

## **THE PREVALENCE OF COAL WORKERS' PNEUMOCONIOSIS IN A NEW COAL FIELD IN LUBLIN/POLAND**

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### **ABSTRACT**

In cooperation between Lublin/Poland and Bochum/FRG, 1130 coal miners were examined by X-rays and a complete lung function investigation including challenge test. The prevalences of X-ray changes and of lung function disturbances are in the same order in both centres. Smoking habits of miners have a clear influence on lung function. X-ray changes show in Lublin, too, a linear relationship between ILO-classification and exposure time.

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## AN ANALYSIS OF THE EFFECTS OF SMOKING AND OCCUPATIONAL EXPOSURE ON SPIROMETRY AND ARTERIAL BLOOD GASES IN BITUMINOUS COAL MINERS IN SOUTHERN WEST VIRGINIA

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### INTRODUCTION

In evaluating the presence of pulmonary disability in coal miners, the Federal Black Lung Program utilizes primarily spirometry and arterial blood gas analysis for objective assessment of the degree of pulmonary insufficiency in a given individual. Emphasis is placed upon the measurement of the forced expiratory volume in one second (FEV<sub>1</sub>) to assess the degree of bronchial obstruction and the arterial oxygen tension at rest and during exercise to assess the efficiency of alveolar gas exchange. Presently utilized disability standards for the FEV<sub>1</sub> and the arterial oxygen tension in the Federal Black Lung Program were established and promulgated in 1980.<sup>1</sup>

The effects of the inhalation of coal mine dust on lung function, particularly the oxygenating function, have been controversial. In fact, the need for arterial blood gas measurements in determining the presence of pulmonary disability in the coal mining population has been questioned in a recent study.<sup>2</sup> Because our experience with the results of pulmonary function tests and arterial blood gas studies performed both at rest and during exercise indicated the importance of arterial blood gas measurements in the disability evaluation of coal miners, a formal analysis of data we had collected over the past few years was undertaken. The results of that analysis constitute the basis of this report.

### METHODS

Both spirometry and arterial blood gas studies were obtained on a cohort of 2725 active miners or ex-miners who were evaluated for disability. With few exceptions the men studied were or had been actively employed as miners in the bituminous coal mines in southern West Virginia. Data collected on each applicant included age, height, weight, smoking history and the number of years employed in mining. For the purpose of this analysis, only the years spent in underground mining were utilized. A minimum of three forced vital capacity tracings were obtained on each subject utilizing a Stead-Wells spirometer. The FEV<sub>1</sub> measurements were obtained from the forced vital capacity tracings. At least two of the FEV<sub>1</sub> values had to agree within 5% for the study to be acceptable. The largest FEV<sub>1</sub> was reported. For the arterial blood gas study an arterial catheter was inserted

usually in the radial artery, occasionally in the brachial artery. Following insertion of the arterial line the subject was permitted to rest in the sitting position for 15 to 20 minutes before a sample of arterial blood was drawn and analyzed immediately for oxygen tension, carbon dioxide tension and pH. Each subject was then exercised on a treadmill for a period of 6 minutes to ensure the achievement of a steady state. The intensity of exercise was increased in incremental steps until the subject was either too fatigued to continue or an oxygen consumption of about 25cc/Kg/minute was achieved which is the oxygen consumption observed in men undergoing moderately heavy manual labor. Subjects were provided rest periods of approximately 30 minutes between incremental increases in exercise. Expired gas was collected to permit the calculation of oxygen consumption and arterial blood samples were obtained during the sixth minute of exercise and analyzed immediately. In the earliest studies the arterial blood samples were analyzed in one blood gas analyzer. In subsequent studies which represented the majority, each arterial sample was analyzed simultaneously in either two or three different blood gas analyzers. All of the blood gas analyzers were calibrated immediately before and after each sample was analyzed. Agreement within 3 mm Hg was required for arterial oxygen tension values and within 2 mm Hg for arterial carbon dioxide tension values for the measurements to be acceptable. The average values for the blood gas tensions so measured was reported. The disability standard for the FEV<sub>1</sub> was 60% of the age, sex and height corrected predicted normal value. For the arterial oxygen tension the disability standard was 60 mm Hg at normal carbon dioxide tension or the oxygen tension adjusted for decreasing carbon dioxide tension.

### RESULTS

Table I indicates that 732 or about 27% of the cohort of 2725 met the presently utilized disability standards of the Federal Black Lung Program. Slightly less than 5% were disabled by the FEV<sub>1</sub> standard alone while almost 18% were disabled by the arterial blood gas standard. Mean age, mean number of pack years of cigarette smoking and mean number of years of underground mining were similar in the four groups analyzed.

All of the subjects disabled by arterial blood gas criteria alone had FEV<sub>1</sub> values above 60% of the predicted normal. Considering any FEV<sub>1</sub> value equal to or above 80% of predicted normal to be in the normal range, values in the 60–79% range then indicate mild bronchial obstruction. Table II indicates that two-thirds of those disabled by the arterial blood gas standard alone had FEV<sub>1</sub> values within the normal range, indicating the absence of physiologically significant bronchial obstruction.

Table III indicates that about 14% of the subjects who had never smoked met disability standards. The majority of those who met disability standards were disabled as the result of arterial blood gas abnormality. Almost 26% of ex-smokers met disability/standards, the majority on the basis of arterial

blood gases alone. Approximately 34% of the subjects who were smokers at the time of the study met disability standards. As in the case of the never smokers and ex-smokers, the majority of smokers met disability standards as the result of arterial blood gas abnormality.

If we combine ex-smokers and smokers into a single group of those who were actively exposed to cigarette smoke, the percentage of those disabled is about 30%. This figure is approximately twice the percentage of disabled who had never smoked.

Table IV indicates a direct relationship between the percentage of those disabled by arterial blood gas alone and the number of years spent underground. On the other hand note

Table I  
Frequency of Disability by Mean Age, Mean Years Underground,  
Mean Years of Smoking and Type of Pulmonary Insufficiency

	<u>Disabled</u>			<u>Non-Disabled</u>
	Spirometry Only	ABG Only	Both	
Number of Subjects	128 (4.7%)	486 (17.8%)	118 (4.3%)	1993 (73.1%)
Mean Age	53.4	54.4	55.1	52.2
Mean Years Underground	23.4	27.2	24.5	23.8
Mean Pack Years	21.4	23.5	25.2	19.3

Table II  
FEV<sub>1</sub> in Those Disabled by ABG Criteria Only

Percentage of Observed FEV <sub>1</sub> to Predicted	<u>Disabled</u>	<u>Non-Disabled</u>
60–79%	160 (32.9%)	399 (20.0%)
≥ 80%	326 (67.1%)	1594 (80.0%)
<b>Total</b>	<b>486</b>	<b>1993</b>

Table III  
Frequency of Disability by Smoking Status and Type of Pulmonary Insufficiency

	<u>Disabled</u>			<u>Non-Disabled</u>	<u>Total</u>
	Spirometry Only	ABG Only	Both		
Never Smokers	21	66	7	564	658
Ex-Smokers	41	141	38	627	847
Smokers	66	279	73	802	1220
Total	128	486	118	1993	2725

Table IV  
Frequency of Disability by Duration of Underground Mining and  
Type of Pulmonary Insufficiency

Years Under- ground	<u>Disabled</u>			<u>Non-Disabled</u>	<u>Total</u>
	Spirometry Only	ABG Only	Both		
1-9	18 (7.3%)	28 (11.3%)	15 (6.1%)	186 (75.3%)	247
10-19	32 (4.6%)	89 (12.7%)	20 (2.8%)	557 (79.8%)	698
20-30	37 (4%)	168 (18%)	43 (5%)	665 (73%)	913
31+	41 (5%)	201 (23%)	40 (5%)	585 (67%)	867
Total	128 (4.7%)	486 (17.8%)	118 (4.3%)	1993 (73.1%)	2725

the relative constancy of the percentage of those disabled by spirometry alone despite the increasing number of years spent underground.

Using the height-weight ratio as an indicator of the presence of obesity, the data did not reveal an increase in prevalence of obese subjects meeting disability standards by arterial blood gas criteria. In fact the data suggest that those individuals with disabling arterial blood gas values tended to be leaner than those without disabling values. Also of interest is the fact that slightly more than one-fourth of the 604 subjects who met arterial blood gas disability standards did so at rest only. The remainder of the 604 subjects met arterial blood gas disability standards at rest and exercise or during exercise only. These two latter observations will be presented and discussed in a subsequent publication.

## DISCUSSION

There is general agreement that the inhalation of coal mine dust in susceptible individuals produces a disease process which has its origins in the small airways<sup>3</sup> and produces the characteristic pathologic lesion known as the coal macule.<sup>4</sup> In a relatively small percentage of those afflicted the disease process goes on to progressive massive fibrosis which may distort the lung airways. Since the 80–90% of the total airway resistance in man resides in the large airways and since the FEV<sub>1</sub> is determined primarily by an increase in airflow resistance in the large airways, it is not surprising that a disease process affecting primarily the small airways will not usually produce a significant decrease in the FEV<sub>1</sub> in the majority of those affected. Thus the fact that about 3% of those subjects who never smoked were disabled by spirometry alone is not an unexpected finding. It is also interesting to note that only slightly in excess of 5% of those who smoked were disabled by spirometry alone. Published studies document separate effects of cigarette smoking and the inhalation of coal mine dust on decrements in FEV<sub>1</sub>.<sup>5,6,7</sup>

On the other hand recent studies have demonstrated the fact that in coal miners abnormalities of alveolar gas exchange consisting of an increased alveolar-arterial gradient for oxygen as well as decreases in arterial oxygen tension occur both at rest as well as during exercise without significant decrement in the pulmonary diffusing capacity.<sup>8</sup> Using radioactive isotopes and sophisticated computer technology Susskind and his group have demonstrated the presence of regional uneven distribution of alveolar ventilation to pulmonary capillary blood flow in nonsmoking bituminous coal miners sufficient to explain an observed increase in alveolar-arterial oxygen gradient and decrease in oxygen tension. In that study 19 of the 20 coal miners studied had impaired gas exchange for oxygen while only 4 of the cohort had minimal airway obstruction.<sup>9</sup> Thus the explanation for impaired gas exchange appears to reside primarily in the presence of uneven alveolar ventilation-pulmonary capillary blood flow relationships which is the most common cause of arterial desaturation in diseases diffusely affecting the small airways.

It must be noted that our data were obtained on miners and ex-miners who were applying for disability and thus represent a cohort of subjects of poor pulmonary health. Our data

are not representative of the universe of coal miners. Yet it is instructive to note the similarity of findings in Schiffman's analysis of anthracite miners in Pennsylvania who had applied for disability benefits.<sup>10</sup> Furthermore, studies in asymptomatic coal miners have demonstrated impairment in alveolar gas exchange for oxygen, both at rest and during exercise, though quantitatively less marked than those noted in our study.<sup>8,11,12</sup>

## CONCLUSIONS

1. The inhalation of coal mine dust produces significant effects on lung function and arterial blood gases in the absence of cigarette smoking.
2. The major functional pulmonary problem produced by the inhalation of coal mine dust appears to be impairment of the oxygenating function of the lung. Published studies suggest that this problem is caused by an increase in regional inhomogeneity of the alveolar ventilation pulmonary capillary blood flow relationships with resultant increase in the size of the physiologic shunt which causes a decrease in arterial oxygen tension.
3. Of lesser frequency, but nonetheless present, was a significant increase in the airway resistance as measured by a decrease in the FEV<sub>1</sub> as the result of the inhalation of coal mine dust.
4. The use of arterial blood gas studies is a justified and important component of disability evaluation among many of those applying for benefits under the Federal Black Lung Program.

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## THE FOURTH ROUND OF THE NATIONAL STUDY OF COALWORKERS' PNEUMOCONIOSIS: A PRELIMINARY ANALYSIS

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### INTRODUCTION

The year 1969 was a landmark time for underground coal miners in the United States, for it was in that year that the Federal Coal Mine Health and Safety Act was passed.<sup>1</sup> This enacted three provisions of benefit to miners: a low dust exposure limit; an x-ray surveillance and job transfer program; and a requirement that research be carried out on the health of coal miners, on dust reduction techniques, and on safety in mines.

Of these three provisions, that involving research activities into the health of miners was satisfied through the creation of a research project known as "The National Coal Study" (now known as the National Study of Coalworkers' Pneumoconiosis (NSCWP)), currently administered by the National Institute for Occupational Safety and Health.

This project was begun in August 1969 with medical surveys at 31 nationally distributed mines. The mines were chosen to represent different coal seams and mining methods. Other criteria for selection were a working force of at least 100 miners, expected continued coal production for at least another 10 years, and preferably some earlier dust measurements. Of the 31 mines, 17 had been environmentally sampled in a study by the Bureau of Mines.<sup>2,3</sup>

The medical surveys were undertaken through use of mobile examination units which went from mine to mine. At each mine the complete workforce was examined by being given a postero-anterior and lateral chest x-ray, by undertaking spirometry, and by answering questions on chest symptoms using a slightly modified version of the British Medical Research Council's symptoms questionnaire.<sup>4</sup> In addition, working and smoking histories were ascertained, and demographic information and height and weight determined. The participation rate at this initial round of surveys (Round 1) was excellent, at 91%.

Two further rounds of surveys were completed subsequent to Round 1. The second round began about three years after Round 1, the methods being virtually the same. Owing to the closure of mines in the period between these rounds, and in order to improve representation, nine additional mines were brought into the study for this round. Round 3 began in 1977, the procedures being again virtually identical to those of the previous two rounds.

Figure 1 shows some information graphically on the timing of the surveys. It also shows the permitted exposure limits in force during this time, and the general trend in dust levels based on the survey reported by Jacobson,<sup>3</sup> and from data collected by the Mine Safety and Health Administration.<sup>5</sup>

The data collected in the three completed rounds have led to the publication of many findings and results on lung disease in U.S. coal miners. It has been shown that CWP prevalence follows a trend with the rank of coal, with tenure in mining, and with job.<sup>6</sup> In addition, indices of lung function and chest symptoms have been shown to be correlated with job and with tenure underground.<sup>7,8</sup> More recently results have been published on longitudinal change in ventilatory function,<sup>9</sup> and on incidence and progression of CWP.<sup>10</sup> Many other reports have been published.

The remainder of this paper is concerned with the rationale for the fourth round, and a description of its design and methods. This is followed by a description of the status of the selected cohort and an examination of selection bias.

### NEED FOR A FOURTH ROUND

A further round of examinations in the NSCWP was deemed necessary for the following reasons:

1. The period of follow-up between rounds 1 and 3 was too short for proper evaluation of the effectiveness of the dust control limit set by the 1969 Act.
2. Participation in Rounds 2 and 3 at 75% and 52% was much lower than the 91% attained at Round 1, leading to uncertainty in the later findings.
3. Rounds 1-3 were concerned only with miners employed at time of examination. The omission of ex-miners may have led to bias in the reported results.

### STRATEGY FOR THE FOURTH ROUND

Continuation of the NSCWP along the lines of the previous three rounds was thought inadvisable for these reasons:

- a. Mine based surveys were starting to prove inadequate as a mechanism for follow-up of miners. The closure of mines and the movement of miners between mines and to other jobs meant that members of the study examined in the early rounds were no longer at the same mines, and therefore being lost to the study.

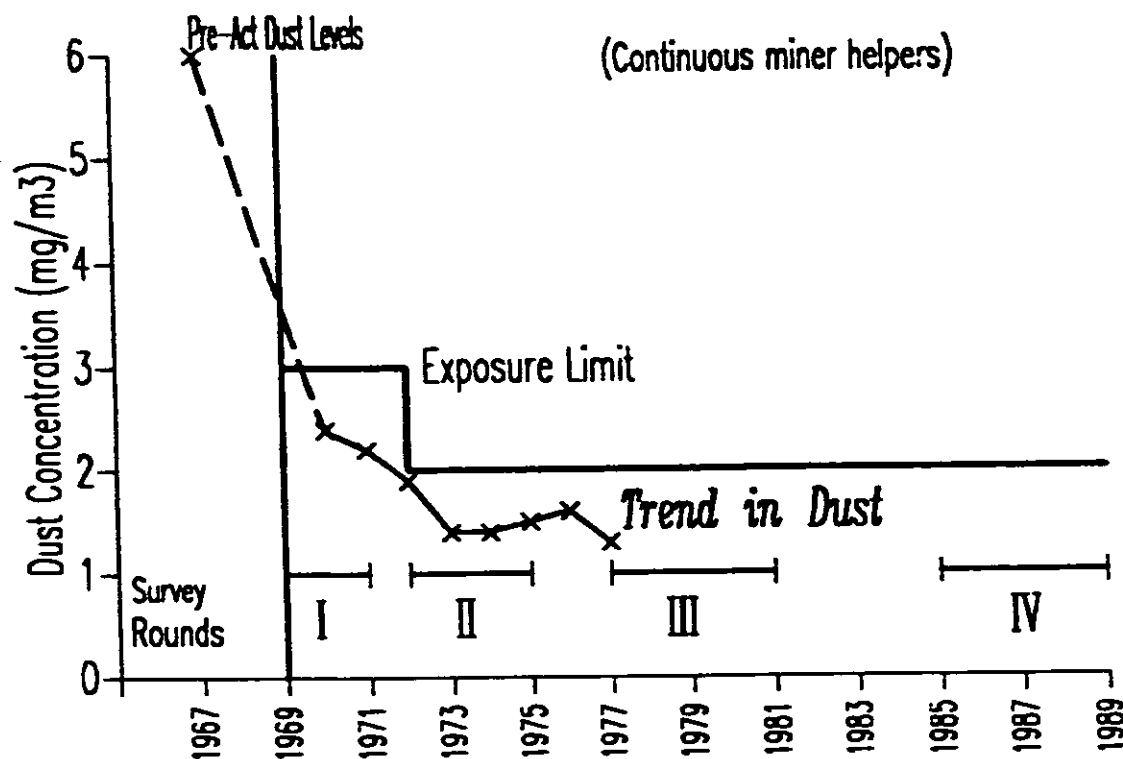


Figure 1. Dust limits, dust exposure trends, and NSCWP surveys, 1967-89.

- b. Mine based surveys were inappropriate for examination of ex-miners.
- c. Experience during the third round had shown that the lack of interest in the study by miners was exacerbated by mine based medical surveys.
- d. Most importantly, the aims of the NSCWP had evolved from research into the relationship between dust characteristics and indices of respiratory health into an evaluation of the effectiveness of the 2 mg/m<sup>3</sup> dust standard. This change in emphasis called for a change in the nature of the design of the study.

For the above reasons it was decided that the fourth round would not be based on mine visits but would rather center around the location and examination of a cohort defined by initial attendance at either Round 1 or Round 2. The intent of this exercise was to measure changes in health over the intervening period. These changes could then be compared to those expected to occur under 2 mg/m<sup>3</sup> based on current knowledge on dust exposure and disease.

#### FOURTH ROUND PLANNING

The fourth round follow-up cohort was formed from two subsets of miners who attended either Round 1 or Round 2 initially. The selection criterion that miners had to be young enough at these rounds for them to have been able to work a further 15 or so years up to the fourth Round was imposed. This led to 3719 miners remaining out of the 9081 Round 1 miners and 3677 out of the 9343 Round 2 miners, making a total of 7396 miners for follow-up.

Without the age criterion the cohort would have consisted of mainly older coal miners, most of whom would have retired before the 4th round. As this investigation was intended to be a study of those potentially able to work the inter-survey period between the first two rounds and round 4, those older than 45 at Round 1, and 48 at Round 2 were excluded from the cohort.

Figure 2 shows the geographical distribution of the cohort of interest. This, of course, follows the distribution of mines originally selected for the study, which itself reflected the general pattern of employment in the various coal fields.

Table I shows some basic statistics on the cohort by round (see Appendix for brief details of the data and methods). The miners of Round 2 were slightly younger and less experienced because many of them had just started work as a result of the hiring boom that took place in coal mining in the early 1970s. In other respects the groups were very similar.

#### DATA COLLECTION METHODS

Two methods of data collection were used. In cases where it was established that a sufficiently large cluster of the cohort miners were working at a particular mine, a survey was held at that mine. Three such mine surveys were held, the number being few because most of the study mines had been shut down or were inactive during the data collection period.

In order to improve participation NIOSH staff spent extensive amounts of time talking to the miners at those mines.

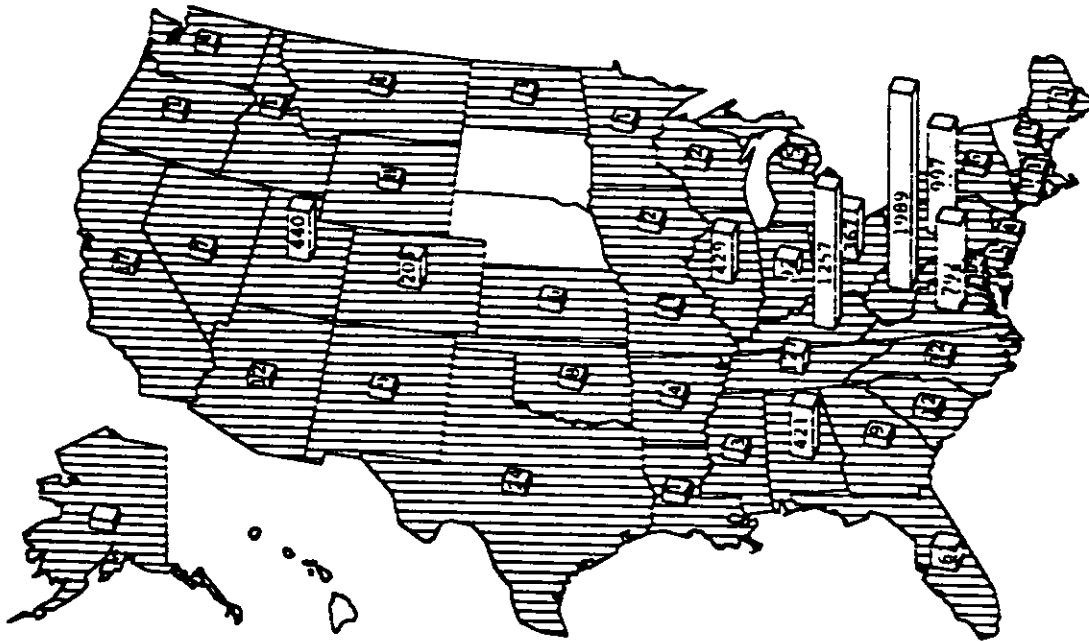


Figure 2. Geographic location of miners.

Table I  
 Details of Selected Cohort: Information from Round 1 and 2

	Round 1	Round 2
Number	3719	3677
Age (yr)	33	30
Tenure UG (yr)	7	5
% Smokers	61	59
% Obstructed	20	19
% CWP Cat 1+	5	2
% CWP Cat 2+	1	0
% Cough	22	19
% Dyspnea	9	13

Notes: all percentages rounded for simplicity of presentation. Zero percentages may actually be less than 0.5%.

In addition, participation was encouraged by the presentation of special stickers, ball hats, and belt buckles.

The remainder of the data collection was undertaken using so-called 'community surveys.' In these, suitable geographical clusters of the cohort were identified and examined, the mobile testing unit being set up at a convenient location, often a hospital, clinic, union building or shopping mall.

Twenty community surveys have been completed to date. The procedure at each was similar and was as follows. Current information on addresses was obtained from the Internal Revenue Service. These addresses were then examined

and suitable clusters identified. Such clusters had to include a reasonable number of miners (150–350) yet not be too extensive (a radius of about 30 miles or less).

Once an area was identified and defined, a suitable location for the mobile examination unit was found. Attention then turned to locating a person who would make telephone contact with the miners and arrange appointments. Meetings were also held with local union officials and others to inform them of the study and to enlist their support.

After a suitable location was established notification letters were sent to all miners. These included a letter of support from the head office of the United Mine Workers of America



(UMWA) and usually another from the local UMWA District President. Once the letters had been sent the telephone person began calling the miners and setting up appointments.

Contact with miners was difficult in many cases owing to unlisted telephone numbers and lack of telephones. Letters were sent where telephone contact proved impossible although the reply rate was low. Whenever possible personal contact was made by visits to the house by the telephone person or by members of the examination team at the time of survey.

Out of the 7396 cohort members, 4712 were selected for examination in the three mine and twenty community surveys held to date. Additional community surveys are planned in order to complete data collection, although it is not expected that all of the cohort will be selected for examination as many are located too remotely or too sparsely to justify a survey in their area. The completed surveys have been held throughout all but one of the states in which the original mines were located, and as a result the 4712 selected miners are distributed by state in roughly the same proportion to the cohort state distribution (Figure 3).

**STATUS OF SELECTED SAMPLE**

Figure 4 shows the breakdown of the 4712 selected cohort members according to status at time of examination (final status). The groups are denoted as follows: 1. Examined; 2. No contact; 3. Moved; 4. Refused; 5. No-shows (had appointments but did not attend); 6. Deceased; 7. Valid reasons for non-attendance; and 8. Probable excuse.

The no contact group consisted of those with whom telephone contact was not made, and who did not return letters. In many cases the person could not be reached when a personal visit was made also. Such people may have left the area, become reclusive, been out of the area or worked away from home, or may have died; certainly, exact determination of the reason was impossible. The crude participation rate was 60%, while if those who had died, moved or had valid reasons for non-attendance were excluded, the rate rose to 68%. If the no contacts are also excluded the rate was 74%.

**STUDY OF PARTICIPATION BIAS (USING EARLIER DATA)**

Since there is the potential for bias, in that the healthy may choose to be tested while the unfit be unable to or refuse (perhaps through fear of loss of health benefits), an examination of bias was made. This was done in two ways. Firstly, bias was measured indirectly by tabulating data from the initial rounds of the study according to status at round 4 (see Appendix for brief details of the data). The second approach is described in the next section of this report.

Table II shows data from the Round 1 part of the cohort tabulated according to the first five of the final status groups described earlier (the valid reasons and excuses groups, being small, were omitted, while the deceased group is not relevant to discussions of bias). The table shows that age differed little between the five groups, while smokers were more frequent in all of the non-examined groups. The refusal group was noteworthy for having the most reports and findings of ill health as well as having the longest tenure. The movers

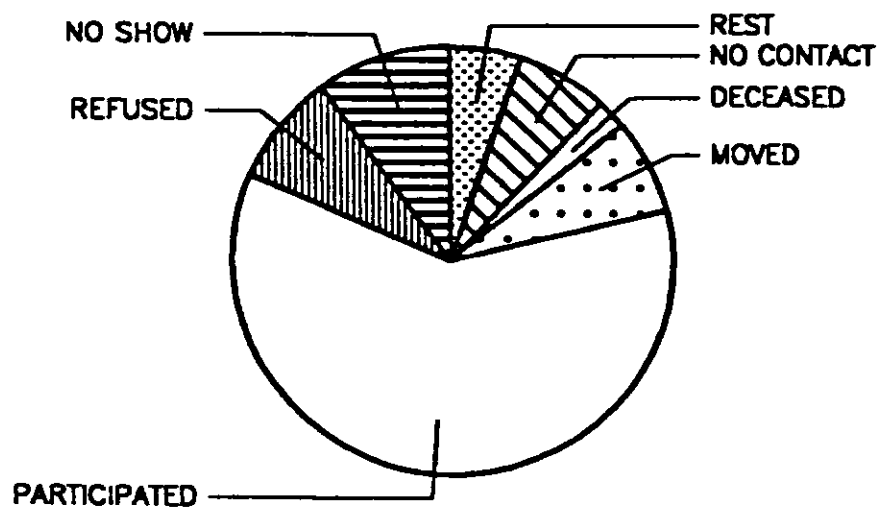


Figure 3. Distribution of complete cohort, and of those selected for examination to date, by state.

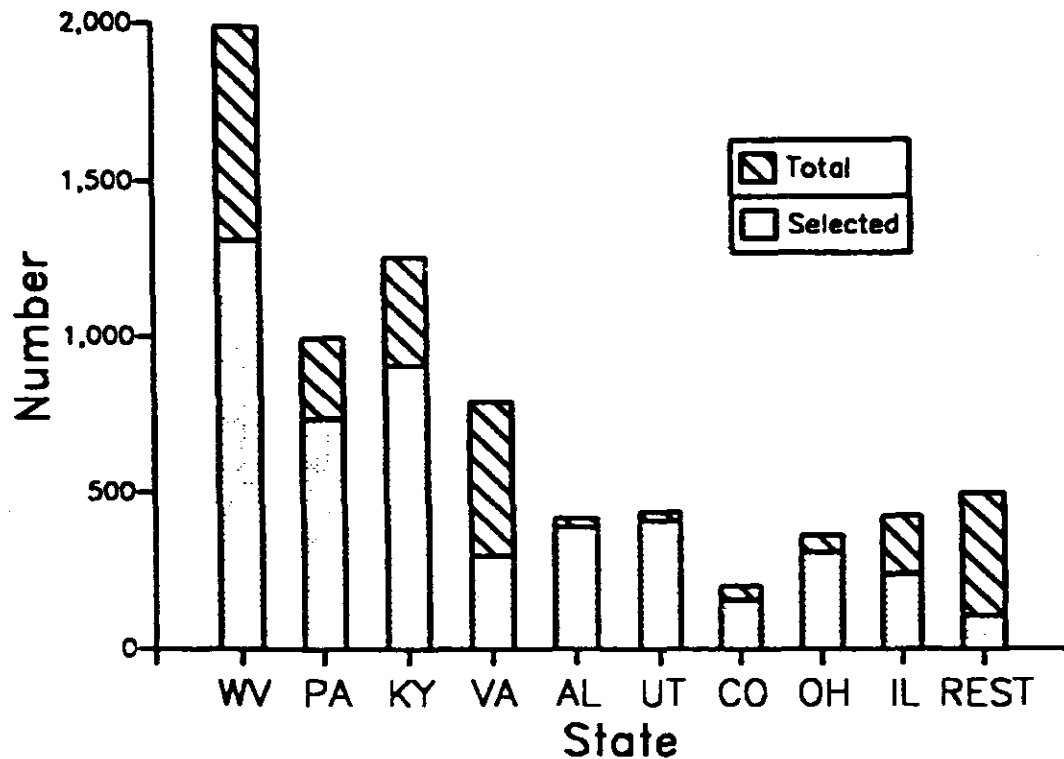


Figure 4. Distribution of final status of selected group.

Table II  
Medical Information at Round 1 by Final Status at Round 4

	Exam- ined	No contact	Moved	Re- fused	No show
Number	1549	125	166	206	186
Age (yr)	33	32	30	33	31
Tenure UG (yr)	7	8	5	9	7
% Smokers	58	62	71	66	67
% Obstructed	20	17	18	24	20
% CWP Cat 1+	5	3	2	8	6
% CWP Cat 2+	1	1	1	1	1
% Cough	20	23	20	26	21
% Dyspnea	7	10	8	9	9

Note: all percentages rounded for simplicity of presentation. Zero percentages may actually be less than 0.5%. Deceased, unknown status, and two other small non-participating groups omitted (n=173).

group had the most smokers but generally had the fewest signs of health problems.

Table III shows the data for the Round 2 part of the cohort. In general the results parallel those seen in Table II. Again the age range between the groups is small, and the exam-

ined group had the fewest smokers. The refusal group had the longest tenure, greatest percentage obstructed, most CWP and high levels of symptoms, as they did in Table II. Similarly, movers were younger, had large numbers of smokers, yet tended to have fewest signs of lung disease. There was

more evidence of lung problems in the no contacts in this Round 2 part of the cohort.

Overall, the results from both portions of the cohort indicate the following. The refusals appeared to have had more exposure to coal dust, smoked more, and had more disease. This excess of disease is balanced in part by the deficit seen in the movers. No-shows in general had about as much ab-

normality as those examined, while the findings were mixed for the no contacts.

In general, there is evidence of bias, but it does not appear severe. This observation is confirmed by the results of Table IV, which shows the data by round for the examined group compared to that for those not examined, and for all of the cohort excepting deceased miners. It shows that only minor

Table III  
Medical Information at Round 2 by Final Status at Round 4

	Exam- ined	No contact	Moved	Re- fused	No show
Number	1357	197	170	203	288
Age (yr)	30	31	28	33	29
Tenure UG (yr)	5	7	4	8	5
% Smokers	56	69	69	60	59
% Obstructed	18	21	18	23	15
% CWP Cat 1+	2	5	2	5	2
% CWP Cat 2+	0	0	0	1	0
% Cough	16	25	16	23	21
% Dyspnea	11	19	13	16	13

Note: all percentages rounded for simplicity of presentation. Zero percentages may actually be less than 0.5%. Deceased, unknown status, and two other small non-participating groups omitted (n=185)

Table IV  
Examination of Bias for Round 1 and Round 2 Cohorts

	Round 1 cohort Examined			Round 2 cohort Examined		
	Yes	No	All	Yes	No	All
Number	1549	801	2350	1357	990	2347
Age (yr)	33	32	33	30	30	30
Tenure UG (yr)	7	7	7	5	6	5
% Smokers	58	66	61	56	63	59
% Obstructed	20	20	20	18	18	18
% CWP Cat 1+	5	5	5	2	1	2
% CWP Cat 2+	1	1	1	0	0	0
% Cough	20	23	21	16	21	18
% Dyspnea	7	9	8	11	15	12

Notes: all percentages rounded for simplicity of presentation. Zero percentages may actually be less than 0.5%. The not examined and total groups exclude deceased miners.

differences existed between those tested and those not tested, the biggest discrepancies occurring for smoking (7–8% difference) and for cough (3–5% difference) and dyspnea (2–4% difference). When the data for the examined group are compared to those for all living miners the differences are trivial, indicating that the examined group may be reasonably representative of the whole.

#### ANALYSIS OF BIAS USING COMPENSATION DATA

The above approach is not particularly satisfactory, since there was a 10–15 year inter-round period during which lung disease could develop. The second approach used more current data from the U.S. Department of Labor (DOL) on Black Lung compensation. To do this, a file of information on name, Social Security number and final status was sent to the DOL. This was matched with the DOL records and a table created showing the percentage in each final status category that had been granted benefits. (While a more powerful analysis would have used DOL medical data in an approach similar to that used in Tables II and III, no formal agreement existed at the time this was written that would have permitted the necessary exchange of data.)

The history of DOL compensation is complicated and much too lengthy for description here in detail. However, two broad periods of time between 1970 and 1988 can be identified during which the regulations were less and more restrictive respectively, viz. pre- and post-1980. Award of compensation was contingent on either ventilation tests or x-ray results during each period, but the criteria were made much more strict after 1980. In addition the rebuttable presumption that lung disease was the result of coal mining was repealed at that time. The result of this tightening was to reduce the approval rate from a high of 46% to 5% (section

435 claims under the 1977 amendments compared to section 718 claims, post 1981 amendment—figures from DOL staff). Since the criteria for these two time periods are so distinctly different the results have been subdivided accordingly.

Table V shows the percentages of miners in each of the final status groups (both rounds combined) who were awarded benefits based on the less and more restrictive criteria respectively, and overall. They show that those examined had the lowest percentage in receipt of benefits, while refusals had the most, followed by the no-contacts, movers and no-shows. This pattern is evident both in those awarded benefits under the less and under the more restrictive criteria, although the differences under the latter criteria are much less pronounced. The overall percentage of miners awarded benefits was 4.9% (excluding deceased miners), compared to the 2.9% seen in those examined, indicating the possibility of bias. Based on the more restrictive criteria, these percentages are 0.9% overall, and 0.8% in the examined group, suggesting the absence of severe bias.

#### CONCLUSIONS

Data collection is continuing in order to fill some of the major gaps in miner selection noted earlier and to increase the number of examined cases in the round 4 cohort. At this point in time about 65% of the combined round 1 and 2 cohorts have been selected for examination. Of those 4805 miners, 60% have been examined. On the basis of earlier data, the examined group appears to be in slightly better health than those alive at time of survey who did not attend. Certain subgroups of the nonparticipants, specifically those who refused, tended to have, and to report, distinctly more signs of ill health. This excess is balanced to some extent by the apparent better health of those who moved. The data from

Table V  
Percentage of Miners Receiving DOL Black Lung Benefits Awarded Under  
Different Regulations by Final Status at Round 4

	Exam- ined	No contact	Moved	Re- fused	No show
<b>Number</b>	<b>2906</b>	<b>322</b>	<b>336</b>	<b>409</b>	<b>474</b>
<b>Benefits approved under less restric- tive regulations</b>	<b>1.9</b>	<b>8.4</b>	<b>5.7</b>	<b>9.3</b>	<b>3.6</b>
<b>Benefits approved under more restric- tive regulations</b>	<b>0.8</b>	<b>0.6</b>	<b>0.3</b>	<b>1.5</b>	<b>1.1</b>
<b>total approved benefits</b>	<b>2.6</b>	<b>9.0</b>	<b>6.0</b>	<b>10.8</b>	<b>4.6</b>

the DOL on black lung benefits confirm that bias may be present, but its actual extent is hard to judge in the absence of medical information.

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## APPENDIX ON DATA AND METHODS

### Symptoms

The questions used were identical for both rounds 1 and 2. Presence of cough was indicated by positive replies to questions 1 or 2, plus a positive reply to question 3, where the three questions are:

1. Do you usually cough first thing in the morning (on getting up\*) in the winter?
2. Do you usually cough during the day (or at night\*) in the winter?
3. Do you cough like this on most days (or nights\*) for as much as three months each year?

\*For those who work at night.

Dyspnea was defined on the basis of positive answers to the following two questions:

4. Are you troubled by shortness of breath when hurrying on level ground or walking up a slight hill?
5. Do you get short of breath walking with other people of your own age on level ground?

### Spirometry

The FEV<sub>1</sub> and FVC data for round 1 were based on the maximum of three blows after two practice blows. In round 2 the maximum was taken from at least five blows after two preliminary blows. In both rounds the same type of rolling seal spirometer was used and the methods were similar. A person was classified as obstructed if his FEV<sub>1</sub>/FVC ratio was less than 0.7 at all three rounds.

### Radiology

CWP was defined in both rounds using small combined opacities. In round 1 the profusion of combined opacities was derived from the maximum of the small rounded and small irregular profusions. In round 2 the recorded profusion of small combined opacities was used, if available; if not, the maximum of the rounded and irregular scores was used, as for round 1. The classification used for these two rounds was the ILO 1971 version.<sup>11</sup>

While the readings quoted for round 2 were derived from the median of three readings, those from round 1 was taken from the reader who noted the least amount of abnormality of three readers, since it has been shown subsequently that his interpretations were much more compatible with abnormality levels reported by others before, during and after round 1.

## **PROGRESSION OF COAL WORKERS PNEUMOCONIOSIS (CWP) IN A COAL MINE**

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### **ABSTRACT**

The paper relates to the chest X-ray examinations of 125 underground coal mine workers. It was a new mine. The miners were freshly recruited from village areas. They were chest X-rayed at entry level and then after 6 years and again after 10 years of working. The first two surveys used MMR 70mm×70mm, 200 mA at 100 kV and the third used 300mm×380mm, 15mA at 85kV. The average respirable airborne dust concentrations at working places as measured by gravimetric dust sampler and label personal sampler were 23.9 and 34.9 mg/m<sup>3</sup> respectively. 1959 ILO Pneumoconiosis Classification was used.

The X-ray results indicated that all the workers were free from CWP at entry level. After 6 years of work, the attack rate of CWP for Z, P and Q categories were 38, 1 and 1 respectively. After another 10 years of work, 15 workers developed CWP of category P-1 and above (12%), P being 10, Q-4, R-1 and Z-1. Thus, the CWP rate of attack in 16 years of underground work were: P—(8%), Q—(3.2%), and R—(0.8%) and the ratio of P:Q:R in 16 years were: 10:4:1. Boom type Road Header cutter-loader coal cutting machines were used at the coal faces.

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No Paper provided.

## A RATIONALE FOR ASSESSING EXPOSURE-DOSE-RESPONSE RELATIONSHIPS FOR OCCUPATIONAL DUST-RELATED LUNG DISEASE

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### INTRODUCTION

The complex chain of processes linking occupational exposure to airborne particles with the occurrence of related lung disease is summarized in Figure 1. Epidemiology is usually concerned with relating the two ends since it is the disease on the one hand which is the 'problem' and exposure at the other which can be monitored and controlled. However, it has long been held that, by a proper understanding of the intermediate processes and its incorporation into the epidemiological framework, substantial further advances will be made possible in epidemiology and risk assessment. From multidisciplinary studies carried out worldwide into (a) the physical nature of the aerodynamic transport of airborne particles in the respiratory tract and their deposition in the lung, (b) the kinetics of their redistribution, clearance and storage, (c) the cellular and pathological responses to the presence of particles in the lung, and (d) epidemiology itself, such understanding is now available. The task now is to bring together and apply the knowledge which has been acquired.

This paper reviews the factors to be considered, including not only the level of initial challenge (i.e., involving considerations of the intensity of exposure, rate of deposition in the lung) but also the time-dependent history of exposure (involving considerations of sampling strategy), chemical composition and indices of biological response. The ultimate objective is a dosimetric approach to the problem. What is presented here is a hypothesis upon which such an approach can be built.

### THE CONCEPT OF 'DOSE'

The concept of 'dose' is a fundamental issue. In the first instance, it involves the mass rate of deposition in the respiratory tract. The usual approach to this is to assume a conventionalized deposition fraction of the airborne particulate and to measure exposure in terms of that fraction. For the alveolar fraction, a number of quantitative definitions have been widely used, notably that recommended by the British Medical Research Council.<sup>1</sup> In risk assessment, however, it is worth noting that such an approach does not allow for possible differences in deposition for workers engaged in different levels of physical activity (where breathing parameters might vary). Some of our estimates for underground mineworkers in different occupational groups (based on previous measurements of breathing patterns for

similar groups of workers and on published lung deposition data) suggest that such effects could lead to differences in alveolar deposition by as much as  $\times 2$ , as compared with exposure measured according to a conventionalized deposition fraction. This suggests in turn that, at least in some epidemiological research, a more flexible approach to dust sampling may be desirable using instruments capable of providing a wider range of information (including particle size distribution and composition). Instruments suitable for this purpose, including dust 'spectrometers', are now available. Some have been the subjects of recent comparative studies carried out in several European laboratories, as reported elsewhere at this Conference by Vincent.

As far as 'dose' is concerned, however, the relationship between exposure and the rate of mass deposition in the lung is just the first stage in the process. The next step is to consider what happens after material has been deposited. In order to express dose in the context of potentially-hazardous inhaled particulate material, a useful starting point is the approach which is widely used for dealing with the dosimetry of inhaled radioactive particles.<sup>2</sup> Thus the hazard-related dose received by lung tissue is equivalent to the integral over time of the amount of particulate material present combined with some modifying 'harmfulness' (or 'damage') function. The latter describes the rate at which the intrinsic property associated with the hazard is transmitted from the material to the tissue and how it changes with the time during which the material is in contact.

In setting out to construct a quantitative dosimetric model, consider first the exposure history. This may be expressed as  $E_n$ , reflecting the mass deposited in the lung during the  $N^{\text{th}}$  day since exposure began. From this, cumulative exposure ( $C$ ) at the  $n^{\text{th}}$  day is

$$C(N) = \sum_{n=1}^N E_n \quad (1)$$

which is the form widely employed in epidemiological studies (where  $E_n$  is usually obtained in terms of the measured concentration of an appropriate dust fraction, time weighted over the working shift).



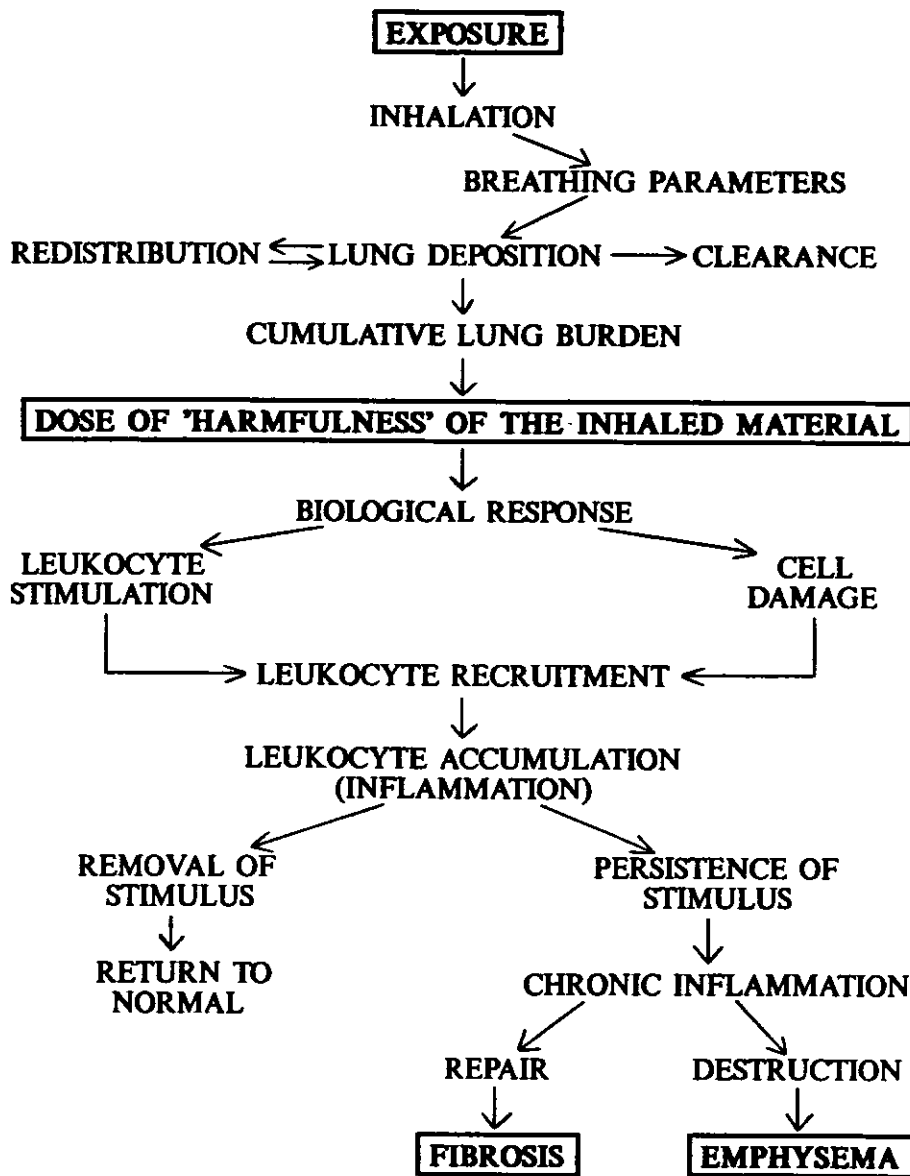


Figure 1. Processes linking exposure, dose and response associated with health effects due to mineral dusts in the deep lung.

Next consider the time-dependent retention of particulate material in the lung. The function  $R_m$  describes the proportion remaining of a particular 'packet' of material at the  $m^{\text{th}}$  day after it has been deposited. The distinction is drawn between  $n$  (which refers to the overall time elapsed since exposure began) and  $m$  (which refers to the time elapsed since a particular packet of material has been deposited in the lung). The value of  $R_m$  (between 0 and 1) is determined by the kinetics of redistribution, clearance and storage of the deposited particles. By combining  $E_n$  and  $R_m$ , the accumulated mass ( $M$ ) after  $N$  days have elapsed may be shown to be

$$M(N) = \sum_{n=1}^N E_n R_{N-n+1} \quad (2)$$

We now introduce the damage function  $G_m$ , which defines the rate per unit mass at which harmfulness is being transmitted to the tissue at the  $m^{\text{th}}$  day after it has been deposited. It may thus be regarded as a hazard-related 'fingerprint' for the material in question. The transferred property which is responsible for initiating the cell damage may be physical, mineralogical or biochemical.

We now have the three essential elements for constructing a dosimetric model. Hypothetical examples are given in Figure 2. These may be combined as follows:

Day	Dose received
1	$E_1 R_1 G_1$
2	$E_1 R_2 G_2 + E_2 R_1 G_1$
3	$E_1 R_3 G_3 + E_2 R_2 G_2 + E_3 R_1 G_1$

and so on. The cumulative dose of harmfulness is equivalent to the sum of all the contributions indicated. Thus at the  $N^{\text{th}}$  day, we have

$$H(N) = \sum_{n=1}^N E_n \left\{ \sum_{m=1}^{N-n+1} R_m G_m \right\} \quad (3)$$

In relation to the epidemiology of dust-related lung disease, it is suggested that Equation (3) should replace Equation (1) and other simplistic forms of dose assessment.

### PRACTICAL CONSIDERATIONS

Practical implementation of the proposed rationale involves quantitative description of the three key elements;  $E$ ,  $R$  and  $G$ .

The first of these is derived from measurements of dust concentration in a way such that the life-time dust exposures of individual workers may be described. This is a complex task. In the first place, it involves choosing a sampling instrument that provides a measurement of the airborne concentration of a dust fraction relevant to the disease in question. In the case of pneumoconiosis, this is the respirable fraction (although there may still be some debate about the particular quantitative criterion by which this should be defined). In turn, there are many instruments available which can provide the required information. In choosing the instrument, considerations of how best to make the measurement relevant to the true exposure of the individual worker raises questions of personal versus static (fixed point) sampling which have been discussed elsewhere.<sup>3</sup> Both types provide the time-weighted shift average of the exposure concentration. The frequency of sampling and its relevance to the assessment of long-term exposure are a matter of sampling strategy, involving considerations of the 'smoothing' that takes place in the body after particles have been deposited (which, in turn, is dependent on  $R$ ).<sup>4</sup> Furthermore, since the exposure history, if it is to be useful, must reflect the life-time experience of the individual worker, and since he (or she) may move around the workplace from time to time, a record of time worked in particular occupations is an important ingredient towards construction of exposure history. Finally, since it is likely that epidemiology will be desirable for workers for whom exposure records in the early years are either non-existent or imperfect, it may be necessary in many cases to retrospectively estimate exposure histories on the basis of intelligent extrapolations backwards, taking into account more recent measurements and engineering histories of the industries in question.<sup>5,6</sup>

As far as  $R$  is concerned, substantial progress in understanding has been made in recent years, mostly based on inhalation studies with animals.<sup>7,8,9</sup> Therefore we now have pharmacokinetic models which are applicable to various toxic and non-toxic, fibrous and non-fibrous materials over wide ranges of exposure level. It is, however, important to note, that such models are relevant strictly only to the animals in question, and need to be validated with respect to humans. Data obtained during epidemiological research in the British coal industry, in particular information from autopsy studies on the lung burdens of mineworkers for whom exposure histories are known, are at present being examined in order to explore the feasibility of establishing such a link.

Although the third quantity,  $G$ , is just as important in relation to dose, it is still more difficult to quantify. In the case of radioactive particulate matter (the starting point for the dosimetric hypothesis), the harmful property which is transferred between the particulate matter and the lung tissue is relatively easy to identify (e.g., ionizing radiation of a well-defined type). For mineral dusts, however, like those encountered in many industrial workplaces, the nature of the property is not known. Quartz is one example where, although there are well-known health hazards associated with inhaling respirable particles, somewhat inconsistent epidemiological findings have emerged, especially when other materials are present. As a result, attempts to determine the basic nature of the harmfulness of quartz have not

yet provided definitive answers. European research, involving several laboratories, is presently in progress to address this question, as described elsewhere at this Conference by Robock.

In setting out to quantify G, mineralogical assessment alone does not provide all that is required. Neither (necessarily) does toxicity evaluation based on in vitro cell viability tests. In our own Institute, we are at present exploring how progress might be achieved by direct reference to the cellular response in the lung itself.<sup>10</sup> Bronchoalveolar lavage studies in rats exposed to dusts known to produce contrasting health

effects (relatively-innocuous titanium dioxide and highly toxic quartz, for example) have been carried out. These have involved measurements of responses reflecting lung injury (e.g., leukocyte recruitment). Some of the results are particularly relevant in the present context—although the conclusions are preliminary at this stage. Some examples are shown in Figure 3, where the dusts were delivered into the lungs of the rats by inhalation and the leukocyte recruitment assessed subsequently (in terms of neutrophil counts). For the titanium dioxide, the results suggest a biological response is provoked which falls after the cessation of exposure. This in turn suggests that the intrinsic 'harmfulness' of the ma-

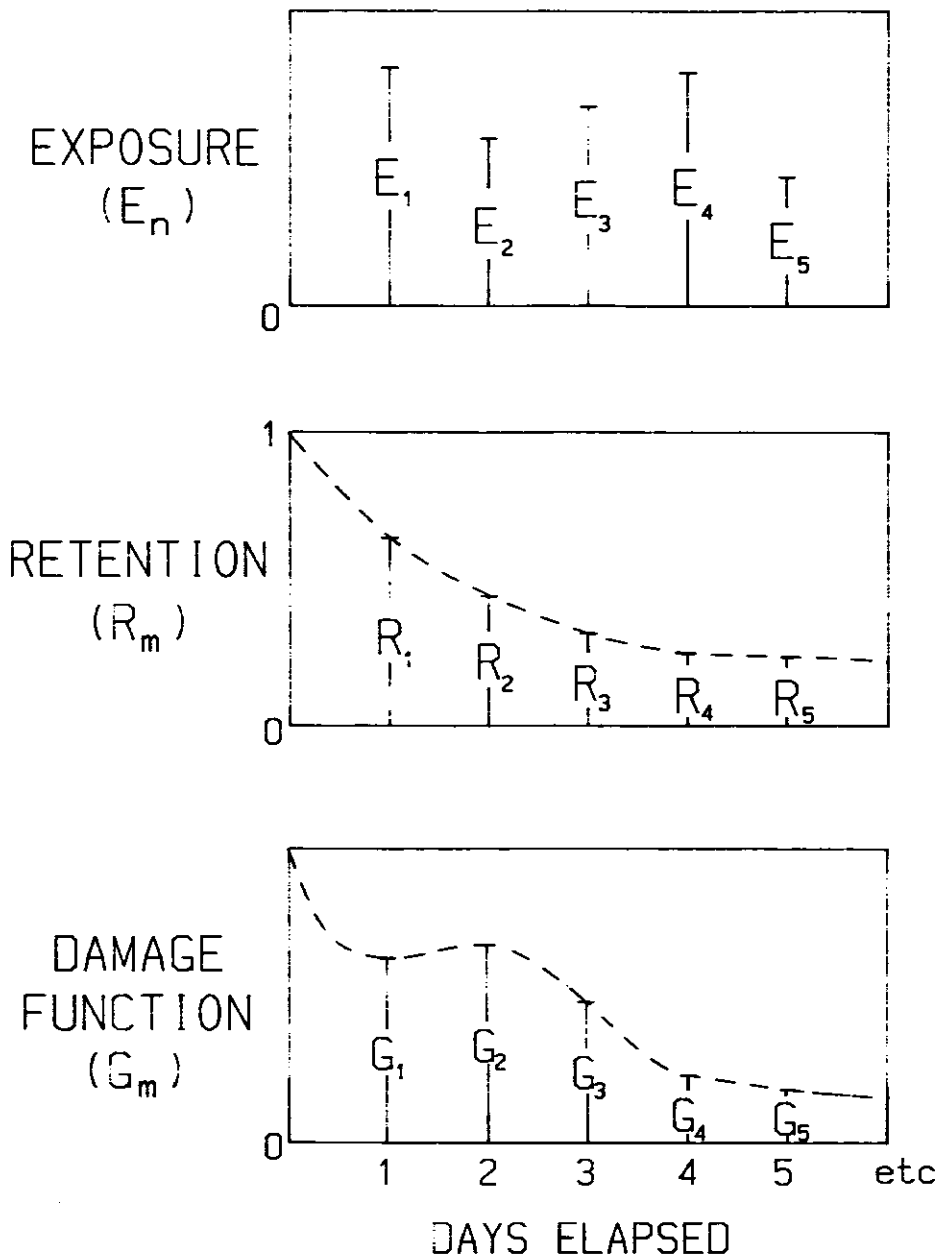


Figure 2. Hypothetical examples to illustrate the quantitative nature of exposure (E), retention (R) and damage function (G).

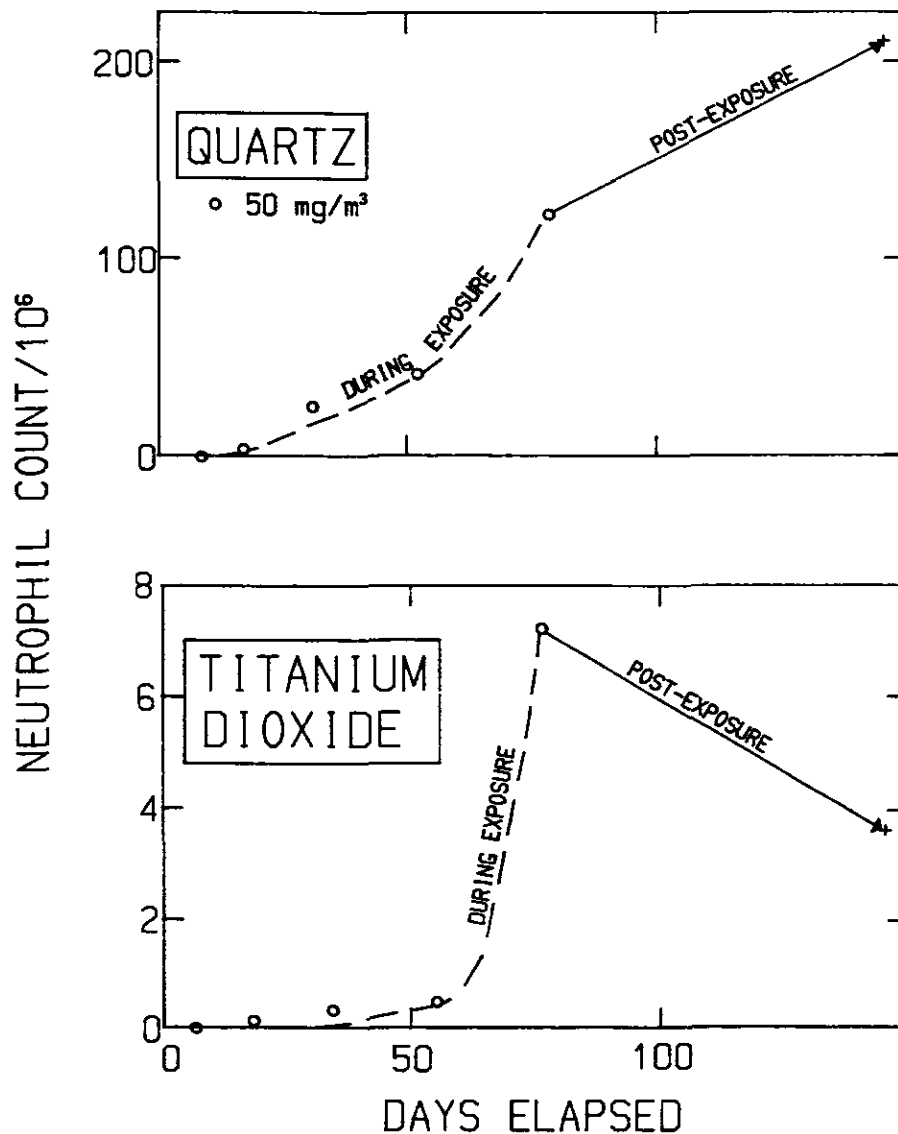


Figure 3. Typical results of cell-lavage study, showing neutrophil response during exposure- and post-exposure for quartz and titanium dioxide inhaled by rats at 50 mg/m<sup>3</sup> (respirable). The results shown are means for four rats.

terial is not persistent but rather the damage function,  $G$ , decays with time. Throughout, its magnitude is relatively small. In contrast, the biological response to the inhaled quartz is much greater in magnitude and is much more persistent. That is,  $G$  is high upon arrival in the lung, and—unlike titanium dioxide—does not decline, even post-exposure. From these findings, the dosimetric implications are clearly consistent with what is known about the contrasting hazards associated with inhaling each of these two materials. Further work is now needed to place such ideas on a more quantitative footing, and to extend them to other, more-realistic mineral dusts.

### CONCLUDING REMARKS

In the preceding, we have discussed the main ingredients of a dosimetric model for assessing the risk associated with inhaling airborne particles. The rationale for its development is summarised in Figure 4. At this stage, it is no more than an initial hypothesis. Before it can be proposed as a working model, it is necessary, (a) to establish the validity of pharmacokinetic models, derived originally from the results of animal inhalation studies, for describing retention in humans, and (b) to establish the validity of (and extend) the biological assays aimed at quantifying  $G$  for dusts relevant to work-

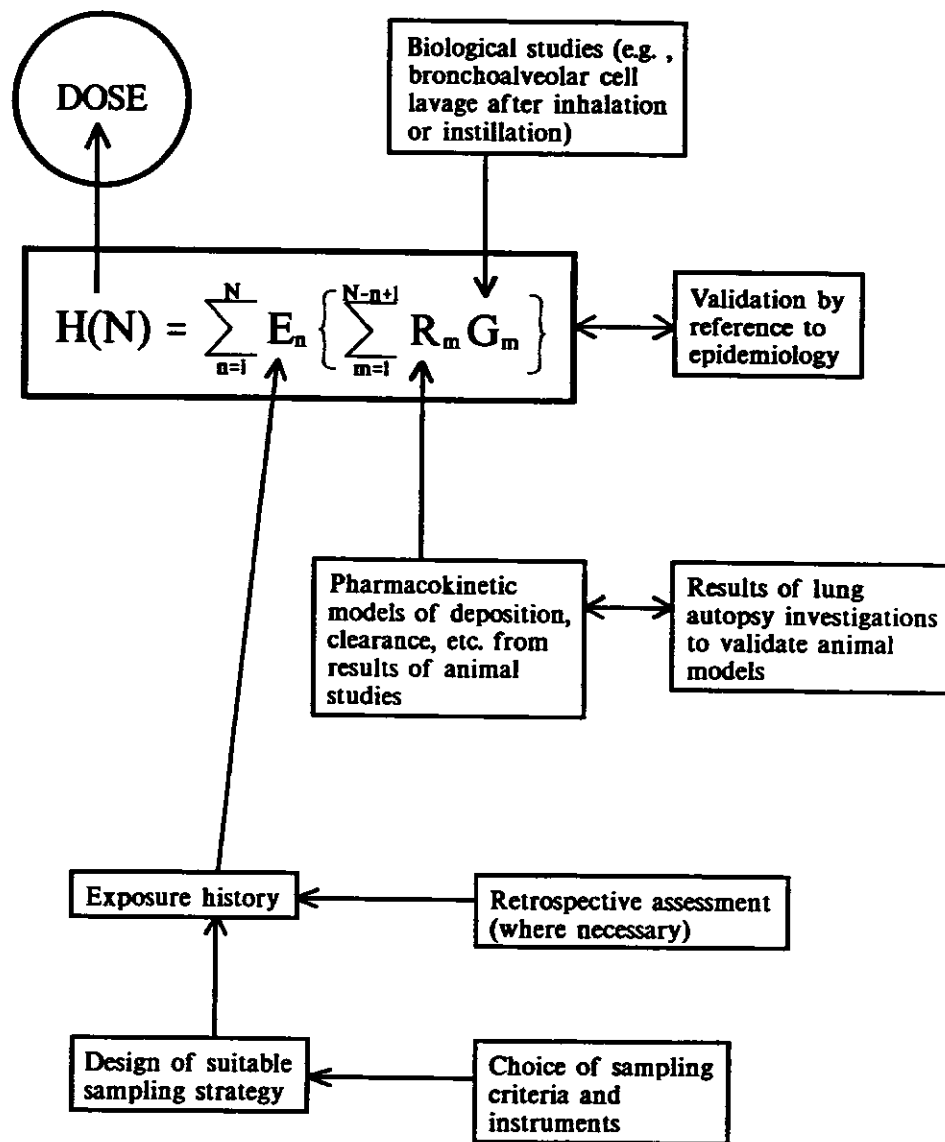


Figure 4. Summary of the rationale for the development of a dosimetric model.

place exposures. Some such studies are in progress. Having once established the working hypothesis, the next step is to validate it with respect to epidemiology for working populations whose exposure and occupational histories are sufficiently well-known. From this scenario, it may therefore be assumed that the emergence of an actual working dosimetric model is still some years away.

The broad benefits of the dosimetric approach to epidemiology have already been mentioned. Notably, as far as epidemiology is concerned, it is anticipated that improved sensitivity (and specificity) and reduced variability in explaining the relationships between the environment and health will be achieved. In turn, improved standards setting, more representative dust sampling strategies, and more effective control procedures (through appropriate worker deployment strategies, technical measures, etc.) will be made possible.

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