2

Quality Assurance and Legal Issues in Healthcare

NAACLS Entry Level Competencies

4.1 Describe the legal and ethical importance of proper patient/sample identification.
8.1 Describe quality assurance in the collection of blood specimens.
8.2 Identify policies and procedures used in the clinical laboratory to assure quality in the obtaining of blood specimens.
9.8 Define and use medicolegal terms and discuss policies and protocol designed to avoid medicolegal problems.

Key Terms

Do Matching Exercise 2-1 in the WORKBOOK to gain familiarity with these terms.

assault
battery
breach of confidentiality
CAP
CAPA
civil actions
CLIAC
CLSI
CoW
CQI
defendant
delta check
deposition
discovery
due care
fraud
GLPs
IHI
implied consent
informed consent
invasion of privacy
IQCP
ISO
malpractice
negligence
NPSGs
plaintiff
QA
QC
quality
quality indicators
res ipsa loquitur
respondeat superior
risk management
SAFER™
SE
standard of care
statute of limitations
threshold value
TJC
tort
vicarious liability

Objectives

Upon successful completion of this chapter, the reader should be able to:

1. Demonstrate basic knowledge of terminology for national organizations, agencies, and regulations that support quality assurance in healthcare.
2. Define quality and performance improvement measurements as they relate to phlebotomy, describe the components of a quality assurance (QA) program, and identify areas in phlebotomy subject to quality control (QC).
3. Demonstrate knowledge of the legal aspects associated with phlebotomy procedures by defining legal terminology and describing situations that may have legal ramifications.

Overview

This chapter focuses on **quality assurance (QA)** and legal issues in healthcare, including the relationship of both to the practice of phlebotomy. Consumer awareness has increased lawsuits in all areas of society. This is especially true in the healthcare industry. Consequently, it is essential for phlebotomists to recognize the importance of following QA guidelines and understand the legal implications of not doing so.

Quality Assurance in Healthcare

Quality is the degree of excellence of something. QA in healthcare includes all the activities and programs put in place to guarantee the excellence of patient care. As patient care becomes more complex and resources continue to shrink, healthcare institutions search for innovative ways to improve performance and guarantee quality patient care by identifying and minimizing situations that pose risks to patients and employees. Managing risk means the organization must be committed to continuous self-evaluation and process monitoring. A system put in place to improve quality by continuous monitoring and analyzing all processes (including personnel involved in those processes) and identifying those processes that need improvement is called a **continuous quality improvement (CQI)** program. Performance measurements and quality improvement projects are now part of the accreditation requirements for all types of healthcare facilities and are found in every aspect of healthcare, including phlebotomy. One of the ways to improve quality is through compliance with and use of national standards and regulations.

National Standard Organizations and Regulatory Agencies

Do Matching Exercise 2-3 in the WORKBOOK to reinforce your understanding of the services offered by national standard organizations and regulatory agencies.

The Joint Commission

One of the key players in bringing quality assessment review techniques to healthcare is **The Joint Commission (TJC)**. This is an independent, not-for-profit organization charged with, among other things, establishing standards for the operation of hospitals and other health-related facilities and services. Its mission is *to continuously improve healthcare for the public, in collaboration with other stakeholders, by evaluating healthcare organizations and inspiring them to excel in providing safe and effective care of the highest quality and value.*

Created in 1951, TJC is the oldest and largest standards-setting body in healthcare, presently accrediting and certifying more than 21,000 healthcare organizations (HCOs) and programs in the United States. TJC-accredited and certified organizations receive a Gold Seal of Approval. To receive and maintain TJC's Gold Seal of Approval, an organization must undergo and pass an on-site evaluation by a survey team at least every three years (every two years for laboratories).

Program-specific screening criteria that focus on quality care and patient safety are used in evaluations and on-site surveys. Criteria for the clinical laboratory incorporate activities intended to reduce total analytical error by improving the preanalytical and postanalytical processes and more oversight of point-of-care testing.

In January 2017, TJC implemented a new method to identify and communicate risk levels connected with deficiencies found during site surveys. The new method is called the **Survey Analysis for Evaluating Risk (SAFER™)**. The intent of the SAFER™ approach is to help HCOs prioritize and focus their corrective actions by providing a visual representation of the survey results. The new method provides an on-site, post-survey tool called the SAFER™ Matrix™ that illustrates the likelihood of harm to a patient, visitor, or staff because of an area of noncompliance. The likelihood of harm associated with the deficiency is rated low (rare, but could happen), moderate (could occasionally happen), or high (could happen at any time). The scope is identified as limited, a pattern, or widespread. Requirements for improvement (RFIs) are due in a 60-day evidence of standards compliance (ESC).

Current TJC standards stress performance improvement by requiring the facility to be directly accountable to the customer. This means that all departments of a healthcare facility should be aware of their customers' expectations and complaints.

To evaluate and track complaints related to quality of care, TJC's Office of Quality Monitoring was created. The office has a toll-free line that can help people register their complaints. Information and concerns often come from patients, their families, and healthcare employees. A complaint may be submitted online, by e-mail, fax, or by mail. When a report is submitted, TJC reviews any past reports and the organization's most recent accreditation decision. Depending on the nature of the reported concern, TJC will:

- request a written response to the reported concern from the organization.
- incorporate the concern into a quality-monitoring database that is used to identify trends or patterns in performance.
- conduct an on-site, unannounced assessment of the organization if the report raises serious concerns

about a continuing threat to patient safety or a continuing failure to comply with standards.
- review the reported concern and compliance at the organization's next accreditation survey.

Patient Safety and Sentinel Events

TJC's commitment to safety for patients and employees in HCOs is a part of their mission for continuous improvement in healthcare provided to the public. One of the ways this is demonstrated is through its sentinel (early warning) event policy. The intent of this policy is to help HCOs identify significant safety issues and take steps to prevent them from happening again. A **sentinel event (SE)** is any unfavorable event that is unexpected and results in death or serious physical or psychological injury. Such an event signals the need for immediate investigation and response. An early warning of an undesirable outcome could be any deviation from an acceptable practice that continues to risk a patient or employee's safety. Loss of a limb or any of its function is specifically included as an SE. According to the policy, if an SE occurs, the HCO is required to:

- perform a thorough and credible analysis of the root cause.
- develop an action plan.
- implement improvements to reduce risk into practice.
- monitor improvements to determine if they are effective.

National Patient Safety Goals (NPSGs)

TJC's **National Patient Safety Goals (NPSGs)** program is part of the overall CQI requirements for accreditation. NPSGs are a method TJC uses to promote and enforce major changes related to patient safety. Criteria used to determine and revise the goals are their cost, effectiveness, and impact on patient care. Established in 2002, the review and annual updates are overseen by a safety expert panel as well as physicians, nurses, risk managers, and other healthcare professionals. The safety practices described in the goals play a significant role in advancing quality care. The goals have specific requirements for protecting patients. The annually updated goals address several critical areas of safety concerns and describe expert-based solutions. As of 2018, the NPSGs for the clinical laboratory are:

- *Identify patients correctly.* Use at least two ways to identify patients when providing laboratory services. For example, use the patient's name, an assigned ID number, telephone number, or other person-specific information, such as date of birth. The patient's room number or physical location cannot be used as an identifier. Label all blood containers and other types of specimens in the patient's presence. The intent is to reliably identify the individual and match the service or treatment to him or her.
- *Improve staff communication.* Get important critical test and diagnostic procedure results to the right staff person on time. The objective is to report critical results to the responsible caregiver within an established time so that the patient can be treated promptly.
- *Prevent infection.* Use the current hand hygiene guidelines from the Centers for Disease Control and Prevention (CDC) or the World Health Organization (WHO). Set goals for improving hand hygiene and use those goals to improve hand hygiene. The intent is to reduce transmission of infectious agents from staff to patients and decrease the incidence of healthcare-associated infections (HAIs).

FYI: The exact language of the NPSGs can be found at www.jointcommission.org.

The Institute for Healthcare Improvement

The Institute for Healthcare Improvement (IHI) is a nonprofit organization formed by the 2017 merger of the original IHI with the National Patient Safety Foundation. The two organizations joined forces to combine knowledge and resources to focus on the patient safety agenda. Their goal is to work with countries, regions, organizations, and individuals to build safety into every system of care to ensure that patients receive the safest, most reliable care throughout the healthcare industry.

Clinical Laboratory Improvement Amendments of 1988

The Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) are federal regulations passed by Congress and administered by the Centers for Medicare and Medicaid Services (CMS). These regulations establish quality standards that apply to all facilities, including clinics and physicians' office laboratories that test human specimens to provide information used to diagnose, prevent, or treat disease and assess health status. The standards address QA, **quality control (QC)**, proficiency testing, laboratory records, and personnel qualifications.

The aim of the standards is to ensure the accuracy, consistency, and reliability of patient test results regardless of the location, type, or size of the laboratory. To assist in administering these regulations, the **Clinical Laboratory Improvement Advisory Committee (CLIAC)** was formed. Its purpose is to provide technical and scientific advice and guidance to the appropriate people in the CMS who are administering the regulations. CLIAC advises on the need for revisions to the current regulatory standards and the impact the proposed revisions will have on laboratory practice.

All laboratory facilities subject to CLIA '88 regulations are required to obtain a certificate from the CMS according to the complexity of testing performed there. Three categories of testing are recognized: waived, moderate (including provider-performed microscopy), and high complexity. Complexity of testing is based on the difficulty involved in performing the test and the degree of risk of harm to a patient if the test is performed incorrectly. Waived tests are tests that are simple and have a low risk of erroneous results. Laboratories subject to CLIA '88 regulations that perform only waived tests must apply for a **Certificate of Waiver (CoW)**.

CLIA requirements are more stringent for laboratories that perform moderate- and high-complexity testing than waived testing, and their facilities are subject to routine inspections. Specimen collection is an important part of CLIA inspections, and laboratories that perform moderate- or high-complexity testing are required to have written protocols for patient preparation, specimen collection, labeling, preservation, and transportation.

After discovering significant gaps in the quality of waived testing practices, CMS began on-site visits to approximately 2% of CoW laboratories across the country. The on-site visits were known in advance and were intended for education and the gathering of information. CMS has now conducted visits in all 50 states and will continue to visit 2% of the CoW laboratories throughout the United States each year. The CLIAC, in cooperation with the CDC, Food and Drug Administration (FDA), and accrediting agencies and manufacturers, is committed to ensuring that the waived laboratories receive the education needed to produce accurate and reliable test results.

One of the educational tools that CLIAC has developed is the 10 QA recommendations for CoW laboratories called **Good Laboratory Practices (GLPs)**. The GLPs emphasize QA in collecting and performing blood work using waived testing kits. They are intended to inform, but are not mandatory. See Box 2-1 for an abbreviated form of the GLPs.

Misconception Alert: How well do you understand the information about CLIA? Some students confused why CLIA was established with how they determine what type of certificate a laboratory should receive. For example, the following question appears in Wolters Kluwer's adaptive learning systems, powered by PrepU:

> CLIA categorizes certificates for laboratories according to:

37% of the students who answered this question mistakenly chose "quality-control standards." CLIA regulations were passed to establish quality standards for laboratories, but the certificates are based on the complexity of testing performed by the laboratory.

BOX 2-1

GOOD LABORATORY PRACTICES

1. Keep the manufacturer's current product insert for the laboratory test in use, and be sure it is available to the testing personnel. Use the manufacturer's product insert for the kit currently in use; do not use old product inserts.
2. Follow the manufacturer's instructions for specimen collection and handling.
3. Be sure to properly identify the patient.
4. Be sure to label the patient's specimen for testing with an identifier unique to each patient.
5. Inform the patient of any test preparation such as fasting, clean-catch urine specimens, and so forth.
6. Read the product insert prior to performing the test.
7. Follow the storage requirements for the test kit. If the kit can be stored at room temperature but this changes the expiration date, write the new expiration date on the kit.
8. Do not mix components of different kits.
9. Record the patient's test results in the proper place, such as the patient's chart or laboratory test log, but not on unidentified Post-it notes or pieces of scrap paper that can be misplaced.
10. Perform any instrument maintenance as directed by the manufacturer.

Adapted from U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services, Clinical Laboratory Improvement Amendments, Good Laboratory Practices. Retrieved on October 25, 2018 from https://www.cms.gov/regulations-and-guidance/legislation/clia/downloads/wgoodlab.pdf.

Do the WORKBOOK Case Study 2-1 exercise to reinforce your understanding of CLIA and CLIAC.

College of American Pathologists

Another agency that influences quality care through standards for the laboratory and phlebotomy is the **College of American Pathologists (CAP)**. This national organization is an outgrowth of the American Society for Clinical Pathology (ASCP), a not-for-profit organization for professionals in the field of laboratory medicine. Membership in CAP is exclusively for board-certified pathologists and pathologists in training. CAP offers proficiency testing and a continuous form of laboratory inspection by a team made up of pathologists and laboratory professionals. The CAP Inspection and Accreditation Program does not compete with TJC accreditation for healthcare facilities because CAP is designed for pathology/laboratory services only. A CAP-certified

laboratory also meets Medicare and Medicaid standards because TJC grants reciprocity (mutual exchange of privileges) to CAP in the area of laboratory inspection.

Key Point: The CAP requires documentation in an employee's personnel file to confirm that the employee is qualified and trained to perform the responsibilities for which he or she is assigned.

Check out Knowledge Drill 2-4 in the WORKBOOK. This exercise will help you summarize the functions of the national agencies and regulations.

Clinical and Laboratory Standards Institute

The **Clinical and Laboratory Standards Institute (CLSI)** is a global, nonprofit, standards-developing organization with representatives from the profession, industry, and government. Its mission is *to develop clinical and laboratory practices and promote their use worldwide.* The organization uses a widespread agreement process to develop voluntary guidelines and standards for all areas of the laboratory. CLSI has grown into a global association of over 2,000 member organizations and more than 1,800 volunteers who are working to improve the quality of medical care through standardization. Phlebotomy program approval, certification examination questions, and the standard of care are based on these important guidelines and standards.

National Accrediting Agency for Clinical Laboratory Sciences

The National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) is recognized by the U.S. Department of Education as an authority on quality clinical laboratory education. Its mission is *to be the premier international agency for accreditation and approval of educational programs in the clinical laboratory sciences and related health professions through the involvement of expert volunteers and its dedication to public service.* NAACLS accreditation process involves an external peer review of the program, including an on-site evaluation, to determine whether the program meets certain established educational standards. The NAACLS approval process for phlebotomy programs requires that the program meet educational standards called "competencies" designed to improve student outcomes and maintain quality education. (See Chapter 1 for more information on NAACLS.)

Do Matching Exercise 2-3 in the WORKBOOK to reinforce your understanding of regulatory agencies and their purpose.

International Organization for Standardization

The **International Organization for Standardization (ISO)** is an independent, non-governmental international organization of 162 national standards bodies from all over the world, whose members share knowledge and develop voluntary international standards that cover many industries, including healthcare. ISO standards are strategic tools that businesses can use to ensure that their products and services are of good quality and are safe and reliable.

FYI: One reason why the organization chose ISO for their acronym instead of IOS is because it is derived from the Greek word *isos*, meaning "equal".

Quality Assurance in Phlebotomy

As members of the healthcare team, phlebotomists must understand the significance of their role in providing quality patient care. Due to the advancements in diagnostic techniques and the evolution of personalized medicine, laboratory testing is an even more important part of patient diagnosis and care than ever before. Doctors depend on the test results to be accurate and timely. In today's climate of greater test volume and increased reliance by the physician on the laboratory, all sources of error must be identified and monitored. Preanalytical (before analysis) factors such as patient preparation, specimen collection procedures, and specimen handling can affect the quality of the specimen and in turn affect the validity of test results. Many of these factors fall under the responsibility of the phlebotomist. To ensure consistent quality, specimen collection and handling policies and procedures should be based on specific guidelines such as those established by TJC, CAP, CLIA, and CLSI. Phlebotomists should strictly adhere to them. Established policies and procedures fall under the overall process of QA.

QA Processes

A QA program strives to guarantee quality service through scheduled reviews that look at the appropriateness, applicability, and timeliness of patient care, for instance, the laboratory's response to a comatose patient in the ER. Over the years as healthcare has become more complex, there has been an increase in QA processes used by providers as they continually look for better ways to achieve their desired aims and outcomes.

Processes that fail result in errors. Therefore, it is important to adopt appropriate process improvement (PI) techniques to identify problems or inadequacies,

BOX 2-2

QUALITY/PROCESS IMPROVEMENT TOOLS

Failure Modes and Effects Analysis (FMEA)	• Systematic process to reduce the risk of harm to patients and employees by preventing failures rather than treating bad outcomes.
	• Asks the questions:
	  • What could go wrong?
	  • Why did it go wrong?
	  • What would be the outcome if it did?

Six Sigma	• Structured and rigorous process use to evaluate preanalytical and postanalytical processes. • Monitors a process to minimize or eliminate waste. • Measures improvement by comparing the process effectiveness before improvement with the process capability after trying various solutions.
Lean Methodology	• Aims to improve patient safety and the quality of healthcare by eliminating waste in the form of unnecessary processes and redirecting efforts to the customer needs. • Strives to make every employee a problem-solver so they can develop action plans that improve, simplify, and redesign work processes. • Steps in this method depend on root-cause analysis to investigate errors and then improve quality and prevent similar errors.

Root-Cause Analysis (RCA)	• Formalized investigation and problem-solving approach used after an event or problem has occurred.
	• Focuses on identifying trends and understanding the underlying or root causes of an event.
	• Required by The Joint Commission:
	  • to be performed in response to all SEs and expects the organization to produce and implement an action plan that is designed to reduce future risk of events.
	  • to monitor the effectiveness of those improvements.

and make changes that prevent errors. Some strategies and tools for improving quality and patient safety, including failure modes and effects analysis (FMEA), Six Sigma, Lean, and root-cause analysis (RCA), are explained in Box 2-2.

FYI: Guidelines or directives are developed for all processes used and play a part in meeting TJC's commitment to continuously improve healthcare for the public.

Quality Indicators

One of the most important aspects of setting up a QA identification and evaluation process is establishing quality indicators to monitor certain areas of patient care. For example, the laboratory must have quality indicators to monitor preanalytical, analytical, and postanalytical processes. An indicator is defined as a measurement or value that provides information on what something is like, such as the state or level of something. **Quality indicators** are measurements or values that provide information on the effectiveness or quality of processes. They must be measurable, well defined, objective, and specific and provide information upon which action can be taken for improvement. Quality indicators that measure adequacy, accuracy, timeliness, effectiveness of patient care, and customer satisfaction can be selected using available inpatient data. Indicators are designed to look at areas of care that tend to cause problems. For example, an indicator on the microbiology QA form shown in Figure 2-1 states: "Blood culture contamination rate will not exceed 3%." A contamination rate that increases beyond the pre-established threshold listed on the form would signify unacceptable performance, in which case action should be taken.

See the Microbiology Quality Assessment Form: Labeling Exercise 2-1 in the WORKBOOK to better understand quality indicators.

Thresholds and Data

Threshold values must be established for all quality indicators. A **threshold value** is a level of acceptable practice beyond which quality patient care cannot be assured. Exceeding this level may trigger intensive evaluation to see

HOSPITAL & HEALTH CENTER

QUALITY ASSESSMENT AND IMPROVEMENT TRACKING

CONFIDENTIAL A.R.S. 36-445 et. seq.

STANDARD OF CARE/SERVICE:

IMPORTANT ASPECT OF CARE/SERVICE:
LABORATORY SERVICES
COLLECTION/TRANSPORT

SIGNATURES:

_____
DIRECTOR

_____
MEDICAL DIRECTOR

_____
VICE PRESIDENT/ADMINISTRATOR

DEPARTMENTS:
DATA SOURCE(S):
METHODOLOGY: [X] RETROSPECTIVE [ ] CONCURRENT
TYPE: [ ] STRUCTURE [ ] PROCESS [X] OUTCOME
PERSON RESPONSIBLE FOR:
- DATA COLLECTION: J. HERRIG
- DATA ORGANIZATION: J. HERRIG
- ACTION PLAN: J. HERRIG
- FOLLOW-UP: J. HERRIG

DATE MONITORING BEGAN: 1990
TIME PERIOD THIS MONITOR: 2ND QUARTER 2009
MONITOR DISCONTINUED BECAUSE:
FOLLOW-UP:

INDICATORS	THLD	ACT	PREV	CRITICAL ANALYSIS/EVALUATION	ACTION PLAN
Blood Culture contamination rate will not exceed 3%				**Population: All patients** **All monthly indicators were under threshold, 3%**	**Share results and analysis with Lab staff and ER staff.**
APR - # of Draws: 713 **# Contaminated: 13**	**3.00%**	**1.8%**	**1.2%**	**% Contamination from draws other than Line draws, by unit:**	
MAY - # of Draws: 710 **# Contaminated: 23**	**3.00%**	**2.8%**	**2.3%**	**APR: ER = 4.7% Lab = 0.7%** **MAY: ER = 11.5% Lab = 1.0%** **JUN: ER = 8.6% Lab = 1.1%**	
JUN - # of Draws: 702 **# Contaminated: 17**	**3.00%**	**2.4%**	**1.9%**	**ER was over threshold for each month of quarter.**	
Total for 1st Quarter - **# of Draws: 2125** **# Contaminated: 50**	**3.00%**	**2.4%**	**1.9%**		

Figure 2-1. A microbiology quality assessment form.

if there is a problem that needs to be corrected. During the evaluation process, data are collected and organized. Data sources include such information as patient records, laboratory results, incident reports, patient satisfaction reports, and direct patient observation. A **corrective action preventative action (CAPA)** plan is established if the data identify a problem or opportunity for improvement. The action plan defines what will change and when that change is expected. The last step in the CAPA process is an effectiveness check, in which steps are taken to verify that the problem has been corrected and has not recurred. Even when the problem appears to be corrected, monitoring and evaluation continue to ensure that care is consistent and that quality continually improves.

Process and Outcomes

QA has traditionally looked at outcomes. Outcomes are in numbers only. For example, a phlebotomy outcome measurement may give the number of times that patient specimens were redrawn because the improper tube was used for collection. It is important to know how often this occurs, but it does not explain why it happened. To improve an outcome, the process must be reviewed. This entails following the process from start to finish. It means standardizing the way performance is measured and activities are evaluated. In the previous example, it would mean looking at what the requester did at the time he or she decided the test was needed, how it was ordered, and how the laboratory processed the request until the time the results were on the patient's chart and in the hands of the person who ordered them. To ensure that the same process is always followed, there must be checks and controls on quality along the way.

Quality Control (QC)

The use of checks and controls to assure quality is called QC. Laboratory QC procedures are used to identify and correct any problems that might affect the quality of patient results. Phlebotomy QC involves using all available QC

Table 2-1. Quality Assurance Versus Quality Control in the Clinical Laboratory

	Quality Assurance (QA)	Quality Control (QC)
Definition	Processes used to create standardization for quality service or product and prevention of problems	Specific activities and techniques that are performed to fulfill the requirements for a quality service or product
As a tool	QA is a managerial tool for laboratory supervisors	QC is a corrective tool for laboratory personnel
Goal	To improve the necessary work processes in the laboratory so that errors do not occur when producing the service or test result	To identify weaknesses or errors in the laboratory processes at the practice level that could cause poor patient service or test result
Objective	Aims to prevent errors by being proactive	Aims to identify and correct errors by being reactive
Action	Establishes a QA plan and accompanying generic processes using available QA tools (e.g., Lean, Six Sigma)	Finds and eliminates sources of errors in specific activities or practices so that the patient's requirements are continually met
Who is responsible?	Everyone on the clinical laboratory team	The phlebotomist or laboratory person performing the activity
When implemented?	Quality assurance activities are determined by the team before work begins	Quality control is about adherence to requirements by the person performing the activity
Example of activities	Development of standards and process checklists, project audits	Following the standards and using the checklists, monitoring performance, determining causes of errors

checks on every operational procedure or process to make certain it is performed correctly.

Key Point: QA and QC are often mistakenly used interchangeably to refer to processes employed to ensure the quality of a service or product. The terms, however, have different meanings (Table 2-1). QA is a program or process that is designed to prevent problems in the future by evaluating present and past performance. QC is a component of a QA program and is used by the laboratory to prevent problems before results are released.

In phlebotomy, it is the responsibility of the person who supervises the phlebotomist to oversee QA and ensure that checks are being done and standards are being met. It is the responsibility of the phlebotomist to meet those standards at all times. Consistently following national standards for phlebotomy procedures is a means of controlling the quality of the results.

Areas of Phlebotomy Subject to QA

Areas of phlebotomy subject to QA include patient preparation, specimen collection, and delta checks.

Patient Preparation Procedures

QA in laboratory testing starts before the specimen is collected. To obtain a quality specimen, the patient must be prepared properly. Instructions on how to prepare a patient for testing can be found by checking the laboratory's test menu or catalog which is electronically available on the web in most cases.

FYI: To check out an online test menu go to www.labcorp.com. You can search for a test by name or choose from an alphabetical list.

Specimen Collection Procedures

The phlebotomist plays an important role in the QA process during the preexamination phase of the testing process. Any step performed incorrectly in this phase can affect the quality of the specimen or of patient care, but the most important step is patient identification (ID).

Identification

Patient ID (see Chapter 8) is the most critical step in specimen collection. Methods are being continually improved to ensure that all ID is done correctly. An example is the use of barcodes for patient information on ID bands, requisitions, and specimen labels instead of typed information. Barcode readers that are used to scan this information (Fig. 2-2) prior to collecting specimens substantially reduce human error.

TJC moved toward stricter patient ID requirements with their revision of NPSGs in 2009, and the organization still includes improving accuracy of patient ID as an NPSG for the laboratory. To meet the TJC safety goal for patient ID, phlebotomists must use at least two person-specific identifiers for patient ID. The patient's room number or physical location cannot be used as an identifier. For outpatients

Figure 2-2. A phlebotomist scans a patient's ID band. (Reprinted with permission from Lynn, PL. Taylor's Clinical Nursing Skills: *A Nursing Approach*. 5th Ed. Philadelphia, PA: Wolters Kluwer; 2019.)

without ID bands, the agency requirements are met when the patient's spoken name is compared with the name on the requisition and the patient provides a second verbal identifier such as birth date or phone number. Acceptable "person-specific" identifiers include:

- The individual's name
- An assigned ID number
- Telephone number
- Date of birth
- Social security number
- Address
- Photograph

Electronic ID, such as barcode readers, meets the standard if the technology includes two or more identifiers since a barcoded wristband could be on the wrong patient.

If the patient is unresponsive, which can happen in the emergency department, patient identifiers can be a temporary "name" and a medical record number or the assigned ED number until the formal ID is confirmed.

Puncture Devices

Ensuring the quality and sterility of every needle and lancet is essential for patient safety. All puncture devices come in sealed, sterile containers and should be used only once. If the seal has been broken, the device should be put in a sharps container and a new one obtained. Manufacturing defects in needles, such as barbs and blunt tips, can be avoided before use by quickly inspecting the needle after unsheathing.

Evacuated Tubes

CLSI has established standards for evacuated tubes to help ensure specimen integrity. Manufacturers print expiration dates on each tube for QA (see Chapter 7, Fig. 7-22) and the lot numbers of the tubes are recorded when received in the laboratory. It is common practice to keep only a limited supply on hand to avoid tossing out tubes that were not used by the expiration date. Outdated tubes should never be used because they may not fill completely, causing dilution of the sample, distortion of the cell components, and erroneous results. In addition, anticoagulants in expired tubes may not work effectively, instead allowing small clots to form and thereby invalidating hematology and immunohematology test results. As part of QC, evacuated tubes should be checked occasionally for adequate vacuum and additive. Results of these and other QC checks should be documented.

Labeling

Labeling must be exact. Labeling requirements as outlined in Chapter 8 should be strictly followed. Inaccuracies, such as transposed letters or missing information, will result in the specimen being discarded. Computer labels (Fig. 2-3) normally contain correctly printed patient information. However, the correct label must be placed on the correct patient's specimen and the date, time of draw, and ID of the person collecting the sample must be noted. All blood containers and other types of specimens must be labeled in the patient's presence as stated in the TJC NPSG Goal 01.

CAUTION: There have been cases in which patient information on computer labels was incorrect because incorrect information was entered into the computer upon patient admission. Proper patient ID procedures can catch such errors.

Technique

Proper phlebotomy technique must be carefully taught by a professional who understands the importance of following national standards and the reasons for using certain equipment or techniques. When a phlebotomist understands the rationale for maintaining the standards, high-quality specimens are ensured.

Key Point: No matter how experienced phlebotomists may be, a periodic review of their techniques is necessary for quality assurance and performance improvement.

Collection Priorities

Specimen collection priorities must be stressed. The importance of knowing how to recognize which specimen request is the most critical or when a specimen involves special collection criteria (e.g., renins or therapeutic drug monitoring [TDM]) can save the patient from unnecessary medication or additional testing. It may even shorten the

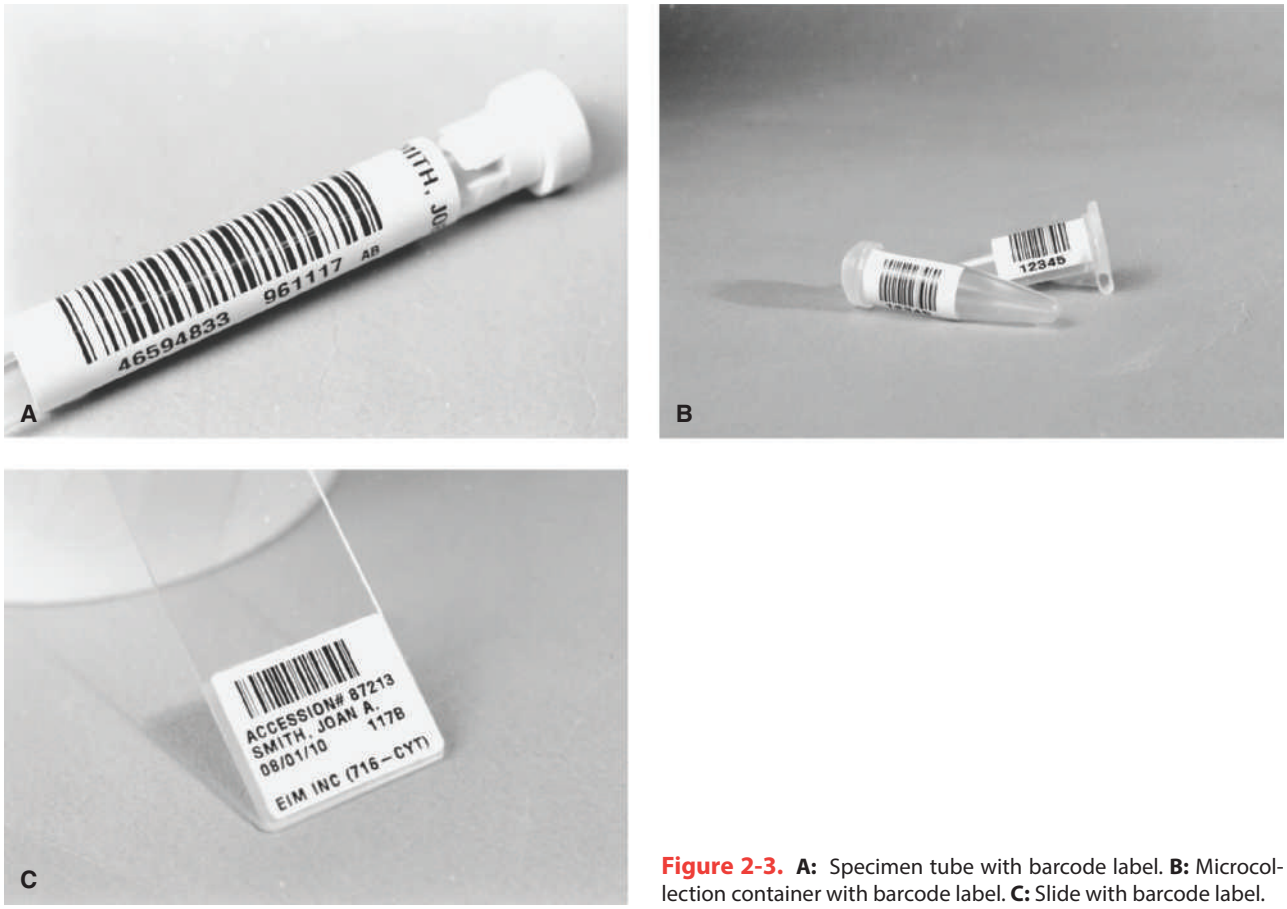


Figure 2-3. **A:** Specimen tube with barcode label. **B:** Microcollection container with barcode label. **C:** Slide with barcode label.

patient's stay in the hospital because in many instances, therapy is based on test values from specimens assumed to have been collected at the right time and in the proper manner.

Delta Checks

Delta checks help ensure quality in testing. A **delta check** compares current results of a laboratory test with previous results for the same test on the same patient. Although some variation is to be expected, a major difference in results would be flagged and could indicate an error that requires investigation.

Documentation

Documentation is critical in all areas of healthcare. Medical errors due to wrong information are prevalent and sometimes deadly.

FYI: A Johns Hopkins study published May 3, 2016 in *The BMJ* (formerly the *British Medical Journal*) estimates that every year, more than 250,000 Americans die from medical errors, making them the third leading cause of death in the United States.

Using the right PI tools and developing the correct documentation are essential for patient safety. Since there is no universal documentation template, forms used for CQI vary by institution. Today's technology allows electronically provided QC forms to be current and available for all personnel when needed.

Documentation can be used for legal purposes if it is legible and includes only standard abbreviations. All records kept in the process of providing healthcare are subject to review by TJC or other accreditation agencies. Easily the most important of these is the patient's record.

The Patient's Record

The patient's record is a chronologic documentation of the medical care given. The law requires that medical records be kept on hospital patients, but it does not require physicians in private practice to keep such records, though most do so in the form of a clinical record. Every notation in the patient's medical or clinical record should be legible, factual, and an objective account of the patient, past and present. The basic reasons for maintaining accurate, up-to-date medical records are as follows:

- To provide an aid to the practice of medicine by documenting treatment and a plan for continued care.

- To provide an aid to communications between the physician and others involved with present and future care for the patient.
- To serve as a legal document that may be used in a court of law.
- To serve as a valuable tool for helping the hospital evaluate performance outcomes. The patient's records include information such as a history of examinations, medical testing, laboratory reports, prescriptions written, and supplies used; these are all very informative for utilization review, a monitoring process for appropriate and cost-effective care.

CAUTION: For confidentiality reasons, access to a patient's medical record is restricted to those who have a verifiable need to review the information.

In 2009, the Health Information Technology for Economic and Clinical Health Act was passed. Two of the key provisions of the bill were the financial incentives to promote electronic record keeping and penalties for those who don't comply. Insurance companies, large medical facilities, and federal and state governments began encouraging the use of electronic medical records (EMRs), and electronic health records (EHRs). EMRs are digital versions of patient charts in physician offices, for example. EHRs go beyond EMRs by being able to share information among healthcare providers to create a total record of a patient's health. In today's healthcare environment, EMR and EHR software and wireless tablets are a necessity for more efficient, cost-effective, quality care. More and more physicians, nurses, and other healthcare providers are using computer data entry for all patient interactions. Studies have shown that electronic patient records improve the quality of care by reducing waste, liability, medication errors, SEs, and duplication of information from general practice to the hospital.

See Labeling Exercise 2-2 in the WORKBOOK for practice in reading a reference manual.

Test Catalogs and Reference Manuals

Searchable online menus or catalogs are examples of QA documents made available to customers and blood collectors at all specimen collection sites. In an outpatient setting, like a clinic or physician's office, there is the option to receive the instruction in the form of a printed reference manual (Fig. 2-4). All of these documents detail how to prepare the patient and any additional information needed to collect a high-quality sample. They typically list the test, CPT code, type of specimen and amount needed, special handling requirements, transport temperature and container type, and causes for specimen rejection.

BOX 2-3

TYPICAL INFORMATION FOUND IN A PROCEDURE MANUAL

- Purpose of the procedure
- Policy
- Specimen type and collection method
- Equipment and supplies required
- Detailed step-by-step procedure
- Limitations and variables of the method
- Corrective actions
- Method validation
- Normal values and references
- Review and revision dates
- Approval signatures and dates

The Procedure Manual

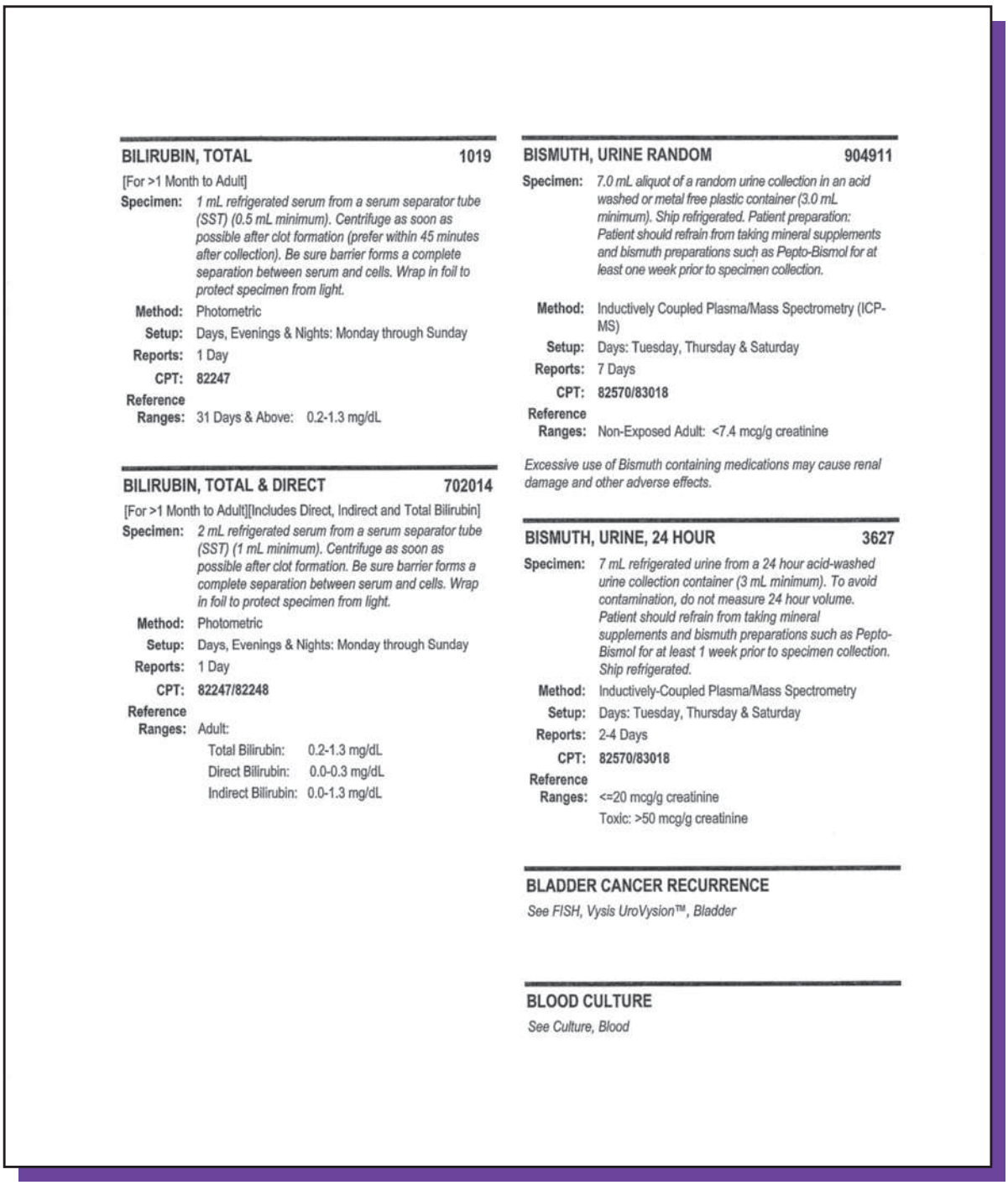
The procedure manual (Fig. 2-5) states the policies and procedures that apply to each test or practice performed in the laboratory. The procedure manual, another QA document, must be made available to all employees of the laboratory for standardization purposes. Accrediting agencies such as CAP and TJC demand that this manual be reviewed and updated biennially (every two years). Box 2-3 lists typical information found in a procedure manual.

The Safety Manual

The safety manual contains policies and procedures related to chemical, electrical, fire, and radiation safety; exposure control; and disaster plans as well as complete details on how to handle hazardous materials. Occupational Safety and Health Administration (OSHA) regulations require every business to have a workplace safety manual. Organizations can receive hefty fines for not having such a manual available for employee use.

The Infection Prevention and Control Manual

In today's healthcare environment, emerging infectious diseases and drug-resistant organisms make managing all aspects of infection control more critical than ever. The infection prevention and control manual outlines policies and procedures for all employees in all areas of the HCO and must comply with federal regulations and accreditation requirements. The manual addresses items such as hand hygiene, precautions to take when dealing with patients or handling specimens, and how to handle accidental contamination, including procedures to be implemented following exposure incidents.



BILIRUBIN, TOTAL 1019

[For >1 Month to Adult]

Specimen: *1 mL refrigerated serum from a serum separator tube (SST) (0.5 mL minimum). Centrifuge as soon as possible after clot formation (prefer within 45 minutes after collection). Be sure barrier forms a complete separation between serum and cells. Wrap in foil to protect specimen from light.*

Method: Photometric

Setup: Days, Evenings & Nights: Monday through Sunday

Reports: 1 Day

CPT: 82247

Reference Ranges: 31 Days & Above: 0.2-1.3 mg/dL

BILIRUBIN, TOTAL & DIRECT 702014

[For >1 Month to Adult][Includes Direct, Indirect and Total Bilirubin]

Specimen: *2 mL refrigerated serum from a serum separator tube (SST) (1 mL minimum). Centrifuge as soon as possible after clot formation. Be sure barrier forms a complete separation between serum and cells. Wrap in foil to protect specimen from light.*

Method: Photometric

Setup: Days, Evenings & Nights: Monday through Sunday

Reports: 1 Day

CPT: 82247/82248

Reference Ranges: Adult:

Total Bilirubin: 0.2-1.3 mg/dL

Direct Bilirubin: 0.0-0.3 mg/dL

Indirect Bilirubin: 0.0-1.3 mg/dL

BISMUTH, URINE RANDOM 904911

Specimen: *7.0 mL aliquot of a random urine collection in an acid washed or metal free plastic container (3.0 mL minimum). Ship refrigerated. Patient preparation: Patient should refrain from taking mineral supplements and bismuth preparations such as Pepto-Bismol for at least one week prior to specimen collection.*

Method: Inductively Coupled Plasma/Mass Spectrometry (ICP-MS)

Setup: Days: Tuesday, Thursday & Saturday

Reports: 7 Days

CPT: 82570/83018

Reference Ranges: Non-Exposed Adult: <7.4 mcg/g creatinine

Excessive use of Bismuth containing medications may cause renal damage and other adverse effects.

BISMUTH, URINE, 24 HOUR 3627

Specimen: *7 mL refrigerated urine from a 24 hour acid-washed urine collection container (3 mL minimum). To avoid contamination, do not measure 24 hour volume. Patient should refrain from taking mineral supplements and bismuth preparations such as Pepto-Bismol for at least 1 week prior to specimen collection. Ship refrigerated.*

Method: Inductively-Coupled Plasma/Mass Spectrometry

Setup: Days: Tuesday, Thursday & Saturday

Reports: 2-4 Days

CPT: 82570/83018

Reference Ranges: <=20 mcg/g creatinine

Toxic: >50 mcg/g creatinine

BLADDER CANCER RECURRENCE

See FISH, Vysis UroVysion™, Bladder

BLOOD CULTURE

See Culture, Blood

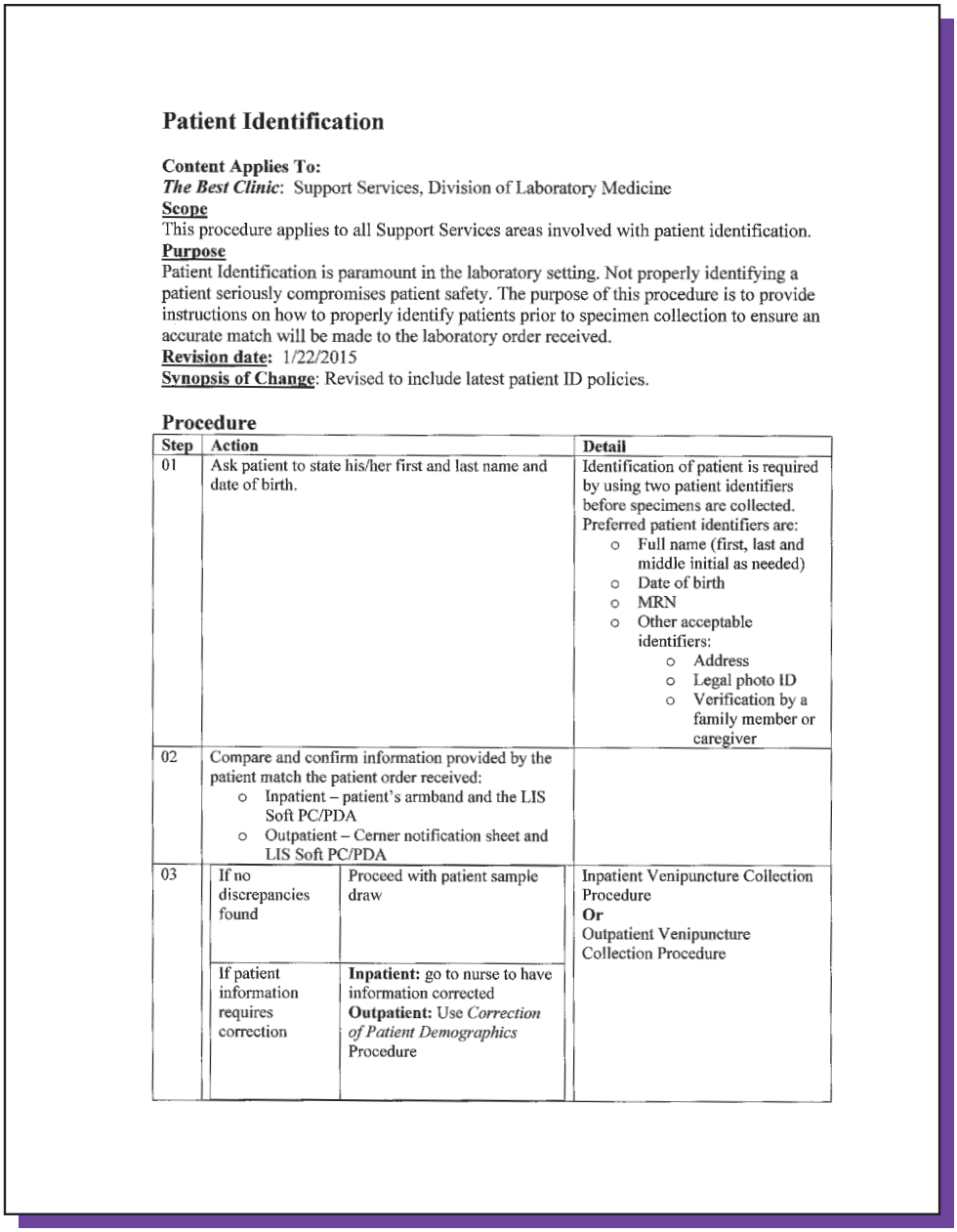
Figure 2-4. A page from a reference manual.

QA Forms

Accreditation standards for agencies such as TJC require the laboratory to have available all documentation on QC checks. In the phlebotomy areas, these may include temperature logs for refrigerators and freezers used for specimen storage, centrifuge maintenance records, heat block temperature logs, event report forms, and incident reports.

Equipment Check Forms

In hospitals and clinics, the facilities department uses a computerized system to monitor freezers and refrigerators. Control checks on the centrifuge require documentation of the maintenance periodically. Just as for freezers and refrigerators, it is the responsibility of the facilities or biomedical services department to



Patient Identification

Content Applies To:
The Best Clinic: Support Services, Division of Laboratory Medicine
Scope
This procedure applies to all Support Services areas involved with patient identification.
Purpose
Patient Identification is paramount in the laboratory setting. Not properly identifying a patient seriously compromises patient safety. The purpose of this procedure is to provide instructions on how to properly identify patients prior to specimen collection to ensure an accurate match will be made to the laboratory order received.
Revision date: 1/22/2015
Synopsis of Change: Revised to include latest patient ID policies.

Procedure

Step	Action		Detail
01	Ask patient to state his/her first and last name and date of birth.		Identification of patient is required by using two patient identifiers before specimens are collected. Preferred patient identifiers are: ○ Full name (first, last and middle initial as needed) ○ Date of birth ○ MRN ○ Other acceptable identifiers: ○ Address ○ Legal photo ID ○ Verification by a family member or caregiver
02	Compare and confirm information provided by the patient match the patient order received: ○ Inpatient – patient's armband and the LIS Soft PC/PDA ○ Outpatient – Cerner notification sheet and LIS Soft PC/PDA		
03	If no discrepancies found	Proceed with patient sample draw	Inpatient Venipuncture Collection Procedure **Or** Outpatient Venipuncture Collection Procedure
	If patient information requires correction	**Inpatient:** go to nurse to have information corrected **Outpatient:** Use *Correction of Patient Demographics* Procedure	

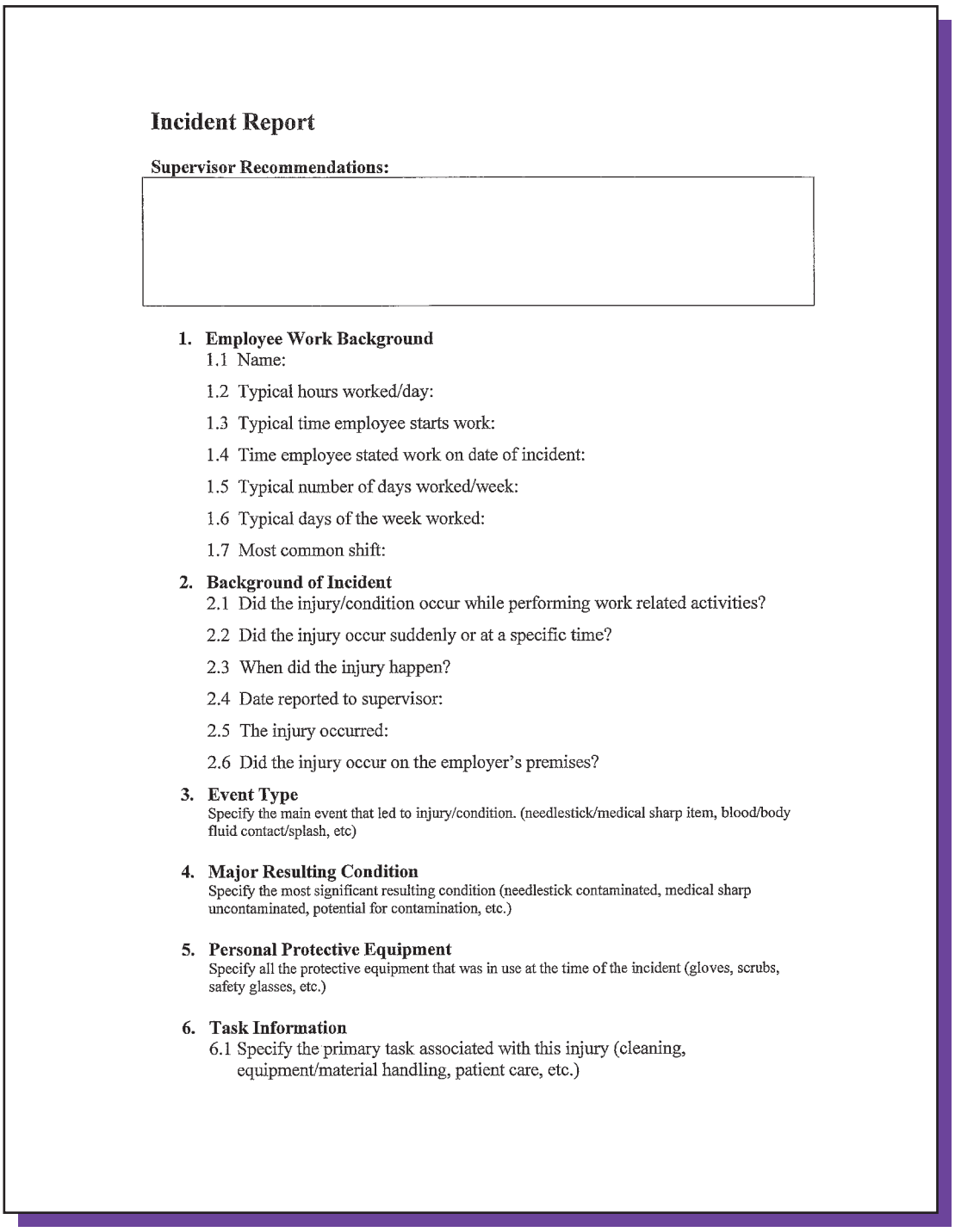
Figure 2-5. A page from a procedure manual.

monitor centrifuges. In a smaller outpatient setting, often called a patient service center (PSC), the temperature logs and centrifuge information are sometimes kept on paper log sheets and recorded daily by the phlebotomy supervisor.

Internal Reports

Confidential incident and occurrence reports must be filled out when a problem occurs. These forms identify the problem, state the consequence, and describe the corrective action. An incident report is to be completed when an occupational injury or exposure, such as an accidental needlestick, has occurred, or a delayed medical condition has developed, no matter how minor. The report like the one in Figure 2-6 should be completed and submitted to the appropriate person even if medical treatment was not required.

An occurrence form is filled out for any errors made in the patient ID, specimen collection, handling, or reporting of the results. This near miss/occurrence report form (Fig. 2-7) would be used, for example, if a complete blood count (CBC) result was reported out and then platelet clumps were found on the slide, causing the result to be inaccurate, or when a nurse calls to say he or she incorrectly labeled the tube sent to the laboratory for chemistry tests. Basically, this form is an audit trail. When



Incident Report

Supervisor Recommendations:

1. **Employee Work Background**
   - 1.1 Name:
   - 1.2 Typical hours worked/day:
   - 1.3 Typical time employee starts work:
   - 1.4 Time employee stated work on date of incident:
   - 1.5 Typical number of days worked/week:
   - 1.6 Typical days of the week worked:
   - 1.7 Most common shift:
2. **Background of Incident**
   - 2.1 Did the injury/condition occur while performing work related activities?
   - 2.2 Did the injury occur suddenly or at a specific time?
   - 2.3 When did the injury happen?
   - 2.4 Date reported to supervisor:
   - 2.5 The injury occurred:
   - 2.6 Did the injury occur on the employer's premises?
3. **Event Type**
   Specify the main event that led to injury/condition. (needlestick/medical sharp item, blood/body fluid contact/splash, etc)
4. **Major Resulting Condition**
   Specify the most significant resulting condition (needlestick contaminated, medical sharp uncontaminated, potential for contamination, etc.)
5. **Personal Protective Equipment**
   Specify all the protective equipment that was in use at the time of the incident (gloves, scrubs, safety glasses, etc.)
6. **Task Information**
   - 6.1 Specify the primary task associated with this injury (cleaning, equipment/material handling, patient care, etc.)

Figure 2-6. Incident report form.

the occurrence is completely documented, it is then reviewed by a supervisor to decide whether counseling is required, the process is flawed, or other action is necessary.

These reports should state facts and not feelings. The function of such a report is not to place blame but to discover problems with the process and state the corrective action taken so that such an event does not happen again.

Key Point: Many healthcare workers and management feel like writing an incident report is like "getting in trouble" and don't understand that part of what risk management (see next section) does is track incidents to see if there is a pattern so that the causes of errors can be addressed. It is important to complete an incident report for all errors to help identify and prevent problems related to patient safety.

Clinical Laboratory
Near Miss/Occurrence Report Form

Patient Name: _____ Patient Location: _____
Medical Rec. #: _____ Occurrence Date: _____ Occurrence Time: _____
Accession #: _____
Test (s): _____
Type of Spec.: _____
Problem Description: _____

Initial steps performed. Mark all that apply:

SPECIMEN INTEGRITY	RESULT (Process/Equipment/Environment)
____ Hemolysis ____ Clotted ____ QNS ____ Incorrect container ____ Leaking/contaminated ____ Transport time exceeded ____ Collected above IV ____ Fluid contaminated from line draw ____ Lipemia ____ Other	____ Repeat – same specimen, new specimen, previous specimen ____ Check patient history ____ Verify QC/instrument ____ Dilution error ____ Wrong cup/specimen/accession ____ Check ABO Acc# _____ ABO/RH_____ Acc# _____ ABO/RH_____ ____ Other:
SPECIMEN IDENTIFICATION	**DISPOSITION**
____ Unlabeled ____ Mislabeled (wrong) ____ Improperly labeled (alignment) ____ Transposed letters/numbers ____ Incomplete label ____ Incorrect collection time ____ Other:	____ Incorrect result ____ Procedure cancelled ____ Erroneous results corrected ____ Procedure credited ____ Notification to _____date/time_____ _____date/time_____ ____ Specimen recollected ____ Unlabeled/leaking specimen discarded ____ Mislabeled specimen in ERROR rack
PATIENT ORDER/INFORMATION	**LABORATORY USE ONLY**
____ Ordered on wrong patient ____ Wrong procedure ordered ____ Wrong encounter ____ Wrong date/time ____ Missing or incorrect requisition ____ Wrong therapy	Date:_____ Employee Name: _____ Counseled By: _____ Repeat Error: Yes No Other Corrective Action Needed: Yes No ____ Written PIP ____ Final Written
Other Departments affected by Near Miss Occurrence: ☐ No ☐ Yes	
	OFFICE USE ONLY
Occurrence by (username): _____ Report completed by: _____Date: _____ Report Reviewed by: _____Date: _____	Midas NMOR: _____Date: _____ Midas Follow up: _____Date: _____ Spec Mislabel: _____Date: _____ FDA Report: _____Date: _____

Figure 2-7. Near miss/occurrence report form.

The QC document called the performance improvement plan (Fig. 2-8) is used when counseling or suspension of an individual is necessary. The document states the deficiency and describes a specific action plan for improvement and the next step if necessary.

Risk Management

Risk, defined as "the chance of loss or injury," is inherent in the healthcare environment. **Risk management** is an internal process focused on identifying and minimizing situations that pose risk to patients and employees. Risk can be managed in two ways: controlling risk to avoid incidents and paying for occurrences after they have happened. Generic steps in risk management involve identification of the risk, treatment of the risk using policies and procedures already in place, education of employees and patients, and evaluation of what should be done in the future.

From the beginning, laboratories have used some sort of QC system to manage certain risks and avoid

HOSPITAL & HEALTH CENTER

PERFORMANCE IMPROVEMENT PLAN

Employee Name:	Facility	Department	Job Title
Previous Action:	**Type**	**Reason**	**Date**

Current Action: (please check one)
☐ Verbal Counseling ☐ Written Warning ☐ Final Written Warning
☐ Suspension – Date ☐ Termination (check reason below)

Termination Reason: ☐ Unexcused Absence/Tardiness ☐ Job Performance ☐ Conduct ☐ Other

I. Describe the performance deficiency giving rise to the counseling (include specific dates, times and policies violated, etc.):

II. Describe specific job performance expectations and areas for improvement:

III. Describe the agreed upon action plan for improvement including date of follow-up to review progress, if applicable:

IV. State the next step if job performance does not improve (warning, discharge, etc.):

V. Department director/supervisor Comments:

Department Director/Supervisor Signature:	Date

VI. Employee Comments:

I understand that all corrective action notices other than a verbal counseling will be placed in my personnel file. My signature below does not indicate agreement regarding the contents of the document; only that I have received a copy for my records.

Employee	Date	Witness	Date
Human Resources	**Date**	**Reason**	

Figure 2-8. Performance improvement form.

unnecessary problems. When the final CLIA regulations were put into place in 2003, they set basic requirements for a QC program without taking into consideration that each clinical laboratory uses different instruments, different procedures, and their own staff in different ways. Soon it became evident that the national standards did not address all risks.

In 2011, CLSI published the guideline, *Laboratory Quality Control Based on Risk Management* (EP-23A). This standard recognized the diversity in laboratories and the need for customization of QC plans. CLSI designed EP-23A as a guide for ensuring quality in each individual laboratory while keeping up with continuous changes in technology.

In 2014, CMS, the government division that oversees and administers laboratory regulations, incorporated key concepts from EP-23A into CLIA policies. This new addition to the existing CLIA quality system is called

the **Individualized Quality Control Plan (IQCP)**. Now instead of a standard, one-size-fits-all approach to QC, laboratories have the option of developing a risk-based, objective approach to QC tailored to the testing in use, patient population, and other aspects that may be unique to that lab. Up until this time, PI tools like Six Sigma, Lean, and RCA as described in Box 2-3 were plentiful, but there had been no comprehensive approach to QC until IQCP. Accrediting agencies, such as CAP and TJC, immediately began incorporating IQCP into their survey process since QC issues were ranked as one of their most prominent deficiencies. CMS acknowledged that each IQCP would be unique since it is designed to fit the needs of only that laboratory. This individualized approach allows laboratories to use whatever PI tools deemed necessary to manage risk.

Risk factors in phlebotomy can be identified by looking at trends in reporting tools such as incident or occurrence reports as described previously. Proper investigation is initiated if a situation is identified that deviates from the normal. When new procedures that reduce risk are instituted, employees are informed immediately and instructed on what to do. Evaluation of occurrences, trends, and outcomes is essential throughout the process, so that errors can be identified and the appropriate changes made. Risk management procedures and other QA measures demonstrate the intent of a healthcare facility to adhere to national standards of good practice. The result is a noticeable reduction of legal issues involving the healthcare consumers as well as the facility's employees, even in issues such as sexual harassment and hostile work environments.

Sexual Harassment

Sexual harassment is a form of sex discrimination and, therefore, violations fall under Title VII of the Civil Rights Act of 1964. Title VII is a federal law that makes it illegal to discriminate in employment on the basis of sex, race, color, national origin, and religion. Retaliation against someone who complains of sexual harassment or helps to investigate a claim is also prohibited under Title VII. This law applies to any employer with 15 or more employees.

Sexual harassment is defined as persistent or offensive conduct related to a person's sex that negatively affects a reasonable person's job. It is a regrettable fact that this type of harassment is a common problem in the workplace today.

Key Point: It is important to note that sexual harassment should not be confused with another form of workplace harassment called a hostile work environment. This hostile form of harassment involves some type of behavior or action that discriminates against a protected classification, such as age, religion, disability, or race. To be classified as a hostile work environment, the communication or behavior must be pervasive and seriously disrupt the employee's work or career progress.

Sexual harassment can occur in many ways, but essentially it happens when there is unwelcome conduct of a sexual nature that is cruel or invasive and undermines morale, affects productivity, and can create a hostile work environment.

Sexual harassment is not limited by gender and does not have to involve the opposite sex. The harasser is not always the victim's supervisor or superior. The person could be a coworker or even someone not employed in the workplace. In the healthcare field, that person could even be a patient.

CAUTION: Always be aware of how you interact with patients to avoid being accused of any type of unwelcome conduct interpreted as sexual in nature.

An employee who experiences or witnesses harassment is responsible for reporting the occurrence to the appropriate person. Direct attempt at resolution, verbally or in writing, is encouraged. It must be made clear by the recipient to the other person involved that the action was unwelcome. Documentation of the interaction or copies of the correspondence should be kept. If the actions persist, a detailed log should be kept. Next, a meeting with the supervisor to file a complaint should be scheduled. If it is uncomfortable to report to a supervisor, then the Human Resources department that is usually responsible for handling such claims should be contacted.

Legal Issues in Healthcare

Technology such as the internet has led to increased awareness and concern by the healthcare consumer. Today, litigation is common in the healthcare industry, in which physicians and other healthcare providers were once considered above reproach. As healthcare providers go about their daily work, there are many activities that, if performed without reasonable care and skill, could result in a lawsuit. It has been proven in past lawsuits that persons performing phlebotomy can and will be held legally accountable for their actions. Although most legal actions against healthcare workers are **civil actions** in which the alleged injured party sues for monetary damages, willful actions by healthcare workers with the intent to produce harm or death can result in criminal charges. Table 2-2 provides a description of criminal and civil actions.

Table 2-2. Criminal and Civil Actions

Action	Definition	Punishment
Criminal	Concerned with laws designed to protect all members of society from unlawful acts by others (i.e., felonies and misdemeanors)	• A felony is a crime (i.e., murder, assault, rape) punishable by death or imprisonment • Misdemeanors are considered lesser offenses and usually carry a penalty of a fine or less than 1 year in jail
Civil	Concerned with actions between two private parties, such as individuals or organizations; constitute the bulk of the legal actions dealt with in the medical office, or other healthcare facilities	• Damages may be awarded in a court of law and result in monetary penalties

FYI: The same act may lead to both criminal and civil actions. For example, in assault and battery cases, a guilty defendant can face imprisonment by the state as well as civil action in which the injured party tries to collect monetary damages.

Do Knowledge Drill 2-5 in the WORKBOOK to better understand the difference between criminal and civil actions.

Tort

The most common civil actions in healthcare are based on tort law. A **tort** is a wrongful act other than breach of contract committed against someone's person, property, reputation, or other legally protected right, for which the individual is entitled to damages awarded by the court. It is an act that is committed without a just cause and may be intentional (willful) or unintentional (accidental). The following list includes definitions of tort actions and related legal terminology:

- **Assault:** An act or threat causing another to be in fear of immediate battery (harmful touching). Battery does not necessarily have to follow an assault; however, the victim must believe the ability to carry out the threat is there.
- **Battery:** An intentional harmful or offensive touching of or use of force on another person without consent or legal justification. Legal justification would be, for example, when a mother gives permission to have blood drawn from her child. Intentional harm may range from permanent disfigurement to merely grabbing something out of another person's hand without permission. Battery is usually both a tort and a criminal offense.

CAUTION: A phlebotomist who attempts to collect a blood specimen without the patient's consent can face a criminal charge of assault and battery as well as a civil suit for damages.

- **Breach of confidentiality:** The failure to keep privileged information private. An example is the unauthorized release of patient information such as laboratory results. This could lead to a lawsuit if it caused harm to the patient, such as the loss of his or her job.

Key Point: Patient confidentiality is protected under the Health Insurance Portability and Accountability Act (HIPAA). HIPAA violations can not only lead to personal civil lawsuits but also government agency fines up to $50,000 and even jail time.

- **Fraud:** A deceitful practice or false portrayal of facts either by words or by conduct, often done to obtain money or property. An example includes billing for services that have not been provided.
- **Invasion of privacy:** The violation of one's right to be left alone. It can involve a physical intrusion or the unauthorized publishing or release of private information, which can also be considered a breach of confidentiality.

Key Point: Invasion of privacy by physical intrusion may be no more than opening the door and walking into a patient's room without asking permission to enter.

- **Malpractice:** A type of negligence (see next bullet) committed by a professional. The training and experience of the accused individual is taken into consideration when deciding whether an act resulting in injury should be labeled negligence or malpractice. A claim of malpractice implies that a greater standard of care was owed to the injured person than the "reasonable person" standard associated with negligence.
- **Negligence:** The failure to exercise **due care**, the level of care that a person of ordinary intelligence and good sense would exercise under the given circumstances. In other words, negligence is doing something that a *reasonable* person would *not* do, or *not* doing something

that a *reasonable* person *would* do. If a medical procedure results in injury and there is no intent to injure, it is called negligence, and the injured person has the right to sue for damages. To claim negligence, the following must be present:

- A legal duty or obligation owed by one person to another.
- A breaking or breach of that duty or obligation.
- Harm done as a direct result of the action.

- ***Res ipsa loquitur:*** A Latin phrase meaning "the thing speaks for itself," which applies to the rule of evidence in a case of negligence. When a breach of duty is so obvious that it does not need further explanation, it is said that the situation speaks for itself. For example, a patient is injured by an uncapped phlebotomy needle that somehow became wedged between the cushion and the side of a phlebotomy chair. The needle obviously caused the injury, but it cannot be proven who was responsible for the needle ending up in the cushion.
- ***Respondeat superior:*** A Latin phrase that means "let the master respond." An employer is liable (legally responsible) for the actions of an employee, even though the employee is the one at fault. Thus, a tort action may be filed if a neglectful or intentional act of an employee results in some type of physical injury to a client. The key points in a claim of *respondeat superior* are that the employee is working within the scope of employment and has had the proper training to perform the required duties.

Key Point: If a neglectful act occurs while an employee is doing something that is not within his or her duties or training, the employee may be held solely responsible for that act.

- **Standard of care:** The normal level of skill and care that a healthcare practitioner would be expected to adhere to in order to provide due care for patients. This duty is established by standards of the profession and the expectations of society. It is the standard of care expected of everyone at all times; a failure to exercise due care is negligence. Employers are responsible for having employees who possess the qualifications and training necessary to meet the standard of care and are ultimately liable if they do not.

Misconception Alert: The meanings of due care and standard of care can be easily confused. For example, when the following question appeared in Wolters Kluwer's adaptive learning systems, powered by PrepU:

The level of care that a person with ordinary intelligence and good sense would exercise under the given circumstances is the definition of:

32% of the students who answered this question mistakenly chose "standard of care." As stated previously, the standard of care is the normal level of skill and care that a healthcare practitioner would be expected to adhere to in *providing* due care for patients. Due care is the level of care that a person of ordinary intelligence and good sense would exercise under the given circumstances.

- **Statute of limitations:** A law setting the length of time after an alleged injury in which the injured person is permitted to file a lawsuit. The time limit is specified in each state's medical malpractice law. The question for all parties involved is when does the clock start? The statute of limitations period typically begins:
  - the day the alleged negligent act was committed.
  - when the injury resulting from the alleged negligence was discovered or should have been discovered by a reasonably alert patient.
  - the day the physician–patient relationship ended or the day of the last medical treatment in a series.
  - in the case of minors, often not until the minor reaches the age of majority.
- **Vicarious liability:** Liability imposed by law on one person for acts committed by another. One example is employer liability under *respondeat superior*, explained previously. Another example is employer liability for negligence by an independent contractor or consultant who was hired. This is based on the principle that the contractor or consultant is acting on behalf of the employer because of the contract between them.

Key Point: A hospital, as an employer, cannot escape liability for a patient's injury simply by subcontracting out various services to other persons and claiming it is not responsible because the party that caused the injury is not on its payroll.

Malpractice Insurance

Malpractice insurance compensates the insured in the event of malpractice liability. Individual workers are not typically targets of lawsuits because of *respondeat superior* or vicarious liability, both of which involve the "deep pockets" theory (let the one with the most money pay). They can, however, be named as codefendants, in which case the employer's malpractice insurance may not cover them. It is important for healthcare personnel to examine the possibility of a civil suit being brought against them and to consider carrying malpractice insurance. The decision to purchase this insurance should be based on financial considerations as well as legal

BOX 2-4

GUIDELINES TO AVOID LAWSUITS

- Acquire informed consent before collecting specimens.
- Be meticulous when identifying patients and patient specimens.
- Carefully monitor the patient before, during, and after venipuncture.
- Respect a patient's right to confidentiality.
- Strictly adhere to CLSI standards and other accepted procedures and practices.
- Use proper safety containers and devices.
- Listen and respond appropriately to patient requests.
- Accurately and legibly record all information concerning patients.
- Document incidents or occurrences.
- Participate in continuing education to maintain proficiency.
- Perform at the prevailing standard of care.
- Never perform procedures that you are not trained to do.

ones. From the legal point of view, it may be desirable to be covered by a separate professional liability policy because the employer may give his or her insurer the right to recover damages from an employee who is found to be negligent. Healthcare personnel may be able to purchase malpractice insurance from their professional organizations.

Avoiding Lawsuits

The best insurance against lawsuits is to take steps to avoid them. A good way to avoid lawsuits is to consistently follow the guidelines listed in Box 2-4. Above all, always remember to respect the rights of patients. This gives them control over the situation and makes them less likely to feel that they have been treated poorly.

Do Knowledge Drill 2-7 in the WORKBOOK to remember the ways to avoid lawsuits.

Patient Consent

Obtaining the patient's consent before initiating a procedure is required. There are different types of patient consent including **informed consent**, expressed (or express) consent, implied consent, HIV consent, and consent for minors. It is important to be familiar with them all and refusal of consent as well.

When you have finished reading this section, do Matching Exercise 2-2 in the WORKBOOK to reinforce your understanding of the different types of consent.

Informed Consent

Informed consent implies voluntary and competent permission for a medical procedure, test, or medication. It requires that a patient be given adequate information regarding the method, risks, and consequences of a procedure before consenting to it. The information must be given to the patient in nontechnical terms and in his or her own language, if possible, meaning an interpreter may be necessary. By law, informed consent for research purposes requires a signed consent document.

Expressed/Express

Expressed consent is a variation of informed consent. It is required for treatment that involves surgery, experimental drugs, genetic testing, or high-risk procedures. Consent should cover what procedures are going to be performed and should not be in a general form that allows the physician full authority to do whatever he or she wants to do. Consent may be given verbally or in writing. Written consent gives the best possible protection for both the treatment provider and the patient, since it must be signed by both, and witnessed by a third party. Verbal consent for treatment should be followed by an entry in the patient's chart covering what was discussed with the patient.

FYI: When a general consent issue goes to court, the court typically takes the word of the patient as to what he or she understood was to take place.

Implied Consent

With **implied consent,** the patient's actions or circumstances imply consent without a verbal or written expression of consent. This type of consent may be necessary in emergency procedures, such as cardiopulmonary resuscitation (CPR), to save a person's life. Laws involving implied consent are enacted at the state level and may differ greatly from state to state.

Key Point: If a phlebotomist tells a patient that he or she is going to collect a blood specimen and the patient holds out an arm, it is normally considered implied consent.

HIV Consent

Legislation governing informed consent for HIV tests has been enacted in most states. The laws specify exactly

what type of information must be given to inform the client properly. Typically, the client must be advised concerning the test and its purpose, how the test might be used, and the meaning of the test and its limitations.

Consent for Minors

As a general rule, a minor cannot give consent for the administration of medical treatment. Parental or guardian consent is required. Healthcare personnel who violate this rule are liable for assault and battery.

FYI: A minor is anyone who has not reached the age of majority as determined by state law.

Misconception Alert: The definition of a minor seems to confuse some students. For example, when the following question appeared in Wolters Kluwer's adaptive learning systems, powered by PrepU:

The definition of a minor is anyone:

42% of the students who answered this question mistakenly answered: "younger than 18 years of age." State law determines the age when a child ceases to be minor and reaches the age of majority (i.e., is recognized legally as an adult). The age of majority in the United States is 18 years of age in most states, but it is 19 years in several states, 21 years in one state, and the age upon high school graduation in six states. Consequently, the correct answer is: The definition of a minor is anyone "who is not the age of majority."

Refusal of Consent

An individual has a constitutional right to refuse a medical procedure, including venipuncture. The refusal may be based on religious or personal beliefs and preferences. A patient who refuses medical treatment is normally required to verify the refusal in writing on a special form.

Law and Ethics: A phlebotomist has a requisition to draw a blood specimen from a preteen on the pediatrics wing of the hospital. She has drawn the child several times before. The child always objected, but the parents told her to go ahead and do the draw. She has always done so with the help of the parent holding the child's arm to keep him from pulling away. Today the parents are not in the room. The child objects to the draw as usual. The phlebotomist enlists the aid of another phlebotomist to hold the child's arm and completes the draw. The child's parents enter the room and are angry because they had requested in writing that the child have no more blood draws. Not only was it unethical to draw the child without checking to see that permission had been given, it violates the law of consent for minors. Both phlebotomists could face a charge of assault and battery for drawing the child without parental permission.

Test yourself on the litigation process with the WORKBOOK exercise Knowledge Drill 2-6.

The Litigation Process

Litigation is the process used to settle legal disputes. Approximately 10% of malpractice lawsuits go to court. The rest are settled out of court, which can happen at any time prior to the final court decision. Malpractice litigation involves the following four phases:

- *Phase 1* begins when an alleged patient incident occurs or the patient becomes aware of a prior possible injury.
- *Phase 2* begins when the injured party or a family member consults an attorney. The attorney requests, obtains, and reviews copies of the medical records involved and decides whether to take the case. If the attorney thinks that malpractice has occurred and takes the case, an attempt to negotiate a settlement is made. If the case is not resolved by negotiation, a complaint is filed by the patient's attorney. Once a complaint is filed, the injured party becomes the **plaintiff**, and the person against whom the complaint is filed becomes the **defendant**. Both sides now conduct formal **discovery**, a process in which both sides exchange information about witnesses and evidence that will be presented at trial. Discovery typically involves depositions and submitting written questions called interrogatories that must be answered by the other party in writing. Giving a **deposition** is a process in which one party questions another under oath while a court reporter records every word. The plaintiff, the defendant, and expert witnesses for both sides may give depositions. Expert witnesses are persons who are asked to review medical records and give their opinions on whether the standard of care was met. A person who lies under oath while giving a deposition can be charged with perjury.

Key Point: A phlebotomist who is not an actual defendant or an expert may have to give a deposition if he or she has information that one or both sides need for the case. Phlebotomists should keep that in mind with their record keeping of any incident and know that they may be called as a fact witness sometime in the proceedings.

- *Phase 3* is the trial phase, the process designed to settle a dispute before a jury. Both sides present their versions of the facts, and the jury determines which version appears to be correct. If the jury decides in the plaintiff's favor, damages may be awarded. At this point, the lawsuit may proceed to phase 4.
- *Phase 4* begins with an appeal of the jury's decision. Although either side has the right to an appeal, the losing party is usually the one to choose this option.

Phlebotomists concerned with CQI and safe practice reduce their exposure to malpractice litigation. With the rapid evolution of medicine and, more specifically, laboratory testing, safe practice includes the phlebotomist's responsibility to stay abreast of all changes to ensure the safe collection of quality specimens. This, in turn, directly affects the quality of clinical laboratory services.

Legal Cases Involving Phlebotomy Procedures

The following are examples of actual legal cases involving phlebotomy procedures. They serve as a reminder that phlebotomy is not an innocuous procedure and that failure to exercise due care can result in injury to the patient and legal consequences.

Case 1: A Negligence Case Settled through Binding Arbitration

A patient had a blood specimen collected at a physician's office. Blood had been collected from him at the same office on several prior occasions with no problem. The phlebotomist, who was new to the patient and seemed to be in a hurry, inserted the needle deeper into the arm and at a much steeper angle than the patient was used to. She redirected the needle several times before hitting the vein. A hematoma began to form. Meanwhile, the patient told the phlebotomist that he felt great pain, but the phlebotomist told him it would be over soon and continued the draw. The pain continued after the draw and the patient's arm later became bruised and swollen. The patient suffered permanent injury to a nerve from compression by the hematoma. The patient was awarded damages at arbitration in an unknown amount.

Case 2: A Negligence Case Settled through Binding Arbitration

A phlebotomist was sent to a woman's home to draw blood for insurance purposes. After missing twice, she made a third attempt, which was also unsuccessful. The phlebotomist commented that she thought "she hit a muscle." The client complained of pain and suffered immediate swelling and bruising in the form of a hematoma. For up to a year after the failed venipuncture attempts, the client had restricted use of her right arm and hand because of tingling and shocking sensations. It was determined that the client had suffered permanent damage to her arm because the phlebotomist was not sufficiently trained and failed to adhere to the standard of care. The client was awarded $1 million in damages at arbitration.

Case 3: A Negligence Case Settled through Binding Arbitration

A college student who had been studying for final examinations and had not eaten or slept well for two days went to an outpatient laboratory to have blood drawn. The phlebotomist failed to observe the student's anxiety and pallor or to listen to the student's concerns. Following the blood collection, the phlebotomist did not ask the patient how she was feeling or if she would like to lie down. As the student walked alone from the blood collection area, she fainted and fell against a stone threshold at the building's exit. She suffered multiple facial fractures as well as permanent scarring to her face; she also lost three front teeth. She was hospitalized for two weeks and missed her college examinations. The outpatient laboratory had not provided a bed for patients to use when feeling faint, nor had it set aside a separate room for emergency situations. The supervisor was not available on site at the time of the accident. The first aid administered to the student before the ambulance arrived was incorrect and resulted in additional harm. At arbitration, the student was awarded $1.5 million in damages.

Case 4: Congleton Versus Baton Rouge General Hospital

The plaintiff went to donate blood at a hospital. She complained of pain during the procedure, and the technician repositioned the needle twice. The technician offered to remove the needle but the plaintiff chose to complete the procedure. After completing the donation, she complained of numbness in her arm. Later evaluation by a neurologist indicated injury to the antebrachial cutaneous nerve. The plaintiff sued and was awarded unknown damages.

Case 5: Jury Verdict Affirmed on Appeal by Kentucky Supreme Court

The plaintiff went to the hospital to have her blood drawn. The phlebotomist placed a tourniquet on the plaintiff's arm and then left the room to answer a phone call. When she returned approximately 10 minutes later, the plaintiff's arm was swollen and had changed color. The plaintiff experienced medical complications and sought treatment. After medical consultation, three physicians concluded that the plaintiff was experiencing nerve problems with her right arm that were related to the tourniquet incident. The plaintiff sued and was awarded $100,000 in damages.

Study and Review Questions

See the EXAM REVIEW for more study questions.

1. **Which of the following is the oldest and largest healthcare standards–setting body in the nation?**
   a. American Medical Association
   b. Centers for Medicare and Medicaid Services
   c. College of American Pathologists
   d. The Joint Commission

2. **The CLIA federal regulations are administered by**
   a. CAP.
   b. CLSI.
   c. CMS.
   d. CoW.

3. **Which of the following are set up to monitor all areas of care that tend to cause problems?**
   a. Internal report forms
   b. Quality indicators
   c. Sentinel events
   d. Threshold values

4. **Proper patient identification includes**
   a. actively involving patients in their own identification.
   b. asking a second person to verify your ID procedure.
   c. checking the requisition against the patient's room number.
   d. scanning patient ID bands with barcode readers only.

5. **Which manual describes the necessary steps to follow in patient preparation for laboratory tests?**
   a. The patient record
   b. The procedure manual
   c. The safety manual
   d. The test catalog

6. **Which of the following can identify trends for risk management?**
   a. Delta checks
   b. Incident reports
   c. Safety data sheets
   d. Test menus

7. **Informed consent means that a**
   a. nurse has the right to perform a procedure on a patient even if the patient refuses.
   b. patient agrees to a procedure after being told of the consequences associated with it.
   c. patient has the right to look at all his or her medical records and test results.
   d. phlebotomist tells the patient why the test is ordered and the meaning of the results.

8. **A national organization that develops guidelines and sets standards for laboratory procedures is the**
   a. CAP.
   b. CLIAC.
   c. CLSI.
   d. NAACLS.

9. **A physician is sued for negligence due to the actions of an inexperienced, contracted phlebotomist hired to cover summer vacations. This is an example of**
   a. assault and battery.
   b. *res ipsa loquitur.*
   c. the statute of limitations.
   d. vicarious liability.

10. **A young adult comes to an outpatient lab to have his blood drawn. The phlebotomist refuses to draw this patient's blood because the patient**
    a. does not have insurance, but offers to pay cash.
    b. has never had his blood drawn before this time.
    c. has not reached the age of majority in the state.
    d. has not eaten breakfast and feels lightheaded.

11. **The NPSGs are**
    a. CLSI's voluntary standards and guidelines.
    b. NAACLS national educational guidelines.
    c. Safety rules set down by CDC and OSHA.
    d. TJC's annual safety requirement goals.

12. **A delta check refers to**
    a. checking the wristband with the requisition.
    b. comparing current test results with previous ones.
    c. documenting all of the results of the QC checks.
    d. reporting new infection control precautions.

13. **Blood culture contamination is a quality indicator for the**
    a. environmental services area.
    b. infection control department.
    c. microbiology department.
    d. specimen processing area.

14. **Failure to exercise due care is**
    a. assault and battery.
    b. invasion of privacy.
    c. negligence.
    d. *res ipsa loquitur.*

15. **The statute of limitations timing can begin**
    a. on the day the negligent act took place.
    b. the first day in a series of medical treatments.
    c. the first day of consulting with a lawyer.
    d. a month after the injury was discovered.

Case Studies

See the WORKBOOK for more case studies.

Case Study 2-1. Scope of Duty

A newly trained phlebotomist is sent to collect a blood specimen from a patient. The phlebotomist is an employee of a laboratory that contracts with the hospital to perform laboratory services, including specimen collection. The phlebotomist collects the specimen with no problems. Before the phlebotomist has a chance to leave the room, the patient asks for help to walk to the bathroom. The patient is a very large woman, but the phlebotomist lends an arm to help her. On the way to the bathroom, the patient slips on some liquid on the floor. The phlebotomist tries but is unable to prevent her from falling. The patient fractures her arm in the fall.

Questions

1. Was it wrong of the phlebotomist to try to help the patient? Explain why or why not.
2. Is the hospital liable for the patient's injury? Explain why or why not.
3. Can the phlebotomist be held liable for the patient's injuries? Explain why or why not.

Case Study 2-2. Quality Assurance in the ED

The phlebotomist arrives in the emergency department (ED) to collect a specimen from a patient headed to surgery as quickly as possible to remove a spike from his head. The atmosphere is hectic because of the serious condition of the patient, but he is awake and able to talk. Sensing that time is of the essence, the phlebotomist checks the wristband, verifies the patient's ID using the electronic barcode system, and proceeds to draw the blood. When the nurse arrives at the blood bank window to pick up the unit of blood for this patient, she notices that the information does not match with what is on her requisition.

Questions

1. What mistake did the phlebotomist make?
2. What do the NPSGs say about patient identification?
3. Why could this incident cause the hospital to be issued a Preliminary Denial of Accreditation?

References

Clinical Laboratory Improvement Amendments (CLIA). Available from www.cms.hhs.gov/clia/.

Clinical and Laboratory Standards Institute. *OMS25-ED1, Handbook for Developing a Laboratory Quality Manual*. 1st ed. Wayne, PA: CLSI; 2017.

Fremgen BF. *Medical Law and Ethics*. 5th ed. Upper Saddle River, NJ: Prentice Hall; 2015.

Kentucky Supreme Court, case #2003-SC-471-DG. Baptist Healthcare Systems, Inc. D/B/A Central Baptist Hospital v Golda H. Miller et al., opinion rendered August 25, 2005.

Sayles N. *Health Information Management Technology: An Applied Approach*. 4th ed. Chicago, IL: AHiMA; 2016.

Yang H, Lee E. *Healthcare Analytics: From Data to Knowledge to Healthcare Improvement*. Hoboken, NJ: Wiley; 2016.

MEDIA MENU

Online Ancillaries

- Animations and videos
- Flashcards
- Audio glossary

Internet Resources

- American Hospital Association (AHA): www.aha.org
- Clinical and Laboratory Standards Institute (CLSI): www.clsi.org
- Clinical Laboratory Improvement Amendments (CLIA): www.cms.hhs.gov/clia
- College of American Pathologists: www.cap.org
- The Joint Commission: www.jointcommission.org
- National Accrediting Agency for Clinical Laboratory Sciences (NAACLS): www.naacls.org/

Other Resources

- McCall R. *Student Workbook for Phlebotomy Essentials.* Enhanced 7th ed. (Available for separate purchase.)
- McCall R. *Phlebotomy Exam Review.* Enhanced 7th ed. (Available for separate purchase.)