The importance of quality control (QC) to quality blood gas testing

September 2012

Sharon S. Ehrmeyer Ph.D.
Department of Pathology and
Laboratory Medicine
University of Wisconsin
1300 University Avenue, Room 6175
Madison, WI 53706
USA

Test results, essential for quality healthcare, constitute more than 70% of patients' health records. Because quality results are so important, governments around the world mandate a series of laboratory practices to ensure quality.

All laboratories in the United States follow the Clinical Laboratory Improvement Amendments (CLIA) requirements. Many laboratories worldwide either follow the International Organization for Standardization (ISO) standards 15189 and 22870 (requirements for quality and competence) or local adaptations of these two standards.

Both CLIA and ISO are based on a quality management system approach that includes essential elements to ensure quality in each phase of the testing process. One of the essential elements in the analytical phase is the daily measurement and evaluation of QC materials on different levels.

QC is especially important for blood gas testing because the results are needed for acute treatment of criticality ill patients. In addition to the extra cost and delay associated with retesting, erroneous results may lead to wrong diagnosis and mistreatment of the patient.

What is quality?

Quality evokes many mental images, depending on one's background and experiences. The true meaning of "quality" is often diminished because it is continually used and associated with so many different products and services. Consequently, in all aspects of our lives, we not only expect quality but demand it, even when we are unsure of the exact definition.

J. M. Juran, who is referred to as the "father" of quality, added a total quality management dimension to the definition and talks about quality in terms of "fitness for intended use" [1].

This definition basically says that quality is "meeting or exceeding customer expectations". W. E. Deming,

considered the "founder" of the modern industrial quality movement, stated that the customer's definition of quality is the only one that matters! [2].

When quality is defined as meeting the requirements or needs of "customers" and satisfying their expectations, the customers and their expectations must be stated. In laboratory testing, our primary customers are patients and their physicians.

Both expect quality information for timely diagnosis and the appropriate treatment that leads to good patient outcome. Other customers, such as those who ultimately pay for the testing, seem to focus only on cost reduction.

But these customers also should be concerned with quality since quality test results eliminate costs associated with retesting (analyst's time, additional reagents, new patient sample, and delay in the result) and potentially the wrong diagnosis and treatment (poor patient outcome, increased hospital stay) due to an erroneous result.

For optimum patient care, all test results depend on a series of corrects throughout the three phases of the testing process – pre-analytical, analytical, and post-analytical [3]:

1. Correct patient identified for specimen collection
2. Correct time for specimen collection
3. Correct specimen collected and processed
4. Correct (accurate) test result generated
5. Correct patient result recorded in correct patient record

The above series begins with the clinician ordering the correct tests and ends with the clinician correctly interpreting the data for timely and appropriate treatment.

Wherever a wrong replaces any one of the corrects, the quality of the test result, and ultimately the patient's treatment and safety, may be compromised. Consequently appropriate policies and procedures must be in place and followed for all three phases of testing.

Why are quality test results so important to quality patient care and patient safety?

Patient safety is the cornerstone of high-quality patient healthcare and can be described as freedom from unintentional or preventable harm due to avoidable, adverse events (medical errors) that directly impact the quality of care [4].

We all know that errors, even under the best circumstances, do happen. Regardless of the source, errors can affect the quality of care and jeopardize patients' safety. This is even truer for critically ill patients requiring rapid interventions based on multiple blood gas and critical care measurements.

It has been stated that "Blood gas and pH analysis has more immediacy and potential impact on the patient care than any other laboratory determination … In blood gas analysis, an incorrect result can often be worse for the patient than no result at all" [5].

In the U.S. more than 10 billion laboratory tests are performed each year and test results constitute more than 70% of patients' health records [6, 7]. The Institute of Medicine reported that anywhere between 44,000 and 98,000 hospitalized patients in the U.S. die each year due to medical errors, and additional reports on medical errors continue to be reported [8, 9, 10].

While poor-quality test results are not attributed directly to medical errors, laboratory results certainly are part of the problem. It is estimated that as many as three-quarters of clinician decisions are based on laboratory tests [7].

The key words in these reports are "mistakes" and "preventable", which means that solutions can be found and practices implemented to check and ensure quality.

Following established standards to ensure quality throughout the testing process

Because quality test results are such an important component of healthcare, many governments and

professional laboratory organizations around the world specify a series of good laboratory practices to ensure quality laboratory results.

In the United States, the government mandates all laboratory testing sites to adhere to the quality requirements specified in the Clinical Laboratory Improvement Amendments (CLIA) [11].

Many laboratories worldwide follow the standards developed by the International Organization for Standardization (ISO). Especially two ISO standards are relevant: 1) ISO 15189:2007, Medical laboratories – particular requirements for quality and competence, and 2) ISO 22870:2006, Point-of-care testing - requirements for quality and competence [12, 13].

Some countries even have made local adaptations of these two standards mandatory for test sites to follow.

The ISO standards were developed by experts from 33 countries and reflect worldwide opinion on what is essential to ensure quality specifically for clinical laboratory testing.

The CLIA and ISO standards are based on a quality management system (QMS) approach that includes widely accepted good laboratory and error-prevention practices and incorporate "Essential Elements" (Table I) for management, technical guidance, and structure of the entire testing process [14].

1. Documents and records
2. Organization
3. Personnel
4. Equipment
5. Purchasing and inventory
6. Process control
7. Information management
8. Occurrence management
9. Internal and external assessment
10. Process improvement
11. Customer service/ satisfaction
12. Facilities and safety

TABLE I: Quality Essential Elements to build the QMS

QC as part of ensuring analytical quality

The characteristics of useful, accurate, precise, reliable, and timely apply to all quality test results including blood gas and critical care results. Ultimately for laboratories to meet all these demands, QC assessment for ongoing quality assurance is essential!

A recent essay by Dr. Westgard discusses how laboratories often operate on false assumptions [15]. Despite their desire for the perfect, error-proof instrument that always yields perfect results, such an instrument does not exist!

If laboratories do not evaluate their analytical processes or use insufficient QC practices that do not detect critical analytical errors, they will not be aware of potential "analytical hazards" and poor quality test results.

What follows focuses on the importance of routine QC to ensure the quality of the analytical phase of testing (#9 of the essential elements in Table I) for blood gas and critical care measurements.

The CLIA and ISO standards require the analysis of different levels of QC materials at specified intervals to evaluate the quality of the measurement system. Typically laboratories statistically evaluate QC data to determine whether instrument performance is within the expected variation [16].

While QC is essential for all laboratory measurements, QC assessments for blood gas and critical care measurements are particularly important because patients requiring these measurements are critically ill and in need of immediate treatment based on these test results.

Wrong results can be fatal! Consequently QC is absolutely necessary and should prequalify the instrument to ensure proper performance before the patient sample is analyzed.

The CLIA regulations, in section §493.1256, require each laboratory to implement "control procedures that monitor the accuracy and precision of the complete

analytic process and … detect errors that occur due to test system failure, adverse environmental conditions, and operator performance" [11].

For most quantitative tests, CLIA requires the analysis of at least two different concentrations of QC materials on days when patient testing is conducted. CLIA's section §493.1267 specifies additional and more stringent requirements for blood gas measurements and directs testing sites to analyze at least one sample of QC material each 8 hours of testing and three levels (low, normal, and high) each day (24 hours) of testing.

CLIA also requires analysts to review the QC results before reporting patient results to ensure that only patient results within quality specifications are reported. All unacceptable QC results must be investigated and appropriate corrective actions taken before reanalyzing samples and reporting patient results.

As part of a laboratory's ongoing quality assurance activities, CLIA mandates a retrospective review of cumulative QC data so that potential analytical problems can be identified and corrected before test result quality is affected.

ISO 15189:2007, in section 5.6, states that a "laboratory shall design internal QC systems that verify the attainment of the intended quality of results" [12]. The intended quality of results is based on the laboratory's quality goal or acceptable error tolerance for test results.

Test sites must design QC practices to ensure that all patient results meet the stated quality goal. ISO 22870:2006 states that the "quality manager is responsible for the design, implementation, and operation of QC that ensures POCT conforms to the quality standards of the central laboratory" [13].

Both ISO standards require corrective actions when QC results are unacceptable and mandate the review of QC data as part of ongoing quality assurance activities to detect and prevent potential errors.

QC verifies the validity of the calibration curve

Both CLIA and ISO standards make clear distinctions between calibration activities and analyzing QC samples. The calibration process uses calibrators of known concentrations to position the instrument's calibration curves to yield correct test results. CLIA, in section §493.1267, directs test sites performing blood gases to:

1) calibrate or verify calibration according to the manufacturer's specifications and frequency, and 2) test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing, and 3) test one QC sample each time patient samples are tested unless calibration is automatically verified every 30 minutes [11].

ISO 15189, in section 5.6.3, requires test sites to perform QC in addition to calibration to ensure that patient results are traceable to specified reference materials [12]. The analysis of three levels of QC verifies the position of the calibration curves across the measurement ranges.

Because these QC and calibration practices are requirements and reflect recognized good laboratory practices, several manufacturers now design instruments to automatically perform calibration at specified intervals and analyze, typically, three levels of QC each day [17-20].

QC mandates and country specific and professional accreditation requirements

While all laboratories in the U.S. adhere to the CLIA requirements and laboratories throughout the world follow ISO 15189 and ISO 22870 standards, countries such as Germany, Australia, and France have adapted the ISO requirements to meet local needs.

In addition to following the ISO requirements, RiliBÄK, the German guidelines, mandate the analysis of at least two QC samples on days that patient samples are measured

and require specific evaluation of the QC data at the time of measurement as well as a retrospective analysis of the QC data at least every three months [21, 22].

The Australian National Association of Testing Authorities (NATA) specifies that "The minimum requirement for blood gas and CO-oximetry QC is a daily assay of control material at two or more control levels, performed concurrently" [23]. Cofrac, the French Notified Body for Laboratories Accreditation, directs laboratories to follow ISO 15189 (and ISO 22870 for POCT) standards [24].

Accreditation will be mandatory by the end of 2016. The French standards mandate each laboratory to implement an internal quality program (section 5.6.1) and participate in a peer group comparison (section 5.6.4).

The analysis of QC materials is mandatory for blood gas testing and two levels per day are recommended. An accompanying document, "Les contrôles de qualité analytique en Biologie Médicale, LAB GTA 06", emphasizes that the calibration solutions cannot be used as QC (section 9.2.2) [25].

Additionally, many laboratories throughout the world voluntarily seek formal accreditation from professional organizations for further recognition of their ability to provide quality testing. The accreditation process, conducted by independent parties, is a systematic and uniform assessment of a laboratory's competence in complying with accepted testing standards producing quality test results [26].

As part of the process, surveyors audit laboratories' facilities, equipment, personnel, methodologies, and record-keeping systems to ensure that an adequate QMS is in place. The regular ongoing analysis of QC materials is an essential component of the QMS.

QC provides essential information

An example of the importance of QC, but not using the information, is the Maryland General Hospital (Baltimore, Maryland USA) case [28]. Over a 14 month period, up to 460 questionable HIV and hepatitis test results were reported despite QC results indicting analytical errors.

> *"I would never accept test results to be used to treat patients if regular QC was not performed on the analyzer. The QC frequency depends on the type of instrumentation, for example in my hospital, we have five blood gas analyzers and we measure QC on three levels, three measurements per day."*
> Dr. Pierre Bouchelouche, MD, Medical Director of the Department of Clinical Biochemistry, Koege Hospital, University of Copenhagen, Denmark [27].

The safety of all these patients was jeopardized. Many of the patients tested during this period were misdiagnosed based on the erroneous results and all of these patients required reassessment. As a consequence for not following testing requirements, numerous personnel were prosecuted and sanctions were placed on the hospital.

Conclusion

Quality – useful, accurate, precise, reliable, and timely tests results – is essential for providing patients with the best possible healthcare. However, even under the best conditions, errors can and do happen! Consequently, laboratories must plan for quality.

Testing standards, such as those mandated by CLIA, ISO, Rilibäk, Cofrac and NATA, assist in the planning process. Each are based on a QMS containing Essential Elements (Table I) to direct test sites to systematically plan and manage the entire testing process to ensure that "corrects" (quality results) are achieved.

All of these standards mandate ongoing QC measurements to evaluate analytical quality. Quality test results are not automatic.

To deliver quality healthcare and ensure patients' safety, laboratories cannot assume that simply following manufacturers' directions and trusting the instrument

automatically will ensure that quality test results are generated.

Because of the criticality of blood gas and critical care measurements, QC must prequalify the instrument before patient samples are analyzed to avoid delays due to instrument problems, reporting incorrect results, and collecting additional patient samples for reanalysis.

References

1. Juran J. Quality control handbook. 5th ed. New York: McGraw-Hill, 1999.
2. Deming WE. Out of the crisis. Cambridge, MA: MIT Press, 1986.
3. Ehrmeyer SS, Laessig RH. Point of care testing and patient safety – a partnership. Point of Care 2008; 4: 223-26.
4. Plebani M. Partners in error prevention. Jan. 2009. Available from: http://acutecaretesting.org/?frames=yes. Accessed May 2012.
5. NCCLS (now Clinical and Laboratory Standards Institute). Blood gas pre-analytical considerations: specimen collection, calibration and controls; (C27-A). CLSI: Wayne, PA, 1993.
6. National Medical Laboratory Professionals. http://www.ascp.org/labweek. Accessed May 2012.
7. Regan M, Forsman R. Disease management. 2006; 9: 122–30. http://online.liebertpub.com/doi/abs/10.1089/dis.2006.9.122. Accessed May 2012.
8. Committee on Quality of Health Care in America, Institute of Medicine. In: Kohn LT, Corrigan JM, Donaldson MS, eds. To err is human: building a safer health system. Washington, DC: National Academy Press, 2000.
9. Alarming trend: medical errors have increased in the U.S. 2011. http://www.helpingyoucare.com/12784/alarming-trend-medical-errors-have-increased-in-the-u-s. Accessed May 2012.
10. Graban M. Statistics on healthcare quality and patient safety problems – errors & harm. 2012 http://www.leanblog.org/2009/08/statistics-on-healthcare-quality-and/. Accessed May 2012.
11. Current CLIA Regulations (including all changes through 01/24/2004): http://wwwn.cdc.gov/clia/regs/toc.aspx. Accessed May 2012.
12. ISO 15189 (2007): Medical laboratories – particular requirements for quality and competence. International Organization for Standardization (ISO) standards.http://www.iso.org/iso/home.html. Accessed May 2012.
13. ISO 22870 (2006): Point-of-care testing – requirements for quality and competence. International Organization for Standardization (ISO) standards.http://www.iso.org/iso/home.html. Accessed May 2012.
14. Clinical and Laboratory Standards Institute. Quality management system: a model for laboratory services; (GP26-A4). CLSI: Wayne, PA. 2011.http://www.clsi.org. Accessed May 2012.
15. Westgard S. Would you drive your car the way you run your QC? http://www.westgard.com/qc-drive.htm. Accessed June 2012.
16. Clinical and Laboratory Standards Institute. Statistical quality control for quantitative measurement procedures: principles and definitions; (GP24-A3). CLSI: Wayne, PA. 2006. http://www.clsi.org. Accessed May 2012.
17. Roche Diagnostics GmbH, cobas b 123 POC System Gebrauchsanweisung, version 2.0, November 2010, RER/No. 0 5337658001, Qualitätskontrolle, Generelles QC-Konzept, D-64.
18. Siemens Healthcare Diagnostics, RAPIDPoint 500 System Bedienungshandbuch, 10629524 Rev. A, 6 Fehlerbehebung, pages 6-45.
19. Bayer HealthCare LLC, Rapidlab 1200 Reference Guide 01999328 Rev A, 2005-6, 1 Learning About the System, pages 31-31.
20. Radiometer Medical ApS, ABL90 FLEX operator's manual, 201112A, 2011, 5 Quality management.
21. New policy of the Federal (German) Medical Council for quality assurance of medical laboratory investigations RiliBÄK.http://www.kvmv.info/aerzte/25/20/Qualitaetssicherung_aktuell_/RiLi-BAEK.html. Accessed May 2012.
22. Pierson-Perry J, Sonntag O. RiliBÄK: quality goals the German way. http://www.westgard.com/rilibak-2.htm . Accessed May 2012.
23. National Association of Testing Authorities (NATA). AS 4633 (ISO 15189) Field Application Document Supplementary Requirements for accreditation in the field of medical Testing. May 2007.
24. French Accreditation Body, Cofrac. http://www.cofrac.fr/en/cofrac/vocation.php. Accessed May 2012.
25. Guide technique d'accréditation: contrôle de qualité en biologie médicale, LAB GTA 06 (2012). http://www.cofrac.fr/fr/documentation/index.php?fol_id=63. Accessed May 2012.
26. The value of uniform accreditation. U.S. Methods and Data Comparability Board. http://acwi.gov/methods/pubs/accred_pubs/value_of_accred.htm. Accessed May 2012.
27. Personnel correspondence. Pierre Bouchelouche, MD, Medical Director of the Department of Clinical Biochemistry, Køge Hospital, University of Copenhagen, Copenhagen, Denmark.
28. Westgard S. Facts of the Maryland General healthcare scandal. http://www.westgardqc.com/essay64.htm. Accessed May 2012.