Quality Assurance in the Cardiopulmonary Laboratory: Assessing Equipment Performance

by Michael Snow, RPFT

One of the more challenging aspects of managing a diagnostic laboratory is assuring quality. An effective quality program provides effective, consistent and cost-efficient services. Increasingly, regulatory agencies are focusing on quality processes and documentation. Hospitals are learning that poor quality leads to higher costs. While this article will focus on equipment performance, an understanding of quality models is essential. Fortunately, models and guidelines are available.

A frequently cited quality model is the National Committee for Clinical Laboratory Standards’ (NCCLS) HS4-P, A Quality System Model for Respiratory Care. An extremely helpful guide, The Pulmonary Function Laboratory Management and Procedure Manual, is available for purchase from the American Thoracic Society. A common theme in both documents is an emphasis on viewing laboratory quality as a process in which quality is a result not only of equipment performance but also of organizational structure, personnel, process control, documentation/records and a commitment to ongoing process improvement.

A quality assurance program must define several elements, including a calibration procedure, defined quality control standards and a formal quality control testing procedure with a critical review of test results. Calibration procedures are usually defined by the manufacturer and should be followed closely. All instruments have an inherent variability that can be observed via careful review of the calibration records. Trending calibration records can provide documentation of equipment failure as well as early warning prior to failure. Defining quality control standards means selecting standards, such as a syringe, isothermal bottle or fixed resistor, which are traceable to an independent value. Staff “normals” can be another useful standard; however, careful assessment of measurement values and the variability of individual staff “normals” must be defined prior to use as a standard.

The frequency of quality control testing and review should be defined based on individual laboratory activity level. If you are testing only one or two days a week, there is no need to do quality control testing daily. Testing frequency is also determined by the ease with which testing can be done. The bottom line, however, is how many inadequate patient tests do you want to perform before finding out the system has a problem?

**Calibration versus quality control**

Assuring equipment performance requires an understanding of the difference between calibration and quality control. Calibration involves providing known inputs and adjusting the outputs to match expectation. For example, in calibrating gas analyzers, you introduce a calibration gas with a known mixture, such as 16% O2 and 5% CO2. The analyzers are adjusted to provide an appropriate output. This is a necessary first step, but it doesn’t ensure quality when measuring gas exchange during exercise testing since it doesn’t test analyzer performance the way it will be used. In actual use, the analyzers are combined with flow measurements, possibly non-rebreathing breathing valves and, more importantly, a patient adding moisture to the sample. The goal for quality control is to provide a measurement standard that mimics the actual use. Another example is calibrating a spirometer with a three-liter syringe. This simply adjusts the output so that when the system sees this displacement or integrated volume again, it provides an output of three liters. But what if the input signal is wrong?

Calibration syringes generally have adjustable collar rings to permit adjustment of volumes to other settings. A common problem is that, through extended use, the collar ring can be moved inadvertently. So instead of delivering 3.0 liters for a full stroke, you may be delivering 3.09 liters, resulting in inaccurate calibration. The spirometer, believing that the input was 3.0 liters, adjusts subsequent measurements downward. Instead of measuring 3.0 liters for a patient FVC, the system measures 2.9 liters. If you believe that the act of calibration has guaranteed a quality output and make no further assessment of quality, potentially, you may introduce a 3% error into your results.

Calibration syringes generally have adjustable collar rings to permit adjustment of volumes to other settings. A common problem is that, through extended use, the collar ring can be moved inadvertently. So instead of delivering 3.0 liters for a full stroke, you may be delivering 3.09 liters, resulting in inaccurate calibration. The spirometer, believing that the input was 3.0 liters, adjusts subsequent measurements downward. Instead of measuring 3.0 liters for a patient FVC, the system measures 2.9 liters. If you believe that the act of calibration has guaranteed a quality output and make no further assessment of quality, potentially, you may introduce a 3% error into your results.

This example illustrates the need for some independent quality assessment after calibration. Generally speaking, the quality control phase should involve testing the system as it is going to
“Quality Assurance” continued from page 1

be used. For example, making a measurement of FVC is a good way to track quality control for a spirometer. However, an important point to remember is that the calibration standard cannot be the quality control standard. If you use the same syringe that was used to calibrate the system, you will not detect the 3% error. The system will report 3.0 liters. For this reason, it is very important to use a different syringe in the quality control phase.

In addition to being independent of the calibration, the quality control standards must be appropriate to the measurements, available on a routine basis and have predictable consistency. Biological standards, such as staff “normals,” are very useful since they test the system in the same way a patient does. The only real drawbacks to using staff “normals” are the lack of a sufficient number in a small laboratory and the fact that they may occasionally become not “normal.” In other words, they are subject to physiologic variability and illness, which may alter their results. On the other hand, a syringe is usually always available, provides very consistent results and can be used for every test except airway resistance. Other types of quality control standards, such as spirometry waveform generators, DLCO or gas exchange simulators, while commercially available, may be too expensive for routine use in a small laboratory. Whatever the selected standard, it should be used regularly as part of a quality control program.

Assessment of variability

Another important aspect of quality assurance is documenting the variability of the instruments and the measurements. All quality control standards have some degree of inherent variability. In order to appropriately assess quality, it is essential to account for this variability. This is perhaps best expressed by plotting quality control data on a Levy-Jennings type plot. An example is shown in Figure 1. The plot shows quality data plotted by time with an identification of the mean and two standard deviations (SD). The mean and SDs provide a statistical description of the distribution of quality control data. Assuming a normal distribution, data points scatter evenly above and below the mean. Assessing SD provides a sense of the measurement variability. Typically, a 2SD range, providing a 95% confidence level, is both reasonable and practical. Setting limits too tight produces too many false alerts.

In practice, the 95% confidence level on the Levy-Jennings plot is used to identify out-of-control conditions. If a quality control standard is greater than 2SDs from its mean, it indicates the need for further assessment. The initial reaction is to repeat the testing with a different staff “normal” to ensure the value is not simply a random error. If subsequent testing confirms the problem, remedial action, such as repeating calibration or requesting service on the system, may be taken. The plot is also useful in detecting trends indicating the early signs of component failure or a shift, which might indicate an unexpected change in protocols.

Clinical meaning of variability

Comparing the SD to the mean value provides an assessment of variability called coefficient of variation, or covariance, expressed as a percent (SD/mean × 100). A smaller covariance indicates more consistent data. This can be useful in several ways. Figures 2 shows a plot of quality control data using staff “normals” for several measurements over the course of a year. The covariance for each measurement is shown in parenthesis. As can be seen, the covariance for SVC is the smallest at 1.63%, while the highest covariance is RAW at 9.11%. This illustrates the type of variability that can be expected for quality control data. For quality assurance purposes, the actual range of values is not as important as the consistency.

Knowledge of the variability of a measurement can be used to determine clinically significant differences. For example, if a patient’s DLCO measurements have a covariance of 5% and on a subsequent visit there is a 12% change, then that change would be more than 2SDs, or a 95% probability that the result represents a significant change. Using 2SDs as the threshold for determining a significant change after bronchodilators is another example. ATS guidelines suggest a 12% and 200mlim improvement is required to demonstrate a significant response for FVC and FEV1. If the patient can achieve a reproducibility of less than 5% on the baseline measurements, then clinical significance may be achieved with a smaller, 10% improvement. Yet another example is a patient who cannot achieve ATS level reproducibility for FVC on his first visit, but shows a marginal increase of 7% on the subsequent visit with easily achieved reproducibility targets. Would the improvement in reproducibility on the second visit, in association with the marginal increase in FVC, indicate a clinically significant improvement even though the absolute change was marginal?

These examples should not be taken as a recommendation to change existing guidelines but rather as encouragement to carefully evaluate trends with the insight gained from the understanding of measurement variability. This careful evaluation is part of the difference between a skilled practitioner and someone who simply passes data along without review.

References:
1. NCCLS documents are available from: National Committee for Clinical Laboratory Standards, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, (610) 688-0100.
Diagnostics Bulletin

Mayo Clinic’s Outpatient Pulmonary Function Laboratory
by Carl Mottram, BA, RRT, RPFT, FAARC, coordinator, pulmonary function laboratories and rehabilitation, Mayo Clinic; assistant professor of medicine, Mayo Medical School; Rochester, MN

The Mayo Clinic’s outpatient pulmonary function laboratory is one of the largest and busiest pulmonary diagnostic laboratories in the world. The lab’s history in pulmonary diagnostic testing is impressive. A succession of medical directors, including Drs. Fowler, Helmholtz, and Hyatt, played significant roles in the description or definition of many of the diagnostic tools we all use today. Our current medical director, Dr. Paul Scanlon, continues this exceptional lineage by serving as principle investigator on numerous research studies, including the heralded multi-center lung health study, which evaluated the long-term effects of smoking cessation.

As a result of our history, our large and diverse patient volume and our research activities, we have a well-established reputation for quality, accurate pulmonary diagnostic testing. The lab is housed in the historic Plummer Building. The Plummer Building, one of the original Mayo Clinic buildings, is on the national historic registry and is topped with a 50-bell clarion, which is still played weekly. The building is also the location of one of the most significant collections of medical literature in the world, as it houses the clinic’s medical library.

Our laboratory encompasses almost the entire third floor, minus the original offices of William and Charles Mayo. Our testing facilities include nine rooms outfitted with complete PFT systems, including plethysmographs, four blood gas rooms, an exercise lab, REE lab, mechanics lab and outreach lab, along with offices and technologist space for the 42 staff who call the lab home. The lab has 120-150 patient visits per day and performs approximately 25,000 pulmonary function diagnostic tests (or about 60,000 unique billable procedures) per year. These procedures range from routine spirometry to the more sophisticated cardiopulmonary exercise and mechanics tests.

We also work collaboratively with our colleagues at our sister facilities in Scottsdale and Jacksonville, each formidable labs in themselves, to provide consistent testing methodologies throughout the Mayo system. And the collaboration does not stop there as we strive for quality pulmonary function testing. We also have a history of working with the major pulmonary diagnostic companies in providing them with valuable feedback in both the methodologies of testing and instrumentation results.

One source of this feedback comes from our large collection of historical biological data on 11 technologists who participate in our in-house QA program. These data not only help us QC our daily testing instrumentation, but also give us an inimitable opportunity when evaluating new testing equipment. Comparison of these data with new testing equipment can often help identify issues that cannot be teased out when using static or mechanical models during the validation process. When we do find testing variance, this gives us the chance to have an open dialogue with the company and discuss product improvement, which we have done on numerous occasions.

When Mike Snow, Bulletin editor, asked me to discuss our lab with you I did have some reservations, because I didn’t want the article to appear as if I were bragging. But then I was reminded of Walter Brennan, an old cowboy figure of my youth (and you have to be old to remember this one), who used to say, “no brag, just fact.” The fact is the lab is very impressive in quality and magnitude of data and the historic locale. The laboratory staff and myself have a lot to be proud of, and as I travel around the country I often share with colleagues the awesome feeling I personally get from working at this facility.

As I said earlier, our lab is right next door to the original offices of Will and Charlie Mayo. This proximity is a constant reminder of the tremendous responsibility we have to serve the patient and provide only the highest quality of patient care. The symbol of the Mayo Clinic is a conjoined triple shield with each shield representing the secular entities of patient care, education, and research. But the Clinic’s mission is “the needs of the patient come first,” and we, as a lab, intend on succeeding in meeting this mission.

Get it on the Web

Want the latest news from the section in the quickest manner possible? Then access the Bulletin on the Internet! If you are a section member and an Internet user, you can get your section newsletter a week and a half to two weeks earlier than you would get it in the mail by going to your section homepage at: http://www.aarc.org/sections/section_index.html. You can either read the Bulletin online or print out a copy for later. The AARC is encouraging all section members who use the Internet to opt for the electronic version of the Bulletin over the mailed version. Not only will you get the newsletter faster, you will be helping to save the AARC money through reduced printing and mailing costs. These funds can then be applied to other important programs and projects, such as ensuring effective representation for RTs on Capitol Hill.

To change your option to the electronic section Bulletin, send an email to: mendoza@aarc.org.

Diagnostics Section Survey

We want to provide you with the information and service you desire for your specialty section membership. Please take a minute to fill out this small survey and fax it back to: 972-484-6010

Why did you join this specialty section?
___ To network with and learn from others working in my specialty
___ To receive information about my specialty area of practice
___ To participate in designing programs and information about my specialty

How many times a year do you want to receive a newsletter?
___ 6 times a year
___ 4 times a year
___ 2 times a year
___ No opinion

Would you rather receive a printed newsletter or more timely and more frequent email updates of news and information?
___ Yes
___ No

Would you prefer to receive this newsletter by reading it on the website?
___ Newsletter
___ Email
___ No opinion

Are You on the Diagnostics Section Email List?
Sign Up Today on Your Section’s Home Page!

http://aarc.org/sections/section_index.html
The AARC is currently seeking information on JCAHO accreditation site visits. Please use the following form to share information from your latest site visit with your colleagues in the Association. The information will be posted immediately on the AARC web site at http://www.aarc.org/members_area/resources/jcaho.html and will also be featured in the Bulletin.

Accreditation visit you are reporting (choose one):

- Home Care
- Hospital
- Long Term Care
- Pathology & Clinical Laboratory Services

Inspection Date: _____________________________________________________________________________
Facility Name: _______________________________________________________________________________
Contact: ____________________________________________________________________________________
(Please provide name and e-mail address.)

1. What was the surveyors’ focus during your site visit?
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________

2. What areas were cited as being exemplary?
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________

3. What suggestions were made by the surveyors?
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________

4. What changes have you made to improve compliance with the guidelines?
__________________________________________________________________________________________
__________________________________________________________________________________________
__________________________________________________________________________________________

Mail or fax your form to:
William Dubbs, RRT
AARC Associate Executive Director
11030 Ables Lane
Dallas, TX 75229-4593
FAX (972) 484-2720

Additional comments: