RESULTS:

The São Paulo State Health Secretariat coordinated the synthesis and economic assessments made by 115 experienced transplantation specialists and health technology evaluators over ten years. Heart, lung, liver, pancreas and hematopoietic cells transplantation PCDTs (with tacrolimus, sirolimus and everolimus alternative immunosuppression) can significantly prevent 27.8 percent, 28.1 percent, 7.2 percent, 11.1 percent and 4.3 percent graft loss or graft *versus* host disease and death, respectively, for refractory transplantees rescue during the first year post-transplantation, saving healthcare resources. Ten-year follow-up data demonstrated partial benefits were sustained. Analysis demonstrated +USD689,655.17, +USD501,567.40, -USD377,802.51, +USD221.289,42 and +USD50.734,08 budget impact, respectively, resulting in an overall USD1,085,443.55 for 2,146 transplantees. The 5 PCDTs were favorably voted by CONITEC plenary members, 155 public contributions were added by patients and stakeholders, and the Brazilian Health Ministry decided to adopt the SUS reimbursement listing.

CONCLUSIONS:

Democratic participation gave PCDTs real-world basis adjustments, SUS innovation and improved compliance.

PP126 MEA In Italy: Correlation Between Time To Payment By Result And Time To Off Treatment Curve

AUTHORS:

Gabriele Vittoria (Gabriele.vittoria@roche.com), Antonio Fascì, Matteo Ferrario, Giovanni Giuliani

INTRODUCTION:

Payment by result agreements have been quite widely used in Italy to provide access for high costs oncologic drugs and minimize uncertainties of real life benefits (1). The aim of this analysis was to overview the Roche experience in terms of Payment by Result (Pbr) in oncology and investigate the relation between timing for the evaluation of treatment failures and observed Time to Off Treatment (TTOT) from Phase III clinical trials (2).

METHODS:

A retrospective analysis of the Roche payment by results schemes in place in Italy was conducted. For each drug included in the analysis it was collected: (i) the negotiated timing to assess the treatment failure for payment by result, (ii) the median time to off treatment curve observed in clinical trials for the experimental drug, (iii) the median time to off treatment observed in clinical trials for the control arm. The mean ratios between timing to assess the treatment failure for payment by result and the time to off treatment observed for the experimental drug or the median time to off treatment observed in the control arm were calculated to identify potential correlations. High level of correlation was expected if ratio was close to 1 (±.2).

RESULTS:

Roche products or different indications of the same product were identified as candidates for the analysis from 2008 to 2016. The timing for the evaluation of treatment failures for Pbr varies between 2 and 9 months, depending on the type of tumor and line of therapy. The mean Time to Payment By Result (TTPbr) / Control arm Time To Off Treatment (cTTOT) ratio was 1.16 (±.37) while the mean Time to Payment By Result (TTPbr) / Experimental arm Time To Off Treatment (eTTOT) ratio was .71 (±.13). Data analysis according to different time periods shows that the mean TTPbr/cTTOT and TTPbr/eTTOT for drugs negotiated from 2008 to 2015 were respectively 1.07 and 1.39 whereas for drugs negotiated in 2016 were respectively and .63 and 1.

CONCLUSIONS:

Good level of correlation between TTPbr and cTTOT was found. This finding is in line with the methodology used by Italian Medicines Agency so far, leveraging the cTTOT as the most appropriate proxy to assess any incremental effect of a new drug compared to the previous Standard of Care. The analysis over time of TTPbr shows that in

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the first years of payment by result negotiation TTPbr is more correlated to the cTTOT whereas in the last years is moving closer to the experimental one.

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PP128 Regional Guidance On Spinal Cord Stimulation For Chronic Pain

AUTHORS:

Anna Cavazzana (anna.cavazzana@regione.veneto.it), Anna Redomi, Elena Poerio, Francesca Bassotto, Rita Mottola, Margherita Andretta, Giovanna Scroccaro

INTRODUCTION:

Chronic Pain (CP) is the uncontrolled pain that affects patients for a long time. CP can be caused by many conditions, sometimes still poorly understood, and its levels can vary from moderate to intense. The management of resistant CP requires a stepwise approach and spinal cord stimulation (SCS) could be considered an extreme strategy. With the aim of ensuring the economic sustainability, the Veneto Region usually establishes rigorous access criteria to high-cost medical devices through its Regional Technical Committee on Medical Devices (CTRDM) and a Health Technology Assessment (HTA) procedure.

METHODS:

The Regional Health Technology Assessment Unit (CRUF) conducted through Pubmed a literature review of randomized controlled trials, systematic reviews, meta-analysis on SCS published from March 2006 to February 2016. International and national clinical guidelines were included in the analysis as well. The regional multidisciplinary Working Group on CP, which involved local clinicians, pharmacists, clinical engineer and health economist, discussed the collected evidence by consensus. Final recommendations on the appropriate use were submitted to the CTRDM for final approval.

RESULTS:

The regional guidance describes the type of pain that can be treated with spinal neurostimulators and the criteria which determine the success of the test procedure. A comparative analysis of spinal neurostimulators available on the market and related patients eligibility criteria have been also included. Moreover, the guidelines stated a list of compulsory requirements in order to become a regional center authorized in performing spinal neurostimulation procedure. Finally, the document describes some indicators for appropriateness monitoring. The CTRDM approved the final version in October 2016.

CONCLUSIONS:

The regional guidance on SCS aims at ensuring the appropriate use of neurostimulators in patients affected by resistant CP. The strict monitoring of agreed indicators is essential for appropriateness and consequently the sustainability of medical devices expenditure throughout the Regional Health Service.

PP129 Methodological Issues With Assessing Newborn Screening Tests

AUTHORS:

Bing Guo (bguo@ihe.ca)

INTRODUCTION:

To outline the methodological issues associated with the assessment of newborn screening for severe combined immunodeficiency, which was conducted to address the policy question of whether this test should be added to an existing newborn screening panel.

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