# CHAPTER 4 QUALITY ASSURANCE AND TEST VALIDATION

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Continued innovations in noninvasive testing equipment provide skilled sonographers and physicians with the technology necessary to assess vascular pathology with improved accuracy and detail. Because of this enhanced ability to diagnose peripheral vascular disorders, an increased reliance on the noninvasive examination findings has developed. This confidence has brought about new paradigms in patient management, such as surgical intervention and anticoagulation therapy, based solely upon the results of ultrasound examinations. However, even with state-of-the-art instrumentation, skilled vascular technologists or sonographers, and experienced interpreting physicians, it is imperative that ongoing quality assurance (QA) activities be carried out to ensure complete, accurate, and high-quality laboratory results.

In the current regulatory environment, third-party payers, government agencies, and the public expect medical imaging facilities to document the appropriateness of diagnostic testing. Regular review of laboratory processes, examination findings, and quality measures is now essential to providing superior patient care and ensuring the overall success of the vascular laboratory.

## DEVELOPING A QA PROGRAM

As defined in Merriam-Webster's dictionary, *quality assurance* refers to "a program for the systematic monitoring and evaluation of the various aspects of a project, service, or facility to ensure that standards of quality are being met."[1] A comprehensive quality improvement program should include three components: quality control (QC), QA, and continuous quality improvement (CQI). All three components are required to be effective in ensuring safety, improving services, and enhancing the level of patient care.[2]

In the vascular laboratory, QC generally relates to the calibration and maintenance of equipment. As part of the quality improvement program, there should be a standardized method of QC for all technology being used in the laboratory, thus minimizing the inaccuracies arising from defective equipment. Typically, the manufacturers of ultrasound systems will provide the recommended QC schedules and methods necessary to ensure properly functioning equipment. Carefully document the QC checks in order to provide a record of maintenance, should this issue ever be raised.

The QA component of the program is designed to assess compliance with established standards, policies, and protocols as well as to document the accuracy and outcomes of the testing procedures. Laboratory personnel should take into consideration current industry standards, research, and accepted thresholds when developing or updating their own QA policies, keeping in mind that some policies may be unique to their particular setting. It is important to ensure that the written technical protocols are followed by all members of the staff when performing examinations. Protocols should clearly define the scanning technique, the assessment of vessels and surrounding organs or tissues, what to document in a normal study, and how to evaluate and document any abnormalities. In addition, it is imperative to have standardized diagnostic criteria for each examination that are applied in the same manner by all interpreting physicians. These criteria should be validated either by comparison to reports in the published literature or through validation procedures performed by the laboratory. Routine monitoring of these two aspects of laboratory practice—protocols and diagnostic criteria—will help ensure a systematic approach to the services provided by the laboratory and lead to improved standardization and more consistent test results.

*CQI* refers to the process of becoming a more successful laboratory overall. This is not a single activity but, rather, an ongoing effort that addresses different aspects of the laboratory over time. Often, this component of the program is driven by the most urgent issues facing the laboratory. Data collection and analysis are most valuable if they address a current problem or are used to improve an already adequate system.

In organizing a laboratory's QA program, formally identify who will collect the data, where and how the data will be obtained, how often data collection will occur, what format will be used to record the information, how improvement will be measured, and how the findings will be shared with laboratory staff. Establish a dedicated forum to review laboratory operations and the QA data.

Laboratories with a commitment to high-quality testing often seek accreditation or take measures to maintain the standards of accreditation. A comprehensive, ongoing QA program is mandatory for accreditation by the Intersocietal Commission for the Accreditation of Vascular Laboratories (ICAVL); standards have been written to provide the minimum requirements necessary to ensure accurate examination results (see Chapter 3).

## COLLECTING DATA

Organizing and tracking the correlation data on an ongoing basis are essential to a successful QA program. The tracking methods used may be part of a commercial software package, a laboratory or hospital database, or based on internally developed forms. In documenting QA as it relates to diagnostic testing, the laboratory should have a method to track patients with positive test findings on a daily basis. This may be as simple as a notebook kept in the testing rooms to catalog patients with positive results that could lead to clinical

**TABLE 4.1**

SAMPLE QUALITY ASSURANCE LOG FOR CAROTID DUPLEX TESTING

| DATE | PATIENT NAME | DUPLEX FINDINGS RIGHT | ANGIOGRAPHY FINDINGS RIGHT | CORRELATION OUTCOME RIGHT | DUPLEX FINDINGS LEFT | ANGIOGRAPHY FINDINGS LEFT | CORRELATION OUTCOME LEFT |
|---|---|---|---|---|---|---|---|
| 01/03/09 | M. Smith | Normal | 20% | − | 80%-99% | 95% | + |
| 01/10/09 | B. Jones | 50%-79% | 60% | + | 80%-99% | 75% | − |
| 01/12/09 | T. Brown | Normal | Normal | + | Normal | 32% | − |
| 01/12/09 | P. Stone | 1%-15% | Minimal plaque | + | 80-99% | 95% | + |
| 01/23/09 | J. Hayes | 80%-99% | 81% | + | 80%-99% | 95% | + |

follow-up, another correlative examination, or surgical intervention. Using this list, the assigned staff can contact the appropriate medical personnel to gather information regarding treatment or further testing of the patient, which can be compared with the findings of the noninvasive vascular examination.

When correlative information is obtained, develop a log (Table 4.1). It is generally easier if a log is kept for each type of test performed in the laboratory in order to streamline the data for analysis. The log should include testing dates, patient identifiers, noninvasive examination findings, and the results of any additional testing or follow-up (e.g., angiography, magnetic resonance angiography [MRA], computed tomography angiography [CTA], or surgical intervention).

## MEASURING ACCURACY WITH CORRELATIVE EXAMINATIONS

Specificity, sensitivity, and accuracy are used to describe the results of a diagnostic test in comparison with a standard examination. These measures express the quality of an examination in different ways. *Specificity* is the probability that a test will be negative when disease is absent (true negative). *Sensitivity* is the probability that a test will be positive when disease is present (true positive). These relationships are shown in Table 4.2. The *predictive value* of a test is a measure of the number of times that the value obtained (positive or negative) is the true value. Thus, the percentage of all positive tests that are true positives is the *positive predictive value*, and the percentage of all negative tests that are true negatives is the *negative predictive value*. *Accuracy* is the number of correct findings whether a patient has disease or not.[3] All of these measures are expressed as percentages. It is important to understand these definitions in order to precisely identify what the source of an overall low accuracy may be or to recognize trends that could potentially necessitate a change in one or more laboratory processes.

**TABLE 4.2**

DEFINITIONS FOR CALCULATING SPECIFICITY, SENSITIVITY, AND PREDICTIVE VALUES*

| | DISEASE ABSENT | DISEASE PRESENT |
|---|---|---|
| Test negative | TN | FN |
| Test positive | FP | TP |

*Test negative or positive is based on the vascular laboratory test. Disease absent or present is based on the standard test.
Specificity = TNs/(TNs + FPs).
Sensitivity = TPs/(TPs + FNs).
FN, false negative; FP, false positive; TN, true negative; TP, true positive.

A matrix is generally the best method for calculating the overall accuracy of a test and identifying any outliers or inaccurate test results. To create a matrix, use the categories for reporting disease from the noninvasive vascular examination for both the x and the y axes. The results that correlate exactly will fall on the diagonal axis within the grid, which represents exact agreement between the vascular laboratory test and the standard test (Table 4.3). To complete the matrix, locate the category reported for the noninvasive vascular examination on the y axis on the far left of the matrix and indicate the correlative examination categories along the top x axis. Using the duplex findings, locate the appropriate category (row) and place the mark under the category located on the horizontal axis (column) representing the correlative examination findings. Keep in mind that the correlative examination findings often are not reported using the same categories as the vascular laboratory test, so the findings may need to be reclassified to fit into the matrix. Table 4.4 demonstrates a comparison of carotid duplex findings with angiographic findings. The right internal carotid artery (RICA) results identified an exact correlation between the duplex and the angiogram findings falling on the diagonal axis within the grid, whereas the left internal carotid artery (LICA) findings demonstrated a noncorrelation between the two examinations.

In looking at the grid, note that the noncorrelation findings located to the left of the diagonal axis are those in which the ultrasound findings overestimated the amount of disease in comparison with the correlative examination. The noncorrelation findings falling to the right of the diagonal axis represent vessels in which the ultrasound findings underestimated the amount of disease when compared with the correlative examination (Table 4.5). Both of these types of outliers affect not only the overall accuracy of the test but the sensitivity and specificity as well. In calculating the overall accuracy, the true normal and abnormal examinations (those on the diagonal axis of the matrix) are added together and then divided by the total number of entries within the matrix (see Table 4.5).

The accuracy of examinations that do not utilize criteria quantifying the severity of disease but rather identify only the presence or absence of disease, such as peripheral venous duplex testing, can be tracked using a modified matrix. Inserting the examination results into this modified grid will identify the true positives, false positives, true negatives, and false negatives, as described in Tables 4.2 and 4.6. This documentation will also provide the information needed to calculate the sensitivity, specificity, predictive values, and overall accuracy (Table 4.7).

**TABLE 4.3**

SAMPLE MATRIX OR GRID FOR CORRELATING THE RESULTS OF A VASCULAR LABORATORY TEST (X AXIS = ULTRASOUND) AND A STANDARD TEST (Y AXIS = COMPARATIVE STUDY)

| | COMPARATIVE STUDY FINDINGS | | | | |
|---|---|---|---|---|---|
| ULTRASOUND FINDINGS | NORMAL | 1%-49% | 50%-69% | 70%-99% | OCCLUSION |
| Normal | TN | | | | |
| 1%-49% | | A | | | |
| 50%-69% | | | B | | |
| 70%-99% | | | | C | |
| Occlusion | | | | | D |

Shaded cells, diagonal axis of exact correlation; TN, true normals.
A, B, C, D = True abnormals (exact agreement).
Accuracy = (TN + A + B + C + D)/Total number of tests performed.

## WHEN CORRELATIVE EXAMINATIONS ARE NOT AVAILABLE

Historically, noninvasive vascular tests have been regularly correlated with imaging methods such as standard contrast angiography, digital subtraction angiography (DSA), and more recently, MRA and CTA. However, with advances in the technology of duplex ultrasound equipment and increased confidence in the ultrasound findings, patients are often treated based upon the noninvasive examination results alone; alternative imaging is not performed. This is particularly true in peripheral venous testing for deep vein thrombosis in which ultrasound is generally considered to be the "gold standard" and contrast venography or other imaging is rarely performed. In addition, patients regularly undergo carotid endarterectomy based on the carotid duplex findings alone.

Because of these changes in clinical practice, the number of alternative imaging examinations performed on patients undergoing vascular laboratory tests has decreased, and therefore, opportunities to correlate examination results have become less frequent. However, this increased confidence in ultrasound does not negate the need to monitor the accuracy of the noninvasive examination findings. In fact, when vascular laboratory tests are used in this way, it becomes even more imperative to regularly assess the image quality and the final interpretation. This can be accomplished through a variety of approaches that do not involve correlative examinations.

One simple method of assessing test validity is to compare the noninvasive examination findings with surgical findings or clinical outcomes. This can be achieved by reviewing the operative report and determining whether the severity of a lesion found at surgery was consistent with the noninvasive test findings. It is also possible to correlate the location of the lesion or abnormality using this approach. *Clinical correlation* refers to reviewing the treatment plan prescribed for the patient based on the noninvasive test results and their subsequent management to see whether their clinical course was generally consistent with the vascular laboratory diagnosis.

Another QA tool is the "over-reading" of the examination results by a second physician. This can be used as a method of QA that compares the final interpretation of each reader and ensures that conclusions are consistent among all of the interpreting physicians. Repeat testing by two separate examiners

**TABLE 4.4**

SAMPLE MATRIX FOR CORRELATING THE RESULTS OF CAROTID DUPLEX FINDINGS WITH ANGIOGRAPHY (SEE TEXT)

| | ANGIOGRAPHY FINDINGS | | | | |
|---|---|---|---|---|---|
| CAROTID DUPLEX FINDINGS | NORMAL | 1%-49% | 50%-69% | 70%-99% | OCCLUSION |
| Normal | | LICA | | | |
| 1%-49% | | | | | |
| 50%-69% | | | | | |
| 70%-99% | | | | RICA | |
| Occlusion | | | | | |

LICA, left internal carotid artery; RICA, right internal carotid artery; shaded cells, diagonal axis of exact correlation.
Carotid duplex findings: RICA = 70%-99% stenosis; LICA = normal angiography findings: RICA = 75% stenosis; LICA = 20% stenosis.

**TABLE 4.5**

SAMPLE MATRIX SHOWING THE DIAGONAL AXIS OF EXACT AGREEMENT AND THE AREAS OF OVERESTIMATION AND UNDERESTIMATION OF DISEASE SEVERITY

| | COMPARATIVE STUDY FINDINGS | | | | |
|---|---|---|---|---|---|
| ULTRASOUND FINDINGS | NORMAL | 1%-49% | 50%-69% | 70%-99% | OCCLUSION |
| Normal | * | | | | |
| 1%-49% | | * | Ultrasound underestimates | | |
| 50%-69% | | | * | | |
| 70%-99% | Ultrasound overestimates | | | * | |
| Occlusion (%) | | | | | * |

*White cells on diagonal axis equal exact correlation.

can provide valuable information regarding the technical consistency of the examination. After the first technologist completes the test, another technical staff member, who is not provided with the findings of the initial test, performs a second examination. The findings of the two examinations are compared for test accuracy and adherence to protocol.

Although these approaches do not provide the information necessary to calculate detailed QA statistics, they do provide additional ongoing assessments of laboratory quality when correlative examinations are less accessible or not readily available.

## PEER REVIEW

A system of peer review provides regular feedback that assists in improving or maintaining the consistency of the laboratory. The peer review process evaluates the quality of examinations and interpretations and should include all members of the medical and technical staff. A specified number of random cases for each staff member is collected at intervals stated in the laboratory policy (e.g., monthly or quarterly). The reviews for these cases should be anonymous whenever possible, and the anonymity maintained by the individual responsible for collecting the QA data. Discrepancies should be defined as minor or major, and discrepancy trends should be tracked. All inconsistencies are noted, forwarded to the appropriate personnel, and discussed at the laboratory QA meeting.

**TABLE 4.6**

SAMPLE MATRIX FOR A TEST TO DETECT DEEP VEIN THROMBOSIS (DVT)*.

| | COMPARATIVE STUDY FINDINGS | |
|---|---|---|
| ULTRASOUND FINDINGS | NO DVT | DVT |
| No DVT | TN | FN |
| DVT | FP | TP |

*This test identifies only the presence or absence of disease.
FN, false negatives; FP, false positives; TN, true negatives; TP, true positives.

### Physician Peer Review

The physician review will include a review of the examination findings and comparison with the final report by another member of the medical staff. Inconsistencies between the test findings and the final report should be documented. As well, the reports should be evaluated for adherence to the diagnostic criteria, report content and format, and timeliness of report availability. A worksheet can be developed that will aid in this process (Fig. 4.1).

**TABLE 4.7**

SAMPLE MATRIX FOR A TEST TO DETECT DEEP VEIN THROMBOSIS WITH CALCULATION OF SENSITIVITY, SPECIFICITY, ACCURACY, AND PREDICTIVE VALUES

| | COMPARATIVE STUDY FINDINGS | |
|---|---|---|
| ULTRASOUND FINDINGS | NO DVT | DVT |
| No DVT | 50 | 1 |
| DVT | 6 | 9 |

Total cases, 66; true positives = 9; true negatives = 50.
Sensitivity = 9/(9 + 1) = 90%
Specificity = 50/(50 + 6) = 89%
Accuracy = 59/66 = 89%
Positive predictive value = 9/(9 + 6) = 60%
Negative predictive value = 50/(50 + 1) = 98%
DVT, deep vein thrombosis.

## Technologist/Sonographer Peer Review

The technologist or sonographer is primarily responsible for the performance of the examination and documentation of the test findings. They are trained to follow a laboratory protocol in order to obtain the most complete study possible for each patient. The technical staff review should consist of random case reviews completed by the technical director. This review should include assessment of examination completeness, adherence to protocol, and technical quality. As with the physician review, develop a worksheet to document and share the review findings (Fig. 4.2).

# UTILIZING THE DATA

The data collected must be analyzed in order to develop plans for improvement. The information is of little value if it is not shared with staff and used as the basis for action plans. It is vitally important to the QA program that all staff members participate in the collection and assessment of the QA data in order to implement any changes required to correct the problems identified. It will then be necessary to collect follow-up data based on implementation of any new processes, protocols, or criteria. Once the QA information has been reviewed and discussed and the reasons for inconsistencies or inaccuracies identified, formulate a plan for action. One scenario of the steps taken when utilizing this approach follows.

## Example QA Data Review

1. It is found that a laboratory's accuracy in carotid duplex testing is low owing to many false-positive duplex findings in the 70% to 79% stenosis category, thus decreasing the overall accuracy to 70%.
2. It is then necessary to investigate whether these findings may be occurring owing to one or more of the following:
   a. Technical errors by one or more technical staff members.
   b. Inappropriately applied diagnostic criteria by one or more medical staff members.
   c. Appropriately applied criteria that remain discordant with the alternative imaging diagnosis (e.g., possible inaccurate correlative imaging studies).
3. It is determined that the diagnostic criteria are being applied incorrectly by some of the physicians interpreting the carotid duplex examinations.
4. A plan is implemented to routinely audit the final reports to ensure accurate application of the diagnostic criteria. This audit will be in effect for 6 months and will be followed by a reevaluation of the correlation between the duplex scans and the alternative imaging. It is anticipated that the number of false positive findings in the 70% to 79% category should decrease by 70%.
5. At the time of reevaluation, the overall accuracy has improved to 80% and the number of false-positive results in the 70% to 79% stenosis category has decreased by 72%.

**VASCULAR LABORATORY QUALITY ASSURANCE**
**Physician / Final Report Review**

Type of Noninvasive Exam: _____
Physician i.d.: _____
Reviewer i.d.: _____

| | Study #1 Date of Exam: | Study #2 Date of Exam: | Study #3 Date of Exam: |
|---|---|---|---|
| Interpretation | | | |
| Report | | | |

**Interpretation Scoring:** No Discrepancies = 1 | Minor Discrepancies = 2 | Major Discrepancies = 3
**Report Scoring:** Accurate/Complete = 1 | Minor Inconsistencies = 2 | Major Inconsistencies = 3

**REVIEW COMMENTS:**
Study #1 _____
Study #2 _____
Study #3 _____

FIGURE 4.1 Sample worksheet for physician peer review

**VASCULAR LABORATORY QUALITY ASSURANCE**
**Technologist/Sonographer Exam Review**

Type of Noninvasive Exam: _____
Date of Exam 1: _____ Date of Exam 2: _____ Date of Exam 3: _____
Technologist: _____

| Criteria | Study #1 | Study #2 | Study #3 |
|---|---|---|---|
| Type of Examination | | | |
| Adherence to protocol | | | |
| Exam is complete and thorough | | | |
| Waveform quality (CW Doppler, PW Doppler, PVR) | | | |
| Image quality (if applicable) | | | |
| Overall technical quality (system settings, accurate measurements and angle technique) | | | |

**Criteria Scoring:** Exceeds = 1 | Meets = 2 | Some Deficiency = 3 | Unacceptable = 4

**Review Comments:**

Study #1 _____
_____
_____
_____

Study #2 _____
_____
_____
_____

Study #3 _____
_____
_____
_____

FIGURE 4.2 Sample worksheet for technologist/sonographer peer review.

## QA MEETINGS

QA meetings should be held routinely and documented with minutes. Meetings may be weekly, monthly, or quarterly based on the needs or unique qualities of the laboratory. Even small laboratories consisting of one or two physicians and technologists should hold formal meetings. Documentation of these meetings is necessary in order to provide proof of information dissemination for historical or legal purposes. All staff members should be held to the processes, protocols, and criteria defined within the laboratory and should be given specific guidelines and expectations regarding their performance. If these specific expectations are not met by staff members, steps must be in place to hold them accountable.

## QA AND ICAVL ACCREDITATION

As previously mentioned, laboratories applying for accreditation through the ICAVL are required to maintain an ongoing QA program that includes a minimum of formal QA meetings twice each year, a minimum number of required correlations for each type of testing performed in the laboratory, and an overall accuracy of 70% or greater for each area of testing. QA is considered necessary to ensure a commitment to high-quality patient care. When applying for accreditation, the laboratory must submit at least the minimum number of correlations required as documented in a log and accompanied by the appropriate QA matrix demonstrating an acceptable level of overall accuracy.

## CONCLUSION

Diagnostic tests in medicine are rarely correct 100% of the time. Inaccuracies in noninvasive diagnostic testing may stem from poorly calibrated equipment, patient characteristics such as bowel gas or body habitus, inadequately trained sonographers, and improper application of diagnostic criteria as well as many other aspects of vascular laboratory practice. Physicians and technologists or sonographers must acknowledge the uncertainties associated with noninvasive diagnostic testing procedures and take the necessary steps to monitor test accuracy and the laboratory services in general.

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