Prevalence of Chronic Obstructive Pulmonary Disease (COPD) in non–smokers

COPD is a disease mainly associated with cigarette smoking. However, excesses of COPD, over and above that due to smoking alone, are associated with occupational exposures to dusts and irritant gases/vapours and fumes (DGVFs), and such exposures can also cause COPD independently of cigarette smoking. To fully characterise the excess risk from occupational exposures requires knowledge of the background rates of COPD in populations who neither smoke nor are occupationally exposed to DGFVs. This "background" rate will be influenced by factors such as history of asthma and respiratory infections, and prevalences of relevant genetic deficiencies related to protease inhibitors.

The aim of this report is to summarise what is known about the prevalence of COPD in adult never-smokers who have not been exposed to DGVFs at work (a control or true background prevalence).

This report was prompted by the results of a recently published study of British coalminers (Soutar et al 2004). The dataset underpinning this evaluation is unusually large and robust, deriving from a population of over 7000 British coalminers for whom detailed dust exposure and spirometry data are available for a 20-year follow-up period.

The results of the study indicated that exposure over a working lifetime to 2 $mg.m^{-3}$ of respirable coalmine dust would lead to a deficit of 993 ml in FEV1 in 12% of dust-exposed non-smoking workers. A deficit of this order of magnitude would be consistent with a diagnosis of COPD. However, the results also indicated that such a deficit in FEV1 would be found in 10% of non-dust exposed male non-smokers aged 60 years. This "control" population was derived mainly from above ground workers from the coal industry. A prevalence of 10% seems surprisingly large as an estimate of COPD prevalence for an unexposed non-smoking "control" population. While an absolute risk of COPD of 12% seems large, the excess risk compared to the control group seems small. This leads to difficulty in interpretation of the findings.

Overall, it was considered to be a worthwhile exercise to explore the literature to determine what is known about the prevalence of COPD in non-dust exposed non-smoking males in the 60-70 year age group.

SUMMARY CONCLUSIONS

From the studies available, it appears that the background prevalence of COPD might vary according to geographical location, with a lower prevalence in rural compared to industrialised areas. Overall, an average background prevalence of COPD in never-smoking non-DGVF exposed males aged 60

years is likely to be about 5%, with a range of 0-8%. The “control” prevalence of 10% in the IOM study is outside this range, but not excessively so.

1. Genetic susceptibility to COPD

As discussed in a review by Marsh *et al.* (2000), genetic deficiency of α_1-protease inhibitor (α_1-PI or α1-antitrypsin) is associated with an increased risk for panacinar emphysema. Patients homozygous for the z allele have less than 15% of the normal levels of circulating α_1-antitrypsin. Homozygosity for the z allele is rare; the prevalence within Caucasian populations equates to 1 in1600 for men and 1 in 500 in women. In general, homozygous smokers present with symptoms of emphysema in the third and fourth decades, approximately 10 years earlier than the average COPD patient (45 yr v 57 yr). Non-smokers also show an accelerated decline in pulmonary function. Heterozygous genotypes (1-5% prevalence) are also at an increased risk for COPD particularly those who smoke. The review by Marsh *et al.,* cites a number of other genetic risk factors for COPD as well as listing several candidate genes for risk of emphysema that are under investigation (eg extracellular superoxide dismutase, secretory leucocyte proteinase inhibitor and cathepsin G).

The variation in background prevalence of COPD observed in different studies of non-smoking non-DGVF exposed males aged about 60 years may possibly reflect the influence of differences in genetic susceptibility. However, the studies reviewed in this assessment have not included any information on genetic status.

2. Scope of this assessment

For this assessment studies were located in two ways:

- Studies cited in a review by the American Thoracic Society (2003). Some of these studies used multiple regression analysis to calculate the likely background prevalence of lung disease. These particular studies have not been used in this assessment.
- Other studies were located by a Medline search of the scientific literature reaching back from the present day to the mid-1960s. Search terms such as “COPD”, “chronic bronchitis”, “emphysema”, “prevalence” and “non-smoking” were used.

Overall 12 relevant studies were identified, and summarised in Table 2. It is unlikely that this is a comprehensive capture of all relevant studies but as all of the studies are fairly large-scale population based studies they are considered likely to be sufficient to provide a reasonable estimate of the background prevalence of COPD.

3. Study summaries

3.1 Studies informing on COPD prevalence in unexposed non-smokers

Data obtained during the US Third National Health and Nutrition Examination Survey were analysed for the purposes of investigating COPD (Hnizdo *et al*, 2002). The survey was conducted in adults aged between 30 and 75 years from different regions of the USA.

Investigations included lung function tests, laboratory examinations and a questionnaire covering symptoms, smoking and occupational histories. Subjects were identified as having COPD if they fulfilled the GOLD diagnostic criteria, i.e. had both $FEV_1/FVC<0.7$ and $FEV_1<80\%$ of the predicted value. Among the study population there were 1398 males and 2971 females who had never smoked.

As expected, the prevalence of COPD increased with age. Among the 725 never-smokers aged 50-59 and the 833 never smokers aged 60-75, the prevalence of COPD was calculated to be 5.0% and 6.9% respectively. These sub-groups included workers from a diverse number of occupational sectors, including chemicals and coal industries, where there was potential for exposure to DGVFs.

This study included 170 never-smokers who were judged to be in occupations with no exposure to DGVFs. These were all office workers. The prevalence of COPD in this sub-group was found to be 2.0%. The age-distribution of this sub-group was not reported but if stratification by age had been undertaken then it is likely that the prevalence of COPD would have been higher than 2% in the older ages groups. Overall, from the results available, it can be reasonably concluded that the prevalence of COPD in non-smoking non-DGVF exposed males aged 60 years would be between 2-5%.

Pulmonary function was assessed in a general population study in Tucson Arizona (Lebowitz, 1977). The population sample consisted of 1132 males and 1327 females. Lung function testing was carried out and information on smoking status, occupational history and respiratory symptoms was collected.

In the sample population there were 76 males aged 45 or above who had never smoked and had never been occupationally exposed to DGVFs. In this sub-group, 15.8% had an FEV1 <75% of the predicted value, and 3.9% had an FEV_1/FVC ratio < 0.8. Among the female subjects very few individuals had been occupationally exposed to irritant substances; consequently the effect of this risk factor was disregarded. Of the 521 females aged 45 or above and who had never smoked, 11.3% had FEV1< 75% of the predicted value and 4.8% had $FEV_1/FVC < 0.8$. However, it is unclear what proportions of these non-smoking subjects would merit the diagnosis of COPD according to the GOLD criteria.

The prevalence of COPD was investigated in 488 men and 708 women aged $\geq$65 yrs from a semi-industrialised district of Finland (Isoaho *et al*, 1994). Information on respiratory symptoms, occupational history and smoking status was obtained. Spirometry was carried out and a diagnosis of COPD was

given if FEV_1/FVC was equal to or less than 0.65. Subjects were also medically examined, and if they were unable to carry out spirometry a diagnosis of COPD was given if they had other features of the disease.

In the study population there were 32 male and 166 female never-smokers who had not been exposed to dusts at work. In these two sub-groups the prevalence of COPD was found to be 0% and 2.4% respectively. The small group size of the male sub-group is a major weakness. The diagnosis of COPD did not conform to current international guidelines.

A study in Norway provided lung function data in a population of never-smokers who had not been occupationally exposed to crystalline silica or asbestos (Gulsvik *et al*, 2001). Only individuals who had no respiratory symptoms, such as morning cough, phlegm, breathlessness and wheezing were included in the study. The exclusion criteria may well mean that the results underestimate the true prevalence of COPD in non-smoking unexposed individuals. In this study lung function testing was carried out in 192 men and 288 women aged 18 -73 years.

Population distributions of FEV_1 and FVC were Gaussian in shape, except for FEV_1 in women, which was negatively skewed. In this study both the mean and fifth percentile values of the FEV_1/FVC ratio were calculated for a number of different age groups. For men aged 55-64 (n=16), mean FEV_1/FVC was 0.84 and the 5th percentile value was 0.78. For the 44 women in this age range, mean FEV_1/FVC was 0.81 and the 5th percentile value was 0.71. For the 7 men aged 65-73, mean FEV_1/FVC was 0.81 and the 5th percentile value was 0.78, and for the 39 women in this age range mean FEV_1/FVC was 0.81 and the 5th percentile value was 0.73.

This study suggests that in male never-smokers aged 55 to 73 who have not been exposed to silica or asbestos with no symptoms of respiratory disease, the proportion of individuals with FEV_1/FVC below 0.7 will be smaller than 5%. However the numbers of subjects used to provide these data are small and the exclusion criteria may have led to a bias towards underestimating the true prevalence of COPD in the study population.

Summary of studies informing on COPD in unexposed non-smokers

There are four studies providing results based on lung function data. Of these studies, the study in the general US population had the largest group sizes in the age range of relevance and was the only study that used current internationally accepted criteria for diagnosing COPD. The results suggest that the prevalence of COPD ranges between 2 – 5% in non-smoking non-dust exposed individuals aged 60 years. The other three studies provide broad support for this finding.

3.2 Studies informing on COPD in non-smokers regardless of occupational exposure status

Lundbäck *et al* (2003) carried out a follow up study of a Swedish cohort. Subjects were recruited into the original study, named the OLIN study, from eight areas of Northern Sweden. The occupational profile of the study population was not described in detail, but workers in industry, service and housewives were represented. For the follow-up study a random sample of the participants who by now were aged 61 or 62 years old were interviewed using a modified version of the MRC respiratory symptom questionnaire and subjected to lung function testing. "COPD" was diagnosed either on the basis of having FEV_1 <80% of the predicted value together with FEV_1/FVC <0.7; or on the proportion of subjects with FEV1/FVC <0.7, or on those with FEV_1 < 80% of the predicted value. The results are shown in the table below: -

Table 1: Results from the Lundbäck et al (2003) Study

	Group size	Spirometry findings	Prevalences
Males 61-62 yr	N = 218	FEV_1/FVC < 0.7	6.3%
		FEV_1/FVC < 0.7 AND FEV_1 < 80% of predicted	0%
		FEV_1 < 80% of predicted	3.2%
Females 61-62 yr	N= 226	FEV_1/FVC < 0.7	4.9%
		FEV_1/FVC < 0.7 AND FEV_1 < 80% of predicted	3.3%
		FEV_1 < 80% of predicted	17.1%

The results indicate that the background prevalences of COPD in non-smokers were 3.3% in females aged 61-62 and 0% in males. It seems unlikely that there would have been substantial occupational exposure to DGVFs in the female population of this age category, and the difference between the male and female findings could have been due to chance.

Respiratory function was assessed in 4035 men and women aged 40 - 69 from 7 different regions of Spain (Peña *et al*, 2000). Information on smoking habits and previous diagnosis with asthma was obtained and spirometry performed. Subjects were classified as having pulmonary obstruction if FEV_1/FVC was below 88% for men and below 89% for women. Subjects were diagnosed with COPD if they were found to have pulmonary obstruction that did not reverse on treatment with a bronchodilator.

Among the male never-smokers there were 152 aged 50-59, and 140 aged 60-69. The prevalence of "COPD" in these two groups was 5.3% and 9.3%

respectively. Among the female never-smokers there were 539 aged 50-59, and 556 aged 60-69, with prevalences of COPD of 2.8% and 5.2% respectively. This study is of limited usefulness due to the diagnostic criteria used. However, it can be reasonably inferred that if the more stringent GOLD criteria had been used for diagnosis then the prevalence of COPD in adult never-smokers would have been lower than those reported above.

A cohort study assessing lung function and a number of other health parameters was carried out in a representative sample of the adult population of Great Britain (Cox, 1987). Subjects aged 18 - 65 were recruited into this study, named the First Health and Lifestyle Survey, after being randomly selected from the registers of 396 electoral wards in England, Wales and Scotland. Spirometry measurements were made in a total of 2484 men and 3063 women. Subjects were identified as having “poor lung function” if the measured FEV_1 was 2 or more standard deviations below the predicted value. From the publications available, no details can be found relating to the predicted values (*possibly they were values given by the European Coal and Steel Community*).

In the age group 40-65 the proportions of male and female never-smokers with poor lung function values were found to be 7% and 6% respectively. By comparison, the proportion of subjects in the whole population (irrespective of smoking status) found to have poor lung function was 10% for males and 11% for females. It is assumed that these cases would have fulfilled the criteria for COPD. No information on the number of individuals in these two groups or on the occupational profile of the sample population was provided; hence the potential contribution of occupational exposures to the observed prevalences of COPD cannot be determined from these results.

The prevalence of respiratory symptoms and lung function was assessed in Burbank and Lancaster, two areas of Los Angeles, California (Detels *et al*, 1979). This study was the first of a series of population studies conducted by UCLA to investigate the effect of air pollution on respiratory health. The control population in this study consisted of 2085 males and 2186 females living in Lancaster, an area considered to have low levels of airborne pollutants. Subjects living in the area were identified from census records and were recruited into the study if they were white and aged at least 7 years old with a non-Spanish surname. Symptoms of respiratory disease were assessed on the basis of questionnaire responses, and lung function was assessed by whole body plethysmography and the single-breath nitrogen test as well as by spirometry.

The age-breakdown of the study populations was such that there were about 1000 males and females aged between 18 – 55, and about 350 males and females aged 55 or above. There was some limited information on the occupational profile of the adult study population. Thirty-nine percent of men and 4% of women reported having worked for at least 1 year in occupations

associated with respiratory hazards, such as a miner, welder, sand blaster, cook or beautician. It was reported that 4% of men and 1% of women had changed jobs because of respiratory problems. These subjects were excluded from the analysis, as were subjects who had moved house because of respiratory problems. Among the adult study population the proportion of never smokers was 31% for men and 51% for women.

In the control population living in Lancaster the proportion of never-smokers aged 60 and above with an FEV1 < 75% of the predicted value was 7.5%, and the proportion with an FVC<75% predicted was 13.4%. In Burbank, the area considered to have higher pollution levels the proportion of never-smokers aged 60 and above who had poor lung function was found to be similar. However, from the way the results were presented it is uncertain what proportion of never-smoking subjects aged $\geq$60 years would have met the GOLD criteria for a diagnosis of COPD, although an upper estimate of 7.5% can be determined.

Summary of studies informing on COPD in non-smokers regardless of occupation

From the studies in this sub-section only the Swedish study used the GOLD definition of COPD. It was found that among never-smokers aged 60, 0% of males and 3.3% of females had COPD based on group sizes of 218 and 226 respectively. In contrast, in a larger scale British survey, among never smokers, it was found that 7% of males and 6% of females aged 40-65 had FEV1 values less than 2 standard deviations below predicted values, implying a higher background population prevalence of COPD in the British study than in the Swedish study. A study in Los Angeles leads to an upper estimate fro the prevalence of COPD in never-smokers of 7.5%.

3.3 Studies in unexposed non-smokers based on previous diagnosis or self-reported symptoms

Viegi *et al (*1991) investigated respiratory symptoms in 1635 adults from a rural area of Italy. Subjects were selected if they were 18-64 years old and had been employed for at least 6 months. Information on respiratory symptoms was collected by questionnaire. Lung function testing was also carried out, but only mean values of FEV_1 and FEV_1/FVC were reported.

The study population included 138 males who had never smoked and had not been occupationally exposed to DGVFs. In this sub-group 4% of subjects reported having chronic cough or phlegm for at least 3 months a year for 2 years or more, although the prevalence of physician-diagnosed COPD was 0%. Mean FEV_1 was 101% of the predicted value, and mean FEV_1/FVC was 0.77. The study population also included 267 females who had never smoked and were not exposed to DGVFs. Two per-cent of this sub-group had chronic cough or phlegm for at least 3 months a year for 2 years or more, and the prevalence of physician-diagnosed COPD was 0.4%. Mean FEV_1 was 96% of

the predicted value, and mean FEV_1/FVC was 0.80. The results from this study suggest a very low (<1%) prevalence of COPD in never-smoking unexposed adults from a rural environment.

A recent US study provided some information on respiratory disease in elderly populations of non-smokers with no previous occupational exposures to DGVFs (Trupin *et al*, 2003).

1001 subjects were recruited into the study after random selection of households in mainland USA, and 1002 subjects were recruited by random selection of households within certain "hot-spot" regions of the USA known to have high age-adjusted mortality rates from COPD. A further 110 subjects were also recruited from these "hot-spots" on the basis of having either COPD or asthma. Information was collected from 889 males and 1172 females aged 55 and 75 during a telephone interview. Subjects were asked about smoking status, occupational history and whether or not a physician had diagnosed them as having COPD.

This study included 589 subjects aged 55-75 who were never-smokers and had not been exposed to DGVFs at work. The proportion of subjects with physician-diagnosed COPD in this group was found to be 8%.

A study of cardiovascular disease provided information on the prevalence of chronic bronchitis in Danish men aged between 53 and 74 years old (Suadicani *et al*, 2001). Subjects were recruited into this study, named the Copenhagen Male Study from 14 companies, and were employed in a range of occupations. In the final part of the study, information on respiratory symptoms, smoking status, lifestyle factors and occupational histories was obtained from 3331 subjects by a modified version of the MRC symptom questionnaire. Chronic bronchitis was defined as having chronic cough and phlegm lasting 3 months or more for at least 2 years. Subjects also had a medical examination.

This study included 1493 non-smokers, and the prevalence of chronic bronchitis in this sub-group was found to be between 6 and 7% (This value was estimated from a bar chart in the study report). This group of non-smokers included subjects who came into contact with DGVFs. However, data were available for a smaller group of 404 non-smokers who were not occupationally exposed to airborne irritants. In this sub-group the prevalence of chronic bronchitis was found to be in the region of 6%.

Summary of studies in unexposed non-smokers based on symptoms and previously-diagnosed disease

A study in Denmark found that 6% of non-smoking unexposed males aged 53-74 reported chronic bronchitis symptoms. A US study that included

subjects from geographical “hotspots” for COPD found that 8% of elderly non-smoking non-DGFV exposed males had a physicians’ diagnosis of COPD. A study in rural Italy found that 4% of non-smoking unexposed males aged 18-64 reported symptoms of chronic bronchitis but 0% had a physicians’s diagnosis of COPD (compared with 0.4% in females). However, the numbers in the age category 50-64 were likely to have been very low. Overall, although only limited data are available, the pattern of evidence is suggesting possible geographical influences on COPD development, with lower risks in a rural environment compared to more industrialised areas. An upper estimate of 8% can be ascertained from these studies as a background prevalence of COPD in non-exposed never-smokers aged around 60 years.

3.4 Studies based on symptoms or previously-diagnosed COPD in non-smokers regardless of occupation

The prevalence of COPD was determined in a large sample of randomly selected Finnish adults intended to be representative of the country as a whole (von Hertzen *et al*, 2000). In this study, named the Mini-Finland Health Survey, there were 7217 subjects aged 30 years and older. 46% of men and 49% of women were aged 55 or over. Respiratory health was assessed from X-rays and lung function tests as well as from a questionnaire. A physician examined individuals with a previous diagnosis of respiratory disease or who reported suggestive symptoms. Cases of chronic bronchitis were diagnosed on the basis of having cough with phlegm production for 3 months a year on consecutive years, and emphysema was diagnosed from physical examination and chest X-rays. No information on the occupational profile of the study population was presented.

The study population included 974 male and 3025 female never-smokers, and the prevalence of chronic bronchitis and/or emphysema in these two sub-groups were found to be 6.5% and 4.5% respectively. Among the entire group of disease cases (including both non-smokers), as expected, mean FEV_1/FVC was found to be lower in the in the subjects who had been diagnosed with chronic bronchitis and/or emphysema than in the other study subjects, but information on the proportion of subjects with poor lung function was not provided.

Chronic bronchitis in ageing men was assessed in a follow-up analysis of a Danish cardiovascular disease cohort study, the Copenhagen City Heart Study (Lange *et al*, 2003). Respiratory symptoms, smoking habits and other lifestyle factors were assessed by questionnaire in 1483 male subjects aged 65 years or older. Subjects were diagnosed as having chronic bronchitis if they self-reported cough and phlegm for at least three months a year for two successive years. Lung function testing was also carried out but the results were not presented in detail. In the study population the proportion of subjects that had been occupationally exposed to dusts and fumes was 28.5%.

From the study report the size of the never-smoking sub-group is unclear, but among never-smokers aged 65 and over the prevalence of chronic bronchitis was found to be 6.7%.

The results of the above two Scandinavian studies suggest a background prevalence of COPD is likely to be no higher than 6-7% in non-smoking males aged about 60 year. However, these studies included men with occupational exposures to DGFVs and so the results may overestimate the true natural background prevalence.

4. Conclusions

A key difficulty for the purposes of this report concerns the ways in which "COPD" has been estimated in the studies available. Prevalences estimated from diagnoses based on symptoms data tend to be higher the prevalences based on spirometry (Table 2). It is the latter that provide the "gold standard" for diagnosing COPD.

From the studies available it appears possible that the background prevalence of COPD might vary according to geographical location, with a lower prevalence in rural compared to industrialised areas. Overall, an average background prevalence of COPD in never-smoking non-DGVF exposed males aged 60 years is likely to be about 5%, with a range of 0-8%.

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Table 2. Estimates of the prevalence of COPD in populations of non-smoking adults

Study (country)	Gender	Age	Number	Exposed to irritants?	Disease criteria used	Disease prevalence
Hnizdo *et al*, 2002 (USA)	M & F	30-75	170	No	$FEV_1/FVC < 0.7$ AND $FEV_1 < 80\%$ of predicted	2.0%
		50-59	725	Yes		5.0%
		60-75	833	Yes		6.9%
Lebowitz, 1977 (USA)	M	≥45	76	No	$FEV_1/FVC < 0.8$	3.9%
					FEV1 < 75% of predicted	15.9%
	F	≥45	521	Yes	$FEV_1/FVC < 0.8$	4.8%
					FVC < 75% of predicted	11.3%
Isoaho *et al*, 1994 (Finland)	M	≥65	32	No	$FEV_1/FVC < 0.65$	0%
	F	≥65	166	No		2.4%
Lundbäck *et al*, 2003 (Sweden)	M	61-62	218	Yes	$FEV_1/FVC < 0.7$	6.3%
					$FEV_1/FVC < 0.7$ AND $FEV_1 < 80\%$ of predicted	0%
					$FEV_1 < 80\%$ of predicted	3.2%
	F	61-62	226	Yes	$FEV_1/FVC < 0.7$	4.9%
					$FEV_1/FVC < 0.7$ AND $FEV_1 < 80\%$ of predicted	3.3%
					$FEV_1 < 80\%$ of predicted	17.1%
Peña *et al*, 2000 (Spain)	M	50-59	152	Yes	$FEV_1/FVC < 0.88$ even after bronchodilator treatment	5.3%
		60-69	140	Yes		9.3%
	F	50-59	539	Yes		2.8%
		60-69	556	Yes		5.2%
Cox, 1987 (Great Britain)	M	40-65	Not reported	Yes	$FEV_1 < 2$ SDs of predicted	7%
	F	40-65		Yes		6%
Detels *et al*, 1979 (USA)	M & F	18-59	Total 1260	Yes	FVC < 75% of predicted	2.2%
					$FEV_1 < 75\%$ of predicted	3.4%
	M & F	≥60		Yes	FVC < 75% of predicted	7.5%
					$FEV_1 < 75\%$ of predicted	13.4%
Viegi *et al*, 1991 (Italy)	M	18-64	138	No	Chronic bronchitis symptoms	4%
					COPD previously diagnosed	0%
	F	18-64	267	No	Chronic bronchitis symptoms	2%
					COPD previously diagnosed	0.4%
Trupin *et al*, 2003 (USA)	M & F	55-75	589	No	COPD previously diagnosed	8%
Suadacani *et al*, 2001 (Denmark)	M	53-74	404	No	Chronic bronchitis symptoms	6%
von Hertzen *et al*, 2000 (Finland)	M	≥30	3322	Yes	Chronic bronchitis AND/OR emphysema	6.5%
	F	≥30	3895	Yes		4.5%
Lange *et al*, 2003 (Denmark)	M	≥65	Not reported	Yes	Chronic bronchitis symptoms	6.7%