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HEI DESK STATEMENT

New Study in US Medicare Recipients of Low-Level Exposure to Air Pollution and Health

Background

The new research study published today in the journal *Science Advances* (Wu, et al., *Evaluating the Impact of Long-term Exposure to Fine Particulate Matter on Mortality Among the Elderly*[1] https://advances.sciencemag.org/) presents the latest results of one of three studies of low level exposure to air pollution and its potential health effects selected competitively for funding by the Health Effects Institute (HEI) in 2016 to examine such relationships in very large populations in the US, Canada, and Europe.

Using a variety of exposure assessment, epidemiological, and statistical techniques, the studies are designed to address current major uncertainties in air pollution health effects at low levels. This is a question that HEI's sponsors raised in detail in discussions surrounding the development of the HEI Strategic Plan, and HEI expects these results will inform future air quality standards decisions in the US, Europe, and other regions. HEI convened an Oversight Panel to monitor progress of these studies and obtained the services of an external QA/QC team to audit the quality and handling of the data used in the studies.

Phase I Reports of US, Canada Results Published, November 2019

HEI convened a Low-Exposure Epidemiology Studies Review Panel of the HEI Review Committee in 2019 to review Phase 1 Reports of the US and Canadian studies. The Panel reviewed the reports in detail and HEI published the reports (including a Commentary from the Panel) in November 2019 in time to inform the then-ongoing review by the US EPA of the National Ambient Air Quality Standards (NAAQS) for $PM_{2.5}$ and ozone (https://www.healtheffects.org/system/files/hei-rr-200-203-press-release_0.pdf).

Final Reports in Progress

The three teams are now nearing completion of their work and have begun to submit their final reports for HEI review. Specifically:

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[1] "Evaluating the Impact of Long-term Exposure to Fine Particulate Matter on Mortality Among the Elderly," Xiao Wu, Danielle Braun, Marianthi-Anna Kioumourtzoglou, Francesca Dominici, Science Advances, June 26, 2020, doi: 10.1126/sciadv.aba5692

- The ELAPSE* Study of the health effects of low levels of air pollution in 28 million Europeans (PI: Bert Brunekreef, Utrecht University, Netherlands) has submitted their final report which is soon to begin detailed review by the Low-Exposure Epidemiology Studies Review Panel, with a final report and Commentary to follow. (***E**ffects of **L**ow-Level **A**ir **P**ollution: A **S**tudy in **E**urope);
- The Harvard US Medicare Study of the health effects of low levels of air pollution in some 68 million Medicare recipients (PI: Francesca Dominici, Harvard T.H. Chan School of Public Health) is expected to submit its final report this June, including a series of additional causal inference and other analyses recommended by the HEI Review Panel when it reviewed the Phase 1 report last fall; and
- The MAPLE* study of the health effects of low levels of air pollution in 10 million Canadians (PI: Michael Brauer, University of British Columbia) is conducting its final analyses and is expected to submit its final report late this year (***M**ortality-**A**ir **P**ollution Associations in **L**ow-Exposure **E**nvironments).

The New Results and Other Publications in Peer-Reviewed Journals

While HEI's final reports are always based on rigorous peer review of all results by our independent Review Committee, investigators are also free to publish in the peer reviewed literature as the data and analysis permit. There have been a number of methods and early results papers from these studies already published in peer-reviewed journals; we encourage such publication since it expands substantially the influence of HEI-funded research in the larger scientific community and in policy making.

The New Medicare Results: The new paper published today in the journal *Science Advances* from the Harvard investigators reports on a detailed analysis in the US Medicare study. The analysis, which will also soon be reviewed rigorously as part of the investigators' final report by the HEI Review Panel, implements many of the recommendations from that Panel following their review of the Phase 1 reports, including that the investigators should (a) apply an enhanced range of causal inference statistical techniques to strengthen their analyses and potential to reach conclusions, and (b) include better controls for potentially important unmeasured confounders, such as time. In the new analyses, they make health estimates using three different causal modeling statistical techniques and then compare those results with analyses using more traditional Cox proportional hazard and Poisson linear regression models. They have now extended their earlier analyses to over 68 million Medicare recipients enrolled during 2000 – 2016.

We expect that HEI's detailed review of the study will enable the issuance of a final report and Commentary of the Review Panel in time to put these results in context, discuss their strengths and weaknesses, and inform future standard-setting decisions.

The investigators of these Medicare results are also developing processes and databases for ensuring that the methods and data used for this research can, to the maximum extent possible, be scrutinized and reproduced; this will include detailed attention to opportunities for data sharing, record linkage, and statistical software. Working to make this research reproducible is an important element in ensuring scientific credibility, and of utmost importance for HEI.

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