METHODS:

The framework and tool were tested using two types of technologies: high volume (underpads, diapers) and highly specialized (transcatheter aortic valve implantation). Companies were invited to participate following standard procurement rules. For each dimension, criteria, metrics and weights were defined, using multidisciplinary hospital teams. In parallel, companies were asked to do the same. Product performance scores were obtained from companies' information. Challenges to implement MEAT in real life were identified through face-to-face meetings.

RESULTS:

The process was well perceived by companies and hospital. Nevertheless, the level of information provided by companies was heterogeneous (quantity and quality). A match in the cost and outcome criteria was observed between hospital and companies; but relative weights assigned differed. Value propositions and robustness of information provided by companies varied across technologies and size of companies. Implementing the MEAT VBP framework and tool need extra time and knowledge.

CONCLUSIONS:

MEAT VBP value technologies ahead of price, leading to the most economic advantageous purchasing. Nevertheless its implementation in real life is limited.

OP169 Usability Evaluation Of A Portable Dry-Electrode Electrocardiography Device In Vietnam

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INTRODUCTION:

According to the Vietnamese Cardiovascular Association, one-fifth of Vietnam's population is suffering from cardiovascular disease (CVD) – now the leading cause of death in the country that accounts for about one-third of total deaths every year. Yet affordable and convenient solutions to monitor and detect CVDs remain limited and not available nationwide. This study aimed to investigate the usability of a portable dry-electrode electrocardiography (ECG) device, paired with a mobile phone, in supporting ECG service delivery in Vietnam.

METHODS:

An evaluation study was designed to combine a portable dry-electrode ECG device to measure and a mobile phone to receive and record ECG signals. Healthy young college students were invited to participate in the study. Three rounds of ECG measurement were administered for each of the participants. Usability of the device was assessed through the reliability of the measures and feasibility of use during intervention. Standard error of measurement (SEM) and intra-class correlation coefficient (ICC) estimations were used for reliability, while structured questionnaire administered before and after measures was used for feasibility assessments.

RESULTS:

A total of 234 participants enrolled in the study. No major difference was found in SEMs between trials one and two (4.96 percent, 90% CI: 4.61 − 5.37) and two and three (4.14 percent, 90% CI: 3.85 − 4.48). A slight improvement was observed in ICC of trials two and three (0.95, 90% CI 0.94 − 0.96) in comparison to one of trials one and two (0.94, 90% CI: 0.92 − 0.95). The SEM and average ICC of all trials were 3.41 (90% CI: 3.17 − 3.69) and 0.96 (90% CI: 0.95 − 0.96) respectively. Forty-five percent of participants thought the device would be suitable for their parents while 69 percent thought the device would benefit their grandparents the most.

CONCLUSIONS:

High consistency of measures demonstrated that the device is reliable to provide ECG service delivery. The study also showed great potential of device usage in primary health care of Vietnam.

OP170 Regulatory And Health Technology Assessment Considerations In Alzheimer's Disease

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INTRODUCTION:

There has been a move towards the development of disease-modifying agents in Alzheimer's disease (AD) and it is likely that early disease-modifying treatments will initially be offered to people who have positive AD markers and mild cognitive impairment (MCI). Consequently, disease-modifying drugs will have distinctive features as compared to currently licensed symptomatic treatments, which makes the implications of these new agents for regulatory and health technology assessment (HTA) processes unclear.

METHODS:

The ROADMAP (Real-world Outcomes across the AD spectrum for better care: Multi-modal data Access Platform) project provides the foundation for a European data platform for real-world evidence in AD, and established an expert advisory group (EXAG) consisting of regulatory and HTA experts. This presentation will summarize the key lessons from the first year of ROADMAP's EXAG and identifies the next steps that are required to prepare Europe's healthcare systems for a disease-modifying drug.

RESULTS:

The EXAG identified a need for: (i) establishing the rationale for the selection of priority outcomes in pre-clinical AD and MCI; (ii) establishing accepted outcomes for defining prevention of AD or delayed AD onset; (iii) exploring modern technology that could assist in testing cognition that could easily be used in clinical practice; and (iv) establishing caregiver-relevant outcomes (e.g. quality of life, loss of income, carer time) that are important to capture; and found that not all evidence to support modelling assumptions can be generated through RCTs, making the case for using real-world evidence.

CONCLUSIONS:

Many of the challenges that the EXAG identified can be solved by generating better real-world data in AD. There is a clear need to agree on the outcomes that will facilitate and inform regulatory and HTA decision-making. Once the gaps in the availability of outcomes in AD will be closed, we will be one step closer towards being ready for a disease-modifying drug.

OP171 Does Parallel Regulatory-Health Technology Assessment Reviews Affect Time To Health Technology Assessment Decisions?

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INTRODUCTION:

Timely recommendation by Health Technology Assessment (HTA) agencies for drug reimbursement is critical to ensure patient access to medicines of therapeutic value. In this study, HTA performance was examined in terms of their outcome and timing by looking at how 103 drugs, which gained regulatory approval from 2013 to 2015, were assessed by HTA agencies from 2014 to 2016.

METHODS:

Products must have received regulatory approval from one of the following regulatory agencies: EMA (Europe), Health Canada (Canada) and TGA (Australia). The first HTA recommendations were then collected from PBAC (Australia), CADTH (Canada), HAS (France), IQWiG (Germany), SMC (Scotland) and TLV (Sweden). The HTA decisions were classified as positive, positive with restrictions, negative and multiple.

RESULTS:

Eighty-four drugs were approved in Europe before Australia and Canada. Of the studied HTA agencies, PBAC had the highest percentage of products recommended within a year from regulatory approval (93 percent). In addition, Australia had the shortest median time between first regulatory submission by any of the three agencies and HTA recommendation (553 days) as compared to Europe (616 days) and Canada (722 days). This can be attributed to the TGA/PBAC parallel process. However, Australia has the highest proportion of products receiving a negative PBAC recommendation (62 percent).

CONCLUSIONS:

The majority of drugs were first submitted for reimbursement in Europe, but the time from regulatory submission to HTA decision was the fastest in Australia.

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