

Table 1: Rating the Quality of Evidence for Therapy or Harm Studies Using the GRADE Approach

| Type of Evidence | Initial Grade | Criteria to Decrease Grade | Criteria to Increase Grade | Overall Quality Grade |
|---|---------------|--|---|-----------------------|
| RCT | High | <u>Quality</u> Serious (-1 grade) or very serious (-2 grades) limitation to study quality | <u>Strong association</u> Strong (+1 grade) or very strong evidence of association (+2 grades) | High Moderate |
| Observational study | Low | <u>Consistency</u> Important inconsistency (-1 grade) | <u>Dose-response</u> Evidence of a dose-response gradient (+1 grade) | Low |
| Any other evidence (e.g., expert opinion) | Very low | <u>Directness</u> Some (-1 grade) or major (-2 grades) uncertainty about directness | <u>Unmeasured Confounders</u> Inclusion of unmeasured confounders increases the effect size (+1 grade) | Very low |
| | | <u>Precision</u> Imprecise or sparse data (-1 grade) | | |
| | | <u>Publication bias</u> High risk of bias (-1 grade) | | |

Abbreviations: Grading of Recommendations Assessment, Development and Evaluation (GRADE); Randomized Controlled Trial (RCT).

Table 2: Formulating Recommendations

| HICPAC Recommendation | Weighing Benefits and Harms for Critical Outcomes | Quality of Evidence |
|------------------------------------|--|--|
| STRONG (Category I) | Interventions with net benefits or net harms | Category IA – High to Moderate |
| | | Category IB – Low to Very Low (Established Practice) |
| WEAK (Category II) | Interventions with trade offs between benefits and harms | Category IC – High to Very Low (Regulatory) |
| | | High to Very Low |
| No recommendation/unresolved Issue | Uncertain trade offs between benefits and harms | Low to Very Low |

Table 3. Updated HICPAC Categorization Scheme for Recommendations

| | |
|-------------------|---|
| Category IA | A strong recommendation supported by high to moderate quality evidence suggesting net clinical benefits or harms. |
| Category IB | A strong recommendation supported by low quality evidence suggesting net clinical benefits or harms, or an accepted practice (e.g., aseptic technique) supported by low to very low quality evidence. |
| Category IC | A strong recommendation required by state or federal regulation. |
| Category II | A weak recommendation supported by any quality evidence suggesting a trade off between clinical benefits and harms. |
| No Recommendation | An unresolved issue for which there is low to very low quality evidence with uncertain trade offs between benefits and harms. |