POSC289 Cost-Effectiveness of Vagus Nerve Stimulation with Anti-Seizure Medication Versus Anti-Seizure Medication Alone in the Management of Drug Resistant Epilepsy in England

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teams of 2 reviewers was employed at each stage with reconciliation of any misalignment within teams or a third reviewer. Data on definitions employed for each term as well as the context for the definition was extracted into a recording spreadsheet. ***Results:*** The search yielded 2,610 abstracts of which 545 full text articles were independently reviewed leading to 214 eligible papers for data extraction. Altogether we found 337 definitions of which 154 were high level terms and 183 were secondary terms. We identified four unique definitions of digital health, mainly defining the terms as a synonym or overarching concept of eHealth, mHealth, telehealth "mHealth" was the most popular high level term 75 (18 original +57 referenced) followed by "eHealth" and "telehealth" with 48 (18+30), and 27 (2+25) total (original + referenced) definitions, respectively. ***Conclusions:*** Our research suggests that including more specific information in the Medical Subject Headings (MeSH) such as the healthcare setting, the specifics of the technology used, patient population and outcomes under consideration as well as the comparison used would enhance future research efforts.

POSC288
EVIDENCE REQUIREMENTS IN THE REGULATORY AND REIMBURSEMENT PROCESSES OF DIGITAL THERAPEUTICS: INSIGHTS FROM THE US, EU4 AND UK

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Objectives: Digital Therapeutics (DTx) are software programmes increasingly used to diagnose, manage and prevent chronic and behaviour-modifiable diseases. The evidence requirements for the regulatory approval and the reimbursement (including health technology assessments – HTAs) for these technologies present distinct challenges for developers, clinicians and patients alike. We derive a set of frameworks to characterise the pathways and the type of evidence supporting the regulatory approval and reimbursement or HTA of DTx in the United States, EU4 (France, Italy, Spain and Germany) and the UK. ***Methods:*** A pragmatic literature review was conducted in BIOSIS Previews®, Embase®, MEDLINE®, QUOSA®, using keywords related to DTx, regulatory and reimbursement frameworks (January 2010 - June 2021). Searches were supplemented with gray literature and official guidance documents. Databases (e.g., online FDA) were searched for DTx approved to date, using Python. Evidence was extracted on: the classification of DTx; the expected design of clinical studies; the role of real-world evidence (pre and post license); the required economic evidence. ***Results:*** Across all assessed countries, the evidence required in the regulatory and reimbursement processes of DTx depends on the level of risk associated with them and their claimed degree of innovation. Importantly, clinical and economic evidence is often generated after DTx are licensed and reimbursed, through their own use, leading to a broader role of real-world data and novel studies methodologies. However, the evolution of evidence requirements appears to take place in a fragmented and reactive manner, particularly in the reimbursement assessment of DTx, with several gaps remaining unaddressed. ***Conclusions:*** DTx are unique technologies, with the potential to reshape the relationship between patients and healthcare providers. Regulators and Payers alike need to ensure that their guidance on evidence requirements maintains the pace of the rapid evolution of these technologies, enabling their adoption whilst ensuring critical risk considerations are adequately addressed.

POSC289
COST-EFFECTIVENESS OF VAGUS NERVE STIMULATION WITH ANTI-SEIZURE MEDICATION VERSUS ANTI-SEIZURE MEDICATION ALONE IN THE MANAGEMENT OF DRUG RESISTANT EPILEPSY IN ENGLAND

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Objectives: To estimate the cost-effectiveness of vagus nerve stimulation (VNS) as an adjunctive therapy to anti-seizure medication (ASMs) when compared with a strategy of ASMs alone for the management of drug resistant epilepsy (DRE). ***Methods:*** A five health state cohort transition model was developed, with a 10-year time horizon, a 3-month cycle length and an English National Health Service perspective. Health states were defined by a percentage reduction in seizure frequency and aligned with randomised trial data informing the first cycle transition probabilities. Thereafter, non-VNS patients remained in state, while a systematic literature review informed further VNS patient transitions up to year 2, after which they remained in state (subject to death or device discontinuation). Extrapolation of registered VNS implant Kaplan-Meier data informed explantation and replacement probabilities. Health state utilities were age and gender adjusted. Published estimates, combined with trial data regarding mean seizure frequency, informed health state resource use. In addition to the base case analysis, scenarios, one-way deterministic and probabilistic sensitivity analyses were undertaken. ***Results:*** Adjunctive VNS has an incremental cost-effectiveness ratio of £17,711 per quality-adjusted life year (QALY) when compared to a strategy of ASMs alone. Results were most sensitive to unit costs of inpatient care, with VNS expected to be dominant if the cost of a non-elective care admission exceeded £2,225. Using the UK National Institute of Health and Care Excellence threshold of £20,000 to £30,000 per QALY, VNS was cost-effective in the majority of scenarios evaluated, inclusive of varying the costs of device implantation, replacement and explantation by 15 percent. ***Conclusions:*** Management of DRE with VNS is a cost-effective option in comparison to ASM therapy alone. This finding is driven by a reduced seizure frequency with VNS, which is consequently expected to improve a patient's health-related quality of life and reduce downstream medical costs.

POSC290
THE MONITOR INTERVENE PREDICT (MIP) VALUE FRAMEWORK: A STRUCTURED APPROACH TO MEASURING HOW DIGITAL HEALTH CAN IMPROVE HEALTH OUTCOMES AND REDUCE BURDEN OF ILLNESS

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Objectives: To outline a value framework for the contribution of digital health to overall disease management from multiple perspectives. ***Methods:*** A targeted literature review (TLR) explored the emergence of value frameworks in the context of key trends in digital health and disease management. Selection criteria: value frameworks, digital, connected, wearable(s), monitoring, intervention, prediction/predictive, analytics, outcomes, HRQOL. A survey of payers (EU5. N=5 per market) was undertaken to externally validate hypotheses generated on the basis of the TLR, and to explore the implications of the insights for improving health outcomes and reducing burden of illness. ***Results:*** The TLR indicated:

- Healthcare is becoming more "connected" with multiple components - digital patient-level, real-world/real-time monitoring; software, algorithms, and apps informing interventions; and analytics predicting outcomes.
- Value Frameworks are becoming increasingly useful and important for structuring the value of holistic disease management

The payer survey confirmed:

- There is a perception of a disconnect between the health outcomes reported in randomized clinical trials and the outcomes seen in a "connected health" environment that embraces real-time monitoring, data informed intervention, and outcomes prediction
- Value contribution may be segmented in different ways:
  - Segmentation 1 based on 3 elements: MONITORING, INTERVENTION, and PREDICTION
  - Segmentation 2 based 3 outcomes: ECONOMIC, CLINICAL, and HUMANISTIC
  - Segmentation 3 based on 3 stakeholder groups: PATIENT, PAYER, and PHYSICIAN
- Payers see value in all 3 elements of the MIP paradigm but see potential ethical, legal, and regulatory challenges emerging from the intervention element

Conclusions: The MIP Value Framework resonated well with payers in this exploratory research. Further exploratory research is recommended with patients and physicians. For the framework to be used in clinical and health technology assessment consideration needs to be given to methodological and clinical validation.

POSC291
ACCELERATION OF DIGITAL HEALTH TECHNOLOGIES IN VALUE-BASED PAYMENT SYSTEMS

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Objectives: To achieve value-based healthcare (VBHC), outcomes that are meaningful to patients should be measured. In the field of dialysis some countries have implemented value-based payment systems to ensure that these outcomes are met by measuring Key Performance Indicators (KPIs). Digital health technologies (DHT) have the potential to support in maximizing these outcomes resulting in a financial upside potential. This study aims to explore which countries have value-based payment systems in dialysis and where investing in DHTs can be of the highest value for providers. ***Methods:*** We have performed a survey of all dialysis provider countries in Europe, Middle East and Africa (n=29) in order to identify value-based driven payment systems. For the countries with such a payment setup we asked for a list of required KPIs to achieve the add-on reimbursement. ***Results:*** We identified four countries with a value-based payment system: France, Czech Republic, Portugal and South Africa. KPIs to achieve the add-on reimbursement in renal care in these countries are: survival- and hospitalization-rate; mineral and bone disease (phosphate); anemia management (hemoglobin and ferritin); dialysis adequacy/treatment compliance (>= 3 sessions/week); quality of dialysis water (monthly water quality tests according to guidelines); nutritional status; number of patient on the transplant waiting list. ***Conclusions:*** Some DHT that are targeting these KPIs are already being