United States Environmental Protection Agency

Health Risk and Exposure Assessment for Ozone

Final Report

Executive Summary

This page left intentionally blank

EPA-452/R-14-004f
August 2014

Health Risk and Exposure Assessment for Ozone

Final Report

Executive Summary

U.S. Environmental Protection Agency
Office of Air and Radiation
Office of Air Quality Planning and Standards
Health and Environmental Impacts Division
Risk and Benefits Group
Research Triangle Park, North Carolina 27711

DISCLAIMER

This final document has been prepared by staff from the Risk and Benefits Group, Health and Environmental Impacts Division, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency. Any findings and conclusions are those of the authors and do not necessarily reflect the views of the Agency.

Questions related to this document should be addressed to Dr. Bryan Hubbell, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, C539-07, Research Triangle Park, North Carolina 27711 (email: hubbell.bryan@epa.gov).

Introduction

As part of the review of the ozone (O_3) National Ambient Air Quality Standards (NAAQS), EPA has prepared this Health Risk and Exposure Assessment (HREA) to provide estimates of exposures to O_3 and resulting mortality and morbidity health risks. The health effects evaluated in this HREA are based on the findings of the O_3 ISA (U.S. EPA, 2013) that short term O_3 exposures are causally related to respiratory effects, and likely causally related to cardiovascular effects, and that long term O_3 exposures are likely causally related to respiratory effects. The assessment evaluated total exposures and risks associated with the full range of observed O_3 concentrations. In addition, the HREA estimated the incremental changes in exposures and risks associated with ambient air quality adjusted to just meeting the existing standard of 75 ppb and just meeting potential alternative standard levels of 70, 65, and 60 ppb using the form and averaging time of the existing standard, which is the annual 4th highest daily maximum 8-hour O_3 concentration, averaged over three consecutive years.

The results of the HREA are developed to inform the O_3 Policy Assessment (PA) in considering the adequacy of the existing O_3 standards, and potential risk reductions associated with potential alternative levels of the standard. For added context regarding existing O_3 air quality and the potential impact to public health, initial nonattainment area designations have been made for 46 areas in the U.S. with ambient O_3 concentrations exceeding the existing standard (77 FR 30160). The figure below provides the locations of nonattainment areas and their respective classifications and includes 227 counties with an estimated 2010 population of just over 123 million people.

As described in the conceptual framework and scope in Chapters 2 and 3, respectively, the HREA discusses air quality considerations (Chapter 4) and evaluates exposures and lung function risk in 15 urban study areas (Chapters 5 and 6, respectively) and risks based on application of results of

8-Hour Ozone Nonattainment Areas (2008 Standard)

Nonattainment area classifications based on the existing O_3 NAAQS.

(Source: http://www.epa.gov/airquality/greenbook/).

epidemiology studies in a subset of 12 urban study areas (Chapter 7). In addition, to place the urban study area analyses in a broader context, the assessment estimated the national burden of mortality associated with recent O_3 levels, and evaluated the representativeness of the urban areas in characterizing O_3 exposures and risks across the U.S. (Chapter 8). To further facilitate interpretation of the results of the exposure and risk assessment, Chapter 9 provides a synthesis of the various results, focusing on comparing and contrasting those results to identify common patterns, or important differences. It also includes an overall integrated characterization of exposure and risk in the context of key policy relevant questions.

Conceptual Framework and Scope

The HREA provides information to answer key policy-relevant risk questions with regards to evaluation of the adequacy of the existing standards and evaluation of potential alternative standards such as:

"*To what extent do risk and/or exposure analyses suggest that exposures of concern for O_3-related health effects are likely to occur with existing ambient levels of O_3 or with levels that just meet the O_3 standard?*

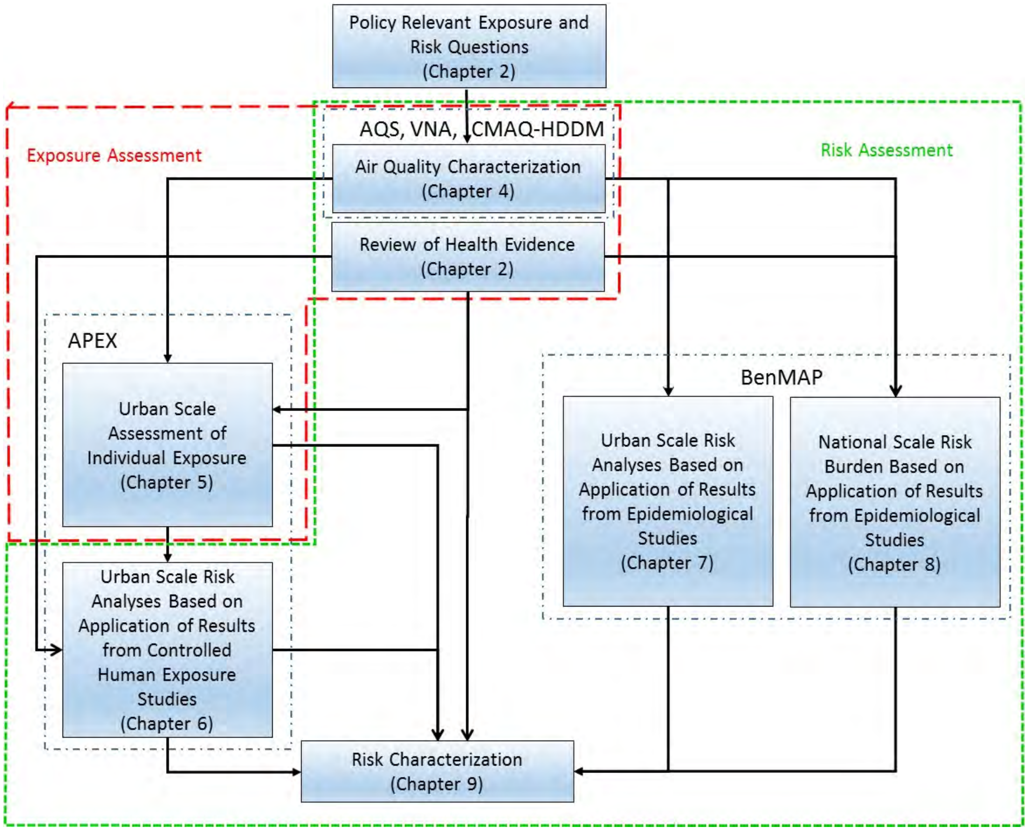
To what extent do alternative standards, taking together levels, averaging times and forms, reduce estimated exposures and risks of concern attributable to O_3 and other photochemical oxidants, and what are the uncertainties associated with the estimated exposure and risk reductions?"

In answering these key questions, the HREA evaluates total exposures and risks associated with the full range of observed O_3 concentrations, as well as the incremental changes in exposures and risks for just meeting the existing standard and just meeting several alternative standards.

With regard to selecting alternative levels for the 8-hour O_3 standards for evaluation in the quantitative risk assessment, we base the range of selected levels on the evaluations of the evidence provided in the first draft PA, which received support from the CASAC in their advisory letter on the first draft PA. The first draft PA recommended evaluation of 8-hour maximum concentrations in the range of 60 to 70 ppb, with possible consideration of levels somewhat below 60 ppb.

Ozone concentrations from 2006-2010 are used in estimating exposures and risks for the 15 urban study areas. Because of the year-to-year variability in O_3 concentrations, the assessment evaluates air quality scenarios for just meeting the existing and potential alternative standards based on multiple years of O_3 data to better capture the high degree of variability in meteorological conditions, as well as reflecting years with higher and lower emissions of O_3 precursors. The 15 urban study areas were selected to be generally representative of U.S. populations, geographic areas, climates, and varying O_3 and co-pollutant levels. These urban study areas include Atlanta, GA; Baltimore, MD; Boston, MA; Chicago, IL; Cleveland, OH; Dallas, TX; Denver, CO; Detroit, MI; Houston, TX; Los Angeles, CA; New York, NY; Philadelphia, PA; Sacramento, CA; St. Louis, MO; and Washington, D.C.

We have identified the following goals for the urban area exposure and risk assessments: (1) to provide estimates of the number and percent of people in the general population and in at-risk populations and lifestages with O_3 exposures above health-based benchmark levels; (2) to provide estimates of the number and percent of people in the general population and in at-risk populations and lifestages with impaired lung function (defined based on decrements in forced expiratory volume in one second (FEV_1) resulting from exposures to O_3; (3) to provide estimates of the potential magnitude of premature mortality



associated with both short-term and long-term O_3 exposures, and selected morbidity health effects associated with short-term O_3 exposures; (4) to evaluate the influence of various inputs and assumptions on risk estimates to the extent possible given available methods and data; (5) to gain insights into the spatial and temporal distribution of risks associated with O_3 concentrations just meeting existing and alternative standards, patterns of risk reduction associated with meeting alternative standards relative to the existing standard, and uncertainties in the estimates of risk and risk reductions.

In working towards these goals, we follow a conceptual framework, shown in the figure above , comprised of an air quality characterization, a review of relevant scientific evidence on health effects, the modeling of exposure, the modeling of risk, and a risk characterization. As shown in this framework, air quality is characterized primarily by the combined use of ambient monitoring data available in the EPA Air Quality System (AQS), and a spatial interpolation approach (Voronoi Neighbor Averaging, VNA), along with Higher-Order Decoupled Direct Method (HDDM) capabilities in the Community Multi-scale Air Quality (CMAQ)[1] model. The modeling of personal exposure and estimation of risks, which rely on personal exposure estimates, are implemented using the EPA's Air Pollution Exposure model (APEX)[2]. Modeling of population level risks for health endpoints based on application of results of epidemiological studies is implemented using the environmental Benefits Mapping and Analysis Program (BenMAP)[3], a peer reviewed software tool for estimating risks

[1] The CMAQ model and associated documentation is available for download at https://www.cmascenter.org/cmaq/.

[2] The APEX model and associated documentation is available for download at http://www.epa.gov/ttn/fera/human_apex.html

[3] The BenMAP model and associated documentation is available for download at http://www.epa.gov/air/benmap/

and impacts associated with changes in ambient air quality. The overall characterization of risk draws from the results of the exposure assessment and both types of risk assessment.

Air Quality Characterization

In this analysis, we employed a photochemical model-based adjustment methodology (Simon et al., 2013) to estimate the change in observed hourly O_3 concentrations at a given set of monitoring sites resulting from across-the-board reductions in U.S. anthropogenic NO_x and/or VOC emissions. This information was then used to adjust recent O_3 concentrations (2006-2010) in the 15 urban study areas to reflect just meeting the existing 8-hour O_3 standard of 75 ppb and for just meeting potential alternative standard levels of 70, 65, and 60 ppb. Because the form of the existing O_3 standard is based on the 3-year average of the 4th highest daily maximum 8-hour average, we simulate just meeting the potential alternative standards for two periods, 2006-2008 and 2008-2010.

The use of the model-based adjustment methodology is an example of how we have brought improvements into this review that better represent current scientific understanding. The model-based adjustment methodology represents a substantial improvement over the quadratic rollback method used to adjust O_3 concentrations in past reviews. For example, while the quadratic rollback was a purely mathematical technique which attempted to reproduce the distribution of observed O_3 concentrations just meeting various standards, the new methodology uses photochemical modeling to simulate the response in O_3 concentrations due to changes in precursor emissions based on current understanding of atmospheric chemistry and pollutant transport. Second, quadratic rollback used the same mathematical formula to adjust concentrations at all monitors within each urban study area for all hours, while model-based adjustment methodology allows the adjustments to vary both spatially across each study area and temporally across hours of the day and across seasons. Finally, quadratic rollback was designed to only allow decreases in O_3 concentrations, while the model-based adjustment methodology allows both increases and decreases in O_3 concentrations, which more accurately reflects the scientific understanding that increases in O_3 concentrations may occur in response to reductions in NO_x emissions in some situations, such as in urban areas with a large amount of NO_x emissions.

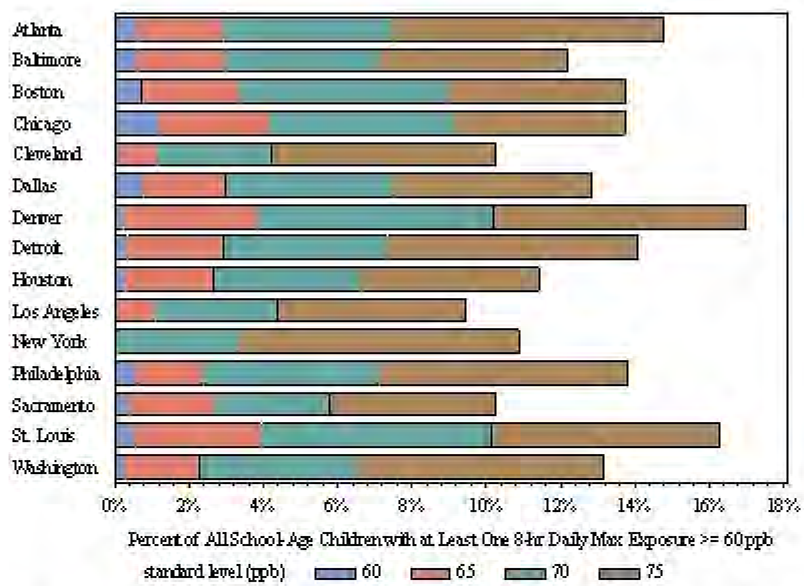
Several general trends are evident in the changes in O_3 patterns across the urban study areas and across the different standards under consideration. In all 15 urban study areas, peak O_3 concentrations tended to decrease while the lowest O_3 concentrations tended to increase as the concentrations were adjusted to just meet the existing and potential alternative standards. In addition, high and mid-range O_3 concentrations generally decreased in rural and suburban portions of the case study areas, while the O_3 response to NO_x reductions was more varied within urban core areas. In particular, while the annual 4th highest daily maximum 8-hour concentrations generally decreased in the urban core of the study areas in response to reductions in NO_x emissions, the seasonal mean of the daily maximum 8-hour O_3 concentrations did not change significantly, though it did exhibit some increases or decreases in the various study areas as the distribution of O_3 was further adjusted to meet lower potential alternative standards.

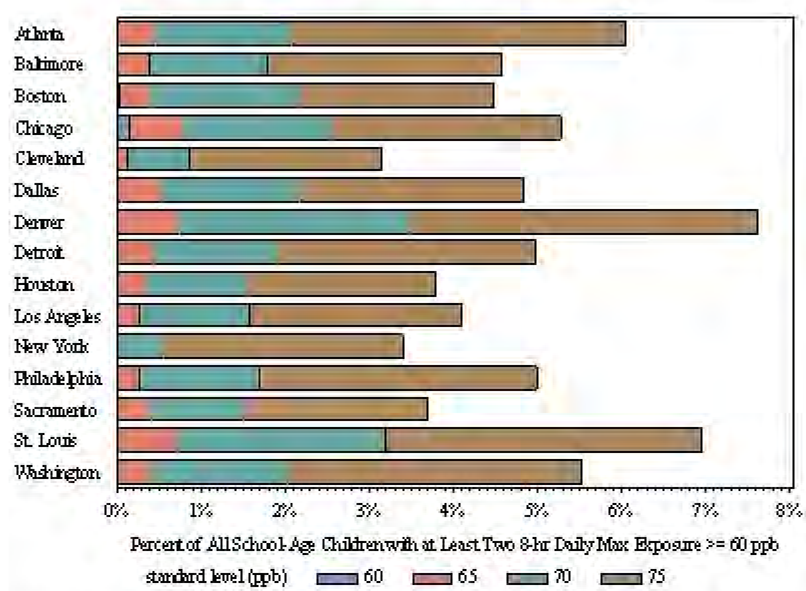
The adjustments to O_3 to reflect just meeting existing and potential alternative standards are made by decreasing only U.S. emissions of anthropogenic NO_x primarily, and in a few instance, both NO_x and VOC reductions. As such, the estimated changes in exposure and risk, based on these air quality changes, are solely attributable to changes in U.S. emissions and are not meant to reflect a specific air emission control strategy that might be used by a state or urban area to meet a standard.

Human Exposure Modeling

The population exposure assessment evaluated exposures to O_3 using the APEX exposure model which uses time-activity diary and anthropometric data coupled with local meteorology, population demographics, and O_3 concentrations to estimate the number and percent of study group individuals above exposure benchmarks. The analyses examined exposure to O_3 for the general population, all school-aged children (ages 5-18), asthmatic school-aged children, asthmatic adults (ages > 18), and older persons (ages 65 and older), with a focus on when exposed individuals were engaged in moderate or greater exertion, for example, children engaged in outdoor recreational activities. Exposure is assessed in the 15 urban study areas for recent O_3 (2006-2010) and for O_3 adjusted to just meet existing and potential alternative standards for two averaging periods (2006-2008 and 2008-2010). The analysis provided estimates of the number and percent of several study groups of interest exposed to concentrations above three health-relevant 8-hour average O_3 exposure benchmarks: 60, 70, and 80 ppb. These benchmarks were selected to provide perspective on the public health impacts of O_3-related health effects that have been demonstrated in human clinical and toxicological studies, but cannot currently be evaluated in quantitative risk assessments, such as lung inflammation and increased airway responsiveness. The O_3 ISA includes studies showing significant effects at each of these benchmark levels.

The analysis found that children are the study group of greatest concern for O_3 exposures due to the greater amount of afternoon time they spend outdoors engaged in moderate or higher exertion activities and that they do so more frequently of any of the at-risk study groups. Based on this, we focus on the results for children in this subsequent discussion. The two figures below show the average across 2006-2010 of the percentage of school-aged children experiencing 8-hour exposure greater than 60 ppb at least once (top)





Average percent of all school-age children exposed at or above 60 ppb at least once (top) and at least twice (bottom) per O_3 season for each urban study area across all study years (2006-2010) considering each standard level.

Note: A standard level of 60 ppb for the New York study area was not modeled. We do not know what the percent risk would be for NY under the 60 ppb alternative standard, but it would not necessarily be zero as indicated by the figure.

and at least twice (bottom) per O_3 season. Based on this information, no more than 17 percent of any study group in any study area, on average, was exposed at least once at or above the 60 ppb benchmark, when meeting the existing standard. When meeting a standard level of 70 ppb, less than 11 percent of any study group in any study area, on average, was exposed at least once at or above the 60 ppb exposure benchmark. Adjusting ambient O_3 to just meet a standard level of 65 ppb is estimated to reduce the percent of persons at or above an exposure benchmark of 60 ppb to 4 percent or less of any study group and study area, on average.

For the exposure benchmark of 70 ppb, on average less than 4 percent of any study group, including all school-age children, in any study area, was exposed at least once at or above the exposure benchmark when meeting the existing standard (not shown). For the highest exposure benchmark of 80 ppb, on average less than 1 percent of any study group in any study area was exposed at least once at or above the exposure benchmark when meeting the existing standard (not shown). As expected, with the lower ambient O_3 levels associated with just meeting lower alternative standard levels, the percentages of at-risk study groups experiencing exposures above the benchmark levels are smaller than when just meeting the existing standard.

In considering two or more exceedances of the 60 ppb benchmark, on average less than 8 percent of any study group in any study area experience such 8-hour exposures when air quality is adjusted to meet the existing standard. There were no persons estimated to experience any multi-day exposures above the exposure benchmark of 80 ppb for any study group in any study area, while less than 1 percent of persons were estimated to experience two or more 8-hour exposures at or above 70 ppb, when meeting the existing standard or any of the alternative standard levels (not shown).

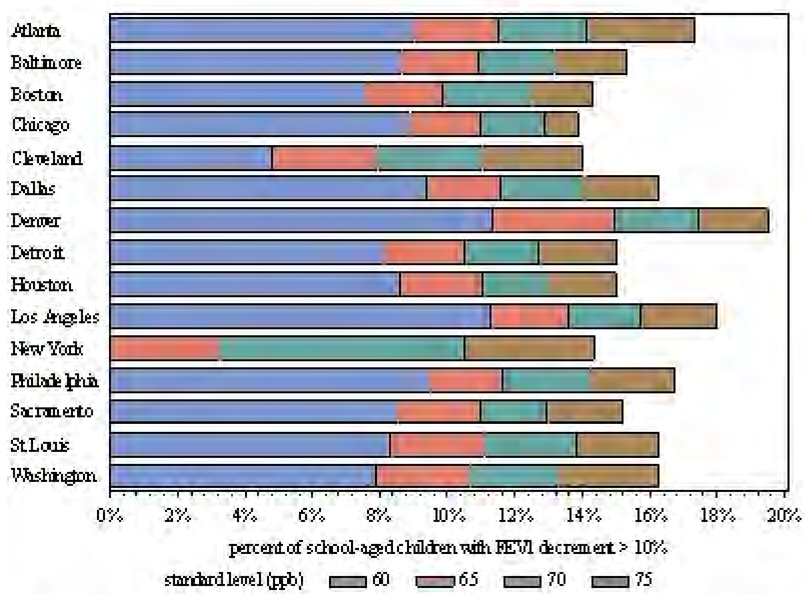
In addition, the exposure assessment also identified the specific microenvironments and activities that contribute most to exposure and evaluated at what times and for how long individuals were in key microenvironments and were engaged in key activities, with a focus on persons experiencing the highest daily maximum 8-hour exposure within each study area. That analysis indicated that children are an important exposure study group, largely as a result of the combination of large amounts of afternoon time spent outdoors and their engagement in moderate or high exertion level activities. Highly exposed children, on average, spend half of their outdoor time engaged in moderate or greater exertion levels, such as participating in sporting activities. In addition, any people spending a large portion of their time outdoors during afternoon hours experienced the highest 8-hour O_3 exposure concentrations given that ambient O_3 concentrations are typically highest during this time of day and other microenvironments evaluated, particularly indoor microenvironments, have much lower O_3 concentrations than ambient concentrations. Simulations of highly exposed adults indicated that they also spent large amounts of afternoon time outdoors engaged in moderate or greater exertion level activities though on average, not participating in these events as frequently as children.

Health Risks Based on Controlled Human Exposure Studies

This analysis uses the estimated O_3 exposures from APEX, combined with results from controlled human exposure studies, to estimate the number and percent of at-risk study groups (all children, children with asthma, adults aged 18-35, adults aged 36-55, and outdoor workers) experiencing selected decrements in lung function. The analysis focuses on estimates of the percent of each at-risk population experiencing a reduction in lung function for three different health effect levels: 10, 15, and 20 percent decrements in FEV_1. These health effect levels were selected based on the published literature and conclusions drawn regarding the adversity associated with increasing lung function decrements (O_3 ISA, Section 6.2.1.1; Henderson, 2006). Lung function decrements of 10 percent and 15 percent in FEV_1 are considered moderate decrements; 10 percent is considered potentially adverse for people with lung disease, while a 15 percent is potentially adverse for active healthy people. A 20 percent decrement in FEV_1 is considered a large decrement that is potentially adverse for healthy people and can potentially cause more serious effects in people with lung disease.

Two types of FEV_1 risk were used to estimate lung function risks. One model was based on application of a population level exposure-response (E-R) function consistent with the approach used in the previous O_3 review. The second model was based on application of an individual level risk function (the McDonnell-Stewart-Smith (MSS) model), newly introduced for this review. The main difference between the two models is that the MSS model includes responses associated with a wider range of exposure protocols used in the original controlled human exposure studies (i.e., variable levels of exertion, lengths of exposures, and patterns of exposure concentrations) than compared to the exposure-response model of previous reviews. The models are similar in that both models have a logistic form and are less sensitive to changes at very low concentrations of O_3 than to higher O_3 concentrations. As a result, the models estimate very few FEV_1 responses > 10% when ambient concentrations are below 20 ppb and very few FEV_1 responses > 15% when ambient concentrations are below 40 ppb. Because the individual level E-R function approach allows for a more complete estimate of risk, we focus on the results of the MSS model for this discussion.

Lung function risks were estimated for each of the 15 urban case study areas for recent air quality conditions (2006-2010) and for air quality adjusted to just meet the existing and alternative standards for two design value periods (2006-2008 and 2008-2010). As with the exposure assessment, we focus on lung function decrements in children as they are the study group likely to have the greatest percentage of that group at risk due to higher levels of exposure and greater levels of exertion. The figure below shows the lung function risks associated with just meeting the existing and potential alternative standard levels, where risk is taken to be the average value for each study area (across all years considered) of the percent of school-aged children with FEV_1 decrement of 10 percent or greater. This figure shows that there are decreases in incremental risk for all 15 cities in the progression from the level of the existing standard, 75 ppb to the alternative standard levels of 70, 65, and 60 ppb. The estimated risks in this figure for Washington, DC, for example, are about 16 percent for



Average percent of all school-age children with at least one FEV_1 decrement ≥ 10 percent per O_3 season in each urban study area across all study years (2006-2010) considering each standard level.

Note: A standard level of 60 ppb for the New York study area was not modeled. We do not know what the percent risk would be for NY under the 60 ppb alternative standard, but it would not necessarily be zero as the existing standard level of 75 ppb and about13 percent for the alternative standard level of 70 ppb. The length of the brown bar is the incremental reduction (3 percent) in the percent of persons at risk, when adjusting air quality from the existing standard of 75 ppb to the 70 ppb alternative standard. The pattern of reductions for lung function decrements larger than 15 and 20 percent are similar to those illustrated here (not shown).

Health Risks Based on Application of Results of Epidemiological Studies

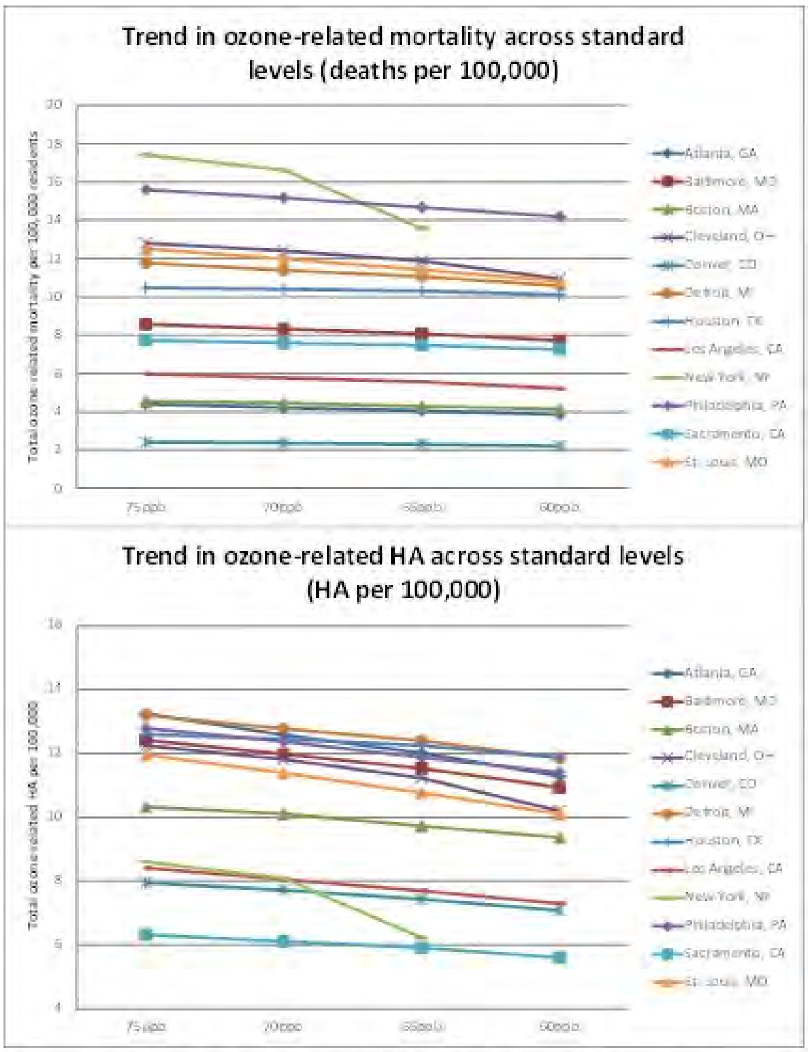
The epidemiology-based risk assessment evaluated mortality and morbidity risks from short-term exposures, as well as mortality risks from long-term exposures to O_3, by applying concentration-response (C-R) functions derived from epidemiology studies. Most of the endpoints evaluated in epidemiology studies are for the entire study population. Because most mortality and hospitalizations occur in older persons, the risk estimates for this portion of the analysis are thus more focused in adults rather than children, and thus differ in focus compared to the human exposure and lung function risk assessments. The analysis included both a set of urban area study areas and a national-scale assessment.

The urban study area analyses evaluated mortality and morbidity risks, including emergency department (ED) visits, hospital admissions (HA), and respiratory symptoms associated with recent O_3 concentrations (2006-2010) and with O_3 concentrations adjusted to just meet the existing and alternative O_3 standards. Mortality and hospital admissions were evaluated in 12 urban study areas (a subset of the 15 urban study areas evaluated in the exposure and lung function risk assessments), while ED visits and respiratory symptoms were evaluated in a subset of study areas with supporting epidemiology studies. The 12 urban areas were: Atlanta, GA; Baltimore, MD; Boston, MA; Cleveland, OH; Denver, CO; Detroit, MI; Houston, TX; Los Angeles, CA; New York, NY; Philadelphia, PA; Sacramento, CA; and St. Louis, MO. The urban study analyses focus on risk estimates for the middle year of each three-year ambient standard simulation period (2006-2008 and 2008-2010) in order to provide estimates of risk for a year with generally higher O_3 levels (2007) and a year with generally lower O_3 levels (2009).

In previous O_3 NAAQS reviews, health risks were estimated for the portion of total O_3 attributable to North American anthropogenic sources (referred to in previous O_3 reviews as “policy relevant background”). In contrast, this assessment provides risk estimates for the urban study areas for O_3 concentrations down to zero, reflecting the lack of evidence for a detectable threshold in the C-R functions (O_3 ISA), and the understanding that U.S. populations may experience health risks associated with O_3 resulting from emissions from all sources, both natural and anthropogenic, and within and outside the U.S.

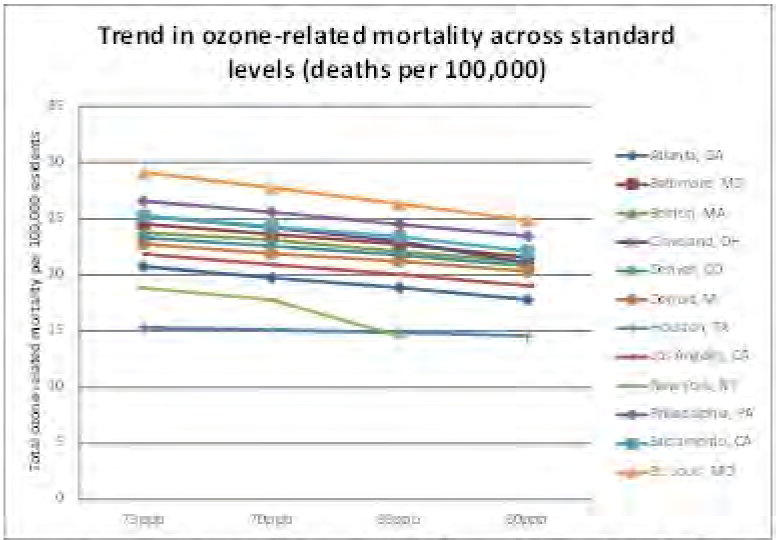
The figure below shows the results of the mortality (top panel) and respiratory hospital admissions (bottom panel) risk assessments for all 12 urban areas associated with short-term exposure to O_3, showing the effect on the incidence per 100,000 population just meeting the existing 75 ppb standard and potential alternative O_3 standards of 70, 65, and 60 ppb in 2007. The overall trend across urban areas is relatively small decreases in mortality and morbidity risk as air quality is adjusted to just meet incrementally lower standard levels. In New York, there are somewhat greater decreases, reflecting the relatively large emission reductions used to adjust air quality to just meet the 65 ppb alternative standard, and the substantial change in the distribution of O_3 concentrations that resulted. Risks vary substantially across urban study areas; however, the general pattern of risk reductions associated with air quality adjusted to just meet alternative standards is similar between urban study areas. Risks are generally lower in 2009 (not shown) relative to 2007; though the patterns of reductions are very similar between the two years. On average, compared with air quality adjusted to just meet the existing standard, mortality and respiratory hospitalization risks decrease by 5% or less for where ambient concentrations are adjusted to meet a standard level of 70 ppb, 10% or less for meeting a level of 65 ppb, and 15% or less for meeting a level of 60 ppb. Larger risk reductions are estimated on days with higher O_3.

We also evaluated mortality risks in the 12 urban study areas associated with long-term O_3 exposures (based on the April to September average of the daily maximum one-hour ambient O_3 concentrations). The figure below shows the results of the long-term mortality risk assessment for all 12 urban study areas, showing the effect on the incidence per 100,000 population considering air quality adjusted to just meeting the existing standard and potential alternative O_3 standard levels of 70, 65, and 60 ppb in 2007. Risks from long-term exposures after adjusting air quality to just meet the existing standard are substantially greater than risks from short-term exposures, ranging from 15 to 30 percent of respiratory mortality across urban areas. However, the percent reductions in risks are similar to those for mortality from short-term exposures, e.g., less than 10 percent reduction in risk relative to just meeting the existing standard in most areas when just meeting the 70 ppb and 65 ppb alternative standards, and less than 20 percent reductions when just meeting the 60 ppb alternative standard level.



Short-term mortality risk per 100,000 population (top) and respiratory hospital admissions risk per 100,000 population (bottom) for 2007 considering each standard level.

Note: A standard level of 60 ppb for the New York study area was not modeled. We do not know what the percent risk would be for NY under the 60 ppb alternative standard, but it would not necessarily be zero as indicated by the figure.



Long-term mortality risk per 100.000 population for 2007 and considering each standard level.

Note: A standard level of 60 ppb for the New York study area was not modeled. We do not know what the percent risk would be for NY under the 60 ppb alternative standard, but it would not necessarily be zero as

Mortality and morbidity risks generally do not show large responses to meeting existing or alternative levels of the standard for several reasons. First, these risks are based on C-R functions that are approximately linear along the full range of ambient O_3 concentrations, and therefore reflect the impact of changes in O_3 along the complete range of 8-hour average O_3 concentrations. This includes days with low baseline O_3 concentrations that are predicted to have increases in O_3 concentrations, as well as days with higher starting O_3 concentrations that are predicted to have decreases in O_3 concentrations when adjusting air quality to just meet the existing and potential alternative standards. Second, these risks reflect changes in the urban area-wide monitor average, that will not be as responsive to air quality adjustments as the design value monitor, and includes monitors with both decreases and increases in 8-hour concentrations. Third, the days and locations with predicted increases in O_3 concentrations (generally those with low- to mid-range starting O_3 concentrations) resulting from adjusting air quality to just meeting the existing or alternative standard levels generally are frequent enough to offset days and locations with predicted decreases in O_3. The focus of the epidemiological studies on urban area-wide average O_3 concentrations, and the lack of threshold levels coupled with the linear nature of the C-R functions mean that in this analysis, the impact of a peak-based standard (i.e., designed to reduce peak concentrations regardless of effects on low or mean concentrations) on estimates of mortality and morbidity risks based on results of those studies is relatively small. However, we are not able to draw strong conclusions about the results across urban study areas, because of the limited number of urban study areas represented for most of the endpoints.

The national-scale epidemiology-based risk assessment evaluated only mortality associated with recent O_3 concentrations across the entire U.S for 2006-2008. The national-scale assessment is a complement to the urban-scale analysis, providing both a broader assessment of O_3-related health risks across the U.S. It demonstrates that there are O_3 risks across the U.S, not just in urban areas, even though the O_3 levels in many areas were lower than the existing standard level. We estimated 15,000 premature O_3-related non-accidental deaths (all ages) annually associated with short-term exposure to recent O_3 levels across the continental U.S. for 2007, May-September. For long-term mortality, we estimated 45,000 premature O_3-related adult (age 30 and older) respiratory deaths annually for 2007, April-September. While we did not assess the changes in risk at a national level associated with just meeting existing and potential alternative standards, just meeting existing and potential alternative standards would likely reduce O_3 concentrations both in areas that are not meeting those standards and in locations surrounding those areas, leading to risk reductions that are not captured by the urban-scale analysis.

Representativeness of Exposure and Risk Results and Associated Uncertainties

As part of this assessment, we conducted several analyses to determine the extent to which our selected urban areas represent: (1) the highest mortality and morbidity risk areas in the U.S.; and (2) the types of patterns of O_3 air quality changes that we estimate would be experienced by the overall U.S. population in response to emissions reductions that would decrease peak O_3 concentrations to meet the existing standard or lower alternative O_3 standard levels.

We selected urban study areas for the exposure and risk analyses based on criteria that included O_3 levels, at-risk study groups, and related factors that were designed to ensure we captured areas and persons likely to experience high O_3 exposures and risks. Based on the comparisons of distributions of risk characteristics, the selected urban study areas represent urban areas that are among the most populated in the U.S., have relatively high peak O_3 levels, and capture a wide range of city-specific mortality risk effect estimates. The analyses found that the O_3 mortality risk for short-term O_3 exposures in the 12 urban study areas are representative of the full distribution of U.S. O_3-related mortality, representing both high end and low end risk counties. For the long-term exposure related mortality risk metric, the 12 urban study areas are representative of the central portion of the distribution of risks across all U.S. counties, however, the selected 12 urban areas do not capture the very highest (greater than 98th percentile) or lowest (less than 25th percentile) ends of the national distribution of long-term exposure-related O_3-related risk.

While we selected urban study areas to represent those populations likely to experience elevated risks from O_3 exposure, we did not include amongst the selection criteria the responsiveness of O_3 in the urban study area to decreases in O_3 precursor emissions that would be needed to just meet existing or potential alternative standards. The additional analyses we conducted suggest that many of the urban study areas may show O_3 responses that are typical of other large urban areas in the U.S., but may not represent the response of O_3 in other populated areas of the U.S. These other areas, including suburban areas, smaller urban areas, and rural areas, would be more likely than our urban study areas to experience area-wide average decreases in mean O_3 concentrations and, therefore, associated decreases in mortality and morbidity risks, as O_3 standards are met. Even though large urban areas have high population density, the majority of the U.S. population lives outside of these types of urban core areas, and thus, a large proportion of the population is likely to experience greater mortality and morbidity risk reductions in response to reductions in 8-hour O_3 concentrations than are predicted by our modeling in the 12 selected urban case study areas.

Because our selection strategy for risk modeling was focused on identifying areas with high risk, we tended to select large urban population centers. This strategy was largely successful in including urban areas in the upper end of the O_3 risk distribution. However, this also led to an overrepresentation of the populations living in locations where we estimate increasing mean seasonal O_3 would occur in response to decreases in O_3 precursor emissions that would be needed to just meet existing or alternative standards. The implication of this is that our estimates of mortality and morbidity risk reductions for the selected urban areas should not be seen as representative of potential risk reductions for most of the U.S. population, and are likely to understate the average risk reduction that would be experienced across the population.

While the best available science information and methodologies are used to estimate exposures and associated health risk, there remain significant uncertainties in each of the four primary analytical areas of this HREA. For example, a number of important uncertainties are identified regarding the modeling approaches used to characterize air quality (i.e., the CMAQ modeling, the HDDM method used simulate alternative air quality scenarios, application of 2007 modeled sensitivities for months and years not modeled), though results of our uncertainty characterization show limited instances of the potential for either under- or over-estimating ambient concentrations while also having a limited range of potential bias, generally less than a few ppb. Similar conclusions are drawn regarding the most important uncertainties in estimating exposures, in particular those concerning concentrations at or above exposure benchmark levels (i.e., the human activity pattern data and afternoon time spent outdoors). Extensive activity pattern data evaluations considering numerous influential factors (e.g., survey year, geographic region, health condition) combined with confidence in the characterization of air quality used as input to exposure calculations suggests a limited potential for bias in our exposure estimates. When considering the FEV_1 risk estimates, the most important uncertainties are found in the lung function risk model itself and the moderate to high sensitivity of FEV_1 responses to changes in values used for certain input variables (i.e., inter- and intra-individual variability in response). Important uncertainties in our epidemiological-based risk estimates are associated with the C-R functions (i.e., overall shape of function at low O_3 concentrations and exposure measurement error) and its application (i.e., the urban study area risk modeling domains are extended beyond the original urban area from which the functions were derived).

Synthesis

To facilitate interpretation of the results of the exposure and risk assessment, this assessment provides a synthesis of the various results, focusing on comparing and contrasting those results to identify common patterns, or important differences. Consistent with the available evidence, we estimated exposures relative to several health-based exposure benchmarks, lung function risks based on a threshold exposure-response model of lung function decrements, and mortality and morbidity risks based on non-threshold C-R functions. These three different analyses result in differing sensitivities of results to changes in ambient O_3 concentrations. Because the three metrics are affected differently by changes in O_3 at low concentration levels, it is important to understand these changes in O_3 at low concentrations in interpreting differences in the results across metrics.

The exposure benchmark analysis is the least sensitive to changes in O_3 in the lower part of the O_3 concentration distribution, because the lowest exposure benchmarks is at 60 ppb, a level above the portion of the overall O_3 concentrations distribution where we observed increases when adjusting air quality to just meet the existing and alternative standards. Because the modeled exposures will always be less than or equal to the ambient monitor concentrations, a benchmark of exposure at 60 ppb is above the range of O_3 concentrations where the model-based adjustment approach estimates increases in concentrations. Thus, this risk metric would most reflect the decreases in O_3 at high concentrations that are expected to result from adjusting air quality to just meeting the existing and potential alternative standards.

The lung function risk analysis is less sensitive than the mortality and morbidity risk assessments to changes at very low concentrations of O_3, because the risk function is logistic and shows little response at lower O_3 doses that tend to occur when ambient concentrations are lower (generally less than 20 ppb for the 10 percent FEV_1 decrement and generally less than 40 ppb for the 15 percent FEV_1 decrement). However, because there are still some ambient concentration increases that occur in the 50 to 60 ppb range where the estimated lung function risk model is more responsive, there may be some reduction in the net risk decrease when adjusting air quality to just meet progressively lower standard levels.

The mortality and morbidity risk assessment is the analysis that is most sensitive to the increases in O_3 in the lower part of the O_3 concentration distribution that we estimated would occur when adjusting air quality to just meet the existing and alternative standards some urban study areas. Mean O_3 concentrations in the urban study areas change little between air quality scenarios of just meeting the existing standard and progressively lower alternative standard levels, because mean concentrations reflect both the increases in O_3 at lower concentrations and the decreases in O_3 occurring on days with high O_3 concentrations. This leads to small net changes in mortality and morbidity risk estimates for many of the urban study areas. However, both the net change in risk and the distribution of risk across the range of O_3 concentrations may be relevant in considering the degree of additional protection provided by just meeting existing and alternative standards.

In conclusion, we have estimated that exposures and risks remain after just meeting the existing O_3 standard and that that in many cases, just meeting potential alternative standard levels results in reductions in those exposures and risks. Meeting potential alternative standards has larger impacts on metrics that are not sensitive to changes in lower O_3 concentrations. When meeting the 70, 65, and 60 ppb alternative standards, the percent of children experiencing exposures above the 60 ppb health benchmark falls to less than 20 percent, less than 10 percent, and less than 3 percent in the worst O_3 year for all 15 case study urban areas, respectively. Lung function risk also drops considerably as lower standards are met. When meeting the 70, 65, and 60 ppb alternative standards, the percent of children with lung function decrements greater than or equal to 10 percent in the worst year falls to less than 21 percent, less than 18 percent, and less than 14 percent in the worst O_3 year for all 15 case study urban areas, respectively. Mortality and respiratory hospitalization risks decrease by 5% or less for a level of 70 ppb, 10% or less for a level of 65 ppb, and 15% or less for a level of 60 ppb. These smaller changes in the mortality and morbidity risks, relative to the exposures and lung function risk reductions, reflect the impact of increasing O_3 on low concentration days, and the non-threshold nature of the C-R function. Larger mortality and morbidity risk reductions are estimated on days with higher baseline O_3 concentrations.

While there remain significant uncertainties identified in each of the analytical areas, we have sufficient confidence in the overall results for them to be useful in informing the policy assessment. Our assessment suggests that the highest confidence should be placed in the results of the human exposure and lung function risk results, largely because they are based on results of controlled human exposure studies and a physiology-based risk model. Medium to high confidence is placed in the results of the assessment of epidemiology-based risks associated with short-term O_3 exposures, because while the large number of studies supporting the C-R relationships provides increased confidence, there still exists uncertainties related to unexplained heterogeneity between locations, exposure measurement errors, and interpretation of the shape of the C-R function at lower O_3 concentrations. Lower confidence is placed in the results of the assessment of epidemiology-based mortality risks associated with longer-term O_3 exposures, primarily because that analysis is based on only one well designed study, and because of the uncertainty in that study about the existence and location of a potential threshold in the C-R function.

References

Henderson, R. (2006). Clean Air Scientific Advisory Committee's (CASAC) Peer Review of the Agency's 2nd Draft Ozone Staff Paper. U.S. Environmental Protection Agency Science Advisory Board. EPA-CASAC-07-001.

Simon, H.; K. R. Baker; F. Akhtar; S.L. Napelenok; N. Possiel; B. Wells and B. Timin. (2013). A direct sensitivity approach to predict hourly ozone resulting from compliance with the national ambient air quality standard. *Environmental Science and Technology*. (47):2304-2313.

U.S. EPA. (2012). Integrated Science Assessment of Ozone and Related Photochemical Oxidants (Final Report). Research Triangle Park, NC: EPA Office of Research and Development. (EPA document number EPA/600/R-10/076F). <http://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=247492#Download>.

This page left intentionally blank

United States Environmental Protection Agency	Office of Air Quality Planning and Standards Health and Environmental Impacts Division Research Triangle Park, NC	Publication No. EPA-452/R-14-004f August 2014