Effects of treatment and the medical assessment of Chronic Bronchitis and Emphysema (PD D12, Chronic Obstructive Pulmonary Disease)

Report by the Industrial Injuries Advisory Council in accordance with Section 171 of the Social Security Administration Act 1992 considering the effects of treatment and the medical assessment of Chronic Bronchitis and Emphysema (PD D12)

Presented to Parliament by the Secretary of State for Work and Pensions
By Command of Her Majesty
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INDUSTRIAL INJURIES ADVISORY COUNCIL

Secretary of State for Work and Pensions

Dear Secretary of State,

EFFECTS OF TREATMENT AND THE MEDICAL ASSESSMENT OF CHRONIC BRONCHITIS AND EMPHYSEMA (PD D12, CHRONIC OBSTRUCTIVE PULMONARY DISEASE)

Eligibility for the prescribed disease PD D12 (Chronic Bronchitis and Emphysema) requires evidence of a loss of one litre of lung function as measured by spirometry. In 2006, a Commissioner advised that the effects of bronchodilator treatments (those that are aimed at dilating the airways) should be taken into account when deciding medical assessments for PD D12. Since then, medical assessors have been applying arbitrary and sometimes variable offsets to the threshold loss of one litre of lung function in claimants taking these treatments. The Department asked the Council to consider how the effects of treatment should be taken into account in the medical assessment of claimants.

During our review we have consulted with respiratory experts and the Department's medical policy makers, tested what is known about the effects of treatment on patients with airflow obstruction, reviewed the evidence base used to frame the original prescription, and evaluated a range of options.

In modern medical terminology, the prescribed disease PD D12 is better known as 'Chronic Obstructive Pulmonary Disease' (COPD). Treatments for COPD are numerous and varied and claimants may be taking several different drugs. In contrast to asthma, the effects of such treatments are likely to be small in patients with COPD; they are also likely to vary to an unpredictable extent between individuals. The Council has concluded that no simple, scientifically valid adjustment factor can be applied which would reflect this variation equitably between claimants.

A further consideration is that the original prescription rests on a series of reasonable approximations. Previously, the Council highlighted, for example, that it would be impractical within the constraints of the Scheme to take account of various factors that are likely to vary between claimants, such as work location, job title, individual levels of exposure to coal dust, short absences from work, smoking habits, and relation between loss of lung function and disability[1]. The relationship between a one litre loss of lung function and the exposure level defined in the prescription is also approximate scientifically, lying within a range of uncertainty noted in previous reports of the Council.

As well as being beyond that which can be justified by the science, and by the resources of the Scheme, applying an offset for treatment in the individual claimant carries the potential to be inequitable. Specifically, it may relatively advantage those taking treatment which has no effect, as they would be judged against a lower measured loss of lung function than other claimants for no sound reason. Given (1) the inexact evidence base used to frame the prescription, (2) the lack of practical means to reflect fairly an ill-defined variability in response to treatment, and (3) this potential for inequity, the Council has concluded that the effects of treatments should be disregarded during medical assessments for PD D12. To formalise this advice in law, the Council proposes that the prescription of PD D12 be amended to clarify that the required one litre loss would apply irrespective of medical treatment.

[1] Industrial Injuries Advisory Council. Chronic Bronchitis and Emphysema. Cm. 2091. November 1992. London: HMSO.

Finally, it is proposed that this opportunity be taken to replace the original, now medically out-dated, term for chronic irreversible outflow obstruction in PD D12 ('Chronic Bronchitis and Emphysema') with its modern equivalent, 'Chronic Obstructive Pulmonary Disease'. In practical terms, this change in terminology will have no impact on claimants or claims activity, but will modernise the disease definition to reflect current medical practice.

Yours sincerely

Professor K Palmer
Chairman

22 July 2014

Summary

1. The Department for Work and Pensions (DWP) has asked the Council to consider the issue of how and to what extent an allowance should be made in the interpretation of spirometry for claimants for PD D12 (Chronic Bronchitis and Emphysema, more commonly referred to nowadays as Chronic Obstructive Pulmonary Disease (COPD)) who use bronchodilator treatment(s) (drugs aimed at dilating the airways and relieving airflow obstruction).

2. This matter arose in the context of a Commissioner's advice in 2006 that the effect of bronchodilators should be taken into account when deciding assessments for cases whose spirometry falls just below the one litre decrement in FEV_1 (forced expiratory volume in one second) defined in the prescription[2]. The Commissioner did not, however, specify how this should be done, writing that "I cannot decide ... because it involves medical issues. It is a decision for an expert tribunal." This led to arbitrary and sometimes variable offsets being applied by medical advisors in claimants of PD D12 taking such treatments.

3. The Council's review has focused on providing an evidential basis on the use and impact of bronchodilator (and other) treatments for COPD on assessments for PD D12, and on recommending a way to regularise assessments of this prescribed disease.

4. The Council has discussed the matter at length and has sought external expert advice. It has also reviewed the medical literature and the historical basis of the prescription.

5. It has established that responses to treatment are variable and unpredictable between individuals, and that any effects in cases of COPD (in contrast to cases of asthma) are likely to be small. The Council has concluded that it is not possible to recommend a scientifically valid adjustment factor that would encompass the very wide variety of different treatments now used in the management of COPD while remaining equitable to individual claimants.

6. Various other sources of variation exist between claimants that can affect loss of lung function and disablement, but which cannot readily be addressed within the constraints of the Scheme on a case by case basis. When PD D12 was originally prescribed the Council highlighted, for example, that it would be impractical to take account of factors such as work location, job title, actual exposures to coal dust, brief spells away from work, and lifetime smoking habits. It also noted the approximate relationship on the one hand between loss of lung function and disability, and on the other between measured loss of FEV_1 and estimated lifetime exposure to coal dust. In the same way, the Council has concluded that it would be impractical to apply an offset to the one litre loss of FEV_1 threshold according to an individual claimant's medical treatment; it is beyond the science and beyond the resources of the Scheme to be this exact.

7. Furthermore, applying an offset for treatment in the individual claimant carries a potential to be inequitable. Specifically, it may advantage those taking treatment which has no effect, as they would be judged against a lower measured loss of lung function relative to other claimants, but for no sound reason.

[2] Social Security Commissioner Decision. March 2006. CI/2683/2004.

8. These considerations have led the Council to recommend that the effects of treatments should be disregarded when interpreting spirometric evidence during medical assessments for PD D12. To formalise this in law, and in light of the Commissioner's previous advice, a clarifying amendment is recommended to the prescription of PD D12.

9. Opportunity is being taken at the same time to recommend modernising the definition of PD D12, from 'Chronic Bronchitis and Emphysema' to 'Chronic Obstructive Pulmonary Disease'. This change will not affect claimants or claims activity in practice, but will bring an outdated terminology into line with modern medical practice.

This report contains some technical terms, the meanings of which are explained in a concluding glossary.

Background

10. In its report of 1992 ('Chronic Bronchitis and Emphysema'; Cm. 2091) the Council recommended that 'chronic bronchitis and emphysema' be prescribed for coal miners with at least 20 years of service underground. The evidence that enabled prescription came from longitudinal studies of British and US coal miners. Later that year, PD D12 was added to the statutory list of prescribed diseases.

11. The prescription defined 'chronic bronchitis and emphysema' in terms of a reduction in one aspect of lung function, forced expiratory air flow in one second (FEV_1), that was "likely to be associated with clinically important disablement".

12. Reduction in airway diameter, as measured by FEV_1, causes disability by reducing exercise capacity.

13. Several considerations bore on the level of reduction in FEV_1 chosen to define entitlement. Firstly, a study of miners from a colliery in South Wales (Soutar *et al.*, 1993) found that a level of FEV_1 of approximately one litre below the predicted value was on average associated with shortness of breath when walking with others on the level ground – i.e. a clinically significant level of disability.

14. Secondly, since FEV_1 is normally distributed and with a standard deviation of about 0.5 litres in men of all ages and heights (Cotes, 2006), after allowing for these factors, such a loss would be two standard deviations below the mean in the reference or control population and would be expected, therefore, to arise in only 2.5% of individuals (being 'below the limit of normal', 'Chronic Bronchitis and Emphysema', Cm. 3240, 1996); defining abnormality in terms of a percentile of the distribution was considered more robust than taking a fixed per cent of predicted FEV_1 in the individual, for reasons laid out in Cm. 3240.

15. Thirdly, research evidence (Marine *et al.*, 1988) showed that risks roughly approximating to such a level of clinically relevant loss were more than doubled in underground miners with a degree of cumulative exposure to coal dust that could be defined practically (equivalent on average to working underground for 20 years in UK mines in the 1960s and 1970s). The research also found that such an elevation in risk existed both in miners who smoked and those who did not – i.e. could be attributed to coal dust exposure, even in miners who smoked.

16. It should be noted that the relation between exposure and loss of FEV_1, on the one hand, and that between loss of FEV_1 and disability on the other, exists 'on the average'. Thus, while 'FEV_1 is a good measure of loss of lung function, its relationship with disability is less clear' ('Chronic Bronchitis and Emphysema', Cm. 3240, 1996). In other words, loss of FEV_1, which is a convenient parameter to measure, relates only approximately (if usefully) to disability in individuals.

17. Similarly, the relation between exposure to coal dust and risk of a one litre loss of FEV_1 was defined 'on average' in the studied populations. It was recognised ('Chronic Bronchitis and Emphysema', Cm. 2091, 1992) that individual miners who had worked underground for 20 years would vary in their actual exposure to coal dust (since exposure levels varied three-fold between mines and within mines over time, while miners varied in their jobs and working patterns); also, that there could be individual variation in susceptibility to the harmful effects of coal dust. However, adequate data on dust levels were not available for many pits and nor were personalised estimates of exposure in individual miners. The Council noted that such averaging, and a simple time rule (20 years underground), might disadvantage a few claimants with higher than average exposures (or susceptibility), but went on to say that it would be impractical for the benefit system to take these uncertainties into account. (Even the average level of the critical "cumulative exposure" to double risk of disabling bronchitis and emphysema was uncertain within a factor of two, lying between 60 and 120 mg yr m-3 ('Chronic Bronchitis and Emphysema', Cm. 3240, 1996, paragraph 46).) The 20 year threshold was chosen to "provide a simple, easily understood and applied criterion" (Cm. 3240, paragraph 52).

18. Since PD D12 was first prescribed, the Council has received various representations on the FEV_1 test, and published several reports. Cm. 3240 resulted in a refined recommendation on eligibility, allowing the few claimants with low absolute values of FEV_1 (below one litre) to claim benefit irrespective of their lung function relative to expected height and age. This change was introduced to address a potential disadvantage among shorter older men, among whom expected FEV_1 would already be relatively low.

19. More recently, the decision of a Social Security Commissioner[3] has led the Council to consider the FEV_1 test in the context of the treatments a claimant may be taking and, in consequence, to prepare this report. Opportunity has also been taken to consider the terminology of the prescription.

A Commissioner's report

20. Chronic obstructive pulmonary disease (COPD) is an umbrella term that embraces several respiratory diseases which often co-exist – chronic bronchitis, emphysema and chronic severe asthma. However, the prescription PD D12 was intended to compensate obstruction that was predominantly or wholly unresponsive to treatment, rather than the component of COPD arising from chronic asthma ('Chronic Obstructive Pulmonary Disease', Cm. 7253, 2007). In this respect, the Council's report Cm. 3240 (1992) commented that "airflow limitation caused by chronic bronchitis and emphysema is predominantly irreversible and, unlike asthma, the level of improvement after inhalation of a bronchodilator .... is minimal." Hence, it continued, "the normal use of bronchodilators ... should not therefore interfere significantly with the results of FEV_1 tests as a measure of the airflow limitation."

[3] The term "Commissioner" has since been replaced by that of "Judge of the Upper Tribunal".

21. In 2006, a Social Security Commissioner considered the case of a miner who applied for PD D12 and whose claim was rejected on the basis that his reduction in FEV_1 was 0.93 litres, i.e. marginally less than the qualifying threshold of a one litre loss. His representative raised a concern that the measurement of [his] FEV_1 could have been "distorted by medications taken by him near the time of the test."

22. In summing up, the Commissioner argued that medical advisors "...should, at least in marginal cases, consider the possible effects of medication when forming a view about the conclusions to be drawn.." from the measurement of FEV_1 but that, since this involved medical judgement, and since he had been presented with opposing views by two medical experts, "...it is a decision for an expert tribunal". In particular, he noted that the terms 'normal' and 'significantly' in Cm. 3240 (paragraph 20 above) left open the possibility that circumstances might exist in which bronchodilators could significantly affect the assessment of FEV_1.

23. In response to this ruling, an amendment to DWP's Medical Service standards was made as follows: "Where the result of spirometry demonstrates a drop in FEV_1 which fails to satisfy the diagnosis criteria, the [medical advisor] should consider whether recent use of a bronchodilator is likely to have artificially inflated the result, and whether, if the test had been carried out without the effect of recent bronchodilator use, the result would have satisfied the diagnosis."

24. This advice implies that losses of FEV_1 of less than one litre could be accepted as meeting the criteria for prescription in claimants taking bronchodilator treatment. However, no advice was given on the likely effects of treatment and thus the level of loss that should be chosen instead. The Council has learned that a variety of arbitrary offsets have been used, which have differed between assessment centres.

25. To place assessments of PD D12 on a more consistent evidential footing, the Council has been asked to advise on the implementation of the Commissioner's ruling. This report sets out various scientific and practical considerations and the Council's recommendations on a way forward.

The Council's determinations

26. In preparing this account, evidence has been taken from those involved in the original prescription; original reports of the Council (Cm. 379, 2091, 3240 and 7253; Position Paper 11) and the key research papers that informed them (e.g. Marine *et al.*, 1988; Soutar *et al.*, 1993) have been revisited. Evidence has been sought also on the reversibility of emphysema and COPD under treatment, the measurement properties of the FEV_1 test, and the Department's medical policies on assessment of PD D12. The issue raised by the Commissioner has been considered also in the context of the prescription.

Scientific matters

27. The Council considers that several medical and scientific arguments are critical in weighing the problem posed.

28. In stating that "...the airflow limitation associated with chronic bronchitis and emphysema is predominantly irreversible, and ... the level of improvement after inhalation of bronchodilator is minimal" the [then] Council intended that no account could or should be taken of variations between individuals in their treatment (Professor A J Newman Taylor, personal communication). If the reversibility were large, this would call into question the diagnosis of the prescribed disease.

29. Crucially, also, in individuals with COPD, the magnitude of treatment effect will be small relative, particularly, to the approximations used in choosing a particular prescribed cut-point for loss of FEV_1 and a prescribed degree of exposure (see above); and small relative to other differences between individuals which, for logistic and scientific reasons, cannot be accommodated by the Scheme and which affect loss of FEV_1 (e.g. smoking habits).

30. Additionally, measurement of FEV_1, although a useful and convenient test, is not precisely reproducible within an individual, since it varies by time of day and between days for a host of known and unknown reasons, including for example, temperature and humidity, recent infection, recent exposure to irritants (e.g. a recently smoked cigarette), and other factors.

31. Another consideration is that the effect of treatment (in health and disease) is liable to vary to an unpredictable extent between individuals, and on repeat occasions within individuals, a point emphasised by the National Institute of Clinical Excellence (NICE; 2010) and a report by Calverley *et al.* (2013). These last authors noted further that a large variety of medicines are now available to patients with COPD with different modes, potencies, and timings of action and that the "effect ...[of] different drugs ... has not been systematically explored." Thus, any proposed offset for such effects would be arbitrary and pretend a degree of precision within individuals that cannot be framed in terms of existing evidence.

32. The evidence on which the original prescription for PD D12 was formulated came from longitudinal studies of changes in FEV_1 in British and US coal miners. It is very likely that a proportion of these miners were taking bronchodilator drugs, although the reports did not mention this or analyse effects separately in those taking or not taking such treatment. Thus, measurements of lung function were made and assessed without reference to treatment.

Other considerations

33. The Council is concerned that the application of an offset to the one litre loss of FEV_1, as presently applied by the Department's medical assessors, effectively creates two different standards by which claims may be assessed – one for those taking certain treatments and one for those who are not.

34. Potentially, this may advantage some claimants: specifically, those taking treatment which has no effect, since for them the threshold extent of loss would be lower than for other claimants not taking treatment, but unjustifiably so.

Options explored by the Council

35. In seeking to address the Commissioner's concern, one option the Council has discussed with the Department is for claimants to be tested as they present, whether on treatment or not. Those found to be close to a one litre loss in FEV_1 could be offered the opportunity to be tested a second time after a period in which they refrain from using inhaled bronchodilators. In this way, the possible effects of treatment would be taken into account.

36. This approach (rather than the use of any arbitrary offset) was used by the Department for Energy and Climate Change (formerly the Department for Trade and Industry) in assessing claims for the same disease in former employees of British Coal. Claimants were advised where possible to avoid the use of "any short acting bronchodilator drugs ... for at least four hours prior to the assessment."

37. In routine clinical practice, the risks inherent in such an approach are regarded as negligible. However, because of policy considerations, the Department felt unable to ask claimants to stop their treatment for purposes of deciding a claim for benefits.

38. Alternatively, the Commissioner's decision might be addressed by testing **all** claimants after short-term use of a bronchodilator drug, rather than adjusting the assessment threshold for those who are on treatment. For reasons of logistics and policy, the Department felt this approach also to be impractical.

39. The foregoing arguments in this paper indicate a third possibility that the Council finds persuasive – that, as originally intended, no offset be made in assessment for potential effects of treatment. This approach would recognise the approximate nature of the evidence base on which prescription is founded, the uncertainties in the science that preclude individualised risk assessment in claimants, and the practical disadvantages and potential inequities in applying an offset in circumstances that are not feasible to define with any exactitude scientifically.

Summary and recommendations

40. The prescription of PD D12 was for disease characterised by obstructed airflow that is essentially irreversible and unimproved by medical treatment. The cut-off of one litre used to define the required loss of FEV_1 was chosen as a broad indication of the level at which most claimants would feel disabled by breathlessness, as a mark of lung function that is below the expected normal range of values, and as a simple, easily applied criterion. Various approximations necessarily formed part of the backdrop to prescription; in particular, the relations between loss of FEV_1 and disability, and between exposure to coal dust and loss of FEV_1 could only be established on the average, while it was recognised that individual claimants spending a similar time underground could differ in their exposures in ways that the Scheme could not measure.

41. As with any fixed cut-off, there will be claimants whose reduction in lung function is marginally outside the limit of a one litre reduction. Also, some claimants with COPD will have lung function that improves to a degree with the use of bronchodilator treatment (the same is true for some healthy people). However, any such response is

variable, unpredictable, and impossible to define scientifically for the wide variety of treatments used in the modern management of COPD. If treatment effects were large, this would call the diagnosis into doubt, being more typical of asthma than of COPD.

42. The expected effects of treatment are small relative to the approximations used in choosing the current prescribed cut-point for loss of FEV_1 and the current prescribed degree of exposure; and small relative to other uncertainties and sources of measurement error and variation that are not considered within the Scheme, including innate variability in FEV_1 measurement.

43. The scientific evidence for prescription was based on studies of lung function in coal miners in whom the effects of such treatments would have been incorporated, although not separately identified. The average effect of such treatments in the sample, if any, would have formed part of the observed measurements.

44. As well as being arbitrary and insecure scientifically, the application of a treatment offset would potentially create inequalities for some claimants.

45. The original basis for prescription recognised the approximate nature of the evidence base, and that it would be impractical within the constraints of the Scheme to take account of such differences between individuals as work location, job title, actual exposures to coal dust, brief absences from work, and lifetime smoking habits. In the same way, the Council considers that it would be impractical to apply an offset to the one litre loss of FEV_1 threshold according to an individual claimant's medical treatment. To paraphrase its words from 1992 ('Chronic Bronchitis and Empysema', Cm. 2091), the [prescription] is designed to take account of all those variations and provide a simple, easily understood and applied criterion.

46. The Commissioner ruled that consideration should be given to the possible effects of medication when forming a view about the overall assessment, and that this was a medical matter requiring the advice of experts. Taking all the above factors into consideration, the Council recommends that the possible effects of treatment should be disregarded in the assessment of PD D12.

47. To clarify this position in law, and to give it appropriate legal underpinning, the Council proposes that the prescription of PD D12 be redefined, such that the required one litre loss of FEV_1 would apply **irrespective** of medical treatment.

Definition of PD D12

48. As noted above, the 1992 Command Paper was cast in terms of 'chronic bronchitis and emphysema', but with the intention of compensating chronic irreversible outflow obstruction (rather than chronic bronchitis in isolation). In modern parlance, some 22 years on, medical practitioners now use the umbrella term 'COPD' instead to refer to the disorder in question. Since a need exists to amend this prescription, it is proposed at the same time to modernise the definition of PD D12, to achieve a closer match with current medical practice. Thus, reference in the prescription to "bronchitis or emphysema or both" should be supplanted by "chronic obstructive pulmonary disease". This change will have no practical effect other than to bring an out-dated terminology up to date. The proposals for amendment of the prescription are set out in full overleaf.

Current prescription

Prescribed disease	Any occupation involving:
D12. Except in the circumstances specified in regulation 2 (d) a) chronic bronchitis; or b) emphysema; or c) both, where there is evidence of a forced expiratory volume in one second (measured from the position of maximum inspiration with the claimant making maximum effort) which is – (i) at least one litre below the appropriate mean value predicted, obtained from the following prediction formulae which give the mean values predicted in litres – For a man, where the measurement is made without back-extrapolation, (3.62 x Height in metres) – (0.031 x Age in years) – 1.41; or, where the measurement is made with back-extrapolation, (3.71 x Height in metres) – (0.032 x Age in years) – 1.44; For a woman, where the measurement is made without back-extrapolation, (3.29 x Height in metres) – (0.029 x Age in years) – 1.42; or, where the measurement is made with back-extrapolation, (3.37 x Height in metres) – (0.030 x Age in years) – 1.46; or (ii) less than one litre.	Exposure to coal dust (whether before or after 5th July 1948) by reason of working – (a) underground in a coal mine for a period or periods amounting in aggregate to at least 20 years; (b) on the surface of a coal mine as a screen worker for a period or periods amounting in aggregate to at least 40 years before 1st January 1983; or (c) both underground in a coal mine, and on the surface as a screen worker before 1st January 1983, where 2 years working as a surface screen worker is equivalent to 1 year working underground, amounting in aggregate to at least the equivalent of 20 years underground. Any such period or periods shall include a period or periods of incapacity while engaged in such an occupation.

Proposed amendment of the prescription

Prescribed disease	Any occupation involving:
D12. Except in the circumstances specified in regulation 2 (d), chronic obstructive pulmonary disease where there is evidence of a forced expiratory volume in one second (measured from the position of maximum inspiration with the claimant making maximum effort) which is – (i) at least one litre below the appropriate mean value predicted, obtained from the following prediction formulae which give the mean values predicted in litres – For a man, where the measurement is made without back-extrapolation, (3.62 x Height in metres) – (0.031 x Age in years) – 1.41; or, where the measurement is made with back-extrapolation, (3.71 x Height in metres) – (0.032 x Age in years) – 1.44; For a woman, where the measurement is made without back-extrapolation, (3.29 x Height in metres) – (0.029 x Age in years) – 1.42; or, where the measurement is made with back-extrapolation, (3.37 x Height in metres) – (0.030 x Age in years) – 1.46; or (ii) less than one litre. The value of one litre in (i) and (ii) above shall be construed as fixed, and shall not vary by virtue of any treatment or treatments taken for chronic obstructive pulmonary disease.	Exposure to coal dust (whether before or after 5th July 1948) by reason of working – (a) underground in a coal mine for a period or periods amounting in aggregate to at least 20 years; (b) on the surface of a coal mine as a screen worker for a period or periods amounting in aggregate to at least 40 years before 1st January 1983; or (c) both underground in a coal mine, and on the surface as a screen worker before 1st January 1983, where 2 years working as a surface screen worker is equivalent to 1 year working underground, amounting in aggregate to at least the equivalent of 20 years underground. Any such period or periods shall include a period or periods of incapacity while engaged in such an occupation.

Diversity and equality

49. IIAC seeks to promote equality and diversity as part of its values. The Council has resolved to seek to avoid unjustified discrimination on equality grounds, including age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender and sexual orientation. During the course of the review of the effects of treatment on COPD no matters related to diversity and equality were apparent.

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Glossary of terms used in this report

FEV_1 (forced expiratory volume in one second)	The volume of air a person can forcefully exhale in one second when making a maximal effort.
Bronchodilator	A drug, usually inhaled, which seeks to dilate the airways of the lungs.
Spirometry	A well-defined and routine procedure used to measure the function of the lungs.
Cumulative exposure	An index of exposure that takes into account both its intensity and its duration to produce a single measure of aggregated or accumulated exposure.
Standard deviation (SD)	A statistic used to measure the spread of data around an average (mean) value. Many biological measures, including height and FEV1, are 'normally distributed', i.e. their values vary across a continuum in populations, such that most observations cluster around the arithmetic mean, with smaller proportions at the upper and lower end of the measurement scale. This creates a classical bell-shaped appearance to the probability distribution of values. For normally distributed data, roughly two-thirds of observations will lie within a range of one SD below the mean to one SD above the mean, while 95 per cent of observations will lie between two SDs below to two SDs above the mean. Thus, 2.5 per cent at the lower end and 2.5 per cent at the upper end will be more extreme 'outliers' than this.

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