DIAGNOSTIC ACCREDITATION PROGRAM

Spirometry Quality Control Plan

Spirometry Quality Control Plan

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Spirometry Quality Control Plan

Introduction

Spirometry is a useful diagnostic test commonly performed in a variety of settings; however, accurate results are dependent on careful technique, and proper equipment calibration and maintenance. The American Thoracic Society (ATS) and European Respiratory Society (ERS) have recommended a number of procedures to reduce variability including the weekly testing of flow volume measurements. Under the College of Physicians and Surgeons of British Columbia, Diagnostic Accreditation Program (DAP) Spirometry Quality Control Program, facility personnel at each site will perform quality control procedures according to the DAP protocol. Only one set of data is required from each spirometer. If the spirometer is used in more than one site, the patient data submitted should be representative of this.

Results are submitted to the DAP twice a year and will give an indication if any areas of concern exist with the spirometer or performance of the tests. An individual report with recommendations will be sent to the facility at the end of each reporting cycle.

Level 1 and level 2 (formerly known as category IIA and IIB) facilities and private clinics performing spirometry require participation in the DAP Spirometry Quality Control Program as part of their accreditation. Continuing accreditation is based upon the satisfactory review of quality assurance and control data submitted to the DAP.

Exemption: If the spirometer used exclusively is the **COPD-6** spirometer, as approved by the Medical Services Commission for case finding, DAP accreditation is not required.

The DAP Spirometry QC Program follows the recommendations of the “Standardization of Spirometry 2019 Update. An Official American Thoracic Society and European Respiratory Society Technical Statement.”[1]

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Spirometry Definitions and Requirements

Calibration/calibration check: Calibration is the procedure for establishing the relationship between sensor-determined values of flow or volume, and the actual flow or volume, using a validated 3-L calibration syringe. Current ambient conditions are entered prior to calibration and the injection rates are varied according to equipment manufacturer's recommendations to *adjust* the output with a known input volume. Calibration check is different in that it does not adjust the spirometer; rather it verifies that the spirometer is within calibration limits.

Linearity testing*:* A spirometer is considered linear if its output is directly proportional to its input, regardless of the flow rate. Loss of linearity is a primary problem with flow sensing spirometers, therefore syringe flow volume loops are performed on a weekly basis to ensure system linearity.

Biologic controls (BioQC): A healthy non-smoking individual will perform spirometry testing monthly to assess the overall operational status of the spirometry system. Results are monitored to assess changes in equipment performance that may be undetected in routine calibration. A second BioQC subject should be identified and able to fill in if the primary BioQC subject cannot perform this function due to absence or illness.

Spirometry Requirements

- The spirometer must be able to accumulate volume for greater than 15 seconds and measure a volume of greater than eight liters (BTPS) with an accuracy of ± 3% of reading or ± 0.05 liters, whichever is greater.
- The facility must have a room thermometer with an accuracy of ± 1°C.
- If room temperature changes by more than 2°C, then another calibration must be performed prior to patient testing.
- Measure height of patients and BioQC subjects accurately.
- Calibration or calibration checks are performed daily or prior to patient testing.
- Linearity checks (flow volume loops) should be performed weekly and after equipment repairs, maintenance or software changes.
- A BioQC should be performed monthly and after equipment repairs, maintenance or software changes.
- A log of all relevant testing data, service, repairs or software changes, should be maintained.
- The 3-L syringe requires revalidation according to manufacturer's recommendations.

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The term **quality contro**l can be defined as the process of monitoring the accuracy and reproducibility of a test procedure, but it also takes into account a number of aspects, any one of which may impact patient results. These include the components that make up the pre-examination, examination, and post-examination:

- patient education and preparation
- procedure
- equipment
- reporting of results

The following chart outlines the steps necessary to ensure proper functioning of the spirometry equipment, and the frequency with which they need to be performed by the therapist, in order to produce accurate patient results. Detailed instructions follow in each section.

Equipment	Procedure	Frequency	ATS/ERS limits of acceptability/recommended limits
Spirometer	Calibration or Calibration Check with 3-L calibration syringe	Daily or prior to patient testing	+ 3.0% of 3 L (2.910–3.090 L)
Spirometer	Linearity tests with 3-L calibration syringe	Weekly	Loops at these flow ranges: < 2 L/s, 4 L/s to 6 L/s, > 8 L/s See Linearity Acceptance Criteria for acceptable results.
Spirometer	Biologic control BioQC)	Monthly	FVC and FEV1 < 3% PEFR < 10%
Syringe	Leak test	Weekly	No leaks
Syringe	Revalidation	As needed	Determined by the expiration on the certificate of calibration

Daily Quality Control

1. Perform calibration or calibration check at least daily or prior to patient testing, as per manufacturer recommendations.
2. Print out a copy of the calibration results. The measured values must be between 2.910 and 3.090 liters.
3. **Verify that the calibration has passed prior to patient testing**.

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See Spirometer Calibration for more information.

Weekly Quality Control

1. Perform 3-L calibration syringe leak test.
2. Perform linearity test with a validated 3-L calibration syringe run in a patient file, named "Syringe, QC," and record results on the DAP Monthly Spirometry Linearity Testing worksheets.
3. **Verify that the linearity tests fall within the acceptable ranges for accuracy and reproducibility.**

See Spirometer Linearity Testing for more information.

Monthly Quality Control

1. Perform BioQC testing: The biologic normal control is performed in the patient file designated for that individual (e.g. BioQC1 or BioQC2). Only one (1) BioQC is required to be tested each month. When this data is entered into the DAP Spirometry QC worksheets, several calculations are performed automatically. Unexpected changes in the BioQC values may alert the user to equipment problems that were not present, or undetected, when calibration procedures were performed.
2. **Verify that the BioQC values are acceptable based on their established ranges.**

See Biological Control (BioQC) Testing for more information.

As-needed Quality Control

1. 3-L syringe revalidation: The 3-L syringe is re-validated according to the frequency determined on the certificate of calibration. If an expiry is not defined on the certificate the revalidation should occur within 2 years of the last date of calibration.

See Spirometer Calibration for more information.

Semi-annual Reporting

1. Submit to the DAP on or before January 15 and July 15:
    a. Worksheets for linearity report (including printout of numerical and graphical data).
    b. Worksheets for BioQC results (including printouts of numerical and graphical data).
    c. For each interpreting physician, printouts of five (5) random and anonymized patient spirograms with interpretation, performed during the six-month reporting period. (including printouts of numerical and graphical data)
    d. Calibration printouts corresponding to the day of each BioQC and patient result submitted.

Logbook

A logbook should be kept to record the following:

- ambient temperature
- barometric pressure
- relative humidity
- calibration FVC values with the 3-L syringe
- calibration pass or fail
- leak test pass or fail
- equipment service, troubleshooting performed, software upgrades, etc.

Example of logbook:

Date	Initials	Temp (°C)	BP (mm/Hg)	RH (%)	Calibration: FVC (2.910–3.090)	Cal (P/F)	Leak test (P/F)	Comments
24/08/12	SW	21	756	72	3.02	Pass	Pass	ATS 2019 software upgrade

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Spirometer Calibration

Calibration Syringe Requirements

To achieve accurate and reproducible spirometry results, measurements from your spirometer should be regularly checked against a precision calibration syringe. The "Standardization of Spirometry 2019 Update"[1] requires daily calibration or calibration checks of flow and volume spirometers using a validated 3-L calibration syringe with an accuracy of ± 15 mL or ± 0.5%.

Calibration is the procedure for establishing the relationship between sensor-determined values of flow or volume, and the actual flow or volume, using a validated 3-L calibration syringe. Calibration should be performed daily or prior to use. Follow manufacturer's instructions. Spirometer should be set to calibration mode.

A calibration check is different from calibration and is the procedure used to validate that the spirometer is within calibration limits, that is to say ± 3.0% of true. A calibration check is required daily or prior to patient testing. Spirometer should be set to calibration check mode. There are no spirometers on the market currently that may be used without at least a calibration check.

Syringe revalidation: As wear and tear can affect the accuracy of the 3-L calibration syringe over time, it should be re-validated as determined by the expiry date on the certificate of calibration, or every two years if the expiry is undefined. There are a number of companies that perform revalidation services of calibration syringes. Proof of syringe validation must be submitted annually to the DAP.

Syringe leak test: The 3-L calibration syringe should be tested for leaks and smoothness of operation minimally on a weekly basis. The syringe should be tested from a full (drawn back) position by placing a hand over the outlet and depressing the syringe handle gently. No air should escape. Secondly the syringe should be emptied, and in an empty position should be checked by again placing a hand over the outlet, then pulling gently on the syringe handle. No air should enter the syringe. Syringes that leak may not measure proper volume and should be sent for service and revalidation.

Syringe smoothness test: Move the syringe handle back and forth to check that the action is smooth, without catching or stuttering. Syringes that do not move smoothly may not deliver proper volume and should be sent for service and revalidation.

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Performing Calibration or a Calibration Check

Calibration or calibration checks must be performed every day prior to patient testing or when quality control is performed. Check your manufacturer's manual for calibration or calibration check directions. The directions will be labeled as a calibration or a calibration check. Some systems are calibrated at the manufacturer's site but still require a calibration check daily or prior to patient or quality control testing.

The following instructions may not be specific to your spirometer, but the examples are meant to represent how the data may look. The displays will vary slightly based on the spirometer you are using.

Enter Ambient Conditions

The facility must have a room thermometer with an accuracy of ± 10°C. If barometer and/or hygrometer are not available, barometric pressure and relative humidity may be recorded from local weather station sources. From your thermometer, barometer and hygrometer enter:

1. Temperature
2. Barometric pressure
3. Humidity

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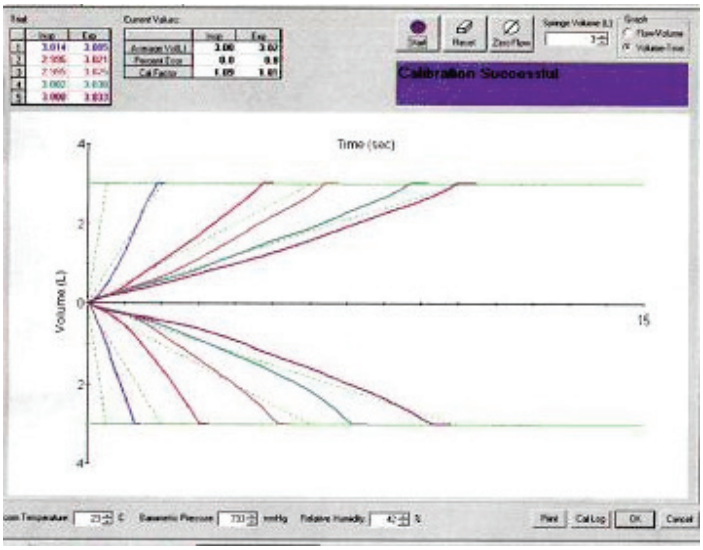
Perform Calibration or Calibration Check

1. Set spirometer to calibration mode or calibration check mode.
2. If filters designed specifically for spirometry testing are used, calibration or calibration checks should be done through the filter.
3. Perform a calibration or calibration check using the validated 3-L calibration syringe according to the ATS/ERS statement "Standardization of Spirometry 2019 Update."[1] Pull the syringe handle out completely and push the 3-L volume into the spirometer at the correct flow.
4. Repeat the calibration or calibration check at least three separate times at three different flow rates, as per manufacturer instructions.
5. Ensure the calibration results are within the required limits ± 3.0% (or 2.91 liters to 3.09 liters).
6. Maintain a copy of the calibration or calibration check in the logbook.
7. Submit a copy of the calibration or calibration check to the DAP for each day of BioQC and patient results submitted in the semi-annual QC package.



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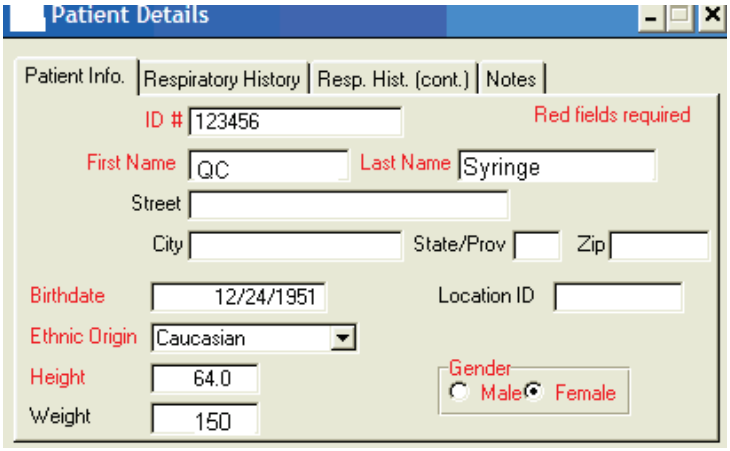
Spirometer Linearity Testing

A spirometer is considered linear if its output is directly proportional to its input regardless of flow rate. The resulting volumes should be accurate and reproducible. The ATS/ERS statement "Standardization of Spirometry 2019 Update"[1] states that linearity testing must be performed weekly. The DAP Spirometry QC Program requires that only one of those tests be recorded for each month on the Monthly Spirometry Linearity Testing worksheet.

The linearity test is completed by performing syringe flow volume loops to simulate patient testing with a known volume at varying flows. Set the spirometer to patient mode and inject air from a 3-L syringe at a slow, moderate, and fast flow rates. The peak flow rates include one injection at a rate of less than two liters per second, one injection at a rate of four to six liters per second, and one injection at a rate of greater than eight liters per second. The FVC volumes achieved at each of these flow rates should meet both the accuracy requirement of ± 3.0%, and should show reproducibility to within 90 mL from highest to lowest flow rate (see Accuracy verification and Reproducibility verification).

Linearity Testing

1. Enter ambient conditions, as previously described.
2. Perform a calibration or calibration check using the 3-L syringe, as previously described.
3. Set up a mock patient study. Enter the patient data as follows:
    - First Name: QC
    - Last Name: Syringe
    - Weight: 150 lbs. (or 68 kg)
    - Height: 64 in. (or 163 cm)
    - Age: 40



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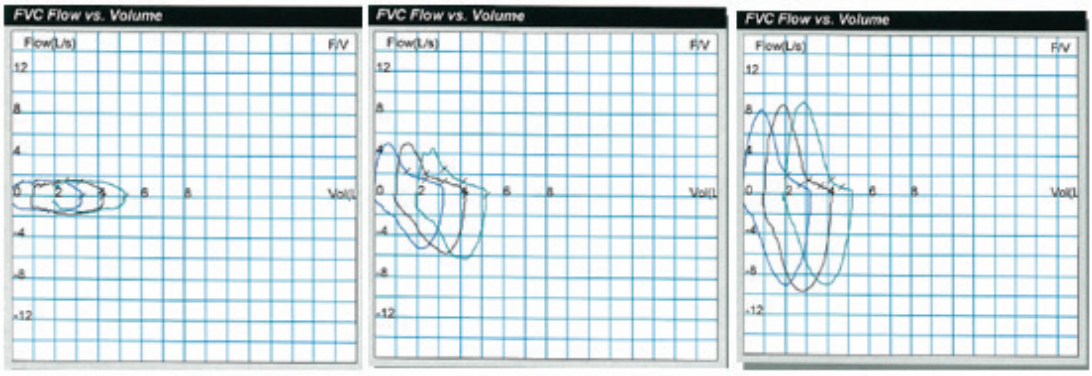
4. Perform linearity tests (flow volume loops) as shown below.
    a. Set spirometer to patient mode. Attach a 3-L syringe to the spirometer with a tight seal (no leaks).
    b. Withdraw syringe until fully inflated to a full three liters.
    c. Perform a minimum of three linearity tests (flow volume loops):
        - one maneuver will be performed with a peak flow of less than two liters/sec
        - one maneuver will be performed with a peak flow between four and six liters/sec
        - one maneuver will be performed with a peak flow greater than eight liters/sec

    Example:



5. Print out the following:
    - All linearity tests displaying each loop at each flow and the actual numeric results.
    - Ambient temperature is an integral piece of information that **must** be recorded somewhere on the flow volume loops printout.
6. Verify linearity meets acceptability criteria as defined below
7. Complete DAP Monthly Spirometry Quality Control Program worksheet (tab labeled Linearity):
    - Fill in the values generated for FVC and FEV1 at each flow rate.
    - Confirm that FVC and FEV1 values are within acceptable limits.
    - Attach the corresponding graphical print-out.

    Note: While Linearity testing is required weekly, only one week per month should be recorded for submission to DAP.
8. Linearity results are submitted along with that day's calibration report, to the DAP twice each year on or before January 15 and July 15.

Linearity Acceptance Criteria

Accuracy verification

Spirometers may measure volume at body temperature (BTPS) or at ambient/room temperature (ATPS). Most spirometers in physicians' offices will report at BTPS. Spirometers reporting at BTPS automatically employ correction factors, at specific temperatures, that convert ATPS to BTPS. Here is an example for an ambient temperature of 21°C:

- Volume of 3-L syringe = 3.00 L
- Correction factor at 21°C = 1.096
- Therefore: 3.00 L x 1.096 = 3.288 L
- Acceptable accuracy is ± 3.0%. Therefore:
    - L minus 3.0% = 3.189 L
    - plus 3.0% = 3.387 L
- The acceptable range at 21°C is 3.189 L–3.387 L

The chart below has already calculated the acceptable ranges at each temperature for spirometers reporting at BTPS. In order to verify the accuracy of your measurement, use the chart to determine the FVC acceptable range for each trial, at your ambient temperature:

BTPS Chart for Acceptable Ranges (± 3.0%)

Factor	oC	Acceptable range (L)	Factor	oC	Acceptable range (L)	Factor	oC	Acceptable range (L)
1.118	18	3.253–3.455	*1.085*	23	3.157 - 3.353	*1.057*	28	3.076–3.266
1.111	19	3.233–3.433	*1.080*	24	3.143 - 3.337	*1.051*	29	3.058–3.248
1.102	20	3.207–3.405	*1.075*	25	3.128 - 3.322	*1.045*	30	3.041–3.229
1.096	21	3.189–3.387	*1.068*	26	3.108 - 3.300			
1.091	22	3.175–3.371	*1.063*	27	3.093 - 3.285			

Reproducibility verification

In order to determine if your spirometer meets reproducibility requirements across various flow rates, the volumes should fall within 0.090 L (90 mL) from largest FVC to smallest FVC. And Peak Expiratory Flow must fall within target range for each trial.

Example 1

The largest FVC trial (3.26) minus the smallest FVC trial (3.18) is **less than** 0.090 L (90 mL) and is therefore acceptable. The peak flows are also within the required ranges (less than 2 L/s, 4–6 L/s and greater than 8 L/s).

Linearity test flow volume loops	**Trial 1: Low flow (less than 2 L/sec)**	**Trial 2: Mid flow (4 to 6 L/sec)**	**Trial 3: High flow (greater than 8 L/sec)**	**Difference in FVC (highest minus lowest: should be < or = 90 mL)**
FVC (liters)	3.24	3.18	3.26	0.080 L (80 mL)
Peak expiratory flow (liters/sec)	1.56	5.46	10.02	

Example 2

The largest FVC trial (3.28) minus the smallest FVC trial (3.08) is **greater than** 0.090 L (90 mL) and therefore is not acceptable. Also, the Peak Expiratory Flow for Trial 1 is 2.56, which is higher than the requirement of less than 2 L/sec and therefore would not be considered an acceptable trial.

Linearity test flow volume loops	**Trial 1: Low flow (less than 2 L/sec)**	**Trial 2: Mid flow (4 to 6 L/sec)**	**Trial 3: High flow (greater than 8 L/sec)**	**Difference in FVC (highest minus lowest: should be < or = 90 mL)**
FVC (liters)	3.08	3.28	3.16	0.20 L (200 mL)
Peak expiratory flow (liters/sec)	2.56	5.46	10.02	

Biological Control (BioQC) Testing

A biological normal quality control (BioQC) refers to a healthy non-smoking individual with normal and stable lung function, who is tested on a regular basis as a "control." Frequently office personnel are asked to perform this function. BioQC should be performed monthly and reported on the DAP Monthly Spirometry Quality Control Program worksheets.

Each site should identify two (2) individuals with normal lung function who are available to perform BioQC spirometry. However, only one (1) individual is required to perform monthly BioQC spirometry. The second person should be available to fill in if the primary BioQC subject cannot perform this function due to absence or illness. Data from two different BioQC subjects should not be combined on the same QC worksheet.

Establishing the BioQC Normal Range

1. In order to establish the normal ranges for the primary and backup BioQC subjects, a minimum of 10 replicates are required. Twenty replicates is the recommendation for statistical accuracy, however 10 replicates will give an adequate baseline with which to compare the monthly QC results.
2. Perform 10 to 20 replicates on each BioQC subject over a period of several days. Ideally this should entail a single test performed each day; however, a maximum of two tests spread out within any single day (e.g. morning and afternoon) may be used.
3. Use the Normal Range Calculator to determine the acceptable ranges for each person. This worksheet takes the average of the replicates and calculates two standard deviations (SD) which constitutes the normal range for this subject.
    - Go to the Community Spirometry page on the College website and save the Spirometry BioQC Normal Range Calculator to your computer.
    - Fill in the values generated by the BioQC subjects. The average, standard deviation (SD) and coefficient of variation (CV) will automatically be calculated.
    - There should be a maximum of 10% between the highest and lowest FVC and FEV1 values.
    - The calculated coefficient of variation (CV) should be 3% or less.
4. Subsequent spirometry testing on each BioQC subject should fall within the ± 2 SD ranges for that subject. The facility should perform troubleshooting if BioQC values fall outside of their acceptable ranges.

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Monthly BioQC Testing

1. The BioQC subject should perform spirometry procedures in the same way as a patient.
2. For consistency, the BioQC subject should ideally be tested:
    a. on the same day of month
    b. at the same time of day
3. An adequate test requires a minimum of three acceptable FVC maneuvers and adherence to repeatability criteria.
    - Repeatability is achieved when the difference between the largest and the next largest acceptable FVC and FEV1, is less than or equal to 150 mL. The results for FVC and FEV1 do not need to come from the same maneuver.
    - The best trial is chosen based on the largest sum of FVC plus FEV1 from acceptable maneuvers.
4. The BioQC result should be recorded for each month on the Monthly Spirometry Quality Control Program worksheets.
    - Go to the Community Spirometry page of the College website and save these forms to your computer.
    - Fill in the values generated by the BioQC subject(s). The average, standard deviation (SD) and coefficient of variation (CV) will automatically be calculated.
    - The CVs for FVC and FEV1 should be less than or equal to 3%.
    - Confirm that the results fall within the acceptable ranges for this BioQC subject.
5. Data from different BioQC subjects must be recorded on separate worksheets (see tabs at the bottom of the spreadsheet). Do not mix BioQC #1 data with BioQC #2 data.
6. BioQC results are submitted along with that day's calibration report, to the DAP twice each year on or before January 15 and July 15.

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Predicted Sets

The National Health and Nutrition Survey (NHANES) III (1999) is the ATS-ERS recommended source of normal values for ages four to 80.

Submission of Data to the DAP

QC must be reviewed and signed off by the medical director or delegate (physician in charge).

Submit completed data to DAP PT/QC specialist by either of the following:

- Scan/email to: ptqc@cpsbc.ca
- Mail to:

  Attn: DAP PT/QC
  Diagnostic Accreditation Program
  College of Physicians and Surgeons of British Columbia
  300–669 Howe Street
  Vancouver BC V6C 0B4

Note: Updated accreditation agreements will be required at the beginning of each four-year accreditation cycle, and whenever there is a change in the medical director for the spirometry service. The accreditation agreement is located on the Community Spirometry section of the website.

References

[1] Standardization of Spirometry 2019 Update. An Official American Thoracic Society and European Respiratory Society Technical Statement. Am J Respir Crit Care Med Vol 200, Iss 8, pp e70–e88