Review of the O_3 NAAQS: First Draft Health Risk and Exposure Assessment (REA)

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CASAC Ozone Panel
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Structure of 1st Draft Health REA

Chapter 1: Introduction

Chapter 2: Conceptual Model

Chapter 3: Scope

Chapter 4: Air Quality Considerations

Chapter 5: Characterization of Population Exposure

Chapter 6: Characterization of Health Risk Based on Controlled Human Exposure Studies

Chapter 7: Characterization of Health Risk Based on Epidemiological Studies

Chapter 8: National-scale Assessment of Short-term Mortality Related to O3 Exposure

Chapter 9: Synthesis and Integration of Results

Overview: Air Quality Considerations

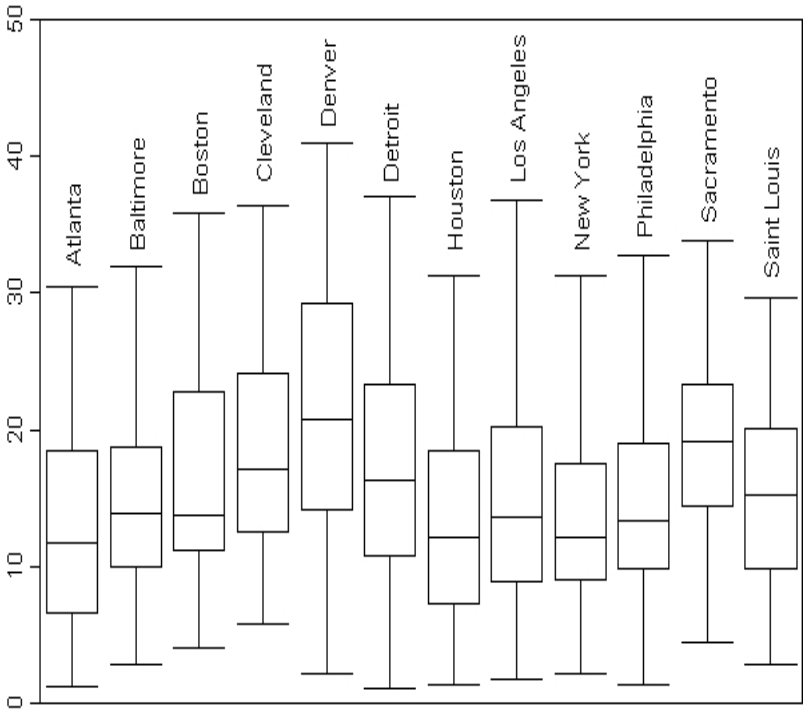
- Urban case study analyses
  - Recent air quality data utilized: 2006-2010, with two 3-year periods for design value calculation (2006-2008 & 2008-2010)
  - Estimation of O_3 concentrations to meet current standard of 75 ppb (and alternative standards for 2nd draft) for 12 case study cities
    - Quadratic rollback method in the 1st draft with concentration lower bound of U.S. background
    - Propose to use CMAQ Higher-order Direct Decoupled Method (HDDM) information for simulating just meeting the current and alternative standard levels in the 2nd draft to better reflect O_3 concentration changes from NOx and VOC emissions reductions

REA Urban Study Areas

- Urban study area selection criteria:
  - O_3 concentrations measured between 2006-2010
  - Availability of data (e.g health study data, baseline-health incidence, air conditioning prevalence data)
  - Inclusion of sensitive populations
  - Geographic heterogeneity

- ***12*** *areas included in the urban area risk assessment in 1st draft (blue and red circles)*
- ***16*** *areas proposed to be included in exposure assessment in 2nd draft (all shown)*
  - → ***4*** *of these areas included in exposure assessment in 1st draft (blue circles)*

Quadratic Rollback and U.S. Background

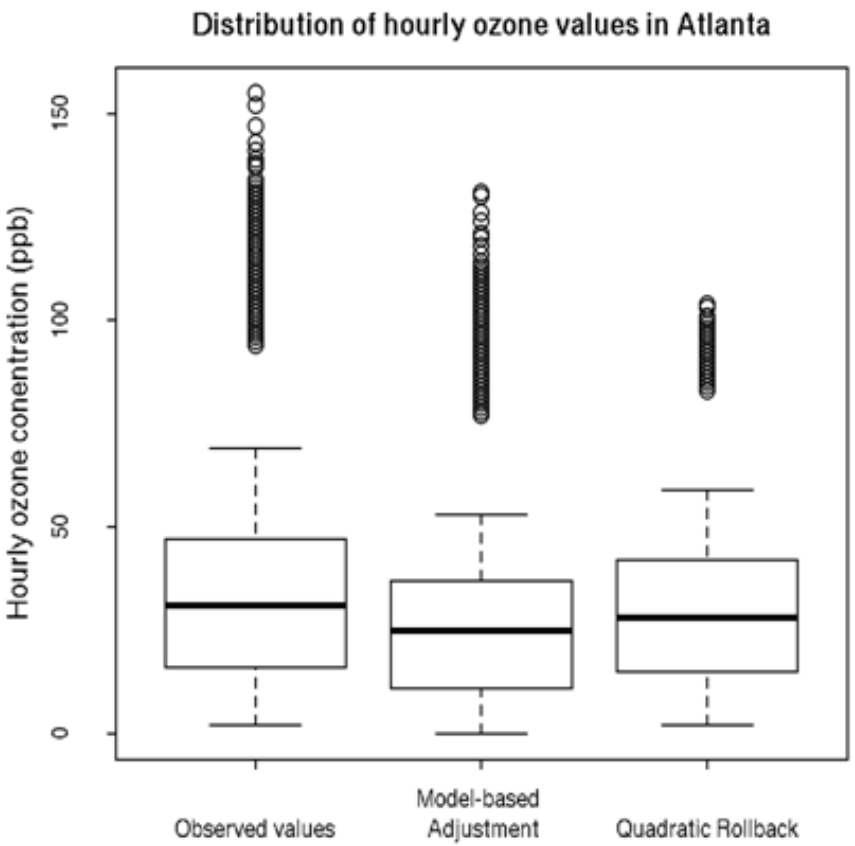


Distribution of U.S. Background values used in Quadratic rollback as the lower bound or "floor" for simulating just meeting the current standard in the urban case study areas

- Monthly average diurnal profiles of U.S. Background concentrations were calculated for each of the 12 urban areas
- Values varied from area-to-area but generally ranged from near 0 ppb (in early morning, nighttime) to 30 to 40 ppb (in afternoon). Median values were between 10 to 20 ppb.
- The average magnitude of the adjustments to account for background was very small (< 0.2 ppb), and even the largest adjustment was less than 5 ppb.

Model-based Adjustment: CMAQ HDDM

- We are proposing to use modeling information from CMAQ HDDM to simulate just meeting the current and alternative levels of the standard for the 2nd draft
  - Better address the various chemical conditions across an urban area
  - More realistically simulate diurnal changes in O3 concentrations (increases and decreases) from emissions reductions
- Case study results in Atlanta demonstrated that:
  - Ozone in urban core is less sensitive to NOx emissions reductions than ozone in outlying areas
  - HDDM adjustment shifts 25th, 50th, 75th, and 95th percentile ozone values lower than quadratic rollback
  - Quadratic rollback shifts highest outlier values lower than HDDM adjustment

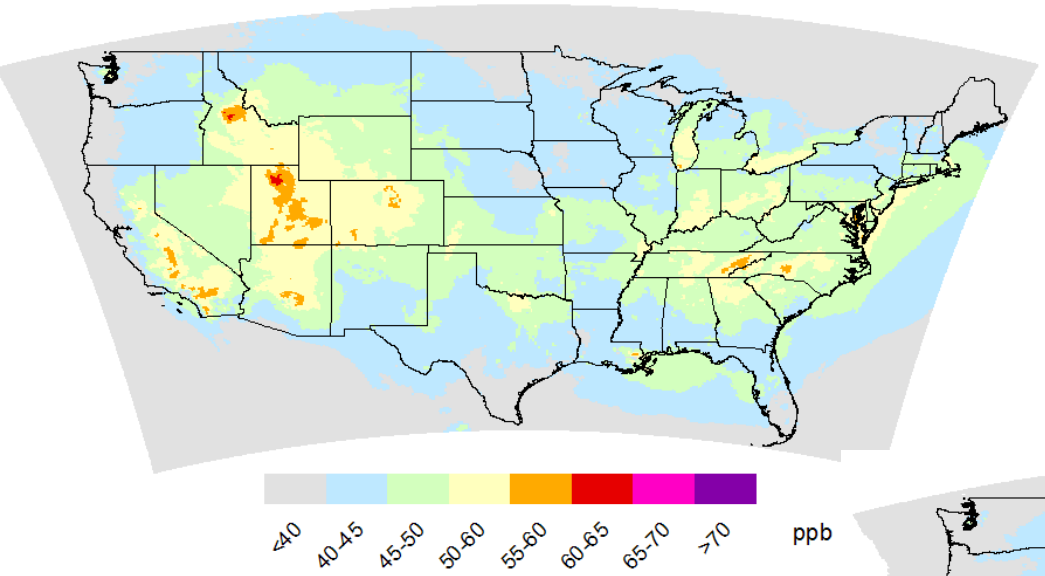


Distribution of hourly ozone values at 10 Atlanta-area monitoring sites comparing Quadratic rollback approach to model-based adjustment

Overview: Air Quality Considerations

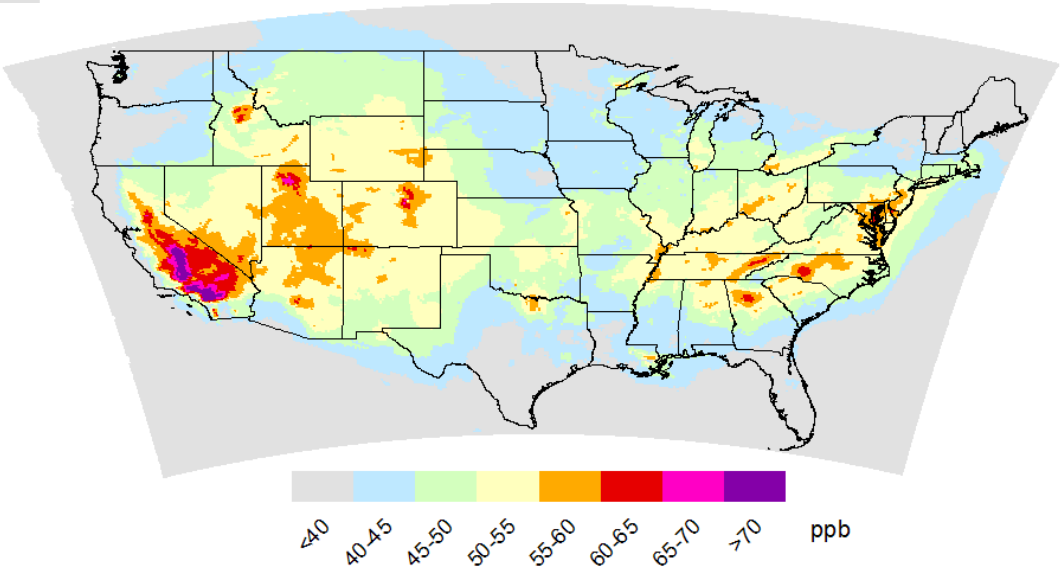
- National-scale risk analysis
  - 2006-2008 O_3 measurements fused with 2007 CMAQ 12 km modeling data using the enhanced Voronoi Neighbor Averaging (eVNA) technique
  - Measurements provide the absolute O_3 concentration values for the "fused surface" while the modeled concentrations determine O_3 concentration gradients between monitors
  - Fused surfaces created for two metrics:
    - Seasonal average 8-hr daily maximum (O_3 season) -- consistent with the metric used by Bell et al., 2004
    - Seasonal average 8-hr daily mean (10am-6pm, Jun-Aug) -- consistent with the metric used by Zanobetti and Schwartz, 2008

Air Quality "Fused Surfaces" for O_3 , 2006-2008



Seasonal average 8-hr daily maximum (O_3 Season)

Seasonal average 8-hr daily mean (10am-6pm, Jun-Aug)



Exposure Assessment

- Exposure estimates for the general population, children, asthmatic children
- Benchmark levels: 0.06, 0.07, 0.08 ppm 8-hour exposures
- Older people (>65) and outdoor workers [2nd draft REA]
- 16 urban areas [4 in 1st draft REA]

Air Pollution Exposure Model (APEX)

- APEX is the evolutionary product of a two-decade long effort
- Designed to assess inhalation exposure to criteria and air toxic pollutants
- Simulates movement of people through their daily activities and their exposure to pollutants
- Probabilistic assessment (variability)

Exposure: New Analyses

- Evaluating attributes of most exposed and highest ΔFEV_1 risk populations
  - O_3 level, time outdoors, exercise
- Qualitative analysis of the effect of Air Quality Index on exposures ("averting behavior")
  - Reduced outdoor activity level: estimated 30% participation rate for asthmatics, 15% for total population
  - Reduced time spent outdoors: 20-40 minutes

Exposure Uncertainty Characterization

- Qualitative Approach
  - Review uncertainty characterizations from prior NAAQS reviews that used APEX modeling
- Results: Important Elements of Uncertainty
  - Time-location-activity patterns
  - Spatial variability in O_3 concentrations (near road)
  - Physiological model for estimating ventilation rates

Lung Function Risk Assessment

- Decrements in Forced Expiratory Volume in one second (FEV_1) > 10, 15, 20% clinically relevant levels
- Based on population exposure-response relationships derived from controlled human exposure studies
- Exposure distributions combined with exposure-response relationships (as in previous reviews)
- Estimating individual level FEV_1 decrements based on the model of McDonnell, Stewart, and Smith (2007, 2010) (new)

Primary Method for Estimating Lung Function Risk (used in previous O_3 NAAQS reviews)

- Exposure-response (E-R) curves based on analysis of data from 6.6-hour clinical studies
- Responses (FEV_1 decrements) measured at the end of 6.6-hour exposures
- Five exposure levels from 0.04 to 0.12 ppm
- Exposure distributions from APEX are combined with the E-R curve to estimate population at risk for $\Delta FEV_1 > 10\%$, 15%, 20%

Updated Exposure-Response Functions

- Exposure-response (E-R) curves being updated with data from additional 6.6-hour studies
- Risk results based on updated functions will be in the 2nd draft REA

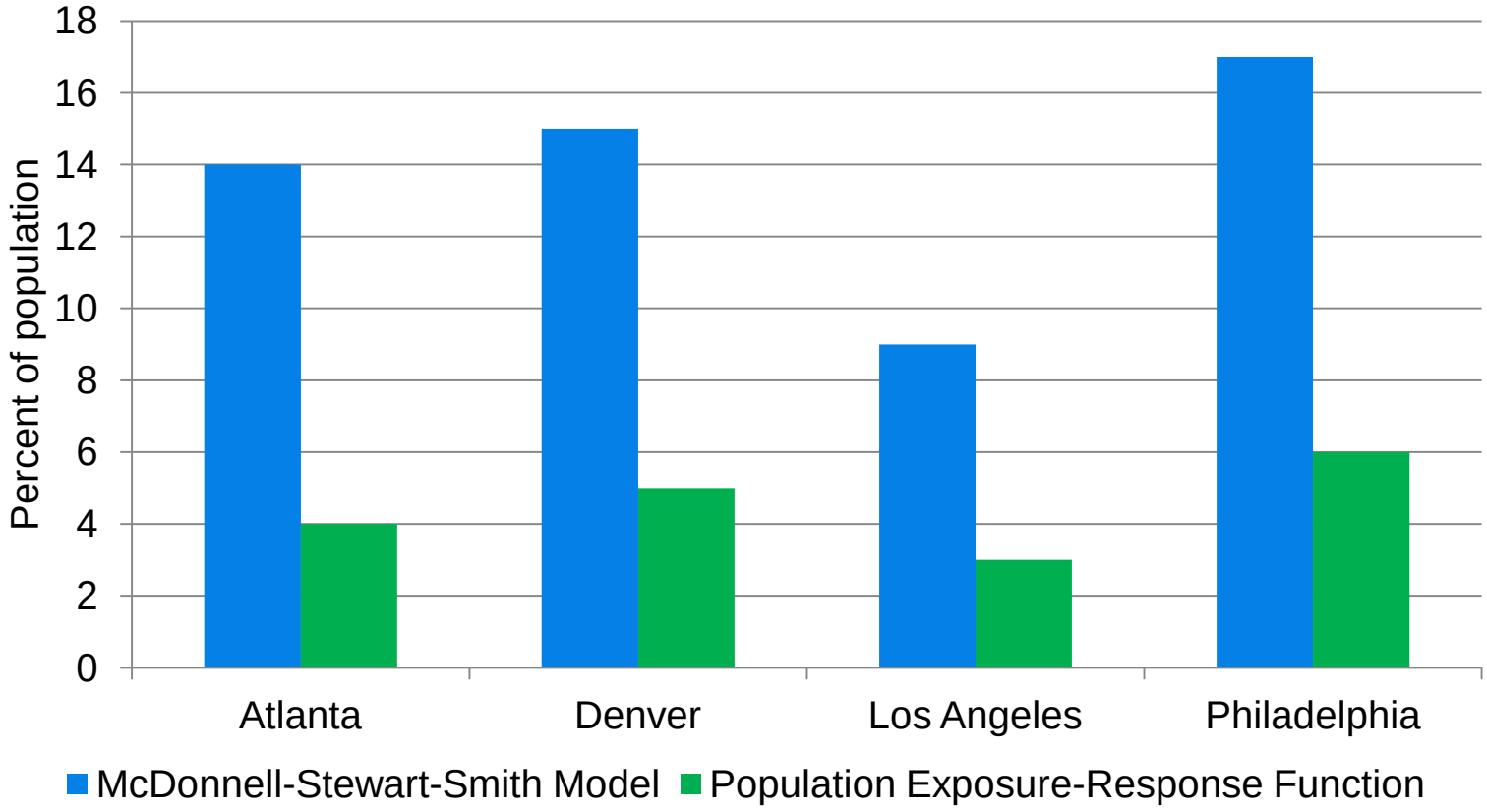
New Model for Reduced Lung Function

- McDonnell, Stewart, and Smith (2007, 2010)
- This model predicts lung function decrement for any pattern of exposure and exercise
- This approach allows us to evaluate the distribution of risk across modeled individuals, and characterize the highest risk individuals

New Model for Reduced Lung Function

- Predictions of ΔFEV_1 based on individuals' ages, heights, weights, time course of ventilation rates, O_3 exposures
- Based on data from 15 EPA studies (241 healthy young adults ages 18 – 35; 0.08 – 0.4 ppm O_3)
- Data from recent low-O_3 and other clinical studies are being used to update the model [2nd draft REA]
- Issues
  - Extension to ages <18 and >35
  - Uncertainty for population not represented by the data is unknown

Percent of population with > 10% FEV1 decrements, 2010, current standard, ages 5-18



Two Types of Risk Assessment

- Goals of the **Urban Study Area** analysis:
  - Provide high-confidence estimates of risk for individual urban areas and associated residential populations
  - Risk evaluated for current conditions, simulated attainment of the current standard and alternative standard levels (2nd Draft REA)
- Goals of the **National-Scale** analysis
  - Estimates mortality attributable to O_3 in the U.S.
  - Evaluate representativeness of 12 urban study areas for general patterns of O_3 exposure and risk seen across the U.S.
  - Only evaluated for current conditions scenario

Key Elements of Analysis Design for Urban Study Area Analysis

- Epidemiological study-based concentration-response functions
  - 1hr and 8hr max/mean metrics used (24hr-based *concentration-response* functions deemphasized)
  - Requires baseline incidence and demographic data
- Population exposure characterized using ambient monitoring data in the form of composite monitors (urban study areas)
- Simulation of current standard based on quadratic rollback
  - US background used as floor for rollback
  - Estimates of total risk down to zero and *lowest measured level* (LML)
  - Emphasis placed on estimates of reductions in risk as higher confidence estimates
- Core set of higher confidence risk estimates supplemented by sensitivity analyses

Health Endpoints Modeled

- Mortality (likely casual relationship)
  - Non-accidental
  - All-cause
  - Cardiovascular
  - Respiratory
- Respiratory effects (causal relationship)
  - Emergency department (asthma, wheeze, all respiratory symptoms)
  - Hospital admissions (unscheduled pulmonary illness, asthma)
  - Respiratory symptoms

Uncertainty and Variability Characterization

- Characterization of uncertainty based on application of WHO's 4-tiered approach
  - Complexity of analysis and significance of regulatory decision supports tier 4 (full probabilistic analysis) – but data limitations prevent this
  - Qualitative evaluation of uncertainty (magnitude and direction of effect/bias for key sources)
  - Limited set of sensitivity analyses for 1st Draft REA
- Variability – evaluated degree to which analysis design provided coverage for key aspects of variability

Long Term Exposure-Related Mortality and Morbidity

- Plan to model respiratory-related mortality for 2nd Draft REA
- Possibly include regional estimates of respiratory mortality as sensitivity analysis
- Available epi evidence characterizing long-term exposure-related morbidity does not support quantitative risk analysis at this time

National-Scale Analysis

- Key aspects of analysis
  - National-scale analysis of short-term exposure-related mortality (premature mortality)
  - Current conditions only
  - Uses fused (CMAQ and monitor) surface
    - 12km gridded CMAQ results (2007)
    - monitoring data (2006-2008)
  - Lowest measured level (average across all cities); risk also modeled down to zero

Key Observations – 1

- Urban Study Area Analysis – *current standard*
  - Short-term exposure-related mortality estimates range up to ~800 annual deaths (~5% of baseline) across 12 urban study areas
  - Choice of epidemiological study can significantly effect spatial pattern of mortality risk
  - Short-term exposure-related ED visits range into the thousands in Atlanta and New York ; HA's range into the hundreds in New York
- National-Scale Analysis – *current conditions*
  - National burden of O_3-related mortality (short-term exposure) ranges between 13,000 and 18,000
  - The representativeness analysis suggests that 12 urban study areas:
    - Capture range of O_3 levels and effect estimates (favor high-end)
    - May not capture high end with regard to baseline mortality rates, oldest populations and air conditioning usage.

Possible Refinements to the Analyses

- Alternative standard levels (definite)
- Expanding sensitivity analyses
- Consider alternative methods to simulate attainment of standard levels
- Model long-term exposure-related mortality endpoint

Questions?