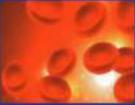
CHAPTER 1









Introduction to Phlebotomy

OBJECTIVES

After studying this chapter, you should be able to:

- 1. Explain why blood is collected by the phlebotomist.
- 2. Outline the phlebotomist's responsibilities to the patient.
- Explain why the phlebotomist has a special responsibility to present a neat, pleasant, and competent demeanor.
- 4. Identify departments within the hospital and explain their function.
- Identify each section of the laboratory and give examples of tests that would be performed in that section.
- Identify members of the laboratory staff; describe the duties of each of these staff members and their education level.
- Describe the importance of communication within the laboratory and that with other departments of the hospital.
- List five patient rights and explain how these patient rights would affect a phlebotomist's job.
- 9. Explain advance directives and how they can direct a patient's care.

NAACLS Competencies Relevant to Chapter 1

Demonstrate knowledge of the health care delivery system and medical terminology.

- Identify the health care providers in hospitals and clinics and the phlebotomist's role as a member of this health care team.
- Describe the various hospital departments and their major functions in which the phlebotomist may interact in his or her role.
- Describe the organizational structure of the clinical laboratory department.
- Discuss the roles of the clinical laboratory personnel and their qualifications for these professional positions.

- List the types of laboratory procedures performed in the various sections of the clinical laboratory department.
- Describe how laboratory testing is used to assess body functions and disease.
- Use common medical terminology.

Demonstrate understanding of quality assurance and quality control in phlebotomy.

- Describe the system for monitoring quality assurance in the collection of blood samples.
- Identify policies and procedures used in the clinical laboratory to ensure quality in the obtaining of blood samples.
- Perform quality control procedures.
- · Record quality control results.
- Identify and report control results that do not meet predetermined criteria.

Communicate (verbally and nonverbally) effectively and appropriately in the workplace.

- Maintain confidentiality of privileged information on individuals.
- Value diversity in the workplace.
- Interact appropriately and professionally with other individuals.
- Discuss the major points of the American Hospital Association's Patient Care Partnership.
- Model professional appearance and appropriate behavior.

KEY TERMS

Advance Directive Document stipulating the kind of life-prolonging medical care permitted for

a patient.

Centralized Phlebotomy Sample collection where the phlebotomist is part of the laboratory team and is

dispatched to hospital units to collect blood samples.

Compatible Substances that can be mixed without reacting with one another.

Decentralized Phlebotomy Sample collection where all members of the health care team share responsibility

to collect blood samples.

Demeanor The outward behavior of an individual.

Esoteric Type of laboratory tests that are not routinely done. These tests are often sent to

another laboratory that specializes in a specific test.

Ethics Professional code of conduct in the treatment of patients. Ingrained in this is

a moral philosophy of how the phlebotomist treats the patient.

Examination All processes that are done to perform the test(s) on the sample to achieve

a result.

Failure A case when the system does not meet user or customer expectations.

Pathology Study of the nature and cause of disease.

Phlebotomy Act or practice of bloodletting as a therapeutic or diagnostic measure.

Postexamination Process in which the results of the testing are communicated to the health

(Postanalytical) care provider.

Preexamination All processes that it takes to collect the sample and get to the point in which

(Preanalytical) the testing of the sample can occur.

Qualitative Analysis The chemical analysis designed to identify the components of a substance.

The results from this analysis are released as a positive (present) or negative

(not present) result.

Quality Assurance Program that strives to have the health care facility guarantee that all areas are

providing the highest quality and most appropriate level of care.

Quality Control Methods to monitor processes and confirm that processes are within the

preestablished limits.

Quality Improvement Review and monitoring of outcomes to strive toward continuous improvement in

performance.

Quantitative Analysis The analysis of a substance to determine the amount or proportions of the

substance. Results will be released as an amount, such as grams per liter.

Root Cause Analysis of an event to determine the actual reason for the incident and corrective

action needed to prevent a recurrence.

Sentinel Event An unexpected occurrence involving death or serious physical and psychological

injury.

Threshold Acceptable level of performance.

Venipuncture Collection of blood from a vein by penetrating the vein with a needle.

hapter 1 of this text covers the basic information that is needed before one can perform phlebotomy. The history of phlebotomy and how it has changed over the years is covered first. Then the duties of the people who will be working with the phlebotomist both in the laboratory and in a health care facility are outlined. The phlebotomist will gain a familiarity with the departments of the laboratory and the testing that is performed in each department. The student will also better understand the agencies that regulate how health care facilities must operate.

HISTORY OF PHLEBOTOMY

Phlebotomy is the process of collecting blood and is defined in Webster's dictionary as
"the act or practice of bloodletting as a therapeutic measure." The history of bloodletting
dates back to the early Egyptians and continues into modern times. It was once thought
that the practice would rid the body of diseases and provide a cure for almost all ailments.
Picture a Roman gladiator bleeding and being carried off on a stretcher to receive the cureall treatment of further bleeding. Perhaps the unfortunate results of the practice are one reason that moment in history did not last very long. In the twelfth century, bloodletting was
practiced by barbers, whose red-and-white barber poles became the symbol of their trade.

Historically, phlebotomy used two basic methods: venesection and cupping. Venesection was the most common. A sharp lancet-type instrument pierced the veins and made them bleed. Lancing the veins was thought to eliminate the "bad" blood and remove the disease.

from the patient. Venesection was often used to reduce fever or to produce a faint so an expectant mother would deliver her baby by the time she recovered.

In cupping, a heated glass cup was placed on a person's back. As the cup cooled, it created a suction that pulled blood to the capillaries under the cup. Then a spring-loaded box containing multiple blades cut the area to produce massive bleeding. Both venesection and cupping produced much scarring.

In December 1799, George Washington, the first president of the United States, had a severe throat infection. The cure for the infection was heavy bleeding. George Washington was bled of more than 9 pints of blood in less than 24 hours and died on December 14, 1799. Soon after his death, the philosophy of bleeding as the cure to disease began to change.

However, it was not until the middle of the nineteenth century that bloodletting was no longer considered the cure for all illnesses. The discovery of microorganisms as the causative agent for many diseases started to change the thinking of how to treat diseases. Blood began to be examined for diagnostic purposes. Urine and feces had been examined since medieval times. The knowledge obtained from these early examinations was small compared with what we can determine today.

A more modern method was to use leeches. It was not uncommon to apply leeches routinely to one's body with the belief that it prevented disease. Leeches still have limited uses today. When a person's finger is reattached after accidental amputation, for example, the arteries and veins do not return to normal blood flow immediately. The blood tends to pool in the end of the finger, causing pain and pressure. A leech is placed on the end of the finger to remove the excess blood and relieve the symptoms. The only problem is that leeches get full rapidly and have to be changed after several hours.

Bleeding of individuals to reduce the patient's amount of blood does occur today to treat diseases called polycythemia vera and hereditary hemochromatosis. The treatment involves withdrawing 500 milliliters of blood through therapeutic phlebotomy. But contemporary bloodletting takes a broader approach. Blood is still removed to cure the person, but it is primarily done to find the cure, not as the cure itself. Blood collection has changed from being therapeutic to being diagnostic. Thousands of different types of diagnostic tests are available. Phlebotomy provides accurate and precise test results so the patient can be diagnosed and treated. But this can be accomplished only after the phlebotomist has provided the laboratory with an accurate sample.

PHLEBOTOMY'S ROLE IN HEALTH CARE

The phlebotomist's primary role is to collect blood for accurate and reliable test results as quickly as possible and with the least discomfort to the patient. The job description can vary greatly from one health care environment to another. The phlebotomist is usually cross-trained in venipuncture, capillary collection, patient care, receptionist duties, sample processing, and computer work. Phlebotomists have become key players on the health care team. They represent the laboratory and the health care center, they are in direct contact with the patient, and they perform tasks that are critical to the patient's diagnosis and care. Phlebotomists are part of a health care team that can be as large as 5,000 people in a large hospital or just 2 or 3 people in a small clinic.

The traditional role of the phlebotomist in a hospital is only one job; to collect blood samples. Eighty-five percent of hospitals follow this centralized phlebotomy approach where the phlebotomist is dispatched from the laboratory to either nursing units or outpatient areas. An example of a typical day for the traditional phlebotomist is to arrive at work around 0430 and then have a list of patients for collection. The reason for this early start is so that the patients are still fasting when their blood is collected. Usually this consists of collecting from 10 patients on the nursing units and then bringing the samples to the

laboratory at 0530. A second group of patient collection orders is then ready, and the phlebotomist starts on the second round of collections. This consists of 15 patients who need sample collection no later than 0700. The remainder of the day is spent in returning to the nursing units to collect one or two blood samples at a time as new tests are ordered. Some time is also spent collecting blood from outpatients who come to the hospital to have their blood drawn. The phlebotomist who works the evening and night shift waits until a test is ordered to be collected. This single-skilled role for the phlebotomist often results in times of no work and other times of more work than can be done in a short time. This time of waiting for work to do is called waiting-to-serve time.

This process works well until there is a large number of patients to draw and the work cannot all be completed by 0700. Difficulties in collecting blood from a patient also add a delay to the collection. Getting the blood collected is not the final process. The tests on the blood must be processed, placed on instruments, and analyzed, and the results reviewed and given to the physician. A physician coming into the hospital to make morning rounds is usually there by 0730, if not sooner. If the results are not available, the physician must delay treatment of the patient. This may result in lengthening of the patient's stay in the hospital and added costs to the patient and the health care system.

It is a continuous challenge to draw blood from a large number of patients quickly and have laboratory information for the physician to review in a timely manner. The decentralized phlebotomy approach to phlebotomy is how 15 percent of the hospitals work to meet this challenge. With decentralized phlebotomy, more people are collecting blood samples during the busy times. It is difficult for a hospital to hire people to come in at 0430 to just draw 10 patients for an hour and then go home. It is easier to use the people who are already working. Everyone who has contact with the patient needs to become multiskilled. The nurse needs to learn how to collect blood samples, and the phlebotomist needs to learn some of the nursing duties. This has become what is commonly called patient-focused care. The duties of the hospital staff revolve more around the patient and the need to treat the patient quickly rather than being restricted to a specific job description. This is similar to the duties of a medical assistant in a physician's office. The job is not restricted to one duty; rather, multiple tasks are done as the need arises.

The routine in the hospital has become more focused on prompt care of the patient. At 0430, or sooner, both the nursing staff and the phlebotomist start collecting blood samples. Since more people are collecting the samples, each person does not have as many to collect. As each individual completes sample collection, the samples are sent to the laboratory. This creates a steady stream of samples flowing to the laboratory and has eliminated the large batches of samples arriving as each phlebotomist finishes. This helps with the workflow for the laboratory, and the results are available for the physician sooner.

When the phlebotomist's blood collection duties are completed, he or she does not return to the laboratory but instead continues to work on the nursing unit. During the rest of the day, the phlebotomist collects blood samples that are needed, handles patient care, and does point of care laboratory tests such as blood sugar/glucose on the patient in the patient's room. This multiskilled training for the phlebotomist makes him or her more versatile and an asset to the organization. In some hospitals, this position is known as a patient care technician.

Each health care facility must determine if a centralized phlebotomy or decentralized phlebotomy program is the best for that facility. There has been much written in the literature debating the pros and cons of each type of program. Studies have shown that with decentralized phlebotomy there is an increase in hemolyzed samples, patient identification errors, and contaminated blood cultures. However, decentralized phlebotomy has been effective in many health care facilities. The key to effectiveness and reduction of errors is based on extensive training of individuals doing the phlebotomy.

Helpful Hint

When interviewing for a phlebotomy position, ask what duties other than phlebotomy you will be performing. It is best to go into a job knowing as much as possible about the extent of your duties. Hybrid phlebotomy, a blend of centralized and decentralized phlebotomy, has been used in some health care facilities to reduce the errors of decentralized phlebotomy. Hybrid phlebotomy typically sends laboratory-based phlebotomists to the nursing units during the early morning collections and then keeps a limited number of phlebotomists available the rest of the day to help patient care technicians with difficult collections.

AREAS OF THE HOSPITAL AND HEALTH CARE SETTING

The phlebotomist will work in diverse health care settings and with all levels of individuals—from the physician with several advanced degrees to support staff with little education. Whatever the level of education or responsibility each individual has, the phlebotomist must maintain professionalism. Patients will also range from the highly educated to individuals who have mental deficiencies. Each one of these individuals is a customer of the phlebotomist and laboratory. The phlebotomist is the "laboratory representative" because he or she is the person from the laboratory with whom most health care staff and patients have contact.

Phlebotomists must be familiar with the organization to function in this complex health care field. They usually work directly with the laboratory but indirectly with nurses, physicians, and the staff in the radiology, pharmacy, and physical therapy departments. Many people from different departments need time with the patient. To be better capable of working together, it is best to understand a little about each area.

The phlebotomist often encounters staff from the electrocardiography department. This department does electrocardiograms (EKGs). An EKG is a recording of impulses of the heart. Impulses from a normal heart make tracing records of a specific size and shape. The abnormal heart shows changes that are different from this pattern. These EKGs are performed in the patient's room, and the phlebotomist often waits for the test to be completed to draw blood.

Another stall member who may visit the patient's room is from the electroencephalography department. This department does electroencephalograms (EEGs), which record the electrical activity of the brain. EEGs help locate and assess the extent of brain injury or determine if there is any brain activity.

The pharmacy department of the hospital is much different from the corner drugstore. The hospital pharmacy dispenses many types of therapeutic drugs that often are much more potent than a prescription taken at home. These drugs are prescribed and monitored under controlled conditions while the patient is in the hospital. The phlebotomist plays an integral part in this monitoring through the blood samples that are collected at specific times. With the results of the samples, the pharmacist is able to consult with the laboratory and the patient's physician to provide the best treatment possible for the patient. Therapeutic drug monitoring is discussed in more detail in Chapter 9.

The physical therapy department works with patients who, due to disease or injury, are no longer able to function to their full physical capacity. The therapy may involve rebuilding deteriorated muscles after a long illness or learning to function after an amputation. Related to physical therapy is the department of occupational therapy, where patients work to overcome their physical handicaps so they can be productive again in their old job or function in a new job. Speech therapy is another area related to physical therapy. Patients who have difficulty speaking or who have lost the ability to speak because of a stroke or disease are retaught how to speak.

Radiology is an area of the hospital that has changed rapidly in recent years. Radiologists used to just x-ray lungs or broken bones, but the field has expanded to include cardiac catheterization, computed tomography (CT) scans, magnetic resonance imaging (MRI), and ultrasound. Each of these techniques has become a subspecialty of radiology that still looks into the body as the traditional x-ray did but in a much more detailed and sophisticated way.

The largest department the phlebotomist works with is the department of nursing. When phlebotomists work closely with many different types of nurses, it leads to the best care to patients. Phlebotomists may need to ask nurses for assistance with patients who are unwilling to hold still or to check with them about the proper time to draw a sample. The ability to work smoothly with other departments of the hospital is a key trait of the best phlebotomists. The phlebotomist who is well liked and cooperates with others for the patients' care is the one who will earn cooperation from other individuals.

Examples of areas of the hospital are shown in Figure 1.1. The clinical laboratory may be in one location or may be decentralized in a variety of locations in the hospital. These include the main laboratory, ambulatory care laboratory (outpatient laboratory), stat laboratory, and surgery laboratory. Each laboratory serves a specific function and often has sections within it.

The patient-focused care concept takes the laboratory out of a physical location and to the patient. As instrumentation for laboratory testing becomes smaller, the instrumentation is located on the nursing unit. This testing that is done at the patient's bedside is also known

ANCILLARY HOSPITAL AREAS AND THEIR PURPOSE

Administration—Keeps the hospital in compliance

Electrocardiography (EKG)—Monitors patients with cardiovascular disease

Electroencephalography (EEG)—Diagnosis of neurophysiological disorders

Environmental Services-Maintains a clean facility

Food Service (Dietary)-Provides diets to patients

Gastrointestinal (GI) Laboratory—Diagnoses gastrointestinal disorders

Laboratory-Provides testing of patient samples

Medical Records—Maintains patient records

Nursing-Provides direct patient care

Occupational Therapy-Provides therapy to help maintain living skills

Pharmacy-Dispenses drugs and advises on drug usage

Physical Therapy—Provides therapy to restore mobility

Radiology-Uses imaging for diagnosis and treatment

Respiratory Therapy—Provides therapy to evaluate the lungs

Speech Therapy-Provides therapy to restore speech

AREAS OF NURSING AND TYPE OF CARE

Coronary Care Unit (CCU)-Increased care of the patient due to a heart condition

Emergency Department-Emergency treatment of patients

Geriatric-Elderly patients

Home Health Care-Follow-up care of a patient at home

Intensive Care Unit (ICU)-increased care due to the critical needs of the patient

Neonatal-Newborn care

Nephrology-Patients on dialysis

Obstetrics-Patients in labor of childbirth

Oncology-Patients with cancer

Orthopedic-Patients with broken bones

Pediatrics-Intants and children

Recovery-Recovery treatment of patients

▲ FIGURE 1.1 Examples of areas of the hospital.

as point of care testing. The instrument is taken to the patient's room, the patient's blood is collected, the blood is tested in the instrument, and results are determined at the patient's bedside. This speeds the process of treatment for the patient. A health care practitioner can examine the patient, order a blood sugar/glucose, and then the patient is tested. Within a few minutes, the health care practitioner can have results and decide to continue or change treatment. Bedside testing eliminates the transportation time of the sample to the laboratory and the wait time to get the results to the nursing unit. However, only a limited number of tests can be performed with the instrumentation available. Federal regulations also limit to some extent what tests can be performed this way. This testing of the blood work at the patient's bedside is often the duty of the multiskilled phlebotomist or nurse.

The function of the laboratory is often not understood by an outsider. All the patient sees is the phlebotomist and is not aware of the many sections and functions within the laboratory (Figure 1.2). The main laboratory is the largest laboratory. The office section of the main laboratory receives and routes laboratory-related telephone calls, sample collection requests, and some patient samples.

In close proximity to the office is the area of sample collection, more commonly known as phlebotomy. From there the phlebotomists are dispatched to collect blood samples from patients throughout the hospital. Patients are most familiar with this section because often the phlebotomist is the only representative from the laboratory they see. Once collected, the samples go to any one of the laboratories within the hospital.

EXERCISE 1 Matching/Identification Directions: Match the ancillary areas of a hospital to their purpose. Purpose Area of hospital Maintains patient records A. Electrocardiography (EKG) Uses imaging for diagnosis and treatment. Electrocephalography (EEG) 3. _____ Provides therapy to evaluate the lungs C. Food Service (Dietary) 4. _____ Diagnosis of neurophysiological disorders Laboratory 5. _____ Monitor patients with cardiovascular disease Medical Records Provides diets to patients Nursing Provides therapy to help maintain living skills Occupational Therapy 8. ______Provides testing of patient blood and body fluid samples Pharmacy 9. _____Provides therapy to restore mobility Physical Therapy Dispenses drugs and advises on drug usage Radiology 11 ______ Provides therapy to restore speech K. Respiratory Therapy 12. _____ Provides direct patient care L. Speech Therapy.

The hematology staff studies blood cells and performs qualitative and quantitative analyses along with microscopic examinations. The CBC, or complete blood cell count (see Figure 1.2), is a routine test, providing the physician with a large amount of valuable information about a patient's state of health.

Coagulation/hemostasis is usually in the same area as hematology. Coagulation/hemostasis is the study of the clotting of blood. Patients have diseases where they bleed too much or form clots too easily (thrombosis). Staff from this section monitors patients on anticoagulant therapy, patients with bleeding or clotting disorders, as well as presurgical patients.

LABORATORY SECTIONS AND THEIR PURPOSE

Administrative Office—Responds to telephone calls, handles specimen collection requests, and handles some specimens

Phlebotomy (Sample Collection)—Collects samples from patients and processes samples for testing or transport

Hematology—Studies the blood in normal and diseased states. Usually limited to the study of cellular components and not the chemistry of blood

Examples of Tests: Complete blood cell count (CBC), hemoglobin, hematocrit, platelet count, sedimentation rate, body fluid cell counts

Coagulation—Study of blood clotting mechanisms as an aid in diagnosis or monitoring of patient therapy

Examples of Tests: Prothrombin time (PT), activated partial thromboplastin time (aPTT), D-dimer, factor VIII, fibringen assay, heparin level, you Willebrand factor (ristocutin)

Urinalysis—Study of urine to aid in patient diagnosis to follow the course of a disease or the body's metabolism

Examples of Tests: Urinalysis, reducing substance, urine pH, urine glucose

Chemistry—Performs biochemical analysis of blood and body fluids to determine the status of a patient

Examples of Tests: Comprehensive metabolic panel, iron studies, renal panel, carcinoembryonic antigen (CEA), glucose, alanine aminotransferase (ALT), aspartate aminotransferase (AST), cholesterol

Microbiology — Cultures samples to determine if pathogenic organisms are present in a sample and determines the organisms' sensitivity to antibiotics (culture and sensitivity)

Examples of Tests: Blood cultures, throat cultures, anaerobic cultures, urine cultures, parasite identification, stool culture, mycobacterial (tuberculceis) culture, virus cultures, fungal cultures, genital cultures, mycoplasma cultures, antibiotic susceptibility testing

Immunology—Studies antigens and antibodies to determine immunity to disease or presence of disease

Examples of Tests: Human immunodeficiency virus (HIV) testing, rubella, syphilis (rapid plasma reagin [RPR]), hepatitis testing

Immunohematology (Blood Bank)—Determines compatibility of blood and blood products that are to be administered to patients

Examples of Tests: Compatibility testing, antibody screens or ABO. Rh determination

Cytogenetics—Study of deficiencies related to genetic diseases

Examples of Tests: Chromosomes analysis, prenatal chromosome screening

Molecular Diagnostics—Using polymerase chain reaction (PCR) technologies to study the presence of various diseases or infections.

Examples of Tests: Methicillin-resistant Staphylococcus aureus (MRSA) infections, HIV and other infectious diseases

FIGURE 1.2 Laboratory sections.

Staff in the urinalysis section performs qualitative and quantitative chemical and microscopic examinations of urine to detect urinary tract infections, diabetes, and liver or kidney diseases. Urinalysis is often performed in or near the same area as hematology in order to share microscopes.

The chemistry section works with the fluid portion of the blood (the serum or plasma) or other body fluids. The staff performs biochemical analysis of blood and body fluids by

manual or automated techniques. A variety of analyzers measures for chemicals such as glucose, electrolytes, blood urea nitrogen (BUN), and creatinine. With almost all instruments, the sample is added to various chemicals and a color (immunofluorescence) or chemical change occurs. For example, the more glucose in the blood, the more intense the color change. In addition to single tests, instruments often run multiple tests on one sample. The panel, a battery of several tests performed on one sample, is a quick method to screen patients for illness. More complex testing is also performed in the chemistry section. Examples of these tests are protein electrophoresis, thyroid studies, aminoglycoside levels, and therapeutic drug monitoring (TDM) (Figure 1.3).

Microbiology studies organisms that are so small they can be seen only with the aid of a microscope. There the technologist identifies aerobic and anaerobic bacteria, fungi, mycobacteria (such as tuberculosis), and parasites. Samples brought to this area include throat cultures, urine cultures, wound and skin cultures, blood cultures, and other types of cultures. Once the organism that is causing the problem is determined, a test called a sensitivity is run to determine what antibiotic would be best to eliminate the problem organism.

The immunology section studies antigen—antibody reactions. Antigens are substances seen as being "foreign" in the body, and antibodies are proteins made by the body to combat specific antigens. Staff in this section performs tests to detect and evaluate human immunodeficiency virus (HIV), hepatitis, infectious mononucleosis, rheumatoid arthritis, and syphilis, and they also perform fluorescent antibody tests.

The blood bank section, sometimes called immunohematology, studies antigens and antibodies as they relate to the red blood cells. This section performs ABO Rh blood typing, type and screen testing, cross-matching/compatibility testing, and screening for antibodies. The primary testing is to determine compatibility of blood cells from a donor with the plasma of the recipient. This cross-matching of donor to recipient determines if the blood that the recipient will receive is compatible. Proper patient identification is critical when the blood the phlebotomist draws will be used to determine a product that will be infused into a patient. A misidentification of a patient opens the possibility that the patient will

These are groups of tests that have been arranged into panels for general information about a patient's health. These panels are approved for use by the American Medical Association (AMA).

Complete Blood Cell Count (CBC): White blood cell (leukocyte) count and differential white count; red blood cell (erythrocyte) count; hematocrit; hemoglobin; red blood cell indices, which include the mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), and the platelet (thrombocyte) count

Electrolyte Panel (Lytes): Sodium, potassium, chloride, carbon dioxide (CO₂)

Hepatic Function Panel: Total protein: albumin; total and direct bilirubin; alkaline phosphatase; AST, also known as serum glutamic oxaloacetic transaminase (SGOT); ALT, also known as serum glutamic pyruvic transaminase (SGPT)

Basic Metabolic Panel: Sodium, potassium, chloride, carbon dioxide (CO₂), glucose, blood urea nitrogen (BUN), calcium, and creatinine

Renal Panel: Sodium, potassium, chloride, carbon dioxide (CO₂), glucose, blood urea nitrogen (BUN), calcium, creatinine, phosphorous, and albumin

Lipid Panel: Cholesterol, triglyceride, high-density lipoprotein (HDL), low-density lipoprotein (LDL)

Comprehensive Metabolic Panel: Glucose, BUN, creatinine, sodium, potassium, chloride, calcium, carbon dioxide (CO₂), albumin, total protein, alkaline phosphatase, AST, ALT, and total bilinibin

FIGURE 1.3 Panels of laboratory tests.

receive the wrong type of blood, with serious complications to the patient, including fatal transfusion reaction. The complications can range from fever to death by kidney failure. Few hospitals draw their own donors. Most hospitals procure the blood they transfuse from a central donor facility, such as the Red Cross or local blood centers. Other products that the blood bank issues to patients are plasma, platelets, and cryoptecipitate.

Cytogenetics is an area found in some of the larger laboratories. This section studies deficiencies that are related to genetic diseases. Genetic testing is expanding rapidly.

Molecular diagnostics testing provides higher sensitivity than many traditional testing methods. Molecular diagnostics detects levels of deoxyribonucleic acid (DNA) and ribonucleic acid (RNA), proteins, or metabolites to determine the severity or presence of various diseases or infections. Most laboratories use polymerase chain reaction (PCR) technology for the testing. Often special types of evacuated tubes will be used for PCR tests.

The area of cytology and histology, also known as pathology, examines tissues and cell smears for evidence of cancer, infection, or other abnormalities. All tissue biopsy samples, surgical samples obtained in surgery, or tissues obtained in minor surgeries at a physician's office are submitted to histology for examination. The samples are prepared by a histologist and then examined macroscopically and microscopically by the pathologist. Cytology samples are processed and then examined microscopically by a cytotechnologist. Most of the cytology samples are Pap tests.

The stat laboratory handles stat (emergency) requests. It is staffed 24 hours a day, 7 days a week. The stat laboratory can do many of the same tests done in the main laboratory but does these tests individually as they are ordered and not in a batch mode (large groups together), as is often done in the main laboratory. It also provides a backup system for the main laboratory in case of instrument malfunctions. Not all laboratories have a separate stat laboratory. Often the stats are handled out of the main laboratory.

Near the outpatient entrance of some hospitals, the ambulatory care laboratory (outpatient laboratory) is found. It provides rapid turnaround of results on frequently ordered tests for outpatients. It also has an active marketing and outreach program that includes services for nursing homes, physicians' offices, and health screening for businesses.

Even with the elaborate testing facilities available in most laboratories, outside laboratories are often needed to do specialized testing. These reference laboratories can be in the same city or many miles away. The samples are transported to the reference laboratory each evening, and results are sent back via computer and Internet lines as soon as the testing is completed.

All these laboratory areas are involved in the goal of the laboratory, which is to get results on the patient's condition to the physician. This encompasses three phases of sample testing: preexamination, examination, and postexamination. The Clinical Laboratory Standards Institute (CLSI) guideline Accuracy in Patient and Sample Identification (GP33-A1) is now using these terms in its standards and guidelines. These were previously referred to as preanalytical, analytical, and postanalytical, respectively.

Preexamination—Starting, in chronological order, all steps that it takes to collect the sample and get it to the point in which the testing of the sample can occur. These include the following:

- The clinician's request
- Patient identification and information
- Correct sample collection
- Correct primary sample identification
- Correct use of all equipment
- Sample preparation or centrifugation
- Proper preparation of sample aliquots
- Maintaining sample integrity until the examination (analytical) process can begin

Examination—A set of operations to determine the value or characteristics of a property. The processes that are done to perform the test on the sample to achieve a result include the following:

- Sample testing
- Maintaining testing equipment and reagents

Postexamination—The process whereby the results of the testing are communicated to the physician. These consists of the following:

- · Reporting of results
- Ensuring accuracy and reliability of delivery of results
- Follow-up to repeat testing or address physician concerns
- · Storage of samples after the examination

The phlebotomist is mainly involved in the preexamination phase of sample testing. The primary duty of the phlebotomist is to collect venous blood samples from patients. Once the sample is collected, it is prepared by the phlebotomist through centrifugation and processing of the sample to make it stable until testing can occur. The first step of patient identification in the preexamination process is the most important step in the process. Correct patient identification is critical to ensure that the remaining phases produce accurate results. Improperly identifying the patient is a common administrative (clerical) error in the process. Proper procedures for patient identification are discussed later in the text.

Helpful Hint

Do not compromise on identifying a patient. If proper identification is not on the patient, wait for the patient to be properly identified before collecting the blood sample.

EXERCISE 2	Fill in the Blanks	
Areas of Nursin	g and Type of Care	
Directions: Identif	y the correct department of the hospital or nursi	ng specialty.
L Caring for a nursing	n elderly patient is done in the specialty	of
2. A newborn b	aby will be cared for in the	unit
3. A patient tha	t is on dialysis will be taken to the	unit.
4. A pregnant w	voman comes to the hospital to have a baby	She will be admitted to
THE PERSON NAMED IN COLUMN 2 I	nes out of surgery and must take time to do enough to go to a hospital room. He will	AND DESCRIPTION OF THE PARTY OF
6. A 5-year-old in	child is very ill and must be admitted to the	hospital. Her stay will be
	has a heart attack and is admitted to the ho	
8. Your son falls	s off his bicycle, cuts himself, and needs stic ——— department.	hes. You take him to the
9. A person with	h broken bones will be cared for in	
	r accident. One person is severely injured a itical need. The patient will be in the	
	dent patient is recovered enough to go ho ntion daily. A nurse will come to the hor care.	
12 A patient the	t has cancer is normally cared for in the	unit

LABORATORIES IN THE TWENTY-FIRST CENTURY

Traditionally, health care in the United States offered patients freedom to choose whatever physician or health care facility they wanted. A third party, usually the insurance company, would pay for all the services at the providers' usual fees. Many people could not afford to pay for the insurance plan if they were unemployed or their employer did not provide subsidized insurance. These patients had no choice in an emergency but to receive services at a hospital but would be unable to pay. This would cause those patients to go into default on the bill, and the hospitals had to raise prices to make up for the lost income. The insurance companies realized that they were paying out considerable money to organizations without restrictions or guarantees. As health care costs continued to rise, the insurance companies tried to find ways to lower costs and control the cost of the premium to the patient or employer.

Managed care was developed as a complex system to coordinate the provision of health services and health benefits. Most of these systems were put in place to control the use of health services and control costs. This was an unusual concept to the United States even though many other countries had national health insurance that controlled many health services. What developed out of this policy were managed care organizations that would contract with health care providers to provide health care services on a capitated (per-member per-month) basis.

Health maintenance organizations (HMOs) were formed to provide health coverage for both hospital and physician services. Members of the HMO are required to use only certain contracted physicians and hospitals for their care. To become one of the contracted physicians or hospitals, the physician or hospital would offer to provide services at a discount. This is in contrast to a preferred provider organization (PPO), which also contracts with certain health care facilities but offers more freedom for patients to choose to whom they go. This freedom results in a higher cost to the patient or the employer.

The United States now has added another option for many patients. The Affordable Healthcare Act has been enacted to help those that could not afford insurance. This requires all people to have health insurance. The theory is that if everyone has insurance, there will be fewer people defaulting on health care bills.

There is continued pressure on laboratories to produce quality testing in less time for less cost. These pressures are a result of the managed care programs that are in all areas of health care. Emphasis is on increasing outpatient services and decreasing length of stay for inpatients. This puts pressure on the laboratory to do the testing faster and more frequently so that there is no delay in the health care practitioner getting results and being able to treat the patient. The sooner the diagnosis and treatment are determined, the sooner the patient can be on the road to recovery.

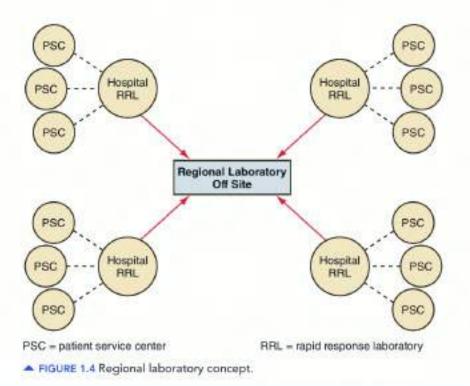
Two methods are being used to treat patients faster with less of a wait on the test results. The first method, mentioned earlier, is point of care testing. The laboratory instrument is taken to the patient, the testing is done in the patient's room, and results are determined at the bedside. The multiskilled phlebotomist often does this type of testing. The results are documented on the patient's chart without any delays. This method of blood testing is usually more expensive than the traditional laboratory test, but often the total cost of care is reduced. With managed care, the hospital is often paid one set fee for a patient. The sooner the patient can be released from the hospital, the less it costs the hospital to care for the patient.

Here is an example of how this system works: The managed care provider pays the hospital \$1,000 per day for a total of 5 days to care for a patient. It costs the hospital \$1,000 per day to care for this patient. If the patient takes 7 days to be well enough to be released, the costs are \$7,000, but the hospital will be paid only \$5,000 by the managed care provider, for a loss of \$2,000. The incentive for the hospital is to complete the patient's care in less than 5 days. This is one way the hospital could avoid a loss.

With point of care testing, the test results are available faster. This provides a faster result for the physician to respond to with treatment, and the patient is released sooner. This in turn benefits the patient because he or she is back to a normal lifestyle sooner.

The second method for avoiding a loss is reducing the hospital's cost to below \$1,000 per day. Consolidation and reengineering of the laboratory are an attempt to make this happen. Laboratories were originally organized around the need to perform inpatient testing. With the emphasis on outpatient surgery and shorter lengths of stay in the hospital, there is an increased demand for outpatient services and presurgery testing. This increase in demand for outpatient services has resulted in hospitals building patient service centers (PSCs) to handle patients. PSCs are located away from the hospital near groups of physician practices. Patients do not have to go all the way to the hospital to get their blood drawn. Patients can have their blood drawn at the service center, which might be in the same building as the physician's office. Patients can even have presurgery work done at the service center and then go to the hospital for surgery. This concept is a benefit to the phlebotomist. Each of these service centers needs to be staffed with a multiskilled phlebotomist. In the hospital the nursing staff might draw the blood, but in the service center the multiskilled phlebotomist collects the samples. Service centers are less expensive to operate than the hospital laboratory. This in turn reduces the costs to the hospital for patient care, resulting in the hospital avoiding a monetary loss in the care of the patient.

Historically hospitals have competed for patients. This vigorous competition is evident in newspaper and television advertisements. The hospital-run laboratory has become a cost that many hospitals wish to remove. Competing hospitals are now forming joint laboratory ventures but still compete vigorously against each other in all other areas. The hospitals join to form a new laboratory company with each hospital as a part owner; sometimes a commercial reference laboratory is another part owner in this joint venture. The employees of the laboratory become employees of the new company and no longer work for the hospital or commercial laboratory. At the center of this joint venture is what is called a regional laboratory. This regional laboratory is usually at an off-site location, central to all the hospitals involved. This laboratory is where most of the PSC and outpatient testing are performed. All the testing from outpatients is sent to one centrally located regional laboratory instead of multiple hospital locations. The advantage is that only one test instrument must be purchased instead of one instrument for each hospital. This also increases the volume of testing done, and more instrument automation can be implemented to reduce labor costs. With the testing coming in from multiple locations, certain tests that are not very common, called esoteric tests, can be performed at the regional laboratory. Before the joint venture, no one hospital would have enough volume to do certain tests. By joining forces, certain not-so-common tests have become common. This provides the physician the ability to order tests and get results back faster than when the testing had to be sent to an out-of-state commercial laboratory. Hospital laboratories reduce the variety of tests that are completed and concentrate on the tests needed for the immediate care of the inpatient and emergency department patient. These hospital-based laboratories are usually termed stat laboratories or rapid response laboratories (RRLs). The key to making all this work is an efficient courier and sample tracking system. Instead of samples being walked to another area of the hospital, they have to be transported to another area of the city. To avoid delays, this has to be fast and efficient (Figure 1.4). This concept opens up a multitude of opportunities for the phlebotomist. The phlebotomist can do venipuncture in any of the sites or can become multiskilled and rotate to any of the areas, taking on tasks from processing samples to being a courier. The opportunities become endless for the individual who is willing to learn and rotate to a variety of locations.



LABORATORY

The staff working in the laboratory has a large range of duties and training, resulting in numerous job titles and roles. The technical positions are either 4-year degree positions or 2-year associate degree positions. A medical laboratory scientist (technologist) has a bachelor's degree and a medical technology or clinical laboratory scientist certification. A technician has a 2-year associate degree in medical technology and a certification. Both roles are needed to make a laboratory run smoothly and efficiently. The secretarial or clerical positions in the office areas of the laboratory require a high school education and some secretarial/clerical training. Knowledge of medical terminology is helpful. The laboratory staff is made up of a wide range of individuals with varying degrees and experience (Figure 1.5).

The phlebotomist position is the one we focus on here. The phlebotomist must have a special demeanor to perform the job. They are interacting with many different people and must be able to appropriately interrelate with everyone. The job of the phlebotomist is to provide samples for accurate and reliable test results as quickly as possible. The phlebotomist needs a high school education and specialized training in phlebotomy: a minimum of 40 hours of classroom training and 100 hours of clinical or practical training is the standard set by the American Society for Clinical Pathology. Individuals with this minimum amount of training may have to work in a clinic, outpatient setting, or small hospital. Once experienced they will be capable of working in a large hospital. Many hospitals and clinics are willing to hire a phlebotomist who has completed only classroom training. The hospital or clinic may offer practical on-the-job training with the hope that the phlebotomist-in-training will learn rapidly and be willing to remain at the institution. Many hospitals have established such training programs to fill phlebotomy positions. Phlebotomists may now take certification exams to prove their knowledge in phlebotomy. Various certification and registry exams accredit the person as a phlebotomy technician. In most states phlebotomists do not have to be certified in order to work. Some states require that phlebotomists obtain a state license before they can work as a phlebotomist. Certification is a voluntary process and controlled and run by a professional organization; licensure is a requirement run by the state.

THE LABORATORY STAFF

Pathologist—Physician who reads and interprets the results of laboratory tests or examines tissues under a microscope to diagnosis and monitor disease. Pathologists are experts in diagnosing such diseases as cancer, diabetes, acquired immunodeficiency syndrome (AIDS), hepatitis, and thyroid conditions. The American Board of Pathology requires 5 years of training following graduation from medical school to be eligible to take examinations leading to board certification as a clinical/anatomic pathologist.

Medical Laboratory Scientist (MLS) or Clinical Laboratory Scientist (CLS)—Holds a minimum of a baccalaureate degree and is responsible for performing a full range of laboratory tests, confirming the accuracy of test results, and reporting laboratory findings to the pathologist and other physicians. Medical technologists work in five major areas of the laboratory; blood banking, chemistry, hematology, immunology, and microbiology.

Medical Laboratory Technician (MLT)—Under the supervision of the medical technologist, performs general tests. Medical laboratory technicians have special training in addition to a high school diploma or an associate degree.

Philebotomy Technician (PBT)—Collects blood samples to be used in many laboratory tests to detect and monitor treatment. Philebotomists have training in addition to a high school diploma.

Cytotechnologist (CT)—Examines cells under the microscope to detect signs of cancer in the earliest stages, when a cure is most likely. Cytotechnologists must hold baccalaureate degrees and have special training to search out the smallest abnormalities in color, shape, or size of cells.

Histotechnologist (HTL)—Prepares body tissue samples for microscopic examination by the pathologist using sophisticated techniques such as immunohistochemistry. Histotechnologists must hold baccalaureate degrees and have special training to freeze, cut, mount, and stain the tissues, often while the patient is still in surgery, thus playing a major role in the diagnosis of malignancy.

 FIGURE 1.5 Laboratory staff. Based on information from the American Society for Clinical Pathology (ASCP), http://www.ascp.org.

California has enacted a set of standards that falls under the Department of Health Services (DHS), Laboratory Field Services section. There have been regulations for many years in California, but in 2003 new categories of phlebotomy technicians were created. Even if phlebotomists are certified by another organization, they must meet the California standards. In California phlebotomists must be licensed before they can hold a phlebotomy job. There are now three separate categories of California phlebotomy technicians requiring three separate qualification standards:

- Limited Phlebotomy Technician—This technician is only able to perform skin punctures. The technician must perform 25 skin punctures (fingersticks) before meeting the qualifications for this standard.
- Phlebotomy Technician I—This technician performs skin punctures and venipunctures. The technician must perform 50 venipunctures and 10 skin punctures (fingersticks) and pass an approved national certifying organization's exam.
- Phlebotomy Technician II—This technician performs skin punctures, venipunctures, and arterial punctures. The technician must perform 20 arterial punctures and meet the requirements of the Certified Phlebotomy Technician 1.

Laboratories often employ an individual with a high school education and laboratory experience to work as a laboratory assistant. A laboratory assistant usually has received on-the-job training. A phlebotomist who has shown exceptional abilities and attitude is often considered for such a program. This kind of internship generally occurs in a clinic or small hospital setting. The length of training varies from one health care center to another.

After the experience, the laboratory assistant often realizes how enjoyable it is to work in a laboratory and seeks further education to qualify for more demanding job responsibilities and a higher salary. This multiskilling of the phlebotomist opens the opportunities for the phlebotomist to do point of care testing, EKGs, and so on.

The medical laboratory technician is a graduate of a 2-year associate degree program. This program is taken through a college or proprietary school that is affiliated with a health care center. The health care center provides the practical experience. Once the training is completed, the student must take a certification or registry exam. Some states also have a licensing requirement. Upon successful passing of the certification exam, the technicians are certified as medical laboratory technicians (MLTs).

Another 2-year associate degree program that includes at least 1 year of clinical experience is the histologic technician (HT). The HT prepares the tissue samples for microscopic examination in the histology section of the laboratory. A person who has completed a baccalaureate degree program in histology and has a year of histopathology experience will qualify to take the certification exam for histotechnologist.

A section related to histology is cytology. In this section a person with a baccalaureate degree and completion of a 12-month accredited cytotechnology program is then eligible to take a certification exam to qualify as a cytotechnologist (CT).

Working in the laboratory as a medical laboratory scientist or clinical laboratory technologist requires a baccalaureate degree. This degree involves attending an approved university for 3 or 4 years and then gaining some clinical training in an accredited laboratory. Once completed, the person may take a certification exam to become a medical laboratory scientist (ML5). The ML5 can advance to a supervisor, a manager, or an administrative director position. The requirements needed to work in a laboratory vary by state.

The person in the laboratory with the most education is the pathologist. The pathologist is a physician who has completed additional schooling and an internship to specialize in pathology. This is a physician specialty, like pediatrics or surgery. The pathologist is sometimes called the physician's physician. The physicians within the hospital consult with the pathologist on disease processes they see in a patient. The physicians also confer with the pathologist to determine if additional tests need to be run on a patient to confirm a particular disease process. The pathologist directs the test protocols and test procedures that are done in the laboratory. He or she does extensive consultation on surgical or autopsy samples, bone marrow procedures, and cytology samples.

Generally, attendance at an approved college or university is needed to qualify for most of these positions. For some positions, mostly MLTs, online distance learning is available. These types of programs combine online distance learning over the Internet with clinical experience in a laboratory. The list of institutions that provide this method of learning continues to grow. The most up-to-date list of institutions providing this opportunity can be found at the ASCP Distance Learning Page at http://www.ascp.org.

To work in the laboratory, nearly all positions require passing certification and/or state licensing exams. Many agencies certify medical laboratory personnel. Some of these agencies, the certification, and title they confer are listed here:

Medical Laboratory Scientist (Medical Technologist)

MLS (ASCP): Medical Laboratory Scientist (American Society for Clinical Pathology)

MT (AMT): Medical Technologist (American Medical Technologists)

CLT (HHS): Clinical Laboratory Technologist (Department of Health and Human Services)

Medical Technician

MLT (ASCP): Medical Laboratory Technician, Certificate (American Society for Clinical Pathology)

MLT (AMT): Medical Laboratory Technician (American Medical Technologists)

Phlebotomist

PBT (ASCP): Phlebotomy Technician (American Society for Clinical Pathology)
RPT (AMT): Registered Phlebotomy Technician (American Medical Technologists)
CPT (ASPT): Certified Phlebotomy Technician (American Society of Phlebotomy
Technicians)

Phlebotomy Technician (NCCT): (National Center for Competency Testing) CPT (NPA): Phlebotomy Technician (National Phlebotomy Association)

The agencies and certifications listed are just a few of those available. The phlebotomy area has the most diversification in agencies granting certification. The agency that is accepted worldwide in laboratories for all certification and registries is the American Society for Clinical Pathology (ASCP). Even though certification has not raised the pay scale for phlebotomists, it has granted recognition to the phlebotomist as an integral part of the laboratory team.

The laboratory has to be highly organized for the team of laboratory professionals to function smoothly. The interaction can be visualized as an organizational chart for the laboratory that delineates the tasks to be performed, the individuals who are to perform the tasks, and the clinical laboratory as a workplace. Organization defines the relationship among tasks, individuals, and the workplace. The basis for this relationship is authority, responsibility, and accountability. For example, a laboratory manager has the authority attached to the position. If the laboratory manager did not have the position, the manager would not have the authority to hire associates. Responsibility refers to the tasks or duties assigned to the position within the organization. Accountability is the obligation to someone higher on the organizational chart.

An organizational chart is a multilevel vertical hierarchy that signifies the relationship of one position to another. It is sometimes referred to as the chain of command. The larger the organization the greater the specialization of tasks each individual is responsible for. A laboratory organizational chart develops into a pyramid with the number of individuals increasing at the base of the pyramid. The laboratory organizational chart usually contains a smaller, adjacent pyramid that includes the pathologists and their relationship to the rest of the laboratory staff. This relationship is shown as a dotted line. Figure 1.6 shows a typical organizational chart.

This organizational chart can be expanded both vertically and horizontally, depending on the size of the laboratory. Communication flows up or down the chart, creating the chain of command. A single laboratory manager is responsible for coordinating the activities for technical procedures, managing support staff, and achieving goals. Workers receive orders from only one manager or supervisor, and they know whom to report to.

Helpful Hint

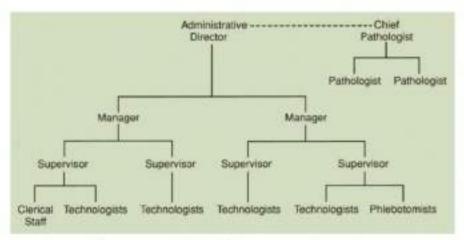
Always think of how you would like to be treated if you were the patient. Professionalism must be demonstrated at all times.

EXERCISE 3 Abbreviations and Certifications

Directions: List the certification abbreviations for the following laboratory staff according to the American Society for Clinical Pathology.

- 1. _____ phlebotomy technician
- 2. _____ cytotechnologist
- medical laboratory scientist
- 4. _____ clinical laboratory scientist
- 5. _____ medical laboratory technician
- 6. _____ histotechnologist

Phlebotomists play an important role in the health care center. They support the organization and are the main representatives of the quality of the laboratory to the patient. Phlebotomists are professionals and must conduct themselves accordingly. They must maintain a clean and nest appearance and must treat the patient with a gentle touch in a calm and unhumied manner.



A FIGURE 1.6 Laboratory organizational chart.

THE PATIENT CARE PARTNERSHIP

The American Hospital Association drafted a Patient's Bill of Rights in 1973, revised it in October 1992, and replaced it with the Patient Care Partnership in 2003. This was drafted to show support of ethical treatment of patients and an understanding of a patient's rights and responsibilities. The goal was to contribute to more effective care. The Patient Care Partnership ensures greater satisfaction of the patient, physician, and health care facility. Support of these patient rights by a health care facility should become an integral part of the healing process. Focus on patient rights existed before the onset of acquired immunodeficiency syndrome (AIDS) and before many of the new medical procedures. But awareness of patient rights is still up to date in its substance. By having an understanding of patient rights, we are able to see how the patient can be treated ethically and professionally.

Effective health care requires a partnership between patients and physicians and other health care professionals. Open and honest communication, respect for personal and professional values, and sensitivity to differences are integral to optimal patient care. As the setting for the provision of health services, hospitals must provide a foundation for understanding and respecting the rights and responsibilities of patients, their families, physicians, and other caregivers. Hospitals must ensure a health care ethic that respects the role of patients in decision making about treatment choices and other aspects of their care. Hospitals must be sensitive to cultural, racial, linguistic, religious, age, gender, and other differences as well as the needs of persons with disabilities.

The American Hospital Association presents the Patient Care Partnership with the expectation that it will contribute to more effective patient care and be supported by the hospital on behalf of the institution and its medical staff, employees, and patients. The American Hospital Association encourages health care institutions to tailor this Patient Care Partnership to their patient community by translating or simplifying the language as may be necessary to ensure that patients and their families understand their rights and responsibilities.

Patient Rights

Patient rights can be exercised on the patient's behalf by a designated surrogate or proxy decision maker if the patient lacks decision-making capacity, is legally incompetent, or is a minor. Following is the list of patient rights:

- The patient has the right to considerate and respectful care.
- The patient has the right to and is encouraged to obtain from physicians and other direct caregivers relevant, current, and understandable information concerning diagnosis, treatment, and prognosis.

Except in emergencies when the patient lacks decision-making capacity and the need for treatment is urgent, the patient is entitled to the opportunity to discuss and request information related to the specific procedures and/or treatments, the risks involved, the possible length of recuperation, and the medically reasonable alternatives and their accompanying risks and benefits.

Patients have the right to know the identity of physicians, nurses, and others involved in their care as well as when those involved are students, residents, or other trainees. The patient also has the right to know the immediate and long-term financial implications of treatment choices, insofar as they are known.

- 3. The patient has the right to make decisions about the plan of care prior to and during the course of treatment and to refuse a recommended treatment or plan of care to the extent permitted by law and hospital policy and to be informed of the medical consequences of this action. In case of such refusal, the patient is entitled to other appropriate care and services that the hospital provides or to transfer to another hospital. The hospital should notify patients of any policy that might affect patient choice within the institution.
- 4. The patient has the right to have an advance directive (such as a living will, health care proxy, or durable power of attorney for health care) concerning treatment or designating a surrogate decision maker with the expectation that the hospital will honor the intent of that directive to the extent permitted by law and hospital policy.

Health care institutions must advise patients of their rights under state law and hospital policy to make informed medical choices, ask if the patient has an advance directive, and include that information in patient records. The patient has the right to timely information about hospital policy that may limit its ability to implement fully a legally valid advance directive.

- The patient has the right to every consideration of privacy. Case discussion, consultation, examination, and treatment should be conducted so as to protect each patient's privacy.
- 6. The patient has the right to expect that all communications and records pertaining to his or her care will be treated as confidential by the hospital, except in cases such as suspected abuse and public health hazards when reporting is permitted or required by law. The patient has the right to expect that the hospital will emphasize the confidentiality of this information when it releases it to any other parties entitled to review information in these records.
- The patient has the right to review the records pertaining to his or her medical care and to have the information explained or interpreted as necessary, except when restricted by law.
- 8. The patient has the right to expect that, within its capacity and policies, a hospital will make reasonable response to the request of a patient for appropriate and medically indicated care and services. The hospital must provide evaluation, service, and/ or referral as indicated by the urgency of the case. When medically appropriate and legally permissible, or when a patient has so requested, a patient may be transferred to another facility. The institution to which the patient is to be transferred must first have accepted the patient for transfer. The patient must also have the benefit of complete information and explanation concerning the need for, risks and benefits of, and alternatives to such a transfer.
- The patient has the right to ask and be informed of the existence of business relationships among the hospital, educational institutions, other health care providers, or payors that may influence the patient's treatment and care.
- 10. The patient has the right to consent to or decline to participate in proposed research studies or human experimentation affecting care and treatment or requiring direct patient involvement and to have those studies fully explained prior to consent. A patient who declines to participate in research or experimentation is entitled to the most effective care that the hospital can otherwise provide.

- 11. The patient has the right to expect reasonable continuity of care when appropriate and to be informed by physicians and other caregivers of available and realistic patient care options when hospital care is no longer appropriate.
- 12. The patient has the right to be informed of hospital policies and practices that relate to patient care, treatment, and responsibilities. The patient has the right to be informed of available resources for resolving disputes, grievances, and conflicts, such as ethics committees, patient representatives, or other mechanisms available in the institution. The patient has the right to be informed of the hospital's charges for services and available payment methods.

The collaborative nature of health care requires that patients, or their families or surrogates, participate in their care. The effectiveness of care and patient satisfaction with
the course of treatment depends, in part, on the patient fulfilling certain responsibilities.
Patients are responsible for providing information about past illnesses, hospitalizations,
medications, and other matters related to health status. To participate effectively in decision
making, patients must be encouraged to take responsibility for requesting additional information or clarification about their health status or treatment when they do not fully understand information and instructions. Patients are also responsible for ensuring that the health
care institution has a copy of their written advance directive if they have one. Patients are
responsible for informing their physicians and other caregivers if they anticipate problems
in following prescribed treatment.

Patients should also be aware of the hospital's obligation to be reasonably efficient and equitable in providing care to other patients and the community. The hospital's rules and regulations are designed to help the hospital meet this obligation. Patients and their families are responsible for making reasonable accommodations to the needs of the hospital, other patients, medical staff, and hospital employees. Patients are responsible for providing necessary information for insurance claims and for working with the hospital to make payment arrangements, when necessary.

A person's health depends on much more than health care services. Patients are responsible for recognizing the impact of their lifestyle on their personal health.

Most of these rights and responsibilities can be directly applied to duties as a phlebotomist:

- The patient has the right to considerate and respectful care. Hospitalized patients are
 out of their normal routine. They may react by being rude or ill-tempered because
 of their illness or fear. Some patients may be confronting their own mortality for the
 first time. It is important for the phlebotomist to remain calm and to show consideration and concern for each patient. The phlebotomist also must face the realization
 of mortality. In the United States, 85 percent of the population dies in the hospital.
 The phlebotomist will at some time walk into a patient's room and find the patient
 deceased, possibly before anyone else knows about the death. Even in death the
 patient must be treated with respect.
- 2. The physician is the patient's primary source concerning diagnosis and treatment. If questions are asked during the phlebotomy procedure, simply state that the physician has ordered blood to be drawn for testing, and refer the patient to the physician. The phlebotomist may question the need for the test to be drawn or realize there was an error on a previous sample, and now the patient has to be redrawn. Questions and concerns should not be discussed with the patient but with the phlebotomist's supervisor or the nurse, outside the presence of the patient.
- Informed consent. The phlebotomist may need to explain briefly how the venipuncture is performed and that these are tests the physician has ordered. The patient's act of extending his or her arm for the procedure is taken as an act of consent.

Hospitals have many functions to perform, including the enhancement of health status, health promotion, and the prevention and treatment of injury and disease; the immediate and ongoing care and rehabilitation of patients; the education of health professionals, patients, and the community; and research. All these activities must be conducted with an overriding concern for the values and dignity of patients.

- Right to refuse treatment. Often by just talking with the patients, they consent to the procedure. If they still refuse, the nursing staff and physician must be informed.
- 5. Consideration of privacy. It is important to remember to be discreet in approaching the patient. Often the phlebotomist may be in the room at the time another procedure is being performed, the patient is completing personal hygiene, or the physician is examining the patient. Under all these different circumstances, it is necessary to approach the situation in a mature fashion.
- 6. Confidentiality. Knowledge concerning a patient's diagnosis is confidential. Matters pertaining to a patient's care should not be discussed in the cafeteria, hallways, or other public areas. Use discretion with such information. Confidentiality can be broken as innocently as when, finding out that a friend of the family is pregnant, the phlebotomist goes home to tell his or her spouse. The spouse then tells someone else, and all the relatives know before the pregnant woman has had the opportunity to tell anyone.
- The patient has the right to know about his or her medical care and can look at his or her records. If the patient asks the phlebotomist to look at the chart, this request should be referred to the nurse or physician.
- 8. The patient has the right to expect a reasonable response to requests for services. The appropriate person to handle these requests is the nurse or physician. Often a patient may request a drink of water, aid in getting out of bed, and so on, from a phle-botomist. Refer these requests to the nursing staff, since the physician may have written specific orders denying the privilege because of upcoming surgery or other aspects related to that patient's care.
- The patient has the right to know of professional relationships and the names of those who are rendering care. A patient may request the phlebotomist's name and title, and it is appropriate for you to give this information.
- 10. Experimentation. Patients who are involved in a medical experiment, be it a new drug or treatment, must first be informed of the proposed course of action. The patient must also be informed of its ramifications and must give informed consent to participate in the study.
- 11. Continuity of care. In these days of multiple specialties and treatment by several physicians at once, it is important to maintain continuity in the care and treatment of patients. For the laboratory this means that samples should be obtained and processed expeditiously to facilitate the care of the patient.
- 12. The patient has the right to examine and receive an explanation of his or her bill. Every care should be taken to ensure that the patient is charged for only those tests that are performed and that billing is handled expeditiously.

The application of these rights is not just a perfunctory duty. Part of a caring philosophy is not only to care for the physical and spiritual needs of those in our care, but also to recognize their dignity as human beings. By internalizing this philosophy of caring, not only does the patient benefit, but as caregivers we benefit as well.

PROFESSIONAL ATTITUDE

Central to the job of drawing blood is the patient, who is often apprehensive about the procedure we perform. It is important not only to obtain a good sample, but to do so with minimal trauma to the patient. Bear in mind that the patient must be treated like anyone would like to be treated. Everyone must follow a professional code of conduct in the treatment of patients. Proper treatment of the patient and the medico-legal responsibility of the phlebotomist are covered in more detail in Chapters 11 and 12.

The phlebotomist's own professional attitude toward the job and duties determines how the patient is treated. If the phlebotomist attempts to draw a patient and does not feel confident about obtaining the sample, a "miss" of the patient will probably result. Even when you try to hide it, a negative attitude will resurrect its ugly head and destroy rapport with patients, coworkers, and supervisors. It is not the events of the day that shape the phlebotomist, it is how the phlebotomist deals with those events. The following is a quotation of Charles Swindoll that sums up the impact of attitude and a code of ethics for how patients are treated.

ATTITUDE

The longer I live, the more I realize the impact of attitude on life. Attitude, to me, is more important than the past, than education, than money, than circumstances, than failures, than successes, than what any other people think or say or do. It is more important than appearance, giftedness, or skill. It will make or break a company—a church—a home. The remarkable thing is we have a choice every day regarding the attitude we embrace for that day. We cannot change our past. We cannot change the inevitable. The only thing we can do is play on the one string we have, and that is our attitude. I am convinced that life is 10 percent what happens to me and 90 percent how I react to it. And so it is with you. We are in charge of our attitudes.

PROFESSIONAL GROOMING

Just as the professional attitude of the phlebotomist can determine how well a phlebotomist is perceived by the patient, so can the grooming of the phlebotomist affect this perception. The average patient the phlebotomist will be working with is an older individual for whom often only conservative grooming and dress is acceptable. Most health care organizations restrict what the phlebotomist is permitted to wear. The dress code will have restrictions such as the following:

- No visible tattoos
- No body piercing other than a maximum of two in the ears
- No fingernails longer than ¼ inch
- No blue jeans or casual attire
- No open-toed shoes
- No T-shirts or sweatshirts

Often the phlebotomist will be most comfortable and acceptable wearing a scrub outfit. In some health care organizations the scrub outfit is furnished.

ADVANCE DIRECTIVES

A phlebotomist may have ethical questions about continuing care for a terminally ill patient. The phlebotomist must carry out the orders requested by the physician. The patient and physician determine how extensive the treatment will be for the patient. All states now follow the Patient Self-Determination Act of 1990. This act requires all hospitals participating in Medicare or Medicaid programs to ask all adult inpatients if they have advance directives. The hospital must document the patient's answers and provide information on state laws and hospital policies regarding advance directives.

Formal advance directives are documents written before incapacitating illness that give instructions about persons' health care if, in the future, they cannot speak for themselves. A person can give someone he or she names (an "agent" or "proxy") the power to make

health care decisions for that person. A person also can give instructions about the type and degree of health care wanted and expected in the event the person cannot voice an opinion. A health care advance directive contains two parts. The first part names an agent who can make decisions for a person in the event he or she is unable. The second part lists predetermined directions on a person's health care that will give some indication of his or her wishes to the agent. This is not limited to cases of terminal illness; it can also be invoked during a temporary illness or injury. Several organizations are helpful in developing an advance directive, including the following:

- American Association of Retired Persons (AARP)
- · ABA Commission on Legal Problems of the Elderly
- American Medical Association

If a patient presents you with questions, refer her or him to these organizations. As a phlebotomist, you are not a legal expert on these issues.

Through advance directives such as living wills and durable powers of attorney for health care, patients can make legally valid decisions about their future medical treatment.

In a living will a person can stipulate the kind of life-prolonging medical care he or she would want if terminally ill and unable to make medical decisions. In the absence of any advance directive by the patient, the decision is left to the patient's family, physician, and hospital, and sometimes a court of law. Usually the family, physician, and hospital can agree without resorting to the courts, and most states seem to permit this even if it is not clearly stated in the law.

Many hospitals have ethics committees or ethics consultation services, one of whose functions could be to help in decision making about incompetent patients without family or about difficult clinical situations. If the hospital is a religious-based institution, then its religious affiliation also has an influence on the decisions. Although these ethics committees and religious affiliations often counsel the physician, patient, and family, the final decisions remain the responsibility of the patient, the physician, and the family or other surrogate for the incompetent patient.

STANDARDS USED IN THE LABORATORY

A particular laboratory that serves hospital inpatients is a "hospital laboratory." An "outpatient laboratory" serves only outpatients. The types of patients the laboratory serves determine whether that laboratory is governed by a variety of rules and regulations. Abiding by these rules and regulations then determines whether that laboratory can qualify for Medicare, Medicaid, and insurance reimbursement. In essence, abiding by these rules and regulations determines whether a laboratory is permitted to function.

The Joint Commission

A large body of regulations govern hospital laboratories, and various agencies issue these regulations and standards (Figure 1.7). A hospital laboratory accepting Medicare or Medicaid reimbursement must meet all applicable state and local requirements and be accredited by the appropriate agency. It is possible for a hospital to be accredited by The Joint Commission or by the American Osteopathic Association (AOA) as a substitute for meeting most of the Medicare requirements. A hospital that has met all the requirements of The Joint Commission or AOA will have met almost all the requirements for Medicare. The Joint Commission is the accrediting agency most hospitals prefer. The Joint Commission was formed in 1951 to give hospitals a way to assure the public of their high standard of care. Since the enactment of the Medicare Act in 1965, The Joint Commission has been an acceptable substitute for Medicare accreditation. To prove that the hospital meets standards, The Joint Commission sends a team of inspectors to the hospital. The inspection focuses on the organization's performance and processes that strive for improving patient outcomes. This inspection evaluates the organization's

REGULATORY AGENCIES

The Joint Commission

Sets standards of care to ensure quality and reliability of health care Surveys are accepted by Medicare (reimbursement) Laboratory tests must meet The Joint Commission's accuracy standards Laboratories must meet procedure standards

College of American Pathologists (CAP)

Proficiency samples are sent to laboratories by CAP for accuracy checks Inspects lab procedures and laboratory results. The Joint Commission accepts CAP inspections.

National Accrediting Agency for Clinical Laboratory Sciences (NAACLS)

International agency for accreditation and approval of education programs in clinical laboratory sciences and related health care professions. Accreditation approved by on-site inspections of facility to ensure program meets certain educational standards. Competencies must be met by student in order for educational program to exist.

Clinical Laboratory Standards Institute (CLSI, formerly NCCLS)

Establishes laboratory guidelines and procedures Consists of representatives of the laboratory and laboratory industry Maintains uniformity of laboratory procedures on a national basis

Clinical Laboratory Improvement Act of 1988 (CLIA)

Enforced by a committee of inspectors

Main goal is to protect patients from receiving inaccurate results

Occupational Safety and Health Administration (OSHA)

Regulations enforced by a committee of inspectors Establishes and enforces safety standards for employees Can issue fines if there are violations

FIGURE 1.7 Regulatory agencies.

compliance with The Joint Commission standards. The inspectors base their inspection on the following:

- Tracing the care delivered to the patients
- Verbal and written information provided to The Joint Commission
- On-site observations and interviews by the inspectors
- Documents provided by the health care organization

As a phlebotomist you may be observed in performing your job and asked questions about the job you do. If the hospital does not pass all the standards during the inspection, the hospital must correct the deficiencies, prove the correction was made, and have a reinspection at a future date.

The Joint Commission Web site offers the patient the opportunity to submit a complaint about any health care organization accredited by The Joint Commission. Once a complaint is registered, The Joint Commission will investigate. The health care organization will then be allowed to respond to the complaint. The severity or frequency of patient complaints could affect the organization's accreditation.

The most serious of events is called a sentinal event. A sentinel event is defined as "an unexpected occurrence involving death or serious physical or psychological injury, or risk thereof. Serious injury specifically includes loss of limb or function. The phrase 'or risk thereof' includes any process variation where a recurrence would carry a significant chance

of a serious adverse outcome." These sentinel events require immediate investigation by the health care organization. The investigation and response would include:

- Investigation into the root cause of the event
- Corrective action and developing a process to prevent the recurrence
- Monitoring the new process to determine effectiveness

College of American Pathologists

In addition to the hospital meeting the standards of The Joint Commission, the laboratory often is inspected voluntarily by another agency, called the College of American Pathologists (CAP). CAP inspects the laboratory and requires it to meet additional standards of performance by sending proficiency test samples to the laboratory throughout the year. These test samples must meet the range of results given for that sample on a repeated basis. If the samples continue to fall outside the range, it indicates to the laboratory that the procedure needs to be changed in some way to correct the deficiency. This sample testing gives the laboratory the opportunity to compare itself to other laboratories throughout the country. CAP also sends a team of inspectors to the laboratory to inspect its performance and record-keeping. Passing the sample testing requirements and the inspection permits the laboratory to state that it is a CAP-approved laboratory. An added benefit is that The Joint Commission will often not inspect the laboratory but will accept the CAP inspection as approval enough.

State Board of Health

Also checking on the performance of hospitals and laboratories is the individual state board of health. Depending on the particular state, this type of inspection can range from a detailed inspection to just a walk-through of the laboratory. The board of health usually accepts The Joint Commission or CAP inspection and then in more detail inspects the rest of the hospital.

Clinical Laboratory Standards Institute

To help laboratories maintain the high level of performance necessary to pass these various inspections, the Clinical Laboratory Standards Institute (CLSI), a nonprofit educational organization, was founded in 1968. CLSI issues publications that describe laboratory procedures, bench and reference methods, and evaluation protocols in all specialties of the laboratory.

First, a proposed guideline of procedures is published. Then the users comment on how the guideline can be modified. The CLSI committee that wrote the document reviews the comments to determine if the guideline should be changed or an appendix should be attached to the document. The document that has gone through the comment period and committee review then becomes a standard. Most of the procedures that are included in the books are based on CLSI-approved standards. This gives all laboratories approved methods of testing that are consistent nationwide. The publications can be a constant source of reference.

Clinical Laboratory Improvement Act

Congress has been involved in the performance standards of the laboratory since it enacted the Clinical Laboratory Improvement Act (CLIA) of 1967. This act mandated comprehensive regulation of laboratories involved in interstate commerce. It was directed at
reference laboratories after there was a public outcry about inaccurate testing and kickback
payments in the reference laboratory system. As a practical matter, CLIA 1967 does not
apply to hospital or physician laboratories. The inspection practices for hospital laboratories just described seem to be sufficient to maintain public and congressional confidence in
hospital laboratories' performance. With The Joint Commission, CAP, and CLIA 1967, all
hospital and reference laboratories had established methods for inspections. The omission
was the physician office laboratory, which was growing larger and larger as more physicians realized the economic benefits of doing some of their own testing. Laboratories are
like all businesses. There are always a few that do not hold rigid standards and turn out

substandard results. Some patients were being charged for tests that were not accurate or were even incomplete. Congress then passed a bill called the Clinical Laboratory Improvement Amendments of 1988. These amendments included the physician office laboratories (POLs) in the federal standards and placed quality assurance requirements on other clinical laboratories. CLIA 1988 shifts the focus away from the education and experience qualifications of personnel to the accurate performance of the clinical procedures themselves. This act requires all clinical laboratories to perform quality testing whose accuracy can be proven statistically.

CLIA 1988 was designed to set safety policies and procedures that protect patients. The standards are based on test complexity and the risk factors associated with incorrect results. The laboratories are monitored by the Health Care Financing Administration (HCFA) of the U.S. Department of Health and Human Services (HHS). They have designated four categories of testing:

- Waived tests. Tests that are simple, unvarying, and require a minimum of judgment and interpretation.
- Physician-performed microscopy tests. Tests in which the physician personally looks under the microscope and makes the judgment and interpretation.
- Moderate-complexity tests. Tests that require more complex testing equipment and a
 moderate amount of judgment and interpretation. Moderate-complexity laboratories
 must employ personnel with specific levels of education.
- High-complexity tests. Tests that require the most complex testing equipment and a large amount of judgment and interpretation. Highly complex laboratories must employ personnel with specific levels of education.

Moderate-complexity laboratories must have employees who can serve as director, technical consultant, clinical consultant, and testing personnel. The highly complex laboratory has an additional category of general supervisor. These positions do not require successful passing of the certification or registry exams. The position a person can fill is based on his or her educational level and experience (Table 1.1).

The goal of the regulations just discussed is to protect the patient. These regulations work to ensure that accurate and reliable testing methods are being used to provide the best results to the patient. The Occupational Safety and Health Act of 1970 regulates the safety and protection of the associate doing testing. The Federal Register Rules and Regulations of December 6, 1991, established new regulations that employers must follow to protect their associates from blood or other potentially infectious materials. The enforcement of the act started on July 6, 1992. This act dictates that the employer is responsible for enforcing the rules and that the Occupational Safety and Health Administration (OSHA) can issue fines of up to \$7,000 per infraction. The range of this act is far reaching and affects all associates and patients of the health care system. Implementation of these regulations can have a financial impact, but their purpose is to provide a safe work environment. Chapter 2 presents more details of the OSHA rules and regulations.

Accrediting Agency for Clinical Laboratory Sciences The National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) is an international agency for the accreditation and approval of educational programs for clinical laboratories and other health care professions. After the school submits information about the educational program being offered, NAACLS sends someone to inspect the school facility to ensure that the program meets certain educational standards. Part of the standard requirement is that each educational program meet certain competencies of performance for each course of study.

Meeting these competencies is a focus of this textbook. The complete list of competencies for phlebotomy is listed in Appendix A. At the beginning of each chapter the objectives of the chapter and the competencies relevant to the chapter are outlined.

TABLE 1.1 Centers for Disease Control and Prevention Personal Requirements for Nonwaived Testing

Category	Education	Experience
1. Director	M.D./D.O., pathologist	1 year of experience
	M.D./D.O.	1 year of experience
	Ph.D.	1 year of experience
	M.S.	2 years' experience or training
	B.S.	4 years' experience or training
2. Technical consultant	M.D./D.O., pathologist M.D./D.O.	1 year of experience
	Ph.D. or M.S.	1 year of experience or training
	B.S.	2 years' experience or training
3. Clinical consultant	M.D./D.O., pathologist M.D./D.O.	1 year of experience
	Ph.D.	Board certified
	M.D./D.O.	State licensed
4. Testing personnel	M.D./D.O.	Ph.D., M.S.
	B.S.	In appropriate science
	Associate degree	In appropriate science
	High school diploma	Appropriate training
5. General supervisor	Director	M.D./D.O.
	Ph.D., M.S. or B.S.	1 year of experience
	Associate degree	2 years' experience

To qualify for a category, the employee must meet one or more of the education and experience requirements. Sources: Center for Disease Control and Prevention, Clinical Laboratory Improvement Act (CLIA) of 1988, Personnel requirements.

57 Federal Register 7172, February 28, 1992. Retrieved May 12, 2016, from http://www.ecfr.gov/egi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b6mode=pt42.5.4938trgn=div5

EXERCISE 4	Abbreviations and Certifications
Directions: List the	abbreviation for the following regulatory agencies.
L	College of American Pathologists
2	Clinical Laboratory Standards Institute
3	Clinical Laboratory Improvement Act
4	National Accrediting Agency for Clinical Laboratory Sciences
5	Occupational Safety and Health Administration

QUALITY ASSURANCE IN PHLEBOTOMY

Phlebotomists must realize that quality is their responsibility. The result of the test that is sent to the physician depends on the quality of the sample that the phlebotomist obtains. Most of the preexamination (preanalytical) process is the responsibility of the phlebotomist. A sample drawn from the wrong patient or a sample that is contaminated or clotted will give inaccurate results. The most common error is administrative (clerical), where the phlebotomist spells the name wrong, mislabels a sample, or draws the incorrect sample tube. Various agencies work to ensure that health care facilities meet standards, rules, and regulations. To monitor compliance with these standards, rules, and regulations, several programs within the health care facility are used. One such program is a quality assurance program. This strives to guarantee that all areas of the health care facility are providing the highest-quality and most appropriate patient care. The quality assurance program must contain an element of quality control in order to function. Quality control comprises the methods of monitoring the processes that are providing patient care, that is, equipment maintenance and calibration of equipment, following phlebotomy standards.

The Joint Commission has outlined 10 steps to a quality assurance plan:

- Assign responsibility.
- Delineate scope of care.
- 3. Identify important aspects of care.
- 4. Identify indicators related to these aspects of care.
- Establish thresholds for evaluation.
- 6. Gather and organize data.
- 7. Evaluate care when thresholds are reached.
- 8. Take corrective action.
- 9. Assess the effectiveness of the actions; document improvement.
- 10. Communicate relevant information.

To supplement this plan, the health care facility must also have a total quality management (TQM) and continuous quality improvement (CQI) plan in place. The TQM plan is a management plan that ensures that the quality expected can be met. This plan establishes the assurance of adequate supplies and personnel, up-to-date procedures, and acceptable patient outcomes (the patient's health improving). The CQI plan aims at more than just meeting the minimum standards. The CQI plan does not accept the status quo; there must be constant efforts to improve what is being done. Both plans focus on the entire health care team seeking patient satisfaction as the final outcome. The phlebotomist must monitor a variety of quality improvement items. Seven examples follow:

- Phlebotomist response time (for inpatients)
- 2. Patient waiting (for outpatients)
- 3. Time it takes to perform a phlebotomy procedure
- 4. Number of redraws due to inappropriate amount of sample
- 5. Number of incorrect tubes drawn
- Number of patients requiring a second attempt.
- 7. Number and size of hematomas

The organization incurs a cost anytime that a sample in the preexamination phase does not meet the criteria for an acceptable sample (e.g., mislabeled, incorrect patient identification, quantity not sufficient, wrong order entry, recollected samples). As the inappropriate sample moves through the process of examination to postexamination, more labor and materials are involved. The cost to recover continues to increase. These are called failure costs. The highest failure cost is when the failure causes harm to the patient. An example of this is a patient being given the incorrect treatment or medication because incorrect results

TABLE 1.2 Six Sigma Levels

Sigma Level	% Accuracy	Defects per Million
6	99.9997	3.4
5	99.98	233
4	99.4	6,210
3	93.3	66,807
2	69.1	308,537

Helpful Hint

The laboratory that reduces or eliminates failure costs removes a significant source of waste to the organization. Failure costs should be considered opportunities for improvement. Do not compromise on identifying a patient. If proper identification is not on the patient, wait for the patient to be properly identified before collecting the blood sample.

Philosophies used to improve both the quality and the profitability of the laboratory are Six Sigma and Lean. Six Sigma works to identify and improve processes using data and customer requirements to reduce errors. The goal is to reduce the defects per million (DPM) or defects per million opportunities (DPMO). The basic idea is to perform error-free work. If you say that completing a task error-free 99 percent of the time is good, this can create too many errors. Examples of 99 percent error-free performances include the following:

- · 20,000 lost articles of mail each hour
- Your heart beating regularly except for 87 hours every year
- Having no electricity for 7 hours each month
- Having unsafe drinking water in your home for 15 minutes every day

The Six Sigma concept describes different levels to achieve depending on the error rate. The goal is to achieve Six Sigma.

The Lean philosophy helps develop work-flow programs to streamline laboratory operations. Sometimes this process is as simple as reducing the number of steps that philosotomists or technicians take in performing their job. Lean was first developed by Toyota for the automotive industry and has been adapted by some laboratories (Table 1.2).

Quality Assurance and Quality Control

Quality assurance and control in phlebotomy rest largely on the phlebotomist and how the phlebotomist performs. The quality assurance (QA) of how well the phlebotomist performs is checked early in the training of the phlebotomist by completion of competency checklists. These checklists are discussed further in Chapter 12. The competency checklists help to verify that the phlebotomist has received the proper training and can follow established procedures to complete a task. This also helps phlebotomists know what care they can give patients. If they have not completed a competency check for a task, they cannot perform that task. For example, if a phlebotomist has completed competency checks for fingersticks on adults but not heelsticks on infants, his or her scope of care would be for adults only.

If the phlebotomist cannot complete all the checks on a competency list, it will help the trainer to document what has been completed and what needs to be reinforced. Subsequent training will be documented, and then the effectiveness of this training and improvement will be noted.

These processes meet the following quality assurance standards of The Joint Commission:

- Assigning responsibility for the phlebotomist
- Delineating the scope of care the phlebotomist can give
- Identifying what aspect of care the phlebotomist can perform
- Noting corrective action needed to help the phlebotomist meet the standards of care
- Assessing the effectiveness of these actions
- Documenting that relevant information for the procedure was communicated to the phlebotomist

Quality control of the phlebotomist and the task of drawing blood are monitored by gathering data from several sources. Thresholds for how many patients a phlebotomist should be able to draw blood from per hour are usually established for each facility. Quality control would be to determine if the phlebotomist is meeting this minimum level or threshold. If phlebotomists are drawing considerably fewer patients than they should, they should be observed to see if their skill level is sufficient or whether they are sticking each patient twice to get the blood. This observance would reveal several other quality issues—from lack of training to dissatisfied patients because of multiple sticks.

Patient satisfaction surveys can be a good quality indicator. Sending these to patients at their home or having them available as patients leave the draw site can tell the supervisor how well the phlebotomist is performing. There should be room for comments on these surveys and also a checklist for patients to mark from excellent to poor on categories such as the following:

- Facility cleanliness
- Professionalism and appearance of staff
- Satisfaction with wait time
- Time spent waiting to be served
- Overall experience
- Skill of the phlebotomist

Using information gathered from these surveys will help to maintain quality standards for the health care facility. The comments from the patients will alert the phlebotomist supervisor to satisfied and dissatisfied patients. Often patients will mention a phlebotomist by name in comments. All this information gathered should be documented to prove that a quality assurance program is in place. Documentation of corrective action should also be maintained.

Calling patients the day after they visited a draw site will give valuable immediate feedback. The visit is still fresh in the patient's mind, and he or she will be able to provide more information.

Another valuable tool in monitoring the customer service of phlebotomists is to hire a "secret shopper." This is a person hired by the laboratory to come to a draw site with an order from a physician. This secret shopper has been trained to look for details in performance. He or she will go through the process of registering and getting blood drawn to see how the phlebotomist performs the task. The secret shopper will then report back to the supervisor on how well the phlebotomist met the standards of performance.

Whatever method is used to monitor performance, quality control consists of multiple facets, including:

- Monitoring the performance of the procedure
- . Determining how well that that performance meets the standard of care
- Documenting what did not meet the standard of the procedure
- Instituting corrective action to correct the deficits

The review and monitoring of the outcomes of these processes in order to continually improve them is quality improvement. The information that was discovered through surveys, secret shoppers, or calling patients is used to strive toward continuous improvement in performance. A quality improvement program will not be satisfied with the way a task is performed. Efforts will be made to continually improve the process and make it better. Making processes better consists of making them faster, easier, less costly, and more comfortable for the patient.

The phlebotomist must satisfy the patient to maintain the health care organization's financial stability. Many insurance companies require health care organizations meet certain levels of patient satisfaction before they allow their patients to go to that health care facility.

EXERCISE 5	Short Answer	
Directions: Write to	he correct term or phrase to complete each sentence.	
	test will include a leukocyte count, erythrocyte count, emoglobin and platelet count.	
2. The carbon dioxic	test includes the analytes: sodium, potassium, chloride, and le.	
dioxide, gluci	wants to test for a patient's sodium, potassium, chloride, carbonose, blood urea nitrogen (BUN), and creatinine, the physician would test.	
4. The compreh	ensive metabolic panel can include what 13 tests?	
a	h. ———	
b		
c	j	
d	k	
e		
g		
5. What constitu	ates a sentinel event?	
6. Name five par	tient rights.	
a		
b		
c		
d		
е		

EXERCISE 6

Requisition Exercise

You have just collected the following tests. What departments in the laboratory will you take these to?

Hometown Hospital USA 125 Goodcare Avenue Small Town, USA

Clinic or room number: 3415	Sample Collection	
Physician Name: Good, James	Date:xx/xx/xxxx	Patient Name: Goodpatient, Samue
Diagnosis code: 748.22	Time:1030	MRN: 123456
	Initials: SS SS	DOB: 12/22/1967
		Sex M
	Special Instructions:	
Basic Metabolic Panel	CBC without diff	X_ Culture, urine
Electrolyte Panel	_X_ CBC with diff	Culture, throat
X Hepatic Function Panel	Reticulocyte count	Culture, stool
Comprehensive Panel	Sedimentation rate, ESR	Ova and Parasite, stool
X Ethanol	Sickle cell screen	
X Acetaminophen	Protime, PT	
Salicylate	APTT	Syphilis RPR screen
Glucose, Fasting		Mononucleosis screen
Glucose Tolhr		ANA screen
Hgb A1C	Urinalysis	Rheumatoid factor screen
	Urine protein	
Other Tests	UUN, urea nitrogen	
	urine electrolytes	ABO
	Creat. Clearance (24 hr.)	Rh
	Urine TOX screen	Antibody Screen
		Type and Cross-match
he samples would be taken to: _		

REVIEW QUESTIONS

b. patient identification.

Multiple Choice

Choose the one best answer.

Choose the one best answer.	
1. Phlebotomists are an important part of	of the health care team because
 a. they represent the laboratory and institution. 	
b. they are in direct contact with the	patient. d. all of the above
	s and tasks. Which of the following is the primary duty?
a. sample processing	c. collecting venous blood samples
b. sample accession	d. collecting arterial blood samples
12	nost education and acts as a consultant to other physicians?
a. pathologist	c. medical laboratory technician (MLT)
b. medical laboratory scientist (MLS	
	drawn, the phlebotomist should do all of the following except
a, contact the patient's nurse or phys	
b. return the requisition to the labor	
5. The most common source of laborato	
a bacterial.	c. administrative.
b. chemical.	d. technical.
6. What laboratory department tests a P	
a. chemistry	c. immunology
b. cytology	d. microbiology
7. What hospital department cares for n	
a. oncology	c. nephrology
b. orthopedic	d. neonatal
8. What hospital department cares for p	atients with cancer?
a. oncology	c. nephrology
b. orthopedic	d. neonatal
9. Where in a hospital would you find a	
a orthopedic	c. nephrology
b. obstetrics	d. neonatal
10. Which of the following is not a preex	mination variable of sample collection?
a. patient identification	c. skin preparation (cleansing)
b. sample transport	d. sample testing
11. What laboratory department tests a re	The state of the s
a, chemistry	c. urinalysis
b. cytology	d. microbiology
12. A geriatric patient is a(n)	ORDER A TEST AS AN ANDREAS MASS
a. patient in labor of childbirth.	c. patient receiving dialysis.
b. newborn.	d. elderly patient.
	p in phlebotomy, and often where an error occurs, is
a. cleansing the site,	e. using a clean needle.

d. using the proper evacuated tube.

14. Therapeutic phlebotomy is performed as a treatment for patients with

a. diabetes mellitus.

c. lymphocytic leukemia.

b. hepatitis.

d. polycythemia vera.

15. What hospital department performs dialysis of patients?

a. oncology

c. nephrology

b. orthopedic

d. neonatal

CRITICAL THINKING

1. What would you do if a patient wanted you to show him his test results?

How would you handle this situation? A terminally ill patient you are ready to collect blood from says, "I don't want my blood drawn. I'm just going to die anyway."

