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Imprecision: Limitations of Using GRADE to Rate the Quality of Evidence on Adverse Effects – a case study

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Background: The GRADE approach is a uniform ratings system that offers a transparent and structured process for developing and presenting summaries of quality of evidence for guideline development.

Purpose: To describe the use of the GRADE approach in a national guideline on neuropathic pain and to discuss the limitations of using GRADE to rate down the quality of evidence on adverse effects as a result of imprecision.

Methods: The GRADE approach was used to assess and summarise the evidence. Key outcomes, both desirable (benefit) and undesirable (adverse effects), were graded and summarized using detailed GRADE evidence profiles. The Guideline Development Group (GDG) was encouraged to discuss and draft evidence statements based on the evidence profiles, particularly through consideration of the balance between desirable consequences (benefit) and undesirable consequences (adverse effects) of the treatments. The identified limitations, as well as the discussion about the inconsistency of the GRADE approach in assessing harm (adverse effects) compared with benefit (positive outcomes) were documented.

Results: The use of GRADE provided a clear structure, direction and transparency in the process of evidence to recommendations. However, there were still limitations, specifically in the inconsistency of applying GRADE to rate down quality of evidence on adverse effects as a result of imprecision, compared with positive outcomes. A detailed discussion of the limitations and how it affected the utility of the GRADE approach will be presented at the conference.

Discussion: The GRADE approach is a useful tool in the development of guidelines. However, there are still methodological issues on how to assess imprecision and its applicability to both the desirable (benefit) and undesirable (harm) effects.