

Standards Provide a Quality Approach to Blood Gas Analysis

May 2007



Melissa J. D. Archangelo

Clinical and Laboratory Standards Institute
940 West Valley Road, Suite 1400
Wayne, PA 19087-1898
USA

Blood gas analysis is a complex field that has a direct impact on patient care in a critical care environment. Healthcare professionals consistently emphasize high-quality results in order to properly treat patients, and recognize the need and usefulness of quality standards.

Using a path-of-workflow analysis as part of a larger, comprehensive quality management system (QMS) will go far in standardization and in providing critical procedural support to staff.

The Clinical and Laboratory Standards Institute (CLSI, formerly NCCLS) provides standards and guidelines to support such quality initiatives, in addition to producing documents that define terminology and discuss performance characteristics from a preanalytical through postanalytical path of workflow.

These documents represent the best practices in the field and are created through a unique consensus process involving input from industry, government and the healthcare professions.

CLSI and the consensus process

CLSI is an international, interdisciplinary, non-profit, standards-developing and educational organization that promotes the development and use of voluntary consensus standards and guidelines within the healthcare community. CLSI is a professional group organized by interested stakeholders with a vast, global member and volunteer base.

With a nearly 40-year history, CLSI is a proven leader with undisputed credibility – continually bringing together professionals to provide critical resources that are the gold standard for best practices in healthcare.

CLSI is committed to responding to the needs of the healthcare community by facilitating the development of tools that aid the user in achieving effectiveness and efficiency in the workplace.

CLSI proactively evolves to stay on the cutting edge of healthcare science and developments by maintaining an

open and unbiased forum to address critical issues in the healthcare community.

CLSI is recognized worldwide for the application of its unique consensus process in the development of standards and guidelines for patient testing and related healthcare issues. CLSI standards and guidelines represent a consensus opinion on good practices and reflect the substantial agreement by interested parties obtained by following CLSI's established consensus procedures.

Robert F. Moran, PhD, FCCM, FAIC, FACB, CLC & AHI(AMT), FIUPAC, mvi Sciences, has been involved with CLSI for over 30 years. He says, "CLSI's consensus process respects the fact that different audiences may be coming from different perspectives."

The process brings together these volunteer participants to standardize each approach and bridge the gap between the parties to create a consensus-supported commonality."

An essential component of the consensus process is the input and involvement of users. Anyone may submit a comment, and all comments are addressed, according to the consensus process, by the committee that wrote the document.

Participation is the key to delivering high-quality standards and guidelines that medical professionals rely on in their day-to-day practice.

The quality management system and a path of workflow

Many manufacturing and service sectors have benefited from utilizing a QMS in their operations.

Healthcare services can implement a QMS by understanding and monitoring the path of workflow and combining that with policies, processes and procedures involved with the quality system essentials (QSEs). QSEs are the set of coordinated management activities that function as the building blocks for quality management [1].

The CLSI library has several documents related to the application of a QMS in healthcare. For example, Application of a Quality Management System Model for Respiratory Services; Approved Guideline—Second Edition (HS4-A2) provides the user with information about the path of workflow for both pulmonary diagnostics and respiratory therapeutics. The document provides detailed examples of how management and staff can prepare flowcharts that outline specific processes.

The HS4-A2 guideline introduces the path of workflow as *"the processes that transform a request for a respiratory-related service or patient assessment, performing the requested intervention or test, evaluating the outcome of the intervention or interpreting the results, and providing the information to the clinician or practitioner coordinating the patient care"* [1].

Outlining and identifying the path of workflow through a particular service builds the required level of quality into the procedures and reduces the potential for medical error.

Having a well-defined path of workflow helps unify the different approaches to care that the many professionals involved with blood gas analysis might bring. Susan Blonshine, RRT, RPFT, AE-C, FAARC, President – TechEd Consultants, Inc., explains:

"The quality principles outline the things one should pay attention to from a preanalytical through postanalytical path of workflow. These principles do not change regardless of the professional group involved, or how one approaches the test request. The CLSI documents help us integrate policy and procedure and quality systems."

Specific standards and guidelines for blood analysis

The field of blood gas analysis has a reputation for being somewhat confusing, because many different measured and derived quantities (i.e., bicarbonate concentration and base excess) are being used.

In addition, personnel – including laboratory technologists, respiratory and critical care practitioners, and others responsible for obtaining and analyzing blood – are involved and bring different approaches to the work. The CLSI guideline, Blood Gas and pH Analysis and Related Measurements; Approved Guideline (C46-A), defines related terminology and discusses performance characteristics as well as preanalytical variables, analytical considerations and quality control issues [2].

The guideline is a single document that consolidates and updates six other related documents, including one that was designated an “American National Standard”, to provide a more comprehensive blood gas resource.

Moran explains, *“The C46-A document is accessible to everyone because it considers the whole spectrum of appropriate specimen collection, preanalytical variables, calibration and quality control. It has contributed to a standardized approach to blood gas analysis, and the constituencies are better served by a single document that covers, in one place, everything one needs to know.”*

Steve Sittig, RRT-NPS, FAARC, Pediatric Clinical Specialist, Pediatric Respiratory Care Department, Mayo Clinic, refers to the C46-A document often as a reference for policies and procedures.

“We use the CLSI documents within our organization and when dealing with people across the country by referencing the information to answer questions on processing, how to follow a path of workflow for running blood gases, and setting up standard procedures”, he says.

CLSI guidelines help standardize procedures and ultimately improve quality of care. George Gaebler, MS Ed, RRT, FAARC, Director Respiratory Care, University Hospital, Upstate Medical University, states:

“Obviously, with accreditation agencies placing such a large emphasis on patient safety, solid standards for quality are a must. All respiratory professionals that

work with arterial blood gas analysis and electrolytes must follow the best quality guidelines that are available to assure the public and our constituents that we are providing the best possible care – that is backed by good science and thorough quality standards.”

Moran says, *“Using the appropriate CLSI document to set up a standard operating procedure is going to ensure the quality of the results and validate that quality by consistent application of the principles explained there. There is a systematic way to track down any perceived errors in the results, because it can be tracked from the preanalytical through analytical to postanalytical stages.”*

Sittig agrees. *“CLSI guidelines help tie all the points together in the path of workflow. The guidelines help organize the process and emphasize the importance of the process in reducing errors in the data.”*

CLSI welcomes comments and questions about the documents; this feedback serves as the basis for updated document editions. All comments and responses are formally addressed and published in the next edition of the document. For more information about Clinical and Laboratory Standards Institute references and best practices, visit www.clsi.org or call +610.688.0100.

The Clinical and Laboratory Standards Institute (CLSI) is committed to developing documents that keep pace with the rapid advancements in technology and healthcare practices. In order to meet this objective, CLSI welcomes input from expert practitioners to identify topics for which CLSI standard/guidelines are needed. Any person or organization, including CLSI committee participants or committees, may propose a new CLSI project by submitting a completed Project Proposal Form at www.clsi.org.

Related documents

CLSI offers a collection of products for healthcare professionals working with blood gas and critical care testing. Related documents include:

Blood Gas and pH Analysis and Related Measurements; Approved Guideline (C46-A), Application of a Quality Management System Model for Respiratory Services; Approved Guideline – Second Edition (HS4-A2), Procedures and Devices for the Collection of Diagnostic Capillary Blood Specimens; Approved Standard – Fifth Edition (H4-A5), Procedures for the Collection of Arterial Blood Specimens; Approved Standard – Fourth Edition (H11-A4), Protection of Laboratory Workers From Occupationally Acquired Infections; Approved Guideline – Third Edition (M29-A3).

References

1. Clinical and Laboratory Standards Institute. Application of a Quality Management System Model for Respiratory Services; Approved Guideline – Second Edition. CLSI document HS4-A2 [ISBN 1-56238-603-4]. Clinical and Laboratory Standards Institute, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19087-1898 USA, 2006.
2. NCCLS. Blood Gas and pH Analysis and Related Measurements; Approved Guideline. NCCLS document C46-A [ISBN 1-56238-444-9]. NCCLS, 940 West Valley Road, Suite 1400, Wayne, Pennsylvania 19387-1898 USA, 2001.