are usually self-limiting and last on average for 4 to 7 days, with patients typically not accessing the public healthcare system (SUS). In severe cases, symptoms include neurological disorders and neonatal malformations. A future Zika vaccine can contribute to decreasing the number of cases and associated complications. However, this has to be balanced against continuing costs to control this and other vector borne diseases. Consequently, information about consumers' willingness to pay (WTP) for a hypothetical Zika vaccine can help with price setting discussions in Brazil starting with the private market before being considered within SUS.

**Methods.** A cross-sectional study was conducted among residents in one of the main provinces of Brazil (Minas Gerais) regarding their WTP for a hypothetical Zika vaccine with agreed characteristics. This included a mean effective protection of 80 percent, with the possibility of some local and systemic side-effects. The discussed price was USD 56.41 (BRL 180.00) per vaccination as this figure was utilized in a previous WTP study for a dengue vaccine.

**Results.** Five hundred and seventeen people were interviewed. However, thirty would not be vaccinated even if the vaccine was free. Most of the resultant interviewees (489) were female (58.2 percent), were employed (71.2 percent), had private health insurance (52.7 percent), had household incomes above twice the minimum wage (69.8 percent) and did not have Zika (96.9 percent). The median individual maximum WTP for this hypothetical Zika vaccine was USD 31.34 (BRL 100.00).

**Conclusions.** WTP research can contribute to decision-making about possible prices alongside other economic criteria once a Zika vaccine becomes available in Brazil alongside other programmes to control the virus.

## VP16 A NICE Way To Manage Managed Access: Case Study In Muscular Dystrophy

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**Introduction.** Managed access arrangements (MAAs) represent a way of enabling patient access to promising treatments while collecting real world data to inform future health technology evaluations (HTE) and commissioning decisions. In July 2016, the National Institute for Health and Care Excellence (NICE) recommended Ataluren for treating Duchenne Muscular Dystrophy within a MAA. NICE is uniquely placed to oversee the implementation and monitoring of this MAA in collaboration with multiple stakeholders to ensure the final outputs meet the needs of a future HTE.

**Methods.** NICE assembled an Ataluren Managed Access Oversight Committee (MAOC) consisting of representatives from the manufacturer, patient organisations, commissioning body and treatment centres. This group were to meet every six months under the chairmanship of NICE with the primary function of reviewing the progress of data collection and identifying operational challenges in implementing the terms of the arrangement.

**Results.** The Ataluren MAOC has convened four times since the MAA commenced and these discussions identified a number of important actions. Data completeness was a concern and prompted stakeholders to collaborate on implementing measures to circumvent this, to ensure data quality for future HTE. Lack of awareness and understanding of the MAA in the patient community was highlighted and resulted in the production of lay information. A review of the statistical analysis plan resulted in the need for an agreement amendment. To ensure an audit trail and appropriate critique, NICE produced an amendment process to define and justify amendments made during the agreement term.

**Conclusions.** MAOC meetings play an important role in monitoring the progress of MAAs and have ensured that implementation issues are identified promptly and resolved with input from key stakeholders. This process allows NICE to coordinate the work of stakeholders to facilitate the success of the MAA, and will be adopted in future NICE MAAs in ultra-rare diseases.

## VP18 Potential Of Real World Evidence For 'IDEAL' Procedures Research

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**Introduction.** Randomized trials and similarly robust research methods generate evidence in carefully controlled settings, often with strict inclusion criteria. But patients in the 'real world' often have multiple comorbidities, and treatments are delivered within diverse environments. Trials are also difficult to fund, and rarely collect longitudinal data. Because of these, and other limitations, researchers are increasingly recognizing the inherent value of real world evidence (RWE). This is not only true for pharmaceutical products, and may have even more relevance in the evaluation of complex interventional procedures and non-medicines healthcare technologies. The Idea, Development, Exploration, Assessment, Learning (IDEAL) Framework guides the developmental 'pipeline' of surgical (and other) procedures, as well as medical device research (IDEAL-D). IDEAL informs the production of high-quality evidence of safety and effectiveness, but there is potential to further expand its applications.

**Methods.** Our aim is to investigate the feasibility of using of RWE alongside the IDEAL Framework in the assessment of procedures and devices. Methodological experts from the IDEAL Collaboration, HTA agencies and other healthcare research organisations are contributing their unique perspectives and experiences to explore these methods. As part of this work, Cedar Healthcare Technology Research Centre (Cedar) has attempted to retrospectively apply the IDEAL criteria to a series of RWE projects conducted on behalf of the National Institute for Health and Care Excellence (NICE) Interventional Procedures and Medical Technologies Evaluation Programmes.

**Results.** Cedar's experience indicates that there may be options for using retrospective routinely-collected linked data and other existing sources to address some of the requirements of IDEAL. Likewise, the IDEAL Framework is expected to be a helpful reference when designing new databases and clinical registries for prospective collection of relevant and informative evidence. Examples from several projects will be shared at the Health Technology Assessment International (HTAi) conference.

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**Conclusions.** Initial signs are that there are likely to be a number of ways in which IDEAL and RWE could complement one another.

## VP19 Cost-Effectiveness Of Combination Inhaled Long-Acting Bronchodilators

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**Introduction.** To inform the development of a national clinical guideline for Chronic Obstructive Pulmonary Disease (COPD), prioritised by the National Clinical Effectiveness Committee (NCEC) in Ireland, a systematic review was conducted to examine the cost-effectiveness of long-acting beta2-agonists (LABAs) in combination with long-acting muscarinic antagonists (LAMAs) compared with LAMA or LABA monotherapy.

**Methods.** Medline, Embase, the Cochrane Library and grey literature sources were searched up to 19 June 2018. Studies evaluating cost-effectiveness published post-2008 in English were included. Screening, data extraction, and quality assessment using the Consensus Health Economic Criteria (CHEC-list) and International Society for Pharmacoeconomics (ISPOR) questionnaires were conducted independently by two reviewers. Costs were adjusted to 2017 Irish Euro using consumer price indices and purchasing power parity as per national guidelines.

**Results.** From a total of 8,661 articles identified, nine studies (all cost-utility analyses) were included in the review. Studies ranged from low to high quality and compared LAMA/LABA combination therapy with LAMA monotherapy. The results reported were mixed, ranging from combination therapy being dominated by (that is, more costly and less effective than) LAMA monotherapy to being dominant (that is, less costly and more effective). However, when excluding low quality, less applicable studies, the remaining six studies reported incremental cost-effectiveness ratios (ICERs) of between EUR 2,770 and EUR 26,462 per quality-adjusted life year (QALY) gained. Only one study additionally compared LABA monotherapy as a comparator, reporting combination therapy to be even more cost-effective than in the LAMA monotherapy comparison.

**Conclusions.** Applying a cost-effectiveness willingness-to-pay threshold of EUR 45,000 per QALY gained, this systematic review found that LAMA/LABA combination therapy is cost-effective compared with LAMA or LABA monotherapy in COPD patients.

## VP21 Economic Burden Of Pertussis Treatment In Brazil, 2014

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**Introduction.** Despite availability of a cheap, widely accessible vaccine, pertussis remains an important cause of morbidity and mortality in children worldwide. A resurgence of pertussis in Brazil peaked at 8,815 cases in 2014. We estimate the economic burden of pertussis hospitalizations and outpatient cases in Brazil in 2014.

**Methods.** Taking the Brazilian public health system (SUS) perspective we obtained numbers of hospitalizations from the National Hospitalization Information System (SIH) for discharge diagnosis ICD10:A37 and numbers of confirmed outpatient cases from the surveillance information system (SINAN). We estimated costs per case for seven age groups (<1, 1-4, 5-9, 10-19, 20-39, 40-64, and 65+ years). Hospitalization costs were obtained from SIH, which reimburses direct medical (hospital stay, healthcare professional services, and physical therapy) and non-medical costs (parent/caregiver stay accompanying a hospitalized child). Cost of outpatient management was estimated from national guidelines (diagnostic exams, medical visits, and medications) and national pricing lists. Total economic burden was derived by multiplying costs/case by numbers of hospitalized and outpatient cases, respectively, and converted to US Dollars (USD) (December 2014: 1 BRL = USD 0.39).

**Results.** A total of 8,815 pertussis cases occurred in Brazil in 2014; 55.9 percent were hospitalized. Total cost to the public health care system was USD 2.6 million, 95 percent for hospitalizations. Cost/case was highest at the extremes of age for both hospitalized <1y, BRL 1,378.54 (USD 537); 65y+, BRL 1,875.00 (USD 731) and outpatient cases BRL 41 (USD 16) for <4y and 20y + . Children <4 years accounted for 95.4 percent of hospitalizations, 51.2 percent of outpatient cases, and 95.4 percent of total costs. Children <1 year accounted for 88.1 percent of hospitalizations, 29.1 percent of outpatient cases, and 89.3 percent of total costs.

**Conclusions.** Pertussis economic burden in an outbreak year was largely due to hospitalizations in children <1y. Additional prevention strategies are required targeting this population.

## VP22 Applying The IDEAL Framework To NICE Interventional Procedure Guidance

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**Introduction.** The IDEAL (Idea, Development, Exploration, Assessment, Learning) Framework measures the maturity of evidence base behind surgical innovation. The NICE Interventional Procedures (IP) programme issues guidance for the United Kingdom National Health Service (NHS) on use of surgical innovation. One of four recommendations can be made: (a) standard arrangements, (b) special arrangements, (c) research only, and (d) do not use. This study aimed to investigate whether the recommendation of NICE IP guidance corresponded with the stage of innovation as determined by IDEAL, thus IDEAL's role in informing future guidance production.

**Methods.** A retrospective sample of 103 pieces of guidance issued between 2015 and 2018 was analysed. One researcher examined the evidence base and determined the corresponding stage of the IDEAL framework, numbered 1, 2, 2a, 3 and 4. The primary outcome measure was the association between stage of evidence on IDEAL framework and the recommendation of published NICE IP guidance.

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