Introduction. In many low- and middle-income countries scarcity of local data on health outcomes and health-related quality of life (HRQoL) is a hindrance to conducting cost-effectiveness analyses. The Tunisian National Authority for Accreditation and Assessment in Healthcare (INEAS) developed a set of methodological guidelines to support pharmaceutical companies in the submission of health technology assessment (HTA) dossiers. The guidelines include INEAS' methodological choices for pharmacoeconomic analysis, which take into consideration the specificities and constraints of the Tunisian context. We aimed to present the principal recommendations of the Tunisian guidelines for pharmacoeconomic studies, with a focus on patient-reported outcome and HRQoL measurement.
Methods. The INEAS pharmacoeconomic analysis guidelines were reviewed and the recommendations regarding outcome measurement and HRQoL were retrieved and reported.
Results. To populate the economic model, INEAS recommends using the best available evidence. Health outcomes should be measured in terms of life-years gained and quality-adjusted life-years (QALYs); disability-adjusted life-years can be used but are not the preferred method. To estimate QALYs, INEAS favors the indirect measure of patient preferences with a validated measurement instrument. Alternatively, other measures of utility may be used, including those identified through a systematic review of the scientific literature and the publications of other HTA agencies. Justification and details of the source of the data must be provided. The utility values selected should be recent and representative of the Tunisian population, as far as possible. The guidelines refer to a set of generic preference-based HRQoL instruments, including the EuroQol five-dimensions (EQ5D), the Health Utilities Index Mark 2 (HUI2) and Mark 3 (HUI3), and the Short-Form Six-Dimension (SF-6D), but do not provide any explicit recommendations on their use.
Conclusions. The INEAS pharmacoeconomic analysis guidelines adhere to international best practices but provide more flexibility for overcoming the lack of local data. The INEAS economic guidelines constitutes a further milestone in the process of implementing HTA in Tunisia and in the Middle Eastern and African regions.

PP47 Modelling Non-small Cell Lung Cancer Treatment: Predicted and Observed Impact Of Immunotherapy In The Netherlands

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Introduction. Patients treated with immunotherapy are divided into two subgroups: (i) long-term survivors (LTS) and (ii) moderate survivors. Nevertheless, clinical trials (RCTs) report only average treatment effects such as hazard rate (HRs). Health economic-models often only input average treatment effects, even though it has been shown that accounting for the LTS subgroup is crucial for accurate projection of long-term survival under immunotherapy. We investigated the incorporation of a statistical mixture cure model (MCM) in a health-economic model for lung cancer as a way to account for LTS while incorporating reported average RCT-based treatment effects.
Methods. We developed a microsimulation model describing disease progression under three treatment lines in advanced lung cancer using Dutch real-world data of chemotherapies treated patients. Here we focus on first-line treatment, for which we used gompertz distribution to simulate time-to-progression. To simulate the impact of immunotherapy, we adjusted base-model assuming MCM for first-line treatment, where the LTS subgroup was not at risk to progress, but instead die from background mortality. The subgroup of moderate survivors on the other hand are at risk to progress with adjusted progression-free HR (PF-HR). We simulated the model with size of LTS (prop_LTS) ranging from 14-34 percent (keynote-001 five-year overall survival [OS], 95% confidence interval) while fixing average RCT PF-HR at 0.5. Model predictions under the different prop_LTS were compared to real-world Dutch OS as well as the long-term RCT five-year OS.
Results. With respect to observed short-term survival outcomes, model predictions were insensitive to assumptions regarding the size of the LTS subgroup. However, to match the five-year RCT OS rate reported (32%), the prop_LTS had to be equal to 34 percent. Under this latter setting for the prop_LTS, the progression HR in the subgroup of moderate survivors was calibrated to be 1.1.
Conclusions. The use of a mixture cure model improves long-term model-based projections with the implicit assumption that moderate survivors have little or no treatment benefit.

PP48 A Micro-Costing Study For Circulating Tumor DNA testing In Oncology

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Introduction. Circulating tumor DNA (ctDNA) is a promising new biomarker with multiple potential applications in cancer care. As part of the "ctDNA on the way to implementation in the Netherlands (COIN)" project, an early, comprehensive Health Technology Assessment (HTA) is ongoing. Information about the costs of ctDNA testing is essential for implementation. Estimating the total cost associated with ctDNA-testing is challenging due to variation in the workflow, wide range in purchase and operational costs of the platforms, and the highly dynamic field. As a first step in the HTA, the aim of this study was to develop a flexible micro-costing

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framework and open-access model for consistent cost calculation of ctDNA-testing.
Methods. First, the complete diagnostic workflow of ctDNA-testing was mapped based on expert discussions. This step-wise workflow was used as the foundation of the framework. Second, the activity-based costing method was used and included costs for personnel, materials, equipment, overhead, housing, and test failures. Third, the framework was validated by experts and by applying the cost calculation model to six case studies.
Results. The diagnostic workflow was mapped from blood sample collection to reporting the diagnostic findings. The framework was developed from a Dutch perspective and takes into account the testing volume. The total cost per sample for the case studies with different workflows and testing volumes ranged from EUR 168 to EUR 7,638.
Conclusions. The developed micro-costing framework can be used to calculate the costs for ctDNA-testing for different workflows. The results from the case studies show the wide range of costs for ctDNA-testing and that the costs are determined by the choice of platform, setting, and testing volume. The open access model allows users to adapt and specify parameters in the diagnostic workflow matching their setting and can be used to support investment decisions and future cost-effectiveness studies.

PP49 Financing The Line Of Care In The First Biochemical Relapse Of Prostate Cancer After [^{68}Ga] PSMA PET- CT

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Introduction. It is estimated that prostate cancer will reach 66 thousand by the triennium 2020-2022 according to the National Cancer Institute (INCA). After initial diagnosis and staging the patient may undergo radical prostatectomy and/or curative radiotherapy. In patients with biochemical relapse (PSA >0.2 ng/ml) initially treated with radical prostatectomy, salvage external radiotherapy is indicated. The [^{68}Ga] Prostate Specific Membrane Antigen Positron Emission Tomography-Computed Tomography (PSMA PET-CT) scan is mainly used for localization of prostate cancer in the setting of first biochemical recurrence and can significantly influence the clinical management of the patient.
Methods. The overall objective of this work is to perform a treatment cost analysis for patients in first biochemical recurrence of prostate cancer after curative radical prostatectomy and after performing [^{68}Ga] PSMA PET-CT from the perspective of the Brazilian Health System (SUS). A decision tree was constructed through consultation with experts to outline the patient's entire treatment. Values per modelled therapeutic procedure were surveyed in two different scenarios, with and without [^{68}Ga] PSMA PET-CT. The average treatment in scenario 1 was stereotaxic radiation therapy (SBRT), and rescue radiotherapy and androgen deprivation therapy (ADT). In scenario 2, it was salvage radiotherapy and ADT. The reimbursement table was prepared from data collected by SUS system. Variations were analyzed using a sensitivity study. Total average values included: individual procedure, according to medical management (up to 3 years) and population percentage with and without [^{68}Ga] PSMA PET-CT.
Results. Values were calculated in Brazilian currency (BRL) for each procedure. The total amount calculated for scenario 1 was BRL 264,965,465.00 (USD 55,642,747.65) and for scenario 2 was BRL 123,585,612.72 (USD 26,162,978.67).
Conclusions. The reimbursement of line of care adopted after [^{68}Ga] PSMA PET-CT is an important information to expand access to the Brazilian population. It shows an increased cost with [^{68}Ga] PSMA PET-CT adoption. A prospective study should be considered with high follow up.

PP51 Strengths And Limitations Of Migraine Management Guidelines In The USA and Europe: A Targeted Literature Review

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Introduction. Migraine, the second leading cause of disability worldwide, remains underdiagnosed and undertreated. Considering the high burden of migraine, we analyzed the strengths and limitations of existing migraine management guidelines.
Methods. A targeted literature review was conducted using MEDLINE on 24 March 2021 to identify current migraine management guidelines (including policies and position statements) published in the English language from France, Germany, Italy, Spain, the United Kingdom, and the USA. This was supplemented by a gray literature search. Disease state or pharmacological management guidelines for adults with migraine comprising any of the following perspectives were included: health economics; payer; health technology assessment; treatment access; and impact of guideline implementation on economic or disease burden. Guidelines were analyzed using the Centers for Disease Control and Prevention (CDC) policy analytical framework, which comprises three domains: problem identification, policy analysis, and strategy or policy development, with ranking criteria for each.
Results. Of 39 selected guidelines, 25 adequately identified problems related to migraine, 35 sufficiently reviewed the literature on migraine treatment, three failed to cite literature, and one lacked sufficient content. Twenty-three guidelines targeted healthcare professionals. Almost all guidelines lacked a stepwise migraine treatment approach; only the American Academy of Family Physicians guideline offered first- and second-line treatment options. Four guidelines mentioned current political forces, and coverage of economic or budgetary impact aspects was limited. Numerous guidelines described the substantial economic burden of migraine and were categorized as 'high' for benefits. Public health impact was categorized as 'high' for 28 guidelines and budgetary impact was rated as

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