the procedure.*

It is, however, premature to present a design for a system to collect, coordinate and report the catheterization data. First, an assessment of the problem areas is essential. Four problem areas can be outlined: timeliness, stability, accessibility and clinical utility. Timeliness concerns the specification of when to collect data so as to define an acceptable interval between the actual occurrence of an event and the recording of that event. Timeliness also concerns the specification of when to report data so that the data is presented as clinical needs arise. Stability has to do with the continued usefulness of data and the procedures used to store and retrieve it over a long period of time. Accessibility defines the mechanisms to extract and review the data. Closely linked to accessibility, clinical utility concerns the uses of the data with an emphasis on the clinical goals and responsibilities of the users.

Pervading these problem areas, there is the issue of the different forms of data arising from catheterization. As will be seen, these different forms require different methods for collection and reporting. Thus, this chapter provides a focus for reviewing subsequent chapters which describe the prior work related to this research and propose a model system to manage cardiac catheterization data.

Timeliness

Some inherent aspects of timeliness of the catheterization data are obvious from Figure 7. Specifically, data is usually collected over several days, with the nucleus of the data being measured or recorded during the actual procedure in a period of one to six hours. Collection of the pre-catheterization data is centered about the acquisition and screening of laboratory tests, chest X-ray, electrocardiogram, exercise test, physical examination and history. These data are collected and reviewed by the clinician prior to scheduling the catheterization and, as such, are the gist in formulating a protocol for the

catheterization.

The optimal time to record and initially report the events related to the catheterization is as they occur, that is, immediately. Studies have shown that clinicians and other medical personnel do not possess exceptional memories for the sequence or exactness of clinical events. Recording or trapping events as soon as they occur suppresses the potential for erroneous data recording (28, 108) and encourages the clinician to use the information management system as an integral component of the clinical task. Of equal importance, the time at which an event is to be reported or made available is dependent on the expected time of the next maneuver which requires knowledge of that event.

Therefore, during the catheterization, the recording and reporting of events must be immediate. This rapid turnaround allows the clinician to be "fully" aware of the patient's condition and therefore best able to perform the appropriate maneuver. Reliance on the raw, visual representation of events during the procedure does not provide the clinician with sufficient information. To this end, all hemodynamic parameters should be automatically extracted from the waveforms and displayed as numeric quantities as soon as possible after measurement. No alternative is acceptable in an environment which is as dynamic as the catheterization laboratory where every event is evaluated prior to instigating each maneuver (see Figure 8). This pivotal aspect of catheterization was demonstrated in the sample case: observation of resting wedge pressure at 19 mmHg was evaluated as an indication that it was safe to exercise the patient. As this pressure is at the upper bound of normal it is likely that review of pressure waveforms alone may have concluded the pressure to be too high to exercise the patient. Had the exercise been foregone, the ultimate diagnosis of the mitral stenosis could have been considerably more serious. However, because the wedge pressure was immediately quantitated and

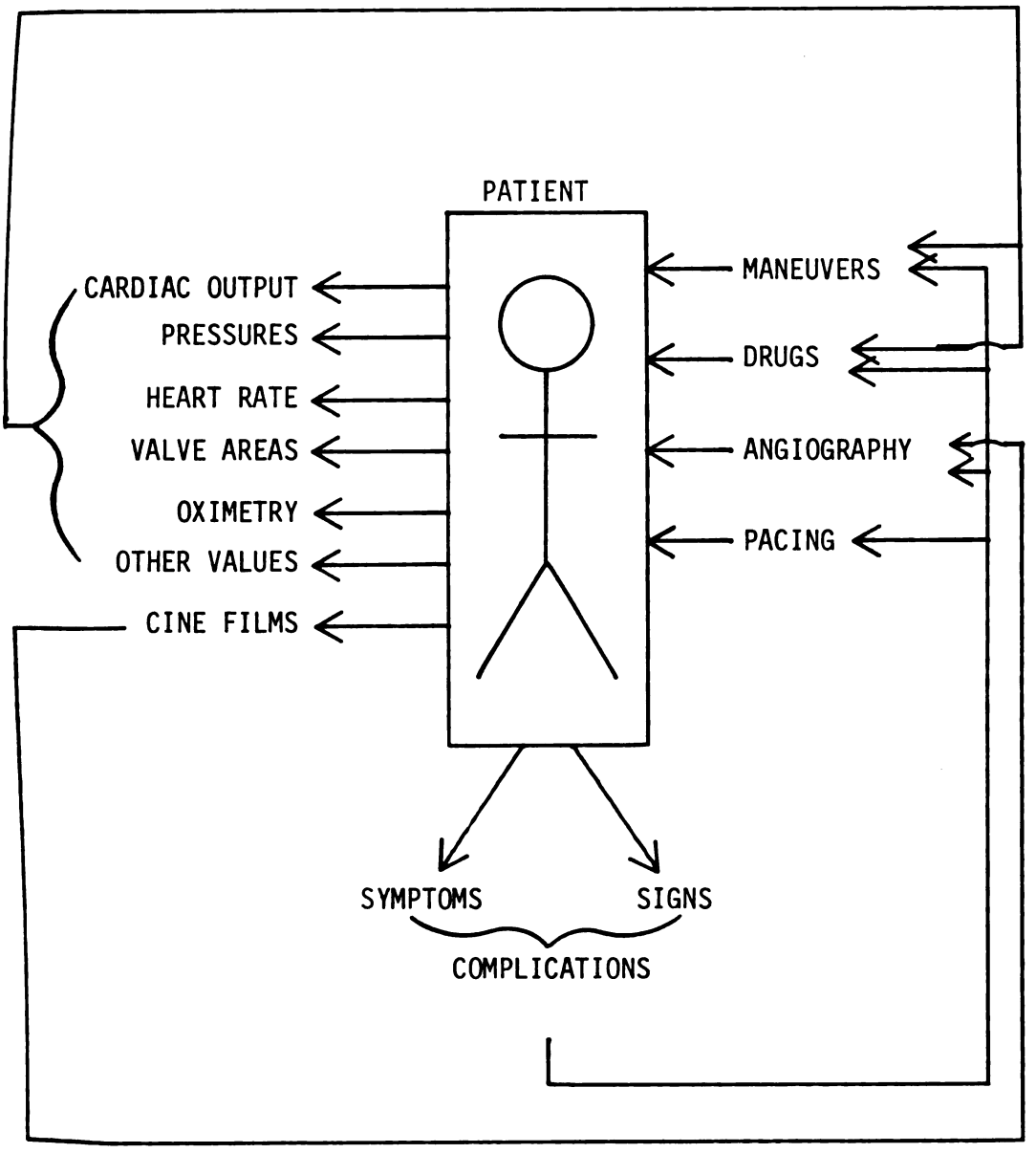


FIGURE 8: DYNAMIC NATURE OF THE CATHETERIZATION LABORATORY. *Note that all events (on the left side) affect virtually all maneuvers (on the right side). Furthermore, note the implications of arising complications during the procedure.*

available, the patient was exercised and so the severity of the mitral stenosis was correctly assessed.

In contrast, specification of other data which completes the catheterization report, but is not essential during the case, is best recorded after the case has been completed. Data reflecting the types of catheters used, the details of each maneuver, the isolation of the significant parameters calculated and the reviewing of angiography films can safely be evaluated at that time. However, to preclude data loss, all data should be fully collected within a few hours after the case is completed.

After all the catheterization and pre-catheterization data has been collected and coordinated, it must be formally reported. The full catheterization report is normally required within 24-48 hours of the completion of the case. Prior to having a full report, several "working" reports should be available in the event the data is needed immediately. Chief among these "working" reports is a log of the maneuvers and events which were recorded during the catheterization procedure. Though perhaps lacking details, this log should outline the events which occurred while the patient was in the catheterization laboratory. This interim report thereby serves to "explain" differing results and to refresh the clinician's memory when preparing the final report. It would, for example, indicate that the sample patient had been exercised, thereby "explaining" the dissimilar wedge pressures and heartrates.

Other "working" reports summarizing major events such as the pre-catheterization data, the parameters calculated from the angiography films and the specification of narrowings and blockages in the coronary arteries also serve to refresh the clinician's memory. Still other reports are necessary. If the patient is scheduled for surgery, reports must be submitted to both the anesthesiologist and the surgeon. A report summarizing the highlighted results

may also be prepared to send to the physician who referred the patient to the laboratory.

With all the reports, the primary objective is to make the data available in an informative and not misleading format before the next clinical maneuver (e.g., surgery) takes place.

Stability

The stability of the data to be collected is of paramount importance in the design of an information management system. No field of medicine is so well understood that research efforts will not alter the importance of certain aspects and not introduce new data elements and cause-effect relationships. It is therefore essential for long-term usage that information management systems not be welded to the data utilized at the time of inception. As the medical specialty evolves, its data management facilities must also evolve. At the same time, the evolution of the system must not render previous data inaccessible or useless for reporting or research.

Catheterization, as a procedure, is continually being studied and re-evaluated. The techniques used and the significance of the data obtained are highly subject to change. Consequently the mechanisms employed to collect and report catheterization data must be balanced between flexibility and standardization. Flexibility implies that data dependencies are minimized. That is, current perceptions of data do not affect the mechanisms to collect or store data. For example, consider the sample case: the patient's left ventriculogram revealed inferior wall hypokinesis which "probably" developed as a result of the rheumatic involvement of the heart muscle. The key word here is "probably". So the data describing the left ventriculogram should be recorded independently from the data describing the rheumatic fever. On the other hand, some standardization of the collection and storage of data is necessary. It is

reasonable that all data reflect measurement units (e.g., mmHg) and/or the actual time when the data was obtained. This standardization is visible in the sample case: wedge pressure = 19 mmHg at 10:15, exercise started at 10:25 and wedge pressure = 30 mmHg at 10:30. Hence, standardization is introduced to enhance the daily utility of the system. Flexibility is maintained to support the research utility of the system.

To further facilitate research using catheterization data, the system should be flexible and archive all data. But preserving all data can result in large volumes of data. In order to contain the proliferation of data and to emphasize those aspects of pre-catheterization tests which are considered relevant, standardization is introduced again. Thus the use of pre-defined descriptions for chest X-rays, electrocardiograms, exercise tests and other pre-catheterization data is preferred. Clearly, free text could also serve to describe the pre-catheterization data. But, whereas free text is flexible and permits description of all possible situations, it is the least researchable form of data. Specifically, content in free text varies dramatically among clinicians according to specialty and experience. In medical services where the staff may rotate (i.e., teaching hospitals) or where there is a large population of clinicians using the service (i.e., private practitioners), the degree of clinician specialty and expertise is especially divergent. As catheterization laboratories are commonly operated in one, or both of these manners, stability is dependent on the use of pre-defined texts (with blanks to fill in) or on the selection of descriptions from lists of possible events (known as menus). These mechanisms provide necessary standardization and, as a bonus, provide guidance to clinicians in training and refresh the memories of clinicians who do not frequently perform catheterizations.

Although there is nothing unusual or exceptional about the sample case,

cases do occur which are exceptional. Nonetheless, the design of a system to manage catheterization data must focus on the majority of cases and forego the excessive complexity of a "thorough" solution. Certainly the unusual case should be "manageable" by the system, but the primary goal is to deal efficiently and concisely with the majority of the cases. Yet, to provide support for all cases, free text descriptions should be considered as a back-up means for data collection. However, careful consideration of pre-defined texts and menus serves to reduce the necessity for free text.

It is not enough to maintain data stability. The stability of reporting mechanisms must also be considered. It is realistic to expect that the form and content of catheterization reports will change over time. To meet this situation, specification of new report forms must not nullify existing report forms. This requirement would not be necessary if catheterization reports were only useful for very short-term periods. But, it is very common for a patient's catheterization report to be reviewed on multiple occasions over a period of years. Indeed, many patients are catheterized repeatedly to evaluate their progress. Clearly, the clinician must be able to obtain copies of previous catheterization reports to effectively evaluate new findings.

Accessibility and Clinical Utility

Accessibility of data is delimited by the clinical utility of the data. The personnel involved in collecting, coordinating and reporting clinical catheterization data generally consist of cardiologists, nurses, technicians and secretaries. Each of these professionals is responsible for aspects of collecting data or preparing the final report. As such, each has a different level of responsibility and accessibility toward the data and the report as well as distinct uses for the data. The cardiologists need full access to the data for entry and review. They require several interim or "working" reports while they are

formulating impressions of the case and the subsequent recommendations for treatment. Nurses and technicians do not require such comprehensive access. Generally, they are responsible for maintaining a log of the maneuvers and events of the catheterization. They also maintain records as to the equipment used, the type and amount of radio-opaque agents and the drugs administered. Secretaries are not responsible for data collection. However, they are the primary personnel involved in printing the final reports. In essence, an information management system must support multiple interfaces, each servicing the needs of the different groups. Thus, each group may function independently, integrating the recording and reporting as a routine aspect of catheterization.

Personnel other than the catheterization staff also require access to catheterization data. Surgeons and anesthesiologists are prominent users of catheterization data. These and other clinicians do not need full access to the data. Rather, the system could restrain their access to a subset which is relevant to their clinical goals. And whereas their need is valid, the accessibility afforded to them must not encroach on the needs of the primary users, the catheterization staff.

Researchers also want access to catheterization data. Perusal of data routinely collected as well as data collected for special studies is a commonplace activity in the catheterization laboratory. In fact, the range of research topics using catheterization data is diverse and immense (39, 97). So, in addition to the access necessary to collect data and prepare isolated reports, the design of an information management system needs to consider the problems of supporting access to the catheterization data as a group or database.

Forms of Data

The data collected, coordinated and reported by catheterization

laboratories can be viewed as being of one, or more, of four data forms: quantitative, graphic, qualitative or time-oriented. These different forms of data convey different information and the certainty and absoluteness associated with each form is variable. More importantly, these different forms of data require different management facilities. As will be seen in the next chapter, more than any other aspect, failure to recognize the varying forms of catheterization data produces systems with rigid interfaces and reduced clinical utility.

Consider first the quantitative data form. These data are absolute. Their meaning is invariant among clinicians. Generally, the quantitative data are represented as single numeric values or as a set of choices from a pre-determined list.

In fact, catheterization is performed primarily to obtain quantitative data, principally hemodynamic parameters. These parameters serve as the primary basis for confirmation or rejection of a provisional, pre-catheterization diagnosis. Other quantitative data, collected prior to catheterization, are employed to formulate a provisional diagnosis and thereby serve as the justification for performing the catheterization.

Of all the data forms, quantitative data are the most readily managed. Calculation of hemodynamic parameters is a complex process which yields numeric values (106). For the majority of cases the pre-catheterization data can be represented as numeric quantities, yes/no choices or classified as being of a specific "type". Electrocardiogram data, chest X-ray results, clinical laboratory tests and physical examination can all be represented as quantitative data. For the rest of the quantitative data, menus and sets of pre-defined text suffice and do not pose extraordinary processing problems (61, 107).

Graphic data are those which are initially presented in visual or "picture"

form. These data can be considered as complete. However, to be clinically useful, they are commonly funneled down to produce a concise description of the raw graphic form. In the catheterization laboratory, the graphic data are analyzed to arrive at a meaning. For example, in the sample case, the contractility of the left ventricle is expressed in the graphic form of cine films. Yet, after analysis, the contractility is first described in a simpler graphic form as two silhouettes (see Figure 6) and finally in a quantitative form as an ejection fraction of 0.50. Often, the process of funneling the graphic data introduces measurement error. In the example, the selection of the two silhouettes is a function of clinician experience. Thus, the certainty in the interpretation of graphic data is highly dependent on clinician expertise.

There are three primary types of graphic data which are gathered during catheterization. The first are pressure waveform tracings. Representing the changing pressures in the heart chambers and vessels, these waveforms are displayed on a video monitor throughout the catheterization. The clinician examines them regularly to evaluate the patient's status and to determine that the measurements being recorded are "clean". Those waveforms which highlight the patient's condition are documented on paper or tape. The documented waveforms then serve as the input to obtain the quantitative hemodynamic parameters. The second type of graphic data are angiography or cine films of specific heart chambers. Intensive review of these films is performed after the catheterization procedure is complete, at which time several of the silhouettes are selected for measurement. Quantitative values are then calculated to reflect the volume of the chamber at different stages of contraction and to reflect the evenness of the contractions. The third type of graphic data are also angiographic films, not of the chambers, but of the vessels surrounding the heart. However, these films do not yield quantitative data as do the films of the

heart chambers. Instead, selective coronary angiography, as well as the films of the great vessels, are studied to detect abnormalities in the flow of blood due to narrowing or blockages.

The management of graphic data requires special equipment and sophisticated analysis techniques. This expense is worthwhile for the catheterization laboratory. The pressure waveforms and angiographic films are the raw data of the cathterization process. The hemodynamic parameters, ventriculography results and coronary artery analysis arise from these graphic forms. Consequently, methods which introduce consistency and standardize the analysis of the graphic data are essential for stability.

The qualitative data are the least absolute of the data types. For example, during catheterization, a patient may complain of chest pain. There is no means for quantitating this pain, as each patient has a unique perception of his discomfort. Moreover, variation among clinician attitudes and capabilities plays a major role in the specification and evaluation of qualitative data. Primarily, qualitative observations are weighed for their impact on the more absolute data and are used to identify quantitative and graphic data which support or reject various diagnoses or conditions. As such, qualitative data frequently play a role in the analysis of the quantitative and graphic data.

During catheterization, qualitative data may occur either predictably (e.g., a patient complaint of chest pain) or unpredictably (e.g., the continued and possibly changing effect of a drug). Primarily used in the selection of one waveform versus another as being more representative of the patient's condition, qualitative data are essential both in terms of avoiding unnecessary proliferation of subsequently calculated quantitative parameters and in avoiding the possible presentation of misleading data. After the catheterization, qualitative review of angiography films is crucial in selecting silhouettes for

analysis and especially in evaluating the severity of narrowings or blockages within vessels.

Predictable qualitative data can probably be described in menus or pre-defined text. The occurrence of unpredictable qualitative data suggests that the menus and pre-defined text offer choices such as "Other" and "See file folder". But these two options do not suffice when the unpredictable data is paramount to the diagnosis. Therefore, free text data entry must be considered for qualitative data.

Data is said to be time-oriented if it relates to an event whose time of occurrence, duration and order of occurrence with respect to other events is important. Time-oriented data and relationships are very important in clinical medicine and medical research. Sequence and duration of events are commonly altered and observed to determine the reasons for varying quantitative or graphic data. Trends can be detected and medical measures can be instituted to encourage or retard them.

The time-oriented form of data is the most commonly overlooked data form of catheterization. Although clinicians are acutely aware that a maneuver (e.g., the administration of a drug or the insertion of a catheter) may affect the recorded data, these maneuvers are not always recorded as they occur. Obviously, special studies for research or special diagnostic procedures are usually well documented. However, the routine case may be deficient in the timed recording of the maneuvers performed and the events observed. As can be seen from the sample case, the notation that the patient was exercised is paramount in interpreting the diverse pulmonary wedge pressures. Time-oriented events can also affect the pre-defined protocol, or the direction of the catheterization (39, 97). Rising pressures may require administration of medication and intensive monitoring until they return to safe levels. Some

maneuvers may produce events which indicate additional maneuvers should or should not be performed. Again, this aspect is illustrated in the sample case: the resting wedge pressure of 19 mmHg was abnormally high, but still low enough to safely permit exercising the patient. In short, all timing aspects are vital, inherent components of catheterization and as such, serve as a primary focus for a clinical information management system for cardiac catheterization.

To collect time-oriented data, the system needs access to a real-time clock. Data can then be stored with actual time (e.g., 10:15) of measurement and the arguments previously presented for the maintenance of stability are thereby upheld.

To summarize, cardiac catheterization presents data in four forms (see Table 2).

Table 2: Forms of Catheterization Data

Quantitative:	name, social security number, risk factors, clinical laboratory results, hemodynamic parameters, ejection fraction
Graphic:	cine films of ventricular silhouettes, vessels and other anatomy, waveform pressure traces
Qualitative:	symptoms, "judgmental factors" of the clinician
Time-Oriented:	procedure description, certain maneuvers, drug studies, hemodynamic parameters

The data forms are not mutually exclusive. For example, hemodynamic parameters are quantitative and, because they are obtained repeatedly, they are also time-oriented. Other data undergo analysis and produce data in other forms (e.g., the analysis of the left ventriculogram). Generally, the quantitative and most graphic data are given extensive attention and are actively recorded. Qualitative data are evaluated, but usually not recorded. Time-oriented data are

selectively recorded, usually for special studies, and are probably overlooked in most cases.

The appropriate recognition and management of the occurrences of each of these four forms of data affords the clinician with the essential information required to confirm or reject a diagnosis. This issue has merited extensive attention from A. R. Feinstein (25) who states that clinicians frequently analyze "parts" rather than the whole situation (p. 44). Stressing the need to consider the timing (sequence and duration) of clinical events, he argues that recognition of the reasons for performing an experiment or study should lead to obtaining data which are useful and presented in a manner which satisfies the information needs of the clinician. Furthermore, he notes that information gathering systems which are based primarily on demographic and laboratory data (both of which are highly quantitative data) and which avoid using the "soft" and numerically unsatisfactory data of symptoms and signs (i.e., the qualitative data) miss the point and problems of clinical activities. In essence, the clinician must guard against data collection and management methods which are "mathematically splendid, computationally effective, and statistically impressive, but clinically absurd" (p. 372).

Even beyond this argument, the timeliness, stability, accessibility and clinical utility of the data must be assessed if the data are to be fully useful. Clearly, the clinician and the researcher both need catheterization data which are complete. But, of equal importance are the means by which the data are collected, coordinated and reported. If these means do not conform to or meet the clinical goals, the overall utility and indeed the existence of the information management system are highly questionable.

Chapter 4: Prior Work

Bluntly stated, aside from this research effort, there does not exist an information management system which fully considers the goals of the catheterization laboratory. This is not to say that nothing useful has been accomplished. Quite to the contrary, extensive efforts have been undertaken to construct information management systems for the catheterization laboratory. However, in every instance, at least one of the components of the information framework has been overlooked.

Manual Methods

Consider first the traditional methods for collecting, coordinating and reporting catheterization data. These methods are predominantly manual, but enhanced through the use of analog equipment to measure pressures in the cardiac chambers and vessels. These pressures are documented with a strip recorder which draws traces of the changing pressure(s) (such as those shown in Figure 4 of Chapter 2). These traces subsequently require significant technician or clinician time for examination and for manual calculation of hemodynamic parameters. After this chore is completed there remains the task of calculating parameters relevant to the function of the left ventricle. For this task, additional time is spent viewing films, selecting ventricular silhouettes, manually measuring the silhouettes and finally deriving quantitative results. Still more viewing of angiographic films is conducted to assess the condition of the coronary arteries and other great vessels. Upon completion of all these tasks the clinician writes a report describing the patient's medical history, physical condition, the catheterization procedure, the calculated measurements, the impressions and the recommended therapy. This report then becomes part of the patient's medical record. All told, this process may require several hours of

clinician time for each patient.

Several weaknesses are inherent in the manual methods of analyzing the raw data from a catheterization. In every situation where manual methods of measurement and/or calculation are employed there is the risk of human error and/or variation in the techniques used. Furthermore, valuable clinician time is wasted in the calculation of routine, well-defined parameters. And because the calculated hemodynamic parameters are not accessible in a timely manner (i.e., they are not accessible during the catheterization procedure), it is possible for the delinquent data to be inconclusive or incomplete. In that event, the patient must be returned to the laboratory for another catheterization. Whereas the procedure risk has decreased in recent years, repeated catheterizations are still undesirable as it exposes the patient to recurrent risks and discomfort.

Introduction of Computer-based Methods

The weaknesses of manual methods combined with the quantitative nature of the majority of catheterization events precipitated the development of computer-assisted techniques for the collection and calculation of hemodynamic data. Investigation into the possible use of computers in the catheterization laboratory was begun at Stanford in 1965 (3). Shortly afterward, other groups at various institutions began similar research, with initial efforts concentrated on computer acquisition of the analog pressure waveforms. Concurrently, several methods were developed to analyze the digitized versions of these waveforms (18, 21). In short order, computers were identified as the optimal tool for calculation of hemodynamic parameters.

Work proceeded using large, time-sharing general purpose computers and high level programming languages. However, use of a time-sharing computer quickly unveiled itself to be an undesirable choice. The nature of the catheterization procedure as a dynamic, real-time environment was realized.

Accordingly, the various researchers almost universally switched to smaller, dedicated, real-time computer systems. But, this move was not without consequences. In order to match capabilities possessed by the larger, general purpose machines, the switch to mini-computers necessitated the use of assembly language, programming "tricks", and other "difficult-to-update" approaches. Compromises were made between flexibility and simplicity. It was conceded as impossible to create a system to handle all possible situations and conditions arising in the catheterization laboratory (4).

In spite of the difficulties encountered, the introduction of the computer as a tool in the catheterization laboratory has been very successful. Several major benefits have been realized. The computer is able to measure the pressures with minimal physician or technician assistance. Furthermore, these measurements are performed in a substantially more consistent manner that was previously possible. Standardization and stability are increased. Now, upon completion of obtaining pressure measurements, the computer immediately quantitates these graphic data and displays appropriate hemodynamic parameters for clinician review. Even the most complex parameters are displayed with minimal delay. The timeliness of these results (within seconds of actual measurement) provides the clinician with a reliable basis for appraisal of the patient's condition. Maneuvers potentially dangerous are omitted and additional diagnostic ones included as the clinician feels appropriate. There is no valuable clinician time spent in performing laborious calculations. The cardiologist is therefore encouraged to obtain a more complete set of data for each patient (45).

In conjunction with the development of computer-based methods for quantitating pressure waveforms, methods for quantitating left ventricular function were implemented. Similarly, the objective of these systems was to

increase the accuracy and stability of the calculations and to improve the timeliness of the results. And similarly, the need for meticulous measurement and complex calculations (106) makes ventricular analysis well-suited for implementation on digital computers. Unlike quantitation of pressure waveforms, the quantitation of ventricular function requires specific clinician input. Two silhouettes (end-diastolic and end-systolic) must be digitized using a spark pen or light pen. The clinician must also supply the computer with a few parameters (e.g., body surface area, peak systolic pressure). Then he may select a method(s) for analysis of the images (e.g., he may select a method for calculating ejection fraction using either Dodge's area-length method or Simpson's rule (106)). The computer displays the results within seconds (21, 95). So, the total time to trace the images, enter parameters, select a method(s) for analysis and display the results is thereby reduced from over one hour to less than ten minutes. The rapid turnaround, accuracy and standardization of the analyses create great appeal for computer-based ventricular analysis systems.

The major drawback to computer systems which quantitate left ventricular silhouettes is the inability to provide long term storage of either the digitized images or the results. This problem arises because the ventricular analysis system usually runs on the same (or similar) computer which runs the catheterization system. As this mini-computer uses minimal peripheral storage, the capability of the ventricular analysis system to preserve data is bounded. Additional problems arise where the same computer is used to operate the two distinct systems. First, the user must physically reload the computer's disks each time the other system is used. This is more than a nuisance to users. A second problem arises in that the two systems are unable to coordinate their results. Each operates in isolation, providing no data base for research.

So far, only the issue of quantitating catheterization data by previous systems has been discussed. Yet these results must also be documented. To meet this need, the computers were programmed to generate a terse report presenting the calculated quantitative results (4, 14, 21, 45). Rather than permit editting of the set of results, every calculated parameter is listed on the report. Consequently, an overwhelming amount of data may be printed. To complicate and confuse matters, the results are not annotated. Successive measurements may be radically different, yet the report does not present any explanation as to the reason for the varying results. So, unless the report is manually annotated by the clinician who performed the catheterization, it is difficult and potentially disastrous for other clinicians to attempt to interpret the reported results. Still worse, some computer systems only report the most recent measurements obtained for each chamber or vessel. This approach may prevent reporting valid and useful results which were obtained earlier in the catheterization, prior to intervention with drugs or contrast agents. Again, facilities for appropriate annotation of the results are not available. Manual annotations are still necessary to accurately explain the reported results. And, once annotated, these reports must serve to document the procedure results and are usually kept by the catheterization laboratory as "working" reports.

Commercial Systems

After varying degrees of success had been attained in the medical institutions, commercial groups began to market "Catheterization Computer Systems". At least nine major companies produce these turn-key systems (18, 20). Chief among them are Hewlett-Packard, Electronics for Medicine/Honeywell, and Mennen Medical, Inc. Each of these companies has developed their product on a small mini-computer (e.g., PDP-11/05, HP2100) with dual floppy disks as peripheral storage. Whereas the use of small computers

has been a benefit to the commercial companies in holding down the overall cost of their products, these systems are still expensive, with prices ranging from $35,000 to $175,000 (18, 21). Real-time operating systems and the use of assembly language and FORTRAN programs are prevalent in these systems. All the vendors claim to calculate any parameter which could possibly be useful and advertise this point to provide a superficial attraction for prospective buyers. The user interaction varies somewhat among the products, primarily in keyboard design. Switches controlling the acquisition of the pressure waveforms and oximetry data also present considerable variety and complexity.

The only emphasis placed on the report generation capabilities of the commercial systems is the orderly presentation of patient identification, height, weight, age, and calculated parameters. The calculated results are usually displayed in tabular form according to vaguely defined portions of the procedure (e.g., DRUG1, DRUG2, EXERCISE). Assistance in the preparation of formal reports is virtually non-existent or at best very primitive (3, 18, 20, 21). Data gathered outside the catheterization laboratory (e.g., electrocardiogram, clinical laboratory results, chest X-ray) are not handled by these sytems. Furthermore, and perhaps foremost, these systems support information for only one patient at a time. There is no automatic long term storage nor is there adequate support for research over sets of patients.

The foregoing discussion is not meant to imply that the commercial systems are totally inadequate. In fact, these systems are in daily use at several prestigious medical centers (4, 10, 65). Notably, at local centers, Stanford Medical Center uses (and develops) the Hewlett-Packard system, Letterman Army Hospital uses the Electronics for Medicine/Honeywell system, and the San Francisco Veterans' Administration Medical Center uses the Mennen Medical system. These products handle the limited tasks they were designed to perform

very well and appear to be well accepted. However, these computer systems fail to assist the clinician beyond the quantitative aspects of catheterization. They are essentially "instruments", useful only during the procedure (21).

Use of Computers to Log Clinical Events

A major aspect overlooked by the aforementioned computer-based systems is the varying nature of the data associated with a catheterization. As stated earlier, the data arising from a catheterization belongs to one or more categories: quantitative, graphic, qualitative and time-oriented. Consequently, data from all these categories should be collected by a comprehensive catheterization computer system. Quantitative data are currently collected by available catheterization systems. Data still in graphic form may be quantitated post catheterization. However, a major failure of current catheterization computer systems is the failure to log qualitative events. Indeed in most systems, all data is recorded without regard to time orientation. Yet, as was explained earlier, the most effective method for capturing the dynamic clinical events occuring in the catheterization laboratory is to maintain a log. Lists of drugs, anesthetic agents and major clinical events must all be noted at the time of their occurrence. Though not applied in catheterization laboratories, the efficacy of computer-based logging has been explored at two prominent university medical institutions.

Clinicians at the Latter Day Saints Hospital in Salt Lake City have developed a computer system for the recording of prominent maneuvers and events occurring in open-heart surgery (28, 29, 73). This system is operated by the anesthesiologist and/or technician who records the manuevers and events using a keyboard and a coding scheme. After the surgery is complete, a terse listing of these maneuvers and events is printed on conventional computer line printer paper. Unfortunately, a significant portion of the items in this report are

listed solely by codes (which are rather cryptic). Although this listing is extensive, it is not expanded further. The codes are not translated to text, nor is the listing manually annotated. It is doubtful that such a document is suitable for placement in the patient's medical record. Moreover, no explanation as to the final use of the report is offered by the authors.

The other system was developed at Case Western Reserve University (108). This system is strictly for use by the anesthesiologist and his staff. Occurrence of intra-operative maneuvers and events is recorded by selecting "event markers". Twenty-six markers are available (each letter of the alphabet can be used only once). But, as specific letters are not rigidly associated with specific events, their association may vary among cases. To complicate matters, each technician and anesthesiologist may employ his own scheme for relating markers to specific events. Fortunately, upon completion of the operation, these markers are annotated. However, this dual phase method of recording the events is highly prone to errors. Through manual translation of the markers it is possible to produce an invalid or misleading log.

In spite of the shortcomings of these logging systems, both systems do capture "fundamental and necessary observations upon the patient" (28). And both systems have demonstrated that they trapped data which were previously "overlooked" or ignored due to "information overload", being "smoothed" or "interpolated" (29, 108).

In both of the logging systems, use of a coding scheme adds unnecessary complexity. In contrast, the use of standardized menus to present the possible clinical maneuvers and events provides a stable, compact and well understood method for recording data (8, 16, 34, 61, 109). Also, menus can be easily updated or expanded. More importantly, misunderstanding of menu entries as opposed to coding schemes rarely occurs. All these features are vital to the

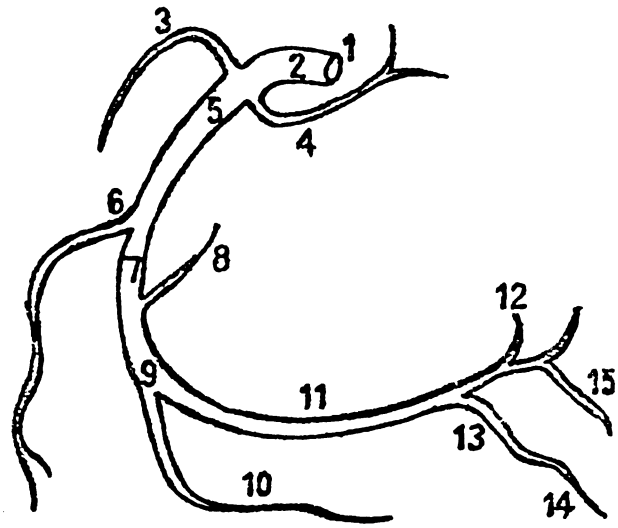
initial success and evolution of a clinical computer system (12, 26, 36). Furthermore, when combined with time orientation, menu selections provide an easily accessible, stable base for the majority of research queries (33, 37, 103).

Recording Coronary Artery Data

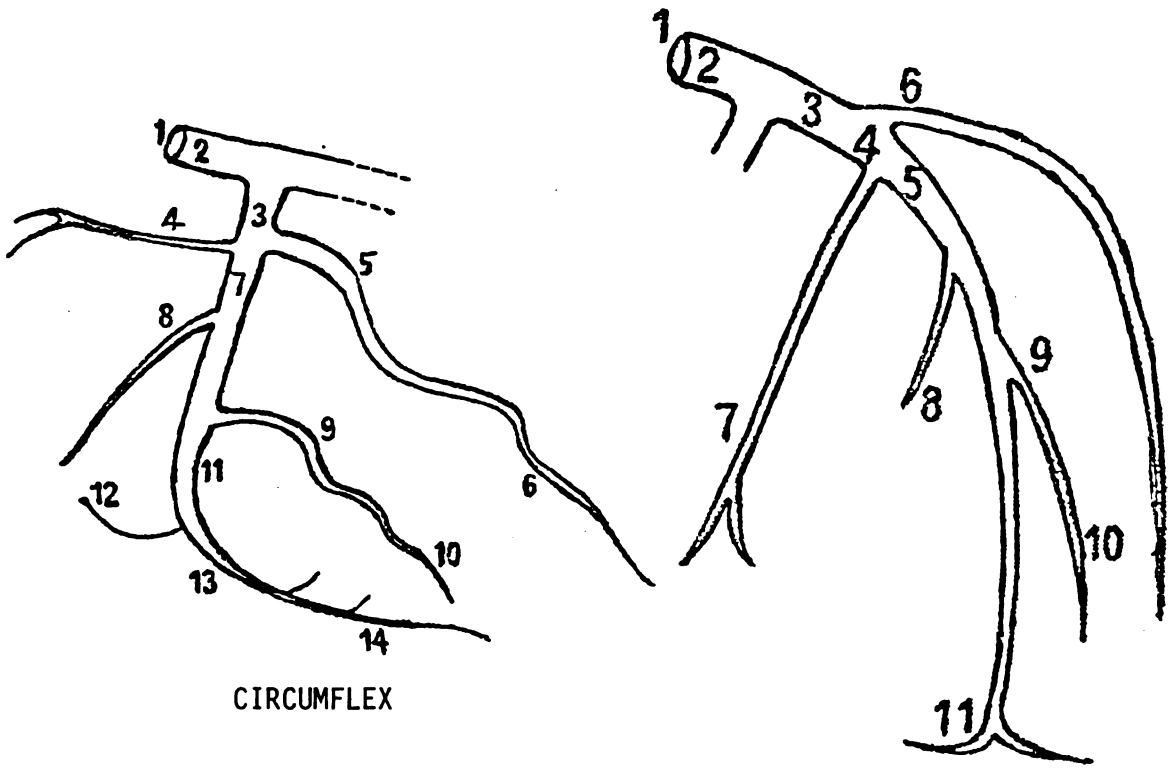
Whereas the computer has been useful in quantitating left ventriculograms, it is rarely used for quantitating other angiographic data. The prominent reason for this is the variation of the anatomy of these vessels (4, 14, 30, 32, 104). Nevertheless, several computer-based techniques have been developed which propose to quantitate and/or record the condition of the coronary arteries.

The majority of efforts to record coronary artery data have almost exclusively relied on the templates and methods developed by Gensini (30). In his work, Gensini has expended a great deal of effort in determining the major anatomical variations and their frequency of occurrence. As a result, he has developed a template for each of three major artery branches: right, left anterior descending and circumflex (see Figure 9). Virtually all cases can be described using these standardized representations. Consequently, they are used extensively by clinical services.

The major drawback of Gensini's approach is the use of mark sense forms for recording occlusions, collateral flow and graftability. These forms are highly prone to errors in both marking and reading. As such, they are unreliable. To make matters worse, when the forms are in error, they are not easily corrected. Generally, a new form must be submitted to replace the erroneous one. Yet, Gensini's method is the most comprehensive computer-based method available. So, in spite of these problems, several others have adopted this approach though undoubtly with recurrent aggravation (6, 19, 64).



RIGHT CORONARY ARTERY



CIRCUMFLEX

LEFT ANTERIOR DESCENDING

FIGURE 9: CORONARY ARTERY TEMPLATES OF GENSINI (30).
See text for discussion.

The quantitative aspect of Gensini's method is found in his method of assigning a score to each artery. This score is determined through a weighting scheme which assigns a value to each major site in an artery. Each weight is then multiplied with another score which represents the percent occlusion at that site. Additional factors contribute the value of collateral flow and the graftability of the site (i.e., the condition of the distal vessel). But the final scores are not used in the immediate evaluation of the patient's condition nor are they included in the catheterization report. Instead, they are used as prognostic indicators for research purposes. In fact, the scoring technique was developed specifically for determining the medical prognosis of certain lesions (e.g., a left main lesion which deprives both the LAD and LCX branches or a combination of single vessel vs. triple vessel diseases). To date, this research has concentrated on evaluating the effects of coronary artery bypass surgery (6, 32).

Even though the process of scoring the arteries is not used in daily care, cardiologists do readily use Gensini's stylized coronary trees in their manually prepared catheterization reports. Because these trees do provide sufficient detail to accurately specify the location and degree of stenosis within the arteries, appropriate therapy can be determined by examining the cardiologist's annotations on these templates.

However, Gensini's templates cannot accommodate the natural variability of human anatomy. So, researchers at Duke are attempting to develop a process where each coronary tree is represented uniquely (86). Their method requires the clinician to define the junctions and endpoints for each artery. Using a graph pen and interactive display screen, these points are entered. The computer then displays a "tree" which appropriately connects the points to create a line image of the artery's structure. Obviously, this approach results in distinct

representations for each patient and therefore reduces standardization. Clearly, methods to access such a data base and select a subset would be complex. Furthermore, variation in the tree representations compounds the difficulty of specifying the site of occlusion(s) to the computer. As expected, the Duke system, like Gensini's scoring system, is not for everyday clinical use, but is intended for prognostic and research purposes.

There appears to be only one system which employs standardized trees (not Gensini's) and interactive graphics to record coronary artery data for everyday clinical use (40). This system simultaneously displays all three major coronary artery branches in a structure similar to the left anterior oblique (LAO) view (see Chapter 2, Figure 2). Data are accepted relating to anatomy, occlusions, distal vessels and collateral flow. There is no facility to collect data describing grafts. The most significant flaw of this system is found in the graphics display device. This unit divides the screen into .5 inch by .2 inch regions. Consequently, the structure of the displayed arteries is angular and the point specificity of anatomical sites is gross. A higher resolution graphics device would allow superior artery representation and site specification thereby greatly improving this system.

Data Completeness

A computer-based information management system does not solely collect and report data. It also assures that the data set for each patient is complete. This then amplifies the validity of both reports and research (38). To date, the most comprehensive computer-based techniques to assure data completeness are exemplified by the methods of artificial intelligence. Of these methods, the division of the set of possible events into triggers (indicating that another data item should be recorded) and categories (a data item(s) which is evaluated or collected when a trigger is encountered), appears most useful in that it promotes

the computer to pinpoint "holes" in the data (91, 98). For example, suppose the system recognized that the drug Hydrocortisone was administered during the catheterization (a trigger). It may then query the clinician as to the "reason" the drug was given (this category involves the specification of a complication). This approach and other methods of artificial intelligence such as matrices which describe relationships between maneuvers and events (2), "layered structures" which support inference of a general description from specific detail (62) and "rules" which prompt the clinician for additional data to complete a scenario (80) provide a basis for ensuring a complete data set for each patient record and for the ensuing report. Moreover, clinicians generally react positively toward such prompts, regarding them as educational tools for both physicians in training and for those in active practice (66).

Computer Generation of Clinical Reports

After the data set is complete, a formal medical report can be generated. This report is a legal document. It must describe all maneuvers which took place during the catheterization and reflect the order in which they occurred. It must indicate the justification for the procedure and highlight the findings. Any complications of the procedure must also be documented in this formal report. Above all, this report must be coherent and clinically useful.

However, none of the mini-computer-based catheterization systems is either flexible or comprehensive in its report generation capabilities. In fact, the prevalent style merely dumps a collection of tables listing the calculated hemodynamic parameters. It is very unusual for these systems to indicate, in a coherent fashion, which drugs are administered, the various maneuvers performed, the arising complications, the sequence of or the times at which significant events occurred (20, 21, 85). Considering that the purpose of catheterization is to observe and record the dynamic behavior of the heart, this

weakness is quite profound.

Yet, several other medical specialties have developed computer systems which result in clinically useful reports, progress notes and department records. Most prominent among these are radiology (9, 11, 42, 60, 61, 75, 78, 79, 81, 102), obstetrics (84, 88, 90), pathology (43, 72),, hypertension (105) and cardiology (6, 13, 19, 49, 56, 67, 94, 96, 100). Efforts have also been made in psychology (63), gastro-enterology (17), surgery (28, 29, 89) and orthopedics (59). With the exception of the radiology and a few cardiology systems, these computer-based reporting systems are used exclusively within the specific medical department. Reports for use external to the department are manually prepared (apparently because the computer-generated report is not considered "presentable").

Each of these systems is successful because it has based data acquisition and organization techniques on the particular properties of the medical specialty and, as much as is possible, on the traditional methods used by those clinicians. The radiology systems rely heavily on the use of standardized graphical representations of anatomical sites which parallel the standard X-ray views. Obstetricians base their systems on computerized checklists which resemble the lists previously marked by hand. Pathology systems frequently utilize specialized and widely accepted coding schemes (e.g., SNOP). Hypertension systems focus on the ability to display data in a time-oriented fashion to highlight physiologic trends.

Following the apparently successful tactic of other medical specialties, the use of data collection and reporting tools which are specific to the categories of data should be the basis of a catheterization reporting system. Graphic tools and standardized templates are ideal for the analysis of ventriculograms and the coronary arteries. Checklists isolate clinical laboratory results, risk factors,

drug usage and family history. Coding schemes support evaluation of the coronary arteries (30). Time-oriented presentation of the maneuvers performed in the laboratory produces the base for the textual description of the catheterization procedure.

Of these report components, it is the textual description of the catheterization procedure which has produced the greatest variety of solutions, none of which consider the time orientation of this component. Indeed, free text descriptions are usually prepared for this component of the report. A few computer systems, notably those employing larger computers, employ word processing in preparation of free text for reports (10, 15, 45). However, it should be noted that this standard (free text) used as a sole mechanism for report preparation does not provide a sound basis for retrieving data or for performing automatic analysis. Therefore, this approach is not desirable.

Other catheterization reporting systems begin by posing a standard, unvarying set of questions to the clinician (41, 47). In many cases, questions which are not applicable to a specific case are asked so that the computer can determine that a maneuver was not performed. The answers to these questions are then structured into terse, unnatural text. Whereas these systems do obtain and report the details, the method of simply posing questions does not reinforce the notion that catheterization is a procedure of time-oriented, inter-related maneuvers and events. The resulting descriptions also ignore this notion. These reports only state the maneuvers performed. They do not indicate the order of events, the intermittent administration of drugs or the occurrence of complications. There is essentially no connection between the data recorded during the actual procedure and the data gathered to provide a detailed description of that procedure.

Use of Multiple Computers and Networks

The long term organization and management of data is a perpetual source of frustration for researchers (68). This situation pervades catheterization laboratories. Current techniques commercially available for the clinician to archive calculated hemodynamic parameters invariably demand the contortions of loading and unloading disks and programs. Analysis of preserved data is even more harried due to the insufficient storage available on floppy disks and to the nonexistence of programs to search the records for desired characteristics (4, 18, 20, 21).

Previous non-commercial efforts to coordinate catheterization data into computerized data bases have presented two approaches. The first approach involves the use of one large computer to quantitate data during the catheterization and also to serve as the recipient of a data base (10, 15, 45, 65, 74, 94). The other approach relies on off-line data entry (with mark sense cards or magnetic tape) of previously quantitated data to a large general purpose computer (6, 19, 31, 47, 56). Neither of these approaches is acceptable. The first approach requires a monumental waste of computer resources which no accountable service could justify. Specifically, to maintain appropriate turnaround, the entire computer must be dedicated to quantitating pressure waveforms for the full duration of the catheterization. No other computational activities could be active; time-sharing would be suppressed. The second approach demands physical user intervention. Besides being a burden, such intervention is a prime site for introduction of error and for loss of data. Although conceded as a long range goal, the only efficient means for data coordination demands an automated link between a dedicated laboratory computer and a time-sharing computer. This need to complement a dedicated laboratory computer with a separate, preferably time-sharing, computer to

coordinate, archive and report the final data for a catheterization laboratory system has been widely recognized (3, 18, 19, 20, 31, 35, 45). An automated network for data transfer also provides the mechanism for increased enhancement and evolution of the information management system (27).

However, the implementation of a computer network is not a trivial task. The issues in the design and function of a computer network can be described in terms of six areas: communication protocol, interconnecting hardware, ease of use, extendibility, error detection / recovery and software complexity. Of these, the most important aspect is the communication protocol (5, 48, 53, 101). This protocol consists of a well defined arrangement for the exchange of messages between two computers for transfer of data and/or activation of programs. The protocol determines whether or not the network can be used by most computers or whether or not it is constrained to a limited subset. The protocol affects the overall utility and delimits the power and flexibility of the network. In view of this influence, the communication protocol is the heart of a network. Consequently, any communication which does not conform to the protocol is considered to be erroneous, resulting in error recovery action and possibly in termination of the communication.

Interconnecting hardware is the second issue in network design, with the methods used varying widely in complexity and cost. Networks also vary dramatically in ease of use. Some networks are fully automatic and transparent to users. Others are extremely sensitive, aborting communication if the user makes the slightest error.

Unfortunately, most networks are not extendible. They perform only the original design goals. Still, others can incorporate new commands into protocols but usually with extensive programming effort. Another important aspect of extendibility is the feasibility of adding new computers to the network. Again,

there is extreme variation in the approach.

Error detection and recovery are essential. Users will assume that the data exchange is valid. The network must ensure validity of data exchange or it must report that unrecoverable errors have occurred. Thorough design of both the communication protocol and the hardware interconnection are essential in isolating transmission errors.

The software to decipher messages and to control message response can range from the primitive to the overwhelmingly complex. In general, the use of front-end processors or telephone lines increases the software complexity (but it may not affect the ease of use). Environments where errors are commonly expected require software which is usually very complex. Hence, as the complexity of the protocol, the hardware interconnection and the error recovery increase, the complexity and size of the software increase.

Accordingly, networking of computers has been accomplished on many levels and the science of networks has become very complex (5, 27, 48, 53, 77, 92). Large networks, such as ARPANET, now allow users in California to use the facilities of computers in Massachusetts without requiring those users to know the intricasies of the distant computer (77). Through the use of standardized communication protocols and customized hardware combined with dedicated processors, powerful networks have given researchers access to one another's data and programs. A major feature of these large networks is that they permit communication and resource sharing among all computers in the network, independent of their hardware or software configurations. Networks such as INFONET, GE, NASDAQ and TYMNET are examples of such large scale networks.

In contrast, the employment of networks in medical systems has taken a rather different direction than that of the nation-wide networks.

Standardization appears to be the last consideration. The techniques used to communicate between two computers is usually hardware and/or software dependent. The facilities developed by Digital Equipment Corporation (DEC) for use by MUMPS systems is prevalent (22, 23, 113, 35, 44, 64) and their other network system for use among most DEC computers, called DECNET, is becoming increasingly common (114). Both of these facilities are based on a collection of control codes which center on internal and unique DEC interpretation (111, 112). As such, these schemes are not acceptable bases for clinical computer systems which may not interpret control codes in accordance with DEC computers. Yet this problem is not unique to DEC. Other medical networks commit a similar error (23, 64, 76, 83). These schemes expect one machine to "log on" to another. The machine initiating communication is responsible for controlling the dialog and must be capable of responding in an almost human-like fashion to the variety of situations which may occur at "log on" time. Furthermore, this "log on" may be performed "blindly", without benefit of response from the other computer. The degree of dependence of such systems to specific hardware and software products makes them unacceptable for evolving clinical computer systems.

All the medical networks fail to use a suitable communication protocol. They fail to observe the techniques of the successful large scale networks. Of those techniques used by successful networks, alpha-numeric keyword protocols are common and they pose the least complexity. Such protocols make use of the ASCII standard which almost all computer systems recognize (77). At the same time no significance is attached to specialized control codes or characters, as these may be interpreted differently by various computer systems. Furthermore, use of keywords is very enduring, easy to learn, use and extend (51, 53). Of equal importance, the addition of a keyword communication protocol capability

to an existing computer system is not obtrusive to the operation of that system nor does it require facilities the system does not possess (3, 20, 21, 113). Such a protocol can allow for control of disposition of transferred data (e.g., to line printers or disk files), activation of programs, sharing of expensive peripherals and backup of software and data on multiple machines. However, there is no currently available commercial network for use on mini-computers which is based on a keyword protocol.

User Acceptance

It is imperative to consider the personnel who will interact with the information management system as even the best computer systems will be rejected if they do not accommodate their prospective users. This principle was dramatized in an extensive survey of published clinical computer systems. It was determined that most of these systems (approximately 81%) failed because they did not meet the needs of the clinicians (26).

Several other groups have also surveyed clinician reaction to the use of computers in medical care (8, 52, 55, 82, 87, 88, 99). The majority of clinicians surveyed agreed that computers could be a benefit in handling hospital problems. Specific complaints against computer systems arose from the usual rigidity of the systems and their inability to evolve (26, 99). Flexible data input and management as well as the resulting reports were acknowledged as important aspects for clinician acceptance (79, 88).

Yet another study concentrated on the attitudes of the house staff (interns, residents, fellows) towards computers in medical care. This group exhibits the least enthusiasm for computer systems (87). As these physicians are in training, they frequently experience new, and possibly frightening, situations. A computer system is expected to pose additional new and uncomfortable experiences. This apprehension is best accommodated if the

system is self-teaching. As such, offering guidance and diplomatically indicating errors can be the key aspects in building the user's confidence (52). The user can then feel he is working with the system as opposed to working against it. Wherever possible, the availability of "orientation" and "routine use" modes of operation also helps to maintain good user acceptance (82). Easy access to computer personnel is also seen as useful in allaying fears of the computer system (55).

In summary, the personnel who interact with the information management system are the determinants of a successful system. Even if the computer can collect, coordinate and report any and all data, malcontent users will discover a way to sabotage the system. This sabotage can be avoided. The key is to design an information management system which is in step with the goals of the clinician. Data must be accessible and timely. The system must be stable, yet accommodating. Above all, the system must not demand extra work from its users.

Chapter 5: A Model Information Management System for the Cardiac Catheterization Laboratory

To properly address the task of managing clinical catheterization data, that task must be viewed in terms of its properties and its usefulness to the clinician. This view was detailed in the discussion of the problem areas and the data forms of catheterization in Chapter 3. In the Chapter 4 it was shown that earlier efforts to utilize computer-assisted information management in the cardiac catheterization laboratory have had serious shortcomings. In fact, the only data management tasks that are supported to popular clinical satisfaction are the quantitation of pressure waveforms to produce hemodynamic parameters, and to a lesser extent, the quantitation of left ventriculograms. The other information needs of the catheterization laboratory are not adequately met by existing systems. This chapter presents a model for managing catheterization data which, to a large extent, overcomes the shortcomings of earlier efforts.

Before proposing the model, a brief review of the major faults of existing systems is useful. Four major faults pervade the computer-assisted systems. First, not all data are collected. Usually, only quantitative data are compiled. An important goal for the model is to support the collection of all catheterization data: quantitative, qualitative, graphic and time-oriented data. Second, none of the existing systems "step" with the clinician. In other words, there is little attempt to synchronize data collection or data presentation with the clinical task at hand. So the model provides for the collection and presentation of data at clinically appropriate times. The model thus "steps" with the clinician and his need for data management. Third, when reports are generated, they are often of poor quality. They may not present all the data. Or,

perhaps worse, they may bury the reader in copious amounts of potentially misleading data. Hence the model promotes the generation of reports which provide essential data and detail. However, only data requested by the clinician is included. Thus, a report presents an orderly subset of the full data set. This subset reveals a concise clinical picture of the patient. Finally, and somewhat astonishing, the data may not be preserved. Hence, valuable clinician time may be wasted in entering data which is not preserved for future clinical use. So the model also provides for archival of the full data set for each patient through the use of a computer network.

All in all, the model presents a comprehensive, innovative approach to the computerized management of cardiac catheterization data. With the exceptions of the quantitation of pressure waveforms and of the left ventriculograms, all aspects of this model are novel approaches to managing catheterization data. For the collection of manuevers and events occuring during catheterization, a method for creating a log of the procedure is proposed. Techniques for editting this log and for verifying its accuracy are outlined. Methods for the generation of a detailed description as well as generalized description of the catheterization procedure are given. A new approach to collecting the data representing the coronary arteries is promoted. Methods are introduced to facilitate the collection of pre-catheterization data. Report generation methods are designed which allow the clinician to select data for inclusion in reports. The resulting reports are legible and concise. Other functions for daily use of a model system are reviewed. Finally, considerations for implementation of the model are discussed.

Because a primary objective of the model is to "step" with the clinician, it is appropriate to discuss the details of the model in terms of its clinical functions. Thus, the remainder of this chapter presents components of the model

according to distinct clinical tasks and information goals of catheterization. For each of these components, solutions to the aforementioned faults will be considered. For some components, specific techniques of data management will be discussed. For other components, where several techniques would achieve the same effect, only general goals and outputs will be discussed.

Collection of Data Arising During Catheterization

The pivotal component of a computer-based information management system for use in the catheterization laboratory is that which is employed during the catheterization procedure. This component serves two purposes. First, it samples and displays the pressure waveforms, and, at the command of the clinician, it translates this graphic data into quantitative hemodynamic parameters. All the parameters calculated are saved along with the time at which they were calculated. The translation is performed immediately and the results are displayed for clinician review. The techniques currently available for quantitation of pressure waveforms are excellent. So no refinements are needed for this process.

The other primary function of the computer to perform during the procedure is to serve as the documentor of the maneuvers and events. Every maneuver which may affect the patient's condition or which serves to indicate a major step of the procedure is recorded through the use of the computer. Complications and other events arising during the case are also documented through the use of the computer. Thus, the model "steps" with the clinician in collecting these data. These events and maneuvers are recorded in sufficient detail to produce a log of the case. Computer interaction time is minimized through the use of pre-defined menus of the possible maneuvers and events. These menu selections are concise, legible text reflecting the order in which maneuvers are usually performed (see Figure 10). In laboratories where a

diversity of basic protocols are performed, a menu for each different type of protocol is useful. So, only those maneuvers which relate to the ongoing protocol appear in the menu (as in Figure 10 for SCA). Separate menus for noting complications (e.g., nausea, chest pain, electrocardiogram abnormalities) and drugs (a list of those commonly administered plus the dosage given) complete the basic set to record clinically useful logs. As with the calculated parameters, the maneuvers and events are saved along with the time at which each was recorded.

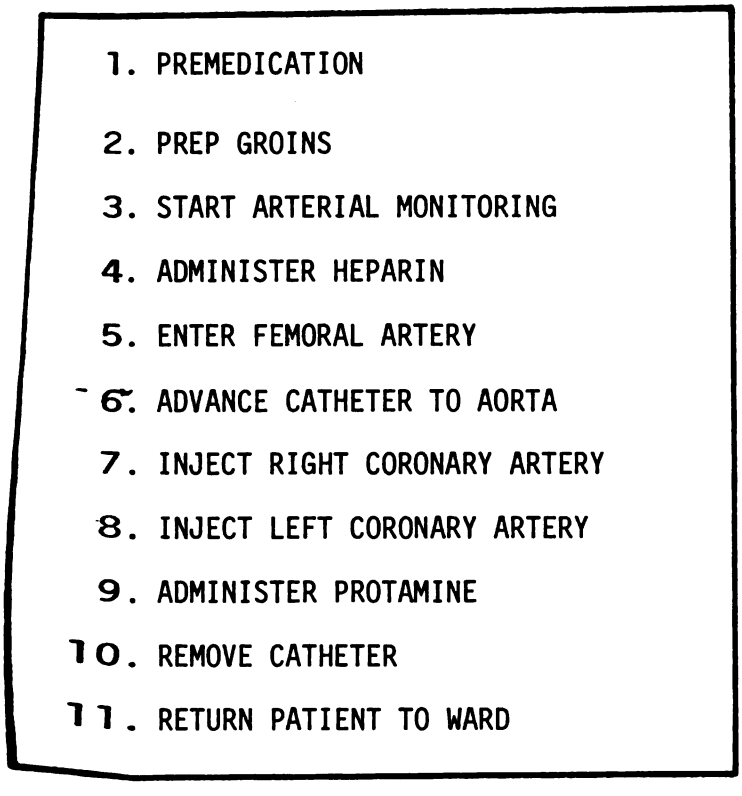


FIGURE 10: MENU OF MANEUVERS FOR A PROTOCOL. *This protocol concerns Selective Coronary Angiography via the Femoral Approach. Each selection represents a major maneuver of the protocol. Selections may be recorded several times and in any order.*

Verification of the Log

Upon completion of the catheterization, the computer generates a legible report of the maneuvers, events and calculated parameters, ordered according to the time at which each was recorded. This report represents a fairly complete log of the catheterization. The clinician can thereby isolate parameters and assess their importance in relation to the maneuvers and events. This log also serves as a "working" report.

However, it is possible for this log to be incomplete or erroneous. Some of the maneuvers may have been inadvertently recorded at a time later than actual occurrence or not recorded at all. Drug doses may also be mis-recorded. Complications are especially susceptible to mis-recording since their occurrences demand increased attention to the patient and thus decreased attention to the computer. Consequently, a means for editting the log is necessary. Ideally, this is done after the case is complete and after the initial log has been reviewed. At that time, drug doses can be validated, any complications verified and the sequence and specification of the maneuvers and events can be adjusted as appropriate. But, the log may also contain errors due to oversight or unfamiliarity. To guard against this, the computer, using "triggers" and "categories" (as explained in the previous chapter), examines the log, prompting for what it evaluates to be missing. Additional editting action can then be taken to complete the log. At this point, the log is considered complete in that the catheterization procedure is documented. However, the log remains as a "working" report, unsuitable to be part of the medical record.

Generation of the Procedure Description

To thoroughly document the procedure, the log is padded with the details for each maneuver and event. For example, to fully describe the manuever

"Enter Femoral Artery" details are necessary to define the type of catheter and whether the left or right femoral artery was entered. This process is conducted according to the order in which those maneuvers and events occurred. Each maneuver and event is translated into a template of one or more natural language sentences. Furthermore, because each template is augmented with menus, the resulting text is customized for each patient (106). Overall, this approach has been demonstrated to be flexible and able to evolve (12, 26, 38). Moreover, the translation from logged maneuvers to natural language text impresses the time-oriented aspects of catheterization on the clinician. As he provides the details for each maneuver and event, the clinician also reviews the procedure. Thus, the reason for performing maneuvers in a specific order is reinforced and the consequences of each maneuver are recalled. This process of review serves a fundamental teaching task. Without such review, the clinician in training may not glean the full benefit of time spent in service to the catheterization laboratory. In fact, casual review of existing, manually prepared catheterization reports indicates that many clinicians do not fully appreciate the impact of the sequence of maneuvers and events as an aspect of catheterization. Therefore, this is an important function for the computer to perform. Collection of maneuver details without regard to their order of occurrence offers little instructional benefit and also contradicts the goal of "stepping" with the clinical task.

In addition to assisting the clinician in padding the log, the computer abstracts the log to a macroscopic level to produce a general description of the procedure for use in referral reports and in the medical record. For example, the entire menu specified in Figure 10 is abstractable to a brief description which identifies both the major maneuvers and the invasive sites: "Selective Coronary Angiography via Left Femoral Artery".

To derive such descriptions, two functions are necessary: abstraction and augmented translation. Abstraction is a process whereby repetitive and routine maneuvers are ignored in order to create a generalized, or macroscopic, description of the catheterization procedure in terms of its major maneuvers. For example, a catheterization which included all the maneuvers in Figure 10 would result in a generalized description of "Selective Coronary Angiography". This function is accomplished through a coding scheme. For each maneuver, there is a list of codes which are used to select phrases from a table. These codes can be three letter keywords (or any other compact codes) which provide an efficient means by which to match maneuvers to phrases. Phrases are textual descriptions which represent major aspects of catheterization. Neither the codes nor the phrases are bound to single maneuvers. Rather, several maneuvers may share a code for the same phrase. Not all maneuvers have codes. Maneuvers which are routinely done in preparation for or as a result of other maneuvers need not support abstraction as they provide no contribution to a generalized description of the procedure. Figure 11 illustrates the linking between a set of maneuvers, codes and phrases.

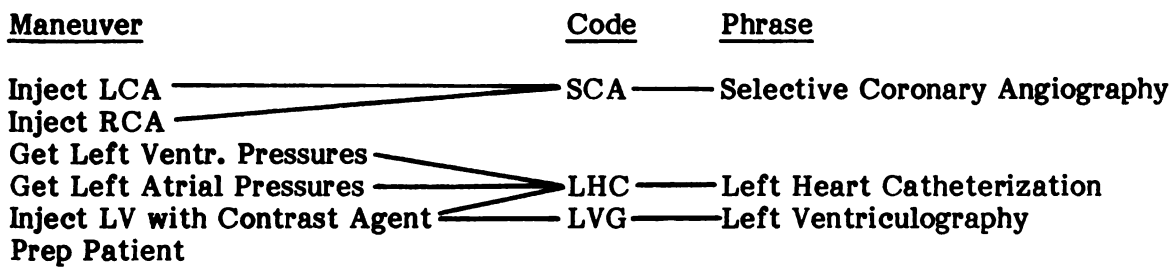


FIGURE 11: RELATIONSHIP BETWEEN MANEUVERS, CODES AND PHRASES.
(see text for discussion.)

Augmented translation is a process whereby detail from the padded log is extracted to provide the anatomical sites used for insertion of catheters. The

detail is then included in the generalized description. Augmented translation is activated by maneuvers which describe the anatomical sites used for insertion of catheters. For each of these maneuvers, the defined site is saved and augmented with detail from the padded log. So, in Figure 10, the maneuver "Enter Femoral Artery" is first translated to "via Femoral Artery". Then the detail specifying either the left or right artery is added to yield, in this case, "via Left Femoral Artery".

In summary, the collection of a time-oriented log during the catheterization procedure impacts two essential components of clinical report generation. First, a detailed, customized description of the catheterization procedure is constructed. Second, macroscopic descriptions for general medical use are automatically abstracted.

Ventricular Analysis

Like the quantitation of the pressure waveforms, the methods to quantitate left ventriculograms are well-explored and demonstrated to be clinically useful. These methods are essentially alike. With each, the clinician traces the border of selected ventricular silhouettes (from X-ray films, see Chapter 2, Figure 5). The traces are digitized and then, using established algorithms (106), a set of quantitative parameters are calculated which describe the size and effective strength of the ventricle. All the methods are stable, timely and produce a "working" report. Furthermore, they save the clinician significant time and produce accurate results.

In the past the same computer has operated both the ventricular analysis component and the catheterization laboratory system. But the two systems have not operated together because the software for each was extensive and as such each system required an entire disk for its software alone. Moreover, to contain the cost of the hardware, the computer supported only one disk drive. Thus, to

use the ventricular analysis component, the disk containing that software had to be inserted into the computer. Then, to use the catheterization laboratory system, the disk with that software was inserted in place of the ventricular analysis software disk. Not only was this inconvenient, but it was also a complicated task because the computer needed to be re-initialized for each insertion of the disks.

Implementation of the ventricular analysis component on a separate computer is the obvious solution. Now the original computer becomes dedicated to the catheterization system and the problematic task of manually changing disks is obviated. Furthermore, because ventricular analysis is not a real-time task, it can operate on a time-sharing computer. Thus, both systems can always be available to the clinicians and neither system is compromised. The catheterization laboratory system remains on the original real-time computer and the ventricular analysis component runs under the convenience of a time-sharing computer. Moreover, as time-sharing computers usually support mass storage, the results of the ventricular analysis can then be archived in a data base. As an additional benefit, implementation of this component on a time-sharing computer encourages inclusion of additional analysis methods which could not be incorporated by the smaller, real-time computer.

Analysis of the Coronary Artery Data

The evaluation of the coronary angiograms poses a more complicated problem than the quantitation of ventriculograms. The coronary arteries, while presenting essentially the same structure in all humans, may vary sufficiently in structure among patients so that each patient's arteries should be considered as unique (30, 39, 97). Not every aspect of this variation can be easily managed through computers. Nor does this model propose a method to confront this variation. That is left to the future (see the section on Future Work in Chapter 8

for a more comprehensive proposal for this data management task). But, in spite of the variation among patients, there is still a great deal that the computer can do in this area.

For the model, the approach of Gensini (30) serves as the base for this component. Specifically, the artery templates of Gensini as well as his scheme for identifying sites within the artery are used (see Chapter 4, Figure 9). But, instead of mark sense forms, interactive graphics serves as the medium for collecting the data. Through interactive graphics, the computer displays each artery template and, through menus, queries the clinician as to the condition of that artery. An example is useful. The computer first displays an artery template as in Figure 12. Notice that the major anatomical sites are numbered. By entering the appropriate number, the clinician selects a site (e.g., 6). Then, using menus, he selects a description for that site (e.g., clear, 100% occluded, 99% occluded, 90% occluded, ...). This process is then repeated as necessary. Next, using similar methods, the data for bypass grafts are collected. For each graft, the site of origin (i.e., a number on the template), the site of insertion (i.e., the site number where the graft enters the coronary artery branch) and the status (e.g., a choice from a menu: patent, occluded, if stenosis - degree of stenosis) are collected. The final steps collect data describing the distal vessel (i.e., is the vessel suitable for bypass surgery) and the collateral flow between the three major artery branches. These data are collected with menus. The arteries are not scored. Instead, the collected data serve to create a textual description of each artery for the formal medical record. An example of the data collected by this component and the resultant text is shown in Figure 12.

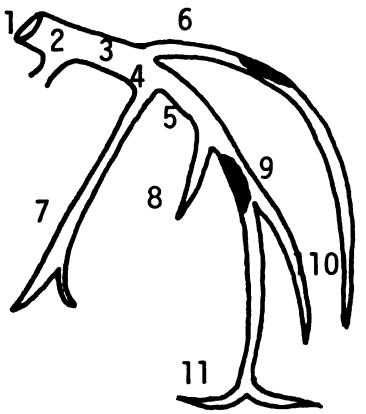


FIGURE 12: RECORDING OF CORONARY ARTERY DATA. *After reviewing the angiography films of the left coronary artery, data was collected and stored as follows: for the LAD, 90% at site 6, 75% at site 9, distals=good, collateral flow=none. After text is generated, the description in the formal report is as follows: The left anterior descending branch of the left coronary artery shows two occlusions. At the first diagonal branch there is a 90% stenosis. At the mid-left anterior descending branch, there is a 75% stenosis. Flow to the distal vessel is good. There is no evidence of collateral flow.*

It is important to note that a major aspect of the component to collect coronary artery data is that the computer participate directly with the clinician through interactive graphics. Thus the clinician can review the data and adjust errors selectively instead of resubmitting the entire set for single mistakes. The remainder of the component closely parallels the successful aspects of Gensini's methods.

Collection of the Pre-Catheterization Data

Data items comprising the pre-catheterization data are the justification for performing the catheterization and, therefore, they are an essential part of the patient record. The least quantitative component of these data is the patient's medical history. Quantitation of the medical history is complicated by variations in style of clinician interviewing and especially by the attitudes and apprehensions of the patient which affect his conveyance of the history. It could be possible to circumvent the clinician-interviewing problem by employing a computer-based component which interacts with the patient. But this approach

is probably not suitable for cardiac patients as they are not always healthy enough to interact with the computer. Furthermore, the complexity and size of such a proposal probably would not justify its expense in computer resources. Consequently, only certain aspects of history are quantitated and free text is used for recording interview results. For those aspects which are considered to be related to heart disease (e.g., has the patient had a myocardial infarction?), a series of yes/no responses trigger the computer to ask the clinician for additional, well-defined results (e.g., If the patient did have a myocardial infarction, when did it occur?). For these results, menu selections or numeric entries suffice.

The physical examination presents problems similar to those of the history. But, in this case, the computer "guides" the clinician through the entering of this data, directing the results into major categories such as "Heart", "Lungs" or "Abdomen". This is acceptable because the primary purpose of the physical examination (as well as that of the history) is to act as a screening tool for catheterization. So, its specific content need not be considered a focal aspect of the total catheterization data set. As such, the entry of free text according to major categories meets the clinical information needs of the catheterization laboratory.

All other pre-catheterization data are quantitative. For clinical laboratory tests, the computer prompts the clinician for results and verifies that they are within acceptable ranges for each test. Chest X-ray, electrocardiogram and exercise test results are defined as one or more selections from menus of the possible outcomes for these tests. As each outcome is selected, the computer compares it to those previously chosen and alerts the clinician if two outcomes are mutually exclusive (e.g., "normal chest X-ray" would conflict with "X-ray shows enlarged heart"). For these tests and the clinical laboratory tests, the

clinician may override the objections of the computer to accommodate unusual cases.

It is not essential that the computer record the pre-catheterization data before the catheterization is actually performed. These data are collected by the clinician as justification for the procedure and they are used to design a procedure protocol. However, the pre-catheterization data do not affect the mechanics employed to collect and quantitate the data arising during the procedure. Therefore, the only time-oriented restriction placed on the collection of this data is that it must be recorded before a final report can be generated.

Highlighting Data for Inclusion in Reports

In every catheterization, some of the hemodynamics are redundant or even misleading. In view of this, the model supports identification, by the clinician, of the "essential" hemodynamics. Only these results are included in the formal report. Thus, the formal report presents a concise description of the patient's condition. This does not imply that any parameters are lost or deleted from the patient's data set. Instead, it serves to allow the clinician to control those selected for general medical use.

The impressions and recommendations also serve to highlight "essential" data. These sections are qualitative summaries of the pre-catheterization data, hemodynamics and ventricular and coronary artery analyses. They reflect current medical knowledge and opinion. As such, they are biased and not ideally suited for research. Accordingly, the use of free text for these report components is acceptable.

Generation of Reports

After sufficient data has been entered for a single case, reports can be generated. As was stated earlier, a "working" report presenting the basic log of

the catheterization procedure is generated immediately upon completion of the case. To complement this report, a report analyzing the completeness of the log is also generated (to be used in editting the log, see Verification of the Log). Additional "working" reports are also useful to the clinicians. Reports presenting the data which justifies the performance of the catheterization, the quantitation of the ventriculogram and the analysis of the coronary arteries are prepared. The generation of the final, complete catheterization report is done at the command of the clinician. This report is a combination of text and tables. Text is dominant, presenting the medical history, physical examination, chest X-ray, electrocardiogram, exercise test, description of the procedure, coronary artery analysis, impressions and recommendations. Tables present clinical laboratory results, hemodynamics, ventricular analysis and risk factors.

All catheterization reports are generated from a standardized format. This format is defined by the clinician and represents the full set of data possible. For each generated report only the relevant portions for each patient are employed. Consequently, all reports are consistent in form. Moreover, data is easily accessed through this stability.

Additional report formats meet the needs of personnel external to the catheterization laboratory (e.g., anesthesia, surgery, referring physicians). These formats are defined using the same technique as that for the catheterization report (i.e., a general template, customized for each case). Consequently, these reports are also stable in structure and content. Yet, most importantly, the specific content for each report is taken from the patient record used to create the primary catheterization report. So, there are no conflicts or contradictions among the reports.

Other Functions

This completes the proposal for a model system which the practicing

cardiologist would use on a daily basis. Yet, there are several other functions to support. Editting of the menus to reflect current methods and results of catheterization is essential. Inclusion of text descriptions for new maneuvers, events and reports is also necessary. These capabilities promote the creation of an accurate, useful report for each patient. Moreover, if the menus, templates and formats reflect current needs and goals, the clinician is less inclined to resist the system.

Another fundamental aspect of the model is to provide guidance for users who are new to its operation. The new user is offered "explanations" as to the nature of the answers the computer is seeking. More experienced users may ignore this aspect of the system. They may enter abbreviated commands or sets of commands. Provision of levels of expertise such as these reassures the novice and does not burden the sophisticated user. Consequently, all users are encouraged to use the system.

Varying levels of access to the data are provided by the model. No unauthorized user may review data on the computer. Only those clinicians responsible for each patient are permitted to enter or modify data for that patient. However, it is possible for the supervising cardiologist to review the data entered for each patient. As a teaching tool, "dummy" patients may be reviewed by all levels of clinicians and students, giving them practice in recognizing key results and reaching appropriate impressions and recommendations.

As an <u>essential</u> routine function, the model supports review of all current patients (i.e., those whose final report has not yet been generated) on a daily basis. Each morning the system generates a report identifying the patients currently under study and highlights areas where data is missing. This function is pivotal to ensuring that all patient records are complete. Every day that a

patient record remains incomplete, the system more intensely and less diplomatically highlights the delinquent clinician. Although this capability may initially seem to be contrary to the concept of creating a cooperative, unobtrusive system, it is a function which is paramount in assisting the chief of the laboratory to prompt all clinicians to fully document cases within a reasonable time frame.

Considerations for Implementing the Model

At this point, the functional specification of a model clinical information management system for a cardiac catheterization laboratory is complete. And, appropriately, only rudimentary statements of computer capabilities have been considered. Now it is appropriate to evaluate the computer capabilities which are fundamental to support the model.

Construction and Format of the Data Base

Until the final report is generated, data may be added, deleted or editted for a patient. But, as soon as the final report is generated, the data for that patient cannot be changed. This data may then be accessed only for review or reporting. This assures that the formal medical report is always accurately reflected by the system.

The construction and format of the data base are transparent to the clinician. The information management system assumes full responsibility for coordinating the data. At no time is the clinician expected to intervene, either through physical means or programming effort. Within the data base, no associations are attached to the data except the explicit relationships of measurement units and, where relevant, time of measurement. Hence, the data are unencumbered by current research inclinations or clinical bias. Moreover, the data for all patients are archived.

Essential Computer Hardware and Software

At least three separate display devices are necessary. The first display unit is used in the catheterization laboratory during the procedure. This unit displays digitized pressure waveforms and calculated hemodynamic parameters. It also displays menus of manuevers and events. The second display unit supports graphics, with a resolution of at least 512 x 512 points for clear and accurate representation of the coronary artery templates. This unit is also used to trace and display the silhouettes of the left ventriculogram. The third unit is a conventional CRT with support for cursor control and partial screen erasure. This terminal is used to collect all other data. The availability of cursor and screen control promotes development of flexible, informative displays. For generation of reports, a high resolution, letter-quality printer is preferred. To maintain a data base, on-line mass storage is essential (the capacity of this storage is dependent on the anticipated case load and the amount of data saved for each patient). Thus, the essential hardware is defined.

The basic software needs are outlined in Table 3, according to the functional components of the model.

Table 3: Software Needs of Model

Quantitate Pressure Waveforms	dedicated, real-time
Record Maneuvers / Events	real-time
Edit Cath Log	time-sharing, interactive
Translate Log to Text	time-sharing, interactive
Analyze Ventriculograms	time-sharing, interactive graphics
Analyze Coronary Arteries	time-sharing, interactive graphics
Enter Pre-Cath Data	time-sharing, interactive
Generate Reports	time-sharing, interactive, background tasks, word-processing
Define / Modify Menus, Templates, Formats	time-sharing, interactive
Archive Data	interactive, data base management system
Verify Data Completeness	background tasks

There is currently no one existing single-computer system which can effectively or efficiently provide all the software needs of the proposed model. This is not to say that it would be impossible to employ only one computer system to support the full model. However, that one computer would have to support dedicated, real-time processing to quantitate the pressure waveforms. So whenever the dedicated support was necessary, all other data management would be suspended. Furthermore, the benefits and convenience of a time-shared computer system would be sacrificed. Consequently, computer resources would not be fully utilized in a single-computer approach. This waste of resources is, in turn, an expense which medical centers cannot justify. Therefore, an essential aspect of this proposed model is that a multi-computer system (multi-CPU) approach be used.

Minimally, two computer systems are necessary. To support data collection during the catheterization procedure, a dedicated, real-time mini-computer system capable of sampling and quantitating pressure waveforms is needed. Interaction with the clinician to collect the maneuvers and events is equally important. The CPU and memory of this system are of sufficient capacity to provide rapid calculation and display of quantitative results. All other data collection, editing, coordinating and reporting are performed on a time-sharing computer system(s). This time-sharing system supports flexible interaction, graphics, word processing, data base management, background tasks and sufficient on-line mass storage for the data base. All of these capabilities are commonly available on most mid-to-large mini-computer systems.

Yet the use of multiple computers is not a trivial solution to enhanced clinical data management. A network which controls the automatic transfer of data and notifies the receiving computer as to what to do with the data is a key aspect of the overall proposal. This network is the tool which promotes

automatic, transparent data coordination among the computers. As such, it cannot be so complex or rigid as to dictate unnecessary limits for data transfer or to impose restrictions on expansion of the data collection, coordination or reporting goals of the information management system.

To summarize, a model information management system is proposed for the collection, coordination and reporting of data for a clinical cardiac catheterization laboratory. The only established methods currently in use for computer-assisted management of catheterization data which are included in the model are the quantitation of pressures and the quantitation of left ventriculograms. Specifically, seven major tasks are addressed.

* collection of non-quantitative data arising during the catheterization procedure
* translation of a log of the procedure into natural text for inclusion in formal reports
* abstraction of a description of the procedure for general medical use
* employment of interactive graphics as a significant improvement to the methods of Gensini for the collection of coronary artery data
* clinician selection of essential data for creation of concise reports
* generation of formal reports for the laboratory and other medical services in a standard format without need for manual intervention
* archival of the full set of data for each patient

This proposal is based on the consideration of the timeliness, stability, accessibility, clinical utility and forms of data which define the catheterization laboratory. It overcomes the major faults of other systems: failure to collect all data, failure to "step" with the clinician's need for data, failure to generate useful reports and failure to archive data. To support the model, a multi-computer approach utilizing a flexible, reliable network is recommended. This

approach promotes optimal support of task-oriented data collection, coordination and reporting in a manner which integrates into the normal procedures of the catheterization laboratory. Emphasis is placed on assuring complete, coherent and timely presentation of essential clinical data.

Chapter 6: Networking

The successful development of an information management system based on the model of the last chapter is contingent on prior successful installment of a computer network. The network must permit the inclusion of existing and acceptable computer systems which quantitate pressure waveforms and/or ventricular silhouettes. Equally significant, the network is expected to function under at least two distinct operating systems: real-time and time-sharing. To guarantee this flexible and relatively unconstrained result, the network cannot be machine dependent. Moreover, virtually all medical computer systems support minimal hardware. Hence, the software to control communication among computers must be able to operate within limited memory space. These conditions, while common to medical computer systems, preclude employment of commercial networks which, at this time, are invariably machine or vendor dependent. Furthermore, available commercial software to control inter-computer communication is usually complex, demanding extensive memory (114).

Consequently, a new approach to networking medical computer systems is fundamental and essential. As a primary task in designing this network, it is necessary to discern what is common among medical computer systems. The single feature which these, and in fact most computers, have in common is the ability to communicate with terminal devices. This elementary communication is based on direct hardware interconnection consisting of a common serial communication method (77) and an industry standard electrical format (115). Therefore, the new network approach is based on equivalent standards.

Direct, dedicated interconnection between communicating computers provides a secure method for data transmission with predictable quality. In this

situation, a shielded cable is attached to a terminal port on each of two computers. This cable then provides a means for data transmission which is as physically and electronically reliable as that used for the transfer of data between a computer's memory and its terminals. No special parity checking or checksums are necessary. In fact, where direct physical interconnection is employed, the use of bit-checking is most likely wasteful of time and, consequently, of resources.

Now that a means for transmission is defined, the mode of transmission can be considered. For the network implemented here, transmission is half-duplex. That is, transmission is one direction at a time. Both computers can send or receive, but at any one time, only one may send and the other may receive. Hence a computer first fully receives a message and then sends a response. This both minimizes the complexity of the software and provides full communication capability. In accordance with the previous restriction to utilize commonly available methods, the use of half-duplex transmission poses no special situation.

However, in contrast to most terminal connections, the connection between computers demands the suppression of echoes. As a default condition, each character transmitted to a computer is echoed. It is this echo which causes the character to appear on the terminal display. In contrast, a computer which transmits a character to another computer does not require an echo. In fact, an echo in this situation could inadvertently be accepted as the response from the other computer. Such response would be inappropriate and subsequently interpreted as erroneous (22). Furthermore, it is possible that each echoed transmission could precipitate an error condition, thereby producing a perpetual error state. So all network transmissions are done in half-duplex with echo suppression. Consistent with the aforementioned restrictions, the suppression of echoes does not require specialized equipment or complex software.

User View of the Network

From the user's viewpoint, the network is a collection of interconnected computers which support different tasks and data. To manipulate these resources, he activates the network software as a function. Conceptually, this function is:

SEND (destination, task, file)

where the destination is the name of the computer to receive the transmissions, the task is a program or function which the receiving computer will activate providing that the communication between the computers is error-free and the file is a name which identifies a sequential file of characters which is to be sent to the destination. After issuing this functional command, the user may perform other tasks independent of the network's action. Thus the user is not responsible for the actual communication between computers. Nor does he control the error recovery in the event of communication difficulties. He must, however, check the response from the SEND function to verify that the communication was successful. Any action which he may take in the event that the communication failed is at his discretion.

Communication Protocol

Now that the interconnection among the computers has been specified and the user view has been described, the common ground for a communication protocol for inter-computer use can be reviewed. A keyword, or command-based communication protocol is advised. This type of protocol is enduring, homogenous and easy to use (53). All commands are defined using only the 'printable characters' consisting of upper case letters, digits and punctuation symbols. No vendor specific codes (e.g., the Control-C of DEC computers) or language specific characters (e.g., APL characters) may be used to define

commands. Furthermore, the ASCII code serves as the base, with the carriage-return code considered to be the terminator of a command. Thus, the network commands are defined with a universally accepted encoding method. The protocol is thereby shielded from assuming the consequences of distinct computer interpretation of non-ASCII characters. By basing all commands in ASCII, it is also possible to include within the network any computer whose software permits the generation and recognition of printing ASCII with carriage-return as a 'line' terminator. This covers a significant set of computer systems. Moreover, use of this character set makes it possible to achieve machine independence and thereby transportability. Accordingly, the protocol has been successfully implemented on an RSX-based PDP-11/35, on a MUMPS-based PDP-11/34 and on a customized PDP-11/05 (50, 69, 70).

The resulting communication protocol consists of strings of characters which are functionally separated into two classes: commands and data. Of these, commands govern the transmission and are the first strings exchanged. In contrast, data strings are exchanged after the communicating systems have agreed on certain conditions, which were defined by prior commands. Once transmission of data has been initiated, all strings are considered to be data until a previously agreed upon 'terminator' string is exchanged. So, a network transaction consists of a series of records. The initial records are commands to specify the form of communication, the final disposition of the data, the definition of a 'terminator' string and the beginning of data. Subsequent records consist of data up to the 'terminator' record. Finally, there may be additional commands to prepare for more data or formal termination of the exchange. In all exchanges, for purposes of reliability and synchronization, it is specified that each record sent, whether command or data, must be acknowledged by the receiver. This approach permits strict control of the communication and

obviates the need for complex buffer management.

The commands of the network protocol are listed in Table 4. They are implemented as 4-character keywords for convenience.

Table 4: Communication Commands

(only commands with an equal sign (=) have arguments)

WAKE	=	ID of computer to receive the data
GETS	=	data or device name for receiver to use
TERM	=	definition of terminator string
TELL	=	ID of task for which data is intended
DATA		(next record is start of data)
DONE		(end of transmission)

A minimum subset of the commands listed in Table 4 is required for a machine to communicate over the network. This minimal set, which is recognized by all computers, is WAKE, GETS, TERM, DATA and DONE. Implementation of a command such as TELL is dependent on the capabilities of a machine's operating system. Use of a device specific command (e.g., GETS="tape drive") is dependent on the resources available to a particular machine. However, transmission of a machine specific command to a machine which cannot carry out that command does not always disrupt communication. The command is simply ignored.

As was previously stated, the protocol requires that each received record be acknowledged by the receiver. Five forms of acknowledgement exist, with timeout (no transmission or acknowledgement within 30 seconds) considered as a sixth possibility. The keyword AWAK is used in response to the WAKE command only. This unique response serves as both acknowledgement and indication of synchronization. ACK is generated as a response to all valid commands and to all data records. Upon completion of transmission of a data set, a 'terminator' string is sent and returned as acknowledgement. The exchange of this special

string (default terminator string is "<<<<") serves to ensure that the two computers have remained in synchronization during the data transmission and that the termination of data transmission has been properly recognized. NACK is generated when a command is received but cannot be performed because a desired resource is unavailable. However, NACK does not imply that the entire communication is aborted. It merely informs the sending computer that a command will not be performed. In contrast, the KILL response indicates a 'fatal' condition and results in both computers aborting the transaction. In view of the consequences of a 'fatal' condition, it is stressed that such a condition only occurs when unrecognized commands are encountered. In such a situation, it is reasonable to assume that the entire transaction may be unsanctioned. Therefore, as a security measure, the transaction is aborted. Furthermore, any prior commands or data exchanged earlier in the transaction (i.e., before the 'fatal' condition) are ignored. Finally, as the sixth form of acknowledgement, a timeout arises when a computer does not respond within 30 seconds of receipt of input and is considered to be an implied KILL. The arbitrary time frame of 30 seconds is probably generous. However, by allowing for so large a time frame, it is vitually guaranteed that other activity and demands on the computer systems will not create sufficient interference to obstruct network communication. As a distinction from other networks, both of the communicating computers in this new network are active in recognizing a timeout condition. Not only does the sender expect an acknowledgement within 30 seconds, but the receiver also expects to receive a new transmission within 30 seconds after sending an acknowledgement. This dual attendance to network activity serves to detect and isolate communication problems precisely.

A state diagram summarizing the network keyword communications protocol is shown in Figure 13.

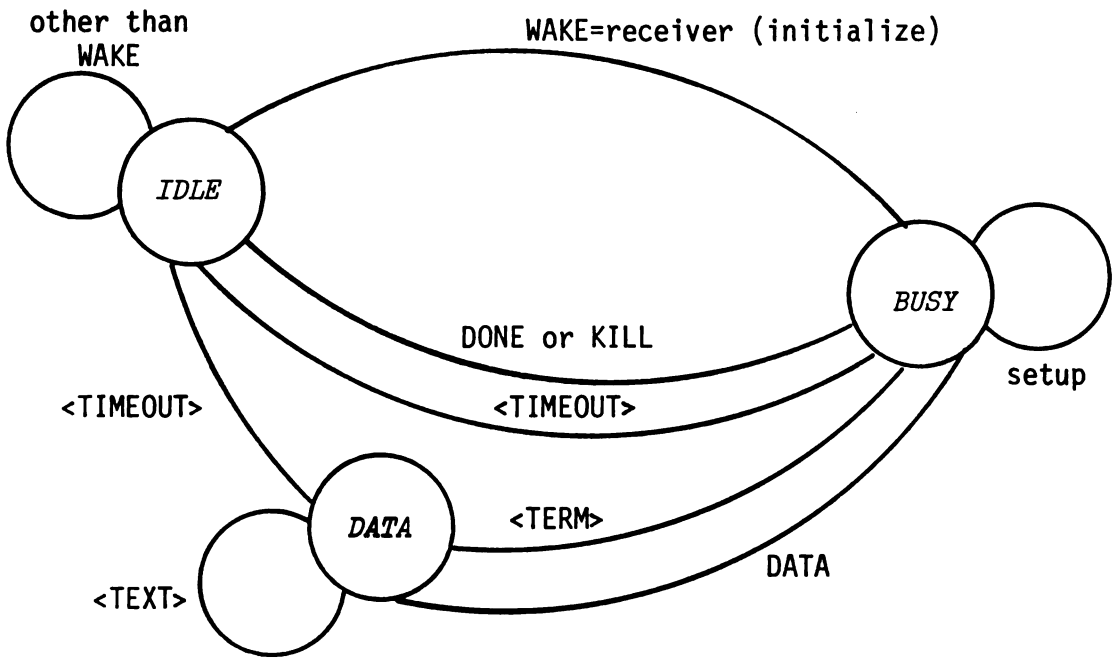


FIGURE 13: STATE DIAGRAM OF NETWORK COMMUNICATION PROTOCOL. *Circles represent states. Arcs represent state transition. Bold, unbracketed arc labels describe actions, with capitalized words as keywords. Default data terminator is "<<<<"*

Use of the Network

The following sample protocol is typical of exchanges between the networked computers. The example (Figure 14) illustrates a transmission of data from a commercial catheterization computer system (in this case a PDP-11/05) to be stored in a database on a MUMPS-based PDP-11/34.

The initial command and acknowledgement ("WAKE", "AWAK") serve to synchronize the computers. The next command issued by the PDP-11/05 ("GETS = CAT (PATID") instructs the MUMPS system where to store the data,

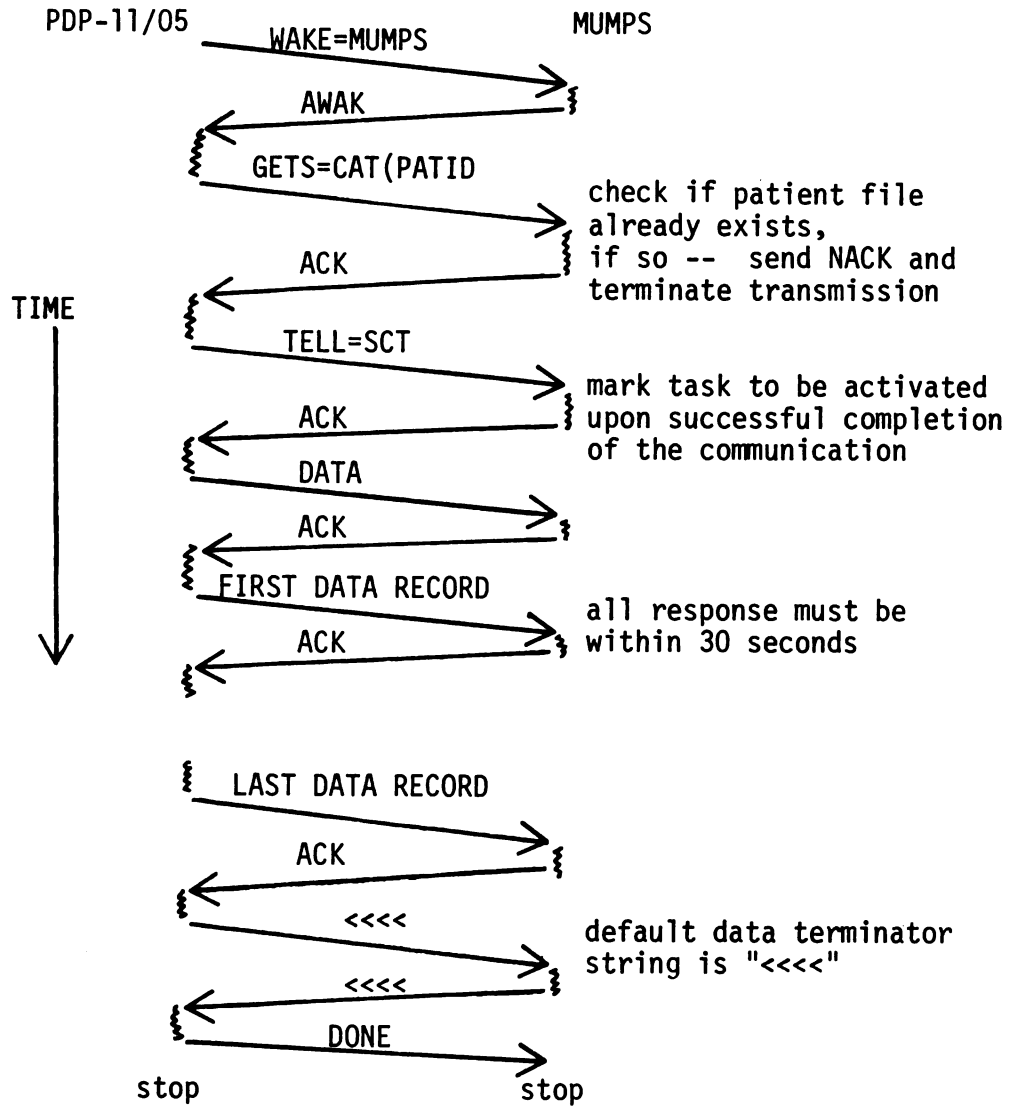


FIGURE 14: SAMPLE NETWORK TRANSMISSION. *See text for discussion.*

that is, within a global named CAT under the node PATID. An acknowledgement is then sent by MUMPS to inform the PDP-11/05 to continue sending commands. The next exchange informs the MUMPS computer that remote activation of a task is requested ("TELL=SCT"). This task is then marked for activation. Actual activation of the task by MUMPS takes place after the transmission of all commands and data is complete and successful. As may be expected, this task (SCT) performs a function related to the freshly received data. The DATA

command is then sent to prepare for transmission of data. The actual catheterization data are subsequently transmitted, with an acknowledgement received for each data record sent. Receipt and acknowledgement of the default terminator string ("<<<< ") concludes the data transmission. The communication is formally concluded after the MUMPS system recognizes the command "DONE".

The communication illustrated in Figure 14 is employed at the completion of every catheterization. Under normal conditions this transmission is completely transparent to the catheterization staff. Any error detection which precludes automatic recovery is brought to the attention of the staff. The communication is then reinitialized.

In most cases, disruption of the transmission is automatically detected and recovery effected by the network software. Generally, this disruption involves a failure to transmit or receive an acknowledgement (ACK). In any case, a timeout is subsequently detected. At that point, both computers reinitialize and the communication is started again from the beginning (i.e., with the WAKE command). Should the communication fail three successive times, the sending computer assumes responsibility for alerting the user.

Re-establishing synchronization after an error is detected is an essential function for a network. The method chosen here was to re-start the communication from the beginning. This choice was dependent on the usr view of the network. However, a different recovery scheme could be employed if the user view was as follows:

SEND (destination, task, buffer)

where destination and task retain the same meaning but buffer is a fixed length character string. From this functional viewpoint, it would be possible for the user to gain control of the error recovery because he would be passing each

record separately and directly to the network software. Thus, if an error developed, the user would be informed immediately and he could re-submit the buffer for transmission. Network efficiency could be gained in that only one record would be retransmitted instead of all the records prior to and including the erroneous one. But this approach is costly in terms of overall system overhead. In fact, for each record sent, the user and the network would have to exchange messages. Furthermore, if there are several buffers to send, the user would be bound to the network task until all the buffers were sucessfully transmitted. So, in consideration of this overhead, the choice was made to delegate error recovery to the network task alone and thereby to promote independence from the users and the applications programs.

Evaluation of Network

The network described provides a necessary tool to develop a multi-computer-based system to support the collection, management and reporting of clinical data for patients undergoing cardiac catheterization. The set of commands is both flexible and sufficient to accomplish all the data transmission and program activation necessary for successful development of the project.

The command-based protocol has demonstrated itself to be easy to use and extend. A simple respecification of the WAKE command in Figure 14 to "WAKE=1135" and the GETS command to specify a RSX file name (e.g., "GETS=DK1:CATH.DOC") plus a reconnection of the serial interface allows the catheterization computer (PDP-11/05) to transmit its calculated results to a PDP-11/35 instead of the MUMPS computer. No reprogramming of the network control software is required to accomplish redirection of data. The protocol and the software are independent of the computer systems. In fact, the network control software runs under three divergent operating systems and is implemented in three distinct languages. More importantly, the protocol is

flexible. It permits the transmission of any data set which can be represented in the specified record format. Unlike some clinical networks (22, 23) the 'links' are not dedicated to unique data transmission needs. Programs as well as data may be exchanged among the computers. Any application desiring to employ the network is free to do so provided that the protocol is observed.

Functionally, the network is transparent to the users of the applications programs. There is no evidence of the computer systems "bogging down" because a transmission is in progress. Of these transmissions, the majority are from the PDP-11/05 to MUMPS, involving approximately 150 data records of 30 characters each occurring up to three times each week day. The transmissions between RSX and MUMPS are not as regular in size or frequency. Initial studies do show that MUMPS can receive data from RSX faster than it is able to transmit data to RSX. This difference has been attributed to the interpretive nature of MUMPS combined with the manner in which it accesses data for transmission (69).

The network also serves as a mechanism to facilitate access and back-up of both data and software. For example, the MUMPS system is able to transmit information to RSX for placement on DEC-tape or listing on the line printer. All projects are able to consider employing any of the resources residing on the networked computers. Accordingly, application programs can now be developed using the best available languages, software and peripherals. Problems can be solved using the full facilities rather than tailoring the problem to fit a limited set of resources available on one computer.

However, extended access to a computer implies that data security receive prime attention (101). Therefore, the network does not permit casual perusal of data on one machine by a user on another machine. A user may interact directly only with the computer to which he is "logged on". So, for example, a user may

not use the editing utilities of RSX if he is "logged on" to the MUMPS system. To compensate, the network permits remote activation of programs residing on other computers. But the user must know the exact specifications for running such programs. To enhance the security, these programs are limited in number and in ability to access priviledged or private data. As a final security measure, and as a tool for evaluation, all activity and requests issued over the network are monitored and recorded in audit files.

The network is reliable. It has been successfully employed to transfer over 400 catheterization patient files from the PDP-11/05 to the MUMPS-based PDP-11/34. It is also routinely charged by MUMPS users to activate tasks under RSX and vice versa. Experimentally, the network is proficient in all its uses.

This is not to say that communication among the computers never fails. In fact, occassional failures do occur. But, the network software is capable of detecting and overcoming these failures. The most pronounced of the possible failures results when hardware errors develop. In this case, full communication between a pair of computers will be unsuccessful. Either one or both of the computers will log the failure in its audit file and the staff will be alerted.

It is also possible that commands or acknowledgements may be garbled in transmission. In this case, the software will determine the record to be invalid and will respond with a KILL. The communication will then be aborted and reinitialized. Because direct, dedicated interconnection among computers is used, this condition is generally an indication of hardware failure and will subsequently affect all transmissions on that line. In the event that an unsanctioned command is precipitating the KILL, then the communication will never succeed and the staff will be able to detect that fact by reviewing the audit file.

If errors develop during the transmission of data, a loss of synchronization

or garbling of subsequent records will arise. In any case, either the 'terminator' string will be unrecognized and/or a timeout will occur. The erroneous transmission will then be aborted and reinitialized.

In summary, the use of direct interconnection among the computers precludes the majority of transmission errors. When errors do penetrate this safeguard, the result is a nonconformation to the communication protocol. Illegal commands, loss of synchronization, failure to transmit within 30 seconds and garbled records are all detected and recorded in an audit file. Automatic recovery and reinitialization of the communication are conducted up to three times. If failure should still occur, manual intervention to validate the hardware is prompted.

General Utility of the Network

The network developed for this research is not equivalent to the large-scale, nation-wide networks. That was not the objective. What is essential for clinical data management is the ability to automatically and transparently transfer data and utilize resources among distinct computers. This objective has been realized.

Moreover, the network is relatively machine independent. This is verified by successful development of the protocol under three diverse operating systems (real-time, dedicated vs. interpretive, time-sharing vs. multi-tasking, time-sharing) and in three different languages (assembly vs. MUMPS vs. FORTRAN). Data and programs are readily transferred among these computers. In addition, the network is employed both transpartenly (by applications) and overtly (by programmers). It has met all design goals and, since its activation over two years ago, there has been no need to modify or extend the network's capabilities.

There are, of course, aspects of machine dependence in the network. All communication is half-duplex with echo suppression. ASCII is the base code. But,

these dependencies do not seriously constrain the network because vitually all computers support this communication mode. The software requires approximately two thousand words of memory. So, it is likely that many microcomputers could not support the network. All other computers should experience no difficulty. Also, support of capability specific commands (e.g., TELL, some instances of the GETS command) is dependent on individual machine capabilities. However, the communication software accounts for such commands. If a command cannot be performed, it is ignored. Hence, even this dependency does not constrain the general utility of the network nor the inclusion of additional computers into the network.

In summary, the overall effect of this network has been to facilitate the development of clinical systems which could not be realized if only one computer system was used. The result is that any medical application can take advantage of any of the resources to which the network provides access. Applications no longer need be curtailed to operate within the limitations of one computer system.

Chapter 7: Implementation of the Prototype System

With the assurance that the network promoted access to essential computer resources, a prototype information management system for the catheterization laboratory was implemented. This prototype mirrors the goals and methods of the model without deviation. Aside from the network, no contributions to computer science result from this implementation. That is as intended. However, the employment of distributed resources and diverse computer science methods for the purpose of managing catheterization data is unique. Moreover, this prototype is unequalled in its ability to meet clinical goals. Accordingly, it constitutes a contribution to medical information science.

To appreciate the prototype information management system, two perspectives are essential. Because the overall goal of this research is to develop a clinically useful system, the perspective of the clinical personnel is dominant. Accordingly, the interaction of the system with these target users is illustrated. In addition, the reports generated and their subsequent use are reviewed.

The other perspective advances the computer science viewpoint. As groundwork, the computers participating in the research are described. Also, the structure and properties of a data base for catheterization is characterized. Then the division of tasks among the computers and the inter-relationships among those tasks are addressed. Certain tasks which represent novel approaches to management of clinical catheterization data are highlighted.

Clinical Perspective

The prototype information management system for the cardiac catheterization laboratory serves the San Francisco Veterans' Administration

Medical Center (SFVAMC). This institution supports clinician training programs in conjunction with the University of California at San Francisco. The patient population of this hospital consists almost exclusively of adult males. As such, this population comprises a subset of the total set of patients and cardiovascular problems which can be examined in the catheterization laboratory.

Within the San Francisco Veterans' Administration Medical Center, the cardiac catheterization laboratory performs approximately 300 procedures each year. Recently, the number of cases has been increasing due to increased referrals from outside hospitals and clinicians. The majority of the cases evaluated by this laboratory involve patients with coronary artery disease. The remainder of the cases primarily involve the evaluation of valvular disease or the visualization of coronary artery bypass grafts (to verify that they are not occluded). The laboratory is staffed by two fully trained, supervisory cardiologists (including the chief of the lab), three technicians and two to three residents specializing in cardiology.

Throughout the illustration of the use of the prototype system two key aspects should be remembered. First, in multiple instances, the computers automatically and transparently transfer data and activate tasks over the network. This essential network capability gives the clinician the impression that only one computer is involved in data management. In fact, the clinician is completely unaware that multiple computers support his information processing needs. He "sees" one computer. Second, and perhaps more significantly, for each data management task, the interface to the clinician is tailored to the data under investigation. Graphics, interaction and report generation are employed as appropriate for the clinical goals. No data is forced into computer-convenient form. Rather, the system conforms to the clinician-convenient form. This key aspect is also a consequence of the network.

To illustrate the clinician convenience of the prototype multi-computer system, a hypothetical patient is introduced. This patient is typical of those evaluated by cardiac catheterization and is assigned the pre-catheterization diagnosis of Coronary Artery Disease. To confirm this diagnosis, a catheterization protocol including left heart catheterization, stress testing, left ventriculography and selective coronary angiography is planned, simulated and reported. Obviously, not every interaction is illustrated. Instead, this demonstration highlights the capabilities and clinical usefulness of the system.

Consider first the specification of the pre-catheterization data. Selection of this option from the main menu (Figure 15) displays the menu in Figure 16. Note that the display now presents the identifying information for the patient and the functional label "Pre-Cath Data" in the header. This functional label is then updated for each component of the system. Selection of choice #3 causes

```
SAMPLE            CATH. # 99999                          10:04  27-SEP-80

        1.  Pre-Catheterization Data
        2.  Edit Catheterization Log
        3.  Post-Catheterization Data
        4.  Fill-in Procedure Description
        5.  Select Hemodynamics
        6.  Left Ventriculography (Mini Cine)
        7.  Coronary Artery Scoring
        8.  Late Complications
        9.  Generate Reports

        Enter choice:  1
```

FIGURE 15: MAIN MENU OF THE PROTOTYPE SYSTEM. *This menu provides access to all the data management tasks of the system, except the dedicated laboratory task (which is always accessible through its own keyboard).*

```
SAMPLE          CATH. # 99999        Pre-Cath Data          10:05  27 SEP 80

        1.  Diagnosis (Pre-Cath)
        2.  Indication for Catheterization
        3.  Clinical laboratory
        4.  Chest X-ray
        5.  Electrocardiogram
        6.  Exercise test
        7.  Risk factors and History
        8.  Present medications

        Enter choice:  3
```

FIGURE 16: MENU FOR PRE-CATHETERIZATION DATA COLLECTION. *Notice that the header of the display identifies both the patient and the data management task currently invoked.*

```
SAMPLE          CATH. # 99999        Clin. Lab.             10:06  27 SEP 80

            SELECT LAB TEST
              [enter # or <return> to stop]: 8

                1. Hct.
                2. Hgb.                    13.0 g/100 ml.
                3. WBC
                4. Cholesterol             700 mg/100 ml.
                5. Triglycerides
                6. Uric Acid
                7. FBS                     80 mg/100 ml.
                8. BUN
                9. Creatinine
               10. Albumin
               11. Total protein


  Enter a numeric value for BUN
                in the range 10 100 mg/100 ml. : 20
```

FIGURE 17: COLLECTION OF CLINICAL LABORATORY TEST RESULTS. *Each result provided is checked against acceptable bounds for that test. Previously entered results are displayed upon entry into this task.*

this label to be updated to "Clin. Lab." (Figure 17). Now the display also includes values which were provided prior to this snapshot. In fact, at any time prior to generation of the final catheterization report (i.e., as long as the patient file is active and on the "working" list), the clinician may access and/or edit any data collected for a patient. Of course, if any data has been collected, it is displayed for review prior to acceptance of additional data.

The system does not blindly accept data. It continually verifies the accuracy and reasonableness of the data. For example, in Figure 17, each laboratory test result is compared to the normal bounds for that test. Should the entered result be outside these bounds, the clinician is alerted. Consider also the collection of chest X-ray data (Figures 18 - 20). The computer warns the clinician that mutually exclusive results have been selected (Figures 18-20). In this case, the clinician chooses to concur with the system. But he is always allowed the option of overriding the system's objections, thereby accommodating "unusual" cases.

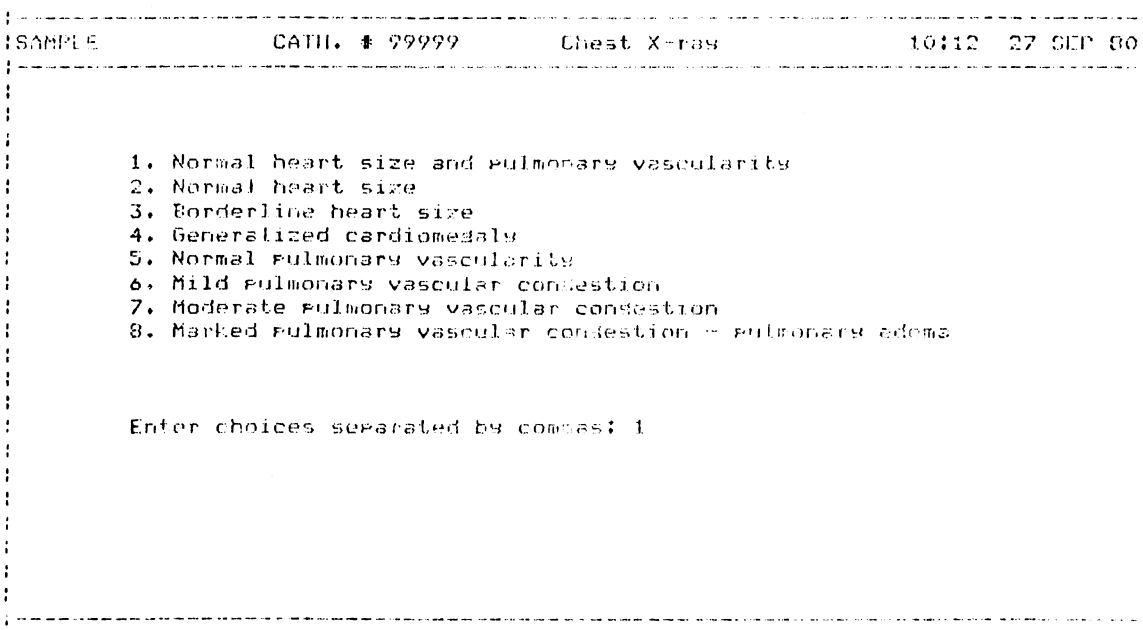


FIGURE 18: COLLECTION OF CHEST X-RAY RESULTS. *The clinician may specify multiple choices.*

```
SAMPLE          CATH. # 99999        Chest X ray          10:13  27-SEP-80

        9. Decreased pulmonary vascularity
       10. Pleural effusion
       11. Left ventricular enlargement
       12. Left atrial enlargement
       13. Right ventricular enlargement
       14. Right atrial enlargement
       15. Tortuous aorta
       16. Aortic post stenotic dilation

        Enter choices separated by commas: 11

        Choice #11 conflicts with previous choice of - #1

        *** Normal heart size and pulmonary vascularity ***

        Do you wish to retain the previous choice? (Y or N): Y
```

FIGURE 19: DETECTION OF CONFLICTING RESULTS. *The clinician has selected two results which are mutually exclusive. The system alerts him to this fact and asks if the previous selection is valid.*

```
SAMPLE          CATH. # 99999        Chest X-ray          10:15  27 SEP 80

        9. Decreased pulmonary vascularity
       10. Pleural effusion
       11. Left ventricular enlargement
       12. Left atrial enlargement
       13. Right ventricular enlargement
       14. Right atrial enlargement
       15. Tortuous aorta
       16. Aortic post stenotic dilation

        Enter choices separated by commas: 11

        Choice #11 conflicts with previous choice of - #1

        *** Normal heart size and pulmonary vascularity ***

        Do you wish to retain choice #11? (Y or N): N
```

FIGURE 20: CLINICIAN VERIFICATION OF CONFLICT. *Because the clinician has verified that the previous selection is valid, the system asks him if the current selection is valid. In this case, the clinician chooses to concur with the system. If he had chosen to retain both selections, the system would have accepted that.*

After the pre-catheterization data has been reviewed, the patient is catheterized. As the procedure progresses, pressure waveforms are measured, quantitated and displayed using a dedicated real-time mini-computer. Clinical maneuvers and events are recorded through menus (Figures 21 - 23) representing the typical maneuvers performed during catheterization. Data is recorded by both clinicians and nurses/technicians, thereby meeting information management needs of both groups.

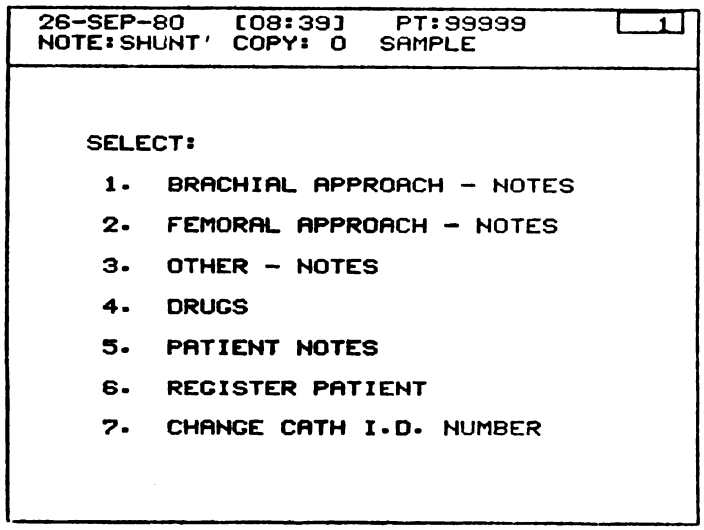


FIGURE 21: MAIN MENU OF DEDICATED LABORATORY COMPUTER. *This menu defines two major menus which reflect approaches to the heart, a menu of less frequent maneuvers, a menu of drugs and a menu of patient notes (complications). It also provides access to a task to register a patient.*

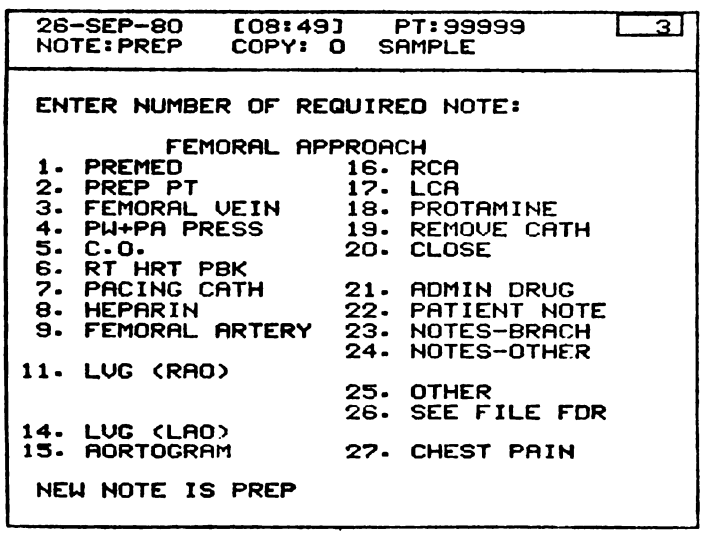


FIGURE 22: MENU OF MANEUVERS FOR FEMORAL APPROACH. *This menu is displayed after the second option is selected from the main menu. It presents the major maneuvers performed when the heart is approached from the femoral veins and arteries.*

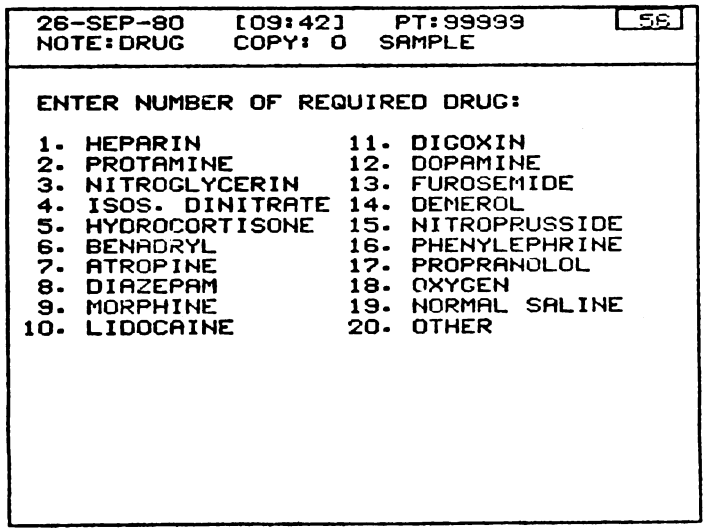


FIGURE 23: MENU OF DRUGS COMMONLY ADMINISTERED. *This menu presents the drugs most commonly used during catheterization. The order of the choices reflects the frequency with which the drug is given. Selection of a drug activates additional queries to obtain the dosage administered.*

Upon completion of the catheterization the system prints a "working" report which logs the recorded maneuvers and events in relation to the calculated hemodynamics (Figure 24). For each entry in this report, the number of minutes since the beginning of the procedure as well as the actual clock time are listed. Sections of the report are identified by headers (e.g., Procedure Note, Left Ventricle; suppression of headers is done for successive printings of data for the same type). This "working" report offers the first evidence to explain the differing hemodynamics. For example, note that between 10:31 and 10:39, the left ventricular peak systolic pressure (LV. PK. SYS.) jumps from 108 mmHg to 125 mmHg. Yet also note that this significant difference is validated by the logged maneuver "Atrial Pacing" at 10:36. Thus the left ventricular peak systolic pressure of 125 mmHg is reasonable and not misleading. Note also the impact on this peak pressure when Nitroglycerin is administered at 10:43. Without these logged manuevers, this set of divergent hemodynamics could be cause for concern. But with a complete log, the catheterization is usefully, clinically documented. To complete the involvement of the dedicated computer, after this "working" report is printed, a condensed copy is transmitted over the network to a time-sharing computer.

```
                SAN FRANCISCO VETERANS' ADMINISTRATION HOSPITAL
                      CARDIAC CATHETERIZATION REPORT

    26-SEP-80  [08:38] - [11:40]  SAMPLE  ID:99999


  0 / [08:38] *** G E N E R A L ***

    PATIENT ID     99999                  HEARTRATE        60 [BPM]
    02 CONS EST      217 [ML/MIN]         AGE            61:04 [YRS]
    WEIGHT            74 [KG]             HEIGHT           178 [CM] -
    B.S.A.          1.91 [SQ M]           NOTE          PREMEDICATION
    HEMOGLOBIN      13.0 [GM %]

  3 / [08:41] *** C A L I B R A T I O N ***

 11 / [08:49] *** P R O C E D U R E   N O T E  ***

    NOTE           PREP PT (F)

 64 / [09:42] ******

    NOTE           ADMIN HEPARIN (F)      ROUTE          IV
                    3000 UN

 69 / [09:47] ******

    NOTE           FEMORAL VEIN

 86 / [10:04] ******

    NOTE           FEMORAL ARTERY

 97 / [10:15] *** A O R T A ***

    HEARTRATE         73 [BPM]            AO. SYST.        92 [MMHG]
    AO. DIAST.        50 [MMHG]           AO. MEAN         69 [MMHG]

100 / [10:18] ******

    HEARTRATE         70 [BPM]            AO. SYST.        90 [MMHG]
    AO. DIAST.        50 [MMHG]           AO. MEAN         68 [MMHG]

113 / [10:31] *** L E F T   V E N T R I C L E ***

    HEARTRATE         60 [BPM]            LV. EDP.          8 [MMHG]
    LV. PK. SYS.     108 [MMHG]           LV. MEG. DP.      0 [MMHG]
    LV. PK DP/DT     772 [MMHG/SEC]       LV. PK. VCE.   23.5 [/SEC]
    LV. VCE. 40    16.8 [/SEC]            LV. VMAX TOT   29.5 [/SEC]
    LV. VMAX DEV   43.3 [/SEC]            LV. MN. SYS.     68 [MMHG]
    LV. MN. DIA.       3 [MMHG]

118 / [10:36] *** P R O C E D U R E   N O T E ***

    NOTE           ATRIAL PACING


                        PAGE -1-  <99999>
```

FIGURE 24: CATHETERIZATION LOG. *This log is printed by the dedicated laboratory computer upon completion of the catheterization. It is the first "working" report. See text for further discussion.*

```
121 / [10:39] *** L E F T   V E N T R I C L E ***

    HEARTRATE        120 [BPM]          LV. EDP.          22 [MMHG]
    LV. PK. SYS.     125 [MMHG]         LV. BEG. DP.       0 [MMHG]
    LV. PK DP/DT     796 [MMHG/SEC]     LV. PK. VCE.   27.7 [/SEC]
    LV. VCE. 40     18.3 [/SEC]         LV. VMAX TOT   32.6 [/SEC]
    LV. VMAX DEV    46.1 [/SEC]         LV. MN. SYS.      90 [MMHG]
    LV. MN. DIA.      10 [MMHG]

124 / [10:42] ******

    HEARTRATE         61 [BPM]          LV. EDP.          20 [MMHG]
    LV. PK. SYS.     130 [MMHG]         LV. BEG. DP.      -1 [MMHG]
    LV. PK DP/DT     800 [MMHG/SEC]     LV. PK. VCE.   29.0 [/SEC]
    LV. VCE. 40     20.7 [/SEC]         LV. VMAX TOT   37.1 [/SEC]
    LV. VMAX DEV    54.7 [/SEC]         LV. MN. SYS.      90 [MMHG]
    LV. MN. DIA.       9 [MMHG]

125 / [10:43] *** P R O C E D U R E   N O T E ***

    NOTE           ADMIN DRUG                          NITROGLYCERIN
    ROUTE          SL                                   0.15 MG

126 / [10:44] *** L E F T   V E N T R I C L E ***

    HEARTRATE         60 [BPM]          LV. EDP.          10 [MMHG]
    LV. PK. SYS.     100 [MMHG]         LV. BEG. DP.      -1 [MMHG]
    LV. PK DP/DT     790 [MMHG/SEC]     LV. PK. VCE.   32.1 [/SEC]
    LV. VCE. 00     24.4 [/SEC]         LV. VMAX TOT   38.5 [/SEC]
    LV. VMAX DEV    58.7 [/SEC]         LV. MN. SYS.      70 [MMHG]
    LV. MN. DIA.       4 [MMHG]

135 / [10:53] *** P R O C E D U R E   N O T E ***

    NOTE           LVG (RAO) (F)

136 / [10:54] *** L E F T   V E N T R I C L E ***

    HEARTRATE         65 [BPM]          LV. EDP.          12 [MMHG]
    LV. PK. SYS.     110 [MMHG]         LV. BEG. DP.       0 [MMHG]
    LV. PK DP/DT     780 [MMHG/SEC]     LV. PK. VCE.   28.1 [/SEC]
    LV. VCE. 40     18.4 [/SEC]         LV. VMAX TOT   32.7 [/SEC]
    LV. VMAX DEV    46.3 [/SEC]         LV. MN. SYS.      88 [MMHG]
    LV. MN. DIA.       5 [MMHG]

138 / [10:56] ******

    HEARTRATE         62 [BPM]          LV. EDP.          12 [MMHG]
    LV. PK. SYS.     108 [MMHG]         LV. BEG. DP.       0 [MMHG]
    LV. PK DP/DT     771 [MMHG/SEC]     LV. PK. VCE.   23.4 [/SEC]
    LV. VCE. 40     16.7 [/SEC]         LV. VMAX TOT   29.4 [/SEC]
    LV. VMAX DEV    43.1 [/SEC]         LV. MN. SYS.      70 [MMHG]
    LV. MN. DIA.       3 [MMHG]

149 / [11:07] *** P R O C E D U R E   N O T E ***

    NOTE           RCA (F)
```


FIGURE 24: CATHETERIZATION LOG (cont.)

```
154 / [11:12] ******
    NOTE            RCA (F)
160 / [11:18] ******
    NOTE            RCA (F)
170 / [11:28] ******
    NOTE            LCA (F)
174 / [11:32] ******
    NOTE            LCA (F)
176 / [11:34] ******
    NOTE            LCA (F)
177 / [11:35] ******
    NOTE            LCA (F)
182 / [11:40] ******
    NOTE            ADMIN PROTAMINE(F)     ROUTE          IV
                       30 MG
```

FIGURE 24: CATHETERIZATION LOG (cont.)

The time-sharing computer then scans the log and a Catheterization Summary is printed (Figure 25). This summary constitutes a second "working" report. Primarily, it serves to validate the completeness of the log. From the clinical viewpoint, this summary is pivotal in assuring a thorough, legal representation of the catheterization. Note that this summary includes inferred

```
                CATHETERIZATION SUMMARY
                -----------------------

NAME: SAMPLE                    CATH #: 99999    DATE: 26-SEP-80

      MINS       TIME    NOTE
      ----       ----    -------------

        0        08:38   PREMEDICATION
        3        08:41   CALIBRATION
       11        08:49   PREP PT (F)
       64        09:42   ADMIN HEPARIN 3000 UN IV
       69        09:47   FEMORAL VEIN
       86        10:04   FEMORAL ARTERY
       97        10:15   CATH INTO AO (F)
       97.10     10:15   AO MEASUREMENTS
      100        10:18   AO MEASUREMENTS
      113        10:31   AO TO LV
      113.10     10:31   LV MEASUREMENTS
      118        10:36   ATRIAL PACING
      121        10:39   LV MEASUREMENTS
      124        10:42   LV MEASUREMENTS
      125        10:43   ADMIN NITROGLYCERIN 0.15 MG SL
      126        10:44   LV MEASUREMENTS
      135        10:53   LVG (RAO) (F)
      136        10:54   PRESS POST LVG
      136.10     10:54   LV MEASUREMENTS
      138        10:56   LV MEASUREMENTS
      149        11:07   RCA (F)
      154        11:12   RCA (F)
      160        11:18   RCA (F)
      170        11:28   LCA (F)
      174        11:32   LCA (F)
      176        11:34   LCA (F)
      177        11:35   LCA (F)
      182        11:40   ADMIN PROTAMINE 30 MG IV



**** NOTICE ****

Time of note: FEMORAL VEIN should precede time of ADMIN HEPARIN (F)
Please add note: PACING CATH (F) to precede: ATRIAL PACING


****** DRUGS ******

For each drug listed, please verify that the reason for
giving the drug is recorded in the log.

At 10:43 ADMIN NITROGLYCERIN 0.15 MG SL


Please check that notes regarding catheter removal
and closure of invasive sites are recorded.
```

FIGURE 25: CATHETERIZATION SUMMARY REPORT. *This report is prepared after the initial log has been reviewed by the system. It is a condensed version of the log which serves to highlight "errors" in the log. See text for further discussion.*

maneuvers (e.g., CATH INTO AO (F)). Those maneuvers which the system has determined to be mis-recorded are listed at the end of this abbreviated log. Other notices to encourage the clinician to add missing maneuver and event notes are also printed.

After reviewing the summary report, the clinician or technician may edit the catheterization log. For the hypothetical patient, several corrections are necessary. First, the time at which the femoral vein was invaded must be corrected (Figures 26 - 27). Next, the addition of notes to indicate the insertion

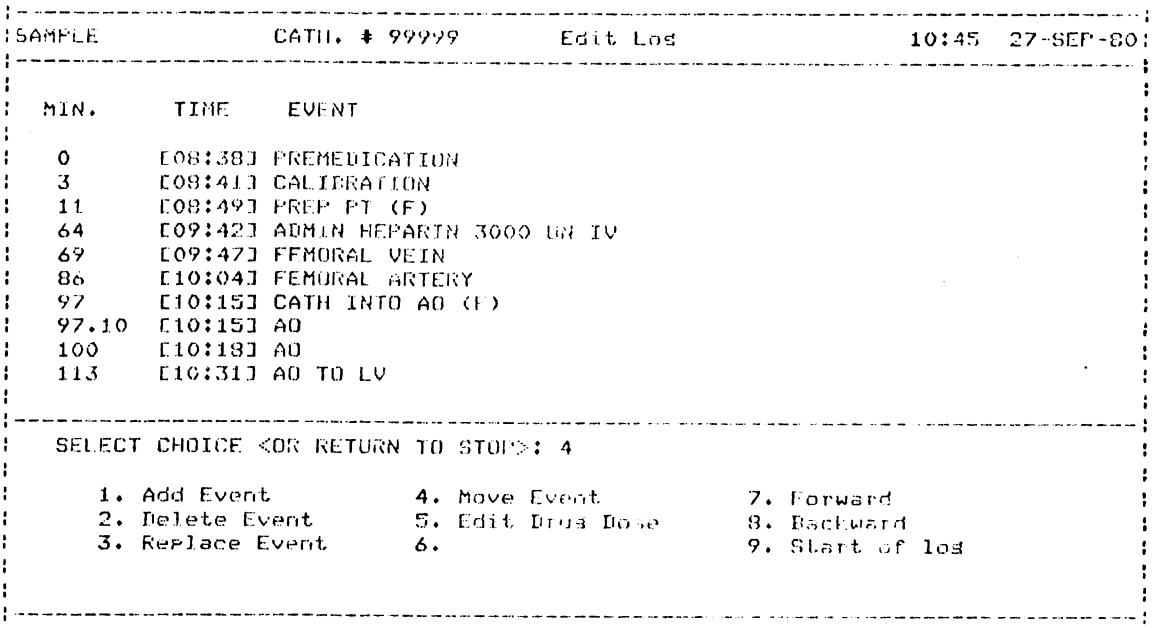


FIGURE 26: EDITTING OF THE CATHETERIZATION LOG. *The options for editting the log are displayed at the bottom of the screen. In this instance, a maneuver has been recorded at the incorrect time, so the clinician selects option #4.*

```
SAMPLE              CATH. # 99999        Edit Log                  10:46  27-SEP-80

  MIN.      TIME     EVENT

   0       [08:38] PREMEDICATION
   3       [08:41] CALIBRATION
   11      [08:49] PREP PT (F)
   64      [09:42] ADMIN HEPARIN 3000 UN IV
   69      [09:47] FEMORAL VEIN
   86      [10:04] FEMORAL ARTERY
   97      [10:15] CATH INTO AO (F)
   97.10   [10:15] AO
   100     [10:18] AO
   113     [10:31] AO TO LV

   Move event: FEMORAL VEIN at 69 (09:47)
      to time: 49 (09:27)

   Is this correct? (Y or N): Y
```

FIGURE 27: ADJUSTMENT OF TIME OF A MANEUVER. *The maneuver FEMORAL VEIN is re-recorded to have taken place at 9:27.*

```
SAMPLE              CATH. # 99999        Edit Log                  10:47  27-SEP-80

  MIN.      TIME     EVENT

   0       [08:38] PREMEDICATION
   3       [08:41] CALIBRATION
   11      [08:49] PREP PT (F)
   49      [09:27] FEMORAL VEIN
   64      [09:42] ADMIN HEPARIN 3000 UN IV
   86      [10:04] FEMORAL ARTERY
   97      [10:15] CATH INTO AO (F)
   97.10   [10:15] AO
   100     [10:18] AO
   113     [10:31] AO TO LV

   Add event: PACING CATH (F) at 57 (09:35)

   Is this correct? (Y or N): Y
```

FIGURE 28: INSERTION OF A MANEUVER INTO THE LOG. *The maneuver PACING CATH (F) was noted to have been overlooked (see Figure 25). Therefore the clinician now enters it into the log.*

of the pacing catheter (Figure 28) and to indicate the event of the patient experiencing chest pain (Figure 29) is performed. (The event of chest pain is recorded to be "simultaneous" to the left ventricular measurements at 10:42 am.) Notice that in Figure 28, the note for FEMORAL VEIN now reflects

```
SAMPLE          CATH. # 99999        Edit Log              10:48  27 SEP 80

 MIN.      TIME     EVENT

  113     [10:31] AO TO LV
  113.10  [10:31] LV
  118     [10:36] ATRIAL PACING
  121     [10:39] LV
  124     [10:42] LV
  125     [10:43] ADMIN NITROGLYCERIN 0.15 MG SL
  126     [10:44] LV
  135     [10:53] LVG (RAO) (F)
  136     [10:54] PRESS POST LVG
  136.10  [10:54] LV

  Add event: CHEST PAIN at 124.1 (10:42)

  Is this correct? (Y or N): Y
```

FIGURE 29: INSERTION OF AN EVENT INTO THE LOG. *It was noted by the system that Nitroglycerin had been given. The clinician adds notes to explain the drug.*

the proper time and is in proper relation to the other maneuvers. Also note that the clinician has the opportunity to reject the editting. Whenever the clinician needs to add a maneuver or event to the log, the system displays menus (Figures 30 - 31) which match those displayed by the dedicated computer during the

```
SAMPLE          CATH. # 99999        Edit Log              10:50  27 SEP 80

                    MENUS

        1.  BRACHIAL APPROACH - NOTES
        2.  FEMORAL APPROACH - NOTES
        3.  OTHER - NOTES
        4.  DRUGS
        5.  PATIENT NOTES

                    ENTER CHOICE: 2
```

FIGURE 30: MENU FOR EDITTING. *This menu is used when the clinician wishes to insert maneuvers or events into the log. It matches the main menu of the dedicated laboratory computer, thereby minimizing confusion.*

```
SAMPLE          CATH. # 99999        Edit Log                10:50  27-SEP-80

                    FEMORAL APPROACH

         1. PREMEDICATION          16. RCA (F)
         2. PREP PT (F)            17. LCA (F)
         3. FEMORAL VEIN           18. PROTAMINE
         4. PWPA PRESS (F)         19. REMOVE CATH (F)
         5. C.O.                   20. CLOSE (F)
         6. RT HRT PRK (F)
         7. PACING CATH (F)        21. ADMIN DRUG
         8. HEPARIN                22. PATIENT NOTE
         9. FEMORAL ARTERY         23. NOTES-BRACH
                                   24. NOTES-OTHER
        11. LVG (RAO) (F)
                                   25. OTHER
                                   26. SEE FILE FOLDER
        14. LVG (LAO) (F)
        15. AORTOGRAM (F)          27. CHEST PAIN

                    ENTER CHOICE: 7
```

FIGURE 31: MENU OF MANEUVERS FOR FEMORAL APPROACH. *This menu is used when editting the log. As with the menu in Figure 30, it matches the menu presented by the dedicated laboratory computer.*

procedure (Figures 21 - 22). This matching of menus removes the possibility of confusion and provides overall consistency. Of course, the edit module also supports menus which the dedicated system does not. These additional menus provide completeness which the dedicated system cannot support.

After editting, the log is an accurate reflection of the catheterization procedure. Now the clinician provides the details for each maneuver and event, while they are still fresh in his mind. To do this the computer displays text which describes, in natural language, each maneuver and event according to the order in which they are recorded. Two examples of this process are provided. Figure 32 illustrates the selection of a catheter type to insert in the first blank of the text for the maneuver FEMORAL VEIN. As with other aspects of the system, the user is always given the opportunity to reject his choice and respecify it. Figure 33 shows the text for LVG (RAO) (F). This text requires numeric entries. Note that for each entry, a label and range are displayed prior to requesting the value.

```
SAMPLE          CATH. # 99999       Procedure Descr.        11:05  27 SEP 80

 Text for : FEMORAL VEIN


 2% xylocaine was used as the local anesthetic.  Using a Cournand
needle and the Seldinger technique a ______ sheath and dilator were
inserted into the ______ femoral vein.  The dilator was removed and
the sheath flushed with heparinized saline.

 Enter 'N' if you wish to suppress this sentence
       'T' if you wish to enter free text BEFORE this sentence:

   SELECT CATHETER

     1. #7 Cordis
     2. #8 Cordis
     3. #9 Cook

   Enter number of choice: 2
```

FIGURE 32: SPECIFICATION OF MANEUVER DETAILS USING MENUS. *To create a natural language description of the catheterization procedure, the maneuvers must be augmented with the details. Each maneuver is presented. In this case, the clinician selects a choice from a menu to inform the system as to the type and size of catheter used.*

```
SAMPLE          CATH. # 99999       Procedure Descr.        11:12  27 SEP 80

 Text for : LVG (RAO) (F)


 The left ventriculogram was done in the 30 degree RAO
projection by power injection of  ______ cc of Isopaque 440 at  ______
cc/sec,  ______ psi.

 Enter 'N' if you wish to suppress this sentence
       'T' if you wish to enter free text BEFORE this sentence:

   FOR cc's of Isopaque

   Enter a value in the range 20 and 50: 30

   Selection is: 30

   Hit <RETURN> if correct or 'N' if not:
```

FIGURE 33: SPECIFICATION OF MANEUVER DETAILS USING NUMERIC RANGES. *This maneuver requires a numeric entry to detail the amount of radio-opaque agent used. The entry is checked against the bounds listed.*

At this point the clinician may want to calculate parameters relevant to the patient's left ventriculogram. So he selects choice #6 from the system's main menu (Figure 15). Accordingly, the graphics display now presents menus for specification of basic data and ventricular silhouette tracings. After this data is entered with a graph pen, a menu of analysis methods is displayed (Figure 34). Selection of an analysis method brings about the quantitation of the silhouettes and subsequent display of the results (Figures 35 - 36). This display is then reproduced on paper, serving as another "working" report.

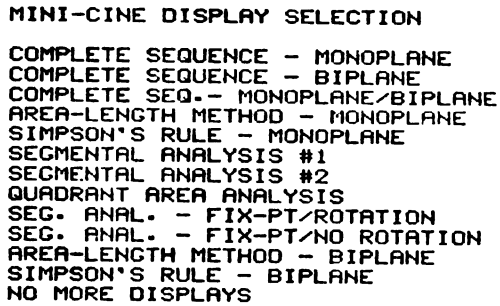


FIGURE 34: MENU OF VENTRICULAR ANALYSIS METHODS. *The prototype system supports several methods to quantitate the ventricular silhouettes. Commonly, the clinician selects two: Area-length Monoplane and Segmental #1. Together, these two methods provide a detailed appraisal of the chamber's function.*

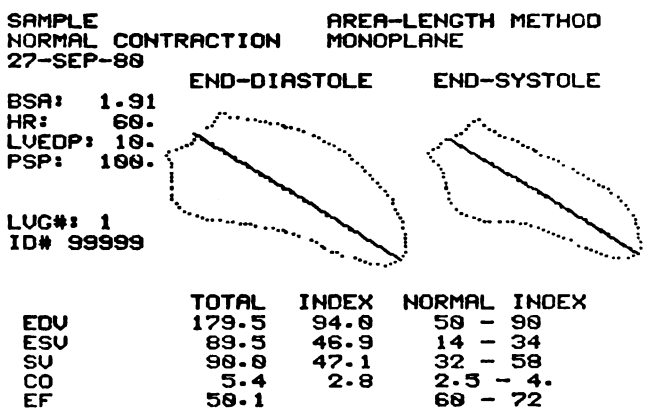


FIGURE 35: DISPLAY OF AREA-LENGTH ANALYSIS RESULTS. *This method of quantitating the silhouettes provides the clinician with data defining the size of the chamber and its effective contractility (i.e., ejection fraction or EF).*

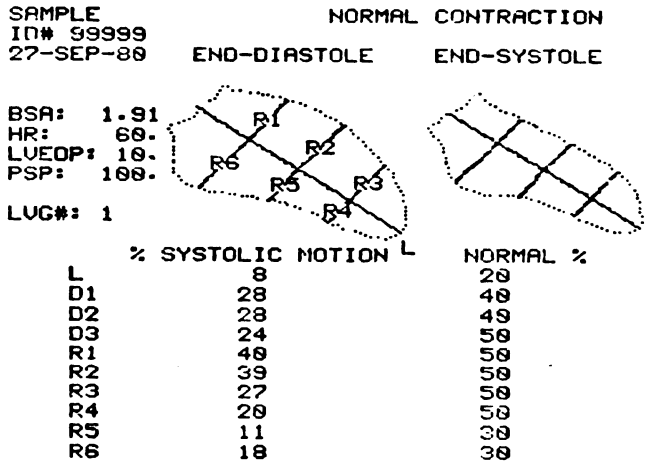


FIGURE 36: DISPLAY OF SEGMENTAL #1 ANALYSIS RESULTS. *This method of quantitating the silhouettes provides the clinician with data defining the wall motion of the chamber. The clinician can then evaluate the evenness of the contraction.*

To analyze the coronary arteries, the same process as that for the ventricular analysis is employed. Again, the clinician interacts with the graphics display using the graph pen. For each artery branch, the data is collected through menus (Figures 37 - 38). Then a summary is displayed and reproduced as hard copy (Figures 39 - 41). Notice that the artery representations are those of Gensini (see Chapter 4, Figure 9). These reproductions owe their quality and smoothness to employment of a high resolution graphics unit.

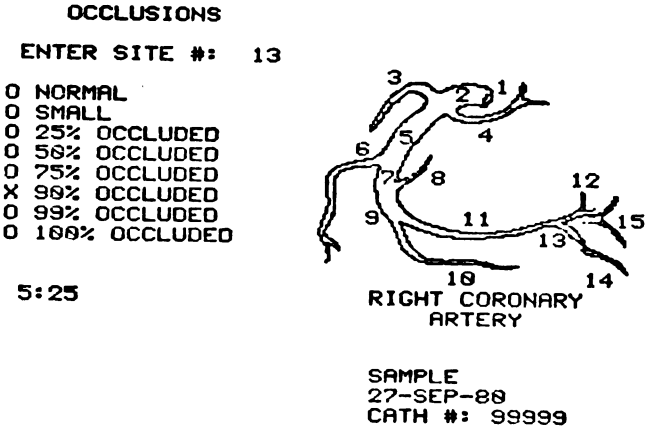
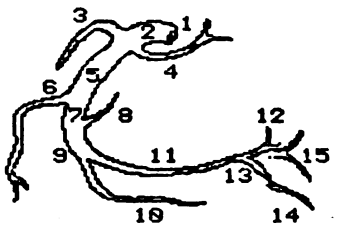


FIGURE 37: SPECIFICATION OF AN OCCLUSION IN AN ARTERY. *The artery has been defined to have one occlusion at site 5, which is 25% occluded. The clinician is currently defining an occlusion at site 13 which is 90% obstructive.*

DISTAL VESSELS

X EXCELLENT
O GOOD
O POOR



RIGHT CORONARY ARTERY

SAMPLE
27-SEP-80
CATH #: 99999

FIGURE 38: SPECIFICATION OF DISTAL FLOW IN AN ARTERY. *The flow of blood to the distal vessels of the right coronary artery is considered to be excellent. Specification of grafts and collateral flow is conducted in a similar manner, using menus.*

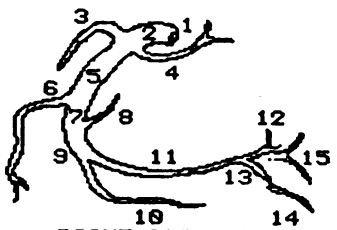
OCCLUSIONS
SITE 5:25% OCCL
SITE 13:90% OCCL

GRAFTS

NONE

DISTALS: EXCELLENT

COLLATERAL FLOW
NONE



RIGHT CORONARY ARTERY

SAMPLE
27-SEP-80
CATH #: 99999

FIGURE 39: SUMMARY OF RIGHT CORONARY ARTERY. *The display presents the full set of data provided for the right coronary artery. The artery has two occlusions, no grafts, excellent distal flow and no collateral flow.*

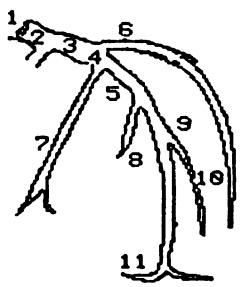
OCCLUSIONS
SITE 3:90% OCCL
SITE 6:SMALL
SITE 7:50% OCCL

GRAFTS

NONE

DISTALS: POOR

COLLATERAL FLOW
FROM: RCA



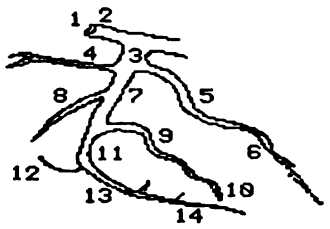
LEFT ANTERIOR DESCENDING

SAMPLE
27-SEP-80
CATH #: 99999

FIGURE 40: SUMMARY OF LEFT ANTERIOR DESCENDING ARTERY. *The artery has three occlusions, no grafts, poor distal flow and receives collateral flow from the right coronary artery.*

OCCLUSIONS

NONE



GRAFTS

NONE

CIRCUMFLEX ARTERY

DISTALS: GOOD

COLLATERAL FLOW
NONE

SAMPLE
27-SEP-80
CATH #: 99999

FIGURE 41: SUMMARY OF CIRCUMFLEX ARTERY. *The artery has no occlusions, no grafts, good distal flow and no collateral flow.*

Consider one more data specification task: the identification of hemodynamics for inclusion in the formal reports. To do this, the computer prompts the clinician to select "times" (i.e., the minutes since the beginning of the catheterization procedure) for each site measured. To assist in identifying these "times", the computer first lists all the times that a site was measured. For further assistance, the clinician may refer to two existing "working" reports: the log (Figure 24) and the Summary report (Figure 25). After a "time" is chosen

```
SAMPLE          CATH. # 99999      Hemodynamics          12:15  27-SEP-80

    *** LEFT HEART ***
    Pressures measured for Ventricle at:
    113 121 124 126 136 138
        Select 'minutes' for report: 126
```

FIGURE 42: SELECTION OF HEMODYNAMICS FOR FORMAL REPORTS. *The clinician selects important hemodynamics to include in the formal reports. The system presents all times when left ventricular pressures were quantitated.*

```
SAMPLE          CATH. # 99999        Hemodynamics          12:15  27-SEP-80

    *** LEFT HEART ***
    Pressures measured for Ventricle at:
    113 121 124 126 136 139

         Data for Ventricle

              HR              60
              EDP             10
              Peak Sys        100
              Beg. Diast      -1
              Mean Sys        70
              Mean Diast      4

   Do you wish to include these results in the final report? (Y or N): Y
   'Label' for these results -
        1. Baseline              5. Pre-Nitro
        2. LVG                   6. Post-Atropine
        3. Post-LVG              7. Pre-Atropine
        4. Post-Nitro            8. Other
   Enter number of choice: 2
```

FIGURE 43: VERIFICATION AND LABELLING OF HEMODYNAMICS. *The clinician has indicated that the hemodynamics calculated at time 126 are to be included in formal reports. He then selects a label for these results to clarify their clinical significance.*

(Figure 42), the computer displays the subset of the parameters to be included in the report (remember: the dedicated computer calculates an abundance of parameters, most of which are not considered essential). The clinician then verifies that these hemodynamics are to be included in reports and a label is attached to clarify their clinical significance (Figure 43). If "Other" is the selected label, the system allows the clinician to define a label of his choice.

The data are now complete and ready for formal reporting. For the clinician, generation of reports is a very simple task. All he has to do is select the type of report desired (Figure 44). If he selects the "Full Cath Report" option, he will be asked to wait while the system verifies that all the data have been collected. If all data are not available to the system, the report will not be generated and the clinician will be informed as to what data is determined to be missing. Actual generation of a report is transparent to the users and does not interfere with the entry of data for other patients.

```
SAMPLE          CATH. # 99999       Report Generation       12:50  27 SEP-80

          1. Conference Report
          2. Anesthesia Report
          3. Full Cath Report
          4. Referal Report (to outside MD)
          5. Legal Report

        Enter choice: 1
```

FIGURE 44: REQUEST FOR REPORT GENERATION. *The clinician requests a conference report to be prepared. The actual generation of the report is transparent to him.*

To print the generated reports, the secretary is alerted by the computer using its memo/mailbox system. If any reports are waiting to be printed, she is prompted to examine the mailbox and will receive a memo such as that in Figure 45. For each type of report generated for each patient, a memo will be sent to her mailbox. She then activates the word processing software and the report is printed.

```
MESSAGE # 1
ON          27-SEP-80
AT          16:05:15
FROM USER: PEEL
        A REPORT IS READY (TYPE CAT). CATH NO. 99999

RETURN TO CONTINUE,
"D" TO DELETE THIS MESSAGE,
"R" TO SEND A REPLY,
"DR" TO DO BOTH:
```

FIGURE 45: MEMO TO INFORM THE SECRETARY THAT A REPORT IS READY. *When the secretary logs on to the computer, it informs her that a memo is waiting for her inspection. This memo, in turn, tells her that a report is ready. In this case, the report is a formal catheterization report for patient #99999.*

Several reports are generated by the prototype information management system for the catheterization laboratory. The most important of these is the formal catheterization report (Figure 46, 9 pages including the Legal report which is the ninth page). This report is the formal documentation of the catheterization. The system is fully responsible for its format. The report is legible, complete and stable in form. Furthermore, if this report is printed on continuous form paper, the secretary does not have to intervene in its printing at all.

CLINICAL RECORD

Report on CARDIAC CATHETERIZATION & ANGIOGRAPHY
or
Continuation of S. F. DATE: 27 Sep 1980
(Strike out one line) (Specify type of examination or date)

(Sign and date)

NAME Sample, Fred A. S.S.# 999-99-9999 Cath. # 99999

Pre-Cath. Diagnosis: Coronary Artery Disease

Procedure: Left Heart Catheterization, Insertion of Pacing Catheter, Atrial Pacing as Stress Test, Left Ventriculogram, Selective Coronary Angiography

Indication for catheterization: Angina, Coronary Artery Disease

HISTORY: The patient is a 61 year old white male truck driver who has had persistent exertional angina of one-half year's duration. He has no prior history of cardiac problems. He has had no other major health problems. He first noticed that he had chest pain whenever he played basketball for over 5 minutes. As time progressed, he became aware that the pain was occurring whenever he exerted himself. Now he feels pain whenever he exerts himself beyond casual walking. He has no other health complaints. He was started on Nitroglycerin .15 mg prn about 4 months ago.

Present Medication: Nitroglycerin .15 mg sl prn

Angina Yes Duration 6 months Type Exertional

Previous myocardial infarctions: No Date:

RISK FACTORS:

Hypertension	No	How long:	
Diabetes Mellitus	No	Treatment:	
Hyperlipidemia	Uknown	Type:	
Smoking	Yes	Pack years:	12

FAMILY HISTORY

Coronary Disease: Parent
Diabetes Mellitus: None
Hyperlipidemia: Unknown

(Continue on reverse side)

PATIENT'S IDENTIFICATION (For typed or written entries give: Name—last, first, middle, grade; date, hospital or medical facility)

Sample, Fred A.
San Francisco VAMC

REGISTER NO.	WARD NO.
999-99-9999	2A

REPORT ON _____ or CONTINUATION OF _____

STANDARD FORM 507
General Services Administration and Interagency Committee on Medical Records
FPMR 101-11.80 6-8
October 1975 507-106

FIGURE 46: FORMAL CATHETERIZATION REPORT. *This is the formal medical record of the catheterization. It becomes a part of the patient's medical record. The entire report is prepared and printed without user intervention. Note that the style is natural and concise. All essential data is presented clearly and orderly. The report is nine pages long.*

CLINICAL RECORD	Report on CARDIAC CATHETERIZATION & ANGIOGRAPHY or Continuation of S. F. DATE: 27 Sep 1980 (Strike out one line) (Specify type of examination or data)

(Sign and date)

PHYSICAL EXAMINATION

Age 61 Sex M Ht. 178 cm Wt. 74 kg BSA 1.91 M2

Blood Pressure: 110/60
Pulse: Regular at 60
Jugular Veins: Within normal limits.
Carotid Pulse: Within normal limits.
Lungs: Clear to P & A
Heart: No unusual sounds. S1 and S2 normal.
Abdomen: Soft.
Extremeties: Normal
Pulses: Normal
Other:

LABORATORY DATA
ECG: Non-specific S-T and T wave changes
ECG with pain: No ECG obtained during pain
Exercise Test: Positive exercise test for ischemia at a heart rate of 120. Patient experienced chest pain. There were 3 mm S-T depression in leads 1, AVL, V3-5.
Chest X-ray: Normal heart size and pulmonary vascularity
Other non-invasive tests:

Hct: Hgb: 13.0 g/100 ml. WBC:
Cholesterol: 700 mg/100 ml. Triglycerides:
Uric Acid: FBS: 80 mg/100 ml.
BUN: 20 mg/100 ml. Creatinine:

PROCEDURE:
Time started: 08:38 am Completed: 11:50 am
Drugs: Heparin 3000un IV, Protamine 30mg IV, Nitroglycerin .15mg sl x 1
Amount of Contrast agent and type: 150 cc Renografin 76, 0 cc Isopaque 440
Film type: Ilford Fluroscopy time: 5 minutes, 22 seconds
Complications: none

(Continue on reverse side)

PATIENT'S IDENTIFICATION (For typed or written entries give Name—last, first, middle, grade, date, hospital or medical facility)	REGISTER NO.	WARD NO.
Sample, Fred A. San Francisco VAMC	999-99-9999	2A

REPORT ON _____ or CONTINUATION OF _____

STANDARD FORM 507
General Services Administration and
Interagency Committee on Medical Records
FPMR 101-11.R0 6-8
October 1975 507-106

FIGURE 46: (cont.) *This page continues with the pre-catheterization data. It also reports some aspects of the procedure.*

CLINICAL RECORD	Report on CARDIAC CATHETERIZATION & or ANGIOGRAPHY Continuation of S. F. DATE: 27 Sep 1980 (Strike out one line) (Specify type of examination or data)

(Sign and date)

Diazepam 10 mg p.o. was given as premedication. The patient was brought to the catheterization laboratory in the fasting state after a routine ECG. Continuous ECG monitoring was instituted using the Frank leads x and y. An I.V. with D5W was started in the left arm using #20 guage B-D I.V. catheter. The right and left groins were prepped and draped in the usual fashion.

2% xylocaine was used as the local anesthetic. Using a Cournand needle and the Seldinger technique a #8 Cordis sheath and dilator were inserted into the left femoral vein. The dilator was removed and the sheath flushed with heparinized saline.

A #6 Goetz catheter was inserted into the sheath and advanced into the right heart and positioned in the coronary sinus. The pacing threshold was 0.5 mA. The pacing catheter was secured to the skin.

3000 units Heparin were given intravenously.

The right groin was infiltrated with 2% xylocaine. Using the Cournand needle and the Seldinger technique, a #8 Cordis sheath and dilator were inserted into the right femoral artery. The dilator was removed and the sheath flushed with heparinized saline.

A #8 Cordis pigtail catheter 523-850 was inserted into the femoral artery and advanced into the aorta. At the level of the diaphragm, the catheter was flushed with Renografin 76. The catheter was flushed every 2-3 minutes with 4-5 cc Renografin 76 while it remained in the arterial system. The aortic pressure was recorded. Under pressure monitoring the catheter was advanced into the left ventricle. The left ventricular pressure was recorded.

As a means of stress testing, atrial pacing was performed for 5 minutes at a rate of 120. The patient experienced chest pain. Nitroglycerin 0.15 mg was given sublingually.

The left ventriculogram was done in the 30 degree RAO projection by power injection of 30 cc of Isopaque 440 at 12 cc/sec, 300 psi. The left ventricular pressure was recorded immediately after the ventriculogram. The catheter was removed.

(Continue on reverse side)

PATIENT'S IDENTIFICATION (For typed or written entries give Name—last, first, middle, grade, date, hospital or medical facility)	REGISTER NO.	WARD NO.
Sample, Fred A. San Francisco VAMC	999-99-9999	2A

REPORT ON _____ or CONTINUATION OF _____

STANDARD FORM 507
General Services Administration and Interagency Committee on Medical Records
FPMR 101-11.50 6-8
October 1975 507-105

FIGURE 46: (cont.) *This page and the next page present the textual description of the catheterization procedure. Note the resulting text for the FEMORAL VEIN (paragraph #2) and for the LVG (RAO) (F) (paragraph #8, beginning). These paragraphs were generated from the log (see Figures 24, 25, 32-33).*

CLINICAL RECORD	Report on CARDIAC CATHETERIZATION & or ANGIOGRAPHY Continuation of S. F. DATE: 27 Sep 1980 (Strike out one line) (Specify type of examination or data)

(Sign and date)

A #8 Cordis right coronary catheter 523-841 was substituted. At the level of the diaphragm in the aorta, the catheter was flushed with Renografin 76. The catheter was flushed with 1-2 cc Renografin 76 every 2-3 minutes while it remained in the arterial system. There was continuous arterial monitoring and recording on tape except during the injections. The right coronary artery was visualized in various projections by hand injection of Renografin 76 without TNG. With the injection, there were T waves inverted in lead x, and the patient experienced mild pain.

A #8 Cordis left coronary catheter 523-843 was substituted. The same flushing and monitoring techniques were performed as during the right coronary artery visualization. The left coronary artery was visualized in various projections by hand injections of Renografin 76 without TNG. With the injection, there were T waves inverted in leads x and y, and the patient experienced pain.

Protamine 30 mg. was given intravenously. The arterial catheter and sheath and the venous catheter and sheath were removed and manual pressure applied to the puncture sites for 30 minutes and 15 minutes respectively.

There were good left and right dorsalis pedis pulses at the end of the procedure. The patient withstood the procedure well and was returned to his room.

(Continue on reverse side)

PATIENT'S IDENTIFICATION (For typed or written entries give: Name—last, first, middle, grade, date, hospital or medical facility)	REGISTER NO.	WARD NO.
Sample, Fred A. San Francisco VAMC	999-99-9999	2A

REPORT ON _____ or CONTINUATION OF _____

STANDARD FORM 507
General Services Administration and
Interagency Committee on Medical Records
FPMR 101-11 80 6-8
October 1975 507-106

FIGURE 46: (cont.) *This is a continuation of the procedure description.*

CLINICAL RECORD

Report on CARDIAC CATHETERIZATION & ANGIOGRAPHY
or
Continuation of S. F. DATE: 27 Sep 1980
(Strike out one line) (Specify type of examination or data)

(Sign and date)

LEFT HEART HEMODYNAMICS

PRESSURES

Baseline

Left Ventricle (10:31am)

Heartrate	60 bpm	Beg. DP	0 mmHg
EDP	8 mmHg	Mn. Sys.	68 mmHg
Pk. Sys.	108 mmHg	Mn. Dia.	3 mmHg

Aorta (10:15am)

Heartrate	73 bpm	Syst.	92 mmHg
Diast.	50 mmHg	Mean	69 mmHg

LVG

Left Ventricle (10:44am)

Heartrate	60 bpm	Beg. DP	-1 mmHg
EDP	10 mmHg	Mn. Sys.	70 mmHg
Pk. Sys.	100 mmHg	Mn. Dia.	4 mmHg

Post-LVG

Left Ventricle (10:54am)

Heartrate	65 bpm	Beg. DP	0 mmHg
EDP	12 mmHg	Mn. Sys.	88 mmHg
Pk. Sys.	110 mmHg	Mn. Dia.	5 mmHg

Atrial Pacing

Left Ventricle (10:39am)

Heartrate	120 bpm	Beg. DP	0 mmHg
EDP	22 mmHg	Mn. Sys.	90 mmHg
Pk. Sys.	125 mmHg	Mn. Dia.	3 mmHg

(Continue on reverse side)

PATIENT'S IDENTIFICATION (For typed or written entries give name—last, first, middle, grade; date, hospital or medical facility)

Sample, Fred A.
San Francisco VAMC

REGISTER NO. 999-99-9999

WARD NO 2A

REPORT ON _____ or CONTINUATION OF _____

STANDARD FORM 507
General Services Administration and
Interagency Committee on Medical Records
FPMR 101-11.80 6-8
October 1975 507-106

FIGURE 46: (cont.) *This page of the report presents the selected hemodynamics (see Figures 42-43).*

CLINICAL RECORD	Report on CARDIAC CATHETERIZATION & ANGIOGRAPHY or Continuation of S. F. DATE: 27 Sep 1980 (Strike out one line) (Specify type of examination or data)

(Sign and date)

1 min Post Pacing

Left Ventricle (10:42am)

Heartrate	61 bpm	Beg. DP	-1 mmHg
EDP	20 mmHg	Mn. Sys.	90 mmHg
Pk. Sys.	130 mmHg	Mn. Dia.	9 mmHg

LEFT VENTRICULOGRAPHY

Normal Contraction

Basic Hemodynamics for Calculations

BSA	1.91 M2	Heartrate	60 bpm
LVEDP	10 mmHg	PSP	100 mmHg

Area-Length Method Monoplane

EDV Total	179.5 ml	EDV Index	94.0
ESV Total	89.5 ml	ESV Index	46.9
EF	50.1 %		

Segmental Analysis

L	D1	D2	D3		
8%	28%	28%	24%		
R1	R2	R3	R4	R5	R6
40%	39%	27%	20%	11%	18%

(Continue on reverse side)

PATIENT'S IDENTIFICATION (For typed or written entries give: Name - last, first, middle, grade, date, hospital or medical facility)	REGISTER NO.	WARD NO.
Sample, Fred A. San Francisco VAMC	999-99-9999	2A

REPORT ON _____ or CONTINUATION OF _____

STANDARD FORM 507
General Services Administration and Interagency Committee on Medical Records
FPMR 101-11.50 G-8
October 1975 507-106

FIGURE 46: (cont.) *This page of the report continues the selected hemodynamics. It also presents the data collected from the Ventricular analysis task (see Figures 34-36).*

CLINICAL RECORD	Report on CARDIAC CATHETERIZATION & or ANGIOGRAPHY Continuation of S. F. DATE: 27 Sep 1980 (Strike out one line) (Specify type of examination or data)

(Sign and date)

ANGIOGRAPHY

Right Coronary Artery

Proximal Right Coronary Artery is 25% occluded.
Posterior Descending Branch is 90% occluded.

Flow to Distal Vessels: Excellent.

Collateral Flow: None

Left Anterior Descending Artery

Left Anterior Descending is 90% occluded.
First Diagonal Branch is small.
First Septal is 50% occluded.

Flow to Distal Vessels: Poor.

Collateral Flow: From Right Coronary Artery

Circumflex Artery

No occlusions noted

Flow to Distal Vessels: Good.

Collateral Flow: None

(Continue on reverse side)

PATIENT'S IDENTIFICATION (For typed or written entries give Name—last, first, middle, grade, date, hospital or medical facility)	REGISTER NO.	WARD NO.
Sample, Fred A. San Francisco VAMC	999-99-9999	2A

REPORT ON _____ or CONTINUATION OF _____

STANDARD FORM 507
General Services Administration and
Interagency Committee on Medical Records
FPMR 101-11.80 6-8
October 1975 507-106

FIGURE 46: (cont.) *This page of the report presents the results of coronary angiography. The text was generated from the input shown in Figures 37-41.*

CLINICAL RECORD	Report on CARDIAC CATHETERIZATION & ANGIOGRAPHY or Continuation of S. F. DATE: 27 Sep 1980 (Strike out one line) (Specify type of examination or data)

(Sign and date)

Impressions: Significant lesion in Left Anterior Descending Artery
Significant lesion in the Posterior Descending Branch of RCA
No significant lesions in the Circumflex Artery
Left Ventriculogram shows anterior hypokinesis
Ejection Fraction is 50%

Recommendations: Bypass to Left Anterior Descending and Post Descending Artery

(Continue on reverse side)

PATIENT'S IDENTIFICATION (For typed or written entries give Name—last, first, middle, grade, date, hospital or medical facility)	REGISTER NO.	WARD NO.
Sample, Fred A. San Francisco VAMC	999-99-9999	2A

REPORT ON _____ or CONTINUATION OF _____

STANDARD FORM 507
General Services Administration and
Interagency Committee on Medical Records
FPMR 101-11.80 S-8
October 1975 507-106

FIGURE 46: (cont.) *This page of the catheterization report presents the impressions and recommendations (which were collected as free text.)*

CLINICAL RECORD	Report on CARDIAC CATHETERIZATION & ANGIOGRAPHY or Continuation of S. F. DATE: 27 Sep 1980 (Strike out one line) (Specify type of examination or data)

(Sign and date)

1. Documentation of Technique:
   Left Heart Catheterization, Insertion of Pacing Catheter, Atrial Pacing as Stress Test, Left Ventriculogram, Selective Coronary Angiography
   Sites affected: left femoral vein, right femoral artery

2. Duration of procedure: 3 hours, 12 minutes

3. Medications used:
   Heparin 3000un IV, Protamine 30mg IV, Nitroglycerin .15mg sl x 1

4. Untoward reactions noted:
   None.

5. Resulting complications:
   None.

6. Late complications:
   None.

(Continue on reverse side)

PATIENT'S IDENTIFICATION (Fill in typed or written entries in this space: last, first, middle, grade, date, hospital or medical facility)	REGISTER NO.	WARD NO.
Sample, Fred A. San Francisco VAMC	999-99-9999	2A

REPORT ON _____ or CONTINUATION OF _____

STANDARD FORM 507
General Services Administration and Interagency Committee on Medical Records
FPMR 101-11.80 6-S
October 1975 507-106
GPO: 1976—261-163/1629

FIGURE 46: (cont.) *This page of the formal catheterization report presents data which is legally necessary for hospital records.*

Three other clinical reports are also routinely generated. These are a Conference report (Figure 47), a report for the Anesthesia department (Figure 48) and a report for the referring physician (Figure 49). Examination of these reports reveals that they consist of the same data as that in the formal catheterization report. What is significant about this fact is that the data was recorded only once under the guidance of the computer and can be reformatted for each report without errors related to omission, typing, labelling or loss. Every report presents the same clinical picture of the patient, yet each is tailored to the clinical goals of the prospective users.

CATHETERIZATION CONFERENCE REPORT

NAME Sample, Fred A. S.S.# 999-99-9999 Cath. # 99999
Pre-Cath. Diagnosis: Chronic Stable Angina Pectoris, Coronary Artery Disease

HISTORY: The patient is a 61 year old white male truck driver who has had persistent exertional angina of one-half year's duration. He has no prior history of cardiac problems. He has had no other major health problems. He first noticed that he had chest pain whenever he played basketball for over 5 minutes. As time progressed, he became aware that the pain was occurring whenever he exerted himself. Now he feels pain whenever he exerts himself beyond casual walking. He has no other health complaints. He was started on Nitroglycerin .15 mg prn about 4 months ago.

Present Medication: Nitroglycerin .15 mg sl prn

RISK FACTORS:

Hypertension	No	How long:	
Diabetes Mellitus	No	Treatment:	
Hyperlipidemia	Uknown	Type:	
Smoking	Yes	Pack years:	10

PHYSICAL EXAMINATION

Age 61 Sex M Ht. 178 cm Wt. 74 kg BSA 1.91 M2

Blood Pressure: 110/60
Pulse: Regular at 60
Jugular Veins: Within normal limits.
Carotid Pulse: Within normal limits.
Lungs: Clear to P & A
Heart: No unusual sounds. S1 and S2 normal.
Abdomen: Soft.
Extremeties: Normal
Pulses: Normal
Other:

LABORATORY DATA
ECG: Premature ventricular contractions, Non-specific S-T and T wave changes
Exercise Test: Positive exercise test for ischemia at a heart rate of 120. Patient experienced chest pain. There were 3 mm S-T depression in lead AVL.
Chest X-ray: Normal heart size and pulmonary vascularity
Other non-invasive tests:

FIGURE 47: CONFERENCE REPORT. *This report presents data which is considered to be useful for the weekly cardiology conference.*

Report of Catheterization Data to Anesthesiology

Name: Sample, Fred A. SSN: 999-99-9999 Cath #: 99999

Date of Catheterization: 26-SEP-80

Age: 61 Sex: Male Height: 178 cm. Weight: 74 kg. BSA: 1.91 M2

Present Medications (at time of cath.)

Nitroglycerin .15 mg sl prn

HEMODYNAMICS

Ejection Fraction: Area-length method: 50.1 (normal contraction)

Baseline

Left Ventricle (10:31am)

Heartrate	60 bpm	Beg. DP	0 mmHg
EDP	8 mmHg	Mn. Sys.	68 mmHg
Pk. Sys.	108 mmHg	Mn. Dia.	3 mmHg

Aorta (10:15am)

Heartrate	73 bpm	Syst.	92 mmHg
Diast.	50 mmHg	Mean	69 mmHg

FIGURE 48: ANESTHESIOLOGY REPORT. *This report presents catheterization data to the anesthesiologist. Only that data which is useful to the anesthesiologist is reported.*

Report to Referring Physician

Name: Sample, Fred A. SS#: 999-99-9999 Cath #: 99999

Age: 61 Sex: Male Height: 178 cm. Weight: 74 kg. BSA: 1.91 M2

Procedures Performed

Left Heart Catheterization, Insertion of Pacing Catheter, Atrial Pacing as Stress Test, Left Ventriculogram, Selective Coronary Angiography

Sites Affected

left femoral vein, right femoral artery

Complications

None.

Impressions: Significant lesion in Left Anterior Descending Artery
Significant lesion in the Posterior Descending Branch of RCA
No significant lesions in the Circumflex Artery
Left Ventriculogram shows anterior hypokinesis
Ejection Fraction is 50%

Recommendations: Bypass to Left Anterior Descending and Post Descending Artery

FIGURE 49: REFERRAL REPORT. *This report is sent to the referring physician if that doctor is not part of the medical center's staff. It presents the abstracted, generalized descriptions of the catheterization and the important conclusions drawn from the data.*

Still one other report is routinely generated. This report identifies those data areas which have not been recorded for each patient (Figure 50). Daily scrutiny and response to this report ensures that each report is complete and available within a timely interval after the catheterization.

CATHETERIZATION REPORT STATUS as of 27-SEP-80

# Days Since Cath	Patient	
3 DAYS	Cath #: 99995 TEST Medical History Late Complications	Cath. Date: 24-SEP-80
2 Days	Cath #: 99997 BROWN, L. Medical History Fluroscopy Data Selection of Hemodynamics for Report Impressions Recommendation Late Complications	Cath. Date: 25-SEP-80
2 Days	Cath #: 99998 DOE, J. Recommendation Late Complications	Cath. Date: 25-SEP-80
1 Day	Cath #: 99999 SAMPLE Record Complete.	Cath. Date: 26-SEP-80

FIGURE 50: STATUS REPORT. *This report is used by the chief of the laboratory to follow the progress of the data collection and report generation. It is vital in assuring timely reports.*

Computer Science Perspective

As was previously stated, this research offers no revelations to pure computer science. Yet there is no other catheterization data management system which utilizes as diverse a set of computer science methods as does the prototype system. This diversity is evidenced through the prototype's utilization of distinct computers, dissimilar programming languages and a multitude of distributed peripherals. Yet this diversity is not a mere embellishment. It is the key to success. Without access to and use of essential and diverse resources, the resulting system would be no better than previous solutions.

Remember, the prototype is one implementation of the model. It is based on the resources available within the catheterization laboratory of the San Francisco Veterans' Administration Medical Center. As such, it is not the only possible implementation. Rather, it is a demonstration of the ideals of the model. It is proof that diverse resources can be coordinated to meet clinical goals.

Resources and Basic Groundwork

Several mini-computer systems are utilized by the catheterization laboratory at the San Francisco Veterans' Administration Medical Center. These computers support a plethora of operating systems, languages and peripherals. Together, they provide a comprehensive set of resources which meet the capabilities essential for enhanced management of cardiac catheterization data (see Table 3, Chapter 5).

Chief among these computers is a dedicated catheterization laboratory system developed by Mennen Medical, Inc. This computer is a Digital Equipment Corporation (DEC) PDP-11/05 with minimal memory and mass storage. A Decwriter is attached as the console terminal. A customized keyboard serves as

the primary input device. Keys for requesting hemodynamic measurements and for selecting menu options dominate the board. Video monitors are situated within the laboratory for visual display of results.

The software which supports this system provides a dedicated, real-time environment. All aspects of the software are written in FORTRAN and assembly language. All interaction is handled via assembly language routines with calls to customized utilities. A very limited selection of maneuvers and events for recording the log of the procedure is offered. However, these menus are not clinically useful and therefore are rarely used. The final report presents a terse listing of the quantitated pressures. The time at which each measurement was obtained is printed with each set of parameters. So this system does support the ability to record and print a partial log. No data base is maintained.

In spite of its limited menus and report capabilities, this dedicated computer-based catheterization system has been used by the laboratory staff for over five years. Its unreproachable benefit is that it performs complex hemodynamic calculations accurately and efficiently, displaying the results within seconds of actual measurement. Furthermore, no special computer skills are necessary for its operation. Accordingly, this system is used for all catheterizations and is well liked by the staff.

But this system is extendable to meet additional clinical goals. Specifically, the following enhancements were applied. First, the method for presenting menus was reprogrammed to offer the clinician a larger, more meaningful collection of possible notations (see Figures 21 - 22). The menu of drug choices was also expanded to reflect currently administered drugs (see Figure 23). Another enhancement introduced this computer into the aforementioned network. Basically, the module which generates the final report was extended to transmit a copy of the report to one of the other computers for

analysis. At no point did any aspect of the enhancement require alterations to existing data structures. Consequently, the system is still able to accept updates from the vendor which conform to its original organization.

In contrast to the dedicated PDP-11/05, all the other computer systems in the catheterization laboratory are time-shared by multiple applications. Of these computers, the RSX-11M-based PDP-11/35 is the most elaborate, both in terms of hardware and software. Prominent equipment attached to this computer are varied graphics equipment, a line printer, several terminals and a letter quality printer. A large set of versatile software including word-processing, device-independent graphics, statistics and memos with mailboxes are supported. And, of course, the network communications protocol also operates under RSX.

Several clinical tasks are supported by the RSX system. Among them is an interactive left ventricular analysis system (95). This task uses the video monitor and a spark pen to display and accept data supplied by the clinician. A hard copy unit is available to reproduce the images displayed on the video monitor. This ventricular analysis task was converted to operate under RSX. Previously it operated under the DOS operating system using the same computer as that used by the Mennen Medical system. Typical of this type of arrangement, the users were forced to manually swap computer discs and reboot the computer. However, through the conversion process, this offensive manual rearrangement was obviated. Furthermore, several user-oriented changes were introduced. The system now allows the clinician to review data prior to quantitation of the silhouettes. Additionally, the task is now tolerant of entry errors and provides coherent error messages and effective recovery.

Still another benefit arises from the installment of the ventricular analysis task under RSX. Now, the equipment and basic software used to enter and

evaluate ventriculography data also serve to accept clinician input about the status of a patient's coronary arteries.

Although not a clinical application, a notable software component of the RSX system is the word-processing package. This package was developed at the San Francisco Veterans' Administration Medical Center initially for use in preparing publications. Since that time, it has developed into a highly general and flexible system which provides all the formatting capabilities necessary for the preparation of clinical reports. This package is easy to use and is well documented (116). Therefore, it is the primary mechanism by which catheterization reports are formatted and printed.

The computer selected to be responsible for the overall coordination of the catheterization data is a MUMPS-based PDP-11/34. Several reasons support this selection. MUMPS provides a highly interactive, flexible computing environment. Its capabilities for data management are excellent as attested to by extensive prior development of clinical support systems (22, 23, 33, 35, 109). In particular, MUMPS is heavily oriented toward string manipulation. This feature is essential for flexible report generation by the prototype system where there is extensive substitution of patient specific data into general purpose formats. Moreover, interaction with users through MUMPS programs is greatly facilitated by the fact that MUMPS will accept any input without regard to its data type (e.g., numeric vs. alpha). Therefore, the programs do not abort when a user inadvertently enters incorrect data. Instead, the error is trapped, handled and reported to the user without consequence to program operation or previously collected data. This flexible, tolerent interface between the computer and the clinician is vital for overall success (26).

The configurations of these three computer systems and their network interconnection is represented in Figure 51.

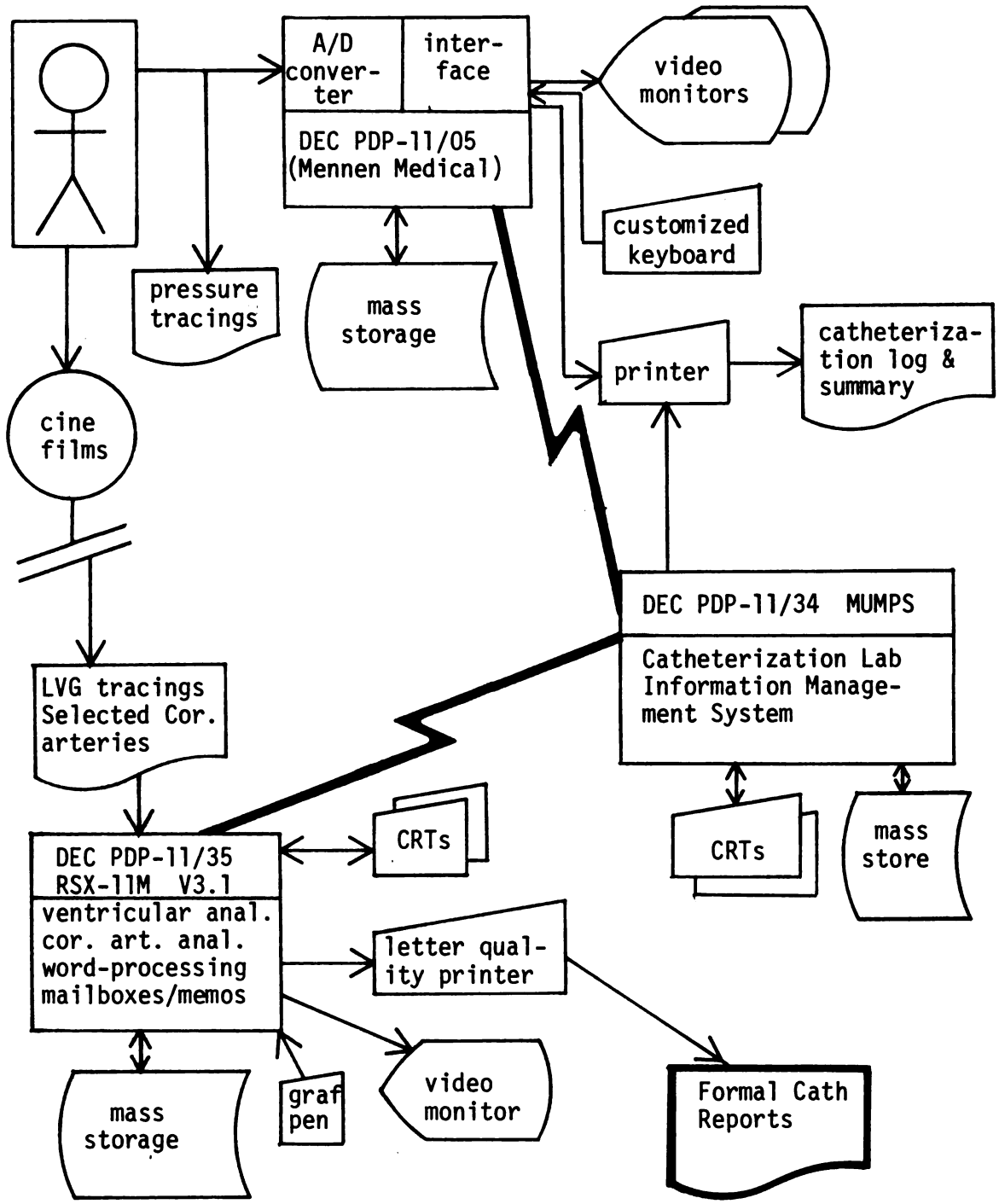


FIGURE 51: CONFIGURATION AND INTERCONNECTION OF THE COMPUTERS. *This diagram illustrates the resources available among the computers. There are three computers: a PDP-11/05, a PDP-11/34 and a PDP-11/35. Each supports a different operating system and different programming languages. See text for further discussion.*

Data Base

The long term organization and management of data is a perpetual source of frustration for researchers (68). This situation pervades catheterization laboratories. Current techniques commercially available for the clinician to archive calculated hemodynamic parameters have invariably demanded the contortions of loading and unloading disks and programs. Analysis of preserved data is even more harried due to the insufficient storage available on floppy disks and to the nonexistence of programs to search the records for desired characteristics (4, 18, 20, 21).

Therefore, a distinct contribution of this research is the "automatic" construction of a comprehensive catheterization data base which is useful clinically as well as for research. The clinician need only be concerned with the task of recording data. The information management system assumes responsibility for coordinating and archiving that data. To achieve this goal, the anticipated needs of researchers, the properties of the data and the available computer resources are all considered.

Physically, the data base is centralized, residing on one computer (i.e., MUMPS). Centralized data bases avoid the need for duplication of data which is necessary in distributed data bases (48). Moreover, the level of sophistication of data manipulation in centralized data bases is superior to that of distributed systems where organizational and synchronization problems are considerable and not yet well explored (1, 7).

Logically, the data base is hierarchical. The clinician's perception of catheterization data parallels this structure. The data occurs in repeating groups (e.g., maneuvers, hemodynamics, medications) and in well defined entities (e.g., procedure log, ventriculography, pre-catheterization data). Of course, there are disadvantages to a hierarchical data base for catheterization data. Of these, the

most significant affects researchers who pose symmetrical queries (i.e., one that requires data of two or more entities per patient record). Such queries may prove to be time consuming and complex to answer (93). Nonetheless, the principle use of this system is expected to be for data collection, coordination and reporting. Therefore, the hierarchical structure is preferred.

Of special concern is the time-oriented aspect of the data. The time-oriented data are organized in a manner similar to the Time-Oriented Database model (TOD) of Fries (33, 103). However, the generality of the TOD approach is not necessary nor feasible. Specifically, the TOD system requires extensive memory and peripheral storage which the available computers do not provide. But this basic approach, where "time" is a key to accessing data has proven valuable in research (37, 46). Consequently, this approach is used to coordinate and store the time-oriented data.

The data is functionally divided into two data bases. The placement of data into one or the other data base is predicated on the degree of absoluteness the data presents. For example, highly quantitated data such as the hemodynamics reside in a primary data base. In contrast, less absolute data such as the history and impressions reside in a parallel data base. In essence, the parallel data base is used to store data which is essential for generating legible, complete catheterization reports, but which is less structured than the data in the primary data base.

Figures 52 - 53 illustrate the hierarchical structure of these data bases. A more thorough discussion of the physical layout of the data within these structures is found in Appendix A.

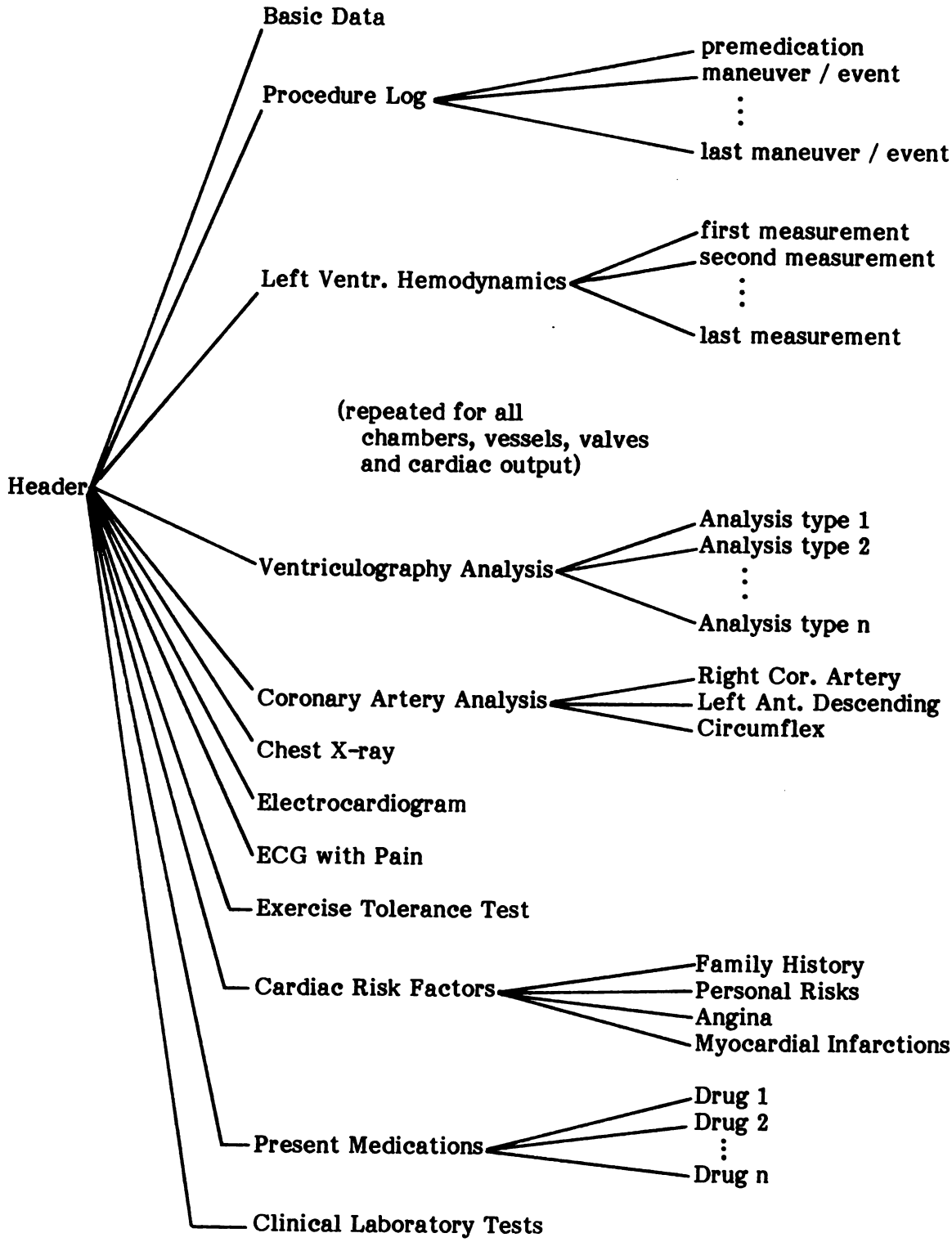


FIGURE 52: PRIMARY DATA BASE. *This hierarchical data base stores the quantitated data. See text for further discussion.*

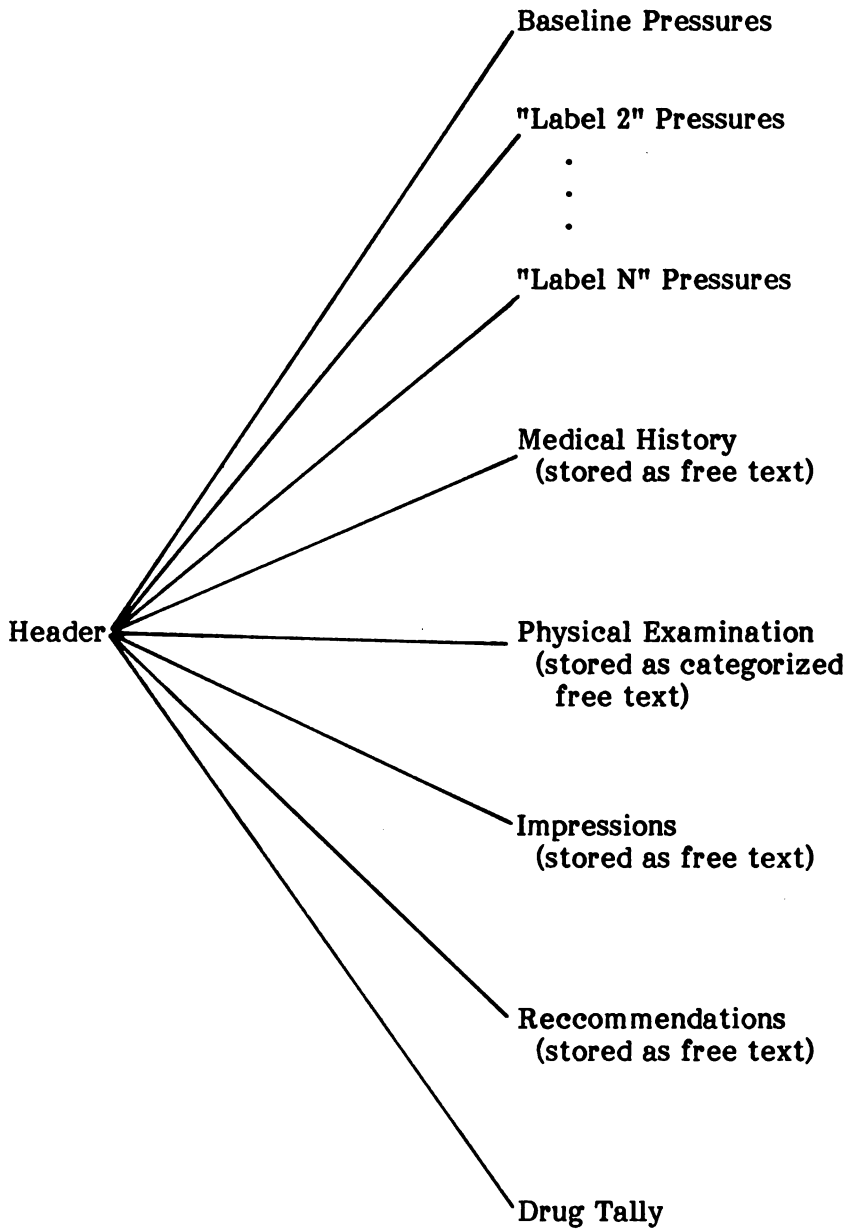


FIGURE 53: PARALLEL DATA BASE. *This data base stores the less quantitative data. The data in this data base is generally very qualitative in form and is used primarily to construct a formal report.*

Division of Tasks Among Computers

Distributed computing reaches peak efficiency and effectiveness when the computers are used for tasks in which they are proficient. Accordingly, a primary objective in implementing the prototype system is to assign data management tasks to computers which can best support those tasks. To accomplish this assignment, the hardware and software capabilities are weighed against the personnel involved and the category of data to be managed. So, in consideration of the model, the available computers, the data categories and the personnel, the data management is divided among the tasks shown in Figure 54.

Consider first the tasks assigned to RSX. Of these, the ventricular analysis and coronary artery analysis tasks are strictly bound to RSX. No other computer supports the essential graphics equipment to manage this category of data. Furthermore, in the case of ventricular analysis, RSX supports the complex mathematics to quantitate the silhouettes. The other tasks assigned to RSX center about the word-processing package. These tasks interact with the secretary. And, as the secretary is familiar with the word-processor, it is appropriate and prudent to assign these tasks to operate within a sphere in which this user is comfortable and competent.

One task is essentially above assignment. This is the dedicated laboratory task, which dominates its own computer.

All other tasks are assigned to MUMPS. This is not merely because it is the only other available computer. Rather, it is because all the other tasks demand flexible interaction and extensive string manipulation.

Notice the role assigned to the network in Figure 54. It is a tool. Logically, it is no different than any of the data paths. Consequently, the distinct computer systems can now be viewed as a single entity, controlled through a single menu (see Figure 15).

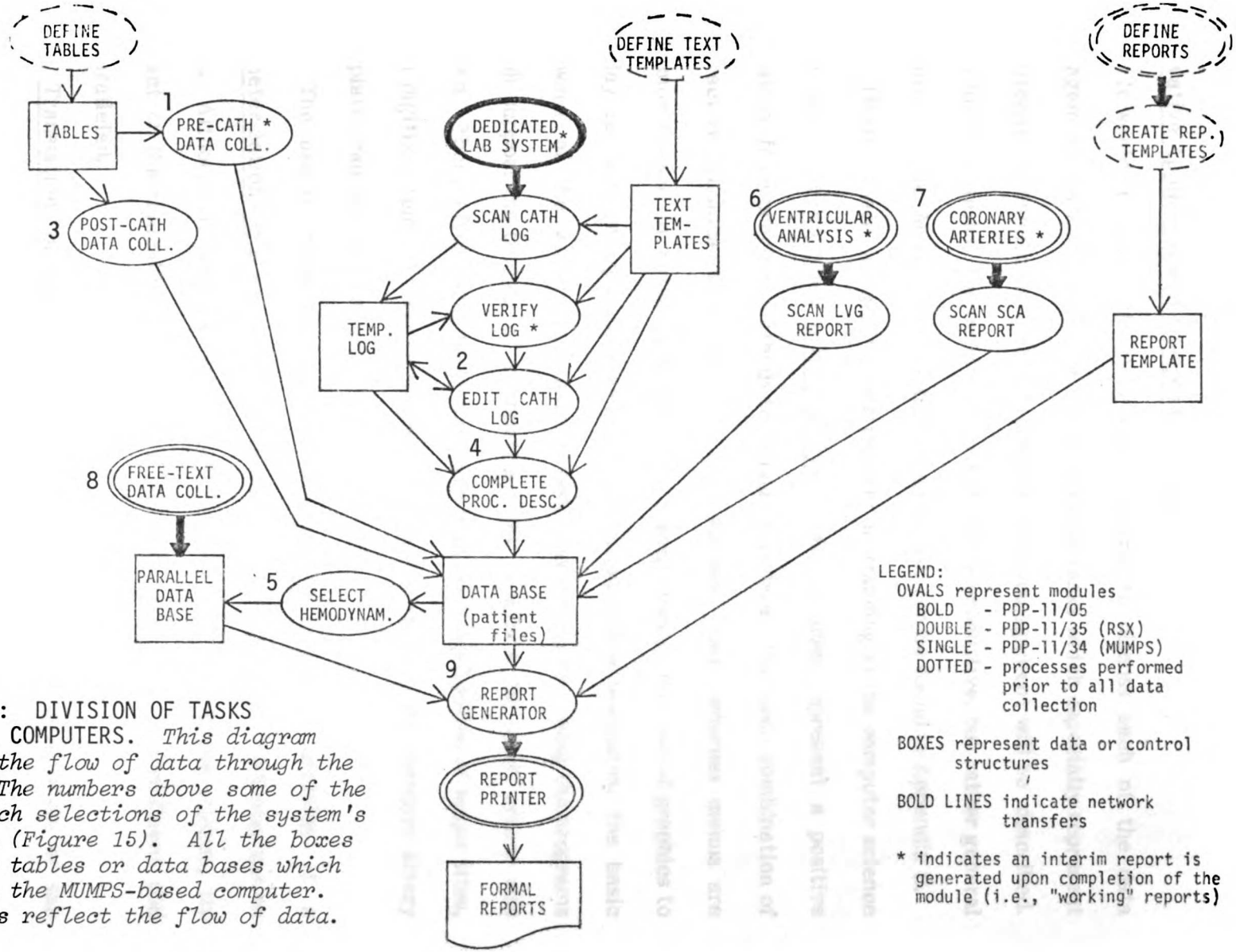


FIGURE 54: DIVISION OF TASKS AMONG THE COMPUTERS. *This diagram reflects the flow of data through the system. The numbers above some of the ovals match selections of the system's main menu (Figure 15). All the boxes represent tables or data bases which reside on the MUMPS-based computer. The arrows reflect the flow of data.*

Innovative Applications of Computer Science

It would be both distracting and tiresome to discuss each of the data management tasks. Therefore, only selected tasks which especially represent significant contributions to catheterization data management will be described. Even for these tasks, the details given will not be exhaustive, but rather general and informative. More precise detail for each task can be found in Appendix B.

Though there is nothing particularly outstanding in the computer science sense about the coronary artery analysis task, it does represent a positive deviation from previous methods to manage this data. The basic combination of interactive graphics and menus is key to its success. And, whereas menus are commonly used in catheterization data management, the use of graphics to display coronary artery templates is new. To create these templates, the basic software of the ventricular analysis task was employed. Using the programs which support the tracing of silhouettes, the template for each artery was traced. Then, after augmenting the trace with the specification of major sites, each digitized template was saved. Now, whenever relevant, the coronary artery templates can be displayed (as in Figures 37 - 41).

The use of menus to record maneuvers and events in creation of a catheterization log is a principle contribution to management of catheterization data. Although it may be simple and uninteresting to computer science, its impact on the clinical interpretation of hemodynamic data is significant and unparalleled.

Translation of the log into a natural language description of the catheterization procedure is facilitated by textual templates. Each maneuver and event translates to a set of sentences which are tailored to each patient through menus (Figure 55).

```
TEMPLATE #3:
   HEADER:     FEMORAL VEIN\\1\2!17\\<RL> femoral vein\10-JUN-80
    SENTENCE #1:    8\PB\\
         PART 1:    TEXT\2% xylocaine was used as the local anesthetic.
         PART 2:    TEXT\Using a Cournand needle and the Seldinger technique a
         PART 3:    MENU\MDN
         PART 4:    TEXT\sheath and dilator were
         PART 5:    TEXT\inserted into the
         PART 6:    MENU\RL
         PART 7:    TEXT\femoral vein.  The dilator was removed and
         PART 8:    TEXT\the sheath flushed with heparinized saline.


TEMPLATE #9:
   HEADER:     LVG (RAO) (F)\*\1\35!36,8,2\LHC,LVG\\10-JUN-80
    SENTENCE #1:    8\PB\\
         PART 1:    TEXT\The left ventriculogram was done in the 30 degree
         PART 2:    TEXT\RAO projection by power injection of
         PART 3:    NUM\20:50\cc's of Isopaque
         PART 4:    TEXT\cc of Isopaque 440 at
         PART 5:    NUM\10:16\cc/sec
         PART 6:    TEXT\cc/sec,
         PART 7:    NUM\200:900\psi
         PART 8:    TEXT\psi.
```

FIGURE 55: TEXTUAL TEMPLATES. *These templates are used to translate the maneuvers of the log into natural language. Two templates are illustrated. The upper template for the maneuver FEMORAL VEIN requires the clinician to select details from menus (MDN and RL). The lower template for the maneuver LVG (RAO) (F) requires the clinician to enter numeric quantities to reflect amounts (denoted by NUM). See the text for additional discussion as to the meaning of the data in the headers of these templates.*

These textual templates meet two goals of the translation. First, they are used to collect the details of each manuever. They are displayed with "blanks" for the non-TEXT parts (as in Figures 32 - 33). Then, according to the "blanked" part (e.g., MENU, NUM), appropriate queries are posed. As a second goal, the text within the templates, combined with the previously collected details, serves as the content which is formatted for the formal report. In contrast to the first goal, this aspect does not require the participation of the clinician. Therefore, it is not done interactively. Instead, formatting of the template text is conducted as a background, transparent task.

The text templates also define the encoding for abstraction of the general medical description. This is illustrated in Figure 55. Notice that the string "LHC,LVG" is contained in the template for LVG (RAO) (F). This particular string identifies two codes: LHC and LVG. These codes are then used to index into a table, thereby coding to a general description (specifically: LHC codes to Left Heart Catheterization, LVG codes to Left Ventriculogram; see Figures 46 and 49 for the use of this encoding). Again in Figure 55, notice that the template FEMORAL VEIN contains the string "<RL> femoral vein". This string is used for augmented translation. In this case, the selection for the menu RL is substituted, thereby identifying an invasive site. Used in combination with the encoded strings, the augmented translation completes the general description.

The textual templates serve still another function. Each template identifies those maneuvers which must precede it. The system uses the precedence scheme to verify that the log is complete and acceptably sequenced. The results of this review are then made available for clinician use (see Figure 25). To support the precedence scheme, each template contains a list of maneuvers. This list is coded, identifying the templates by number. For example, in Figure 55, FEMORAL VEIN lists "2!17" as prior maneuvers (which means

either template #2 or template #17 must precede this template, #3). In the sample figure, LVG (RAO) (F) lists "35!36,8,2". Here, templates 2 and 8 and either 35 or 36 must precede.

Verification and construction of a complete and orderly log also require several temporary tables. The most prominent among these contains the temporary procedure log. By convention, only complete data resides in the data base. Therefore, this table, which is indexed according to time, is used to facilitate editting. To further facilitate scanning, editting and reviewing of the log, a table of the times indexed according to template numbers is maintained. For each occurrence of a manuever its time is recorded in this table. Other tables maintained to assist in completing the log are a table of the drugs administered and a table of the times at which complications occurred.

The methods employed to support the definition and generation of reports represent an approach never before considered for catheterization data management. For the prototype system, the approach centers about a table of descriptors and the word-processing package. The entries in the descriptor table provide the user with a shorthand way of describing general patient data or aspects of a report (Figure 56). When these descriptors are used in conjunction with word-processing commands, the user can define the content and format of a report. For example Figure 57 illustrates a portion of the definition of the Referral Report (see Figure 49) using the word-processor under RSX. Notice that the descriptors are flanked by asterisks (e.g., **AGE**). After the user is satisfied with the report format, it is transmitted to MUMPS, where the format is scanned and the descriptors are validated. If any unknown descriptors are encountered, an account is transmitted back to RSX and the user is alerted. Otherwise, the report definition is stored, without modification, as a template.

So, when a report is generated, the appropriate template is scanned and

```
AGE       Patient Age in Years
ALB       Results of Albumin test
ANG       Returns Yes or No for Angina
ANGST     List of characteristics of Angina
ANGYR     Returns number of years patient has had Angina
BEG       Cath Begin Time (am / pm)
BLP       Baseline Pressures
BSA       Patient Body Surface Area
BUN       Results of BUN test
CDT       Date of Catheterization (or Today)
CHL       Results of Cholesterol lab test
  .
  .
  .
```

FIGURE 56: REPORT DESCRIPTORS. *This is a partial list of the available descriptors which can be used to define patient data. They are used in conjunction with word-processing commands to define and format reports.*

```
CENT_Report to Referring Physician
SKIP=2.
TABL=0.,Name:  **NAM**
TABL=25.,SS#: **SSN**
TABL=37.,Cath #: **CN**
SKIP=2.
TABL=0.,Age: **AGE**
TABL=8.,Sex: **SEX**
TABL=15.,Height: **HT** cm.
TABL=26.,Weight: **WT**  kg.
TABL=38.,BSA: **BSA** M2
SKIP=2.
TABL_0.,Procedures Performed
SKIP=2.
PARA
**PRO**
PARA
SKIP=1.
TABL_0.,Sites Affected
SKIP=2.
PARA
**SIT**
PARA
```

FIGURE 57: DEFINITION OF REFERRAL REPORT. *This is a portion of the definition of the referral report (see Figure 49). The report descriptors are used with the word-processing commands to define a general report format which can be customized for each patient.*

copied to a report table with the descriptors replaced by patient specific data. This is accomplished by using the descriptors as keys into a table. This table, in turn, contains MUMPS code which is then extracted as data. This data/code is subsequently evaluated and patient data is returned. The returned data may be single items, multiple lines of text or formatted tables.

Throughout the prototype system, menus are employed not only to collect data, but also in the generation of reports. As much of the collected data is stored in a coded form, the report generator uses the menus to decode them and produce natural language descriptions of that data. Accordingly, the menus play an important role in the system.

Yet, so far, the term "menu" has been used in a general context. Actually, the menus are of four basic forms. The first form simply consists of a list from which the user may select as many as are appropriate. Menus of this form are

```
 #1   Chronic Stable Angina Pectoris
 #2   Unstable Angina Pectoris
 #3   Recent Onset Angina
 #4   Atypical Chest Pain
 #5   Murmur of Aortic Stenosis
 #6   Murmur of Aortic Insufficiency
 #7   Murmur of Mitral Stenosis
 #8   Murmur of Mitral Insufficiency
 #9   Murmur of Pulmonic Stenosis
#10   Murmur of Tricuspid Insufficiency
#11   Pericardial Disease
#12   Murmur Suggesting IHSS
#13   Congestive Cardiac Failure
#14   Congenital Heart Disease
#15   Coronary Artery Disease
#16   Research
#17   Other
```

FIGURE 58: MENU FORM #1. *This form of menu presents choices from which the user may select as appropriate.*

used to collect the pre-catheterization diagnosis, the indication for the catheterization, the ventricular analysis types, the maneuvers and events and the coronary artery data. An example of this menu form is shown in Figure 58.

The second form of menu supports "conflict lists". These lists are used in determining whether or not selected choices are mutually exclusive. If mutually exclusive choices are selected, the system alerts the clinician. Menus of this form are for chest X-ray (Figure 59), electrocardiogram, and exercise tolerance test. Note that in Figure 59, choice #5 (Normal pulmonary vascularity) conflicts with choice #17 (Dilated pulmonary artery).

Also supported in the second menu form is a sub-menu option. This option is activated if the selected choice contains a sub-menu. At that time (after the choice is determined to be conflict-free), the sub-menu is presented to the clinician. An example of this option is seen in Figure 60. In the electrocardiogram menu, the choice of #16 activates the sub-menu ISA (which offers a choice of myocardial areas where ischemia is noted).

The third menu form is used in collecting the patient's present prescribed medications. This menu form identifies all acceptable dosing schemes for a drug. For each dosing scheme there is a route of administration, a dosage range, a range or list of the frequency of administration and the dosing units. A partial list of the known present medications is shown in Figure 61. At this time only one drug requires multiple dosing schemes (#49 Isosorbide dinitrate).

The fourth menu form is used to store the definitions of clinical laboratory tests. For each test considered, the name, units of measurement, possible range of results and the range of results for normal patients are recorded. The ranges are subsequently used to alert the clinician of abnormal results at the time of data entry. The form of this menu is illustrated in Figure 62.

```
#1    Normal heart size and pulmonary vascularity\3:4:6:7:8:9:10:11:12:13\
#2    Normal heart size\3:4:11:12:13:14:\
#3    Borderline heart size\1:2\
#4    Generalized cardiomegaly\1:2\
#5    Normal pulmonary vascularity\6:7:8:9:10:17\
  .
  .
  .
#24   See original x-ray report\\
```

FIGURE 59: MENU FORM #2. *This menu form augments the basic capabilities of form #1 by supporting the recognition of mutually exclusive selections. Those selections which conflict with a choice are listed by number, separated with colons (e.g., for #3, the list is "1:2").*

```
#1    Normal\\\\2:3:4:5:6:7:8:9:10:11:12:13:14:15:16:17:18:19:20:21\
#2    Anterior Myocardial Infarction\\\\1:11\
#3    Inferior Myocardial Infarction\\\\1:11\
#4    Lateral Myocardial Infarction\\\\1:11\
  .
  .
  .
#16   S-T and T wave changes indicating ischemia in ____\ISA\area\\1:17\
#17   Non-specific S-T and T wave changes\\\\\\\1:11:16\
  .
  .
  .
#30   See original ECG report\\\\\
```

FIGURE 60: MENU FORM #2 WITH SUB-MENUS. *This form of menu is similar to a basic form #2 menu, but it also allows a sub-menu to be presented to the clinician when appropriate selections are made. For example, choice #16 supports a sub-menu, ISA.*

```
#1    Acetaminiphen (Tylenol)\0\\\\\
#2    Allopurinol\1\p.o.\\\\
#3    Aminophylline\1\p.o.\200-400\qid,tid\mg\
#4    Amitriptyline (Elavil)\0\\\\\
#5    Amphetamine\0\\\\\
#6    Amphojel\0\\\\\
#7    Ampicillin\0\\\\\
#8    Antihistamines\0\\\\\
#9    Benadryl\1\p.o.\25-50\qid,tid\mg\
 .
 .
 .
```

FIGURE 61: MENU FORM #3. *This menu is used to support collection of prescription medications. See text for discussion.*

```
#1    Hct.\%\30-65\37-45\
#2    Hgb.\ g/100 ml.\8.0-19.0\12.0-18.0\
#3    WBC\/mm2\4000-15000\5000-8000\
#4    Cholesterol\ mg/100 ml.\150-1500\180-240\
#5    Triglycerides\ mg/100 ml.\50-1500\50-150\
#6    Uric Acid\ mg/100 ml.\2.5-15.0\2.5-8.0\
#7    FBS\ mg/100 ml.\65-400\65-110\
#8    BUN\ mg/100 ml.\10-100\10-20\
#9    Creatinine\ mg/100 ml.\0.7-20.0\0.7-1.4\
#10   Albumin\ g/100 ml.\2.0-6.0\3.5-5.0\
#11   Total Protein\ g/100 ml.\3.0-10.0\6.0-8.0\
```

FIGURE 62: MENU FORM #4. *This form of menu is used to collect data for clinical laboratory results. A similar version is used to collect the durgs administered during the catheterization.*

Assurance of timely report generation and availability is attained by marking data components as collected. This marking is done in a "working" patient table under MUMPS. This table maintains an entry for each patient whose final catheterization report has not yet been generated (see Figure 63). Several fields are available to reflect the status of data collection. Accordingly, each data collection task of the system submits an update to this table when appropriate, either directly (by tasks assigned to the MUMPS system) or indirectly (using the network).

```
CATH #    NAME \ DATE \ FIELDS ...

99995     TEST\24-SEP-80\4\1\\1\1\\1\1\1\1\1\1\1\1\...
99997     BROWN, L.\25-SEP-80\4\\\1\1\\1\1\1\1\1\1\1\...
99998     DOE, J.\25-SEP-80\4\1\1\1\1\1\1\1\1\1\1\1\...
99999     SAMPLE\26-SEP-80\4\1\1\1\1\1\1\1\1\1\1\1\...
```

FIGURE 63: "WORKING" PATIENT TABLE. *This table is used to record the status of data collection and report generation for each patient. It is reviewed daily to create the Status report (see Figure 50).*

Generation of the Status Report (see Figure 50) is dependent on the "working" patient table. Every night the system reviews this table and formats a report highlighting delinquent data collection. This report is then transmitted from the MUMPS-based computer to the report printing computer (RSX) for clinician inspection the next morning.

Chapter 8: Summary, Future Work and Conclusions

This dissertation represents an effort to advance the management of clinical cardiac catheterization data. In this effort, several contributions to medical information science have been realized. A machine-independent computer network has been developed. In conjunction with the implementation of this network, it has been demonstrated that resources on diverse computer systems can be collectively utilized to meet clinical data management goals. And, finally, a new and enhanced system for managing cardiac catheterization data has evolved.

To justify this research, two fundamental tasks were performed. First, the goals of managing clinical catheterization data were outlined. This discussion centered about the timeliness, stability, accessibility, clinical utility and forms of data which define the catheterization environment. Then, in the context of this profile, the efforts and contributions of previous research were evaluated. It was thereby determined that a new and more comprehensive approach to managing clinical cardiac catheterization data was essential.

To meet the clinical goals of the catheterization laboratory, a model was proposed. This model concentrated on general requirements for creating a clinician-convenient system which would support collection, coordination and reporting of comprehensive data. It was further stated that implementation of the model would require diverse computer resources and multiple computers. Therefore, an essential aspect of the model centered about the employment of a computer communication network.

The first task in constructing a prototype of the model was to design and implement a network which could run under diverse computer systems with limited physical resources. Such a network was created and has operated

successfully for over two years.

Then, using the network to link the necessary computers and resources, the prototype system for clinical use was developed. This prototype introduced several innovative applications of computer science methods for the purpose of managing clinical data. The use and outcomes of the prototype were demonstrated and discussed.

Future Work

Whereas the prototype system has been shown to be proficient in meeting clinical goals, there are areas where additional efforts could further enhance its overall utility. Some of these areas would add to the clinical usefulness of the system. Primarily, these efforts would enchance the research utility of the system.

A significant challenge is offered in enhancing the methods for collection of coronary artery data. The objective here would be to design a graphics technique to customize the templates of the coronary arteries for each patient. This technique need not be concerned with repositioning every deviation of the patient's anatomy. Rather, a method for "moving" some branches of an artery is needed. Also, this technique could allow the clinician to "draw" additional branches, grafts and collateral flow. It could also support deletion of branches. To define occlusions, the clinician would "draw" the obstruction. So, for example, the artery template for the left anterior descending artery could be transformed to appear as in Figure 64. In fact, this process matches that which is performed in manual reporting systems.

This is not to say that the prototype is deficient, because it does meet the basic clinical goals of recording and reporting coronary artery data. However, for research purposes especially, the prototype may not provide sufficient accuracy. Yet to develop this alternate method for collection of coronary artery

data, a higher resolution graphics display device (the available devices allow for a 512 by 512 grid) is necessary. And, if the higher resolution display device is capable of color display, this alternative could be expanded to color code the occlusions according to severity. Moreover, the task of extracting and comparing this enhanced data for research poses an additional challenge.

FIGURE 64: ADJUSTMENT OF ARTERY TEMPLATE. *This figure illustrates the benefits of a graphics system to support "moving" a branch and "drawing" occlusions. The dotted branch is the standard site for the branch, but the clinician "moved" it. Now it can be seen that the occlusion does not affect that branch of the artery.*

The report printing process could also be improved. Currently, the catheterization reports are printed using a letter quality printer (with either single sheets or continuous unbursted forms). However, this medium does not provide for representation of the graphic data for either the ventricular silhouettes or the templates of the coronary arteries. Therefore, acquisition of a letter/graphics output printer (such as a Versatec printer/plotter) would allow the system to print not only the text, but also the ventricular silhouettes and the coronary arteries.

The prototype could also be used as an instructional aid. As previously

stated, the system can maintain a set of hypothetical patients and these patients can be worked up by the clinicians in training. But there is no facility for the instructor to review the student's entries and conclusions. It would be useful if the supervising cardiologist could enter "notes" which the trainee would review later.

To assist the clinician in reaching impressions and recommendations, the system could draw attention to "unusual" results to ensure that they do not escape review. This does not suggest automated diagnosis. Rather, a means for reminding the clinician is suggested.

Examination of the parallel data base of the prototype system (which holds the less structured data such as the history and impressions) reveals a plethora of data which may be useful to researchers and clinicians. To support queries of this data, methods are necessary which can review and extract appropriate words or phrases. Because these data are "free text" and therefore totally unformatted, this task is possibly non-determinant and certainly complex. Yet the majority of data contained in the general medical record are of this form. Methods to recognize clinical phrases in relation to other phrases would allow systems to be less dependent on restricted menu formats and would provide means to collect all data for a patient.

Equally, the development of a query system to phrase questions and receive responses from the system is needed. Although the report generator does pose pseudo-queries for a specific patient, the data requested are usually contained in a single record of the patient's file. Queries referring to time-oriented issues cannot be posed or answered at this time.

Though the prototype has been demonstrated, the formal evaluation of the model is beyond the scope of this dissertation. Therefore, a long term, well structured evaluation of the prototype system needs to be conducted. To

accomplish this, auditting capabilities are being added to the system. These audit functions are transparent to the users and do not affect the system's operation. The incidences of editting the log, recording pre-catheterization data and other functions will be studied to locate sites for fine tuning the system. Comments from the clinical staff are being encouraged. It is expected that the results from this study will provide useful insight to the design and development of distributed clinical computer systems for the collection, coordination and reporting of data.

Conclusions

The prototype system represents a significant advancement in the management of clinical data for the cardiac catheterization laboratory at the San Francisco Veterans' Administration Medical Center. Yet it is unrealistic to believe that its impact is bound to catheterization data management alone. In fact, the goals of most clinical services parallel those of the catheterization laboratory. Moreover, the goals of data management of hospitals in general can be described according to the same framework.

Furthermore, it is becoming increasingly apparent that the era of single computer medical systems is fading. More and more clinical services and hospitals are realizing that multiple computers and diverse resources are the keys to successful and useful data management. Accordingly, the issue of coordinating these medical information management tools is advanced by this research.

This research verifies that diverse computer resources can be coordinated to meet clinical goals. In essence, computer-based management of clinical data is no longer defined by the limitations of a single computer. Rather, it is shown that consideration of clinical needs and goals is the dictating force which defines essential resources.

REFERENCES

1. Adiba, M., Chupin, J.C., Demolombe, R., Gardarin, G., Le Bihan, J. "Issues in Distributed Data Base Management Systems: A Technical Overview", Proc 4th International Conf on Very Large Data Bases, (Sep 13-15, 1978), 89-110.

2. Adlassnig, K.P., Gergely, T., Grabner, H., and Grabner, G., "A Computer Assisted System for Diagnostic Decision Making System WAMIS", Proc Medinfo77, IFIP, (1977), 213-218.

3. Alderman, E.L., Spitz, A.L., Sanders, W.J., and Harrison, D.C., "Use and Value of the Computer in the Cardiac Catheterization Laboratory", CHEST 71(4):526-530, April 1977.

4. Alderman, E.L., Spitz, A.L., Sanders, W.J., and Harrison, D.C., "A Cardiologist's Evaluation of a Computer Cardiac Catheterization System", Computers in Cardiology, IEEE, (Oct 2-4,1974), 81-83.

5. Anderson, G.A. and Jensen, E.D. "Computer Interconnection Structures: Taxonomy, Characteristics, and Examples", Computing Surveys 7,4 (Dec 1975), 197-213.

6. Austen, W.G., Edwards, J.E., Frye, R.L., Gensini, G.G., Gott, V.L., Griffith, L.S.C., McGoom, D.C., Murphy, M.L., Roe, B.B. "A Reporting System on Patients Evaluated for Coronary Artery Disease", (AHA Committee Report), Circ 51 (April 1975), 5-40.

7. Bakker, A.R. "Centralized versus de-Centralized Hospital Information Systems", Proc Medinfo77, IFIP, (1977), 895-899.

8. Barnett, G.O. and Greenes, R.A. "Interface Aspects of a Hospital Information System", Ann NY Acad Sci 161 (1969), 756-768.

9. Barnhard, H.J., Jacobson, H.G., and Nance, J.W. "Diagnostic Radiology Information System (DRIS)", Radiologe 14 (1974), 314-319.

10. Brandenburger, G.H., Hieb, B.R., Garfield, S.A., Krone, R.J., Ludbrook, P.A., Cox, J.R.Jr., Oliver, G.C. "A New Cardiac Catheterization Laboratory Computer", Computers in Cardiology, IEEE, (Oct 7-9,1976), 343-346.

11. Brolin, I. "MEDELA: An Electronic Data-Processing System for Radiological Reporting", RADIOLOGY 103 (May 1972), 249-255.

12. Bross, I.D.J., Gregory, A.R., Rathod, C., Bross, D.S. "Unobtrusive Biomedical Data-Input Systems", Bio-Medical Computing 4 (1973), 219-228.

13. Brown, D. "Augmenting a PDP-9/MIIS System: Software and Hardware", (personal communication from Dr. D.H. Glaser, Oct 17, 1977)

14. Brower, R.W., Meester, G.T., Zellenberg, C., Hugenholtz, P.G. "Automatic Data Processing in the Cardiac Catheterization Laboratory", Comp Prog Biomed 7,2 (1977), 99-110.

15. Clayton, P.D., Urie, P.M., Marshall, H.W., Warner, H.R. "A Computer System for the Cardiovascular Laboratory", Comps in Card, IEEE, (Oct 2-4, 1974), 89-93.

16. Collen, M.F. Hospital Computer Systems. John Wiley & Sons, Inc., New York, 1974.

17. Cornee, J., Chanon, M., Trouve, C., and Rodriguez, M. "Computer Management of Medical Records, External Consultations, and Archives in a Gastro-Enterology Department", Meth Info Med 16,1 (1977), 11-19.

18. Covvey, H.D., Olley, P.M., Wigle, E.D. "A Review of Commercial Computer-Based Systems in the Cardiac Catheterization Laboratory", Cath and Cardiovasc Diag 4 (1978), 439-474.

19. Covvey, H.D., Dubien, R.J., Sevcik, K.C., and Wigle, E.D. "An Information System for Clinical Cardiovascular Research: Yesterday and Today", Proc Medinfo77 (1977), 657-661.

20. Covvey, H.D., Olley, P.M., and Wigle, E.D. "Computers in the Cath Lab: Look Before You Leap", Cath & Cardiov Diag 3 (1977), 341-345.

21. Covvey, H.D., Olley, P.M., and Wigle, E.D. "A Critical Review of Commercial Computer Systems for the Cardiac Catheterization Laboratory", Comps in Card (Oct 7-9, 1976), 327-341.

22. Cruce, J.L. "Variations on Computer Conversations (1) A Young Computer Network", Proc MUMPS Users Group (1976), 16-20.

23. Cruce, J.L., and Simmons, R.L. "Variations on Computer Conversations II: Maturing Computer Network", Proc MUMPS User's Group (1977), 12-19.

24. DeBakey, M.E. and Gotto, A. The Living Heart. David McKay Company, Inc., New York, N.Y., 1977.

25. Feinstein, A.R. Clinical Judgment. Robert E. Krieger Publishing Co., Huntington, New York, 1967.

26. Friedman, R.B., and Gustafson, D.H. "Computers in Clinical Medicine, A Critical Review (Guest Editorial)", Comps & Biomed Res 10 (1977), 199-204.

27. Fry, J.B. and Sibley, E.H. "Evolution of Data-Base Management Systems", Computing Surveys 8,1 (March 1976), 7-42.

28. Gardner, R.M. "Monitoring of Physiological Data In a Clinical Environment", Annual Review of Biophysics and Bioengineering (1972), 211-224.

29. Gardner, R.M. and Clemmer, T.P. "Computerized Protocols Applied to Acute Patient Care", Advances in Automated Analysis (1976), 158-163.

30. Gensini, G.G. Coronary Arteriography. Future Publishing Company, Mount Kisco, New York, 1975.

31. Gensini, G.G. "Automation in Acquisition, Storage and Retrieval of Clinical Hemodynamic and Angiographic Data", Comps & Card (Oct 2-4, 1974), 85-88.

32. Gensini, G.G., Kelly, A.E., Esente, P., and Szenczy, C. "Acquisition and Management of a Clinical and Angiographic Database in Patients with Ischemic Heart Disease", Comps in Card (Oct 2-4, 1975), 65-68.

33. Germano, F.,Jr. "The Design of a Mini-Based Time-Oriented Medical Record Databank System", Proc MUMPS User's Group (1977), 49-60.

34. Giebink, G.A. and Hurst, L.L. Computer Projects in Health Care Health Administration Press, Ann Arbor, Michigan, 1975.

35. Glaser, B., Merier, G., Zeelenberg, C., van Dalen, F.J. "Thoraxcenter Utility System (TUS): Level 1 Available", Comps in Card (Oct 7-9, 1976), 405-408.

36. Greenes, R.A., Barnett, G.O., Klein, S.W., Robbins, A., Prior, R.E. "Recording, Retrieval and Review of Medical Data by Physician-Computer Interaction", NEJM 282,6 (5 Feb 1970), 307-315.

37. Groner, G.F., Hopwood, M.D., et al "An Interactive Data Management and Analysis System for Clinical Investigators", J of Lab and Clin Med 92,3 (Sept 1978), 325-340.

38. Groner, G.F., Palley, N.A., and Shapiro, N.Z. "A Structural Characterization of Clinical Research Participants and their Activities", Rand Corporation Report R-1540-NIH, January, 1975.

39. Grossman, W.(ed.) Cardiac Catheterization and Angiography. Lea & Febiger, Philadelphia, 1976.

40. Hamilton, K.K., Alderman, E.L., Silverman, J.F., Sanders, W.J. "Computer Reporting of Coronary Arteriograms Using Interactive Graphics", Computers in Cardiology, IEEE, (Sep 26-28, 1979), 111-116.

41. Hamilton, K.K., Alderman, E.L. "An Interactive Text Generator for the Production of Standardized Medical Reports", Computers in Cardiology, IEEE, (Sep 12-14, 1978), 369-372.

42. Harris, D.K.(ed.) "Computerized Radiology Reporting System", Comps and Med 5,4 (July/Aug 1976).

43. Hercz, L., Laszlo, A., and Reesal, M.R. "A Computerized Information System for Pathology", Meth Inform Med 14,4 (1975), 181-188.

44. Hoare, M.R., Tech, B., Meester, G.T. "Computer-Aided Shunt Detection Re-Visited", Computers in Cardiology, IEEE, (Sep 12-14, 1978), 375-378.

45. Hood, W.P.,Jr., Strand, E.M., Wixson, S.E., Mantle, J.A., Smith, L.R., Zisserman, D., Rogers, W.J., Russel, R.O.,Jr., and Rackley, C.E. "Catheterization & Angiographic Analysis Computer Applications", Computers in Cardiology, IEEE, (Oct 2-4,1975), 131-135.

46. Hopwood, M.D., Groner, G.F., et al "An Evaluation of the CLINFO Data Management and Analysis System", Rand Corporation Report R-2260-NIH, Nov 1977.

47. Horowitz, L.M., Schreiber, B.B., Conners, R.B., Dwyer, E.M. "A Natural Language Reporting System for the Cardiac Catheterization Laboratory", Computers in Cardiology, IEEE, (Sep 12-14, 1978), 131-140.

48. Jasper, D.P. "Principles of Network Design", from Computer Networks: A Tutorial, IEEE, October 1975.

49. Juergens, J.L. and Kiely, J.M. "Physician Entry of Cardiac Physical Findings into a Computer-Based Medical Record", Mayo Clinic Proc 44 (June 1969), 361-366.

50. Keltz, P.D., Pfeil, C.N., Gertz, E.W., Okawachi, M.H., Korte, R.L. "A Minicomputer Network for Diverse Operating Systems and Languages", Proc 13th Annual Hawaii International Conf on System Sciences, Vol III, ed. B. Shriver, (Jan 3-4, 1980), 316-324.

51. Keltz, P.D., Pfeil, C.N., Houser, A.R., and Gertz, E.W. "Command-Based Graphics for Non-Computer Specialists", Proc the 13th Annual Hawaii International Conference on Systems Science, Vol III, ed. B. Shriver, (Jan 3-4, 1980), 542-549.

52. Kennedy, T.C.S. "Some Behavioral Factors Affecting the Training of Naive Users of an Interactive Computer System", Int J Man-Machine Studies 7 (1975), 817-834.

53. Kimbleton, S.R. and Schneider, G.M. "Computer Communication Networks: Approaches, Objectives, and Performance Considerations", Computing Surveys 7,3 (1975), 129-173.

54. Klarman, H.E. "The Financing of Health Care" (in Doing Better and Feeling Worse ed. J.H. Knowles), W.W. Norton & Co., Inc., New York, 1977.

55. Klonoff, H. and Clark, C. "Measuring Staff Attitudes Toward Computerization", Hosp & Comm Psychiatry 26,12 (Dec 1975), 823-825.

56. Krone, R.J., Igielnik, S., Miller, J.P. "A Computerized Cardiology Report Generating/Data Management System", Computers in Cardiology, IEEE, (Sep 1979), 469-472.

57. Little, R.C. Physiology of the Heart and Circulation Year Book Medical Publishers, Inc., Chicago, Ill., 1977.

58. Longmore, D. The Heart. World University Library, McGraw-Hill Book Company, New York, N.Y., 1971.

59. Lusskin, R.L., Korein, J., Thompson, W.A.L., and Heffernan, T. "Computer Management of Clinical Information: Capture and Retrieval of Clinical Orthopedic Data by Means of the Variable-field-length Format", Bull NY Acad Med 48,8 (Sept 1972), 1014-1032.

60. Mani, R.L. "RAPORT Radiology System: Results of Clinical Trials", Am J Roentgenol 127 (1976), 811-816.

61. Mateosian, S.R.(ed.) "Current Medical Information Systems", Technical Report #22, Laboratory of Med Info Sci, Aug 1976.

62. Mathew, R.J., Kulikowski, C.A., and Kaplan, K.R. "A Multileveled Representation for Knowledge Acquisition in Medical Consultations Systems", Proc Medinfo77, 151-156.

63. Meldman, M.J., Harris, D., Pellicore, R.J., and Johnson, E.L. "A Computer-Assisted, Goal-Oriented Psychiatric Progress Note System", Am J Psychiatry 134,1 (Jan 1977), 38-41.

64. Merier, G., Glaser, B., and Brower, R. "An Interactive Computer System for Assessment of Coronary Bypass Surgery", Proc MUMPS User's Group, (1976), 80-84.

65. Meyer, J.L., Kline, S.A., Blank, S.G., and Friedman, W. "Quality Control in a Computerized Cardiac Catheterization System", Computers in Cardiology, (Oct 7-9, 1976), 347-352.

66. McDonald, C.J. "Use of a Computer to Detect and Respond to Clinical Events: Its Effect on Clinician Behavior", Ann Int Med 84 (1976), 162-167.

67. O'Rourke, M.F. and Smith, R.L. "A Practical System of Computerized Medical Records for Documentation and Decision Making in the Coronary Care Ward", Med J Aust 1 (1975), 301-304.

68. Palley, N.A. and Groner, G.F. "A Survey of Clinical Investigators and Their Information Processing Activities", Rand Corp Report R-1539-NIH, July 1974.

69. Pfeil, C.N., Keltz, P.D., Gertz, E.W. "Characterization of a MUMPS System within a Machine Independent Computer Network", Proc MUMPS Users Group, (May 14-16, 1980), in press.

70. Pfeil, C.N., Keltz, P.D., Korte, R.L., Gertz, E.W. "Medical Mini-Computer Systems: Increased Resource Utilization Through Networking", Proc of the Society for Computer Medicine, (Nov 8-10, 1979), in press.

71. Phibbs, B. The Human Heart A guide to heart disease. C.V.Mosby Co., St. Louis, 1975, 77-78.

72. Platt, R.C., Wong, R.L., Lantner, K.W., and Gaynon, P.S. "POLARS: A Pathology On-Line Logging and Reporting System", Comp Biomed Res 7 (1974), 83-99.

73. Pryor, T.A., Morgan, J.D., Clark, S.J., Miller, W.A., and Warner, H.R. "HELP -A Computer System for Medical Decision Making", Computer (Jan 1975), 34-38.

74. Rickards, A. "The Use of a Mini Computer for On Line Data Analysis and Management of Cardiac Catheterization Data", Computers in Cardiology, IEEE, (Sep 26-28, 1979), 117-120.

75. Robinson, R.E.,III and Meschan, I. "Computerized Radiological Reporting with Word Retrieval Using MT/ST", Radiology 101 (Nov 1971), 323-329.

76. Saffer, S.I., Mishelevich, D.J., Fox, S.J., Summerour, V.B. "NODAS -The Network-Oriented Data Acquisition System for the Medical Environment", Proc of NCC, AFIPS, (1977), 295-299.

77. Schwartz, M., Boorstyn, R.R., and Pickholtz, R.L. "Terminal-Oriented Computer-Communication Networks", Proc. IEEE 60,11 (November 1972), 1408-1423.

78. Seltzer, R.A. "The Impact of Computerized Radiological Reporting Systems on the Radiologist", Radiology 118 (Mar 1976), 737-739.

79. Seltzer, R.A., Reimer, G.W., Cooperman, L.R., Rossiter, S.B. "Computerized Radiographic Reporting in a Community Hospital: A Consumers Report", Am J Roentgenol 128 (May 1977), 825-829.

80. Shortliffe, E.H. Computer-Based Medical Consultations: MYCIN. American Elsevier Publishing Co, New York, 1976.

81. Simon, M., Leeming, B., Bleich, H., et al "Computerized Radiology Reporting Using Coded Language", Radiology 113 (Nov 1974), 343-349.

82. Slack, W.V., VanCura, L.J., Greist, J.H. "Computers and Doctors: Use and Consequences", Comp & Biomed Res 3 (1970), 521-527.

83. Sobolewski, J.S. "Hierarchical Computer Network for Cardio-vascular Data Acquisition and Population Studies", Computers in Cardiology, IEEE, (Oct 2-4, 1975), 69-74.

84. South, J., Rhodes, P. "Computer Service for Obstetric Records", Br Med J 4 (2 Oct 1971), 32-35.

85. Spitz, A.L., Alderman, E.L., and Harrison, D.C. "Experience with a Multistation, Expanded Function Computerized Cardiac Catheter-ization Laboratory", Computers in Cardiology, IEEE, (Oct 2-4, 1975), 121-126.

86. Starmer, C.F. and Smith, W.M. "Problems in Acquisition and Representation of Coronary Arterial Trees", Computers in Cardiology, IEEE, (Oct 2-4, 1974), 143-147.

87. Startsman, T.S. and Robinson, R.E. "The Attitudes of Medical and Paramedical Personnel Toward Computers", Comps & Biomed Res 5 (1972), 218-227.

88. Stead, W.W., Brame, R.G., Hammond, W.E., Jelovsek, F.R., Estes, E.H., and Parker, R.T. "A Computerized Obstetric Medical Record", Obstetrics & Gynecology 49,4 (Apr 1977), 502-509.

89. Stillman, R.M., Mitchell, W.G., Shaftan, G.W., Sawyer, P.N., and Kountz, S.L. "The Computer as an Unbiased Medical Investigator", Am J Surg 132,8 (Aug 1976), 209-213.

90. Studney, D.R., Adams, J.B., Gorbach, A., Guenthner, S., Morgan, M.M., and Barnett, G.O. "A Computerized Prenatal Record", Obstetrics & Gynecology 50,1 (July 1977), 82-86.

91. Swanson, D.B., Feltovich, P.J., and Johnson, P.E. "Psychological Analysis of Physician Expertise: Implications for Design of Decision Support Systems", Proc Medinfo77, IFIP, (1977), 161-164.

92. Tanenbaum, A.S. Computer Networks. Prentice Hall, Inc., Englewood Cliffs, New Jersey, 1981.

93. Tsichritzis, D.C., Lochovsky, F.H. "Hierarchical Data-Base Management", Comp Surveys, 8(1), (March 1976), 105-123.

94. Trost, R.F., Glaser, D.H., and Brown, D.B. "A Comprehensive Data Management Technique for Clinical Research", presented at 14th Annual Meeting of the San Diego Biomedical Symposium, Feb 1975.

95. Vagdall, S. "Mini-Cine Documentation", internal document of the Cardiac Catheterization Laboratory at the San Francisco Veterans' Administration Medical Center

96. Van Bemmel, J.H. "The Role of Computers in Cardiology and Clinical Physiology", Proc Medinfo77, IFIP, (1977), 819-827.

97. Verel, D., Grainger, R.G. Cardiac Catheterization and Angiocardiography Churchill Livingstone, Edinburgh, London, and New York, 1978.

98. Vinsonhaler, J.F., Wagner, C.C., and Elstein, A.S. "The Inquiry Theory: An Information Processing Approach to Clinical Problem Solving", Proc Medinfo77, IFIP, (1977), 157-160.

99. Wallace, A.G. and Rosati, R.A. "Computers Can Change Cardiology", Circ (editorial) XLVII (Mar 1973), 439-442.

100. Watson, R.J. "Medical Staff Response to a Medical Information System with Direct Physician-Computer Interface", Proc Medinfo77, IFIP, (1977), 299-302.

101. Wess, B.P.Jr. "Disitributed computer Networks in Support of Complex Group Practices", Proc 2nd Annual Symposium on Computer Applications in Medical Care, IEEE, (Nov 5-9, 1978), 469-477.

102. Wheeler, P.S., Simborg, D.W., and Gitlin, J.N. "The Johns Hopkins Radiology Reporting System", Radiology 119 (May 1976), 315-319.

103. Wiederhold, G., Fries, J.F., and Weyl, S. "Structured Organization of Clinical Data Bases", Proc of NCC, AFIPS, Montvale, New Jersey, (1975), 479-485.

104. Willems, J.L., Piessens, J. "Implementation and Experiences with a Computer Based Coronary Artery Reporting and Information System", Computers in Cardiology, IEEE, (Sep 29 - Oct 1, 1977), 465-470.

105. Wilson, D.H. and Robbins, G.P. "Integration of the Computer in Medical Practice", Proc of 5th Annual Conf for SCM.

106. Yang, S.S., Bentivoglio, L.G., Maranhao, V., and Goldberg, H. From Cardiac Catheterization Data to Hemodynamic Parameters F.A. Davis Company, Philadelphia, PA., 1978.

107. Yianilos, P.N. and Harbort, R.A. "A Table-Driven Report Generator for Medical Records", Presented at 31st ACEMB, (Oct 21-25, 1978).

108. Zollinger, R.M., Kruel, J.F., and Schneider, A.J.L. "Man-Made versus Computer-Generated Anesthesia Records", J of Surg Res 22,4 (April 1977), 419-424.

109. Computers in Patient Care and Medical Education Status Report. Laboratory of Computer Science, Harvard Medical School and Massachusetts General Hospital, 1974.

110. 1980 Britannica Book of the Year Encyclopaedia Britannica, Inc., Chicago, Ill., 1980.

111. MUMPS-11 Language Reference Manual. Digital Equipment Corporation, Maynard, Mass., 1976.

112. MUMPS-11 Programmer's Guide. Digital Equipment Corporation, Maynard, Mass., April, 1977.

113. Systems Programmer's Manual for the Mennen Medical, Inc. Computer-Supported Catheterization Laboratory System. Mennen Medical, Inc., Clarence, New York, May 1977.

114. Introduction to Mini-Computer Networks. Digital Equipment Corporation, Maynard, Mass., 1974.

115. Authorized ADP Schedule Price List. Digital Equipment Corporation, Maynard, Mass., 1978.

116. Word Processing Operator's Manual V3.3, Internal document of the Cardiac Catheterization Laboratory at the San Francisco Veterans' Administration Medical Center, Sep. 4, 1980.

GLOSSARY

Angiocardiography
: The process of injecting radio-opaque dyes into the various chambers or coronary arteries. Usually accompanied by filming of X-ray motion films (Cinē films). These films are later reviewed for detection of abnormalities of the blood flow through these arteries.

Aorta
: The major artery. It carries blood from the left ventricle to the systemic circulatory system.

Atrium (Atria)
: The thin walled chambers of the heart which receive blood from the veins. There is an atrium for the right side of the heart and a separate atrium for the left side of the heart. Blood collects in the atria before it is pumped into the respective ventricles.

Brachial Approach
: A general approach to catheterizing the heart. The systemic circulation is entered via the brachial veins and arteries in the upper arm(s) just above the elbow.

Cardiac Catheterization
: A complex invasive procedure where catheters are introduced into the great vessels and chambers for measurement of hemodynamics and injection of radio-opaque agents for X-ray films.

Cardiac Output
: The amount of blood pumped by the heart, expressed per unit of time (usually as Liters per Minute).

Category
: A mechanism which is activated upon encountering a trigger.

Catheters
: Long, narrow, hollow, flexible tubes which can be threaded through the systemic circulation to the heart and great vessels, through which pressures can be measured and contrast agents can be injected.

Chamber
: A cavity of the heart. There are four chambers, two atria and two ventricles.

Cinē Films
: X-ray motion films. Used to film chambers and vessels which have been injected with a radio-opaque agent.

Circumflex Artery
: A major branch of the Left Coronary Artery.

Collateral Flow
: The flow of blood from a branch of a coronary artery to another branch of a coronary artery. (Not normally present, it develops due to severe obstruction in the vessel receiving the collateral flow.)

Coronary Arteries
: The arteries which carry blood and nourishment to the heart tissues. Unobstructed flow through these arteries is essential for normal heart function. There are two coronary arteries: Right Coronary Artery and Left Coronary Artery (with two major branches: Left Anterior Descending and Circumflex).

Coronary Artery Bypass Surgery
: A surgical procedure where a graft is attached to aorta and distal to the site of obstruction in the coronary artery. Thereby, the blood can flow through the graft and circumvent the obstruction.

Coronary Artery Disease (CAD)
: Generally refers to obstructions in the Coronary Arteries which reduce the flow of blood to the heart tissues. The major cause of mortality and morbidity in the United States.

Data Base
: Any organized collection of data.

Diastole
: A phase or period of the cycle of the heart when the muscle is relaxing and largest in size and lowest in internal pressure.

Disks
: Physical devices used by computers to store data. Many sizes are available. Floppy disks are smallest, holding, at best, 125,000 characters. Other, larger models hold millions of characters.

Echocardiogram
: A non-invasive test to measure the size and movement of the chambers and valves in the heart.

Electrocardiogram (ECG or EKG)
: A non-invasive test to measure the electrical properties of the heart.

Event
: Something which arises during the catheterization, such as hemodynamics or complications.

Exercise test
: A non-invasive test to measure the electrical properties of the heart when the patient is stressed. Also referred to as Stress testing or Treadmill testing.

Femoral Approach
: A general approach to catheterizing the heart where the systemic circulation is entered via the femoral veins and arteries in the groin.

Graph Pen
: A pen shaped device used to transmit X-Y coordinates to a computer. The user may combine single point entries (for selecting menu options) or continuous point entries (for drawing silhouettes).

Great Vessels
: The major arteries and veins surrounding the heart. There are four: Aorta, Pulmonary Artery, Pulmonary Veins, Vena Cava.

Hardware
: The physical components of a computer.

Hemodynamics
: The pressures and flows created by the pumping action of the heart.

Ischemia
: Condition caused by a decrease in oxygen provided to heart tissue. Generally causes "chest pain" or angina.

"Layered" Structures
: A partitioning of knowledge or data for purposes of inference (62).

Log
: A record of maneuvers, events and calculated parameters. Each entry is marked with its time of occurrence.

Maneuver
: A task which is deliberately performed during the catheterization procedure, such as inserting a catheter or administering a drug.

Mass Storage
: Usually refers to disks (on-line). May also involve magnetic tapes (off-line).

Menu
: A list of choices which is presented to the user via computer interaction.

Myocardial Infarction
: Death of part of the heart tissue due to ischemia. Commonly referred to as a "heart attack".

Network (Computer)
: A systematic interconnection of two or more computers for the exchange of messages.

Oximetry
: The measurement of oxygen in the blood in the vessels and chambers of the heart.

Protocol (Catheterization)
: A carefully planned approach which allow for the measurement and examination of all parameters necessary to evaluate a patient's heart condition.

Protocol (Network Communication)
A formal set of conventions governing the form and order of message exchange between two computers.

Pulmonary Artery
The artery which carries blood from the right ventricle to the lungs.

Pulmonary Veins
The major veins which carry blood from the lungs to the left atrium.

Pulmonary Circulation
The veins and arteries which transport blood through the lungs.

Real-Time
A computer operating system. Invariably dedicated to a single task.

Resolution
The degree of precision offered by a video display. Low resolution results in angular, imprecise displays. High resolution promotes smooth curves and precise displays.

Software
The programs which run on a computer.

Systemic Circulation
The veins and arteries which transport blood through the body, excluding the lungs.

Systole
A phase or period of the cycle of the heart when the muscle is contracting and smallest in size and highest in internal pressure.

Task
A collection of programs designed to perform a well-defined function.

Time-sharing
A computer operating system. The computer serves several users / tasks "simultaneously".

Trigger
A mechanism which sparks activation of another mechanism (category).

Valves
The "doors" between the heart chambers and veins and arteries. These valves open to permit blood to flow forward and close to prevent backwash of blood. There are four major valves: Aortic, Pulmonic, Mitral, Tricuspid.

Vena Cava
The major veins which carry blood from the body to the right atrium.

Ventricle
The muscular chambers of the heart. The right ventricle pumps blood into the pulmonary artery and the lungs. The left ventricle pumps blood into the aorta and on into the body.

Ventriculography
: A procedure where a radio-opaque agent is injected into the ventricle for filming an X-ray film. The film is later reviewed for evaluation of the size and contraction capability of the chamber.

Video Display
: A device which can display graphic and/or printed material.

Appendix A: Data Base Structure

This appendix describes the data base structure for a patient file. Diagrams illustrating the hierarchy of the data were presented in Chapter 7 (see Figures 52 - 53). However, here the details as to the data contents of each node are given. Both the primary and the parallel data base are described.

Following each description, a sample file for the hypothetical patient of Chapter 7 is presented (Figures A1 and A2). This patient has Coronary Artery Disease and is typical of the majority of cases presenting to the catheterization laboratory at the San Francisco Veterans' Administration Medical Center.

The data base is maintained on the MUMPS computer. In several of the data base records there appear special delimitor characters. These delimitors (e.g., backslash "\", at sign "@", colon ":") are used to separate the record into data fields.

Each patient file contains a header record or node which contains the patient's name, catheterization number, sex, responsible clinician and hospital ward. The first subordinate node (Basic Data) stores static patient parameters consisting of the pre-catheterization diagnosis (coded), the indication for catheterization (coded), initial heartrate, estimated oxygen consumption, age, weight in kilograms, height in centimeters, body surface area and hemoglobin. Also stored as Basic Data are the abstracted major steps of the catheterization (coded) and the invasive sites.

The Procedure Log node serves as a header to those nodes which contain the maneuvers and events of the catheterization. This header records the time the procedure began, its duration in minutes, the date of the catheterization, the radio-opaque agents, X-ray film type and fluroscopy time. The nodes representing maneuvers and events are stored according to the time at which

they occurred. This time is calculated to be the number of minutes since the beginning of the procedure. Simultaneous events are recorded separately (examination of the example data base in Figure A1 shows this - only the integer portion of the minutes refers to actual clock time). For each record the first field signifies the record type as either a site indentifier (e.g., LV for left ventricle), "DRUG" for drug administration, "COMPL" for complications, "CAL" for calibration of the measuring system to the patient, or a numeric value which identifies a maneuver or event. An asterisk (*) following this record type identifier indicates that the computer has inferred that a maneuver took place. These inferred maneuvers are inserted into the log based on the occurrence of hemodynamic measurements (i.e., the storage of site identifiers). Next in the record is the clock time for each measurement, followed by a text description of the record type. If the record type is a maneuver or event which translates to text (as opposed to a site), there follows the appropriate parameters to include with that text when generating a formal report.

The actual calculated hemodynamics for the anatomical sites are recorded under "site" nodes (such as Left Ventricular Hemodynamics). As with the procedure log, each entry is stored according to the time of measurement. Each site has a defined set of hemodynamic parameters. These are stored in a single record using the blackslash as a field delimitor. If a site is not evaluated during the catheterization, there will not be a node for that site. As an example of this, the data base for the hypothetical patient only records hemodynamics measurements for the left ventricle and aorta. Nodes for other chambers and vessels are not created for this patient.

Data recorded under the Ventriculography Analysis node reflect parameters calculated by the Ventriculography module which runs under RSX. Each of the subordinate nodes represents a different type of analysis for

different types of heart contractions. If an analysis type is not performed, then there will not be a node for that type. For each type, basic data and calculated data are recorded in a single field using the backslash as a field delimitor. Generally the only analysis types performed are Area-length and Segmental. The contraction is usually considered to be normal (as opposed to Post Nitro or other abnormal or artificial contractions).

Each of the three coronary artery branches is recorded using the same format for each one. Up to three records are stored for an artery branch. The first record represents the sites of the artery (as defined by Gensini (30), see Chapter 4, Figure 9). These sites are separated by backslash delimitors. Each non-null field implies that the status of the artery at that site is not normal. Coded entries in the field signify either reduced size of the branch or the presense of occlusion. The second record, which is optional, represents the status of any bypass grafts. This record identifies the proximal and insertional sites of the graft. The status of the graft is recorded similarly to that of the sites of the artery. The final record represents the condition of the distal vessels (from the other branches).

The remaining nodes of the data base are used to store pre-catheterization data. For the nodes Chest X-ray, Electrocardiogram, ECG with Pain (i.e., those changes which were noted during the Electrocardiogram when the patient felt pain) and Exercise Tolerance Test a single record is used to store the results. In each of these records, the backslash is used as a field delimitor to separate the coded test results. Cardiac Risk Factors are stored in up to four subordinate nodes. The Family History uses fixed fields to record occurrence of disease in parents, siblings, grandparents and distant relatives. Diseases covered include Coronary Artery disease, hyperlipidemia, hypertension, diabetes mellitus, cancer and peripheral vascular disease. The Personal Risks node records data regarding

the presense of disease in the patient, any treatment he may be receiving and his smoking habits. The Angina node records the clinician's evaluation of the patient's angina (chest pain due to lack of oxygen to cardiac tissues). The Myocardial Infarction node records data which describes any heart attacks the patient may have suffered. The Clinical Laboratory Tests node records the results of blood and urine tests. These results are recorded in a single record delimited by backslashes. A null entry implies that the test results are not known.

The parallel data base records data which serves as a functional aid to the generation of formal clinical reports. The Header record contains a list of the reports and subreports which have been generated for the patient (as coded labels to the report template). The nodes Baseline Pressures, "Label 2" Pressures, ..., "Label N" Pressures serve to guide the report generator in the orderly presentation of the hemodynamic data. In each of these nodes the "label" is used to attach meaning to the pressures for clinical interpretation. The remainder of each node contains the sites (coded) and times for the hemodynamics to be displayed.

The nodes Medical History, Physical Examination, Impressions and Recommendations are header nodes under which the free text used to describe each of these report components is stored. Interspersed among the free text are word processing commands which are used to format the text for the reports. Because this data is free text, it would be difficult to identify specific content and it is expected, therefore, that this data will not be the object of many queries. So, to maintain the compactness and easy accessability of the primary, and highly quantitative, data base this bulky free form data resides in the parallel data base.

The Drug Tally node also serves as a header node. Each node subordinate to

this node stores the name of a drug administered during the catheterization followed by the total dosage given.

```
<data BASE RECORD FOR PATIENT #99999

<header>          Sample,Fred,A.\99999\M\E. Oertz\2A\

<basic Data>      15\1.4\ 60\217\ 61:04\ 74\178\1.91\13.0\
                  LMC\RCE\ATRF\LVG\SCA\
                  left  femoral vein\right  femoral artery\

<Procedure Log>   08:38\192\26-SEP-80\Renografin 76:150,
                  Isovue 440:0\Ilford\5:22\
  <time 0>        1:[08:38]PREMEDICATION@1:Diazepam 10 mg p.o.
  <time 3>        CAL:[08:41]CALIBRATION
  <time 11>       2:[08:49]PREP PT (F)@1:left :#20 Quase B-D
                  I.V. catheter. @2:The right and left groins
  <time 47>       3:[09:47]FEMORAL VEIN@1:#8 Cordis :left
  <time 57>       6:[09:55]PACING CATH (F)@1:#6 Goetz catheter
                  @3:0.5
  <time 64>       7:[09:42]1\ADMIN HEPARIN\3000\UN IV@1:3000
  <time 86>       8:[10:04]FEMORAL ARTERY@1:right :right
  <time 97>       34*:[10:15]CATH INTO AO (F)@1:#8 Cordis
                  Pigtail :523-850
  <time 97.1>     AO:[10:15]AO
  <time 100>      AO:[10:18]AO
  <time 113>      36*:[10:31]AO TO LV@1
  <time 113.1>    LV:[10:31]LV
  <time 118>      59:[10:36]ATRIAL PACING@1:5:120.
  <time 121>      LV:[10:39]LV
  <time 124>      LV:[10:42]LV
  <time 124.1>    62:[10:42]CHEST PAIN
  <time 125>      DRUG:[10:43]3\ADMIN NITROGLYCERIN\0.15\MG SL
  <time 126>      LV:[10:44]LV
  <time 135>      9:[10:53]LVG (RAO) (F)@1:30:12:300
  <time 136>      10*:[10:54]PRESS POST LVG@1@3
  <time 136.1>    LV:[10:54]LV
  <time 138>      LV:[10:56]LV
  <time 149>      11:[11:07]RCA (F)@1:#8 :523-841 @2:without
                  TNG. @3:inverted :lead x, :mild pain.
  <time 154>      11:[11:12]RCA (F)
  <time 160>      11:[11:18]RCA (F)
  <time 170>      12:[11:28]LCA (F)@1:#8 :523-843 @2:without
                  TNG. @3:inverted :leads x and y, :pain.
  <time 174>      12:[11:32]LCA (F)
  <time 176>      12:[11:34]LCA (F)
  <time 177>      12:[11:35]LCA (F)
  <time 182>      13:[11:40]2\ADMIN PROTAMINE\30\MG IV@1:30
  <time 184>      14:[11:42]REMOVE CATH (F)@1:30:15
  <time 192>      15:[11:50]CLOSE (F)@1:his room.
```

FIGURE A1: DATA BASE RECORD FOR SAMPLE PATIENT OF CHAPTER 7.

```
<Left Ventricular Hemodynamics>
  <time 113>     60\8\108\0\772\23.5\16.8\29.5\43.3\68\3
  <time 121>     120\22\125\0\796\27.7\18.3\32.6\46.1\90\10
  <time 124>     61\20\130\-1\800\29.0\20.7\37.1\54.7\90\9
  <time 126>     60\10\100\-1\790\32.1\24.4\38.5\58.7\70\4
  <time 136>     65\12\110\0\780\28.1\18.4\32.7\46.3\88\5
  <time 138>     62\12\108\0\771\23.4\16.7\29.4\41.3\70\3

<Aortic Hemodynamics>
  <time 97>      73\92\50\69
  <time 100>     70\90\50\68

<Ventriculography Analysis>
  <Area-length - normal contraction> 1\1.91\60\10\100\1\
                 179.5\94.0\89.5\46.9\90.0\47.1\5.4\2.8\50.1\
  <Segmental - normal contraction> 1\1.91\60\10\100\1\
                 8\28\28\24\40\39\27\20\11\18\

<Coronary Artery Analysis>
  <Right Coronary Artery>
                 <Occlusions>    \\\\25\\\\\\\\90\\\\\\\\
                 <Distals \ Collaterals>    E\\
  <Left Anterior Descending>
                 <Occlusions>    \\90\\\SM\50\\\\\\\\\\\\\\
                 <Distals \ Collaterals>    P\R\
  <Circumflex Artery>
                 <Occlusions>    \\\\\\\\\\\\\\\\\\\\
                 <Distals \ Collaterals>    G\\

<Chest X-ray>    1\

<Electrocardiogram>    17\

<ECG with Pain>    1\

<Exercise Tolerance Test>    4\120\pain\3\1, AVL, V3-5\

<Cardiac Risk Factors>
  <Family History>    P,,,\,,,\?,?,?,?\,,,\,,,\,,G,R\
  <Personal Risks>    \\?\12\
  <Angina>            6,Exertional\

<Present Medications>    1
  <Drug 1> Nitroglycerin:.15 mg sl prn\

<Clinical Laboratory Tests>    \13.0\\700\\\80\20\\\
```

FIGURE A1: DATA BASE RECORD FOR SAMPLE PATIENT OF CHAPTER 7 (cont.)

```
PARALLEL DATA BASE CONTENTS FOR PATIENT #99999

<Header>:    CR1\AN1\FR1\HDR\TRL\MAN\HEM\SCA\LR1\RF1\

<Baseline>   Baseline\2;;10:31am;113;1\6;;10:15am;97;1
<Label 1>    LVG\2;;10:44am;126;1
<Label 2>    Post-LVG\2;;10:54am;136;1
<Label 3>    Atrial Pacing\2;;10:39am;121;1
<Label 4>    1 min Post Pacing\2;;10:42am;124;1

<Medical History>
             SPAC=1.
             PARA
             LMAR=3.
             RMAR=3.
             DENT=4.
             SKIP=1.
             TABL_0.,HISTORY:
             The patient is a 61 year old white male truck
             driver who has had persistent exertional angina
             of one-half year's duration.  He has no prior
             history of cardiac problems.  He has had no
             other health problems.  He first noticed that
             he had chest pain whenever he played basketball
             for over 5 minutes.  As time progressed, he
             became aware that the pain was occurring
             whenever he exerted himself.  Now he feels
             pain whenever he exerts himself beyond casual
             walking.  He has no other health complaints.
             He was started on Nitroglycerin .15 mg prn
             about 4 months ago.
             PARA
             LMAR=0.
             RMAR=0.
             DENT=0.
```

FIGURE A2: PARALLEL DATA BASE RECORD FOR SAMPLE PATIENT OF CHAPTER 7.

```
<Physical Examination>
        GAPS=OFF
        SPAC=1.
        PARA
        SKIP=1.
        TABL=0.,PHYSICAL EXAMINATION
        SKIP=2.
        TABL=0.,Age_____
        TABL=4.,61
        TABL=9.,Sex_____
        TABL=12.,M
        TABL=18.,Ht._____
        TABL=21.,178 cm
        TABL=27.,Wt._____
        TABL=30.,74 kg
        TABL=36.,BSA_____M2
        TABL=39.,1.91
        SKIP=2.
        LMAR=3.
        TABL=0.,Blood Pressure:
        DENT=8.
        110/60
        PARA
        TABL=0.,Pulse:
        DENT=5.
        Regular at 60
        PARA
        TABL=0.,Jugular Veins:
        DENT=7.
        Within normal limits.
        PARA
        TABL=0.,Carotid Pulse:
        DENT=8.
        Within normal limits.
        PARA
        TABL=0.,Lungs:
        DENT=3.
        Clear to P & A
        PARA
        TABL=0.,Heart:
        DENT=3.
        No unusual sounds.  S1 and S2 normal.
        PARA
        TABL=0.,Abdomen:
        DENT=7.
        Soft.
        PARA
```

FIGURE A2: PARALLEL DATA BASE RECORD FOR SAMPLE PATIENT IN CHAPTER 7 (cont.)

```
        TABL=0.,EXTREMETIES:
        DENT=9.
        Normal
        PARA
        TABL=0.,Pulses:
        DENT=5.
        Normal
        PARA
        TABL=0.,Other:
        DENT=5.
        PARA
        SKIP=1.

<Impressions>
        SPAC=1.
        PARA
        LMAR=3.
        DENT=4.
        MOVE=5.
        TABL=0.,Impressions:
        TABL=9.,Significant lesion in Left Anterior Descending
        Artery
        SKIP=1.
        TABL=9.,Significant lesion in the Posterior Descending
        Branch of RCA
        SKIP=1.
        TABL=9.,No significant lesions in the Circumflex Artery
        SKIP=1.
        TABL=9.,Left Ventriculogram shows anterior hypokinesis
        SKIP=1.
        TABL=9.,Ejection Fraction in 50%
        SKIP=1.
        PARA
        LMAR=0.
        DENT=0.

<Recommendations>
        SPAC=1.
        PARA
        LMAR=3.
        DENT=4.
        MOVE=20.
        TABL=0.,Recommendations:
        TABL=13.,Bypass to Left anterior Descending and Post
        SKIP=1.
        TABL=16.,Descending Artery
        PARA
        LMAR=0.
        DENT=0.

<Drug Tally>
        HEPARIN\3000 UN
        PROTAMINE\30 MG
        NITROGLYCERIN\0.15 MG X 1
```

FIGURE A2: (cont.)

Appendix B: Software Tasks

This appendix presents descriptions of the major tasks of the system. The purpose of these descriptions is to provide an overveiw of the flow of control and function of the tasks supporting the prototype computer-based information management system for the cardiac catheterization laboratory.

The focal point of this overview is the diagram of the inter-relationships of the different tasks and major control and data structures (see Chapter 7, Figure 54). For each task there is a description of its function, the control and data structures it uses, the computer it runs on and a list of reports prepared by it.

Briefly, a control structure is defined as any data which impacts the action taken by a task. In contrast, a data structure is used by the system for comparative or display needs. It is possible for one task to consider data for control purposes while another task views that same data for display needs.

DEDICATED LAB SYSTEM (11/05)

This task consists of a proprietary system developed by Mennen Medical, Inc. The purpose of this system is to sample, in real time, the dynamically changing pressures in the heart and its surrounding vessels and to produce calculated parameters to reflect those measurements. The system has been enhanced (at the San Francisco Veterans' Administration Medical Center) to also record maneuvers and events related to the procedure (e.g., administration of drugs, performance of major steps in the procedure, and the occurrence of complications). At the completion of a catheterization, a report is printed. The system has also been modified to transmit a condensed version of this report over the network to MUMPS for analysis and long-term storage.

Interaction with this system is via a special purpose keyboard and a video monitor. Also in the configuration are an analog to digital converter and a hard-copy printer.

The majority of the software for this task is written in assembly language. Routines to calculate hemodynamic parameters are written in FORTRAN. All I/O and file management is handled through calls to system utilities.

CONTROL STRUCTURES

Because this system is proprietary, it would not be proper to fully describe the techniques it uses to control data collection, analysis and display. However, it is very rigid in its capabilities and does not readily allow for any form of editting of any result which has been recorded. Consequently, any editting of the report has to be performed under MUMPS after it has received a copy of the report.

Of the sections enhanced to record manuevers and events occurring during the case, they are table driven. The tables which control the menus are embedded within the code. Unfortunately, the table structure which the system uses to prepare the final report are not accessable by other routines and so there is duplication of essentially similar tables.

REPORTS: Log of hemodynamics, maneuvers and events (printed on a Decwriter) (see Chapter 7, Figure 24). A condensed version of this report is transmitted over the network to MUMPS (Figure B1).

```
WAKE=MUMPS
GETS=CAT(9999.9
TELL=SCT
DATA
26-SEP-80  [08:38]-[11:40] SAMPLE   ID:99999
  0 / [08:38] *GEN*
PATIENT ID     99999
HEARTRATE         60 [BPM]
02 CONS EST      217 [ML/MIN]
AGE            61:04 [YRS]
WEIGHT            74 [KG]
HEIGHT           178 [CM]
B.S.A.          1.91 [SQ M]
NOTE           PREMEDICATION
HEMOGLOBIN      13.0 [GM %]
  3 / [08:41] *CAL*
 11 / [08:49] *PN*
NOTE           PREP PT (F)
 64 / [09:42] **
NOTE           ADMIN HEPARIN (F)
ROUTE          IV
                3000 UN
 69 / [09:47] **
NOTE           FEMORAL VEIN
 86 / [10:04] **
NOTE           FEMORAL ARTERY
 97 / [10:15] *AO*
HEARTRATE         73 [BPM]
AO. SYST.         92 [MMHG]
AO. DIAST.        50 [MMHG]
AO. MEAN          69 [MMHG]
100 / [10:18] **
HEARTRATE         70 [BPM]
AO. SYST.         90 [MMHG]
AO. DIAST.        50 [MMHG]
AO. MEAN          68 [MMHG]
113 / [10:31] *LV*
HEARTRATE         60 [BPM]
LV. EDP.           8 [MMHG]
LV. PK. SYS.     108 [MMHG]
LV. BEG. DP.       0 [MMHG]
LV. PK DP/DT     772 [MMHG/SEC]
LV. PK. VCE.    23.5 [/SEC]
LV. VCE. 40     16.8 [/SEC]
LV. VMAX TOT    29.5 [/SEC]
LV. VMAX DEV    43.3 [/SEC]
LV. MN. SYS.      68 [MMHG]
LV. MN. DIA.       3 [MMHG]
118 / [10:36] *PN*
NOTE           ATRIAL PACING
```

FIGURE B1: CONDENSED CATHETERIZATION LOG.
(see text for discussion, continued on next pages)

```
121 / [10:39] *LV*
HEARTRATE          120 [BPM]
LV. EDP.            22 [MMHG]
LV. PK. SYS.       125 [MMHG]
LV. BEG. DP.         0 [MMHG]
LV. PK DP/DT       796 [MMHG/SEC]
LV. PK. VCE.      27.7 [/SEC]
LV. VCE. 40       18.3 [/SEC]
LV. VMAX TOT      32.6 [/SEC]
LV. VMAX DEV      46.1 [/SEC]
LV. MN. SYS.        90 [MMHG]
LV. MN. DIA.        10 [MMHG]
124 / [10:42] **
HEARTRATE           61 [BPM]
LV. EDP.            20 [MMHG]
LV. PK. SYS.       130 [MMHG]
LV. BEG. DP.        -1 [MMHG]
LV. PK DP/DT       800 [MMHG/SEC]
LV. PK. VCE.      29.0 [/SEC]
LV. VCE. 40       20.7 [/SEC]
LV. VMAX TOT      37.1 [/SEC]
LV. VMAX DEV      54.7 [/SEC]
LV. MN. SYS.        90 [MMHG]
LV. MN. DIA.         9 [MMHG]
125 / [10:43] *PN*
NOTE              ADMIN DRUG
                NITROGLYCERIN
ROUTE             SL
                   0.15 MG
126 / [10:44] *LV*
HEARTRATE           60 [BPM]
LV. EDP.            10 [MMHG]
LV. PK. SYS.       100 [MMHG]
LV. BEG. DP.        -1 [MMHG]
LV. PK DP/DT       790 [MMHG/SEC]
LV. PK. VCE.      32.1 [/SEC]
LV. VCE. 40       24.4 [/SEC]
LV. VMAX TOT      38.5 [/SEC]
LV. VMAX DEV      58.7 [/SEC]
LV. MN. SYS.        70 [MMHG]
LV. MN. DIA.         4 [MMHG]
135 / [10:53] *PN*
NOTE              LVG (RAO) (F)
136 / [10:54] *LV*
HEARTRATE           65 [BPM]
LV. EDP.            12 [MMHG]
LV. PK. SYS.       110 [MMHG]
LV. BEG. DP.         0 [MMHG]
LV. PK DP/DT       780 [MMHG/SEC]
```

FIGURE B1: CONDENSED CATHETERIZATION LOG (cont.)

```
LV. PK. VCE.    28.1 [/SEC]
LV. VCE. 40     18.4 [/SEC]
LV. VMAX TOT    32.7 [/SEC]
LV. VMAX DEV    46.3 [/SEC]
LV. MN. SYS.      88 [MMHG]
LV. MN. DIA.       5 [MMHG]
138 / [10:56] *LV*
HEARTRATE         62 [BPM]
LV. EDP.          12 [MMHG]
LV. PK. SYS.     108 [MMHG]
LV. BEG. DP.       0 [MMHG]
LV. PK DP/DT     771 [MMHG/SEC]
LV. PK. VCE.    23.4 [/SEC]
LV. VCE. 40     16.7 [/SEC]
LV. VMAX TOT    29.4 [/SEC]
LV. VMAX DEV    41.3 [/SEC]
LV. MN. SYS.      70 [MMHG]
LV. MN. DIA.       3 [MMHG]
149 / [11:07] *PN*
NOTE              RCA (F)
154 / [11:12] **
NOTE              RCA (F)
160 / [11:18] **
NOTE              RCA (F)
170 / [11:28] **
NOTE              LCA (F)
174 / [11:32] **
NOTE              LCA (F)
176 / [11:34] **
NOTE              LCA (F)
177 / [11:35] **
NOTE              LCA (F)
182 / [11:40] **
NOTE              ADMIN PROTAMINE(F)
ROUTE             IV
                     30 MG
<<<<
DONE
```

FIGURE B1: CONDENSED CATHETERIZATION LOG (cont.)

SCAN CATH LOG (MUMPS)

This task scans the condensed report transmitted over the network from the Dedicated Lab System (Figure B1). The contents of this report are stored in four locations. Computed hemodynamics (i.e., numerical values) are stored in the patient's file. Maneuvers and events such as catheter insertion, left ventriculography, etc. are stored in a temporary log (TPR). This task also inserts inferred maneuver notes into the log. For example, if the task scans a set of left ventricular pressures, it will infer that a catheter was advanced into the left ventricle. Inferred maneuvers are not included in the menus of the Dedicated Laboratory System because, as clinical maneuvers, they demand the full attention of the clinician. As such the staff is generally too busy to interact with the computer and record these maneuvers. Not all maneuvers can be inferred, so only those which can be absolutely inferred are considered by this task. This aspect of scanning the log to insert inferred maneuvers is used to provide essential, connective text between manually recorded maneuvers. This temporary log is then used by two subsequent tasks to assist in preparation of the textual description of the procedure. The drugs administered during the case are stored in a drug table (TDL). The complications noted during the procedure are stored in a complication table (TCL). This task is transparent to the user. It is activated (under MUMPS) after the network has successfully transmitted the condensed log. It then runs as a MUMPS background job.

CONTROL STRUCTURES

The scanning of the computed values is controlled by a set of routines: Chambers, Great vessels, Valves, Cardiac output, etc. Each of these routines relies on embedded tables to recognize labels (e.g., LV. EDP., AO. SYST.) and to extract the associated values. Each anatomical site has a number associated with it for specifying the location within the data base to store the values.

This task also constructs four tables which are used as data and/or control structures by other tasks. These tables are 1: a temporary log (TPR), 2: a table of "times" at which each maneuver occurred (TDU), 3: a table of drugs administered (TDL) and 4: a table of complications (TCL).

DATA STRUCTURES

This task uses two data structures. The first is the condensed report transmitted from the Dedicated Lab System . The other structure is the text templates which define the possible phrases used to describe the procedure (TEM, see Chapter 7, Figure 55). The maneuvers (e.g., RCA (F)) and events (e.g., CHEST PAIN) extracted from the report are compared against the entries in the table of templates. Errors are noted in the error log.

REPORTS: None

VERIFY LOG (MUMPS)

This task examines the temporary log created by the scanner. It constructs a summary which informs the clinician of mis-recorded maneuvers and events. To determine which maneuvers and events are missing this task scans the temporary log. For each entry which refers to a maneuver, a list of preconditions for that maneuver is extracted. The log is then checked to verify that each of these preconditions has been recorded. If any precondition is not in the log, it is identified in a summary report. If the precondition is recorded, but its time of recording is after that of the current maneuver, an indicative message is included in the summary report.

CONTROL STRUCTURES

This task uses one control structure which is the a temporary table which serves to indicate whether an event has been recorded (TDU). If an event has been recorded (either as an original part of the log or later, as an editted event) then that time of the event is stored in the table using the event code as an address into the table. Use of this temporary table removes the need for the task to repeatedly scan backwards through the log to check if an event has been recorded.

This task does not attempt to insert maneuvers or events into the log. The specification of the times for mis-recorded events is the clinician's or technician's responsibility.

DATA STRUCTURES

This task uses two data structures. The first is the temporary log (TPR). The second data structure is the table of template names (TEM).

REPORTS: Summary of catheterization log with comments regarding mis-recorded maneuvers and events (see Chapter 7, Figure 25).

EDIT CATH LOG (MUMPS)

This task runs under MUMPS. Its function is to allow the staff to edit the catheterization log prepared by the Dedicated Lab System running on the PDP-11/05. The user may add or delete any maneuver or event (including inferred maneuvers). He also may specify an alternate time for which a maneuver or event should be recorded (see Chapter 7, Figures 26 - 31). Drug doses are tallied and verified. Complications are reviewed and verified.

DATA STRUCTURES

This task uses two data structures. The first is the temporary log (TPR) prepared by the Log Scanner. This is used to display the current status of the log. The other structure is the table of Text Templates (TEM). The contents of this table are used to offer the user the possible changes and/or additions to the log. In any case, the log is displayed for the user to examine and he may choose to edit it or not.

Appropriate adjustments are made to both data and control structures to reflect the editted log. Upon completion, the user may obtain an updated summary report.

REPORTS: The user may request an updated summary of the catheterization log (see Verify Log).

COMPLETE PROCEDURE DESCRIPTION (MUMPS)

At the time that this routine is activated, the log is assumed to be an accurate reflection of the catheterization case. Therefore, this routine controls the selection of parameters relevant to the maneuvers and events contained in the log. For the most part, these parameters are chosen from menus. Some may be numerical entries. If an event is recognized as "OTHER", a 'short' free text description is accepted. The cardiologist is given several opportunities to review the text and affect corrections. The resulting description becomes a major part of the final report.

DATA STRUCTURES

This task uses several data structures. The first is the temporary log reviewed through the Edit Log task (TPR). The second is the table of text templates (TEM). The contents of each text template define whether the task should display a menu, ask for numerical input, or ask whether the optional text should be included (see Chapter 7, Figures 32 - 33).

The task records the menu selections and numeric entries in the temporary log (TPR). As the details of each maneuver and event are recorded, the task also abstracts the major steps (e.g., Left Heart Catheterization, Selective Coronary Angiography) of the catheterization (storing them in table TMA). It also translates the invasive sites (e.g., femoral vein, brachial artery) and stores them in a table (TS). Upon completion of this task, the temporary log (TPR), major steps and invasive sites are copied to the patient's file.

REPORTS: None

PRE-CATH DATA COLLECTION (MUMPS)

The purpose of this set of tasks is to interactively collect data related to the status of the patient prior to cardiac catheterization. Several tasks are used to collect this data. Each uses a combination of menus and some free text type-in to handle such items as name, ID#, etc. The tasks collect pre-catheterization diagnosis, indication for catheterization, chest X-ray results, electrocardiogram results (and changes noted if the patient experienced pain), exercise tolerance test results, risk factors (e.g., smoking, previous heart attack), current medications taken and clinical laboratory results. The user is allowed frequent opportunity to correct entry errors and may review / correct the data as long as the patient remains on the "working" list (WP). A patient is removed from this list when the final report is generated. Receipt of patient data from the dedicated lab system or RSX or entry of pre-catheterization data will place a patient on the "working" list (unless a previous report for that case has been completed).

CONTROL STRUCTURES

Each of the pre-catheterization data collection tasks is based on a table containing menu selections. Most of the menus are of form 2 (see Chapter 7, Figures 59 - 60), which support the evaluation of conflict lists and the activation of sub-menus. Data for chest X-ray (CXR), electrocardiogram (ECG), electrocardiogram with pain (ECP) and exercise tolerance text (EXT) are collect using this form of menu.

Other menus are of form 1 (see Chapter 7, Figure 58). Data for pre-catheterization diagnosis (PCD), indication for catheterization (IFC) and responsible clinician (MD) are collected with these basic menus.

The present prescription medications are collected through a menu of form 3 (PMD, see Chapter 7, Figure 61). Clinical laboratory is collected using a menu of form 4 (LAB, see Chapter 7, Figure 62).

DATA STRUCTURES

This task stores the user selections in the patient's file.

REPORTS: None

POST-CATH DATA COLLECTION (MUMPS)

The purpose of this set of tasks is to interactively collect data concerning the catheterization after the case is completed. This involves the use of menus and minimal free text entry. Data to be collected is the type and amount of radio-opaque agents used, the x-ray film type and the time of X-ray exposure (fluroscopy time).

CONTROL STRUCTURES

This task uses several tables which contain menus to present to the user.

DATA STRUCTURES

This task stores the user selections in the patient's file.

REPORTS: None

VENTRICULAR ANALYSIS (RSX)

This task runs under RSX on the PDP-11/35. Its purpose is to allow a cardiologist to trace silhouettes of an X-rayed left ventricle. It takes these traces (at the ventricle's largest and smallest sizes) and using a few other parameters, calculates values which reflect the pumping capability of the ventricle. This task was developed several years ago at the Veterans' Administration Medical Center to run under the DOS operating system. Since that time, it has been converted to run under RSX and its file controls and interaction with the user have been greatly improved. This is a very popular component of the catheterization system as it can calculate in under two minutes that which usually takes the cardiologist over an hour to calculate.

This task is written in FORTRAN. It uses a sonic pad and spark pen for graphic input and a video screen for display. A hard copy unit is available for output.

At the time when this task was converted to run under RSX it was also modified to prepare a summary report of the calculated results. Upon completion of reviewing the results for a patient, the task submits this summary report for transmission over the network to MUMPS. This step is transparent to the user.

CONTROL STRUCTURES

The branching logic of this task is straightforward. Data is entered directly through menus. After all the data has been collected, the user selects the analyses to perform from a menu. Then the calculations are performed and the results are displayed. This task is very large and heavily overlayed. It is a superset of the analysis methods generally available commercially.

DATA STRUCTURES

The task uses a very large COMMON block to store data. In this block are the point coordinates of the ventricular traces and the user supplied parameters. The values calculated by the various analysis methods are not stored in COMMON and are not saved. The data which is saved on disk consists of only the data in the COMMON block. So if the user wishes to review this data at a later date, the results are recalculated. If the X-rays used to obtain silhouettes is taken from 2 angles, then there are four traces. In this case (known as biplane, instead of monoplane), the extra two traces are also saved with the COMMON block.

REPORTS: Copies of the display screen which shows the ventricular images and the calculated parameters (see Chapter 7, Figures 34 - 36). This task also prepares a condensed version of the results to transmit over the network to MUMPS (see Figure B2).

```
WAKE=MUMPS
GETS=MCO(9999,9
TELL=SMC
DATA
 DATA IS NEW
 MINI-CINE - SUMMARY
 SAMPLE          99999   27-SEP-80   NORMAL CONTRACTION
 BSA:  1.91 HR: 60. LVEDP: 10. PSP:  100. LVO#: 1
 MAL*** AREA-LENGTH METHOD - MONOPLANE ***
 TOTAL  INDEX
 EDV    179.5    94.0
 ESV     89.5    46.9
 SV      90.0    47.1
 CO       5.4     2.8
 EF      50.1
 SEG1*** WALL MOTION ANALYSIS - % SYSTOLIC CHANGE ***
 L     8
 D1   28
 D2   28
 D3   24
 R1   40
 R2   39
 R3   27
 R4   20
 R5   11
 R6   18
<<<<
DONE
```

FIGURE B2: CONDENSED VENTRICULOGRAPHY REPORT. *(see text for discussion)*

CORONARY ARTERIES (RSX)

This task allows the clinician to interactively indicate the sites of blockages within the coronary arteries. For each of the three artery branches considered, the clinician first selects the sites of blockages, then identifies any grafts and their condition, then enters the condition of the distal vessels and finally identifies any collateral flow between the current artery and any of the others.

The task is written in FORTRAN. The equipment used consists of a sonic pad, spark pen, video display and hard copy unit. As with the Ventricular Analysis, this task also prepares a summary report of the findings which is transmitted to MUMPS via the network at the end of the session.

CONTROL STRUCTURES

The task uses three files, one for each artery branch, to control the display of the artery tree. Each of these files contains the point coordinates for an artery tree and a set of numerical labels for identifying the major sites of that artery.

DATA STRUCTURES

The findings specified by the clinician are saved in a file accessed through the patient's catheterization number. This file contains all the findings for all three arteries. Its size and structure are fixed and it may contain several blank entries. The various sections of this file are defined by the different routines of the task (e.g., grafts, distals).

REPORTS: Copies of the display screen showing an image of the artery (from the Gensini templates) and a summary of the artery's status (see Chapter 7, Figures 37 - 41). This task also prepares a condensed report to transmit over the network to MUMPS (see Figure B3).

```
WAKE=MUMPS
GETS=SCA(9999,9
TELL=SCA
DATA
 99999  SAMPLE                    27-SEP-80
 RCA
 ***
 OCCLUSIONS
 SITE: 5 - 25
 SITE: 13 - 90
 ***
 GRAFTS
 ***
 DISTALS
 COND: E
 ***
 COLLATERALS
 ***
 END
 LAD
 ***
 OCCLUSIONS
 SITE: 3 - 90
 SITE: 6 - -1
 SITE: 7 - 50
 ***
 GRAFTS
 ***
 DISTALS
 COND: F
 ***
 COLLATERALS
 REC FROM: R
 ***
 END
 CFX
 ***
 OCCLUSIONS
 ***
 GRAFTS
 ***
 DISTALS
 COND: G
 ***
 COLLATERALS
 ***
 END
<<<<
DONE
```

FIGURE B3: CONDENSED CORONARY ARTERY REPORT *(see text for discussion)*

SCAN LVG REPORT (MUMPS)

This task scans the condensed report prepared by the Ventricular Analysis task (Figure B2). As it scans the report it builds a record for each type of analysis (e.g., area-length method - monoplane) which is stored in the data base in the patient's file.

This task is transparent to the user. It activated automatically by the network after the successful transmission of the report to MUMPS. Any errors encountered are recorded in the error log on MUMPS.

CONTROL STRUCTURES

The control structures for this task are embedded in the scanning routines. As the scanner recognizes each type of analysis, it calls a sub-scanner to disassemble that part. Each sub-scanner uses an embedded table to identify the labels (e.g., EDV, EF, D1) and extract the associated values.

DATA STRUCTURES

As this task scans the report, it stores the extracted parameters in the patient's file.

REPORTS: None

SCAN SCA REPORT (MUMPS)

This task scans the condensed report prepared by the Coronary Artery task (Figure B3). As it scans the report it builds a record for each artery which is stored in the data base in the patient's file. For each artery there is a separate record to indicate the status of occlussions (blockages in the arteries), grafts, distal vessels and collateral flow.

This task is transparent to the user. It is activated automatically by the network after the successful transmission of the report to MUMPS. Any errors encountered are recorded in the error log on MUMPS.

CONTROL STRUCTURES

The control structures for this task are embedded in the scanning routines. As the scanner recognizes each type of analysis, it calls a sub-scanner to disassemble that part. Each sub-scanner uses an embedded table to identify the labels (e.g., SITE:, BEG:, % OCC:) and extract the associated values.

DATA STRUCTURES

The extracted parameters are stored in the patient's file.

REPORTS: None

FREE-TEXT DATA COLLECTION (RSX)

This task allows for the entry of large blocks of free text for inclusion in the final catheterization report. It runs under RSX on the PDP-11/35. The blocks of free text cover the following areas: Medical history, Physical exam (with a basic structure enforced with free form answers), Impressions and Recommendations. The basic form of each of these sections will conform to the Word Processing software commands utilized by RSX for report formatting (as will the remainder of the catheterization report). Each will be stored initially as a separate file under RSX. Upon completion of preparation, these files will be transmitted to MUMPS for storage in data base which is separate from, but parallel to, the main data base.

CONTROL STRUCTURES

The major control of the entry of free text is provided in the form of indirect command files supported by RSX. These files control the naming of patient files and oversee that the appropriate text is entered in each file.

The contents of each file conform to the word processing commands allowed by the software under RSX. The entry of free text can be performed by a secretary who is familiar with this system.

REPORTS: None

SELECT HEMODYNAMICS TO REPORT (MUMPS)

This task allows the cardiologist to select the results which he wishes to include in the final report. These results are displayed in a tabular format. To select a set of hemodynamics to list the cardiologist need only specify the type (e.g., Left Ventricle, Aorta, Mitral Valve) and the time they were measured (e.g., 215, this is the number of minutes since the beginning of case). He may then attach a label to these results (e.g., Baseline, LVG). The cardiologist will have a preliminary copy of the catheterization log in the form of the report printed by the Dedicated Lab System (see Chapter 7, Figure 24) or that prepared by the Verigy Log task (see Chapter 7, Figure 25) to assist in selection of the relevant values and times.

Additionally, the computer will display the times at which the desired type of hemodynamics were recorded. The clinician can review the hemodynamics and reject them if they are not considered essential to the final report (rejected hemodynamics are not deleted from the patient's file, rather, they are merely not reported). See Chapter 7, Figures 42 - 43.

This task also allows the clinician to enter manually calculated hemodynamics. These are stored with those hemodynamics calculated by the Dedicated Lab System, but are marked as "manual calculations".

CONTROL STRUCTURES

This task will rely on embedded tables to identify the possible sets of hemodynamics (e.g., LV for left ventricle). To indicate which of the value sets to print in the final report. The label, site name (e.g., LV) and the time will be recorded in a temporary table.

DATA STRUCTURES

After all hemodynamics are selected, the temporary table is converted to a form ordered by the labels attached by the clinician. The hemodynamics to report are then stored in the parallel data base.

REPORTS: None

DEFINE REPORT (RSX)

This task allows the user to define a report template for the report generator to use. The format of the report is specified using commands of the Word Processor under RSX combined with parameters which indicate the patient data to insert. The user can display the format and make as many adjustments as necessary. After the report format is deemed satisfactory, it is given a name and transmitted to MUMPS for review. MUMPS then scans the template and stores it. If MUMPS encounters any unrecognized entries (signified by asterisks) it prepares an error report which is transmitted to RSX for the user to examine (see Chapter 7, Figure 57).

CONTROL STRUCTURES

The indirect command file system under RSX controls the specification of a name for the format and its subsequent request for transmission over the network to MUMPS. The means for specifying the format rely on the word processing commands supported by RSX.

DATA STRUCTURES

A table of report descriptors is used to idenfity the patient specific entries (see Chapter 7, Figure 56).

REPORTS: None

CREATE REPORT TEMPLATE (MUMPS)

This task runs under MUMPS and takes the report format defined under RSX and stores it as a report template under MUMPS. The various parameters in the report (denoted by asterisks) are compared to a table of possible parameters which define where the parameter can be located within a patient file. These definitions of data locations are essentially MUMPS code. When accessed by the Report Generator, they are initially treated as data and then as code.

Use of any undefined parameters in the report format results in an error report being sent back to the RSX user.

CONTROL STRUCTURES

The major control structure used by this task is the table which specifies the location of parameters within patient files (RD, see Chapter 7, Figure 56). For each entry in this table there is the name of the parameter (as it appears in the original report format with asterisks removed) and the MUMPS code to extract the parameter from the data base. Each entry is located by computing a hash address based on the letters of the parameter.

DATA STRUCTURES

The report template is stored in a table (RTM - used here as a data structure). The name of the report is used as a key to hash an address for the start of the template. Also stored with the template are the date of its creation and a formal label.

REPORTS: Possible error report

REPORT GENERATOR (MUMPS)

This task generates a report for a catheterization patient using a report template as a guide. The user must supply the identification for a patient and the name of the report template to use. The task then starts a background job to scan the template and extract the data for the patient. During this time the "file" for that patient is locked and may not be used by any other tasks. Upon successful completion of the report generation, the file is unlocked and the network is requested to transmit the resulting report to RSX along with a message to insert in the secretary's mailbox informing her that a report is ready.

CONTROL STRUCTURES

The Report Generator relies on template definitions (RTM) to control the creation of a formal report. When access to the patient file is necessary, it relies on the access information stored in the table of parameters (RD).

DATA STRUCTURES

The report is stored in a table. This table remains intact until the patient is removed from the "working list" (WP, see Chapter 7, Figure 63). At that time the reports for that patient are erased. A list of the reports generated for each patient is saved in the parallel data base.

REPORTS: That which was requested. See Chapter 7, Figures 45-50.

REPORT PRINTER (RSX)

This is not really a task but a process. When the secretary has been informed that a catheterization report is ready to be printed, she will set up a letter quality printer, activate the word processor and specify the name of the patient report to print. The word processor (under RSX) will then assume control of the printing of the report.

CONTROL STRUCTURES

Control is through the word processing software under RSX.

REPORTS: Not applicable

DEFINE TABLES (MUMPS)

This task allows the user to define the contents of the tables used to control the collection of pre and post catheterization data. It does not allow the user to define the structure of the tables, only the content. There are separate sub-sections for each of the data types (e.g., Chest X-ray, ECG, Clinical laboratory).

CONTROL STRUCTURES

Control of specification of menu entries, conflict lists, pre-conditions, etc. is embedded in the code.

DATA STRUCTURES

Relevant tables (PCD, IFC, CXR, ECG, ECG, EXT, PMD, LAB) are constructed.

REPORTS: Lists of table contents can be printed.

DEFINE PROCEDURE TEXT TEMPLATES (MUMPS)

This task allows the user to define text templates to be used to generate a description of the catheterization procedure. Most of the templates are identified by labels which are output by the Dedicated Lab System in its condensed report. Additional, rarely performed events, are also entered in the table of these templates. The process of defining a template is interactive. The user supplies a name and the task controls the acceptance of a textual definition, perhaps containing some blanks. It then queries the user as to how these blanks are to be interpreted (e.g., as menus, numerical input, free text?).

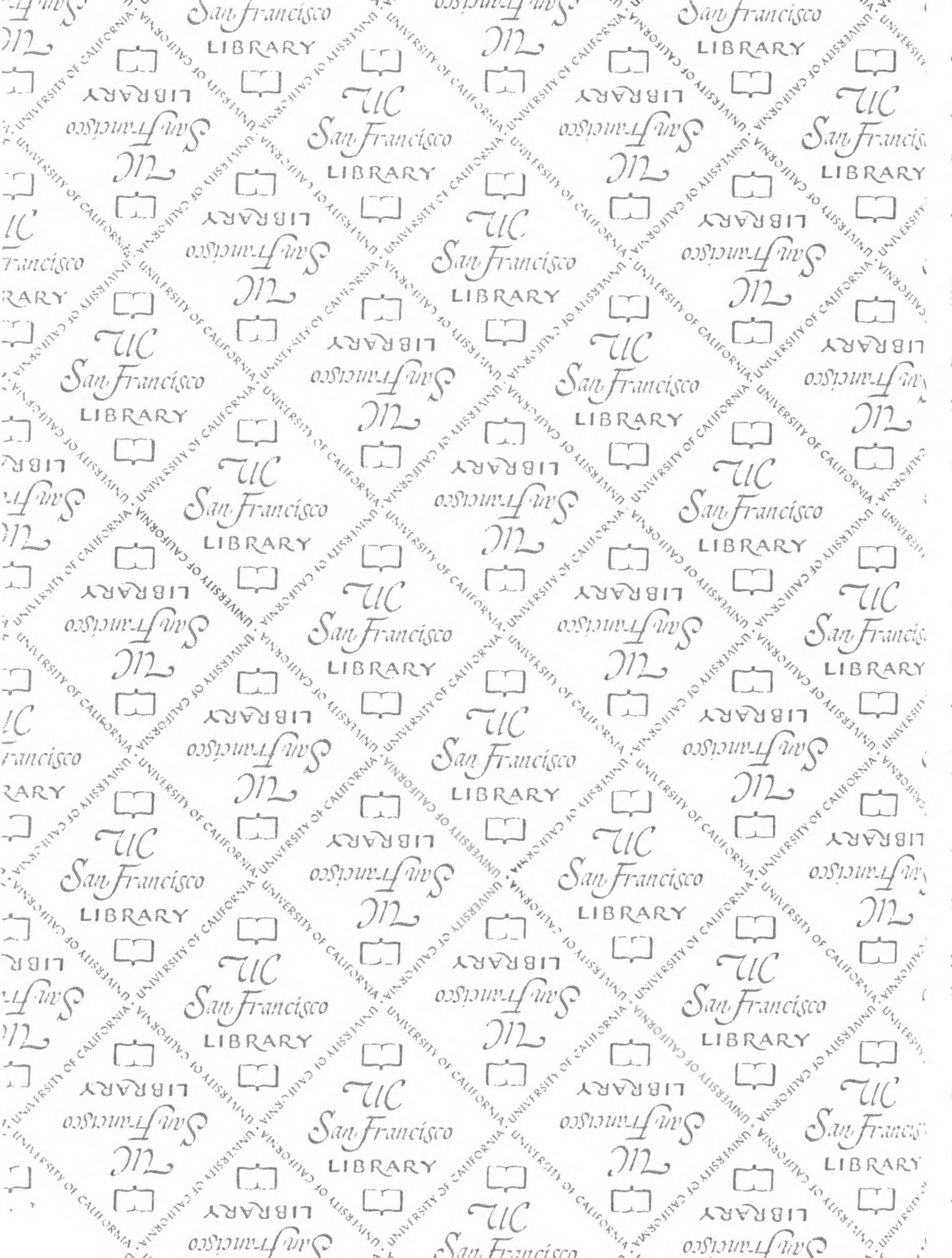
CONTROL STRUCTURES

Control of the definition of text templates is embedded in the code.

DATA STRUCTURES

This task creates the table of text templates for the maneuvers (TEM) and the text templates for the complications (CL).

REPORTS: List of all template names or a listing of a set of template names and their associated text and sub-menus and numeric entries.


UC
San Francisco
LIBRARY
UNIVERSITY OF CALIFORNIA · UNIVERSITY OF CALIFORNIA

UC San Francisco LIBRARY
UNIVERSITY OF CALIFORNIA