13 RISK CHARACTERIZATION

13.1 HEALTH EFFECTS EVIDENCE

13.1.1 Epidemiological Evidence

The data on the health effects of particulate matter have been examined in animal toxicity studies, controlled human exposure studies, and human epidemiology studies. By far the most compelling evidence for adverse health effects of airborne particulate matter at currently experienced levels in the atmosphere has come from the epidemiological studies. These have the advantage of providing indications of the potential for impact on public health of exposure to particulate matter and other air pollution. Many of these studies have used large administrative databases that enhance the objectivity and measurability of the endpoints. Increases in all-cause mortality in 43 regressions carried out in 20 cities across North and South America and Europe were significantly associated with daily or short-term (several days) variations in particulate matter, as PM_{10}, British Smoke Shade or Black Smoke (BS), $PM_{2.5}$, or sulphate (SO_4^{2-}). The magnitude of the mortality risk for PM_{10} was small (in relative terms, but not in absolute numbers of persons affected), varying between 0.4 and 1.7% per 10 µg/m^3 increase in PM_{10}, with a mean of 0.8% and a median also of 0.8% (n=23), for a wide range of mean concentrations (28 to 115 µg/m^3). For the fine fractions, $PM_{2.5}$ and BS, the mean relative risks of death for an increase of 10 µg/m^3 were also elevated, at 1.5% for $PM_{2.5}$ (n=9) and 1.0% for BS (n=6). For the fine sulphate fraction, one study provided an estimate of 2.2% increase in mortality per 10 µg/m^3 increase in SO_4^{2-}.

As was the case with the acute mortality results, increased hospitalizations in almost all studies (n=26) were shown to have significant associations with daily increases in particulate matter of some kind. The relative risk of increases in respiratory hospital admissions for a 10 µg/m^3 increase in PM_{10} was between 0.45 and 4.7% with a median of 1.7% (n=16). These effects were observed at PM_{10} mean concentrations between 25 and 53 µg/m^3. BS, a somewhat smaller particle than PM_{10}, was associated with respiratory hospital admissions in six of eight studies. The relative risk varied from 0.4 to 12.3% for mean BS levels between 12.7 and 75 µg/m^3. Despite the two negative studies, and the few number of studies in which BS was regressed with other co-occurring air pollutants, the weight of evidence suggests some independent association of BS with respiratory disease. Results for directly measured $PM_{2.5}$, available only for Toronto and Montréal in three analyses, demonstrated positive associations with respiratory admissions, with relative risks (univariate analyses) of 2.5 to 9.6% for a 10 µg/m^3 increase in $PM_{2.5}$. Sulphate was associated with respiratory admissions in all eight studies that examined this measure of particulate matter, with increases of 2 to 9% for a 10 µg/m^3 increase in SO_4^{2-}, at mean concentrations between 3.3 and 11.9 µg/m^3. SO_4^{2-} appears to be a good surrogate for fine particles from combustion sources. A 2.7% increase in respiratory admissions per 10 µg/m^3 increase in SO_4^{2-} (co-regressed with ozone) was indicated in southern Ontario in the best conducted study of the series of eight examined (Burnett et al.,1994, 1995). This was calculated to be equivalent to a 1.1% increase (95% CI 0.7 to 1.5%) per 10 µg/m^3 $PM_{2.5}$, based on site-specific monitoring and conversion factors.

Effects on lung function and respiratory symptoms, although much less serious health consequences than hospitalizations or most certainly than mortality, have the potential to have an impact on a much greater fraction of individuals in the population than the effects resulting in hospitalizations or death. Most studies dealt with children; the evidence is clear that both normal and symptomatic or asthmatic children are affected by air pollution, with increases in respiratory symptoms such as cough or wheeze and/or small reductions in lung function in association with short-term increases in particles (Hoek et al., 1990; Johnson et al., 1990; Pope et al., 1991; Vedal et al., 1991; Pope and Dockery 1992; Roemer et al., 1993; Schwartz et al., 1994; Peters et al., 1996). There was some evidence in one study that children with pre-existing symptoms of respiratory disease (such as wheezing or chronic coughs) were more adversely affected by air pollution than normal or non-symptomatic children; the symptomatic children had lower lung capacity or function to begin with, and their lung function/capacity was more adversely affected than normal or non-symptomatic children (Pope and Dockery, 1992). Asthmatic adults also were affected by increases in daily or short-term particle levels, with decreases in lung function (Peters et al., 1996) and increases in respiratory symptoms (cough, etc.) (Ostro et al., 1991; Pope et al., 1991; Perry et al., 1993; Peters et al., 1996) mostly in association with fine particles.

Days absent from school in children (Ransom and Pope 1993) and respiratory-related activity restrictions in adults in several US cross-sectional studies (Ostro 1987, 1990; Ostro and Rothschild 1989) have also been found to be increased in periods with high particulate matter air pollution; increases of 2.8 to 16% in reduced activity (for example remaining indoors) were associated with increases of 10 µg/m^3 in fine particles or SO_4^{2-}. This latter has implications for the economic cost of particulate matter air pollution with respect to the potential for days lost to work.

The results, particularly for mortality and hospitalization data, but also for some lung function and respiratory symptom studies, were highly consistent under differing PM exposure conditions. These associations could not be explained by the influence of weather, season, yearly or daily variations, or other non-pollutant factors.

Most of the mortality and hospitalization analyses examined one or more air pollutants in addition to particulate matter, whose independent association with mortality remained remarkably stable and consistent, despite the problems of disentangling its effects from the other air pollutants SO_2, NO_2, CO, and ozone.

Moreover, in all except a few locations, the magnitude of the PM association was greater than any other air pollutant considered. The independence, consistency, robustness and magnitude of the PM association across so many locations with differing air pollutant mixtures supports the position that particulate matter of some kind is the best indicator of the air pollution effect on mortality, although effects due to (an)other independently acting air pollutant(s), notably ozone, are also likely in some locations.

There is no clear evidence of a "threshold" level for the positive associations between particulate matter and both daily mortality and hospitalization rates. That is, any increase in ambient particulate matter is associated with a statistical increase in mortality and hospitalization rates. While these endpoints have been emphasized because of their ability to provide some measure of quantifiability, they are only the tip of the iceberg with respect to other adverse health effects including exacerbation of respiratory symptoms such as bronchitis, reduced lung function, restricted activity due to illness, loss of workdays or school absences, and increased costs for medication. These particulate matter-adverse health associations are observed at concentrations currently occurring in Canada, which are low by comparison to international standards or to the concentrations observed in pollution episodes in the 1950's and 1960's in which thousands died.

13.1.2 Experimental Human Evidence

Overall, the clinical data do not lend much support to the observations in the epidemiological studies. Relatively few studies are available, and most have been done using acidic aerosols. None of the human clinical studies have used particle generation systems that reflect the complexity of ambient particles. Responses to acidic particle exposures of both normal and asthmatic individuals show considerable intersubject variability in response. Changes in lung function, mucociliary clearance, and airway reactivity have not been seen in normal subjects at ambient concentrations of acidity or acid sulphate or nitrate aerosols. Asthmatic individuals, especially asthmatic children and adolescents, appear responsive to lower concentrations of acidic aerosols, with different threshold concentrations resulting in bronchoconstriction and small decrements in lung function. Conclusive evidence of enhanced responsiveness in the elderly, or in individuals with chronic obstructive pulmonary disease (COPD) is not available. Little evidence of dose-response relationships can be found in the clinical toxicologic literature. The two major reasons for the lack of support by the clinical studies for the findings of the epidemiology studies are the extreme paucity of data on relevant exposures, and the ethical impossibility of investigating effects in precisely those persons most likely to be affected by air pollutants.

13.1.3 Animal Toxicology Evidence

Most animal toxicology studies of particles deposited as aerosols or by the intratracheal instillation route have involved exposures to single materials. Previous particulate matter reviews have focussed on the toxicology of sulphate aerosols. Acidity, particle size, the anionic component and age of the experimental animal were factors determining a bronchoconstrictive effect. The recent evidence reviewed in this document shows effects on the lung attributable to a particle effect, separate from effects related to the composition of the particle.

Acute exposures of laboratory animals to a variety of types of particles, almost always at concentrations well above those occurring in the environment, have been shown to:

- cause decreases in ventilatory function;
- affect mucociliary clearance;
- increase alveolar macrophages and polymorphonuclear leukocytes in the alveoli;
- cause alterations in immunologic responses (particles with known cytotoxic properties, e.g., metals, affect the immune system to a significantly greater degree);
- alter the lung's defence mechanisms against microbial infections (appears to be related to composition and not the particle effect);
- increase or decrease the ability of macrophages to phagocytize particles (related to composition);
- cause a range of histologic, cellular, and biochemical disturbances, including the production of proinflammatory cytokines and other mediators by the lung's alveolar macrophages, (may be related to particle size, with greater effects occurring with ultrafine particles);
- cause increases in mortality (related to chemical composition and to the susceptibility of the host animal).

The most likely particle types to induce acute adverse effects include metals, organics, acids, and acidic sulphates of the fine particle mode, possibly occurring as coatings on fine or even ultrafine carrier particles.

Subchronic and chronic exposures to some types of particles at mass concentrations > 1mg/m^3 result in significant compromises in various lung functions similar to those seen in the acute studies, including in addition:

- reductions in lung clearance;
- induction of histopathologic and cytologic changes (regardless of particle type, mass concentration, duration of exposure or species examined);
- production of chronic alveolitis and fibrosis.

Evidence for particle-induced pulmonary carcinogenicity in the animal studies indicates that high levels of essentially any particle type will cause lung tumours in rats, although the particle effect is very unspecific.

The interpretation of results from experimental particle inhalation studies in animals and their significance for human exposures involves considerable uncertainties. These uncertainties relate to dosimetry of the respiratory tract, differences in the sensitivities of specific target cells, differences in cell populations in the individual airway generations of animal species, differences in metabolic activity of lung cells, and differences in the lifespan between laboratory animals and humans. Therefore, the animal studies contribute primarily to an understanding of the mechanisms which lead to particle effects in humans rather than to quantitative estimates of human health risks.

13.2 POPULATIONS AT RISK

It has been hypothesized that the observed association of PM with adverse health effects on a population basis, may be due to exacerbation of pre-existing conditions, or it may be an enhanced response of a sub-population of sensitive individuals. The epidemiology data appropriately identifies the same susceptible population as would be expected clinically, however, no exposure patterns for these susceptible groups are available. While many studies have investigated the status of persons with asthma in relation to air pollution exposure, surprisingly few have addressed the other groups. Much of the evidence on particulate exposure is based on studies of community samples, particularly children who can be readily reached through schools. It should be noted that designing either human clinical studies or animal studies to address the issue of exacerbation of disease states, is very difficult.

13.2.1 The Elderly

The relative risk of increased mortality due to air pollution has been shown to be elevated for the elderly as compared to younger adults. In Santiago, the RR for total mortality was increased from 1.07 for adults <65 years, to 1.10 for those >65 y, or an age-related increase of about 3% per 100 µg/m^3 PM_{10} (Ostro et al., 1996). In the re-analysis of the Philadelphia TSP data by Samet et al. (1995), the association between mortality and TSP was not significant for persons <65 years, but was for those over 65.

This finding replicates the original findings of Schwartz and Dockery (1992) who showed that the RR rose to 1.095 for the elderly $\geq$ 65 years, compared to 1.027 (only marginally significant) for those less than 65 years (Schwartz and Dockery 1992). Schwartz (1994) presents a very clear analysis of the relationship between age and untimely mortality associated with particle exposure by comparing the impacts of the London fog episode in December 1952 to the findings from Philadelphia. Daily pollutant levels were about ten times lower in Philadelphia than during the London fog episode. The results were qualitatively similar for the elderly. Relative risks in London were significantly elevated for all 10-year age groups above 35, while in Philadelphia the RR was significant only for the two age groups 65-74y and 75+ years. However, in Philadelphia, a marginal elevation in RR began to be evident for age groups 45+ and 55+. A recent study examining mortality and both PM_{10} and BS in Amsterdam showed an increase in RR spanning 1.19 for adults < 65 years to 1.26 for those $\geq$ 65 years, using the BS metric. Increased risk of mortality was not so evident using the PM_{10} metric, due to reduced availability of ambient PM_{10} data points (Verhoeff et al. 1996). One of the only analyses that found no apparent effect of particulate air pollution (as BS) on mortality in the elderly was that of Sunyer et al. (1996) in Barcelona Spain, although some effect was observed for the gaseous pollutants NO_2 and O_3. Although the percentage of excess deaths for total and cardiovascular mortality was lower for the elderly $\geq$ 75 years than for younger persons, it was slightly higher for respiratory mortality in Athens (Katsouyannis et al., 1990).

13.2.2 Infants and Children

The London fog episodes of particulate and sulphur oxide pollution did not indicate that children other than very young infants $\leq$ 1 year were at higher risk of mortality than other age groups in the population, although the pollution levels were very much above what would be encountered today. In comparing the mortality experience of Philadelphia to London, Schwartz (1994) did not find a comparable rise in mortality for the under one-year age group, but he did note a significant elevation for 5-12 year olds, which was ascribed to increased outdoor exposure for this age group in Philadelphia. Young children were not found to have an elevated risk for respiratory mortality associated with exposure to PM_{10} in Sao Paulo Brazil, although an elevated risk was observed in the elderly in the same city. On the other hand, studies on less serious outcomes including hospitalizations, doctors' visits, lung function, and respiratory symptoms suggest that younger children may constitute a sensitive subpopulation (Raizenne et al., 1989, 1996). Adolescent asthmatics were found to be more sensitive than adult asthmatics to acid aerosols, and to respond to concentrations of acid aerosols that were an order of magnitude lower than those causing a response in normal subjects (Koenig et al., 1989). It is possible that children are more susceptible to particulate matter air pollution because of their activity patterns which often include more outdoor exposure than would be the case for adults.

13.2.3 People with Pre-existing Respiratory or Cardiovascular Disease

People with asthma and COPD have long been considered particularly susceptible to air pollution exposure. Unfortunately, the effects of exposure to particles, and other environmental pollutants, on respiratory diseases such as asthma, are not well understood. The increased airways responsiveness of the asthmatic enhances responses to environmental pollutants, in contrast to the non-asthmatic without increased responsiveness. It is possible that inhalation of allergenic particles (pollen, fungal spores, etc.) may lead to hypersensitivity reactions expressed as allergic rhinitis or asthma. In controlled exposure studies, adult asthmatics have not generally been shown to respond to particulate air pollution with reductions in lung function and increased respiratory symptoms unless concentrations were above about 200 $\mu g/m^3$ (Utell et al., 1983). However, adolescent asthmatics are more sensitive than adults, responding in clinical studies at concentrations as low as 68 $\mu g/m^3$, in the same range as ambient concentrations (Koenig et al., 1989). Although the mortality and hospitalization studies are not very informative on who is at increased risk, some acute and the long-term panel and cohort studies confirm that asthmatics are more susceptible to particulate pollution than normal individuals (Dockery et al., 1989; Abbey et al., 1996).

Animal models of pre-existing lung disease indicate that particle deposition is reduced with chronic bronchitis, emphysema and fibrosis. Recent work on animal models with pre-existing disease showed that in bronchitic rats exposed for three days to concentrated air pollution (at 250-270 $\mu g/m^3$), mortality was observed in 37%, compared to no mortality in control normal rats exposed to those concentrations.

Pathological findings in the bronchitic rats included airway inflammation, bronchoconstriction, pulmonary vascular congestion, and a doubling of pulmonary neutrophils (Godleski et al., 1996). This is one of the first examples of an animal model that could explain the rapid mortality associated with increased particulate matter seen in many epidemiology studies.

13.3 THE WEIGHT OF EVIDENCE REGARDING THE ROLE OF PM

The best evidence that particulate air pollution is causally associated with cardiorespiratory illness is provided by the mass of epidemiological data. These point to a "pyramid of effects" headed by increases in mortality and in hospitalizations for cardiorespiratory diseases, and progressing downward to decreases in lung function in children and in asthmatic adults, increases in respiratory symptoms that can lead to increases in respiratory-related activity restrictions and days lost from work or school, and long-term or chronic effects including reduced survival, reduced lung function and capacity in children, and increases in development of chronic bronchitis and asthma in some adults.

These studies were conducted under a broad range of environmental conditions in many cities on three continents, by a number of different investigators. They nonetheless displayed a remarkable degree of consistency of effects and coherence between different endpoints.

Although the epidemiology studies are observational and population-based studies rather than experimental, and as such do not provide mechanistic evidence, they have been weighted more heavily than the animal toxicology or controlled human chamber studies for several reasons:

- they are the most direct way of assessing the adverse health outcomes of "real world" complex mixtures of pollutants to which people are exposed;
- human populations, unlike laboratory animals, are highly heterogeneous, including individuals who encompass a large range of susceptibilities, disease status and exposures, and whose responses cannot be predicted from classical toxicology studies;
- population studies based on large administrative databases (for example the hospital admissions study in southern Ontario based on a population of 8.7 million people) can demonstrate the impacts of pollution on public health, and possibly even to enable some partial estimate of the costs to society;
- no extrapolation is necessary when assessing the effects on public health of a particular concentration of air pollutant or of an ambient air objective, as measured by the ambient monitoring network, despite our lack of knowledge about the exposure of each individual in the population. We need only know that the correlation is reasonable between the ambient monitor and the personal exposure.

In evaluating the epidemiology studies as a whole, many issues arise, key among them being that of causality. While it is generally accepted that statistical associations drawn from well-conducted randomized experimental studies (animal or human) provide the strongest evidence for causal relationships, little evidence is available from non-epidemiology studies to support or refute a causal relationship based on the associations observed in the epidemiology studies. Observational study designs (case-control study, cross-sectional study or survey, ecologic study and the cohort study) are used to investigate the consequences of exposure in epidemiology studies. Associations found in a particular study may reflect chance, bias, or cause; rarely does a single study provide evidence of an association that is sufficiently compelling to conclude that the association is causal. Uncontrolled bias is a frequently invoked explanation for associations found between air pollution exposure and health. The findings of epidemiologic studies of air pollution and health need to be interpreted within the context set by our understanding of mechanisms of disease pathogenesis, relevant toxicologic evidence, and the findings of other epidemiologic studies.

Some uncertainties in the evidence of a causal relationship in the observed association between adverse health impacts and increases in airborne particles include:

- lack of an accepted biologically demonstrated mechanism;
- lack of quantitative support from experimental animal and/or human clinical studies;
- difficulty in discerning what, exactly, is the toxic moiety;
- confounding, and difficulty of separating out the effects of other co-occurring pollutants;
- problems of misclassification of personal exposure to ambient particles;

- dependence on ecological or community-based exposures, including analytical studies;
- uncertainty regarding the appropriate pollutants to include in statistical modelling.

The lack of an unaccepted biological mechanism for particle-induced effects is on the way to being resolved (see later sections of this Chapter), particularly since there is good biological plausibility for the observed association. The limited quantitative animal and/or human experimental data is also being resolved through the search for demonstrated mechanisms of action, especially in the animal studies. With respect to the clinical studies, more work is needed on actual air pollutant mixtures with the gases. However, clinical studies may never be able to provide complete answers due to the moral and ethical barriers that must remain (see Section 13.1.2).

The problem of deciphering which of the many types of particles is responsible for the associated adverse health effects is a difficult one, due to several factors, not least of which are the high correlations between different particle metrics. Within the past few years, several large, well-conducted studies have been published that support the hypothesis that some form of fine particle metric is more closely associated with respiratory illnesses than the larger particles. However, the larger particles have not been eliminated from consideration, particularly for associations with certain endpoints such as cardiovascular disease. The difficulties with establishing which particle(s) are responsible may be caused by the nature of the etiological agent(s). In the end, it may prove to be several particle metrics, or even that particles do not act alone but in concert with other pollutant gases.

One of the most difficult questions has been, and continues to be, the role played in the toxicity of particulate matter by other gaseous pollutants. Many available studies simply did not, or could not, consider several of these co-occurring gaseous pollutants. Moreover, they are often highly correlated with particulate matter which makes separation of the effects virtually impossible in many locations. Only one or two of all the available mortality and hospitalization studies examined all four gaseous criteria air pollutants. On the other hand, the consistencies of the associations in such a large number of studies in different locations with a variety of pollutant mixtures give some degree of assurance that the relationships have not been confounded by the gaseous pollutants.

Misclassification of personal exposure is of concern, although not a serious obstacle, in studies of air pollution and health. Epidemiological studies often rely on a single or several fixed ambient monitors to characterize the pollution level in a given community. Personal exposures to particles have only been weakly associated with outdoor concentrations in some studies. Individual personal exposures are not known, therefore, there is no direct link between individual exposure and individual outcomes (i.e., exposure and effect). However, the epidemiological data considered in this review is observational and not experimental in nature, that is, exposures are based on populations, not individuals. Reliance on area monitors may be an advantage because, as explained in Chapter six, ambient fine particles measured at a central site can serve as an indicator of population exposure. Fine particles < 1 to 2.5 µm are fairly uniform across an urban area and have a slower rate of deposition that leads to more homogeneity. They also penetrate indoors more readily than coarse particles. Consequently, the associations between fixed monitoring measurements and health outcomes on a population basis may be reflecting a fine particle effect. Therefore, on a population basis, the adverse health effects are associated with concentrations measured at the central site ambient monitors. Personal exposure is not misclassified; the personal exposure data is lacking, though error in exposure estimates generally leads to an underestimation both of risks and of their statistical significance.

The criteria first proposed by Bradford Hill (1965) and modified by succeeding epidemiologists have been used here to provide a framework for considering the epidemiological data with respect to possible causality of association between particulate matter and adverse health.

Probability *(demonstration of a statistical relationship)*

Recent concerns about adverse effects of particulate air pollution on health largely reflect the publication, since 1990, of a large series of analyses based in part on ecologic analyses of routinely collected administrative data. Results show positive associations, often highly statistically significant, between daily mortality rates in urban areas and various measures of particle concentrations, including TSP, PM_{10}, $PM_{2.5}$, BS, and SO_4^{2-}. Various measures of morbidity, including hospitalizations, lung function decrements, increases in symptoms such as chronic cough, restricted activity, days of work lost and school absences have also demonstrated associations with high ambient particulate matter, in some cases PM_{10}, and in others $PM_{2.5}$, or other fine particle measures (BS or SO_4^{2-}). This health evidence has been more extensively reviewed in Chapter 12.

Strength of Association *(relative risks; weak relationships are susceptible to confounding and may reflect a poor measure of exposure or outcome)*

Estimates of the effect on mortality (per 10 µg/m^3 rise in PM) are on the order of 0.4 to 1.7% increase for PM_{10}, mean 1.5% increase for $PM_{2.5}$, and 2.2% increase for SO_4^{2-}. The effect on hospitalization for one or more respiratory endpoints varied between 0.45 and 4.7% per 10 µg/m^3 increase in PM_{10}. The respiratory sub-categories' COPD and pneumonia hospitalizations for the elderly ($\geq$ 65 years) were also significantly associated with PM_{10} (2 to 5.7% for COPD and 1.1 to 1.9% for pneumonia, both per 10 µg/m^3). The increased risk for hospitalizations due to COPD was higher (4.0%) than the overall increase in risk (3.7%) for all respiratory diseases in all age groups. Sulphate has a strong association with respiratory hospitalizations, on the order of 2.0 to 2.7% increase which is equivalent to a 0.7 to 1.1% increase per 10 µg/m^3 increase in $PM_{2.5}$. As expected, $PM_{2.5}$ and SO_4^{2-} appear to be more potent than PM_{10} in inducing mortality and morbidity. Particulate matter was shown to have associations with cardiovascular disease hospitalizations but the magnitude of the associations was generally smaller than those for respiratory-related hospitalizations. Exacerbation of asthma, increases in respiratory symptoms, and lung function decrements tended to be slightly larger.

Although the magnitudes of these estimates, or increased risks, are seemingly small and unimportant, they represent large numbers of people, since most of the population is exposed, and serious public health impacts.

Consistency *(Has the association been repeatedly observed by different persons, in different places, circumstances and times?)*

Mortality: The results of these studies have been remarkably consistent in indicating a positive association between particulate air pollution and daily mortality. These associations were seen in 43 analyses in 20 cities across North America, South America, England and Europe. Additional sites found these relationships with the particle metric TSP, not considered here. The US cities included in the analyses range from large metropolitan areas, e.g., New York City and Philadelphia, to smaller cities with polluting industry, e.g., Steubenville and Utah Valley. The estimates of the effects have been similar, in spite of the problems of misclassification of personal exposure to ambient particles, and different health care systems. While most of the studies used the time-series analysis, widely differing applications were employed, with similar results.

Morbidity: The animal studies clearly show effects on the lung resulting from the inhalation of particulate matter, effects that can be attributed to a particle effect rather than to the inherent chemical toxicity of the particle. The epidemiology research has used diverse study designs to examine the association between morbidity and PM, including time-series studies, cross-sectional studies, short-term cohort or "panel" studies, and longer-term cohort studies. The array of health outcomes considered in these studies is equally diverse. Significant associations for particulate matter and respiratory hospitalizations were demonstrated most studies examined. Regression modelling indicated adverse effects of particle exposure on lung function level in children and adults, increased respiratory symptoms and medication use, restricted activity days, and increased frequency of reported chronic respiratory disease (Ostro and Rothschild, 1989; Schwartz, 1993). Consistent associations between fine particle air pollution, as SO_4^{2-}, and increased hospital admissions due to cardiovascular diseases have also been reported in Canada and in the US.

Thus, the epidemiological studies do provide evidence of a consistent association between exposure to particulate matter and several of these critical health outcomes.

Specificity of effect *(precision of the association between particles and adverse effects – does X lead only to Y)*

Evidence shows that particulate air pollution-related increases in both mortality and hospitalizations are associated with respiratory effects. Asthma, COPD, and pneumonia or other upper- and lower-respiratory infections are sub-categories of respiratory disease that also have positive associations with particles. Some investigators included non-respiratory categories in their analyses as controls, and found no positive associations. Several studies also found associations with cardiovascular disease (both mortality and hospitalizations) although of weaker magnitude than the respiratory-related associations. Overall, the evidence is considered strong regarding the specifity of effect to respiratory and cardiac outcomes.

Specificity of cause *(– does only X lead to Y)*

With respect to specificity of the agent, the evidence for particulate matter as the causal agent, as opposed to certain gaseous pollutants, is strong in the majority of studies. Although the associations have been observed in a wide range of locations, with differing mixtures of air pollutants, the relationship between PM exposure and effect has been quite consistently positive. The evidence is further discussed below in the section on confounding. The question of which particle metric remains unsettled, but current evidence suggests that some form of fine particles, less than or equal in size to 2.5 µm, is the best predictor of adverse health outcomes.

Temporal Relationship *(Is the exposure followed by the effect?)*

Most investigators have examined the lag time between pollution peaks and onset of effects, some even investigating “reverse lag”, or several days prior to the episode to ensure that the time sequence was correct. Daily peaks of particulate matter were followed within 24 hours to several days by untimely mortality, hospitalizations, lung function changes and respiratory symptoms. Thus, the time pattern of exposure and effect adds to the coherence of the picture, except for the rapidity of the effects on mortality.

The lag period for mortality was surprisingly short, being less than 24 hours in a number of studies. This has created some problems in trying to explain what mechanism could be responsible for these sudden deaths, since not enough time would have elapsed for sufficient tissue damage to account for mortality to occur, nor for infections to have progressed to this stage so rapidly unless there were an acute coronary artery spasm and subsequent massive myocardial infarction (see Chapter ten).

Concentration – Response Relationship *(observation of a gradient of risk associated with the degree of exposure)*

Lack of an observed threshold, with responses increasing monotonically from very low ambient concentrations up to much higher levels, was observed with remarkable consistency in many epidemiology studies on acute and chronic mortality and hospitalizations. While many of these data sets have been analyzed with regression techniques that assume a linear relationship between the response variable and the predictor variable, a number of the newer studies have been analyzed using non-parametric models that do not assume any particular shape for the dose-response curve. In addition, the sensitivity of the concentration-response relationship in the epidemiological data to alternative analytical techniques has been explored in a number of the newer studies. Results have been shown to be robust to alternative methods of analysis.

The concentration-response curves for mortality and morbidity versus PM_{10} and the fine fraction particle ($PM_{2.5}$ and SO_4^{2-}) concentrations appear to be linear in the majority of mortality and hospitalization analyses in many locations in the US and Brazil (Dockery et al., 1992; Pope et al., 1992; Saldiva, 1995; Schwartz et al., 1996). This linear relationship is supported by American studies using TSP as the metric (Schwartz, 1991; Schwartz and Dockery, 1992a; Schwartz and Dockery, 1992b). Nonparametric smoothing techniques have been applied to data from several of these locations, and have generally confirmed the approximately monotonic concentration-response relationship, at least in the lower exposure range (Schwartz, 1994a; Samet et al., 1995; Schwartz, 1995; Pope and Kalkstein, 1996; Schwartz, 1996; Burnett et al., 1997).

The linear concentration-response model represents only one biologically plausible representation of the relationship between particle exposure and health risk. Alternative models, e.g., curvilinear and threshold, have also been suggested by the data in several studies. In several European locations that included PM_{10} and $PM_{2.5}$ metrics, the concentration-response curve was curvilinear, with a steeper, linear component at lower concentrations and a slight flattening (lower slope) at very high concentrations. This curvilinear response was seen in data from Koln (TSP and PM_7) (Spix et al., 1996), from Erfurt, Germany for undefined large suspended particulate matter (Spix et al., 1993), from Amsterdam, NL for both BS and PM_{10}, (Verhoeff et al., 1996), and from Athens, Greece for BS (Touloumi et al., 1994).

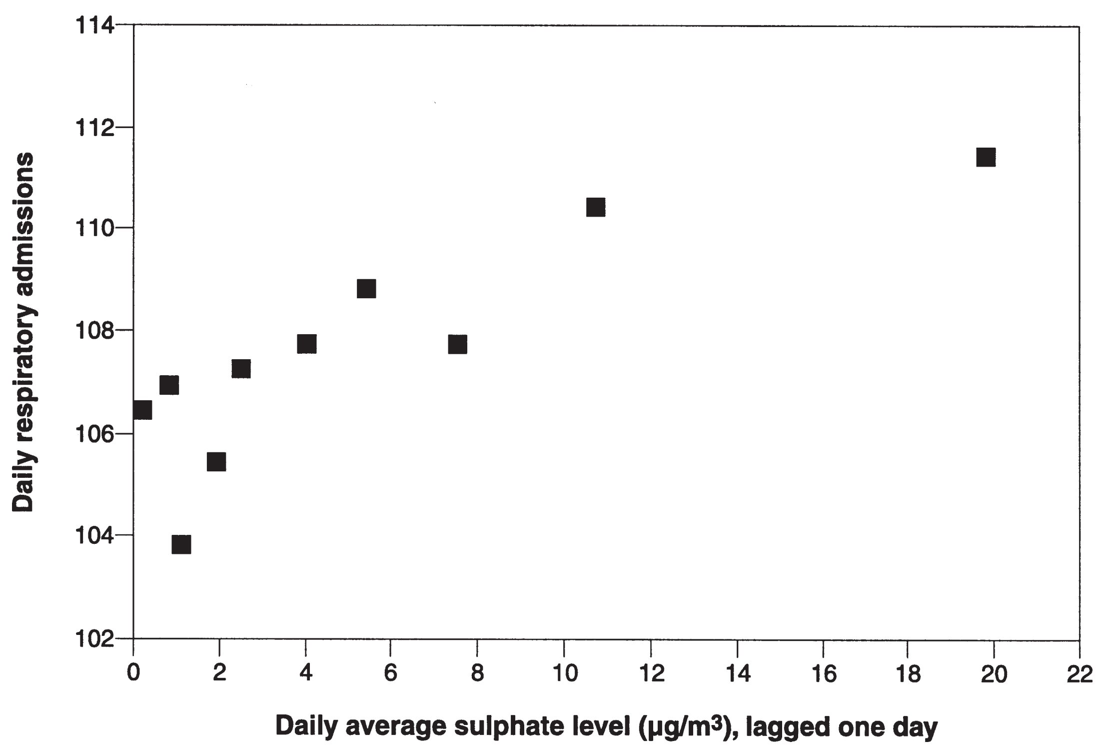
The hospitalization data present a similar picture to the mortality data with respect to the shape of the concentration-response curve. One of the best examples is provided in the study by Burnett et al. (1995) on the association between sulphates and respiratory hospitalizations in southern Ontario (Figure 13.1). The decile curve appears to be slightly curvilinear, and rises monotonically from zero to 20 μg/m^3 of sulphate (lagged one day) without any evidence of a threshold, with a slightly reduced slope at the higher concentrations above about 8-10 μg/m^3. This contrasts with the more obvious linear ozone response in the same study. A threshold for PM_{10} effects was suggested in a re-analysis (by quintiles) and extension of the Utah Valley data by two years (Lyon et al., 1995). The data suggested a 24 hour threshold between 36 and 46 μg/m^3, while the authors suggested 50 μg/m^3. Several other quintile analyses could also be construed as providing support for a weak threshold, due to the low, non-significant relative risks at the lower quartiles or quintiles (Schwartz, 1991; Dockery et al., 1992; Schwartz and Dockery, 1992a,b; Spix et al., 1996). However, overall the data provide much more support for a non-threshold linear or curvilinear response.

In contrast to the epidemiological results, little evidence for a dose-response relationship has been found in the experimental literature despite the fact that the range of particle concentrations used in the human clinical studies usually exceed population exposures associated with the ambient environment. Even at high particle concentrations, acidic aerosols have been found to produce only small decrements in lung function in susceptible subpopulations.

Biological plausibility and possible mechanisms of action

The interpretation of data indicating increased mortality with increased particle concentrations is complex. Studies of extreme particulate air pollution episodes (e.g., the London fog in the 1950s and 1960s) present evidence that high levels of particulate matter are directly associated with increased mortality in the population. The cause of death of these individuals was evident and the role of particles in contributing to the death readily confirmed.

Figure 13-1 Average Number of Adjusted Respiratory Admissions Among All 168 Hospitals by Decile of the Daily Average Sulfate Level (μg/m^3), 1 day Lag.



Source: Burnett et al., (1995).

When evaluating the effects of low level ambient particles, we need to clearly separate acute adverse effects, i.e., mortality and morbidity correlated with daily changes in ambient levels, from chronic effects that reflect long-term exposure to low levels of particulate pollution. Establishing a mechanism for mortality associated with daily variations in particulate air pollution is difficult because of the very short lag period, or in some cases no lag period, between recording elevated particle concentrations and the occurrence of death.

The most clinically relevant links between particulate air pollution and mortality probably relate to exacerbation of severe pre-existing cardiac or respiratory disease, most likely including (1) exacerbation of severe asthma or COPD; (2) increased susceptibility or progression of an acute respiratory infection; (3) worsening of pulmonary edema, due perhaps to either a permeability defect or left ventricular dysfunction; and (4) malignant cardiac arrhythmias. Other hypothesis include “premature” death or harvesting or acute oxidative stress.

In an animal model with bronchitic rats, the bronchitic animals were shown to be extremely sensitive to low doses of freshly concentrated ambient particles by comparison to healthy animals, and died after a few days’ exposure. This model of pre-existing disease fits the hypothesis that particulate air pollution, even at low ambient levels, is affecting individuals who have already compromised health. However, in considering the mechanisms by which low concentrations of inhaled particles could lead to mortality, there are uncertainties.

Particle dosimetry in the respiratory tract is an excellent starting point for discussions of biological plausibility, as it addresses key issues from a perspective independent of specific particle composition. When different ventilatory regions of the lung are compromised in pre-existing conditions such as asthma, COPD or congestive heart failure with respect to their ventilatory capacity, those regions of the lung that are still healthy can receive a disproportionately high dose of particles. This, in turn, places those remaining healthy regions at even greater risk by further compromising the lungs’ reserve capacity. An increase in ambient particle concentrations of 20-40 µg/m^3 would translate into relatively small increases in peripheral lung particle deposition. From a pathophysiological perspective, it seems unlikely that such particle concentrations could worsen ventilation-perfusion ratios in a healthy or injured lung to the point of producing hypoxemia sufficient to cause pulmonary edema due to left ventricular failure, increased permeability or malignant arrhythmia. Similar clinical arguments exist when attempting to relate exacerbations of respiratory infections to increased particle loads.

Particle exposure could increase susceptibility to infection with bacteria or respiratory viruses, leading to an increased incidence of death from pneumonia. Although pneumonia rarely results in death within 24 hours of onset, serious infections of the lower respiratory tract can develop and evolve over days or weeks. This would not support the observed acute, untimely mortality. It would, however, support the observed effects on increased respiratory infections seen in panel studies in children and adults. Moreover, hospital admissions should increase, and have been observed to do so, and the widespread availability of ventilatory support would tend to further blunt any immediate effect of particle exposure on pneumonia mortality. As yet no precise mechanism of action has been established which could explain individual deaths at the ambient particle levels measured in most of the recent epidemiology studies.

The involvement of ultrafine particles may provide a means to explain the epidemiological observations of rapid effects of low ambient particle concentrations in cardiorespiratory disease (Seaton et al., 1995; Oberdorster et al., 1995). The urban particulate cloud, part of which is derived from combustion sources, may contain up to millions of nanometre sized particles per ml or cc, with a gravimetric concentration of only 100-200 µg/m^3. The particle surface area is therefore greatly enlarged, and can carry adsorbed metals, acids, and toxic organic molecules down to the deep recesses of the lung. Ultrafine particles are not as readily phagocytized and are therefore, more likely to react with the lung and be transferred to the interstitium. Seaton (1995) therefore proposed that ultrafine particles could be responsible for the adverse effects seen in the epidemiology studies, due to their actions in provoking alveolar inflammation, which leads to changes in blood factors and coagulability, thus causing the release of mediators able to provoke attacks of acute respiratory illness in predisposed individuals.

These suggested biological mechanisms, while still requiring more research and confirmation, help to close a major gap in our understanding, thus providing some support for the idea of causality. Precise mechanisms of action have yet to be established, although they are only one component in establishing a causal relationship between particulate matter and mortality and morbidity impacts.

Coherence *(Is the effect seen in a variety of related endpoints as could be expected?)*

The large series of epidemiology studies have demonstrated a “pyramid of effects” for outcome severity, frequency and extent of public health impact associated with particulate matter. Many studies have associated PM with cardiorespiratory mortality**.** Increased mortality is generally associated with increased hospitalizations and one would expect that hospital admissions would also be elevated, to a greater degree than mortality, since not all affected people would die. Similarly, emergency department and doctors’ visits, respiratory symptoms, lung function, respiratory-related reduced activity, and days’ absent from work or school due to respiratory illnesses would be expected to be elevated. All of these have in fact been observed. In addition, the slopes of the response curves also tended to increase as the effects went down the scale of seriousness on the “pyramid of effects”, which adds to the coherence.

Therefore, a robust pattern of coherence between endpoints both qualitatively and quantitatively is provided by the associations shown between particulate matter and a broad range of endpoints from the least to the most serious.

Alternative explanations and the possibility of confounding *(Should the observed associations be considered to be causal or to reflect the effects of uncontrolled confounding or other methodological artifacts?)*

Confounding factors of potential concern in the analyses of health impacts and daily fluctuations in particulate matter include seasonal – yearly – and/or day-today trends, temperature, and epidemics of infectious diseases, especially influenza. Weather, which can be highly correlated with particulate matter, exerts an independent, often stronger effect than PM on health endpoints such as mortality or hospitalizations. Most of the mortality and hospitalization studies controlled for temperature in the analysis in a variety of ways, and most also took the non-linear relationship of temperature with disease into account. Other meteorological variables, most frequently humidity or dew point temperature (which is related to humidity), were usually also incorporated. Some studies (e.g., Schwartz 1993, 1994, 1996; Ito and Thurston 1996) undertook sensitivity analyses to ensure that weather was not unduly influencing the results. Associations were observed in warmer and colder climates, dryer and more humid or maritime climates, and in locations where peaks occurred in the winter (Europe) as well as others (US and Canada) where summer peaks due to vehicles and secondary photochemical action were observed. The method of control did not seem to influence the results very much and the consistency suggests that climatic factors have been adequately taken into account and are not important confounders of the PM-disease association.

Epidemics of infectious diseases, particularly influenza, can bias the particle-adverse health relationship if unrecognized. Epidemics of influenza or another infectious disease could explain the association of particulate pollution with mortality only if the higher concentrations of particles invariably corresponded to times with outbreaks. In some analyses, modelling was also used to control for confounding by known influenza epidemics or by calendar year as a surrogate. It also seems unlikely that some weather-related or methodological confounding factor, known or not yet identified could be responsible for the positive associations of PM and mortality and morbidity in such a wide variety of locales.

Perhaps the most difficult question to deal with regarding the possibility of confounding has been the role played by other gaseous pollutants (measured or unmeasured) and the concern that the association which has been ascribed to particles is actually reflecting the association of one or more of these other air pollutants. Airborne pollution always occurs as a mixture of agents, of which particulate matter is only one. The gaseous pollutants ozone, SO_2, NO_2 and sometimes CO are those usually considered. Since the sources of the gaseous pollutants are often the same as those for particulate matter, their correlation coefficients can be very high ($r \geq 0.8$) in some locations. When strong correlations between the pollutants are present, disentangling their effects in regression analyses is very difficult or even impossible. In such cases, some authors (Dockery et al., 1996; Schwartz et al., 1996b) recommend that the best course of action is to rely on comparison of the PM effect in many different locations where the pollutant mixtures are all different.

Since other pollutants may also exert effects on the health outcomes, they may bias the results, and/or the regression coefficient for PM can include the effects of the confounder (these can be negative as well as positive). If other covariate pollutants are not examined at all in the analysis, the suspicion exists that any effect observed is due to the unexamined covariate instead of the pollutant of interest.

The agent most often associated with mortality and hospitalizations independently of particulate matter is ozone. Some studies did not consider ozone in their analysis, leaving open the possibility that part of the effects ascribed to particles could have been due to ozone, particularly for studies looking at summertime effects, when ozone can be high. In addition, some investigators have used 24 hour ozone measurements which do not reflect the nature of the response to high diurnal ozone peaks, and tend to hide the "signal" of this strongly cyclic pollutant from the background noise. In North America, SO_2 is not usually highly correlated with PM, and it generally has not been found to be a predictor of mortality or increased hospitalizations in North American studies. NO_2 and CO were only occasionally examined or regressed together with PM. The almost invariably high NO_2-PM correlation coefficient implies some instability of results when both are considered together. CO appeared to have some association with mortality and hospitalizations that was independent of any effects due to PM (Burnett et al., 1995; Pantazopoulou et al., 1995).

In analyses designed to help separate out the effects of one pollutant from another, the association of particulate matter with adverse health outcomes reported in the epidemiology literature was remarkably robust to inclusion (one at a time) of all four of the normally present gaseous air pollutants (SO_2, NO_2, CO and ozone). Moreover, the magnitude of this association was often (but not always) greater than any of these other air pollutants individually or combined. The magnitude, robustness, and consistency of this association across so many locations with differing air pollutant mixtures supports the position that particulate matter of some kind is the best indicator for the effects of air pollution on adverse health outcomes.

Particulate matter is the only regulated air pollutant whose chemical nature is unknown. Moreover, in different locations, and even in the same location at different times, its physical size and chemical properties differ, depending on its sources, which can be both local and regional, via long-range transport. In addition, the various metrics that have been and continue to be employed for measuring particulate matter make comparisons between studies more difficult, if not impossible, in some cases. Particulate matter with a median aerodynamic diameter (d_a) less than 10 µm (PM_{10}) and matter with a d_a of $\leq$ 2.5 µm have been emphasized in this review since they represent the size fractions with maximum penetration to the thoracic and pulmonary regions of the respiratory tract respectively, and thus are the biologically relevant fractions. Review of the finer fraction of PM_{10} indicates that one or more of these are probably more closely linked than PM_{10} to adverse health outcomes (Schwartz et al. 1996; Vedal 1996). $PM_{2.5}$, a subset of PM_{10}, is at this time the best general indicator of the pulmonary toxicity of the fine fraction of PM_{10}.

In the past few years, many studies using this metric in addition to PM_{10} have become available. Other fine fraction metrics include sulfates and particle strong acidity (H^+), two more chemically defined inorganic species, also measured as mass. Although these two measurements have provided strong associations with adverse health outcomes in certain locations, and have been suggested as the metric of choice to act as a surrogate for fine particles in standard-setting (Lippman and Thurston 1996), they are too area-specific to be used as general metrics for regulatory purposes (i.e., not all areas experience elevated levels of sulphates or aerosol acidity). Other optical-based fine particle measurements include Black Smoke or British Smoke (BS) (widely used in Europe), coefficient of Haze (CoH), used in Canada and formerly in some areas of the US, and km, a visibility measurement used in California. Although these are difficult or impossible to correlate with mass measurements, they have been qualitatively useful in correlating particle exposures with adverse population health effects, and in providing some further insights into the toxicity of fine particles. Although considerable work is being done with ultrafine particles on the biological mechanism of action in the etiology of disease, only one or two epidemiology studies have attempted to (or been able to) examine ultrafine particles either as mass or as a numerical value.

In a number of recent studies, several mass-related particle measurements including two or more of TSP, PM_{10}, $PM_{2.5}$, $PM_{10-2.5}$ (PM_{10} coarse fraction), sulphates, or particle strong acidity (H^+) have been investigated together trying to pinpoint more precisely which component is responsible for the adverse effects observed. These metrics all tend to be highly correlated with each other (correlation coefficients are usually over 0.6, and range as high as 0.99), partly because they arise from the same combustion sources. Even the best and most statistically powerful multiple regression analysis cannot separate out the effects of two or more closely correlated agents with any degree of certainty, and they cannot successfully be co-regressed. However, the database of locations is now sufficiently large, with differing pollutant mixes, that we are beginning to be able to detect which of these metrics are more important from the health point of view. Tables 12.7-12.9 present results from some studies in which fine and coarse particles were regressed together. Thus far, we can conclude that fine particle metrics generally appear to be more predictive of health outcomes than coarse particle metrics, although in some locations, coarse particles remain important and cannot at this time be dismissed.

13.4 CONCLUSIONS – CAUSALITY REVISITED

The evaluation of the causal nature of a relationship without supporting results from direct experiments is neither easy nor entirely objective. While it is generally accepted that statistical associations drawn from well-conducted, randomized experimental studies provide the strongest evidence for causal relationship, little evidence is available from the non-epidemiology studies. However, epidemiological observations have often preceded the biologic knowledge of the day. Examples include the first epidemiological studies linking smoking and lung cancer, the transmission of cholera by drinking water, and the efficacy of cowpox vaccine against smallpox, the latter predating knowledge of virology by almost 200 years. A fundamental purpose of epidemiology is to establish a cause for observed adverse effects on public health with enough certainty that taking appropriate action to mitigate those effects will be possible.

According to the evidence presented in the preceding sections the strength and consistency of the epidemiological evidence for mortality and morbidity effects at current levels of particulate air pollution is remarkable, robust, consistent and compelling. Particulate matter, as both PM_{10} and $PM_{2.5}$, has been associated, in a large number of well run daily or short-term time-series studies and long-term cohort studies, with mortality involving both respiratory and cardiac diseases, cardiorespiratory hospitalizations, increases in respiratory symptoms such as chronic bronchitis and decreases in lung function and lung capacity in children after both acute and longer term exposure, reduced activity due to respiratory illnesses, and work or school absences. A strong pattern of coherence is provided both qualitatively and quantitatively by the associations shown between particulate matter and a broad range of endpoints from the least serious to the most. Although the magnitude of the estimates of increased risk are seemingly small, they were often highly statistically significant. Moreover, the adverse health effects represent a large impact on the general population, since most of the population is exposed. The time pattern of exposure and effect adds to the coherence of the picture, with the exception of the rapidity of the effects on mortality (preliminary mechanistic research may soon provide an explanation for this observation). It should be noted that biologic plausibility is not an absolute requirement for a conclusion of causality.

The evidence is considered to be strong regarding the specificity of the effect for respiratory and cardiovascular outcomes. While alternative explanations for these associations could be the presence of unmeasured confounders and/or highly correlated covariates, a number of studies have reduced, but have not eliminated these concerns altogether. On the other hand, these associations have been noted across a wide range of exposure levels and pollutant mixtures in a wide variety of locations. This gives some confidence that confounding cannot be responsible for all of the associations which have been observed. The evidence is hard to judge, but on balance, is sufficient enough to conclude that particulate matter per se is associated with adverse health effects.

The data provide little evidence of a threshold, with estimates of mortality and morbidity increasing with increasing particle concentrations. That is, any increase in ambient particulate matter is associated with a statistical increase in adverse health effects. On a population basis, the hypothesis is that what we're seeing is exacerbation of pre-existing disease, or enhanced response of a subpopulation of sensitive individuals. Pre-existing disease includes COPD (chronic bronchitis, emphysema, asthma, pneumonitis), upper and lower respiratory tract infections, influenza and health disease.

While caution is necessary in judging relationships to be causal, this should not be used simply as a cover for dislike of the consequences of accepting such a relationship. Although the mode of particulate action is not clear, the coherency, consistency and temporal pattern of the evidence of different health outcomes strongly suggest a causal relationship between PM pollution and cardiorespiratory outcomes. There remains no good understanding on what is the most "biologically" relevant index of particulate matter, although there is sufficient evidence to conclude that the causal relationship between particulate matter and cardiorespiratory disease is drive by the fine particle fraction $\leq$ 2.5 µm.

13.5 RECOMMENDATIONS FOR RESEARCH

- Further research, both *in vitro* and *in vivo*, is needed on the basic mechanism(s) of toxicity of particles to elucidate a biologically plausible mechanism of action of particles. This need is critical in view of the provisional nature of conclusions on causality from the indirect evidence provided by the ecological epidemiology data set.
- Animal studies are required that examine the interactions between particles and the gaseous pollutants, in particular ozone, which has a well-defined mode of action shown to have associations with adverse respiratory health independent of those due to particulate matter.
- Further epidemiology studies are needed to investigate the association between exposure to particles and acute effects on health to determine which component (size, number or mass) of the particle mixture has the greatest effect on health.
- The effects of all the combustion-related gaseous pollutants on the associations between particulate matter and mortality and hospitalization requires further investigation, in view of some preliminary indications that these are critically important.
- Studies of the effects of hourly variations in particles levels on health outcomes should also be undertaken.
- Research is needed on the composition and physical-chemical characteristics as well as on the behavior of the ultrafine particles occurring in the urban environment under different meteorological conditions.
- Additional PM_{10} data is required to allow characterization of the extreme (upper portion) of the frequency distribution and determine what processes are responsible for events leading to extreme concentrations of particles.
- Continued expansion of the PM_{10} monitoring network, particularly size selective sampling, in Canada is recommended.
- Collection of data on shorter time frames is recommended to enhance our understanding of exposures.
- Additional information is required on the relationship between particle levels and indicators of morbidity (symptoms and pulmonary function changes) to fully establish coherence across the entire range of demonstrated and expected health outcomes associated with exposure to PM_{10}.
- Research is also needed to better understand the limited data that suggests personal exposures often exceed estimates of exposures from fixed samples by a significant factor.
- More research is needed on the chronic effects of long-term exposure to air pollution.
- Research on the cardiopulmonary effects of particle number and composition, rather than simply particle mass, is also needed.

14 IDENTIFICATION OF THE REFERENCE LEVELS FOR PARTICULATE MATTER

The Federal/Provincial Working Group on Ambient Air Quality Objectives and Guidelines is required to identify an ambient Reference Level, defined as a level above which there are demonstrated effects on human health and the environment. It provides a basis for establishing goals for long term air quality management. This Chapter addresses the scientific information that forms the basis for the development of this level in this Chapter.

No dose-response relationship has been identified for the effects of particles on vegetation, nor have any no effect- or lowest-observed adverse effect levels (NOAELs or LOAELs) been identified. Much of the evidence is related to particle composition rather than the effect of particle size. Therefore, the Working Group will not identify a Reference Level for vegetation. Likewise, the paucity of data related to particulate matter and effects on materials precludes the identification of a Reference Level for material impacts.

The effects of particulate matter on visibility are due primarily to the fine particle fraction. Therefore, defining a Reference Level to protect visibility is not appropriate based on $PM_{10.}$ Defining an acceptable level of visibility, or an index of change in visibility that is reliably and uniformly perceived by the public, however, is extremely difficult. Therefore, the Working Group cannot identify a $PM_{2.5}$ Reference Level to protect visibility at this time.

Subjective measures of respiratory health such as school absenteeism, days of work loss and restricted activity are usually collected through survey instruments. The data on these measures are valid indicators of respiratory health, however, because the data is limited, they are not appropriate indicators on which to base the identification of a human health Reference Level. Spirometry measures small and reversible changes in lung function, a robust measure generally. Again, the limited experimental data also prevents the identification of a Reference Level.

The relationship between both PM_{10} and $PM_{2.5}$ and cardiorespiratory hospital admissions and mortality examined via large administrative databases is the strongest both qualitatively and quantitatively.

According to the weight of evidence presented in Chapter 13, the strength and consistency of the epidemiological evidence for mortality and morbidity effects at current levels of ambient PM are remarkable, robust, consistent and compelling. The associations between PM and both mortality and hospital admissions are consistent across geographic locations, including many cities in North America, Europe and South America, where sources and concentrations of PM are different. As each individual who dies or is admitted to a hospital must have a diagnosed and recorded condition, the data could be considered more reliable for deriving a Reference Level than subjective measures of particle impact. Another key feature of the hospital admissions studies is that they allow for the measurement of effects in all age groups. A significant number of hospital admissions are seen across all age groups. A greater number of mortality studies, both acute and chronic, are available, and several of these are also statistically robust and are based on large administrative databases. However, it is very likely that the daily hospital admissions studies capture a larger segment of the affected population than do the daily mortality studies.

Positive associations have been observed between particulate matter and both daily mortality and hospitalization rates with no clear evidence of a threshold level. That is, any increase in ambient particulate matter is associated with a statistical increase in mortality and hospitalization rates. The lack of evidence of a threshold precludes the possibility that a sufficiently low level of exposure will be free of any degree of impact. Therefore, a Reference Level identified from this data will in fact be an estimate of the lowest ambient PM level at which statistically significant increases in health responses can be detected and not a level where impacts will not occur.

Dose-response information derived separately from the linear regression slopes was available from quintile/quartile analyses, or from nonparametric regressions, from five US and one South American daily mortality studies and three daily hospitalization or emergency department visit studies. None of the studies assumed any particular shape for the dose-response curve. Most of the studies presented information on PM_{10}.

Quintile analysis of three daily mortality studies from the US (Dockery et al., 1992; Pope et al., 1992; and Schwartz, 1993) showed an average PM_{10} 24 h LOAEL of 35 µg/m^3 (relative to quintile one, which is recognized as not necessarily a level without adverse effects). After weighting (by one standard error) to give more weight to studies with tighter confidence intervals, the estimate decreased to 30 µg/m^3 averaged over 24 h. Since the quintile values depend on the average concentration for each location, eliminating cities with higher average concentrations from consideration in establishing a LOAEL is reasonable. Therefore, the Brazilian city, Sao Paulo was not used further to help define the Reference Level. The data from Lyon et al. (1995) were also not used because of discrepancies in its quintile analysis and a faulty overall analysis.

The US six-cities daily mortality study provided additional information on each of the six cities individually, and a combined analysis. The latter analysis revealed a combined 24 h mean PM_{10} LOAEL of 25 µg/m^3 (Schwartz et al., 1996). In Boston MA, the estimated 24 h LOAEL was also 25 µg/m^3 compared with Portage, WI, where no association was found between mortality and PM_{10}, and the estimated 24-hour mean ambient PM concentration was 18 µg/m^3. The lowest level at which statistically significant increases in mortality were detected in the Schwartz study (1993) was 20 µg/m^3 PM_{10} averaged over 24 h based on a nonparametric dose-response curve with monotonic increases in mortality associated with PM_{10} concentrations ranging from 10 to 140 µg/m^3. Thus, three possible Reference Levels, 20, 25, or 30 µg/m^3 averaged over 24 h, are suggested by the mortality data. Of these, the mid value of 25 µg/m^3 is given considerable weight due to the high quality and the size (duration times responses) of the study on which it is based.

Similar types of analysis were done for hospitalizations or emergency department visits, providing LOAELs, at the second quartile of ambient PM_{10} data, of 20 µg/m^3 (Schwartz et al., 1993), 36 µg/m^3 (Schwartz, 1994b; Schwartz and Morris, 1995) and 4.13 µg/m^3 SO_4^{2-} (equivalent to 25 µg/m^3 PM_{10} based on site specific conversion factors, Burnett et al., 1995). Nonparametric dose-response plots for increased pneumonia and chronic obstructive pulmonary disease (COPD) admissions (Schwartz 1994a), and a decile plot for increased admissions for respiratory disease (Burnett et al., 1994) provide support for a 24 h LOAEL of 20-25 µg/m^3. Of the hospitalization studies, when identifying the Reference Level, considerable weight is given to the southern Ontario study, which identified a LOAEL for PM_{10} of 25 µg/m^3 (Burnett et al., 1995). This study is one of the largest of its kind (which lends statistical power to the study), the analysis is robust, it used six years of daily sulphate measurements (an excellent surrogate for fine particles and a reasonable one for PM_{10}), and encompassed a large geographic area in Canada.

Thus, both the mortality studies and the hospitalization studies support the identification of 25 µg/m^3, averaged over 24 h, as the Reference Level for PM_{10}.

Deriving Reference Levels for fine particles is more difficult because of the paucity of studies which examined fine particles, especially by nonparametric methods or quartile/quintile analysis. While many European studies examined British Smoke Shade or Black Smoke (BS), which measures fine particles with mean aerodynamic diameters of approximately 5 µg/m^3, none could provide site-specific conversion factors for $PM_{2.5}$. The choice of $PM_{2.5}$ as a measure on which to base the fine particle Reference Level was originally made to account for the bimodal nature of particles in the atmosphere, and for their bimodal deposition in the body. The fine fraction, with a cutpoint of 2-3 µm aerodynamic diameter, is preferentially deposited deep in the lungs compared with the larger particles that are deposited higher up in the respiratory tract. It is unlikely that conclusive epidemiological evidence will be forthcoming in the near future that would argue for abandoning $PM_{2.5}$ monitoring in favour of an even smaller size fraction. Non-mass measurements such as number counts or optical-based measurements have been suggested as appropriate metrics on which to base Reference Levels, however, they have rarely been used in epidemiology.

$PM_{2.5}$ has been most clearly associated with adverse health effects in the epidemiological studies, and overall, in most but not all studies, $PM_{2.5}$ has been shown to have a robust association with mortality. In addition $PM_{2.5}$ can be considered a general surrogate for fine particle effects in all regions of the country, where fine particle concentration and composition vary widely. While particle strong acidity (H^+) is an attractive choice of metric because of its biological plausibility as a toxic agent, it has proven to have an inconsistent association with adverse health endpoints.

The six-city mortality study, given considerable weight in the PM_{10} analysis, also provided LOAEL estimates for $PM_{2.5}$ (Schwartz et al., 1996). Over the entire six cities, the 24 h median LOAEL was 14.7 µg/m^3 for $PM_{2.5}$, with the association between daily mortality and $PM_{2.5}$ being highly significant. The slope of the concentration-response curve was as steep or steeper at lower concentrations than at higher ones. Three of six cities individually showed associations between mortality and $PM_{2.5}$ (24 h mean LOAELs were 15.7 µg/m^3, 18.7 µg/m^3 and 20.8 µg/m^3). Two cities with low mean 24 h $PM_{2.5}$ concentrations (11.2 µg/m^3 and 12.2 µg/m^3) showed no significant associations between daily mortality and $PM_{2.5}$, while the association in the sixth city was only marginally significant due to confounding by coarse particles, for which the correlation coefficient with $PM_{2.5}$ was high (r=0.69). The latter three cities were not considered further. Thus the composite LOAEL from this study, and the three individual city results, with significant associations, reveal LOAELs ranging from 14.7 µg/m^3 to 20.8 µg/m^3, averaged over 24 hours.

The only hospitalization study that provided a quartile or decile analysis using any fine particle measure was the Burnett et al. (1995) study on cardiorespiratory admissions in southern Ontario. In an analysis similar to a quartile analysis, the lowest concentration at which a statistically significant increase in cardiorespiratory hospitalizations was observed was a mean sulphate value of 4.13 µg/m^3. This is equivalent to a mean $PM_{2.5}$ concentration of 15 µg/m^3, based on site-specific conversion factors. A decile analysis was also provided, showing a curvilinear relationship down to zero, with a near-linear steep slope at all levels below 6 µg/m^3 SO_4^{2-}. As noted in the rationale for PM_{10} Reference Levels, this was a well designed and carried out study with sufficient power to give confidence in its results. Since SO_4^{2-} and $PM_{2.5}$ are usually highly correlated, in the range 0.7-0.9 in southern Ontario, the SO_4^{2-} measurement is considered an excellent surrogate for fine particles in this study.

Two recently published chronic cross-sectional studies showing decrements in lung function (Raizenne et al., 1996) and increases in respiratory symptoms (Dockery et al., 1996) also provide a limited measure of support for adverse effects at the mean 24 h LOAEL of 14.5 µg/m^3 (range 5.8 to 20.7 µg/m^3).

Thus, the mortality and morbidity (hospitalization, lung function, and respiratory symptoms) data point to 24 hour average of 15 µg/m^3 as a $PM_{2.5}$ Reference Level.

While mortality and hospitalizations have been emphasized because of their ability to provide some measure of quantification, they are only the tip of the iceberg with respect to other adverse health effects including exacerbation of respiratory symptoms, reduced lung function, restricted activity due to illness, loss of workdays or school absenteeism, and increased medication use. These particulate matter-adverse health associations, which the Working Group believes to be causal, are observed at the concentrations currently occurring in Canada.

Recognizing the coherent, consistent evidence for a continuum of effects associated with PM, the Working Group recommends that the Reference Level for particulate matter less than, or equal to 10 µm (PM_{10}) be 25 µg/m^3, averaged over a 24 h period, and that the Reference Level for particulate matter less than or equal to 2.5 µm ($PM_{2.5}$) be 15 µg/m^3, averaged over a 24 h period. Both Reference Levels are estimates of the lowest ambient PM level at which statistically significant increases in health responses can be detected based upon available data and current technology. The identified Reference Levels should not be interpreted as thresholds of effects, or levels at which impacts do not occur.

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