Introduction. Risk prediction models, using either machine learning or statistical algorithms, can act as inputs of a cost-effectiveness model when predicting costs and effectiveness of an intervention. This systematic review has two objectives: to evaluate methodological quality of the published models to predict diabetic coronary heart disease (CHD) risk; to evaluate whether the models were sufficiently reported to judge their applicability to the cost-effectiveness modelling.
Methods. A targeted review of journal articles published in English, Dutch, Chinese, or Spanish was undertaken in PubMed, Embase, Scopus, Web of Science, and IEEE Explore from 1 January, 2016 to 31 May, 2021. To assess the methodological quality and reporting of the models, we used PROBAST (Prediction model Risk Of Bias Assessment Tool), CHARMS (a Checklist for critical Appraisal and data extraction for systematic Reviews of prediction Modelling Studies), and a checklist (Betts 2019) summarizing the application of cardiovascular risk prediction models to health technology assessment.
Results. Our search retrieved 6,579 hits, of which 18 models were eligible for inclusion. Among them, four studies developed machine learning models (2 recurrent neural networks, 1 random forest models, and 1 multi-task learning model) while 14 studies developed statistical models (8 Cox models, 5 logistic models, and 1 microsimulation model). More than 70 percent of models were of high methodological quality in aspects of participants (89%), predictors (72%), and outcomes (72%), while only five models (28%) in aspects of statistical analysis. For the reporting, only two models provided sufficient evidence in all aspects (i.e., participants, predictors, and outcomes) for judging their applicability to the cost-effectiveness modelling. Most models were reported sufficiently regarding participants (78%) and outcomes (72%), but only three models regarding predictors (17%).
Conclusions. To apply the CHD risk prediction models to cost-effectiveness modelling, concerns remain regarding the potential risk of bias due to inappropriate use of analysis methods, and regarding insufficient reporting on how to measure and assess the predictors.

PP39 Evidence Generation For Reimbursement Of Digital Health Applications (DiGAs) In Germany

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Introduction. In 2019, the German government established a new evaluation procedure for digital health applications (DiGAs) to facilitate their reimbursement by statutory health insurance. The procedure involves the assessment of a DiGA's "positive healthcare effect", which is defined as a medical benefit and/or "a patient-relevant improvement of structure and processes". If the available clinical evidence is insufficient to prove the manufacturer's claim on the positive healthcare effect, but the claim seems plausible, the DiGA is provisionally reimbursed, and further clinical evidence within twelve months must be generated. DiGAs eligible for provisional or permanent reimbursement are publicly listed in the DiGA directory. In contrast to the usual pathways for reimbursement of healthcare technologies which involve IQWiG as the national HTA agency and the G-BA (Federal Joint Committee) as the decision-making body, the DiGA procedure is currently carried out by the national competent authority (BfArM) and thus outside the joint self-government. Furthermore, legal evidence requirements for DiGAs are comparatively low.
Methods. This work analyzed the suitability of clinical studies that intended to prove a DiGA's medical benefit. For this purpose, the key elements for clinical studies published in the DiGA directory and clinical trial registries were extracted and compared with the usual evidence requirements in the reimbursement context.
Results. As of October 2020, 20 DiGAs have successfully undergone the application procedure. Fourteen DiGAs (70%) were provisionally accepted. A randomized controlled study (RCT) design was chosen for all clinical studies to be conducted for further evidence generation. However, in four cases (28%), it is questionable whether the clinical study is suitable to demonstrate a medical benefit mainly due to the choice or operationalization of the primary endpoint (n=2), the timing of the endpoint survey (n=2) and/or the choice of the control intervention (n=1).
Conclusions. Even though all currently ongoing or planned clinical studies with DiGAs are RCTs, not all of them are adequate to demonstrate a medical benefit according to the usual evidence requirements.

PP40 Health Apps To Manage Depression: Can We Separate The Grain From The Chaff? EvalDepApps Project

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Introduction. The use of mobile applications in the treatment of health issues is more frequently becoming common practice. Apps are fast, versatile, and manageable tools that allow the empowerment of patients and professionals, and can reduce the possible stigmatization suffered by some patients, mainly in mental health. There are more than 325,000 health apps on the market, but their impact remains unclear. There are several initiatives to define how health applications should be assessed, however, all of them address only partial aspects of the evaluation. The theoretical frameworks existing to date highlight the need to develop new tools and methodologies to assess mobile applications whose objective is the management of specific pathologies.
Methods. The primary goal of the EvalDepApps project is to develop and pilot an assessment tool for mobile applications whose main objectives are the treatment, monitoring or social support of people suffering from depression. The project is inspired by the results and

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lessons learnt from a previous project, EVALAPPS, whose central aim was to develop a tool to assess health apps targeted toward the management of overweight and obesity. The first steps of the Eval-DepApps project are: (i) to explore and characterize the current landscape of mobile applications available in the market to treat depression through a systematic appraisal, and (ii) to review the existing evidence about the effectiveness and safety of these applications through systematic research of the existing evidence.
Results. Preliminary results show that all the depression management studies were by design based on cognitive-behavioral therapy (CBT) interventions (n=17) and the main management tools included in the services (web or apps) are psychoeducation and coaching (14), together with self-monitoring and feedback messaging (13).
Conclusions. Moreover, although health apps seem to be an interesting strategy to treat depression, there are very few apps available on the markets (30) and the supporting evidence is very limited. This result uncovers a need for further systematic and clinically oriented validation and testing of such apps.

PP41 COVID-19 Modeling To Support Decision Making In Brazil: A Scoping Review

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Introduction. In the context of the COVID-19 pandemic, which required urgent responses from health systems, and ongoing decision making in a context of limited and evolving evidence, modeling played a significant role in supporting public policy making. Nonetheless, particularly in low and middle-income countries, modeling groups are scarce, and usually not routinely involved in supporting public health policy making. We aimed to appraise COVID-19 modeling work in Brazil during the pandemic.
Methods. We performed a scoping review following PRISMA guidelines to identify groups conducting COVID-19 modeling to support health decision-making in Brazil. Search strategies were applied to MEDLINE, LILACS, Embase, ArXiv, and also included National data repositories and gray literature. We excluded reports of models without modeling results. Titles, abstracts, data repository descriptions and full-text articles identified were read and selected by two reviewers. Data extracted included modeling questions, model characteristics (structure, type, and programming), epidemiologic data sources, main outcomes reported, and parameters. To further identify modeling groups that might have not yet published results, snowball sampling was performed, and a short survey was sent electronically. Investigators and policymakers were invited to an online interview, to obtain further information on how they interacted, communicated, and used modeling results.
Results. We retrieved 1,061 references. After removing duplicates (127), 1,016 abstracts and titles were screened. From an initial selection of 142 abstracts, 133 research groups were identified, of which 67 didn't meet the eligibility criteria. Of these, 66 groups were invited for an interview, of which 24 were available, including 18 modeling groups from academic institutions, and four groups from State Health departments. Most models assessed the impact of mitigation measures in cases/hospitalization/deaths and healthcare service demand. Interaction and communication with decision-makers were not well established in most groups.
Conclusions. Despite a large number of modeling groups in Brazil, we observed a significant gap in modeling demand and communicating its results to support the decision-making process during the COVID-19 pandemic.

PP42 Impact Of The COVID-19 Pandemic On Scottish Medicine Consortium Submission Characteristics, Acceptance Rates, And Time To Advice

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Introduction. Scottish Medicine Consortium (SMC) meetings were suspended in March 2020 in response to the coronavirus disease 2019 (COVID-19) pandemic. This led to a high number of submissions awaiting appraisal, prompting interim process changes to ensure minimal disadvantages to patient access. We expanded the eligibility criteria for the shorter (abbreviated) submissions process and expedited advice for submissions the New Drugs Committee (NDC) intended to accept. This study aimed to evaluate the impact of the COVID-19 pandemic and these interim process changes on the characteristics of submissions received, acceptance rates, and time to advice publication.
Methods. Data for all submissions received between January 2015 and November 2021 (n=720) were extracted from an organizational database. Characteristics of and acceptance rates for submissions received before and after the start of the pandemic were compared using chi-squared and one-proportion Z-tests, respectively. Additional analyses explored the number of submissions received per month and the time from receipt of submission to NDC and SMC decision.
Results. The numbers of full and abbreviated submissions increased from March 2020 (6% in each case), with a corresponding decrease in the number of medicine-indication pairs (e.g., pembrolizumab for breast cancer) for which companies did not submit (8%; p=0.01). An increase in the SMC acceptance rate was also observed (62 to 72%; p=0.03). Fewer submissions were received in 2020 (n=65), compared with the pre-pandemic average (mean=79.6), whereas the total in 2021 to date was higher than average (n=92). Time series analysis suggested an increasing trend in monthly submissions (from approximately 6 to 9), which is the likely reason for the increase in average time to decision (146 versus 170 days).
Conclusions. Process changes in response to the pandemic have been effective in expediting advice for submissions with sufficiently robust evidence. This demonstrates agility and efficiencies for submitting

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