THE SOUTH AFRICAN SOCIETY OF OCCUPATIONAL MEDICINE

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South African Society of Occupational Medicine
FOUNDED IN 1948

SPIROMETRY IN THE WORKPLACE

GUIDELINE DOCUMENT 15

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Endorsement: South African Thoracic Society

ISBN: 978-1-991204-70-7 (Revised ed PDF)

First Revision: 2011
Second Revision: 2021

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1. INTRODUCTION

Spirometry is a widely used tool for measuring airway physiology and plays a central role in the prevention of work-related lung disease. If performed to a high standard the spirometry result is accurate and repeatable, however it can be challenging to meet these standards. Adequate training, enthusiasm and care when performing the test and quality assurance processes are therefore required. It is important that all staff use the same procedure to conduct and evaluate the validity of this test to ensure continuity, comparability and consistency in results. It is desirable that all persons involved in workplace spirometry attend a SASOM endorsed training course and hold an up-to-date certificate of competence in occupational spirometry.

Purpose

To ensure high quality results of spirometry conducted in the occupational health setting.

Scope

This document outlines the preparation, performance and post test procedures for spirometry conducted in the occupational health setting including quality assurance, quality control and the prevention of infection. It is applicable to all who perform or supervise the performance of spirometry and interpret or review test results.

Desired Outcomes

- Documented evidence of linearity calibration checks prior to the first participant of the day on every day that tests are conducted.
- Minimally 3 acceptable blows that meet repeatability criteria in each of the pre- and post-bronchodilator testing sessions. Should this not be achievable minimally 2 usable blows that meet repeatability criteria in each of the pre- and post-bronchodilator testing sessions.
- First data validation by the spirometrist whilst the participant is still present.
- COVID-19 specific infection prevention and control plus full participant safety throughout.

Responsibilities

Occupational Medical Practitioners (OMPs), Occupational Health Nurses (OHNs):

- Undertake and complete a SASOM endorsed training course in occupational spirometry and hold a certificate of competence issued by the course organisers.
- Ensure all staff conducting the spirometry procedure unsupervised achieve a Certificate of Competence in Occupational Spirometry prior to conducting spirometry on workers.
- Competency should be monitored and retraining of spirometrists should be offered when deficiencies are identified.
- Ensure all involved staff are familiar with and using this guidance document.
- Provide all necessary hardware, software and accessory documents as required.
- Be readily available to support spirometrists during testing when there is difficulty achieving acceptable / usable and repeatable spirometry on a worker.
- Ensure standardised spirometry and quality assurance processes are adhered to.

Spirometrist/s:

- Undertake and complete a SASOM endorsed training course in occupational spirometry.
- Be familiar with and adhere to this spirometry guidance document.
- Aim to conduct a linearity (or at least multiflow) calibration check on each day that workers are tested.
- Aim to conduct at least three technically acceptable trials that meet repeatability criteria at each testing session on each worker,
- Perform data validation checks whilst the worker is still present - acceptability / usability / repeatability and data quality grading checks. Re-test the worker until at least a quality grade A, B or C test is reached. Call for assistance from the Occupational Medical or Nurse Practioner (OHP / OHNP) if test results are not of good quality.
- Save and store the spirometry data as per this guidance document.
- Spirometrists who are not achieving 90% acceptable or usable and repeatable spirometry should be evaluated to uncover the reason and undertake retraining if appropriate.
- Attend spirometry refresher training every 3- 5 years.

Abbreviations, Terms and Definitions can be found in Appendix A.

2. QUALITY ASSURANCE IN SPIROMETRY

Refers to all the procedures put in place to reduce test quality variability in spirometry measurements including:

2.1 Equipment performance:

The spirometer used should meet the ATS and ERS recommendations for occupational spirometry testing. (Appendix B)
Linearity calibration checks should be conducted using an accurate 3L syringe with calibration checked within the time period stipulated by the manufacturer at flows taking approximately 0.5s, 3s and 6s [1]:

- Every day of testing before the first worker of the day is tested.
- When the ambient air temperature is changing rapidly (>3°C in <30 min).
- If the linearity calibration check has failed.
- When equipment has been relocated.
- When the equipment has been repaired.
- When software updates have been done.

A linearity calibration is valid when the difference between the measured and syringe volume should be ≤3% (2.91 – 3.10L) [1,2].
If a bacterial filter is used for testing it should be in place when conducting the calibration check.
Biological calibration is recommended by some guides but is optional.[1, 2]

2.2 Infection prevention:

Should be practical and sensible including good ventilation, hand washing by the spirometrist and worker before and after testing, disinfection of surfaces and spirometer, use of disposable filters and mouthpieces, using gloves when handling contaminated equipment and workers blowing away from the spirometrist.

COVID-19 specific infection prevention measures are listed in Appendix C. See also Appendix D for a COVID-19 infection risk screening questionnaire and Appendix I for the SASOM position statement on spirometry in COVID-19.

2.3 Human resources:

All staff involved should hold Certificates of Competence in spirometry and undergo refresher training every 3 - 5 years.

2.4 Worker safety:

Ensure that the physical environment is safe and that a chair is available in case of dizziness or syncope. Carefully check for contraindications to testing noting these in the employee medical data record. (See Appendix E for Relative contraindications to spirometry and Appendix F for a pre-spirometry contraindications screening questionnaire).

2.5 Spirometry audits and data review:

In large test centres with multiple spirometrists, a quarterly quality review of each spirometrist by a senior colleague is suggested. This review would be in the form of 10 randomly selected spirograms and 5 linearity calibration checks reviewed for compliance with this standard.

2.6 Record keeping:

Calibration records should be saved for 40 years and a log of technical problems found and solved, as well as all changes in protocol, computer software, or equipment.
Maintain a procedure manual documenting the details of equipment type, spirometer configuration, manufacturer's guidelines, calibration log, service and repair records, personnel training, and standard operating procedures.

3. PREPARING FOR SPIROMETRY

3.1 Indications:

Indications for workplace spirometry are:

- Fitness certification (to assess if an employee's ventilatory performance meets the minimum medical requirements for a job).
  - This may occur at pre-employment, pre-placement, or at designated intervals or return to work after a respiratory illness.
  - Assessment of fitness to wear respiratory protective equipment (RPE) may require spirometric assessment. Not all RPE usage requires spirometric assessment.
- Medical surveillance (to identify adverse effects of workplace exposure to respiratory hazards).
  - This may be done as a baseline at pre-employment and pre-placement, and also at exit. In between, it should be repeated at designated intervals.
  - This includes monitoring workers for exacerbations of disease and recovery from exacerbations.
- Assessment of ventilatory impairment.
  - To assess the pattern of ventilatory impairment in symptomatic workers.
  - To identify workers requiring further evaluation / referral.
  - To assess workers for disability evaluations and workers' compensation.
  - To assess workers as part of a rehabilitation programme.
- Compliance with regulations, where spirometry is prescribed.

3.2 Contraindications:

Potential risks of spirometry are primarily related to maximal pressures generated in the thorax and their impact on abdominal and thoracic organs, venous return and systemic blood pressure, and expansion of the chest wall and lung. The physical effort required can increase myocardial demand. Caution must be used for workers with medical conditions that could be adversely affected by these physiological consequences (see Appendices E. and F.)[2]

3.3 Environment:

Testing should occur in a quiet and comfortable environment that is separated from the waiting room and other workers being tested. Drinking water should be available. Tissues or paper towels should be offered to help workers deal with secretions. The worker should be seated erect, with shoulders slightly back and chin slightly elevated in a chair with arms (to prevent falling sideways should syncope occur), without wheels[2].

All spirometry outcomes must be reported at BTPS (body temperature, ambient barometric pressure saturated with water vapor). The ambient temperature must always be recorded with an accuracy of +/-1°C. In situations when the ambient air temperature is changing rapidly (>3°C in 30 min), continuous temperature corrections may be necessary. Spirometrists should be aware

of potential problems with tests performed outside the range of ambient temperatures and barometric pressures specified by the manufacturer for their spirometer.

3.4 Worker:

Medical records should be reviewed, and the worker interviewed for contraindications and activities that may affect the interpretation of the test result including:

- Smoking and/or vaping and/or water pipe use within 1 hour before testing.
- Consuming intoxicants within 8 hours before testing.
- Performing vigorous exercise within 1 hour before testing.
- Wearing clothing that substantially restricts full chest and abdominal expansion.
- Appropriate bronchodilator withholding time (*see Reference 1 Standardization of Spirometry 2019 Update*), unless the objective of the spirometry is to evaluate function while on treatment (for example, for workers' compensation impairment evaluations).

*Note: *If the adequacy of treatment is being assessed, the worker should use his/ her inhalers as usual before the test. For instance, work exacerbated asthma. Also, in the same way for workers' compensation evaluation and fitness for work assessments inhalers and other medication should be used as usual to measure impairment whilst on optimal treatment.*

Height should be measured and recorded to the nearest millimetre (mm) in the Frankfort positioning (i.e. without shoes, feet together, standing tall, with eyes level and looking straight ahead using the stadiometer). Height should be re-measured annually thereafter.

Weight should be measured and recorded within 0.5kg in light clothing, shoes off and pockets emptied.

4. CONDUCTING SPIROMETRY

4.1 Explain:

Explain what the test measures, why you are conducting the test and how to do it.

4.2 Demonstrate:

Demonstrate by using* a separate mouthpiece and showing positioning of the mouthpiece and sealing of lips around the device, during inspiration and maximum exhalation. Blast the air out as hard and fast as possible. Continue exhalation for as long as possible. Remain upright, with feet on the ground, and no rebreathing during the procedure.

*Note: "*Using" means to demonstrate what is required during performing spirometry that avoids close contact between testers and clients have been suggested, especially during periods of concern about transmission of infections. The spirometrist should use a bacterial filter during the demo, and blow towards an open window. Using videos in one such suggestion to avoid close contact, but an appropriate one for South Africa is not yet available.*

4.3 Test:

Ensure zero flow, that the nose is closed then instruct the worker to inhale fully, close the mouth over the mouthpiece and blast the air out into the spirometer as fast as he / she can for as long as he / she can until the lungs are empty, giving full encouragement throughout the blow. The worker should then inhale maximally back to total lung capacity before the test is complete. The worker may be tested seated or standing maintaining an upright posture throughout. The same posture must be maintained for every testing session thereafter for the worker (this should be noted in the record). Repeat the procedure between 3 and 8 times with 30 second rests between

blows at which time feedback is given to the worker on what he did correctly and what can be improved on in the technique of his blow. (See Figure 3.)

4.4 Evaluate test validity:
Check that acceptability or usability, and repeatability criteria are met to an overall test quality grade of A, B or C before the test is concluded and the worker leaves[1].

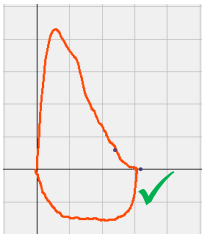
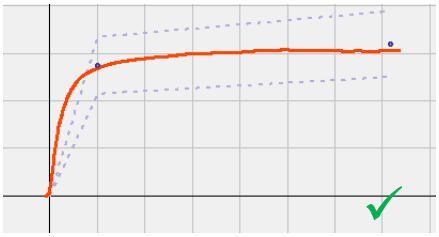
5. EVALUATION OF THE TEST RESULT FOR VALIDITY

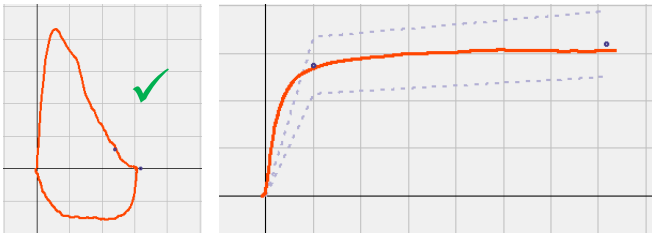
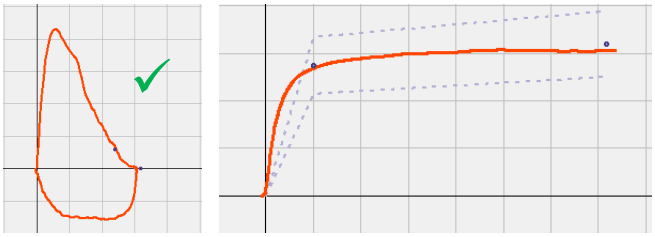
Follow the next 10 steps to ensure the validity and correct interpretation of the test result:

5.1 Calibration and subject data:
Check that there is a record of a valid linearity calibration check on the day of testing. Check that age, height, birth gender and ethnicity have been correctly entered into the spirometer. Incorrect entry of this data will affect predicted values, lower levels of normal (LLN) and Z score results.

5.2 Reference values and ethnic correction:
Check that the Quanjer GLI 2012 reference values have been selected. For people of ethnic origin other than those of Caucasian (white) ethnicity the "other" ethnicity option in the GLI 2012 should be used.

5.3 Acceptability / usability:
Some spirometry errors can falsely elevate or decrease the FVC and FEV_1 measurements. FVC and FEV_1 are checked separately for acceptability and usability. The check has 3 outcomes – acceptable, usable, not usable.

Where on blow	Exact part of blow	Explanation and specifics guide	F/V and V/T graphs	Values required to be considered acceptable
Start of test	1. Start	The worker blows immediately and fast showing no hesitation or false start	Smooth unhesitating start rising vertically from point 0 after a maximal inhalation	Back extrapolated volume (BEV) <5% of the FVC or 0.100L, whichever is greater
			 BEV = 0.09L ✓	
	2. Rise to peak	The worker blows with maximal effort in the first instant of the blow	The rise to peak is close to vertical and upright with no hesitation, artefacts or sloping right	Time to peak should be ≤ 150milli seconds (0.15s). This parameter may be looked at to judge but is not mandatory for acceptability.

Where on blow	Exact part of blow	Explanation and specifics guide	F/V and V/T graphs	Values required to be considered acceptable
			PEFT = 0.07 s ✓	
	3. Peak	Should be sharp and tall indicating maximum effort	Must be tall and pointed, not round or flat. Should be without artefact	Persistently flattened expiratory or inspiratory peaks with good efforts by the client may indicate upper airway obstruction. Although infrequently encountered in workplace spirometry the condition should be considered.
				
Middle of test	4. Downward curve	Should be without cough, leak, tongue in tube, teeth not biting, biting on the mouthpiece too hard or glottis closure	The downward trial of the F/V graph should be smooth and continuous without artefact	• No cough in 1st sec (for FEV_1) • No glottic closure (for FVC) • No evidence of an obstructed mouthpiece/spirometer • No evidence of leak • No evidence of a faulty zero-flow level • No extra breaths
				
End of expiratory test	5. End of forced expiration (EOFE)	The worker blows out completely to residual volume	The flow volume tracing should gradually become horizontal as it approaches the volume axis, and as zero flow is reached.	• Expiratory plateau (≤ 0.025L in the last 1s of expiration) OR • Expiratory time ≥ 15s OR • The two largest FVCs are within the repeatability tolerance of 150mls for
	6. Time		The volume time graph	

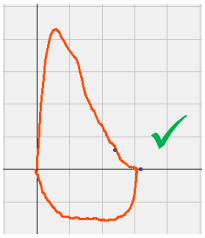
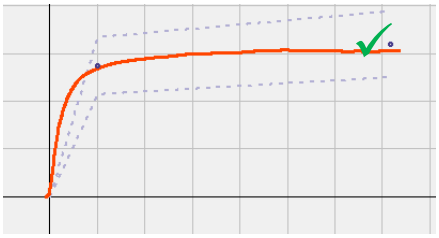
Where on blow	Exact part of blow	Explanation and specifics guide	F/V and V/T graphs	Values required to be considered acceptable
			should reach a plateau or each blow should end at the same time repeatedly	adults.
				

FIGURE 1. (Above) Acceptability criteria related to each section of the blow

Acceptability and Usability Criteria	Required for acceptability		Required for usability	
	FEV1	FVC	FEV1	FVC
Must have BEV ≤5% of FVC or 0.100 L, whichever is greater	Yes	Yes	Yes	Yes
Must have no evidence of a faulty zero-flow setting	Yes	Yes	Yes	Yes
Must have no cough in the first second of expiration*	Yes	No	Yes	No
Must have no glottic closure in the first second of expiration*	Yes	Yes	Yes	Yes
Must have no glottic closure after 1 s of expiration	No	Yes	No	No
Must achieve one of these three EOFE indicators: 1. Expiratory plateau (≤0.025 L in the last 1 s of expiration) 2. Expiratory time ≥15 s 3. FVC is within the repeatability tolerance of or is greater than the largest prior observed FVC	No	Yes	No	No
Must have no evidence of obstructed mouthpiece or spirometer	Yes	Yes	No	No
Must have no evidence of a leak	Yes	Yes	No	No
If the maximal inspiration after EOFE is greater than FVC, then	Yes	Yes	No	No
FIVC - FVC must be ≤0.100 L or 5% of FVC, whichever is greater				
Repeatability criteria (applied to acceptable FVC and FEV_1 values)				

FIGURE 2. (Above) Summary of Acceptability, Usability, and Repeatability Criteria for FEV_1 and FVC as a reproduction of Table 7 of the ATS / ERS Standardisation of Spirometry 2019 update with permission[1]

* FVC and FEV_1 are each considered separately for usability. FEV_1 usability does not consider any error after the first second, whereas FVC does.

Challenge	**Steps to overcome the challenge**
Before acceptable and repeatable blows are achieved, the participant wants to stop testing.	Explain reasons why you are testing. Listen to their reasons for wanting to stop. Allow them to rest. Encourage the participant to continue, reschedule or discontinue testing.
Participants do not wish to take the bronchodilator or will not inhale the medication correctly	Explain that the bronchodilator will not harm them, that it will open the airway if there is bronchoconstriction and even if the airway is normal it will not harm them.
Participant not blowing hard enough at the start of the test.	Re-explain, re-demonstrate. If the participants are willing allow them to watch and learn from each other. Show the participant on the flow/ volume graph how you are looking for a tall, pointed peak rather than a rounded lack of peak. Draw the correct test for them on paper.
Glottis closure	Encourage the participant to practice together with the technician without too much effort so that they do not get too tired. Re-explain and re-demonstrate.
Participants do not blow well when seated	Allow participant to stand. Technician to stand with the participant and verbally encourage and engage.
Not closing mouth over the spirette properly at the start causing air leakage	Watch the participant carefully. Stop the blow if air leakage is noticed. Re-explain and re-demonstrate.
Language barriers	Look for an interpreter. Exercise patience. Continue to try to explain. Observe that what you have explained is what they are doing. Use extra body language and non-verbal cues to communicate.
Persistent coughing	Rest. Give participant water. Encourage participant to cough to clear as much phlegm as possible before next blow.
Variable effort	Show the participant the flow volume and volume time curves and how their changing techniques are giving different results every time and how you want every blow to look identical.
Battling to co-ordinate blocking nose and blowing	Use a nose clip rather than fingers.
Stopping blowing before lungs are empty	Show the participant on the flow/volume graph. Re-explain, re-demonstrate and tell them they must listen for the beep from the spirometer or you will tell them when to stop.
Obstruction of the mouthpiece with the tongue	Tell participant to place the mouthpiece on top of the tongue or to keep the tongue out of the way in the bottom of the mouth.
Bending	Tell the participant to stay upright and assist with placing your hand on their shoulder and gently bringing them back if they bend when blowing.

FIGURE 3. (Above) Challenges to achieving acceptability criteria and how to overcome these.

5.4 Repeatability and test quality grade:

Repeatability: The best two measurements should fulfil repeatability criteria. For FEV_1 and FVC; the best two values should be ≤150ml of each other.

Where	What part of the blow	Explanation and specifics guide
Graphs	Flow / volume Volume / time graphs	• Acceptability criteria have been checked. • Minimum of 3 blows and maximum 8 blows. • Graphs should be superimposed.
Numerical values	FVC	• FVC repeatability is achieved when: • The difference between the largest and the next largest FVC is ≤150ml.
	FEV_1	• FEV_1 repeatability is achieved when: • The difference between the largest and the next largest FEV_1 is ≤150ml.
		Exception: blowing induced bronchoconstriction

FIGURE 4. (Above) Repeatability criteria and how to check repeatability criteria in adults

Test quality grade: FVC and FEV_1 are graded separately using the table below. Pre and post bronchodilator manoeuvres are given separate quality grades. Tests with grades of A, B, or C are usable; tests with grade D are suspect; tests with grade E might be used by the interpreter only to show values 'within the normal range' or at 'at least as high as,' without demonstrated repeatability; and tests with grade F should not be used. (1)

Grade	Number of Measurements	Repeatability
A	≥ 3 acceptable	Within 150ml
B	2 acceptable	Within 150ml
C	≥ 2 acceptable	Within 200ml
D	≥ 2 acceptable	Within 250ml
E	≥ 2 acceptable OR 1 acceptable	> 250ml N/A
U	0 acceptable AND ≥ 1 usable	N/A
F	0 acceptable and 0 usable	N/A

FIGURE 5. (Above) Test Quality Categories for FEV_1 and FVC as a reproduction of Table 10 of the ATS / ERS Standardisation of Spirometry 2019 update with permission[1]

5.5. Lower levels of normal (LLN):

Measurements for a given individual are usually given both in raw data units (L, L/S etc) and as a percentage of predicted (%pred) of a reference value or, more appropriately, the Z score which is difference from a predicted mean for similar persons expressed as the number of standard deviations.

%pred: The cut-points between normal and abnormal using %pred are ≥80%pred for FVC and FEV_1 and ≥70% (actual) for FVC / FEV_1. (This is the "old" way and using the LLN is preferable.)

Z score LLN: The Z-Score LLN for every measurement is ≥ -1.64 which is equivalent to the 5th percentile of population values. Wherever possible interpretation should be done using Z scores [1,2], especially for identifying abnormal spirometric parameters.

5.6. Best trial / best test:

Best FEV_1 and FVC: The highest FEV_1 and highest FVC from any of the acceptable trials. The FEV_1/FVC ratio should be calculated from these two best values.

Best trial: The blow from an acceptable curve with the highest sum of FVC and FEV_1.

5.7. Interpretation:

See point 6. below.

5.8. Test result grading:

See point 6. below.

5.9. Recording and reporting:

The purpose of recording and reporting is that any person who picks up the spirogram at a later date will know exactly what happened at the time of testing and will have clues as to factors during testing that will affect interpretation.

Once testing is complete and before the test is stored, standardised operator comments are strongly recommended by The Standardization to Spirometry 2019 update including the following [1]:

Relating to worker condition	Relating to quality of each manoeuvre
• No comment • First attempt at spirometry. • Reference values are based on ethnicity that may not be suitable for this worker. • Worker used bronchodilator(s) prior to test (enter drug, dose and time used). • Worker smoked < 1 hour prior to test • Worker had difficulty understanding directions. • Worker reported consumptions of an intoxicant. • Observed symptoms e.g. cough, wheeze, dyspnoea or cyanosis. • Other.	• No comments. • Cough during the first second of expiration. • Glottis closure. • Early termination. • Hesitant start of test. • Obstructed mouthpiece or breathing tube. • Leak around mouthpiece. • Not at TLC prior to expiration. • Operator changed manoeuvre. designation from acceptable to unacceptable. • Other.

Relating to bronchodilator responsiveness testing	Relating to quality of testing session
• Facility bronchodilator responsiveness testing protocol followed for type, dose and delivery, method of administration and wat time before post bronchodilator testing. • Post bronchodilator measurements obtained using other bronchodilator(s), doses(s), delivery method or wait time. • Other.	• No comments • Acceptability and / or repeatability criteria not met despite worker's best efforts. • Spirometry induced bronchospasm. • Worker was too tired to continue. • FEV_1 dropped more than 20% from baseline. • Motivation difficulties. • Coordination difficulties. • Other.

5.10. Recordkeeping:

Every workplace will store their spirometry records in a different way. Storage should be such that easy retrieval of the equipment information, the test and matching calibration verification are easily accessible. This way, later on records retrieval and troubleshooting of problematic spirometry test results will be made easy.

What records should be stored:

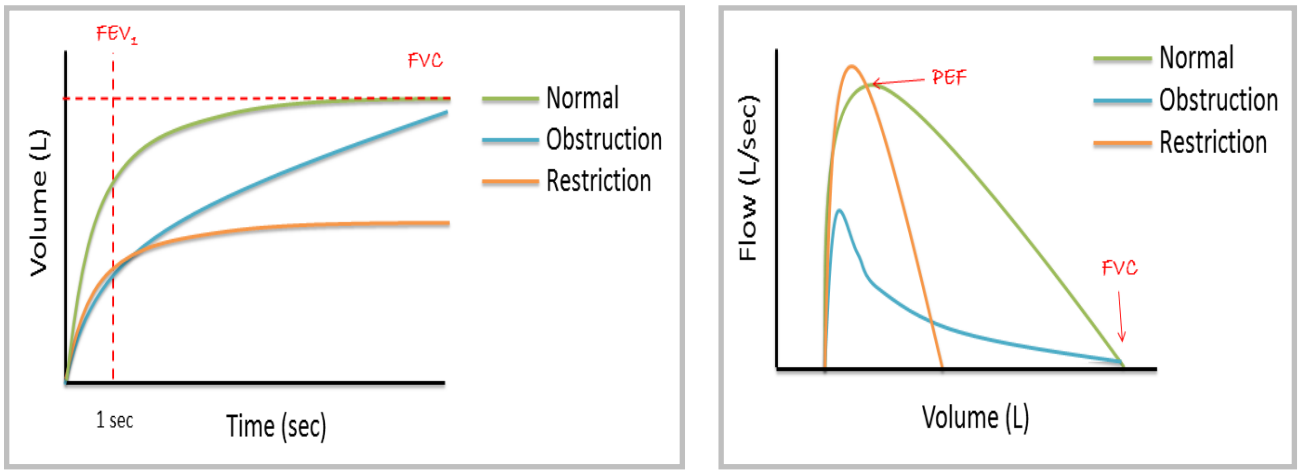
Equipment	Personnel records
• The model, serial number, and identification number of the spirometer. • Manufacturers warranties. • Spirometer manual. • Dates and versions of computer software and hardware updates or changes. • A quality control log which records calibration checks. • Any routine maintenance records, upgrades, repairs performed and the results, the date and time of each.	• Operator and manager training records. • Certificates of Competence in Foundational Spirometry Training. • Spirometry Refresher Training Certificates. • On the job audit results evaluation and feedback to operators. • Records of operator continuing education. • Any CPD points gained in the worker.
Test reports • The spirometry test procedure. • Operator's name date and time of test. **Paper copies** • Where workplaces are still storing paper records, a copy should be kept in the worker's file. • If the calibration and spirometry test print outs are on thermal paper, the report should be photocopied and attached to the original as thermal paper fades over time.	**Digital copies** • Computerized spirometry systems store this all spirometry related information in a digital database. • Reports generated should be saved indefinitely. • A back up of the digital storage facility should be kept off site or a secure cloud based back up should be made.

6. INTERPRETATION

Interpretation should be approached in a logical step by step manner.

6.1 Analyse the shape of the flow / volume and volume / time curves:

Analysing the shape of the flow/volume and volume/time graphs can provide information regarding the type of defect. The flow/volume curves can take on a few distinguishable shapes that correspond to a certain type of pathology.



Figures taken from Moffat J, Spirometry. Natalie's casebook.
http://www.nataliescasebook.com/tag/spirometry

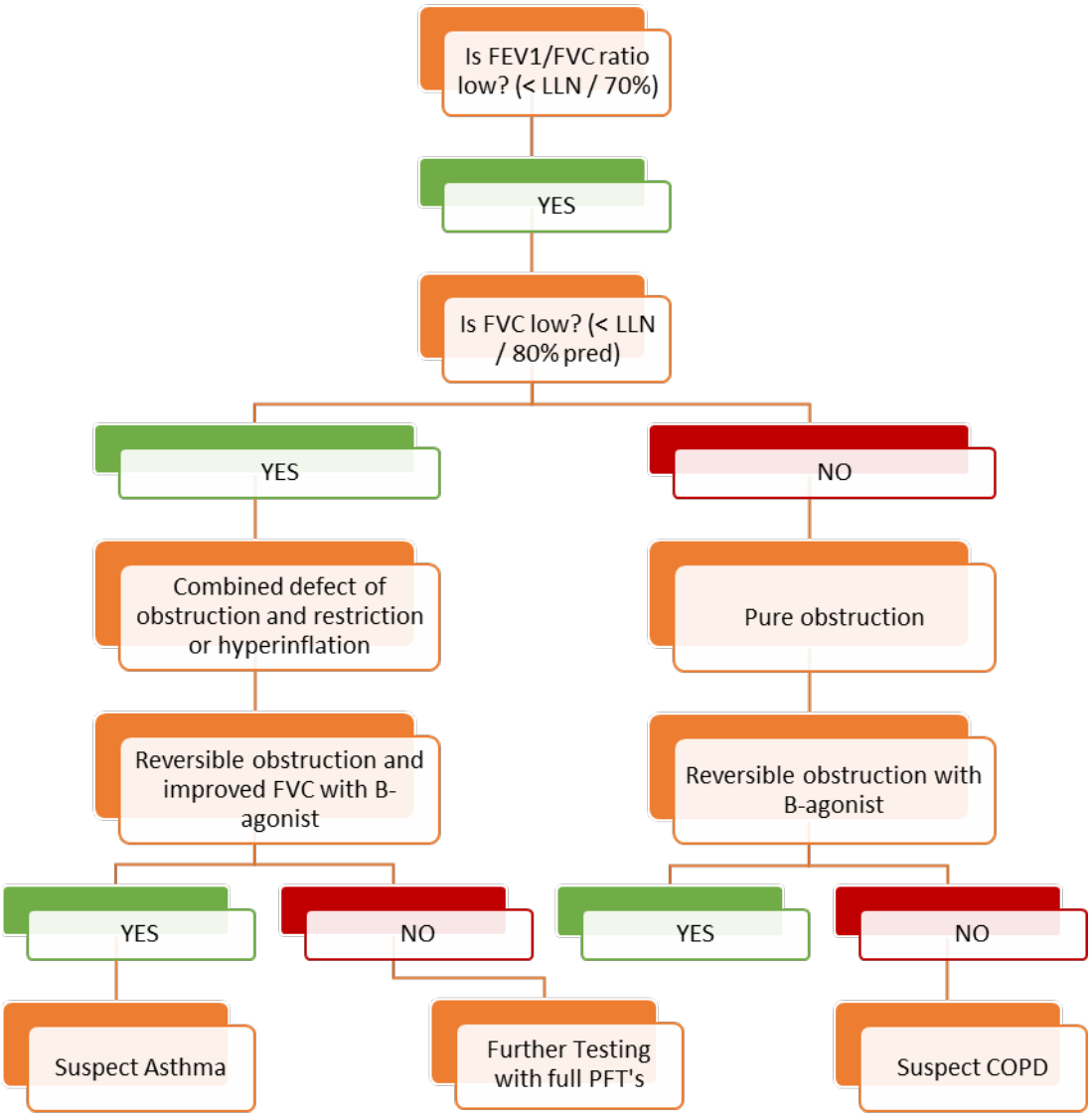
FIGURE 6. (Above) Flow-volume and volume time graphs showing normal, obstructive and restrictive spirometry patterns.

6.2 Assess the numerical values:

Obstruction

To separate normal from abnormal test results, first examine the FEV_1/ FVC to determine whether an obstructive pattern is present, and then evaluate the FVC to determine if a restrictive pattern may exist. The FEV_1 is examined post-bronchodilator if the FEV_1/ FVC indicates a possible obstructive pattern, as shown in Figure 7 These algorithms pre-suppose acceptable/usable tests trials.

Diagnostic Flow Diagram for Obstruction



Algorithm based on "Differences in spirometry interpretation algorithms: Influence on decision making among primary-care physicians March 2015 npj Primary Care Respiratory Medicine 25(1):15008DOI: 10.1038/npjpcrm.2015.8 https://www.researchgate.net/figure/Spirometry-interpretation-algorithm-endorsed-by-the-Ontario-Thoracic-Society-algorithm_fig1_273913636

FIGURE 7.1. (Above) Spirometry interpretation algorithm – obstructive impairment

Restriction

Algorithm based on "Differences in spirometry interpretation algorithms: Influence on decision making among primary-care physicians March 2015 npj Primary Care Respiratory Medicine 25(1):15008DOI: 10.1038/npjpcrm.2015.8 https://www.researchgate.net/figure/Spirometry-interpretation-algorithm-endorsed-by-the-Ontario-Thoracic-Society-algorithm_fig1_273913636

FIGURE 7.2. (Above) Spirometry interpretation algorithm – restrictive impairment

6.3 Grade the pattern:

Assess the severity of the abnormality by using the table below:

Criteria for Rating permanent Impairment due to Pulmonary Dysfunction					
Pulmonary Dysfunction					
Class	**Class 0**	**Class 1**	**Class 2**	**Class 3**	**Class 4**
Whole person impairement rating (%)	**0**	**2%-10%**	**11%-23%**	**24%-40%**	**45%-65%**
Severity Grade (%)		**2 4 6 8 10 (A B C D E) (Minimal)**	**11 14 17 20 23 (A B C D E) (Mild)**	**24 28 32 36 40 (A B C D E) (Moderate)**	**45 50 55 60 65 (A B C D E) (Severe)**
History	No current symptoms	Dyspnea controlled with intermittent or continuous treatment	Constant mild dyspnea despite continuous treatment	Constant moderate dyspnea despite continuous treatment	Constant severe dyspnea despite continuous treatment
	and / or	*or*	*or*	*or*	*or*
	Intermittent dyspnea that does not require treatment	Intermittent mild dyspnea despite continuous treatment	Intermittent moderate dyspnea despite continuous treatment	Intermittent severe dyspnea despite continuous treatment	Intermittent extreme dyspnea despite continuous treatment
Physical findings	No current signs of disease	Physical findings not present with continuous treatment	Constant mild physical findings despite continuous treatment	Constant moderate physical findings despite continuous treatment	Constant severe physical findings despite continuous treatment
		or	*or*	*or*	*or*
		Intermittent mild physical findings	Intermittent moderate findings	Intermittent severe findings	Intermittent extreme findings
Objective Tests					
FVC	FVC ≥80% of predicted	FVC between 70% and 79% of predicted	FVC between 60% and 69% of predicted	FVC between 50% and 59% of predicted	FVC below 50% of predicted
	and	*or*	*or*	*or*	*or*
FEV_1	FEV_1 ≥80% of predicted	FEV_1 between 65% and 79% of predicted	FEV_1 between 64% and 55% of predicted	FEV_1 between 45% and 54% of predicted	FEV_1 below 45% of predicted
	and	*or*	*or*	*or*	*or*
FEV_1 / FVC (%)	FEV_1 / FVC (%) > lower limits if normal and / or (>75%of predicted)				
	and	*or*	*or*	*or*	*or*
Dlco	Dlco ≥75% of predicted	Dlco between 65% and 74% of predicted	Dlco between 55% and 64% of predicted	Dlco between 45% and 54% of redicted	Dlco below 54% of predicted
	or	*or*	*or*	*or*	*or*
Vo_2 max	>25mL / (kg min)	between 22 and 25mL / (kg min)	between 21 and 18mL / (kg min)	between 17 and 15mL / (kg min)	< 15mL / (kg min)
	or	*or*	*or*	*or*	*or*
	>7.1 METs	6.1 - 7.1 METs	5.1 - 6.0 METs	4.3 - 5.0 METs	<4.2 METs
* FVC indicates forced vital capacity; FEV_1 forced expiratory volume in the first second; Dlco, diffusion capacity for carbon monoxide; Vo_2 max, maximum oxugen consumption; and METs, metabolic equivalents (multiples of resting oxygen uptake).					

Taken from: https://ama-guides.ama-assn.org/view-large/146982

FIGURE 8: (Above) AMA Table for severity grading.

**Note: Practitioners unfamiliar with the AMA Guide's principles and practices of application should use Figure 8 simply to classify subjects into none, minimal, mild, moderate and severe impairment. The assessment of fitness to do a particular job or task by merely applying the AMA classification without additional considerations is inappropriate.*

6.4 Bronchodilator responsiveness testing:
Is commonly undertaken as part of spirometry testing when an obstructive pattern is found on pre bronchodilator testing. Grading of impairment when there is obstruction is done on post bronchodilator values.

6.5 Comments:
The spirometrist should document any quality issues, date of last calibration check and other relevant information that may aid in interpretation.

6.6 Compare results to previous tests:
Assess technical quality of spirometry and repeat testing if indicated based on spirometry quality, and other relevant information below. Obtain comprehensive medical and occupational history and physical exam including:

a. Work, exposure and smoking histories.
b. Respiratory symptoms, timing in relationship to work.
c. Physical exam, including lung exam and chest wall deformities.
d. Results of other workplace measurements, if available.

If a worker is determined to have “excessive” loss of function, two follow-up steps are recommended:

1. Technical error should be ruled out by re-evaluating the test results for validity and repeating the spirometry test if needed.
2. The worker should be referred for further medical evaluation including an assessment of the complete clinical picture and additional tests of pulmonary function.

6.7 Recordkeeping:
Spirometry test reports, equipment maintenance records and personnel training and evaluation records should be kept for 40 years.

7. EVALUATING PULMONARY FUNCTION CHANGE OVER TIME

The Longitudinal Normal Limit (LNL) is the lowest result that might be expected for a worker’s lung function during periodic spirometry test results because of normal aging and measurement variability. It is calculated from the baseline lung function[5].

If a test result falls below the LNL this may indicate significant deterioration of pulmonary function. For this evaluation to be possible the spirometry data used for these assessments must be of a high quality through standardised testing procedures, competent spirometrists and well maintained equipment[5].

7.1 Employees with baseline results >100 % Pred
Compute a LNL for the follow-up FEV_1 % Pred or FVC % Pred using:

- Baseline % Pred x 0.85

7.2 Employees with baseline results ≤100% Pred
Compute a LNL for the measured FEV_1 or FVC using:

- 0.85 x baseline measured value - (baseline predicted minus follow-up predicted)

Each serial test can be compared with the LNL to determine whether the worker’s pulmonary function has deteriorated significantly relative to his or her own measured baseline result.
Both methods give the same results if a worker’s baseline exceeds 100% Pred, but only method 2 should be used for those with lower baseline values[5].

If a test result falls below the longitudinal LNL calculated using either method, it should be confirmed by a retest. Once confirmed, medical evaluation is recommended, even if the test results remain in the traditional normal range. Evaluation of workplace exposures should be considered if the subject was exposed to respiratory hazards. Finally, if multiple measurements are available over 4 to 6 or more years, a slope of lung function measurements over time can be calculated. ACOEM recommends that slopes that are steeper than 90 to 100 mL/year should be flagged as significant losses of function, even if the worker's test results remain in the normal range[5].

See 6.3 Grading for the American Medical Association (*AMA) Criteria for Rating Permanent Impairment due to Pulmonary Dysfunction.*

8. REFERRAL CRITERIA FOR ADDITIONAL MEDICAL INVESTIGATION

8.1 Review preemployment, follow-up questionnaires and spirometry, if available.
Additional diagnostic medical investigation and testing is indicated when an abnormality is found:

a. If airflow obstruction, spirometry with bronchodilator and/or treatment response.
b. If restrictive pattern, full pulmonary function tests (lung volumes, diffusing capacity) and chest imaging (chest x-ray, CT scan).
c. If asthma, consider peak flow recordings at and away from work.
d. If interstitial lung disease, DLco testing and consider CT scan.
e. If airflow obstruction that is not fully reversible consider occupational aetiologies, even in smokers (e.g. occupational chronic obstructive pulmonary disease, bronchiolitis obliterans).

8.2 If a possible work-related problem is identified, consider other at-risk workers for additional health investigations, consider the need for workplace hazard control and consider whether the condition is compensable under South African legislation.

NOTE

The SASOM guidelines are active working documents that are reviewed regularly or as changes take place in legislation, the work or the workplace. Your inputs and comments are therefore regarded as most valuable. Please send them to info@sasom.org

9. REFERENCES

1. Townsend MC. ACOEM Guidance Statement. Spirometry in Occupational Health—2020. JOEM Volume 62, Number 5, May 2020. Retrieved from: https://acoem.org/acoem/media/PDF-Library/Publications/Spirometry_in_Occupational_Health_2020-15-(2).pdf Accessed 14 Sept 2020
2. Graham BL, Steenbruggen I, Miller MR et al. American Thoracic Society Documents. Standardization of Spirometry 2019 Update. An Official American Thoracic Society and European Respiratory Society Technical Statement. Retrieved from: https://www.atsjournals.org/doi/pdf/10.1164/rccm.201908-1590ST . Accessed 14 Sept 2020.
3. Quanjer PH, Pretto JJ, Brazzale DJ et al. Grading the severity of airways obstruction: new wine in new bottles. Eur Respir J 2014; 43: 505–512. Retrieved from: https://erj.ersjournals.com/content/erj/43/2/505.full.pdf . Accessed 14 Sept 2020.
4. Moffat J, Natalie's casebook. Spirometry. Retrieved from:
5. http://www.nataliescasebook.com/tag/spirometry Accessed 22 Sept 2020
6. Townsend MC. Evaluating Pulmonary Function Change Over Time in the Occupational Setting. Journal of Occupational and Environmental Medicine: December 2005 - Volume 47 - Issue 12 - p 1307-1316 doi: 10.1097/01.jom.0000188332.10217.4b. Retrieved from: https://journals.lww.com/joem/Fulltext/2005/12000/Evaluating_Pulmonary_Function_Change_Over_Time_in.17.aspx?WT.mc_id=HPxADx20100319xMP Accessed: 30 January 2021
7. Scott A. Helgeson, Kaiser G. Lim, Augustine S. Lee,Alexander S. Niven, and Neal M. Patel . Aerosol Generation during Spirometry. Ann Am Thorac Soc, 2020 Dec;17(12):1637-1639. doi: 10.1513/AnnalsATS.202005-569RL. Accessed 30 Dec 2020. Retrieved from: https://www.atsjournals.org/doi/full/10.1513/AnnalsATS.202005-569RL. Accessed: 30 January 2021
8. Quanjer PH. ERS SpirXpert website: Accessed: https://spirxpert.ers-education.org/en/spirometry/expressing-spirometric-test-results/the-great-utility-of-the-standard-deviation-score/ Retrieved: 30 Jan 2021
9. Hansen JE. Lower Limit of Normal Is Better Than 70% or 80%. 2011. Chest Journal. Volume 139, Issue 1, P6-8, January 01, 2011. DOI:https://doi.org/10.1378/chest.10-1117. Rerieved from: https://journal.chestnet.org/article/S0012-3692(11)60004-4/fulltext Accessed: 30 January 2021.
10. Smith, Gray, McGinty, et al. Choosing the Better GLI2012 Equation in South African Population Groups. AJRCCM. Published August 06, 2020. Retrieved from: https://panafricanthoracic.org/images/pdf/Spiro_WG/PAAS_2_blue_journal Accessed: 13 Apr 2021
11. Masekela R, Koegelenberg CFN, Gray DM. Guidance to the applicability of the Global Lung Initiative spirometry reference equations for South African populations. SAMJ. February 2021, Vol. 111, No. 2. Retrieved from: http://www.samj.org.za/index.php/samj/article/view/13186 Accessed: 12 April 2021.

APPENDIX A: TERMS

Abbreviation	Definition	Explanation
Acceptability	Acceptability check	Checking the performance of each individual curve for a satisfactory start, middle and end of test
ATPS	Ambient temperature, barometric pressure saturated with water vapour	A volume of gas saturated with water vapour at ambient temperature and barometric pressure. This is the condition of an expired gas equilibrated in a spirometer.
ATS	American Thoracic Society	"A non-profit organisation focused on improving care for pulmonary diseases, critical illnesses and sleep-related breathing disorders. It was established in 1905 as the American Sanatorium Association and changed its name in 1938 to the American Trudeau Society. In 1960, it changed its name again to the American Thoracic Society." (6)
BD	Bronchodilator	A drug that causes widening of the bronchi, for example any of those taken by inhalation for the alleviation of asthma (10)
Best Test	Best trial	An acceptable blow that has the largest sum of the FEV_1 and the FVC.
BEV	Back extrapolated volume	The volume of gas that has already been expired from maximal lung volume to Time 0 and is included in the FEV_1 and FVC measurements. (2)
BioQC	Biological control	When a healthy non-smoking individual performs spirometry testing weekly on him / herself so as 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.
	Bronchoconstriction	Constriction of the airways in the lungs due to the tightening of surrounding smooth muscle, with consequent coughing, wheezing, and shortness of breath.
	Bronchodilation	Expansion of the bronchial air passages
BDR	Bronchodilator Responsiveness Testing	Spirometry before and after an inhaled bronchodilator to assess whether the medication improved airflow.
BTPS	Body temperature, pressure saturated with water vapour	Air is at body temperature in the lungs and is saturated with water vapour. The spirometry software uses the BTPS correction to adjust the measured result from the subject obtained in the spirometer at ambient conditions to what the volume originally was in the lungs.
Cal Check	Calibration check	Part of quality control. The process of confirming that the

Abbreviation	Definition	Explanation
		spirometer is reading volume correctly
Cal Syringe	Calibration Syringe	Used in the calibration and calibration check processes. A syringe used to inject a measured amount of air into the spirometer. A 3L syringe is most commonly used but 1 and 2L syringes are also sometimes used depending on the spirometry equipment and manufacturers.
EOFE	End of Forced Expiration	The end of forced expiration is not necessarily the end of the manoeuvre (which may include FIVC) but rather the end of forced expiration.
EOT	End of test	The point during the forced expiratory manoeuvre when a plateau is reached
EOTV	End of test volume	The volume measured at the end of the spirometry test.
ERS	European Respiratory Society	"A non-profit organization with offices in Lausanne, Brussels and Sheffield. It was founded in 1990 in the field of respiratory medicine. The organization was formed with the merger of the Societas Europaea Physiologiae Clinicae Respoiratoriae (founded in 1966) and the European Society of Pneumology (founded 1981). The organization's membership is made up of medical professionals and scientists working in the area of respiratory medicine."(7)
FEF_{25}	Forced expiratory flow at 25% of the FVC	The maximal expiratory flow measured at the point where the first 25% of the FVC has been expired. Measured in L/s.
FEF_{50}	Forced expiratory flow at 50% of the FVC	The maximal expiratory flow measured at the point where 50% of the FVC has been expired. Measured in L/s.
FEF_{75}	Forced expiratory flow at 75% of the FVC	The maximal expiratory flow measured at the point where 75% of the FVC has been expired. Measured in L/s.
FEF_{25-75}	Forced expiratory flow measured between 25% and 75% of the FVC	The average expired flow of air measured over the middle half of the FVC manoeuvre (between 25% and 75% of the FVC). Also known as the mid expiratory flow. Measured in L/s.
$FEV_{0.5}$	Forced expiratory volume in the 1st ½ of a second	The maximum volume air breathed out in the first half a second of forced expiratory manoeuvre. Measured in L.
$FEV_{0.75}$	Forced expiratory volume in the 1st ¾ of a second	The maximum volume air breathed out in the first three quarters of a second of a forced expiratory manoeuvre. Measured in L.
FEV_1	Forced expiratory volume in the 1st second	The maximum volume air breathed out in the first second of forced expiration. It is a measure of how quickly full lungs can be emptied. Measured in L.

Abbreviation	Definition	Explanation
FEV_1 / FVC	Forced expiratory volume in 1 second to forced vital capacity	The FEV_1 expressed as a fraction (or percentage) of the FVC and gives a clinically useful indicator of the presence of airflow obstruction.
FEV_6	Forced expiratory volume at 6 seconds	The FEV_6 refers to the volume of air measured at 6 seconds of the FVC
FIVC	Forced inspiratory vital capacity	The maximal volume of air inhaled with maximal effort from a position of maximal expiration to maximum inspiration. Measured in L.
FVC	Forced vital capacity	The maximum volume of air breathed out with maximum effort from maximum inspiration to maximum expiration. Measured in L.
GLI 2012	Global Lung Initiative 2012	Published multi-ethnic reference values for spirometry for the 3–95year age range
HT	Hesitation Time	The time from the point of maximal inspiration to Time 0. (should be ≤2 seconds)
L	Litres	The unit of measurement for volume in spirometry
L/s	Litres per second	The units of measurement for airflow in spirometry
LABA	Long acting beta2 agonist	Long-acting bronchodilator
Lin	Linearity Testing	The process by which the volume measured by the spirometer is checked at different flow rates
LLN	Lower Level of Normal	Lower limit of normal is the cut-off point for abnormality of a measurement. Different mathematical definitions are used. We favour a z-score to represent the LLN (e.g. z-score -1.64). Other definitions use % of a predicted value to be LLN (e.g. 80% predicted)
LS	Longitudinal studies	Data collected from the same individual at regular intervals over an extended period of time. The values of a current test are compared to the individual's previous test results.
MDI	Metered dose inhaler	Device that delivers a measured amount of medication as a mist that the subject can inhale during bronchodilator reversibility testing.
Mixed	Mixed obstructive restrictive defect	Small lungs and unable to blow out quickly
NHANES III	National Health Examination and Nutrition Survey	Race-specific spirometric reference values derived from the National Health and Nutrition Survey in the United States used for clinical evaluation of pulmonary function.
Obstruction	Obstruction	Limitation of airflow: unable to blow out quickly. A low FEV_1/FVC.
PEF(R)	Peak expiratory flow	The highest rate of expired airflow during the FVC

Abbreviation	Definition	Explanation
	(rate)	manoeuvre. Measured in L/s.
PEFT	Peak expiratory flow time	The highest rate of expired airflow during the FVC manoeuvre. Measured in seconds.
PIF(R)	Peak inspiratory flow (rate)	The highest rate of inspired airflow during the FIVC manoeuvre
Point zero	Zero time point	In the measurement of the FEV_1, point zero is the point selected as the start of the test, obtained using back extrapolation.
Pneumotach	Pneumotachometer	A spirometer that measures the flow rate of gases by detecting pressure differences across the fine mesh.
Pred	Predicted normal values	Expected values for various lung volumes and flow rates, derived from healthy non-smoking populations against which the subject's blow is measured. The values are adjusted for sex, age, height, and race.
%pred	% of predicted	Ratio of subject's actual results compared to predicted normal values, expressed as a percentage.
PFT	Pulmonary function test	A group of tests that measure how well the lungs work.
QA	Quality Assurance	Routine measures put in place at every stage of the spirometry procedure so as to ensure the highest quality results and minimise variability in measurements
QC	Quality Control	The checks done to ensure that the spirometer and software is measuring accurately (truthfully) and precisely (every time). Quality control is a part of quality assurance and includes calibration checks and biological calibration.
Real time	Real time tracing	A spirogram that can be watched as the forced expiratory manoeuvre is performed.
	Repeatability check	The criteria applied to assess the variability between the three best tests within one test sitting
	Reproducibility	Between occasion long term variability in test results i.e. measuring change over time in spirometry test results in one individual
Restriction	Lungs that cannot expand	Limitation to inspiration: small lungs. A relative reduction in FVC relative to FEV_1.
Restrictive Lung Disease		Diseases that reduce the ability of the lungs to expand fully but do not necessarily affect air flow.
RT	Rise Time	From 10 – 90% of the peak flow
RV	Residual Volume	The amount of air remaining in the lungs after the deepest exhalation possible. Cannot be measured on a spirometer.
SABA	Short-acting beta2	Short-acting bronchodilator

Abbreviation	Definition	Explanation
	agonist	
Severity	Severity grading	Lung function pattern has a bearing on exercise capacity, disability and employment, quality of life, morbidity and mortality. For general purposes severity of lung function pattern is based on FEV1 % predicted.
	Spacer	An add-on device used to increase the ease of administering aerosolized medication from a metered-dose inhaler (MDI).
Spirogram	Record of the spirometry test	A single tracing or graphic recording of breathing manoeuvres. Given as volume/time or flow/volume tracings depending on the type of spirometer used.
Spirometer	Instrument used for spirometry testing	An instrument used to measure inspiratory and expiratory lung volumes and flow rates
Spirometry	Measurement of breath	A physiological test of lung function that measures how much, and how quickly, air can be exhaled in a single blow from full lungs.
	Stadiometer	A device for measuring height that typically consists of a vertical ruler with a sliding horizontal rod or paddle which is adjusted to rest on the top of the head.
TLC	Total Lung Capacity	The volume of air in the lungs at maximal inspiration
TV or VT	Tidal Volume	The volume of air that is inhaled or exhaled with each breath during quiet, relaxed normal breathing,
VC	Vital Capacity	The amount of air that can be exhaled by an individual after taking the deepest breath possible, whether or not the air is exhaled forcefully (FVC) or slowly (VC).
V/T	Volume Time graph	Tracing of volume (on the "y" or vertical axis) against time (on the "x" or horizontal axis) for a forced expiratory manoeuvre
	Worker	The person undergoing the spirometry test
Z-Score	A standard score	A Z-score signifies how many standard deviations a result is from the mean predicted value.

APPENDIX B: EQUIPMENT PERFORMANCE [1]

Four elements contribute to accurate spirometer performance: [1]

1. ATS/ERS and ISO26782 recommend minimum performance-based standards for spirometers of all types.
2. Prototype spirometers and their software should undergo validation testing, preferably by an independent testing laboratory, to demonstrate they meet these specifications.
3. Spirometer users should perform daily accuracy checks (i.e. ‘‘calibration checks’’) of the spirometer so that defective spirometers can be removed from service until they are repaired.
4. If sensor errors develop during subject testing, users need to recognize the errors and delete the resulting invalid tests even if not labelled as errors by the spirometer’s software.

Though these elements of accurate spirometer performance have not changed significantly since 2011, increasing attention has been paid to their implementation. The OSHA Guidance document endorses these elements as best practice for assuring accurate equipment performance and presents a list of recommended features for newly purchased spirometers.

1. Obtaining written verification documenting spirometer validation testing by a third-party laboratory. The letter should be obtained from the spirometer manufacturer and indicates that a spirometer model prototype measured at least 21 of the 24 ATS waveforms with acceptable accuracy and precision. In 2019, the ATS/ERS recommended using ISO standard waveforms to evaluate spirometers.
2. The spirometry system has a dedicated calibration check routine consistent with the 2005 ATS/ERS recommendations.
3. Graphical displays meeting a minimum size requirement provide real-time volume-time and flow-volume curves during the test to enhance spirometrists coaching.
4. The spirometer software automatically performs quality assurance checks on expiratory manoeuvres during each spirometry test. ‘‘However, spirometrists should be trained not to rely exclusively on these quality-control prompts, since technical errors may occur that are not among those recognized by the software.’’
5. The spirometer can:
   a. store values from at least eight manoeuvres within one testing session
   b. the spirometry software can save and recall curves and results from at least three acceptable manoeuvres and preferably from all curves.
6. The spirometry data file retains results for all parameters defined in the 2005 ATS/ERS recommendations.
7. Spirometers must provide electronic transfer of spirometry data files using a NIOSH approved procedure for the format, content, and data structure specified by the 2005 ATS/ERS recommendations.

Ref: ACOEM Guidance Statement Spirometry in Occupational Health - 2020

APPENDIX C: COVID-19 SPECIFIC INFECTION PREVENTION PROCEDURES

The forced exhalatory manoeuvres frequently leads to coughing and the production of sputum, which generates aerosols in the form of droplets. It also requires spirometrists and worker to be in close proximity and thus, even with the use of bacterial viral filters, and considering COVID-19, enhanced infection prevention and control is crucial[6].

Recommendations

To protect the worker and staff, there are a number of safety precautions, that should be implemented when conducting spirometry testing in workplace clinics. These infection prevention measures may lead to longer testing times and need for more consumables resulting in pre-planning and slowdown in the flow of the workers during visits.

All workers should be assumed to be COVID-19 positive. The screening and triage should be implemented through asking the worker about the potential risk of having COVID-19 and contacts, using the pre-spirometry COVID Infection Risk Screening Questionnaire found in Appendix D. Any workers with symptoms of COVID-19 or flu like symptoms should not undertake spirometry under any circumstances. In case of suggestive symptoms or history of exposure to a positive contact the worker should be tested for COVID. COVID-19 workers must not undergo spirometry during the disease phase and for a minimum of 30 days post infection[6].

Special IPC Measures (hierarchy of controls) to consider during COVID

- Isolation (Perspex barrier, separate room)
- Ventilation (fresh air via open windows, HVAC, or even extraction – or perform the test outside!)
- Elimination
  - cleaning & disinfection practices of the area plus the equipment - between cases and daily.
  - consider properly installed UV-C germicidal light as an adjunct to ventilation.
  - spirometrist should have had the COVID-19 vaccine.
- Substitution (use a questionnaire-based screen plus clinical exam where possible, as a substitute for spiro's).
- Administrative (increase time between spiro's, fewer spiro's, safe work procedure).
- PPE for operator (FFP2 / FFP3 / N95) mask, goggles, apron).

Before the procedure:

1. Screening
2. Do not test those with confirmed COVID-19 and for 30 days post infection.
3. Do not test those with COVID-19 or flu like symptoms.
4. Test outside or in a designated well-ventilated spirometry room (where windows can open).
5. Waiting areas to have 1.5 meters between persons. Maintain a distance of 1.5 meters between the spirometrist and worker during the instructional phase of testing.
6. Workers to attend alone.
7. Workers to wear masks and wash hands before and after entering the spirometry testing room.
8. Spirometrists to wear personal protective equipment (PPE) including a face mask (FFP3 or FFP2) gloves and eye-protection e.g., goggles or face shield. Disposable gloves should always be used when doing spirometry. These should be discarded after each worker and after cleaning of the surfaces. PPE is necessary in all circumstances during the pandemic. Use of PPE in high-risk areas must be managed within the same space and staff should not move outside the area without removing the PPE.
9. When spirometry is performed outdoors, an FFP3 or FFP2 mask is preferred if available. Alternatively, a surgical mask can be used.
10. For naturally ventilated rooms, the windows must be open. For mechanically ventilated buildings such as by HVAC systems, the ventilation rate should be set to at least 12 air changes per hour.
11. Spirometrist to disinfect all surfaces before and after testing.

After the procedure:

1. Reorganise testing schedules to include extra time for post-test cleaning/ decontamination procedures of the surfaces of the spirometer and environment. Regular equipment and surface cleaning protocols should be strictly adhered to.
2. Clean and disinfect the spirometer and testing area as per the infection prevention protocol.
3. For workers undergoing testing indoors, change PPE after each worker. If it is not possible to change the PPE after each worker, ensure that one spirometrist is designated to the spirometry testing for that day to avoid cross-contamination.

During the procedure:

1. Spirometrist to wear full PPE throughout (face mask, eye protection, apron, gloves).
2. Spirometrist not to move outside the spirometry testing room without removing the PPE.
3. Use single use disposables e.g. mouthpiece, noseclip, filter.
4. Use a single use disposable inline bacterial viral filter with every worker.
5. Spirometrist to remain 1.5 meters away and to the side of the worker.
6. If the spirometry is performed indoors in a designated room and the weather allows, please keep all windows open during all times.

Recommendations for post-COVID-19 pandemic

Return to pre-COVID-19 standards for the delivery of lung function testing.

APPENDIX D: PRE-SPIROMETRY COVID INFECTION RISK SCREENING QUESTIONNAIRE

These questions must be asked by the spirometrist to the worker prior to performing the spirometry test. The purpose is to identify any infection risks that may make spirometry unsafe for the worker and / or spirometrist.

1. Do you have a high temperature? (Above 37.8°C or higher) *If yes, do not test at this time.*	Yes	No
2. Do you have a sore throat? *If yes, do not test at this time.*	Yes	No
3. Do you have difficulty breathing / shortness of breath? *If yes, do not test at this time.*	Yes	No
4. Do you feel unusually weak? *If yes, do not test at this time.*	Yes	No
5. Are you struggling to taste food and drinks normally? *If yes, do not test at this time.*	Yes	No
6. Has your sense of smell changed? *If yes, do not test at this time.*	Yes	No
7. In the last 14 days have you been in close contact with someone who is suspected to have COVID -19 or has been diagnosed positive with COVID-19? *If yes, do not test at this time.*	Yes	No
8. In the last 14 days have you attended or visited a healthcare facility that has treated patients that are COVID-19 positive? *If yes, do not test at this time.*	Yes	No

Ref: Questionnaire adapted from the Karri app school screening questionnaire

APPENDIX E: RELATIVE CONTRAINDICATIONS FOR SPIROMETRY

Table 2. Relative Contraindications for Spirometry

Due to increases in myocardial demand or changes in blood pressure
Acute myocardial infarction within 1 wk
Systemic hypotension or severe hypertension
Significant atrial/ventricular arrhythmia
Noncompensated heart failure
Uncontrolled pulmonary hypertension
Acute cor pulmonale
Clinically unstable pulmonary embolism
History of syncope related to forced expiration/cough
Due to increases in intracranial/intraocular pressure
Cerebral aneurysm
Brain surgery within 4 wk
Recent concussion with continuing symptoms
Eye surgery within 1 wk
Due to increases in sinus and middle ear pressures
Sinus surgery or middle ear surgery or infection within 1 wk
Due to increases in intrathoracic and intraabdominal pressure
Presence of pneumothorax
Thoracic surgery within 4 wk
Abdominal surgery within 4 wk
Late-term pregnancy
Infection control issues
Active or suspected transmissible respiratory or systemic infection, including tuberculosis
Physical conditions predisposing to transmission of infections, such as hemoptysis, significant secretions, or oral lesions or oral bleeding

Spirometry should be discontinued if the patient experiences pain during the maneuver. Relative contraindications do not preclude spirometry but should be considered when ordering spirometry. The decision to conduct spirometry is determined by the ordering healthcare professional on the basis of their evaluation of the risks and benefits of spirometry for the particular patient. Potential contraindications should be included in the request form for spirometry.

APPENDIX F: PRE-SPIROMETRY CONTRAINDICATIONS SCREENING QUESTIONNAIRE

These questions must be asked by the spirometrist prior to performing the spirometry test. The purpose is to identify any contraindications that may make spirometry unsafe for the worker and to identify conditions / practices that could falsely elevate or depress the spirometry test measurements, thereby leading to incorrect interpretation.

1. Have you had an injury to the chest or an operation in the last 6 weeks? *If yes, do not test at this time.*	Yes	No
2. Have you been admitted to hospital in the last 6 weeks? *If yes, do not test at this time. Ask OMPs opinion about whether it is safe to test or not.*	Yes	No
3. Have you coughed up blood in the past 6 weeks? *If yes, do not test at this time. Refer to doctor / OMP.*	Yes	No
4. Have you had a respiratory/chest infection (such as flu, pneumonia, bronchitis) in the last 3 weeks? *If yes reschedule to test for 2 weeks' time if possible.*	Yes	No
5. Have you used an inhaler in the last 24 hours? *If yes, continue to test but before testing record the type of medication and the time of last administration.*	Yes	No
6. Have you taken any other medicines in the past 24 hours? *If yes, continue to test but before testing record what drug was taken and why. If on TB treatment, do not test.*	Yes	No
7. Have you got any pain now that could limit you from blowing with effort? *If yes reschedule the test for when the worker is pain free if possible.*	Yes	No
8. Are you currently suffering from acute diarrhoea, vomiting or nausea that may limit you from blowing with effort? *If yes reschedule the test for when the worker is feeling well or reschedule if possible*	Yes	No

Ref: Questionnaire adapted from the Lung Health in Africa Across the Life Course (LuLi) research project pre-spirometry screening questionnaire and Education for Health Africa educational content

APPENDIX G: INFORMATION ON GLI REFERENCE VALUES[7]

International collaboration of more than 40 countries has resulted in the publication in 2012 of standardised GLI spirometry reference equations by the European Respiratory Society Task Force that can be used globally for people aged from 3 to 95 years. The GLI Equations are comprised of an equation that requires an additional spline function from a look-up table. This spline function helps to improve the accuracy in which normal lung growth and decline are characterised and avoids misinterpretation of spirometry data.[7] These new recommendations for spirometry growth charts, from the GLI 2012 spirometry prediction equations now represent the most robust and scientifically valid equations available at this time. These prediction equations have now been endorsed by all international respiratory societies[7] and need to be implemented for use in everyday practice in South Africa.

When changing over to using the GLI reference values (recommended), absolute (raw) values of lung function will not be affected. The predicted value for a given height and age may differ but will be a better reflection of the worker's results. You will need to refer to updated trend reports when comparing new measurements with those taken prior to this change to avoid unnecessary misinterpretation and anxiety of workers. In addition to standardising the results for each worker, results will be standardised across different workplaces[7].

* Note: Since data on PEF and other instantaneous flows were not collected for the GLI-2012, it is not possible for manufacturers to depict such predicted contours or a representative flow-volume curve using GLI-2012 prediction equations[7].

Ethnicity when using GLI Reference Values

Choosing the most appropriate reference values for an individual can be difficult. The assignment of ethnicity for an individual can be uncertain, particularly for those of mixed ethnicity. Good data is lacking for many populations and there may be morphologic changes with subsequent generations of an immigrant population. Shown below are the populations for which each of the GLI-2012 equations are known to be representative[7].

Group	Country/region
Caucasian	Europe, Israel, Australia, USA, Canada, Mexican Americans, Brazil, Chile, Mexico, Uruguay, Venezuela, Algeria, Tunisia
Black	African American
South East Asian	Thailand, Taiwan and China (including Hong Kong) south of the Huaihe River and Qinling Mountains
North East Asian	Korea and China north of the Huaihe River and Qinling Mountains

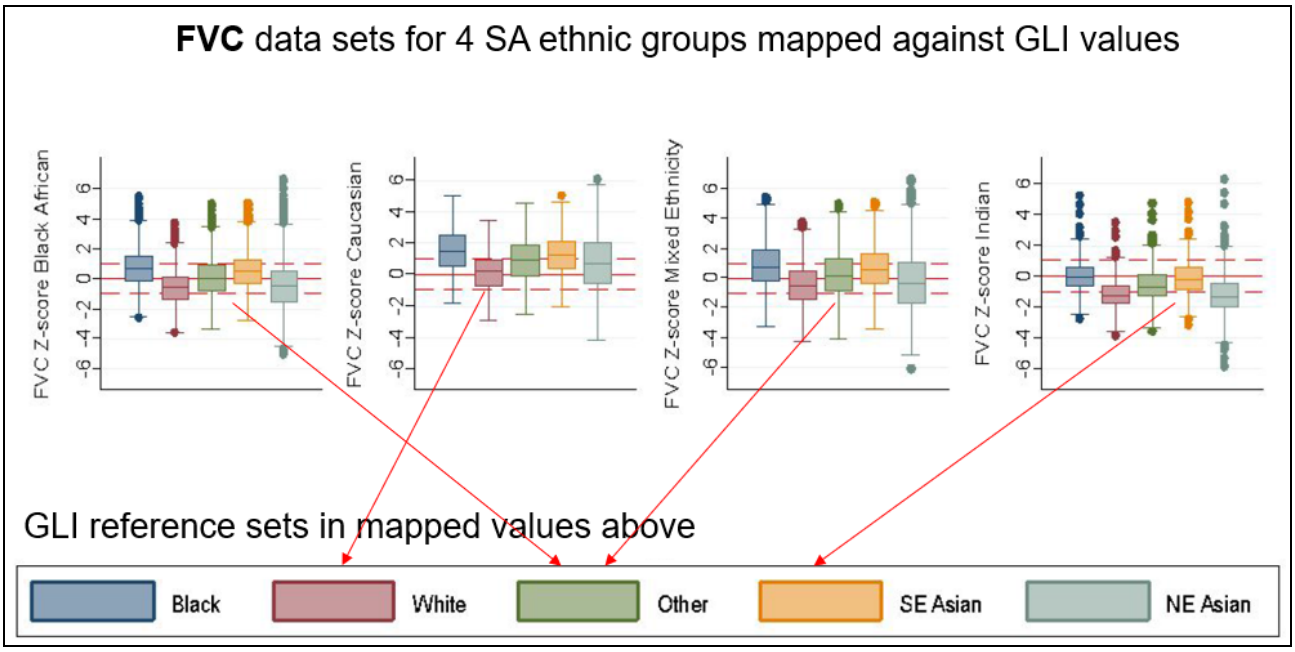
Guidance to the applicability of the Global Lung Initiative spirometry reference equations for South African populations

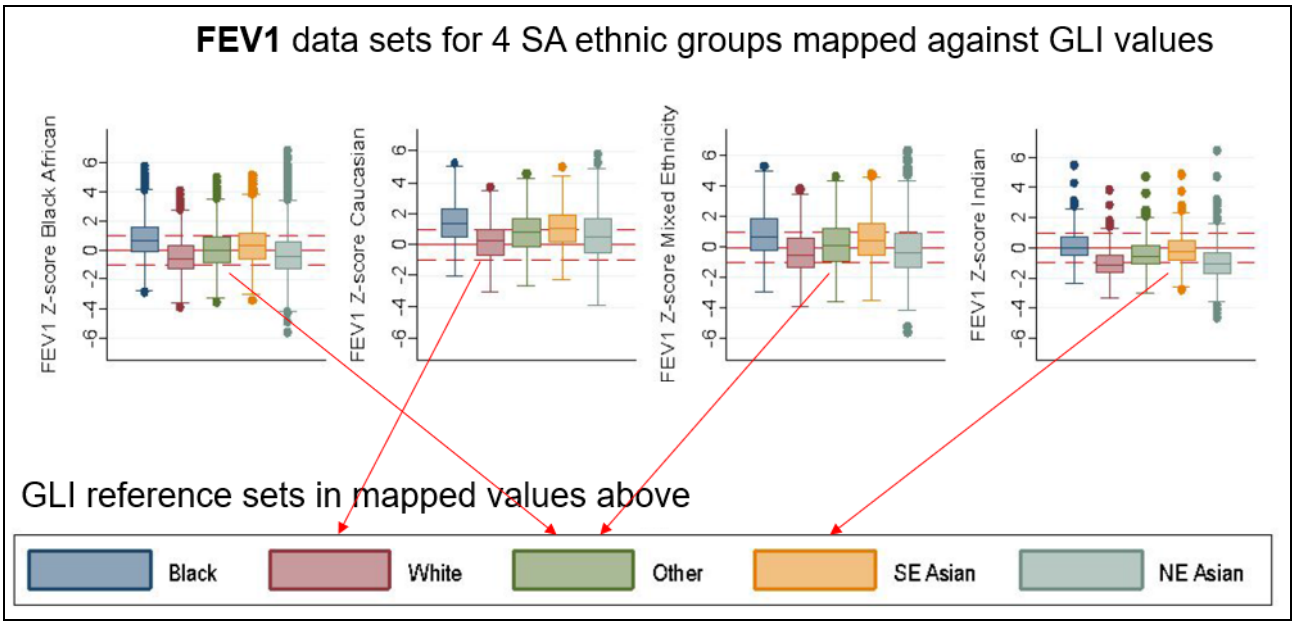
"Based on the findings of the retrospective African data set, a prospective study in >3 000 South African (SA) adults and workerren of various ethnicities was performed in 2018 / 2019 to assess the appropriate GLI references that should be utilised in the SA context. Based on the results of this study, we would strongly recommend that for SA black African and mixed-ethnicity populations the GLI-'Other' reference equation should be utilised when performing spirometry. … The GLI-White equation should be utilised for white South Africans. A critical finding of this study, which has been replicated in multiple studies, is that the forced expiratory volume in 1 second (FEV_1)/forced vital capacity (FVC) ratio is stable and is independent

of the reference utilised and can be relied on to diagnose airway obstruction in a good-quality test and using age-adjusted cut-offs for disease. [10]

GLI-2012 provides a fifth set of equations, “Other”, made up as a combination of the four groups above, which may be applied as a first approximation to individuals not represented by one of the groups or who are of mixed ethnicity. This should be noted in the report and results interpreted with awareness of increased uncertainty[7].

These graphs are taken from the paper published by Smith, Gray, McGinty et al (06/08/2020).





Additionally, when using GLI reference values we suggest correcting for race and gender at birth.

APPENDIX H: USE OF LLN AND Z SCORE RATHER THAN PERCENT OF PREDICTED

Despite its widespread adoption percent predicted is not scientifically founded. In fact, 'Nowhere else in medicine is such a naive view taken of the limit of normal' (Sobol). The indiscriminate use of 80% of predicted as the 'lower limit of normal' (LLN) in spirometry for what may be considered 'normal' has been considered as statistically invalid and cannot be justified[8].

Using 80% predicted LLN shows a progressively increasing LLN as age increases with no statistical reasoning. This as a marker of abnormality, would create a large percentage of false-positive results in both young and elderly subjects and could be regarded as a potential problem when diagnosing and monitoring respiratory disease[8].

Both the ERS and ATS have endorsed the LLN as 1.645 SD below the mean value applying the 5th percentile LLN. The 'Z-score' or Standard Residual (SR) show the number of standard deviations a result is from the mean value. There is great utility in using the z-score, *i.e.* the difference between observed (y) and predicted (Y) value divided by the residual standard deviation (RSD) about the mean predicted value; z-score = (y - Y)/RSD. [8]

The great advantage is that the Z score can be used for any index; regardless of whether we are dealing with the haemoglobin concentration, standing height, serum creatinine concentration or FEV_1, the Z score discloses how rare or common the observation is. For example, if the Z score is smaller than -1.64 then the observation occurs in only 5% of the reference population. A Z score > +1.96 is encountered in only 2½ per cent of all healthy subjects[8].

Using a fixed cut off for FEV_1 / FVC in interpretation

The GOLD guideline threshold FEV_1/FVC ratio of 70%, whether before or after bronchodilator administration, is deeply flawed. Despite good intentions, an invalid easy-to-remember number is still invalid. The categorization under-detects airway obstruction in many younger individuals and over-detects airway obstruction in many older individuals. Using LLN and Z score for interpretation corrects this incorrect previous practice[8].

APPENDIX I: SASOM POSITION STATEMENT SPIROMETRY IN COVID

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SASOM Position Statement on the South African Thoracic Society (SATS) Updated Position Statement on Pulmonary Function Testing

SASOM is of the opinion that the risk in the current Covid-19 South African pandemic is still high, so spirometry should be limited to cases where there is an important clinical or other substantial indication, taking all the updated *SATS requirements issued on 23 September 2020* (refer attachment) into consideration. In all other instances, testing should be deferred where the perceived risk outweighs the benefit.

The following important factors must be considered:

1. A pre-spirometry risk assessment should be done, to determine whether the benefit of the test outweighs the risks.
2. The necessary controls for the work environment, equipment, staff and procedure must be in place, with particular attention to:
   - 2.1. good ventilation and / or extraction
   - 2.2. surface / fomite disinfection
   - 2.3. isolation - a separate room / cubicle for the procedure is recommended
   - 2.4. the potential for viral transmission via the device being used; care must be taken regarding the test device's *filter systems* and / or *blowing circuit* to prevent exhaled virus from entering the room or contaminating the equipment.
3. Taking care that such a Covid-19 safe facility is in place and taking all the updated *SATS requirements issued on 23 September 2020* into consideration, the following could be considered as substantial indications:
   - 3.1. Pre-placement pre-employment baseline spirometry in individuals with exposure to known chemical irritants, sensitisers and other allergens.
   - 3.2. Periodic spirometry in individuals with exposure to known chemical sensitisers and other allergens.
   - 3.3. Spirometry at exit medical in individuals with exposure to known chemical irritants, sensitisers and other allergens.
   - 3.4. In cases where occupational asthma or other respiratory illnesses requires evaluation and treatment.

Dr Andre Kotze
SASOM Vice Chairman

19 October 2020

SOUTH AFRICAN THORACIC SOCIETY

Registration number 054-939-NPO

23 September 2020

UPDATE:

POSITION STATEMENT OF THE SOUTH AFRICAN THORACIC SOCIETY ON PULMONARY FUNCTION TESTING

The South African Thoracic Society (SATS), in line with other international respiratory societies, recommends that pulmonary function testing (PFT) can be reintroduced where there is a clinical or other substantial indication for testing, provided personnel and subjects are adequately protected from contracting SARS-CoV-2. While it remains the employer's responsibility to provide pulmonary function clinical technologists and other individuals involved with a safe working environment, SATS recommends the following:

1. There should be an important clinical or other substantial indication (including compensation and research) to perform testing. Deferring testing should be considered where the perceived risk outweighs the benefit.
2. Personnel performing the test should be assessed for risk of severe COVID-19 disease, and high-risk personnel should not be forced to perform PFTs.
3. Individuals undergoing lung functions should be screened, and risk for COVID-19 assessed by questionnaire (see updated case definition at https://www.nicd.ac.za/wp- content/uploads/2020/07/NICD_DoH-COVID-19-Guidelines_Final_3-Jul-2020.pdf).
4. For the asymptomatic individuals, PCR test before PFTs could be considered depending on the prevalence of COVID-19 in the community and available resources (including testing access).
5. PFTs may be performed 4 weeks after symptom onset in individuals who had proven or highly likely symptomatic COVID-19, and a negative screen (as per points 3 and 4).
6. Testing capacity/volumes should at the present time preferably be escalated to no more than 50% of pre-COVID capacity, to allow for adequate time between subjects to ensure safety in addition to measures to ensure social distancing. Subjects should sit at least 1.5 meters apart in the waiting area, and wear cloth or ideally, surgical face masks.
7. The contact time between personnel and subjects should be minimised, wherever possible, by the use of instructional videos and other means of preparing / teaching patients how to perform forced expiration and other manoeuvres.

8. PFTs should be performed in a well-ventilated area and with only the subject and limited personnel (i.e. only those performing testing) present. Before starting testing each day the testing area should be disinfected and ventilated.
9. Practical considerations include having the subject blow away from the technician and equipment and asking subjects to where masks inside the room when not performing PFTs.
10. Personnel should be supplied with personal protective equipment (PPE) and educated on its use. PPE should include fit-tested N95 respirators, eye protection, gloves, and aprons.
11. Surfaces that may have been touched by the subjects or contaminated by droplets and equipment should be disinfected after each subject's PFTs has been performed.
12. In-line disposable filters should be used (and discarded as medical waste) after each subject and operators must be familiar with SANS26782 and other minimal standards with regards to filters.
13. All other infection prevention recommendations as per the current SATS Guideline for Office Spirometry (S Afr Med J. 2013; 103: 52-61) should be adhered to.

ISSUED BY THE COUNCIL OF THE SOUTH AFRICAN THORACIC SOCIETY

Prof Coenie Koegelenberg (SASTS President)