PD93 Uncertainty Metric To Guide PICOS Assessment And Evidence Synthesis Planning For Joint Clinical Assessment Submission

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Introduction: With the European Union Regulation on health technology assessment (HTA) approaching, there is concern about how to accommodate the large number of expected population, intervention, comparator, outcome(s), and study type (PICOS) questions and their uncertainty. Navigating uncertainty will prove essential to anticipate evidence requirements. This abstract presents preliminary results of the development of a metric that assesses uncertainty surrounding PICOS questions to eventually guide planning of evidence synthesis for joint clinical assessment (JCA) submission.
Methods: The metric will consist of pillars representing overarching themes of uncertainty. Each pillar will contain several elements influencing uncertainty for proposed PICOS questions. This study was conducted in two phases. In phase one, targeted literature searches of peer-reviewed and gray literature were conducted to identify the overarching metric pillars. These pillars were then validated by expert opinion. Similar research methods were used in phase two to inform the content of each of the pillars. Here we present the findings for phase one.
Results: The targeted literature review in phase one resulted in multiple candidate elements for the uncertainty pillars. Elements were selected based on expert opinion, resulting in five main pillars. These pillars were considered most valuable for the determination of uncertainty surrounding individual PICOS questions and were considered crucial to HTA acceptance. Phase one resulted in the following pillars: (i) indication and subpopulations; (ii) type of intervention and comparators; (iii) societal and patient unmet need; (iv) type and quality of evidence source informing evidence synthesis; and (v) methodology of evidence synthesis.
Conclusions: This study lays the foundation for a metric to assess the uncertainty surrounding proposed PICOS questions for JCAs. The metric identifies existing uncertainties for PICOS questions, assesses potential issues for HTA acceptance, and guides possible evidence synthesis planning. A clear framework for anticipating uncertainty will prove essential in managing resources and expectations.

PD94 Adapting Existing Evidence-Based Clinical Practice Guidelines: A Case Example with Sexually Transmitted Infections Guidelines In Catalonia, Spain

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Introduction: In the field of sexually transmitted infections (STI), high quality clinical practice guidelines (CPGs) have already been developed using rigorous methodology. To avoid duplicating effort, make cost-effective use of available resources, and facilitate customization to reflect local contexts, we adapted a CPG for prevention, care, and control of STIs in Catalonia, Spain.
Methods: The Guideline Adaptation Group (GAG) used the ADAPTE framework to guide transcontextual adaptation. The ADAPTE model has three phases: set-up; adaptation, with five main criteria for determining the relevance of a CPG and the adaptability of its recommendations (quality, currency, content, consistency, and acceptability or applicability); and finalization. We used the Spanish version of the AGREE II instrument to rate and select appropriate CPGs and the RIGHT-AD@pt checklist to guide reporting of the adaptation process. Each recommendation was given a level of evidence and a grade using the GRADE framework.
Results: Once the feasibility of carrying out the adaptation was confirmed, the governance structure was defined, which comprised a steering committee (n=8 members) and an expert committee (n=93 members). Clinical questions were defined from 164 recommendations taken from a CPG published in 2009. The systematic search identified 759 records published from 2016 to 2023. Of these, 57 CPGs met the inclusion criteria. On average, items 10 and 12 of the AGREE II scored between five and seven points (moderate to high quality methodological rigor). Content and consistency are being analyzed and matrices are being prepared to assess acceptability and applicability.
Conclusions: The ADAPTE methodology provides structure, rigor, and efficiency to the transcontextual adaptation of CPG recommendations. We expect that its application will provide practical and timely recommendations on the prevention, care, and control of STIs in the Catalan context.