Clinical and economic assessment of different general population strategies of pertussis vaccine booster regarding number of doses and age of application for reducing whooping cough disease burden: a systematic review

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CRD summary
This review concluded there was insufficient evidence in the general population to support use of pertussis booster vaccination strategies aimed at reducing whooping cough, including a booster at 12 to 24 months of age, pre-school age, during adolescence or every 10 years. Overall, the authors’ cautious conclusions appeared to adequately reflect the paucity and quality of the included data.

Authors' objectives
To determine the clinical effectiveness and cost-effectiveness of different strategies of administering pertussis vaccine to reduce the incidence of whooping cough in the general population.

Searching
MEDLINE, EMBASE and The Cochrane Library were searched from inception to June 2006. Search terms were reported. A number of health- and vaccine-related websites were searched. Reference lists of retrieved articles were screened for additional studies. No language restrictions were applied.

Study selection
Randomised controlled trials (RCTs), observational studies (cohort studies, case-control studies and descriptive studies), mathematical predictive models and economic evaluations were eligible for inclusion if they evaluated mortality and the fatality rate from whooping cough after the administration of a primary dose and booster dose of pertussis vaccine. The intervention had to be administered in a developed country and be aimed at the whole population (children, adults and the elderly); studies that targeted specific age groups were excluded from the review. Eligible comparators were any alternative vaccination strategies administered in the general population, including no booster dose. Secondary outcomes included hospitalisation, consultations, notifications and cost outcomes.

Included case-control studies used retrospective follow-up that ranged over a period of four to 24 years. Two thirds of the studies used previous participants in clinical trials and evaluated booster doses of acellular vaccine in children aged 17 to 24 months old (assuming an estimated coverage of 100%). Two-thirds of the included cohort studies assessed booster doses in 12- to 24-month olds; the remaining study assessed a pre-school booster strategy in an historical cohort.

Descriptive studies mostly used a before-and-after analysis based on national data and assessed the number of notified pertussis cases. Most included mathematical models used an age-structured compartmental model that used data from the literature and historical statistical data. The time period covered by the models ranged from 1940 to 2050. Most models covered all ages with three primary doses and two booster doses. Assumed coverage ranged from 60% to 100%.

Two reviewers independently assessed the eligibility of the studies; any disagreements were resolved through a third independent reviewer.

Assessment of study quality
Two reviewers independently assessed the quality of the included studies. The criteria used were not defined. Discrepancies were resolved by discussion.

Data extraction
One reviewer extracted the study data using a piloted data extraction form. A second reviewer independently checked the data for accuracy. Discrepancies were resolved through discussion. Odds ratios (ORs) or relative risks (RRs) with 95% confidence intervals (CIs) were extracted or calculated for observational studies. The percentage protection in the...
eligible age group and in the indirect population (infants up to six months) was calculated.

Methods of synthesis
Studies were grouped according to the timing of the booster dose (12 to 24 months, pre-school and adolescent, and adolescent and adult booster every 10 years). Due to differences in study design and quality, the data were combined in a narrative synthesis and summarised in tables.

Results of the review
Twenty-two studies (21 publications) were included in the review: 10 observational studies (three cohorts, three case-control studies and four descriptive studies); four mathematical models; and eight economic evaluations. Details of the individual quality of the studies were not reported.

One cohort study and two case-control studies consistently reported ORs/RRs that ranged from 2.8 to 3.0 for no booster compared with a booster at 12 to 24 months; the remaining cohort study failed to record any pertussis cases. One mathematical model predicted an 83% increase in pertussis cases in children aged two to 10 years and a 27% increase in children aged up to two years if the 12-24 month booster was eliminated from the vaccination schedule in Australia.

Three before-and-after studies of national data reported a reduction of between 35% to 55% in pertussis incidence in eligible age groups after a pre-school booster. A case-control study reported effectiveness equivalent to 41% for the pre-school booster strategy in comparison with no booster; a survey of doctors in France reported no effect for the pre-school booster strategy.

None of the observational studies assessed the effectiveness of the adolescent booster strategy. Two mathematical models predicted decreases in pertussis incidence of 22% and 18% in infant populations and 64% and 37% in adolescent populations.

Three mathematical models assessed the use of booster vaccinations every 10 years in adolescents and adults. One predicted a 27% decrease in severe pertussis cases in all ages. The other two models predicted a decrease in pertussis incidence in adults of 24% and 50%, 21% and 39% in adolescents and 18% and 33% in infants.

Cost information
Eight economic evaluations were included in the review. Four were carried out in USA, two in Canada and two in England and Wales. Reported incremental cost effectiveness ratios for the pre-school booster strategy ranged from £14,500 to £35,000 per quality adjusted life year (QALY) and the cost per life year gained ranged from £25,800 to £49,500, from the perspective of the healthcare provider. The estimated cost per life year gained for the adolescent booster strategy compared to no booster was over £55,900 from the healthcare provider perspective. A break-even cost per vaccination of $32 was reported for the 10-year adolescent and adult booster strategy, with a cost per QALY of $1.5 million from the perspective of the healthcare provider.

Authors’ conclusions
There was insufficient evidence to support the use of any of the four booster vaccination strategies assessed (booster at 12 to 24 months of age, pre-school booster, adolescent booster or adolescent and adult 10-year boosters).

CRD commentary
This review answered a well-defined review question with clear inclusion criteria. A number of databases, websites and reference lists were checked for studies. Defined search terms were used and no language restrictions were applied. It appeared that the risk of publication and language biases was likely to be low. The risk of reviewer error and bias also appeared to be low, as each stage of the review process was checked by a second reviewer. The authors stated that study quality was assessed, but the criteria used and the findings of this assessment were not reported. The authors summarised data from higher-quality studies in a table, but given the types of studies included in the review of effectiveness, the data may not be reliable. The authors’ use of a narrative synthesis appeared appropriate given the differences between the included studies (particularly in terms of their interventions, study designs and outcomes). Overall, the authors’ cautious conclusions appeared to adequately reflect the paucity and quality of the included data.
Implications of the review for practice and research

Practice: The authors did not state any implications for practice.

Research: The authors stated that it may worth investigating the effects of non-universal booster vaccinations strategies that involved targeting specific groups of individuals, such as healthcare workers, expectant parents and individuals in close contact with young children.

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