Should diffusing capacity quality control be treated like other laboratory devices?

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To the Editor:

Diffusing capacity of the lung for carbon monoxide (D_{LCO}) is an important pulmonary function test for the diagnosis and management of obstructive, restrictive and pulmonary vascular disease. The 2017 European Respiratory Society (ERS)/American Thoracic Society (ATS) standards for single-breath carbon monoxide uptake in the lungs recommends that a weekly D_{LCO} simulation be performed with a calibrated 3-L syringe [1]. This type of simulation provides quality control values for both D_{LCO} and alveolar volume (V_A). After accounting for system dead space, an acceptable simulated V_A is defined as 3±0.3 L (gas conditions at atmospheric temperature, pressure, dry). We previously suggested that fixed arbitrary ranges for spirometry calibration verification were inferior to limits based on the performance of the device (±2 standard deviations), which is commonly used to determine quality control ranges in laboratory medicine [2]. This recommendation was included in the 2019 ATS/ERS spirometry technical standard [2, 3]. We believe that a similar recommendation is appropriate for V_A simulation.

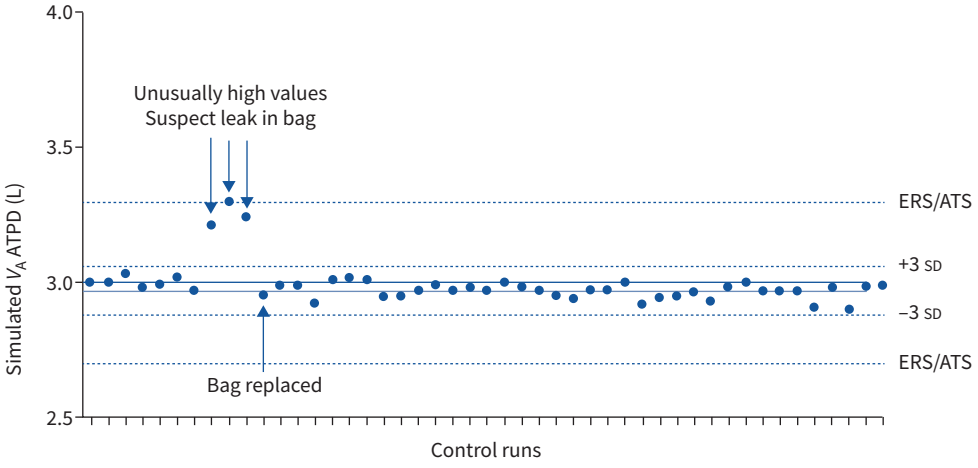

FIGURE 1 Levey–Jennings graph of simulated alveolar volume (V_A) quality control testing with a 3-L calibration syringe. The solid line on the ordinate below the line at 3 L represents the measured mean of serial testing (2.97 L), the dotted lines show the 2017 European Respiratory Society (ERS)/American Thoracic Society (ATS) diffusing capacity standards and 3 standard deviation (SD) limits. ATPD: gas conditions at atmospheric temperature, pressure, dry.

Figure 1 shows the results of serial V_A simulation on a classical system that uses plastic bags for the collection of discrete gas samples (Medisoft BodyBox, Sorinnes, Belgium; ComPAS software, Morgan Scientific, Haverhill, MA, USA). The eighth data point in figure 1 is 3.21 L, an unusual value on this device. During the troubleshooting process the test was repeated and values of 3.3 L and 3.24 L were recorded. The mean value for serial simulated V_A on this device was 2.97 L with a standard deviation (SD)

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The ERS/ATS D_{LCO} standards recommend that a weekly D_{LCO} test should be performed with a 3-L syringe and the V_A from this should be 3±0.3 L. This report suggests that a tighter range (±3 SD) provides better D_{LCO} quality control than fixed arbitrary limits. https://bit.ly/3EvkEj0

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of 0.03 L, and a coefficient of variation of 1%. The data points 8–10 in figure 1 were 8, 11 and 9 SD above the measured mean respectively, yet all of these values were within the ERS/ATS limits of acceptability. A leak in the expiratory sample bag was suspected and, following the replacement of the bag, the simulated V_A was 2.95 L, within the ±3 SD range for this device. The ±3 SD range for this device and the ERS/ATS limits are shown in figure 1, suggesting that a ±3 SD range for simulated V_A is potentially more effective at identifying D_{LCO} system errors than the fixed, arbitrary ERS/ATS limits. Our previous recommendation for spirometer quality control ranges was ±2 SD; however, other laboratory devices (*e.g.* blood gas analysers) are not truly out of control unless the recorded value exceeds ±3 SD. In addition, using ±3 SD rather than ±2 SD may minimise unneccesary troubleshooting of D_{LCO} devices.

One approach to developing better limits for V_A simulation would be to stipulate that the mean V_A should be within 3% of the standard 3-L syringe (2.91–3.09 L) and the limits of acceptability should be ±3 SD of the measured mean. Further research is needed to analyse data from multiple devices and laboratories to determine acceptable quality control limits that are generalisable to most laboratories. Ideally, manufacturers could incorporate these calculations and Levey–Jennings graphs into their software to make V_A simulation data easier for end-users to analyse. V_A simulation limits based on performance rather than fixed arbitrary values may provide better quality control of D_{LCO} devices.

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Conflict of interest: J.M. Haynes reports consulting fees from Morgan Scientific Inc., Haverhill, MA, USA; lecture honoraria from Washington Society for Respiratory Care, American Association for Respiratory Care, Ohio Society for Respiratory Care, FOCUS Respiratory Conference, Pennsylvania Society for Respiratory Care; travel support from National Board for Respiratory Care, American Association for Respiratory Care, FOCUS Respiratory Conference; board leadership on the National Board for Respiratory Care; outside the submitted work. G.L. Ruppel reports lecture honoraria from MGC Diagnostics, outside the submitted work. D.A. Kaminsky reports speaker fees for the Cardiorespiratory Diagnostics Seminar from MGC Diagnostics, Inc., and contributor fees from UptoDate, Inc., outside the submitted work.

References

1 Graham BL, Brusasco V, Burgos F, *et al.* 2017 ERS/ATS standards for single-breath carbon monoxide uptake in the lung. *Eur Respir J* 2017; 49: 1600016.
2 Haynes JM, Ruppel GL. Should spirometer quality control be treated like other laboratory devices? *ERJ Open Res* 2019; 5: 00249-2018.
3 Graham BL, Steenbruggen I, Miller MR, *et al.* Standardization of spirometry 2019 update. an official American Thoracic Society and European Respiratory Society technical statement. *Am J Respir Crit Care Med* 2019; 200: e70–e88.