

## TAKING PULMONARY LABORATORY QUALITY CONTROL TO A HIGHER LEVEL *by Robert Crapo MD*



In previous articles we have discussed how quality control reduces noise and errors and thereby increases the clinical value of the tests we deliver. Precise and accurate instruments are critical. Our most recent experience shows almost all instruments meet ATS standards but not always on the first try. What that means is that instruments that meet current recommendations are readily available. Maintaining the instruments and assuring they continue to perform well is your task. Beyond that are the problems of interactions among the patient, the instrument and the technician. I propose we change the pulmonary laboratory culture to align more closely with the clinical chemistry laboratory culture where the primary focus is on the delivery of quality measurements. This means all of us, technicians, supervisors and medical directors, need to be involved. I asked the people attending my session at the 2005

Focus meeting in Cleveland to raise their hands if they had regular or even semi-regular contact with their medical director relating to test quality. Less than 10% raised their hands. It will be harder to change the culture without engaging your medical director but it can certainly be done by the front line technicians and supervisors. A good starting place is a good laboratory procedure manual. This will focus you on the critical elements of the test procedures and give you some ideas about what elements could be tracked. If you don't already have one, consider having the laboratory buy one. The American Thoracic Society (contact: [bnance@thoracic.org](mailto:bnance@thoracic.org)) manual comes in an electronic format so it can be easily updated and edited. It has detail on the procedures, quality control and reporting.

Nothing will substitute for a technical staff with a genuine interest in the work they're doing. The critical elements for quality control are instrument maintenance, calibration, good procedures, and daily feedback to the staff on test quality. It is also vital to track selected elements to check for "drift" – this is part of what determines if a chemistry or blood gas lab gets accredited. As a start, you could track biologic control data. In spirometry, for example, technicians can perform the test on each other once a week and graph the results. The graph can be done by hand or using any number of computer programs. You're looking for variability and trends. It is important that the numbers not become more variable and hopefully they become less variable over time. You can also see if the data are trending up or down or if there is a sudden shift. A change in variability or a shift should trigger an investigation. In our lab, for example, we use a diffusing capacity simulator rather than biocontrols to track DLCO. The machines are tested once a week on Friday – one Friday we saw a significant increase in DLCO. The consequent examination of the instrument uncovered a small leak in the rolling seal. When the leak was fixed, the simulation values went back to baseline. Since most of you don't have a simulator [They are marketed by Hans Rudolph], you can use other methods. In addition to biologic controls, you can look to see how often your tests meet the acceptability and repeatability criteria. For DLCO, you could determine how often the inspired values meet the ATS standard (>90% of the largest previous vital capacity), how often breath hold time is between 9 and 11 seconds, and how often the variability meets the standard of being within + 2-3 standard units. This could be recorded daily and summarized graphically over months.

Ultimately, your comparative data will be your baseline data. Once the baseline has been established, you can set goals for improving areas you see are weak.

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Here are some guidelines for reasonable targets. In research settings, spirometry acceptability criteria are met 95-98% of the time and repeatability criteria are met 85-97% of the time. We know the clinical setting is not likely to meet the research setting levels partly because sick patients are less likely to meet standards. A retrospective analysis of 500 patients tested in our laboratory (relatively high acuity setting) in 1995 showed repeatability criteria for FVC and FEV1 were met about 88%, breath hold times on the DLCO were met 95% of the time. In general, we met quality criteria between 80 and 90% of the time. That's the baseline from which we can set goals to try and improve. The fact that they are high does not allow us to relax or to attribute the failure to the patients (out of our control). At the very least, it is a level below which we do not wish to fall.

In our laboratory, we do a few things to help the technicians meet quality control elements. We started by creating a table of the essential quality elements for spirometry and DLCO. The technicians checked appropriate Q.C. boxes for each trial. This has been a good tool; just having to mark the box focused the technicians on quality issues. It's now incorporated into their thinking and the check boxes are no longer needed. Implausible values (e.g., a vital capacity >140% predicted) launches a check to make sure the instrument is working correctly. In the patient test mode, we slowly inject a 3 liter of air with a calibrated syringe looking for zeroing or sensor contamination errors. We'll probably keep doing it because we have found - and fixed - a couple even after the machine met its morning calibration check.

If you are interested, Mary Townsend has written an excellent paper (Is my lung function really that good? Chest 2004, 125:1902-1909).

Finally, an important step is to evaluate test quality in the interpretation. This step must be taken by the person interpreting the test. The ATS standard is that the first comment in all interpretations of lung function is to comment on test quality. An interpretation without this assurance is, in my opinion, suspect. All tests will not meet the quality standards because some patients will be unable to perform adequate tests so the interpreter has to state a judgment on the reliability of the test data. When the medical director is engaged in this process and making comments on the test quality, you can expect things to change. In our laboratory, the technicians read the reports after interpretation and that engages the whole laboratory in the quality control process. I can think of no more important step in moving to a new level.

In summary, tests should be reviewed for test quality and technicians should be aware of the physician assessment of test quality. Pulmonary labs should track several quality elements and technicians should learn to recognize patterns of abnormality, and sub maximal efforts. Invalid results should be removed from the patient record or at least commented on and the staff should meet to discuss quality issues. This is a human system that can be lubricated with compliments when performance is good and the whole process should be approached with a positive teaching attitude avoiding a punitive or critical tone. It is important to remember that not all patients can perform the test to the standards. We're looking for control of the things within our control.

*Supporting Families of ICU Patients... Continued from page 56*

Procedures, Laboratory Tests, X-rays and Scans. The ICU Team explains the role of each clinician found in the ICU including a respiratory therapist and it links over to the AARC website.

Though there is no federal patient bill of rights at "Patient Bill of Rights" a Bill of Rights is presented that represents what most hospitals and medical facilities might use with slight variations.

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