The cost-effectiveness of vaccinating pregnant women against seasonal influenza in England and Wales


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 assessed the cost-effectiveness of seasonal influenza vaccination for pregnant women, considering the timing of vaccination and the length of protection. The authors concluded that vaccinating pregnant women against seasonal influenza might be cost-effective, when there was protection for a single season and some benefits for infants. The study had a robust cost-effectiveness framework and was well presented. The authors’ conclusions appear to be valid.

Type of economic evaluation
Cost-utility analysis

Study objective
This study assessed the cost-effectiveness of seasonal influenza vaccination for pregnant women, considering issues around the timing of vaccination and the length of protection.

Interventions
Seasonal influenza vaccination for women in their second or third trimester of pregnancy was compared with no vaccination. The optimal periods for vaccination were varied from September to May and infant protection was considered.

Location/setting
UK/primary care.

Methods
Analytical approach:
The analysis was based on a decision tree that considered the impact of vaccination on outcomes in cohorts of vaccinated or unvaccinated pregnant women and their infants. The time horizon was two years and the authors stated that the analysis was carried out from the perspective of the NHS in England and Wales.

Effectiveness data:
The clinical data were from a selection of relevant studies and UK sources were used, where available. For example, the data on hospitalisations for influenza were from the Hospital Episode Statistics (HES) database and from a laboratory database, while general practitioner (GP) consultations data were from the Royal College of General Practitioners’ Weekly Returns Service. Regression techniques were used to calculate the true number of hospitalisations and deaths due to influenza. The placebo arms of published clinical trials were used for intensive care admissions. Where data were not available for pregnant women, estimates for the general population were used. The authors used their own judgement to select the most appropriate estimates for some inputs. Vaccine efficacy was the key clinical input and was from a 2007 Cochrane review that pooled the results of several randomised studies.

Monetary benefit and utility valuations:
The loss in quality of life associated with an episode of symptomatic influenza was the mean of estimates reported in two published studies. One study combined health state values, from the placebo arms of four clinical trials, using a disease-specific Likert scale. The other study assessed the utility values directly from patients with laboratory-confirmed influenza, during the 2009 influenza pandemic, using the European Quality of life (EQ-5D) instrument. The disutility associated with hospital admission was based on expert opinion.
Measure of benefit:
Quality-adjusted life-years (QALYs) were the benefit measure and a 3.5% annual discount rate was applied to those accrued in the second year.

Cost data:
The economic analysis included the costs of hospitalisation, intensive care, GP consultation, GP prescription, and vaccine acquisition and administration. The resource use was from published sources, including national surveillance databases and hospital registries. The unit costs were from NHS sources, such as NHS Reference Costs, and the British National Formulary. All costs were in UK pounds sterling (£) and the price year was 2008. Those incurred in the second year after vaccination were discounted at a rate of 3.5%.

Analysis of uncertainty:
A probabilistic sensitivity analysis was undertaken, using a Monte Carlo simulation, to examine the impact of variations in all the epidemiological and economic parameters together. Conventional probability distributions were assigned to the model inputs. The relative influence of each input on the results was assessed by means of a multivariate regression analysis. Cost-effectiveness acceptability curves were constructed. A deterministic one-way sensitivity analysis was carried out on the attack rate and the quality of life lost, with clinically apparent influenza. Two scenarios varying the efficacy of vaccination in the second season (beyond the September following vaccination) were considered. In one, the vaccine continued to provide full protection, and in the other, the vaccine provided no protection.

Results
In the cohort of 200,000 women who were expected to be vaccinated each season, vaccination saved 96 QALYs (95% CI 16 to 180), cost £2.2 million (95% CI 1.4 million to 3.0 million), and saved health care expenditure of £590,000 (95% CI 280,000 to 1.1 million). In the base case, assuming infants were partially protected through their mothers and there was no vaccine efficacy after the first season, the incremental cost per QALY gained was £23,000 (95% CI 10,000 to 140,000). This ratio rose to £28,000 when infants were not protected, and fell to £15,000 when infants and mothers were protected for the second season.

In the base case, 69% of simulations were considered cost-effective at a threshold of £30,000 per QALY, and 38% at £20,000 per QALY. In the scenario without infant protection 54% were cost-effective at £30,000 and 20%, at £20,000 per QALY. In the scenario with second season protection 87% were cost-effective at £30,000 and 70% at £20,000 per QALY. The most influential inputs were the quality of life lost with clinically apparent influenza and the cost of vaccine administration.

Vaccination starting between September and December was cost-effective in the base case, while it could be cost-effective up to May when the protection lasted beyond the first season, using a threshold of £30,000 per QALY.

Authors' conclusions
The authors concluded that vaccinating pregnant women against seasonal influenza might be cost-effective, when there was protection for a single season and some benefit for infants.

CRD commentary
Interventions:
The selection of the comparators was appropriate as the proposed vaccination was compared against no immunisation. The best time to start a vaccination programme was investigated.

Effectiveness/benefits:
The methods and conduct of a literature review were not reported and the sources of data were presumably known to the authors. Appropriate sources were generally used to derive the clinical inputs. Clinical trials were used for the vaccine efficacy and limited details of their methods were reported, but their design should have ensured the validity of these data. Hospital databases were used for the number of deaths, which should reflect the real-world impact of influenza. Regression analyses were conducted for some data and they were described in detail in an appendix. The authors pointed out that some assumptions were required due to a lack of published information for pregnant women, but extensive sensitivity analyses were carried out on the most uncertain inputs. The disutility associated with specific
health conditions was derived from both patients and experts and the analysis highlighted the importance of these assumptions for the cost-effectiveness results. QALYs were appropriately selected as the benefit measure as the disease complications might affect the mortality and morbidity of pregnant women.

Costs:
The economic analysis was satisfactorily carried out and the cost categories were consistent with the perspective stated. Extensive data on the calculation of the number of hospitalisations and quantity of GP services were presented in the appendix. A breakdown of cost items was provided and the impact of alternative cost assumptions was investigated. The data sources were clearly reported for each item and were typical for the UK. Other characteristics of the economic analysis, such as the price year and discounting were provided.

Analysis and results:
The results were clearly presented and an appropriate incremental approach was used to synthesise the costs and benefits of the two strategies. Alternative assumptions were considered to assess the uncertain impact of vaccination on the health of both mothers and infants and the duration of the vaccine efficacy was investigated. The uncertainty was satisfactorily addressed, in a probabilistic analysis, and the methods and results were clearly reported. The statistical calculations for the values of selected clinical and economic inputs were clearly described. The results were specific to the UK context and could not easily be transferred to other contexts.

Concluding remarks:
The study had a robust cost-effectiveness framework and was well presented. The authors’ conclusions appear to be valid.

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