



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

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Carrico et al., 'Public Health Impact and Return on Investment of Belgium's Pediatric Immunization Program', *Front Public Health*. 2023 Jun 22;11:1032385. doi: 10.3389/fpubh.2023.1032385.

Background – We evaluated the public health impact and return on investment of Belgium's pediatric immunization program (PIP) from both healthcare-sector and societal perspectives.

Methods – We developed a decision analytic model for 6 vaccines routinely administered in Belgium for children aged 0-10 years: DTaP-IPV-HepB-Hib, DTaP-IPV, MMR, PCV, rotavirus, and meningococcal type C. We used separate decision trees to model each of the 11 vaccine-preventable pathogens: diphtheria, tetanus, pertussis, poliomyelitis, *Haemophilus influenzae* type b, measles, mumps, rubella, *Streptococcus pneumoniae*, rotavirus, and meningococcal type C; hepatitis B was excluded because of surveillance limitations. The 2018 birth cohort was followed over its lifetime. The model projected and compared health outcomes and costs with and without immunization (based on vaccine-era and pre-vaccine era disease incidence estimates, respectively), assuming that observed reductions in disease incidence were fully attributable to vaccination. For the societal perspective, the model included productivity loss costs associated with immunization and disease in addition to direct medical costs. The model estimated discounted cases averted, disease-related deaths averted, life-years gained, quality-adjusted life-years gained, costs (2020 euros), and an overall benefit-cost ratio. Scenario analyses considered alternate assumptions for key model inputs.

Results – Across all 11 pathogens, we estimated that the PIP prevented 226,000 cases of infections and 200 deaths, as well as the loss of 7,000 life-years and 8,000 quality-adjusted life-years over the lifetime of a birth cohort of 118,000 children. The PIP was associated with discounted vaccination costs of €91 million from the healthcare-sector perspective and €122 million from the societal perspective. However, vaccination costs were more than fully offset by disease-related costs averted, with the latter amounting to a discounted €126 million and €390 million from the healthcare-sector and societal perspectives, respectively. As a result, pediatric immunization was associated with overall discounted savings of €35 million and €268 million from the healthcare-sector and societal perspectives, respectively; every €1 invested in childhood immunization resulted in approximately €1.4 in disease-related cost savings to the health system and €3.2 in cost savings from a societal perspective for Belgium's PIP. Estimates of the value of the PIP were most sensitive to changes in input assumptions for disease incidence, productivity losses due to disease-related mortality, and direct medical disease costs.

Conclusions - Belgium's PIP, which previously had not been systematically assessed, provides large-scale prevention of disease-related morbidity and premature mortality, and is associated with net savings to health system and society. Continued investment in the PIP is warranted to sustain its positive public health and financial impact.

