

Briefing for Westminster Hall debate on the meningitis B Vaccine

April 2016

The British Society of Immunology (BSI) is the largest immunology society in Europe. We represent over 3000 immunologists working in academia, clinical medicine, and industry. Our main objective is to promote and support excellence in research, scholarship, and clinical practice in immunology for the benefit of human and animal health. Vaccination protects against disease by boosting immunity, and is one of the most cost-effective interventions that we have to improve human health.

Meningitis is a rare albeit devastating disease that can severely affect young children and families. The BSI is acutely aware of the burden of this disease and the extraordinary public debate that has arisen around the issue of Men B vaccine provision. We also acknowledge the feeling of parents and the public who quite rightly believe that every effort should be made to protect children from this serious infection.

As with all interventions, implementation of a new vaccines programme must be considered within the context of a finite pool of NHS resources. The Joint Committee on Vaccination and Immunisation (JCVI) decided that offering the vaccine to children under 1 year old would be a marginally cost-effective solution and would protect the group where disease incidence is highest. Extensive modelling and analysis could not find a cost effective intervention strategy in older age groups based on the evidence available at that time.

The JCVI is a highly-expert scientific advice mechanism and the most appropriate means for informing national immunisation policy. It is fully supported by the BSI. In this briefing we set out to describe some of the background to decision making about vaccine supply. We also propose a set of principles which we believe reinforces the openness, integrity, and accountability of the JCVI's functions and ensures its recommendations are implemented effectively

Key points:

- The UK is the first authority in the world to make a decision on the provision of the Men B vaccine. The lack of comprehensive real-world evidence was a complicating factor in the analysis carried out as part of the JCVI's modelling. Information gathered in real time from the programme's roll out will be important in gaining an improved insight into the vaccine's protective effects.
- Under the Government's standard methodology for assessing cost-effectiveness, implementation of a Men B immunisation campaign was found to be cost effective only in children under 12 months old. Other strategies, where immunisation was expanded to older age groups, did not meet the required thresholds for cost-effectiveness based on the evidence available at that time. However, as further evidence emerges the cost effectiveness estimate may change.
- Concern has been expressed that the discounting rate applied in the JCVI's methodology inappropriately devalues the long-term benefits gained through childhood vaccination. The JCVI has acknowledged this and we await the findings of a working group commissioned to examine issues relating to the methodology.
- In this briefing we propose a set of four principles that reinforce the integrity of the committee's decision making process and ensure that the JCVI's recommendations are implemented appropriately. These principles seek to preserve the committee from outside interference, to encourage openness and public engagement in its processes, to ensure its recommendations are implemented promptly and to ensure that action is taken to promote vaccine uptake post-implementation.

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Why is the Men B vaccine only offered by the NHS in the child's first year of life?

The Men B vaccine is offered routinely on the NHS for all babies born on or after 1st May 2015. The decision to offer the vaccine on the NHS to this specific age group is based on recommendations made by the Joint Committee on Vaccination and Immunisation (JCVI).

The JCVI is an independent committee of scientists, clinicians and laypersons whose role it is to advise the Government on immunisation policy. The JCVI's basic function is to make the best possible judgement in relation to impact and cost effectiveness on who is vaccinated, how often, and when. If the JCVI finds that a particular vaccine strategy is cost effective, the Government is obliged to accept and implement its recommendations.

The UK is the first authority to assess the cost effectiveness of Bexsero, the Men B vaccine, and to decide on its use. This is a difficult task, not least because the vaccine is new and has never before been administered on a large scale. Due to the rarity of the disease it has been impractical to carry out classic double blind placebo controlled efficacy trials and estimates of its efficacy are largely based on evidence gained in the lab. This lack of real world evidence was a complicating factor in the modelling conducted by the JCVI and means that, as the vaccine is rolled out, we are still learning vital information about efficacy, duration of protection, and side effects.

In doing their calculations the JCVI modelled various intervention scenarios. In one of these, providing the vaccine for children under 1 year of age, the intervention was found to be only just cost-effective (and this cost effectiveness was dependant on the Government being able to negotiate a low vaccine price with the manufacturer). Other strategies, such as vaccinating all children under 5, or even extending it to adults, were found not to meet cost effectiveness requirements at any vaccine price.

Cost effectiveness is a major, but not the sole, parameter that needs to be considered in introducing healthcare innovations. In implementing any potential intervention, there may also be ethical and political considerations. It is the view of the BSI that decisions should be primarily

based on scientific evidence, implemented with sensitivity and judgement.

Discounting

Concern has been expressed regarding the methods used by JCVI in their calculations, specifically the use of a 3.5% discounting rate in analytic models.ⁱ Discounting in economic evaluation implies that the costs and benefits of an intervention occur at different points of time and are valued differently. Generally, it is preferable to realise the benefits of an intervention as early as possible and therefore in health economics an exponential model is used to devalue impacts over time. This means that with a discount rate of 5% the costs and benefits of an intervention devalue at a constant rate of 5% per year. In essence, the further away the effects of an intervention are from the date of its implementation, the more they are discounted in value.

The JCVI is bound to a discount rate of 3.5% (the same used in NICE technology appraisals and across wider government). Some have argued that for vaccines, where the benefits of the intervention are yielded over the long-term, a discounting rate of 3.5% bases too much on immediate health gains rather than those that stretch into the future (for example costs saved from not having to care for children severely disabled by meningitis). In NICE Public Health Guidance a discount rate of 1.5% is used in recognition of this fact. Patient groups believe that this methodology should be applied to childhood vaccines. In their modelling, JCVI agreed to consider both discounting rates for the costs and benefits – the first time this had ever been done – and found an improved cost-effectiveness at the lower rate.

In recognition of this and other factors the committee asked the Department of Health whether they could re-examine the modelling methodology used in making recommendations on vaccines. The findings of this working group will be reported shortly and we would strongly urge their report to be made public by the Department of Health. Reducing the discounting rate applied in assessing vaccine cost-effectiveness opens up the possibility that other strategies may be deemed cost-effective in the future, based on new information.

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Principles

The JCVI formulates its advice and recommendations based on an appraisal of the best available evidence. Its processes are robust and comprehensive and the body is an effective mechanism for the conception of national immunisation policy. We believe the following principles underline this and should be upheld throughout the committee's processes and beyond into implementation.

- 1. The JCVI must always be immune from political interference.** As an independent and expert committee the JCVI and its members are best placed to inform UK immunisation policy and its methodology for doing so. There is no evidence that the scientific advisory process has been compromised, but its decision-making has come under considerable political (and public) scrutiny. It is important that the committee, while being cognisant of the public mood, maintains its objectivity in its mission and receives full backing from the Government and is not vulnerable to overt or covert lobbying of any kind.
- 2. The JCVI must explain its decisions clearly and concisely.** There is considerable scope for greater transparency and public engagement in the conduct of JCVI's work. Meeting minutes and agendas are published online, but the experience of Men B shows that more can be done to communicate these decisions. Lay participation and consultation in the decision making process is also important in considering issues which can be at the centre of charged public debate.
- 3. The JCVI's recommendations must be implemented in promptly.** The Health Protection (Vaccination) Regulations 2009 place a duty on the Secretary of State for Health in England to ensure that the recommendations are implemented. However implementation can be slowed by factors such as vaccine supply and cost negotiation efforts (negotiating on the Men B vaccine price took over a year). While it is important to ensure that NHS funds are used efficiently, the 127 cases of vaccine-preventable meningitis B

that occurred in children less than 12 months old last year highlight the need to expedite these proceedings.

- 4. Once the JCVI's recommendations have been implemented, there must be concerted action to promote uptake and ensure excellent coverage.** Uptake of the Men B vaccine has been strong. However, for other vaccines immunisation uptake is variable and significant inequalities exist between different areas (*see BSI briefing*)ⁱⁱ. Delivery of national immunisation programmes require strong linkage between actors at both the national (e.g. NHS England and Public Health England) as well as the local (e.g. Directors of Public Health) levels to reduce unacceptable variations in uptake that needlessly expose some communities to avoidable communicable diseases.

ⁱ House of Commons Petitions Committee (2016). Petition on the meningitis B vaccine – oral evidence

ⁱⁱ Written evidence submitted by BSI to Health Select Committee inquiry on public health (2015).