



Pathways to Implementation of the NRC Recommendations

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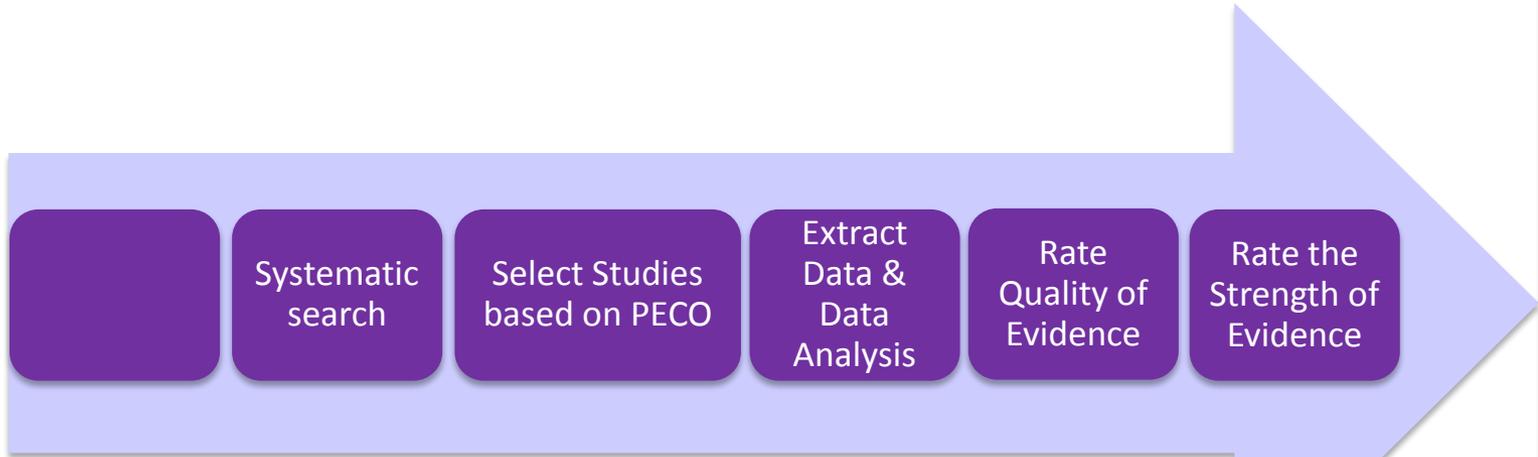
Program on Reproductive
Health and the Environment



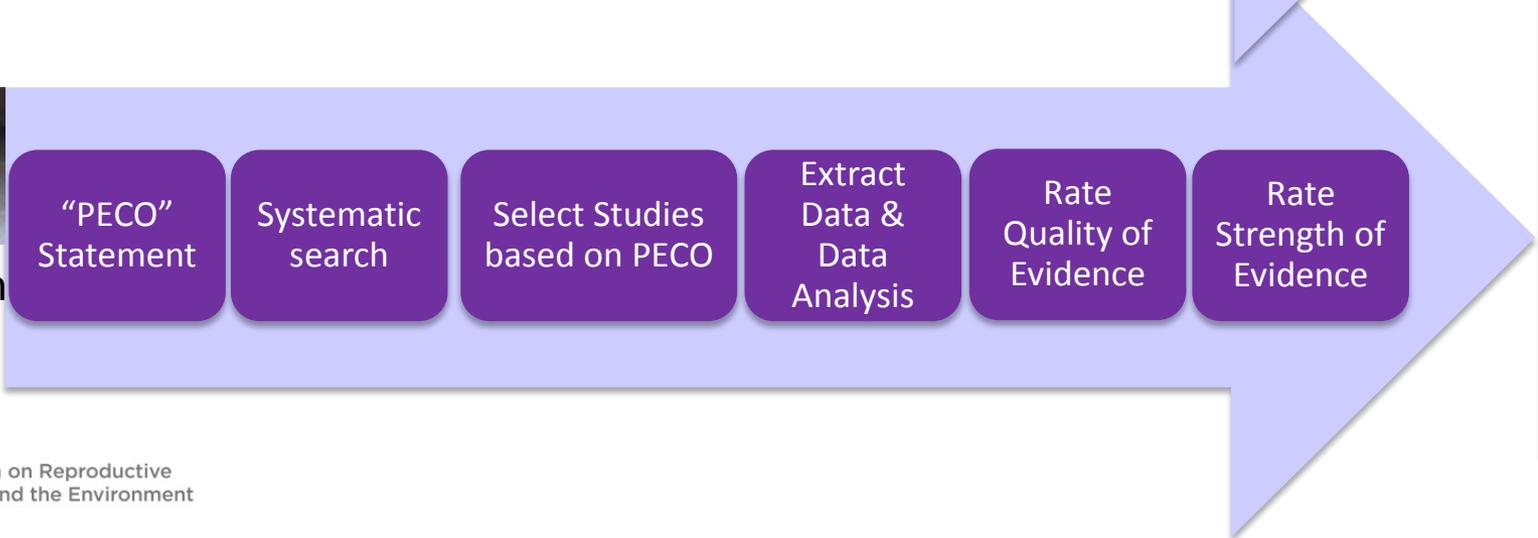
Identify evidence more transparently and efficiently



Human Data



Non Human Data



Overall Conclusion



Rate Quality of Evidence

- Risk of Bias

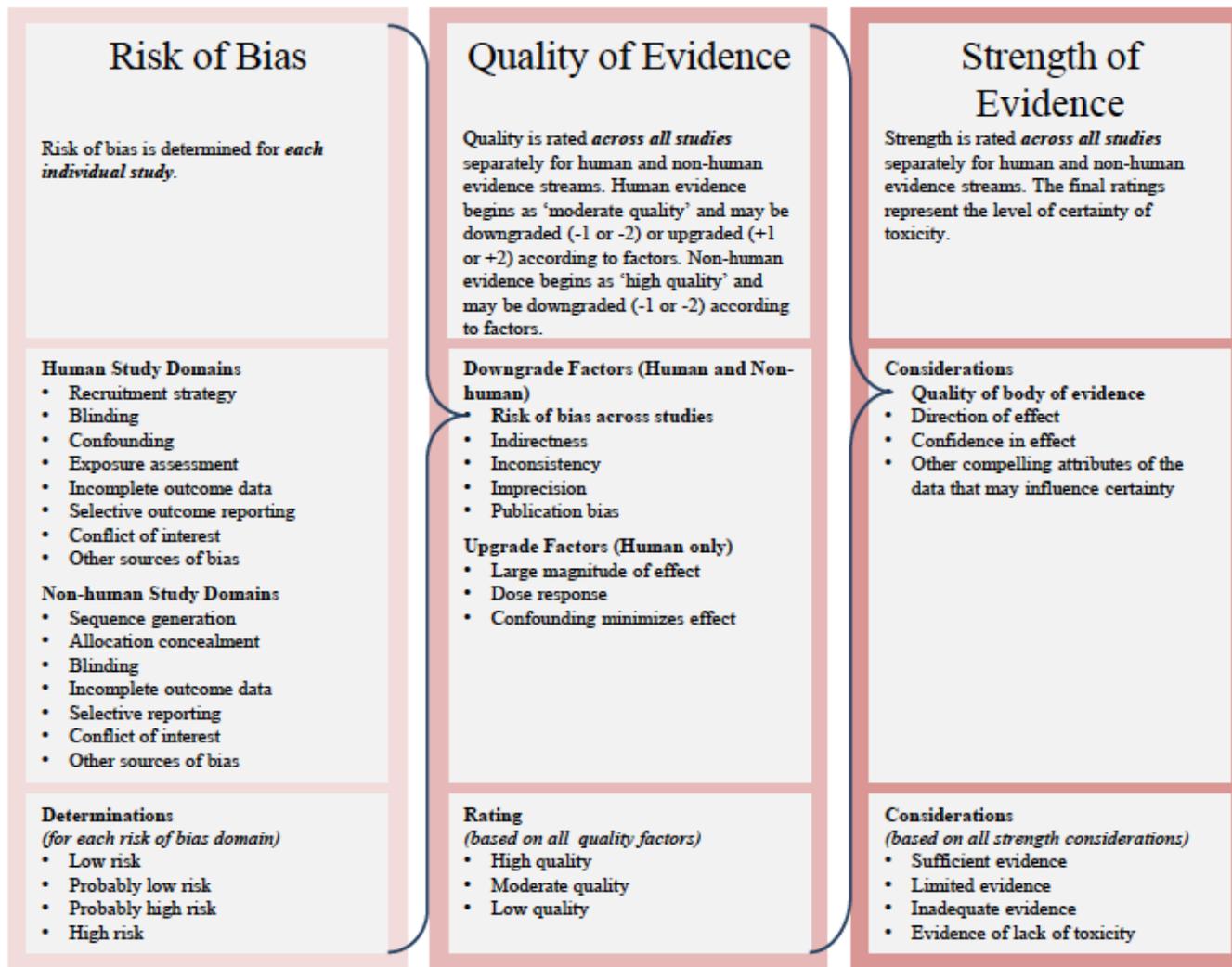


Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

- Rating quality of evidence



Figure 1. Evaluating Study Quality and Strength of Evidence



Recruitment Strategy
Blinding
Confounding
Exposure assessment
Incomplete outcome data
Selective outcome reporting
Other sources of bias
Conflict of Interest

Apelberg et al. 2007

Arbuckle et al. 2012

Chen et al. 2012

Fei et al 2008

Fei et al. 2007

Fromme et al. 2010

Halldorsson et al. 2012

Hamm et al. 2010

Kim S. et al. 2011

Kim S.K. et al. 2011

Maisonet et al. 2012

Monroy et al. 2008

Nolan et al. 2009

Savitz et al. 2012a

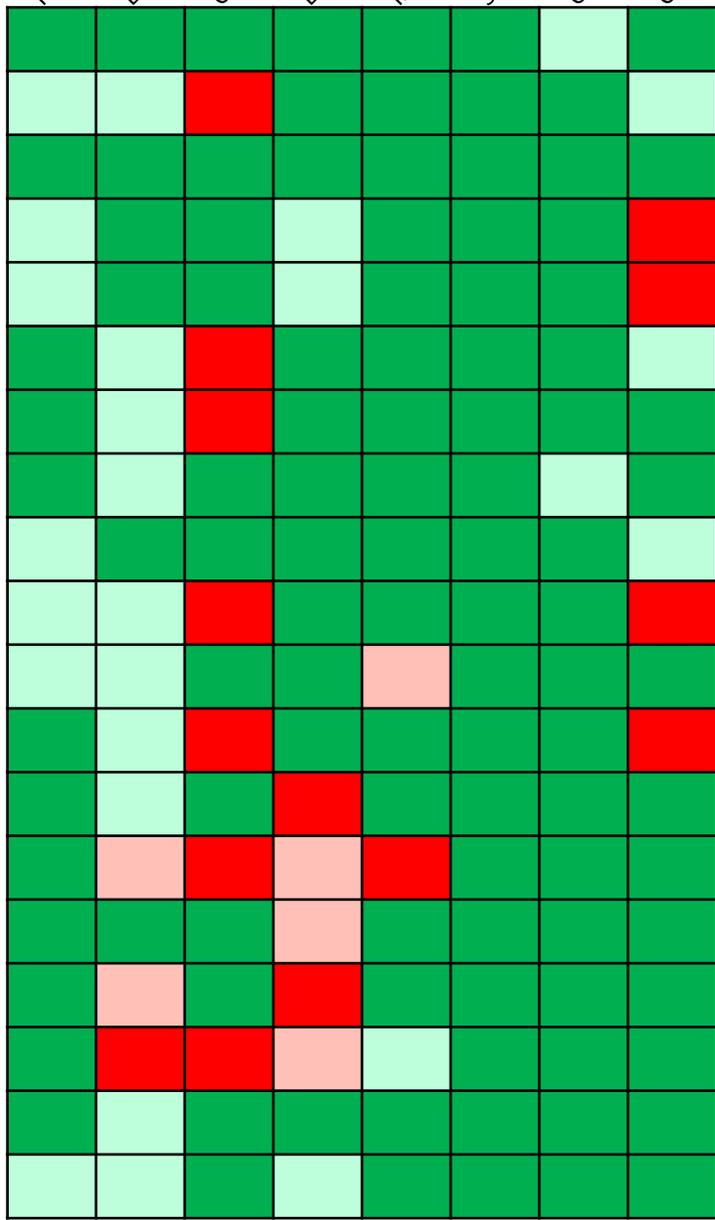
Savitz et al. 2012b (study 1)

Savitz et al. 2012b (study 2)

Stein et al. 2009

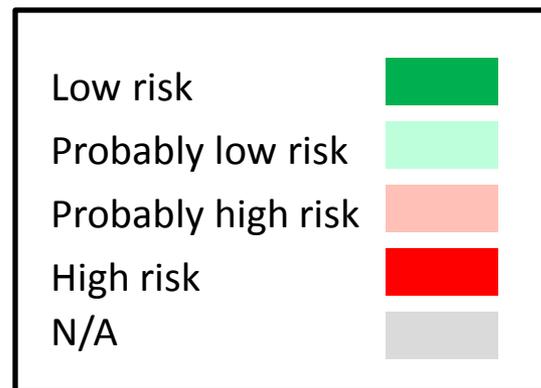
Washino et al. 2009

Whitworth et al. 2012

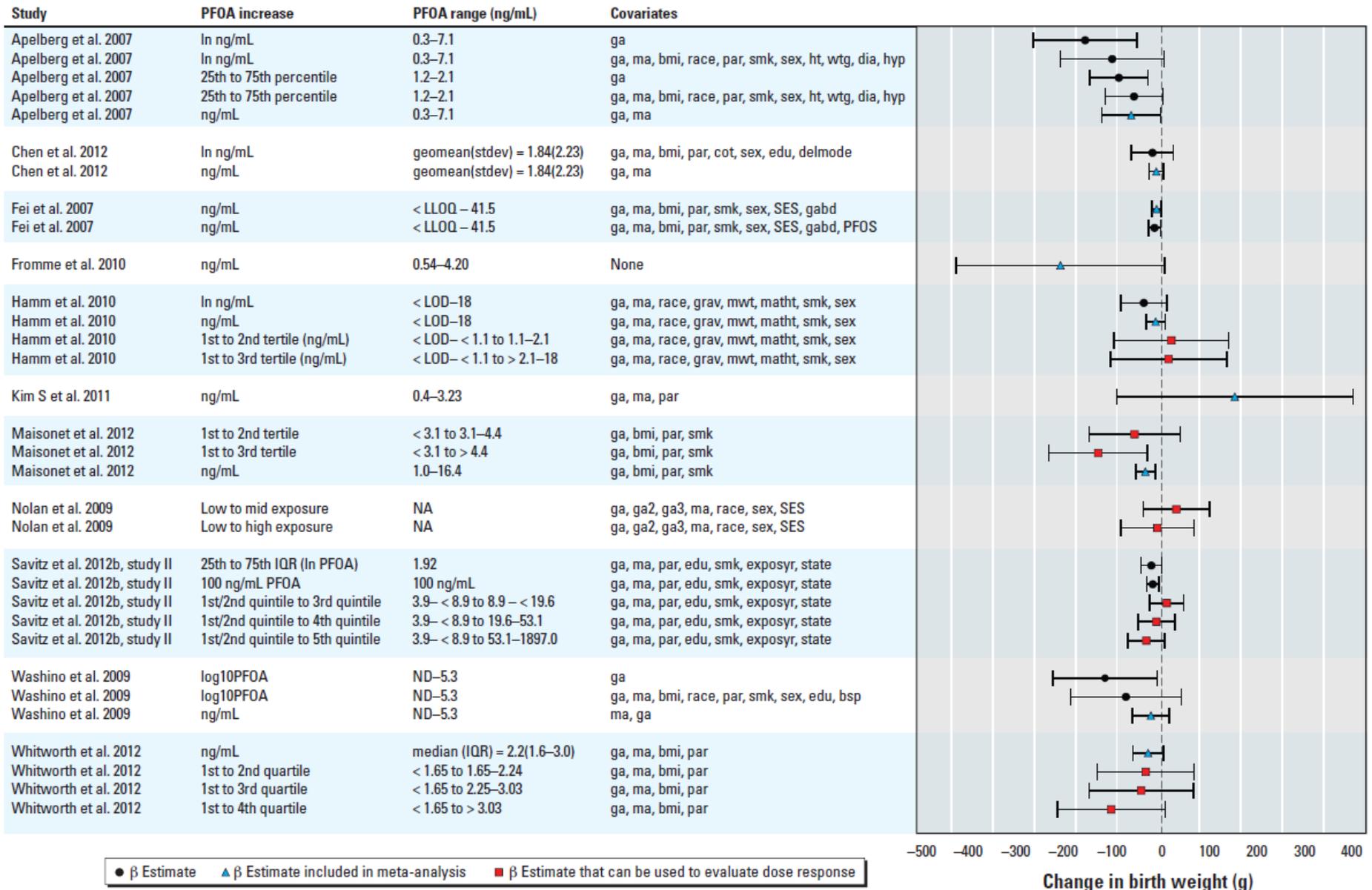


Results: Risk of Bias Human Evidence N=19

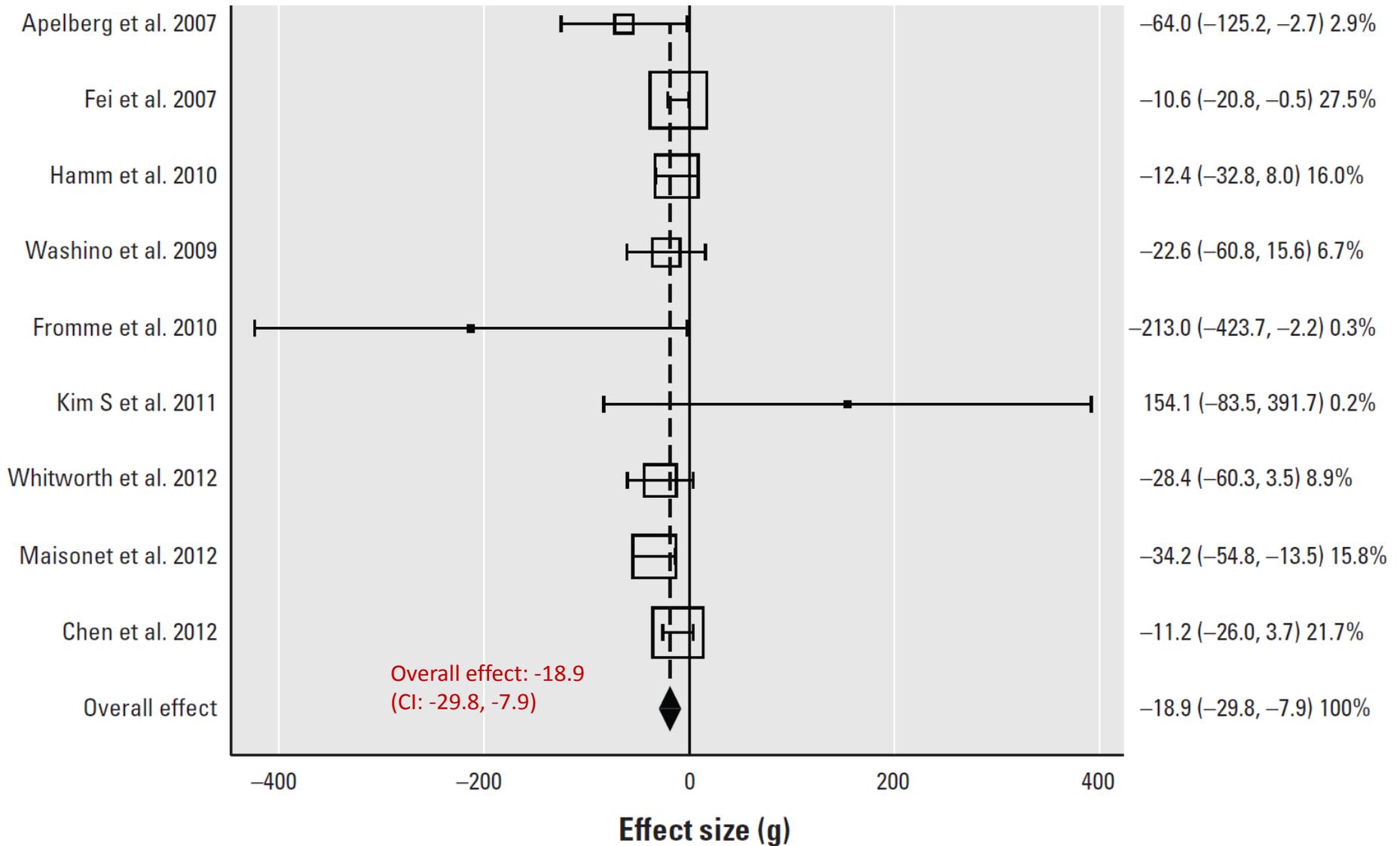
For individual studies (N=19)



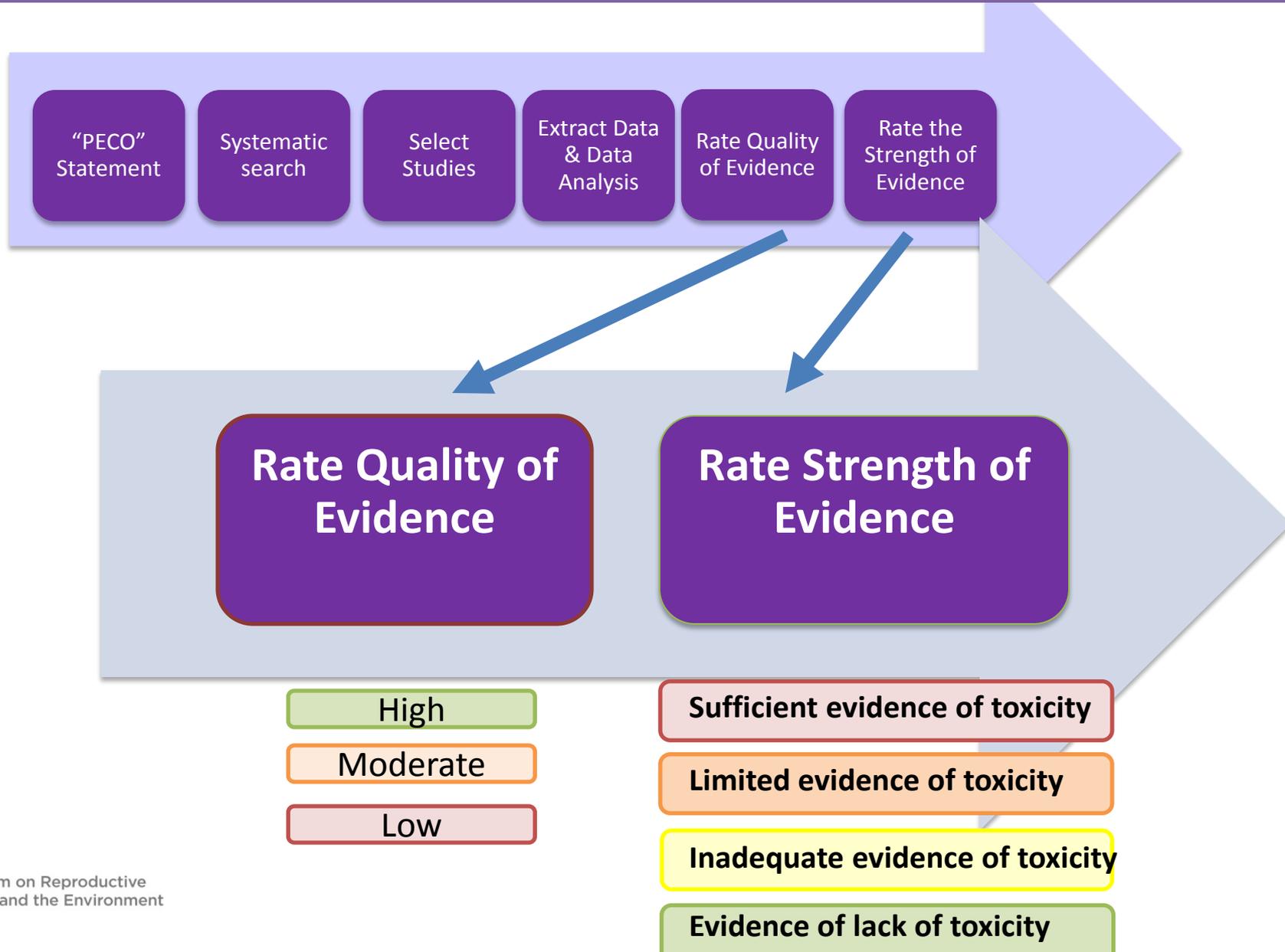
Individual Studies for PFOA & BW



Meta-analysis for Birth Weight (n=9 studies)



Rate the Quality and Strength of the Evidence



Summary of Quality of Evidence for PFOA



| | | Evidence Stream | |
|---------------------|--|-----------------|---------------------|
| | | Human | Non-human mammalian |
| Downgrade | Starting rating | Moderate | High |
| | Risk of Bias | 0 | -1 |
| | Indirectness | 0 | 0 |
| | Inconsistency | 0 | 0 |
| | Imprecision | 0 | 0 |
| Upgrade | Publication bias | 0 | 0 |
| | Large magnitude effect | 0 | N/A |
| | Dose response | 0 | N/A |
| | All possible confounding would confirm negative result | 0 | N/A |
| Grade | | 0 | -1 |
| Final rating | | Moderate | Moderate |



Strength of Evidence

Human Evidence = “Sufficient”

CRITERIA:

1. Quality of evidence: **Moderate**
2. What is the direction of effect? **Decrease in fetal growth with PFOA exposure**
3. What is the confidence in the effect? **A new study would be unlikely to change the certainty in the direction of the effect**
4. Are there other compelling attributes of the data that influence certainty?

Sufficient evidence of toxicity

The available evidence includes consistent results from well-designed, well-conducted studies and the conclusions are unlikely to be strongly affected by the results of future studies. A positive relationship was observed between exposure and outcome where chance, bias and confounding can be ruled out with reasonable confidence.

Used criteria and considerations used by IARC, the U.S. Preventive Services Task Force, and U.S. EPA for

Summary of Recommendations for Systematic Review Methods

1. Doable!
2. Protocol (prespecified approach) is essential
3. Apply consistent, systematic approach for evaluating each evidence stream separately, then integrate
4. Build off existing methods for a structured, complete and transparent methodology for integrating evidence:
OHAT/ Navigation Guide/GRADE
5. Support infrastructure and research



Thank you



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Health and the Environment



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