



International Alliance for  
Biological Standardization



## The Role of Real-World Evidence for Regulatory and Public Health Decision Making for Accelerated Vaccine Deployment

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**Title: Exploring the Cost-Effectiveness of Respiratory Syncytial Virus (RSV) Preventive Interventions in children with Real-World Evidence generated by the IMI-RESCEU project**

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**Background:** Respiratory syncytial virus (RSV) leads to a large burden in paediatric wards across Europe. A monoclonal antibody (mAb) and a maternal vaccine (MV) have demonstrated effective protection against RSV among vulnerable infants in their clinical trials, hence, the recommendation and implementation of RSV prevention strategies are under consideration by public health decision makers. The cost-effectiveness of the interventions using robust and up-to-date real-world evidence (RWE) is imperative to inform decision making.

**Methods:** The REspiratory Syncytial virus Consortium in EUrope (RESCEU), funded by Innovative Medicines Initiative (IMI), aimed to generate robust evidence on the disease burden and economic impact of RSV involving multi-stakeholders across Europe. A large amount of RWE was generated in multiple countries from national registries, and prospective observational studies. We developed a decision analytical model to evaluate potential MV and mAb programmes applying the RWE as model inputs. We estimated the RSV-related economic burden and assessed the cost-effectiveness of various programmes in Norway, Denmark, England, Scotland, the Netherlands, and Finland. We also made multi-model comparisons utilising available RWE.

**Results:** At a common price of €50 per dose, seasonal mAb (October to April), and seasonal mAb plus a catch-up program in October can be cost-effective from payers' perspective, depending on the country and the willingness-to-pay threshold. Year-round MV can also be preferred in most countries if priced lower than mAb. From a full societal perspective (including leisure time lost), the seasonal mAb plus catch-up program was cost saving for all countries except the Netherlands. Apart from interventions' characteristics (price, efficacy, and duration of protection), the results are also sensitive to RSV hospitalisation estimates and quality-adjusted life year losses.

**Conclusions:** RWE generated by RESCEU supports the decision-making process in multiple countries regarding the implementation of RSV prevention strategies. However, there are still large data gaps, especially on RSV disease burden and intervention effectiveness. More RWE is urged to further inform decision makers, the scientific community, and the general public.

