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 of the study was to estimate the cost-effectiveness of systematic vaccination of children against rotavirus in the Castilla y Leon region of Spain. The authors concluded that the results suggested that systematic rotavirus vaccination was not cost-effective at current vaccine prices. There were a few limitations in the study methodology and reporting. The authors’ conclusions appear to reflect the available evidence.

Type of economic evaluation
Cost-effectiveness analysis, cost-utility analysis

Study objective
To estimate the cost-effectiveness of systematic vaccination of children against rotavirus in the Castilla y Leon region of Spain.

Interventions
Vaccination against rotavirus using RotaTeq administered to children at two, four and six months of age or Rotarix administered at two and four months of age. The comparator was no vaccination.

Location/setting
Spain/primary care

Methods
Analytical approach:
The authors used a decision-tree model to combine data from an observational study of the burden of disease and a clinical trial of the effectiveness of RotaTeq and Rotarix. These estimates were supplemented with additional data from the published literature. The time horizon of the analysis was five years (birth to age five). The authors stated that two perspectives – healthcare payer and societal – would be used.

Effectiveness data:
The primary clinical effectiveness estimates were burden of rotavirus and vaccine efficacy. The burden of rotavirus infections was estimated based on the following health care outcomes: in-patient hospitalisations, visits to emergency departments, consultations with general practitioners (GP) and ill children at home. These outcomes were derived from a single clinical retrospective observational study from the Hospital Clinico Universitario of Vallodolid in Catilla y Leon. The authors assumed that there would be no deaths due to rotavirus in the region. Visits to the emergency ward were estimated to be three times higher than the number of hospitalisations. Vaccine efficacy data was taken from published data for a phase III clinical trial on RotaTeq and Rotarix. The authors assumed that each vaccine was fully effective from the first dose and remained effective over the five years. Vaccine coverage was assumed to be 100%.

Monetary benefit and utility valuations:
Utility decrements were applied in the base-case for a child and two caregivers for each episode of rotavirus gastroenteritis. Utility estimates were based on published Canadian values for children and caregivers who attended their GP for rotavirus gastroenteritis. Utility estimates were derived using the HUI2 questionnaire administered to caregivers to evaluate their children’s utility loss and the EQ-5D questionnaire administered to caregivers to evaluate their own utility loss. Utilities were calculated over three visits covering a two-week period. Future benefits were discounted at a rate of 5% per year.
Measure of benefit:
The primary measure of benefit was the quality-adjusted life-year (QALY).

Cost data:
Cost categories included acquiring and administering vaccines, treatment of rotavirus diarrhoea (including hospitalisation, emergency department visits and GP or paediatric visits) and indirect costs of absenteeism for caregivers (lost productivity). Vaccine costs were based on prices paid by the health service in the study setting. It was assumed that the vaccine would be administered alongside other routinely administered vaccines at no additional cost of recruiting children for vaccination. Costs of treating rotavirus diarrhoea were based on estimates from hospitals in the study setting. Costs of lost productivity was based on estimates from the literature for duration of absence multiplied by a daily salary rate. Costs were reported in Euros (€). Future costs were discounted at a rate of 5% per year.

Analysis of uncertainty:
The authors used one-way sensitivity analysis on the price of vaccines to determine the profitable price of the vaccine.

Results
Vaccination of a cohort of 100,000 children with Rotarix was expected to result in discounted medical costs of €19,963,042 and non-medical costs of €1,512,116. Vaccination with RotaTeq was expected to result in discounted medical costs of €22,005,828 and non-medical costs of €3,273,909. A strategy of no vaccination was associated with total discounted medical costs of €3,974,553 and non-medical costs of €10,217,004. Vaccination against rotavirus using Rotarix was expected to save €15,988,489 in direct medical costs and €8,704,888 in non-medical costs compared with no vaccination; using RotaTeq the expected savings were €18,031,275 in direct medical costs and €6,943,096 in non-medical costs.

The expected total number of QALYs lost in a cohort of 100,000 children vaccinated against rotavirus was expected to be 51.8 using Rotarix, 113.60 using RotaTeq and 350.3 with no vaccination. Universal vaccination was expected to result in a gain of 298.5 QALYs using Rotarix and 236.69 using RotaTeq.

The incremental cost per QALY gained for a rotavirus vaccination programme using Rotarix was estimated to be €52,603 from the healthcare payer perspective and €23,436 from the societal perspective, each compared with no vaccination. The equivalent cost per QALY gained for RotaTeq was estimated to be €74,959 from the healthcare payer perspective and €45,625 from the societal perspective. Sensitivity analysis indicated that RotaTeq became profitable (net benefit) at about €35 per dose and Rotarix at about €60 per dose, each from a societal perspective. From the health service payer's perspective, vaccines were found to be profitable (cost-utility) at about €60 per dose for Rotarix and €35 for RotaTeq (assuming a willingness-to-pay threshold of €30,000).

Authors' conclusions
The authors concluded that the results suggested that systematic rotavirus vaccination was not cost-effective at current vaccine prices.

CRD commentary
Interventions:
The interventions were described in sufficient detail and were compared with no vaccination (normal practice in the study setting). The authors justified the choice of interventions and stated that Rotarix and RotaTeq were two vaccines that had recently completed clinical trials and were being considered for routine infant immunisation in several countries. It was unclear whether any alternative vaccines were available in the study setting.

Effectiveness/benefits:
Estimates of the vaccine efficacies and incidence rates of health care outcomes were reported clearly. Sources used to derive the estimates were reported but were not discussed in detail. It was unclear whether the phase III trial used to derive efficacy estimates was randomised and sample sizes and inclusion criteria were not reported; these limited assessment of the quality of data in the model. The authors did not report the methods used to identify relevant studies from the published literature so it was unclear whether the best available data were used. The source of utility data was described in detail and was relevant to age group and disease area for the children in the study. Values were based on...
Canadian children and this may have limited the applicability to other settings.

Costs:
The costs included in each analysis were appropriate to the perspectives adopted and were reported clearly. Costs included in the societal perspective were limited to production loss costs; other costs relevant to this perspective could have included transport costs and diaper costs. The authors identified the exclusion of these costs and unassessed costs of adverse events as a limitation of the study. Sources used to derive costs were reported clearly. Key sources included national and regional resources appropriate for the location and setting. The authors did not provide the price year or discuss any cost adjustment methods. Discounting of future costs was appropriate given the time horizon of the model.

Analysis and results:
The model was described clearly and a diagram was supplied. Use of a five-year time horizon was justified as the authors stated that most rotavirus diarrhoea cases occurred in the first five years of life. Use of an incremental analysis was appropriate to explore the relative cost-effectiveness of vaccination against an alternative option of no vaccination. It was unclear whether other relevant comparators were omitted.

Analysis of uncertainty was limited to a one-way sensitivity analysis in which only vaccine costs were altered; an analysis in which all parameter estimates were altered between viable ranges in one-way, multiway or (ideally) probabilistic sensitivity analysis would have given a better indication of the impact of uncertainty on the results. The authors did not justify the lack of a comprehensive assessment of uncertainty but as the key effectiveness assumptions in the analysis were favourable towards the vaccination strategies it was reasonable to assume that the authors’ conclusion would remain robust when accounting for parameter uncertainty. The results were presented in adequate detail.

Concluding remarks:
There were a few limitations in the study methodology and reporting. The authors’ conclusions appear to reflect the available evidence.

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