pilots have identified other areas that could benefit from further refinement, for example the active engagement of patient group representatives and clinical experts, rules and principles related to the handling of confidential information.

CONCLUSIONS:

Based on the limited number of REA pilots for medicines it is too early to draw final conclusions on the state of EU-level collaboration. But first signals indicate a positive development compared to REA pilots conducted in JA2. Interim evaluations are recommended to assess progress, and capture learnings for future pilots.

OP164 Hospital Budget Impact Of High-Cost Drugs: The Case Of Nusinersen

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INTRODUCTION:

Nusinersen is an orphan drug for spinal muscular atrophy (SMA) recently approved for marketing. Its high cost, striking but limited evidence of efficacy, and strong demand by media and patient organizations have generated a health policy conflict. We analyze the flaws of available evidence on nusinersen and its budget impact at a pediatric hospital, and report a collaborative strategy for drug procurement and financing.

METHODS:

Nusinersen is the highest-cost drug assessed by our hospital-based health technology assessment (HB-HTA) program so far. At the time of our assessment, only interim-analysis data of the pivotal randomized trial submitted to Federal Drug Administration (FDA) for approval and the European Medicines Agency (EMA) report containing unpublished final results were available. These secondary sources and other published phase II results were appraised. As a referral hospital, we concentrate most of the 300 SMA patients in our country. Hospital budget impact estimation included drug and hospitalization costs for the first and following years. The HTA report was submitted to the Ministry of Health to address this financing issue.

RESULTS:

The available evidence of efficacy raised serious methodological and clinical uncertainties. First-year treatment cost per patient was estimated in ARS 13,008,688 (USD 752,000, 10 percent of pharmacy annual drug budget). Hospital budget impact (70 eligible patients) was ARS 910,608,160 (USD 52,000,000; 18 percent of total annual hospital budget). Our recommendation was to contact central level authorities to resolve both drug financing and patient access by negotiating a shared-risk approach for an expanded access program, allowing further data collection for reassessment after 12 months. This, in turn, fostered mutual collaboration and consensus within the health system where several lawsuits were demanding drug coverage. Negotiation with the industry was initiated by the Ministry.

CONCLUSIONS:

This case is a clear example of forthcoming ultra-high-cost drugs unaffordable by hospital budgets. Their acquisition opportunity cost is a health policy matter requiring to display collaborative coping strategies with Ministries and other stakeholders including industry.

OP166 How Responsive Is Industry To Value Based Procurement?

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INTRODUCTION:

The European Union (EU) directive (2014/24) on public procurement strives to stimulate innovation and seeks for methodologies to implement a quality/cost based approach to search for the most economically advantageous tendering (MEAT). MedTech Europe launched the MEAT value-based-procurement (VBP) framework and tool which considers product's value from different perspectives/dimensions. Results from the first EU pilot, testing the feasibility to use the MEAT framework at a university hospital, are presented.

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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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