Results: The updated treatment algorithm captured and quantified the impact of nuanced comorbidity management called for in guidelines. In a cohort of newly diagnosed T2D patients, 81 percent initiated an SGLT2 inhibitor within five years, predominantly due to increasing cardiovascular risk, versus zero percent when escalation was dictated by HbA1c alone. Broad, early use of SGLT2 inhibitors resulted in an additional 0.73 predicted QALYs and GBP10,757 (USD13,600) in predicted lifetime cost savings per patient versus a "traditional" approach. Cost savings were primarily due to avoided renal events; extrapolation to the national level predicted cost savings to the payer of GBP2.8 billion (USD3.5 billion), which traditional models cannot capture.
Conclusions: The modernized Cardiff model incorporates multifactorial prescribing guidelines and contemporary evidence around cardio-renal protection and is more adept at modeling costs and outcomes of multidimensional antidiabetic treatments; traditional glucose-centric modeling methods may introduce bias. Economic modeling and HTA processes must adapt to follow the complexities of modern disease management and remain relevant as healthcare systems address the cardiovascular-kidney-metabolic syndrome epidemic.

OP05 Efficiency Frontier Analysis Of Ciltacabtagene Autoleucel For Relapsed/Refractory Multiple Myeloma In Brazil

Marcus Carvalho Borin (marcusborin@gmail.com), Ludmila Gargano Álex Brunno do Nascimento Martins, Bárbara Rodrigues Alvernaz dos Santos, Isabela Freitas, Francisco de Assis Acurcio, Juliana Alvares-Teodoro and Augusto Guerra Jr

Introduction: Multiple myeloma (MM) is a challenging hematological malignancy, primarily treated with autologous stem cell transplantation (ASCT). However, relapse or refractoriness is inevitable, necessitating alternative treatments. This study evaluates ciltacabtagene autoleucel (Carvykti®), a novel therapy, against a second ASCT, using an efficiency frontier approach to assess its therapeutic value and cost-effectiveness.
Methods: We conducted a comparative analysis using data from CARTITUDE-1 clinical trials and a Brazilian real-world cohort (2002 to 2015) of MM patients treated under SUS (Brazilian Healthcare System). We estimated survival curves and area under the curve (AUC) for both interventions over 48 months and projected the curves for a 10-year horizon using parametric distributions. Cost-effectiveness was assessed by calculating the incremental cost per month of survival. Efficiency frontier methodology was employed to determine a proportional price for ciltacabtagene autoleucel, based on the cost and median survival benefits compared to the second ASCT.
Results: Ciltacabtagene autoleucel demonstrated a 7.27 percent increase in AUC for overall survival over 48 months compared to the second ASCT. The incremental cost was BRL54,219.15 (USD11,133.30) per month of survival. Over a 10-year horizon, the estimated cost for ciltacabtagene autoleucel was significantly higher than that for the second ASCT. Using the efficiency frontier approach, the cost of ciltacabtagene autoleucel should not exceed BRL228,226.42 (USD46,863.74), considering its survival benefit and cost of production.
Conclusions: Ciltacabtagene autoleucel demonstrates significant anti-tumor activity in relapsed/refractory MM, with a notable survival advantage. Efficiency frontier analysis suggests a maximum justified cost, providing a framework for pricing decisions. This study highlights the importance of balancing innovation with cost-effectiveness in healthcare decision-making.

OP06 Utilizing Health Technology Assessment Outputs To Develop Health Technology Management Protocols In The Irish Setting

Claire Gorry (claire.gorry1@hse.ie), Maria Daly, Rosealeen Barrett, Karen Finnigan, Amelia Smith, Stephen Doran, Bernard Duggan, Sarah Clarke and Michael Barry

Introduction: Increasingly in Ireland, there are specific criteria attached to reimbursement approval for new medicines. Health technology assessment (HTA) identifies where uncertainty is greatest in relation to clinical and cost-effectiveness evidence and budget impact estimates; our health technology management (HTM) approach uses these outputs from HTA to design protocols to manage these uncertainties in the post-reimbursement phase.
Methods: A bespoke managed access protocol (MAP) is developed for each medicine reimbursed under this approach, informed by uncertainties highlighted in the HTA, directions from the decision-maker, and relevant particulars arising from commercial negotiations. Individual patient reimbursement applications are submitted via an online application system linked directly to the national pharmacy claims system. Pharmacists review the applications and approve reimbursement support where the patient meets the reimbursement criteria. The process is adaptive, allowing expansion of the criteria to include previously excluded patient cohorts, and the addition of new indications. It can also work across differing reimbursement arrangements (hospital/primary care).
Results: The MAP for liraglutide for weight management confines reimbursement to patients with a body mass index greater than or equal to 35 kg/m^2, prediabetes, and high risk for cardiovascular disease. Phase I reimbursement support lasts for six months; patients not attaining greater than or equal to five percent weight loss are deemed non-responders as per the HTA, and reimbursement support

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is discontinued. The MAP for dupilumab confined reimbursement support to adults with refractory moderate-to-severe atopic dermatitis, where cost-effectiveness was plausible in the HTA. The MAP for calcitonin-gene-related-peptides monoclonal antibodies confines reimbursement support to patients with chronic migraine, refractory to at least three prophylactic treatments, where cost-effectiveness was plausible in the HTA.
Conclusions: Across these MAPs, over 3,000 patients accessed novel treatments for chronic illnesses in September 2023. HTM provides an effective mechanism to facilitate access to high-cost medicines for targeted patient groups, while providing increased oversight and budgetary certainty. Key to acceptance is utilization of HTA outputs to implement evidence-based HTM measures targeting specific uncertainties as highlighted in the HTA report.

OP07 Technical Aspects Of Artificial-Intelligence-Based Tools Applied In Health Technology Assessment Processes: A Scoping Review

Denis Satoshi Komoda (deniskomoda@gmail.com), Marilia Mastrocolla de Almeida Cardoso, Ana Renata Lima, Marília Berlofa Visacri, Carlos Roberto Silveira Correa and Brígida Dias Fernandes

Introduction: In the last decade, artificial intelligence (AI) has been increasingly applied in health technology assessment (HTA) to accelerate evidence synthesis, optimize resources allocation, and guarantee timely delivery of trustworthy technologies in health. The aim of the present scoping review is to map AI models applied in HTA, and technical characteristics of AI-based automation and semi-automation applied in HTA.
Methods: A search strategy containing core expressions "AI" and "HTA" and correlated terms was conducted in nine specialized databases (health and informatics) in February 2022. Inclusion criteria were publications testing AI models applied in HTA. Study selection was performed by independent pairs, with consensus meetings. No filters were applied. Data on year and country of publication, HTA phase, subsets of AI (e.g., machine learning [ML], neural networks), type of algorithm (e.g., support vector machine [SVM], K-nearest neighbors), and performance scale were extracted. Data were analyzed as descriptive frequency statistics. Used metrics will be presented narratively.
Results: Sixty-one publications were included. The first study identified was published in 2006, and since then the number of publications has been consistently growing, with 11 publications in the year 2021. Canada, USA, and the UK concentrate 72 percent of publications (44 in 61) equally distributed. The most common HTA phase was the evidence synthesis, with 59 studies (96%). The main task performed was study screening/selection (66.6%). The majority of ML models (80.9%) contained two learning nodes or fewer, and applied SVM and decision-tree-based algorithms. Inter-rater agreement, accuracy, and 95 percent recall were the most common scales observed.
Conclusions: Although recent developments in AI applied to HTA show increasing potentiality, studies are concentrated in the study selection phase of evidence synthesis. Many areas need further development, such as horizon scanning and policymaking processes. Additionally, studies reporting time gain and economic gain outcomes are scarce and should be considered for the development of future studies in the field.

OP08 Health Technology Assessments Of Artificial Intelligence: Special Considerations And Development Of A Checklist

Leona Batten, Antonia Needham-Taylor (Antonia.Needham-Taylor@wales.nhs.uk), Clare England and David Jarrom

Introduction: Artificial intelligence (AI) technologies are becoming more widespread in daily life, including in health and care settings. AI is being developed for use in many areas, including diagnostics, treatment planning, and patient monitoring. There are new challenges and additional considerations when performing a health technology assessment (HTA) for AI use in healthcare.
Methods: Health Technology Wales has developed additional guidance and a checklist of considerations for researchers to use when undertaking an HTA on AI. These documents were created as a result of involvement in discussions with healthcare services around AI; attendance at meetings and training sessions with government, healthcare, and academic institutions; and observations from undertaking our first HTAs investigating AI technologies.
Results: We identified seven main areas to consider: (i) the AI model being used and its training datasets; (ii) clarity on where in the clinical pathway the AI sits and whether this is appropriate for the local healthcare service; (iii) clear identification of the target patient population and whether there are gaps in the evidence base for subgroups; (iv) who uses the AI and the training required; (v) possible barriers and inequities in usage, particularly if the AI is patient facing; (vi) ongoing monitoring of the AI model; and (vii) data security and usability.
Conclusions: HTA assessment of AI presents new challenges for HTA bodies. Additional outcomes for assessment (including user acceptability) may be required, and an awareness of background information that allows for contextualization of the technology and clear indication of its usefulness in the local healthcare setting is key. The development of guidance related to AI technologies may enable rigorous evaluation.

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