improved participants engagement in the reporting protocol, and greatly enhanced their reporting quality. The study demonstrated that robust evidence of a practical utilization of SMS in a disease reporting system to replace the traditional paper-based one has great potential for a scale-up and national-wide implementation.

VP214 Criteria That Influence The Brazilian Public Decision-Making

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INTRODUCTION:

In Brazil, the National Committee for Health Technology Incorporation in the public health system (CONITEC) advises the Ministry of Health about incorporation, exclusion and alteration of health technologies in Brazilian public health system (SUS). Decision making considers multiple criteria, included or not in legislation. This analysis was the first step for a multiple-criteria decision analysis (MCDA) building. This study aims to identify criteria that influence Health Technology Assessment (HTA) for SUS.

METHODS:

Five real cases of controversial recommendations of technology incorporation made by CONITEC were reviewed by listening to the plenary recordings and reviewing committee minutes. The choice was guided by convenience, with prioritization according to CONITEC's members, using a pre-defined standardized form. Weight in decision making was also raised and identified. Selected technologies judgments were: Trastuzumab for metastatic/advanced Breast Cancer; Fingolimod for Multiple Sclerosis; Clozapine, Lamotrigine, Olanzapine, Quetiapine and Risperidone for Bipolar Affective Disorder; Hematopoietic stem cell transplantation for Sickle Cell Disease; and Positron Emission Computed Tomography (PET-CT) for Lung Cancer and for hepatic metastasis from Colorectal Cancer.

RESULTS:

The choice of different technologies allowed verifying specific criteria used for the incorporation of each type of technology, as well as the similar criteria discussed and used by all these technology types. In addition, some identified criteria were specific to the Brazilian reality, such as: "Incorporation by other countries", "Potential technologies without registration in Brazil" and "Off-label use". These criteria were not previously identified in studies conducted in other countries. Some criteria have been identified in all decisions, such as: efficacy, disease severity, quality and confidence in the evidences, logistic challenges for implementation, unmet needs, budget impact and treatment costs. Relative impact of cost-effectiveness was considered low.

CONCLUSIONS:

CONITEC's recordings are an important source to understand the Brazilian decision-making process. To identify the important criteria can help to standardize and improve the HTA process.

VP216 Health Technology Assessment's Balance Between Additional Data, Adoption, And Patient Access

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INTRODUCTION:

Historically, many Health Technology Assessment (HTA) bodies were developed with a focus on addressing rapidly rising drug costs and the unique need to evaluate each drug as a *de novo* entity. The degree to which the unique needs for evaluating technologies *vis*

https://doi.org/10.1017/S0266462318000041 Published online by Cambridge University Press

a vis drugs are reflected in distinct HTA methods and activity is to date understudied.

METHODS:

We examined HTA's reviews of two technologies: WATCHMAN™, a device to reduce the risk of stroke in certain patients and Alair™, a procedure-based treatment for severe asthma. Both technologies have been extensively reviewed by HTA bodies and payers in many countries. These HTA reviews are compared to a convenience sample of these HTA's bodies reviews of drugs and qualitative differentiators between these two categories explored.

RESULTS:

The differences and similarities (for example, in rigor and necessity of evidence) between US Section 510(k) clearances, US premarket approval (PMA), and US new drug application (NDA) regulatory pathways have not been clearly understood by HTA or reflected in their methodologies employed. Additionally, emergent methodologies such as Bayesian statistical analyses may encounter challenges within technologies reviews. HTA bodies may not be cognizant of development timelines or the timelines of comparators. Finally, HTA bodies may overestimate device adoption rates.

CONCLUSIONS:

The differences in evidence requirements for regulatory approval between US 510(k), US PMA, and US NDA pathways have not been reflected in different methodological approaches within HTA bodies reviews. Opportunities and novel methods are needed for HTA bodies to derive imputed comparisons between technologies that may have inherently incongruent timelines. Finally, HTA bodies could benefit from methods to more accurately estimate projected adoption curves. Challenges exist using frameworks, paradigms, and methodologies initially established for, and commonly used for, pharmaceuticals on device evaluations; leaders of HTA methods can improve the situation by providing guidance and recommendations for more appropriate HTA methods to evaluate devices.

https://doi.org/10.1017/S0266462318000041 Published online by Cambridge University Press