A STUDY OF THE HOSPITAL UTILIZATION OF CLINICAL LABORATORY TESTS

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ABSTRACT

A study has been made of the utilization of laboratory testing in a major teaching hospital. Two measures of laboratory utilization were considered: 1) the total number of tests performed in the chemistry laboratory over the past ten years and 2) tests used in the management of a group of patients with a diagnosis of uncomplicated acute myocardial infarction over a period of fifteen years. In each case, test volume data was compared with technological, environmental and cultural change within the hospital and laboratory. Both groups of data showed an approximately exponential growth in chemistry test utilization over the past decade. Over 90% of the total test volume in each year comprised a group of 23 tests. Although there was a dramatic increase in the number of different tests utilized, from 100 to over 600, during the period studied, new tests contributed little to the increase in test volume. Significant changes in laboratory technology occurred during the period studied, in particular the introduction of automated and multichannel analyzers. There was evidence that these technological changes caused a small increase in laboratory test growth rate, but the effect was predominantly in the facilitation of increased demand. Clear evidence was obtained of a change in physician behavior; there was a marked reduction in the average interval between tests and a greater tendency to use tests for monitoring as opposed to diagnosis in more recent years.

Name and Title of Thesis Supervisor: Edward B. Roberts, David Sarnoff
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Chapter 1 INTRODUCTION

1.1 The Cost of Health Care

Health care expenditure in the United States has increased exponentially from $4 billion in 1940 to $118 billion in 1975. The increase in Gross National Product during the same interval has been from $100 billion to $1520 billion. Thus the fraction of GNP spent on health care has been increasing, as shown in Table 1.1. A major cause of this cost increase has been a technological and scientific revolution in medicine which has taken place in the last three decades. Increased costs were justified because of the very high value placed on health, and even life itself. It is apparent that as health care costs continue to rise, choices must be made between medical care and other desirable goods and services (1). As a result, in recent years the costs and resulting benefits of health care have come under critical examination and are a major public policy issue in the United States and most other industrialized nations.

Health care consumers annually spend about 25% of their total expenditures on pharmaceuticals, medical supplies and other products; the remaining 75% is spent on wages, fees and other non-product items as shown in Figure 1.1 (2). Hospital care and physicians services are the two largest sectors of health care costs and together account for almost two thirds

TABLE 1.1

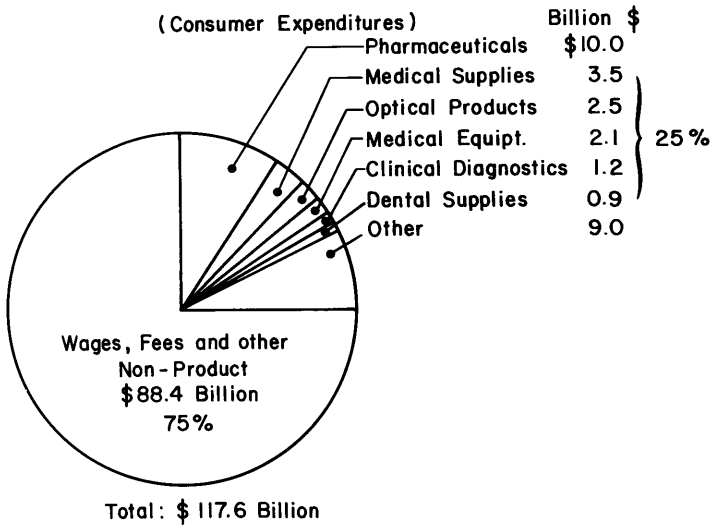
HEALTH CARE EXPENDITURE AS A FRACTION OF GNP

Year	Health Care Expenditure	Fraction of GNP
	$ billions	%
1940	3.86	3.87
1950	12.03	4.22
1960	25.86	5.13
1965	38.89	5.69
1966	42.11	5.61
1967	47.88	6.03
1968	53.77	6.22
1969	60.62	6.52
1970	69.20	7.08
1971	77.16	7.31
1972	86.69	7.49
1973	95.38	7.37
1974	104.03	7.36
1975	118.50	7.82

Source: Social Security Administration

FIGURE 1.1

Product Analysis of Health Care Expenditures, 1975

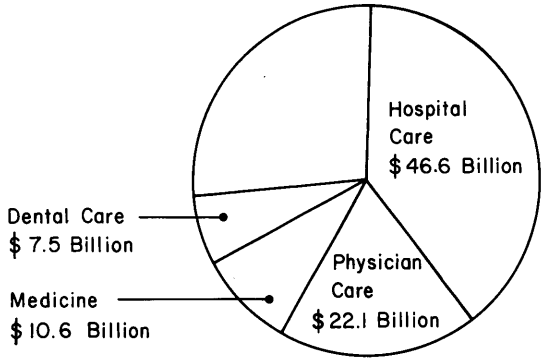


Total: $117.6 Billion

Source: Arthur D. Little, Inc. estimates

FIGURE 1.2

Sectoral Analysis of Health Care Expenditures, 1975



Source: Division of Health Insurance Studies, Social Security Administration

of total expenditures (Figure 1.2). Not unexpectedly, hospital services have shown the fastest rising costs in the health care area and it has been suggested that the rapid growth of hospital costs is now the central problem of U.S. health care policy (3). The rapid rise in hospital costs reflects the increasing sophistication and complexity of the care provided. The cost of clinical laboratory services was among the leading elements of these accelerating hospital costs. Patients admitted to hospitals today expect and receive a battery of diagnostic tests and procedures which are also used to monitor their progress during the course of their hospital stay. Neither patients nor the physicians who care for them have been satisfied with less than technical excellence in medical care.

1.2 Laboratory Medicine

The practice of medicine has changed substantially during this century, largely as a result of diverse and continuing technological innovation (4). It can be argued that physicians' ability to alter the outcome of the disease was almost non-existent until the development of twentieth century pharmaceuticals. Successful application of these powerful therapeutic agents is dependent on accurate diagnosis which is increasingly achieved through sophisticated technological means.

Diagnostic laboratory methods used in modern medicine

include: (a) visualization: endoscopy, x-ray, nuclear and ultrasonic imaging, (b) physiological measurements: pulmonary function, EKG, EEG and (c) clinical laboratory: hematology, microbiology, immunology, biochemistry. Laboratory medicine can be characterized by 1) high impact of technology, 2) increasing use and 3) increasing costs. It is, therefore, not surprising that there is a growing interest in the cost/benefit analysis of laboratory medicine (5). Much of this interest is focused on the clinical laboratory although studies have been made of some other areas, e.g. x-ray (6).

There are approximately 15,000 clinical laboratories in the U.S. not including small physicians' office laboratories (7,8). About half of the total are hospital laboratories, while the remainder are independent.

1.3 The Clinical laboratory

Laboratory medicine has participated in a major way in the technological revolution. Significant innovations have transformed this branch of medicine from a relatively primitive "cottage industry" into a highly sophisticated, highly automated system of impressive analytical capacity, capable of producing analytical data at a very rapid rate and quantity. Among the innovations that have brought about this transformation are the following (9):

(1) The introduction of quality control procedures into the clinical laboratories in the 1950s providing the essen-

tial element of reliability and confidence in results (10).

(2)The introduction of multichannel automatic analyzers in the early 1960s permitted the rapid generation of large volumes of relatively reliable data with minimal technical manpower (11).

(3)The introduction of electronic data processing facilitating the internal handling and transfer of laboratory data from the clinical laboratory to the clinicians.

1.3.1-Clinical Laboratory Development

These technological developments have permitted the clinical laboratories to respond effectively to the increased clinical demands for laboratory services. There has been a remarkable increase in the utilization of laboratory services over the past 20 years. According to national surveys, for the period 1970-1975, the number of clinical laboratory tests increased at an annual rate of 13.8% in hospital laboratories (7,8); clinical chemistries comprise about 30% of all laboratory tests. Figures from England and Wales indicate similar laboratory growth patterns. In 1961, 21 million laboratory tests were performed while this figure rose to 46 million in 1971 and reached over 90 million by 1976, showing again an accelerating rate of growth. Laboratory utilization at the teaching hospital of the University of Minnesota tripled in volume from 1963-1976, despite little change in the number of patients or other patient-related factors. In another study

from the teaching hospital of the University of Rochester in 1971, Griner (12) found chemistries accounted for approximately 40% of all laboratory charges and 10% of the total hospital bill; between 1965 and 1970, the number of chemistry laboratory tests increased by 95%.

The overall increase in use of laboratory tests masks variability in growth for patients with different diseases. However, studies of selected medical conditions in hospitals have also demonstrated accelerated increase in laboratory utilization. A study of patients hospitalized for acute myocardial infarction between 1939 and 1969 showed exponentially increased chemistry tests as well as x-ray and bacteriological examinations without significant changes in the duration of hospitalization or patient mortality (13).

There are also significant differences in laboratory utilization by different physicians treating comparable patient populations in a clinic setting (14), for similar patients treated in different teaching hospitals (15) and in a teaching hospital compared to a community hospital (16).

1.32 Clinical Laboratory Costs

As indicated above, increasing clinical laboratory costs have been a major contributor to the increasing costs of hospital services. This does not reflect laboratory inefficiencies, but rather the greater utilization of services and expansion of new services; only 50% of the 13% increase in

costs in 1975 was due to increased unit costs. This 6.5% increase in the cost of services is remarkably low, and probably reflects increased efficiency of the laboratories related to automation.

1.4 Factors Contributing to Increased Clinical Chemistry Testing

These factors may be divided into three major categories:

1. Laboratory factors
2. Patient factors
3. Physician factors

1. Laboratory factors:

(a) Increased capability and reliability of results, with development of automated multichannel analysis.

(b) Advances in medical knowledge, particularly in the discovery of new relationships between biochemical alterations and disease. There has been a remarkable increase in available laboratory tests from 100 tests in 1950 to more than 600 at present. One contributing factor is that old technology is replaced but not completely retired, resulting in an increased test pool size.

(c) Perceived need to keep up with the latest technology, in part necessitated by the increased demands on the laboratories by the clinicians.

2. Patient factors:

(a) The method of payment has changed, with increase in

third party payments for health care through private insurance carriers, Medicare and Medicaid providing broader insurance coverage. These are associated with decreased out-of-pocket expenses, particularly as a consequence of their availability as a fringe benefit as well as the deductibility of health insurance costs from income taxes.

(b) Local factors such as "case mix" and type of hospital. The introduction of increasingly complex technology and sophisticated services, such as intensive care units has also stimulated laboratory utilization.

3. Physician factors:

(a) The type and location of training of the physicians has a major influence on laboratory utilization. Most physicians are trained in university teaching hospitals, which tend to utilize the laboratories to a greater extent than community hospitals (16), and which are the location of clinical research into the introduction and evaluation of new laboratory tests. Furthermore their role-models are specialists who, as a group, tend to use laboratories to a greater extent; physicians who were found to be high users tended to be members of groups in which the leadership exhibited this characteristic.

(b) Pressure by superiors and peers on house officers to do comprehensive work-ups and avoid missing diagnosis,and to avoid failure to monitor and detect changes in the

patient's condition.

(c) The type of practice also has an influence. With increasing specialization, the attending physicians become less comfortable with medical problems outside of their area of expertise and are more reluctant to criticize and constrain laboratory usage by house officers in these relatively unfamiliar areas.

(d) Increase in the practice of defensive medicine, in response to increased threat of malpractice suits. The consequent increased tendency to order additional tests is much less significant in the clinical laboratory areas such as clinical chemistry, than in radiology.

(e) The increased emphasis on preventative medicine has led to the concept of frequent, regular systematic evaluation of the healthy individual, including multiphasic laboratory screening in which chemistry testing plays a significant role.

(f) Relatively inadequate physician education in clinical laboratory medicine, giving rise to an insufficient awareness of particular test characteristics such as reliability, or the diagnostic implications of various levels of test sensitivity and specificity.

(g) The initiation of quality assurance programs in hospitals. These seek to establish minimal standards of care

for various diseases, and monitor conformance with these standards. In quantitative terms, these programs are not a significant factor in recent increases in clinical laboratory utilization, since they are concerned with minimal standards of laboratory usage rather than the issue of excess utilization.

1.5 Objectives

The objective of the present study was to examine in depth the increase in laboratory utilization in a university teaching hospital. This hospital has a reputation for excellence and serves as a model for the examination of factors contributing to increasing laboratory test volumes.

The approach we have taken is to examine both the laboratory as a whole and as utilized in a well-defined group of patients having a common principal diagnosis. In each case we have reviewed the changes in laboratory testing over an extended period, ten years for the laboratory as a whole, and fifteen years for the patient group. In addition, technological, environmental and cultural changes within the hospital have been documented where possible. This set of data allows us to evaluate the relative importance of factors affecting the utilization of laboratory tests.

Chapter 2 METHODOLOGY

2.1 The Hospital

The hospital is a 452-bed voluntary, non-profit hospital with an international reputation in the fields of cardiology, oncology, endocrinology, hematology and kidney disease, among others. It pioneered many of the radiology techniques now in standard use throughout the world, and has been a leader in pediatrics and in the development of immunologic techniques to insure survival of transplanted organs. It is a major teaching hospital in which patient care is integrated with medical student, graduate and post-graduate physician training and health-related research.

The hospital admits 14,000 inpatients annually, with an additional ambulatory and emergency case load of 235,000 patients. All major specialities and sub-specialities with the exception of maternity inpatient services are available.

The medical staff has a core of 240 full-time salaried physicians. They are augmented by 400 house officers and post-doctoral fellows and more than 500 members of the associate, consulting, special and scientific staffs, and over 750 nurses. The nursing complement comprises registered nurses, licensed practical nurses, aides, technicians and others. Four hundred fifty medical and dental students rotate from the two health schools each year, and more than 800 students participate annually in a broad range of associated health professions training programs.

Much of the daily activity at the hospital is tied to the health-related research vital to the continued growth of medical knowledge and improved patient care. Supported largely by government agencies and private foundations and organizations, over 300 research programs budgeted at $8 million are conducted annually.

During the period of the current study, one major new hospital building was completed in 1973, adding approximately 96 adult beds, including a four-bed coronary care unit (CCU), which became operational in March 1973.

2.2 Study of Total Clinical Chemistry Laboratory Testing (1969-1978)

The data on the numbers of tests performed by the clinical chemistry laboratory was obtained from monthly computer print-outs which enumerated the frequency of all tests performed during that period. This computer program was first initiated in 1972, so that earlier data was not available through this source. Aggregate data on the total number of chemistry tests beginning in 1969 was available from another hospital source; these figures for total tests from 1972 onward corresponded very well with figures obtained from the computer print-outs. The monthly frequency of each of 23 major tests was determined for the period 1972-1978. These tests constitute over 90% of the total testing performed by the clinical chemistry laboratory.

Data on admissions, total patient days and length of

stay were obtained from summary monthly reports of hospital activity.

The interpretation of the aggregate laboratory utilization data is somewhat complicated by changes in patient mix which could contribute to shifting patterns of laboratory utilization. Such shifts are evident from an examination of Table 2.1 which indicates the number of patient days according to service in this hospital, in recent years. While there has been some overall increase in patient days, associated with expansion of the bed capacity in 1973, there have also been shifts in the relative occupancy levels on different services. For example, there has been a progressive increase in surgical patients: adult surgery, thoracic surgery and dental surgery (combined in earlier records) grew from about 15,600 patient days in 1970-71 to 25,600 in 1977-79, while adult medicine increased only from 31,400 to 35,360 during the same period. Orthopedic surgery also grew significantly during this period.

2.3 Myocardial Infarction Study (1963 - 1978)

The purpose of this portion of the study was to compare the utilization of clinical chemistry laboratory testing, in a comparable group of patients, during the last 15 years. We selected acute myocardial infarction because these patients generally require a substantial volume of laboratory testing, and have benefitted from increasingly sophisticated and specialized care. Patients with uncomplicated myocardial infarction were selected from among a larger group of patients with

TABLE 2.1

THE DISTRIBUTION OF PATIENT DAYS ACCORDING TO CLINICAL AREAS

DEPARTMENT	1970-71	1971-72	1972-73	1973-74	1974-75	1975-76	1976-77	1977-78
ADULT								
Medicine	31,430	29,168	33,021	35,842	35,048	38,305	34,465	35,361
Surgery					15,939	19,676	21,535	20,328
Thoracic Surgery	15,627	15,037	17,086	19,278	3,207	3,674	4,778	4,625
Dental					532	586	491	652
Otolaryngology	1,349	1,703	1,729	2,089	1,999	1,547	1,797	2,151
Gynecology	5,738	5,893	6,880	7,473	7,469	7,963	6,825	6,495
Urology	3,622	3,167	3,291	2,576	2,714	3,188	3,127	2,525
Orthopedics	7,488	8,606	7,913	9,757	12,211	11,918	12,413	11,446
Neurosurgery	2,241	2,924	4,415	4,461	4,669	5,777	5,668	5,774
Neurology	3,137	4,171	4,288	5,299	5,038	4,913	5,063	5,184
Opthalmology	414	362	507	431	447	469	317	400
Adult Total	72,046	71,031	79,130	87,206	89,273	98,016	96,479	94,941
PEDIATRIC								
Medicine	13,667	14,229	13,536	14,752	14,818	15,426	15,637	14,197
Psychiatry					832	767	1,088	1,335
Infectious Disease	283	--	2,086	3,039	3,131	2,813	2,137	2,888
Surgery	5,204	4,743	4,348	4,391	3,300	3,104	3,758	4,161
Thoracic Surgery					1,338	1,282	1,503	1,419
Otolaryngology	536	427	386	441	421	469	389	335
Dental	168	165	164	180	146	80	93	105
Urology	2,194	1,949	1,899	2,186	2,164	2,693	1,901	274
Orthopedics	2,920	3,341	3,726	4,385	4,633	4,155	4,336	4,863
Neurosurgery	2,098	1,389	1,582	1,072	940	1,151	898	978
Neurology	1,057	1,059	1,063	937	870	700	905	2,034
Ophthalmology	226	228	257	230	243	187	226	164
Pediatric Total	28,353	27,530	29,047	31,613	32,836	32,827	32,871	32,753

that discharge diagnosis. For the period 1963 through 1968 the study group was finally selected from among those with myocardial infarcts by direct review of hospital charts. Starting in 1970, the discharge diagnoses (in the form of International Classification of Disease Adapted -ICDA-8) were stored in a computer program, so that a print-out of all patients with the discharge diagnosis of acute myocardial infarction could be obtained. From these data, cases with uncomplicated acute myocardial infarcts were selected and their hospital charts were reviewed. Only cases without cardiac arrythmias, congestive heart failure or other complications were selected for further analysis of laboratory utilization.

For each patient studied, the hospital record was examined and all clinical chemistry determinations were tabulated on a daily basis. This yielded a comprehensive chart tabulating all chemistry tests for the admission according to hospital day. Examples are illustrated on Tables 2.2 and 2.3. The frequency of abnormal tests were also recorded; tests were designated as abnormal if the values fell outside of the normal limits set by the laboratory. (These are indicated with an asterisk [*] designation in the examples.)

Tables 2.4a and b compare some of the general features of the patients in the study. The average age of the patients and the frequency of males to females did not change significantly throughout the study. There was a gradual reduction

TABLE 2.2

TEST	8/7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
SMA-6 - I (6 tests)																			
Sodium														+					
Potassium														+					
Chloride														+					
CO_2														+					
BUN	+																		
Creatinine	+																		
Glucose		+*							+*								+		
Bloodgases (3 tests)																			
Enzymes (4 tests)																			
SGOT	+*	+*				+		+						+					
SGPT																			
LDH	+*	+*				+*		+*						+					
CPK																			
Isoenzymes																			
LDH																			
CPK																			
SMA-6 - II (6 tests)																			
Calcium																			
Phosphate																			
Total protein																			
Albumin																			
Bilirubin																			
Cholesterol																			
Alkaline phosphatase						+													
Others																			
Digoxin																			
Pronestyl																			
TOTAL	4	3	-	-	-	3	-	2	1	-	-	-	-	6	-	-	1	-	-

Patient: G,M.

Age: 79

Hospital #158-110

Dates of Hospitalization: 8/7/63 - 8/25/63

19 Days

Total Tests - 20

+ Test(s) reported
* Abnormal result

TABLE 2.3

Patient: A,E. Age 60
Hospital #99 87 39
Dates of Hospitalization:
2/16/77 - 3/2/77 - 15 days
Total tests - 118

TEST	2/16	17	18	19	20	21	22	23	24	25	26	27	28	3/1	2
SMA-6 - I (6 tests)	+	+	+	+				+	+					+	
Sodium					+		+				+	+	+		+
Potassium	+		+		+		+				+	+	+	*	+
Chloride				*	+*		+*	*	*		+*	+*	+*	*	+*
CO_2	*	*	*	*	+*		+*		*		+*	+*	+		+*
BUN	*	*	*	*				*	*					*	
Creatinine	*	*	*	*				*	*					*	
Glucose	+	+													
Bloodgases (3 tests)															
Enzymes (4 tests)															
SGOT	++	+*	+*												
SGPT	++	+	+												
LDH	++	+*	+*												
CPK	++	+*	+*												
Isoenzymes															
LDH															
CPK	++	+*	+*												
SMA-6 - II (6 tests)	+	+													
Calcium															
Phosphate															
Total protein															
Albumin															
Bilirubin															
Cholesterol	*	*													
Alkaline phosphatase	+														
Others															
Uric Acid	+*	+*				+			+*		+*	+*	+*	+*	+
Amylase	+*	+													
T_5 Uptake		+													
T_4		+													
Free T_4		+													
TOTAL	27	23	12	6	4	1	4	6	7	-	5	5	5	6	5

TABLE 2.4a

YEAR	NAME	SEX	AGE (years)	LENGTH OF STAY	TOTAL TESTS
1963	C,R.	M	54	15 days	12
	C,A.	M	48	16 "	26
	D,M.	F	56	17 "	23
	F,A.	F	72	27 "	67
	G,A.	F	69	24 "	95
	G,B.	M	63	19 "	52
	G,M.	F	79	19 "	20
	L,F.	F	70	23 "	53
	M,F.	F	62	21 "	32
	M,D.	M	68	33 "	71
	S,R.	M	62	21 "	37
	P,J.	F	52	22 "	19
	W,A.	F	45	22 "	28
	Y,J.	M	69	29 "	23
Average			62 yrs.	22 days	30
1967	H,H.	M	59	19 days	63
	M,J.	M	73	18 "	41
	M,F.	M	41	17 "	36
Average			58 yrs.	18 days	47
1968	B,V.	M	58	15 days	47
	F,A.	F	72	27 "	67
	G,J.	M	59	21 "	64
	G,J.	M	57	23 "	60
	H,J.	M	60	22 "	34
	L,J.	M	68	25 "	67
	M,E.	F	55	19 "	41
	S,A.	F	61	23 "	32
	Z,L.	M	76	24 "	56
Average			63 yrs.	22 days	52
1970	B,F.	M	49	25 days	74
	C,N.	M	50	19 "	32
	F,F.	M	81	20 "	54
	M,A.	F	68	28 "	52
	P,S.	M	40	23 "	61
	S,G.	F	72	18 "	43
	V,C.	F	60	16 "	55
Average			60 yrs.	21 days	53

TABLE 2.4b

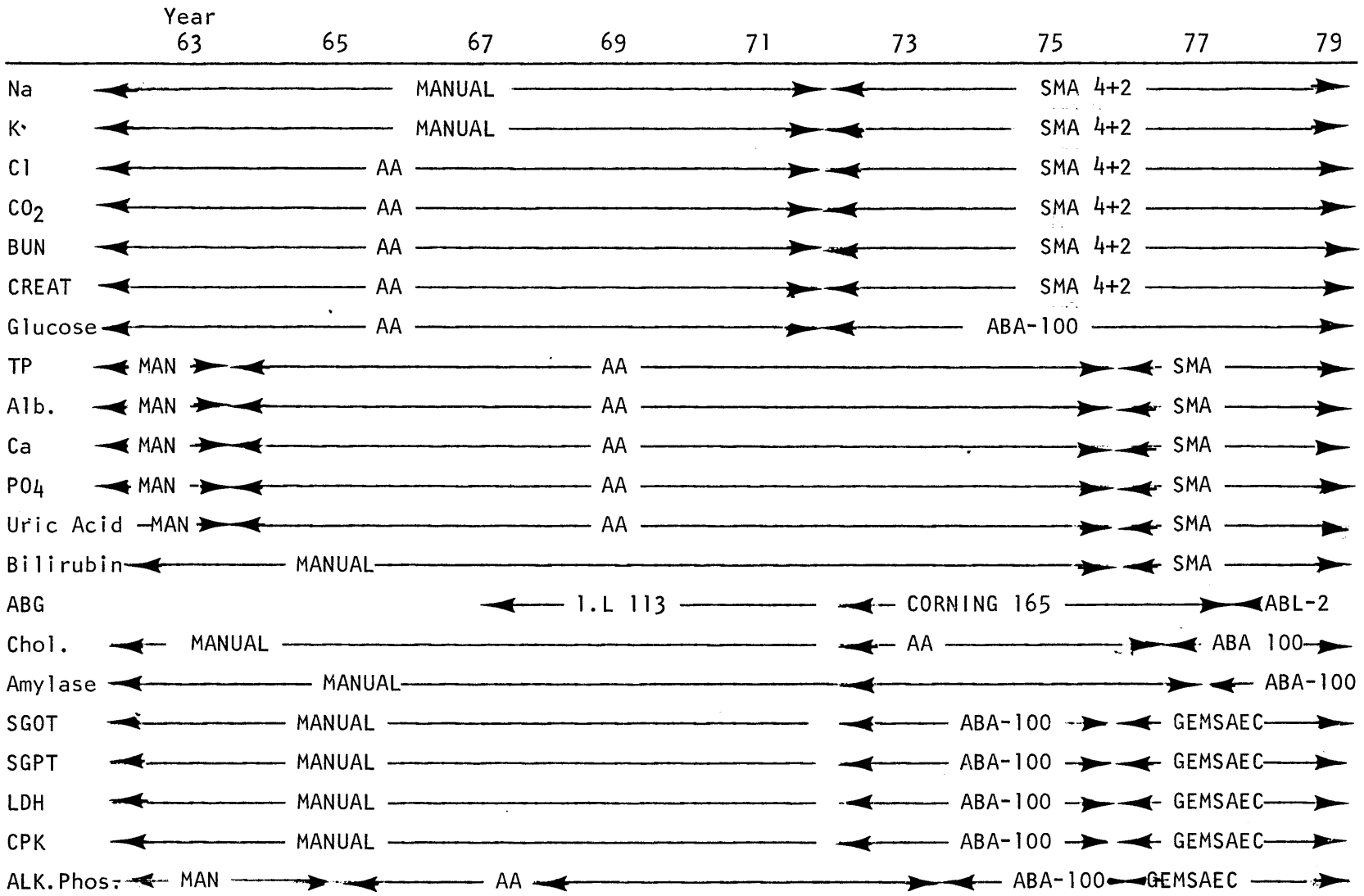
YEAR	NAME	SEX	AGE (years)	LENGTH OF STAY	TOTAL TESTS
1973	B,F.	F	80	15 days	39
	F,J.	M	64	11 "	24
	G.E.	F	70	16 "	90
	G,E.	M	54	15 "	106
	H,H.	F	67	21 "	59
	L,M.	M	75	15 "	66
	L,G.	M	65	25 "	95
	N,M.	M	64	16 "	121
	R,M.	M	71	16 "	51
	S,H.	M	72	24 "	106
	W,A.	F	66	12 "	76
Average			62 yrs.	17 days	75
1975	B,H.	M	68	14 days	76
	D,L.	M	73	21 "	87
	G,E.	F	76	15 "	101
	G,R.	F	78	14 "	75
	K,B.	F	92	18 "	92
	P,C.	M	55	21 "	88
Average			74 yrs.	17 days	87
1977	A,E.	F	60	15 days	118
	F,H.	F	60	19 "	179
	F,R.	M	55	16 "	286
	L,G.	M	69	18 "	143
	M,F.	M	58	19 "	80
	P,S.	M	59	22 "	160
	S,K.	M	34	12 "	69
	W,H.	M	70	17 "	84
Average			59 yrs.	17 days	139
1978	A,L.	M	63	17 days	165
	E,A.	M	75	20 "	179
	G,E.	M	58	10 "	85
	M,M.	F	61	15 "	139
	M,R.	M	70	17 "	207
	M,M.	F	62	13 "	245
Average			65 yrs.	15 days	170

in the average length of stay of these patients (from about 21-22 days to about 15-17 days) and a remarkable increase in total clinical chemistry laboratory determinations from 1963 to the present. The detailed analysis of the changes in utilization will be provided in Chapter 3, and constitute a major element of the study.

2.4 Technological Change Within the Chemistry Laboratory

The chemistry laboratory of the hospital underwent progressively increased automation during the period of this study. The timing of the introduction of various new instruments is outlined in Table 2.5. All determinations were performed manually before 1963; at which time dedicated individual Technicon AutoAnalyzers (AA) were introduced for the determination of serum chloride (Cl), carbon dioxide (CO_2), blood urea nitrogen (BUN), creatinine (Creat.) and glucose (Gl). In 1964, additional autoanalyzers were introduced for the determination of total serum protein (TP), serum albumin (Alb), calcium (Ca), phosphate (PO_4), uric acid and alkaline phosphatase (Alk. Phos.). The next major change was the introduction in 1968 of blood gas analyses using an Instrumentation Laboratory, Inc. (IL-113). This was supplemented by a Corning 165 instrument in 1972. In the same year (1972), other significant changes in automation were introduced. A Technicon SMA 4+2 was introduced for the simultaneous determination of NA, K, Cl, CO_2, BUN and Creatinine. Serum glucose and the

TABLE 2.5


Year
63
65
67
69
71
73
75
77
79
Na
MANUAL
SMA 4+2
K
MANUAL
SMA 4+2
Cl
AA
SMA 4+2
CO_2
AA
SMA 4+2
BUN
AA
SMA 4+2
CREAT
AA
SMA 4+2
Glucose
AA
ABA-100
TP
MAN
AA
SMA
Alb.
MAN
AA
SMA
Ca
MAN
AA
SMA
PO_4
MAN
AA
SMA
Uric Acid
MAN
AA
SMA
Bilirubin
MANUAL
SMA
ABG
I.L 113
CORNING 165
ABL-2
Chol.
MANUAL
AA
ABA 100
Amylase
MANUAL
ABA-100
SGOT
MANUAL
ABA-100
GEMSAEC
SGPT
MANUAL
ABA-100
GEMSAEC
LDH
MANUAL
ABA-100
GEMSAEC
CPK
MANUAL
ABA-100
GEMSAEC
ALK.Phos.
MAN
AA
ABA-100
GEMSAEC

major enzymes (SGOT, SGPT, LDH and CPK*) were determined utilizing the Abbott ABA-100. Alkaline phosphatase was determined with this instrument in 1973.

The next major technological improvement occurred in 1976 when a second Technicon SMA-6 was introduced for the determination of TP, Alb, Ca, PO_4, uric acid and bilirubin. A GEMSAEC was also introduced for all enzyme determinations at this time; serum cholesterol was determined by ABA-100 in 1977, and amylase in 1978. Finally, arterial blood gases were determined by the technologically superior Radiometer ABL-2 in 1978.

A brief description of some of the main features of these instruments follows:

a. AutoAnalyzer (Technicon Instruments, Inc.)

The AutoAnalyzer (AA), developed by Skeggs (17), represents a first attempt to introduce automation (or at least, mechanization) into the clinical chemical laboratory. The AutoAnalyzer utilized the principle of continuous flow: a pump moves the sample blood serum and necessary reagents along a series of plastic tubes continuously. Appropriate methods are used to separate serum proteins, dilute the

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* SGOT is the abbreviation for serum glutamic oxaloacetic transminase; SGPT stands for serum glutamic pyruvic transminase; LDH is lactic acid dehydrogenase, and CPK is creatinine phosphokinase.

sample and add reagents in controlled proportions. Further details of AutoAnalyzer methodology are given elsewhere (18). Generally, the method of measurement is photometric, although other detectors can also be used. In photometric measurements, reagents are added to the sample to produce a colored product with the required sample component, and the intensity of the color is measured in a photoelectric colorimeter.

Samples are processed by an AutoAnalyzer at the rate of 60 per hour. Each sample is placed in a small plastic cup which in turn is loaded into a turntable for sequential presentation to a sampling probe. The instrument is calibrated by replacing samples with reference standards of known composition. The output of the analyzer is either a chart recording of sample peak heights (which are proportional to color intensities) or a printed table of sample concentrations. Once the serum samples are loaded into the turntable, the analyzer can run unattended, which represents a considerable saving in operator time over earlier manual methods (19).

b. SMA-6 (Technicon Instruments, Inc.)

The SMA 6/60 (Sequential Multiple Analyzer) is a continuous flow analyzer which performs six different chemical tests per sample at a rate of 60 samples per hour. Different combinations of the six tests (the test profile) are possible but the most common is the four serum electrolytes (Na, K, Cl, CO_2) plus two others (BUN, Creat.). Here, Na and K are

measured with a flame photometer while the other tests utilize a photoelectric colorimeter, as in a single channel AutoAnalyzer. Another common combination (in use with the second SMA-6 in this hospital) is calcium, phosphate, total protein, albumin, bilirubin and cholesterol.

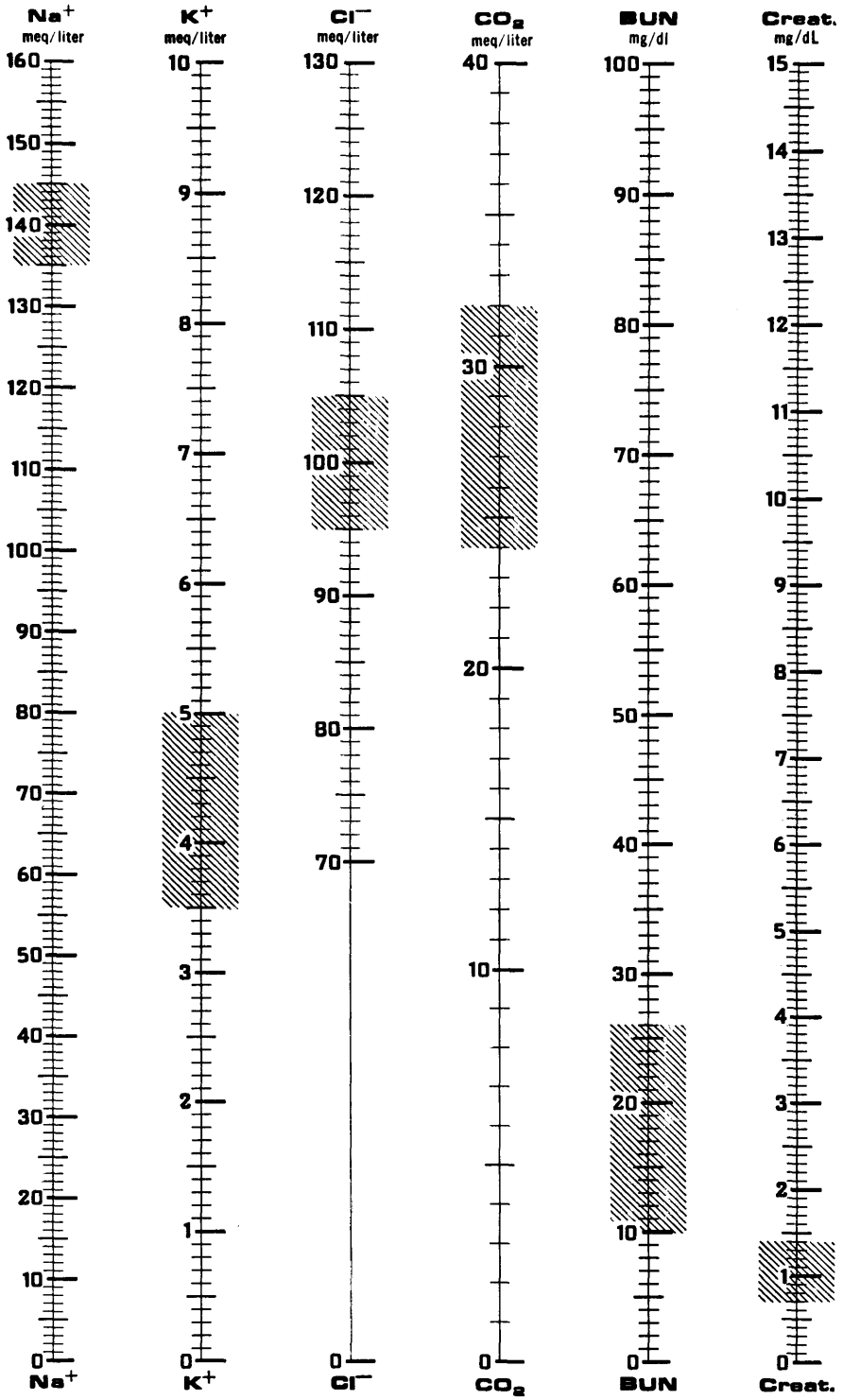
Operation of the SMA-6 is not substantially different from a single channel AutoAnalyzer. Serum samples are loaded into cups in a sampler turntable and thereafter the instrument operates automatically. One technician is sufficient for routine operation of the instrument. The results are obtained on a chart recorder which is designed to be easily read; the recorder output for a single patient sample is shown in Figure 2.1.

c. ABA-100 (Abbott Laboratories, Inc.)

The ABA-100 is an automated discrete sample clinical analyzer comprising a spectrophometer, a pipettor-dilutor, and an electronic data-processor and printer. Samples and appropriate reagents are dispensed into wells of a disposable plastic multi-cuvet mounted in a water bath. The required sample component reacts with the reagents to produce a colored product. The intensity of this color is measured for each sample in turn by the spectrophotometer; color intensity is proportional to required analytical concentration. The instrument can be programmed to repeat measurements at fixed intervals of up to 20 minutes. Depending on the mode of operation and time interval selected, the instrument is capable

FIGURE 2.1

SMA 6/60 SERUM ANALYSIS CHART



of up to 150 measurements per hour, about 5-20 times the rate for equivalent manual procedures.

d. GEMSAEC (Electro-Nucleonics, Inc.)

The GEMSAEC analyzer, which was developed by Anderson (20), represents an alternate approach to laboratory instrumentation from the ubiquitious continuous flow analyzers. GEMSAEC is one of five commercially available centrifugal analyzers which operate by photometric measurement of color in samples contained in separate chambers in the periphery of a rapidly rotating disc. Before commencing analysis, samples and reagents are premeasured into appropriate wells machined into the disc. During an analytical cycle, the disc is rotated and centrifugal force moves samples and reagents outwards into a corresponding cuvette. Here mixing occurs and color develops in proportion to the analytical concentration of the required component in the sample. Sixteen samples can be accommodated in a disc and a photometric absorption reading is made on each sample during each revolution of the disc. The method offers particular advantages in kinetic assays which are used to determine enzyme activities in blood serum. Kinetic methods of analysis relate the rate of formation of color to analytical concentration. Centrifugal analyzers generate large amounts of data - a consequence of the high speed rotation of the disc. A computer is therefore used to effect data reduction.

e. Blood Gas Analyzers

Arterial blood gas analysis (ABG) conventionally requires measurement of pH and the partial pressures of oxygen (PO_2) and carbon dioxide (PCO_2) dissolved in the sample. Practical electrochemical sensors had been developed for measurement of these three parameters by the late 1950s. The IL 113 (Instrumentation Laboratory Inc.) represents an early example of a blood gas analyzer. It comprises two units: a thermostat bath containing the three electrode sensors and an analog meter provided with three different scales for each measurement. In operation, it was necessary to select each scale in turn by means of a switch.

The Corning Model 165 represents a second generation of blood gas analyzers. It incorporates a digital display and, in addition to the basic pH, PO_2 and PCO_2 measurements, will also calculate total carbon dioxide concentration, bicarbonate ion concentration and base excess. This latter derived parameter requires a knowledge of the sample hemoglobin concentration, which is entered into the Model 165 through a calibrated dial. Push buttons are provided to allow any one of the six parameters to be displayed.

The ABL-2 (Radiometer) is a second generation of the first computerized blood gas analyzer. In addition to measuring blood pH, PO_2 and PCO_2, a direct measurement of hemoglobin is made. Derived parameters are: bicarbonate, total carbon dioxide, base excess, standard base excess, standard bicar-

bonate and oxygen saturation. The three basic measurements of pH, PO_2 and PCO_2 are shown simultaneously on three digital displays. All measured and derived parameters are printed on a strip printer. The ABL-2 also directly measures ambient barometric pressure which is necessary for automatic calibration of the instrument, another unique feature. Automatic calibration occurs every two hours or at the users' initiation. This feature is particularly effective in improving the reliability of blood gas analysis - earlier instruments had required the technician to obtain a barometric reading of atmospheric pressure, calculate the partial pressures of the standard gas mixtures and then perform several calibration adjustments to the analyzer.

2.5 Environment

2.5.1. Malpractice Insurance Rate Changes

As a consequence of increased malpractice litigation, the cost of malpractice insurance has increased at a remarkably high rate in recent years. Table 2.6 indicates the changes in premium rates between 1965 and 1977, for five classes of physicians in Massachusetts (100/300 limits). While some rate increases began between 1968 and 1972 (particularly in higher risk classes), the major increases went into effect in 1972 and continued at this high rate of increase through 1974. Further increases continued up to

TABLE 2.6

MALPRACTICE COSTS

PHYSICIANS & SURGEONS RATES 100/300 LIMITS

YEAR	CLASS A	B	C	D	E
1965	$ 87.00	$109.00	$ 208.00	$ 276.00	$ ---
1966	103.00	130.00	272.00	408.00	---
1968	95.00	167.00	284.00	396.00	494.00
1969	119.00	210.00	357.00	497.00	622.00
1972*	138.00	242.00	522.00	726.00	907.00
1972	209.00	368.00	794.00	1,104.00	1,380.00
1973	288.00	506.00	1,092.00	1,518.00	1,898.00
1974	403.00	708.00	1,529.00	2,125.00	2,657.00
1975	469.00	824.00	1,757.00	2,447.00	3,060.00
1976	548.00	1,250.00	2,081.00	3,010.00	3,810.00
1977	552.00	1,425.00	2,556.00	3,644.00	4,158.00

* Rates - 25/75 Limits

the present, but not at the approximately 30% rate of increase seen in 1972-1974.

Chapter 3. TOTAL CHEMISTRY LABORATORY UTILIZATION

3.1 Total Tests Performed

During the period 1969-78, the total number of tests performed per year in the analyzed chemistry laboratory increased from 270 thousand to over 930 thousand. Total test volumes for intermediate years are shown in Table 3.1 and a trend curve for test volumes is shown in Figure 3.1. Total test volumes grew exponentially from 1969 until 1974. The rate slowed briefly in 1975, but the increased growth rate recurred in 1976 and 1977, moderating somewhat in 1978. Table 3.1 shows the growth in tests as a % over the previous year and as an absolute rate (first derivative of total test volume with respect to time). It may be noted that the growth rate is slightly higher during the period 1972-74 than during 1975-77.

Changes in total laboratory utilization may reflect changes in the utilization of the hospital in its entirety, as well as utilization of chemistry tests in patient care. We, therefore, calculated the average number of tests per hospital admission and per patient day of admission for each year during the period 1969 to 1978. These results are compared with the total number of tests per year in Figure 3.2 and Table 3.2. The general shape of the curves showing tests per day and tests per admission is very similar to that of the total tests. We conclude that hospital

TABLE 3.1

GROWTH IN TOTAL CHEMISTRY TESTS

Year	Total Tests (thousands)	% Increase Over prior year	Absolute Growth Rate (Tests/year) (thousands)
1969-70	268.9	-	-
1970-71	272.3	1	20.3
1971-72	309.5	13	85.2
1972-73	442.80	38	139.3
1973-74	588.20	33	98.1
1974-75	639.00	9	83.8
1975-76	755.70	18.2	126.7
1976-77	892.30	18	89.5
1977-78	934.77	5	-

FIGURE 3.1

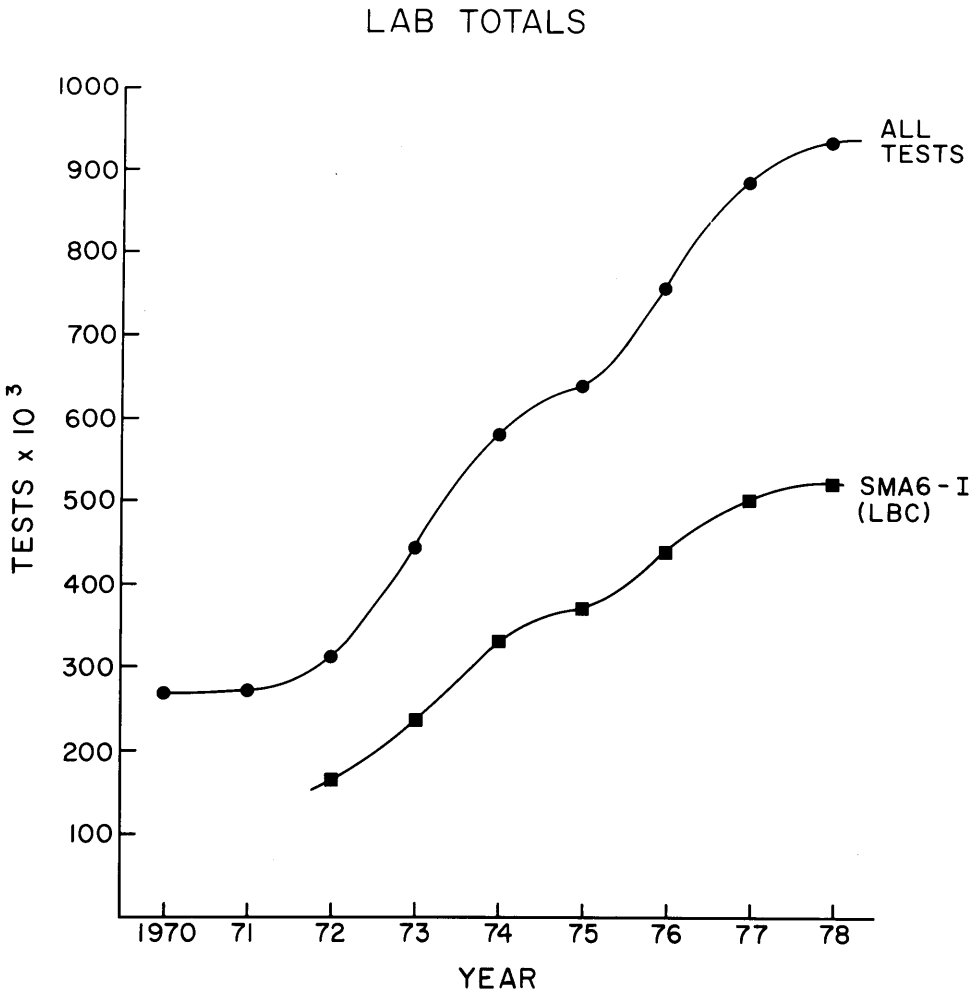

LAB TOTALS
1000
900
800
700
600
500
400
300
200
100
TESTS x 10 3
ALL TESTS
SMA6 - I (LBC)
1970
71
72
73
74
75
76
77
78
YEAR

FIGURE 3.2

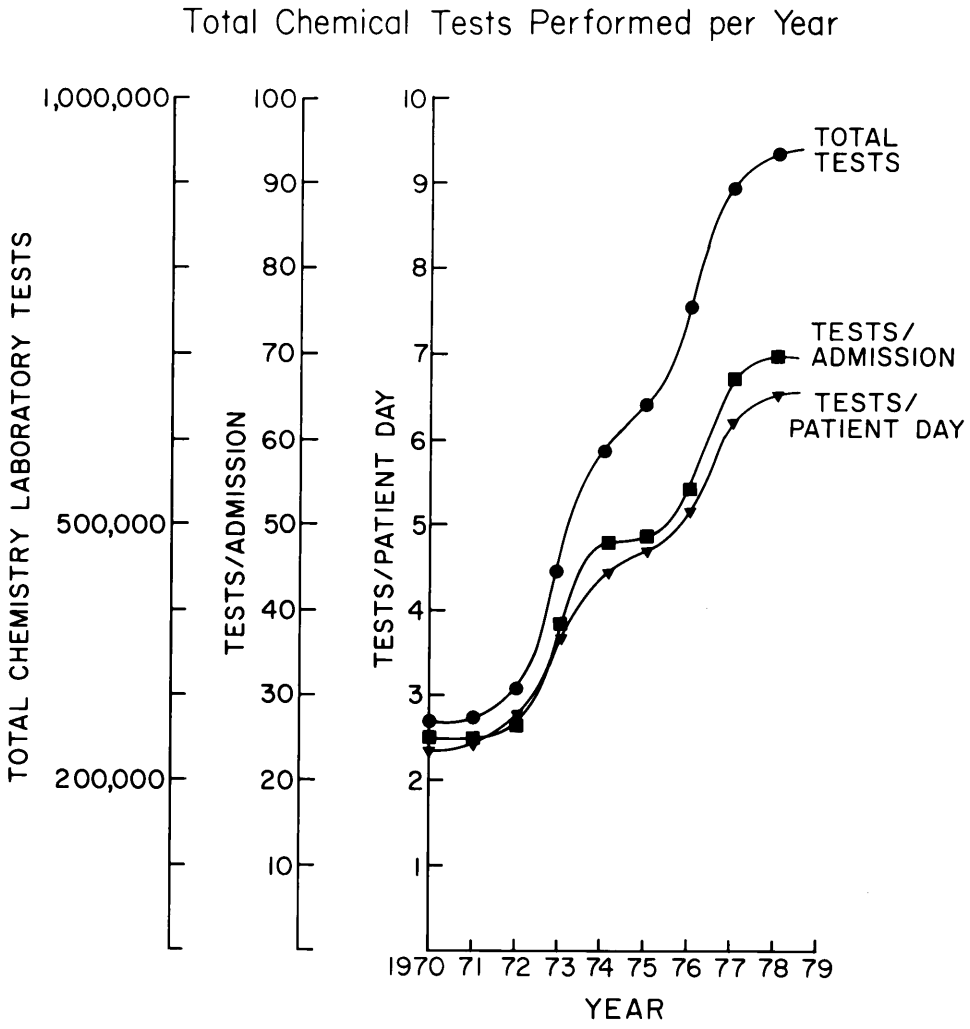

Total Chemical Tests Performed per Year
TOTAL CHEMISTRY LABORATORY TESTS
1,000,000
500,000
200,000
TESTS/ADMISSION
100
90
80
70
60
50
40
30
20
10
TESTS/PATIENT DAY
10
9
8
7
6
5
4
3
2
1
TOTAL TESTS
TESTS/ ADMISSION
TESTS/ PATIENT DAY
1970 71 72 73 74 75 76 77 78 79
YEAR

TABLE 3.2

GROWTH IN TOTAL CHEMISTRY TESTS PER ADMISSION OR PATIENT DAY

Year	Total Admissions	Tests/ Admission	Total Patient Days	Tests/ Pt. Day
1969-70	10,671	25.2	117,280	2.30
1970-71	11,089	24.7	114,041	2.39
1971-72	11,608	26.7	112,941	2.74
1972-73	11,459	38.5	121,828	3.63
1973-74	12,295	47.8	132,839	4.42
1974-75	13,426	47.7	135,786	4.71
1975-76	14,012	54.0	147,184	5.14
1976-77	13,164	67.6	142,879	6.24
1977-78	13,366	69.9	140,952	6.56

occupancy has had some effect on total tests ordered, but that other factors are of greater importance. However, interpretation of these results must be made cautiously because, as will be shown later in the myocardial infarction study, the distribution of tests is not uniform over the length of hospital stay. There is a greater test use immediately following admission than immediately prior to discharge.

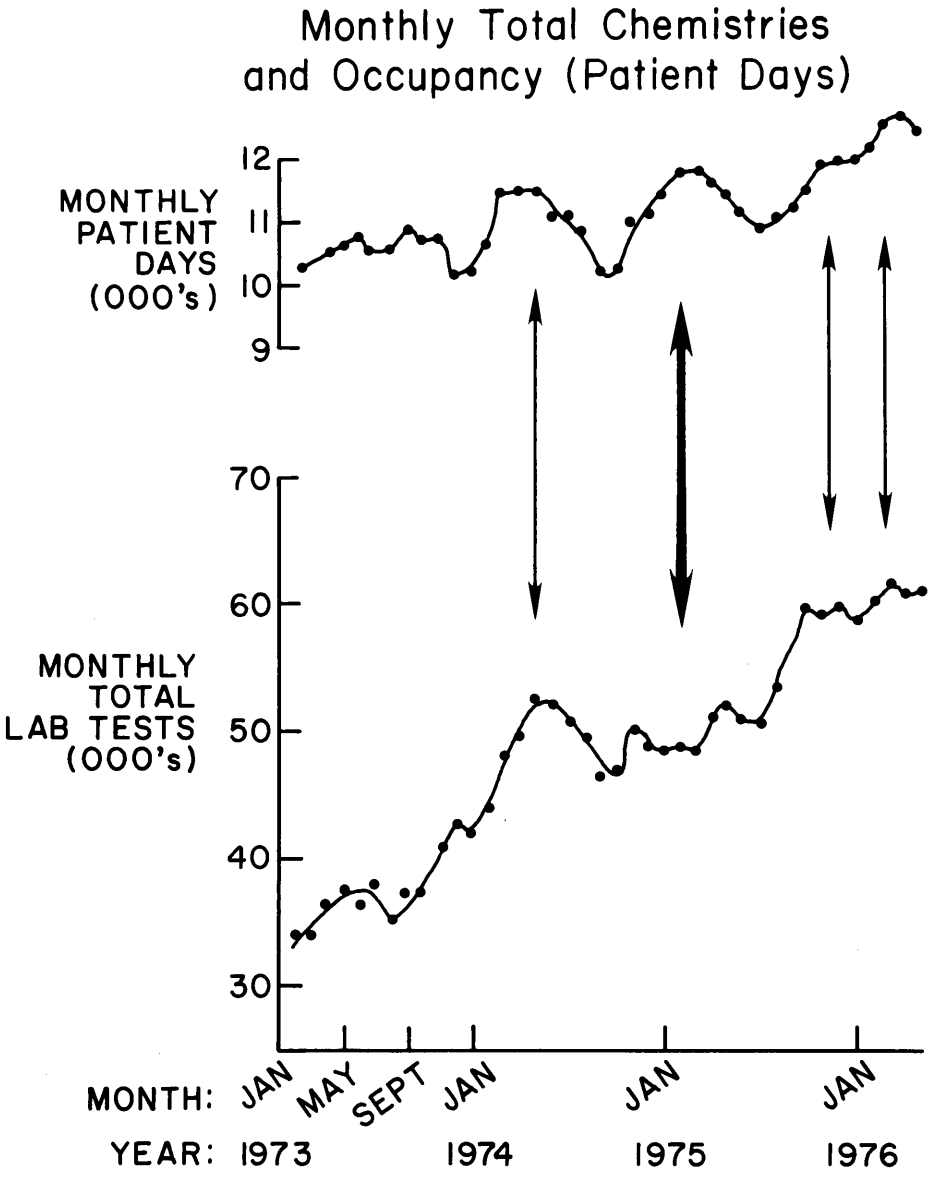
The yearly total test data presented in Table 3.1 and Figure 3.1 shows an anomalously low growth rate during 1974-75. In order to obtain further insight into the reasons for this variance, we examined the monthly total chemistry test performed from 1973 until 1976 and compared them with the monthly hospital occupancy rate (patient days). Monthly variations were in some cases extreme, in the range of 10-20%. Some correlation between monthly patient days and total test volume was apparent; Table 3.3 shows the correlation coefficient for each year. Moderate positive correlations exist for 1973, 1974 and 1976 ($r = 0.55$ to 0.85) but for 1975, a moderate negative correlation ($r = -0.44$) was found. Little information is obtained by graphical examination of the data until it is smoothed. Figure 3.3 shows 3-month moving averages as a function of time for monthly total tests and patient days. Positive correlation are noted (by narrow arrows) in mid 1974 and at the end of 1975. In the first quarter of 1975, there is a peak in

TABLE 3.3

CORRELATION BETWEEN MONTHLY TOTAL TESTS AND PATIENT DAYS

Year	Average Length of Stay ± 1 s.d. (days)	Average Monthly Total Tests (thousands)	Average Monthly Patient Days	Correlation Coefficient
1973	10.71 ± 0.28	36.8	10.3	0.553
1974	10.79 ± 0.32	49.3	11.1	0.845
1975	10.19 ± 0.57	51.1	11.5	-0.435
1976	10.74 ± 0.27	63.1	12.1	0.743

FIGURE 3.3



** All data points are 3-month moving averages.*

TABLE 3.4

AVERAGE LENGTH OF STAY IN THE HOSPITAL UNDER STUDY

Month Year	1973	1974	1975	1976
Jan		11.50	11.13	10.52
Feb	11.07	10.89	10.63	10.4
Mar	10.57	10.72	10.48	10.68
Apr	10.39	11.08	9.92	10.5
May	10.47	10.63	9.60	10.46
June	10.42	10.55	9.30	10.77
July	11.00	10.63	9.57	10.79
Aug	10.68	10.72	9.8	10.8
Sept	10.53	10.98	10.18	10.9
Oct	10.66	10.55	10.5	11.4
Nov	11.24	10.95	10.2	10.9
Dec	10.75	10.22	10.9	10.8

patient days of hospital occupancy which correlates negatively with the total tests performed (thick arrow). Also, in 1975, the average length of stay of a patient in the hospital is significantly lower than in 1974 or 1976 (Tables 3.3 and 3.4). It is concluded that there was a short-term change in hospital utilization during this period, particularly from April to August, 1975; associated with the admission of a group of patients with reduced length of hospitalization.

3.2 Distribution of Tests

The frequency of use of 23 major tests over the period 1972 to 1978 is shown in Table 3.5. Here, tests have been grouped according to the technology used in 1978. In each year, these tests account for over 90% of the tests performed. The percentage fraction of total tests not included in this set of 23 tests shows some variation from year to year, but there is no clear growth trend. While the introduction of new tests undoubtedly contributes to the total test volume, it is not a significant factor in the increase in chemistry laboratory utilization.

The so-called "LBC"* group of tests (Na, K, Cl, CO_2, BUN, Creatinine) represents slightly over half of the total tests performed. This fraction has been remarkably constant from 1971 onwards, as shown in Table 3.6. The growth in LBCs parallels the growth in total tests performed; see Figure 3.1 Growth in LBCs during the period 1972-74 is greater

*LBC is an acronym standing for 'Lectrolytes, BUN, Creatinine

TABLE 3.5

TESTS	1972	1973	1974	1975	1976	1977	1978
TOTAL	309.5	442.8	590.2	639.8	755.7	892.3	934.8
SMA6-I*	166.0	236.7	337.7	370.6	437.3	506.3	524.8
Enzymes	38.2	49.6	59.8	67.0	75.0	91.4	94.8
SMA6-II+	40.4	55.59	66.5	75.9	81.5	94.5	95.0
Glucose	21.4	29.2	34.8	36.3	45.3	47.8	49.0
Alkaline Phosphatase	8.6	10.9	13.4	15.9	16.6	21.3	20.8
Blood Gases	8.1	16.6	23.9	26.3	35.6	43.01	44.6
Cholesterol	3.4	4.0	5.4	5.9	5.9	7.52	8.4
Amylase	3.0	4.79	5.94	7.3	8.1	12.5	14.0
Subtotal	289.2	407.4	547.5	605.2	705.3	824.3	851.0
% of Total Tests Unaccounted	6.6	8.0	7.2	5.4	6.7	7.6	9.0

*SMA6-I: Na,K,Cl,CO_2,BUN,Creatinine +SMA6-II: Ca,PO_4,Total Protein,Albumin,Bilirubin,Uric Acid

TABLE 3.6

GROWTH IN LBC AND ENZYMES

YEAR	TOTAL "LBC"	% INCREMENT OVER PRIOR YEAR	LBC/TOTAL	TOTAL ENZYMES	% INCREMENT OVER PRIOR YEAR	ENZYMES/TOTAL
1971-72	166,030	--	.52	38,190	--	.12
1972-73	236,700	43	.53	49,640	30	.12
1973-74	337,690	43	.57	59,830	21	.10
1974-75	370,600	10	.58	65,980	10	.11
1975-76	437,330	20	.58	74,960	14	.10
1976-77	506,310	16	.57	91,380	21	.10
1977-78	524,880	4	.56	94,770	4	.10

than during 1975-77. There was a substantial change in laboratory technology for LBCs in 1972 when the first SMA-6 was introduced; it is possible that this technological advance accelerated the growth in LBC tests performed during the two years following its introduction. Mechanisms for the technology diffusion could include realization by house staff that the laboratory was reporting LBC data more promptly. No formal attempt was made to publicize the arrival of the SMA-6. Figure 3.4 shows trends in the remaining tests for which annual totals were available. The anomalous region between 1974 and 1975 is apparent for glucose and blood gases, but less so for enzymes. The growth in enzymes and SMA-6 - II tests is accelerated from 1976 to 1977, again following major technological advances in the laboratory for both test methodologies.

3.3 Chemistry Test Costs

The relative direct cost of the increased test volumes was determined for each year of the study; the data are summarized in Table 3.7.

From 1972 to the present, there has been an increase in the productivity of the technical staff of the chemistry laboratory. Total tests/full time equivalent employees (FTE) increased from 12.1 in 1972 to 20.7 in 1978, an increase

FIGURE 3.4

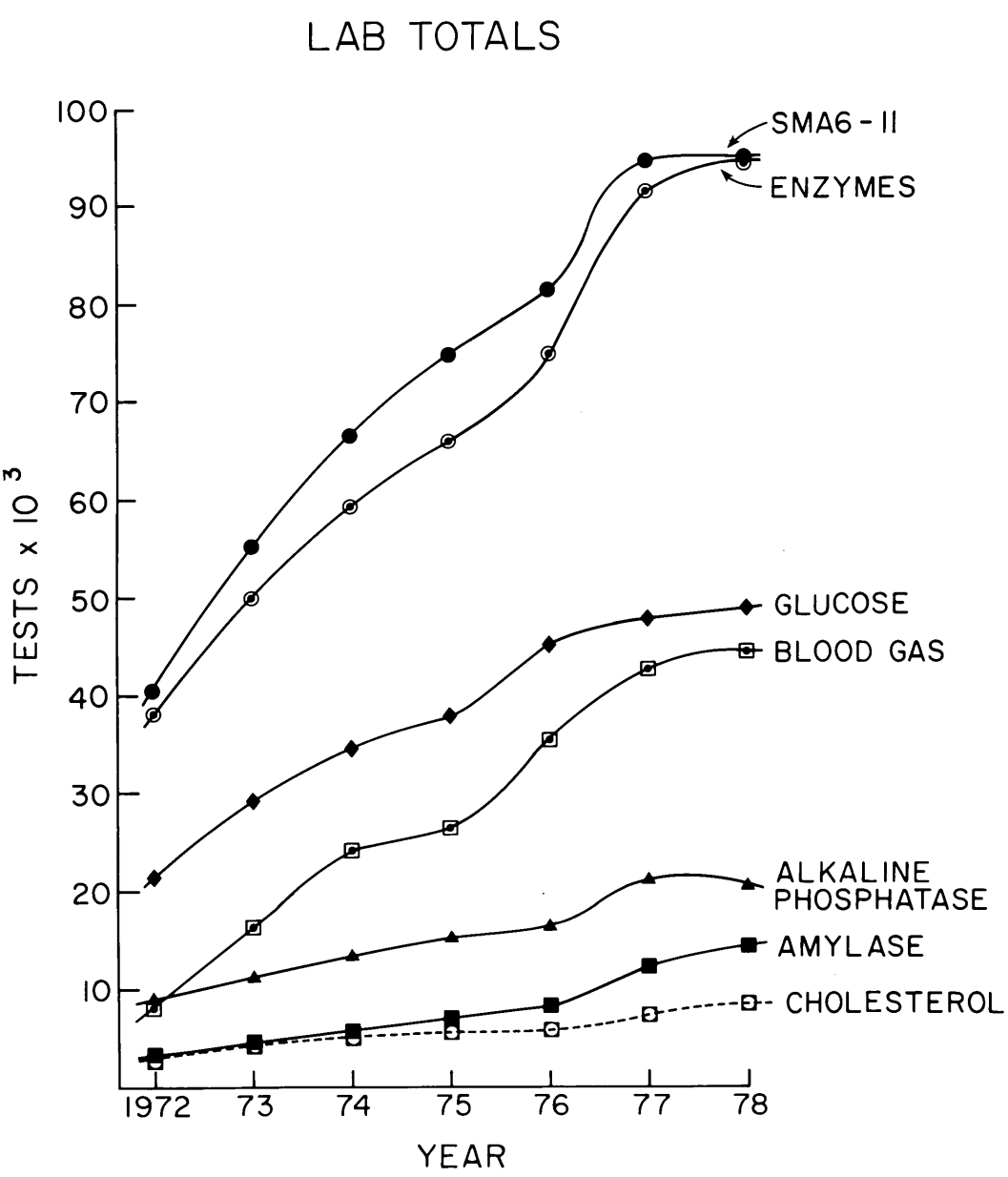

LAB TOTALS
100
90
80
70
60
50
40
30
20
10
TESTS x 10 3
SMA6 - II
ENZYMES
GLUCOSE
BLOOD GAS
ALKALINE PHOSPHATASE
AMYLASE
CHOLESTEROL
1972
73
74
75
76
77
78
YEAR

TABLE 3.7

RELATIONSHIP OF CHANGES IN TOTAL CHEMISTRY TESTING TO STAFF AND COST DATA

	STAFF			COSTS			
Year	Total Tests x 10^3	FTE*	Tests/FTE	Payroll $ x 10^3	Non-Payroll $ x 10^3	Ratio $\frac{\text{Total Tests}}{\text{Total Costs}}$	Ratio $\frac{\text{Cost (\$)}}{\text{Tests}}$
1972	320	26.5	12.08	196	69	1.21	.83
1973	443	27.5	16.11	263	108	1.19	.84
1974	588	33.2	17.71	322	129	1.30	.77
1975	615	34.2	17.98	404	152	1.11	.90
1976	756	39.0	19.38	540	240	0.97	1.03
1977	892	44.4	20.09	664	324	0.90	1.11
1978	935	45.4	20.69	746	370	0.84	1.19

*FTE = Full Time Equivalent Employees

of 71%. At the same time, there has been a very significant increase in both payroll and non-payroll costs resulting in a net reduction in the number of tests produced per total cost (from an average of 1.21 tests/dollar in 1972 to .84 tests/dollar in 1978. This change reflects a significant inflation in both payroll and non-payroll costs. For example, the cost/F.T.E. has increased from $7400 in 1972 to $15,270 in 1978 reflecting increases in direct compensation and fringe benefits (including social security and retirement). Non-payroll costs showed an even more remarkable six-fold increase during this period, reflecting both volume increases and higher reagent costs for more sophisticated and expensive tests. The net increase in cost/test predominantly reflects the inflationary factors, and in real dollars probably reflects a modest increase in productivity related to automation.

Chapter 4. MYOCARDIAL INFARCTION STUDY

4.1 Chemistry Test Utilization

The average number of chemistries performed on patients in the study groups (described in section 2.3), at intervals from 1963 to 1978 is illustrated in Figure 4.1 & 4.2. The increases in total chemistries seems broadly divisible into several phases. An early growth phase from 1963 to 1967 (phase 1) during which the average number of tests per hospital stay increased from about 30 to 50 tests, an increase of approximately 66% during this four year period (or an average exponential rate of growth of approximately 14% per year). There was little growth in testing from 1967 through 1970, but a second major growth spurt is evident by 1973 (phase 2) during which the averages rose to approximately 75 tests/admission in 1973, about 90 tests in 1975, and to approximately 140 in 1977. This constituted an exponential rate of increase of approximately 16% per year during this period. This growth rate is even more remarkable considering that the average length of hospital stay has reduced over this period. These data are

FIGURE 4.1

Average Number of Tests per Hospital Stay
(± 95% confidence limits)

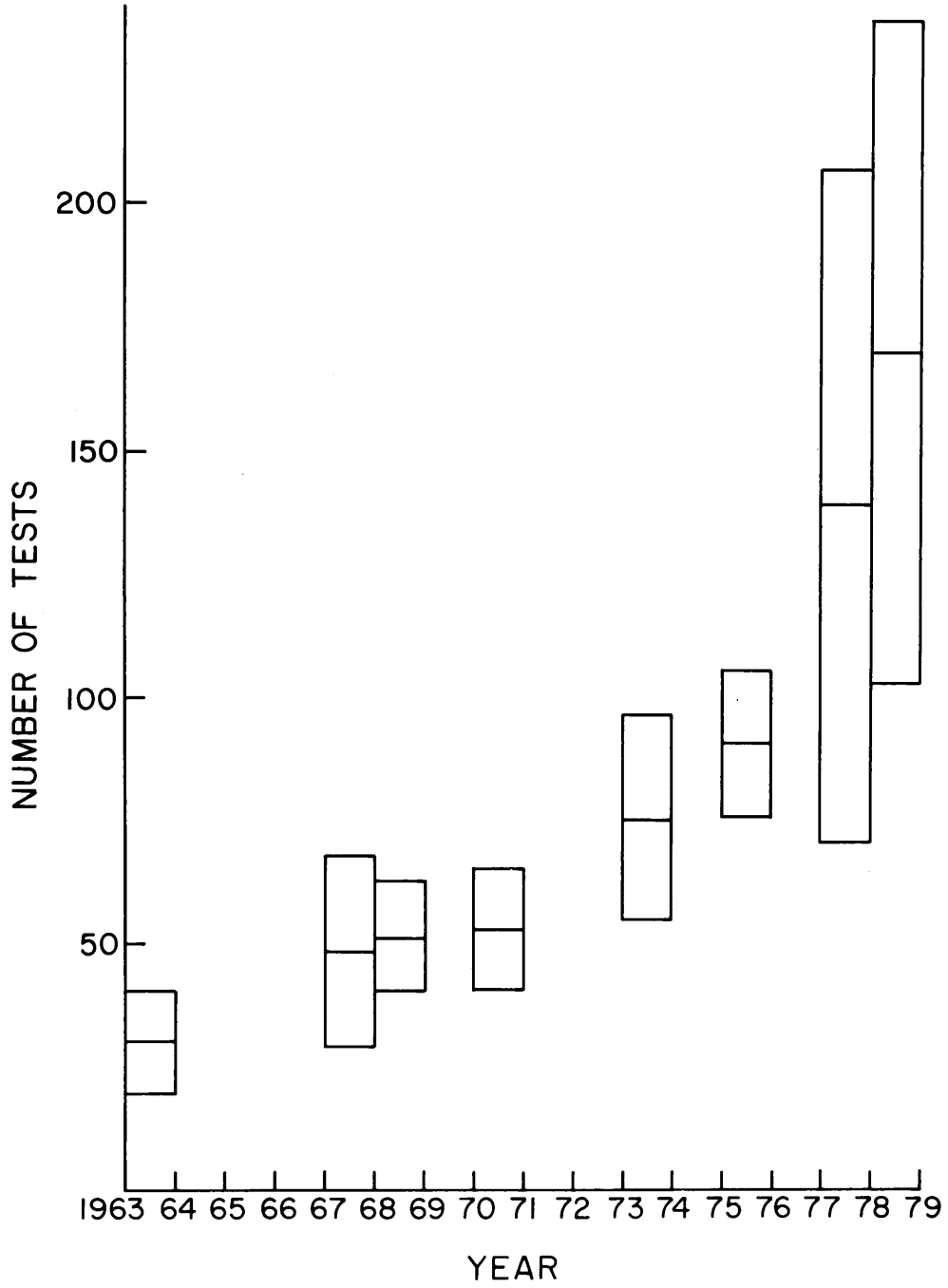
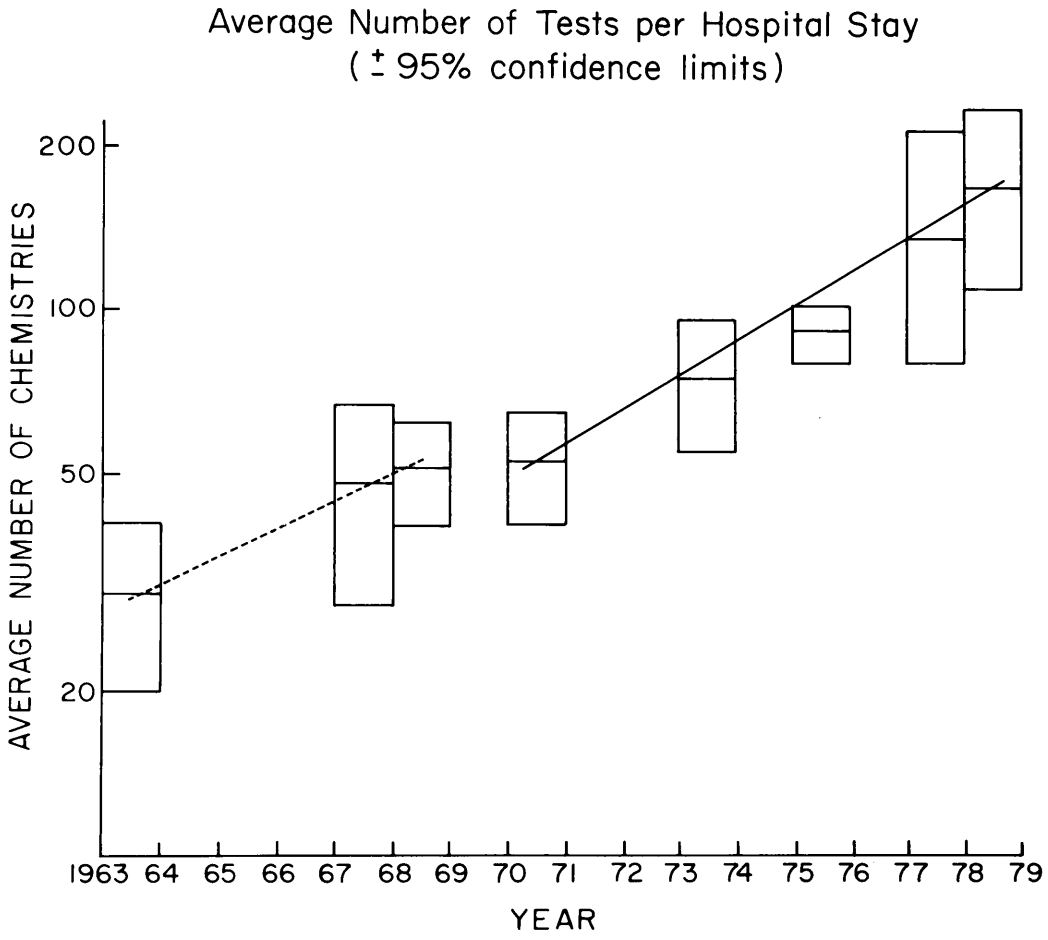


FIGURE 4.2



* SEMI-LOG PLOT

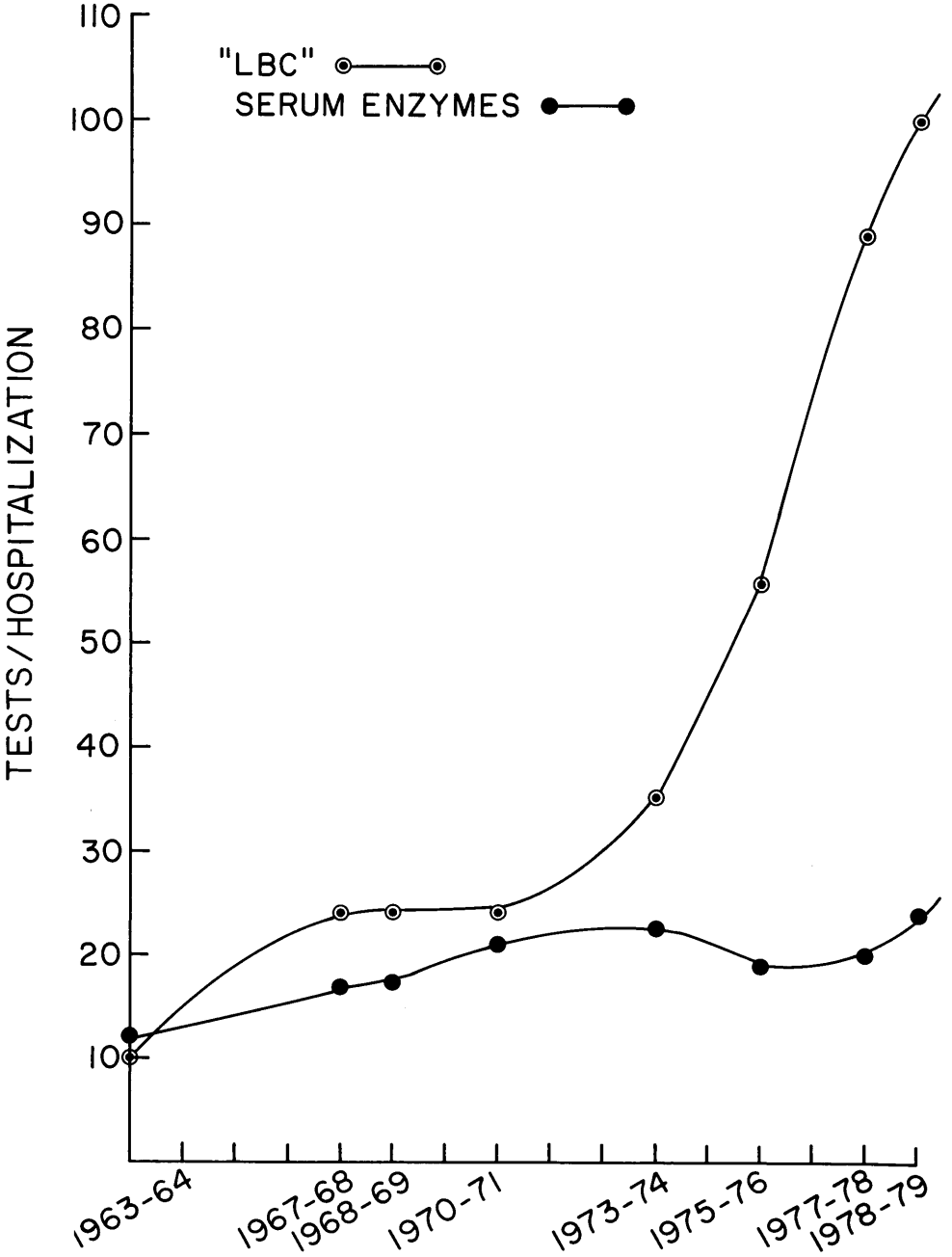
indicative of a marked increase in the intensity of laboratory usage in these patients.

The overall pattern of increase parallels the behavior for the hospital as a whole. Those determinations also showed a relative plateau in the early 1970s followed by a rapid rise from 1972 to 1977 (corresponding to phase 2 of the myocardial infarction study). The anomalous plateau observed in the hospital-wide study is not as evident.

Figure 4.3 summarizes the data for the so-called "LBC" group of determinations (electrolyes, BUN, and creatinine). These data reveal a pattern of growth almost identical to that seen for the total chemistries. This is not surprising since this group of tests constitute a very large proportion of the total clinical chemistry tests performed. In contrast, the changes in the average numbers of serum enzyme determinations did not show the same marked growth rate evident in the case of the LBCs.. This markedly different pattern indicates that, in this group of patients, the serum enzymes testing was not under the same growth stimulating

FIGURE 4.3

Average Number "LBC s" and Serum Enzymes per Hospital Stay



influences observed with the LBC or in the hospital population at large. This is an intriguing observation, and might provide some insight into the causes of the increased laboratory utilization, since, in this group of patients, the enzymes are used for diagnostic purposes (in contrast to the monitoring functions of the LBC determinations - see below).

In the period before the application of serum isoenzyme techniques in 1977 (which permit the differentiation of isoenzyme patterns of serum enzymes that are characteristic of different diseases and which might cause elevations in their overall levels), multiple and serial enzyme determinations were required to clearly establish the characteristic sequential pattern of serum enzyme increase and decline associated with acute myocardial infarction. Thus, the pattern and frequency of serum enzyme analysis was not as susceptible to variation as were other varieties of tests, particularly the "LBCs".

4.2 Intervals Between Tests

Ordering patterns of clinical tests have undergone significant changes during the period of study. A major

change is an increase in the frequency of testing resulting in progressively shorter intervals between consecutive tests. This shift is evident from Figure 4.4 which shows the frequency of various intervals between consecutive tests, for electrolytes, BUN and creatinine determinations. Although the most frequent intervals between tests in 1963 is one day, very significant numbers of tests were ordered at longer intervals, some with intervals greater than 6 days. As a consequence the average interval between tests in 1963 was 4.2 days. The intervals between consecutive tests fell progressively during the subsequent periods of study, with increasingly frequent requests for daily determinations. By 1978, almost all tests were requested at daily intervals, with an additional significant number of repeated tests requested on the same day. The average interval between tests is reduced to .87 days in 1978. The patterns obtained for the serum enzymes exhibited some differences (Fig.4.5). The tendency to order these tests predominantly at daily or 2-day intervals was already evident in 1963, but there was a slower progression in the direction of daily ordering of these tests. The average interval between individual serum enzyme determinations was 1.7 days in 1963, but the interval shortened to 1.1 days by 1978 (Table 4.1).

It should be noted that the increase in daily testing was not solely a consequence of the availability of automated instrumentation, since a significant number of instances of

FIGURE 4.4

INTERVALS BETWEEN CONSECUTIVE TESTS

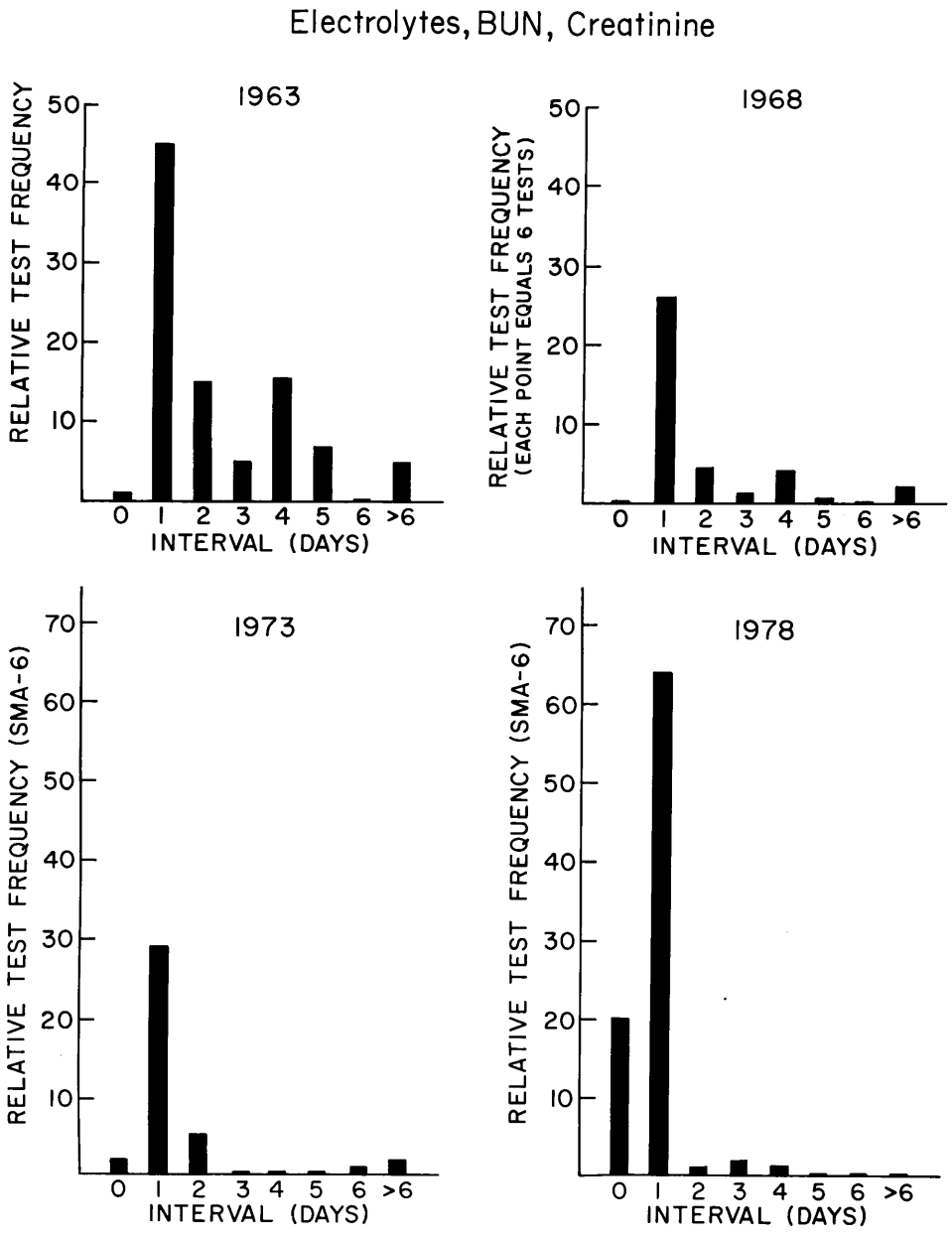


FIGURE 4.5

INTERVALS BETWEEN CONSECUTIVE TESTS

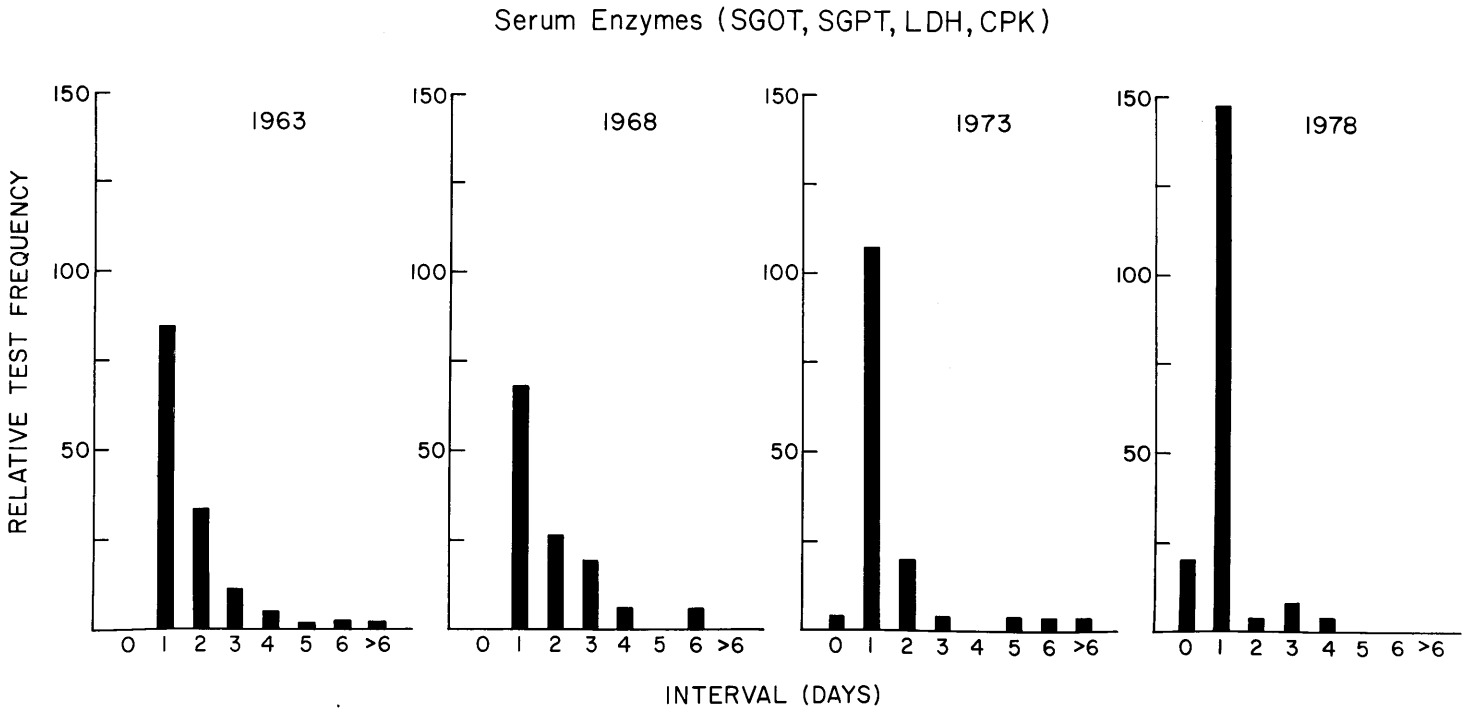


TABLE 4.1

WEIGHTED INTERVALS BETWEEN TESTS

Year	"LBC" (Electrolytes, BUN, Creatinine) Intervals (Days)	Serum Enzymes Intervals (Days)
1978	.87	1.1
1975	1.6	N.D.
1973	1.7	1.5
1970	2.9	N.D.
1968	2.9	2.0
1963	4.2	1.7

daily testing was observed in 1963 (admittedly less frequently than in 1973). Thus although the laboratory could respond to this intensity of demand in 1963, these daily requests were significantly less common before 1973.

4.3 Frequency of Abnormal Tests

The percent of total number of tests that were found to be abnormal was determined at each of the intervals studied (Table 4.2). With respect to the serum electrolytes, BUN and creatinine, there was a generally progressive reduction in the percent of abnormal tests between 1963 and 1977. Comparable changes were not observed for the serum enzyme determinations, since myocardial infarction results in predictable patterns of serum enzyme abnormalities and is consequently not as open to such fluctuation.

4.4 Test-Ordering Patterns (Grouping)

4.4.1-Frequency of test combinations: With the development of multichannel instruments such as the Technicon SMA-6, which could provide simultaneous determinations of multiple different laboratory tests from a given sample, the question arises whether such instruments stimulate the physicians to request groups of tests (according to their availability from these instruments) rather than individual tests (as was common formerly). We approached this question by examining the frequency with which the combinations of the 6 "LBC" tests (combined in the SMA 4+2) had been ordered simultaneously, during

TABLE 4.2

Percent Abnormal Tests - Electrolytes, BUN, Creatinine

Year	1963	1968	1970	1973	1975	1977
% Abnormal	48	37	39	34	24	28

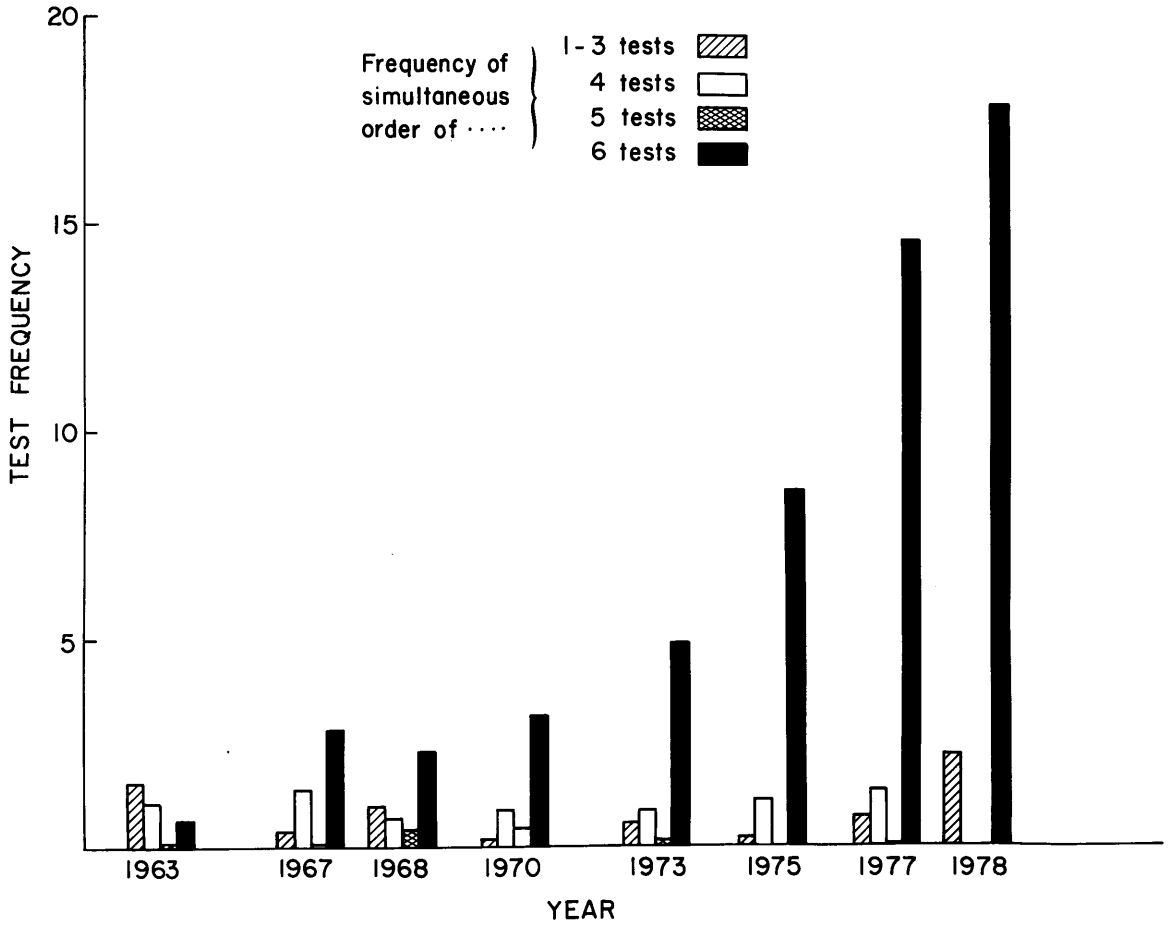
the period prior to the acquisition of that instrument in 1972, and whether the frequency increased after this time.

Figure 4.6 illustrates the ordering patterns for electrolytes, BUN and creatinine within the study group at different periods in the study. The frequency with which groups of either 1-3,4,5 or 6 of these tests were ordered simultaneously is plotted for each year of the study. (These figures are adjusted for the number of patients in each sample.) The data indicate that, although the frequency of ordering all of the six tests simultaneously increased following the acquisition of the multiple determination instrument, this pattern was already evident as early as 1967 and was well established by 1970, two years before the SMA-4+2 was operational in the laboratory.

In 1963, the majority of test requests were for combinations of 1 to 3 of the six tests; many of these were requests for single tests. By 1968, a majority of tests was ordered in groups of 6, with a significant frequency of combinations of 4 or 5 tests. By 1970, the trend has progressed still further, with combination of 4 or more tests now the rule, and the combination of all six becoming more common. By 1973, the proportion of combinations of six tests had increased further with only small numbers of test requests in other categories. By 1978, almost all tests are requested as the six test battery, with relatively infrequent groups of 1 or 2 tests; groups of 4 or 5 tests had become uncommon.

FIGURE 4.6

Group Ordering of "LBC s"



This clearly indicates that, in this sample, the practice of ordering the combination of six tests ("LBC") antedated the availability of the multichannel SMA 4+2. The decision to offer a combination of these 6 tests seems to reflect an attempt by the instrument manufacturers to be responsive to a pre-existent propensity to order a combination of these tests. While the availability of this combination in a single instrument may have encouraged the ordering of tests in combination, the instrumentation did not initiate the trend, in this instance.

4.5 Comparison of the Frequency of Diagnostic and Monitoring Functions

The clinical utility and purpose of laboratory tests varies within the hospital stay. During the initial period of hospitalization, the laboratory tests are used predominantly to assist the clinician in the diagnosis of a patient's illness. In the case of acute myocardial infarction, evidence of certain serum enzyme abnormalities is an important factor in the diagnosis, and serial determinations during the first 3 hospital days is common. Other tests are also useful in the differential diagnosis as well as evaluation of the function of other organ systems which may be impaired; these also are generally ordered within the first few days of hospitalization. In contrast to this diagnostic utilization, tests obtained during the remainder of the hospitalization tend to serve a "monitoring function", assisting in the evaluation of the

patient's current condition and response to therapy.

We have analyzed the laboratory utilization data with respect to the incidence of diagnostic or monitoring tests; the data are presented in Figure 4.7. For the purpose of this comparison, diagnostic tests are defined to include all tests ordered within the first 3 days of hospitalization, as well as any test ordered for the first time after this 3-day period. All others are termed "monitoring" tests. As can be seen, the numbers of both monitoring and diagnostic tests per hospitalization rose throughout the test period. However, the proportion of monitoring tests rose significantly from 1975 to the present, despite the drop in length of stay. While the ratio of diagnostic to monitoring tests varied from 1.0 - 1.2 from 1963 to 1973, the ratio declined to .75 in 1975 and finally to .60 in 1977 and 1978. The data indicate that the increased intensity of monitoring activities constitutes a major element in the increased laboratory utilization in recent years.

Still another demonstration of this phenomenon is evident by comparison of the average number of tests performed during the first and last 5 days of the hospital stay (Table 4.3). In general, the data show a progressive increase in the number of tests in these two intervals from 1963 to the present. Considering the initial 5-day period, the number of tests increased from an average of 3.8 in 1968 to 21.8 in 1978. Similarly, the number of tests ordered during the last

FIGURE 4.7

Average Number of Chemistries per Patient as Diagnostic or Monitoring Functions

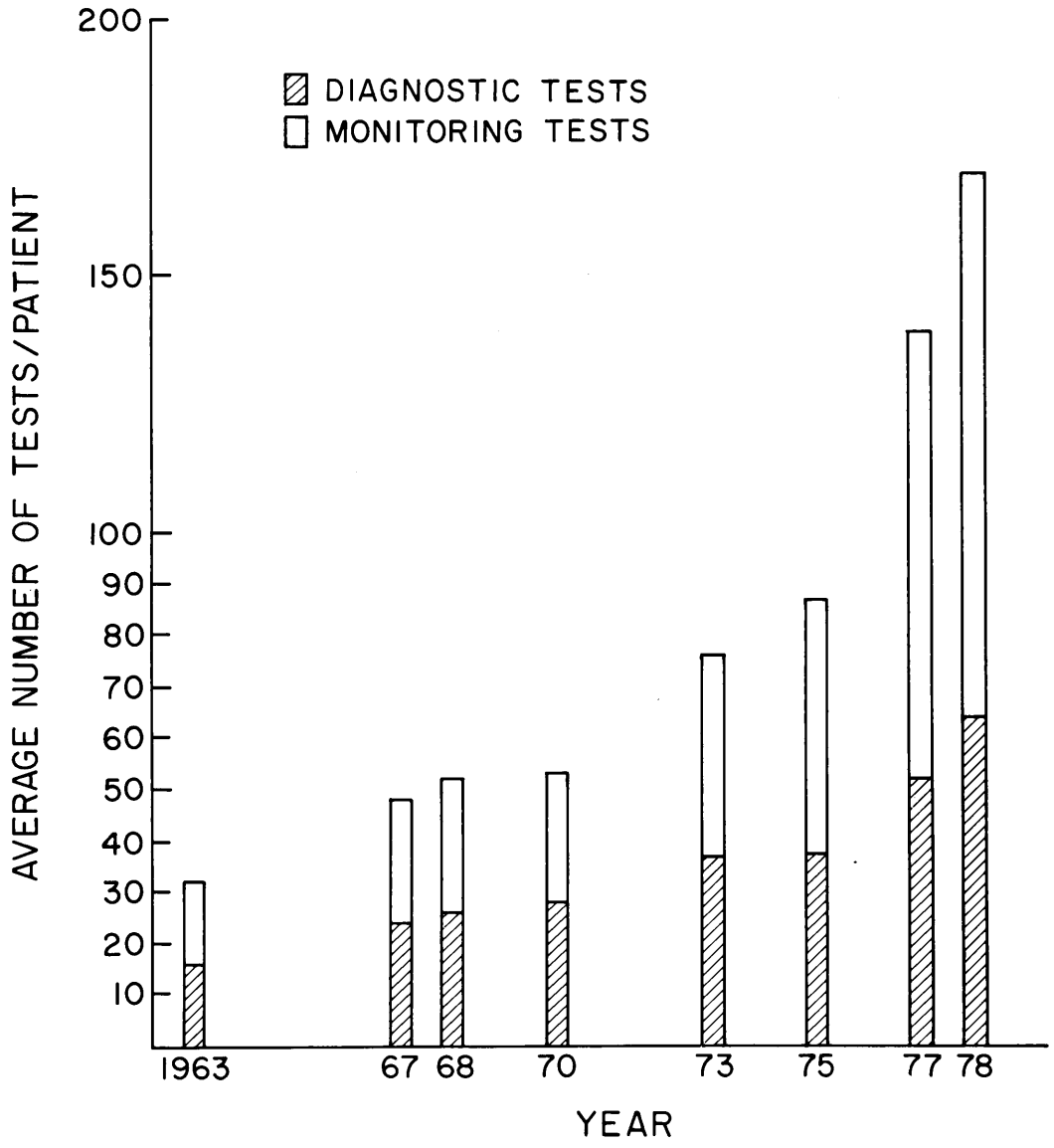


TABLE 4.3

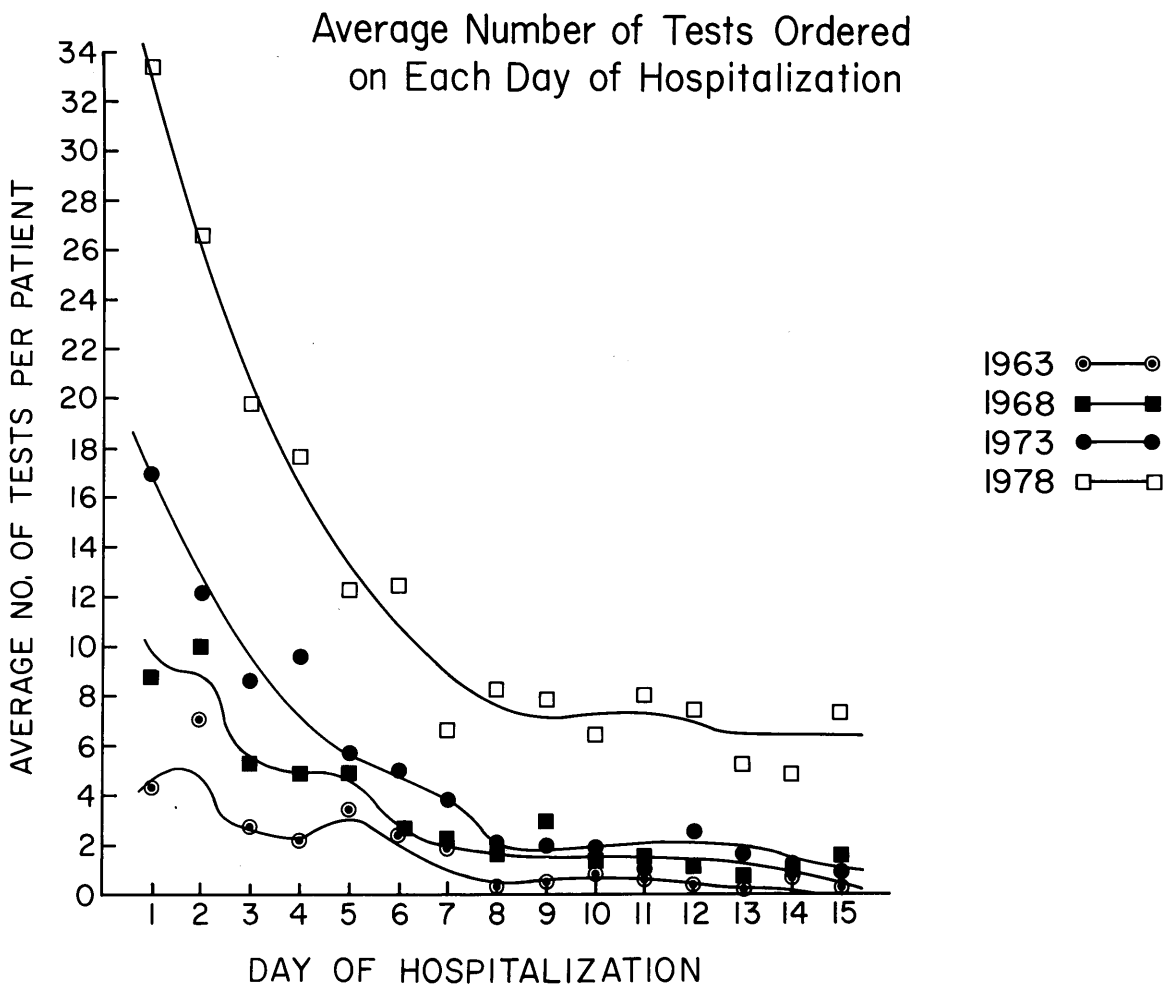
AVERAGE NUMBER OF TESTS
FOR FIRST AND LAST FIVE DAYS OF HOSPITAL STAY PER PATIENT

Avg.# Tests per day per patient	Year 1963	67	68	70	73	75	77	78
5 days after admission	3.8	4.7	6.2	6.9	9.7	11.0	14.9	21.8
5 days prior to discharge	0.25	0.8	0.29	0.49	1.2	1.4	4.1	5.3
First 5 days / Last 5 days	15.1	5.8	21.3	14.1	7.8	7.9	3.6	4.1

five days of hospitalization increased progressively from an average of 0.25 tests in 1963 to 5.3 in 1978 (the 1967 value is anomalous, resulting from a single patient in whom a large number of tests were ordered just before discharge). The significant increase from 1975-1977 predominantly reflects the large increases in LBCs observed during the period (Figure 4.3). The ratios of first/last days shows a marked decline, indicating that late, sustained monitoring is progressively increasing as a proportion of the total.

A third approach to demonstrating the changes in test ordering pattern from 1963 to the present involved the comparison of the average number of tests ordered on each day of the hospitalization. The data for 4 of the test periods are illustrated in Figure 4.8. In 1963 and 1968, the highest test frequencies occurred within the first 4-6 days of hospitalization, with averages falling below 1 test/day soon thereafter. By 1973, the initial levels of testing were substantially greater and, thereafter, persisted for a longer duration, while averages in the range of 2 tests/day were maintained throughout most of the period of hospitalization. By 1978, this pattern had become even more marked; very high levels were maintained for the first week, and moderate levels (in the range of 6 to 8 tests/day) were sustained throughout most of the remainder of the hospitalization.

FIGURE 4.8


Average Number of Tests Ordered
on Each Day of Hospitalization
AVERAGE NO. OF TESTS PER PATIENT
0
2
4
6
8
10
12
14
16
18
20
22
24
26
28
30
32
34
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15
DAY OF HOSPITALIZATION
1963
1968
1973
1978

This also indicates that early progressively higher levels of sustained monitoring activity is also evident in the more recent groups (in 1973 and particularly in 1978).

The time after admission required to reach the average level of testing was calculated for each of the four years; it decreased progressively from 6.9 days in 1963 to 6.0 days in 1978. This result is consistent with an increased level of monitoring activity, giving rise to this shift of the "day of average testing" to an earlier period after admission.

Chapter 5. DISCUSSION

5.1 Laboratory Test Utilization

Our study of the total chemistry test utilization revealed an exponential growth in tests over the period of 1971-1977, in this medical center. This growth pattern is comparable to that observed in laboratory testing throughout the United States, during the same period (7, 8, 21, 22). Since most of these studies provided aggregate data, summarizing the behavior of many hospitals or of all laboratory tests within a given hospital, they may be influenced by a variety of factors resulting from uncontrolled changes in the patient population. For example, one might argue that some of these increases are the result of changes in the average severity of illness, and that patients now tend to be relatively more ill than in prior years. What is more likely is that some patients who had been admitted in the past (for a diagnostic work-up, for example) would now obtain these tests as outpatients due to increasing pressure from PSRO organizations. One might also speculate that with improvement in therapy(such as antibiotics) seriously ill patients with chronic diseases are kept alive for longer periods before finally succumbing to their illness. These terminally ill patients would require particularly intense treatment and laboratory monitoring. One might also speculate that since both Medicare and Medicaid have facilitated the availability of health care to two groups

(the elderly and the poor) who might be expected to have more serious health problems, these have affected the case-mix of the hospitals in an adverse way.

In order to avoid these sources of variability, we have also elected to study the lab utilization in a well-defined, though small, group of patients. They were selected as having uncomplicated myocardial infarction, and are as close to a homogeneous group of patients as we were able to identify. We selected this group of patients since the diagnosis and treatment involved a substantial utilization of clinical laboratory services, particularly chemistry. Furthermore, there has been some expansion in the range and variety of laboratory tests useful in these patients over the period of this study. For example, serum creatinine phosphokinase (CPK) enzyme first came into use in this laboratory in about 1970, while serum isoenzyme determination of serum lactic dehydrogenase (LDH) and CPK was instituted in about 1977. The general increase in automation would also heavily impact on these patients because of the heavy use of serum electrolytes (particularly potassium) and blood gases in their therapeutic monitoring.

The data suggest that the increased laboratory utilization seen in this defined hospital group was not substantially different from the behavior of the general hospital population. Both showed a remarkable growth in the chemistry testing, with exponential increase in the range of 14% per year from

1970 to 1977, a figure which is in general agreement with the experience throughout the country. (The only significant discrepancy was evident in 1973 and 1974 when total tests grew at a greater rate than the myocardial infarction patients, as a consequence of incremental increases in hospitals beds up to about 120% of the 1972 level).

From the mid 1950s through the 1960s, some hospitals reported that the number of laboratory tests ordered per patient doubled every five years. Typical was Yale-New Haven Hospital which in 1954 performed 48,000 laboratory procedures; in 1959, 98,000; and in 1964, 200,000 associated with only a slight increase in patient census (23). In the 1970s the rate of hospital testing expanded at a slightly faster pace. From approximately 2 billion tests performed in 1971, the number climbed to about 3 billion in 1974 and to roughly 5 billion in 1977 (24). Of these, approximately 30% were clinical chemistry tests, at a cost in 1977, of approximately 3 billion dollars.

5.2 Factors Influencing Laboratory Utilization

5.2.1 Patient Factors

The major patient related factor is the nature of reimbursement for health care delivery; namely the increase in third party payment for health care with the advent of Medicare and Medicaid. In 1974, for example, 21% of patients' bills in the hospital under study were reimbursed by Medicare, 18% by Medicaid, 42% by Blue Cross and only 19% by the patients themselves or through commercial insurance.

5.2.2 Technological Factors

Laboratory factors include increased capability and reliability of the results, and the development of automated multichannel analyzers. Two major technological factors may affect laboratory utilization: the introduction of new tests without retiring older tests and the impact of automated analyzers, particularly those which perform a profile of tests which the physician would not otherwise have ordered. Our study of both the total tests ordered in the chemistry laboratory and tests ordered for a group of myocardial infarction patients has shown that 23 tests account for over 90% of the test volume. The total test volume has, of course, been growing with time so that the unaccounted 10% represents a growing number of tests. However, most of the growth in laboratory utilization is due to greater use of established tests.

Two major technological advances occurred in the analyzed chemistry laboratory during the period studied: the introduction of the first SMA6 in 1972 and the second SMA 6 and GEMSAEC in 1976. Following both events the rate of increase in test volume for LBCs, SMA6-II chemistries and enzymes was slightly greater than would have been expected from prior trend data. It may be suggested that such technological advances do have a small, albeit short lived (1-2 year), effect in escalation of laboratory tests. The tendency for physicians to order LBCs in groups of six was established before the introduction of the SMA6 in 1972; this profile-ordering pattern certainly

became dominant in subsequent years, which may be attributable to the presence of the SMA6.

The basic question which must be answered regarding the impact of technology is whether test utilization expands to the capacity of the laboratory or whether the laboratory primarily keeps pace with the demands of the physician. In other words, is laboratory utilization subject to a technological (instrument induced) push or a need (physician demand) pull. Our data do not provide an unambiguous answer to this question. LBCs had apparently reached a plateau prior to introduction of the SMA6 in 1972, but grew rapidly afterwards. However, it may be argued that the SMA6 was acquired in response to an unmet physician demand. Our subjective conclusion is that laboratory test volumes are largely determined by physician need and that new automated technology has a minimal causative effect.

5.2.3 Physician-Related Factors

Specialization: The physician-related factors seem to play the predominant role in the remarkable increase in laboratory utilization. The effect of a high degree of subspecialization has already been discussed. In the particular hospital used in the study, the degree of subspecialization is rather extreme, with a high degree of subspecialization in internal medicine, pediatrics and surgery and very few general

internists, pediatricians or surgeons on the staff. The staff is essentially full-time (and until recently were salaried employees of the hospital); all have teaching appointments at the medical school, and many are actively engaged in clinical research.

There is a very active house staff training program, complemented by extensive fellowship training in subspecialities (particularly in internal medicine). Responsibility for ordering of laboratory tests rests predominantly with the house staff; daily rounds are held with the attending physician on service for the month, at which time the current status of each patient is reviewed. The hospital is generally recognized as an excellent hospital in which to obtain clinical training; several hundred applicants apply each year for 12 internship positions in medicine . This implies a substantial degree of independence of the house staff, in whom major responsibility for day-to-day patient care is vested. The medical services are entirely organized into subspecialty divisions (e.g. cardiology, hematology, nephrology, endocrinology, gastroenterology, etc.) and all patients are assigned to one of these, as appropriate. The presence of medical student "externs" on each service may tend to increase laboratory utilization somewhat, in order to satisfy their natural curiosity. This degree of subspecialization undoubtedly contributes to the exceptionally high level of laboratory

testing.

Lack of effective interaction/consultation with laboratories: There is no formal interaction/consultation between clinical laboratory directors and the clinicians/house officers who utilize the laboratory data. No attempts have been made to intervene or otherwise influence the ordering of laboratory tests by clinicians/house officers (other than attempts to discourage unnecessary "stat" [urgent] requests for exceptionally rapid reporting of results). On the contrary, the laboratory has attempted to respond to the increased demands with increased services, automation, and more extensive coverage to almost 24 hour service, seven days a week.

Malpractice: Another general physician related factor is the increasing threat of malpractice suits, resulting in an increase in "defensive medicine", a term applied to the use of diagnostic procedures to avoid litigation. Physicians have felt compelled, in some instances, to carry out laboratory testing in cases in which the physical examination and history have already yielded an unquestionable diagnosis. The major increase in rates began in 1972 and may have contributed to the increased laboratory utilization evident at that time.

Influence of technology: A much more significiant factor relates to the attitide toward technology shared by physician and patient alike. (For a comprehensive discussion

of this point, see Reiser's book "Medicine and the Reign of Technology"[4]). Reiser notes that the increased reliance on technologically-produced data at the expense of the physical examination and history has been a matter of concern in medicine for a number of years. In 1921, Tieken wrote, "For years, physicans and many of our well-known teachers have leaned so much towards laboratory methods that physical diagnosis has almost become a lost art" (25) and the dependency has significantly increased since then. Beginning in the 1930s and accelerating by the 1950s the newer generations of professors of medicine seemed interested principally in the biochemistry of disease and "a number shifted almost directly from the laboratory into professorial chairs at hospitals and medical schools" (4). The physician/scientist, steeped in laboratory and clinical investigation, was the model against which all academic physicians were measured.

Furthermore, another factor in the increased attachment to machine-produced evidence occurring during the 20th century "originated in part from contemporary faith in science and technology, and a belief that a scientific spirit entered clinical practice through technology" (4). Laboratory data, provided by means of a sophisticated instrument,seemed to satisfy the desire of the physician for precisely expressed clinical evidence. Progress in medicine was measured by some according to the degree to which quantitative measurements

replaced qualitative clinical judgments. At the same time, an increasing proportion of health costs were borne by private and government insurance, which also covered patients for laboratory and x-ray examinations (the proportion increasing to almost 75% of the population by 1974 [26]). It is likely that, with little cost constraint, both physician and patient encourage the increased utilization of laboratory technology in the detection and evaluation of illness. Furthermore, as a result of increased automation, the laboratories tend to be increasingly cost effective, generating more tests at a reduced real cost/test. A more crucial issue, not usually addressed, is the question of the extent to which the biochemical changes in blood serum reflect the critical alterations which are occurring within the diseased cells. The ready availability of serum should not obscure the fact that it only indirectly reflects the intracellular events which are more crucial to the understanding of disease. This high expectation of serum is, in some sense, analogous to the older belief (now discredited) that the chemical composition of the urine could provide major insights into the nature of the disease processes in general. While the value of the characterization of serum elements is obvious, its real limitations should also be appreciated.

Behavioral factor: Most marked changes seem to reflect behavorial characteristics of the clinician - particularly

evident in the myocardial infarct study.

Most noticeable was the increased intensity of chemistry testing. Not only was there a marked increase in total levels, but the intervals between consecutive tests progressively shortened so that, by 1978, most tests are ordered daily (and the average intervals is shortened to below 1 day). Furthermore there are greater levels of sustained monitoring activity throughout the course of hospitalization. While there was some shortening of average length of stay (from 22 to 15 days), this does not account for the markedly greater testing levels throughout the hospital stay in recent years. One factor undoubtedly relates to the "crisis orientation" evident within the Coronary Care Unit (CCU). The constant monitoring of cardiac status also seems to lead to an urgency regarding other monitoring activities; the current procedures include daily orders for "LBCs" and enzymes for all patients (orders are written on the day of admission).

Another remarkable feature of the growth in clinical chemistry tests is that the proportion of LBC/total remains relatively unchanged (from about 52% in 1972 to 56% in 1978) in spite of an almost 3-fold increase in testing. This also suggests an increase in intensity of testing, rather than a change in quality.

The increasing "packaging" of the LBC requests is also remarkable. Although there is not a strong rationale,a priori, to combine BUN & creatinine requests with electrolytes (Na,

K, Cl and CO_2), this is now the preponderant manner of ordering them. This pattern antedated the advent of the SMA-6 which linked these 6 determinations in a multichannel instrument. This linkage is more remarkable when one considers the expected rate of change in these two groups of tests. Serum potassium levels might undergo quite rapid shifts, under certain clinical circumstances, but BUN and creatinine would be expected to show relatively slow (and predictable) alterations under most clinical circumstances. Consequently, changing K levels might require more rapid investigation than BUN/creatinine changes. In general, change in these 2 groups should require different frequency of study and, consequently, the practice of universally grouping these tests seems to be questionable.

5.3 Determination of Appropriate Levels of Laboratory Utilization

As is evident from the foregoing discussion, there are a great many causes of increased laboratory utilization over the past 30-40 years. We have, thus far, avoided the issue of whether this remarkable growth in utilization is necessarily indicative of unneccessary and inappropriate usage and should be vigorously discouraged. While most people will agree that some of this growth is unnecessary, there may be significant differences of opinion on how much of it would fit into that category. Short of a case-by-case review of hospital records, how can the question of the appropriateness of laboratory

testing be resolved? What sort of evidence might be utilized in establishing evidence of excessive, unnecessary usage?

One simple approach would be to determine the proportion of abnormal and normal values, with the implication that the tests yielding normal values were likely to be unnecessary (15) This simple view is unfortunately open to objection. The conversion of a test value from abnormal to normal may indicate the efficacy of therapy, while in other instances, it is required to ascertain that certain undesirable side effects of therapy had not occurred. Furthermore, in some instances, normal values are very valuable in resolving certain diagnostic problems (27). For example, if alternative A has a higher incidence of abnormal values with the given test than condition B, a <u>normal</u> value provides indirect support favoring condition B.

At the other extreme, an increased proportion of abnormal tests results does not necessarily indicate effective laboratory utilization. It might also reflect unnecessary laboratory testing consequent to excessively frequent and repetitious requests for the tests which were already demonstrably abnormal, and could not reasonably be expected to have been significantly altered in the interval. If an additional condition of "necessity" is introduced requiring "usefulness" of the data (in terms of its initiating some change in treatment), even the abnormality of the test result would not guarantee

its "necessity".

Another approach to the establishment of appropriate levels of laboratory utilization is the development of "group norms" which would establish some level of current practice as a correct standard. This has the advantage of relative simplicity, but it does not resolve the difficulty of establishing that the "normal" behavior is actually appropriate.

This brief discussion of the problem of establishing an unequivocal method of establishing the "proper" level of laboratory utilization, for different categories of diseases and patients indicates the problems inherent in any sample monitoring schemes (such as determining percent abnormal, or test frequency).

5.4 General Recommendations

The best alternative suggested by a number of authors (3, 9,23,28) involves a controlling role of the clinical laboratory directors and clinicians in the education and monitoring of laboratory usage. Educational programs might involve the appropriate use of particular tests, significance of abnormal values and relation of test results to disease, as well as the costs of laboratory tests; these programs would be directed to medical students, house officers and attending staff. There is some evidence that educational programs such as these can influence laboratory utilization, but these programs must be repeatedly reviewed to remain effective (29).

Key individuals in the implementation are the directors of the clinical laboratories, who would need to play an expanded role as laboratory consultant, advising on the use and interpretation of laboratory tests, design diagnostic test strategies for different types of disease, and establish a test monitoring system to provide continuing review of current laboratory utilization.

The fundamental problem of the consequences of increased dependence of the clinician upon diagnostic technology still remains unresolved. Its use can enlarge the physicians' knowledge of disease, but they may rely too much on such technology, and not enough on diagnostic capability based upon their own ability and experience. Otherwise the physician "risks becoming merely an intermediary between the patient and the medical judgments rendered by technical experts and machines" (4).

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