

Research Proposal to CARB

Study of PM2.5 and Life Expectancy in California, 1960-2020

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Abstract

The relationship between fine particulate matter (PM2.5) and mortality in the United States and California has been highly criticized and controversial since 1993. All aspects of the controversy were presented in the February 26, 2010 CARB 'Dr' Tran Symposium on "**Estimating Premature Deaths from Long-term Exposure to PM2.5**" (https://cal-span.org/meeting/carb_20100226/). Unfortunately, the criticisms of this relationship have been ignored by CARB. My recent critiques of the epidemiology of PM2.5 death claims in California are the November 2, 2022 Enstrom Criticism of the SCAQMD 2022 Air Quality Management Plan (<http://scientificintegrityinstitute.org/SCAQMDSES110222.pdf>) and the December 10, 2021 Enstrom Public Comment to the EPA CASAC PM Panel (<http://scientificintegrityinstitute.org/PMPanel121021.pdf>). A recent critique of the statistics of PM2.5 death claims is contained in the May 15, 2021 Young "Shifting Sands Report I--Keeping Count of Government Science: P-Value Plotting, P-Hacking, and PM2.5 Regulation" (<https://www.nas.org/reports/shifting-sands-report-i/full-report>). The long-term controversy regarding PM2.5 science and regulations has similarities to the emerging controversy regarding COVID-19 science and public policy (<https://www.dailynews.com/2022/12/31/the-shameful-suppression-of-pandemic-public-policy-dissidents/>).

This study is in response to the December 30, 2022 CARB proposal solicitation "**A Study of Pollution Exposure and Life Expectancy Across Time in Different Generations in California**" (<https://ww2.arb.ca.gov/resources/documents/study-pollution-exposure-and-life-expectancy-across-time-different-generations>). This study will evaluate the two Hypotheses stated below. This evaluation will be done by examining: 1) the patterns and trends of ambient and personal exposure to PM2.5 in California from 1960 to 2020 and 2) the relationship of PM2.5 to total mortality and life expectancy in California from 1960 to 2020. In particular, the study will assess all existing PM2.5 exposure and epidemiologic studies with results in California (including cohort studies, time-series studies, and population surveys), making use of detailed CARB and EPA measurements of PM2.5. The project will use these data to create maps that document the magnitude of exposures and mortality effects in throughout California. These maps showing exposures and health impacts can be used to inform CARB's regulatory and program development and support CARB's work to better protect all Californians.

Hypotheses to be Tested

Hypothesis 1: PM2.5 is Not Related to Total Mortality or Life Expectancy in California

Hypothesis 2: Current Personal Exposure of Californians to PM2.5 is Below the Level of Health Effects

Key Professional Personnel

Principal Investigator

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CEO of CGStat and Adjunct Professor of Statistics at North Carolina State University

Retired NISS Division Director and 2018-2020 EPA Scientific Advisory Board Member

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<https://www.nas.org/blogs/article/introducing-stanley-young-director-of-the-shifting-sands-project>

Co-Investigator

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Robert L. Obenchain, PhD, FASA

Risk-Benefit Statistics Expert and Developer of R Statistical Software

Former Statistician at Bell Labs and Eli Lilly and Former Adjunct Professor of Statistics in NC & IN

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Resource Investigators: Use will be made of their existing extensive body of research on epidemiology, statistics, and toxicology relevant to PM2.5 and mortality. They will be asked to contribute to this study in any way that they can.

Edward J. Calabrese, PhD

University of Massachusetts Professor of Environmental Health Sciences (Toxicology)

Leading Expert on Toxicology Thresholds, History of LNT, and Hormesis

Amherst, MA

<https://www.umass.edu/news/article/umass-amherst-professor-edward-calabrese-featured-22-episode-video-series-examining>

<https://hps.org/publicinformation/ate/cat78.html>

L. Anthony Cox, Jr., PhD

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Richard L. Smith, PhD

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Scope of Work

This study will examine fine particulate matter (PM2.5) exposure and its relationship to life expectancy (total mortality) in California from 1960 to 2020. PM2.5 exposure and total mortality will be examined by geographic areas and by socioeconomic factors. The California communities with the highest pollution burdens will be identified.

Task 1. Conduct a literature review: The investigators will conduct a comprehensive literature review of research that examines PM2.5 exposure and its relationship to life expectancy (total mortality) in California since 1960.

Task 2. Develop particulate pollution exposure profile: The investigators will use the best available PM2.5 and surrogate exposure data from CARB and EPA to create a pollution profile across California since 1960 with the finest possible spatial resolution.

Task 3. Obtain mortality and health data and covariates: The investigators will obtain California mortality data since 1960 from their own existing resources, the California Department of Public Health, the National Center for Health Statistics, and other available sources.

Task 4. Link exposure to life expectancy and health impacts: Using the results from Task 2, data from Task 3, and all existing epidemiological research on PM 2.5 impacts on total mortality in California, the investigators will examine the relationship between PM2.5 and life expectancy (total mortality) in California since 1960. To the extent possible, the investigators will investigate specific subgroups, including vulnerable populations by race, income, and location. To the extent possible, the investigators will identify and control for confounding factors.

Task 5. Create GIS maps for the study results including subgroups: The findings on exposure and life expectancy from Tasks 2 and 4 will be produced statewide and displayed using GIS mapping software. The GIS maps of PM2.5 and life expectancy will be presented with the finest possible resolution for all of California.

Task 6. Address impacts in disadvantaged communities: There will be extensive public outreach and the study methods and results will be shared at the beginning and the conclusion of the study using online meetings and clear and descriptive written material in lay person's language. The investigators will do this public outreach in conjunction with and assistance from CARB.

Task 7. Reporting and data delivery: The investigators will submit regular progress reports and a final report to CARB, and will participate in progress update meetings and a seminar at the conclusion of the project with the cooperation of CARB. The investigators will make available non-confidential raw data and all data analysis results generated through the course of the project. Additionally, the investigators will prepare manuscripts of their findings and submit them for peer-review and journal publication.

Existing Data Resoures

1960-2003 ACS CA CPS I cohort of 118,000 Californians (see Enstrom 2003 & 2005 & 2006)

1982-1988 ACS CPS II cohort of 1.2 M Americans, with 120,000 Californians (see Enstrom 2017 & 2018)

1987-2019 NHIS Mortality Follow-up Cohort of up to 200,000 Californians (see Parker 2018, Pope 2019)

2000-2019 NIH-AARP Cohort of 160,368 Californians (see Thurston 2016, Enstrom 2017, and NIH-AARP)

2000-2016 Medicare Cohort of about 7 M Californians (to be obtained from Wu 2020 and Medicare)

1960-2004 public use files with individual information on all California deaths (possessed by Enstrom)

2000-2012 public use files with individual information on all California deaths (see Young 2017)

2013-2022 public use files with individual information on all California deaths (to be obtained via CARB)

1967-2022 detailed California PM2.5 and PM exposure data obtained and published by CARB and EPA

Budget

No funds are requested from CARB. This study will be entirely funded by the personal assets of the Investigators. However, CARB is expected to cooperate in providing detailed California air pollution data, recent California death records, and other relevant resources that it possesses or uses.

Existing Findings in Support of the Hypotheses

Six primary reasons that PM2.5 does not *cause* premature deaths and is not related to deaths:

- 1) No Etiologic Mechanism: This is no experimental proof that lifetime inhalation of 1-5 grams (<100 µg/day) of PM2.5 *causes* death
- 2) Weak Epidemiologic Risk: Tiny positive relative risks ($1.0 < RR < 1.1$) do not prove that PM2.5 *causes* death and reductions in PM2.5 levels have not clearly resulted in reduced mortality risks
- 3) Ecological Fallacy: PM2.5 monitors of ambient air provide an inaccurate measurement of the personal PM2.5 exposure of an individual and personal PM2.5 exposure has not been used to assess deaths
- 4) Uncontrolled Confounding Variables: Co-pollutants, temperature, geography, and other factors can reduce or eliminate an apparent relationship between PM2.5 and mortality
- 5) Access to Underlying Data: Enstrom's independent analysis of American Cancer Society data (CA CPS I and CPS II) shows that underlying data is essential for transparency and reproducibility of PM2.5 results
- 6) California Studies Show NO Relationship: Full meta-analysis shows NO relationship between PM2.5 and total mortality in six prospective cohort studies and several daily time-series studies in California

Evidence that Personal Exposure of Californians to PM2.5 is Below the Level of Known Health Effects:

PM2.5 deposited in lungs in 80-year lifetime assuming an ambient inhaled PM2.5 level of $10 \mu\text{g}/\text{m}^3 = 10 \mu\text{g}/\text{m}^3$ inhaled x 50% deposited in lungs x $10 \text{ m}^3/\text{day}$ x 365 days/year x 80 years = 1.46 grams; 1.46 grams per lifetime is equivalent to $50 \mu\text{g}/\text{day}$ and about the amount in the smoke of one cigarette.

PM2.5 deposited in lungs in 80-year lifetime assuming personal exposure to PM2.5 of $5 \mu\text{g}/\text{m}^3 = 5 \mu\text{g}/\text{m}^3$ inhaled x 50% deposited in lungs x $10 \text{ m}^3/\text{day}$ x 365 days/year x 80 years = 0.73 grams; 0.73 grams per lifetime is equivalent to $25 \mu\text{g}/\text{day}$.

Table 1. Unpublished Early Evidence that PM2.5 is Not Related to Total Mortality in CA
California ACS CPS I Cohort Study That Analyzed Air Pollution and Total Mortality During 1960-1998
Relative Risk (RR and 95% CI) of Total Mortality Associated with Increase of 10 µg/m³ in PM2.5

Air Pollution Measure	F-U Years	RR	95%CI(L)	95%CI(U)
1961 Three-levels of Self-Reported Air Pollution Exposure	1962-1972	0.992	0.962	1.022
1961 Three-levels of Self-Reported Air Pollution Exposure	1962-1998	1.006	0.992	1.020
1955-1974 Total Suspended Particulates (TSP)	1962-1972	0.995	0.990	1.000
1955-1974 Total Suspended Particulates (TSP)	1962-1998	1.001	0.998	1.003
1963-1972 Black Smoke as Surrogate for PM2.5	1962-1972	0.981	0.954	1.008
1963-1972 Black Smoke as Surrogate for PM2.5	1962-1998	0.990	0.976	1.004

For details, see April 25, 2003 Enstrom and Lipfert Unpublished Manuscript Table 5
<http://www.scientificintegrityinstitute.org/CACPSII042503.pdf>

Table 2. Published Cohort Evidence that PM2.5 is Not related to Total Mortality in CA
Six California Cohorts That Analyzed Ambient PM2.5 and Total (All-cause) Mortality During 1977-2009
Relative Risk (RR and 95% CI) of Total Mortality Associated with Increase of 10 µg/m³ in PM2.5

California Cohort Studies	Author Year	RR Table	F-U Years	RR	95%CI(L)	95%CI(U)
Adventist Health Study (AHSMOG)	McDonnell 2000	T3+	1977-1992	1.000	0.950	1.050
CA ACS Cancer Prevention (CA CPS I)	Enstrom 2005	T7	1983-2002	0.997	0.978	1.016
Medicare (MCAPS) Western US	Zeger 2008	T3	2000-2005	0.989	0.970	1.008
CA ACS Cancer Prevention (CA CPS II)	Krewski 2010	T2	1982-2000	0.968	0.916	1.022
California Teachers Study	Ostro 2015	Appx	2001-2007	1.010	0.980	1.050
CA NIH-AAPR Diet and Health Study	Thurston 2016	T2 F3	2000-2009	1.017	0.990	1.040
Fixed Effects Meta-Analysis		Summary RR		0.999	0.988	1.009
Random Effects Meta-Analysis		Summary RR		0.999	0.988	1.009

Q Test Statistic = 4.7683 I² -4.86%

Cochrane's Q Test for Homogeneity of Studies (Null Hypothesis: Studies are Homogenous)

P-Value = 0.4448 → Since Studies satisfy Test for Homogeneity, Fixed and Random Effects Meta-Analysis
 Yield Summary RR = 0.999 (0.988-1.009), which is statistically consistent with 1.000 (NO relationship)

For calculations and references, see September 26, 2018 Intrepid Insight Statistical Review Table B7
<http://www.scientificintegrityinstitute.org/IIPM25Deaths092618.pdf>

Table 3. Published Time-Series Evidence that PM2.5 is Not related to CA Total Mortality

California Five County Time-Series Study That Analyzed PM2.5 and Total Mortality During 1997-2002

Relative Risk (RR and 95% CI) of Total Mortality Associated with Increase of 10 µg/m³ in PM2.5

California County	Daily PM2.5 Level	T-S Years	RR	95%CI(L)	95%CI(U)
Fresno	1997-2002 PM2.5 One-Day Lag	1997-2002	1.014	1.002	1.025
Los Angeles	1997-2002 PM2.5 One-Day Lag	1997-2002	0.996	0.991	1.001
Riverside	1997-2002 PM2.5 One-Day Lag	1997-2002	0.990	0.980	1.000
Sacramento	1997-2002 PM2.5 One-Day Lag	1997-2002	1.016	1.004	1.028
San Diego	1997-2002 PM2.5 One-Day Lag	1997-2002	1.014	1.002	1.026
Five County Meta-Analysis Summary RR			1.0009	0.9972	1.0046

Reference: Franklin M, Zeka A, Schwartz J. Association between PM2.5 and all-cause and specific-cause mortality in 27 US communities. J Expos Sci Environ Epidem 2007 doi:10.1038/sj.jes.7500530 (<http://www.scientificintegrityinstitute.org/JESEE2005.pdf>)

California Eight Air Basins Time-Series Study That Analyzed PM2.5 & Total Mortality During 2000-2012

Odds Ratio-Relative Risk (RR and 95% CI) of Total Mortality Associated with Increase of 10 µg/m³ in PM2.5

California Air Basin	Daily PM2.5 Level (Assumed)	T-S Years	RR	95%CI(L)	95%CI(U)
Mountain Counties	2000-2012 PM2.5 One-Day Lag	2000-2012	0.9995	0.9978	1.0010
Sacramento Valley	2000-2012 PM2.5 One-Day Lag	2000-2012	1.0010	0.9999	1.0020
Salton Sea	2000-2012 PM2.5 One-Day Lag	2000-2012	1.0000	0.9980	1.0020
San Diego	2000-2012 PM2.5 One-Day Lag	2000-2012	1.0006	0.9994	1.0020
San Francisco	2000-2012 PM2.5 One-Day Lag	2000-2012	1.0010	1.0001	1.0020
San Joaquin	2000-2012 PM2.5 One-Day Lag	2000-2012	1.0007	1.0000	1.0010
South Central Coast	2000-2012 PM2.5 One-Day Lag	2000-2012	1.0005	0.9990	1.0020
South Coast	2000-2012 PM2.5 One-Day Lag	2000-2012	1.0000	0.9999	1.0001
California Eight Air Basin Meta-Analysis Summary RR			1.0003	1.0001	1.0006

References:

Young SS, Smith RL, Lopiano KK. (2017) Air quality and acute deaths in California, 2000-2012. Regulatory Toxicology and Pharmacology 88, 173-184. DOI: 10.1016/j.yrtph.2017.06.003 (<http://www.scientificintegrityinstitute.org/RTPPM25TSYoung072517.pdf>)

You C, Lin DJK, Young SS. (2018) PM_{2.5} and ozone, indicators of air quality, and acute deaths in California, 2004–2007. Regulatory Toxicology and Pharmacology 96:190-196. DOI: [10.1016/j.yrtph.2018.05.012](https://doi.org/10.1016/j.yrtph.2018.05.012) (https://www.stat.purdue.edu/~dkjlin/documents/publications/2018/2018_RTP.pdf)