

USDA Nutrition Evidence Library Conclusion Statement Evaluation Criteria

Criteria for judging the strength of the body of evidence supporting the Conclusion Statement

Elements	Grade I: Strong	Grade II: Moderate	Grade III: Limited	Grade IV: Grade Not Assignable*	Rationale
Risk of bias (as determined using the NEL Bias Assessment Tool)	Studies of strong design free from design flaws, bias, and execution problems	Studies of strong design with minor methodological concerns OR only studies of weaker study design for question	Studies of weak design for answering the question OR inconclusive findings due to design flaws, bias, or execution problems	Serious design flaws, bias, or execution problems across the body of evidence	
Quantity • Number of studies • Number of subjects in studies	Several good quality studies Large number of subjects studied Studies have sufficiently large sample size for adequate statistical power	Several studies by independent investigators Doubts about adequacy of sample size to avoid Type I and Type II error	Limited number of studies Low number of subjects studied and/or inadequate sample size within studies	Available studies do not directly answer the question OR no studies available	
Consistency of findings across studies	Findings generally consistent in direction and size of effect or degree of association, and statistical significance with very minor exceptions	Some inconsistency in results across studies in direction and size of effect, degree of association, or statistical significance	Unexplained inconsistency among results from different studies	Independent variables and/or outcomes are too disparate to synthesize OR single small study unconfirmed by other studies	
Impact • Directness of studied outcomes • Magnitude of effect	Studied outcome relates directly to the question Size of effect is clinically meaningful	Some study outcomes relate to the question indirectly Some doubt about the clinical significance of the effect	Most studied outcomes relate to the question indirectly Size of effect is small or lacks clinical significance	Studied outcomes relate to the question indirectly Size of effect cannot be determined	
Generalizability to the U.S. population of interest	Studied population, intervention and outcomes are free from serious doubts about generalizability	Minor doubts about generalizability	Serious doubts about generalizability due to narrow or different study population, intervention or outcomes studied	Highly unlikely that the studied population, intervention AND/OR outcomes are generalizable to the population of interest	

*Standard conclusion statement is used to communicate that there is either insufficient evidence or no evidence available to answer the question.