

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.

#### REFERENCES:

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2. Italian Medicines Agency (2015) – National Report on Medicines use in Italy. 33,18-89.

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## PP128 Regional Guidance On Spinal Cord Stimulation For Chronic Pain

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#### 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.

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## PP129 Methodological Issues With Assessing Newborn Screening Tests

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#### 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.

## METHODS:

We conducted a systematic review of published primary studies and critically appraised the methodological quality of selected studies (1).

## RESULTS:

Fifteen studies were included; six focused on screening test performance, and seven on treatment effectiveness, and two on the effectiveness of a newborn screening program. The methodological issues identified included: (i) Overall poor methodological quality ratings of included studies using the QUADAS-2 (Quality Assessment of Diagnostic Accuracy Studies-2). This tool was originally developed for assessing diagnostic accuracy studies where subjects usually receive both index test and reference standard so a 2×2 table can be constructed; however it is almost impossible to apply this cross-sectional approach to studies of a screening test for a rare disease like severe combined immunodeficiency. (ii) Case control design using healthy controls could inflate estimates of test accuracy compared to studies using a cohort of consecutive patients, possibly due to spectrum effects and limited-challenge bias. This type of study is useful in the early phase of test development, but estimates of test accuracy based on this type of study should be interpreted with caution. (iii) Some screening programs reported no false negatives, indicating a sensitivity of 100 percent. However, lack of a systematic search for “missed cases” created uncertainty in arriving at a true value for the sensitivity. (iv) Variations in inclusion of pre-term infants, races/ethnicities, and screening protocols made it difficult to compare screening test performance across different studies.

## CONCLUSIONS:

Although severe combined immunodeficiency screening was the first addition to the US Recommended Uniform Screening Panel following an evidence-based review process, caution needs to be exercised when interpreting research findings due to important methodological issues.

## REFERENCES:

1. Institute of Health Economics. *Newborn blood spot screening for galactosemia, tyrosinemia type I, homocystinuria, sickle cell anemia, sickle cell/beta-thalassemia, sickle cell/hemoglobin C disease, and severe combined immunodeficiency*. Edmonton (AB): Institute of Health Economics; 2016.

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## PP130 Nudging In Public Health: Accountability For Practical Wisdom

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### INTRODUCTION:

Nudging is the application of behavioural sciences aimed at influencing behaviour in a non-prescriptive way. It is a tool of public health decision makers to produce health gain. Just like decisions in the field of Health Technology Assessment (HTA), nudging decisions are inevitably value laden. The current European Network for HTA (EUnetHTA) approach to evaluate ethical aspects encompasses mainly utilitarian and principlistic approaches. The aim of this project is to incorporate the virtue ethics approach in public health decision-making processes based on the example of nudging.

### METHODS:

The narrative analysis of nudging is based on a systematic literature search conducted from 28 October to 13 November 2015 in the following databases: Medline via Ovid, Embase, and TRIP Database. A total of sixty-two articles were listed as relevant as a result of searches and, in addition, twenty-five more articles were found through hand searching.

### RESULTS:

Regardless of the potential issues related to nudging (manipulation or coercion), nudging is considered cost-effective and inevitable because of the malleability