

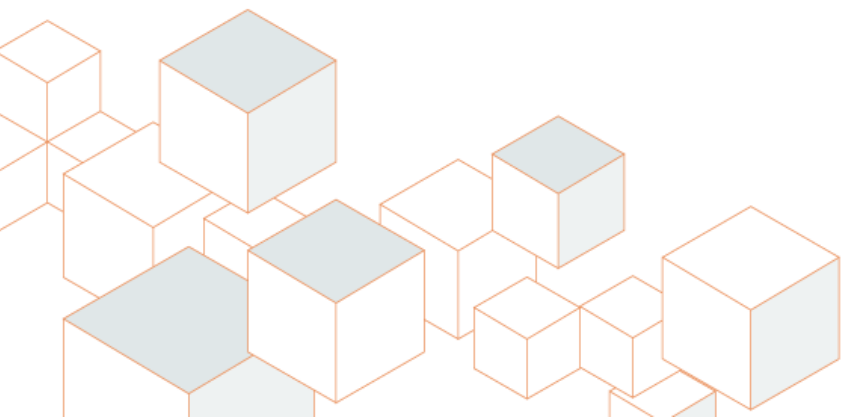


THE EPA BI-MONTHLY MEETING INORGANIC ARSENIC SCIENCE DISCUSSION

KIMBERLY WISE, PhD

ACC CENTER FOR ADVANCING RISK ASSESSMENT SCIENCE AND POLICY

JUNE 26 – 27, 2014



SCIENCE ISSUE 3: INTEGRATING RESULTS OF EPIDEMIOLOGIC STUDIES



RoB for Epidemiology Studies

Deemed Most Critical

- Confidence in the observed association based on a study design that allows for evaluation of an association between the exposure and the outcome;
- Confidence in the exposure assessment;
- Confidence in the outcome assessment; and
- Confidence in the overall internal validity of the study.

Method Concerns?
Confounding?

Study	Primary (P) or Supporting (S)	Selection			Confounding		Performance			Att.	Detection				SRB	Other
		Randomization	Allocation Concealment	Comparison Group	Confounding (Design)	Unintended Exposure	Experimental Conditions	Protocol Deviations	Blinding (During Study)	Missing Outcome Data	Blinding (Outcome Assessment)	Confounding (Analysis)	Exposure Characterization	Outcome Assessment	Outcome Reporting	Internal Validity
Chen et al. (2013c)	P	n/a	n/a	++	++	+	n/a	+	n/a	++	++	-	++	++	+	++
Chiou et al. (1997)	P	n/a	n/a	+	++	+	n/a	+	n/a	++	+	-	+	+	+	++
Chiou et al. (2001b)*	P	n/a	n/a	++	++	+	n/a	+	n/a	++	+	+	+	+	+	++
Chiou et al. (2005)	P	n/a	n/a	+	-	+	n/a	+	n/a	++	++	++	+	++	+	++
Cuzick et al. (1992)	S	n/a	n/a	-	-	-	n/a	+	n/a	+	+	-	-	+	+	+
Enterline and Marsh (1982)	S	n/a	n/a	-	-	-	n/a	+	n/a	+	+	-	-	++	+	++
Ghosh (2013)	S	n/a	n/a	-	-	-	n/a	+	n/a	+	-	-	-	-	+	++
Gong and O'Bryant (2012)	S	n/a	n/a	+	++	+	n/a	+	n/a	+	-	-	-	+	+	++
Guha Mazumder et al. (2012)	P	n/a	n/a	++	++	+	n/a	+	n/a	++	-	-	+	++	+	+
Guo et al. (2007)	S	n/a	n/a	-	-	-	n/a	+	n/a	-	-	-	-	-	+	-
Hawkesworth et al. (2013)	P	n/a	n/a	++	++	++	n/a	+	n/a	++	+	++	+	++	+	++
Hertz-Picciotto et al. (2000)	S	n/a	n/a	+	+	-	n/a	+	n/a	+	+	+	-	++	+	++

Integrating Epidemiology Data Using HBWoE Approach

Evaluate the available epidemiology data that are relevant to determine whether there is sufficient evidence to support an association between substance X exposure and adverse effect Y.

- ☐ Were results from the epidemiology data consistent for different types of exposure metrics (e.g., peak exposure, cumulative exposure)?
- ☐ Were results dependent on the robustness of exposure measurements?
- ☐ Were co-exposures considered in the interpretation of the study results?
- ☐ Were there consistent exposure-response associations within and across studies?
- ☐ Were there potential statistical limitations among the epidemiology studies?
- ☐ Are the exposure parameters relevant to environmental exposure levels?

