(FDA) and the European Commission (EC) to help improve health outcomes. To ensure sustainability, digital health interventions (DHI) require funding by payers. Evidence-informed decision and policy making requires an assessment of the impact on relevant outcomes vs current healthcare practice. Various national and international organizations are involved in creating or guiding the development of standards for the evidence required for digital technologies.

Methods. We undertook an intensive individual investigation of the websites of leading payer and health technology assessment (HTA) bodies in France, UK, Germany, Belgium, Austria, Finland, Canada, Australia, and the USA to identify new frameworks and any updated information. As the objective focused on evaluation frameworks which were used across DHIs by a particular payer to support pricing and reimbursement decisions, we excluded individual case studies where DHIs had been assessed, regulatory frameworks for approval of DHIs and frameworks which assessed feasibility or applicability of a DHI since these were not directly influencing the decision for funding.

Results. We found six frameworks which directly address digital health interventions for the purposes of pricing and reimbursement: NICE Evidence Standards, FinCCHTA, MSAC, Germany BfArM, Belgium RIZIV and France HAS. The context for the framework and the requirements were compared on parameters including those normally found in HTA and for criteria related to digital technologies. The parameters included varied considerably across the frameworks as did the level of evidence expected to be available for the assessment. In some cases, these related to the level of risk or impact of the intended DHI.

Conclusions. While DHIs are increasingly used in health, HTA is struggling to adapt to assess these technologies. Due to the multidisciplinary nature of digital health (combination of health care and technology), and the speed and rate of change of innovations in this area, an approach based upon the risk assessment posed by the technology seems reasonable. In this way the level of effort can be tailored to those interventions which seek to influence care or predict outcomes rather than those which are tailored to increased awareness of the patient about their condition.

PD46 Multi-Criteria Decision Analysis In Healthcare: Scientometric And Bibliometric Analysis

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Introduction. Multi-criteria decision analysis (MCDA) is a useful tool in complex decision-making situations and has been used in medical fields to evaluate treatment options and drug selection. We aimed to provide valuable insights on the use of MCDA in health care through examining the research focus of existing studies, major fields, major applications, most productive authors and countries, and most common journals in the domain using a scientometric and bibliometric analysis.

Methods. Publications related to MCDA in health care were identified by searching the Web of Science Core Collection on 14 July 2021. Three bibliometric software programs (VOSviewer, Bibliometrix, and CiteSpace) were used to conduct the analysis.

Results. A total of 410 publications were identified from 196 academic journals (average yearly growth rate of 32% from 1999 to 2021), with 23,637 co-cited references by 871 institutions from 70 countries or regions. The USA was the most productive country (n=80), while the Universiti Pendidikan Sultan Idris (n=16), Université de Montréal (n= 13), and Syreon Research Institute (n=12) were the most productive institutions. The biggest nodes in every cluster of author networks were Aos Alaa Zaidan, Mireille Goetghebeur, and Zoltan Kalo. The top journals in terms of number of articles (n=17) and citations (n=1,673) were Value in Health and the Journal of Medical Systems, respectively. The research hotspots mainly included the analytic hierarchy process (AHP), decision-making, health technology assessment, and healthcare waste management. In the recent literature there was more emphasis on coronavirus disease 2019 (COVID-19) and fuzzy Technique for Order Preference by Similarities to Ideal Solution (TOPSIS). Big data, telemedicine, TOPSIS, and the fuzzy AHP, which are well-developed and important themes, may be the trends in future research.

Conclusions. This study provides a holistic picture of the MCDA-related literature published in health care. MCDA has a broad application in different topic areas and would be helpful for practitioners, researchers, and decision makers working in health care when faced with complex decisions. It can be argued that the door is still open for improving the role of MCDA in health care, both in its technologies and its application.

PD47 Associations Of Orphan Designation And Other Drug Development-Related Factors On Rollout Times And Health-Technology-Assessment Recommendations Of New-Active-Substances

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Introduction. The orphan designation has been used by the European Medicines Agency to incentivize the development of drugs treating rare diseases with high-unmet medical needs by supporting their development process and economic returns. This study evaluated the impact of the regulatory orphan designation and other drug development-related factors on the rollout times and Health-Technology-Assessment (HTA) recommendations of new active substances (NASs).

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Methods. A total of 656 HTA appraisals from 6 European countries were collected for NASs that received regulatory approval between 2012 and 2020. Multivariable logistic (positive and positive with restrictions vs. negative HTA recommendation as dependent variable) and linear regression (rollout time as dependent variable) models examined associations with regulatory orphan designation, expedited process, product type (biotechnological vs chemical), and jurisdiction (France, England, Germany, Poland, Scotland and Sweden). Rollout time was defined as months elapsed from regulatory submission to HTA recommendation (mean± standard deviation).
Results. Multivariable logistic regression analysis identified disparities in HTA recommendations between countries. Every month increase in rollout time conferred a 3 percent reduction in the odds of a positive recommendation ($p<0.001$). Review and product type did not show associations with HTA recommendation. Interestingly, orphan products showed a 99% increase in the odds of obtaining a positive HTA recommendation compared to non-orphan (p-value=0.003). We found 244 appraisals (37%) assessing an orphan product, of which 202 (83%) received a positive HTA recommendation.
Multivariable linear regression analysis indicated that orphan products presented a 4.4-month rise in rollout time when compared to non-orphan products ($p<0.001$). The mean rollout time in months for orphan products were 25±12 in France, 30±15 in England, 21±9.1 in Germany, 37±16 in Poland, 25±12 in Scotland and 27±14 in Sweden.
Conclusions. Orphan designated products showed greater odds of receiving a positive HTA recommendation compared with non-orphan. A more detailed review of orphan products could result in their longer rollout time compared with non-orphan counterparts. Considerable differences were found between HTA recommendations and rollout times between jurisdictions.

PD48 Does Unmet Need Influence The Scottish Medicines Consortium Health Technology Assessment Decisions For Rare Disease Conditions?

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Introduction. The Scottish Medicines Consortium (SMC) defines end-of-life medicines as drugs used for treating conditions that usually lead to death within three years using currently available treatments. Orphan medicines are drugs used for the treatment of very rare conditions and ultra-orphan drugs are used for the treatment of extremely rare conditions. The objective of this study is to determine the influence of unmet need on SMC health technology assessment (HTA) decisions for rare disease conditions.
Methods. The reimbursement data between 2004 and 2021 from SMC for rare disease conditions were included. These data were categorized based on the presence of an unmet need, that is, drugs considered under the orphan or ultra-orphan process, or those that fulfilled SMC end-of-life criteria. A chi square test was conducted to determine an association between the presence of an unmet need and the HTA decision. HTAs without a decision were excluded.
Results. A total of 91 HTAs were included in the analysis of which, 57.1 percent (n = 52) were recommended, and 42.9 percent (n = 39) were not recommended. Out of the recommended reviews, 32.7 percent (n = 17) addressed an unmet need and 67.3 percent (n = 35) did not. Recommended drugs had positive clinical evidence and high cost-effectiveness or the submission of a patient access scheme while negative decisions were associated with lower or uncertain cost-effectiveness. The chi square test result showed no association between the presence of an unmet need and the HTA decision ($p = 0.315$).
Conclusions. Unmet need does not influence the SMC HTA decisions for rare disease conditions. Economic elements were the driving factors in the decision-making process.

PD49 Burden And Cost Of Anterior Cruciate Ligament Reconstruction And Reimbursement Of Its Treatment In Indonesia: An Observational Study

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Introduction. The number of anterior cruciate ligament reconstruction (ACLR) procedures is increasing. However, the likelihood of not allocating sufficient funds for the ACLR procedure in a developing country, especially in Indonesia, is high. This study aimed to analyze costs for ACLR procedures in Indonesia's resource-limited context, determine the burden of ACLR, and propose national prices for ACLR reimbursement.
Methods. A retrospective observational study was conducted on the cost of ACLR from a payer perspective using inpatient billing records from 1 January 2019 to 31 December 2019 from four hospitals. The national burden of ACLR was calculated and national prices for reimbursement were developed.
Results. Of the 80 ACLRs performed, 53 (66%) were isolated ACLRs and 27 (34%) were combined with meniscus treatment. The mean hospital costs incurred per ACLR procedure were USD 2,853 (IDR 40.4 million), which was mainly attributed to the orthopedic implants (USD 1,387; IDR 19.6 million). The costs of ACLR with combined meniscus treatment were estimated to be 35 percent higher than for isolated ACLR. The national burden of ACLR revealed a total budget of USD 367.4 million (IDR 5.2 trillion) per 100,000 patients for ACLR with additional meniscus treatment and USD 271.3 million (IDR 3.8 trillion) per 100,000 patients for the isolated ACLR procedure.

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