An economic analysis of rotavirus vaccination in Italy
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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
The objective was to compare the cost-effectiveness of a national programme of immunisation against rotavirus, for Italian infants younger than five years old, versus no immunisation, to prevent gastroenteritis. The authors considered the vaccination programme to be effective in the prevention of rotavirus gastroenteritis and, from the societal perspective, it was cost-effective in any scenario. The methods were satisfactory, and these methods and the results were adequately reported. The authors’ conclusions appear to be appropriate.

Type of economic evaluation
Cost-effectiveness analysis

Study objective
The objective was to compare the cost-effectiveness of a national programme of immunisation against rotavirus, for Italian infants younger than five years, versus no immunisation programme, to prevent gastroenteritis.

Interventions
The vaccination to prevent rotavirus gastroenteritis was offered by the public health service and was compared with no such vaccination.

Location/setting
Italy/primary care.

Methods
Analytical approach:
A decision tree was used to synthesise the data from an observational study, clinical trials, and expert opinion. It simulated a cohort of 520,000 infants from birth to five years old. The authors stated that the perspectives were those of both the Italian National Health Service (NHS) and society.

Effectiveness data:
Annual hospitalisations, emergency visits, and family paediatrician home visits, as well as the incidence of rotavirus gastroenteritis by age group, were identified from the Rotavirus gastroenteritis Epidemiology and Viral types in Europe Accounting for Losses in public health and society (REVEAL) study, which was a prospective, multi-centre, observational cohort study conducted in seven European countries. The efficacy of the vaccine was from a large, double-blind, placebo-controlled trial. The vaccine coverage and the waning of the vaccine effect were based on expert opinion.

Monetary benefit and utility valuations:
Not relevant.

Measure of benefit:
There were four measures of benefit, which were the number of paediatric rotavirus gastroenteritis cases; the number of hospitalised rotavirus gastroenteritis cases; the number of emergency visits; and the number of family paediatrician home visits. These benefits were discounted at 3% per annum.

Cost data:
The costs of hospitalisation, direct medical costs, non-medical costs, and indirect costs were included. These cost data
were identified, using diagnosis-related groups, from the Italian Ministry of Health. Some data were also from the REVEAL study. The vaccination costs were reported. All costs were in Euros (EUR) and were discounted at a rate of 3% per annum.

Analysis of uncertainty:
A univariate deterministic sensitivity analysis was performed and the best- and worst-case scenarios were estimated. The break-even price for the vaccine was calculated, for all the various scenarios. The results of this analysis of uncertainty were presented in tables.

Results
With no vaccination, there were 13,520 hospitalisations, 49,400 emergency visits, and 59,280 paediatrician home visits. With the vaccination programme, there were 2,841 hospitalisations, 10,380 emergency visits, and 15,057 paediatrician home visits. Suggesting that 10,679 hospitalisations were avoided, 39,020 emergency visits were avoided, and 44,223 paediatrician visits were avoided, with the vaccination programme.

With no vaccination, the total costs, from the Italian NHS perspective, were EUR 27,439,739, and from the Italian societal perspective, they were EUR 70,518,128. With the vaccination programme, the costs, from the Italian NHS perspective, were EUR 36,497,667, and from the societal perspective, they were EUR 46,193,931.

From the Italian NHS perspective, the incremental cost-effectiveness of vaccination was EUR 96.44 per case prevented. From the societal perspective, vaccination was dominant, as it was more effective and less costly.

The univariate analysis showed that, from a societal perspective, vaccination created savings in any scenario. From the NHS perspective, all the scenarios were associated with net losses.

Authors' conclusions
The authors considered that the vaccination programme was effective in the prevention of rotavirus gastroenteritis and was cost saving, under any scenario, from the societal perspective.

CRD commentary
Interventions:
The selection of the comparators appears to have been appropriate for reflecting the options available in the Italian setting. Vaccination was not offered by the Italian public health service, at the time, and so the usual care was included.

Effectiveness/benefits:
The derivation of the clinical inputs was not reported in detail, but a large, double-blinded, placebo-controlled trial was used, for the vaccination effectiveness, and this was potentially a high-quality source. The benefit measures captured the incidence of the disease rather than its health impact, but this might have been appropriate if the disease episodes were very short, with no long-term adverse outcomes. This benefit measure was disease specific, which means that the value of this intervention cannot be compared with the values of other interventions for other diseases.

Costs:
The economic analysis considered two perspectives, which makes the results interesting to both the Italian NHS and society. Most of the data were from a previous study and only the key cost categories were presented. This makes it difficult to assess the quality of the cost data. Other data sources were reported, but they were not clearly described. Discounting was reported, but the price year was not.

Analysis and results:
The base-case results and the results of the one-way sensitivity analysis were both clearly reported in a table. The issue of uncertainty was satisfactorily investigated and was well discussed.

Concluding remarks:
The methods were satisfactory, and these methods and the results were adequately reported. The authors’ conclusions appear to be appropriate.
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