Introduction. Patients with spinal deformity require implanted spinal rods to be specifically shaped to their anatomy. Spinal rods which are manually shaped in the operating theatre are prone to fracture and malpositioning. This emphasizes the need for preoperative planning, intraoperative imaging, and accurate shaping of the implant. The application of machine learning (ML) has enabled precision in shaping patient-specific rods, with the potential to reduce adverse events. Our objective is to assess the economic value of this technology, early in its lifecycle, in the context of Health Technology Assessment (HTA) in Australia.
Methods. A budget impact analysis was performed to quantify the economic value of patient-specific spinal rods from an Australian payor perspective. Clinical outcomes were sourced from literature review, and cost inputs were obtained from Medicare, Private Health Data Bureau and Hospital Casemix Protocol Data databases.
Results. Preliminary analysis indicates that a reduction in the rate of revision surgery due to decreased instrument failure results in cost-savings to the healthcare system, despite a higher outlay for the patient-specific rods. Adolescents who may have remained sagittally malaligned after the implantation of manually bent rods are expected to derive the greatest benefit from this ML application. The key uncertainty in this analysis is the limited real-world data of this emerging technology. ML is an iterative process of continuous improvement, identifying correlations within the data collected. As additional surgical data are integrated into predictive models, we anticipate ML technology will enhance decision-making support in surgical strategy and enable better implant precision, resulting in further decreased operating time, reduced mechanical complications, and increased healthcare savings.
Conclusions. ML technology is enabling precision in patient-specific implants, which is expected to drive healthcare cost-savings due to a reduction in instrument failure. Fewer replacement surgeries are an important patient-relevant outcome, especially for adolescents with spinal deformity. This preliminary analysis demonstrates the economic value of ML enabled patient-specific rods to Australian payors, early in its lifecycle.

PP17 Is the PriTec Tool Useful In The Identification Of Disruptive Healthcare Technologies?

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Introduction. A disruptive technology has been defined as an innovation that completely changes the way things are done. Early identification of potential disruptive health technologies has become a key point in the agenda of decision makers and health technology assessment (HTA) bodies. The PriTec tool is an automatically executable web application that was developed in 2009 by the Galician HTA Agency to facilitate decision-making regarding the selection of technologies for post-launch observation. The tool has been updated to allow scoring and ranking of technologies before their introduction into the healthcare portfolio. The aim of this work was to propose a framework for assessing the usefulness of the PriTec tool in relation to identifying possible disruptive innovations.
Methods. To evaluate the applicability of the PriTec tool for distinguishing disruptive from non-disruptive innovations, we selected a few examples from prior acknowledged disruptive and non-disruptive innovations. These technologies were scored against the predefined criteria and the results were compared and analyzed globally and by type of domain. The PriTec tool assesses six domains of technologies: clinical condition, comparative effectiveness and safety, economic impact, implementation consequences, and dissemination speed.
Results. Disruptive technologies (e.g., transcatheter aortic valve implantation or point-of-care tests) had higher weighted global scores than non-disruptive technologies. In the domain analysis, the scores for implementation consequences were higher for disruptive than for non-disruptive technologies. Both types of technologies had similar scores in the other domains.
Conclusions. The PriTec tool seems to be useful for identifying potential disruptive technologies through its implementation domain. Further validation strategies are required to confirm the tool's applicability and to improve its accuracy in the field of health disruption. The tool could be used by governments, horizon scanning organizations, and HTA organizations to promote the evidence-based detection of disruptive technologies in clinical practice. However, it is advisable that the tool be further tested and validated in other contexts.

PP18 Horizon Scanning For Clinical Biosimilar Medicines: Informing The Lifecycle Of Health Technology Assessment And Market Access

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Introduction. The National Institute for Health and Care Research (NIHR) Innovation Observatory (IO) national horizon scanning research centre, has a remit to notify its stakeholders, including the National Institute for Health and Care Excellence (NICE), about innovative interventions; including biosimilar medicines in the pipeline. Biosimilar medicines bypass many developmental steps, making them substantially cheaper to manufacture for providers, which increases market availability and improves treatment access for patients.
Methods. Since 2017, the NIHR IO has monitored biosimilars in clinical development that align to the NICE health technology assessment remit. The data set explored was exported from our internal medicines innovation database - MInD.

Data sets were created that included information on the characteristics of biosimilars and their associated clinical trials. Analyses and visualization creation were carried out using Microsoft Excel and Microsoft Power BI.

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Results. A total of 100 unique biosimilar medicines in 136 clinical trials were included in the MInD since April 2017. Of these, 44 percent of biosimilars are currently EMA-approved (Nov 2021). Adalimumab was the reference medicine with the most unique biosimilars identified (12%). Seventy-two percent of the biosimilars in MInD were indicated for non-oncology conditions, twenty percent for oncology condition and eight percent for both.
There were 46 biosimilars unapproved, which were in active development. Of these biosimilars 17.4 percent are indicated for an oncology condition, 78.3 percent for non-oncology conditions, and 4.3 percent for biosimilars for both. Aflibercept was the reference product with the most (eight) biosimilars in active development.
There were 56 individual clinical trials in the MInD that list a biosimilar in development. For 26 trials, the primary completion date (PCD) was prior to 2021, whilst 28 trials listed a PCD post-2021, and 2 PCD's were unavailable
Conclusions. Our analysis identified high levels of active clinical development for biosimilars. The majority of biosimilars being developed are indicated for non-oncology conditions, with many in trials due to readout in the near future. Early identification, monitoring and reporting of biosimilars allows for expedited patient access and benefits, including cost-savings for health services.

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PP19 Reimbursable Health Apps (DiGA) In Germany: Which Factors Impact The BfArM's Assessment And Directory Listing? – Updated Research

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Introduction. Since May 2020, reimbursement can be requested for Digital healthcare applications (DIGAs) in Germany. The prerequisite for reimbursement is a listing in the Federal Institute for Drugs and Medical Devices (BfArM) DiGA-directory, granted after successful completion of an assessment process. In June 2021, IQVIA first evaluated the BfArM's decision-making and identified criteria that may positively impact a directory listing. In November 2021, the research was updated to consider the latest developments.
Methods. Published information for each app in the DiGA-directory was qualitatively compared according to pre-specified criteria by two independent reviewers. With no data available for denied apps, only DiGAs with permanent or preliminary listings were compared.
Results. By 26 November 2021, twenty-four apps had received a positive assessment. Permanently listed apps (n=6) focused on health status improvements and/or patients' health competency. None claimed to improve patients' quality of life. Results from at least one randomized controlled trial (RCT) showed efficacy with medium or strong significant effect sizes (Cohen's d > 0.4) versus standard of care (SOC). For preliminarily listed DiGAs (n=18), final results of positive care effects were not yet provided, but applications included study designs for RCTs including definitions of primary endpoints. The BfArM accepted the trial designs to be suitable to measure an app's positive effects on health care within twelve months after listing. Since the last analysis, no preliminarily listed apps have been granted permanent DiGA-status. Evaluation periods were extended by up to five months for three apps. With none of the trials for preliminary apps being completed, possibilities for assessment remain limited. Claims for either medical benefit and/or patient-relevant structural/procedural improvements do not seem to impact the type of listing.
Conclusions. Updated research confirmed previous findings. For a DiGA-directory listing DiGA, the (planned) provision of RCT data seems to be gold standard. Medium to strong effects on the improvement of health status compared to SOC appear to be important for a permanent listing. Evaluation periods of five preliminarily listed apps are expected to be completed in December 2021, allowing for further analyses in the future.

PP20 Effectiveness And Safety Of Autogenic Training As A Treatment For Medical Conditions

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Introduction. Autogenic training consists of reaching a state of deep relaxation through mental representations of physical sensations in different parts of the body. It is a promising technique for improving the psychological well-being of people with chronic diseases, but there are no clinical practice guidelines recommending the use of autogenic training in this population. The aim of this work was to identify, critically evaluate, and synthesize the available evidence on the safety and effectiveness of autogenic training in the prevention and treatment of medical conditions.
Methods. We conducted a systematic search for systematic reviews and randomized controlled trials (RCTs) in MEDLINE, Embase, CINAHL, PsycINFO, and the Cochrane Central Register of Controlled Trials. The selection and assessment of risk of bias of the included studies was carried out independently by two reviewers.
Results. A total of 2,420 references were identified after eliminating duplicates. Of these, 141 were selected for reading the full text, and 13 systematic reviews and 18 RCTs were included. Compared with no intervention or delayed treatment, autogenic training significantly reduced levels of anxiety and depression as well as some physical symptoms (e.g., headaches and atopic dermatitis).
Conclusions. Autogenic training could be useful for improving the psychological well-being and physical symptoms of patients with

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