2 Quality Assurance and Legal Issues in Healthcare

OBJECTIVES

Study the information in your TEXTBOOK that corresponds to each objective to prepare yourself for the activities in this chapter.

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, and 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.

MATCHING

Use choices only once unless otherwise indicated.

MATCHING 2-1: KEY TERMS AND DESCRIPTIONS

Match each key term with the *best* description.

Key Terms

1. _____ Assault
2. _____ Battery
3. _____ Breach of confidentiality
4. _____ CAP
5. _____ CAPA
6. _____ Civil actions
7. _____ CLIAC
8. _____ CLSI
9. _____ CoW
10. _____ CQI
11. _____ Defendant
12. _____ Delta check
13. _____ Deposition
14. _____ Discovery
15. _____ Due care
16. _____ Fraud
17. _____ GLPs
18. _____ IHI
19. _____ Implied consent
20. _____ Informed consent
21. _____ Invasion of privacy
22. _____ IQCP

Descriptions

A. Compares current test results with previous results for the same test on the same patient
B. Develops voluntary standards and guidelines for the laboratory
C. False portrayal of facts either by words or by conduct
D. Failure to keep privileged medical information private
E. Implies voluntary and competent permission for a medical test or procedure
F. Intentional offensive touching or use of force without consent or legal justification
G. Legal actions in which the alleged injured party sues for monetary damages
H. Legal term for an act or threat causing another to be in fear of immediate battery
I. Level of care a sensible person provides under given circumstances
J. Nonprofit organization focused on patient safety
K. Organization formed to assist in administering CLIA regulations
L. Organization that offers proficiency testing and laboratory inspection
M. Patient's actions suggesting consent to a procedure
N. Person against whom a complaint is filed
O. Plan that describes corrective and preventative actions needed to address a problem
P. Process in litigation in which both sides exchange information about witnesses and evidence
Q. Process in which one party questions another under oath with a court reporter present
R. Program designed for continuous monitoring and analyzing to identify processes that need improvement
S. Risk-based, objective approach to QC tailored to the testing in use at the lab
T. Ten QA recommendations for laboratories doing waived testing
U. Type of certificate for laboratories that perform waived testing only
V. Violation of one's right to be left alone

Key Terms

23. _____ ISO
24. _____ Malpractice
25. _____ Negligence
26. _____ NPSGs
27. _____ Plaintiff
28. _____ QA
29. _____ QC
30. _____ Quality
31. _____ Quality indicators
32. _____ *Res ipsa loquitur*
33. _____ *Respondeat superior*
34. _____ Risk management
35. _____ SAFER™
36. _____ SE
37. _____ Standard of care
38. _____ Statute of limitations
39. _____ Threshold value
40. _____ TJC
41. _____ Tort
42. _____ Vicarious liability

Descriptions

A. Acronym for the TJC method used to identify and communicate deficiency risk levels
B. Accredits and certifies healthcare organizations
C. Components of a CQI program that are required for TJC accreditation
D. Established policies and procedures intended to guarantee excellence of patient care
E. Failure to exercise due care
F. Injured party in the litigation process
G. International organization that develops international standards for many industries
H. Latin phrase meaning "let the master respond"
I. Latin phrase meaning "the thing speaks for itself"
J. Length of time after alleged injury in which a lawsuit can be filed
K. Level of acceptable practice beyond which quality cannot be assured
L. Level of skill that provides due care for patients
M. Liability imposed on one person for acts committed by another
N. Measurements or values that provide information on the quality of processes
O. Process focused on identifying and minimizing risks to patients and employees
P. The degree of excellence of something
Q. Type of negligence implying a greater standard of care was due the injured person
R. Unexpected unfavorable event that results in death or serious injury
S. Use of checks and controls to assure quality
T. Wrongful act committed against one's person, property, or reputation

MATCHING 2-2: TYPE OF CONSENT

Type of Consent

1. _____ Informed consent
2. _____ Expressed consent
3. _____ Implied consent
4. _____ HIV consent
5. _____ Minor consent
6. _____ Refusal of consent

Description

A. Constitutional right to decline a medical procedure
B. Consent is suggested by actions
C. Implies voluntary and competent permission
D. Parental/guardian consent required for medical treatment
E. Required before surgery or high-risk procedures
F. State laws specify the information that must be given

MATCHING 2-3: NATIONAL STANDARD AND REGULATORY AGENCIES

Match the organizations and regulatory agencies to the service they provide to the laboratory community. Choices may be used more than once.

Organizations and Regulatory Agencies

A. CAP
B. CLIA
C. CLSI
D. NAACLS
E. TJC

Services Provided

1. _____ Developed NPSGs as an overall CQI requirement for accreditation
2. _____ Federal regulations establishing quality standards for all laboratories including physicians' offices
3. _____ Accredits and certifies healthcare organizations and programs throughout the United States
4. _____ CLIAC was formed to assist in administering these regulations
5. _____ Develops voluntary guidelines and standards for all areas of the laboratory
6. _____ An authority on quality clinical laboratory education
7. _____ An exclusively pathologists' organization that inspects and accredits laboratories
8. _____ Developed sentinel event policy for patient safety in healthcare settings
9. _____ Performs external peer reviews for accreditation and approval of laboratory programs
10. _____ Inspects and accredits laboratories other than The Joint Commission

LABELING EXERCISES

LABELING EXERCISE 2-1: MICROBIOLOGY QUALITY ASSESSMENT FORM

Answers to the following questions can be found on the Quality Assessment and Improvement Tracking form here. Circle the answer on the form; write the number of the question in or near the circle; then write out the answer on the appropriate line.

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

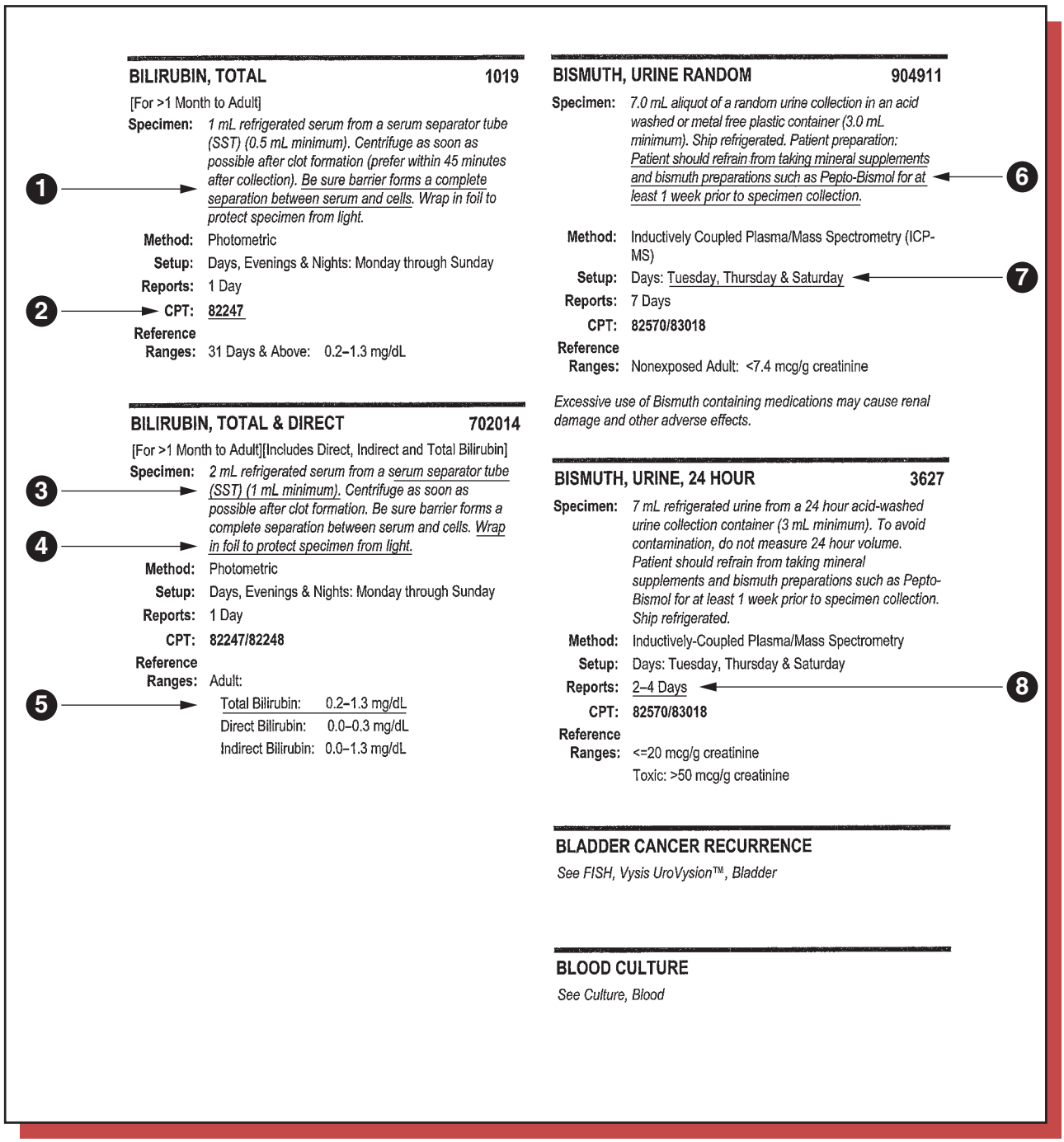
DATE MONITORING BEGAN: 1990
TIME PERIOD THIS MONITOR: 2ND QUARTER 2009
MONITOR DISCONTINUED BECAUSE:
FOLLOW-UP:

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%**		

1. What is being used by the microbiology department as a blood culture quality indicator? _____
2. What is the acceptable threshold? _____
3. What was the actual percentage contamination for the first quarter? _____
4. Which month has the highest contamination from ER draws? _____
5. What was the rate of contamination by the laboratory in the same month? _____
6. What is the action plan for blood culture QA? _____

LABELING EXERCISE 2-2: REFERENCE MANUAL

Describe what each numbered item on the underlined portion of the reference manual page tells the reader about the laboratory test. Write the answer on the corresponding lines below.



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 1 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: Nonexposed 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

1. _____
2. _____
3. _____
4. _____
5. _____
6. _____
7. _____
8. _____

KNOWLEDGE DRILLS

KNOWLEDGE DRILL 2-1: CAUTION AND KEY POINT RECOGNITION

The following sentences are taken from "CAUTION and KEY POINT" statements found throughout Chapter 2 in the TEXTBOOK. Using the TEXTBOOK, fill in the blanks with the missing information.

1. The CAP requires (A) _____ in an employee's personnel file to confirm that the employee is (B) _____ and (C) _____ to perform the responsibilities for which he or she is (D) _____.
2. There have been cases in which patient (A) _____ on computer labels was (B) _____ because incorrect information had been entered into the computer upon patient (C) _____. (D) _____ patient ID procedures can catch such errors.
3. No matter how (A) _____ phlebotomists may be, periodic review of their (B) _____ is necessary for (C) _____ assurance and performance (D) _____.
4. For (A) _____ reasons, access to a patient's medical record is (B) _____ to those who have a verifiable (C) _____ to review the information.
5. Always be aware of how you (A) _____ with patients to avoid being (B) _____ of any type of (C) _____ conduct interpreted as (D) _____ in nature.
6. A phlebotomist who attempts to collect a blood specimen (A) _____ the patient's (B) _____ can face a criminal charge of (C) _____ and (D) _____ as well as a(n) (E) _____ suit for damages.
7. Invasion of privacy by physical (A) _____ may be no more than opening the door and (B) _____ into a patient's room without asking (C) _____ to (D) _____.
8. If a neglectful act occurs while an employee is doing something that is (A) _____ within his or her duties or (B) _____, the employee may be held (C) _____ (D) _____ for that act.
9. A hospital, as a(n) (A) _____, cannot escape (B) _____ for a patient's injury simply by (C) _____ out various services to other persons and claiming it is not responsible because the party that caused the (D) _____ is not on its (E) _____.
10. If a phlebotomist tells a patient that he or she is going to collect a blood specimen, and the patient (A) _____ out an arm, it is considered (B) _____ (C) _____.

KNOWLEDGE DRILL 2-2: SCRAMBLED WORDS

Unscramble the following words using the hints given in parentheses and the letters that have been placed in the correct boxes. Finish writing the correct spelling of the scrambled word in the corresponding boxes.

1. aedtl (this check helps ensure quality)

d				

2. drisotacin (used to monitor QA)

				c	a				

3. fatpiflin (an injured party)

	l			n				

4. gingeencel (not an issue if you are reasonable)

		g			g				

5. hedlsorth (exceeding this is not good)

	h			s				

6. laquity (must be assured in healthcare)

			l		t	

7. savoriciu (a kind of liability)

	i	c						

8. talycodinfeitin (privacy)

	o	n							i					

9. tinselen (a type of event)

				i			

10. ulastas (a harmful touch)

	s	s				

11. yencoptmec (an educational standard)

		m		e		e			

12. yodicvers (exchange of information)

				o			r	

KNOWLEDGE DRILL 2-3: TRUE/FALSE ACTIVITY

The following statements are all false. Circle the one or two words that make the statement false, and write the correct word(s) that would make the statement true.

1. Documentation can be used for legal purposes if it is recent and includes only standard symbols.
2. A sentinel event (SE) is any unfavorable event that is unexpected and results in unremarkable or minor physical or psychological injury.
3. You must use at least four ways to identify patients when providing laboratory services.
4. A CAP-certified laboratory also meets Medicare/Medicaid standards because CLIA grants reciprocity (mutual exchange of privileges) to CAP in the area of laboratory regulations.
5. CLSI's mission is to develop clinical and laboratory programs and promote their curriculum worldwide.
6. Quality indicators must be measurable, well defined, subjective, and nonspecific.
7. Instructions on how to prepare a patient for testing can be found by checking the laboratory's procedure manual.
8. The Joint Commission moved toward stricter patient ID requirements with their revision of CLSI standards in 2009.
9. Phlebotomists must "actively involve" nurses in their identification process during any specimen collection.
10. OSHA regulations require every business to have an infection control manual.
11. An IQCP form is to be completed when an occupational injury or exposure occurs.
12. Patient confidentiality is protected under state law.
13. The most common civil actions in healthcare are based on criminal law.
14. A minor is anyone who has not reached the age of 18 years.
15. The patient's record is a concise documentation of the medical care given.

KNOWLEDGE DRILL 2-4: NATIONAL AGENCIES AND REGULATIONS

The following table identifies by name and abbreviation and summarizes the description, purpose, and functions of agencies and regulations described in Chapter 2 of the TEXTBOOK. Using the TEXTBOOK, fill in the blanks with the missing information.

Agency/Regulation Name/Abbreviation	Description	Purpose	Functions
1. The Joint (A) _____	An independent, (B) _____ _____ _____ organization	Establish (C) _____ for the operation of hospitals and other health-related facilities and services	• Key player in bringing (D) _____ review techniques to healthcare • Oldest and largest (E) _____ body in healthcare • Accredits and certifies more than (F) _____ healthcare organizations and programs in the United States
2. (A) _____ of American (B) _____	The membership in (C) _____ is (D) _____ board-certified (E) _____ and pathologists in training	Influence (F) _____ improvement in phlebotomy through (G) _____	• Offers (H) _____ • Offers continuous form of laboratory (I) _____ by a team of pathologists and laboratory managers
3. (A) _____ and Laboratory (B) _____ Institute	A (C) _____, nonprofit, standards-developing organization with representatives from the (D)_____, industry, and government	Uses a widespread agreement process to develop (E) _____ guidelines and standards for all areas of the laboratory	• Provides guidelines and standards on which phlebotomy program approval, (F) _____ examination questions, and the (G) _____ are based

4. (A) _____ Laboratory (B) _____ Amendments of 1988	Federal regulations administered by the (C) _____ (abbreviation) whose regulations establish (D) _____ standards for all facilities that test (E) _____ specimens for the purpose of providing information used to diagnose, prevent, or treat disease or assess health status	To ensure the accuracy, (F) _____, and reliability of patient test results, regardless of the (G) _____, type, or size of the laboratory	• Provides (H) _____ and scientific (I) _____ and guidance • Requires moderate and complex laboratory facilities to have routine inspections • Requires (J) _____ protocols for all laboratory procedures
5. (A) _____ (B) _____ Agency for Clinical Laboratory Sciences	A recognized authority on quality (C) _____ laboratory education	Provides accreditation or (D) _____ for clinical laboratory education programs	• Provides external (E) _____ review of programs to determine if they meet certain established educational standards • Requires that phlebotomy programs meet educational standards called (F) _____

KNOWLEDGE DRILL 2-5: CRIMINAL AND CIVIL ACTIONS

On the line provided, write the correct type of legal action (civil or criminal) associated with the descriptive statement.

1. _____ Concerned with actions between two private parties
2. _____ Constitutes the bulk of legal actions dealt with healthcare
3. _____ Individual may be charged with a felony or a misdemeanor
4. _____ Involves injurious acts by others in society
5. _____ Monetary penalties awarded in a court of law
6. _____ Punishable by fines and/or imprisonment

KNOWLEDGE DRILL 2-6: THE LITIGATION PROCESS

Number the following phases in the litigation process in chronological order from 1 through 7.

A. _____ A deposition is taken

B. _____ An appeal is filed by the losing party

C. _____ The attorney decides whether to take the case or not

D. _____ The attorney files a complaint

E. _____ The injured party consults an attorney

F. _____ The patient becomes aware of prior possible injury

G. _____ Trial phase with a judge and a jury

KNOWLEDGE DRILL 2-7: GUIDELINES TO AVOID LAWSUITS

The following are statements concerning ways to avoid lawsuits. Finish each statement with the missing information from the TEXTBOOK.

1. Acquire informed consent _____.
2. Be meticulous when _____.
3. Carefully monitor the patient _____.
4. Respect a patient's _____.
5. Strictly adhere to CLSI standards _____.
6. Use proper safety _____.
7. Listen and respond appropriately to the _____.
8. Accurately and legibly _____.
9. Document _____.
10. Participate in continuing education to _____.
11. Perform at the prevailing _____.
12. Never perform procedures that you are not _____.

SKILLS DRILLS

SKILLS DRILL 2-1: REQUISITION ACTIVITY

Answer the following questions concerning the test requisition shown below.

Any Hospital USA
1123 West Physician Drive
Any Town USA

Laboratory Test Requisition

PATIENT INFORMATION:

Name: Smith (last) John (first) (MI)

Identification Number: 09365784 Birth Date: 06/21/67

Referring Physician: Payne

Date to be Collected: 03/15/19 Time to be Collected: 0600

Special Instructions: line draw only

TEST(S) REQUIRED:

_____ NH4 – Ammonia	_____ Gluc – glucose
_____ Bili – Bilirubin, total & direct	_____ Hgb – hemoglobin
_____ BMP – basic metabolic panel	_____ Lact – lactic acid/lactate
_____ BUN – Blood urea nitrogen	_____ Plt. Ct. – platelet count
_____ Lytes – electrolytes	_____ PT – prothrombin time
_____ CBC – complete blood count	_____ PTT – partial thromboplastin time
_____ Chol – cholesterol	_____ RPR – rapid plasma regain
_____ ESR – erythrocyte sed rate	_____ T&S – type and screen
_____ EtOH – alcohol	_____ PSA – prostatic specific antigen
__X__ D-dimer	Other __HIV__

1. A new phlebotomist does not know anything about collecting a D-dimer or an HIV test. Where can the collection information on these tests be found?
2. What does patient consent involve when drawing an HIV sample?

SKILLS DRILL 2-2: WORD BUILDING

Divide each of the words below into its elements (parts): prefix (P), word root (WR), combining vowel (CV), and suffix (S). Write the word element and its definition on the corresponding lines. Write the general meaning of the word in the space provided. If the word does not have a certain element, write "NA" (not applicable) in its place. (See Chapter 4 of the TEXTBOOK for word element definitions and examples.)

Example: pathologist

Elements *NA* / *path* / *o* / *logist*
P WR CV S

Definitions _____ / *disease* / _____ / *specialist in the study of*

Meaning: a specialist who studies and interprets disease

1. tachometer

Elements _____ / _____ / _____ / _____
P WR CV S

Definitions _____ / _____ / _____ / _____

Meaning:

2. phlebotomy

Elements _____ / _____ / _____ / _____
P WR CV S

Definitions _____ / _____ / _____ / _____

Meaning:

3. postanalytical

Elements _____ / _____ / _____ / _____
P WR CV S

Definitions _____ / _____ / _____ / _____

Meaning:

4. chronology

Elements _____ / _____ / _____ / _____
P WR CV S

Definitions _____ / _____ / _____ / _____

Meaning:

SKILLS DRILL 2-3: CMS WEBSITE

Go to the Centers for Medicare and Medicaid Services website (CMS.gov). Click on the section "Outreach & Education." Under the heading "Reach Out," click on "Get digital media." Then click on "Get digital media resources."

1. List the media resources available for current and timely educational information.

   (1) _____

   (2) _____

   (3) _____

2. What do the media resources offer?

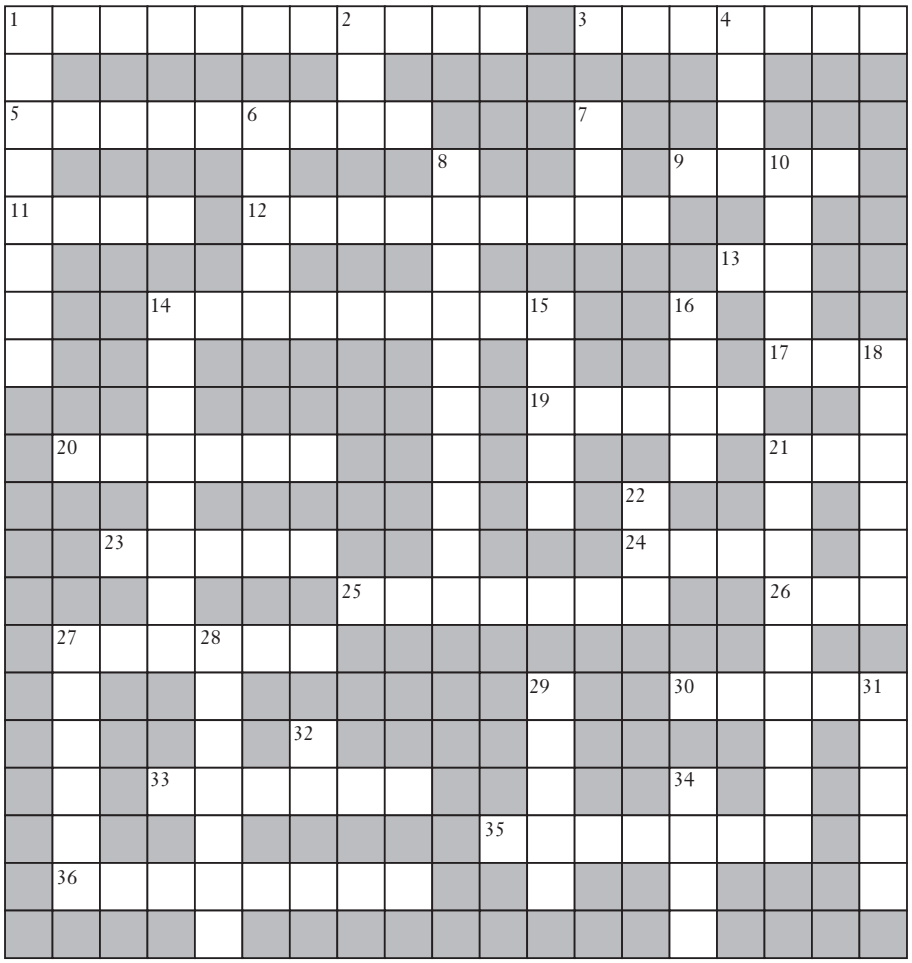
   (1) _____

   (2) _____

   a. _____

   b. _____

CROSSWORD



ACROSS

1. A type of negligence
3. Black stripes corresponding to letters and numbers
5. Person against whom the complaint is filed
9. Information collected for analysis
11. Clinical and Laboratory Standards Institute
12. The state of being liable
13. Quality assurance (abbrev.)
14. Injured party in a lawsuit
17. Common name for complete test package
19. Where 10% of malpractice lawsuits end up
20. Complete medical file of a patient
21. Level of normal care, _____ care
23. Anyone who has not reached the age of majority
24. Begins legal proceedings
25. To give permission for medical procedure
26. Agency that manages federal HC programs (abbrev.)
27. A _____ of confidentiality
30. Type of legal action in which the party sues for monetary damages
33. National agency that accredits laboratory programs
35. Assurance or control
36. To examine and judge the worth of

DOWN

1. Provides healthcare to persons over 65 years of age
2. Number of QA recommendations for CoWs
4. Federal rules and regulations for all diagnostic laboratories
6. Check that compares current results with previous ones
7. Turnaround time
8. A process used to settle disputes
10. Follow a path by means of evidence to get to outcome
14. Lawyers are said to _____ law
15. Realities or truths
16. To do damage or injury
18. General courses or drifts
21. Involves taking depositions and submitting interrogatories
22. Another abbreviation for SGOT
27. Hematoma/injury and discoloring of skin
28. Intentional threat of immediate harm
29. Deceitful practice
31. Based on the law
32. Use of checks and controls (abbrev.)
34. Chance of injury, damage, or loss

Chapter Review Questions

1. Which organization establishes standards for the operation of hospitals and other healthcare facilities and services?
   a. American Hospital Association
   b. College of American Pathology
   c. National Accrediting Agency
   d. The Joint Commission

2. The agency that manages the federal healthcare programs of Medicare and Medicaid is the
   a. CAP.
   b. CLIA.
   c. CLSI.
   d. CMS.

3. Which is an early warning policy to help healthcare organizations identify unfavorable actions and take steps to prevent them?
   a. Quality indicators
   b. Sentinel event
   c. Six Sigma
   d. Threshold values

4. Which are measurable, objective guides that are established to monitor certain areas of patient care?
   a. Indicators
   b. Outcomes
   c. Policies
   d. Procedures

5. Which manual describes the chemical, electrical, and radiation concerns for the laboratory?
   a. Infection control manual
   b. Procedure manual
   c. Safety manual
   d. Test catalog

6. One of the generic steps in risk management is
   a. assessment of test menus.
   b. education of the employees.
   c. evaluation of medical records.
   d. review of employees' records.

7. Informed consent means that
   a. a patient's medical records are available for review by all healthcare workers.
   b. all consequences of a medical procedure have been given to the patient.
   c. the patient received a book outlining all procedures and their consequences.
   d. the patient's confidentiality has been breached during the assessment process.

8. Which national organization develops guidelines and sets standards for laboratory procedures?
   a. CAP
   b. CLIAC
   c. CLSI
   d. NAACLS

9. A phlebotomist hired by a hospital as a temporary employee commits a negligent act for which the hospital is liable. This is an example of
   a. assault and battery.
   b. *res ipsa loquitur.*
   c. *respondeat superior.*
   d. standard of care.

10. A phlebotomist collects a sample from a 16-year-old patient without obtaining parental or guardian consent. The phlebotomist could be charged with which of the following?
    a. Assault and battery
    b. Invasion of privacy
    c. Statute of limitations
    d. Vicarious liability

11. National Patient Safety Goals (NPSGs) are
    a. rules set by CDC and overseen by OSHA.
    b. standards set by NAACLS for educational programs.
    c. The Joint Commission's specific safety requirements.
    d. voluntary guidelines and protocol written by CLSI.

12. A comparison of current test results with previous results for the same test on the same patient is called a
    a. delta check.
    b. quality indicator.
    c. risk control.
    d. sentinel event.

13. Which of the following forms states the concern and describes the corrective action when a problem occurs?
    a. Equipment check form
    b. Delta review form
    c. Internal report
    d. Quality control check

14. A type of negligence committed by a professional is called
    a. assault.
    b. battery.
    c. invasion of privacy.
    d. malpractice.

15. Failure to keep privileged medical information private is called
    a. breach of confidentiality.
    b. invasion of privacy.
    c. *res ipsa loquitur.*
    d. vicarious liability.

16. Risk factors in phlebotomy can be identified by
    a. adhering to national standards of good practice.
    b. consistently following OSHA guidelines.
    c. looking at trends in internal reporting forms.
    d. managing patient safety and sentinel events.

17. One of TJC's safety goals for the clinical laboratory includes
    a. standardizing all outpatient phlebotomy practices.
    b. improving the turnaround time for test results.
    c. sanitizing collection carts and equipment daily.
    d. labeling all specimens before leaving the patient.

18. EMR stands for
    a. electronic medical record.
    b. emergency medical radiofrequency.
    c. employee medical restrictions.
    d. equipment manufacturer's rating.

19. A phlebotomist using an armband for patient ID must also
    a. check the room number for additional verification.
    b. have the patient state his or her full name and DOB.
    c. match the order date with the date on the wristband.
    d. write down location of the patient on the requisition.

20. Which are the initials for the type of plan established when data identify a problem?
    a. CAPA
    b. FMEA
    c. IQCP
    d. NPSG

Case Studies

CASE STUDY 2-1: QUALITY ASSURANCE IN A COW LABORATORY

The CoW laboratory in a large internal medicine group practice performed over 50 waived tests a day. The medical assistants and the phlebotomists who performed the waived testing were all trained OJTs. It was obvious from the inconsistent results recorded on the cumulative report that everyone's technique differed somewhat. When notification came from CLIA that they would be visiting the site within the next month, the lead physician decided that a QA process had to be put into place. He directed the laboratory staff to the CLIA website for instructions on waived testing standardization in the form of GLPs issued by CLIAC.

Questions

1. What are CLIA and CLIAC?
2. Why is CLIA visiting their site?
3. What are the GLPs, and what makes them valuable in standardizing the waived testing process?
4. What are other examples of QC components that could be put in place in this laboratory setting?

CASE STUDY 2-2: BLOOD DRAW FAILS DELTA CHECK

It was a busy day in the hospital laboratory since two phlebotomists were out for medical reasons. An order came from the fourth floor for a timed draw. Joe, a phlebotomist from a temporary agency, was still there, even though he was supposed to have gotten off 2 hours earlier. No one was there to collect the specimen except Joe. Knowing how important it was, he decided to go ahead and collect it. When he arrived in the room, the patient was seated in a chair between the beds. Joe asked the patient his name and in which bed he belonged. When the seated patient answered with the right last name and pointed to the correct bed, Joe proceeded to collect the specimen from him while he sat in the chair. Joe labeled the specimen tubes at the nursing station while noting the draw on the desk clipboard. When a second specimen was drawn from the patient later that morning, it failed the delta check. The second specimen was recollected, and the results showed the specimen that Joe had drawn to be in error.

Questions

1. What is a delta check?
2. What do you see that could have caused this discrepancy?
3. What should Joe have done differently?
4. What were Joe's obligations to the laboratory after his regular shift?
5. Who is ultimately responsible for Joe's actions while he is at work?

CASE STUDY 2-3: NERVE INJURY

A phlebotomist prepares to draw three tubes of blood from an outpatient. The only vein that is visible is the basilic vein on the right arm. He was taught that the basilic vein is the last choice for venipuncture because it is hard to anchor and a major nerve lies close to it, but it is so large he decides that he can draw it without a problem. When he inserts the needle, sure enough, the vein rolls and the needle slips beside the vein. The patient cries out in pain, and jerks her arm. The needle goes even deeper, but blood begins to flow into the tube, so he continues the draw. The patient tells him it is hurting and to pull the needle out, but the tubes are filling quickly, so he continues to fill all three before ending the draw. The woman is still in pain and her arm begins to swell in the area of the draw. The phlebotomist quickly wraps a pressure bandage around the arm and tells her she is free to go. The patient is later diagnosed with permanent nerve injury and sues the clinic.

Questions

1. Can the phlebotomist be held liable for the woman's injury?
2. What tort might be involved in this case?
3. Do you think the standard of care was breached? Why or why not?