CLINICAL AND LABORATORY STANDARDS INSTITUTE®

7th Edition

# GP41

## Collection of Diagnostic Venous Blood Specimens

This standard provides procedures for the collection of diagnostic venous blood specimens, including line draws, blood culture collection, and venipuncture in children.

A standard for global application developed through the Clinical and Laboratory Standards Institute consensus process.

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# Collection of Diagnostic Venous Blood Specimens

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## Abstract

Clinical and Laboratory Standards Institute standard GP41—*Collection of Diagnostic Venous Blood Specimens* provides a descriptive, stepwise process and procedures reflecting the quality system essentials format for diagnostic venous blood specimen collection. Special considerations for collections from vascular access devices, blood culture collection, and collections in isolation environments are included, as well as how to handle emergency situations. An expanded appendix section provides helpful tips for collecting specimens from pediatric and other challenging patients.

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# Foreword

Numerous errors can occur during the collection and handling of blood specimens, which pose significant and avoidable risks to the patient and the phlebotomist. When global standards are not fully implemented, it is more likely that patients will be injured during the procedure, biologically representative specimens will not be obtained from patients, and test results will not be comparable from one facility to another.

The process and procedures detailed in this standard are intended to prevent specimen collection errors that threaten specimen quality, protect health care professionals from accidental exposure, and prevent patients from the injuries, complications, and medical mistakes that can result from improperly collected specimens.

Since 1977, CLSI has recognized the importance of the preexamination phase of laboratory testing, including correct blood specimen collection and handling. Highly sophisticated testing technology cannot produce a good result from a poorly collected specimen.

## Overview of Changes

This standard replaces the sixth edition of the standard (GP41-A6, formerly H03-A6), which was published in 2007. Many changes were made in this edition. One of the most prominent changes involved reorganizing the content into a process with multiple procedures, which is consistent with CLSI instilling QMS principles into its documents. This standard now articulates a sequence of chronological procedures that compose the process of successfully and safely performing a venipuncture. The QSEs are foundational building blocks that function effectively to support the laboratory's path of workflow. Although not all aspects of the QSEs may be mandatory to perform the venipuncture procedure, adherence to the QSEs ensures that the venipuncture is performed at a higher level of overall quality.

Other changes include:

- Greater detail on patient ID, specimen labeling, patient positioning, collecting from mastectomy patients, tourniquet use, adverse reactions, needle relocation, prioritizing veins in the antecubital area, and preventing iatrogenic anemia
- Changes to what constitutes acceptable venipuncture sites
- Significant revision of the information on collecting specimens from vascular access devices and during infusions
- Information on trace elements tubes in regards to the order of draw
- Comprehensive sections on remedies for difficult collections
- Updated references

**KEY WORDS**

**Antecubital anatomy**
**Blood specimen**
**Complications from phlebotomy**
**Patient identification**
**Phlebotomist**
**Phlebotomy**
**Veins**
**Venipuncture**

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# Chapter 1

# Introduction

## This chapter includes:

- Standard's scope and applicable exclusions
- Standard precautions information
- "Note on Terminology" that highlights particular use and/or variation in use of terms and/or definitions
- Terms and definitions used in the standard
- Abbreviations and acronyms used in the standard

# Collection of Diagnostic Venous Blood Specimens

**NOTE:**

These procedures are intended as an appropriate model for adoption by all health care providers responsible for blood specimen collection in outpatient and inpatient settings.

## 1 Introduction

### 1.1 Scope

This standard establishes criteria for suitable venous blood specimen collection for medical laboratory testing. These procedures are intended as an appropriate model for adoption by all health care providers responsible for blood specimen collection in outpatient and inpatient settings.

### 1.2 Standard Precautions

Because it is often impossible to know what isolates or specimens might be infectious, all patient and laboratory specimens are treated as infectious and handled according to "standard precautions." Standard precautions are guidelines that combine the major features of "universal precautions and body substance isolation" practices. Standard precautions cover the transmission of all known infectious agents and thus are more comprehensive than universal precautions, which are intended to apply only to transmission of bloodborne pathogens. Published guidelines are available that discuss the daily operations of diagnostic medicine in humans and animals while encouraging a culture of safety in the laboratory.[1] For specific precautions for preventing the laboratory transmission of all known infectious agents from laboratory instruments and materials and for recommendations for the management of exposure to all known infectious diseases, refer to CLSI document M29.[2]

### 1.3 Terminology

#### 1.3.1 A Note on Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization whenever possible. Harmonization is a process of recognizing, understanding, and explaining differences while taking steps to achieve worldwide uniformity. CLSI recognizes that medical conventions in the global metrological community have evolved differently in different countries and regions, and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. CLSI recognizes its important role in these efforts, and its consensus process focuses on harmonization of terms to facilitate the global application of standards and guidelines.

***Additional important notes:***

Professionals who perform procedures in the preexamination phase of laboratory testing work in a wide variety of health care disciplines with diverse titles depending on the place of employment (eg, phlebotomist, patient care technician, medical assistant, nurse, laboratory assistant, laboratory technician, or medical technologist). For the purposes of this standard, this individual will be referred to as "phlebotomist."

It is understood that many terms are used to describe those to whom health care services are provided. As such, throughout this standard, use of the term "patient" refers to inpatients, outpatients, clients, and any other individual seeking services from health care providers.

In the context of this standard, "shall" and "must" are used to indicate a requirement to be followed in order to conform to the standard and from which no deviation is permitted, while the term "should" allows for user discretion.

### 1.3.2 Definitions

**angle of insertion** – the angle formed by the surface of the skin and the needle entering the skin.

**antecubital** – situated anterior to the cubitis, or elbow.[3]

**distal** – remote; farther from the point of reference[3]; **EXAMPLE:** The wrist is distal to the elbow.

**hematoma** – a localized collection of blood, usually clotted, in an organ, space, or tissue, usually due to a break in the wall of a blood vessel.[3]

**iatrogenic anemia** – anemia caused by diagnostic blood sampling.

**medial** – pertaining to the middle; closer to the median plane or midline of a body or structure.[3]

**median** – situated in the midline of a body or structure.[3]

**phlebotomy** – the act of drawing or removing blood from the circulatory system through a puncture to obtain a specimen for analysis and diagnosis.

**preevacuation** – the creation of a vacuum, induced during the manufacture of the tube or by the user immediately before use.

**proximal** – nearest; closer to the point of reference[3]; **EXAMPLE:** The wrist is proximal to the metacarpal bones.

**recumbent** – lying down or reclining backward.

**rolling veins** – superficial venous vasculature that is not firmly anchored superficially and that moves laterally during venous access attempts.

**specimen** – discrete portion of a body fluid, breath, hair, or tissue taken for examination, study, or analysis of one or more quantities or properties assumed to apply for the whole.[4]

**syncope (fainting)** – a loss of consciousness over a short period of time, caused by a temporary lack of oxygen in the brain.

**vascular access device (VAD)** – a device inserted temporarily or permanently into a vein and/or artery to allow access to the circulatory system for the administration of fluids or medications, or for various procedures.

**venipuncture** – the puncture of a vein for surgical or therapeutic purposes, or for collecting blood specimens for analysis.

### 1.3.3 Abbreviations and Acronyms

| | |
|---|---|
| **AED** | automated external defibrillator |
| **APTT** | activated partial thromboplastin time |
| **CPR** | cardiopulmonary resuscitation |
| **EDTA** | ethylenediaminetetraacetic acid |
| **ID** | identification |
| **IV** | intravenous |
| **LIS** | laboratory information system |
| **NCE** | nonconforming event |
| **PICC** | peripherally inserted central catheter |
| **PPE** | personal protective equipment |
| **PT** | prothrombin time |
| **QMS** | quality management system |
| **QSE** | quality system essential |
| **SPS** | sodium polyanetholsulfonate |
| **VAD** | vascular access device |

# Chapter 2

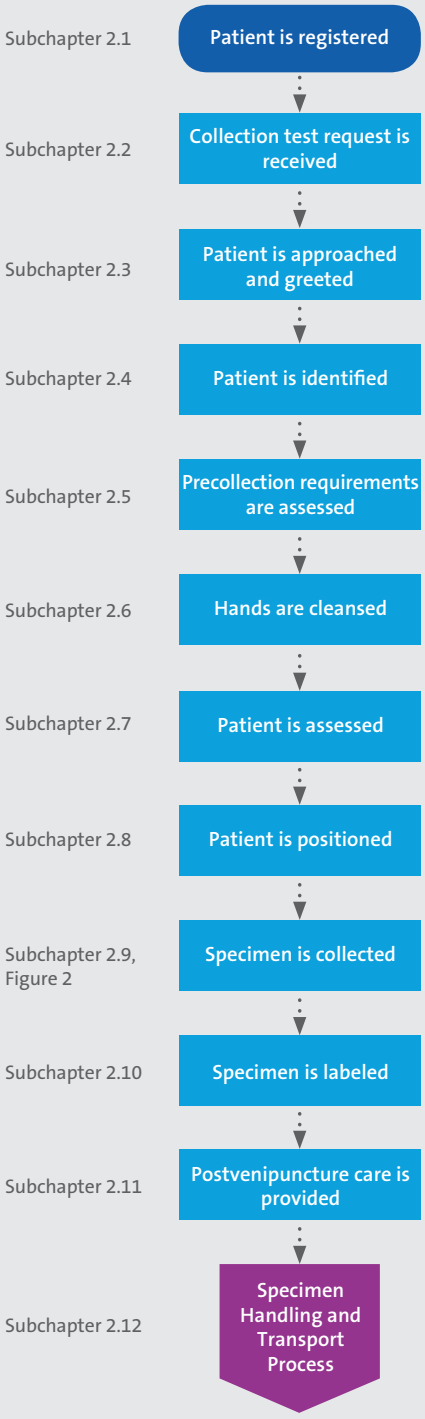
# Blood Specimen Collection Process

## This chapter includes:

- A blood specimen collection process flow chart
- Detailed information related to each blood specimen collection process activity

# 2 Blood Specimen Collection Process

Figure 1 outlines the blood specimen collection process.




* Five basic symbols are used in process flow charts: Oval (signifies the beginning or end of a process), Arrow (connects process activities), Box (designates process activities), Diamond (includes a question with alternative "Yes" and "No" responses), Pentagon (signifies another process).

**Figure 1. Blood Specimen Collection Process ***

## 2.1 Patient Is Registered

Proper patient identification begins at the registration process. Registration occurs when a patient is admitted to a hospital or to a long- or short-term care facility or when presenting to a blood collection center. This process also encompasses requests for home collections. Regardless of the setting, the patient's identification must be properly entered into the facility's database or verified if the patient demographics already exists in the database. The registration process may involve the issuance of a medical record number and the application of an ID band onto the patient.

**When verifying the patient's identification at the time of registration, the following information must be obtained and/or verified:**

- Full name
- Date of birth and sex
- Full address
- Proof of ID (ie, government-issued card with photo or other photo ID card)

A patient-specific identifier (ideally an identification number obtained from the government-issued card or a medical record number) must be determined by the facility and must also appear on all patient ID bands and/or labels. For patients who do not have all of the above identifiers (eg, anonymous or homeless patients, newborns), the facility must establish alternative patient-specific identifiers.

## 2.2 Collection Test Request Is Received

Upon receipt of the request for blood collection, the phlebotomist must:

- Check all information on the request for completeness.
- Ensure a complete match between labels and request.
- Resolve any and all discrepancies before proceeding with the collection.
- Contact the appropriate provider, supervisor, and/or other responsible party for any other clarifications.

The test request should include:

- Name of the health care provider or other authorized person requesting the test
- Patient's full name (first and last, and middle if applicable or available)
- Patient-specific identifier
- Patient's sex
- Patient's age or date of birth (according to facility policy)
- Test(s) to be performed
- Site of collection, when appropriate
- Date and, if appropriate, time specimen is to be collected
- Any additional information and instructions relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results

In some facilities, test requests are entered directly into the electronic records system. If the laboratory transcribes or enters the test request or authorization information into a record system or LIS, the laboratory must ensure that the information is transcribed or entered accurately.

## 2.3 Patient Is Approached and Greeted

The phlebotomist must observe inpatient areas for conditions and details pertinent to the procedure, including, but not limited to:

- Signage, bracelets, and other indicators communicating patient-specific precautions
- Presence of an ID band
- Availability, location, and condition of sharps containers
- Obstacles preventing access to the patient
- Presence of supplies and/or equipment to perform proper hand hygiene
- Conditions that prevent proper patient and limb positioning
- Conditions requiring assistance of another health care professional (eg, turning off intravenous [IV] fluids)
- Presence of vascular access device (VAD)

The phlebotomist must react appropriately to signage and correct any condition that may impede successful completion of the procedure.

The phlebotomist identifies himself or herself and states his or her purpose. Sleeping patients must be awakened before proceeding. The phlebotomist must demonstrate empathy and respect upon approaching the patient. Table 1 outlines the approaches to use depending on the situation.

**Table 1. Approaches for Greeting the Patient**

| Situation | Recommended Approach |
|---|---|
| Hospitalized patients | • Knock on the door upon entering, or otherwise announce entry. |
| Long-term care facility patients | • Check in at nursing station.<br>• Inquire about recommendations for assistance or restrictions concerning any of the patients.<br>• Knock on the door upon entering, or otherwise announce entry. |
| Outpatient phlebotomy patients | • Summon the patient from the waiting area.<br>• Lead patient to phlebotomy area and ensure patient is safely positioned. |
| Home collections | • Contact patient before arrival.<br>• Request that pets be isolated in a room away from the location for specimen collection.<br>• Ring doorbell or knock on the door.<br>• Do not enter home without permission unless instructed beforehand to do so by patient, caregiver, or guardian. |

## 2.4 Patient Is Identified

Patient ID is crucial. The phlebotomist must ensure that the blood specimen is drawn from the individual designated on the test request and/or labels. All inpatients must have ID bands affixed to their person unless exempted by facility policy (eg, residents in long-term care facilities, patients in psychiatric wards). If any discrepancies are identified, specimens are not to be collected until all inconsistencies are resolved. The phlebotomist must report any discrepancy, however minor, to the responsible caregiver as determined by facility policy.

Extra care is required in high-risk situations for both outpatients and inpatients. Examples of high-risk situations include:

- Siblings or twins
- Newborns
- Common names (eg, John Smith)
- Look-alike or sound-alike names (eg, Annie Jones or Anne E. Jones)
- Multiple patients sharing a room

When multiple health care professionals are involved in the same process (eg, one health care professional escorts a patient from the waiting room to the point of specimen collection and another performs the phlebotomy procedure), patient ID must be reverified at the point of exchange.

When requesting information from the patient, the phlebotomist shall solicit a verbal response by asking open-ended questions that require specific information and cannot be answered with a simple yes or no.

**NOTE:**

Specimens are not to be collected until all identified discrepancies are resolved.

Phlebotomists must not show the test request to the patient or verifier during the ID process to solicit affirmation of patient ID. For conscious patients who cannot speak, the phlebotomist must consider using forms of ID for which the patient provides his/her identifiers in writing, typing, or other text format.

### 2.4.1 Patients With Identification Bands (Inpatients or Outpatients)

1. Ask patient to state his/her full name and spell his/her first and last names.
2. Ask patient for his/her date of birth.
3. Confirm the information provided verbally by comparing it with the ID band, which must be attached to the patient.
4. The information provided with the ID band (including complete name and patient-specific identifier) must be matched to the information on the test request and/or all specimen labels. The phlebotomist must not rely on a bed tag, ID bands not attached to the patient, or on charts or records placed on the bed, nearby tables, or equipment.

### 2.4.2 Patients Without Identification Bands

For outpatients or inpatients on wards where ID bands are not applied as a matter of facility policy (eg, long-term care facilities, psychiatric wards), take the following steps:

1. Ask the patient to state his/her full name and spell his/her first and last names.
2. Ask patient for his/her date of birth.
3. Ask the patient to provide a proof of ID (preferably a photo ID) that bears the patient-specific identifier determined by the facility. If the patient does not have a proof of ID readily available, phlebotomists must follow facility policy for alternative forms of ID, eg, soliciting the required information from a caregiver or family member, and must document the name of the verifier or alternative ID process.
4. Compare the information provided by the patient (including complete name and patient-specific identifier) to the information on the test request and/or all sample labels.

### 2.4.3 Identification of Patients Who Are Unable to Participate in the Identification Verification Process

There are situations in which the patient cannot participate in the ID verification process. If a patient has a language barrier, the facility should have a system available for contacting interpreter services to facilitate interaction with the laboratory. Some patients may be too young to participate in the ID verification process or may be semiconscious, unconscious, comatose, or cognitively impaired. In any of these circumstances, the phlebotomist must follow these steps:

1. Ask the patient's health care professional, a relative, or a friend to identify the patient by providing, not affirming, the same information required in Subchapters 2.4.1 or 2.4.2.
2. Compare the information provided with the information on the labels and/or test request. Compare these data with those on the patient's ID band, if one is affixed to the patient.
3. Document the name of the individual who has identified the patient and his or her title (if health care professional) or relationship to the patient in the patient's or specimen's records.

### 2.4.4 Procedure for Assigning Temporary Designation to Unidentified Emergency Patients

The unidentified emergency patient must be given a temporary but clear designation until accurate ID is made. For a person who cannot be identified immediately:

1. Assign and record a temporary ID number or alphanumerical designation to the patient in accordance with facility policy.
2. Ensure the name and permanent or temporary ID is affixed to the patient's body at all times, either by ID band or some similar device.
3. Complete the necessary labels either by hand or electronically.
4. Apply the labels to the test request and specimens immediately after the collection.
5. When a permanent ID number is assigned to the patient, make sure the temporary ID number is cross-referenced to the permanent number to ensure correct ID and correlation of patient and test result information.

**NOTE:**

The unidentified emergency patient must be given a temporary but clear designation until accurate ID is made.

## 2.5 Precollection Requirements Are Assessed

The phlebotomist must verify that the patient has complied with all precollection requirements.

**NOTE:**

The phlebotomist must obtain consent for the procedure as defined by facility policy.

### 2.5.1 Providing Information and Obtaining Consent

Information given to the patient regarding the intended testing and specimen collection must be in accordance with facility policy and regulatory requirements.

The phlebotomist must obtain consent for the procedure as defined by facility policy. Facilities must establish the means by which consent is implied or obtained. Blood collection must not be performed against the patient's or guardian's consent. If the patient withdraws consent during the procedure, the phlebotomist must safely end the collection immediately. The phlebotomist must report the patient's objections to the physician or other health care professional.

### 2.5.2 Physiological Factors

Those who collect specimens for laboratory testing should have an understanding of what physiological factors affect test results and how (eg, activity level, diet, medications, posture, and time of day [circadian rhythm]).

Some specimens require collection at a specific time because of medications, fasting requirements, and/or biological variations (circadian rhythm). It is important that timed tests are collected at the precisely specified interval(s). Examples of tests requiring timed specimens include:

- Tolerance tests (eg, glucose tolerance test)
- Cortisol
- Therapy monitoring (eg, prothrombin time [PT], activated partial thromboplastin time [APTT], digoxin, and other drugs)

The procedure for holding meals and notifying appropriate personnel that the patient's blood specimen has been collected must be conducted according to facility policy.

## 2.6 Hands Are Cleansed

The phlebotomist must perform hand hygiene immediately before patient contact according to facility policy and established guidelines.[5,6] See CLSI document M29[2] for additional information. Soap and water must be used for visibly soiled hands and for patients known to be infected with *Clostridium difficile*.[7]

## 2.7 Patient Is Assessed

The phlebotomist should ask the patient if he/she has problems with blood draws or other conditions or complications pertinent to blood

specimen collection. If latex supplies are used, the phlebotomist must ask the patient if he/she has a hypersensitivity to latex. Severe hypersensitivity has been reported, and anaphylactic shock cases have occurred. In such hypersensitive individuals, latex supplies (eg, gloves, tourniquets, bandages, adhesives) must not be used.[8-11] Refer to Subchapter 2.9.3.1 for tourniquet information.

Patients with a history of syncope must be recumbent.

No food, liquid, chewing gum, or other objects (eg, thermometer) should be in the patient's mouth at the time the specimen is collected, except for essential medical treatment (eg, newborns receiving oral fluids, patients on ventilators).

**NOTE:**

If latex supplies are used, the phlebotomist must ask the patient if he/she has a hypersensitivity to latex.

## 2.8 Patient Is Positioned

For patient safety, the phlebotomist must collect all specimens with the patient positioned comfortably in a seated or recumbent position. The patient's arm should be positioned horizontally or slanting slightly downward on a suitable support (armrest, table, etc.) with the arm extended to form a straight line from the shoulder to the wrist. The phlebotomist may assist the patient in extending his/her arm into the proper position. A slight bend at the elbow may be necessary to avoid hyperextension and assist in vein location. The phlebotomist must not forcibly extend the arm of a patient if full extension is not possible due to stroke, injury, or other circumstances.

### 2.8.1 Seated Position

#### 2.8.1.1 Inpatient and Outpatient Facilities

Patients undergoing a blood draw in a seated position must sit in chairs that have safety features (eg, arm rests or commercial venipuncture chairs) to provide support and prevent falls if the patient loses consciousness. When chairs with safety features are not available, the specimen must be collected with the patient in a recumbent position (see Subchapter 2.8.2).

Patient specimens must not be collected while the patient is sitting upright on an examination table, side of a bed, or on any surface without arm rests or other barriers designed to prevent falls. The phlebotomist should assist patients in positioning as needed. If the chair has wheels, the chair must be secured to prevent movement during the procedure.

If the patient is in an adjustable bed, the phlebotomist should lower the head of the bed, if necessary, to facilitate arm extension unless this is against either facility policy or the physician's orders.

**NOTE:**

Patient specimens must not be collected while the patient is sitting upright on any surface without arm rests or other barriers designed to prevent falls.

#### 2.8.1.2 Home Collections

Patients whose specimens are collected in their home, where chairs with safety features are not available, must be placed in a recumbent position or in a chair with arm supports.

### 2.8.2 Recumbent Position

The phlebotomist must position the patient on his/her back in a comfortable position by reclining the bed or phlebotomy chair or having the patient lie flat after verification with the health care provider. For patients with whom communication is difficult (eg, sedated, cognitively impaired, language barrier), the phlebotomist should recline the patient with assistance, if necessary.

## 2.9 Specimen Is Collected

Figure 2 outlines the specimen collection process.

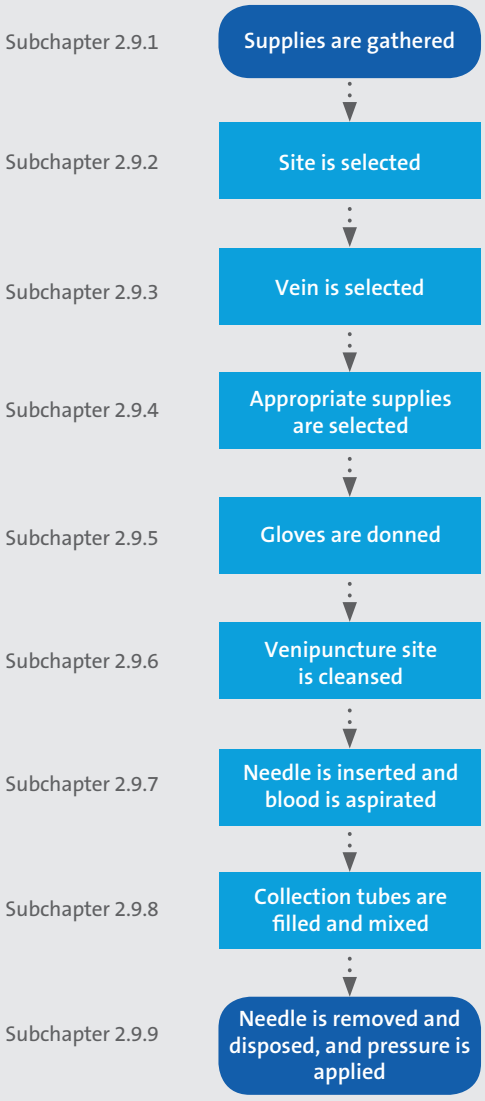



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**Figure 2. Specimen Collection Process Flow Chart***

### 2.9.1 Supplies Are Gathered

The phlebotomist gathers all supplies and must inspect for defects and applicable expiration dates. **NOTE:** Devices must not be preassembled by the collector before the patient is identified. See Subchapter 6.4 for information on supplies used for specimen collection.

**NOTE:**

Devices must not be preassembled by the collector before the patient is identified.

### 2.9.2 Site Is Selected

The preferred venipuncture site is the antecubital fossa, which is the area of either arm that is anterior to (in front of) the bend of the elbow where a number of large veins lie relatively near the skin's surface.

When antecubital veins are not acceptable or are unavailable, veins on the back of the hand are also acceptable for venipuncture (see Figure 3).

Collections outside of the recommended venipuncture sites must not be attempted without a thorough knowledge of the area's anatomy and the risks involved, and any such attempt must also be made according to facility policy.

Arterial punctures shall not be considered an alternative to venipunctures, because results obtained from arterial specimens are not equivalent for many analytes.[12] Arterial blood sampling can also be more painful to the patient and pose greater risk of injury and complications.[13]

Veins on the palmar surface of the wrist and the lateral wrist above the thumb to the mid-forearm must not be used.[14-21]

**NOTE:**

The preferred venipuncture site is the antecubital fossa; however, veins on the back of the hand are also acceptable.

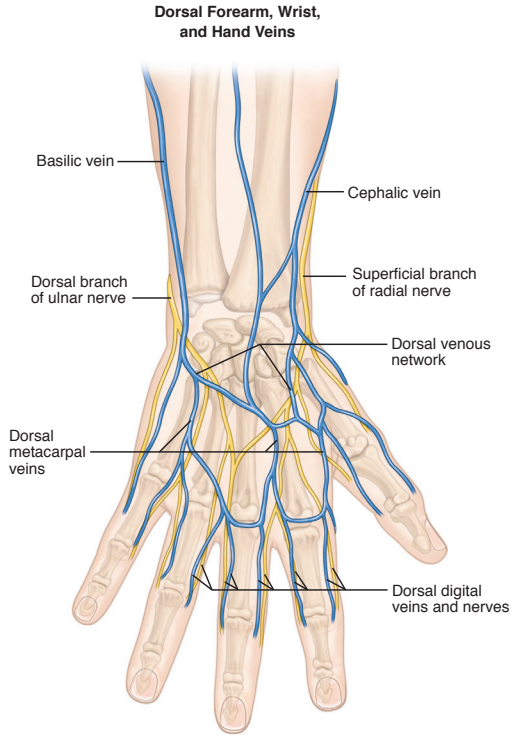



**Figure 3. Dorsal Forearm, Hand, and Wrist Veins** (Reproduced with permission. McCall RE, Tankersley CM. *Phlebotomy Essentials*. 6th ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2015. Reprinted with permission from Lippincott Williams & Wilkins. http://lww.com.)

Venipuncture must not be performed on the scalps of newborns without physician permission and specialized training. Draws must not be attempted on the ankles or any part of the lower extremities without documented permission of the physician because of the potential for significant medical complications (eg, phlebitis, thrombosis, tissue necrosis). Draws outside of acceptable areas should not be undertaken without thorough knowledge of the anatomy and associated risks and should be in accordance with facility policy.

A physician must provide written permission before a venipuncture is performed on the side on which a mastectomy has been performed because of the potential for complications due to lymphedema, a potentially devastating complication that leads to progressive edema, pain, and recurrent infections. Studies on the safety of venipunctures performed on the same side of the body as mastectomy are scant and inconclusive, and treatment of lymphedema remains largely ineffective.[22-24]

Although lymph-node preservation is now given a high surgical priority, the health care professional drawing blood from such patients typically does not have access to information on the extent of lymph-node removal, nor sufficient training to assess the prevailing risk. The requirement for physician permission includes patients with bilateral mastectomies, irrespective of the time that has elapsed since mastectomy.

Table 2 provides precautions and limitations when selecting the venipuncture site.

**Table 2. Site Selection Limitations When Collecting Venous Blood Specimens**

| Sites That Must Not Be Used | |
|---|---|
| **Site** | **Rationale** |
| Fistula, arm with a fistula, or vascular graft | • Threatens the integrity of fistulas and vascular grafts, which can lead to serious patient complications |
| Arteries[12,13] | • Risk of misinterpretation of results and patient mismanagement if arterial blood is used rather than venous blood; **NOTE:** Arterial and venous blood specimens are not equivalent for many analytes.<br>• Poses a significantly higher risk of injury and complications than venous access |
| Veins on lateral and palmar surface (underside) of the wrist[14-21,25] | • Increased risk of nerve, tendon, and arterial involvement |
| Infected sites | • Potential for altered test results, exacerbation of infection, and patient discomfort |
| **Sites That Require Physician's Permission** | |
| **Site** | **Rationale** |
| Limbs on the side of a mastectomy | • Risk of lymphedema and the potential for altered test results[22-24] |
| Any part of the lower extremities | • Risks tissue necrosis in diabetic patients and thrombophlebitis in patients with coagulopathies |
| **Sites That Should Be Avoided** | |
| **Site** | **Rationale** |
| Extensive scarring, healed burns | • Palpation and needle insertion complications<br>• Inability to detect adverse reactions |
| Hematoma | • May cause discomfort to the patient and potential altered test results |
| Above and below infusing fluids or from a VAD | • Possible contamination of specimen with IV fluids[26] (see Subchapter 5.3.2) |
| Inflamed sites (including inflamed tattoos) | • Patient discomfort and possible complications |
| Edematous sites | • Potential for altered test results |
| Extremity affected by stroke and injury | • Inability to detect adverse reaction, eg, nerve injury, pain, infection |

Abbreviations: IV, intravenous; VAD, vascular access device.

## 2.9.3 Vein Is Selected

### 2.9.3.1 Tourniquet Is Applied

To facilitate vein palpation and specimen collection, the phlebotomist must apply a single tourniquet just proximal to the site being considered, but not so close that it will impede the procedure. Without tourniquet application, the phlebotomist may not be able to prioritize the antecubital veins for safety as required in Subchapter 2.9.3.3.

When used inappropriately, tourniquets pose a risk to patients and may affect test results. Hemoconcentration has been shown to cause erroneously high values for protein-based analytes, packed cell volume, and other cellular elements. Affected analytes include but are not limited to

**NOTE:**

Tourniquet application must not exceed one minute before accessing the vein in order to prevent hemoconcentration.[30]

albumin, calcium, potassium, red blood cells, white blood cells, differential, hemoglobin, hematocrit, glucose, triglyceride, total protein, and alkaline phosphatase.[27-30] To prevent patient complications and ensure accurate test results:

- Tourniquet application must not exceed one minute before accessing the vein in order to prevent hemoconcentration.[30]
- If a tourniquet has been in place for longer than one minute before accessing the vein, it must be released and reapplied after two minutes before the venipuncture is performed.
- Studies on the effect of tourniquet constriction on lactate are inconclusive when released within the recommended time.[31-33] Follow facility policy.
- Nonlatex tourniquets must be used to prevent latex sensitivity and allergic reactions.
- Because of the prevalence of methicillin-resistant *Staphylococcus aureus* and other pathogens on previously used tourniquets, single-use tourniquets are recommended to prevent the spread of health care–acquired infections.[34-38] Alternatively, inpatients may be assigned a tourniquet upon admission to be exclusively used for their venous access procedures. Follow facility infection control policy and procedures.
- Constriction must not be excessive or uncomfortable to the patient.

**NOTE 1:** For patient comfort, the tourniquet may be applied over clothing to prevent pinching of the skin; alternatively, a gauze or other pad can be used as a barrier between the tourniquet and skin.

**NOTE 2:** A blood pressure cuff inflated below the patient's diastolic pressure may be used to apply constriction in place of a tourniquet.[39] The application of a blood pressure cuff must be performed only by those with knowledge and training in using such devices.

#### 2.9.3.2 General Antecubital Anatomy

Antecubital vein location varies from person to person; however, two basic vein distribution arrangements, referred to as the "H-shaped" and "M-shaped" patterns, are seen most often. The H-shaped pattern is so named because the most prominent veins in this pattern—the cephalic, median cubital, and basilic veins—are distributed on the arm in a way that resembles a slanted H (or N). The most prominent veins of the M-shaped pattern—the cephalic, median cephalic, median basilic, and basilic veins—resemble the shape of an M. The H-shaped pattern is predominant in most populations.[40,41]

Refer to Figure 4 for a description of the superficial veins of the upper extremity anterior surface in both the H- and M-shaped patterns.

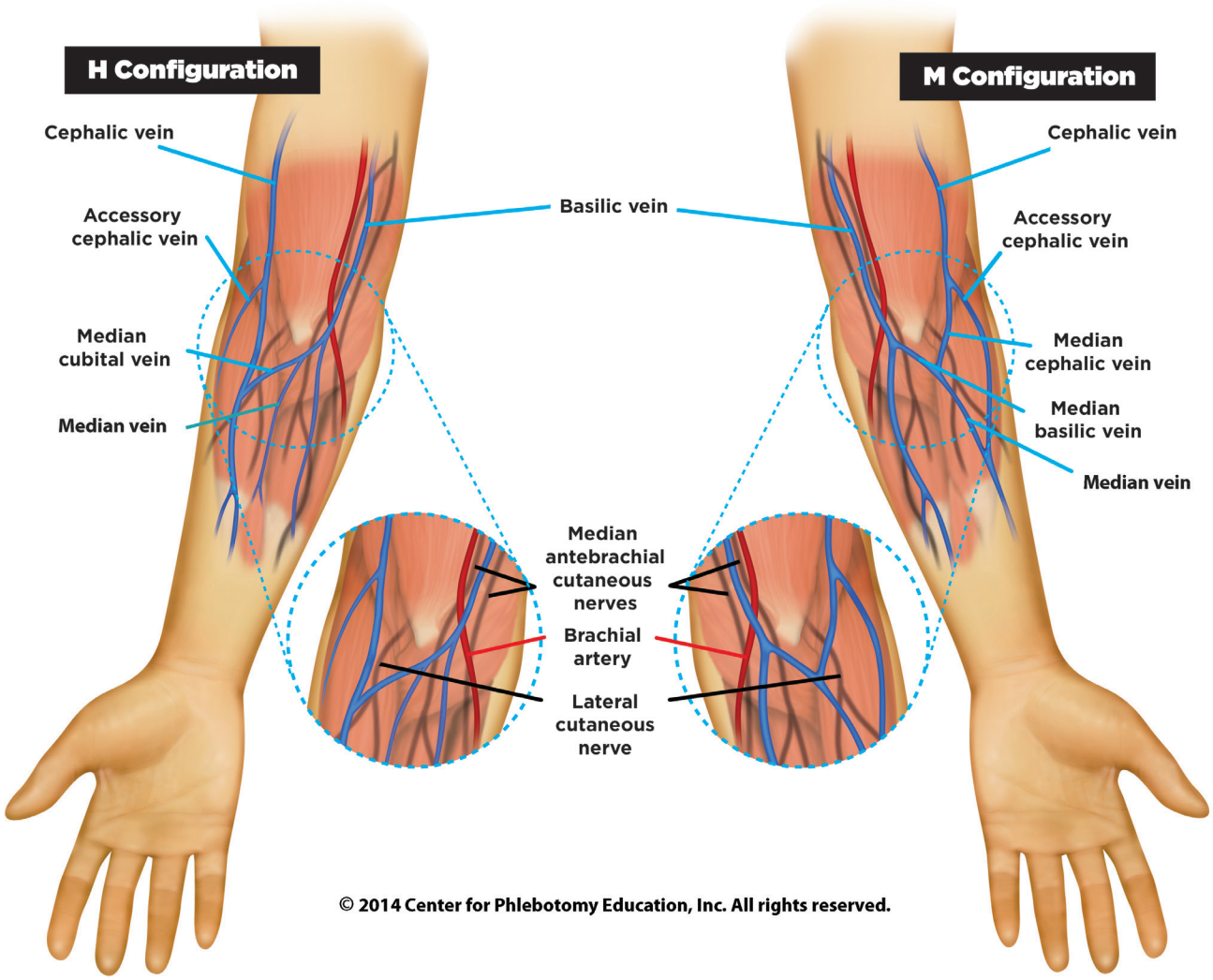



**Figure 4. Superficial Veins of the Anterior Surface of the Arm** (Reproduced with permission. Center for Phlebotomy Education, Inc. All rights reserved. Unauthorized duplication prohibited.)

### 2.9.3.3 Vein Prioritization

Because the brachial artery and several major nerves pass through the antecubital area, vein selection must include an understanding of the anatomy and risk involved in order to prevent arterial puncture and nerve injury. The median cubital and median veins are supported anatomically, because they both overlie the bicipital aponeurosis, a fibrous membrane that offers some protection to underlying structures such as nerves and arteries.[42] Prioritizing veins according to risk can minimize the potential for injury and complications (see Figure 5).

**The phlebotomist must prioritize antecubital vein selection as follows:**

1. **Veins in the median aspect (center), ie, median and lateral aspect of the median cubital veins:** Attempt to locate these veins on either arm before considering alternative antecubital veins.

2. **Veins in the lateral aspect (outer), ie, cephalic vein and the accessory cephalic vein:** While injuries to the lateral nerve during venipuncture are rare, these veins must not be considered unless other veins in the median aspect of the antecubital area have been ruled out.[21]

3. **Veins in the medial aspect (inner), ie, basilic vein and medial aspect of the median cubital vein (see Figure 5):** Venipuncture attempts to these veins are more likely to injure the brachial artery and the median antebrachial cutaneous nerves.[40] Therefore, collections from the veins in the medial aspect of the antecubital area must not be considered unless no other vein provides confidence that it can be safely and successfully accessed.

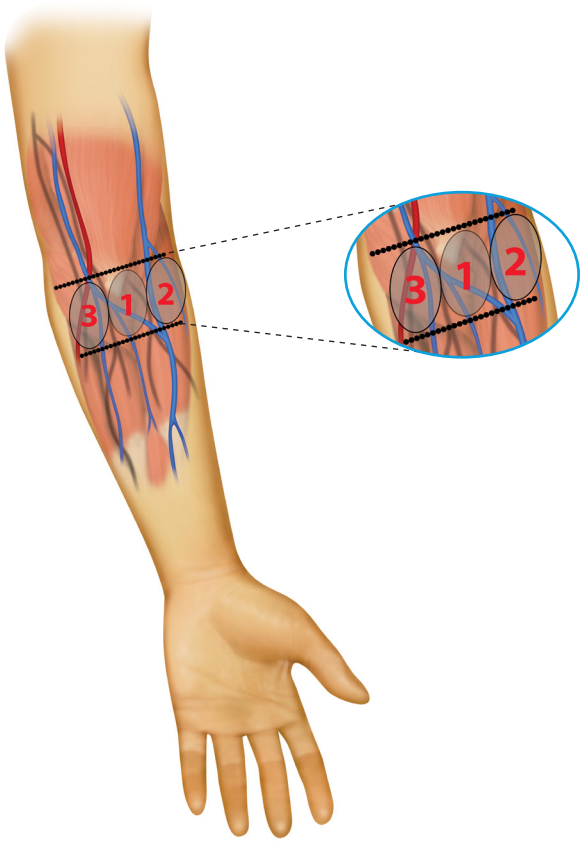



**Figure 5. Prioritization of Antecubital Veins** (Reproduced with permission. Center for Phlebotomy Education, Inc. All rights reserved. Unauthorized duplication prohibited.)

#### 2.9.3.4 Clenching the Fist

Although fist-clenching is not a mandatory requirement, veins become more prominent and easier to enter when the patient forms a fist. If forming a fist is required to facilitate vein location and during needle entry, the phlebotomist may ask the patient to clench and hold the fist until blood flows into the collection device. Patients must not be instructed or permitted to vigorously open and close the hand ("pumping"). Hand pumping can cause significant elevations in the potassium concentration in specimens collected, risking complications and patient mismanagement.[43]

**NOTE:**

Patients must not be instructed or permitted to vigorously open and close the hand ("pumping").

### 2.9.4 Appropriate Supplies Are Selected

The phlebotomist must inspect all supplies for possible defects and applicable expiration dates.

**NOTE:** Devices must not be preassembled by the collector before the patient is identified.

#### 2.9.4.1 Needles

The phlebotomist must select the appropriate device and needle gauge based on the physical characteristics of the vein and the volume of blood to be collected (see Subchapter 6.4.4).

#### 2.9.4.2 Tubes

Tubes must be selected according to the test requested and laboratory requirements. Consideration should be given to the physical characteristics of the vein, the volume of blood required for testing, and the risk for iatrogenic anemia (see Subchapter 4.5).

### 2.9.5 Gloves Are Donned

**NOTE:**

Gloves must remain intact during the procedure. Fingertips of the gloves must not be removed.

The phlebotomist must put new gloves on before the venipuncture is performed, with consideration for latex hypersensitivity as discussed in Subchapter 2.7.

Gloves must remain intact during the procedure. Fingertips of the gloves must not be removed. Facility policy must be followed for isolation patients or other situations that may require donning gloves earlier in the procedure (see Subchapter 5.4).

### 2.9.6 Venipuncture Site Is Cleansed

The puncture site must be cleansed to minimize microbiological contamination of the specimen and patient infection.

#### 2.9.6.1 Cleansing Method for Venipuncture

1. Cleanse the site with friction using a clean gauze pad with 70% isopropyl alcohol solution, or a commercially prepared alcohol pad. If the specimen is being collected for a blood alcohol level analysis, use a nonalcohol-based cleanser. For blood culture collections, use the facility's prescribed disinfectant (see Subchapter 5.1.1).
2. Allow the area to air dry. This practice prevents the patient from experiencing a burning sensation when the venipuncture is performed and allows optimal decontamination.

**NOTE:** Studies and articles suggest back-and-forth friction is superior to circular concentric cleansing.[44-47]

#### 2.9.6.2 Touching the Site After Cleansing

If venipuncture proves difficult and the vein requires repalpation after cleansing, the site must be cleansed again. Refer to Subchapter 2.9.3.1 if recleansing results in prolonged tourniquet constriction.

### 2.9.7 Needle Is Inserted and Blood Is Aspirated

#### 2.9.7.1 Evacuated Tube Method

The following steps must be performed when using the evacuated tube method:

1. If preevacuation is required, evacuate the tubes immediately before use according to the manufacturer's instructions.
2. If not preassembled by the manufacturer, thread the appropriate needle into the holder until it is secure.
3. If possible, ensure the patient's arm or other venipuncture site remains in a downward position to prevent reflux or "backflow" from the collection tube into the vein.[48]
4. Hold the patient's arm firmly distal to the intended puncture site. Draw the skin taut to anchor the vein 1 to 2 inches (2.5 to 5 cm) below the venipuncture site in such a manner that anchoring does not impede needle insertion (see Figure 6). **NOTE:** Anchoring the vein from above is not recommended due to the risk of an accidental needlestick.

**NOTE:**

Anchoring the vein from above is not recommended due to the risk of an accidental needlestick.

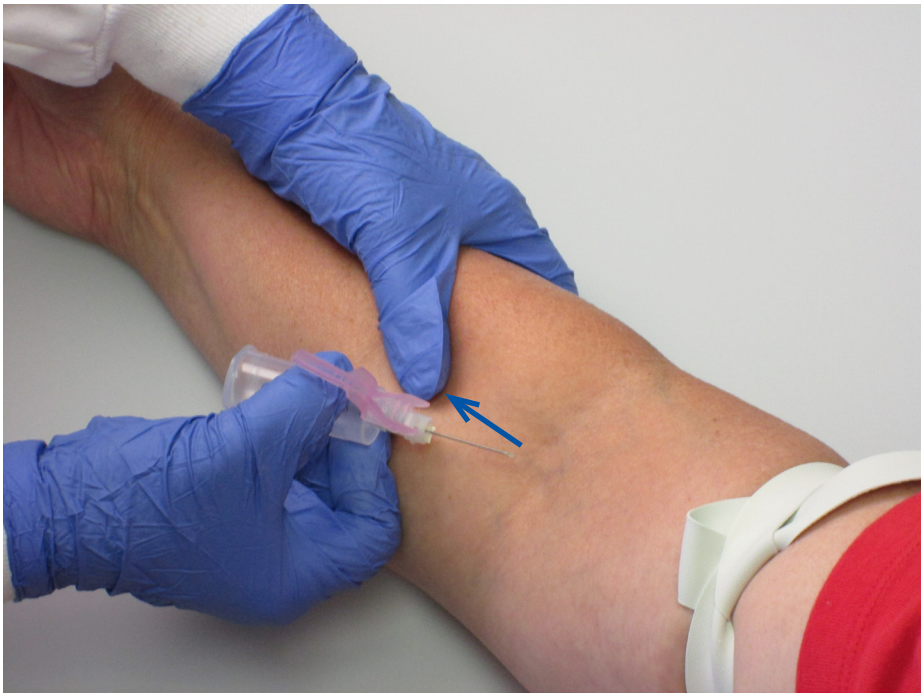
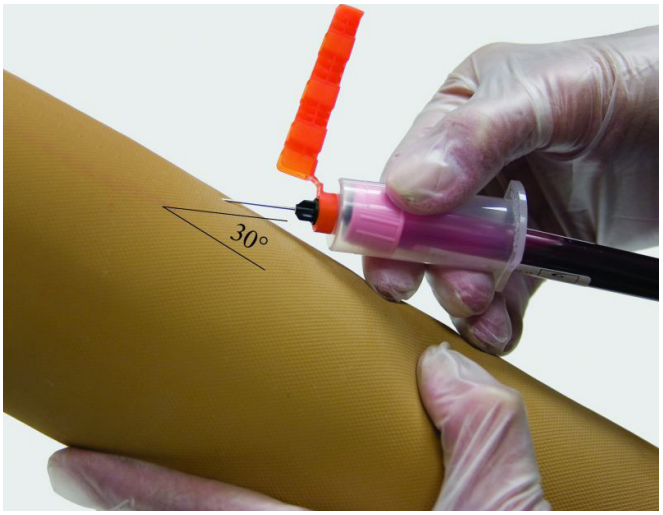


**Figure 6. Anchoring the Vein** (Reproduced with permission. Center for Phlebotomy Education, Inc. All rights reserved. Unauthorized duplication prohibited.)

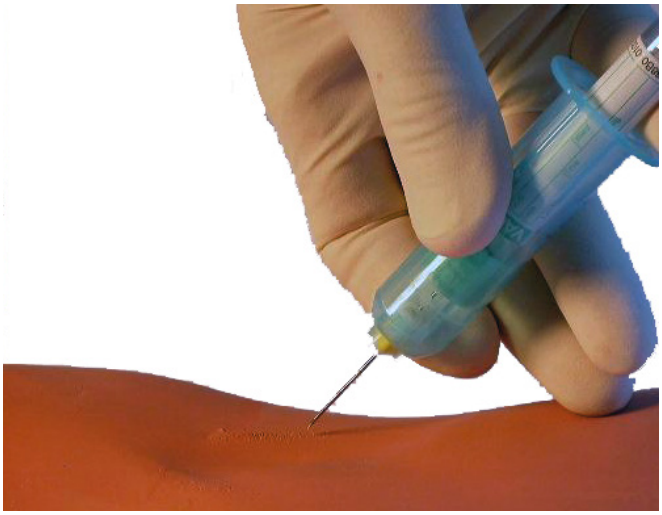
5. To prepare the patient, inform him/her that the venipuncture is about to occur. **NOTE:** From this point on, be prepared to react to syncope and sudden unexpected movement (see Subchapter 4.7). Also, be prepared to remove the needle if the patient complains of unusual pain or symptoms of nerve injury or withdraws consent (see Subchapter 4.2 for more information).

6. With the bevel up, puncture the vein with a steady, forward motion in the direction of venous blood flow while keeping the needle in line with the vein and at an angle of 30° or less (see Figure 7). Once inserted, advance the first tube so that the interior needle (ie, back end) pierces the closure and blood flows freely into the tube. Maintain needle placement while advancing the tube using the flanges of the holder to stabilize the device. Maintain tube placement as the tube fills.

**NOTE:** When using a winged blood collection set, maintain needle placement by holding or otherwise securing the device throughout the collection.




**Proper Angle of Insertion.** (From: McCall RE, Tankersley CM. *Phlebotomy Essentials.* 6th ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2015. Reprinted with permission from Lippincott Williams & Wilkins. http://lww.com.)



**Improper Angle of Insertion.** (Reproduced with permission. Center for Phlebotomy Education, Inc. All rights reserved. Unauthorized duplication prohibited.)

Figure 7. Angle of Insertion

7. Instruct the patient to open his or her hand, unless it is felt that doing so would cause vein collapse. Do not allow the patient to pump the hand (see Subchapter 2.9.3.4).

8. Release the tourniquet as soon as blood flow is established to minimize hemoconcentration, unless it is felt that doing so would cause vein collapse (see Subchapter 2.9.3.1).

#### 2.9.7.2 Syringe Method

In general, venipuncture using a traditional needle and syringe should be avoided for safety reasons. If conditions require a syringe collection, the following procedure is recommended:

1. Assemble the needle and syringe. Break the seal of the plunger according to the manufacturer's instructions, ensuring all air is expelled before use. **NOTE:** This step is not required for all aspiration systems.

2. To prepare the patient, inform him/her that the venipuncture is about to occur. **NOTE:** From this point on, be prepared to react to syncope and sudden unexpected movement (see Subchapter 4.7). Also, be prepared to remove the needle if the patient complains of shooting or persistent pain or if the patient withdraws consent.

3. With the bevel up, puncture the vein with a steady, forward motion (ie, proximal, in the direction of the blood flow) while keeping the needle in line with the vein and at an angle of 30° or less (see Figure 7). Keeping the needle as stable as possible in the vein, slowly withdraw the desired amount of blood by pulling the syringe plunger/piston rod back with a slow, steady motion. Avoid excessive pulling pressure, which could hemolyze the specimen.

4. Instruct the patient to open his or her hand, unless it is felt that doing so would cause vein collapse. Do not allow the patient to pump the hand (see Subchapter 2.9.3.4).

5. Release the tourniquet as soon as blood flow is established to minimize hemoconcentration, unless it is felt that doing so would cause vein collapse (see Subchapter 2.9.3.1).

### 2.9.8 Collection Tubes Are Filled and Mixed

All additive tubes must be filled to their stated volumes (see Subchapter 2.9.8.2). Closures must not be removed to fill tubes or transfer blood from one tube to another.

To ensure accurate test results, prevent specimen rejection, and achieve optimal blood to additive ratio, allow blood to fill the tube until the maximum stated volume is reached (ie, vacuum is exhausted). Visually assess the tube to ensure adequate filling.

When the tube is filled to its stated volume (ie, vacuum is exhausted), remove/disconnect the tube from the needle/holder and mix by gentle inversion. If additional tubes are required, insert/connect the next tube to the needle/holder and fill all remaining tubes according to the recommended order of draw (see Subchapter 2.9.8.1). Always remove the last tube collected from the needle/holder and release the tourniquet before withdrawing the needle from the vein if it was not released.

### 2.9.8.1 Order of Draw

**The order of draw is the same for specimens collected by syringe, tube holder, or into tubes preevacuated at the time of collection.**

1. Blood culture tube or bottle
2. Sodium citrate tube (eg, blue closure)
3. Serum tubes, including those with clot activator and gels (eg, red, red-speckled, gold closures)
4. Heparin tube with or without gel (eg, dark green, light green, speckled green closures)
5. EDTA tube with or without gel separator (eg, lavender, pearl, pink closures)
6. Sodium fluoride/potassium oxalate glycolytic inhibitor (eg, gray closure)

The order of draw above is recommended for both glass and plastic venous collection tubes when drawing multiple specimens for medical laboratory testing during a single venipuncture. Its purpose is to avoid possible test result error due to additive carryover.[49-53]

The placement of tubes not listed here should take into consideration the potential for their additive to alter results obtained from the next tube if carryover were to occur.

#### 2.9.8.1.1 Clot Activator Tubes

Plastic serum tubes containing a clot activator may cause interference in coagulation testing. Only blood culture tubes, glass nonadditive serum tubes, or plastic serum tubes without a clot activator may be collected before the coagulation tube.

#### 2.9.8.1.2 Trace Elements

Studies have established that trace elements in blood collection equipment may contaminate the specimen with trace elements from

their components.[54,55] The presence and level of contamination vary depending on the trace element measured, tube type, and tube and needle manufacturer. This may necessitate special handling or changes to the order of draw to minimize contamination when collecting for trace element testing. The tube manufacturer's recommendations should be consulted. The phlebotomist must not use a syringe for trace element collections that include testing for cobalt and chromium because the plunger tip contributes such elements to the specimen.[56,57]

#### 2.9.8.1.3 Sodium Carryover

The concentration of sodium in sodium citrate or sodium heparin tubes has not been proven to alter the sodium concentration in tubes that follow should carryover occur. However, they need to be properly filled to achieve the recommended concentration of sodium.

### 2.9.8.2 Filling Tubes From a Syringe

The phlebotomist must proceed with the following recommendations when transfer of blood from a syringe to a blood collection tube is required:

1. Activate the safety feature of the needle or winged blood collection set as soon as the needle is withdrawn. Remove and discard the assembly and apply a safety transfer device to the syringe.
2. Immediately insert the first tube into the safety transfer device and pierce the closure with the needle. Allow the tube to fill without applying any pressure to the plunger until flow ceases. This technique helps to maintain the correct blood to additive ratio when an additive tube is used.
3. Fill tubes in the same order of draw listed in Subchapter 2.9.8.1.

### 2.9.8.3 Mixing Tubes

Immediately after filling any tube that contains an additive, the phlebotomist must mix the blood gently and thoroughly by inverting the tube slowly for the required number of inversions per the manufacturer's instructions. For multiple tube collections, the blood can be mixed while the next tube is filling. To avoid hemolysis, the blood must not be mixed vigorously.

**NOTE:**

Immediately after filling any tube that contains an additive, the phlebotomist must mix the blood gently and thoroughly by inverting the tube slowly for the required number of inversions per the manufacturer's instructions.

### 2.9.8.4 Special Considerations for Tubes Used for Coagulation Tests

Studies have shown that the PT/international normalized ratio, APTT, and some special coagulation assay results are not adversely affected if tested on the first tube collected, without the use of a discard tube.[58-64] These studies dispel the misperception that specimens for most coagulation

**IMPORTANT NOTE:**

**CAUTION:** A patient must not be allowed to bend his/her arm at the elbow as a substitute for pressure, as this technique is not adequate to prevent hematoma formation.[68,69]

assays should be obtained after first collecting a discard tube to avoid the effect of tissue thromboplastin.[65,66] See CLSI document H21[67] for additional details.

However, when a winged blood collection set is used for venipuncture and a coagulation tube is the first tube needed, the phlebotomist must first collect a discard tube. The discard tube is used to prime the tubing of the collection set, which ensures maintenance of the proper anticoagulant to blood ratio in the first tube filled. The discard tube must be a nonadditive or a coagulation tube and does not need to be completely filled.

### 2.9.9 Needle Is Removed and Disposed, and Pressure Is Applied

The phlebotomist must remove the needle, place a clean gauze pad lightly over the venipuncture site, immediately activate the safety feature, and apply pressure to the venipuncture site. Patients may apply direct pressure as long as the phlebotomist constantly monitors the site to ensure pressure is adequate.

**NOTE:**

All safety devices must be activated according to the manufacturer's instructions.

**CAUTION:** A patient must not be allowed to bend his/her arm at the elbow as a substitute for pressure, as this technique is not adequate to prevent hematoma formation.[68,69]

Cotton and rayon balls are not recommended for applying pressure because of the possibility of dislodging the platelet plug at the venipuncture site.

**NOTE:** Some safety features activate before the needle is removed from the vein. All devices must be activated according to the manufacturer's instructions.

**NOTE:**

Specimen tubes must be labeled immediately after the phlebotomy and in the patient's presence.

The phlebotomist must safely discard the unit into an easily accessible sharps container, consistent with applicable regulations (see Subchapter 6.4.9). Needles must not be resheathed, bent, broken, or cut, nor removed from disposable syringes unless attaching a safety transfer device.

## 2.10 Specimen Is Labeled

Specimen tubes must be labeled immediately after the phlebotomy and in the patient's presence. For each specimen, the laboratory must require the following information:

- Patient's first and last name
- Patient-specific identifier
- Collection date and time
- Identity of the person who collected the specimen

The phlebotomist must compare the labeled tube to the patient's ID band or have the patient verify that the information on the labeled tube is correct. If an ID band is not available and the patient cannot verify the information, the facility must have a policy to ensure the specimens are labeled properly.

### 2.10.1 Labels

The label's size must be sufficient to contain all required information. Labels must be applied on the specimen tubes in a manner that ensures all the information is visible. When using labels containing a bar code, proper positioning of the label for bar code readers must be taken into account. See CLSI document AUTO12[70] for additional information.

### 2.10.2 Manual Systems

If manual systems (eg, handwritten labeling) are used, the information specified in Subchapter 2.10 must be written on each specimen at the time of collection and ultimately entered into the LIS or written on paper records such as the test request. The information written on the specimen must be verified to match the information entered into the LIS or written on the paper records.

### 2.10.3 Electronically Generated, Machine-Readable Labels

Use of electronically generated, machine-readable labels is encouraged, and they should be generated at the time of collection. If such labels are not generated at the time of collection, the information system must be checked to verify that the correct date, time, and collector identity are entered once collection has occurred. If incorrect, this information must be corrected manually in the information system. If the labels also include date, time, and collector identity, these items must be checked, and corrected if necessary.

Each specimen must have a unique electronic ID mechanism linking the specimen to the data in the information system (eg, a bar code or radio frequency ID chip).

When electronically generated, machine-readable labels are used, they must show, at a minimum, the patient's first and last name and the patient-specific identifier. The collection date and time and the collector's identity must be available in the LIS. The collection date and time must be added on the specimens if more than one specimen is expected to be collected for that patient within a specified period, eg, glucose tolerance tests.

## 2.11 Postvenipuncture Care Is Provided

Patients must be assessed for the potential for syncope and given instructions on postvenipuncture care. See Subchapters 4.6 to 4.10 for information on emergency situations.

The phlebotomist must:

1. Check that bleeding has ceased and observe for hematoma. Specifically, the phlebotomist must observe the site for excessive, prolonged bleeding or subcutaneous bleeding for at least five to 10 seconds before bandaging.[71] If bleeding has not stopped, pressure must be applied as long as necessary to stop the bleeding. When bleeding has stopped, apply a gauze bandage or self-adhering bandage tightly around the arm to keep the pad in place. Latex-free adhesives must be available.
2. Assist the patient to regain his or her original position if needed. Instruct the patient to leave the bandage on for at least 15 minutes. The phlebotomist should also caution the patient against subjecting the site to pressure (from purse straps, tote and/or shopping bags, etc.) and to protect the arm from exertion for several hours so as not to reopen the wound.
3. Before leaving the patient's room, return items (bedrails, furniture, equipment, etc.) to their original location and/or position.

## 2.12 Specimen Is Handled and Transported

For accurate results, some specimens require special handling, such as:

- Cooling to slow metabolic processes
- Transportation at body temperature (37°C) to prevent precipitation or agglutination
- Protection from light to prevent analyte breakdown

Appropriately labeled blood collection tubes must be sent to laboratories designated to perform the required testing procedures. Proper transport conditions must be maintained to preserve specimen integrity. For additional information on blood specimen handling and processing, refer to CLSI document GP44.[72]

# Chapter 3

# Blood Specimen That Cannot Be Obtained

## This chapter includes:

- Recommendations to follow in situations in which blood cannot be obtained

**NOTE:**

Repositioning the needle without establishing vein location is considered blind probing and must not be performed.

## 3 Blood Specimen That Cannot Be Obtained

Repositioning the needle without establishing vein location is considered blind probing and must not be performed. Blindly relocating the needle can be painful and result in nerve damage, arterial perforation, or hematoma, all of which can result in complications that can lead to permanent disability.

When blood does not flow upon initial needle insertion or when blood flow stops during collection, the phlebotomist must assess the situation before considering the following actions:

- If it is perceived that needle placement is too shallow, advance it slightly farther.
- If it is perceived that the needle has penetrated too far into the vein, withdraw it slightly.
- If it is perceived the vein has collapsed upon the bevel of the needle (see Figure 8), release the vacuum pressure (ie, remove the tube or release the plunger of the syringe), wait for the vein to fill, and reapply the vacuum pressure. If the tourniquet has been released, recruit an assistant, if possible, to reapply constriction. If blood flow cannot be established, a repeat puncture may be necessary using a smaller needle and/or smaller volume tubes.
- Apply another tube of the same type in case the current one is defective (ie, lacks vacuum).

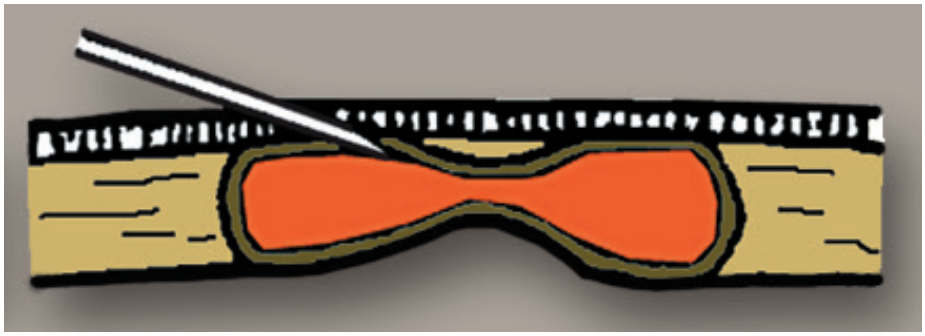


**Figure 8. Image of a Vein Collapsed Onto the Bevel of the Needle** (Courtesy and © Becton, Dickinson and Company. Reprinted with permission.)

A calculated lateral relocation in some areas may be attempted only if precise vein location has been determined. However, sideways needle relocation, even calculated, must not be attempted in the medial aspect of the antecubital fossa, where nerves and the brachial artery are most vulnerable to injury (see Figure 4).

To perform a calculated relocation, the phlebotomist must release the vacuum applied to the vein by removing the tube from the interior needle of the tube holder or discontinue pulling the plunger of the syringe. The phlebotomist must withdraw the needle until it is just beneath the dermis, re-anchor the vein, reorient the needle toward the perceived position of the vein, and advance the needle. The phlebotomist must reapply the tube or withdraw the plunger.

When a cautious and calculated relocation has failed, the tourniquet and needle must be removed, the safety device activated, and pressure applied to the puncture site. Any additional attempts at specimen collection must be started from the beginning of the procedure, preferably at the other arm or another part of the body. The same needle must never be used for additional subsequent punctures.

It is not advisable for the same phlebotomist to attempt a venipuncture more than twice. If possible, another qualified person should attempt to collect the specimen, or the physician should be notified. If the specimen cannot be obtained, the attempt must be recorded, along with ID of the phlebotomist. Facility policy must be followed. Additional information on difficult collection situations is provided in Appendix A.

**NOTE:**

It is not advisable for the same phlebotomist to attempt a venipuncture more than twice.

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# Chapter 4

# Complications

## This chapter includes:

- Blood collection–related injury
- Preventing hemolysis
- Monitoring blood volume
- First aid and emergency situations

# 4 Complications

## 4.1 Accidental Arterial Puncture

If accidental arterial puncture is suspected during the procedure (eg, rapidly forming hematoma, rapid filling of tube), the phlebotomist must remove the needle immediately and apply direct forceful pressure to the puncture site for a minimum of five minutes and until active bleeding has ceased. The nursing staff and physician must be notified and the incident documented according to facility policy.

**NOTE:** The phlebotomist must consult with the laboratory to determine the suitability of the suspected arterial specimen for testing.

## 4.2 Nerve Injury

**The following symptoms suggest possible nerve injury:**

- Shooting, electrical pain
- Severe or unusual pain
- Tingling or numbness in the limb
- Onset of tremor of the limb

If the phlebotomist observes any of these symptoms or if the patient verbalizes them at any time during the venipuncture procedure, the needle must be removed immediately even if the collection is incomplete. If a second procedure is to be attempted, the phlebotomist must perform the venipuncture on a different site, preferably on the opposite arm. Complications from nerve damage can be permanently disabling and include, but are not limited to, lack of limb mobility, lack of grip strength, and lingering pain.[73-81]

The phlebotomist must document the incident, report to the health care provider, and recommend that the patient seek medical evaluation according to facility policy.

## 4.3 Hematoma

During venipuncture, blood may leak out of the vein and clot under the skin. Depending upon how much blood leakage has occurred, a hematoma may appear as a nonswollen, purplish bruise or may be a swollen, raised bruise near the venipuncture site. To prevent a hematoma when performing a venipuncture, the phlebotomist must:

- Remove the tourniquet before removing the needle.
- Maintain needle placement throughout the collection.
- Remove the tube from the holder before needle removal.
- Before bandaging, take steps to determine whether the puncture site is sealed according to Subchapter 2.11.

If a hematoma begins to form during the venipuncture, the phlebotomist must remove the needle immediately and apply pressure. The phlebotomist must follow facility policy for hematoma care.

**NOTE:**

If a hematoma begins to form during the venipuncture, the phlebotomist must remove the needle immediately and apply pressure.

## 4.4 Hemolysis

To prevent hemolysis when performing a venipuncture, the phlebotomist should:

- Avoid collecting through a VAD or during an IV start.[82-84]
- If using a syringe and needle, make sure the needle is fitted securely on a syringe to avoid frothing.
- When using a syringe, avoid pulling the plunger back too forcibly.[85]
- Avoid forcefully transferring the syringe's contents into the tube.[85]
- Discontinue sluggish draws that can be caused by collapsed veins and improper needle placement.
- Because the interior diameters of needles vary, avoid the use of 25-gauge needles if frequent hemolysis is observed.[86,87]
- Avoid tourniquet constriction longer than one minute.[88]
- Avoid mixing the specimens vigorously.
- Gently transport the specimen to avoid shaking.

## 4.5 Monitoring Blood Volume Collected

Maximum blood volume information is intended to guide health care workers in effectively coordinating test orders and blood collection to minimize the risk of iatrogenic anemia, especially for the pediatric or critically ill patient.

The total amount of blood collected on each collection from pediatric and other patients susceptible to iatrogenic (phlebotomy-induced) anemia must be monitored and limited based on weight, blood draw, and/or specified time period to prevent iatrogenic anemia.[89-91]

**NOTE:** The blood volume for children is approximately 75 to 80 mL/kg and is higher in newborns.[92] Some references suggest 65 to 70 mL/kg when calculating total blood volume in adults. Blood specimen collection should be limited to 1% to 5% of total blood volume within a 24-hour period and to 10% of total blood volume over an eight-week period for pediatric or critically ill patients. See Appendix B for additional information.[93]

## 4.6 First Aid

Health care personnel with advanced emergency first-aid training should be on site to evaluate and treat patients who develop complications during venipuncture. These emergency first-aid responders should be identified to phlebotomists, and their emergency contact phone numbers should be posted in phlebotomy collecting areas.

Employees who have direct patient contact or work in areas where first aid is not immediately available should be trained in first aid. A basic first aid kit should be available and restocked periodically.

Cardiopulmonary resuscitation (CPR) training is recommended for workers situated in the absence of an infirmary, clinic, or hospital in proximity to the workplace, or who have direct patient contact.

An automated external defibrillator (AED) may be located in or near the patient care areas for the emergency treatment of irregular, sporadic, or absent heart rhythms. If an AED is available for use, staff should be trained in CPR and in AED operation. AEDs and supplies should be checked periodically by a person specifically trained to do so.

CLSI document GP17[94] provides detailed information on medical laboratory safety, including first aid.

**IMPORTANT NOTE:**

**CAUTION:** Ammonia inhalants may be associated with adverse effects and must not be used.[95-97]

## 4.7 Dizziness, Syncope, or Unexpected Nonresponsiveness

Throughout the procedure, phlebotomists must be prepared for the patient to lose consciousness, and be ready to react according to facility policy. See Appendix D for additional information on preventing syncope.

**CAUTION:** Ammonia inhalants may be associated with adverse effects and must not be used.[95-97]

The procedure for dealing with a patient who has fainted or is unexpectedly nonresponsive is:

1. If the needle is in the patient's arm, remove the tourniquet. Then, remove the tube and needle, activate the safety feature, discard the needle, and apply pressure.
2. Where practical, lay the patient flat or lower his/her head and arms, if the patient is sitting. If the patient is seated in an adjustable venipuncture chair, recline the patient.
3. Loosen tight clothing.
4. Maintain the patient in a recumbent position until fully recovered. If the patient has fainted, notify the designated first aid–trained personnel. Continue monitoring the patient until first aid–trained personnel arrives.

## 4.8 Nausea

The procedure for dealing with a patient who is experiencing nausea is:

1. Make the patient as comfortable as possible and provide an emesis basin or carton.
2. Instruct the patient to breathe deeply and slowly.
3. Apply cold compresses to the patient's forehead.
4. Notify the designated first aid–trained personnel according to facility policy.

## 4.9 Vomiting

The procedure for handling a patient who vomits is:

1. Give the patient an emesis basin or carton and have tissues ready.
2. Give the patient water to rinse out his/her mouth.
3. Notify the designated first aid–trained personnel according to facility policy.

## 4.10 Convulsive Seizures

When dealing with a patient who is having convulsions, follow the procedure below.[98]

1. Remove the tourniquet and collection tube, withdraw the needle, activate the device's safety feature, and apply pressure.
2. If possible, move patient to the floor or support him/her on the chair.
3. Move sharp objects and furniture away from the patient.
4. Cushion the patient's head if he/she has collapsed onto the floor.
5. Note the time that the seizure started.
6. Notify the designated first-aid trained personnel.
7. Stay with the patient until he/she has fully recovered.
8. Talk calmly and reassuringly to the patient during and after the seizure.
9. Allow the convulsions to happen. Do not restrain the patient. Report the frequency and duration of seizures to emergency personnel.

## 4.11 Incident Reports

Following facility guidelines, the phlebotomist must immediately report to his/her supervisor all complications and incidents occurring during the draw, including exposure to blood and other infectious materials.

# Chapter 5

# Special Situations

## This chapter includes:

- Collection of specimens for blood culture and therapeutic drug monitoring
- Collections from VADs
- Collections from patients in isolation settings

**NOTE:**

To minimize the risk of contamination with skin flora, the venipuncture site requires a minimum 30-second friction scrub with an appropriate disinfectant.

# 5 Special Situations

## 5.1 Blood Culture Specimens

### 5.1.1 Skin Disinfection

To minimize the risk of contamination with skin flora, the venipuncture site requires a minimum 30-second friction scrub with an appropriate disinfectant. When using commercially packaged preparation kits, the phlebotomist must follow the manufacturer's instructions for use. Many disinfectants have been used clinically during the past 50 years, including rubbing alcohol (70% isopropyl), tincture of iodine, povidone-iodine, iodophors, chlorine-peroxide, and chlorhexidine gluconate.[99]

Iodine-containing preparations require sufficient time to disinfect surfaces (30 seconds for tincture of iodine and 1.5 to two minutes for iodophors). Iodine should be removed from the skin once the procedure is complete (see CLSI document M47[100]). Chlorhexidine gluconate requires the same amount of time as tincture of iodine but is not associated with allergic reactions and does not need to be cleaned off the skin after the venipuncture is completed. Chlorhexidine gluconate is the recommended skin disinfectant for older infants, children, and adults. However, it needs to be used with care in premature infants or infants under 2 months of age, because it can cause irritation or chemical burns.[101,102]

Disinfection for the blood culture collection typically includes[45,103]:

- Cleansing the site with 70% isopropyl alcohol
- Allowing the alcohol to air dry
- Applying the main disinfectant
- Allowing the disinfectant to remain in contact with the skin for the manufacturer's recommended duration

The phlebotomist must not palpate the vein after skin disinfection unless a sterile glove is worn or the disinfection procedure is repeated.

**NOTE:**

Immediately before performing the venipuncture, the phlebotomist must disinfect the rubber septum on the blood culture bottle(s) or tube(s) with 70% isopropyl alcohol and allow it to dry.

### 5.1.2 Blood Culture Collection

Immediately before performing the venipuncture, the phlebotomist must disinfect the rubber septum on the blood culture bottle(s) or tube(s) with 70% isopropyl alcohol and allow it to dry.

Routine blood cultures normally include paired aerobic and anaerobic blood culture bottles. When less than the recommended volume of blood is collected for culture, the aerobic bottle should be filled to its recommended volume first. Any remaining blood should then be inoculated into the anaerobic vial.

Blood cultures can be collected directly into collection tubes containing sodium polyanetholsulfonate (SPS). No other anticoagulant is acceptable.

The blood from an SPS tube can then be transferred to blood culture medium. Collecting blood directly into blood culture vials (eg, using a multisample needle and tube holder assembly or drawing from a VAD with a tube holder assembly) is not recommended because of the risk of broth-medium reflux back into the vein and the volume of blood collected into the bottle or tube cannot be controlled. **NOTE:** At least one manufacturer markets blood culture bottles approved for direct filling. Manufacturer's instructions must be followed. Blood culture bottles should be kept upright when these devices are used. Blood culture bottles and/or tubes should be inverted gently several times to prevent clotting. Some studies show a significant reduction in blood culture contamination when the first 1 mL of blood is discarded before filling blood culture bottles or tubes. When tubes were used for the discard, their stoppers were disinfected with alcohol before collection. More studies are necessary to recommend a discard before all blood culture collections.

Blood cultures obtained from VADs, such as IV catheters and ports, are associated with greater contamination rates than blood cultures obtained by venipuncture.[104-108] Although blood occasionally may need to be obtained from VADs, it should be paired with a second culture obtained by venipuncture to assist in interpretation of a positive result.

There are time and temperature requirements for collection, transport, and storage of specimens for blood culture. Refer to the manufacturer's instructions for specific blood volume requirements. Refer to CLSI document M47[100] for additional details.

## 5.2 Therapeutic Drug Monitoring

For therapeutic drug monitoring, the medication dose, the time the last dose was administered, and the specimen collection time must be recorded accurately in the laboratory records (paper or electronic) containing collection information.

## 5.3 Vascular Access Devices and Infusions

VADs include a wide range of infusion catheters and ports. The most commonly encountered device is the short peripheral catheter. It is inserted in the arm or hand and used for infusion of fluids, medications, and blood products. These catheters are approximately 1 inch (2.5 cm) in length and may be left in place for up to 96 hours or longer, depending on facility policy and patient condition. Longer peripheral catheters of 4 to 6 inches (10 to 15 cm) are occasionally used. Peripherally inserted central catheters, commonly known as PICC lines, are generally inserted into a vein in the arm and threaded up toward the heart. Catheter tips rest in the central vasculature, such as in the inferior or superior vena cava. Multilumen catheters, which are tunneled through the patient's chest wall into a large central vein, and implanted ports are also considered central catheters.

**NOTE:**

Whenever possible, blood must be collected from the opposite arm when an IV fluid is being administered into a patient's arm.

**NOTE:**

See Appendix C for a procedure for collection proximal to an IV site.

### 5.3.1 Intravenous Fluids

Collecting blood from an arm that is being infused with IV fluid carries a potential risk for erroneous and misleading test results.[26,109] Whenever possible, blood must be collected from the opposite arm when an IV fluid (including transfused blood products) is being administered into a patient's arm. When not possible, collections from an arm in which fluids are being infused should be below (distal to) the infusion site. Specimen collections above an IV site have a very high chance of contamination with fluid and/or medications and are not recommended unless all other options have been exhausted. See Appendix C for a procedure for collection proximal to an IV site.

Results for analytes that are present in the infusing fluids have the highest risk of inaccuracy. When blood is collected from an arm with infusing fluids, the site and the fluids being infused must be documented or otherwise reported to the laboratory to facilitate their inclusion with test results. Temporarily discontinuing IV infusions must be performed only by authorized health care professionals according to specific facility policy.

It is recommended that specimens collected distal or proximal to an IV site be identified as such (with left or right arm indicated). This information should accompany the results.

Some laboratories use capillary puncture blood collection when venous access is not readily available.

If blood needs to be collected on an arm in which IV fluid is being infused, the procedure should be completed distal to the IV site.[26] This procedure must be followed when collecting blood distal to an IV site:

1. Ask the responsible health care professional to turn off the IV infusion for at least two minutes before venipuncture. Care must be taken to ensure that the flow has been completely discontinued.
2. Apply the tourniquet between the IV site and the intended venipuncture site.
3. Perform the venipuncture. Alert the responsible health care professional that the specimen collection has been completed and the infusion may be restarted.

### 5.3.2 Blood Sampling From Vascular Access Devices

While blood specimens are best collected by direct venipuncture, doing so is not always feasible. Care must be exercised when obtaining blood specimens by venipuncture in extremities where VADs are present. It is well established that collecting blood through VADs significantly increases the likelihood of hemolysis.[84] Blood specimens obtained from any type of VAD can potentially be contaminated with fluids and/or

medications, which will produce erroneous test results. Withdrawing a discard volume can help reduce problems with fluid- or medication-contaminated specimens. **NOTE:** Specimens intended for coagulation testing should not be collected with the same VAD lumen in which anticoagulant medications had been infusing or where heparin has been used to maintain line patency. When following this recommendation is not possible and unexpected high levels are reported, peripheral venipuncture is recommended to confirm the high level before changing medication.[14]

Venipuncture must never be attempted above a PICC insertion site. To do so risks catheter puncture. When performing venipuncture in an extremity with a PICC in place is unavoidable, the tourniquet must be placed below the PICC insertion site. The blood specimen may then be obtained below the tourniquet.

Tourniquet application and venipuncture in the arms and hands is generally permissible in patients with multilumen catheters and implanted ports that have been tunneled through the chest wall. Facility policy must be followed.

Phlebotomists must have completed thorough and documented training before collecting blood from VADs. Facility policy must be followed. To obtain a specimen from a VAD, the properly trained health care professional must:

1. Completely turn off all infusing IV fluids and blood products.[14]
2. Flush the VAD with 5 to 10 mL preservative-free 0.9% sodium chloride, using the largest available VAD lumen, or follow facility and manufacturer's guidelines. If a specimen is collected for drug levels, the specimen must be collected from a catheter lumen not being used for infusion of the same drug.[14] Withdraw a discard amount equal to two times the dead-space volume for noncoagulation testing. When drawing coagulation studies from a catheter lumen in which anticoagulation therapy had been infusing, withdraw six times the dead-space volume.[110,111] As a general guideline, 5 mL of blood may be a sufficient discard volume for the majority of central lines; however, some central lines require up to 11 mL as a discard volume. If a standard peripheral IV catheter (approximately 1 inch [2.5 cm] in length) must be used, a discard of 1 mL should be sufficient. Knowing the dead-space volume when drawing coagulation studies is important to ensure accurate coagulation results. Calculating discard volumes is particularly important in order to prevent iatrogenic anemia in pediatric and critically ill patients. If drawing directly into tubes, use a plain, nonadditive tube or a tube of the same type as the first tube to be collected.

**NOTE:**

Phlebotomists must have completed thorough and documented training before collecting blood from VADs.

**NOTE 1:** When drawing coagulation specimens from saline locks, withdraw twice the dead-space volume and discard before collecting the specimen to be tested (see CLSI document H21[67]).[112]

**NOTE 2:** If blood cultures are the only tests being collected, a discard is not required (see CLSI document M47[100]).

3. Obtain the specimen. If drawing directly into tubes, refer to Section 6.4.13 for information on venous blood collection systems. Safety transfer devices must be available for transferring from a syringe into a blood collection tube. A needle must not be used to transfer from a syringe.

4. Flush the VAD with 5 to 10 mL of preservative-free 0.9% sodium chloride or follow facility and manufacturer's guidelines.

5. Make a notation in the patient record that the specimen was collected with a VAD.

See CLSI document H21[67] for more details.

## 5.4 Patient Isolation

Patients are isolated to prevent the spread of disease to or from other patients, visitors, or employees.[113] Immunocompromised patients may also be placed in isolation to be protected from outside contamination.

### 5.4.1 Isolation Systems

Each hospital determines the system that protects its particular mix of patients, visitors, and employees from health care–acquired infections. It is important that employees understand and use the appropriate precautions set forth by facility policy.

Hospital procedures for collecting blood specimens from isolation patients are available through the facility's infection control practitioner, infection control committee, or hospital epidemiologist and must be followed. Such a protocol is illustrated in Subchapter 5.4.2.2. Some hospitals may provide for disinfection, dedication, or disposal of equipment used in isolation rooms.

Gowns, gloves, masks, etc., should be kept in the clean area. In some hospitals, a stand containing these supplies is kept outside the room. Some facilities have an anteroom that serves as the "clean area," where caregivers and visitors entering the room can remove their coats, other apparel, and personal items, then don appropriate personal protective equipment (PPE) before entering.

### 5.4.2 Isolation Room

#### 5.4.2.1 Procedure to Follow Before Entering the Isolation Room

1. Read and follow the isolation sign and instructions on the door. It explains the type of isolation PPE to be worn and the procedure to use.
2. Check the orders and assemble an adequate amount of necessary equipment for the patient.
3. Leave the collection tray or cart outside the room.

#### 5.4.2.2 Procedure to Follow in the Isolation Room

1. Read and follow facility policy for donning PPE and for tourniquet use for isolation patients. **NOTE:** If any paper records need to be brought in and out of the patient's room, they need to be placed into a plastic protective cover before coming into the room. The protective cover will need to be discarded in the anteroom.
2. Wash hands. Put on gloves.
3. Take **only** the required supplies into the isolation room.
4. Place paper towels or other suitable protective barrier on the table and place the supplies on them.
5. Obtain blood specimens in the usual manner, avoiding any unnecessary contact with the patient and items in the room.
6. After mixing, place the filled tubes on the protective barrier.
7. Perform postvenipuncture care as described in Subchapter 2.11.
8. Dispose of blood collection assembly into a sharps container, consistent with applicable regulations and according to facility policy. Discard any other disposable supplies before leaving the isolation room.
9. Dispose of the tourniquet in the proper container. Some facilities assign a tourniquet for exclusive use on each isolation patient. Facility policy must be followed for single-patient tourniquet use.
10. Label tubes.

#### 5.4.2.3 Procedure to Follow in the Anteroom

1. If required by facility policy, decontaminate the tubes before leaving the isolation room.
2. Place tubes in a secondary container (eg, sealable, leakproof plastic bag) that will hold the specimen if the primary container breaks or leaks in transit to the laboratory.
3. Remove and dispose of PPE in the proper container while in the anteroom. Masks and respirators should be removed outside of the patient's room or in the anteroom.[114]
4. Wash hands according to facility policy and Centers for Disease Control and Prevention guidelines. See CLSI document M29[2] for additional information.

# Chapter 6

# Quality Management System Elements

## This chapter includes:

- Descriptions of the quality system essentials (QSEs) as they apply to the venipuncture process

# 6 Quality Management System Elements

A QMS is required for a laboratory's work operations to fulfill stated quality objectives. The QMS can be divided into 12 QSEs, as described in CLSI document QMS01.[115] The QSEs are foundational building blocks that function effectively to support the laboratory's path of workflow. Each staff member should know, understand, and be able to describe the QSE activities that pertain to his or her job responsibilities, and apply them as required in order to operate within the standard of care.

An overview of the QSEs that pertain to collection of diagnostic blood specimens by venipuncture is presented in the following subchapters. For a more complete description of each QSE, refer to CLSI document QMS01.[115]

**NOTE:**

Facilities must have a policy that includes the disinfection of phlebotomy trays and carts, equipment, and outpatient collection stations on a scheduled basis and, at minimum, whenever contaminated with visible blood or other potentially infectious material.

## 6.1 Customer Focus

The facility should continuously solicit feedback from its customers and compare the input with the facility's ability to meet customer needs and expectations and measure the success of its efforts. Internal customers may include all individuals working in the preexamination functions of specimen collection, processing, and distribution. External customers may include patients, other health care professionals, testing laboratories, and accrediting organizations.

Employees should be empowered to solicit customer input and a mechanism should be in place to report positive and negative customer feedback. Staff members should be given guidance on how to handle situations when a customer's expectations are not met. Negative feedback should be reported immediately so that a prompt investigation can be initiated into the complaint's validity and cause. Actions taken as a result of the complaint should be communicated to the customer.

## 6.2 Facilities and Safety

The facility must ensure that the physical environment for venipuncture procedures and the safety program reflect QMS requirements. Facilities must have a policy that includes the disinfection of phlebotomy trays and carts, equipment, and outpatient collection stations on a scheduled basis and, at minimum, whenever contaminated with visible blood or other potentially infectious material.

Phlebotomists should perform venipuncture in a clean, well lit, quiet, and private environment. Reasonably soundproof rooms for pediatric patients should be considered. The room should have facilities to allow the phlebotomist to wash his/her hands between patients.

### 6.2.1 Venipuncture Chairs

Venipuncture chairs should be designed for the maximum comfort, accessibility, and safety of the patient and phlebotomist, and must meet the requirements stated in Subchapter 2.8.1.1. Both armrests of the chairs should be adjustable so the best venipuncture position for each patient can be achieved.

### 6.2.2 Phlebotomy Area

The following elements should be considered when designing the phlebotomy area:

- A central desk should be considered to serve as a dedicated area for processing daily and future test requests. It should contain a telephone system for handling emergency test request calls, including a paging system for contacting any phlebotomist who is collecting specimens outside the central area. The central desk may also be used to greet patients and to enter their information into the paper or electronic database.
- Work benches and tables should be set up in an ergonomic manner for the phlebotomist to function with minimum physical stress. Supplies should be placed within reach.
- The storage area should be large enough to accommodate necessary supplies.
- Counter space should be adequate and clean for efficient specimen sorting, labeling, and handling.
- Time-recording devices (eg, time stampers, information system) should be located for convenient specimen collection time recording.
- The reception and collection areas should be designed for maximum protection of patient privacy and confidentiality.
- The collection area must be set up to facilitate patient monitoring throughout the procedure.

### 6.2.3 Accessibility

Facilities should be designed and furnished to accommodate any patient. Considerations need to reflect regional guidelines and standards. The following considerations are highly recommended.[116]

- Allow or make modifications to policies, practices, and procedures to make health care services fully available to individuals with disabilities.
- Remove physical barriers to services when possible. If not possible, offer adequate services without barriers to ensure safe delivery of specimen collection services in an alternate setting or location.

- When redesigning and building new facilities, it is recommended that applicable regional guidelines and standards regarding accessibility be consulted.[116]

The facility should have:

- An entrance of sufficient width to allow access to the outpatient phlebotomy area
- A clear path to the collection station
- Adequate space on either side of the phlebotomy chair, wheelchair, stretcher, table, etc., to allow for safe and effective transfers and collection of blood specimens
  - Do not place a phlebotomy chair, wheelchair, or table against a wall in such a way that it prohibits access to one side of the patient.
- Suitable devices, such as a mobile phlebotomy chair arm for wheelchair-bound patients, to ensure an adequate and safe surface to complete the procedure
- A minimum space of 30 inches (76 cm) wide and 48 inches (122 cm) deep on one side of the phlebotomy chair (eg, accessible to a patient on crutches)
- Sufficient turning space in the phlebotomy area or room for a patient in a wheelchair to make a 180° turn
- At least one bariatric-size chair for patients who need additional space
- Reclined or reclining furniture in the vicinity to lay a patient in a recumbent or semirecumbent position due to syncope risk or ill health
  - In large outpatient collection centers, two recliners or a suitable alternative are recommended in case one is occupied.
- Hydraulic chairs to raise and lower patients to adequate height, which may help prevent back problems for the phlebotomist
- Wedges, blankets, pillows (with disposable case), and other devices that may be helpful in positioning a patient
- Phlebotomy chairs with movable arms and reticulating surfaces to help move patients to and from the chair

## 6.3 Personnel

The institution must ensure an adequate number of qualified, well-trained, competent personnel are available to perform and manage venipuncture processes.

The necessary education, training, skills, experience, and where applicable, certification and licensure for each job title related to venipuncture processes must be determined (see CLSI document GP48[117] for details on phlebotomy training programs).

**To achieve and maintain the desired competence to perform the necessary tasks, personnel must participate in the following activities:**

- Initial orientation to the organization
- Initial, ongoing, and remedial training
- Initial and periodic competence assessment and performance evaluation
- Continuing education and professional development

See CLSI document QMS03[118] for more details.

Personnel records must be kept current and include:

- Job qualifications
- Competence assessments and performance evaluations
- Continuing education records
- Dates of employment
- Staff identification (eg, signatures, initials, and codes) where applicable

## 6.4 Purchasing and Inventory

Supplies in the preexamination phase of laboratory testing include durable (ie, reusable) and consumable (ie, disposable) materials. Consumable materials with an expiration date must not be used beyond the date provided. Sterile consumables must be assessed for package/container integrity and discarded if any evidence exists that the sterility might have been compromised.

The laboratory should have a process for qualifying suppliers, making selection decisions, and acquiring the supplies. Evaluation of safety equipment should include input from the end user (phlebotomist). Blood collection devices should have safety features to prevent accidental exposure.

The facility must ensure that an appropriate inventory of these supplies is kept at all times. For identified critical materials, records are required for:

- Date received
- Lot number
- Whether quality requirements were met and whether there are any follow-up requirements or actions
- Date material is placed in service or disposition if not used

The supplies described in the following subchapters should be available at any location where venipunctures are regularly performed.

### 6.4.1 Phlebotomy Carts

Phlebotomy carts, designed to roll smoothly and quietly over all types of surfaces without tipping over, may be useful. The top shelf or surface should be used for easy access to the necessary collection supplies, but the bulk of supplies are typically kept below in storage drawers.

### 6.4.2 Blood Collection Trays

Blood collection trays should be lightweight and easy to handle, with enough space and compartments for the various necessary supplies. Facilities must have a policy that includes the disinfection of trays on a scheduled basis and, at minimum, whenever contaminated with visible blood or other potentially infectious material. Trays must not be placed on patient surfaces (eg, beds, bedside trays, tables) unless the surface is protected from contact with the tray by a protective barrier (eg, disposable pad).

### 6.4.3 Gloves

Disposable latex, polyethylene, or nitrile gloves provide barrier protection.

Patients and phlebotomists may develop dermatitis from prolonged exposure to latex materials (eg, gloves, tourniquets). Facilities should consider nitrile, polyethylene, or other nonlatex alternatives, including gloves without a powdered lubricant. Phlebotomists may wear cotton gloves under latex or plastic gloves.

**NOTE:**

The facility must establish compatibility between needles, holders, and tubes before use.

### 6.4.4 Needles and Holders

Several different blood collection systems are available that use different principles. Refer to the manufacturer's instructions for use.

The facility must establish compatibility between needles, holders, and tubes before use. Tube holders and syringes must not be preassembled before patient identification unless packaged as preassembled devices by their manufacturer. For more information on venous blood collection tubes and additives, refer to CLSI document GP39.[119]

Needles must be sterile and single-use. Needles and winged blood collection sets are color-coded according to their respective gauge sizes. The gauge number indicates the size of the needle. A large gauge number indicates a small needle, while a small gauge number indicates a large needle. Typical sizes for venipuncture range from 21 through 23. The use of some 25-gauge needles increases the risk of hemolysis and rejected specimens.

Use of safety-engineered blood collection devices is strongly encouraged. Their use must reflect the most current regulatory and accreditation requirements.

In order to prevent potential worker exposure, the safety feature must be activated immediately after specimen collection and discarded according to manufacturers' instructions and regulatory and accreditation requirements.

Devices must be stored in a secure location to prevent injury to other personnel (eg, housekeeping) and theft for illicit use.

**CAUTION:** Safety-engineered devices not used according to manufacturers' instructions for use may result in an increased risk of accidental needlestick injury.

**NOTE:**

Use of safety-engineered blood collection devices is strongly encouraged.

**IMPORTANT NOTE:**

**CAUTION:** Safety-engineered devices not used according to manufacturers' instructions for use may result in an increased risk of accidental needlestick injury.

### 6.4.5 Venous Blood Collection Tubes

Venous blood collection tubes are sterile and manufactured to withdraw a predetermined volume of blood. Instructions furnished in the manufacturer's package insert of venous blood collection tubes should be available. Blood collection tubes must be stored in accordance with the manufacturer's recommendations. For information on venous blood collection tubes, refer to CLSI document GP39.[119]

### 6.4.6 Tourniquets

Supplies and/or devices used to constrict blood flow must be available. Examples include:

- Latex-free, single-use disposable tourniquets. If the recommended single-use tourniquets are unavailable, multiple-use tourniquets must be discarded or disinfected when visibly soiled. Although reusable rubber or fabric-type tourniquets with closure tape, plastic clip, buckle, or similar types of fastening are available, they are not recommended from an infection control standpoint.
- Blood pressure cuff inflated to just below the patient's diastolic blood pressure.[39] Do not use higher pressures, as that may impair arterial blood flow to the extremity.

### 6.4.7 Antiseptics

Antiseptics are used to clean the skin before venipuncture. For example:

- 70% isopropyl
- Appropriate antiseptic for blood cultures (see Subchapter 5.1.1)

**NOTE:**

Neither cotton nor rayon balls are recommended for postvenipuncture care.

### 6.4.8 Gauze Pads

Gauze pads (ie, 2 × 2 inches [5 × 5 cm] or 3 × 3 inches [7.5 × 7.5 cm]) must be available. Neither cotton nor rayon balls are recommended for postvenipuncture care because of the possibility of dislodging the platelet plug at the venipuncture site.

### 6.4.9 Puncture-Resistant Disposal Container

An approved sharps container, consistent with applicable regulations, must be available for disposal of the contaminated needle assembly. Such containers typically have a color regulated by each country and a biohazard symbol.

### 6.4.10 Cooling Devices

An ice slurry or other cooling device should be available for specimens that require immediate chilling.

### 6.4.11 Bandages

Adhesive bandages, preferably hypoallergenic, and/or gauze pads must be available. Gauze wraps should be available for sensitive or fragile skin.

### 6.4.12 Warming Devices

Warming devices may be used to dilate blood vessels and increase flow. When using commercial warmers, manufacturers' recommendations must be followed. Warming techniques and devices must not exceed 42°C[120,121] (see CLSI document GP42[122]).

### 6.4.13 Venous Blood Collection Systems

The phlebotomist must select the appropriate blood collection system according to the patient's physical characteristics, the instructions provided by the testing laboratory, and the tests requested.

Whenever possible, blood specimens should be collected by venipuncture using a blood collection system that collects the blood directly into tubes. For greater detail on venous blood collection tubes and additives, refer to CLSI document GP39.[119] Holders, needles, and tubes are designed by manufacturers to work as a complete set. Use of a mismatched third party product could result in system failure (eg, using a holder from "Company A" with needles from "Company B" and/or tubes from "Company C"). The laboratory must ensure compatibility among all components. If a third-

party product is considered, the device must be tested by the laboratory and/or phlebotomist and used only if found compatible. When venous blood collection tubes are used, the phlebotomist must select the correct types and sizes.

#### 6.4.14 Syringe

Syringes must be sterile and discarded after use. Sterility of the device should be ensured before use.

#### 6.4.15 Winged Blood Collection Set

A winged blood collection set consists of a needle for accessing the vein and a tubing that terminates with one of two adapters to fit onto either a syringe or tube holder. Unless preassembled, a tube holder or syringe must be attached before use.

#### 6.4.16 Safety Transfer Devices

Safety transfer devices must be available for transferring specimens from a syringe into a blood collection tube. A needle must not be used to transfer blood from a syringe.

### 6.5 Documents and Records

The facility needs a system that manages both its paper and electronic records to ensure that all patient records are created, identified, changed, reviewed, retained, stored, and maintained in a manner that meets its QMS requirements.

The laboratory must develop approved policies, processes, and procedures for collection of diagnostic venous blood specimens.

See CLSI document QMS02[123] for more information on document and records.

A test requirement directory, collection manual, or other reference document listing the tube and volume requirements for various tests, specimen handling instructions, and precautions is required in order to select the appropriate collection device. This directory must be available for anyone collecting blood specimens at the facility or sending specimens to the laboratory for analysis.

**NOTE:**

The laboratory must develop approved policies, processes, and procedures for collection of diagnostic venous blood specimens.

### 6.6 Information Management

The facility must incorporate a commitment to confidentiality of patient-related information into its processes for managing incoming and outgoing information according to regulatory and accreditation requirements.

## 6.7 Nonconforming Event Management

The facility must put in place a nonconforming event (NCE) management program. The purpose of an NCE program is to:

- Identify and characterize problem-prone processes in a medical laboratory's path of workflow and within the supporting processes of the QMS.
- Improve process quality and, thereby, improve both patient and employee safety.
- Prioritize initiatives, allocate resources, and implement process and procedure changes that support continual improvement (CI) (refer to Subchapter 6.9).
- Gain management's commitment to removing the cause of NCEs.

Examples of phlebotomy-related NCEs in the preexamination phase include:

- Deviations from approved phlebotomy procedures
- Sample mislabeling
- Improper sample collection, transport, handling, and/or processing practices
- Customer service incidents
- Safety infractions
- Breaches of confidentiality

The NCE process must include the following activities:

- Documentation of each NCE episode and associated actions
- Classification of the event type and its seriousness
- Immediate remedial action, when possible
- Investigation and corrective action

See CLSI document QMS11[124] for more information on NCE management.

## 6.8 Assessments

The facility must establish a program to identify quality indicators. Quality indicators are selected by management to provide evidence that the facility is meeting its quality goals. Quality indicators are observations, statistics, or data that typify the performance of a given work process.

Some examples of venipuncture indicators include:

- Presence of accurate patient ID (eg, wristband) at the time of specimen collection
- Blood culture contamination rates
- Specimen rejection rates due to collection error (eg, hemolysis, quantity not sufficient)
- Patient satisfaction surveys
- Staff responsiveness to stat or routine orders

Action is needed when the information from indicators demonstrates unacceptable performance or trending in that direction. See CLSI document QMS12[125] for more information on quality indicators.

## 6.9 Continual Improvement

Staff members need to understand that they have an important and ethical responsibility to submit suggestions for improvements, especially when the suggestion leads to increased patient safety.

See CLSI document QMS06[126] for more information on continual improvement.

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# Chapter 7

# Conclusion

**NOTE:**

Strict adherence to this standard is essential so that blood specimens are collected in a manner that preserves the integrity of the specimen and prevents collection method–related erroneous test results and undesirable patient outcomes.

## 7 Conclusion

Phlebotomy is the most common invasive medical procedure in health care. Strict adherence to this standard is essential so that blood specimens are collected in a manner that preserves the integrity of the specimen and prevents collection method–related erroneous test results and undesirable patient outcomes. The quality of care a patient receives can be drastically compromised by deviating from this standard.

Individuals investigating patient injuries that have occurred during phlebotomy must rely heavily on this standard to establish the standard of care. To effectively manage these risks and those arising from managing patients according to laboratory results altered during the collection process, every health care facility's policy must reflect the prevailing standard of care. Deviations in practice should be disciplined with remedial training. Public trust is placed with all who manage and train blood collection personnel to ensure their compliance and competence.

# Chapter 8

# Supplemental Information

## This chapter includes:

- References
- Appendixes
- The Quality Management System Approach
- Related CLSI Reference Materials

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# Appendix A. Difficult Collection

## A1 Venipuncture in Children

Venipuncture in pediatric patients can result in pain and anxiety. Traumatic experiences early in life may cause long-lasting effects, including a decreased threshold of tolerance, a lessened capacity to cope with pain and anxiety, and heightened pain perception.[1]

Except where indicated below, the phlebotomist must follow the procedures for adult venipuncture as described in this standard.

Strategies to consider for reducing stress and anxiety for the pediatric population include:

- **Applying verbal communication skills.** Use age-specific vocabulary to communicate at the patient's level.[2]
- **Patient participation.** When possible, giving a patient a role to play can lessen anxiety by empowering the patient.
- **Distractions.** Age-appropriate distractions (stimuli) have been shown to minimize stress and anxiety associated with painful medical procedures.[2] Videos, movies, interactive electronic games, and involvement in counting or singing songs can be used.[3,4]
- **Parents as coaches.** Parental anxiety and stress can have a negative effect on the child's coping mechanisms. It may be helpful for parents to participate by contributing coping strategies and direction and by providing positive reassurance.[5]
- **Comfort positioning.** To help minimize anxiety, it is recommended that children be held by parents when possible.[6]
- **Use of an assistant.** An assistant to stabilize the arm and comfort the patient is essential for every pediatric draw and preferable to restraining devices.
- **Drugs and devices.** Pharmacological approaches and nonpharmacological alteration of nerve transmission has been shown to help minimize pain associated with medical procedures.[7] These tactics include:
  - Devices used to provide vibration and cold to minimize pain transmission[8]
  - Topical anesthetics
    - These medications are typically prescribed by qualified health care professionals and have been shown effective in reducing pain responses during pediatric venipuncture. However, they may require health care personnel who are licensed to administer medication.[9]
- **Performing heel punctures and finger punctures.** These methods may be more successful alternatives to venipuncture for pediatric patients. Refer to CLSI documents GP42[10] and NBS01[11] for detailed information.

Smaller-bore needles (eg, 23-gauge) and winged blood collection sets are recommended for accessing smaller, fragile veins. Syringe use should also be considered, because the vacuum pressure of an evacuated tube exerted on fragile vasculature can result in vein collapse and an unsuccessful collection.

## Appendix A. (Continued)

The use of low-volume collection tubes is also recommended to:

- Minimize the vacuum pressure that could otherwise cause vein collapse.
- Minimize the volume of blood needed, thereby minimizing the duration of the collection and the risk of iatrogenic anemia.

### A2 Other Difficult Situations

Patients may present with a variety of conditions and characteristics that can challenge phlebotomists, including:

- **Elderly patients.** Geriatric patients may present with difficult-to-locate veins, decreased vein elasticity, rolling and collapsing veins, or structurally fragile vasculature. Limited range of motion can prevent manipulation and impede vein location. In addition, dehydration and low blood pressure can contribute to difficulty in locating veins. Prewarming venipuncture sites may help locate veins. To prevent veins from rolling, anchor veins securely. To prevent vein collapse, the use of low-volume tubes, small needles, and syringe systems with gentle pulling pressure is recommended.
- **Obese patients.** Veins may be deep, challenging palpation and impeding vein location. Longer needles may help access deeper veins. Rolling veins may also present a challenge. Bariatric chairs for outpatients will prevent discomfort and embarrassment. For successful vein location, prewarming venipuncture sites can be helpful in this population as well. The use of a vein-finder device and a bariatric blood pressure cuff may enhance vein location. Adipose tissue can mimic the feel of a vein; experienced personnel may be required. Anchoring veins securely is critical to a successful venipuncture.
- **Drug-addicted patients.** Drug addiction can contribute to scarring of the epidermis and the vasculature, complicating the palpation of veins. Firmly anchoring scarred veins is essential to prevent rolling. Excessive scarring may preclude the use of traditional venipuncture sites. However, draws outside of acceptable sites should be avoided. Patient recommendations for needle insertion may not be appropriate.
- **Oncology patients.** Chemotherapy can alter the vasculature and affect vein patency and palpability. Chemotherapy can also contribute to rolling veins. The same techniques and equipment suggested for elderly patients (above) to help locate veins, prevent vein collapse, and prevent rolling veins are recommended.
- **Needle-phobic patients.** Patients who fear needles may have had a negative encounter with sharps, or chronic conditions requiring regular painful medical procedures. Needle-phobic patients have a heightened sensitivity to the pain associated with venipuncture. Present yourself to the patient with confidence and try to complete the procedure as quickly as possible, following all steps properly. Reclining the patient, the use of distraction techniques, and exercising an abundance of patience and compassion are helpful when drawing from needle-phobic patients.

## Appendix A. (Continued)

- **Cognitively impaired and combative patients.** Patients in this category may exhibit unpredictable and sudden motions and behaviors that could present a danger to themselves, the phlebotomist, and those near the patient. There should be at least one additional person or employee to assist and help immobilize the patient as necessary. If the phlebotomist feels the procedure cannot be performed safely, assistance should be requested or the physician or caregiver should be notified. Do not place equipment within reach of the patient. Always ensure unobstructed access to an exit to provide an escape route. Phlebotomists should not position the patient between themselves and the exit. A clean gauze pad should be readily available and the tourniquet quickly released in the event the needle is violently removed or repositioned. If the needle accidentally goes much deeper into the arm, the phlebotomist must inform the physician, nursing staff, or responsible health care professional and report the accident according to facility policy.

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# Appendix B. Sources for Establishing Maximum Blood Volumes to Be Collected From Patients Susceptible to Iatrogenic Anemia

Monitoring patients susceptible to iatrogenic anemia is critical to ensure that frequent diagnostic sampling does not complicate their care and/or threaten their well-being. At least three sources provide guidance for establishing maximum blood volumes to be drawn.

Two texts include a chart recommending maximum volumes to be collected in one collection and during a single admission from newborns and pediatrics, based on the weight of the patient.[1,2]

A booklet includes a weight-based chart of maximum blood volumes to be collected at one time from patients weighing up to 176 pounds.[3] It calculates the maximum volume of blood to be 2 mL/kg of body weight.

The World Health Organization published recommendations for policies limiting the volume of blood withdrawn from pediatric patients.[4]

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# Appendix C. Collections Proximal to an Intravenous Infusion Site

Collecting blood proximal to active intravenous (IV) sites is not recommended. However, if no other options are available, the procedure for collections proximal to an IV infusion site is:

1. Ask the responsible health care personnel to turn off the IV infusion for at least two minutes before venipuncture. Care should be taken to ensure that the flow has been completely discontinued.

2. Apply the tourniquet just proximal to the vascular access device, but not so close that it will impede the procedure or constrict the catheter within the vein.

3. Perform the venipuncture. Alert the responsible health care professional that the specimen collection has been completed and the infusion may be restarted.

4. Document in the patient record that the specimen was obtained proximal to an active IV site and include the type of fluid being infused.

# Appendix D. Preventing Syncope

The following steps may be taken to reduce and even prevent syncope incidents[1,2]:

- Before collection, briefly explain to the patient what steps will occur during the blood collection.

- Ask the patient before collection if he or she has ever fainted during a blood collection procedure.

- If a patient indicates a history of syncope, place him/her into a recliner or other suitable chair that allows for reclining with feet elevated to chest level, or have the patient lie down on a bed or stretcher.

- Distract the patient.
  - When possible, use two employees to participate in the collection process. One employee completes the collection, while the second employee distracts and comforts the patient. Ask the patient distracting questions on topics of interest to the patient, such as vacations, hobbies, or current events.

- Before needle insertion:
  - Instruct the patient to look at the second phlebotomist or at an object and breathe slowly and deeply, forcing air through pursed lips. Practice this step several times and instruct the patient to do this frequently and on demand by the phlebotomist, including at the time of needle insertion.

  - Instruct the patient to clench and unclench his/her thigh and lower leg muscles.

  - Instruct the patient to point his/her toes toward the chest and rotate ankles in a circle.

  - While distracting the patient, prepare all equipment and locate a suitable vein, explaining to the patient that the puncture is not yet imminent.

- While needle is inserted:
  - Once a suitable vein is located and the puncture is imminent, continue the breathing steps and leg exercises. Just before insertion, instruct the patient to take a deep breath. Insert the needle when the patient forces the air out through his/her lips.

  - Continue to instruct the patient to exercise the legs gently, point and unpoint the toes, and breathe. The breathing step is vital to maintaining blood chemistry. Alterations in blood chemistry may lead to adverse reactions, including syncope.

- After needle is withdrawn:
  - Continue to support the patient with these techniques even after withdrawal of the needle, because the syncope response may be delayed.

  - Keep the patient in this position for five to 10 minutes and continue monitoring the patient after he/she stands up. Syncope often occurs at this point. Be prepared to respond to a syncope event.

## Appendix D. (Continued)

- The facility should establish a process for alerting the staff to patients who are at risk for syncope (eg, notation in the patient's medical record that will be accessed upon every visit).

- Provide the syncope-risk patient with this helpful advice regarding future venipunctures:
  - Consume one or two 8-ounce glasses of water two hours before blood collection (unless contraindicated by fluid restrictions or diagnosis).

  - Suggest that a syncope-risk patient always bring a friend or relative when coming for blood collection.

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# The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system (QMS) approach in the development of standards and guidelines, which facilitates project management; defines a document structure using a template; and provides a process to identify needed documents. The QMS approach applies a core set of "quality system essentials" (QSEs), basic to any organization, to all operations in any health care service's path of workflow (ie, operational aspects that define how a particular product or service is provided). The QSEs provide the framework for delivery of any type of product or service, serving as a manager's guide. The QSEs are as follows:

| | | | |
|---|---|---|---|
| Organization | Personnel | Process Management | Nonconforming Event Management |
| Customer Focus | Purchasing and Inventory | Documents and Records | Assessments |
| Facilities and Safety | Equipment | Information Management | Continual Improvement |

GP41 covers the QSE indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section.

| Organization | Customer Focus | Facilities and Safety | Personnel | Purchasing and Inventory | Equipment | Process Management | Documents and Records | Information Management | Nonconforming Event Management | Assessments | Continual Improvement |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | X | | | | | |
| | | | | | | AUTO12 | | | | | |
| | | GP17 | | | | | | | | | |
| | | | | | | GP39 | | | | | |
| | | | | | | GP42 | | | | | |
| | | | | | | GP44 | | | | | |
| | | | | | | GP48 | | | | | |
| | | | | | | H21 | | | | | |
| | | M29 | | | | | | | | | |
| | | | | | | M47 | | | | | |
| | | | | | | NBS01 | | | | | |
| QMS01 | QMS01 | QMS01 | QMS01 | QMS01 | QMS01 | QMS01 | QMS01 | QMS01 | QMS01 | QMS01 | QMS01 |
| | | | | | | | QMS02 | | | | |
| | | | QMS03 | | | | | | | | |
| | | | | | | | | | | | QMS06 |
| | | | | | | | | | QMS11 | | |
| | | | | | | | | | | QMS12 | |

# Path of Workflow

A path of workflow is the description of the necessary processes to deliver the particular product or service that the organization or entity provides. A laboratory path of workflow consists of the sequential processes: preexamination, examination, and postexamination and their respective sequential subprocesses. All laboratories follow these processes to deliver the laboratory's services, namely quality laboratory information.

GP41 covers the medical laboratory path of workflow processes indicated by an "X." For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section.

| Preexamination | | | | Examination | | | Postexamination | |
|---|---|---|---|---|---|---|---|---|
| Examination ordering | Sample collection | Sample transport | Sample receipt and processing | Examination | Results review and follow-up | Interpretation | Results reporting and archiving | Sample management |
| X | X | X | X | X | X | | | |
| | AUTO12 | | AUTO12 | AUTO12 | | | | AUTO12 |
| | GP39 | | | | | | | |
| | GP42 | | | | | | | |
| | GP44 | GP44 | GP44 | | | | | |
| GP48 | GP48 | GP48 | GP48 | | | | | |
| | H21 | H21 | H21 | | | | | |
| | M47 | M47 | M47 | M47 | M47 | | M47 | |
| QMS01 | QMS01 | QMS01 | QMS01 | QMS01 | QMS01 | QMS01 | QMS01 | QMS01 |

# Related CLSI Reference Materials*

**AUTO12** **Specimen Labels: Content and Location, Fonts, and Label Orientation. 1st ed., 2011.** The purpose of this standard is to reduce human errors currently associated with the lack of standardization of labels on clinical laboratory specimens. The standard identifies the required human-readable elements to appear on specimen labels and specifies the exact locations, fonts, and font sizes of these elements.

**GP17** **Clinical Laboratory Safety. 3rd ed., 2012.** This document contains general recommendations for implementing a high-quality laboratory safety program, which are provided in a framework that is adaptable within any laboratory.

**GP39** **Tubes and Additives for Venous Blood Specimen Collection. 6th ed., 2010.** This document contains requirements for venous blood collection tubes and additives, including technical descriptions of ethylenediaminetetraacetic acid (EDTA), sodium citrate, and heparin compounds used in blood collection devices.

**GP42** **Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens. 6th ed., 2008.** This document provides a technique for the collection of diagnostic capillary blood specimens, including recommendations for collection sites and specimen handling and identification. Specifications for disposable devices used to collect, process, and transfer diagnostic capillary blood specimens are also included.

**GP44** **Procedures for the Handling and Processing of Blood Specimens. 4th ed., 2010.** This document includes criteria for preparing an optimal serum or plasma specimen and for the devices used to process blood specimens.

**GP48** **Essential Elements of a Phlebotomy Training Program. 1st ed., 2017.** This guideline is a resource for health care professionals and educators for development and implementation of curricula for phlebotomy training programs and courses.

**H21** **Collection, Transport, and Processing of Blood Specimens for Testing Plasma-Based Coagulation Assays. 5th ed., 2008.** This document provides procedures for collecting, transporting, and storing blood; processing blood specimens; storage of plasma for coagulation testing; and general recommendations for performing the tests.

**M29** **Protection of Laboratory Workers From Occupationally Acquired Infections. 4th ed., 2014.** Based on US regulations, this document provides guidance on the risk of transmission of infectious agents by aerosols, droplets, blood, and body substances in a laboratory setting; specific precautions for preventing the laboratory transmission of microbial infection from laboratory instruments and materials; and recommendations for the management of exposure to infectious agents.

* CLSI documents are continually reviewed and revised through the CLSI consensus process; therefore, readers should refer to the most current editions.

## Related CLSI Reference Materials (Continued)

**M47** **Principles and Procedures for Blood Cultures. 1st ed., 2007.** This document provides recommendations for the collection, transport, and processing of blood cultures as well as guidance for the recovery of pathogens from blood specimens taken from patients who are suspected of having bacteremia or fungemia.

**NBS01** **Blood Collection on Filter Paper for Newborn Screening Programs. 6th ed., 2013.** This document highlights specimen collection methods, discusses acceptable techniques for applying blood drops or aliquots to the filter paper segment of the specimen collection device, and provides instructions on proper specimen handling and transport to ensure quality specimens are consistently obtained for newborn screening analysis.

**QMS01** **Quality Management System: A Model for Laboratory Services. 4th ed., 2011.** This document provides a model for medical laboratories that will assist with implementation and maintenance of an effective quality management system.

**QMS02** **Quality Management System: Development and Management of Laboratory Documents. 6th ed., 2013.** This document provides guidance on the processes needed for document management, including creating, controlling, changing, and retiring a laboratory's policy, process, procedure, and form documents in both paper and electronic environments.

**QMS03** **Training and Competence Assessment. 4th ed., 2016.** This guideline provides a structured approach for developing effective laboratory personnel training and competence assessment programs.

**QMS06** **Quality Management System: Continual Improvement. 3rd ed., 2011.** This guideline considers continual improvement as an ongoing, systematic effort that is an essential component of a quality management system. A continual improvement program may consist of fundamental processes and common supporting elements described in this guideline.

**QMS11** **Nonconforming Event Management. 2nd ed., 2015.** Grounded in the principles of quality management, risk management, and patient safety, this guideline provides an outline and content for developing a program to manage a laboratory's nonconforming events.

**QMS12** **Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality. 1st ed., 2010.** This document provides guidance on development of quality indicators and their use in the medical laboratory.

## NOTES

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