



TCEQ Comments on HEI Literature Systematic Review

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What information should the committee review to assess the epidemiological literature related to the onshore development of oil and natural gas from unconventional resources?

- Industrial process information. Exploration occurs in phases, beginning with site preparation (4-6 weeks typically), progressing to drilling (2-4 weeks), then fracturing (3-5 days per direction), and ending with production (years). Each phase has a different length of time and different potential emissions. Well depth, well density, presence of confining layers, regulatory requirements (emission controls, casing requirements, etc.) and many other factors affect the potential for exposure.
- Typical emissions profiles. In Texas, we've looked at several thousands of samples and nearly all cases involving elevated pollutants arose from human or mechanical failures. If this research is intended to be broadly applied to the industry, the operating conditions should be representative of the broad industry and the literature should ensure that ambient concentrations are not the result of individual operator errors. Alternatively, the consequences of operator error should be kept as a separate category
- Study design. Results from proximity studies are dubious. Similarly, ecological studies are not strong enough for definitive conclusions.
- Comparison values should be determined *a priori*. The committee should agree on what constitutes an adverse effect before the review begins, recognizing that the committee's determination and that of the study authors may differ.
- Bradford Hill considerations. (strength of association, consistency, specificity, temporality, dose-response or biological gradient, biological plausibility, coherence)



What criteria should the committee use to evaluate study quality?

- Study design.
 - Comparison group. Are the exposed and control groups appropriate?
 - Is the study design capable of determining effects of interest to the committee?
- Exposure. Ambient concentrations measured at a site several miles away are not always representative of personal exposure. The study authors should justify their choice of exposure data. This justification should include the following:
 - Sample averaging time.
 - Measurement technology. Ideally, studies will report on instrument reliability or reference a separate article that does.
 - Sample size.
 - Exposure duration. Is the length of expected exposure appropriate for the development of the health endpoint of interest?
 - Consideration of other sources (many chemicals associated with O&G activities can come from multiple sources).
- Effects or outcome measures.
 - Reliable measurements. Frank effects have a high degree of certainty, but hospital admissions data, for example, can be uncertain because it can be confounded by other health issues.
- Strength of association and adversity/clinical relevance of effect.
- Confounding/Modifying. Study authors should attempt to control for known confounders and modifiers, such as socioeconomic status, co-pollutants, spatio-temporal variation, etc.
- Appropriate statistical analyses.
- Discussion of limitations.



What do you see as key contributions that the Committee can make to the science and the public dialogue around the development of oil and natural gas from shale and other unconventional resources?

In Year 1, I expect that there will be a productive discussion of the review approach and inclusion/exclusion criteria. Ideally, a systematic review that follows published and generally accepted guidelines would be used to develop a review suitable for publication by sometime the following year. I would expect that the committee would provide useful suggestions and a thorough scientific peer review. I would suggest comprehensive inclusion criteria and limited exclusion criteria to include as many studies as possible.

Looking beyond the initial Human Health Study Critique task, what do you see as key contributions from the Committee's review of literature and research planning in Year 1 and beyond?

A well-articulated problem statement. The current project discussion is quite broad. For example, will the research consider all forms of unconventional exploration (tight gas, shale gas, coalbed methane)? All steps in the process (site preparation, production)? Will the research focus on air, water, soil, or all media? Any particular health endpoints?

- An understanding of the weight-of-evidence for selected health endpoints, as well as limitations in the current knowledge base.