

hospital length of stay (4.16 days; $p < .0001$). When stratified by treatment approach, the adjusted incremental cost was USD13,862 for TAVR ($p < .0001$) and USD16,656 for SAVR ($p < .0001$).

CONCLUSIONS:

While infrequent, postoperative delirium significantly increased hospital cost and length of stay following transcatheter or surgical aortic valve replacement (AVR). Despite a significantly higher comorbidity burden, TAVR was associated with lower postoperative delirium rates compared to SAVR. Moreover, post-TAVR delirium may be associated with less resource consumption than post-SAVR delirium. Future studies should seek to determine whether general anesthesia avoidance in appropriately selected transfemoral TAVR patients can further decrease rates of delirium.

OP16 A Patient-centered Value Framework For Healthcare In Hemophilia

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INTRODUCTION:

Hemophilia is a rare, inherited bleeding disorder affecting an estimated 400,000 people worldwide (1). Characterized by spontaneous bleeding and long-term, irreversible joint damage, persons with hemophilia are often limited in normal day-to-day activities, including work/school, and require comprehensive care at specialized treatment centers. With replacement therapies extending survival by decades and vastly improving quality of life (QoL), routine prophylaxis is considered the standard-of-care in developed countries. However, due to the cost of replacement factor, access to treatment remains a challenge, and increased scrutiny over funding has been augmented by growing demands on healthcare budgets (2). Thus, the hemophilia community shares a unified goal of

objectively defining patient-centered value in hemophilia care.

METHODS:

Using a three-tiered outcomes hierarchy model initially described by Porter (3), an international, multidisciplinary panel of health economics outcomes researchers and hemophilia experts developed a value framework for decision makers to assess value of various healthcare interventions in hemophilia.

RESULTS:

The three tiers for assessing value are: (i) Health status achieved/retained; (ii) Process of recovery; and (iii) Sustainability of health. Tier one measures survival, quality of life (QoL), and hemophilia-specific outcomes of bleeding frequency, musculoskeletal complications, and severe bleeds, as well as function/activity (that is, lifestyle impairment). Tier two measures time to initial treatment or recovery and time missed at education/work, as well as disutility of care (that is, inhibitor development, pathogen transmission/infections, orthopedic intervention, and venous access). Tier three measures avoidance of bleeds, maintenance of productive lives, and long-term health, while capturing long-term consequences of insufficient therapy or age-related complications. Applicability of the framework can be demonstrated in areas of healthcare delivery, treatment regimen, and innovation for new therapies.

CONCLUSIONS:

This value framework represents an initial collaboration with stakeholders to define and organize an array of patient-centric outcomes of importance in hemophilia into a practical tool that can influence treatment and funding decisions in hemophilia care.

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OP19 Unlocking The Potential Of Established Products: Need For Incentives

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INTRODUCTION:

Re-purposing of established products (EPs) – defined as marketed for 8 years or more – may represent a high value for patients and society. It has been recognized by the European Commission as an important factor contributing to greater access to new therapies. Due to a lower development cost, it could also represent a cost-effective alternative and help to reduce pressure on healthcare budgets. However, it is perceived that no financial incentives exist for the pharmaceutical industry to invest in new indications for EPs. The objective of this research was to review current European regulations and propose strategies stimulating development in this field.

METHODS:

We performed a targeted literature review and held two international expert panel workshops to discuss current policies and their implications, and issue recommendations for changes.

RESULTS:

Within the current regulatory framework EPs face price cuts due to generic competition, reference pricing (RP), price re-negotiations or systematic price cuts, after a period of marketing presence. Extension of indications

does not permit to increase or maintain the price. Generic substitution regardless of indication poses another challenge. Limited incentives in the form of an additional year of market protection exists only for new indication(s) registered within the first 8 years following initial approval. The expert panel proposed several strategies to stimulate development in this field, including: (i) extending the period in which registering a new indication results in additional market protection beyond 8 years and extending the duration of additional market protection; (ii) delaying inclusion in RP for EPs with a new value adding indication; (iii) establishing a differential pricing by indication; (iv) preventing temporarily generic substitution when an EP is prescribed for a new indication.

CONCLUSIONS:

Current regulations represent a serious disincentive to develop new indications for EPs. Regulatory and pricing policy changes are needed to stimulate development in this important field.

OP21 Involving Clinical Experts In Prioritizing Topics For Health Technology Assessment: A Randomized Controlled Trial

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INTRODUCTION:

The National Institute for Health Research Health Technology Assessment (NIHR HTA) Programme commissions research to inform health services in the United Kingdom. The program prioritises research ideas from literature, guidelines, patients, and clinicians, to decide which research should be funded. We get clinical input on these ideas through (i) committees of clinicians and patients and (ii) seeking written advice from multiple clinicians — a refereeing process. Chairs of our committees suggested that the material we sent to clinicians was too extensive and the method of