Factsheet II: GRADE – Evidence Appraisal

8

This document is part of the
Care Pathways Toolkit for **Healthcare Professionals** & **Patient Representatives**

WP6 TASK 6.2

JARDIN

Co-funded by the European Union

"Co-funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or European Health and Digital Executive Agency. Neither the European Union nor the granting authority can be held responsible for them."

FACTSHEET II: GRADE – Evidence Appraisal

The Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) process is a systematic approach used to assess the quality of evidence and strength of recommendations in clinical guidelines. It helps ensure that recommendations are based on rigorous, transparent, and reproducible methods.

The final quality assessment, which applies to the body of evidence is classified one of four possible levels: *high, moderate, low, or very low* – depending on the type and size of study. The quality of evidence is primarily assessed based on the type of study design (e.g., randomized controlled trials (RCTs) are considered higher quality), risk of bias, inconsistency of results, indirectness (whether the evidence applies to the target population), imprecision (sample size and variability), and publication bias.

The strength of a recommendation is classified as either: **Strong**: The benefits of an intervention clearly outweigh the harms (or vice versa), and the recommendation is actionable for most patients; or **Weak/Conditional**: The balance of benefits and harms is less clear, and individual patient preferences, values, and circumstances may affect the decision.

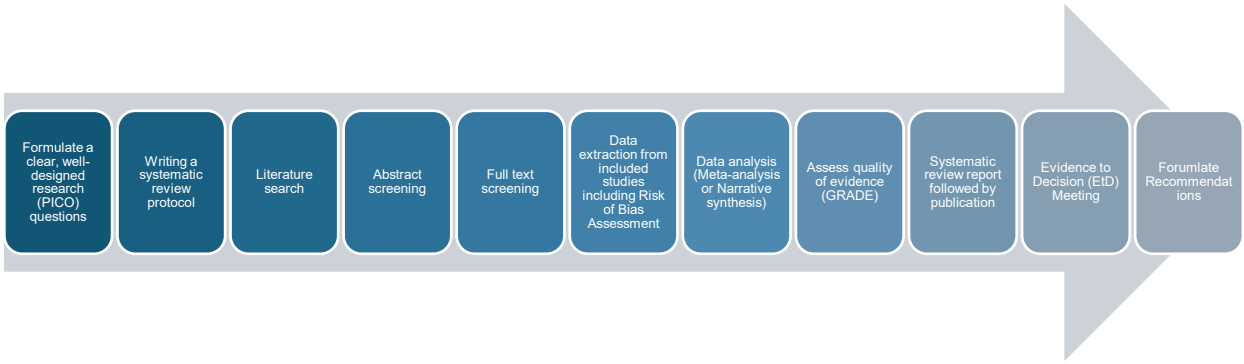
The strength of a recommendation is influenced by five categories: *risk of bias, imprecision, inconsistency, indirectness, and publication bias.*

- **The quality of the evidence**: Higher-quality evidence typically supports stronger recommendations.
- **The balance between benefits and harms**: If benefits clearly outweigh harms (or the opposite), a strong recommendation is more likely.
- **Patient values and preferences**: In cases where there is uncertainty about the evidence or a trade-off between benefits and harms, the guideline developers consider how different patients might value outcomes.
- **Resource use and cost-effectiveness**: The cost and availability of interventions may influence the strength of a recommendation, especially in resource-constrained settings.

These categories help to determine the degree to which you can trust that results reported in the literature are likely to be those you will see if you were to use the interventions for ‘real’ patients. **GRADE is, however, not appropriate for making guidelines recommendations when there is no evidence, conflicting evidence, or very low-quality evidence, and consensus statements are more appropriate in these scenarios.**

After assessing the evidence and considering the strength of recommendations, guideline developers can make a final recommendation. This might include recommendations for treatment, diagnostics, or other interventions. Recommendations are typically supported by a clear rationale for why they are being made.

Overview of the GRADE Process:



Patient involvement in the literature review process is considered best practice under the GRADE methodology. Patient representatives can help shape the PICO questions as part of the scope of the literature review, reviewing the main findings and take part in the Evidence to Decision discussions to formulate the recommendations.

EtD Meeting make judgements for each outcome for which there is a desirable effect, taking into account the value that patients place on each outcome. By considering the balance of consequences (evidence to recommendation) using the EtD Framework based on *quality of evidence, balance of benefits/harms, values and preferences (equity), resources use (cost, feasibility) and acceptability.*

Patient representatives should be involved and supported to contribute to the 'Evidence to Decision Meeting' to:

- weigh the benefits and harms, burdens, and cost of a treatment differently.
- consider to what extent are patients willing to accept the possibility of adverse effects against a favourable clinical outcome.
- help ensure that patients will support outcomes of the guideline.
- provide transparency of the discussions and rational for formulating the initial recommendations.

Formulate Recommendations:

Recommendations should be clearly formulated based on strong or conditional/weak (strength) of evidence and being clear of either 'for' or 'against' (direction) of the recommendation, being transparent, clear and actionable.

"The panel recommends that ….should…"

"The panel suggests that ….should…"

"The panel suggests to **not**…"

"The panel recommends to **not**…"

This file is part of the

Care Pathways Toolkit for **Healthcare Professionals** & **Patient Representatives**

Please refer to this document to access all resources:

https://jardin-ern.eu/?resource=care-pathways-toolkit

JARDIN

Co-funded by the European Union

https://jardin-ern.eu/

"Co-funded by the European Union. Views and opinions expressed are however those of the author(s) only and do not necessarily reflect those of the European Union or European Health and Digital Executive Agency. Neither the European Union nor the granting authority can be held responsible for them."