### EBSJ Evidence Assessment: Definition of Risk of Bias (RoB)

**Articles on treatment**

| Risk of bias description | Studies of therapy | Criteria |
|--------------------------|--------------------|---------|
| Low risk                | Good quality RCT   | Random sequence generation, Allocation concealment, Intent-to-treat analysis, Blind or independent assessment for author's primary important outcomes, Covariates applied equally, F/U rate of 80% or >10% difference in follow-up between groups, Controlling for possible confounding |
| Moderately low risk     | Moderate or poor quality RCT | Violation of one or two criteria for good quality RCT |
| High risk               | Poor quality RCT   | Violation of three or more of the criteria for a good quality RCT |

**Articles on prognosis or risk**

| Risk of bias description | Studies of prognosis | Criteria |
|--------------------------|----------------------|---------|
| Low risk                 | Good quality cohort  | Prospective design, Patients at similar point in the course of their disease or treatment, F/U rate of ≥80%, Patients followed long enough for outcomes to occur, Accounting for other prognostic factors, Objective and unbiased outcome measure used |
| Moderately low risk      | Moderate quality cohort | Prospective design, with violation of one of the other criteria for good quality cohort study, Retrospective design, meeting all the rest of the criteria in good quality cohort |
| High risk                | Poor quality cohort  | Prospective design with violation of two or more criteria for good quality cohort, or Retrospective design with violation of one or more criteria for good quality cohort, or A good case-control study, or A good cross-sectional study, or Any case series design |

### Determination of Overall Strength (Quality) of Evidence (SoE)

After individual article evaluation, the overall quality of the body of evidence with respect to each outcome is likely to involve several concepts outlined by the Grades of Recommendation Assessment, Development and Evaluation (GRADE) Working Group and recommendations made by the Agency for Healthcare Research and Quality (AHRQ). Qualitative analysis is performed considering the AHRQ required and additional domains. The table below provides an outline of the methods used to determine the final SoE.

The following four possible levels and their definition will be reported:

- **High**: High confidence that the evidence reflects the true effect. Further research is very unlikely to change our confidence in the estimate of effect.
- **Moderate**: Moderate confidence that the evidence reflects the true effect. Further research may change our confidence in the estimate of effect and may change the estimate.
- **Low**: Low confidence that the evidence reflects the true effect. Further research is likely to change the confidence in the estimate of effect and likely to change the estimate.
- **Insufficient**: Evidence either is unavailable or does not permit a conclusion.

All AHRQ "required" and "additional" domains are assessed. Only those that influence the baseline grade are listed in table. Baseline strength: Risk of bias (including control of confounding) is accounted for in the individual article evaluation. High = majority of articles RCTs; Low = majority of articles cohort (observational) studies.

### Definitions of the Different Levels of Evidence for Reliability Studies

Level of evidence ratings for Cochrane reviews and other systematic reviews are assigned a baseline score of High if RCTs were used. Low if observational studies were used. The rating can be upgraded or downgraded based on adherence to the core criteria for methods, quality, and quantitative analyses for systematic reviews (there is a reference/evaluation table for this).

| Level | Study type | Criteria |
|-------|------------|----------|
| 1     | Good quality study | Broad spectrum of patients with the expected condition, Adequate description of methods for replication, Blinded performance of tests, measurements, or interpretation |
| 2     | Moderate quality | Violation of any of the criteria for a good quality study |
| 3     | Poor quality study | Violation of any of the criteria |
| 4     | Very poor quality study | Violation of all three of the criteria |

### Study Designs

| Outcome | Strength of evidence | Conclusions and comments | Baseline | Downgrade | Upgrade |
|---------|----------------------|--------------------------|---------|----------|---------|
| Outcome | High                 | Summary of findings      | RCTs    | Consistent, direct, and precise estimates | No |
| Outcome | Moderate             | Summary of findings      | Low RCTs| Consistent, direct, and precise estimates | Yes | Large effect |
| Outcome | Low                  | Summary of findings      | RCTs    | Inconsistent | Not listed | No |

**Required domains**: risk of bias, consistency, directness, precision. Plausible confounding that would decrease observed effect is accounted for in our baseline risk of bias assessment through individual article evaluation. Additional domains: dose-response, strength of association, publication bias.

**Single study = "consistency unknown."**

### Strength of Evidence for Existing Systematic Reviews

*Good quality study* refers to the distribution of results, self-reported pain, and testing for interaction (2) and cannot compare this risk to those that do not smoke.

*Example of objective outcomes: weight loss, change in blood pressure, speed of walking, reoperation, death, etc.; examples of subjective outcomes are patient reported outcomes and self-reported pain.*