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ORIGINAL PAPER

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Introduction of pneumococcal vaccine to standard immunisation programmes in Europe: what are we waiting for?

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Over the last few years we have witnessed development, extensive pre-licensure testing, efficacy trials and successful implementation of a seven-valent pneumococcal conjugate vaccine (Prevenar). It was approved for use in infants in the United States in February 2000 and has there been used routinely since June 2000. In a centralised procedure in the European Union, licensure was also received from the European Agency for the Evaluation of Medicinal Products (EMEA) in February 2001. Yet, nowhere in Europe has universal pneumococcal immunisation for infants or children been implemented in national programmes.

In this supplement, presentations given by leading experts as well as representatives of the manufacturer on the occasion of an international expert meeting on pneumococcal vaccination in childhood in Frankfurt, Germany, in January 2002 are summarised.

Drs. Black and Shinefield, the principal investigators of the pivotal efficacy trial in infants performed in Northern California a few years ago, share their extensive experience with us. They report on the safety, immunogenicity, and efficacy of the seven-valent conjugate vaccine in their trial, both in the whole study population and in the subset of infants who were preterm or of low birth weight. Moreover, the effectiveness of the vaccine in the general population in the year after it was licensed is reviewed. Prevenar was safe and immunogenic in young children and effectively prevented both invasive pneumococcal disease caused by vaccine serotypes (efficacy point estimate of 97.4%) and episodes of otitis media (efficacy point estimate of 7.0%). In low birth weight and preterm infants, the vaccine was equally immunogenic and effective (100%) compared to normal-weight, full-term infants. Of note, the rates of local and systemic adverse events in low birth weight and preterm infants were in the same range as those in full-term infants. Importantly, in the 1st year of post-licensure use of Prevenar in Northern California, the reduction of invasive pneumococcal disease in the infant population was greater than expected based on vaccination rates (indicating herd immunity) and no corresponding increase in disease caused by nonvaccine serotypes has been observed. This is reassuring.

Dr. von Kries and his collaborators demonstrate the epidemiological exercise of combining national surveillance data (Germany) on the serotype distribution of pneumococci causing invasive disease in infants and young children, the primary vaccine target group, with the results from the Californian efficacy trial. When reliable data are available, as it is the case for Germany and many other European countries, this exercise will allow us to calculate the expected impact of an universal immunisation programme in a given country. This group's findings are crystal clear and not surprising: with a different epidemiological background, overall efficiency of the vaccine is likely to be less compared to the United States. Of course, the antigen components for the vaccine were chosen based on the most prevalent serotypes in the United States which are not necessarily the same in other countries. Importantly, however, efficiency would still be 70% or more. Dr. Hausdorff, a scientist with Wyeth-Lederle Vaccines, elaborates further on this issue. What appears to be variability in epidemiology from country to country may be confounded by various factors, which are known to influence the distribution of serotypes. These include age, different compliance with diagnostic procedures (e.g. blood cultures), and local antibiotic resistance levels.

Finally, Dr. Fletcher, Director Adjoint, International Scientific Affairs of Wyeth Lederle Vaccines, Paris, France, familiarises us with the decision-making process for the recommendation of a new vaccine in France, using Prevenar as an example. Licensure of the vaccine by EMEA was followed by the registration in France a

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month later (March 2001) and unanimous recommendation for universal immunisation of all children between 2 months and 2 years of age was recommended shortly thereafter by the Comité Technique des Vaccinations, a group of vaccination experts appointed by the French government. Currently, implementation of this recommendation is awaiting approval by the Conseil Supérieur d'Hygiène Publique de France, the decisive authority.

Given the published evidence of efficacy, efficiency and safety of pneumococcal conjugate vaccine, what hinders us to use them universally in our children? From my personal experience with both formal and informal discussions, the former from being a member of the German national immunisation commission and the latter from numerous small group meetings, the reasons are many-fold. Of course the vaccine costs more than most other vaccines used in childhood. Therefore, health insurance providers in general are still reluctant to reimburse the cost. However, investment in prevention is investment that will pay off in the future and paediatricians should not give up in raising their voices in the interest of our children. Also, data have been lacking on the compatibility of Prevenar given together with DTPa-IPV-Hib/HepB combination vaccines, the standard immunisations in most European countries today. The studies needed have now been performed, the preliminary results look promising and are currently being examined by regulatory authorities. Approval will definitely make universal recommendation easier; and last but not least, acceptance of another vaccine to be added to the already busy schedule of routine immunisations in childhood requires acceptance on the recipients' side, i.e. the parents. Education about the real risks of invasive pneumococcal infections will be the key to successful implementation.

Let's not forget that prevention is the queen of medicine. May this compilation of papers add to the confidence that immunising against pneumococci is a reasonable and useful procedure which our children deserve.

Note: the author has no direct or indirect financial interest in the use of Prevenar nor is he or has he recently been a paid consultant for Wyeth-Lederle.