decision-makers to reach a deeper understanding of how the intervention can be made to work most effectively. A critical review goes beyond mere description of identified articles and includes analysis and conceptual innovation. An effective critical review synthesizes material from diverse sources, provides an opportunity to 'take stock' and evaluate what is of value related to a previous body of work.

**Results.** User patterns of clinical videoconferencing turned out to be dependent on contextual factors like clinical condition, motivation, technological skills, professional and organizational arrangements, trust and the perceived value they add compared with "services as usual". The pattern of what works, for whom and under which circumstances was heterogeneous and dynamic. The review types helped identify and conceptualize new user categories, and understand the complex patterns of use.

**Conclusions.** The in-depth accounts of different clinical use resulting from such a review provide decision makers with a highly practical understanding of complex social interventions which is likely to be of use when planning and implementing programs at a national, regional or local level. A critical-realist review of digital services can complement controlled studies and evidence summaries in HTA.

## OP64 Implementation Of Whole Exome Sequencing For Rare Diseases

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**Introduction.** The Victorian Department of Health and Human Services provided AUD 25 million (i.e. USD 17.3 million) over four years to determine the place of whole exome sequencing (WES) for patients attending public genetics clinics. Comparative analysis of WES and 'usual care' determined that WES increased diagnosis rate (from 14 to 58 percent), changed clinical management in one third of patients and identified relatives and couples at high risk of recurrence in future pregnancies. Translating this into routine care requires co-design with clinical and laboratory stakeholders.

**Methods.** Victoria's clinical and laboratory genetics service system uses a 'hub and spoke' model. Representatives from these were invited to join a 'Clinical Adoption Group' (CAG) to oversight implementation of new government funding (AUD 2 million (i.e. USD 1.4 million) per year) to ensure statewide access to, and funding of, WES for children with rare undiagnosed genetic conditions. The CAG developed terms of reference, 'traffic light' evidence-based eligibility criteria, a pricing model and reporting mechanism, and recommended funding for sequencing, curation, curator training and multidisciplinary team (MDT) meetings to support implementation.

**Results.** Funding was distributed across hub and spoke sites reflecting clinical and laboratory demand and workforce requirements. All cases demonstrated clinical utility and were reviewed at MDT meetings. To date, 37 percent of patients have received a diagnosis changing management, with equity of access between metropolitan and regional areas demonstrated. Eligibility criteria are reviewed as new evidence is published to ensure new evidence is incorporated, although curation capacity limits turn-around-times.

**Conclusions.** Co-designing a statewide and evidence-based clinical model has resulted in sector (i.e. clinician and laboratory) buy-in and supported broad access to funded WES. In addition, the sector has developed a better understanding of how evidence informs policy and funding decisions, which has resulted in delivering equitable WES that provides early diagnosis leading to changed clinical management and cessation of unnecessary interventions.

## OP65 Pharmacoeconomic Evaluation Of Orphan Drugs: Impact Of Extra Criteria?

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**Introduction.** There is ongoing debate as to whether conventional pharmacoeconomic evaluation (PE) methods are appropriate for orphan medicinal products (OMPs). The National Centre for Pharmacoeconomics (NCPE) in Ireland has a well-defined process for conducting pharmacoeconomic evaluations of pharmaceuticals, which is the same for OMPs and non-OMPs. The objective of this study was to identify whether supplementary criteria considered in the pharmacoeconomic evaluation of OMPs would affect final reimbursement recommendations.

**Methods.** A literature search was conducted to identify criteria. Orphan drug pharmacoeconomic evaluations completed by the NCPE between January 2015 and December 2017 were identified and supplementary criteria, where feasible, were applied.

**Results.** Fourteen pharmacoeconomic evaluations were included in the study. Three criteria that could feasibly be applied to the NCPE evaluation process were identified, all three of which essentially broadened the economic perspective of the pharmacoeconomic evaluation. Higher cost-effectiveness threshold: Despite being arbitrarily raised from EUR 45,000/QALY to EUR 100,000/QALY, only one orphan drug demonstrated cost-effectiveness at this higher threshold. Weighted QALY gain: here, a weighted gain of between one and three is applied to drugs demonstrating QALY gains between 10 and 30, respectively. No OMPs included in the study showed a QALY gain of more than 10. Thirteen demonstrated QALY gains less than 10 and one could not be evaluated. Societal perspective: six submissions incorporated societal perspective as a scenario analysis. Despite incremental cost-effectiveness ratios (ICERs) being reduced between 4 percent and 58 percent, only two OMPs demonstrated cost-effectiveness at the higher threshold (EUR 100,000/QALY).

**Conclusions.** Application of supplementary criteria to the pharmacoeconomic evaluation of OMPs had a minor effect on three products assessed. However, for the majority, the final cost-effectiveness outcomes remained the same. The study highlights that other criteria are being considered in the decision to reimburse.

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