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

AUTHORS:

Dalila Gomes (dalilafg@gmail.com), Betânia Leite, Fabiana Araujo Figueiredo da Mata

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

AUTHORS:

Flavia Salomon (flasalomon@gmail.com), Eliete Simabuku, Jose Beutel, Eduardo De Oliveira, Roberta Rabelo, Clarice Petramale, Artur Felipe de Brito, Kathiaja Miranda Souza

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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