

## PP58 SARS-CoV-2: A Rapid Review Of The Transmission Risk From Vaccinated Populations

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**Introduction.** Since the vaccine roll out, research has focused on vaccine safety and efficacy, with large clinical trials confirming that vaccines are generally effective against symptomatic COVID-19 infection. However, breakthrough infections can still occur, and the effectiveness of vaccines against transmission from infected vaccinated people to susceptible contacts is unclear.

Health Technology Wales (HTW) collaborated with the Wales COVID-19 Evidence Centre to identify and examine evidence on the transmission risk of SARS-CoV-2 from vaccinated people to unvaccinated or vaccinated people.

**Methods.** We conducted a systematic literature search for evidence on vaccinated people exposed to SARS-CoV-2 in any setting. Outcome measures included transmission rate, cycle threshold (Ct) values and viral load. We identified a rapid review by the University of Calgary that was the main source of our outcome data. Nine studies published following the rapid review were also identified and included.

**Results.** In total, 35 studies were included in this review: one randomized controlled trial (RCT), one post-hoc analysis of an RCT, 13 prospective cohort studies, 16 retrospective cohort studies and four case control studies.

All studies reported a reduction in transmission of the B.1.1.7 (Alpha) variant from partial and fully vaccinated individuals. More recent evidence is uncertain on the effects of vaccination on transmission of the B.1.617.2 (Delta) variant. Overall, vaccine effectiveness in reducing transmission appears to increase with full vaccination, compared with partial vaccination. Most of the direct evidence is limited to transmission in household settings therefore, there is a gap in the evidence on risk of transmission in other settings. One UK study found protection against onward transmission waned within 3 months post second vaccination.

**Conclusions.** Early findings that focused on the alpha variant, showed a reduction in transmission from vaccinated people. There is limited evidence on the effectiveness of vaccination on transmission of the Delta variant, therefore alternative preventative measures to reduce transmission may still be required.

## PP59 Multidimensional Evaluation Of The Reducer Device In Patients With Refractory Angina

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**Introduction.** Treatments for coronary heart disease patients have had major developments in recent decades, both in the pharmacological and interventional fields, and this has helped to prolong the survival of these patients. However, the growing number of patients who show persistent and disabling symptoms of angina proves that at the same time their quality of life has not been equally improved.

**Methods.** We conducted a multidimensional assessment coherent with health technology assessment methodology on the Coronary Sinus Reducer System (CSRS). CSRS is the latest line of therapy for patients with coronary artery disease who are ineligible for revascularization, demonstrate reversible ischemia, and have refractory angina pectoris (AP) despite optimal standard medical therapy. We performed a literature review in order to gather evidence on efficacy and safety of the device and on the economic and organizational impact of the procedure. In the economic domain we developed a cost-utility model based on a decision tree and a five-year time horizon budget impact model.

**Results.** Several studies in the literature have shown that this therapy is related to an increase in quality of life and an improvement in symptoms of refractory angina. The economic evaluations conducted show how the therapy, despite an increase in the resources absorbed in the first years of implementation, reaches a cost saving profile in the medium term due to positive outcomes, while leading to an increase in the quality of life in patients suffering from refractory angina.

**Conclusions.** The treatment of refractory angina remains a challenge for today's medicine. Patients suffering from this condition are often described as "no option" patients. Thus, despite there is a need of further evidence to establish even more robustly the economic sustainability of the device, especially on its effectiveness in the medium-long term, the device should be taking into account in those patients who could benefit from it in terms of relieving the symptoms of angina and improving their quality of life.

## PP61 Plugging the Gap of Fetoscopy in Congenital Diaphragmatic Hernia Pregnancies: Value for Money?

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**Introduction.** Fetoscopic endoluminal tracheal occlusion (FETO) for congenital diaphragmatic hernia (CDH) fetuses increases the neonatal survival rate. However, FETO also increases the number of preterm prelabour rupture of membranes (PPROM) and preterm deliveries (PTDs) as fetal membrane defects after fetoscopy do not spontaneously heal. To solve this issue, an advanced sealing plug is being developed. Through early-stage health economic modelling, we estimated the potential value of this innovative plug in terms of costs and effects and determined the properties for it to become cost-effective.

**Methods.** We applied early-stage health economic modelling to the case of performing FETO in singleton pregnant women whose fetus is prenatally diagnosed with CDH. We simulated a cohort of women using a state-transition model over a 45-year time horizon. In our best-case scenario analysis, we compared the current care strategy to a perfect plug strategy, which reduces PPRM and PTDs by 100 percent, to determine the maximum quality-adjusted life years (QALYs) gained and costs saved. Using threshold analysis, we determined the minimum percentage of reduction in PPRM and PTDs for the plug to be considered cost-effective. Model parameters' impact on outcomes was investigated in a sensitivity analysis.

**Results.** Our model indicated that a perfect plug strategy would yield an additional 1.94 QALYs at a cost decrease of EUR 2,554 per patient per year. These values were strongly influenced by the percentage of very preterm deliveries. Threshold analysis showed that, for EUR 500 per plug, the plug strategy needs a minimum relative reduction of 1.83 percent in PPRM and PTDs (i.e., PPRM: 47.50 to 46.63 %, PTDs: 71.50 to 70.19 %) to be cost-effective.

**Conclusions.** Our model-based approach showed clear potential for the plug strategy when applied in the context of FETO for CDH fetuses, as only a small reduction in PPRM and PTDs is needed for the plug to be cost-effective. Its value is expected to be even higher when used in conditions suffering from more very preterm deliveries. Continuation of investment in the innovation's research and development seems to provide value for money.

## PP62 Recommendations On Methodologies To Obtain Comparator Efficacy In Health Economic Assessments Of Tumor-Agnostic Drugs

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**Introduction.** Guidance on appropriate methods to obtain a comparator arm for the cost-effectiveness analysis of tumor-agnostic drugs is needed. In recent years, multiple tumor-agnostic drugs have been submitted to health technology assessment (HTA) bodies based on data from single-arm basket trials. These target a specific genetic mutation, as opposed to targeting a specific tumor type. Since HTA bodies are interested in the comparative effectiveness of a treatment, manufacturers have used several methods to obtain a synthetic control arm in their submissions. This study provides an overview of the recommendations by HTA bodies on the methodology to obtain comparator efficacy.

**Methods.** A targeted literature review will be conducted focusing on the methodology used to obtain a comparator arm in the context of tumor-agnostic drugs. The search will cover key HTA organizations; including the National Institute for Health and Care Excellence (NICE), Haute Autorité de Santé (HAS) and the Canadian Agency for Drugs & Technologies in Health (CADTH). Methodologies used in entrectinib and larotrectinib submissions will be extracted. Particular focus will be given on the impact of the applied methodology to the reimbursement decision, as well as key critiques by the HTA

bodies. Key search terms will include the following: 'tumor-agnostic', 'histology independent', 'HIT', 'entrectinib', 'larotrectinib'.

**Results.** An overview of the results will be presented. These will include the applied methodology for obtaining a comparator arm, critiques and recommendations from HTA bodies, and the impact these methodologies had on the overall reimbursement decision. This will enable comparison of HTA decision-making across regions, and key evidence gaps that need to be further explored.

**Conclusions.** The results of this study could be useful in the future assessment of tumor-agnostic drug submissions, focusing on the methodology used to obtain comparator efficacy.

## PP66 Safety, Effectiveness And Cost-effectiveness Of Scalp Cooling Devices For The Prevention Of Chemotherapy-induced Alopecia

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**Introduction.** Chemotherapy-induced alopecia (CIA), although reversible, is one of the most common and distressing side effects of cancer therapy, affecting approximately 65 percent of all patients and influencing treatment decisions in some of them. Scalp cooling (SC) is a method aiming to prevent CIA. Our study aims to evaluate the real value of SC devices.

**Methods.** A systematic review of the available scientific literature on the safety, effectiveness and cost-effectiveness of the use of SC compared with no intervention was performed. Overall effect size was estimated through a meta-analysis. An economic analysis in the Spanish context from the Spanish National Healthcare System (NHS) and social perspectives was performed.

**Results.** Thirteen randomized controlled trials (n = 832) were included but only nine contributed to the meta-analysis. A large effect in favor of SC reducing hair loss was found (RR=0.57; 95% CI: 0.46-0.69). No differences were observed according to the type of cancer, although there was a small positive effect for breast cancer. A higher effect was found in patients treated with a combination anthracyclines/taxanes treatment compared to those treated only with anthracyclines. The only economic evaluation found in the literature was conducted in The Netherlands and concluded that Paxman system was less costly than usual care from societal perspective and no differences in quality adjusted life years (QALYs) were observed. The de novo economic analysis showed that the strategies including SC devices generated more costs and QALYs (given some