



Cost–benefit of the introduction of new strategies for vaccination against pertussis in Spain: Cocooning and pregnant vaccination strategies



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ABSTRACT

Background: Pertussis remains a public health problem in countries with high vaccination coverage. Classic vaccination approaches have failed to effectively control the infection. The incidence of pertussis hospitalizations in infants is high, especially in those younger than 3 months who are in high risk of a severe disease and death. Additional strategies are recommended for short-term protection of this vulnerable population. In this study, we estimated the impact of 2 strategies for pertussis prevention in infants younger than 1 year of age—a cocoon vaccination strategy and the vaccination of pregnant women (VPW)—and the cost–benefit of these approaches relative to the current vaccination policy in Spain.

Methods: A cost–benefit analysis was conducted from the perspective of the publically-funded Spanish healthcare system, based on the yearly number of hospitalizations during the period of 2009 to 2011. We calculated the absolute risk reduction, the number of parents that would need to be vaccinated to prevent 1 hospitalization or death in infants <1 year, and the net benefit-to-cost ratio of each strategy.

Results: From 2009 to 2011, the incidence of pertussis in Spain was 153.44 hospitalizations per 100,000 infants <1 year. The absolute risk reduction for hospitalization would be 42.1/100,000 with cocooning and 75.2/100,000 with VPW. The number of parents needed to vaccinate with the cocoon strategy to prevent 1 pertussis hospitalization would be 4752 and to prevent 1 death, more than 900,000. With VPW, 1331 pregnant women would have to be vaccinated to prevent 1 hospitalization and 200,000 to prevent 1 death. The benefit-to-cost ratio was 0.04 for cocooning and 0.15 for VPW.

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1. Introduction

Current immunization programs in developed countries do not suffice to control the high incidence of pertussis-related hospitalizations and deaths in children, even though primary vaccination coverage is above 95% [1–3].

In Spain, children receive three primary doses (2, 4, 6 m) and two booster doses of diphtheria, tetanus and pertussis vaccine (15–18 m and 4–6 y) since 2001. In 2005, wP vaccine was replaced by aP vaccine in all autonomous communities [4]. The incidence of pertussis increased to 7 cases per 100,000 population in 2012 and 2013, and 40% of affected individuals were infants younger than 1 year of

age [5]. Thus, new additional strategies are needed to control this infection at short term.

Approaches that include the entire population, such as immunization of adolescents and adults, do not reduce the number of cases in the pediatric population at short term [6]. A study performed in the Netherlands to analyze the impact of vaccination strategies implemented from 1996 to 2010 reported that the booster dose at 4 to 6 years of age implies an indirect effect and resulted in a decrease of notifications and hospitalizations among infants aged 0 to 2 months [2].

Family members and other people living with infants, particularly the mother, are the main source of infection and transmission of pertussis [7,8]. In UK, vaccination of pregnant women reached an approximate coverage of 60% in 2013, which was related to a 78% reduction in confirmed pertussis cases and a 68% reduction in hospitalizations in infants under 3 months of age respect to the same period in 2012 [9]. Therefore, this approach [10] and the “cocoon” strategy, in which both parents and other cohabitants are

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Table 1
Assumptions used for calculations and information sources.

| Variable | Case base | Sensitivity analysis | Information source |
|--|-----------|---|--|
| Hospitalized incidence rate (per 100,000 inhabitants) | | | |
| 0 to 2 months | 119 | 71–191 | |
| 3 to 4 months | 26 | 16–44 | |
| 5 to 6 months | 5 | 4–7 | MBDS |
| 7 to 11 months | 4 | 2–6 | |
| <12 months | 153 | 93–247 | |
| Mortality (per 100,000 inhabitants) | 0.84 | 0.41–1.46 | |
| Cases with infection source, % | | | |
| Maternal | 21 | 15–42 | Uriona SM et al. [6]; Wiley KE et al. [14] |
| Either parent | 40 | 30–60 | Uriona SM et al. [6]; Wiley KE et al. [14] |
| Tdap vaccine effectiveness in adults, % | 85 | 70–92 | Ward et al. [33]; Zhang et al. [13] |
| Protection by maternal antibodies in VPW, % | 60 | 40–80 | Gall et al. [35] |
| Live births (Spain, 2012) | | 454,648 | INE |
| Deliveries (Spain, 2012) | | 456,130 | |
| Cost, euros | | | |
| Tdap dose | 8 | Maximum price (without VAT) in 2012 Framework Agreement | |
| Dose administration | 9 | DOGC | |
| Contact tracing | 300 | Author's estimation (Appendix 1) | |
| Hospitalization | 3000 | DRG (MBDS) | |

DOGC, Official Journal of the Catalanian Government; DRG, Spanish diagnosis-related group; INE, Spanish Statistics Institute; MBDS, minimum basic data set; VPW, vaccination of pregnant women.

vaccinated [11], may be more effective than current programs for preventing pertussis in children younger than 1 year.

In addition to morbidity and mortality criteria, assessment of strategies to protect this vulnerable pediatric population from pertussis should include individualized pharmaco-economic studies [12,13] to take into consideration the local epidemiologic situation [14]. The differences in the incidence of pertussis among countries of the European Union, recognized by the ECDC, besides the differences among them in the vaccination schedules, limit extrapolation of models from other countries [15]. In Spain there has been a real concern for the increased incidence of pertussis, and additional vaccination strategies have been proposed [16], but information on the impact of these additional strategies is scarce.

In this study, we estimated the impact and the benefit-to-cost ratios of two new additional vaccination approaches (the cocoon strategy and vaccination of pregnant women) in reducing pertussis hospitalizations and deaths in children younger than 1 year in Spain, relative to the current vaccination programs used in our country.

2. Materials and methods

A cost-benefit analysis with a time horizon of one year was conducted from the perspective of the publically-funded Spanish healthcare system, using the cohort of children born in 2012 as the reference. We compared the cost and health benefits of two additional vaccination strategies to protect children aged <1 year: vaccination of pregnant women (VPW) in the third trimester of gestation and the cocoon immunization strategy, including only vaccination of the mother and father. A decision tree model was used because it is well-suited for an acute care episode with a short convalescent period [17]. Spanish health system covers direct cost. Data for the study were obtained from Spanish public healthcare databases, and published information from other countries when data for Spain were not available.

2.1. Vaccination strategies

For the purposes of the study, the efficacy of the acellular diphtheria-tetanus-pertussis (Tdap) vaccine was defined as 85% in individuals aged 15–65 years [18,19]. In the cocoon strategy,

vaccination would be performed in the immediate postpartum period, and immunity would be acquired at 2 weeks. The percentage of children <1 year infected by their parents was obtained by reviewing the results of contact-tracing studies. In a recent systematic review [8], the parents were the source of transmission in 39% to 57% of cases. In a study performed in our setting [7], the mother was the source of infection in 21% of cases, and either parent in 39%.

In the VPW strategy, the mother would be vaccinated between week 29 and week 36 of gestation, 85% of mothers would be protected at the time of delivery, and 60% of neonates born of vaccinated mothers would be protected during the first 2 months of life by passage of maternal antibodies across the placenta [20,21].

2.2. Risk of hospitalization and death

The yearly number of pertussis hospitalizations in children <1 year from 2009 to 2011 was used to estimate the annual incidence of this condition, because there is evidence for under-reporting of pertussis in the national disease surveillance system [22]. We used the data included in the Minimum Basic Data Set (MBDS) for hospital discharges with a pertussis-related primary or secondary diagnosis (ICD-9-CM 033 codes) during the last epidemic cycle in Spain, occurring between 2009 and 2011. Coverage of the MBDS in Spain is 100% of hospitals within the national healthcare system; 99.5% of the Spanish population has access to this system. Pertussis is usually more severe in the population aged <1 year, and it is very likely that all cases are diagnosed and hospitalized [23]. Hence, it was assumed that all cases occurring in this period had been detected and included. The denominator used was the number of live births, obtained from the Instituto Nacional de Estadística (INE, Spanish Statistics Institute; <http://www.ine.es/inebmenu/mnu.dinamicapob.htm>).

Mortality was calculated based on the 12 pertussis-related deaths in children 0 to 2 months of age that occurred in the period of 2009 to 2011.

2.3. Absolute reduction in the risk of hospitalization or death

The absolute decrease in hospitalization risk was estimated according to the parameters listed in Table 1. For the cocoon strategy, the vaccination effectiveness (VE) of a dose of Tdap was

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