Companies face multiple challenges when determining their economic value due to their complexity and high cost, while payers must balance the need for these vital innovations with sensitivity to rising costs. The study objective was to evaluate the current HTA frameworks in Europe and identify the potential barriers/solutions to reimbursement of brand-on-brand (BoB) combination therapy.

METHODS:

A targeted literature review of HTA agency websites was undertaken to identify any literature/guidance relating to HTA decision-making for combination oncology therapies in France, Germany, Sweden, and the UK.

RESULTS:

In France and the UK, BoB HTA decisions reflect clinical- and cost-effectiveness. Combination therapies have been accepted for use in France and the UK, for example, dabrafenib plus trametinib, are assessed through standard HTA processes, exemplifying that positive reimbursement is not unattainable where there is an unmet need and high clinical value. Despite this flexibility, many therapies will fail to prove their cost-effectiveness, resulting in delays or arbitrary pricing decisions. Potential solutions are the use of the 'efficiency frontier', as typified by the German HTA system, giving more 'scope' to expensive innovations; or the Swedish HTA approach, which applies variable cost-effectiveness thresholds according to therapeutic area, disease severity, and social criteria. Other possibilities include indication-specific pricing, multiple-criteria decision analysis, and net monetary benefit with willingness-to-trade weights. One likely issue to arise is when different companies are involved, necessitating co-operation. In this scenario, a simplistic solution would be arbitration of the division of the combined price, circumventing the need for HTA agencies to make changes to decision-making criteria.

CONCLUSIONS:

Constructive debates and collaboration between industry and decision-makers are vital to achieve a harmonized HTA process for high-cost combination therapies which offer advanced benefits and improved safety outcomes, whilst satisfying HTA bodies and providing better access for patients.

PP41 Toward Rules For Stakeholders' Involvement In Regional Health Technology Assessment Units

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INTRODUCTION:

Health services users must participate in health technology assessment (HTA) activities. Users, caregivers, and citizens have the practical experience of healthcare and social services. HTA outputs are more useful when values and preferences of patients, caregivers, and citizens are taken into account. Despite this, the best methods of stakeholders' involvement, timing for doing so, selection of participants, and the type of users to recruit depending of methods and contexts remain unspecified. Herein, an involvement policy has been developed to formalize the participation of users, caregivers and citizens in the services offering of a regional HTA unit.

METHODS:

A steering committee composed of stakeholders (i.e. user, caregiver, citizen, User Experience Service representative, manager, provincial HTA body representative, HTA unit members) was constituted to discuss user involvement in a regional HTA unit. A preliminary vision statement emerged from this committee, and included objectives and principles for users, caregivers, and citizens participation. This statement was deliberated using a Delphi consensus method. Three rounds of deliberations were needed to reach a strong consensus.

RESULTS:

Four objectives and four principles that should underlie the development of an involvement policy reached consensus. Participants agreed that users, caregivers, and citizens should: i) propose principles of involvement for each HTA projects; ii) co-realize evaluations with HTA professionals; iii) contribute to evaluation processes; and, iv) be involved in some management decisions of regional HTA units. Four principles to formalize users, caregivers and citizens' involvement in regional HTA units also emerged. These principles were about utility

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and feasibility of involvement as well as ethical and methodological considerations.

CONCLUSIONS:

Users, caregivers, and citizens must participate in the activities of regional HTA units. Each of them have different roles and can contribute to evaluation processes. Their involvement in HTA activities is warranted for co-producing better evaluation more adapted to users' needs in healthcare and social services.

PP43 MACBETH In Brazilian Hospital-Based HTA: Thrombosis Prophylaxis

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INTRODUCTION:

Instituto Nacional de Traumato-Ortopedia (INTO) administrates the Enoxaparin drug to prevent deep vein thrombosis (DVT) after extensive orthopedic surgeries. Nevertheless, new oral anticoagulants that offer more comfort and efficacy, but present higher risk of bleeding, have been putting in question the use of Enoxaparin. Making use of the MACBETH method, this study develops a Multicriteria Value Measurement model to evaluate such drugs.

METHODS:

MACBETH was applied in helping INTO to evaluate two drugs (Rivaroxaban and Enoxaparin), taking into account drug benefits and risks, through a series of interviews and decision conferences attended by INTO stakeholders that acted as evaluators in the model-building process, supported by M-MACBETH DSS (www.m-macbeth.com). Following MACBETH preference elicitation process, the evaluators were asked to make qualitative pairwise comparison judgements of difference in value between stimuli for constructing quantitative value and weighting scales. These scales allow measuring the relative value of the drugs on each evaluation criterion, separately and globally. The value measurement process was informed by a literature review and meta-analysis of randomized clinical trials with a critical appraisal of the evidence.

RESULTS:

We report a model-structure with eight criteria, hereafter presented by decreasing order of their weighting: Death from any cause, Clinically significant bleeding, Proximal DVT, Distal DVT, Existence of antidote, Thrombocytopenia, Costs, and Comfort. From the value model developed and after performing sensitivity and robustness analyses, Rivaroxaban was considered a robust option for thrombosis prophylaxis, under the MACBETH value framework and at the light of a simple additive aggregation of those eight criteria.

CONCLUSIONS:

This study shows how a value measurement socio-technical framework, combining MACBETH with scientific evidence within a participatory group evaluation process, can support health technology assessment in a user-friendly and effective way. MACBETH facilitates transparent and robust decision-making in the face of complex evaluation problems that the hospital often faces.

PP44 Effectiveness Of Insulin Glargine Versus Detemir In Type 1 Diabetes

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INTRODUCTION:

The use of long-acting insulin analogues have been reported in patients with type 1 diabetes mellitus who exhibit important oscillations of their daily blood glucose, although the therapeutic benefits are lacking. The aim of this study was to evaluate the effectiveness and safety of the insulin analogue glargine compared detemir to support health decision-making.

METHODS:

We performed a systematic review with meta-analysis of observational studies (cohort and registry), available in the MEDLINE (Pubmed), Latin American and Caribbean Health Sciences (LILACS), EMBASE and Cochrane Library databases (accessed August 2017), including research in

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