Project Protocol

Evaluation of Individual Medical Procedures

Project Lead: Judit Erdös

Authors: AIHTA staff for individual reviews

Quality Assurance Gregor Goetz

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Objective:

Each year, the Austrian Federal Ministry of Health (MoH) receives proposals from service-providers for inclusion of new medical procedures in the MoH catalogue of procedures as a prerequisite for reimbursement [1-3]. The procedures are prioritized by the Ministry of Health and the assessments contracted out to the Austrian Institute for Health Technology Assessment (AIHTA). The aim of this project is to evaluate the comparative efficacy and safety of these procedures to assist reimbursement decisions.

Methods:

The EUnetHTA Core Model® [4] and and relevant methodological guidance documents developed by the Subgroup for the Development of Methodological and Procedural Guidance of the Member State Coordination Group on Health Technology Assessment (HTACG) [5] are used to inform the systematic reviews. The certainty of evidence is assessed using the GRADE approach [6].

Mapping the literature: A preliminary literature search is conducted to identify systematic reviews (SRs). If a recent, relevant SR with low risk of bias, as assessed using ROBIS [7], is identified and its eligibility criteria sufficiently align with the review question, it may serve as the basis for the assessment.

Protocol: A review protocol specifying the PICO question is uploaded on the open science foundation (OSF) before data extraction begins [8]. Any subsequent deviations from the protocol and post hoc methodological decisions are documented and justified in the final report.

Systematic search: A systematic literature search is conducted for each topic in at least two bibliographic databases. If a suitable existing SR is identified, its literature search may be updated to identify additional relevant studies.

Abstract- and Full-text screening: Two reviewers screen independently potentially relevant literature. Rayyan [9] or other equivalent platforms [10] are used to assist these working steps.

Risk of bias (RoB) assessment: The risk of bias of included studies is assessed using appropriate, validated tools selected according to study design, with reference to resources provided by the LATITUDES Network [11]. Two reviewers are involved in this working step.

Data extraction: Data are extracted using predefined and piloted data-extraction tables. One reviewer extracts the relevant data, and a second reviewer verifies the extracted information for accuracy and completeness.

Synthesis: A narrative synthesis is conducted using the GRADE approach [6]. Quantitative synthesis (meta-analysis) is performed where clinically and methodologically appropriate [12].

Stakeholder involvement: At least one clinical expert is involved within the respective SR. Manufacturers may be contacted primarily for relevant information on CE marking and ongoing studies.

References:

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[10] Affengruber L., van der Maten M. M., Spiero I., Nussbaumer-Streit B., Mahmić-Kaknjo M., Ellen M. E., et al. An exploration of available methods and tools to improve the efficiency of systematic review production: a scoping review. BMC Med Res Methodol. 2024;24(1):210. Epub 20240918. DOI: 10.1186/s12874-024-02320-4.

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[12] Deeks J. J., Higgins J. P. and Altman D. G. Chapter 10: Analysing data and undertaking meta-analyses. In: Higgins J. P. and Thomas J., editors. Cochrane Handbook for Systematic Reviews of Interventions Version 64, 2023.