OP59 The Tunisian Guidelines For Pharmacoeconomic Analysis: What We Need To Know

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Introduction. As a new milestone in health technology assessment (HTA) implementation in Tunisia, L'Instance Nationale de l'Evaluation et de l'Accréditation en Santé (INEAS)—the Tunisian HTA body—published a set of methodological guidelines to support HTA dossier submission by the pharmaceutical industry. Including, 'guide for submitting clinical data for an HTA at INEAS', 'methodological choices guide for pharmacoeconomic analysis at INEAS', and 'methodological choices guide for budget impact analysis at INEAS'. We aim to report the major methodological recommendations of the pharmacoeconomic analysis guideline.
Methods. The 'methodological choices for pharmacoeconomic analysis at INEAS' guideline was reviewed and the major recommendations were retrieved and reported.
Results. The reference analysis required by INEAS is the cost-utility analysis systematically combined with a cost-effectiveness analysis (cost per life-year gained) from the public payers' perspective. The choice of any other type of analysis must be duly justified. Comparators should include alternative treatments which are considered to be 'the standard of care' (i.e., interventions routinely used in Tunisia for the same indication) and in which public resources are invested. The time horizon should be sufficiently long to reflect all differences in costs and outcomes. Additionally, a discount rate of 5 percent per year is recommended. The best available evidence for efficacy, safety and quality of life is required. An indirect measure of patient preference, through a validated measurement instrument is preferred for utility calculation. Cost inputs should be identified from Tunisian sources. Health resource utilization should reflect the care pathway in Tunisia. INEAS favors the use of a recognized model. Uncertainty and impact of the input parameters on the results should be assessed and reported through probabilistic and deterministic sensitivity analyses. Model validation tests to assess face validity and internal validity should be performed, and a discussion of the methods used provided. Demonstration of external validity is required. Results should be presented in incremental cost-utility and cost-effectiveness ratios.
Conclusions. The recommendations of 'methodological choices for pharmacoeconomic evaluation at INEAS' is an important step to facilitate and harmonize pharmaceutical companies' submissions and to enhance the use of these analyses in decision-making.

OP60 Methodological Guidance And Doctrine Of The French National Authority For Health For Economic Evaluation

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Introduction. The French National Authority for Health (HAS) "defines and issues guidelines and medico-economic opinions on prevention, healthcare, prescription, and best care strategies, and contributes to their comparison or ranking to support public health and optimize health insurance spending." Based on a decade of producing cost-effectiveness evaluations, the Economic Evaluation and Public Health Committee (CEESP) issued two documents to frame its activity related to the economic evaluation of health products: (i) the new guidance highlights the expectations of the CEESP regarding cost-effectiveness evaluations; (ii) the doctrine elucidates the grading of methodological reservations expressed during the technical appraisal of manufacturers' submissions, the CEESP's statements regarding its findings, and the key messages it wishes to convey to public decision-makers, especially to negotiate healthcare product prices.
Methods. We aim at sharing the content of these documents and describing the willingness of the CEESP to support decision-makers in implementing evidence-based pricing policies.
Results. The new guidance provided an opportunity for HAS to stress the importance of interpreting the evaluations, which are often perceived as highly technical. In this perspective, several guidelines call for more reasoned reflection on the objectives of the evaluation upon its conception, along with a constant effort to justify the methodological choices made and an extensive interpretation of the results produced.
The doctrine highlights two steps taken by the CEESP, mainly built on analyzing the cost-effectiveness evaluation's uncertainty. First, the ability to characterize the level of the ICER in a context where no thresholds for willingness-to-pay exist in France; second, the suggestion of specific regulation schemes to increase the cost-effectiveness of the products.
Conclusions. The CEESP developed the new guidance and its doctrine as conditions to ensure the usefulness of the economic evaluation for decision-making.

OP62 Patients' Opinion On Health Technology Assessment Reports: An Analysis Of Brazilian Health Technology Assessment In 2021

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Introduction. The Brazilian health technology assessment (HTA) process includes calls for public consultations, in which society can give its opinion on reports emitted by the National Committee for Health Technology Incorporation (CONITEC). Open and closed queries for public consultation are performed by official formularies and can be accessed online at CONITEC webpage. Queries are divided into two categories of reports: clinical protocols and guidelines, and incorporation/exclusion demands. Incorporation/exclusion queries are subdivided in two additional categories: opinion and experience, or technical. In this study we analyze the weight of patients' participation in opinion and experience queries and their opinion (pro or con) on inclusion/exclusion of health technologies.
Methods. Formularies concerning concluded public consultations on health technology incorporation/exclusion reports were extracted from CONITEC website from 1 January to 26 November 2021. Entries on the opinion and experience formularies included amongst others, a close-ended question about the opinion of participants on health technology incorporation/exclusion reports ("favorable"/"against"/"neither"). In this study, we analyzed patients' opinion contained within concluded public consultations on incorporation/exclusion of health technologies.
Results. A total of 63 health technology incorporation/exclusion queries were performed in the analyzed period, of which there were only four exclusions. A total of 32,209 contributions were registered. "Patients", "Health professionals", "Family or caregivers", "Interest on the theme", accounted for 99.4 percent (13.5, 16.7, 32.3, 36.7%, respectively). Patient participation accounted for 4,367 (13.5%) entries. The total number of opinions in favor of the presented documents by the "Patients" was 4,268 (97.7%), 59 (1.4%) disagreed and 40 (0.9%) had no opinion.
Conclusions. Public consultation of official HTA reports is a very useful tool to legitimize decisions through social participation. Although patient participation is not numerically the most important category to contribute on public consultation queries, patients are, if not the most influential stakeholder, the main recipient of decisions concerning health technologies incorporations. Further analyses shall investigate experience narratives included in public consultation queries.

OP63 Patient and Public Perspectives On The Scottish Medicines Consortium Detailed Advice Document

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Introduction. The Scottish Medicines Consortium (SMC) conducts early health technology assessment (HTA) of new medicines, the primary output of which is a document referred to as the Detailed Advice Document (DAD). This comprises an overview of all data considered on the clinical and cost-effectiveness of the medicine, as well as the input from patient groups (PGs), patients, and carers. In 2020, SMC commenced a stakeholder evaluation of the DAD including a workshop with PGs and public partners (members of the public who volunteer with SMC) to explore the potential for using the DAD more widely.
Methods. PGs and public partners, all having significant experience of engaging with SMC, participated in the workshop. Feedback was gathered using virtual post-it notes, collated and analysed for key themes. We also gathered oral feedback from participants. Sample DADs were distributed for two medicines recently appraised, one of which included a Patient and Clinician Engagement (PACE) meeting. These were chosen because they reflect different aspects of public and patient involvement at SMC, including how this is presented in the DAD.
Results. Overall, the workshop participants (n=7) recognised the DAD was a useful document for the clinicians who are its primary audience. Its language was perceived to be challenging, including complex information that is not accessible to a wide audience and may only be fully understood by those with a good understanding and knowledge of HTA. This was a key barrier to using the DAD more widely, in particular the health economics information. Suggestions for broadening the audience of the DAD included summaries of key points and an introductory section clarifying the purpose of the DAD and its intended audience, along with signposting to the plain language summary produced by SMC. These will be implemented where possible.
Conclusions. Improving how SMC communicates decisions to patients and the public, by working in partnership with these stakeholders, will help strengthen public involvement throughout the HTA process.

OP64 NICE Listens: Engaging The Public On How To Address Health Inequalities In Health Technology Assessment And Guideline Development

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Introduction. Involving and engaging the public is an essential step to engender trust and confidence in HTA organizations. In 2021 the National Institute for Health and Care Excellence (NICE) launched NICE Listens, a new programme of deliberative public engagement seeking to address topics that have complex social, moral, or ethical dimensions. Health inequalities (HI), defined as unfair and avoidable differences in health across populations, was the first topic. The aim was to understand how the public would like NICE to act in regard to HI. Despite repeated attempts to tackle HI in England, the gaps in life expectancy between the most and least deprived continue to widen. NICE has committed to addressing HI in its five-year strategy and NICE Listens forms part of a comprehensive engagement strategy to understand how best to do this.

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