



TCEQ Perspectives on the Health Effects Review of Ozone

Hot Air Topics
Air and Waste Management Association

Feb. 11, 2016



Conversations about the Ozone Rule

July 17, 2015 - Meeting with EPA Administrator McCarthy and Acting Assist. Administrator McCabe

July 29, 2015 – Meeting with EPA Office of Air Quality Planning and Standards (OAQPS)

Sept. 22, 2015 – Meeting with the Office of Management and Budget (OMB)

Oct. 22, 2015 - Hearing for the House Committee on Science, Space & Technology: EPA's 2015 Ozone Standard: Concerns over Science and Implementation

<https://science.house.gov/legislation/hearings/full-committee-hearing-epa-s-2015-ozone-standard-concerns-over-science-and>



Overview

- Ozone dose-response (not concentration-response) and exposure data should be used to interpret health effects data and determine risk
- Ozone dose, based on EPA-derived exposure patterns, shows only marginal changes when lowering the daily 8-hour maximum ozone concentration from 75 to 70 or even to 65 ppb
- Ozone dose and exposure analyses casts doubt on ozone-attributable mortality, as does the EPA modeling
- According to the EPA's modeling, ozone attributable asthma exacerbations and respiratory hospitalizations will not statistically significantly decrease with a decreasing ozone standard



Background

- NO_x is responsible for both formation and scavenging of O_3
- O_3 reacts with indoor surfaces and ventilation, scavenging it from indoor air – O_3 is effectively an outdoor pollutant
- O_3 is a highly-reactive, poorly water soluble gas at room temperature, and is a respiratory toxicant
- Inhaled O_3 :
 - Is scavenged by antioxidants in the respiratory tract
 - When antioxidants are depleted, it causes a neural reaction that decreases breathing volume, in addition to other responses such as inflammation

Human Controlled Exposure Studies



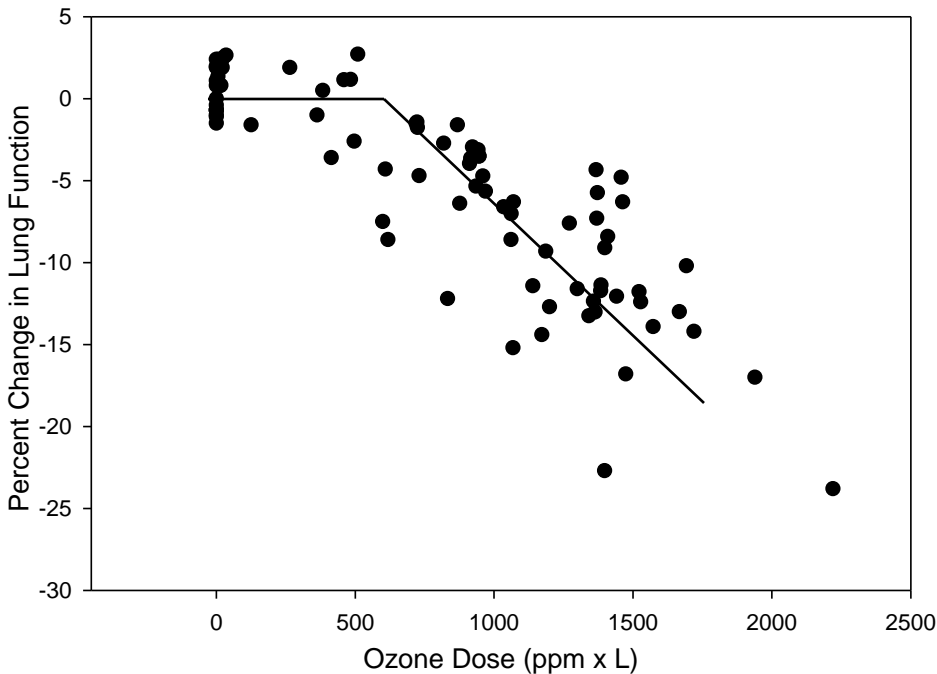
- Healthy volunteers are exposed to ambient or near-ambient concentrations of O_3 while exercising at moderate to vigorous exertion for 50 min/hr for 6.6 hours (Ref)
- Averaged 33 L/min ventilation rate; we're breathing ~ 5 L/min now
- These studies measure primarily forced expiratory volume in 1 second (measures how deep a breath you can take)
- FEV_1 decreases with increasing air toxicant
- Reversible effect (within minutes to hours)



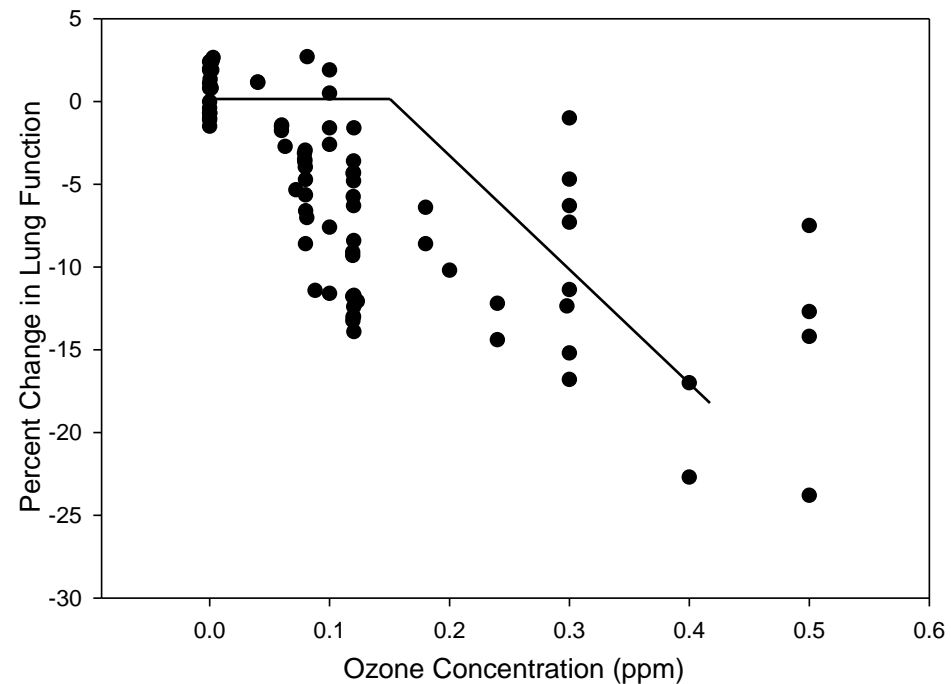
Ozone Dose vs Concentration

Dose = Concentration x Ventilation Rate x Duration

Ozone Dose-Response

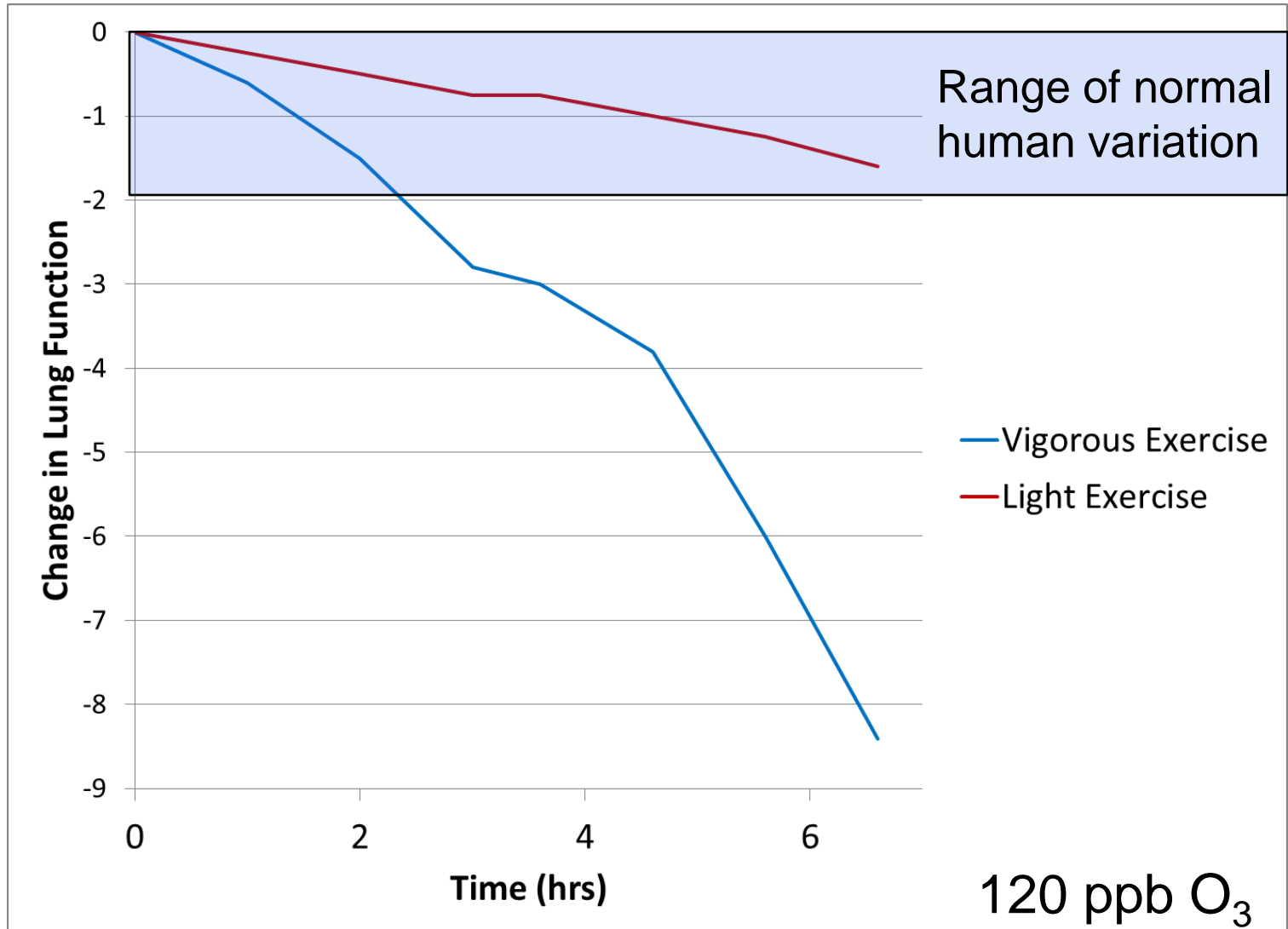


Ozone Concentration-Response





Characteristics of Human Exposure Studies - Exercise





Ozone Dose

Dose = Concentration x Ventilation Rate x Duration

Example Exposure Scenario

Ventilation Rate & Duration

**Exposure
Concentration**

75 ppb
70 ppb

(daily 8-hr
maximum
average)

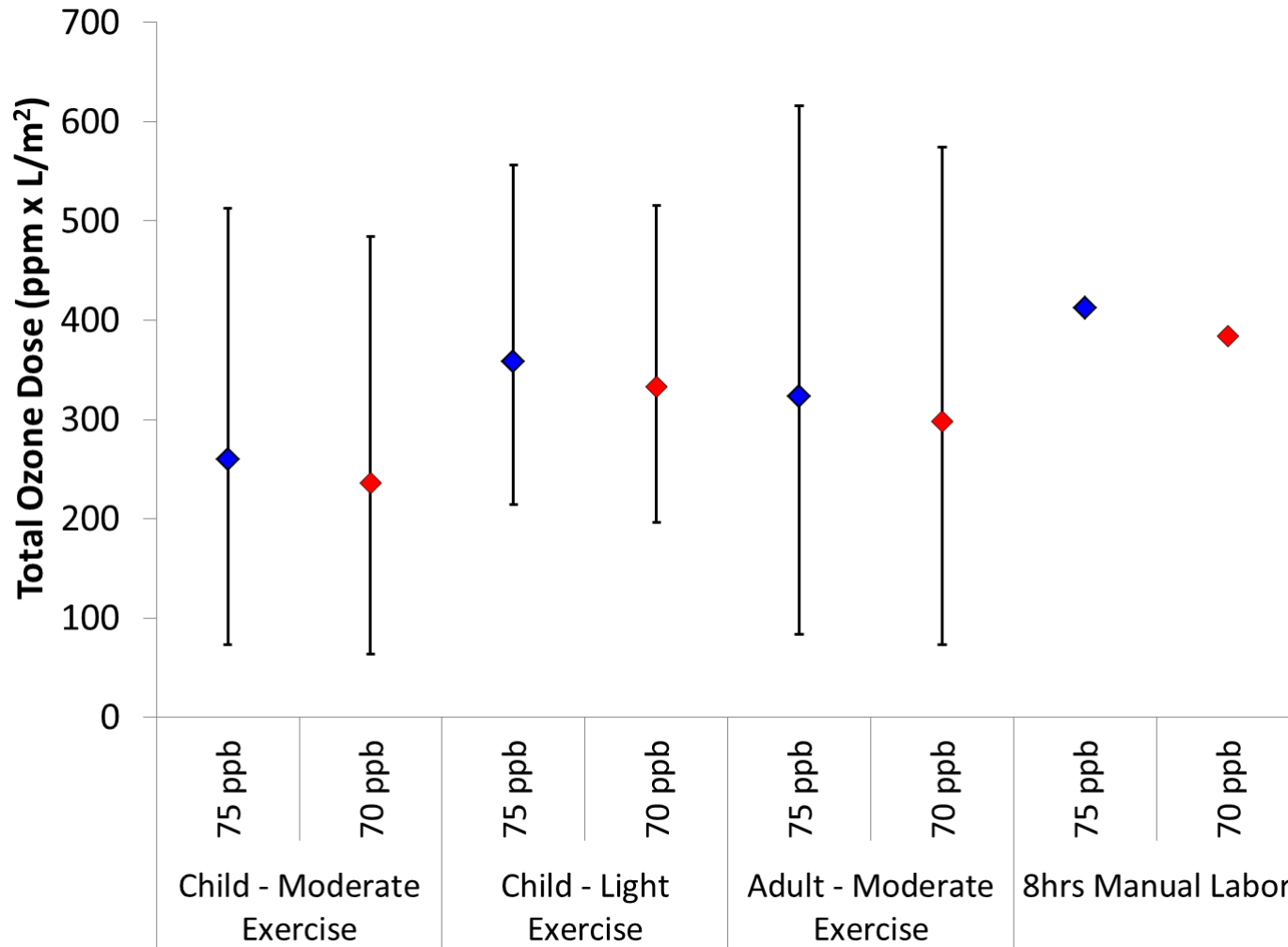
Population & Exercise	Ventilation Rate (L/min)	Duration (hrs)
Child, moderate exercise ¹	21.6 (± 5)	2.6 (± 2)
Child, light exercise ¹	11.3 (± 3)	7.4 (± 2)
Adult, moderate exercise ¹	26.1 (± 6)	6.3 (± 3)
Manual labor ²	22	8

¹US EPA 2009. Metabolically derived human ventilation rates: a revised approach based upon oxygen consumption rates.

²US EPA 1994. Methods for derivation of inhalation reference concentrations and application of inhalation dosimetry



Ozone Dose & Exposure Examples



Most ozone doses (based on EPA-derived exposure patterns) would **change very little with a changing ozone standard** 9



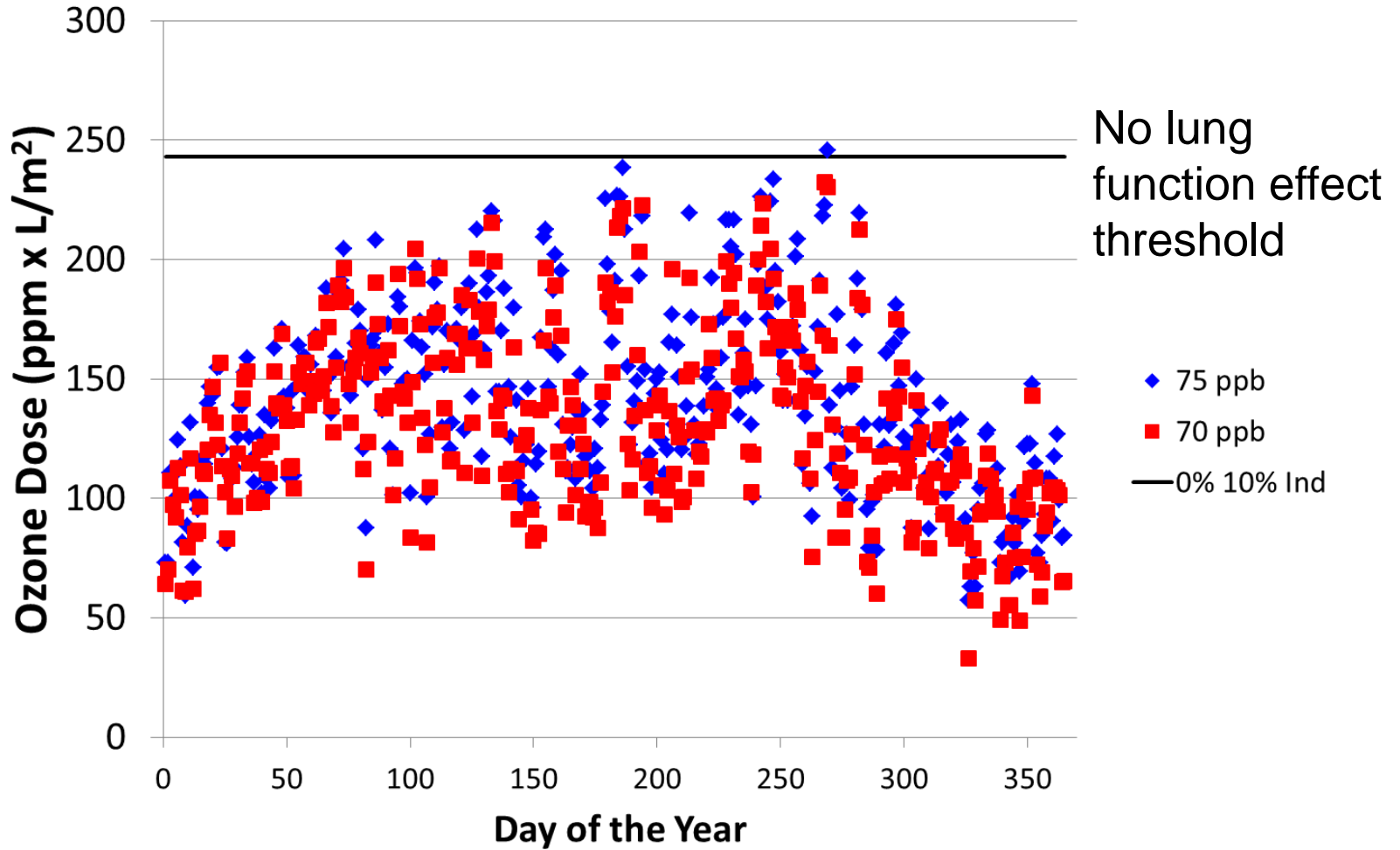
Assumptions for Ozone Dose & Exposure Example

- Exposure occurs on **one of the 4 days per year** that the 8-hour daily maximum ozone concentration exceeds 75 or 70 ppb (based on EPA's form of the ozone standard)
- Exposure occurs **outdoors**, to an **exercising** individual
- Exposure occurs during the **maximum average time frame**
- EPA considered dose and exposure in their MSS and APEX models, however:
 - No confidence intervals were provided with the point estimates of ozone exposure and lung function decrements, making it difficult to assess the certainty of the conclusions that can be drawn from the estimates
 - Problems with the APEX model include exposure over-estimation by up to 10-fold (HREA Appendix 5, Section 5G-5), which according to the document "is subject to further investigation"



Ozone Dose for Children in 2013

Ozone Dose for 6-11 year old children exercising moderately in Texas in 2013

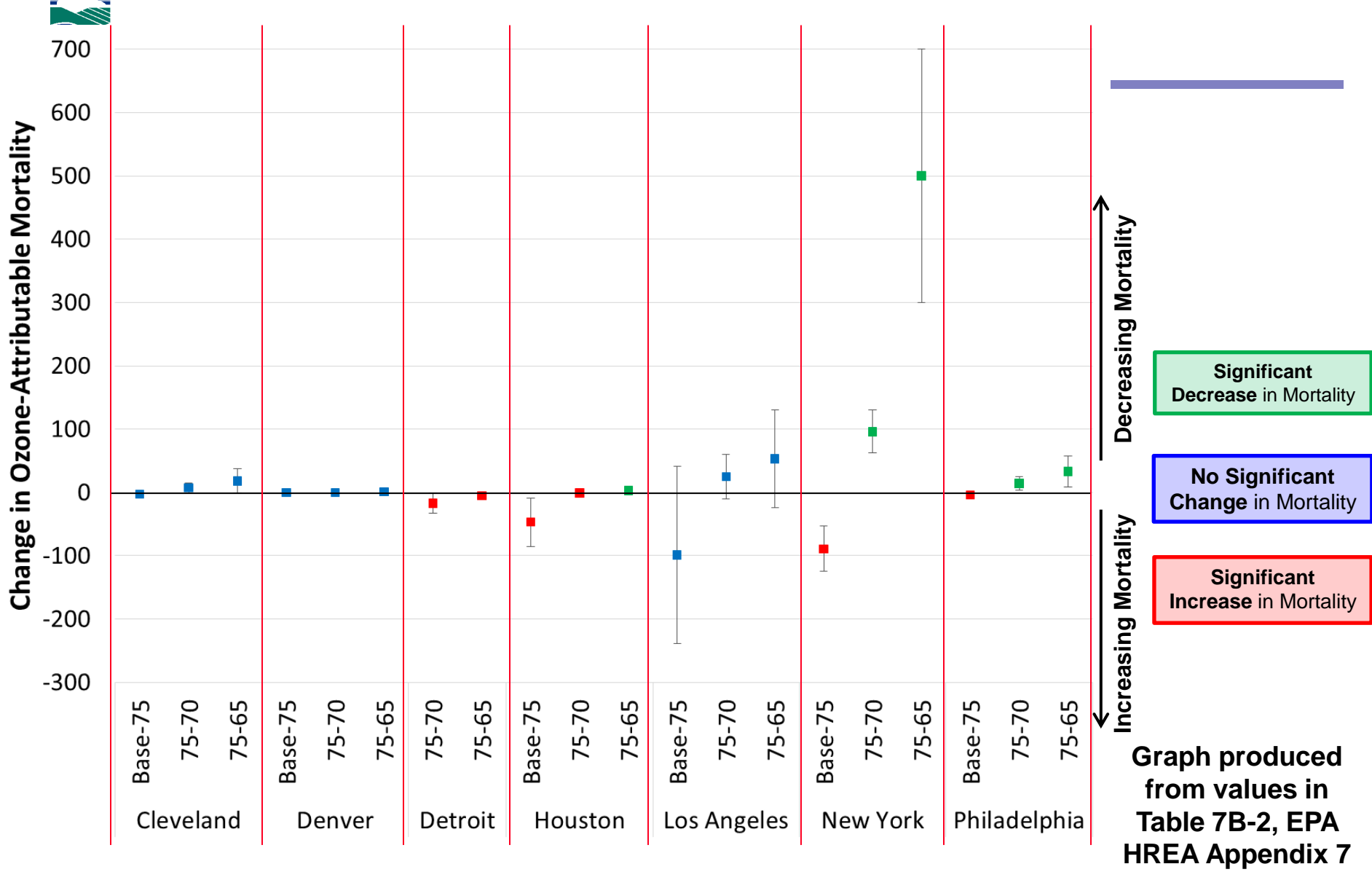




Dose, Exposure & Epidemiology

- Epidemiology studies provide information about potential health effects of an agent on the entire population
- Health endpoints of interest: premature mortality, asthma exacerbations, hospital admissions
- Because of uncertainties (listed below) epidemiology is best used **qualitatively**
- Uncertainties with epidemiology data used by EPA:
 - No individual-level consideration of ozone exposure (don't consider being outdoors, exercising, etc.)
 - **Biological plausibility** of mortality and severe morbidity being **caused** by ozone
 - **Lack of statistically significant effects** of ozone on health endpoints, as analyzed by EPA (a statistically significant effect can be measured by whether or not the 95% confidence interval, or error bars, include zero in the estimate)

Change in Ozone-Attributable Mortality with Decreasing Ozone

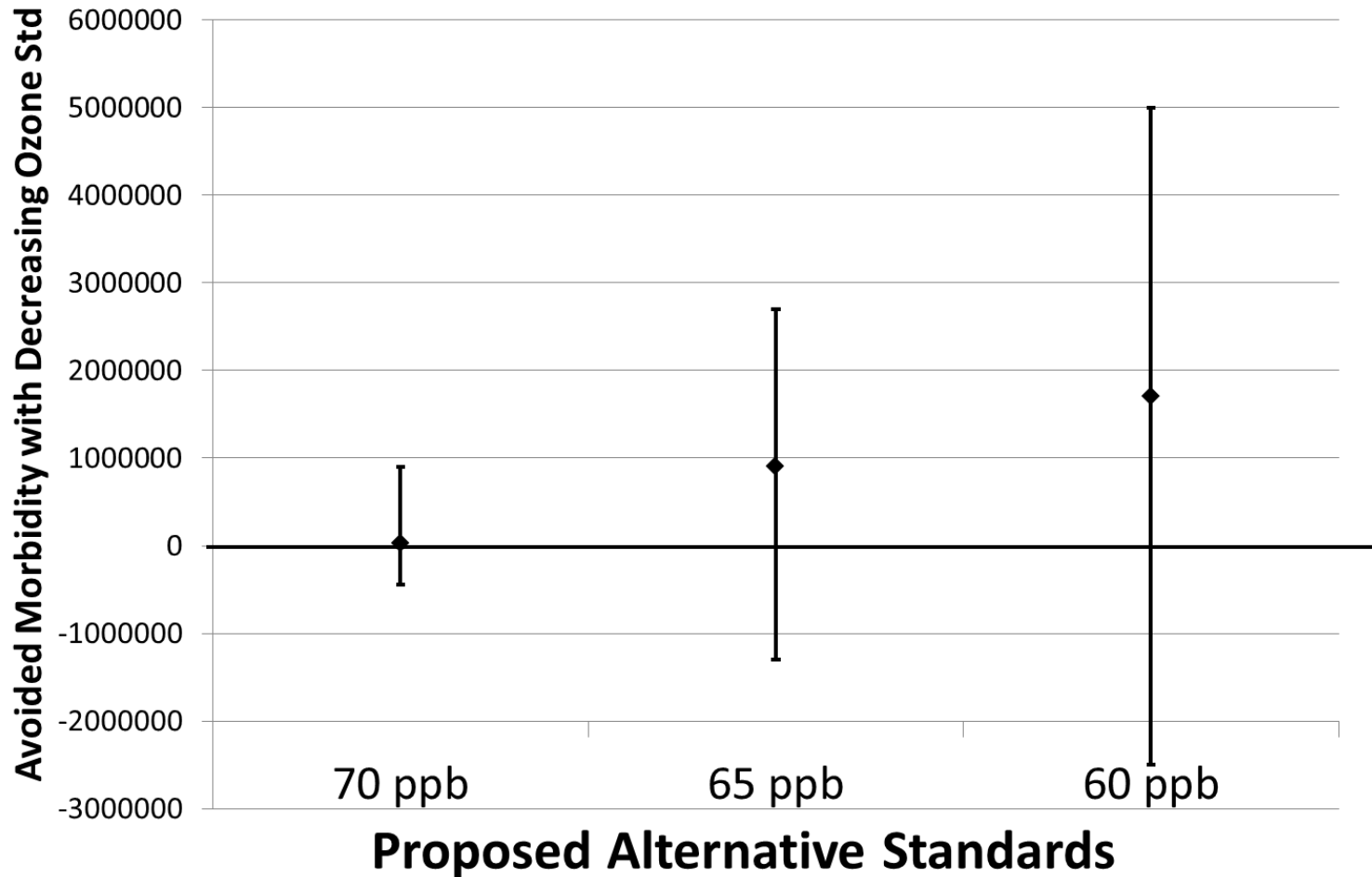


Most cities show **no change in mortality** (and some show **increased mortality**) with a decrease in the ozone standard



Effect of Decreasing Ozone Standards on Asthma Attacks

Avoided Asthma Attacks (age 6-18)

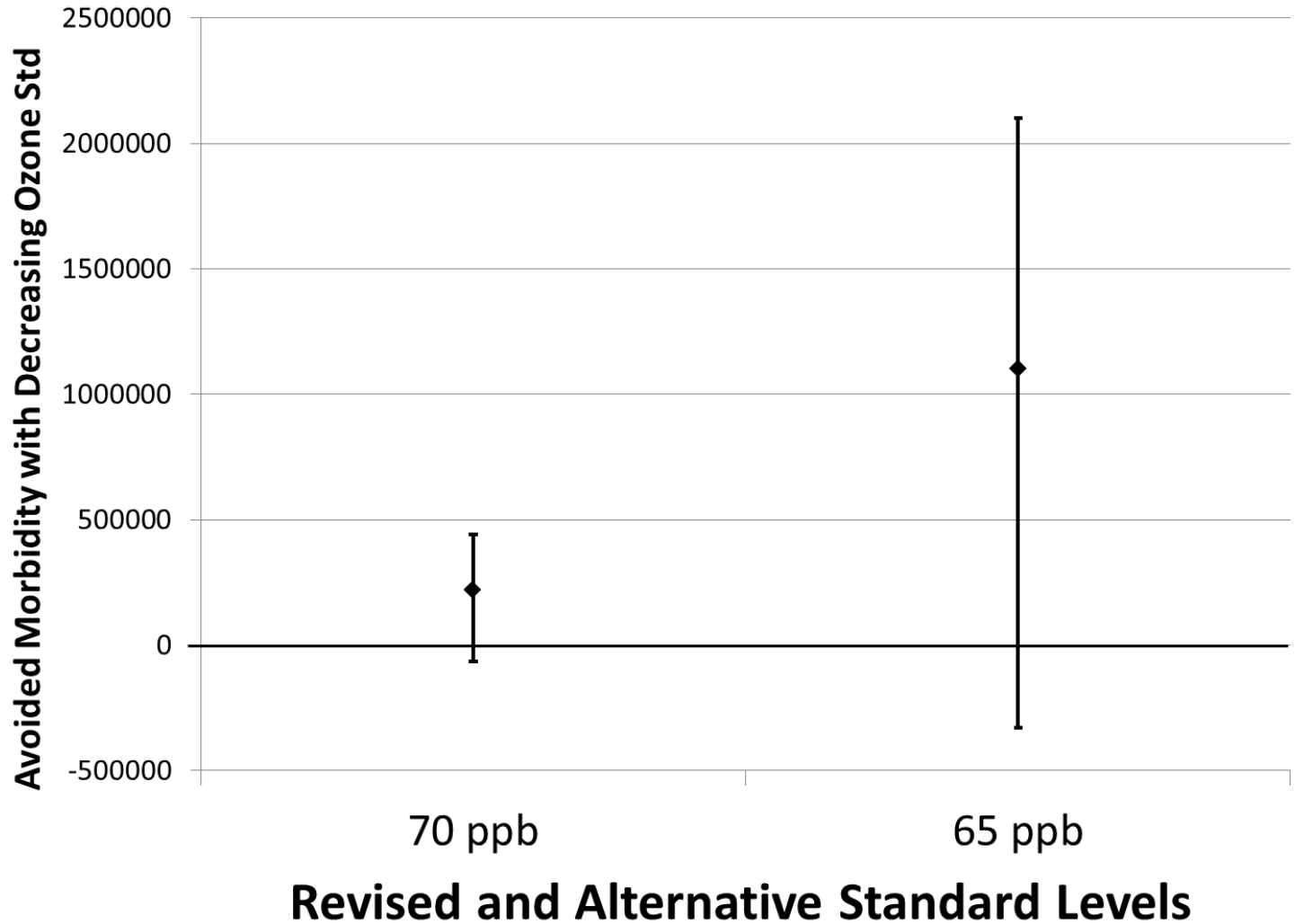


Graph produced from values in Table 5-19, EPA Ozone RIA 2014

The EPA projects **no statistically significant change in asthma attacks** with a decrease in the ozone standard



Effect of Decreasing Ozone Standards on Asthma Attacks



Graph produced from values in Table 6-20, EPA Final Ozone RIA 2015

The EPA projects **no statistically significant change in asthma attacks** with a decrease in the ozone standard



Future Work

Investigation of the EPA's APEX/MSS model for ozone risk assessment, because:

- Assuming a standard of **60 ppb**, the EPA estimates that in 12 study cities:
 - **70,000 children** will have at least one exposure to \geq 60 ppb ozone for 8 hours at moderate exertion
 - From the clinical studies, $< 10\%$ of these children will experience a 10% or greater FEV₁ decrement
 - **1,404,000 children** will experience at least one 10% FEV₁ decrement
 - Would expect this to be 0.1 to 1 x of 70,000; not 20 times more

From Tables 1 & 2, Ozone Final Rule, 2015

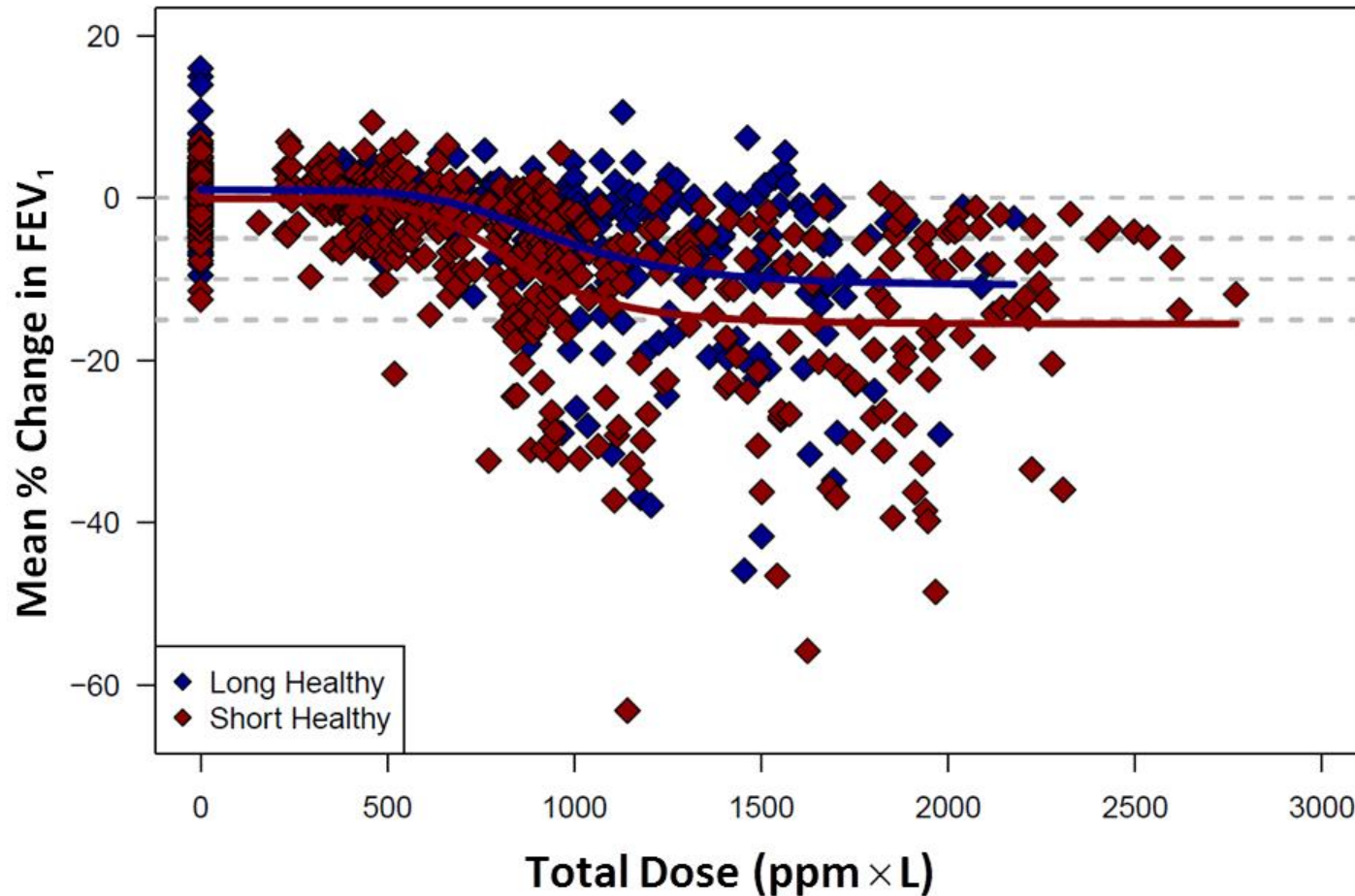


Exposure Assessment

- Uses the Air Pollution and Exposure Model (APEX)
- Considers multiple inputs:
 - Individual information – time-activity patterns, activity levels, etc.
 - Population information – census tracts, employment distributions, etc
 - Air Quality
 - Meteorology
 - Microenvironmental information – Air exchange rates, time spent in vehicles, etc
- Simulate thousands of people over an ozone season
- Output number of people exposed to ≥ 60 ppb for 8 hours while also moderately exercising

Risk Assessment

- Starts with the clinical data:



Risk Assessment

- McDonnell, Stewart & Smith described this in an equation - the MSS Model:

$$X(t_1) = X(t_0)e^{-\beta_5(t_1-t_0)} + \frac{C(t_1)}{\beta_5}V(t_1)^{\beta_6}(1 - e^{-\beta_5(t_1-t_0)})$$

$$\% \Delta FEV_{1,it} = e^{U_i} \left[\frac{\beta_1 + \beta_2(A_i - \bar{A})}{1 + \beta_4 e^{(-\beta_3 X_{it})}} - \frac{\beta_1 + \beta_2(A_i - \bar{A})}{1 + \beta_4} \right] + \varepsilon_{it}$$

Describes variation in response between individuals

Describes lung function change by ozone concentration, duration of exposure and ventilation rate

Describes variation in response within an individual

- Results from the exposure assessment are inputs into the MSS model, and an FEV₁ decrement is calculated



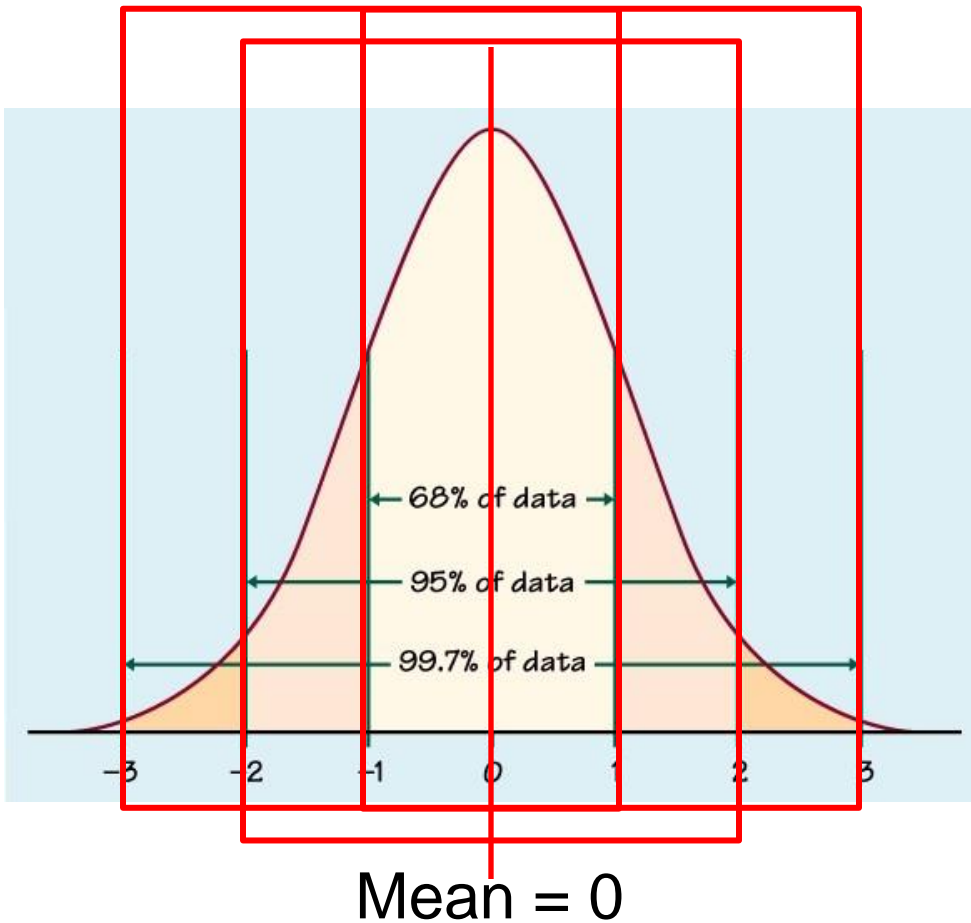
Concerns with Individual Error Term

- General or inter-individual error term is intended to capture unexplained influences on lung function decrement
- EPA has designated this error term to change on a daily basis in the APEX/MSS model
- Concerns with daily changes:
 - Only a few studies have exposed people to ozone on multiple consecutive days
 - Available data shows that subsequent exposures to ozone have less and less effect on lung function (adaptation)
 - A person exposed months later will show a similar response to ozone
 - Therefore, expecting a person to significantly change (for the better or the worse) in their response to ozone is unrealistic



Concerns with Individual Error Term

Estimate of children expected to experience 1 or more 10% FEV₁ decrements in an ozone season:



Error Term Distribution	% with 10% FEV ₁
Core (+/- 2 SD)	31.7%
Mean	17.7%
1 SD	20.1%
3 SD	91.7%

From Table 6-16, Ozone HREA, 2014



Conclusions

- Ozone dose-response (not concentration-response) and exposure data should be used to interpret health effects data and determine risk
- Ozone dose, based on EPA-derived exposure patterns, shows only marginal changes when lowering the daily 8-hour maximum ozone concentration from 75 to 70 or even to 65 ppb
- According to the EPA's modeling, ozone attributable asthma exacerbations and respiratory hospitalizations will not statistically significantly decrease with a decreasing ozone standard
- Future plans are to investigate the discrepancies in the risk assessment results from the APEX/MSS models



Contact Information

- Michael Honeycutt, Division Director, Toxicology Division – michael.honeycutt@tceq.texas.gov
- Sabine Lange, Section Manager, Toxicology Division – sabine.lange@tceq.texas.gov
- Lindsey Jones, Toxicologist, Toxicology Division – lindsey.jones@tceq.texas.gov