finding a priori criteria for deciding when to use one method versus another.

RESULTS:

The published literature is sparse and there are no specific criteria available for deciding when to use one method of development versus another. The proposed multi-step algorithm identifies similar steps in the production of all types of CPGs: the set-up phase; establishing the need for a new CPG in consultation with a guideline development group and local stakeholders; developing research question(s); conducting searches for suitable existing guidelines; and finalizing the guideline. HTA can help set the health question(s) and identify and screen existing CPGs. When CPGs are not available, HTA methods are implemented to update the evidence in a blend of de novo and adaptation processes by reviewing umbrella reviews, systematic reviews, and primary studies. Quality appraisal of existing guidelines and syntheses of evidence in a rapid review fashion help determine whether there are enough studies to support the guideline scope.

CONCLUSIONS:

Deciding which method of guideline development to employ requires ample methodological expertise, an intimate knowledge of the clinical practice environment, and access to detailed contextual information. The proposed multi-step algorithm shows how to successfully leverage HTA resources to support CPG production and move research evidence into practice.

PP146 Cost-Effectiveness Of Nivolumab Plus Ipilimumab In Advanced Melanoma

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INTRODUCTION:

This study was done to assess the cost effectiveness of nivolumab plus ipilimumab (NIV+IPI) versus nivolumab alone (NIV) for previously untreated patients with advanced melanoma (AM) from the Dutch health system perspective.

METHODS:

A Markov model was constructed with a lifetime horizon. Future effects and costs were discounted at 1.5 and four percent, respectively. Risks of progression and death were based on progression-free survival rates obtained from a phase III clinical trial (NIV+IPI and NIV versus ipilimumab). Conjectural overall survival rates were calculated indirectly by using progression-free survival and overall survival rates from another trial (NIV versus dacarbazine), and were extrapolated later using the Weibull distribution. Utility values of health states and disutility values of adverse events were derived from the literature. Unit costs were derived from the Dutch Diagnosis Treatment Combination Care Products Tariff, Erasmus University Medical Center prices, and Dutch pharmacy purchase prices. Chronic management costs of AM and treatment costs of adverse events were calculated based on the results of a survey of clinicians that determined the necessary healthcare services and their utilization rates.

RESULTS:

On average, over a lifetime an AM patient treated with NIV+IPI was estimated to live 4.2 years and 2.6 quality-adjusted life-years (QALYs) at a discounted net cost of EUR 262,824 per patient, while a patient treated with NIV was estimated to live 3.3 years and 2.0 QALYs at a discounted net cost of EUR 195,341 per patient. The incremental cost-effectiveness ratio was EUR 70,770 per life-year saved, and the incremental cost-utility ratio was EUR 115,533 per QALY gained.

CONCLUSIONS:

At a willingness-to-pay threshold of EUR 80,000 per QALY gained, NIV+IPI may not be a cost-effective tool, compared with NIV, for preventing the high mortality and morbidity associated with AM from the Dutch health system perspective.

PP147 Olaratumab With Doxorubicin For Advanced Soft Tissue Sarcoma

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https://doi.org/10.1017/S0266462318002775 Published online by Cambridge University Press

INTRODUCTION:

The National Institute for Health and Care Excellence (NICE) invited the manufacturer of olaratumab (Lartruvo®), Eli Lilly & Company Limited, to submit evidence for the clinical and cost effectiveness of this drug, in combination with doxorubicin, for advanced soft tissue sarcoma (STS) not amenable to surgery or radiotherapy, as part of the Institute's Single Technology Appraisal. The Peninsula Technology Assessment Group critically reviewed the submitted evidence.

METHODS:

Clinical effectiveness was derived from an open-label, randomized controlled trial, JGDG. The economic analysis was based on a partitioned survival model with a time horizon of 25 years. The perspective was of the UK National Health Service (NHS) and Personal Social Services. Costs and benefits were discounted at 3.5 percent per year. The company's evidence was submitted in anticipation that olaratumab would be considered as an alternative to doxorubicin, which has been used as a first-line treatment for advanced STS. To improve the cost effectiveness of olaratumab, the company offered a discount through a Commercial Access Agreement with the NHS England.

RESULTS:

In the company's submission, the mean base-case and probabilistic incremental cost-effectiveness ratios (ICERs) for olaratumab plus doxorubicin versus doxorubicin alone were GBP 46,076 (USD 61,403) and GBP 47,127 (USD 62,804) per quality-adjusted life-year (QALY) gained, respectively; the probability of this treatment being cost effective at the willingness-to-pay threshold of GBP 50,000 (USD 66,632) per QALY gained, applicable to end-of-life treatments, was 0.54. The respective estimates in our analysis were approximately GBP 60,000 (USD 79,959) per QALY gained, and the probability of cost-effectiveness was 0.21. The increase in the ICERs was primarily due to differences in extrapolation of overall survival, and drug administration costs.

CONCLUSIONS:

Based on the available evidence, olaratumab in combination with doxorubicin improves the survival of patients with advanced STS. However, this treatment is unlikely to be cost-effective. Olaratumab is now recommended for use within the Cancer Drugs Fund.

PP148 Your Money Or Your Life? Are Price Negotiations Health Technology Assessment Best Practice?

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INTRODUCTION:

Many countries use Health Technology Assessment (HTA) organizations to evaluate the clinical and economic impact of new therapeutic interventions. In some markets, HTA outcomes directly link to reimbursement decision-making based on the manufacturer's submitted price (e.g. NICE and SMC [UK]). In others, the HTA outcome leads to price negotiations with manufacturers by a separate body (e.g. HAS/CEPS [France] and G-BA/GKV [Germany]). This research compares major examples of each approach to inform a discussion on whether such price negotiations align with HTA best practice.

METHODS:

Publically-available technology assessment outcomes for G-BA/GKV, NICE and SMC (01/01/2011-31/12/2015) were extracted and compared.

RESULTS:

Of 112 G-BA benefit assessments, 45 percent offered no additional benefit with automatic reference pricing; 55 percent offered additional benefit, qualifying for price negotiations; 77 percent had prices negotiated, 14 percent had price fixed by court, and eight percent withdrew from market. Of 156 NICE Single Technology Appraisals, 51 percent were recommended, 17 percent restricted, 20 percent not recommended, and 12 percent non-submissions. Of 497 SMC appraisals, 35 percent were accepted, 28 percent restricted, 17 percent not recommended and 19 percent non-submissions. Forty-eight percent and 24 percent of NICE and SMC positive appraisals were associated with a Patient Access Scheme (PAS), with 86 percent and 88 percent being simple discounts schemes, respectively.

CONCLUSIONS:

Making reimbursement decisions for new medicines based on a clear set of criteria may be the most objectively fair and transparent method of HTA;

https://doi.org/10.1017/S0266462318002775 Published online by Cambridge University Press