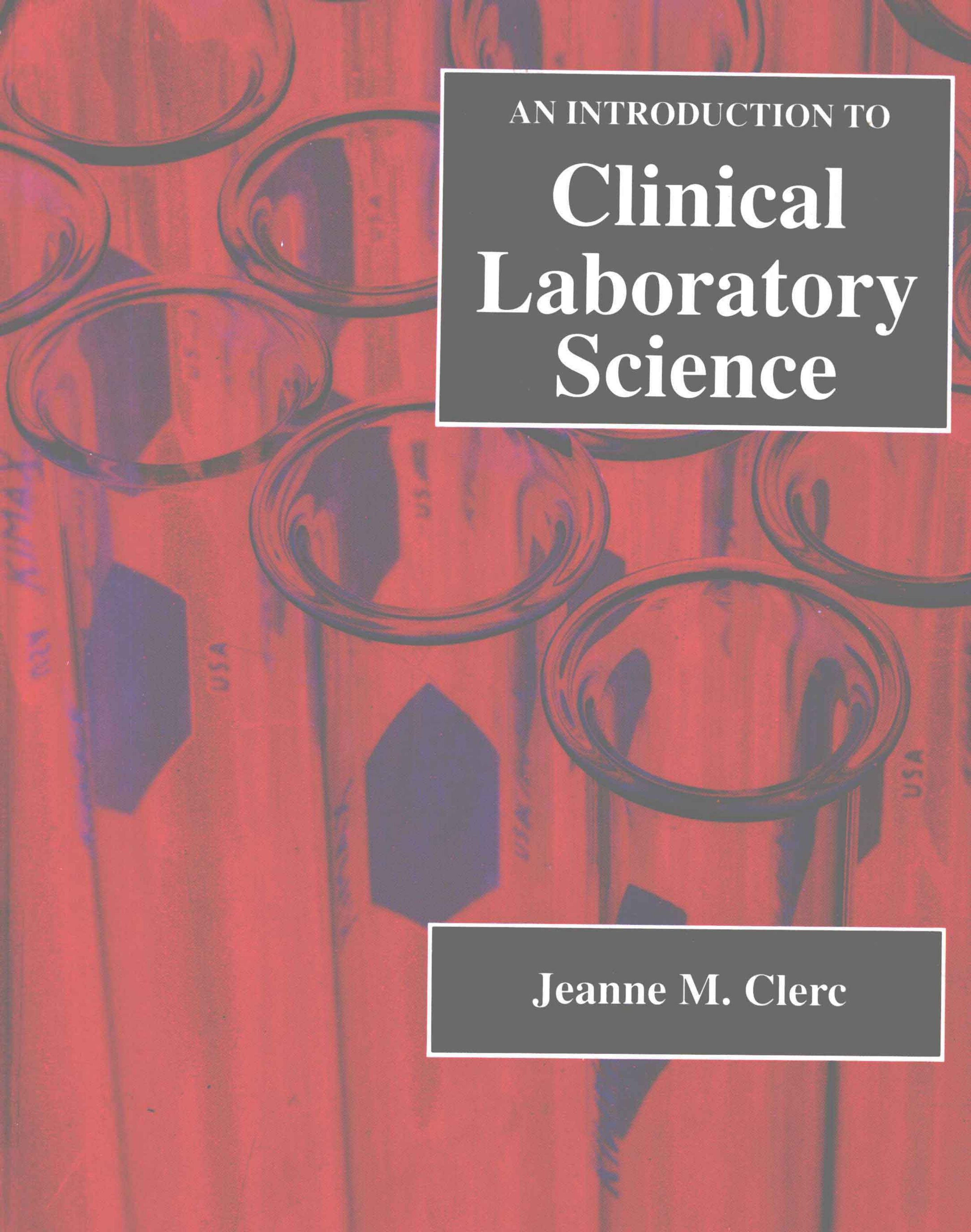

AN INTRODUCTION TO

Clinical Laboratory Science

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AN INTRODUCTION TO CLINICAL LABORATORY SCIENCE

This book is dedicated to the memory of my father,
Eugene H. (Jack) Clerc.

PREFACE

This book provides a description of clinical laboratory science (CLS). Many readers may not recognize this term, but are more familiar with the older term "medical technology." The American Society for Medical Technology (ASMT) and CLS educators encourage use of the new term. The text uses this new terminology primarily, and when appropriate lists synonymous words and terms.

The CLS profession faces new challenges in the 1990s. The shortage of qualified laboratory personnel is certainly one of them. Changes in the health care system over the past 10 years have been dramatic, and the future promises to bring more.

This text is primarily intended for college students who have chosen or are considering CLS as their field of study. Information is provided on career opportunities and educational requirements. In addition, it is critical that students entering the profession be groomed as professional practitioners as well as laboratory scientists.

With this in mind, ethics, communication skills, and commitment to professional organizations become important components of a CLS curriculum. Students also must have a good understanding of laboratory and health care organizations to function effectively in a rapidly changing environment. AIDS, federal and state governmental regulations, implementation of diagnosis-related groups (DRGs), and licensure issues all are "hot topics" for the 1990s, and are discussed in this text.

Related laboratory professions, such as cytotechnology, histotechnology, and nuclear medicine, also are considered clinical laboratory sciences. It is hoped this text will provide the type of information that will entice students to enter the clinical laboratory profession and the information essential for their becoming truly knowledgeable "health professionals."

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I am grateful for the sabbatical leave provided by Eastern Michigan University, which allowed me the time to complete this project.

Last, I would like to say thanks to my parents and family. Their love and support are deeply cherished.

Jeanne M. Clerc, Ed.D., MT(ASCP)SH

CONTENTS

Chapter 1

Definition of Clinical Laboratory Science

NATURE OF THE WORK

Medical technology, or clinical laboratory science (CLS), is a rapidly evolving industry of major proportions. In the United States alone, we spend some $20 billion each year for tests performed in more than 100,000 clinical laboratories.[3]

The practice of modern medicine would be impossible without the tests performed in the clinical laboratory. Although physicians depend heavily on laboratory results, ordinarily they do not perform the tests themselves. That is the job of clinical laboratory personnel.[7] A medical team of pathologists, clinical chemists, microbiologists, medical technologists, cytotechnologists, laboratory technicians, and assistants work together to determine the presence, extent, or absence of disease and provide data needed to evaluate the effectiveness of treatment.[2, 5]

Many clinical laboratories are highly automated, and job duties reflect this. Laboratory personnel work with a wide variety of specialized, high-precision instruments, including automatic analyzers, centrifuges, electronic counters, and computers. Many tests require the operation of complex electronic instruments to obtain such precise measurements as identifying quantities of certain hormones in the blood through the use of special radioactive chemicals. Clinical laboratory scientists work with all types of body tissues and fluids, from blood and urine to cell samples.

Clinical laboratory scientists may work in all general areas within the laboratory or may specialize in certain areas, for example, clinical chemistry, the determination of the presence and quantity of chemical substances in the blood; hematology, the specialization of abnormal conditions and diseases affecting the blood; microbiology, primarily concerned with detection of bacteria, fungi, viruses, and other organisms in the body; and immunohematology (blood banking), concerned with crossmatching and transfusing blood products. In these instances they may be known as chemistry, hematology, microbiology, or blood bank technologists.[6]

Because changes in body fluids, tissues, and cells often are a sign that something is wrong, clinical laboratory testing plays a crucial role in the detection and diagnosis of disease. Physicians also order laboratory work for other reasons. Test results may be used to establish values against which future measurements can be compared; to monitor treatment, as with tests for drug levels in the blood, which can indicate whether a patient is adhering to a prescribed drug regimen; to reassure patients that a disease is absent or under control; or to assess the status of a patient's health, as with cholesterol measurements.

Clinical laboratory scientists also monitor basic test results to ensure that each test is valid and that it meets high standards of precision, accuracy, and quality control.[6]

Depending on level of skill, the worker may run simple tests or perform complex analyses that require a number of steps to arrive at the information needed by the physician. The types of tests that clinical laboratory personnel perform and the amount of responsibility they assume vary with employment setting, but depend to a large extent on the kind of educational preparation they have.[7]

The profession is not bound by the four walls of the laboratory. Because the field is constantly changing, in response to new technologies, health care cost-containment pressures, and variations in health care needs, the nature of the work for laboratory scientists broadens each year.[3]

MEDICAL TECHNOLOGY OR CLINICAL LABORATORY SCIENCE?

Many definitions have been proposed for the term "medical technology." In simplest terms, medical technology is a *profession concerned with providing information based on the performance of analytical tests on human body substances to detect evidence of or prevent disease or impairment and to promote and monitor good health.*

This simple definition of medical technology focuses on the laboratory information function these practitioners provide, that is, on clinical laboratory data. A more current definition takes into account the important fact that since its origins the field has grown in complexity and responsibility from an ancillary, or supporting, occupation limited to generating test data to its status today as a diverse profession that includes roles other than clinical practice.[3]

In response, the terminology in laboratory science has changed. In the past, the narrow title Medical Technologist (MT) was used to denote a graduate of a baccalaureate program in laboratory science; now the title Clinical Laboratory Scientist is preferred. The literature and certain professional organizations still may refer to the field as Medical Technology (MT). The broader term "Clinical Laboratory Sciences" (CLS) more accurately reflects the career opportunities available in a variety of settings. CLS includes other laboratory personnel, such as histologists, histotechnologists, nuclear medicine technologists, cytogeneticists, and cytotechnologists.

Clinical laboratory scientists and other laboratory professionals are found throughout the health care delivery system, for example, in hospitals, independent commercial laboratories, clinics, physicians' offices, Red Cross and other blood banks, public health departments, and ambulatory care centers. Some clinical laboratory scientists work overseas, in the Peace Corps or Project Hope, or in government or private facilities in other countries.[3] Options outside the health care mainstream include biogenetics, occupational health, independent consulting, environmental health, industrial research, higher education administration and education, product development, marketing, sales, veterinary science, and criminology. The field of CLS offers baccalaureate graduates basic preparation in many areas.[3]

The field of clinical laboratory science is confusing to the public. The profession has low visibility within society and the health care system. Clinical laboratory professionals historically have had limited contact with patients. Most people know less about them than about other health care workers, such as nurses. Even so, the information the clinical laboratory professional provides is critical for the appropriateness of the care provided by nurses, family physicians, surgeons, pharmacists, and other health professionals. Each depends, in part, on accurate laboratory data to help plan or implement treatment and care for the individual patient.[3]

There are many reasons for the public's confusion about laboratory personnel. First, qualified laboratory personnel are known by a number of professional titles, for example, Clinical Laboratory Scientist (CLS) vs. Medical Technologist (MT), or Clinical Laboratory Technician (CLT) vs. Medical Laboratory Technician (MLT). Second, they work in a large number and variety of settings. Third, there is lack of consensus, even within the profession, as to what various clinical laboratory practitioners should be called and what their roles should be.[3]

Because of these overlapping titles and job descriptions, the task of counting laboratory personnel is an estimate at best. Estimated employment in 1986 of clinical laboratory technologists and technicians was 239,000. A 24% growth rate in employment from 1986 to 2000 is anticipated, which will mean an additional 57,000 personnel.[9]

SCOPE OF PRACTICE

The American Society for Medical Technology (ASMT), the oldest and largest of the professional societies devoted exclusively to clinical laboratory science, summarizes the scope of practice of the profession, which describes in general terms the services provided by clinical laboratory scientists. Clinical laboratory personnel, as members of the health care team, are responsible for[1]:

1. Assuring reliable test results which contribute to the prevention, diagnosis, prognosis, and treatment of physiologic and pathologic conditions. This assurance requires:
   a. Producing accurate test results.
   b. Correlating and interpreting test data.
   c. Assessing and improving existing laboratory test methods.
   d. Designing, evaluating, and implementing new methods.
2. Designing and implementing cost-effective administrative procedures for laboratories, including their services and personnel.
3. Designing, implementing, and evaluating processes for education and continued education of laboratory personnel.
4. Developing and monitoring a quality assurance system, to include:
   a. Quality control of services.
   b. Competence assurance of personnel.
5. Promoting an awareness and understanding of the services they render to the consumer/public and other health care professionals.

PROFESSION OF CLINICAL LABORATORY SCIENCE

Webster's New World Dictionary of the American Language[8] defines a profession as "a vocation or occupation requiring advanced training in some liberal art or science, and usually involving mental rather than manual work, such as teaching, engineering, writing, etc., especially medicine, law, or theology (formerly called the learned professions)."

Becoming a profession is a gradual process. Basic qualifications must be met to be considered an accepted, established profession. These qualifications include[4]:

1. Having a distinct body of knowledge in the discipline.
2. Maintaining standards of excellence.
3. Formulating a code of ethics.
4. Endeavoring to elevate the profession to a position of dignity and social standing.
5. Organizing and developing a professional, qualifying association.
6. Setting criteria for recruitment and training.

Tremendous gains have been made in each of these areas during the 1980s. Discussions on the doctorate as the terminal degree in clinical laboratory science indicates that there is a distinct body of knowledge. The ASMT strives to improve the image, in collaboration with other professional organizations. Now certification examinations are available through the National Certification Agency for Medical Laboratory Personnel (NCA), which is supported by ASMT. Both the American Society of Clinical Pathologists (ASCP) and ASMT have taken a proactive role in recruiting laboratory personnel. Further strides in these areas are anticipated in the 1990s.[4]

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Chapter 2

History of Clinical Laboratory Science

The beginnings of the hospital clinical laboratory cannot be pinpointed. Prior to World War I there were few laboratory technicians. However, there were many individuals prior to World War I who helped lead the development of the modern clinical laboratory.

PRIOR TO 1990

Intestinal parasites such as *Taenia* and *Ascaris* were mentioned in writings dating to 1500 BC. Identification of intestinal parasites is still done today in the clinical laboratory.

Writings of Hippocrates (460–370 BC) indicate he knew of tuberculosis, malaria, mumps, and anthrax.

The study of urine sometimes helped in disease diagnosis during the Middle Ages (1096–1438 AD). It was found that certain urine samples attracted ants and that such urine had a sweet taste. It is likely these urine samples were from persons with diabetes mellitus.

A prominent physician at the University of Bologna in the 1300s employed Allesandra Giliani to perform certain tasks, including a few pioneer clinical laboratory tests.

Marcello Malpighi (1628–1694), a microscopist and anatomist, is considered by some the "father of pathology and histology."[7]

Antonj van Leeuwenhoek (1632–1723) is credited with the invention of the compound microscope. He described blood cells, was able to see protozoa, and classified bacteria.[7]

Developments in the 1800s included the establishment of cell theory and the development of organic chemistry, physiologic chemistry, and bacteriology. It was possible to grow bacteria, stain them, and study them under the microscope.

Dr. Douglas, at the University of Michigan, opened the first chemical laboratory and began laboratory instruction in 1844. The department of pathology was established there in 1850.

Rudolph Virchow (1821–1902) founded the Archives of Pathology in Berlin in 1847.

Hermann von Fehling (1812–1885), a German chemist, performed the first quantitative test for urine sugar in 1848.[4, 7]

Dr. William H. Welch taught the first laboratory course in pathology in an American medical school in 1878. He became the first professor of pathology at the Johns Hopkins University in 1885.[4]

The first clinical laboratory was opened at The Johns Hopkins Hospital, aided by donations from the Eaton estate, in 1896.[4]

1900 TO WORLD WAR II

The 1900 US census makes reference to 100 male technicians employed in the United States. The 1922 census indicated there were 3,500 technicians by 1920, the majority being women. These numbers included dental and industrial workers as well as laboratory technicians. Physicians were still doing most of their own laboratory work.[4, 5]

A Manual of Clinical Diagnosis was published by James C. Todd[8] in 1908. Later editions were a joint effort of Dr. Todd and Dr. Arthur Sanford; more than 17 editions of that book, now entitled *Clinical Diagnosis and Management by Laboratory Methods*, have been published.

George Papanicolaou (1862–1962), a US scientist, described the Pap smear, or Pap test, in which cells collected from the cervix and vagina are examined to detect cancer cells.[3, 7] He helped train pathologist assistants, forerunners to laboratory technicians and technologists, in an apprentice setting.[3]

About the time of World War I the typical hospital pathology department was small and ill-equipped. Pathologists operating the department spent most of their time doing relatively simple blood cell counts, urinalyses, and a few chemical determinations. There were few surgical procedures. Tissue analyses and autopsies were rare. In the 1920s, pathologists and the clinical laboratories played a more major role in health care. Pathologists learned much from treating the wounded of World War I, and they applied these techniques in civilian hospitals. Great scientific discoveries were adopted in the hospital clinical laboratories in a short time. During this period more medical journals were beginning to be published.[6, 10]

In 1923 one of the first schools to train laboratory workers was instituted at the University of Minnesota. The school still exists.

During the 1920s and 1930s state societies of clinical pathologists were formed. By 1936 pathologists had established the American Board of Pathology, defined the requirements of the specialty, and were recognized by the American Medical Association (AMA).

In 1937 blood banking became a practical procedure in American hospitals. Blood banking is now an essential service in a hospital clinical laboratory. The procedures of compatibility testing and preparation and storage of blood are performed in the blood bank.[6, 8]

POST–WORLD WAR II

The technology of medicine that developed during World War II had a marked effect on laboratory medicine. Pathology and clinical laboratories continued to grow after World War II. New knowledge of health and disease problems proliferated. Antimicrobial agents were in general use. Rapid advances in instrumentation produced the most visible effect. Diagnostic radioisotopes, exfoliative cytology, molecular biology, practical virology, and fluorescent studies were introduced.[4, 6, 8]

In the 1950s almost all clinical chemistry procedures were performed manually. The chemistry bench contained an assortment of reagent bottles. The technologist, usually a woman, would assemble a rack of specimens and several racks of empty test tubes. A sectioned drawer in the bench held a collection of pipets.

To process a specimen, the technologist reached for a clean pipet and transferred the appropriate amount of serum to a clean test tube. She often made use of a boiling water bath heated by a Bunsen burner. She then moved to a colorimeter or spectrophotometer and took a reading for each specimen. Then she would record the readings on a log sheet, perform the necessary calculations, and note the results on the log sheet and the patient's report.[1]

Today technologists usually set up an instrument for an entire shift or day, transfer unmeasured specimens into special containers, inspect printed results, record quality control data, and perform routine instrument maintenance.[1]

The introduction of quality control concepts and procedures to the clinical laboratory is one of the major achievements of the past 40 years. Levey and Jennings introduced their quality control chart to clinical chemistry in 1950. In 1958 Freier and Rausch presented the first comprehensive daily quality control program for laboratories. Later quality control methods were improved and broadened into the concept of quality assurance, dealing with reporting, data management, and the use of tests and data.[2]

Chromatography was discovered by Tswett in 1906, and led to the development of gas-liquid chromatography by Martin and James in 1952.[2]

Ouchterlony's radial immunodiffusion method in gel was described in 1949. Grabar and Williams used some of these principles to develop immunoelectrophoresis in 1953. In 1966 Laurell introduced "rocket" immunoelectrophoresis.

In 1957, Technicon introduced the first commercial continuous-flow automatic analyzer, the AutoAnalyzer, designed by Leonard Skeggs. This allowed for reliable, rapid analysis of several blood constitutents within a reasonable amount of time. Larger multichannel automated instruments soon followed. Screening batteries became part of the admission examination in hospitals and clinics.[2]

The first radioimmunoassay method was developed based on the 1960 Berson-Yalow studies on the state of ^{131}I-insulin in plasma. With radioimmunoassay, concentrations of substances such as hormones, pharmaceutical agents, and vitamins could be determined. Better understanding of diabetes mellitus soon followed.

Other advances in laboratory medicine in the 1950s and 1960s included absorption spectrophotometry, flame photometry, and atomic absorption. The field of cytogenetics was developed, and several major chromosomal abnormalities were discovered, including the Philadelphia chromosome found in 1960 by Nowell and Hungerford in chronic myelogenous leukemia. The major histocompatibility complex (the HLA system) was uncovered by Dausset and coworkers in 1965, aiding in successful organ transplants.

The 1960s marked the beginning of government interest and participation in health care through federal legislation and the advent of Medicare and Medicaid. The nationwide introduction of Diagnosis Related Groups (DRGs) in 1983 imposed a new cost consciousness on medicine, the hospital industry, and clinical laboratories.

In the 1970s and 1980s, automated instruments allowed for discrete sampling and random