Executive Summary

The largest ever parliamentary petition has asked for wider access to the MenB vaccine for children. The government’s initial response to the petition has been to reiterate the conclusions of the JCVI in March 2014, stating that it is not cost effective to immunise older age groups.

Meningitis Research Foundation (MRF) wants to see an end to this devastating disease. We acknowledge that with limited NHS resources, government must allocate money in the most effective way possible, but it is possible to achieve wider cost effective protection from MenB disease by:

- Evaluating whether vaccinating teenagers can eliminate the infection where it most commonly originates - in teenager’s noses and throats, and so protect the whole population
- Addressing the bias in the rules for cost-effectiveness evaluations in health so that vaccines against severe childhood illnesses (including MenB vaccine) no longer face an uphill struggle.

As soon as real-world evidence of the effectiveness of the MenB vaccine infant programme emerges, a one-off catch up campaign for children under 5 is needed, as denying this would only be on the basis of a defective cost effectiveness framework.

We firmly believe that prevention is the key to defeating meningitis and septicaemia, yet whilst there continue to be cases that vaccines cannot prevent, public and health professional awareness will always be important. Within our submission we draw committee members’ attention to the resources and awareness raising activity we currently undertake. If government chooses to invest further into awareness raising, we hope it will work with the meningitis charities to make the best use of existing resources and avoid duplication.
SECTION 1: Response to the petition - Meningitis Research Foundation’s evidence

Introduction

1. Meningococcal B infection has for decades been the single largest cause of meningitis in the UK. It strikes without warning, affecting mainly healthy children and is one of the few illnesses in modern Britain that can kill a healthy child within hours of the first symptoms. Babies, toddlers and adolescents are most at risk of this disease which leads to death in 10% of all cases and to long-term after effects in a further 36%[1].

2. Introducing MenB vaccine for babies in 2015 was a major step forward, but restricting the vaccine to only this narrow highest risk age group can never prevent the majority of cases[2].

3. The tragic death of Faye Burdett and others too old to have routine vaccination provoked an unprecedented demand for the vaccine privately. A petition to widen access to the MenB vaccine was signed by 823,345 people - the largest petition on record.

4. The meningitis charities gave oral evidence at the request of the Petitions and Health Committees on 22nd March 2016. MRF now submits this written evidence to underpin our oral testimony and also to answer specific requests from the committee.

What we do

5. Meningitis Research Foundation:
   - Funds research into the prevention, detection and treatment of meningitis and septicaemia and shares the knowledge gained by research so everyone can benefit
   - Raises awareness of meningitis and septicaemia and promotes best practice in diagnosis and treatment
   - Supports those affected by meningitis and septicaemia

6. We firmly believe that prevention is the key to defeating meningitis and septicaemia, yet whilst there continue to be cases that vaccines cannot prevent public awareness will always be important.

7. Section 2 provides information about our awareness raising and educational activity. Our symptoms information is targeted towards different age groups of people at risk from these infections, and we produce specific information for communities where risks are higher following outbreaks. We use a similarly focussed approach in developing resources for health professionals according to their role in diagnosing, treating, or preventing the diseases.

8. All our materials have been developed in consultation with experts in the respective fields and have been pre-tested or evaluated by the specific group at which the resource is aimed. Where national NICE and SIGN guidelines exist, information is consistent with these guidelines. Many materials have been produced as a direct result of research funded by MRF and are reviewed and updated regularly.
What are we asking for?

9. The meningitis charities have submitted a joint statement and a ten point action plan to the Petitions and Health Committees, asking government to:
   - Secure commitment to funding and delivery of an adolescent intervention study with MenB vaccine.
   - Address the unfairness of the cost effectiveness framework for preventing severe childhood illness and ensure that the peace of mind health benefits of vaccination are included in the framework.
   - Prioritise effective protection for the most vulnerable in the short term by undertaking a one off catch-up for children under 5.

10. We now present more detailed background information on these points.

Population evaluation of MenB vaccine in adolescents

11. Vaccinating teenagers could be the key to protecting the whole population from MenB if we can show that MenB vaccination kills the bacteria where they live, in our noses and throats, particularly in this age group. Teenagers harbour the bacteria and unwittingly spread the infection to other more vulnerable people, including young children[3]. If MenB vaccine can prevent this, the whole population would be protected, including the 1-11 year olds who are the focus of the current petition, as it would knock out the infection at source before it can spread.

12. What we have learned from the massively successful MenC vaccine, which saw cases of disease reduce from around 1000 to just a handful each year is that effective prevention relies only partly on directly protecting people by vaccinating them. More importantly it relies on protecting the wider population by stopping the spread of the disease[4]. This means attacking the bacteria where they live and grow.

13. We know that these bacteria live harmlessly in the noses and throats of many people, but are most commonly carried by teenagers[3]. Teenagers who carry the bacteria then unwittingly pass them between each other, and on to other more vulnerable age groups.

14. Vaccinating teenagers could be the key to defeating MenB by going right to the home of the bacteria, so they cannot survive and circulate amongst the wider population.

15. The cost effectiveness model the JCVI used when they recommended an infant MenB programme shows that if MenB vaccination can reduce the acquisition of bacteria amongst vaccinated people by just 30%, then vaccinating teenagers is the most cost effective strategy in the long term[2]. If the vaccine reduces acquisition by only 20%, teenage vaccination would still be cost effective even under the current cost effectiveness rules[2].

16. There is already some indication that the MenB vaccine Bexsero® could reduce acquisition of meningococcal bacteria by 20 to 30 percent[5] but the evidence is not sufficiently conclusive for the JCVI to recommend vaccinating them. This is why they called for government to back a population based evaluation of MenB vaccine in adolescents in June 2013[6] and again in February 2014[7], but this has not yet taken place, and there is no government commitment to ensuring it happens.

17. We urge the government to act on the JCVI recommendation for an evaluation of the impact of MenB vaccine on carriage of the bacteria in adolescents. We want ministers to commit to funding a population based evaluation and to designate an accountable person within the Department of Health to ensure that it happens without delay.
18. The JCVI considered 3 iterations of a cost effectiveness model of MenB vaccination\[8\]. In their final analysis, which included evidence from MRF and other stakeholders, the JCVI recommended introduction of the MenB vaccine for babies at a fraction of the NHS list price\[9\].

19. During the deliberations over cost effectiveness, the JCVI expressed concern about how difficult it was for them to capture the impact of a severe, fatal and rare disease, particularly in children, and called for the establishment of a working group to specifically address this issue\[10\]. The resulting working group, the Cost Effectiveness Methodology for Immunisation Policy and Procurement (CEMIPP) working group, first met in September 2014 and is yet to report its recommendations\[11\].

20. The CEMIPP scope has changed significantly from the aims described by the JCVI\[12\]. MRF represents a coalition of meningitis and liver disease patient groups and has been invited to attend and contribute to some CEMIPP subgroup meetings. We are grateful for the opportunity to contribute to discussions, but this does not mean that the patient groups automatically endorse CEMIPP’s final recommendations, which we have yet to see.

21. The main CEMIPP working group reports directly to DH and is due to report its recommendations soon. We urge the DH to allow an open public consultation on these recommendations without delay.

22. The specific concerns MRF has regarding the current cost effectiveness rules are as follows:

- The discount rate of 3.5% is too high
- Peace of mind benefits gained from vaccination are not included in the analysis
- Public preferences for prioritising prevention, severity of illness and health gains in children are not well reflected in the rules
- The JCVI’s rules on uncertainty are too risk averse

**The discount rate of 3.5% is too high**

23. **Interventions with immediate costs but long term health benefits and cost savings to the NHS are disadvantaged because a much greater importance is placed on immediate health gains and costs compared to those running further into the future.**

24. The cost effectiveness of MenB vaccination was assessed using a 3.5% discount rate\[2\] as per NICE guidance\[13\]. It is well established that a discount rate of 3.5% can undervalue the benefits of preventative and public health interventions such as vaccination since large costs are borne upfront, but the benefits accrue over decades\[14-16\]. For example, although the true lifetime costs of treating a child who suffers brain damage due to bacterial meningitis at 3 years of age are £3.3 million, when a discount rate of 3.5% is applied, these projected costs drop to just £1.1 million\[17\]. In addition, the life years saved from preventing the death of a baby with a life expectancy of 81 years, drops from 80 to only 27.7 when a discount rate of 3.5% is applied (fig 1).

25. Current NICE guidance\[13\] acknowledges this bias and advises that where large health benefits are attained over long periods i.e. beyond 30 years, a discount rate of 1.5% can be used. In addition, when NICE considers public health interventions (which tend to have high upfront costs and long term benefits), a 1.5% discount rate is routinely used for costs and benefits\[18\].
(1) The discount rate used in the cost effectiveness analysis is too high

#DontDiscountMenb

The current discount rate halves the value of my life every 20 years

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Vaccines have life-long benefits, but are disadvantaged because the discount rate slashes the value of health benefits running far into the future.

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**Figure 1: Discounting infographic**
26. Figure 2 shows the effect that the discount rate has on the relative contribution of costs and benefits over a 150 year timeframe.

![Discounting Graph](image)

**Figure 2: The effect of discounting on the relative contribution of future costs and benefits**

27. The published cost effectiveness model used by the JCVI when they recommended Bexsero showed that with a 1.5% discount rate, a catch up programme up to age 5 alongside routine MenB vaccination for the under 1s would be cost effective[2].

28. CEMIPP will make a recommendation on the most appropriate discount rate to use in cost effectiveness analysis of vaccines.

29. We urge the DH to report CEMIPP’s conclusions for public consultation without delay. An improvement on the currently used 3.5% discount rate could make a catch up programme for the under 5s cost effective.

Peace of mind benefits gained from vaccination are not included

30. The petition asking for wider protection from MenB was signed by more than 820,000 people. This, and the unprecedented demand for the vaccine privately, shows how anxious parents are about meningitis. Parents gain peace of mind by getting their children vaccinated but this benefit is not quantified in the cost effectiveness analysis.

31. Over the past 20 years Department of Health surveys have consistently shown that meningitis is the illness that parents most fear[19, 20]. It is also feared by clinicians. In 2014, when the JCVI initially found the MenB vaccine not cost effective at any price a letter was signed by 330 medical professionals arguing for the cost effectiveness to be reassessed.

32. In their terms of reference it states that CEMIPP are set to make recommendations on the potential inclusion of peace of mind benefits of vaccination into the cost effectiveness framework. However, at present there is no widely accepted mechanism for measuring or considering peace of mind benefits.

33. We urge the DH to report CEMIPP’s conclusions for public consultation without delay and for the government to commit funding for research into how peace of mind benefits from vaccines can be included within the cost effectiveness framework. Including peace of mind benefits from vaccination may make a catch up programme for the under 5s cost effective.
Public preference is not well reflected in the rules

34. Extensive, peer-reviewed research shows that society prioritises health interventions for the most severely ill and for children and also values preventative over curative interventions. These preferences are not well reflected in the cost effectiveness rules (or framework).

35. The NICE framework for assessing cost effectiveness uses a measure of health called the Quality Adjusted Life Year (QALY). The QALY takes into account both the quality and length of life saved by an intervention.

36. The aim of cost effectiveness analysis is to ensure that government can purchase the greatest number of QALYs possible, i.e. the greatest health gain, for the money available. The approach assumes that a QALY gained for a group of patients is exactly the same as a QALY gained for another group of patients regardless of patient characteristics or how QALYs are added. This means that small gains in health amongst many are equal to large health gains in a few patients (fig 3).

37. The current approach has advantages because it is relatively simple and transparent, but research tells us that it does not align with societal preferences, so public funds are not invested as the public would want them to be. A compounding factor is that the tool used to calculate QALY loss, the EQ-5D is insensitive to health impacts in children, so QALY loss is underestimated.

38. NICE recognises that societal preferences and methodological constraints should be taken into account in the decision-making process and in the past has given a special weighting to severe illness and children[21]. The JCVI took a similar approach in their final assessment of the cost effectiveness of Bexsero by applying a quality adjustment factor to the QALYs gained from vaccination[2]. However, it is unclear how this issue will be resolved in future cost effectiveness analyses.

39. The JCVI tasked CEMIPP with assessing how prevention of severe illness in children could be adequately assessed in light of the limitations of the current methodology. We urge the DH to report CEMIPP’s conclusions for public consultation without delay. Any changes to the cost
effectiveness methodology would affect whether a catch up programme for the under 5s is
deemed cost effective.

**The JCVI rules on uncertainty are too risk averse**

40. The JCVI must follow strict rules on the uncertainty of the calculated cost effectiveness of
vaccines. NICE is not obliged to adhere to such a strict set of rules when making decisions about
treatments.

41. The JCVI aims to harmonise its methodology with NICE in order to “ensure consistency across
programmes that relate to different technologies drawing on the same NHS budget” [22]. Yet the
rules that the JCVI must follow about the uncertainty of cost effectiveness calculations are not the
same as those used by NICE.

42. The rules about uncertainty were first specified in the JCVI’s code of practice in July 2013 in a report
from the working group on uncertainty (annex5) [22]. The rules are rigid and take an extremely risk
averse approach to uncertainty. In contrast, although NICE considers uncertainty in cost
effectiveness estimation in their decision making process there is no specific set of rules that must
be adhered to, so they have more flexibility.

43. There is real concern that the rigid uncertainty rules that the JCVI must follow will put vaccines at
a considerable disadvantage compared to treatments.

**A one off catch-up for children under 5**

44. Children aged 1-4 are the next highest risk group for MenB infection after babies. 8% of children
aged under 5 who got MenB disease died in 2014/15. The public want to see an end to these
preventable deaths.

45. In the cost effectiveness analysis that underpinned the JCVI recommendation for an infant
programme, a catch up for the under 5s could have been cost effective under a discounting regime
of 1.5%. The addition of peace of mind benefits to the equation would make the catch up
programme even more favourable.

46. As soon as real-world evidence of the effectiveness of the MenB vaccine in the infant programme
emerges, a one-off catch up campaign for children under 5 is needed, as denying this would only
be in the basis of a defective cost effectiveness framework.
SECTION 2: Awareness and promoting best practice in diagnosis and treatment (see link at bottom of page for snapshots and descriptions)

Babywatch – Symptoms information for babies in the Red Books

47. Babywatch is Meningitis Research Foundation’s most well recognised and popular resource. The most effective way we distribute it is via the ‘Red Books’ - Personal Child Health Records held for each child by their parents. It is now bound directly into Red Books by Harlow Printing (who print all the Red Books), but only where health trusts and CCGs request it (350,000 each year, currently about half the UK birth cohort). MRF and Harlow printing have asked the RCPCH committee for it to be included as part of the National Core record on at least 2 occasions (and offered to cover costs) but our request has been declined.

48. Outside of the Redbooks we distribute another 300,000 Babywatch cards annually, primarily via our annual mailing to GP surgeries, and an annual mailing to maternity units.

Diagnosis and Treatment in General Practice - Meningococcal Meningitis and Septicaemia Guidance Notes for GPS

49. We send this BMA-endorsed booklet to all GP surgeries along with public awareness and symptoms resources, including Babywatch every year. This represents 63,000 pieces of literature.

Resources for the Hospital setting

50. We send our widely endorsed algorithms for management of meningitis and meningococcal septicaemia in the paediatric and adult settings, as well as our handbook for doctors in, and a quick reference card for nurses training to clinical directors in 854 different hospital departments twice a year to correspond with the intake of new junior doctors.

51. We also produce a discharge checklist to encourage health professionals to make sure follow up arrangements are in place for children who have had meningitis or meningococcal septicaemia and put them in contact with the meningitis charities in line with NICE clinical guideline 102. We publicise the RCPCH e-learning tool on management of bacterial meningitis and meningococcal septicaemia which we were involved in writing.

Schools, sixth form and universities campaigns- Stop the Spread

52. We send awareness posters and symptoms cards to 10,144 schools, 2,978 sixth forms and 1,446 universities and higher education colleges to encourage uptake of the adolescent MenACWY vaccines and increase awareness of symptoms.

53. We also have other occasional mailings to nurseries and we mail Am I at Risk? to settings where cases of meningococcal disease have occurred in consultation with local Health Protection Units.

54. Although we have previously received Department of Health funding for the development of many of our health professional resources, within England and Wales distribution is entirely funded by MRF from public donations. We are constantly seeking ways to better target our resources to reach those who will be able to make best use of them and would welcome advice or funding to assist with this.

Meningitis Research Foundation awareness materials
References


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