

Clarifying Comments to the Clean Air Scientific Advisory Committee on EPA's "Integrated Science Assessment for Particulate Matter (External Review Draft)"

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I wanted to make a clarifying comment about study quality vs. relevance based on EPA's discussion at the Clean Air Scientific Advisory Committee (CASAC) meeting.

EPA staff indicated that they addressed study quality in the HERO database. This winnowing down of studies in the database is based on the relevance of study topics for the ISA, it is not based on quality.

EPA staff also discussed some specific aspects of study quality that they had considered (for example, confounding). However, they did not discuss any criteria for addressing quality (in this case, how it would be determined whether confounders were adequately addressed). Specific criteria are not presented in the ISA or in the Preamble, and the impact of confounders on the interpretation of results is not discussed for a majority of the studies discussed in the ISA. As a result, study results were often taken at face value, when in many cases, the lack of adjustment for confounding seriously undermined results.

This is not just the case for confounding, but other aspects of study quality, as well.

Finally, it was mentioned that another way EPA staff considered study quality was while reviewing studies. Even if this is the case, because it is not documented in the ISA for each study, it is not transparent or reproducible, and it's unlikely this was done in a consistent manner across reviewers. It's very encouraging that EPA considered study quality, but because it was not done in a transparent, systematic, or reproducible manner, based on clear criteria, it really is a missed opportunity.