

CWP and PMF from a working lifetime exposure to respirable coal mine dust (Althouse *et al.* 1998, Attfield and Seixas, 1995; Attfield and Moring, 1992b; Goodwin and Attfield, 1998; Kuempel, *et al.* 1997, 1995). Whenever overexposures (*i.e.*, excursions above the applicable dust standard) occur, the long-term mean exposure of miners may be increased, thereby causing an upward shift on the exposure-response curve. Such a shift then places these overexposed coal miners at increased risk of developing and dying prematurely from simple CWP and PMF.

The Attfield and Seixas epidemiological study (1995) is the most appropriate to use in estimating the benefit of reduction of overexposures. The authors applied scientific rigor to the collection, categorization, and analyses of the radiographic evidence for the group of 3,194 underground bituminous coal miners who participated in Round 4, 1985–1988, of the National Study of Coal Workers' Pneumoconiosis (NSCWP). Radiologic evidence was carefully collected and analyzed by multiple independent, NIOSH certified B readers to identify stages of simple CWP and PMF. In the targeted population of 5,557 miners, the participating miners (3,280) were similar to the non-participants (2,277) with regard to age at the first medical examination and prevalence of simple CWP category 1 or greater. The non-participants had worked slightly longer, yet had lower prevalence of simple CWP category 2 or greater, than the participants. This study describes the differences among current miners and ex-miners (health-related or job-related) in the relationships between the estimated cumulative exposure to respirable coal mine dust and prevalence of simple CWP category 1 or greater. Such data and relationships were not available in other U.S. studies and non-U.S. studies.

A potential limitation in the U.S. studies is the possible bias in the exposure data, which has been the subject of several studies (Boden and Gold, 1984; Seixas *et al.*, 1991; Attfield and Hearl, 1996). An advantage of the Attfield and Seixas 1995 study (and the earlier studies based on the same data set) is that the larger mines included in these epidemiological studies were shown to have exposure data with relatively small bias (Attfield and Hearl, 1996). Another limitation in exposure data used in the U.S. studies is that the airborne dust concentrations used to estimate individual miners' cumulative exposures to respirable coal mine dust were based on average concentrations

within job category (these average values were combined with data of each individual miner's duration employed in a given job). The earlier U.S. exposure-response studies of miners participating in the first medical survey of the NSCWP (Attfield and Moring, 1992b; Attfield and Hodous, 1992; Kuempel, *et al.*, 1995) relied primarily on exposure measurements from a dust sampling survey during 1968–1969 to estimate miners' exposures before 1970 (Attfield and Moring, 1992a). An advantage of the Attfield and Seixas 1995 study is that, in addition to the pre-1970 exposure estimates, more detailed exposure data were available to estimate miners' exposures from 1970 to 1987, during which the mean airborne concentrations were stratified by mine, job, and year (Seixas, *et al.*, 1991).

The most complete exposure data available are those for coal miners in the United Kingdom (Hurley, *et al.*, 1987; Hurley and Maclaren, 1987; Soutar and Hurley, 1986; Marine, *et al.*, 1988; Maclaren, *et al.*, 1989). These studies include medical examinations and individual estimates of exposure for more than 50,000 miners for up to 30 years. The U.S. studies are consistent with these U.K. studies in demonstrating the risks of developing occupational respiratory diseases from exposure to respirable coal mine dust. These risks increase with increasing exposure concentration and duration, and with exposure to dust of higher ranked coal. The QRA and associated benefits for this rulemaking were based on the Attfield and Seixas (1995) study because, in addition to the advantages described above, it best represents the recent conditions experienced by miners in the U.S. The QRA, Significance of Risk discussion, and Benefits estimates follow in Sections VI, VII, and IV (a)(2), respectively. The international studies provide an important basis for comparison with the U.S. findings, and several of the recent international studies are described in detail here.

Bourgard, *et al.*, (1998) conducted a 4-year study of a group of French coal miners who were employed in underground and surface mines. The investigators examined the prognostic role of cumulative dust exposure, smoking patterns, respiratory symptoms, lung CT scans, and lung function indices for chest x-ray worsening and evolution to simple CWP and PMF. Bourgard, *et al.*, (1998), through selection of a younger worker population (*i.e.*, 35–48 years old at start of study), attempted to focus on the early stages of simple CWP. In essence, they hoped to identify those miners who

needed to be relocated to less dusty workplaces or who needed to be clinically monitored. Bourgard, *et al.* (1998) found a significant association between cumulative dust exposure and what was termed chest x-ray "worsening" (*i.e.*, increase in reader-designated category signifying progression of simple CWP). In addition, they found that miners with pneumoconiosis, wheezing, decreased lung function, and high cumulative dust exposure at the first medical examination were those most likely to show worsening on their chest x-rays four years later.

Love, *et al.* (1997, 1992) reported on occupational exposures and the health of British opencast (*i.e.*, surface or strip) coal miners. They studied a group of approximately 1,200 miners who were employed at sites in England, Scotland, and Wales. The mean age of the men was 41; many had worked in the mining industry since the 1970s. To determine dust exposure levels, full-shift personal samples were collected. Most were respirable dust samples which were collected using Casella cyclones according to the procedures described by the British Health and Safety Executive (HSE). Thus exposure determinations would be comparable to exposure determinations obtained in U.S. surface coal mines since both measure respirable dust according to the British Medical Research Council (BMRC) criteria.

These investigators found a doubling in the relative risk of developing profusion of simple CWP category 0/1 for every 10 years of work in the dustiest jobs in surface mines. These respirable coal dust exposures were under 1 mg/m³. Love, *et al.* (1992, 1997), like other investigators, emphasized the need for monitoring and controlling exposures to respirable coal mine dust, particularly in high risk operations (*e.g.*, drillers, drivers of bulldozers).

Meijers, *et al.* (1997) studied Dutch coal miners who were examined between 1952 and 1963, and who were followed until the end of 1991. They reported an increased risk of mortality from simple CWP and PMF among miners who had generally worked underground for 20 or more years. Their conclusions were based upon dramatic increases in standardized mortality ratios (SMRs). There were several limitations in this study, however.

Morfeld, *et al.* (1997) published a recent paper that investigated the risk of developing simple CWP in German miners and addressed the occupational exposure limit for respirable coal dust in Germany. Their study included