CLINICAL LABORATORY MANAGEMENT

A Guide for Clinical Laboratory Scientists

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PREFACE

What has prompted many another text motivated this one. Nothing else seemed to be quite suited for introducing the principles of management to students in clinical laboratory sciences programs. With the steep increase in test volume brought about by automation, sophisticated instrumentation, and computers has come a concomitant trend toward complexity in clinical laboratory operation. Clinical laboratories are now big business, and we glibly refer to "the laboratory industry." The clinical laboratory scientist, in addition to applying the principles of the sciences to the development and performance of diagnostic tests, is expected to manage work flow and supervise people. This book is intended to provide a beginning for learning those skills.

While there was no text for students, there are many highly skilled laboratory managers. Some of them, known either personally or by reputation as being able to operate efficient clinical laboratories, agreed to share their knowledge of management practices—often acquired on the job without the benefit of a single course in business or management. Several hospital administrators and other experts in their own fields also contributed valuable chapters.

The result is a collection of articles centering about three themes. Preceded by an overview that places clinical laboratories in perspective within the health care setting, these chapters focus on personnel supervision, work management, and the external forces that affect clinical laboratories.

The contributors, chosen mainly for their expertise, are widely dispersed geographically. None had the opportunity to read chapters written by others. We, the editors, purposefully permitted some duplication in content among the chapters to avoid destroying the context of a chapter as well as to enhance students' learning of new material through reinforcement.

Another note on style: Despite the fact that approximately 75 percent of laboratorians are female, the male pronouns are used throughout. No sexism is intended: rather, we opted for correct, uncomplicated grammatical construction.

The book is intended for clinical laboratory sciences students in the latter stage of a baccalaureate degree program, for recent graduates, and for newly appointed section supervisors in clinical laboratories. This text presumes no prior knowledge of management practices. However, a general familiarity with the workplace is necessary; otherwise, the reader will have no point of reference for many of the examples cited. Although the terms used and techniques described are at a basic level, we hope that readers can adapt some of them for their own use or will be stimulated to consult more definitive texts and articles listed at the ends of the chapters.

The gestation period of this book was long. We are grateful for the contributors' forbearance, and hope that they are pleased with the product.

We thank our colleagues, the faculty members in the clinical laboratory sciences programs at the University of Minnesota and the University of Alabama in Birmingham. They often freed us from other duties so that we had time to work on this project. We appreciate their suggestions and some valuable insights made by students and former students.

We are grateful to others for their contributions. Several laboratory managers, Karen Olsen, Shirley Pohl, Gloria Gilbert, Terry Duffy, and Joan Logue, provided useful ideas. Sarah Boardman, formerly of Little, Brown and Company, initiated this project, and Barbara Ward, Elizabeth Welch, and the staff of Little, Brown and Company have given continuing encouragement. The services of Julia Stair, the copyeditor, and of Linda

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We invite criticisms and suggestions from readers.

P. A. A.
K. R. K.
K. R. V.

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1. AN OVERVIEW

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1. CLINICAL LABORATORIES —A SURVEY

KEY WORDS

accreditation The process by which an agency or organization evaluates and recognizes a program of study or an insitution as meeting certain predetermined qualifications or standards. Examples: CAHEA accredits programs in the clinical laboratory sciences; JCAH accredits hospitals.

AMT (American Medical Technologists) A professional certifying organization composed primarily of certificants of AMT, who tend to be graduates of 1- and 2-year proprietary programs.

ASCP (American Society of Clinical Pathologists) A professional organization composed of pathologists.

ASMT (American Society for Medical Technology) A professional association composed primarily of medical technologists (clinical laboratory scientists) but which also offers membership to others in the clinical laboratory sciences.

Board of Registry of ASCP A certifying agency for personnel in clinical laboratory sciences. The Board of Registry provides examinations for generalists (e.g., medical technologists), categorical personnel (e.g., cytotechnologists), and specialists (e.g., specialists in blood banking—SBB).

CAHEA (Committee on Allied Health Education and Accreditation) A committee of the American Medical Association (AMA) that accredits education programs in at least 26 allied health areas. CAHEA is concerned with program accreditation and is not involved in certification or licensure of individuals.

CDC (Center for Disease Control) A multipurpose governmental center which conducts investigations of infectious diseases, offers a proficiency testing program, is involved in laboratory inspections, and offers continuing education programs for laboratory personnel.

certification The process by which a nongovernmental agency or association grants recognition to an individual who has met certain predetermined qualifications specified by that agency or association. Examples: The Board of Registry, AMT, ISCLT, and NCA offer certification examinations to qualified individuals.

clinical laboratory A facility in which analyses are performed on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment, or for the assessment of the health of humanity.

CPI (consumer price index) The average index of prices for consumer goods and services, based on a 1967 figure of 100. Goods and services that cost $100 in 1967 cost $259 in 1980; the medical care goods and services component cost $278.

defensive medicine A phrase used to denote a practice in which physicians overutilize tests, procedures, or treatments out of fear of litigation (being sued).

independent laboratory (private) A clinical laboratory not subject to the supervision of a hospital or its staff and physically located outside a hospital setting (freestanding).

ISCLT (International Society for Clinical Laboratory Technology) A professional association composed primarily of certificants of ISCLT, who tend to be trained on the job.

JCAH (Joint Commission on Accreditation of Hospitals) A commission, formalized in 1948, that accredits hospitals, based on hospital efficiency and professionl performance. Accreditation by JCAH is voluntary, however, most hospitals seek JCAH accreditation in order to qualify for grants, receive Medicare payments, and gain status for staff and educational programs.

licensure The process by which an agency of government grants permission to persons meeting predetermined qualifications to engage in a given occupation or to use a particular title, or grants permission to institutions to perform specified functions. Example: California, Florida, Tennessee, and New York City require licensure of laboratory practitioners.

NAACLS (National Accrediting Agency for Clinical Laboratory Sciences) An accrediting agency established specifically for occupations in clinical laboratory sciences: cytotechnologist, histologic technician, medical laboratory technician, medical technologist, and nuclear medicine technologist. NAACLS conducts accreditation functions for education programs and approves minimum educational standards ("Essentials") for such programs. Final program accreditation is through CAHEA.

NCA (National Certification Agency for Medical Laboratory Personnel) A certifying agency that offers certification examinations for laboratory generalists: clinical laboratory scientists (CLS) and clinical laboratory technicians (CLT), as well as for cytogenetics technologists (CG).

professional fee A fee added to the cost of some product or service. Example: A pathologist may receive a professional fee for the tests performed in the laboratory that he directs.

proficiency testing A process in which a specimen, provided by an external agency (such as CDC), is analyzed by a participating laboratory. Results obtained are then sent to the external agency and comparisons are made with a "true" value, based on values obtained from reference laboratories. Also, the written tests given by HEW to supportive level personnel to help them meet the standards required by Medicare legislation.

registration The process by which qualified individuals are listed on an official roster maintained by a governmental or nongovernmental agency.

third-party payers Insurance carriers, such as Blue Cross-Blue Shield, or Medicare, that pay for health care goods and services, rather than the patient paying directly.

INTRODUCTION

To understand the complexity of clinical laboratories, it is necessary to understand their types, locations, personnel, and services, as well as the challenges of managing them. This chapter is a starting point from which other chapters will be developed. It (1) describes laboratories in terms of numbers, kinds, personnel, and types of health care services offered; (2) provides a perspective on clinical laboratories as they fit into health care delivery and their effect on the economy of the United States; and (3) reviews specific challenges that face laboratory management.

STATUS OF LABORATORIES – GENERAL CONSIDERATIONS

Survey of Facilities

The most comprehensive survey of the numbers and kinds of clinical and public health laboratories was conducted in 1971 by the American Society for Medical Technology (ASMT) [3]. The facilities surveyed included hospital, public health, private, clinical, and specialty laboratories.[1] The following information was obtained from 95 percent of clinical laboratories identified in the United States:

1. Number, location, and type of laboratory
2. Service areas
3. Participation in proficiency testing programs
4. Status of laboratory director
5. Status of laboratory personnel
6. Laboratory accreditation

In 1976, the Laboratory Management Consultation Office, at the Center for Disease Control (CDC), Atlanta, Georgia, updated the 1971 ASMT census [9]. In 1971, there were 12,296 clinical and public health laboratories in the United States. By 1976, this number had increased 11 percent to an estimated 13,626. Further results and comparisons of the two studies will be discussed.

Distribution of Clinical Laboratories in the United States

Table 1-1 shows the statewide distribution of laboratories and the total change in their numbers and corresponding percentages from 1971 to 1976. As could be expected, the

[1] The survey did *not* include laboratories in blood banks, nursing home facilities, doctor's offices with fewer than five physicians, or clinical research laboratories. A 1974 survey, however, reported that some 82 percent of office-based practitioners (physicians) did perform some kind of in-office laboratory work (*Lab. World*, September 1974).

largest states (California, Texas, and New York) have the most laboratories, accounting for 28 percent of the total in 1976.

In the studies, laboratories were divided into governmental (26 percent of the total in 1976) and nongovernmental (74% of the total in 1976) (Table 1-2). In 1976, 53 percent of all laboratories, 7,235 in number, were located in hospitals; private (independent) laboratories made up the next largest group, comprising 23 percent; laboratories associated with physician group practices comprised 13 percent while other categories (outpatient clinic, health department, industrial, HMO, and "other") totaled 11 percent.

Laboratories associated with hospitals were further categorized by numbers of beds of affiliated hospitals:

Hospital Bed Size	*No. of Hospital Laboratories*	*Percent of Total Hospital Laboratories*
<50	1,724	24
50–99	1,717	24
100–199	1,446	20
200–299	867	12
300–399	521	7
>400	960	13
Total	7,235	100

Most hospital laboratories, then, exist in relatively small institutions; almost one-fourth are in hospitals with fewer than 50 beds and more than two-thirds are in hospitals with fewer than 200 beds.

Laboratory Service Areas

Data indicate that the three most common service areas in laboratories are those of urinalysis, hematology, and general clinical chemistry. Table 1-3 gives a more complete breakdown of laboratories by the kinds of services offered.

Participation in Proficiency Testing

A laboratory that participates in proficiency testing is one that periodically analyzes a specimen provided to it by an external agency such as a state board of health, the College of American Pathologists (CAP), or the CDC. The agency then compares the laboratory's result with a "true" value based on the results obtained from reference laboratories. Table 1-4 shows the numbers and percentages of laboratory service areas that participated in proficiency testing in 1971 and 1976. Participation is far from complete. In 1971, of the laboratory service areas operating, only 49 percent participated in proficiency testing; by 1976, only 60 percent. The increase in participation in proficiency testing during this interval was significant in toxicology, radioimmunoassay, and cytopathology. In the areas of serology (nonsyphilis) and virology, however, the percentage of laboratories performing proficiency testing had actually decreased.

More disturbing than the lack of participation in proficiency testing has been the reluctance of some agencies to release information on the results of the testing. Although CDC publishes its proficiency testing data, its efforts are concentrated primarily on independent laboratories, which comprise only about one-quarter of all clinical laboratories. The CAP has not released data regarding its program, noting in early 1980 that it was unable to extract such information from its computers. The philosophies of the state boards of health regarding publication of proficiency test results also vary.

Table 1-1. Distribution of U.S. Laboratories

State	No. (1971)	Percent of Total for 1971	No. (1976)	Percent of Total for 1976	Percent Change from 1971 to 1976	
					Decrease	Increase
Alabama	190	1.5	200	1.5		5.3
Alaska	42	0.3	51	0.4		21.4
Arizona	168	1.4	170	1.2		1.2
Arkansas	170	1.4	182	1.3		7.1
California	1,414	11.5	1,740	12.8		23.1
Colorado	161	1.3	173	1.3		7.5
Connecticut	130	1.1	133	1.0		2.3
Delaware	24	0.2	29	0.2		20.8
Florida	452	3.7	466	3.4		3.1
Georgia	312	2.5	306	2.2	1.9	
Hawaii	75	0.6	72	0.5	4.0	
Idaho	81	0.7	150	1.1		85.2
Illinois	501	4.1	478	3.5	4.6	
Indiana	182	1.5	230	1.7		26.4
Iowa	193	1.6	204	1.5		5.7
Kansas	210	1.7	217	1.6		3.3
Kentucky	216	1.8	259	1.9		19.9
Louisiana	194	1.6	210	1.5		8.2
Maine	61	0.5	65	0.5		6.6
Maryland	140	1.1	173	1.3		23.6
Massachusetts	330	2.7	352	2.6		6.7
Michigan	427	3.5	468	3.4		9.6
Minnesota	347	2.8	353	2.6		1.7
Mississippi	191	1.6	186	1.4	2.6	
Missouri	264	2.1	303	2.2		14.8
Montana	102	0.8	110	0.8		7.8
Nebraska	168	1.4	140	1.0	16.7	
Nevada	53	0.4	49	0.4	7.5	
New Hampshire	46	0.4	47	0.3		2.2
New Jersey	268	2.2	276	2.0		3.0
New Mexico	113	0.9	118	0.9		4.4
New York	646	5.3	814	6.0		26.0
North Carolina	278	2.3	280	2.1		0.7
North Dakota	87	0.7	101	0.7		16.1
Ohio	455	3.7	448	3.0	1.5	
Oklahoma	275	2.2	303	2.2		10.2
Oregon	192	1.6	218	1.6		13.5
Pennsylvania	455	3.7	469	3.4		3.1
Rhode Island	44	0.4	49	0.4		11.4
South Carolina	149	1.2	135	1.0	9.4	
South Dakota	96	0.8	88	0.6	8.3	
Tennessee	248	2.0	258	1.9		4.0
Texas	1,093	8.9	1,262	9.3		15.5
Utah	79	0.6	94	0.7		19.0
Vermont	30	0.2	32	0.2		6.7
Virginia	185	1.5	218	1.6		17.8
Washington	259	2.1	345	2.5		33.2
West Virginia	130	1.1	167	1.2		28.5
Wisconsin	283	2.3	333	2.4		17.7
Wyoming	48	0.4	48	0.4	0.0	
Washington, D.C.	39	0.3	54	0.4		38.5
Total	12,296	100.0	13,626	100.0		10.8

Source: From H. Lawton et al., The national clinical and public health laboratory survey, 1977. *Am. J. Med. Tech.* 43(9):885, 1977. Reprinted with permission.

Table 1-2. Number of U.S. Laboratories Classified by Supporting Agency and Setting – 1971 to 1976

	1971[a]	1976[b]	Percent of Total for 1976	Percent Change from 1971 to 1976	
				Decrease	Increase
By Setting					
Hospital	6,616	7,235	53,1		9.4
Federal	447	528	3.9		
State, county, city	2,100	2,156	15.8		
Nongovernmental	4,069	4,551	33.4		
Private (independent)	2,922	3,163	23.2		8.2
Group practice	1,293	1,731	12.7		33.9
Outpatient clinic	624	461	3.4	26.1	
Health department	392	411	3.0		0.6
Industrial	127	89	0.7	29.9	
HMO[c]	–	75	0.6		
Other	321	461	3.4		43.6
By Supporting Agency					
Governmental	3,288	3,509			6.7
Nongovernmental	9,008	10,117			12.3
Total	12,296	13,626	100.1%		

[a]Census of all laboratories.
[b]Estimated from survey of one-third of laboratories.
[c]No corresponding data from 1971 for this classification.
Source: Modified from H. Lawton et al., The national clinical and public health laboratory survey, 1977. *Am. J. Med. Tech.* 43(9):885, 1977.

*Table 1-3. Estimated Number of Laboratories That Perform Various Services (1976)**

Service Performed	Laboratories Offering Service	Percent of Total
Urinalysis	12,591	92.4
Hematology	12,416	91.1
Clinical chemistry – blood and CSF	11,884	87.2
Bacteriology	10,467	76.8
Syphilis serology	10,420	76.5
Parasitology	9,146	67.1
Immunohematology	8,043	59.0
Nonsyphilis serology	6,094	44.7
Mycology	5,847	42.9
Cytopathology	4,444	32.6
Histopathology	4,273	31.4
Radioimmunoassay	3,805	27.9
Endocrinology	3,288	24.1
Toxicology	3,145	23.1
Oral pathology	2,442	17.9
Cytogenetics	817	6.0
Virology	557	4.1
Other	1,025	7.5
Total laboratories	13,626	

*Estimated from survey of one-third of laboratories.
Source: Modified from H. Lawton et al., The national clinical and public health laboratory survey, 1977. *Am. J. Med. Tech.* 43(9):885, 1977.

Those that do not publish, cite as their major reason fear that disclosure of poor results might hinder laboratories from participating further. Instead, state boards of health try "internally" to assist those laboratories that perform poorly. As a result, other than CDC data, information regarding the quality of laboratory tests in specific laboratories is unavailable.

Laboratory Directors

A director is responsible for the technical activities of the laboratory, including reports of results. Most laboratory directors (75% in 1971 and 1976) were physicians (Table 1-5). In 1971 the ratio of physicians directing part-time compared to those directing full-time was 2 : 1, with 6,096 laboratories being served by physicians working on a part-time basis. By 1976 the ratio of part-time directors to full-time directors had been reduced to 1 : 1. In 1976, 1,014 laboratories (7%) still had *no* director.

In 1976, persons holding doctorate degrees directed 78 percent of the nation's laboratories; holders of master's degrees directed 2 percent; bachelor's degrees 8 percent; and associate's degrees 1 percent. In 1976, 10 percent of all laboratories had either no director or one without an academic degree.

Laboratory Technical Personnel

Information regarding laboratory technical personnel is given in Tables 1-6 and 1-7. A total of 130,000 full-time and part-time professional and technical personnel were working in U.S. laboratories in 1971; 200,000 or 217,000 workers were estimated in 1976 [7, 9]. In 5 years, then, the number of personnel had risen by two-thirds. The vast