GRADE method for guideline developers

- Care question (PICO)
- Define critical and important outcomes
- Generate an estimate of effect for each outcome (systematic review)
- Rate the quality of evidence for each outcome, across studies
- RCTs start with high quality ⊕⊕⊕⊕,
  observational studies with a low quality ⊕⊕○○

Rating is modified downward:

(-1 or -2 levels)

- Study limitations (high risk of bias)
- Imprecision
- Inconsistency of results
- Indirectness of evidence
- Publication bias likely

Rating is modified upward:

(observational studies without further limitations)

- Large magnitude of effect (RR >2 (+1) or >5 (+2))
- Dose response (+1)
- Confounders likely to minimize the effect (+1)

GRADE method for guideline developers

Final rating of quality for each outcome:

high, moderate, low, or very low
- Rate overall quality of evidence (lowest quality among critical outcomes)

Decide on the direction:

(for/against) and grade strength of the recommendation (strong/weak) considering:
- Quality of the evidence
- Balance of desirable and undesirable outcomes
- Values and preferences
- Decide of any revision of direction or strength is necessary based on:
  resource use

Definitions:

Study design refers to the design of the study:
RCT or observational design: prospective or retrospective cohort study, case control study, case series or case report

Study quality refers to the methodological quality of the study (risk of bias due to limitations in the study design, e.g. lack of allocation concealment in RCTs or no adjustment for confounding in observational studies)

Inconsistency: widely (unexplained) different estimates of the treatment effect across studies

GRADE: evidence profile

Quality assessment

No of studies (Design)	Limitations	Imprecision	Inconsistency	Indirectness	Publication bias
study 1 (RCT)					
study 2					
ect					

Summery of findings

No of studies (Design)	Number of patients		Absolute risk			
	group 1	group 2	Relative risk (95% CI)	Control risk	Risk difference (95% CI)	Quality
study 1 (RCT)						
study 2						
ect						