PP96 Joint Clinical Assessments – Implementation And Lessons For The Next Stage Of EU HTA

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Introduction. The European Network for Health Technology Assessment (EUnetHTA) was a voluntary cross-border initiative on HTA harmonization established by European Commission in 2005. Between 2016-2021, EUnetHTA completed 56 Joint Assessments (28 drugs; 28 other technologies) including 14 reviews of COVID treatments.
Methods. We conducted a review of the 14 EUnetHTA joint assessment reports of drugs in non-COVID 19 indications. We cross-referenced recommendations with national guidance in 30 member countries (including UK) and conducted an analysis of time to national assessment, choice of comparator, direct reference to EUnetHTA assessment, and time to reimbursement decision.
Results. Six products in oncology, 2 in endocrine and metabolic diseases, 2 in infectious and parasitic diseases, and cardiovascular, digestive system, eye disorders and central nervous system (one each) were identified. On average, EUnetHTA published its recommendation 52 days after market authorization for oncology products and 33 days for non- oncology products. EUnetHTA recommendations considered on average 4 comparators (range 1-8) as part of the assessment. All of the 6 oncology products have been assessed by national HTA bodies, however uptake was low with an average of 5 reports referencing the EUnetHTA report. Similarly for the non-oncology products assessed only 3 of 30 HTA bodies cite the EUnetHTA report. Citing HTA bodies were: AETSA (Spain), HAS (France), INFARMED (Portugal), NoMA (Norway), and TLV (Sweden). There was no clear reduction in the time to reimbursement for these products in these markets.
Conclusions. According to EUnetHTA, there has been an increased use and dissemination of joint assessment reports since 2016. Our analysis shows that the level of implementation across countries is heterogeneous despite publication of the EUnetHTA reports shortly after market authorization. The future the EU HTA will depend on the timeliness, rigor and transparency of joint clinical assessment reports and improved uptake of these reports at a national level.

PP97 Recommendations For Generating South African Health-Related Quality Of Life Data For Cost-Utility Analyses

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Introduction. Health-related quality of life (HRQoL) data are necessary for conducting cost-utility analyses (CUAs) as part of health technology assessments (HTAs), but the lack of robust HRQoL data may delay or even prevent patient access to medicines when National Health Insurance is introduced in South Africa. This study aimed to make recommendations for evidence generation activities to support national HTA in the public health sector, with a focus on creating South African HRQoL data suitable for CUAs.
Methods. A systematic review of HRQoL research in South Africa formed the basis for three analyses. The first analysis quantified and evaluated the suitability of HRQoL studies for CUAs. The second analysis determined the performance indicators of the research output and identified collaborative networks through bibliometric analyses. The third analysis critiqued the translation methodology of the HRQoL instruments retrieved in the systematic review.
Results. Based on the published literature, existing HRQoL data are unlikely to support CUAs because they were derived from observational or cross-sectional studies that lacked the methodological details necessary to determine their scientific merit according to HTA requirements. Overall, there was a lack of research continuity in this field, with numerous isolated research networks. Despite the strong contribution of South African based researchers and organizations in this area, their performance was below that of international counterparts. Since only a few HRQoL instruments suitable for CUAs would be valid in the South African context, HRQoL research output in South Africa could be optimized by using more rigorous study designs and by the expansion of researcher networks to include those working in HTA and related fields. The three-level EQ-5D is the tool best suited for use in South Africa, so its utilization should be encouraged and supported by establishing a South African value set.
Conclusions. Future data generation activities should incorporate the recommendations from this study because existing South African HRQoL data are likely to be inadequate for conducting CUAs in national HTA.

PP98 Occupational Therapy For Adult Persons With Cognitive Impairments: A Systematic Overview On Clinical Efficacy

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Introduction. Damage to the central nervous system (CNS) in adulthood, may lead to cognitive impairments. In Germany, occupational therapy is most often prescribed for neurological diagnoses, including stroke and traumatic brain injury (351 and 343 cases per 100,000, respectively in 2018). For cognitive impairments, the primarily prescribed remedies are sensorimotor-perceptive, motor-functional and neuropsychologically oriented treatment or training of cognitive performance. Here we report the results of a health

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technology assessment (HTA) report on the clinical efficacy of occupational therapy for patients with cognitive impairments.
Methods. To assess clinical efficacy, a systematic overview was conducted based on published systematic reviews and HTA reports from the last ten years summarizing randomized controlled trials (RCTs) retrieved from four bibliographic databases. The target population included adult patients with cognitive impairments caused by diseases of the CNS, excluding moderate to severe dementia. The intervention studied is occupational therapy compared to no occupational therapy. Outcomes were cognitive abilities, independence, self-determination, health-related quality of life (QoL), and participation in activities of daily living (ADL).
Results. Five systematic reviews comprising 1,316 patients were included. There is evidence for a small statistically significant positive effect on "general cognitive function" (10 RCTs, n=470) and on ADL (4 RCTs, n= 405). A non-quantified positive effect was reported on behavior control (1 RCT, n=96), and conflicting evidence on QoL (2 RCTs, n=214). No effect was found for individual components of cognition (5 RCTs, n=202), self-efficacy (1 RCT, n=98) and social participation (2 RCTs, n=194). The level of the evidence was low for all endpoints due to the high risk of bias and small sample sizes.
Conclusions. Based on this systematic overview, it cannot be demonstrated but also not ruled out that occupational therapy for cognitive impairment is an effective therapy for adults with cognitive impairments. The evidence is very uncertain due to small effects and high risk of bias, low statistical power, and heterogeneity of interventions and study populations.

PP100 Improving The Assessment Of Effectiveness For Digital Applications Using The B Statistic: Using WtsWrng As A Case Study

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Introduction. The performance of diagnostic health technologies is usually assessed by comparing them with standard care using the kappa statistic. These comparisons are made based on comprehensive clinical information (e.g., anamnesis and complementary tests). However, not all digital applications (DAs) execute over complete information, which leads to work under non-uniform distribution of values. Using kappa statistic in this situation has serious methodological limitations. Kappa assumes that the marginal values are uniformly distributed and highly weights the discordant values when calculating concordance, which underestimates the real effectiveness of DAs (i.e., observed concordance). We aimed to present the application of the B statistic to WtsWrng, a symptom triage DA for individuals.
Methods. WtsWrng was used by 382 patients at the emergency department of a hospital. Diagnoses provided by WtsWrng, given 19 symptoms, were compared with those logged in the hospital's electronic clinical records at discharge. Observed concordance was calculated using contingency tables. The concordance using the kappa and B statistics were compared for the 12 most frequent diagnoses at hospital discharge. Sensitivity and specificity were also calculated.
Results. Real observed concordance fluctuated from 0.4 to 0.98 for the 12 most frequent diagnoses, eight of which had a concordance greater than 0.8. The results ranged from -0.005 to 0.37 when using the kappa statistic and from 0.36 to 0.99 when using the B statistic. The sensitivity and specificity of WtsWrng were greater than 0.8 for three and eight of the 12 diagnoses, respectively.
Conclusions. The results show that the B statistic is closer to the real observed concordance when kappa statistic assumptions are not fulfilled by a DA. Therefore, the B statistic is better suited for assessing the effectiveness of this type of technology. Analysis of WtsWrng using the B statistic showed that its diagnoses were close to those provided by clinicians, which were arrived at using complete clinical information. Moreover, the high specificity of the WtsWrng DA suggests that it is a good tool for determining the appropriate use of healthcare resources.

PP101 Development Process Of The Economic Guidelines In Tunisia

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Introduction. Health technology assessment (HTA) has become a critical support to health policy decision-making. The HTA evaluation process requires transparency, formalized processes, clear timelines, and standardization according to international best practice. Tunisia is establishing an HTA-based decision-making system through the National Authority for Accreditation and Assessment in Healthcare (INEAS) to ensure impartiality and fairness in decision-making, which is important for an emerging democracy. INEAS opted for a participatory approach in developing the national health economic guidelines to better engage healthcare sector stakeholders in the HTA process. We aimed to present the main phases of the process used to develop the Tunisian health economic guidelines, the methodological choices for pharmacoeconomic evaluations, and the methodological choices for budget impact analyses.
Methods. The different phases of developing the guidelines were listed and reported.
Results. The guidelines were developed under a technical cooperation program of the World Health Organization and involved collaboration between the Institut national d'excellence en santé et en services sociaux (INESSS in Quebec, Canada) and INEAS. The first version of the guidelines was drafted following a review of international HTA guidelines and best practice reference books, taking into account the Tunisian healthcare system context. This first draft was discussed in a workshop with the main health system stakeholders and then peer reviewed by international experts. Based

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