Results. Hospitals need to submit jointly with the manufacturer comparative evidence on clinical efficacy, safety and cost when applying for additional compensation (Neue Untersuchungs- und Behandlungsmethoden [NUB] application) for new high risk class MDs being subject to §137h. A fast track assessment by IQWiG/G-BA follows within four months resulting in benefit proven, potential benefit or no benefit compared to alternatives. The latter can lead to exclusion from reimbursement. Until now one MD was granted a benefit, two treatments were assigned a potential benefit and six MDs no benefit, while 55 percent of drugs evaluated under AMNOG were granted an additional benefit. Compared to drugs, the required evidence for MDs is similar. Whereas assessment time is shorter, manufacturers can seek advice from G-BA upfront for free and need to collaborate closely with hospitals.

Conclusions. Half of MDs examined did not qualify for an assessment under §137h. Unlike for drugs evaluated under AMNOG, the majority of new MDs failed to be granted potential benefit as a treatment alternative and might be excluded from reimbursement. Manufacturers are challenged to generate high quality, comparative evidence within their studies.

PP26 Shift From Regional To Federal Funding: Methodological Considerations

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Introduction. Australia has a two-tier public funding system, and many genetic tests are funded by different states and territories prior to being considered for public funding by the Federal government. In this context, health technology assessments (HTAs) of genetic tests for heritable conditions are problematic. We aimed to discuss the possible impacts on HTA methodology of a shift from regional to federal funding for genetic testing for heritable conditions.

Methods. Several HTA reports and economic models on genetic tests considered by the Medical Services Advisory Committee (MSAC) were reviewed and compared to 'real world' clinical practice.

Results. Every HTA of germline testing performed for the MSAC have so far compared genetic testing versus no genetic testing. However, testing for BRCA1/2 for patients with breast cancer currently occurs in Familial Cancer Centres, and testing for germline mutations for familial hypercholesterolaemia currently occurs through specialist lipid clinics. In both settings, the index patient and family members are given multidisciplinary support, including genetic counselling. The HTA comparison therefore did not reflect what the true clinical and cost-effectiveness impact of federal funding would be. Federal funding means that tests may be ordered by a broader range of specialists or general practitioners. The evidence identified was predominantly sourced from specialised centres, where knowledge regarding how to interpret the tests is high. The clinical utility of these tests largely depended on how clinicians understood and conveyed the results.

Conclusions. The benefit of testing may have been overestimated due to the comparator and setting used (i.e. specialised and centralized care, associated with high clinical utility). Any HTA of genetic testing for heritable conditions, which could result in a shift in the delivery of testing or care for the patient, should consider the applicability of the evidence identified. Further, it should assess the subsequent impact this may have on the effectiveness and cost-effectiveness of the test and the quality of care provided for patients and their family.

PP27 Additional Capabilities In Health Technology Assessment To Support Decision Making

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Introduction. Decision-making regarding an open or a closed fluid waste management system (FWMS) in the planning of thirty operating rooms (ORs) of a new hospital at the CHU de Québec-Université-Laval was an opportunity to explore additional capabilities in health technology assessment (HTA) to support evidence-based planning.

Methods. Issues related to FWMSs in ORs were assessed from multiple data sources including: (i) systematic review in indexed database and grey literature, (ii) waste management laws and regulations, (iii) local registry of reported incidents/accidents, (iv) occupational health and safety database, (v) electronic patient records (EPRs), (vi) field evaluation of two closed FWMSs, (vii) costs, and (viii) survey on FWMSs in ORs of other Quebec hospitals.

Results. Closed FWMSs in ORs could reduce health care professional exposure to blood and body fluids (BBF) according to two low-quality studies. Cases of occupational and patient exposure to BBF with closed FWMSs, some of which had severe issues, were reported to the U.S. Food and Drug Administration. Depending on the volume, discharge of BBF to the sanitary sewer may be authorized upon the approval of the competent municipal authorities. Compared to an open system, a closed FWMS has the potential to reduce manipulation of canisters during the cases because of large canister capacity (24 L). However, local data showed that BBF and irrigation fluid amounts in ORs are <2 L in 84 percent of cases and >2 L in a minority of surgeries, whereas a closed FWMS is associated with higher costs for BBF volumes <12 L. Other issues were observed during field evaluation (e.g., occupational noise). Closed FWMS implementation in other hospitals was very limited in the survey.

Conclusions. Available evidence does not support the widespread use of a closed FWMS. Use of mixed-methods in this particular HTA allowed to assist decision makers on the choice of an FWMS in the OR planning.

PP28 Adoption Of Non-Pharmaceuticals In Galicia: Beyond Conventional Health Technology Assessment

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Introduction. The specificities of non-pharmaceuticals can require adapting classical health technology assessment (HTA) methodologies and developing additional regional approaches to support decision-making processes. However, little information exists regarding the explicit approaches used in different countries. The aim of this work is to provide an overview of the role and activities of the Galician HTA agency (avalia-t, Spain) regarding assessment, appraisal and continued evaluation across the whole life cycle of non-pharmaceutical technologies.

Methods. In depth review and analysis of the activities undertaken by avalia-t during the past five years to support the introduction and appropriate use of non-pharmaceutical health care technologies at the regional level.

Results. A multidisciplinary Commission judges the added value of new non-pharmaceuticals and establishes the indications and conditions for use. HTAs, which are mandatory for all relevant technologies, rely on the best available evidence on safety and effectiveness but also provide fit for purpose contextualized information based on organizational data and administrative registers. Interaction with multidisciplinary stakeholders is commonly needed to complement the evidence base (ad hoc working groups, face to face discussions), and post-launch studies can be implemented to analyze the utilization and results in real world practice. Performance indicators and other HTA based products can also be required to ensure the quality of health care (e.g., appropriate use indications, quality indicators, evidence based patient information). In addition, technical and scientific advice/support can be provided at different decision levels of the health organization to promote the quality of care and appropriate use of technologies (e.g., regional mental health program, suicide management strategy, bariatric surgery surveillance registry).

Conclusions. Rigorous, comprehensive and systematic processes for supporting non-pharmaceutical technology adoption and implementation are required. Although it is acknowledged that core information does not differ substantially within countries, contextualized information is recognized as essential for establishing the conditions for use at the regional level.

PP30 Do Conditional Regulatory Pathways Affect Health Technology Assessment Recommendations?

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Introduction. In an effort to expedite the approval of drugs treating serious illnesses or addressing unmet medical need, conditional approvals have been used by the European Medicines Agency. In this study, the effects of conditional approvals were investigated in terms of health technology assessment (HTA) recommendations and timing in Europe.

Methods. First HTA recommendations of new active substances (NASs) issued between 2015 and 2017 were collected from the National Institute for Health and Care Excellence (England), Haute Autorité de Santé (France), Institute for Quality and Efficiency in Health Care (Germany), Scottish Medicine Consortium (Scotland) and Tandvårds-Läkemedelförmånsverket (Sweden). The HTA recommendations were then classified into the following categories: positive, positive with restrictions, negative and multiple and if the regulatory approval pathway had been standard or conditional.

Results. Of this cohort of NASs that received an HTA recommendation, eight of 56 in England, 12 of 83 in France, 11 of 77 in Germany, nine of 58 in Scotland and four of 49 in Sweden were approved via a conditional review. Generally, except in England, there were a higher proportion of positive first recommendations for conditional approvals when compared to standard approvals, with Germany showing the largest proportional difference (43 percent) between the two pathways and also a faster time to recommendation. This may relate to the proportion of conditional assessments that were orphan medicines. With the exception of Germany, the time taken from regulatory approval to first HTA recommendation for products with conditional approvals is higher than those for standard approvals, with the largest difference seen in Sweden (241 days longer).

Conclusions. Conditionally approved NASs showed a variable HTA outcome; although there was generally a higher proportion of positive recommendations thus enabling more likely access in conditional approvals, the timing from regulatory approval to HTA recommendation was longer compared with standard approvals. This warrants a better understanding of the factors and uncertainties underlying these recommendations, supporting timely access of NASs with conditional approval.

PP31 Medical Device Regulation: What Is New?

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Introduction. In 2017, the European Union (EU) commission released the final versions of the Medical Device Regulation (MDR) and In-vitro Diagnostic Device Regulation. These regulations will replace the EU directives (Medical Device Directive [MDD], In-vitro Diagnostic Device [IVDD], and Active Implantable Medical Device [AIMD]). EU regulations are effective in all EU countries at date of publication. In contrast, the EU directives must be implemented in national law first.

Methods. Guidelines and respective legislation, consultation results and methods/medical device (MD) evaluations were reviewed and analyzed. Decision criteria and reasoning, assessment outcomes and potential impact on price negotiations were the main aspects for comparison.

Results. Manufacturers have to be aware of the importance of clinical data for demonstrating the compliance of their products. This applies both to the approval of the products and the "post-market activities" and particularly to the "post-market clinical follow-up" for which requirements for Class I and II products need to be further developed. The MDR requires manufacturers to collect clinical data before and after approval, which could lead to excessive documentation requirements. The term "sufficient clinical data" from the MDR is unclear. A functional Eudamed specification is necessary, which enables an automated

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