Methods: Firstly, a systematic literature review was carried out on PubMed and Scopus, and the Critical Appraisal Skills Programme (CASP) tool was applied to assess the evidence's quality. A health technology assessment (HTA) evaluation was conducted (EUnetHTA, 2016), adopting the perspective of a public hospital in Italy, comparing two scenarios—traditional and innovative—related to traditional protheses and the DSA approach. Seven experts (orthopedic surgery, physical medicine, and rehabilitation and physiotherapy) were involved for the administration of a qualitative questionnaire. For the economic evaluation, a cost-effectiveness analysis and budget impact analysis were defined. Finally, a multiple-criteria decision analysis was performed.
Results: The literature search yielded 314 citations published until December 2022: eight were eligible for analysis. Three were the system analysed: 'OPRA', 'ISP' and 'OPL'. The efficacy of the systems is linked to a better distribution of bone stress: an increase in bone mineral density was recorded near the implants (respectively 28%, 27%, and 18% – after 60 months). The safety of DSA depends on the design and integrity of the connection between tissues and implant. The impact on the budget is an increase of 27 percent in costs for each patient treated. Concerning the social and ethical implications, DSA results in the preferable approach (1.48 vs 0.34), as it can limit social costs (0.29 vs −0.29).
Conclusions: The comparative evaluation was carried out using a scoring method: the main advantages related to innovative prostheses are based on effectiveness and safety, as well as social impact and organizational impact, especially due to the ability of the prostheses to reduce the risk of adverse events and long rehabilitation, with important clinical benefits and organizational savings for the hospital management.

OP03 Regionalization And Patient-Centered Care: A Rapid-Realist Review And Implications For Health Technology Assessment

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Introduction: Healthcare regionalization is the movement of responsibility of health care towards a regional body. It has been introduced in many countries and exists in many forms across high-, middle- and low-income countries. Supporters of regionalization purport that a more actively managed system, with better coordination and integration, could lead to improved quality and patient-centered care. However, evidence for this is unclear.
Methods: Systematic searches combining terms for regionalization and patient-centered care in MEDLINE identified 5,765 titles for review. Three levels of screening were conducted by two independent reviewers: title only, abstract and title, and full-paper review. Rapid-realist synthesis methodology was used to gather a deeper understanding of the relationship between healthcare regionalization and patient-centered care, seeking to identify potential mechanisms and the context in which these operate. We also sought to determine whether novel methodologies such as this can be used by health technology assessment (HTA) bodies in an efficient manner that produces results directly applicable to decision-makers.
Results: Studies from high-income countries, including Canada, New Zealand, Australia, and Italy, were included. The realist synthesis identified mechanisms by which whole healthcare-system regionalization can help or hinder the rollout of patient-centered care. Mechanisms were classified in relation to specific dimensions of patient-centered care including access and "patient as person." Facilitators to the use of rapid-realist review in health policy include similarity of screening, searching, and extraction to traditional systematic review. Barriers include the scope of the literature considered relevant, length of time to familiarize with the method, and presentation of the findings in an accessible way for policymakers.
Conclusions: This is the first realist synthesis of the relationship between whole healthcare-system regionalization and patient-centered care. Regionalization may help or hinder achievement of patient-centered care. Policymakers should note barriers to, and facilitators of, patient-centered care in the context of large-scale health system reform. Rapid-realist review has applications for HTA, particularly in the exploration of non-standard interventions.

OP04 The Modernized Cardiff Model: Multifaceted Modeling In The Era Of Cardiovascular-Kidney-Metabolic Syndrome

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Introduction: In the era of cardiovascular-kidney-metabolic syndrome, thorough evaluation of medicines with multiple treatment effects/indications demands a multifaceted modeling philosophy, despite the requirement of health technology assessment (HTA) models to focus on one disease. Using Cardiff, a model previously built for type 2 diabetes (T2D), we illustrate the changes needed to capture contemporary, holistic, patient-centered decision-making, and argue that HTA bodies should revise their approach.
Methods: The upgraded model enables therapy selection and escalation determined by HbA1c thresholds, cardiovascular risk (QRISK3), comorbidities (established cardiovascular or chronic kidney disease), and weight (body mass index ≥35 kg/m^2). Risk factor trajectories were updated by incorporating UKPDS-90 equations and other relevant data sources. Clinical outcomes were predicted using new risk equations incorporating cardiovascular outcomes trial data whenever possible. The updated model was applied to assess quality-adjusted life years (QALYs) and lifetime costs in newly diagnosed T2D patients in the UK, modeled via a conventional glycemic-centric approach versus a multifactorial treatment algorithm. Extrapolation to the national level utilized estimates of annual incidence.

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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

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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

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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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