ORIGINAL ARTICLE

Dust related risks of clinically relevant lung functional deficits

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Aim: To quantify the risks of clinically important deficits of FEV1 in coal miners in relation to cumulative and average concentrations of respirable dust.
Methods: Data were studied from over 7000 men who had been surveyed in the late 1970s. Linear regression equations for the association between FEV1 and self-reported breathlessness on mild exertion were used to define clinically important levels of FEV1 deficit, and the probabilities that individuals with different dust exposures would experience these deficits were calculated.
Results: Levels of FEV1 were lower among breathless men than among others, with a large overlap of the distributions. The relations between standardised FEV1 and breathlessness were constant over all age and smoking groups. A decrease of 100 ml in FEV1 was associated with an increase of 1.12 in the odds of reporting breathlessness. FEV1 deficits of −0.367, −0.627, and −0.993 l (designated as ''small'', ''medium'', and ''large'' deficits) were, on average, associated with proportional increases of risks of breathlessness by factors of 1.5, 2.0, and 3.0 respectively. Cumulative respirable dust exposure ranged up to 726 gh/m^3, mean 136 gh/m^3 (British Medical Research Council measurement convention). An increase of 50 gh/m^3 was associated with an increase of about 2% in the proportion of men with small deficits in FEV1. For medium deficits the increases ranged from 1.5% to 2%, depending on age. A similar pattern was seen for large deficits, but with smaller increases.
Conclusions: In the unlikely event of continuous exposure at the proposed new maximum respirable dust limit for British mines of 3 mg/m^3 (ISO-CEN measurement convention) for a working lifetime, the risk of a medium deficit of FEV1 for a non-smoker at age 60 would be estimated to be 34%, compared with 25% for zero dust exposure; for smokers, about 54% compared with 44%.

Control limits for respirable dust in coalmines are based on well defined exposure response relations for risks of pneumoconiosis. However, it is now accepted[1 2] that occupational respiratory disability in coalminers can result not only from pneumoconiosis but also from functional lung damage[3–7] and emphysema[8 9] independently of pneumoconiosis. The present paper quantifies the risks of defined deficits in lung function in British miners irrespective of the underlying pathology.

Definition of what constitutes a clinically important degree of functional impairment is important for the expression of risk for regulatory purposes. Some studies have attempted such definitions; one expressed as arbitrarily defined percentages of predicted values of forced expiratory volume in one second (FEV1)[10] and another based on specified FEV1 deficits derived by comparison with symptoms of disability.[11] Both provide useful information on risks; however neither of the studies is complete—one being based on a population of miners studied in the 1960s, a large proportion of whose dust exposure was estimated rather than measured; the other on a more recent population with a greater proportion of measured exposures, but at only three collieries.

The current study is based on a large British population of underground coalminers with reliable exposure estimates, and initially examines the relation between level of lung function and self-reporting of respiratory symptoms. Using results from that analysis, several possible levels of ''clinically important'' functional impairment are proposed. The associations between the risks of such impairments and cumulative exposure to respirable coalmine dust are then examined.

AIMS

The aim of the study was to provide information to inform the setting of dust standards to prevent occupational respiratory disability in miners. Specifically, the research questions were:

1. What deficits of FEV1 influence detectably the level of exertional breathlessness in miners?
2. What definitions of clinically relevant deficits of FEV1 does this suggest?
3. What are the quantitative relations between cumulative exposure to respirable coalmine dust, and risks of these clinically relevant deficits, overall, and specifically over the range of low exposures likely to be encountered in modern British mines?

METHODS

Study population

The respiratory data come from the fifth round of medical surveys in the late 1970s (PFR 5) as part of the Pneumoconiosis Field Research (PFR) conducted on behalf of the then National Coal Board. The study population was 7188 British coalminers from nine collieries. The study population was known to have a 31% prevalence of symptoms of chronic mucus hypersecretion (chronic bronchitis), and a 7% prevalence of radiographic small round opacities category 1/1 or greater. Seventy nine men had large opacities (progressive massive fibrosis).

The research, originally conducted at a time when present consent procedures were not customary, was approved by coal industry management and unions at national and local level, and senior personnel visited each colliery before each survey to explain the studies to management and unions. Participation was voluntary, and was considered to represent informed consent.

Abbreviations: ECSE, European Coal and Steel Community; FEV1, forced expiratory volume in one second; FVC, forced vital capacity; PFR, Pneumoconiosis Field Research

Personal and medical data

Data available for each individual miner included a unique identification number, which included a code for the colliery at which they worked at the time of the PFR5 survey, age at survey, and height. Smoking habit at PFR5 for each individual was determined from questions included in the respiratory symptoms questionnaire[12] and was classified as lifelong non-smoker, current cigarette smoker, current ''other'' smoker (that is, current smoker of cigars and/or pipe but not cigarettes), and ex-smoker.

Lung function data (measured at the same surveys) comprised almost always three technically satisfactory measurements of FEV1 and forced vital capacity (FVC) from Gaensler spirometers.[3] These bell spirometers with timing mechanisms were used throughout the research, for the sake of standardisation, with regular calibration and servicing, and technician comparisons. The maxima of each of these measurements were used in the analysis.

Individuals who answered positively to ''Do you have to walk slower than other people on level ground because of your chest?'' were classified as having self-reported breathlessness.

Exposure data

Cumulative exposure to respirable coalmine dust up to PFR5 was calculated for each individual based on the intensive dust sampling conducted from the early 1950s through and past the survey dates. The methods used in the PFR have been widely documented elsewhere.[13] Briefly, times spent in a wide variety of occupations were extracted from weekly payroll records. Mean respirable dust concentration measurements, summarised by quarter, were derived from regular air sampling for each of these occupational groups. Instrument carriers kept the dust samplers close by throughout the sampled shift (portal to portal), so the measured concentrations represent ''personal'' samples, though not as intimately personal as lapel mounted samplers. Cumulative exposure in each occupational group was calculated as the product of mean respirable dust concentration in the group and the total time spent by the individual in that group. Exposures were summed over all occupational groups in which an individual worked and over time, to give a cumulative lifetime dust exposure. Dust concentrations before the research began in the early 1950s were assumed to be the same as in the first 10 years of the research.

Statistical methods

Observed levels of FEV1 were compared to those predicted using the European Coal and Steel Community (ECSC) prediction equations.[14] Comparisons internal to the study group were also performed using multiple linear regression of the study data to predict FEV1 levels among asymptomatic non-smokers adjusting for age and physique.[15] These predictions were very similar to those from the ECSC equations. Standardised FEV1 was calculated for each man as observed minus predicted FEV1.

The association between self-reported symptoms of breathlessness and FEV1 was quantified using logistic regression methods,[16] with a binary response representing the presence or absence of breathlessness. Explanatory variables included age, smoking habit, FEV1, and relevant interactions. Results from the logistic regression analyses were expressed as odds ratios and their associated 95% confidence intervals. Possible non-linearity in the association of breathlessness and the continuous explanatory variables was examined using generalised additive models.[17] By using smoothing splines (a form of moving average) these methods allow the data to dictate and display the shape of the smooth curve that fits best. The association between breathlessness and FEV1 was used to select levels of FEV1 that might represent clinically relevant deficits, based on the odds of reporting breathlessness at various levels of FEV1.

The association between FEV1 and exposure to respirable coalmine dust, adjusted for age, physique, and smoking habit, was examined using multiple linear regression and included the investigation of both linear and non-linear relations with age and dust exposure.

The proportions of the study population experiencing the above deficits were then estimated for various levels of cumulative dust exposure. From the best fit regression model, estimated values of FEV1 were calculated for various values of cumulative dust exposure for different age and smoking groups. Under the assumption that the distribution of levels around this estimated value followed a normal distribution, with mean equal to the fitted value and standard deviation calculated from the residual mean square of the regression model, it was then possible to estimate the probability that any individual would have an FEV1 below any specified value.

The statistical analyses were carried out using the Minitab[18] and Genstat[19] statistical software packages. Graphics were produced using Sigmaplot graphical software.[20]

RESULTS

Study group and exposures

The average age of the 7188 men forming the overall study group was 43.8 years (range 16.1 to 71.7). More than 60% of the study group smoked at the time of survey. Figure 1 shows the distribution of cumulative dust exposures.

Lung function

Of the 7188 men, 7115 (98%) completed three technically satisfactory lung function tests. Individuals who did not complete three tests had levels of FEV1 that were on average lower than those completing the test satisfactorily (mean 2.79 l compared with 3.31 l), consistent with poor respiratory health causing difficulties for the breathing tests. Exclusion of these men would have entailed the loss of a group who potentially were of major interest, and they were therefore included in the analysis. Other work in progress shows that estimates of the effects of age, height, smoking habit, and cumulative dust exposure on FEV1 are relatively unaffected by exclusion of men with fewer than three valid tests. The mean levels of maximum FEV1 were lower among current and ex-smokers than among non-smokers, particularly among those aged between 35 and 64.

Respiratory symptoms

A total of 1267 (18%) men reported symptoms of breathlessness. Prevalence of breathlessness increased with age overall, and within each smoking group, and prevalences among current cigarette smokers and ex-smokers were higher than among non-smokers. Higher prevalence in current pipe or cigar (''other'') smokers was due primarily to their older age distribution.

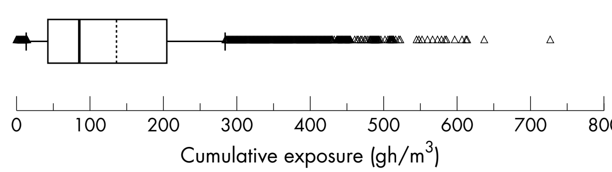

Figure 1 Boxplot summarising distribution of cumulative exposures. (Box from 25th to 75th percentile, whiskers to 10th and 90th. Median is solid line, mean dotted.)

Table 1 Logistic regression model of risk of symptoms of breathlessness

	OR	95% CI
Baseline odds*	0.022	
Age (per 10 years)	2.92	2.07–4.12
Age^2 (per 10^2 years)	0.89	0.83–0.96
Height (per 5 cm)	1.07	1.01–1.13
Smoking (*v* non-smoker):		
Current cigarette smoker	1.61	1.29–2.01
Current other smoker	1.61	1.15–2.25
Ex-smoker	1.57	1.22–2.02
Observed FEV1 (per 100 ml decrease)	1.12	1.10–1.13

*Baseline refers to a 25 year old non-smoker, 1.7 m tall, with an FEV1 of 3 l.

Association between FEV1 and symptoms of breathlessness

The association between symptoms of breathlessness and FEV1 was examined using logistic regression analysis. The best fitting model is shown in table 1.

There was evidence of a non-linear association between age and risk of reporting breathlessness, with significant linear and quadratic terms in age. The odds ratio for the quadratic term was less than 1, reflecting that the increase in the probability of breathlessness with age was less steep among older men (particularly those aged 60 or over, where there were relatively few study members). Higher risks of breathlessness in current and ex-smokers compared to non-smokers were confirmed, with odds ratios of around 1.6. Risk of reporting breathlessness was significantly associated with observed FEV1. Additional models with FEV1 %predicted gave similar results but fitted slightly less well. Finally, there was evidence that risks of breathlessness were slightly higher among taller men, after adjustment for smoking, age, and FEV1.

Conveniently it was found (analyses not shown) that the influence of FEV1 on probability of breathlessness was effectively constant across all ages, smoking groups, and levels of FEV1. The model provided a reasonable fit to the observed data (see Cowie *et al*, 1999[21] for detail).

Clinically relevant deficits of FEV1

The results from the logistic regression analysis can be used to select levels of FEV1 that might represent clinically relevant deficits. We have chosen here to consider three levels of clinically relevant deficits, of increasing severity. These are 0.367 l (associated with an odds ratio for breathlessness of 1.5), 0.627 l (associated with a ratio of 2), and 0.993 l (associated with a ratio of 3).

Clinically relevant deficits of FEV1 were represented in terms of absolute level to allow the subsequent calculation of the probability of such a level of FEV1 occurring in relation to dust exposure levels. This was done by subtracting the deficits from the predicted values of FEV1 for men of specific ages and average height, calculated using the ECSC standard prediction equations.[22] Table 2 shows the resulting absolute FEV1 values for ranges of ages and deficits.

Table 2 Absolute values of FEV1 in litres calculated as predicted FEV1 (at average height) minus specified deficit

Age (years)	Predicted FEV1	Deficit (litres) (increase in odds for risk of breathlessness) 0.367 (1.5)	0.627 (2.0)	0.993 (3.0)
30	4.122	3.755	3.495	3.129
45	3.644	3.277	3.017	2.651
60	3.080	2.713	2.453	2.087

Table 3 Results from regression model of maximum FEV1 in relation to age, height, smoking, colliery, and dust exposure

	Coefficient	*t*
Constant	4.00	137.8
Age (linear term, years)	−0.035	−28.4
Height (cm)	0.042	38.5
Smoking (*v* non-smoker)		
Current cigarette smoker	−0.023	−0.8
Current other smoker	0.109	1.1
Ex-smoker	0.126	3.1
Additional age effect for:		
Current cigarette smoker	−0.0078	−5.9
Current other smoker	−0.0073	−2.0
Ex-smoker	−0.0085	−4.8
Cum exposure (gh/m^3)	−0.00063	−7.4

Differences in FEV1 between collieries were allowed for but are not shown. The association between dust exposure and level of FEV1 was statistically significant whether or not the terms for colliery differences were included.
The table shows coefficient and the ratio of the coefficient to its standard error (*t*). Ratio values of 2 or more indicate statistical significance at the 5% level.

Lung function in relation to dust

The best fitting linear regression model for the association between lung function and dust exposure is shown in table 3.

As expected, FEV1 decreased with age and increased with height, with a curved relation for age (not shown) reflecting a slower loss of FEV1 for the under 35s and a steeper loss for those aged 35 and over. The decrease in FEV1 with age was also less steep for lifelong non-smokers than in the smoking groups. Other models indicated significant differences between the levels at different collieries, but the reasons for these differences are not clear, in this and in previous work,[4] and we have here presented results averaged over the collieries, to represent coal mining generally.

There was a statistically significant association between cumulative dust exposure and FEV1, with an average deficit of 0.63 ml per gh/m^3 exposure (0.51 ml per gh/m^3 if colliery differences were not included in the model.

For each specified age, smoking group, and colliery the estimated value of FEV1 was calculated from the regression model in table 3, and the probabilities of clinically low levels of FEV1 were calculated. Figure 2 shows the estimated proportions of the study group with FEV1 below the specified levels for a range of cumulative exposures. Results are presented for a colliery with average levels of FEV1, separately for non-smokers and current cigarette smokers and for those aged 30, 45, and 60 years.

The predicted percentage of men with low FEV1 increased with age. The difference between non-smokers and current smokers in the predicted proportion of men with low levels also increased among older men, due to the steeper decrease in FEV1 with age among smokers. There was generally good agreement between predicted and observed prevalences.

The predicted increase in the percentage of men with clinically relevant deficits of FEV1 associated with a specific increase in cumulative dust exposure varied according to the average level of FEV1 estimated from the linear regression model (and thus with age, height, smoking habit, and dust exposure), although the differences are small (ranging from about 0.5% to 2.2% per 50 gh/m^3).

Table 4 shows the estimated proportions of 60 year old men with small, medium, and large deficits, associated with a 35 year working lifetime exposure to specified average concentrations of respirable dust.

The table shows that, for a non-smoker, a lifetime exposure to an average concentration of 2 mg/m^3 is associated with a

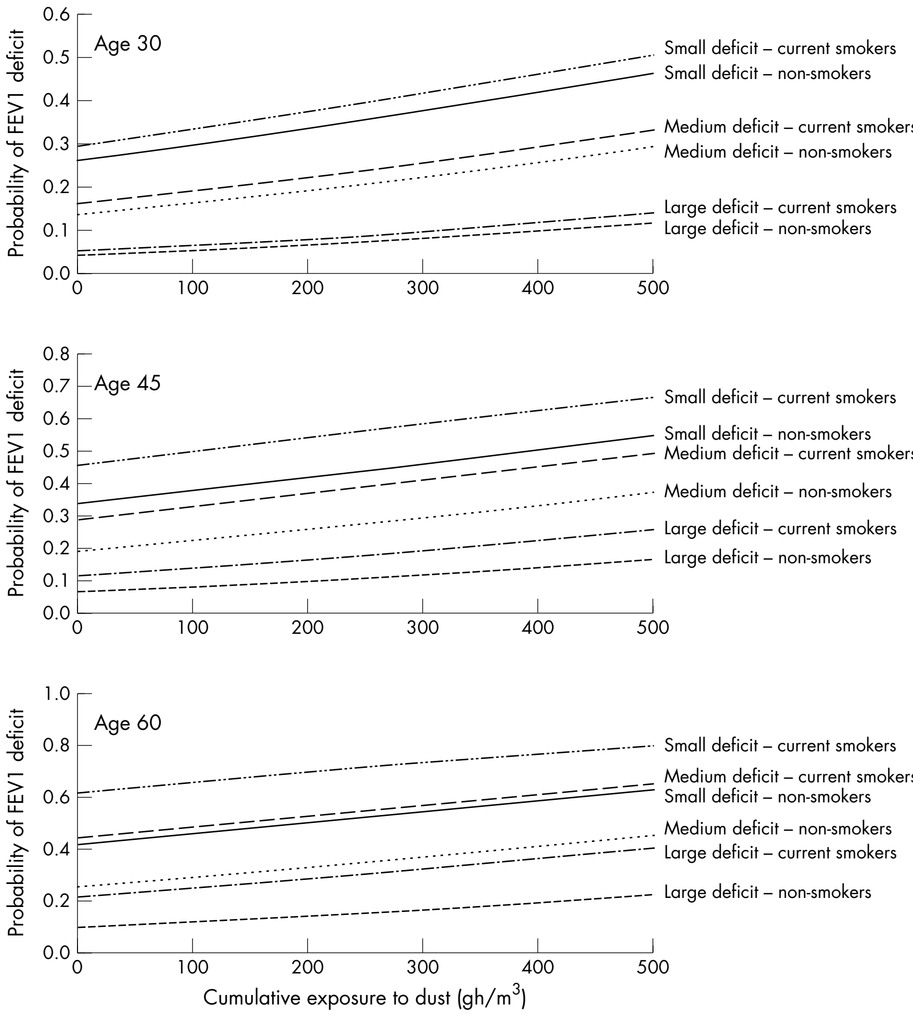

Figure 2 Estimated probability of clinically relevant deficits of FEV1 by cumulative exposure to respirable dust.

prevalence of small deficits of around 47%, compared to 41% among unexposed men of the same age, rising to a prevalence of almost 55% after a lifetime exposure to an average concentration of 5 mg/m^3. For current smokers the predicted prevalences are 61% for unexposed men rising to 67% at 2 mg/m^3, and almost 74% at 5 mg/m^3.

Differences of 1 mg/m^3 in average concentration over a working lifetime are associated with increases in prevalence of small and medium deficits of FEV1 of around 2.5% (ranging from 2.2% to 2.8%). For large deficits the increase in prevalence associated with a 1 mg/m^3 increase in average concentration is around 1.5% in non-smokers (range 1.1% to 1.6%) and higher at around 2% (range 1.8% to 2.4%) in current smokers.

DISCUSSION

Definition of what constitutes a clinically important degree of functional impairment is important for the expression of risk for regulatory purposes. In the current study we have examined the association between functional impairment and the probability of reporting breathlessness. The level of FEV1 is known to be related to exercise performance,[23] respiratory symptoms,[24] risks of heart attack,[25] and stroke,[26] and to mortality from chronic obstructive pulmonary

Table 4 Estimated percentage of study group with FEV1 less than 2.71, 2.45, or 2.09 l by estimated dust concentration for a 35 year working lifetime for non-smokers and current smokers of age 60 and of average height (1.70 m)

			Concentration (mg/m^3)					
Deficit	**FEV1**	**Smoking**	**0**	**1**	**2**	**3**	**4**	**5**
Small	2.71	Non	41.3	44.1	46.7	49.4	52.0	54.6
		Current	61.5	64.2	66.6	69.0	71.2	73.5
Medium	2.45	Non	25.1	27.5	29.7	32.0	34.4	36.9
		Current	43.7	46.5	49.2	51.8	54.4	57.0
Large	2.09	Non	9.8	10.9	12.2	13.5	15.0	16.6
		Current	21.7	23.5	25.6	27.8	30.0	32.4

Small, medium, and large refer to deficits associated with increased risks of breathlessness of 1.5, 2.0, and 3.0 respectively.

disease.[27] We recognise that the background frequency of breathlessness in our study population is likely to have been influenced not only by lung function but also by heart disease, physical fitness, and mental attitude. In this context, use of a differently worded questionnaire might have identified a different prevalence of breathlessness. Traditionally, arbitrary values such as 80% of predicted value are used to identify subjects with unusually low FEV1. This is based on the population variation in FEV1, but is not closely associated with disability, and arbitrarily assumes that symptoms are related to the proportional rather than absolute loss of function for all ages and smoking groups. In the event we found that the relation between symptoms and absolute deficits of FEV1 was constant across all ages and smoking groups, confirming our approach of defining relevant absolute deficits of FEV1 by comparison with symptoms, and then describing the association between exposure to coalmine dust and the probability of having FEV1 at or below these levels.

Reliability of the data

The analyses were based on data collected using well defined and validated standardised protocols and methods, from over 7000 men who were working in collieries representative of the English and Welsh coal industry in the late 1970s. Exposure characterisation was based on highly detailed records of work and of environmental conditions in occupations in those collieries.

Identification of breathlessness by questionnaire is subjective, though these reported symptoms have been observed in many studies to increase in prevalence with age, and among smokers, providing evidence of the validity of the classification. Evidence of a small increase in reporting of breathlessness among taller men was unexpected. Reasons within the current study population might include differences in seam height, mechanical breathing efficiencies or the workload associated with limb size or body mass.

Relations between FEV1 and age, physique, and smoking habit were as expected, and predicted values among asymptomatic non-smokers, based on the study data, were similar to those calculated using the ECSC standard prediction equations. Extensive validation of the data previously and during the current study, together with the strong plausibility of the associations with age, physique, and smoking, suggests that the data used in the current analyses are reliable.

The main potential limitations of these cross sectional studies of working coal miners are the omission of leavers, and possible cohort (generational) effects. We do not know the extent to which the omission of ex-miners in this study has affected the results. Relations between dust exposure and pneumoconiosis are similar in miners and ex-miners,[28] and for the most part this applies also to the relation with lung function.[4] This suggests that the restriction to current miners is unlikely to have influenced substantially the conclusions from this study. However there is some evidence that a small group of ex-miners may show an atypically severe response to dust.[29] Additionally non-response at a survey is associated with lower lung function at earlier surveys,[30] so it is possible that the present study has slightly underestimated the risks. Any cohort effects are likely to have been absorbed partly into the estimates of the effect of age.

Association between FEV1 and symptoms of breathlessness

On average, levels of FEV1 were lower among men who reported symptoms of breathlessness than among those who did not, for both observed level of FEV1 and FEV1 standardised for age and height. However, there was a large overlap between the distributions of FEV1 for those with and without symptoms of breathlessness and, as expected, it was not possible to identify a single level of FEV1 that separated the two groups.

For individuals whose FEV1 levels were already reduced (whether due to ageing, smoking habits, or other causes) a difference in FEV1 level had the same relative effect on the odds of reporting breathlessness as the same difference among healthy individuals whose FEV1 levels were higher.

Association between FEV1 and cumulative exposure to dust

The expected decrease in FEV1 with age was apparent, with a slightly curved association between the two variables. The fitted curve showed a slow loss of FEV1 with age among younger men, which then became steeper among those aged 35 or over. There was no evidence of a steeper loss of FEV1 with age among older men (aged 55 or more) compared to those aged between 35 and 54. However, in this study, all men were currently working in the coal industry at the time of survey, and older men with greater losses of FEV1 may preferentially have left the industry.

On average, an exposure to 100 gh/m^3 dust was associated with a reduction in FEV1 of 0.063 l. This is of similar magnitude to that found in analyses of earlier PFR data from 20 collieries where 100 gh/m^3 of exposure was associated with a reduction in FEV1 of 0.06 l.[3] Soutar and Hurley[4] in a cross sectional study that included both current and ex-miners estimated a broadly similar reduction in FEV1 of 0.076 l per 100 gh/m^3.

Comparisons of these risk estimates for clinically important functional deficits with those derived by earlier studies[10 11] are difficult because the results are expressed in forms that are not directly comparable. They do, however, appear to be of similar orders of magnitude.

Implications for standard setting

Table 4 shows the estimated risks of lung function deficits over a working lifetime at a range of concentrations, based on individual cumulative exposures to dust. The cumulative exposure has been divided by the time spent in the industry to calculate an average dust concentration over a working lifetime. Clearly, for at least some individuals their exposures will not have been experienced at an even level across their working lives and further investigation of the FEV1 deficits in relation to measured exposures in shorter (for example, three months) time periods may provide more information on the effects of different concentrations on the probability of FEV1 deficits, and on possible thresholds of concentration.

Comparisons with the effects of smoking can be derived from table 4. For example for a current smoker aged 60 years who experienced an average working lifetime concentration of 4 mg/m^3, a 54% risk of a medium deficit of FEV1 is predicted. This is made up of a 9.3% chance related to this dust exposure, 20% related to smoking, and 21% background.

The dust concentrations described so far in this paper refer to the old British Medical Research Council convention and related instruments for measuring respirable dust.[31] Many new regulations and standards refer to the more recent ISO-CEN convention.[32] Translation from BMRC to ISO requires division by about 1.4 (de Klerk *et al*,[33] discussing reports by Groves *et al*[34] and Liden and Kenny[35]). Thus the proposed new 3 mg/m^3 standard for British mines is equivalent to about 4.2 mg/m^3 (say 4 mg/m^3) in the old units. In view of the day-to-day variation in dust concentrations, meticulous observance of a maximum limit would result in average concentrations well below the limit. In practice, uncertainties related to unmonitored days and the actions taken when higher concentrations occur make predictions of risk under

Main message

- Even at low concentrations of respirable dust experienced over a working lifetime, small but significant increased risks of clinically important lung function deficits are predicted.

Policy implications

- Exposure over a working lifetime to 2 mg/m^3 (the current surface coal dust limit) is associated with a 7% increased risk of a medium sized deficit of FEV1.

these circumstances difficult. In the unlikely event of exposure to this limit continuously for a working lifetime, reading across approximately in table 4, the risk of a medium deficit of FEV1 for a non-smoker at age 60 is about 34%. For continuous exposure to 2 mg/m^3 (ISO units), the equivalent risk would be about 30%. For zero dust exposure, the risk is about 25%. For smokers the risks related to continuous exposures at 3, 2, and 0 mg/m^3 are about 54%, 50%, and 44% respectively.

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