PD149 Comparison Of The Draft European Union Health Technology Assessment Template With Germany's AMNOG Template

Eva-Maria Reuter (Evamaria.Reuter@ams-europe.com), Thomas Klein-Hessling, Carolin Rittmeyer, Maria Katharina Schweitzer and Sebastian Werner

Introduction: European Union Health Technology Assessment (EU HTA) aims to use resources more efficiently, ensure high quality assessments, and promote the widespread availability of medicinal products. We compared the draft EU HTA template (EUnetHTA21 submission dossier template) with Germany's Arzneimittelmarkt-Neuordnungsgesetz (AMNOG) template to assess their conformity and to estimate whether the draft EU HTA template requires more or less effort than the AMNOG template.
Methods: Four experts (two statisticians and two medical writers) independently compared 39 categories of both templates following the four-eyes principle. The categories were defined based on the formal and methodological requirements as well as on the specific instructions regarding content, data presentation, and documentation in both templates. We assessed each category for conformity between templates (low, medium, high) and determined the EUnetHTA21 template's additional effort (much less, less, equivalent, more, much more) relative to the AMNOG template. The comparison was carried out under the assumption that only a single research question on a population, intervention, comparator, and outcome (PICO) would be addressed in both submission procedures.
Results: We found that the draft EUnetHTA21 template and the AMNOG template had substantial conformity in most categories (21/39), indicating comparable or identical formal and methodological requirements. For 10 of the 39 categories the conformity between templates was rated as medium. Low conformity was found for eight of the 39 categories, including categories outside one template's scope. For most categories (20/39) we expect an equivalent effort per PICO. More or much more effort is expected for 13 of the 39 categories. For only six of the 39 categories, less or much less effort is expected for the draft EUnetHTA21 template, compared with the AMNOG template.
Conclusions: The analysis highlights strong similarities between the templates but shows increased effort per PICO with the draft EUnetHTA21 template. This effort will be further increased with multiple PICO questions. This could challenge the feasibility of the EU HTA process, especially considering the short timeframe required. The template comparison will be updated once the final EU HTA template is available.

PD150 How Is Genetic Testing Evaluated? An Updated Systematic Review Of Assessment Frameworks

Valentina Baccolini (valentina.baccolini@uniroma1.it), Giuseppe Migliara, Antonio Sciurti, Erica Pitini, Anna Ewa Kaminska, Valentina Soccodato, Jessica Iera, Immacolata Leone, Carolina Marzuillo and Paolo Villari

Introduction: Assessment of the risks and benefits of genetic and genomic tests has long been addressed using ad hoc evaluation methods. They are mostly ACCE-based, focus on technical aspects, and often overlook economic and organizational considerations. The few health technology assessment (HTA) based approaches, though more comprehensive, lack validation and implementation. This review's purpose was to identify evaluation frameworks for genetic and genomic tests and to synthesize their key aspects.
Methods: PubMed, Scopus, Web of Science, Google Scholar, and Google Search were used to identify records describing any assessment framework for genetic or genomic tests. As this was an update of a previous systematic review, the search was restricted to records published from 1 October 2020. Inclusion criteria were documents describing evaluation frameworks for genetic or genomic tests that were original, specifically created, and covered at least three evaluation components (analytic validity, clinical validity, clinical utility, economic aspects, or ethical, legal, and social implications). This study was supported by the European Commission and the Ministry for Universities and Research under the National Recovery and Resilience Plan (M4C2-I1.3 Project PE_00000019 "HEAL ITALIA").
Results: Overall, 22,862 records were retrieved and 12,546 unique records were screened, of which 67 documents were assessed for eligibility. However, none of these met the inclusion criteria and no additional framework was found. In contrast, a total of 37 studies reporting 30 different frameworks were included from the previous systematic review. The analysis of these frameworks revealed that they were published between 2000 and 2019 and were mostly based on the ACCE model (n=13), on the HTA process (n=6), or both (n=3). Others referred to the Wilson and Jungner screening criteria (n=3) or to a mixture of different criteria (n=5).
Conclusions: A pressing need exists for a universally accepted evaluation framework for genetic and genomic tests. A shift from ad hoc assessments to a general HTA methodology, potentially based on the EUnetHTA Core Model®, is needed. By integrating solid theoretical and methodological principles, a validated, comprehensive, and widely shared tool for evaluating genetic tests can be realized, promoting consistency across Europe and beyond.

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