provided there is no clinical impairment. This study reinforces the importance of the public consultation and social participation in the process of health technologies incorporation in Brazil, considering its capacity to add new information to the decision-making process.

PD61 HTA Regional Network In The Central Region Of Brazil: Survey In 2016

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INTRODUCTION:

The Federal District in Brazil has about 2.9 million inhabitants and the public health system is focused on medical specialties, with one university hospital and twenty regional hospitals. This ecosystem is favorable for fostering health technology assessment (HTA) to improve the efficiency and effectiveness of health care. The objective was to identify institutions that could form a HTA network to support decision-oriented evidence in the public health system.

METHODS:

Stakeholders from the hospitals and training/research institutions in the Federal District were surveyed. An online questionnaire (Google Docs) was developed to identify the potential and capacity of institutions to analyze or produce clinical and economic evidence. Two HTA seminars were held to spread knowledge about HTA and to encourage stakeholders to complete the survey.

RESULTS:

The questionnaire response rate was thirty-five percent (25/70). Fifteen institutions were cited by the respondents as having the potential to build a HTA network. Twelve of the institutions produced rapid reviews and clinical guidelines, but only three of these had an organized priority setting process or produced assessments at the request of the hospital manager. The challenges identified were training and willingness of decision makers to organize HTA units in the hospitals.

CONCLUSIONS:

An executive group was created which defined a strategy to support the implementation of HTA units as part of the HTA National Network (REBRATS). A regulation proposal was also created to encourage decision makers to activate a HTA network in the Federal District.

PD62 Off-Label Use Of Medicines For Public Health Needs

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INTRODUCTION:

The use of drugs for clinical conditions that differ from those approved in prescribing information (product labels) is known as off-label use. In Brazil, the Brazilian Health Regulatory Agency (ANVISA) is the official organization that regulates the use of health technologies. For technologies to be incorporated into the Brazilian public health system, registration with ANVISA is mandatory. However, occasionally, it is necessary to evaluate technologies for off-label use in the interests of public health. This study aimed to identify the health technologies recommended by the National Committee for Health Technology Incorporation (CONITEC) with an off-label indication between January 2012 and October 2017.

METHODS:

A descriptive study was undertaken using data available on the CONITEC website.

RESULTS:

The study identified seven drugs with a favorable recommendation for off-label use: everolimus, sirolimus, and tacrolimus as immunosuppressants in transplant recipients; clozapine for bipolar affective disorder; pentoxifylline for cutaneous leishmaniosis mucosa; risperidone for adults with autism spectrum disorder, and bevacizumab for age-related macular degeneration and diabetic macular edema. For these decisions the Committee considered the scientific evidence available for the indication proposed, the severity of the disease, and the existence or absence of alternative treatments. This was possible because Brazilian legislation allows

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ANVISA to authorize the off-label use of health technologies provided that the analysis is supported by scientific evidence regarding effectiveness, accuracy, and safety for the intended purpose.

CONCLUSIONS:

The off-label use of health technologies is a worldwide practice that can favor vulnerable populations and neglected diseases. This practice should be seen as positive when there is evidence supporting off-label use, and such decisions should not be influenced by political, economic, or marketing considerations.

PD64 Diagnostic Accuracy Of The Nitrate Reductase Assay Technique

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INTRODUCTION:

The conventional drug sensitivity test is traditionally used in Brazil to diagnose drug-resistant tuberculosis. However, the test can take up to 60 days to return a diagnosis, which is considered too long for certain vulnerable populations. Therefore, this study analyzed the available scientific evidence on the accuracy and time to diagnosis of the nitrate reductase assay for diagnosing resistant tuberculosis, compared with the conventional drug sensitivity test.

METHODS:

We searched MEDLINE, Embase, and The Cochrane Library for systematic reviews with meta-analyses. The articles were screened by title and abstract. The full-texts of potentially relevant articles were then screened according to the inclusion criteria.

RESULTS:

Three systematic reviews with meta-analyses were selected that compared the nitrate reductase assay with the conventional drug sensitivity test. The accuracy of the nitrate reductase assay was satisfactory in most of the results when compared with the sensitivity test, except for one study that showed low sensitivity for the detection of streptomycin resistance. In addition, the nitrate reductase assay had a shorter time to diagnosis than the drug sensitivity test.

CONCLUSIONS:

The results of this study reinforce the idea that the nitrate reductase assay may diagnose drug-resistant tuberculosis earlier than the conventional drug sensitivity test and be a helpful strategy for controlling the disease, especially in vulnerable populations that are more likely to be affected by tuberculosis. For a broader analysis of the benefit of the assay, it is suggested that studies investigate the impact of the shorter time to diagnosis on morbidity and mortality in patients with drug-resistant tuberculosis. In addition, economic analyses comparing the nitrate reductase assay with the sensitivity test are recommended to evaluate the cost-benefit ratio.

PD65 The Acquisition Of Eculizumab By Judicial Proceeding In Brazil

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INTRODUCTION:

Eculizumab is a monoclonal antibody indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) or with atypical hemolytic uremic syndrome (aHUS). In Brazil in recent years eculizumab was the most expensive drug requested through court orders, obliging public health managers to import it from the USA. From 2012 to 2016, approximately BRL 424 million (USD 112 million) was spent on eculizumab. The purpose of this study was to assess the regulatory situation and the scientific evidence on the safety and efficacy of eculizumab.

METHODS:

A literature search was conducted in PubMed, The Cochrane Library, and the Centre for Reviews and Dissemination databases on September 2017. The websites of regulatory agencies were also searched.

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