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**Record Status**
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

**CRD summary**
This study examined the cost-effectiveness of a vaccination programme against paediatric rotavirus gastroenteritis (RVGE) in comparison with no vaccination in children aged less than five years. The authors concluded that this vaccine would substantially reduce the consumption of health care resources and lead to substantial health benefits in Belgium, especially from the societal perspective. The study was based on valid methodology that was well reported, but the lack of an incremental analysis makes it difficult to assess the authors’ conclusions.

**Type of economic evaluation**
Cost-effectiveness analysis

**Study objective**
This study examined the cost-effectiveness of a vaccination programme against paediatric rotavirus gastroenteritis (RVGE) in comparison with no vaccination in children aged less than five years.

**Interventions**
The vaccination programme consisted of a pentavalent rotavirus vaccine, three doses of which were administered between the ages of six weeks and 20 to 22 weeks (with intervals of at least four weeks between doses). The comparator was no vaccination.

**Location/setting**
Belgium/primary care.

**Methods**

**Analytical approach:**
This economic evaluation was based on a published decision analytic model with a five-year time horizon, which was updated with more recent data. The authors stated that the perspectives of both the health care system and society were adopted.

**Effectiveness data:**
The clinical data came from published studies that were selected. The bulk of evidence for epidemiological parameters was based on a recent prospective, multi-centre, observational study, namely the Rotavirus Gastroenteritis Epidemiology and Viral Types in Europe Accounting for Losses in Public Health and Society (REVEAL) study. A subgroup of 127 Belgian children was used to update the previous model with country-specific and recent epidemiological inputs. The key clinical endpoint was the vaccine efficacy, which was retrieved from a large, double-blind, placebo-controlled, phase III efficacy and safety trial involving over 70,000 children in 11 countries. Assumptions were made for vaccine coverage rates and some other parameters.

**Monetary benefit and utility valuations:**
Not relevant.

**Measure of benefit:**
The model outputs were RVGE episodes, hospitalisations, nosocomial infections, consultations with general practitioners or paediatricians, cases not seeking medical care, and deaths due to paediatric RVGE infections. None of
these were combined with costs in cost-effectiveness ratios. The benefits were discounted at an annual rate of 1.5%.

Cost data:
The economic analysis included vaccine costs, but not those for its administration as the vaccine was delivered concomitantly with other paediatric vaccines, medical costs, direct non-medical costs, and indirect costs. Medical costs included consultations with health care professionals, laboratory tests, medications, dietary products, over the counter medications, and hospitalisations. Direct non-medical costs included transportation, nappies, and parents’ accommodations and indirect costs included workdays lost by parents to take care of their sick child, childcare, and baby-sitting. Most of the cost data were estimated from the REVEAL study using local tariffs and official sources. The economic analysis also considered the cost per case of nosocomial RVGE infection, which was estimated based on authors’ calculation. Vaccine cost was calculated using the official vaccine price, the Belgian reimbursement rate, and the ceiling co-payment. A 3% annual discount rate was applied to costs, which were in Euros (EUR). The price year was not explicitly reported, but 2007 prices were used to estimate the vaccine cost.

Analysis of uncertainty:
A deterministic sensitivity analysis was undertaken on the key model inputs such as the ratio of patients seeking or not seeking medical care, the vaccination coverage rate, the impact of the extra length of stay due to a nosocomial RVGE infection, incidence rates, hospital costs for hospitalised children, and discount rates. The alternative assumptions were either based on authors’ opinions or were derived from published sources that were not considered in the base-case analysis.

Results
In a cohort of 118,366 Belgian infants, assuming a coverage rate of 90%, the vaccination programme prevented 21,194 RVGE episodes (a reduction of 76.3%, compared with no vaccination), 4,852 hospitalisations (-82.8%), 998 cases of nosocomial infections (-58.2%), 7,148 consultations with health care professionals (-76%), 8,194 cases not seeking care (-76%), and 2 deaths (-84.6%).

Taking into account the health care savings due to reduced cases of RVGE infections and the costs of vaccine, the immunisation programme led to an incremental cost of EUR 7.01 million from the perspective of the health care system and EUR 5.51 million from the perspective of society.

The sensitivity analysis showed that the base-case results (both for the burden of disease and cost reduction) were relatively robust.

Authors’ conclusions
The authors concluded that a pentavalent rotavirus vaccine in children aged up to five years would substantially reduce the consumption of health care resources and lead to substantial health benefits in Belgium, especially from the societal perspective.

CRD commentary
Interventions:
The selection of no vaccination as the comparator was appropriate to reflect the current pattern of care in the authors’ setting. A clear description of the vaccination administration schedule was given.

Effectiveness/benefits:
The authors made their own selection of the relevant sources of data for the decision model. The key source of clinical evidence was described with respect to its sample size and study design. These features should ensure the validity of the clinical data. Little information on the other sources of data was provided, except for the clinical trial used to derive the treatment efficacy and safety data. The most uncertain model inputs were subjected to sensitivity analyses, in order to determine their impact on the study findings. The key clinical outputs were disease-specific and may not be comparable with the benefits of other health care interventions.

Costs:
The analysis of costs was carried out from two different perspectives, which makes the findings relevant to different
payers. The cost categories, their sources, the calculations, and the assumptions made were explicitly reported, but no detailed breakdown of cost items was provided. The unit costs and resource quantities were presented separately only for a few items. This may hinder the possibility of replicating the analysis in other settings. The price year was not reported, but could have been 2007. Some economic inputs were varied in the sensitivity analysis.

Analysis and results:
The results were presented extensively and transparently both for costs and benefits. The model structure and key parameters were appropriately presented and justified. However, no incremental analysis was performed and only deterministic sensitivity analyses were carried out. This makes it difficult to correctly interpret the results and fully assess the uncertainty around these results. The model was adapted to Belgium from one used in the French context, and can be adapted to other European countries.

Concluding remarks:
The study was based on valid methodology that was well reported, but the lack of incremental analysis makes it difficult to assess the authors' conclusions.

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