WHAT DO POLICY MAKERS AND RISK ASSESSORS NEED TO KNOW ABOUT ADVERSE AIR POLLUTION EFFECTS AT LOW LEVELS OF EXPOSURE?

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BOTTOM LINE: WE NEED TO KNOW…..

- What is the evidence of effects occurring at the level of the existing standard and at potential lower alternative standard levels for at least $PM_{2.5}$, $PM_{10-2.5}$, O_3, SO_2, and NO_2?
- What is the nature of concentration-response functions for the full range of potential population exposures, including any information about potential thresholds, non-linearities in the functions, and confidence bounds around the function?
- What is the relationship between effects occurring at specific levels of a surrogate exposure measure (e.g. central site monitor or average of monitors in an urban area) and personal exposures?
- To what extent do associations in epidemiological studies, particularly those at relatively low pollutant concentrations, reflect causal relationships? Are exposure surrogates for individual pollutants indicators of pollutant mixtures/sources or directly causal, especially at low concentrations?
- What is the evidence for interactions between pollutants at lower concentrations?

HOW ARE EPIDEMIOLOGY RESULTS USED BY EPA?

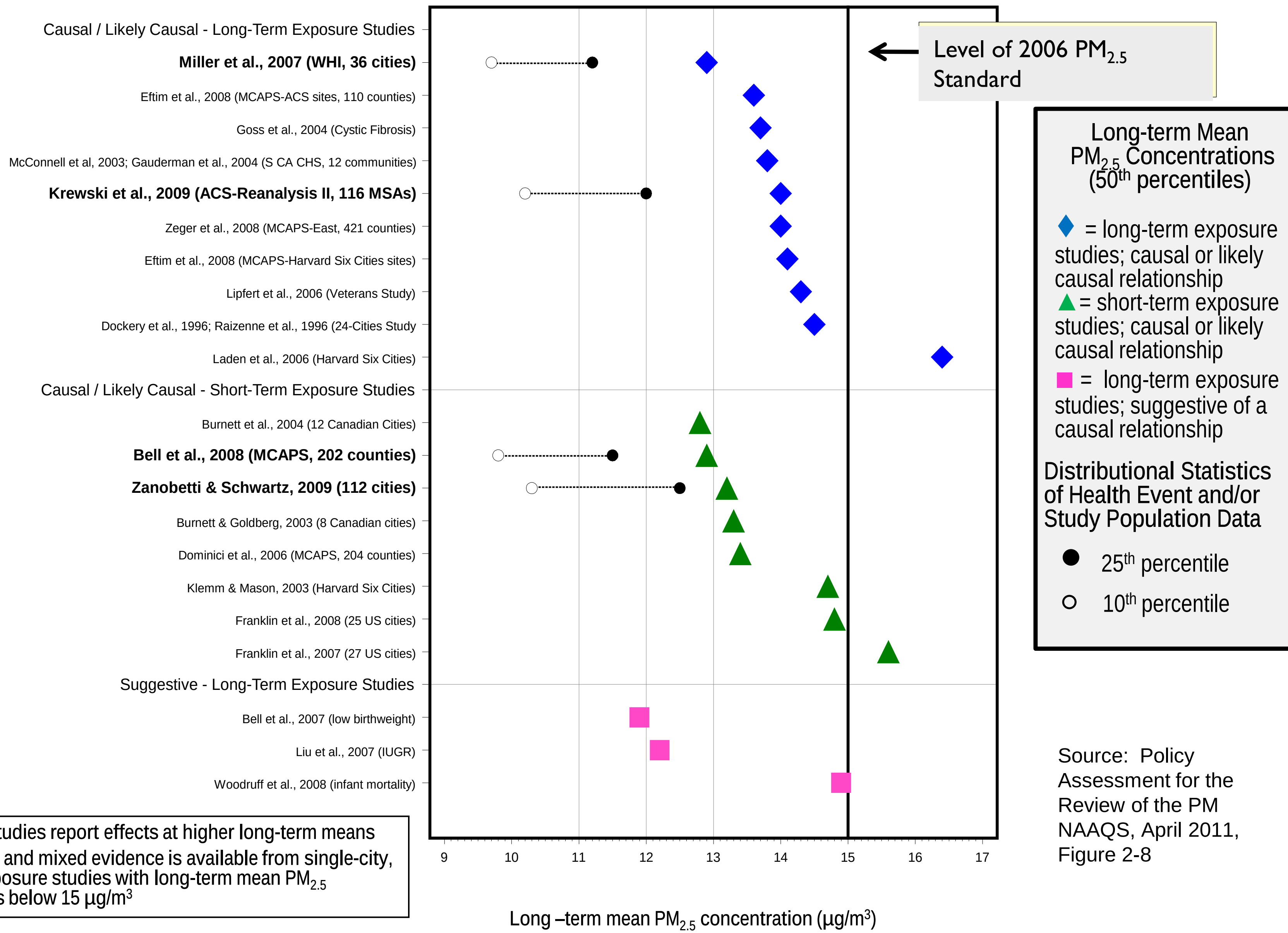
- NAAQS reviews
  - Integrated science assessment
  - Risk assessment
  - Policy assessment
- Regulatory Impact Analyses
  - NAAQS reviews
  - Implementation rules
  - Co-benefits of air toxics and GHG rules
- National and international health burden assessments

EPIDEMIOLOGY IN NAAQS REVIEWS: RISK ASSESSMENT

- In some previous reviews, risks assessed only down to "policy relevant background" (PRB) or lowest observed levels (LML) in epidemiology studies
  - In the 2006 PM review, based on CASAC comments, risks were estimated with a 10 µg/m^3 assumed threshold, with a slope adjustment – CASAC called for additional research regarding thresholds and non-linearities in C-R functions
  - In the 2012 PM review, risks were estimated in excess of either PRB for evaluating effects associated with short-term PM2.5 concentrations or LML for evaluating effects associated with long-term PM2.5 concentrations
  - In the 2008 O_3 review, risks were estimated in excess of PRB
- Generally, risk assessments focus on estimating risk in a representative set of urban areas
  - In recent reviews, also included a national burden assessment for recent air quality conditions
- In most recent O_3 review:
  - Risks estimated down to zero concentrations for short-term exposure studies
  - For long-term O_3 exposure, risks were estimated both for models with and without a threshold

EPIDEMIOLOGY IN NAAQS REVIEWS: POLICY ASSESSMENT

- Focus has been on identifying studies where air quality concentrations are at or below the existing or alternative NAAQS level(s)
- Idea is that if significant effects are seen at the level of the existing NAAQS, there is support for the NAAQS not being adequate to protect public health
  - Also evaluate epidemiological evidence at potential alternative NAAQS levels
- Discussions also include the shape of the C-R function, potential for thresholds to exist and be detected, and width of the confidence intervals around different portions of the C-R functions

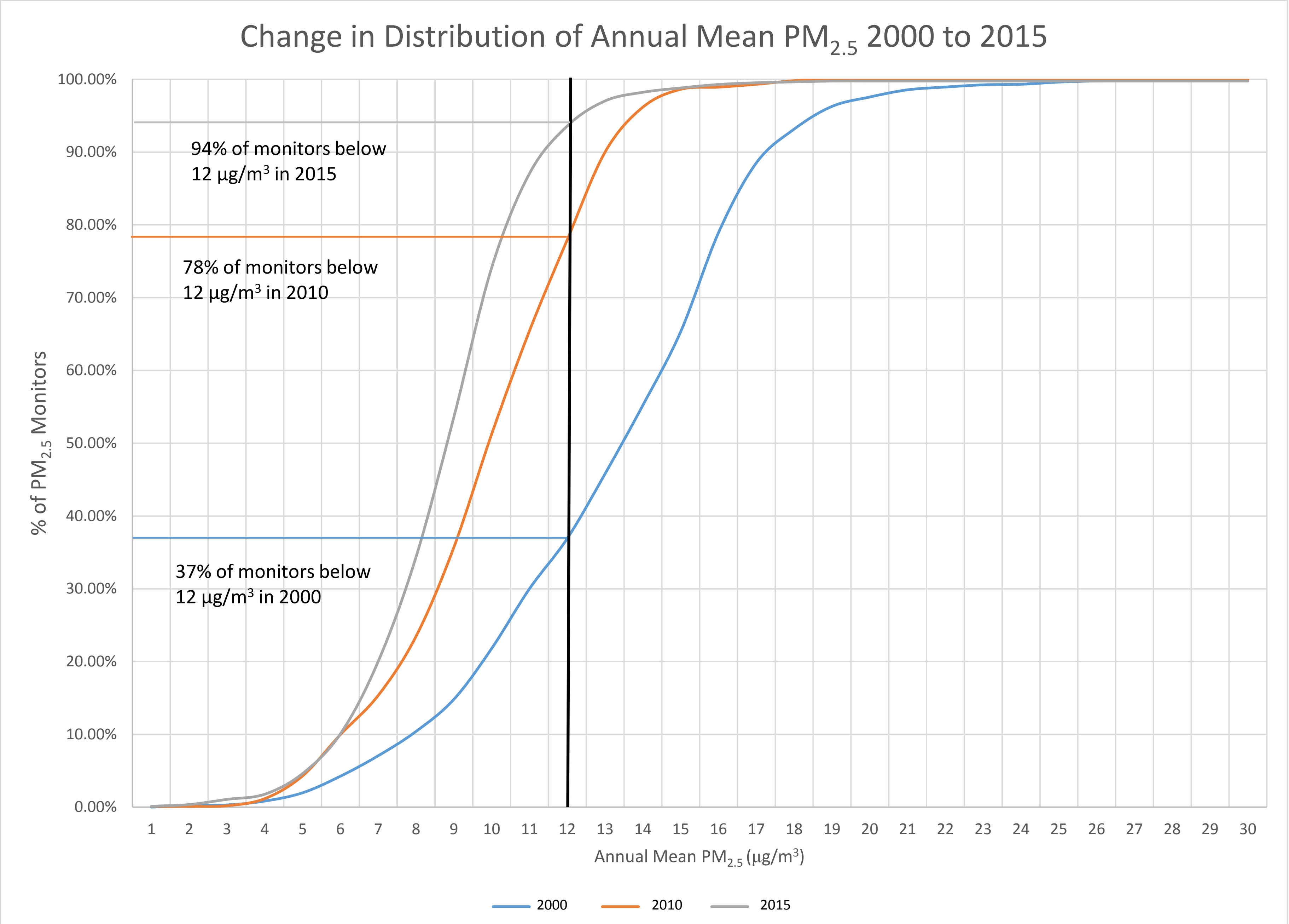


- Additional studies report effects at higher long-term means
- More limited and mixed evidence is available from single-city, short-term exposure studies with long-term mean $PM_{2.5}$ concentrations below 15 μg/m^3

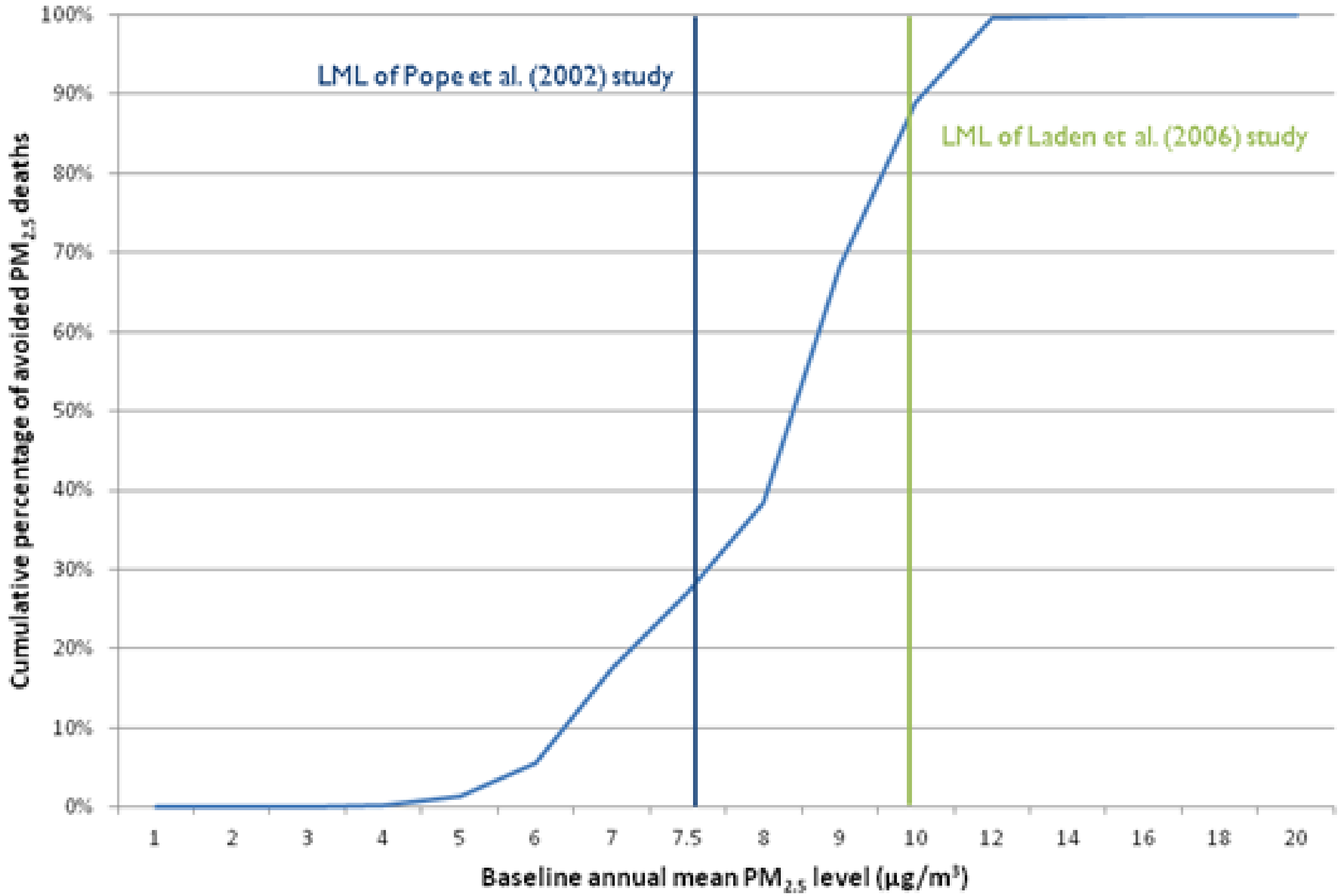
Source: Policy Assessment for the Review of the PM NAAQS, April 2011, Figure 2-8

EPIDEMIOLOGY IN BENEFITS ASSESSMENTS

- Generally follow the same approach as in risk assessments, but apply C-R functions nationally, and for a broader set of health endpoints
- Because of national scope, C-R functions are applied to more areas with relatively low concentrations of pollution
  - Projection of air quality to the future also results in air quality distributions that are lower than today due to impact of existing regulations
  - The proportion of projected air quality distributions below the NAAQS has increased as more regulations are put in place
  - Use of non-threshold C-R functions means that all unit reductions in air pollution, regardless of starting concentrations, have the same impact per exposed person (with some geographic differences due to baseline incidence rates)
- For some rules, like the $PM_{2.5}$ NAAQS, $PM_{2.5}$ benefits are more narrowly geographically focused in areas with higher levels of pollution



Change in Distribution of Annual Mean PM2.5 2000 to 2015
% of PM2.5 Monitors
100.00%
90.00%
80.00%
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
94% of monitors below
12 µg/m3 in 2015
78% of monitors below
12 µg/m3 in 2010
37% of monitors below
12 µg/m3 in 2000
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30
Annual Mean PM2.5 (µg/m3)
2000
2010
2015



Of the total PM-related deaths avoided:

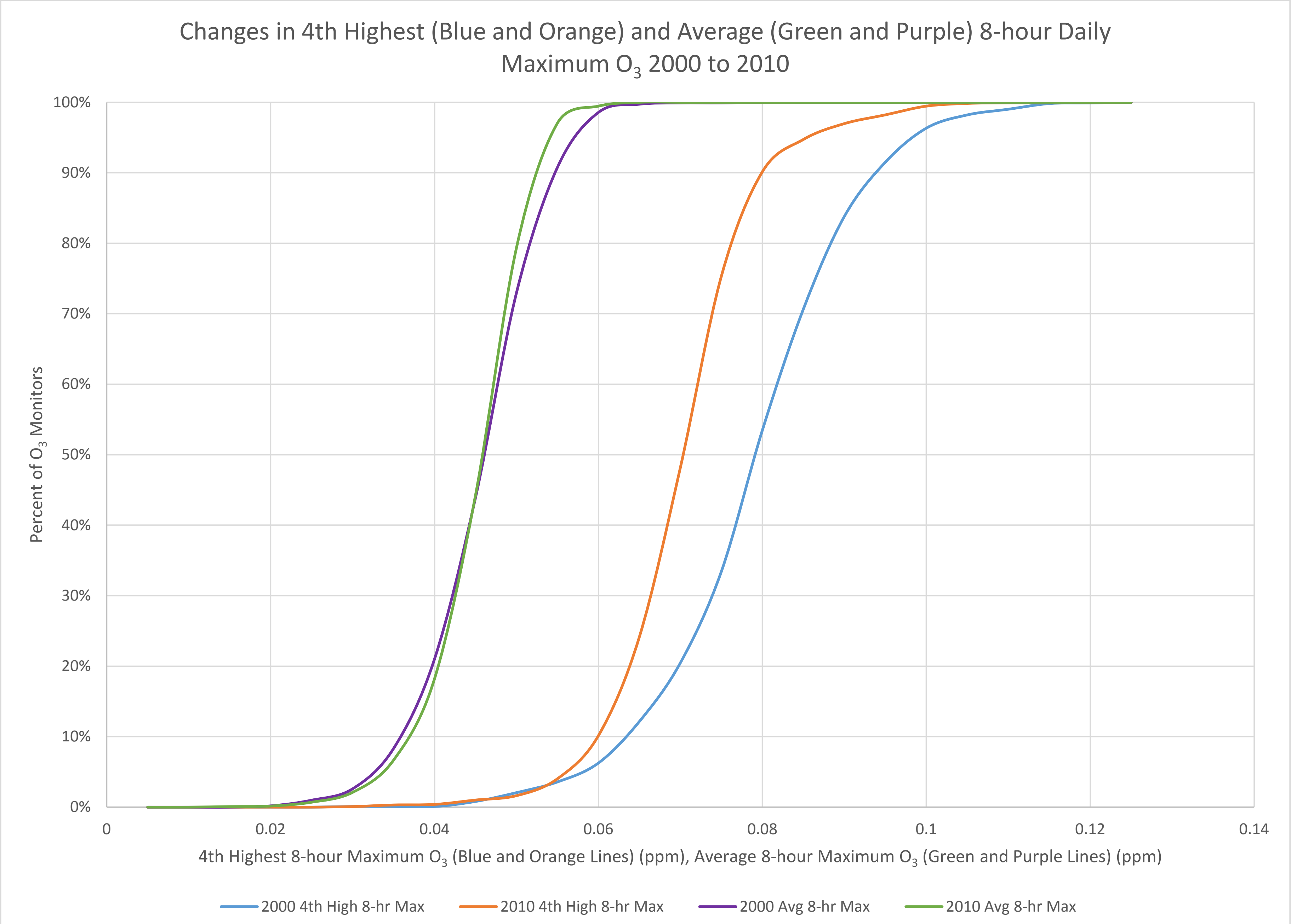
73% occur among population exposed to PM levels at or above the LML of the **Pope et al.** study.

11% occur among population exposed to PM levels at or above the LML of the **Laden et al.** study.

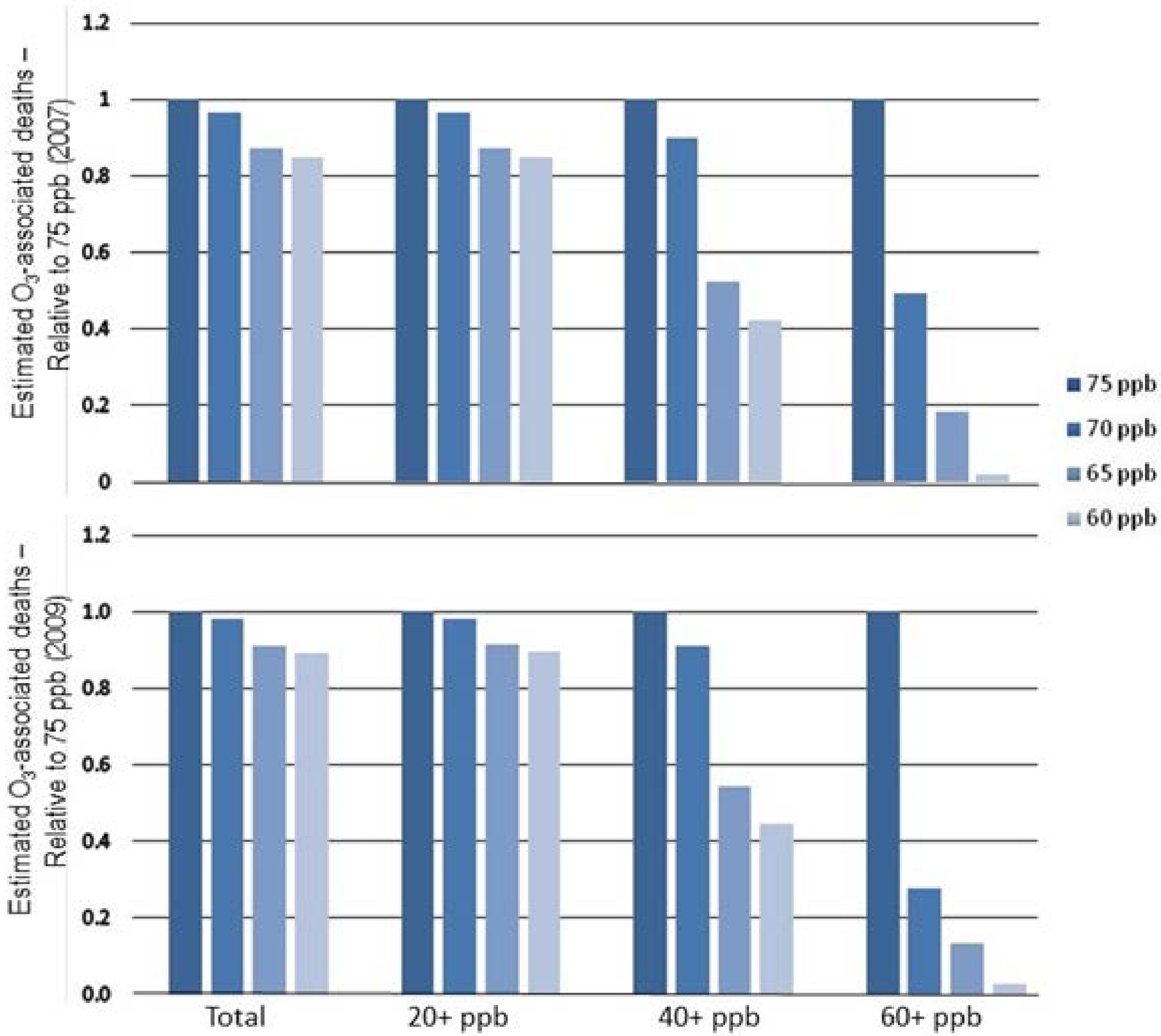
MATS RIA Figure 5-15. Cumulative Percentage of Total PM-Related Mortalities of the Mercury and Air Toxics Standards in 2016 Avoided by Baseline Air Quality Level

EFFECTS OF OZONE CHEMISTRY ON EPIDEMIOLOGY BASED RISK ESTIMATES

- Because of ozone chemistry, reductions in NOx in some urban centers can increase O_3 concentrations, generally in cooler months and at lower starting O_3 concentrations
- Using non-threshold C-R functions, increases in O_3 at low concentrations increase risk on some days and offset risk reductions occurring from decreases in high concentrations of ozone on other days, resulting from the same NOx emissions reductions
- Epidemiology studies use composite monitors which can mask gradients in ozone. Because the composite monitor is an average of very high O_3 areas (which result in risk reductions) and very low O_3 areas (which in some cases result in risk increases), using the composite monitor dampens the responses of overall urban area risk to meeting existing and alternative standards
- We need better understanding of confidence in the shape of the C-R functions at lower concentrations, since we do not have clinical studies at very low levels to provide additional support, and C-R functions that better account (spatially and temporally) for exposure

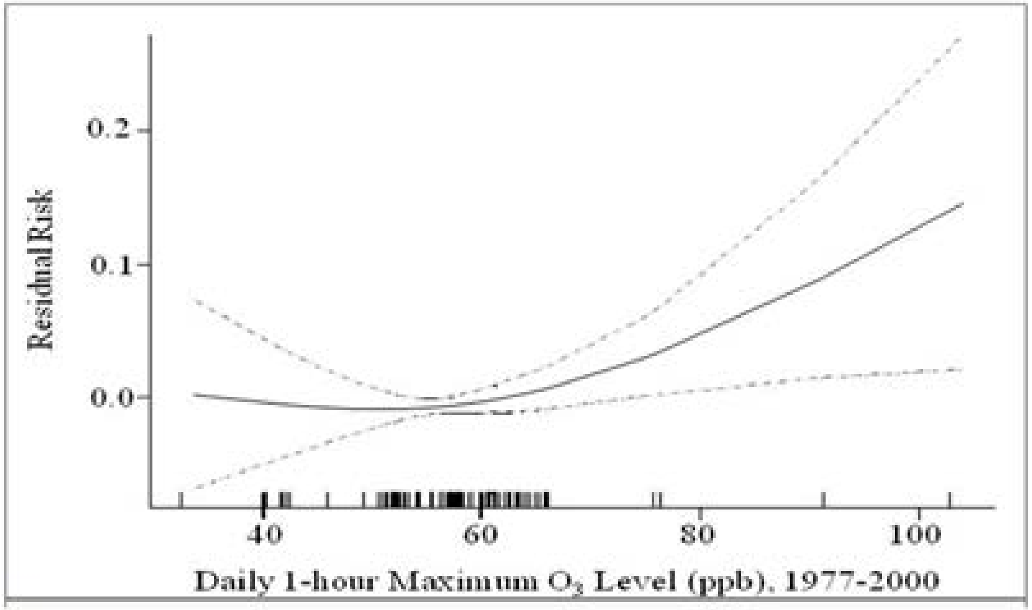


Changes in 4th Highest (Blue and Orange) and Average (Green and Purple) 8-hour Daily Maximum O3 2000 to 2010
Percent of O3 Monitors
100%
90%
80%
70%
60%
50%
40%
30%
20%
10%
0%
0
0.02
0.04
0.06
0.08
0.1
0.12
0.14
4th Highest 8-hour Maximum O3 (Blue and Orange Lines) (ppm), Average 8-hour Maximum O3 (Green and Purple Lines) (ppm)
2000 4th High 8-hr Max
2010 4th High 8-hr Max
2000 Avg 8-hr Max
2010 Avg 8-hr Max



O_3 Policy Assessment Figure 4-13. Estimates of O_3-Associated Deaths Attributable to Full Distributions of 8-Hour Area-Wide O_3 Concentrations and to Concentrations at or above 20, 40, or 60 ppb - Deaths Summed Across Urban Case Study Areas and Expressed Relative to 75 ppb

DIFFERENTIAL UNCERTAINTY IN C-R FUNCTIONS ACROSS RANGES OF CONCENTRATIONS



Concentration-response relationship between risk of death from respiratory causes and ambient O_3 concentration study metric (Jerrett et al., 2009)

Overall relative risk for an increment in O_3 concentration of 10 ppb was 1.040 (95% confidence interval, 1.010 to 1.067)

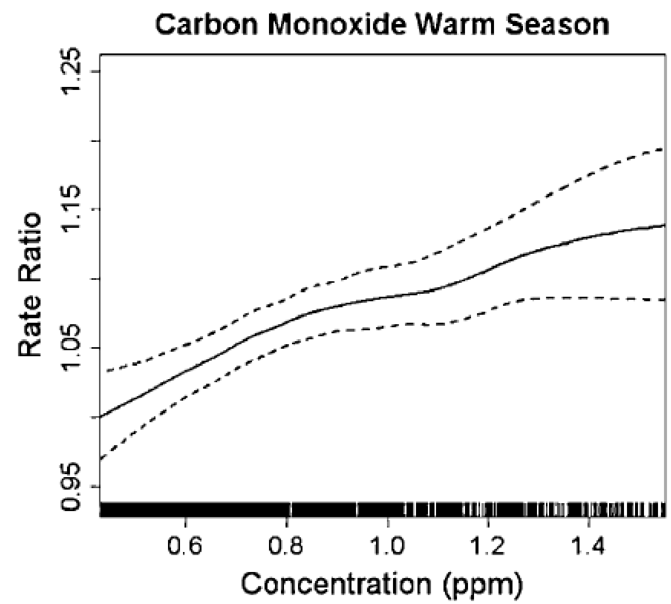
- Authors now provide both the overall effect estimate (slope) of the C-R function assuming a log-linear form and a spline representation of the overall C-R function
- These spline fits have the tightest confidence intervals where the greatest data density exists
- At very high and very low concentrations, data are more sparse, and so the shape of the C-R function is less certain
- As regulations shift the AQ distribution, risk and benefit assessments have to rely more on the lower part of the C-R function with less data support

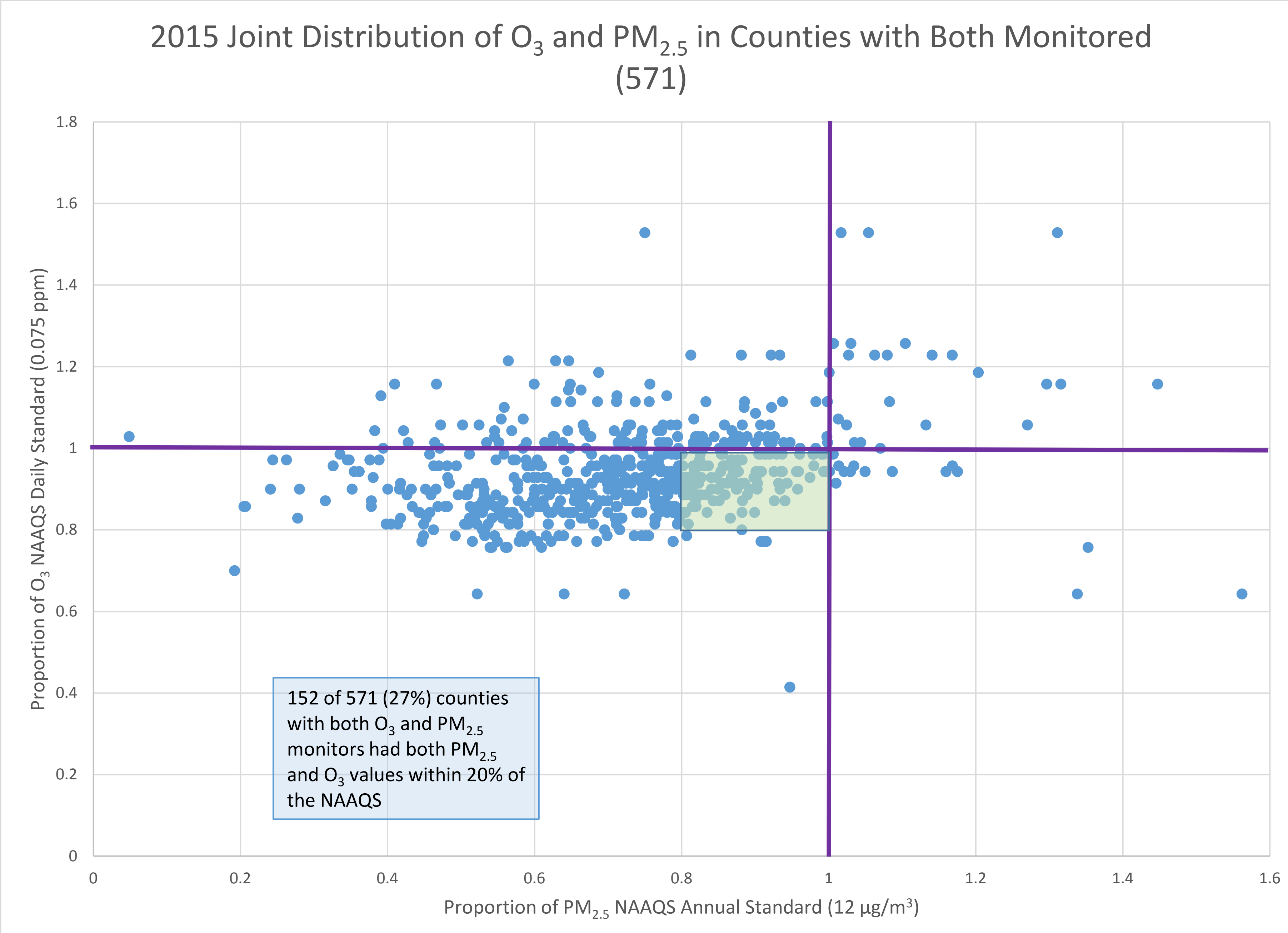
POTENTIAL IMPORTANCE OF WITHIN CITY GRADIENTS

- Most epi studies use average monitor values across an urban area, which smoothes out any within city gradient.
- This can mask whether exposures to high concentrations are driving the relationship
- Some at-risk populations may be experiencing much higher than average exposures
  - Is this as likely when looking at annual or seasonal averages as for daily metrics?
  - What is the role of population mobility? Are individual exposures better captured by an average over different exposure environments in a city or by concentrations where they live? Or, should exposures reflect time-activity patterns using models such as APEX?
- Within city gradients may become more prominent in the future as regional sources of SO_2 and NOx are regulated (by 2020, EGU SO_2 is projected to fall to 1.3 million tons, a >90% reduction from 1990) – what is left may be more local sources of pollution
  - This may be especially important for evaluating local or regional implementation benefits
  - EPA's Detroit multipollutant pilot study showed that by targeting emissions reductions where there are high concentrations of at-risk populations, benefits of meeting the NAAQS can be doubled with little additional cost

OTHER CONSIDERATIONS

- Would be good to understand the role of pollutant interactions at low concentrations, or at least spatial and temporal correlations
- At low concentrations, highly sensitive populations may experience effects that are not shown in the general population, as such, studies at lower concentrations may need to focus on those subpopulations.
- Low from the NAAQS perspective is anything below the NAAQS, but certainly directly below the existing NAAQS is helpful
- Low from the benefits perspective may be very low (approaching natural background or zero)
- To what extent does the lack of toxicological or controlled human exposure studies at very low concentrations challenge the interpretation of causality at those concentrations?
  - At lower levels, are we more concerned that individual pollutants are acting more as indicators for certain sources or multipollutant mixtures?
- Would be good to know if exposures close to but not exceeding the NAAQS for multiple pollutants continue to provide public health protection
  - O_3 and $PM_{2.5}$ still of most concern, but also interested in NO_2 and SO_2

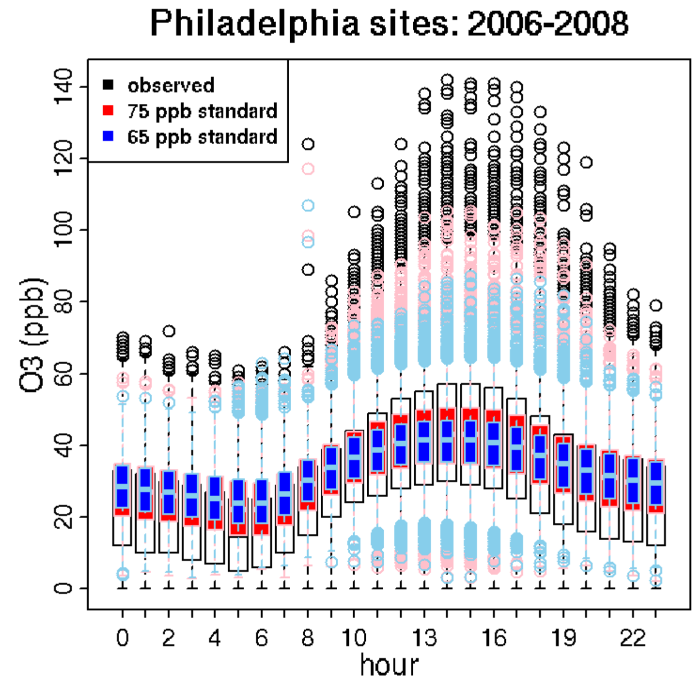


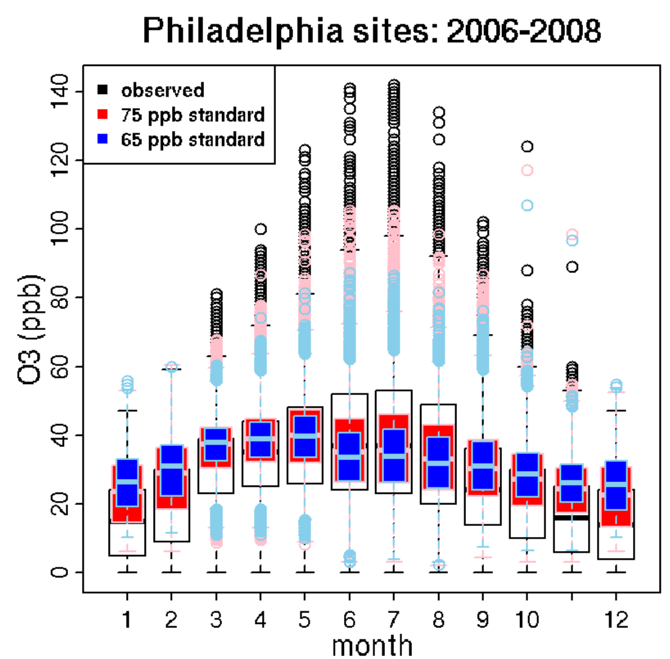

2015 Joint Distribution of O3 and PM2.5 in Counties with Both Monitored (571)
Proportion of O3 NAAQS Daily Standard (0.075 ppm)
Proportion of PM2.5 NAAQS Annual Standard (12 μg/m3)
1.8
1.6
1.4
1.2
1
0.8
0.6
0.4
0.2
0
0
0.2
0.4
0.6
0.8
1
1.2
1.4
1.6
152 of 571 (27%) counties with both O3 and PM2.5 monitors had both PM2.5 and O3 values within 20% of the NAAQS

SUPPLEMENTAL MATERIAL

SPECIAL ISSUES FOR OZONE

- To simulate just meeting alternative O_3 standard levels, across the board NOx reductions were applied for most urban areas analyzed
- Because of ozone chemistry, reductions in NOx in some urban centers can increase O_3 concentrations, generally in cooler months and at lower starting O_3 concentrations
- O_3 concentrations generally decrease when observed O_3 concentrations are high, and during daytime hours and warm months
- Annual 4th highest daily maximum 8-hour concentrations generally decrease when NOx reductions are applied, however, they decrease more quickly away from urban core areas
- Seasonal mean concentrations generally decrease away from urban core areas, and have varied responses near urban core areas depending on local NOx and VOC emissions and local atmospheric chemistry





MDA8=daily maximum 8-hr average