Benefits of Developing an Individualized Quality Control Plan

James H. Nichols[1]*

A clinical laboratory can benefit from developing an individualized QC plan (IQCP)[2] in many ways. This editorial will explore some of the lessons we learned from developing our IQCPs and the advantages of interacting with clinical staff through the IQCP process. The Centers for Medicaid and Medicare Services adopted changes to the Clinical Laboratory Improvements Amendments (CLIA) interpretive guidelines on January 1, 2016, that give clinical laboratories the option to perform a minimum of two concentrations of QC each day or develop an IQCP (*1*, *2*). An IQCP allows the laboratory to reduce the frequency of QC to the minimum recommended by the manufacturer provided the laboratory has conducted a thorough risk assessment. IQCPs apply to CLIA non-waived tests. Sites conducting CLIA waived testing only need to follow manufacturer instructions and pay a biennial fee for renewal of their CLIA certificate. The Clinical and Laboratory Standards Institute approved the EP23-A guideline to help laboratories develop an IQCP (*3*).

Many newer laboratory and point-of-care testing (POCT) instruments have built-in and manufacturer-engineered control processes, some conducted with each test, that can monitor the quality of the sample, the instrument, and the chemistry of the reactions, making external QC redundant. An IQCP allows a laboratory to balance external QC with the quality processes found on their instrumentation. Inspectors will be looking for three parts to a laboratory's IQCP: (*i*) a risk assessment where the laboratory has mapped the total testing process, identified hazards or weak steps in the testing process, and defined actions to mitigate risk and minimize these hazards or possibility of errors occurring; (*ii*) the QC plan, which is a summary of the hazards and actions identified in the risk assessment; and (*iii*) the quality assessment or laboratory benchmarks or monitors for the effectiveness and continuous improvement of the QC plan.

Many laboratories may be asking, "why?" "Why do I need to develop an IQCP? What is to be gained that will offset the resources and time required to develop an IQCP?" Our hospital started the process with similar questions from the staff. We began with a simple test, a blood gas analyzer, and continued with the development of IQCPs for several other POCT methods, core laboratory analyzers, and microbiology tests. Clinical laboratories can benefit from developing an IQCP in more ways than just being able to define the frequency of QC for a particular test. Laboratories will gain a deeper appreciation of the overall testing process, staff variations in practice outside of the laboratory, and how to better partner with clinicians. Here are some of the benefits to be gained from developing an IQCP.

[1]Vanderbilt University School of Medicine, Nashville, TN.
***Address correspondence to the author at:** 4918D TVC (The Vanderbilt Clinic), 1301 Medical Center Dr., Nashville, TN 37232-5310. Fax 615-343-9563, e-mail james.h.nichols@vanderbilt.edu.
DOI: 10.1373/jalm.2016.020222

[2] **Nonstandard abbreviations:** IQCP, individualized QC plan; POCT, point-of-care testing.

First, our processes are not uniform. To develop our blood gas IQCP, representatives met from each of the areas conducting blood gases: respiratory care, pediatric intensive care units, POCT, and the core laboratory. When mapping our processes, we discovered that not everyone was labeling samples the same way. With the newer, electronic order entry systems, clinical staff simply "status collect" a sample to print out a barcode label for the sample that can be read by our laboratory instrumentation. However, other units were continuing with the older, manual workflow, where staff collected samples, hand-wrote the labels upon collection, and then ordered the tests to print out the barcoded labels after returning to the nursing workstation. This manual workflow included more steps, increased chances for error, and delayed analysis of blood gas samples. Getting everyone together in the same room to discuss the workflow allowed us to discover the discrepancies, harmonize our processes, and streamline the steps involved, reducing the possibility for errors and expediting the analysis of blood gas samples after collection.

Additionally, this is an opportunity to improve efficiency. Our life-flight helicopter service has 7 locations throughout the mid-state region. While managed under the same CLIA certificate, each location acts independently, ordering their own blood gas and electrolyte supplies. This step multiplies the documentation required to meet CLIA moderate-complexity requirements. Each location must validate every shipment of reagent cartridges, perform independent monthly QC, and conduct separate 6-month calibration verification and test correlations. By centralizing the management and receipt of supplies, staff could reduce the number of shipment validations performed and decrease the number of non-patient tests conducted. Once validated at the main office, cartridges can then be distributed to each site. The low, normal, and high QC levels were also discovered to be the same solutions that were being marketed in the linearity set for calibration verification. Therefore, analyzing monthly QC provides a 3-level linearity that can suffice for 6-month calibration verification. Sites were also ordering cartridges on a 4–6 weeks basis, so these reagents were consumed well before 6-month calibration verification would be required. The discussion of workflow when developing the IQCP allowed restructuring of reagent management to centralize and perform a single validation for shipment of reagent cartridges, stock a larger 3–4 month supply, distribute cartridges to individual sites, perform monthly QC to validate site storage conditions, and replace 6-month calibration verification with monthly 3-level QC. This process saved on the number of non-patient cartridges consumed and, more importantly, the staff time and resources to analyze and document multiple site validations.

Next, the IQCP supports our QC rationale and quality actions. The frequency of performing QC, refreshing technologist competency, and other quality activities are often driven by either regulation or manufacturer recommendations. Developing an IQCP can give purpose to those actions. Our life-flight IQCP discussion raised questions for why we were performing so many validations. The final strategy focused each activity for a specific reason, which ultimately justified the resources required in our final IQCP. The frequency of QC should be event-driven, such as validation of reagent shipments, after major maintenance, or at regular intervals depending on the historical stability of the reagents. Despite manufacturer recommendations for monthly QC, we might increase the frequency to weekly or biweekly in areas with high staff turnover or those having compliance issues. Specific hazards, such as risk of sample clots, could be addressed by a staff reminder so samples are adequately mixed after collection. Visiting the nursing units, we noted some staff collecting samples and then sitting the sample on the bed or side table while tending to the patient's phlebotomy or

line. Labeling and mixing the tube occurred after. By the time staff finished bandaging the patient and discarding the needle, the sample had already started clotting. These issues were improved by giving a refresher on technique and recommending good mixing before completing phlebotomy. The clot detection on the analyzers simply warned of the problem. The action of refreshing nursing technique was required to fix the issue.

Lastly, IQCPs enhanced our communication. Developing an IQCP requires laboratory professionals to get out of the laboratory and meet the staff, watch their workflow, and discuss ways to optimize processes. This step creates an opportunity for the laboratory to interact with clinicians and other members of the healthcare team. We found that processes did not exactly match the way the policy was intended in all areas of the hospital. Hemolysis has historically been a complaint from a few outpatient clinics. Visiting those clinics and watching the staff revealed areas for improvement. But that visit also put a face on the laboratory and demonstrated a desire to listen and work with the clinicians. Bringing together clinicians from multiple disciplines offers the opportunity to partner, not just on IQCPs, but on other issues as well. Most importantly, the clinicians now have a laboratory contact to call when future problems arise.

An IQCP is more than defining QC frequency. IQCPs identify weaknesses in our processes where errors can occur and uncover discrepancies in workflow, providing an opportunity to harmonize, streamline, and improve efficiencies in the entire testing process: preanalytic, analytic, and postanalytic. The previous Centers for Medicaid and Medicare Services option for equivalent quality control (EQC) was myopic and only considered the analytic testing phase. The IQCP risk assessment highlights the potential for error in the preanalytic and postanalytic phases where most of the errors occur. Once these hazards are identified, the laboratory has a variety of actions to address those risks. This step is the individual aspect of the IQCP, since different institutions may address the same risk in a different manner. Once a strategy is chosen to address risks, the rationale and resources to complete those tasks are justified and tied directly to each risk through the summary QC plan. So, clinical laboratorians will realize why they are doing what they do, rather than just claiming it meets a laboratory regulation. An IQCP is an opportunity to add value to the laboratory by providing a venue for the laboratorian to interact with clinical staff. The action of developing an IQCP engages laboratory staff to partner with clinicians on a quality improvement initiative that goes beyond the test. The IQCP is ideally the start of a continuous quality improvement cycle and development of a longer-lasting relationship between the laboratory and clinicians, with the goal of enhancing patient care.

Author Contributions: *All authors confirmed they have contributed to the intellectual content of this paper and have met the following 4 requirements: (a) significant contributions to the conception and design, acquisition of data, or analysis and interpretation of data; (b) drafting or revising the article for intellectual content; (c) final approval of the published article; and (d) agreement to be accountable for all aspects of the article thus ensuring that questions related to the accuracy or integrity of any part of the article are appropriately investigated and resolved.*

Authors' Disclosures or Potential Conflicts of Interest: *Upon manuscript submission, all authors completed the author disclosure form.* **Employment or Leadership:** J.H. Nichols, CLSI and *JALM*, AACC. **Consultant or Advisory Role:** None declared. **Stock Ownership:** None declared. **Honoraria:** None declared. **Research Funding:** None declared. **Expert Testimony:** None declared. **Patents:** None declared.

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