CLINICAL AND LABORATORY STANDARDS INSTITUTE®

1st Edition

GP48

Essential Elements of a Phlebotomy Training Program

This guideline is a resource for health care professionals and educators for development and implementation of curricula for phlebotomy training programs and courses.

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

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Essential Elements of a Phlebotomy Training Program

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Abstract

Clinical and Laboratory Standards Institute guideline GP48—*Essential Elements of a Phlebotomy Training Program* is a resource for developing curricula for phlebotomy training programs and courses. This guideline is designed for college and proprietary school educators, nurse educators, educational coordinators, laboratory directors and managers, phlebotomy supervisors, and any other health care professionals or educators responsible for the development and/or implementation of a specimen collection training program. It suggests what should be taught, rather than how to teach it.

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Foreword

Up to 93% of errors occurring in the laboratory diagnostic process occur in the preexamination phase.[1,2] Yet, health care facilities and career training programs providing instruction on blood and nonblood specimen collection procedures have few resources to guide them. As a result, key concepts may be inadvertently missed, putting patients, specimen collection personnel, and test results at risk.

Properly trained specimen collection personnel are critical to patient care. When patient specimens are collected and handled by properly trained personnel, test results are likely to be accurate. When results are accurate, physicians are able to diagnose, medicate, and manage their patients with the best possible outcomes. However, training programs vary significantly in content, which leads to a wide range of practical guidance in the field. When inadequately trained personnel compromise specimen quality, patients may be misdiagnosed, over- or undermedicated, and generally mismanaged. Inadequate training is also associated with increased test turnaround times, the spread of hospital-acquired infections, personnel exposure to bloodborne pathogens, patient injury, and legal liability.

This guideline provides the global community of educators, whether they conduct training at health care facilities or teach at academic or proprietary programs, with guidance in developing a comprehensive laboratory specimen collection training program. By using this guideline, educators will be able to develop a program that teaches essential elements of collection, handling, and processing of patient blood specimens in a manner that 1) protects them from accidental exposure; 2) protects patients from injury; and 3) ensures specimen quality and, hence, accurate test results. The information provided in this guideline serves as a guide for properly training specimen collection personnel. Implementation of the recommendations contained within this guideline may vary based upon a number of factors and will be highly dependent on those variables and the institution in which the program is being implemented. Therefore, due to the likelihood of variability, a timeframe for program implementation and completion is not provided.

This guideline was developed using CLSI's QMS model as a framework. This 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. Organizing phlebotomy training programs in alignment with QMS principles ensures that applicable regulatory and accreditation requirements are covered and helps identify gaps in program content. A detailed description of the model is provided in CLSI document QMS01.[3]

The content recommendations in this guideline may not be universally applicable, but are appropriate for most settings. The topics order should not be interpreted as the order in which the topics should be taught. The training facility should arrange the content to fit its educational preferences.

Advanced practices outside the traditional role of specimen collection personnel (eg, performing electrocardiograms, draws from vascular access devices) are facility and region specific and are not included in this guideline.

The ultimate goal of this guideline is to help ensure all health care professionals with minimal or primary responsibilities in the preexamination processes are exposed to a high-level training curriculum.

NOTE: The content of this guideline is supported by the CLSI consensus process, and does not necessarily reflect the views of any single individual or organization.

KEY WORDS

Blood collection procedures
Educator
Phlebotomy
Preexamination
Samples
Skin puncture
Specimens
Training
Venipuncture

Chapter 1

Introduction

This chapter includes:

- Guideline's scope and applicable exclusions
- Background information pertinent to the guideline's content
- "Note on Terminology" that highlights particular use and/or variation in use of terms and/or definitions
- Terms and definitions used in the guideline
- Abbreviations and acronyms used in the guideline

Essential Elements of a Phlebotomy Training Program

NOTE:

GP48 is a resource for developing curricula for training programs and courses; it is not meant to substitute for or replace a curriculum.

1 Introduction

1.1 Scope

The intended users of this guideline are college and proprietary school educators, nurse educators, educational coordinators, laboratory directors and managers, phlebotomy supervisors, and any other health care professionals or educators responsible for the development and/or implementation of a specimen collection training program.

This guideline suggests what should be taught, rather than how to teach it. It is also beyond the scope of this guideline to provide instruction on how to perform specimen collection procedures, which are covered in CLSI documents GP41,[4] GP42,[5] and NBS01.[6] GP48 is a resource for developing curricula for training programs and courses; it is not meant to substitute for or replace a curriculum.

GP48 is not intended to prepare trainees for certification. Certification programs may have their own unique requirements.

1.2 Background

It is impossible to overstate the importance of comprehensively training those who collect, transport, handle, and/or process laboratory specimens. It is important that they take seriously the contribution they make, not only to patients' well-being, but to the health care team's ability to manage patients' care toward the best possible outcome.

Effective and efficient patient management depends on comprehensive training in all aspects of phlebotomy. Inadequately trained personnel cannot protect patients from medical mistakes directly attributable to specimens altered during collection, transport, handling, and processing, and from injuries caused by substandard techniques.

A wide variety of accurate and current documents, textbooks, training aids, educational resources, and other materials is necessary to implement the essential elements recommended in this guideline.

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

GP48 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					
					AUTO02	AUTO02					
						AUTO12					
						C34					
						C49					
						GP16					
						GP34					
						GP39					
						GP41					
						GP42					
						GP44					
						H21					
						H56					
		M29									
						NBS01					
QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01	QMS01
			QMS03								
QMS14											

Related CLSI Reference Materials*

AUTO02 **Laboratory Automation: Bar Codes for Specimen Container Identification. 2nd ed., 2005.** This document provides specifications for use of linear bar codes on specimen container tubes in the clinical laboratory and for use on laboratory automation systems.

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.

C34 **Sweat Testing: Sample Collection and Quantitative Chloride Analysis. 3rd ed., 2009.** This document addresses appropriate methods of collection and analysis, quality control, and the evaluation and reporting of test results.

C49 **Analysis of Body Fluids in Clinical Chemistry. 1st ed., 2007.** This document provides guidance for the application of widely available measurement procedures for testing body fluids and for reporting and interpreting those results. It emphasizes defining the common clinical situations for this use; acceptable practice for measuring analytes without extended method verification for abnormal body fluid; influence of biologic and analytic variation on interpretation of results; and variability in comparing results between different instrument manufacturers. This document does not consider serum, plasma, whole blood, or fluids for which assays typically have performance claims in the measurement procedure documentation.

GP16 **Urinalysis. 3rd ed., 2009.** This document addresses procedures for testing urine, including materials and equipment; macroscopic/physical evaluation; chemical analysis; and microscopic analysis.

GP34 **Validation and Verification of Tubes for Venous and Capillary Blood Specimen Collection. 1st ed., 2010.** This document provides guidance for conducting validation and verification testing for venous and capillary blood collection tubes.

GP39 **Tubes and Additives for Venous and Capillary Blood Specimen Collection. 6th ed., 2010.** This standard contains requirements for the materials, manufacturing, and labeling of venous and capillary blood collection devices.

GP41 **Collection of Diagnostic Venous Blood Specimens. 7th ed., 2017.** This standard provides procedures for the collection of diagnostic specimens by venipuncture, including line collections, blood culture collection, and venipuncture in children.

* 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)

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 for Common Laboratory Tests. 4th ed., 2010.** This document includes criteria for preparing an optimal serum or plasma sample and for the devices used to process blood specimens.

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

H56 **Body Fluid Analysis for Cellular Composition. 1st ed., 2006.** This guideline provides users with recommendations for collection and transport of body fluids, numeration and identification of cellular components, and guidance for qualitative and quantitative assessment of body fluid.

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.

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.

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

QMS14 **Quality Management System: Leadership and Management Roles and Responsibilities. 1st ed., 2012.** This guideline presents concepts and information intended to assist a laboratory in meeting leadership requirements for its quality management system. Guidance is provided for leaders to effectively design, implement, and maintain the cultural, structural, and functional aspects of their laboratory's organization that are critical to managing and sustaining quality.

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