HTA253
PAYER PERSPECTIVES ON THE IMPACT OF THE COVID-19 PANDEMIC ON HEALTH TECHNOLOGY ASSESSMENTS (HTA) IN EUROPE

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Objectives: The COVID-19 pandemic has had a tremendous impact on healthcare systems, economies, and many aspects of everyday life. The core objectives of this research were to assess the impact that the pandemic has had on HTA assessments in Europe, outline key issues faced by payers, and determine payers' outlook on future implications. ***Methods:*** A qualitative, web-based survey was fielded via the Rapid Payer Response™ online portal (RPR®) to 15 current payers with experience in market access and reimbursement from the UK (NICE, NHS, CCG), Germany (G-BA, KV), France (CNEDiMTS, CT), Italy (AIFA, regional), and Spain (AEMPS, CIPM, MSSSI/MoH). ***Results:*** 9/15 (60%) payers expressed that the pandemic resulted in delays in HTA assessments, with an average delay of 6 to 12 months. German payers did not experience delays, noting that timelines are regulated by law. Delays in the other countries resulted in fewer completed HTA assessments per year compared to pre-pandemic years for 7/15 (47%) payers, with 6/15 (40%) feeling that access to medicines during the pandemic was impacted. Key challenges expressed by payers included clinical trial delays, de-prioritisation of non-COVID diagnoses or care, tighter healthcare budgets, and lack of staff due to COVID-related leave or re-allocations. 7/15 (47%) payers have already experienced or anticipate a quick return to pre-pandemic conditions, whereas the other 8/15 (53%) expect long-lasting effects on HTA and access in the coming years. Payers noted that pharmaceutical manufacturers could better support the HTA process by increasing preparedness and transparency, prioritising agents for review, and meeting more rigorous clinical trial design and evidence expectations. ***Conclusions:*** Payers across all scope countries except Germany conveyed that the COVID-19 pandemic has had a significant impact on HTA assessments, which may have longer-lasting implications. Close collaboration and alignment between pharmaceutical manufacturers and HTA bodies may allow for a more efficient recovery.

HTA254
ROADBLOCKS TO EFFECTIVE PATIENT ENGAGEMENT IN HEALTH TECHNOLOGY ASSESSMENT IN EUROPE: A REVIEW OF PATIENT-PERCEIVED CHALLENGES

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Objectives: Patient engagement (PE) in health technology assessment (HTA) is vital to understanding the unmet needs and impact of a disease and its treatment and informs healthcare resource allocation. With current guidelines for PE in early development, there is significant variability in PE among various HTA bodies. We aimed to identify the challenges perceived by patients and patient organizations for involvement in the HTA process in Europe. ***Methods:*** We performed a targeted literature review in PubMed to identify qualitative studies published from 2012 to 2022 assessing the challenges reported by patients and their representatives for active participation in HTA activities in Europe. We also reviewed guidance published by prominent HTA bodies in EU4 and the UK that address these challenges. ***Results:*** Twelve cross-sectional studies reporting patient-, caregiver-, and patient-organization-perceived challenges in HTA engagement were identified. Commonly reported barriers were overlooking patient inputs (n=8), limited disease-specific patient representation (n=7), time constraints (n=6), inadequate communication (n=5), conflicting vision (n=3), preconceptions about patient inputs (n=2), disease-associated stigma (n=2), and limited PE knowledge (n=1). Further, the lack of information (n=8), resources (n=6), training (n=6), transparency (n=5), and remuneration (n=4) substantially limited PE in HTA. The National Institute for Health and Care Excellence (NICE) and the Institute for Quality and Efficiency in Health Care (IQWiG) ensure that the lived experience of patients regarding the technology being assessed is adequately captured early in the HTA process, whereas PE in HTA is still in the early stages in France, Spain, and Italy. ***Conclusions:*** Methodological challenges and lack of concrete guidelines limit meaningful patient contributions to the HTA process. It is important for HTA bodies to work toward a shared vision ensuring timely patient participation at every stage of the HTA process, as PE supports equity, relevance, accountability, and credibility of the decision-making process.

HTA255
RECOMMENDATIONS ON THE USE OF ARTIFICIAL INTELLIGENCE AND MACHINE LEARNING IN SYSTEMATIC LITERATURE REVIEWS SUBMITTED AS PART OF THE EVIDENCE PACKAGE IN HEALTH TECHNOLOGY ASSESSMENT

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Objectives: The benefits of a health intervention are commonly assessed through a process known as a health technology assessment (HTA) whereby the interventions benefits are systematically assessed. This requires the searching, selection, extraction, and critical assessment of all available clinical and economic published literature. This may result in a systematic literature review (SLR) with many published studies having to be assessed within a limited timeframe. Advanced analytic techniques such as artificial intelligence (AI) and machine learning (ML) afford reviewers the opportunity for increased efficiency. We aimed to review available guidance on the use of AI/ML in HTA-based SLRs. ***Methods:*** We reviewed relevant documents including methodological guidance for the following HTA bodies: NICE (England), HAS (France), G-BA (Germany), NCPE (Ireland), SMC (Scotland), TLV (Sweden), CADTH (Canada) and PBAC (Australia) to understand their acceptance of AI and ML in SLRs submitted as part of HTA. We additionally reviewed guidance from Cochrane as this is a respected body in the field of SLRs with HTA bodies commonly aligning to their recommendations. ***Results:*** Currently, no explicit reference is made regarding use or acceptance of AI and ML in any available document in relation to the conduct of SLRs for HTA. NICE and NCPE expect two reviewers to be involved in the SLR but do not state whether AI/ML is suitable as one of these; SMC refers readers to NICE methodologies. Significantly, Cochrane, which is often referred to and referenced by HTA bodies for guidance on best practise in SLRs, is undertaking workstreams to understand how to best exploit AI/ML in SLRs to improve efficiency and output quality. ***Conclusions:*** Although AI/ML is not currently acknowledged as best practise in HTA-based SLRs, there are strong indications that the field is moving in this direction and further guidance from HTA bodies is required.

HTA256
EARLY HEALTH TECHNOLOGY ASSESSMENT OF THE LYMPHOCYTE ANTIGEN 75 BIOMARKER FOR CUTANEOUS MELANOMA

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Objectives: Despite the availability of novel treatment options for patients with advanced melanoma, adjuvant treatment selection and hence prognosis for these patients continues to be suboptimal. Sentinel lymph node biopsy (SLNB), the standard practice to classify patients' melanoma stage and guide adjuvant treatment decisions, can fail to accurately identify a significant proportion of patients that require adjuvant treatment with immunotherapy. A new biomarker, LY75, could be used in the diagnostic pathway to improve adjuvant treatment decisions, patient outcomes and cost-effectiveness. The aim of this study was to perform an early health technology assessment to evaluate the potential added value of LY75 in terms of costs and quality-adjusted life-years (QALY). ***Methods:*** A decision tree combined with a probabilistic state-transition model was constructed to compare care as usual (CAU) to six strategies that included LY75 testing in different positions in the diagnostic pathway. We performed a fully incremental analysis and examined uncertainty through sensitivity and scenario analyses. ***Results:*** Five of the six strategies resulted in QALY gains and higher costs compared to CAU, with incremental cost-effectiveness ratios between €1,608 and €26,900 per QALY gained. Deterministic and probabilistic sensitivity analyses showed that the most valuable strategies added LY75 testing for patients ineligible for adjuvant treatment under CAU. Sensitivity and specificity of LY75 and SLNB, and prevalence of low severity disease were the most influential drivers of cost-effectiveness. ***Conclusions:*** Compared with CAU, LY75 can be a cost-effective add-on or even replacement of SLNB to guide adjuvant treatment decisions, given Dutch willingness to pay thresholds. Given the early stage of the LY75 evidence, not all diagnostic strategies can be readily implemented, or even researched (including the most cost-effective strategy); hence, our future study will explore the optimal research and development roadmap for LY75 testing in patients with melanoma.

HTA257
MOVE-OUT: A TRIAL OF TWO HALVES – THE IMPACT OF HETEROGENEITY ON COST-EFFECTIVENESS OUTCOMES FOR COVID-19

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Objectives: In the phase 3 MOVe-OUT trial, non-hospitalised, unvaccinated adults with COVID-19 (at risk for severe illness) were randomised to molnupiravir or placebo. Our objective is to investigate the short-term costs and outcomes associated with molnupiravir (versus standard of care (SoC), defined as 'no systematic treatment') from the Irish-payer perspective. ***Methods:*** An acute-phase (one-month) decision tree was programmed in R. On entering the model, all patients are at risk of hospitalisation; a proportion are admitted to intensive care units (ICU). Treatment effectiveness was informed by the MOVe-OUT trial, with external data and clinical opinion used to estimate ICU admission risk. Irish direct-medical costs were included. Summary statistics of cost per hospitalisation, ICU admission, and death avoided were calculated; no explicit payer-threshold was considered. One-way sensitivity and probabilistic analyses were performed. ***Results:*** Using the final analysis of MOVe-OUT, it was estimated that treating 1,000 patients with