Meningococcal B Vaccine

Abstract:

Bexsero, a 4 component protein-based meningococcal B vaccine (4CMen B) manufactured by Novartis was authorised for use by the European Medicines1 in January 2013. The development of 4CMen B has taken long years of research because of the similarity between the serogroup B capsule and the human antigen neural-cell adhesion molecule. It necessitated a new approach called reverse vaccinology which involves which is reprogramming of bacteria and the identification of proteins that provoke an immunological response. The 4CMen B vaccine has 4 antigenic components. The clinical trials have involved 8000 children. One month after the third dose, 84-100 per cent had a satisfactory immunological response2. The new vaccine should protect against 73% of the strains that cause the disease. The recommended immunisation for infants is 3 doses commencing at 2 months with 2 further doses at least 1 month apart. For unvaccinated older children 2 doses are recommended. Since 1993 serogroup C conjugate vaccine has been available for the prevention of meningococcal C disease and has led to a dramatic reduction in the incidence of the disease.

Although the vaccine is the culmination of 15 years of development it has already been subject to controversy. In the UK, the Joint Committee on Vaccinations and Immunisations (JCVI) has recommended not to introduce the vaccine to the immunisation schedule. The basis of the decision made by the JCVI was that the vaccine would not be cost-effective. The JCVI was reasonably confident that the vaccine would not protect, how long it would protect and if will stop the bacteria from spreading. However, before introducing a new vaccine or drug, it is important to be sure that not only is it safe and effective, but bearing in mind the increasing financial pressures on the NHS, it also has to be cost-effective. We need to know how well it will protect, how long it will protect and if it will stop the bacteria from spreading from person to person. David Salisbury, director of immunisation at the UK department of health stated that we have a new vaccine against Men B but we lack important evidence.

The JCVI decision not to recommend meningococcal B vaccination for the present has raised considerable debate. This is understandable because meningococcal disease has struck fear into generations of parents and doctors. It can cause death in a pre-school child in a short few hours. The mortality rate may be as high as 10% per cent and among survivors one in five will have long term morbidity including neurological damage, limb loss and limb loss. The initial diagnosis can be difficult to distinguish other intercurrent illnesses. In particular it may resemble the ‘flu in neurological sequelae and limb loss. The initial diagnosis can be difficult to make due to some cases it is associated with post-immunisation pyrexia which could lead to anxiety among parents about the vaccine programme in general. The Committee noted that over the last 10 years the incidence of invasive meningococcal disease decreased by 16% and meningococcal B disease will further decrease if population reduction in smoking and influenza continues, both are known risk factors. It was suggested that routine infant immunisation with Bexsero would prevent directly around 25% of cases over the lifetime of each single vaccinated birth cohort. JCVI concluded that routine infant or childhood immunisation with Bexsero was highly unlikely to be cost-effective at any vaccine price and could not be recommended. Dr David Elliman, immunisation expert at the University of Bristol and London School of Hygiene and Tropical Medicine. He expressed his disappointment that over the last 10 years the incidence of meningococcal disease further decreased by 16% and meningococcal B disease will further decrease if population reduction in smoking and influenza continues, both are known risk factors. It was suggested that routine infant immunisation with Bexsero would prevent directly around 25% of cases over the lifetime of each single vaccinated birth cohort. JCVI concluded that routine infant or childhood immunisation with Bexsero was highly unlikely to be cost-effective at any vaccine price and could not be recommended. Chris Head from the Meningitis Research Foundation has expressed his disappointment at the decision. Measuring the cost burden of meningococcal disease is difficult because the sequelae are wide-ranging and variable. The Foundation supports a population based evaluation of the vaccine.

There were also concerns raised around the vaccines effectiveness, its coverage and impact on transmission of Men B bacteria. Another issue is that in some cases it is associated with post-immunisation pyrexia which could lead to anxiety among parents about the vaccine programme in general. The Committee noted that over the last 10 years the incidence of invasive meningococcal disease decreased by 16% and meningococcal B disease will further decrease if population reduction in smoking and influenza continues, both are known risk factors. It was suggested that routine infant immunisation with Bexsero would prevent directly around 25% of cases over the lifetime of each single vaccinated birth cohort. JCVI concluded that routine infant or childhood immunisation with Bexsero was highly unlikely to be cost-effective at any vaccine price and could not be recommended. Chris Head from the Meningitis Research Foundation has expressed his disappointment at the decision. Measuring the cost burden of meningococcal disease is difficult because the sequelae are wide-ranging and variable. The Foundation supports a population based evaluation of the vaccine.

JFA Murphy

Editor

1. European medicines agency press release on Bexsero 2012

3. JCVI interim position statement on use of Bexsero meningococcal B vaccine in the UK. July 2013
4. Head C. Immunisation against meningococcus B. Lancet 2013;382:935

Comments: