This guideline describes the essential elements of systems and processes required to ensure accurate patient identification. The principles in this document may be applied to manual or electronic systems. Design considerations covered include criteria for accuracy, differences in inpatient vs outpatient settings that impact patient identification, language and cultural considerations, and standardization of processes across the health care enterprise.

A guideline for global application developed through the Clinical and Laboratory Standards Institute consensus process.
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For further information on committee participation or to submit comments, contact CLSI.

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Abstract

Clinical and Laboratory Standards Institute document GP33-A—Accuracy in Patient and Sample Identification; Approved Guideline describes the essential elements of systems and processes required to ensure accurate patient identification. The principles in this document may be applied to manual or electronic systems. Design considerations covered include criteria for accuracy, differences in inpatient vs. outpatient settings that impact patient identification, language and cultural considerations, and standardization of processes across the health care enterprise. Guidance on system implementation and user training is included. Validation of patient identification systems/programs and ongoing monitoring as a quality measure are also covered. This document is intended for health care providers who will design, select, implement, monitor, and evaluate patient identification systems.

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Accuracy in Patient and Sample Identification; Approved Guideline

1 Scope

The identification (ID) process begins with the patient, either at the time of registration for admission to a health care facility, or on presentation for sample collection, and ends with reporting the results of the examination. This document outlines all points in the path of workflow related to patient and sample ID.

The essential elements of systems and processes required to ensure accurate patient ID are described. The principles in this document are applicable to manual or electronic systems. Considerations covered include criteria for accuracy, differences in inpatient vs outpatient settings that impact patient ID, language and cultural considerations, and standardization of processes across the health care enterprise. Guidance on system implementation and user training is included. Validation of patient ID systems/programs and ongoing monitoring as a quality measure are also covered.

This document is intended for health care providers (HCPs) who design, select, implement, monitor, and evaluate patient ID systems or any individual responsible for specimen collection.

2 Introduction

An accurate test result on the wrong patient is at best of no value and, at worst, could lead to incorrect or harmful treatment or intervention. Accurate patient ID is the crucial first step to ensuring patient safety in the delivery of health care processes. Failures in accurate patient ID can have serious and adverse consequences for patients, including incorrect treatment, lack of treatment, injury, disability, and death.2

In recent years, data regarding rates of ID errors have become available. For example, data from a College of American Pathologists Q-Probes study of ID errors in primary and secondary sample labeling involving clinical laboratories3 showed an overall ID error rate of 1 error per 2638 billable tests (379 per million) and reported 345 adverse patient events during a five-week tracking period at 120 participating institutions. A more recent Q-probes study of 147 laboratories showed a labeling error rate of 0.92 per 1000 labels.4

In transfusion medicine,5,6 wrong blood in the tube (WBIT), in which a tube contains blood from a person different from the person named on the tube submitted for pretransfusion compatibility testing, has received increased attention because of the implications of transfusing incompatible blood components. A survey of 27 United Kingdom hospitals for samples for pretransfusion testing showed a 3.2% rejection rate, primarily for missing or incomplete information, and a WBIT rate of 1 in 1303 to 1501 samples.7 A multicenter international study found a median international WBIT rate of 1 in 1986 collected samples.8

A College of American Pathologists Q-Tracks study involving quarterly ID band monitoring at 217 institutions found an initial median ID band error rate of 7.4% with the most common ID band error as missing ID bands. Continuous monitoring of ID bands by program participants was associated with a reduction in ID band error rate to 3.05%.9

It is important to recognize that any process involving human intervention, including bar coding and radiofrequency identification (RFID), is still subject to error, so constant vigilance is required.

One hospital adopted a “zero tolerance laboratory sample labeling” process, which led to a 75% reduction in labeling errors.10

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3 Terminology

3.1 A Note on Terminology

CLSI, as a global leader in standardization, is firmly committed to achieving global harmonization wherever 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 the United States, Europe, and elsewhere; that these differences are reflected in CLSI, International Organization for Standardization (ISO), and European Committee for Standardization (CEN) documents; and that legally required use of terms, regional usage, and different consensus timelines are all important considerations in the harmonization process. In light of this, CLSI’s consensus process for development and revision of standards and guidelines focuses on harmonization of terms to facilitate the global application of standards and guidelines.

To align the use of terminology in this document with that of ISO, the terms preexamination, examination, and postexamination were adopted in place of preanalytical, analytical, and postanalytical, and the term sample replaces the term specimen where appropriate. The users of GP33-A should understand that the fundamental meanings of the terms are identical in many cases, and are defined in the guideline’s Definitions section (see Section 3.2). The terms in this document are consistent with those defined in the ISO 15189, ISO 17025, and ISO 9000 series of standards. The term “ID band” used in this document is also known as “wristband.”

3.2 Definitions

analyte – component represented in the name of a measurable quantity (ISO 17511).11

examination – set of operations having the object of determining the value or characteristics of a property; NOTE: In some disciplines (eg, microbiology), an examination is the total activity of a number of tests, observations, or measurements (ISO 15189).12

health care provider – individual authorized to deliver health care to a patient (ISO 17593); NOTE: This is a global term used to describe a person obtaining the sample and can include physician, nurse, medical technologist, laboratory assistant, respiratory therapist, care assistants, and phlebotomists.

measurand – quantity intended to be measured (ISO/IEC Guide 99).14

postexamination procedures – processes following the examination, including systematic review; formatting and interpretation; authorization for release; reporting and transmission of the results; and storage of samples after the examinations (ISO 15189).12

preexamination procedures – steps starting, in chronological order, from the clinician’s request and including the examination requisition, preparation of the patient, collection of the primary sample, and transportation to and within the laboratory, and ending when the analytical examination procedure begins (ISO 15189).12

reproducibility (measurement) – measurement precision (closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions) under reproducibility conditions of measurement (condition of measurement, out of a set of conditions that includes different locations, operators, measuring systems, and replicate measurements on the same or similar objects) (ISO/IEC Guide 99).14
The Quality Management System Approach

Clinical and Laboratory Standards Institute (CLSI) subscribes to a quality management system approach in the development of standards and guidelines, which facilitates project management; defines a document structure via a template; and provides a process to identify needed documents. The approach is based on the model presented in CLSI document HS01—*A Quality Management System Model for Health Care*. The quality management system 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:

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Adapted from CLSI document HS01—*A Quality Management System Model for Health Care*.

Path of Workflow

A path of workflow is the description of the necessary steps to deliver the particular product or service that the organization or entity provides. For example, CLSI document GP26—*Application of a Quality Management System Model for Laboratory Services* defines a clinical laboratory path of workflow, which consists of three sequential processes: preexamination, examination, and postexamination. All clinical laboratories follow these processes to deliver the laboratory’s services, namely quality laboratory information.

GP33-A addresses the clinical laboratory path of workflow steps indicated by an “X.” For a description of the other documents listed in the grid, please refer to the Related CLSI Reference Materials section on the following page.

Adapted from CLSI document HS01—*A Quality Management System Model for Health Care*. 

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Related CLSI Reference Materials∗

EP18-A2 Risk Management Techniques to Identify and Control Laboratory Error Sources; Approved Guideline—Second Edition (2009). This guideline describes risk management techniques that will aid in identifying, understanding, and managing sources of failure (potential failure modes) and help to ensure correct results. Although intended primarily for in vitro diagnostics, this document will also serve as a reference for clinical laboratory managers and supervisors who wish to learn about risk management techniques and processes.

GP21-A3 Training and Competence Assessment; Approved Guideline—Third Edition (2009). This guideline provides background information and recommended processes for the development of training and competence assessment programs that meet quality and regulatory objectives.

GP32-A Management of Nonconforming Laboratory Events; Approved Guideline (2007). This guideline provides an outline and the content for developing a program to manage a health care service’s nonconforming events that is based on the principles of quality management and patient safety.


H04-A6 Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard—Sixth Edition (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.

H11-A4 Procedures for the Collection of Arterial Blood Specimens; Approved Standard—Fourth Edition (2004). This document provides principles for collecting, handling, and transporting arterial blood specimens to assist with reducing collection hazards and ensuring the integrity of the arterial specimen.

HS01-A2 A Quality Management System Model for Health Care; Approved Guideline—Second Edition (2004). This document provides a model for providers of health care services that will assist with implementation and maintenance of effective quality management systems.

MM13-A Collection, Transport, Preparation, and Storage of Specimens for Molecular Methods; Approved Guideline (2005). This document provides guidance related to proper and safe biological specimen collection and nucleic acid isolation and purification. These topics include methods of collection, recommended storage and transport conditions, and available nucleic acid purification technologies for each specimen/nucleic acid type.

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