

GETTING STUDIES RIGHT TO SUPPORT DRUGS, DEVICES,
AND BIOLOGICAL PRODUCTS IN HEALTHCARE

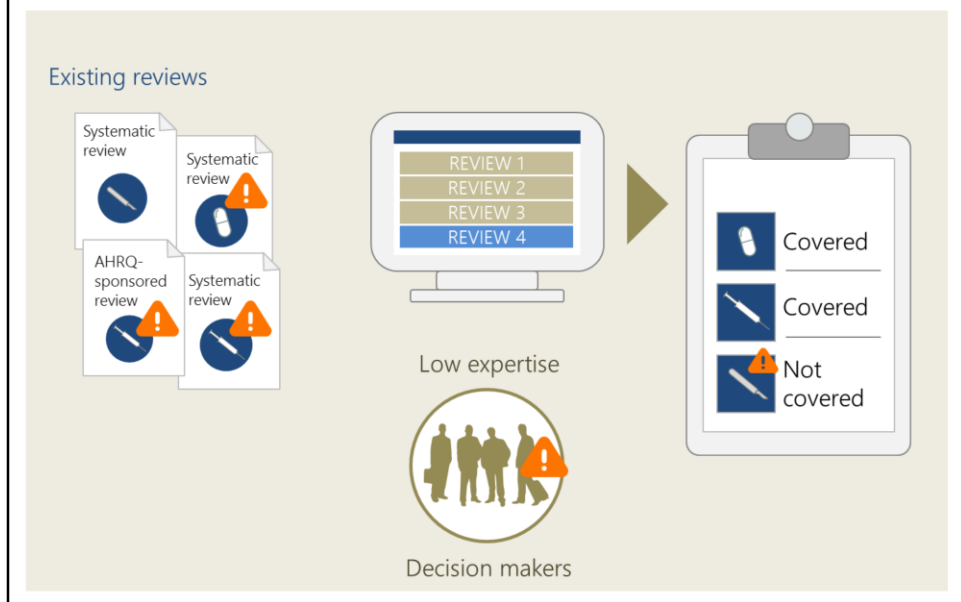
Strategic Solutions, Inc.
Clinical Research Services

Marissa J. Carter, PhD, MA, MAPWCA
Strategic Solutions, Inc., Cody WY, USA



LITERATURE APPRAISALS AND ANALYSIS

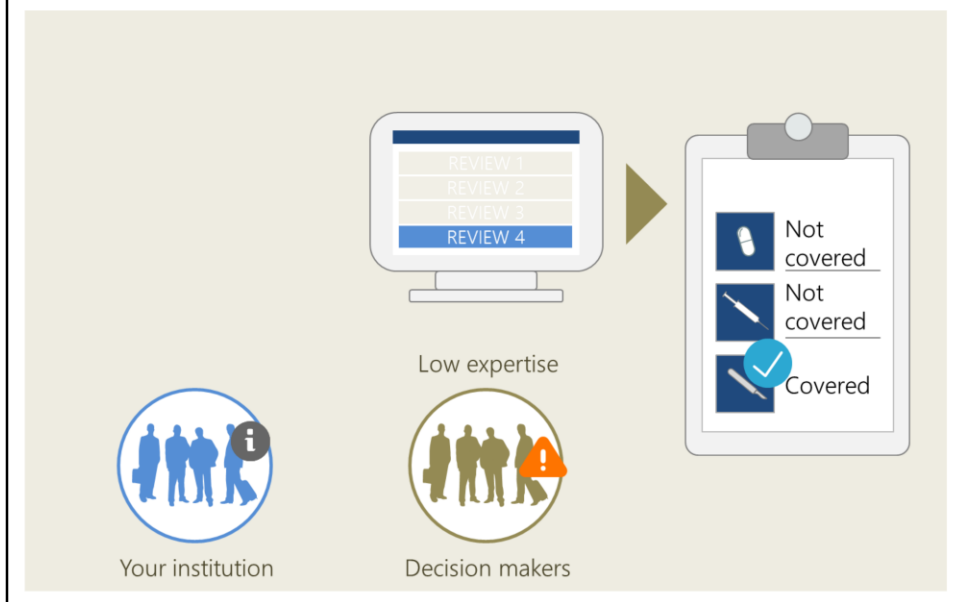
Centers for Medicare/Medicaid & Other Payer Coverage Issues



0- NCDs and LCDs can be decided by groups of individuals who lack expertise in systematic review methodology and/or meta-analysis.

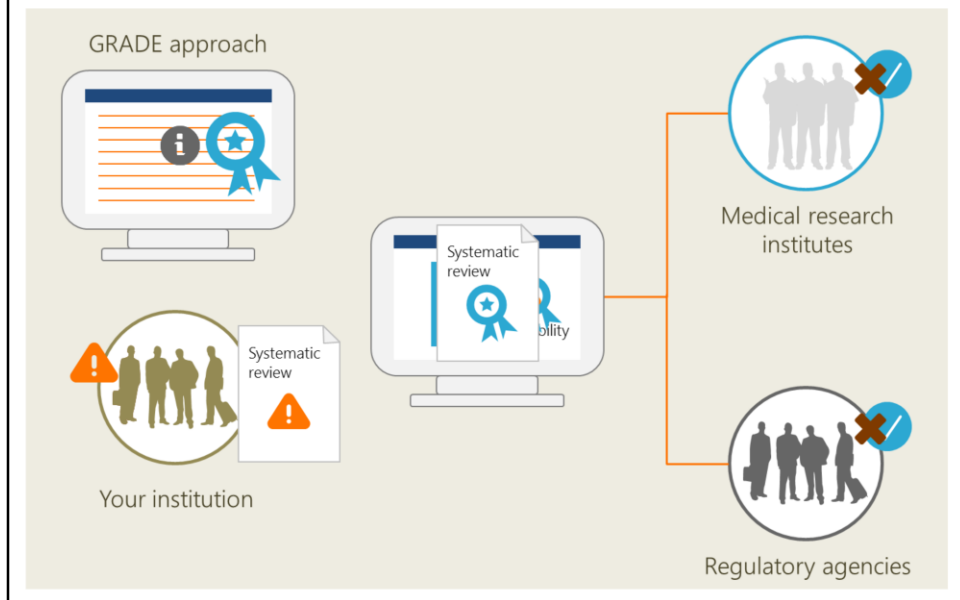
1- To change LCDs, especially if they seem non-credible or plain unfair requires independent systematic review methodology

Centers for Medicare/Medicaid
& Other Payer Coverage Issues



0- Continued education of such entities is a good long-term strategy. Where systematic reviews are lacking or existing ones biased it may be useful to sponsor such activity. AHRQ-sponsored systematic reviews may be another target if they are not well done

Methodology



0- Systematic reviews can be focused on efficacy, safety, or health economic outcomes. The credibility of Cochrane reviews depends on the expertise and experience of its authors. A system by itself is no guarantee that it will be used appropriately

1- The GRADE approach is fast becoming the gold standard. It is the method of choice for most Medical research institutes and regulatory agencies. By using the GRADE approach you can increase the credibility of your reviews.

Meta-analysis



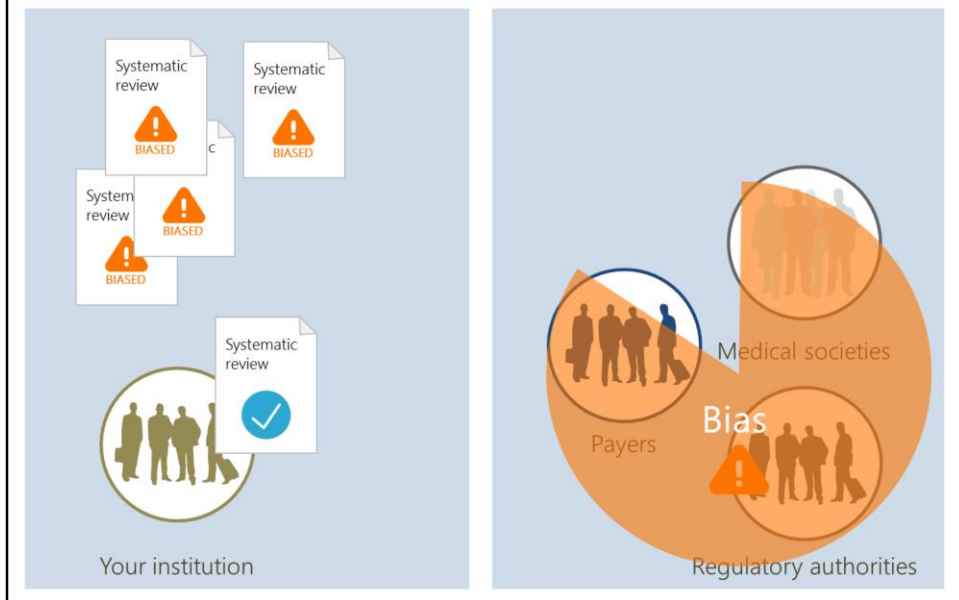
0- There are different types of meta analysis.

1-The most common form of meta-analysis is simple (mathematically) but in the hands of the inexperienced it can be a disaster

2-Network mapping analysis is a new approach to estimating the effects of one or more drugs/devices against others (head to head)

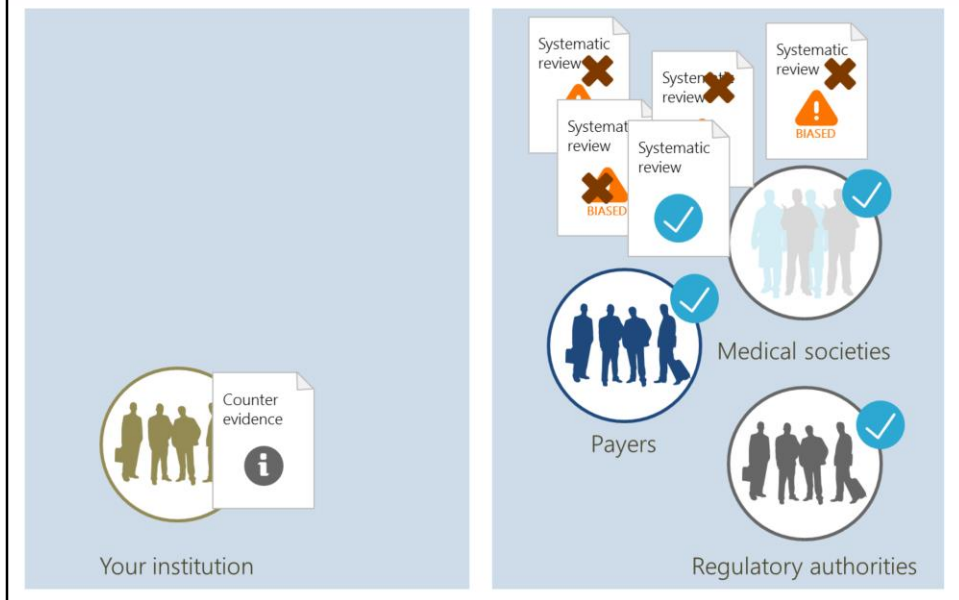
3- More sophisticated forms include meta-regression, whether conducted in frequentist or Bayesian fashion

Biased Systematic Reviews



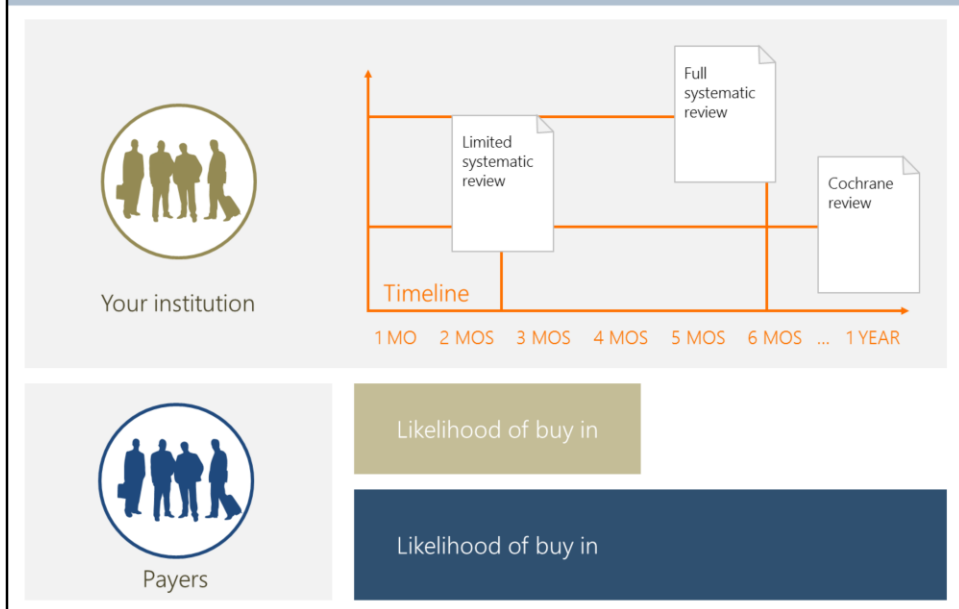
0- Sadly, many systematic reviews are flawed or biased due to inexperience on the part of authors. Occasionally the bias can be deliberate. Cochrane reviews can be another example but depends on authors
Understanding bias in systematic reviews requires major expertise/practice in the methodology.

Biased Systematic Reviews



0- Countering biased reviews requires active education of payers, medical societies, regulatory authorities because medical journals frequently don't permit overt criticism of systematic reviews

Study Cost and Timeline



- 0- Small, limited systematic reviews to address LCD issues, for example, can be reasonably inexpensive and be conducted within a couple of months
- Full-blown systematic reviews and major meta-analysis/regression is expensive and can take many months
- Cochrane reviews often take a year or more because they are run on a volunteer basis
- 1- Reviews can increase likelihood of payer buy-in

ANY QUESTIONS?

Email us at info@strategic-solutions-inc.com
or call us at 1-307-587-5352 (office hours
Monday through Friday, 9am-5pm,
Mountain Time, (GMT-7))