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process does not include assessment of a budget impact model as suggested by the ESF.

MT3

COMPLETENESS AND CONCORDANCE BETWEEN ELECTRONIC MEDICAL RECORDS (EMR) AND SUBMITTED INSURANCE CLAIMS IN GERMAN HOSPITALS UTILIZING PERCUTANEOUS LEFT VENTRICULAR ASSIST DEVICES (PLVADs): CONSIDERATIONS FOR OUTCOMES RESEARCH

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Objectives: Real-World Evidence (RWE) are being used to assess medical technologies. Within the context of complex conditions that challenge traditional research designs, RWE research supports the safety, efficacy, and long-term effectiveness of innovations. Nevertheless, little is known on exactly how many and how well various covariates are captured in systems designed originally for financial needs instead of clinical research. Failure to appropriately differentiate records can lead analyses to inappropriate conclusions. We sought to understand any loss of information in the submission process when compared with EMR data of patients treated with PLVADs in two major German hospitals. Methods: Six consecutive clinical cases were extracted from EMR systems encompassing the patient discharge letter, the catheterization lab protocol, any internal and external transfer letters, laboratory values, medication administered, Intensive Care Unit (ICU) records and data from the device controller. These pilot cases were then compared with the coder submitted claim and assessed for completeness and concordance. Results: 22 key patient history variables were identified all of which were available in claims. 12 ECG-based required indicators could be approximated. CAD severity scores, echocardiography findings and peri-procedural characteristics were essentially unavailable. Diagnostic and procedural concordance ranged 70.59-75.60. Additional missing information related to timing of diagnoses in acute settings, and out-of-hospital medication regimens.

Conclusions: Fidelity of German claims data remains moderately high and is acceptable in this complex therapy area. However, a high amount of data elements cannot directly be captured in claims and, thus, must be undertaken to additionally collect and match patients correctly. Analysing the timing of various procedures and peri-procedural complications using the time-stamp information available is vital to define appropriate subgroups. We provide a list of cardiovascular risk factors, procedural characteristics, ICU admission and lab values that should be available for constructing reliable control groups.

MT6

OVERTURE OF ARTIFICIAL INTELLIGENCE IN MEDICINE: A REVIEW OF FRAMEWORKS

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Objectives: Artificial intelligence (AI) is rapidly expanding in medicine even while lacking formal oversight. We sought to identify and describe considerations for the oversight of AI in medicine. The search included key topics such as ‘algorithm performance’, ‘machine learning’, ‘informatics’, ‘medication device’, ‘medical device legislation’, and ‘evaluation study,’ and spanned the time period 2014-2021. Frameworks were included if they described translational considerations for AI. The included frameworks were summarized descriptively. Content analysis was used to identify considerations for the oversight of AI in medicine. An evaluation matrix methodology was used to map each consideration across the different translational stages for each framework. Results: Six frameworks were included in the review, and were either published as peer reviewed journal articles or white papers from consortium and professional organizations. Content analysis of the frameworks revealed five overarching considerations related to the oversight of AI in medicine, including: transparency, reproducibility, ethics, effectiveness, and engagement. All frameworks included discussions regarding transparency, reproducibility, ethics, and effectiveness, while only half of frameworks discussed engagement. The evaluation matrix revealed that frameworks were most likely to report AI considerations for the translational stage of development, and least likely to report considerations for the translational stage of surveillance. Conclusions: Frameworks provided broad guidance for the oversight of AI in medicine, but notably offered less input on the role engagement approaches for oversight, and for any strategies for general surveillance stage of translation. Identifying and optimize strategies for engagement is essential to ensure that AI can meaningfully benefit patients and other end-users.

MT9

US PAYMENT MANAGEMENT OF DIGITAL THERAPEUTICS AND FUTURE OUTLOOK

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Objectives: To review US payer policies and rationale for coverage of approved digital therapeutics (DTx) in order to better understand the likely evolution of payer management and future outlook for DTx. Methods: Information on coverage and management of FDA approved prescription DTx from top 20 largest US public and commercial payers and Pharmacy Benefit Managers (PBM) were obtained in a review of literature, websites, press releases, and public domain sources. Using this information, anticipated payer evidence requirements for DTx were considered based on current trends and developments identified. Results: The first example of US payers managing DTx came when the PBM Express Scripts announced the introduction of a digital health formulary (2019). The formulary includes 15 solutions from digital health developers including remote monitoring services and digital therapeutics for eight common chronic conditions. The digital health options are for caregiver care, COVID-19 care, diabetes care, cardio vascular care, pulmonary care, behavioral health care, women’s health care, and musculoskeletal care. A case study for virtual careDTx solution, demonstrates improved outcomes related to glycemic events and cost savings. Another case study for asthma and COPD DTx solution, Propeller, showed improved adherence and lower utilization of rescue medication, which reduces hospitalization. The review of case studies for approved and covered DTx helps to understand study design and outcome measures needed. Conclusions: The COVID-19 pandemic has transformed the digital health space by accelerating acceptance and usage of DTx and this trend is likely to continue into the future. As a result, US payers that have not already done so will need to develop policies to manage coverage and payment for DTx. With increased payer management, manufacturers should track outcomes of assessments for DTx to be informed of clinical trial and real-world evidence needs to support approval and coverage.

MT10

OPENNESS TOWARDS THE USE OF TELEMEDICINE AND UNIVERSITY-EDUCATED ADVANCED PRACTICE NURSES (APNs), BASED ON A SURVEY OF THE PUBLIC AND GENERAL PRACTITIONERS

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Background: The COVID-19 pandemic has once again raised awareness of the potential of telemedicine as a cost-effective and, given the human resource constraints, tremendous opportunity to reach out to patients. However, the adoption of virtual technologies as well as advanced practice nurses (APN) behind such services may not fully be supported by healthcare providers and patients. The aim of our study was to assess the attitudes of general practitioners (GPs) and lay people towards telemedicine and to explore the openness of the Hungarian population and primary care physicians towards virtual healthcare and the extended scope of university
registered nurses. Methods: Non-random, purposive sampling was performed. Data were collected by means of a questionnaire, separately for physicians and laypersons, which included socio-demographic, telemedicine-related and APN preference questions. Data analyses were performed using SPSS 25.0 statistical software. Descriptive statistics and Mann-Whitney test were used for comparisons (p<0.05). Results: The public was more open to accept the use of smart devices than APs (p<0.001), but doctors preferred internet contact more compared to laypersons (p<0.001). If doctors and APNs were believed to have the same level of competency, lay people would equally choose to see a doctor or an APN nurse (p=0.005). More than 50% (60.5%) of doctors would only approve APNs working independently if they did so under professional supervision. Conclusions: Telemedicine is generally welcome by GPs. Assuming equal service quality, laypersons did not reject nurse consultation. The provision of telemedicine health services in GP practices should also be part of the APN competency. Development of a legal framework for independent APN services and designing telemedicine protocols are warranted.

**MT11**

**ARE MHEALTH INTERVENTIONS TO PREVENT DIABETES COST-EFFECTIVE? A SYSTEMATIC REVIEW**

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Objectives: To synthesize evidence on the cost effectiveness of mHealth interventions designed to prevent diabetes. Methods: We conducted a systematic review of economic evaluation studies evaluating mHealth interventions used to prevent the development of diabetes. Studies included those published between January 2000 and December 2020 underwent a blinded review by two researchers using pre-specified criteria. Studies meeting criteria were analyzed for key economic evaluation component including study setting and population, decision analysis model, economic perspective, outcomes of mHealth interventions and published evidence demonstrating the value of mHealth interventions for people with pre-diabetes. The most common perspective was the healthcare system perspective (3 studies). We found strong evidence for cost-effectiveness of the online diabetes prevention program and SMS messaging. A study on digital behavioral counseling programs showed supportive evidence for the cost-effectiveness of such intervention. A different study on an online diabetes prevention program showed evidence of cost-effectiveness at a willingness to pay threshold of $20,000. One study resulted in a poor cost-effectiveness assessment of the mHealth intervention because the health effects of the mHealth arm were negative relative to the comparator with no significant effect on the prevalence of intermediate hyperglycemia and type 2 diabetes. Conclusions: Our results suggest there is limited evidence demonstrating the value of mHealth interventions for people with pre-diabetes. The growing popularity of mHealth interventions across chronic conditions including pre-diabetes should warrant additional economic evaluations to facilitate stakeholders’ assessment of their value prior to widespread adoption.

**MT12**

**CHANGES IN HEALTHCARE RESOURCE UTILIZATION IN PATIENTS USING AN FDA-AUTHORIZED PRESCRIPTION DIGITAL THERAPEUTIC FOR OPIOID USE DISORDER OVER A 12-MONTH PERIOD**

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Objectives: The rising incidence of opioid use disorder (OUD) in the U.S. places a substantial burden on the healthcare system. This study examined changes in all-cause healthcare resource utilization (HCRU) among patients prescribed an FDA-authorized prescription digital therapeutic (PDT) for OUD. Methods: A 12-month retrospective analysis of HealthVerity PrivateSource20 closed claims data was conducted in OUD-diagnosed adults with at least 8 months of continuous enrollment before (pre-index) and after (post-index) PDT initiation (index). HCRU included facility and clinician service encounters. Incidence rate ratios (IRRs) were compared before pre-index and post-index periods using a repeated-measures negative binomial model, adjusted for number of days of follow-up. Results: Of 901 eligible patients (median age 36 years, 62.4% female, 73.9% Medicaid-insured recipients) the majority had one prescription (72.3%), but doctors preferred internet contact more compared to laypersons (p<0.001). If doctors and APNs were believed to have the same level of competency, lay people would equally choose to see a doctor or an APN nurse (p=0.005). More than 50% (60.5%) of doctors would only approve APNs working independently if they did so under professional supervision. Conclusions: Telemedicine is generally welcome by GPs. Assuming equal service quality, laypersons did not reject nurse consultation. The provision of telemedicine health services in GP practices should also be part of the APN competency. Development of a legal framework for independent APN services and designing telemedicine protocols are warranted.

**MT13**

**EVALUATING REAL-WORLD IMPACT OF SUBSIDY DECISION ON SLEEP TESTS UTILISATION FOR THE DIAGNOSIS OF OBSTRUCTIVE SLEEP APNOEA**

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Objectives: Lab-based polysomnography (PSG), for diagnosing obstructive sleep apnoea (OSA), is a subsidised inpatient service in Singapore’s public healthcare institutions (PHIs). The alternative, home sleep test (HST), is cheaper and can be prescribed in the outpatient setting. Following health technology assessment performed by Agency for Care Effectiveness, HST was listed as a subsidised service in PHIs in May 2019. This study aims to assess the impact of the subsidy decision on sleep tests utilisation on tests utilisation data submitted by PHIs from January 2018 to June 2021. Segmented regression models were used to assess the degree of level change (LC) and trend change (TC) of HST and PSG. Data points during Singapore’s most stringent COVID-19 restrictions were modelled as “wild” points to account for potential confounders. Autocorrelation was tested and corrected by including an autoregressive or moving average term in the models.

Results: Subsidy implementation increased the use of HST, from 12% of all sleep tests pre-subsidy to 26% post-subsidy. Despite multiple periods of intermission, associated with COVID-19 restrictions, HST showed subsidy implementation led to a significant level change in HST utilisation [LC: 0.01 (95% CI: 0.001 - 0.018); 3TC: 0.04 (95% CI: 0.014 - 0.07)]. There was also a trend towards reduction in PSG, though this did not reach statistical significance [LC: -0.001 (95% CI: 0.000 - 0.001); TC: -0.02 (95% CI: -0.06 - 0.02)]. As HST is much cheaper than PSG, total charge avoided by the healthcare system in 10 years is projected to be in the range of SGD9 million to SGD14 million.

Conclusion: Extension of subsidy to HST appeared to have improved accessibility of sleep tests for OSA diagnosis and resulted in cost saving to Singapore’s healthcare system.

**MT14**

**POPULATIONS, INTERVENTIONS, AND OUTCOMES IN DIGITAL BIOMARKER-BASED INTERVENTIONS’ SYSTEMATIC REVIEWS: A SCOPING REVIEW**

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Objectives: The purpose of this study is to examine the populations, interventions, and outcomes of systematic reviews of digital biomarker-based interventions. Methods: The search timeframe was limited to 2019-2020 in PubMed and the Cochrane Library using the following search formula: “digital biomarker” OR “digital biomarkers” OR implantable OR implantable wearable OR wearable or wearables OR non-invasive OR non-invasive wearable OR non-invasive wearable OR digestible OR digestible. English full-text studies were searched to find systematic reviews (SRs) of digital biomarker-based interventions that included at least one human randomized controlled trial and reported changes in participants’ health status. Two reviewers independently extracted data and screened titles/abstracts and full-text articles for compliance with the inclusion criteria. International Classification of Diseases (ICD)-11, International Classification of Health Interventions (ICHI), and International Classification of Functioning, Disability, and Health (ICF) tools were used to categorize populations, interventions, and outcomes, respectively. Descriptive-analytical and tabular methodologies were employed to examine the data. Results: The inclusion requirements were satisfied by 43 SRs. The populations were classified into nine ICD-11 chapters. Patients with XI Circulatory system (n=8, 19%) were the most common, followed by XXII external causes (n=6, 14%), IX Metabolic diseases (n=5, 12%), and XI Respiratory system (n=5, 12%). Nine SRs studied nonclinical populations (21%). Most digital biomarker-based interventions (n=7) for nonclinical populations were linked to health-related behaviors (physical activity). Mobility (n=7) also was the most applied intervention for Circulatory system patients. Following after one’s health (physical activity) (n=6) and weight management (n=5) were the most often stated outcomes in studies. Conclusions: Digital biomarker-based research is becoming more popular in various settings and among the general public, with the primary goal of changing physical activity.

**MT15**

**PATIENT-INFORMED VALUE ASSESSMENT OF TELEHEALTH CARE SERVICES: CONCEPTUALIZATION TO IMPLEMENTATION**

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