

PD36 Assigning GRADE Levels To An Overview Of Reviews Using General Principles Identified From Current GRADE Guidelines

Andrew Dullea (dulleaa@tcd.ie), Lydia O'Sullivan, Kirsty O'Brien, Patricia Harrington, Maeve McGarry, Susan Ahern, Maeve McGarry, Kieran A. Walsh, Susan Smith and Máirín Ryan

Introduction: Existing guidelines on overviews of reviews and umbrella reviews recommend an assessment of the certainty of evidence but provide limited guidance on how to apply GRADE to such a complex evidence synthesis. We present one approach to applying GRADE to an overview of reviews developed using general principles derived from current GRADE guidelines.

Methods: The methods were developed in an iterative and exploratory fashion following discussion with 11 methodologists and health services researchers. Key principles were distilled on the five GRADE domains (risk of bias, inconsistency, imprecision, indirectness, and publication bias) from the relevant GRADE guidelines, particularly those on test accuracy.

Results: A 'general principles' approach of applying the five domains of GRADE to an overview of reviews and arriving at an overall summary judgment for outcomes was developed. These methods were successfully applied to an overview of reviews on 18F-prostate specific membrane antigen positron emission tomography and computed tomography in the staging of patients with high-risk or recurrent prostate cancer.

Conclusions: Our approach distilled key principles from relevant GRADE guidelines and allowed us to apply GRADE to a complex body of evidence. Such an approach may be of interest to other researchers working on overviews of reviews or umbrella reviews.

PD37 Development Of A Tool For Quality Assessment Of Health Economic Evaluations

Nayê Balzan Schneider (nayebalzens@gmail.com), Celina Borges Migliavaca, Cinara Stein, Débora Dalmas Gräf, Gabrielle Nunes Escher, Sérgio Decker, Maicon Falavigna and Carisi Polanczyk

Introduction: Health economic analyses compare the necessary investments and health outcomes for two or more technologies, assisting in resource allocation. How these analyses are conducted directly affects the results obtained. Therefore, it is essential to consider their quality during decision-making. The aim of this study

was to develop a domain-based tool for the critical assessment of cost-effectiveness and cost-utility studies.

Methods: We conducted a scoping review to identify tools available for the critical assessment of health economic analyses and extracted their recommendations. Based on the tools' items and the discussions of a working group, we identified domains related to the methodological quality of health economic analyses for inclusion in the new tool. The items extracted during the scoping review were classified according to the previously defined domains and were used to identify complementary aspects that should be included in the new tool.

Results: We identified 21 tools, all of which were checklists containing seven to 80 items. The following four quality domains were established for the new tool: (i) applicability of the research question; (ii) model structure; (iii) model parameters; and (iv) precision of the results. Assessment of each domain was guided by signaling questions. The first domain assessed the applicability of the research question to the desired setting; the second evaluated whether the model adequately represents the complexity of the clinical condition; the third assessed the quality (certainty) of the key parameters used in the model; and the fourth evaluated the certainty of the incremental cost-effectiveness or cost-utility ratio.

Conclusions: The tool was developed to integrate critical aspects that affect the methodological quality of health economic analyses, which are often missing in other tools. The quality of reporting was not included as a domain because it is already covered by existing tools. A multidisciplinary panel with different key stakeholders is being organized to review and refine the first version of the tool.

PD38 Ensuring Study Validity To Inform Health Technology Assessments Globally

(Emily) Beth Devine (bdevine@uw.edu), Penny Whiting, Sue Mallett, Robert Wolff and Jelena Savovic

Introduction: Assurance that supporting evidence is based on valid and unbiased assessments, evaluated using rigorously developed risk of bias (validity assessment) tools, is fundamental to good decision-making. Among those available, selecting and correctly using the best tool that is fit-for-purpose is challenging. Collaboration across the global evidence synthesis and health technology assessment (HTA) communities promotes best practices and harmonizes tool use across jurisdictions.

Methods: We have established the LATITUDES Network (<https://www.latitudes-network.org/>), a publicly available website library of validity assessment tools and resources to guide decision-makers in selecting and applying tools appropriate for particular contexts, including informing HTA reimbursement decisions, clinical guideline development, and stand-alone evidence synthesis projects. The internationally representative leadership team comprises five evidence synthesis experts who have been supported by a competitively awarded academic innovations grant. The 23-member advisory panel representing five continents provided expertise to finalizing criteria for tool inclusion, identifying key tools, and suggesting inclusion of

additional tools. Formal launch took place at the 2023 Cochrane Colloquium.

Results: Officially launched in September 2023, the LATITUDES Network indexes validity assessment tools developed for healthcare studies in an online library. To date, 10 key tools are featured to help reviewers identify the optimal tool for their use. Nineteen additional tools have met all screening criteria and are also recommended. Information characterizing each tool (e.g., citation and training materials) is provided. Seven tools are currently under development. A mechanism for users to suggest new tools is provided. Additional tools and information on toolkits and online training materials, as well as links to courses and events, will be added over time.

Conclusions: LATITUDES aims to be the primary resource that provides key information to reviewers conducting validity assessments for evidence synthesis, clinical guideline development, and HTA decision-making. It is intended to increase the robustness of evidence synthesis by improving the process of validity assessment, helping scientists use tools more effectively and efficiently, promoting best practices, and harmonizing validity assessment across the globe.

PD39 First Approach For Assessing Statistical Significance In Industry Funded Matching-Adjusted Indirect Comparison Studies: A Scoping Review

Cecilia Farinasso, Aline da Rocha, Flávia Medeiros, Lays Marra, Patricia Parreira, Layssa Oliveira, Vinicius Ferreira, Rosa Lucchetta (rc.lucch@yahoo.com.br) and Haliton Alves De Oliveira Junior

Introduction: When indirectly compared trials are too heterogeneous to provide a reliable estimate, matching-adjusted indirect comparison (MAIC) studies can be employed. This technique is commonly used for oncology treatments. MAIC is an indirect comparison that adjusts effect-modifying variables through propensity score methods. The objective of this study was to map the characteristics of MAIC studies in oncology.

Methods: We performed a scoping review of the characteristics of MAIC studies that applied MAIC to compare active treatments in oncology. The literature search was last updated in August 2023 in PubMed, Embase, and the Cochrane Library. We extracted sources of funding, outcomes reported, and whether the results were significantly in favor of the trial for which individual patient data (IPD) were available or for the aggregate data. We then calculated the relative risk (RR) and confidence interval (CI) of an outcome favoring the IPD trial technology that was also funded by industry.

Results: A total of 90 studies were included in the review. The pharmaceutical industry was the most frequent funder (n=78; 87%); the source of the IPD data was not reported in 68 studies (76%). In total, 391 efficacy outcome estimates were reported in base case analyses. The risk of favoring IPD while being funded by industry was 93 percent, while the risk of favoring IPD while having other sources of funding was 61 percent (RR 1.520, 95% CI: 1.146, 2.016; p=0.004). Specifically, the RR was 1.246 (95% CI: 0.891, 1.743) for overall survival and 1.426 (95% CI: 0.959, 2.120) for progression-free survival.

Conclusions: MAIC results are influenced by the choice and number of effect-modifying variables used for matching the population. National Institute for Health and Care Excellence guidelines consider it necessary to provide evidence that the matched estimate will be less biased than the unmatched one. We have concluded that industry funded MAIC studies may be more likely to report results favoring IPD than studies with another funding source.

PD40 Pilot Healthcare Programs - Bridging The Evidence Gap For Innovative Technologies

Jarosław Gruszka (jaroslaw.gruszka@aotm.gov.pl), Katarzyna Sejbuk-Rozbicka, Magdalena Koperny, Maciej Dzik, Aleksandra Pelczarska, Joanna Syta and Kamila Malinowska

Introduction: The scarcity of high quality evidence is a common constraint on the willingness to publicly fund innovative technologies. Our aim was to prepare a Methods and Process Guide to support the development of pilot healthcare programs in Poland. Such guides play a pivotal role in enhancing the quality of pilot programs and confidence in public funding decisions in health care.

Methods: We reviewed guidelines for pilot healthcare programs published by the World Health Organization (WHO) and other healthcare organizations and analyzed the pilot healthcare programs in Poland. The Ministry of Health in Poland and the general public will be invited to provide feedback on the Guide.

Results: Pilot programs serve as valuable testing grounds for healthcare solutions in low risk, small-scale clinical practice settings. A pilot program may be considered for interventions with proven safety and effectiveness, and when the intervention is complex, its implementation requires testing, or the intervention is considered high cost. Our Methods and Process Guide defines key elements of pilot healthcare programs, including objectives, starting criteria, conducting conditions, and monitoring rules. Public consultation on the Guide is underway.

Conclusions: The publicly available Methods and Process Guide should enhance the methodological rigor of pilot healthcare programs in Poland. Well-designed pilot programs are expected to provide high quality real-world data that will facilitate public funding decisions for innovative technologies.