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ScienceDirect
Health Policy 89 (2009) 225–238
HEALTH POLICY
www.elsevier.com/locate/healthpol

Cost-effectiveness of introducing the conjugated pneumococcal vaccine to routine free immunizations for infants in Lazio, Italy

Paolo Giorgi-Rossi [a,*,1], Monica Merito [a,b,1], Piero Borgia [a]

[a] *Agency for Public Health, Lazio Region, Via di S. Costanza, 53, 00198 Rome, Italy*
[b] *Laboratory of Economics and Management, Sant'Anna School of Advanced Studies, Piazza Martiri della Libertà, 33, 56127 Pisa, Italy*

Abstract

Objective: To examine the health outcomes and costs of a hypothetical pneumococcal vaccination campaign among the general infant population in the Lazio region (Italy).
Methods: We developed a model simulating direct medical costs and health outcomes of vaccinating infants with conjugated pneumococcal vaccine (PCV-7) compared to the costs (in and outpatient) of treating the disease, from a public health service perspective. According to vaccine trials' outcomes, we considered vaccine effectiveness in preventing part of the invasive pneumococcal disease (IPD), pneumonia of any aetiology, and acute otitis moedia. Age-specific incidence, mortality and health care costs came from local surveillance and surveys; the vaccine costs €40/dose. Annual budgetary impact and macro-health benefits were predicted for 2005–2014. Cost-effectiveness was expressed as net healthcare costs per disability-adjusted life-year (DALY) gained.
Results: After 10 years, five cases of meningitis, 20 IPD, 933 pneumonia, 406 pneumonia-related hospitalisations, and 3160 otitis cases would be averted annually by vaccinating. The annual cost of vaccination would be €4.9 m, and annual costs averted would be €1.4 m. Additional healthcare costs of a mass vaccination would decrease over time from €5.1 m to €3.5 m per year. At baseline, net cost per averted DALY was €18.0 k, if health benefits are not discounted, and €51.7 k adopting a 3.5% discount rate; it was 12% lower with a hypothesis of high IPD incidence and 68% lower if the vaccine cost 50% less.
Conclusions: The cost of the vaccine makes the campaign more expensive than today's recommended infant vaccinations. Nevertheless, the cost-effectiveness of introducing PCV-7 in Lazio compares favourably with previous estimates in similar countries.

Keywords: Cost-effectiveness; Budget impact; Vaccination; Economic; Conjugate pneumococcal vaccine

1. Background

Pneumococcal disease in children is one of the most relevant infectious diseases in industrialised countries for three major reasons: (1) *Streptococcus pneumoniae* causes a large spectrum of diseases, some of

* Corresponding author. Tel.: +39 0683060438; fax: +39 0683060463.
E-mail address: giorgirossi@asplazio.it (P. Giorgi-Rossi).
[1] These authors contributed equally to this work.

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doi:10.1016/j.healthpol.2008.05.016

them extremely common, such as pneumonia and acute otitis moedia [1–4]; (2) after the decline of the *Haemophilus influence b* (Hib) following the diffusion of the anti-Hib vaccine, it is the most common aetiological agent in infant meningitis [5–8]; (3) a safe, effective heptavalent conjugate vaccine is now available [9–11].

The decision currently faced is whether to introduce this new vaccine in routine mass vaccination of newborns. In particular, the vaccine is highly effective against meningitis and other invasive diseases [9], which are very severe but extremely rare events [5], but less effective against pneumonia and otitis, which are less severe but occur with extreme frequency [10]. The vaccine is very expensive compared to other routinely administered vaccines. The current vaccination schedule for newborns is very heavy and vaccines against eight or nine different diseases [6] are now administered at the same time, and adding another may be unacceptable to parents. Therefore, introducing a new vaccine also must be carefully evaluated in light of possible negative effects on general compliance to current routine vaccines [12].

In Italy the National Immunization Plan 2005–2007 introduced the pneumococcus conjugated vaccine (PCV) in the infant vaccination schedule devolving implementation policies to each region: completely free for all or free only for newborns at risk. Because the Lazio Region's Health Authority is now facing this decision, the Agency for Public Health set up an integrated surveillance system of bacterial meningitis and performed an analysis of the epidemiological and economic burden of pneumococcal disease in the region, which was used to perform the economic analysis we present.

The goal of our study was to examine the hypothetical health outcomes and costs of introducing a pneumococcal vaccine to the recommended schedule for the general infant population in the Lazio region (Italy) by analysing the budget impact and cost-effectiveness. The budget impact evaluated aggregate effects on annual healthcare expenditures and population health status changes from the public health service perspective. Cost-effectiveness was expressed as net healthcare costs per averted disability-adjusted life-year (DALY).

2. Methods

2.1. The model

A decision analytic model in Microsoft® Excel 2003 simulated direct medical costs and health outcomes of a universal pneumococcal vaccine program for infants in the region of Lazio. Local population size was drawn from the Italian national statistical institute [13] data on Lazio residents under 10 years of age in 2005 and population forecasts for 2006–2014. In the model, annual cohorts of newborns were hypothetically offered the 7-valent conjugated penumococcal vaccine (PCV-7) and were followed over time. Deaths were assumed to have occurred at the end of each year using standard life tables by sex for the year 2002. According to vaccine trials' outcomes we considered incidence, case fatality and vaccine effects for invasive pnemococcal disease (IPD), pneumonia of any aetiology, and acute otitis media (AOM). We compared illness episodes and deaths averted by universal vaccination with those rates in a non-vaccinated population. The structure of the model is shown in Fig. 1. The public health service perspective was assumed in the analysis. Health service use and direct medical expenditures included the costs of the vaccine program (vaccine doses, vaccine delivery, and administrative costs) as well as outpatient and inpatient care for treating vaccine-preventable diseases. Age and sex-specific epidemiological parameters and cost data were used whenever available. Annual budgetary impact and macro-health benefits were computed over the 10-year period needed for the vaccine program to cover all ages that have a high incidence of preventable infections. In the budget impact analysis we followed the first cohort of newborns for 10 years and the last one only for 1 year. After 10 years, cross-sectional (i.e. across age cohorts) costs and benefits should be at a steady state. Cost-effectiveness results have thus been computed based on costs and benefits of the vaccine program at year 10. Cost-effectiveness was expressed as net healthcare costs per DALY averted at baseline and in the sensitivity analysis.

2.2. Epidemiological parameters

Information about age-specific (2–23 months, 24–59 months, and 5–9 years) incidence and mor-