

APPENDIX AVAILABLE ON THE HEALTH EFFECTS INSTITUTE–ENERGY WEBSITE

Special Report 1

POTENTIAL HUMAN HEALTH EFFECTS ASSOCIATED WITH UNCONVENTIONAL OIL AND GAS DEVELOPMENT: A SYSTEMATIC REVIEW OF THE EPIDEMIOLOGY LITERATURE

HEI-Energy Research Committee

APPENDIX C. STUDY QUALITY ASSESSMENT INSTRUMENT

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HEI-Energy Special Report 1, HEI-Energy Research Committee, Appendix C

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Study Quality Assessment Instrument

CRITERIA	EXPLANATION	
Study Population		
Study sample representative of underlying population	Is the study population truly representative of the population defined by the authors to answer the study question?	
Inclusion/Exclusion Criteria Specified	Inclusion and/or exclusion criteria should be specified to define the appropriate study population and as a method to control for confounding	
Baseline characteristics similar between exposure groups (cohort studies) or cases and controls (case- control studies)	Are sociodemographic measures, health risk factors, community-level factors etc. balanced between index and reference groups?	
Attrition not systematically different (studies with multiple observations over time, only)	Is there differential loss to follow-up or participant non- response among the exposure groups, outcome groups, or by other characteristics?	
Same population over study period	Did population characteristics change differentially due to moves into or out of study area?	
Control group appropriate to address review question (<i>case-control only</i>)	Is the control group truly outcome-negative and was the control group derived from a population that represents that exposure frequency of the source population?	
	Outcome Assessment	
Outcome ascertained using valid and reliable measures	Was outcome information ascertained using reliable and reproducible data sources?	
Outcome assessors blinded to exposure status	Was outcome data ascertained without knowledge of exposure status or level?	
No systematic differences in outcome ascertainment or reporting between exposure groups	Was outcome ascertainment subject to recall bias, non-respondent bias, or reporting bias?	
	Exposure Assessment	
Measurements of chemical or non- chemical agents	Was exposure measured using media samples or personal monitors?	
Methods address the review question	Overall, does the measurement or metric represent UOGD exposure?	
Non-differential between outcome groups (<i>case-control only</i>)	Was exposure characterized using the same methods between index and control groups?	
Study period sufficient to capture exposure variability (<i>studies that</i> <i>characterize "unexposed" as the</i> <i>period before UOGD development</i> <i>only</i>)	Was exposure data collected over a period that accurately represents separate pre-UOGD development and UOGD activity intervals?	
Selection of exposure groups that represent the full range of variability in UOGD	Was the referent (unexposed) group truly unexposed? Did the authors describe rationale for exposure categorization? Did the authors describe rationale for the distances chosen as proximity measures?	

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Differentiates between active and non-active wells	Do the authors differentiate between active and non-active well periods?	
Differentiates between UOGD and its various phases	Do the authors differentiate between pad preparation, drilling, stimulation, and production phases?	
Timeframe sufficient to expect to see an association between exposure and outcome if it existed.	Was lag-time considered in assessing the exposure-outcome relationship? Was exposure assigned of the correct time-at-risk period?	
Exposure assessment performed using valid, reliable and sensitive methods.	Studies using measurements: Were samples collected using calibrated and reliable instruments (both accurate and precise)? Studies using metrics/modelled exposure: Were distance measures accurate? Were geocoding methods reported and accurate?	
	Confounding	
Potential confounding variables assessed across exposure groups (cohort studies) or cases and controls (case-control studies)	Did the authors control for any covariates in their analysis? Were covariates assessed using the same methods between study groups?	
Controlled for background conditions	Did the authors isolate the impact of UOGD from unintended exposures (e.g. traffic pollution, non-UOGD wells, industrial sources) that might bias results (through multivariate analysis, stratification, subgroup analysis etc.)?	
Controlled for baseline characteristics	Did the authors isolate the impact from risk-factors associated with both the exposure and the outcome (pregnancy risk factors, chronic conditions, etc.) that might bias results (through multivariate analysis, stratification, subgroup analysis etc.)?	
Assessed time trends	Did the authors control for outcome trends in the period before UOGD development or account for changing trends over time?	
Analytical Methods		
Analytical methods appropriate for study design	Are the statistical methods used to assess the outcome appropriate to the data? Did the statistical techniques take into account issues such as small sample size, clustering, rare outcomes, multiple comparisons, repeated measures in longitudinal designs, multilevel data, multicollinearity etc.?	
Report measures of precision and variability	Examples include: confidence intervals, standard errors or standard deviations for normally-distributed data, interquartile ranges for non-normally distributed data.	
Report which statistical tests were used	Authors describe which tests they used to report measures of significance and effect	
Perform sensitivity analyses to test robustness of results to alternative specifications	Investigators test alternative model specification to test for confounding, model fit, cutpoint bias, effect modification, and other relevant parameters	
Presentation and Interpretation		
All findings reported for analysis described in paper	Did the authors selectively report findings?	

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Discussion adequately addresses	Did the authors discuss all study limitations and how those	
study limitations	limitations impact study results?	
Appropriate and complete	Did the authors provide an accurate interpretation of the results	
interpretation of results	given study limitations?	

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