(iv) uncertain financial implications to the healthcare system due to a lack of available local costs.
Conclusions: Early HTA on medical technologies identified from HS can be a useful tool to guide subsidy decisions; however, several challenges exist. Careful selection of technologies and timing of evaluation are critical. Seeking stakeholder inputs earlier would ensure shortlisting appropriate technologies with greater clinical need for HTA.

PP128 A Transparent Methodology To Assess Innovativeness Of Health Technologies At Marketing Authorization Time

Ludmila Gargano (ludgargano@gmail.com), Isabela Freitas, Luila Henriques, Ariane André, Juliana Álvares-Teodoro, Francisco Acurcio and Augusto Guerra Jr.

Introduction: Defining drug innovation can be challenging and there is no consensus on what a truly "innovative" medicine is. The Italian Medicine Agency (AIFA) has established an approach to assess innovativeness based on therapeutic need, added therapeutic value, and quality of evidence. However, judgment can be subjective and may not be adequate for assessment at the time of marketing authorization, when only preliminary evidence – often from non-comparative or non-randomized trials – are available. We developed a transparent methodology for early assessment of innovativeness at the time of marketing authorization, based on AIFA guidelines.
Methods: Since the perspective was the marketing authorization date, only data available at agency's Medical Review or pivotal trial publications were considered. AIFA criteria were revisited, using oncology medicines approved in the last 10 years as a base case. Impact of preliminary evidence and inadequate study design was considered.
Results: Each assessment should refer to the first approved specific indication and predefined clinically relevant outcomes. When more than one study was presented, best methodological quality, larger sample and/or longer follow-up was selected. Four domains were established: Therapeutical need: existence and clinical benefits of alternative therapies; Clinical benefit added when compared to those alternatives; Suitability of study design considering adequate comparator group, relevant outcome assessed and randomization; Risk of bias. For each domain, clear and specific criteria were defined in consensus by a group of experts in health technology assessment (HTA) and were applied to all cancer drugs evaluated.
Conclusions: Efficacy evidence available for marketing authorization are often based on preliminary data, arising from single randomized clinical trials or even non-comparative studies, which difficult early assessments of innovativeness. For this reason, transparent and reproducible methodologies can be useful not only to HTA bodies, but also for other key stakeholders in the pharmaceutical market, such as investors, researchers, doctors, and governments.

PP129 Health Technology Assessment Adaptation: Pharyngolaryngeal Biopsies (OLB) For People with Suspected Head and Neck Cancer in the Outpatient Setting

Charlotte Bowles (charlotte.bowles@wales.nhs.uk), Rebecca Boyce, Gareth Hopkin, Matthew Prettyjohns, Sophie Hughes, Elise Hasler, Katie McDermott and Susan Myles

Introduction: In the UK over 12,400 yearly cases of head and neck cancers are reported (2021). Pharyngolaryngeal biopsies (OLB) may improve the speed of diagnosis and treatment of head and neck cancers under local anesthetic. The Scottish Health Technologies Group (SHTG) published advice on this technology in 2018. Since this, additional evidence has been published to warrant a health technology assessment (HTA) for Wales. The aim of this review was to provide update on the clinical and cost-effectiveness of OLB when compared to undergoing biopsy in an operating theatre (OTB) under general anesthetic to inform decision making in Wales.
Methods: A rapid review was undertaken of relevant databases since 2018 of the clinical evidence, health economics and patient perspectives relevant to Wales. Health Technology Wales (HTW) developed a de-novo cost-utility analysis comparing OLB to OTB over a lifetime horizon. Inputs were sourced from the SHTG budget impact analysis, updated with values more relevant to a Welsh setting.
Results: From consultation to biopsy procedure, the mean number of days was 1.3 for OLB compared to 17.4 days under OTB ($p < 0.05$). The mean time from consultation to start of treatment was 27 days for OLB compared to 41.5 days for OTB ($p < 0.05$). The economic analysis found a resulting ICER of GBP21,011 (EUR23,824.23) in a population with 2,183 at risk patients. As OLB was associated with lower costs (GBP816 per person) (EUR925.26) and fewer quality adjusted life years than OTB (-0.04), this ICER corresponds to OLB being considered a cost-effective diagnostic strategy.
Conclusions: HTW guidance was able to recommend use of OLB within the diagnostic pathway for head and neck cancers within Wales. For people with a positive test, OLB is sufficient to confirm a diagnosis but should not be used to rule out a diagnosis due to the potential in reducing the time to diagnosis and treatment in a cost-saving way.

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