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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