

Table. Applying Class of Recommendation and Level of Evidence to Clinical Strategies, Interventions, Treatments, or Diagnostic Testing in Patient Care (Updated May 2019)

This table defines the Classes of Recommendation (COR) and Levels of Evidence (LOE). COR indicates the strength the writing group assigns the recommendation, and the LOE is assigned based on the quality of the scientific evidence. The outcome or result of the intervention should be specified (an improved clinical outcome or increased diagnostic accuracy or incremental prognostic information).

Classes of Recommendation

COR designations include Class 1, a strong recommendation for which the potential benefit greatly outweighs the risk; Class 2a, a moderate recommendation for which benefit most likely outweighs the risk; Class 2b, a weak recommendation for which it's unknown whether benefit will outweigh the risk; Class 3: No Benefit, a moderate recommendation signifying that there is equal likelihood of benefit and risk; and Class 3: Harm, a strong recommendation for which the risk outweighs the potential benefit.

Suggested phrases for writing Class 1 recommendations include

- Is recommended
- Is indicated/useful/effective/beneficial
- Should be performed/administered/other

Comparative-effectiveness phrases include treatment/strategy A is recommended/indicated in preference to treatment B, and treatment A should be chosen over treatment B.

Suggested phrases for writing Class 2a recommendations include

- Is reasonable
- Can be useful/effective/beneficial

Comparative-effectiveness phrases include treatment/strategy A is probably recommended/indicated in preference to treatment B, and it is reasonable to choose treatment A over treatment B.

For comparative-effectiveness recommendations (COR 1 and 2a; LOE A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

Suggested phrases for writing Class 2b recommendations include

- May/might be reasonable
- May/might be considered
- Usefulness/effectiveness is unknown/unclear/uncertain or not well-established

Suggested phrases for writing Class 3: No Benefit recommendations (generally, LOE A or B use only) include

- Is not recommended
- Is not indicated/useful/effective/beneficial
- Should not be performed/administered/other

Suggested phrases for writing Class 3: Harm recommendations include

- Potentially harmful
- Causes harm
- Associated with excess morbidity/mortality
- Should not be performed/administered/other

Levels of Evidence

For LOEs, the method of assessing quality is evolving, including the application of standardized, widely-used, and preferably validated evidence grading tools; and for systematic reviews, the incorporation of an Evidence Review Committee. LOE designations include Level A, Level B-R, Level B-NR, Level C-LD, and Level C-EO.

Those categorized as Level A are derived from

- High-quality evidence from more than 1 randomized clinical trial, or RCT
- Meta-analyses of high-quality RCTs
- One or more RCTs corroborated by high-quality registry studies

Those categorized as Level B-R (randomized) are derived from

- Moderate-quality evidence from 1 or more RCTs
- Meta-analyses of moderate-quality RCTs

Those categorized as Level B-NR (nonrandomized) are derived from

- Moderate-quality evidence from 1 or more well-designed, well-executed nonrandomized studies, observational studies, or registry studies
- Meta-analyses of such studies

Those categorized as Level C-LD (limited data) are derived from

- Randomized or nonrandomized observational or registry studies with limitations of design or execution
- Meta-analyses of such studies
- Physiological or mechanistic studies in human subjects

Those categorized as Level C-EO (expert opinion) are derived from

- Consensus of expert opinion based on clinical experience

COR and LOE are determined independently (any COR may be paired with any LOE).

A recommendation with LOE C does not imply that the recommendation is weak. Many important clinical questions addressed in guidelines do not lend themselves to clinical trials. Although RCTs are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.