

**Assessment of the commissioned IOM Position Paper on
Coalmine dust as a benchmark for standards for other poorly soluble
dusts**

This position paper was commissioned by HSE at the end of 2004. The aims were: -

- (i) To use the coalmine dust data from Pneumoconiosis Field Research (PFR) programme to characterise the exposure-response relationship for the risk of dust-induced COPD.
- (ii) To see if the data on coalmine dust could be used as a benchmark for setting standards for other poorly soluble dusts;
- (iii) To use the data to judge the adequacy of the current generic COSHH position on respirable dust.

Background

1. It has been identified that about 15% of the societal burden of COPD is attributable to occupational exposure to dusts and irritants. Given the large societal burden of COPD, and the diverse pattern of occupational dust exposure across many different industry sectors, it seems important to understand, at a quantitative level, the exposure-response relationship for the risk of developing dust-induced COPD, and in this regard, to also determine the adequacy of the current UK regulatory position on dusts.

2. The particle size of inhaled dust is important when considering the issue of occupational COPD. It is uncertain whether or not it is the thoracic or the respirable fraction that is the more toxicologically relevant to COPD development, but as all the available epidemiological evidence pertains to respirable dust, and as workplace air sampling for thoracic dust is not normally carried out, this paper will focus only on respirable dust.

3. *Coalmine dust.* The Institute of Occupational Medicine (IOM) has collated a very large dataset covering over 7000 coalminers. The data were collected over 38 years as part of the National Coal Board's Pneumoconiosis Field Research (PFR) programme. The PFR programme initially covered 25 collieries, then 24, then after the first 10 years, 10 collieries continued in the study until 1977. For each miner there is a detailed history of respirable dust exposure, such that this possibly comprises the largest and most detailed single study on any dust¹.

¹ It should be noted that the dust measurements in the PFR programme were taken using the MRC respirable dust sampler, which in recent years has been superseded in the UK by the ISO/CEN respirable dust sampling convention. This means that all the dust measurements in the IOM dataset need to be reduced by 20% to reflect current measurement methods.

4. Coalmine dust is a mixture of various minerals, including coal dust and dust from the surrounding geological strata such as clays. Unless the coalmine dust contains a significant proportion of quartz, and this is rarely the case in British coalmines, then it can be regarded as being of low intrinsic toxicity, and hence could be regarded as a suitable benchmark for other poorly soluble dusts of low toxicity.

IOM Analysis of lung function data from PFR Programme

5. The IOM paper presents a brief re-analysis of the PFR coalmine data, showing the annual decline in FEV₁ in relation to coalmine dust exposure (the aim was to allow the data to be more directly comparable with that from other studies). It also presents a brief summary of data from workers exposed to other dusts, talc, heavy clay, PVC, opencast miners, and wool textile dust. The lung function data were not analysed in such a way as to clearly indicate exposure-response relationships for COPD, although earlier analyses by the IOM (Cowie et al 1999, Soutar et al 2004) allow some conclusions to be drawn in this regard.

6. In this IOM re-analysis, multiple linear regression models adjusted for height, age and smoking revealed an average annual decline in FEV₁ of 0.89 ml per mg.m⁻³.year of cumulative exposure to respirable coalmine dust.

7. This would equate to an average loss of FEV₁, over and above the normal age-related loss, of 178 ml after a 40 year working lifetime with average exposure to 4 mg.m⁻³ (after adjusting the dust concentrations for the change to the ISO/CEN convention for measuring respirable dust). Given that the normal age-related loss in FEV₁ is 25-30 ml per year (up to 1200 ml loss over 40 years) it may be considered that an additional loss of 178 ml would be of no clinical significance or health concern for most individuals.

8. However, it needs to be borne in mind that the loss of 178 ml in FEV₁ is the average estimated loss at 4 mg.m⁻³, and that there will be a distribution around this value, with some individuals exposed to 4 mg.m⁻³ being more severely affected.

9. The re-analysis by the IOM does not clearly inform on this distribution. However the earlier analyses by the IOM of this same dataset on >7000 underground coalminers reveal the distribution more clearly as shown in the table below.

10. The selected deficits in FEV₁ shown in the table were based on analyses of the relationship between symptoms data and lung function among the study population. A loss of 367 ml in FEV₁ was associated with a 1.5-fold increased risk of reporting breathlessness. As can be seen from the table below, the risk of this deficit is 55% in non-smokers exposed to 4 mg.m⁻³ compared to 41% in non-dust exposed controls (excess risk of 14% at 4 mg.m⁻³).

| Estimated percentages of study group with selected FEV ₁ deficits by estimated dust concentration for a 35-year working lifetime for non-smokers and current smokers of age 60 and average height (1.7m). (adapted from Table 3.18 in Cowie et al 1999) | | | |
|--|---------|----------------------|------------------------------------|
| FEV ₁ deficit (ml) | Smoking | Non-dust exposed (%) | 4 mg.m ⁻³ (ISO/CEN) (%) |
| -367 | Non | 41 | 55 |
| | Current | 62 | 74 |
| -627 | Non | 25 | 37 |
| | Current | 44 | 57 |
| -993 | Non | 10 | 17 |
| | Current | 22 | 32 |

11. A deficit of 627 ml was found to be associated with a 2-fold increase in the reporting of breathlessness. The risk this deficit was 37% in non-smokers exposed to 4 mg.m⁻³, compared to 25% in non-dust exposed controls (excess risk of 12%).

12. A deficit of 993 ml was associated with a 3-fold increased risk of reporting “*walking slower than other people on the same level because of my chest*”, with a risk of this deficit of 17% in non-smoking coalminers exposed to 4 mg.m⁻³ over a working lifetime, compared to a risk of 10% in non-dust exposed controls (excess risk 7%).

13. The non-dust exposed control group for this study population comprised surface workers at coalmines in the PFR programme, and it may not be appropriate to describe such workers as “non-dust exposed”. Surface workers are likely to have had regular dust exposure, albeit to lower levels than the underground miners, and the use of these workers as a non-dust exposed control group may have caused an underestimate of the true effect of dust exposure. A literature search and a written report produced by Richard Lomax in ICU, showed that the background rate of COPD in non-smoking non-occupationally dust exposed males aged 60 was about 6-8%, depending on the geographical location of the study population. Hence, the “control” value in the IOM paper is somewhat higher than may have been expected, but not excessively so. It should be noted that the definition of “COPD” in the HSE literature review broadly conformed to GOLD (Global Initiative for Chronic Obstructive Lung Disease) criteria (FEV₁/FVC < 70%, FEV₁ ≥ 80% predicted) and hence may not be as severe as the 627ml and 993ml losses observed in the coalmine cohort.

14. In conclusion, taking the results of the re-analysis by the IOM (2005) together with earlier analyses by the IOM, it can be concluded that exposure to coalmine dust at an average level of 4 mg.m⁻³ over a working lifetime, would be expected to cause a long-term deficit in FEV₁ of about 178 ml on

average. A loss of this magnitude would be of minimal health significance in most individuals. However, a moderate percentage (at least 12%) of workers exposed to 4 mg.m^{-3} would be expected to suffer more marked losses in FEV_1 of at least 627 ml after a working lifetime, and a minimum of 7% workers would be expected to suffer a loss of 993 ml (7% is taken as a minimum estimate given that the control group was likely to have had significant dust exposure such that the use of surface workers as a non-dust exposed control group would have led to an underestimate of the effect of coalmine dust).

Use of coalmine dust data as a benchmark for setting standards for other poorly soluble dusts.

15. The IOM report compares lung function and respiratory symptoms data for the underground coalminers with data on talc, PVC dust, heavy clay, wool dust, and opencast miners. It concludes that there is a broad consistency between the results, and that the data on coalmine dust could be used as a benchmark for setting standards for other poorly soluble dusts. However, as HSE chemicals policy has shifted away from standard-setting this aspect will not be discussed further.

Adequacy of the current generic COSHH position on respirable dusts.

16. *Current UK Regulatory Position:* Only a small fraction of workplace dusts have specific occupational exposure limits under COSHH, and of these, the underpinning epidemiological evidence-base is very limited. Under the COSHH Regulations, respirable dust of any kind can become a substance hazardous to health when present at concentrations in air equal to or greater than 4 mg.m^{-3} (8-hour TWA). There is no documented scientific basis for this value and (up until now) no understanding of what it represents in terms of health protection.

17. COSHH Essentials categorises dusts that are not classified for health effects in hazard band A, which has a target exposure range of $1\text{-}10 \text{ mg.m}^{-3}$. This target exposure range lacks a toxicological basis and furthermore it refers to inhalable dust; there is no specific COSHH Essentials position on respirable dust. The COSHH Essentials control advice for dusts in hazard band A may be perfectly adequate; it is just lacking in any toxicological justification.

18. Using the data from the PFR programme as a surrogate for poorly soluble dusts in general, it can be concluded that exposure to 4 mg.m^{-3} of respirable dust over a working lifetime would cause a loss in FEV_1 of 178 ml loss in the majority of individuals. This is a relatively small loss compared to the effect of ageing. However, a moderate proportion (~12%) of workers would develop larger losses in FEV_1 as a result of the dust exposure, losses of a magnitude that raise concern for respiratory health.

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References

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Soutar C et al (2004) Dust concentrations and respiratory risks in coalminers; key risk estimates from the British Pneumoconiosis Field Research. *Occup Env Med*; **61**; 477-481