standard treatment in patients with diabetic foot ulcers. The effectiveness measure was quality-adjusted life years (QALYs). We ran extensive sensitivity analyses, including a probabilistic sensitivity analysis.

RESULTS:

Sixteen RCTs and four observational studies were included for the effectiveness and safety meta-analysis. The primary outcome was the proportion of chronic wounds completely healed: 143 patients out of 334 (42.8 percent) were cured in the standard treatment arm and 251 patients out of 375 (66.9 percent) in the PRP arm, relative risk (RR) 1.68 (95% CI: 1.22–2.31). It was unclear whether there was a difference in the risk of infection (RR 0.53, 95% CI: 0.10–2.71) or adverse events (RR 1.05, 95% CI: 0.29–3.88) between PRP and standard care. Three studies were considered for the cost-effectiveness analysis. In the base case analysis, PRP led to higher QALYs and healthcare costs with an estimated incremental cost-effectiveness ratio (ICER) of EUR 41,767 (USD 48,323)/QALY.

CONCLUSIONS:

PRP treatment is more expensive and more effective than standard treatment. The estimated ICER is above the acceptability threshold in Spain.

PD43 Value-Based Procedure For Updating The Italian Health Benefit Package

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INTRODUCTION:

In Italy, the central government sets the health benefit package (denominated "Livelli Essenziali di Assistenza" - LEAs) of the National Health System (NHS), which must be provided to all residents. In 2004, the Italian Ministry of Health established a new technical body, the National LEA Commission, responsible for updating LEAs.

METHODS:

Recently, the Ministry has commissioned to the National Institute of Health (NIH) the development of a new value-based procedure for updating the health benefit package for the Italian NHS, supporting the National LEA Commission. A review and comparison of value frameworks and decisional models was performed in order to select a framework and a model that can be applied to the Italian context, design an administrative process for the update procedure, and propose approaches for: (i) the assessment of services currently included in the health benefit basket and of those planned to be incorporated, (ii) the process of appraisal and decision-making to be adopted by the Commission.

RESULTS:

The NIH outlined an evidence and value-based three-step (i.e. priority setting, assessment and appraisal) administrative process that integrates roles and responsibilities of the different Italian healthcare institutions involved in LEA updating and HTA.

CONCLUSIONS:

The NIH is proposing to the Ministry of Health and to the National LEA Commission a new evidence and value-based procedure for updating the health benefit package for the Italian NHS. This procedure is entering a pilot phase in which potential gaps can be identified and minimized for its subsequent implementation.

PD44 Multi-Comparator Incremental Cost-Effectiveness Ratio: A New Framework For Cost-Effectiveness Analysis

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INTRODUCTION:

Current practice in cost-effectiveness analysis (CEA) involves the estimation of the incremental cost-effectiveness ratio (ICER) between a new intervention and one alternative comparator reflecting the standard of care. As this focuses on pairwise comparisons, rather than considering the whole range of available alternatives at any given time, this method fails to capture the full impact of bringing the new intervention to market.

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METHODS:

A multi-comparator ICER (MC-ICER) evaluating the impact of the new technology on patients treated with all comparators used in clinical practice, rather than a theoretical 'second-best' alternative only, was estimated. This can be achieved by weighting the incremental costs and benefits for each comparator by its change in market share to generate an MC-ICER. This is shown using a stylized example with three comparators.

RESULTS:

The traditional ICER against the second-best alternative was USD 200,000 per QALY, while the estimated multi-comparator ICER is USD 133,548 per QALY, corresponding to a 33 percent decrease. This reflects the fact that patients who switch to the new intervention are not only those who had been previously treated with one particular comparator, as is assumed in a traditional CEA. The difference between the traditional ICER and the MC-ICER depends on how the new intervention impacts on the uptake of each comparator.

CONCLUSIONS:

Results show that, when comparator selection was made excluding dominated and extendedly-dominated alternatives, the MC-ICER, produced using the method described above, is lower than the traditional ICER comparing the new intervention to the second-best comparator. This captures the fact that patients may switch to the new intervention not only from the second-best comparator, but from the whole range of alternative treatments. Such patient movements determine the real impact, or opportunity cost, of the new intervention on the healthcare system and, therefore, should be captured in CEA alongside traditional one-way ICERs.

PD47 Implanted Hypoglossal Nerve Stimulation For Obstructive Sleep Apnea

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INTRODUCTION:

The hypoglossal nerve stimulation (HNS) produces a tongue protrusion for the treatment of mod-severe obstructive sleep apnea (OSA). It is one of the emerging health technologies prioritized to assess its possible inclusion on the Spanish National Health System. The objective of this study is to evaluate the efficacy and safety of this system in the treatment of OSA.

METHODS:

An early assessment (horizon scanning) was performed. The searched databases were: PubMed, WOS, Tripdatabase, Dynamed, Cochrane Library and ICTRP. Clinical studies of OSA patients treated with HNS published until 01 March 2017 were reviewed. Outcomes considered were: AHI (Apnea Hypopnea Index) ODI (Oxygen Desaturation Index) ESS (Epworth sleepiness scale) and AE (adverse events).

RESULTS:

Four devices of HNS were founded: Inspire™, HGNS®, Aura6000™, and Nixoah™. We found two randomized controlled trials (RCT). The Inspire™ RCT showed significant results on mean differences on AHI (−16.9, 95% CI −24.7 to −9.0); ODI (−15.1, 95% CI −22.7 to −7.5) and ESS (−4.5, 95% CI −7.5 to −1.4) in 46 patients, after one week of follow-up. The HGNS® RCT showed non-significant differences on AHI (device active 22.1 ± 5.2 vs control 29.7 ± 6.2), ODI (11.4 ± 4.1 vs 19.5 ± 5.2) and ESS (9.8 ± 1.0 vs 14.1 ± 2.5) in 21 patients at 6 months. A systematic review that included 6 cases series (3 with HGNS®, 2 with Inspire™ and 1 with Aura6000™) without device subgroup analysis and 7 cohorts studies (6 with Inspire™ and one with Aura6000™) showed significant differences comparing AHI, ODI and ESS results to before treatment values. Major AE reported from the studies varied from 4 to 4.5%. No study with Nixoah™ was found.

CONCLUSIONS:

Inspire™ seems to be an effective option for OSA patients although the evidence is scarce and of low quality for all HNS devices. It would be necessary further well-designed studies.

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