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ABSTRACT/STUDY OVERVIEW

Effect of Introduction of the Pneumococcal Conjugate Vaccine on Drug-Resistant Streptococcus Pneumoniae (SP)

By mean of epidemiological methods this study quantifies the burden of drug-resistant infections in the U.S. general population before and after the introduction of the Pneumococcal Conjugate Vaccine.

Pneumococcal conjugated vaccine was introduced in the U.S. in 2000 for all children up to 2 years of age or for children 2 to 4 years old with chronic illness and at higher risk of invasive infections. The conjugated vaccine targets 7 of the 90 serotypes of pneumococcal serotypes. Although market access was granted by regulators based on evidence of vaccine efficacy, at the time of launch it was still unknown whether the routine vaccination would lead to the emerging of new antibiotic resistance in the population and if the immunization could result in an increased rate of infections by non-vaccine pneumococcal serotypes.

Population-based data from the Active Bacterial Core Surveillance (part of the CDC Emergency Infection Program) were used to evaluate the effect of conjugate vaccine on invasive infections caused by antibiotic resistant strains in the general U.S. population. The surveillance program includes a population of 1.4-1.6 million Americans nationwide. The study included data in the period 1 Jan 96-31 Dec 2004. All cases of invasive pneumococcal diseases were identified. The U.S. Census Bureau data were used to estimate national rates of infections (# cases/ 100,000 population) in the general U.S. population and within selected age groups (i.e. young children and elderly individuals 65 years or older). Changes in rate of invasive infections were calculated comparing disease incidence rate in 1999 (before introduction of vaccine) with incidence rate in 2004 (after introducing vaccination).

Following the introduction of routine vaccination in the US young children population in 2000 the overall burden of invasive pneumococcal infections in the US population decreased substantially. The infection rate decline between 1999 and 2004 was more marked in the target age group, with a decline of 81% and 60% in children up to 2 years, and 2 to 4 years old, respectively. In the general population the decline was estimated to account for 50% reduction in the antibiotic-resistant invasive infections, with small geographical variations across the U.S. Notably in the period 1999-2004 the number of annual deaths due to strains resistant at least to one antibiotic decreased from 2500 to 1600. Such a decrease in the rate of disease due to resistant strains would result in a reduced number of treatment failures and complications caused by treatment-resistant infections.

Only a small increase in treatment-resistant infections caused by non-vaccine serotypes could be detected, from 0.1/100,000 in 1999 to 0.5/100,000 in 2004.

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SUPPORT FOR DECISION-MAKING

What type of decision did the study support? How was the study used?

The study provided evidence to support the herd immunity effect of Pneumococcal conjugate vaccine. The introduction of vaccination in the U.S. reduced substantially the burden of antibiotic-resistant infections not only in the vaccine target population, but in the overall population, while the feared increase infection rate by non-vaccine pneumococcal serotypes was only marginal.

This observational study generated valuable scientific evidence that could not be otherwise obtained with any randomized trials.

The data were highly weighted by regulators and policymakers, including Health Technology Assessment Agencies in Europe for approval and reimbursement from an indication limited to high-risk infants (10% coverage) to universal vaccination (>95% coverage).

Publication Reference(s).

- Kyaw et al., NEJM, 354, 1455-63, 2006

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