

Consultation briefing: the future of vaccines and preventing ill health in the UK

Consultation on the 2016 report into the cost effectiveness methodology for immunisation programmes and procurement (CEMIPP).

 $\underline{\text{https://www.gov.uk/government/consultations/cost-effectiveness-methodology-for-vaccination-programmes}$



The consultation

There is a government consultation on a new report on vaccine-decision making that will have a huge impact on the future of health prevention – especially vaccines – and could signal a move away from preventing illness in the UK in favour of funding treatments.

An interpretation of this report by government advisors says that they would set 'a stricter hurdle for vaccines to be found cost-effective compared to other drugs (or public health interventions) assessed by NICE and potentially signal a move away from prevention.'

The report could reduce access to new vaccines and potentially new treatments by reducing the amount the NHS would be willing to pay for health benefits (known as 'reducing the QALY threshold').

The benefits of vaccines could be undervalued if the report recommendations are implemented now.



The origins of the report

Improving access to vaccines to save lives

Experts raise concerns about vaccine rules being inappropriate for some diseases

The Joint Committee on Vaccination and Immunisation (JCVI) are the government's official advisors on vaccines. They were concerned that methods used for assessing which vaccines to fund undervalue the benefits of preventing uncommon, severe diseases in childhood, such as meningitis. This meant that access to some live-saving vaccines could be restricted. For example, the MenB vaccine (which prevents the most common form of meningitis in children) was at first rejected as not cost-effective. When it was finally introduced, it was only available for babies.

A government working group called **CEMIPP** was set up

The Cost Effectiveness Methodology for Immunisation Programmes and Procurement (CEMIPP) working group was set up in 2014 to address this question.

The aim was to consider whether the method for appraising the cost effectiveness of vaccination programmes should change.

However, the scope quickly changed due to internal government interference.

Young children continued to die because they could not get the MenB vaccine

The tragic death of a young girl, Faye Burdett, sparked a huge public outcry and led to a petition - over 820,000 people called for greater access to the MenB vaccine.

The Health Secretary told petitioners to wait for the report

Jeremy Hunt told the petitioners that government could not fund greater access to the vaccine but that the CEMIPP report was looking into some of the issues and would be published soon.

Internal government interference causes delays

At the same time, an internal government working group, called the Appraisal Alignment Working Group (AAWG), were considering reducing the amount of money the NHS should be willing to spend on the health benefits drugs offer by around 25%. The CEMIPP group were told they HAD to consider this for vaccines too.

The report became delayed because of the implications of this.

CEMIPP report was not published for 2 years.

The CEMIPP report HAD to reduce the amount the NHS would be willing to pay for the health benefits offered by new vaccines.

Instead of being published, the report was held behind government doors for 2 years.

The report now failed to address the original issues raised by the JCVI.

Government plan for implementing the report makes things worse for vaccines.

The AAWG's interpretation of the report bundles three of the report's recommendations together, and say that these should be adopted for vaccines now. They say this would set 'a stricter hurdle for vaccines to be found cost-effective compared to other drugs (or public health interventions) assessed by NICE and potentially signal a move away from prevention.'



What the report says

The government are consulting on a report which could have an impact on which vaccines you get throughout your life, from childhood vaccines (such as the MenB vaccine) right through to vaccines in old age (such as the shingles vaccine). The report is linked to decisions about which vaccines to fund.

The UK's health budget is set by government and so the NHS has to make choices about what to buy that will benefit the most people in the best way. The budget is divided up to buy things that improve our health, such as treatments, vaccines and medical devices.

This means that a new vaccine programme needs to buy 'healthy life' for the population AND needs to be good value for money compared to other things that could improve health in other ways.

Before the Government can fund a vaccine, experts have to calculate the value of the benefits the vaccine gives (how many lives it would save or how much improved health everyone would get) for each pound they would spend on it. This is to try and make the best use of resources and the most value for money in terms of health.

The report considers how to calculate the benefits of vaccines.

Why is there a report?

The Joint Committee for Vaccination and Immunisation (JCVI) advise the government on vaccines. In 2013, after considering whether vaccination should be introduced to protect children against MenB (meningococcal B infection, the leading cause of meningitis in UK children), they were concerned that current methods for assessing which vaccines to fund could undervalue the benefits of preventing uncommon, severe diseases in childhood.

As a result, the Cost Effectiveness Methodology for Immunisation Programmes and Procurement (CEMIPP) working group was set up in 2014 to consider whether the method for making decisions about which vaccines to fund should change.

What does the report say?

The CEMIPP report gives 27 recommendations. However, the AAWG's interpretation of the report states three recommendations are particularly significant and should be bundled together, although there is no evidence for why they should be linked. This same AAWG interpretation makes it clear that adopting these recommendations now would set 'a stricter hurdle for vaccines to be found cost-effective compared to other drugs (or public health interventions) assessed by NICE and potentially signal a move away from prevention.' The three recommendations are:

- 1. A lowering of the cost-effectiveness threshold from £20,000 per QALY to £15,000 per QALY.
 - This would make a stricter hurdle for new vaccines to be funded compared to existing methods.
- 2. A lowering of the discount rate for health impacts from 3.5% per year to 1.5% per year.
 - This would put greater value on the lifelong benefits of vaccines future health benefits would be taken into account to a greater extent than existing methods. This would make it easier for vaccines to pass the cost-effectiveness test and be introduced.
- 3. An indefinite 'time horizon of analysis' (i.e. the time period over which benefits of a vaccine are considered), but with methods in place to introduce a 'cap' on future benefits.
 - This could counteract the positive effect of reducing the discount rate future benefits of vaccines would be taken into account to a lesser extent.



1. QALY threshold

A lowering of the cost-effectiveness threshold from £20,000 per QALY to £15,000 per QALY.

• This would make a stricter hurdle for new vaccines to be funded compared to existing methods.

To compare the 'value' of the benefits a vaccine offers compared to other things, experts use a measure called a Quality of Life Year (QALY). One QALY means one year of perfect health.

They use this to calculate how much healthy life the vaccine would offer per pound spent.

For example, if a tablet was for sale that could prevent someone from dying, and instead guarantee them an additional year in perfect health, that would give one QALY.



BUT if a different tablet gave an additional two years of life at half the quality of health, this would also give one QALY.



The current rules says that the government can afford to spend around £20,000 to buy one QALY.

The report suggests lowering this to £15,000 for vaccines. This would make a stricter hurdle for new vaccines to be funded compared to existing methods and make them less likely to be introduced.

It would also mean that the benefits of vaccines were treated less favourably than other drugs and health care interventions because they would still consider spending around £20,000 per QALY for those.



Meningitis Research Foundations position on QALY threshold

MRF is responding to the consultation and will provide a full, evidenced argument to REJECT this recommendation.

- The government should not lower the QALY threshold.
- There is academic and public opposition to lowering the threshold. 1,2
- The recommendation is based on one study from the University of York³ which did not consider vaccination at all.
- The recommendation to lower the threshold did not originate with CEMIPP, they were told they had to include this as it was likely to be adopted across the rest of the NHS.
- It would not address the concerns raised by the JCVI about disadvantaging vaccines for rare, severe childhood illness in fact it would make matters worse, potentially reducing the availability of vaccines for children.
- Lowering the threshold only for vaccines, not treatment, would cause an unfair disadvantage and worsen the imbalance that already exists. Government spending on vaccines is a very small fraction of the NHS budget: 0.4% in 2009/10⁴. Yet preventing illness can save avoidable costs to the NHS across primary and emergency care, hospitals, and long-term care.
- This lower threshold has already met with resistance from the National Institute for Health and Care Excellence, who said it "would mean the NHS closing the door on most new treatments"⁵. However, lowering the QALY threshold for vaccines could signal a move towards reducing it across all areas of health.
- UK health spending, including both public and private expenditure, is substantially less of its national income than countries such as the US, Japan, Germany, and France if the UK were to spend the same proportion of national income on health as Germany in the next year, this would add an extra £30 billion to the health budget.⁶ The UK is ranked 6th out of the seven countries that form the G7 (a group of large developed economies) for healthcare expenditure as a proportion of Gross Domestic Product (GDP)⁷. A bigger 'pot' of money for health is required, not a lower threshold.

¹ Mason H, Jones-Lee M, Donaldson C. Modelling the monetary value of a QALY: a new approach based on UK data. Health Econ 2008, Oct 14

² Claxton K, Martin S, Soares M et al. Methods for the estimation of the National Institute for Health and Care Excellence cost-effectiveness threshold. Health Technol Assess 2015: 19 (14): 1–503.

³ Barnsley et al. Critique of CHE Research Paper 81:Methods for the Estimation of the NICE Cost Effectiveness Threshold. Office for Health Economics Occasional Paper 13/01

⁴ Ethgen O, Baron-Papillon F, Cornier M. How much money is spent on vaccines across Western European countries? Human Vaccines & Immunotherapeutics. 2016;12 (8):2038-2045. doi:10.1080/21645515.2016.1155013.

⁵ Sir Andrew Dillon. Carrying NICE over the threshold. National Institute of Health and Care Excellence, Blog 19 February 2015. https://www.nice.org.uk/news/blog/carrying-nice-over-the-threshold

⁶ Charlesworth A and Johnson P. Securing the future: funding health and social care to the 2030s. Institute for Fiscal Studies and Health Foundation. May 2018

⁷ Lewis J. UK Health Accounts 2016: Healthcare expenditure statistics produced to the international definitions of the System of Health Accounts 2011. 25 April 2018



2. Discounting

A lower discount rate for health benefits from 3.5% per year to 1.5% per year.

• A lower discount rate would put greater value on the lifelong benefits of vaccines – future health benefits would be taken into account to a greater extent than they are today.

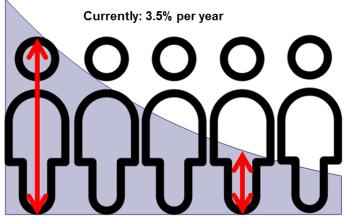
Experts have to determine the value of the health benefits of vaccines that may not materialise until a number of years in the future.

For example: the HPV vaccine given to teenagers protects against cervical cancer that usually appears later in life; the MenB vaccine protects against an illness that usually occurs in childhood but can lead to amputations and brain damage that can impact someone's life forever; smallpox no longer exists because previous generations were vaccinated against the disease which continues to protect the current generation and all future generations.

Currently, health benefits that happen in the future are "discounted" – meaning that they are worth less and considered less important than health benefits gained now.

This means that funding an intervention which resulted in immediate health benefits would be preferred to one which resulted in benefits say 10 years into the future.

Experts do this because they believe that is how society views things, and to account for things we don't yet know could happen (such as new treatments/therapies that could make dramatic improvements to health).



Start: full health benefits of vaccines considered

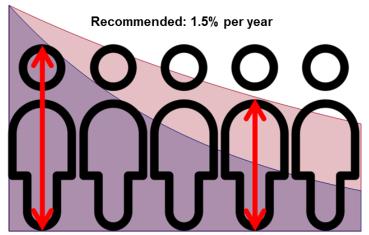
30 years' time: about 1/3 of the impacts of a vaccine included

Currently economists reduce the value of health benefits by 3.5% per year.

- A year of life saved in 30 years' time is worth only about one third of a year of life saved now.
- Saving the life of a baby today –
 who would otherwise have lived
 for around 80 years will only
 count for about 27 years of
 health gained in the calculations
 used to decide if it should be
 funded.



The current discounting approach places less value on vaccinations that aim to prevent death or disability in young children, who once immunised might be expected to live a long life, than other long-term public health interventions.



Start: full health benefits of vaccines considered

30 years' time: about 2/3 of the impacts of a vaccine included

The report says economists should only reduce the value of health benefits by 1.5% per year. This would put greater value on the lifelong benefits of vaccines – future health benefits would be taken into account to a greater extent than existing methods. This could make it easier for vaccines to get funded and more likely to be introduced.

- This means a year of life saved in 30 years' time would be worth two thirds of a year of life saved now.
- Saving the life of a baby today who would otherwise have lived for around 80 years – will count for about 46 years of health gained in the calculations used to decide if a vaccine should be funded.

This new approach would put greater value on the lifelong benefits of vaccines



Meningitis Research Foundations position on discounting

MRF is responding to the consultation and will provide a full, evidenced argument to SUPPORT this recommendation.

- The government should lower the discount rate from 3.5% per year to 1.5% per year, as recommended.
- There is good academic evidence for lowering the discount rate. 8,9
 - An argument for the use of lower discount rates for the evaluation of vaccines was presented by Dr Bhash Naidoo, Associate Director of Research and Development, NICE, at the NICE citizens council meeting entitled 'How should NICE assess future costs and health benefits?', November 2011. Dr Naidoo argues that the higher discounting at 3.5% results in a disproportionately high NHS spend on acute treatments over preventative interventions.
- NICE uses a 1.5% discount rate when considering other public health interventions⁵ (JCVI rather than NICE is responsible for appraising vaccines, but JCVI's Code of Practice requires it to use the same methods as NICE).
- Lowering the discount rate to 1.5% would be in line with methods used to consider other interventions where benefits are sustained over a very long period.
- Lowering the discount rate is the key recommendation in the CEMIPP report as it addresses the reason the CEMIPP working group was set up in the first place.
- It would address the JCVI's concern that the current rules disadvantage vaccines for rare, severe childhood illness. It would also help to answer the concerns of over 820,000 petitioners who called for wider access to the MenB vaccine.

⁸ Christensen, Hannah, et al. "Re-evaluating cost effectiveness of universal meningitis vaccination (Bexsero) in England: modelling study." BMJ 349 (2014): g5725.

⁹ Camejo, H. Starkie, X. Li, and G. Van Kriekinge. "Does it matter? Discounting and its role in the cost-effectiveness of preventative interventions. The case of HPV vaccination." Public Health 129.7 (2015): 989-992.

⁵ Methods for the development of NICE public health guidance (third edition), Process and methods [PMG4] Chapter 6 Incorporating Health Economics. Published date: September 2012 https://www.nice.org.uk/process/pmg4/chapter/incorporating-health-economics



3. Time horizons

- 3. An indefinite 'time horizon of analysis' (i.e. the time period over which impacts of a vaccine are considered), but with methods in place to introduce a 'cap' on the value of benefits which accrue in the future.
- This could counteract the positive effect of reducing the discount rate and future benefits of vaccines would be taken into account to a lesser extent.

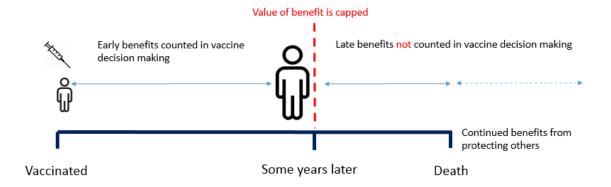
Vaccines offer benefits that last a lifetime, and even beyond an individual lifetime if they prevent other people getting a disease by stopping the spread.

Because of this, the CEMIPP report recommends that experts consider the benefits of vaccines over an indefinite period on a case by case basis when deciding if they should fund them.

However, the report also recommends putting methods in place that could introduce a 'cap' on the value of benefits which accrue in the future, even if benefits are still predicted for a long time. This would mean benefits occurring after a certain amount of time would not count at all when making funding decisions.

The report has not clarified exactly how long this timescale should be and is unclear how it will be applied because the working group could find no straightforward method for fixing the 'cap' at a particular length of time. However, the government consultation is suggesting there should be a fixed cap. This would make it harder for vaccines to be introduced as it ignores the long term health benefits of vaccines.

It would counteract the positive effect of reducing the discount rate, and future benefits of vaccines would be taken into account to a lesser extent.



On this recommendation the consultation needs to address if a cap should be applied, what timescale should be considered and how the capped sensitivity analysis should influence the final result of the analysis.



Meningitis Research Foundations position on time horizons

MRF is responding to the consultation and will provide a full, evidenced argument to REJECT this recommendation.

- The government should not introduce an arbitrary 'cap' on the future benefits of vaccines.
- The report provides no evidence or consensus of opinion from health economists to warrant a cap.
- There is evidence of the opposite opinion health benefits which run far into the future should be better accounted for in the cost effectiveness analyses by applying lower discount rates.
- For some diseases, particularly cancers, in which pre-teen children are vaccinated to
 prevent cancers that appear in late middle age, a fixed cap could make it impossible to
 introduce vaccines. For meningitis a fixed cap could stop nearly all the benefits of
 vaccinating from being counted.
- Allowing the JCVI to consider what time horizon is sensible when considering a new vaccine against a particular disease based on their expertise (a 'sensitivity analysis') is reasonable, but a fixed cap applied across all vaccines would be damaging to public health.



What would all this mean for vaccines?

Overall the recommendations suggest:

- Reducing the amount the government is willing to pay for the benefits offered by a vaccine
- Valuing the future benefits of vaccines more than they currently do
- But capping the total amount of benefit a vaccine can give to a set timescale, even if benefits are predicted beyond that

Government advisors believe these recommendations have to be taken together (although there is no evidence for doing this). Taken together these recommendations would mean that vaccines would be treated less favourably than other drugs and health care interventions.

On the whole, this would mean that vaccines were valued at a lower level and less likely to be introduced.

If all the recommendations were implemented for vaccines now it would place an unfair preference on NHS spending that waited for people to get ill, rather than preventing illness.

Eighty per cent of new drugs would continue to be recommended for use in the NHS. Meanwhile vaccines would have to stay below a cost limit 25% lower than the basic limit for treatments.

Meningitis Research Foundations position on the CEMIPP report

- These recommendations should not be taken together as there is no evidence for the need to combine them. Implementing these three recommendations for vaccines now would mean that vaccines would be treated less favourably than other drugs and health care interventions. It would limit access to vaccines for children and adults.
- The Department of Health should give clear steps and a timetable outlining how they will
 address the original concerns from JCVI relating to preventing uncommon, severe
 diseases in childhood, such as meningitis. It is clear that the original objective of the
 report has been forgotten. This could be achieved by accepting the recommendation for
 lowering the discount rate.
- Lowering the discount rate is the one evidence-based recommendation which would address the JCVI concerns and better account for lifelong and future benefits of vaccines, and the Government should implement this now.
- Government should reject recommendations that would unfairly cap the full benefits of vaccines.
- Government should reject the recommendation to cut the amount of money the NHS
 would be willing to spend on the benefits vaccines offer by 25% as this has been widely
 criticised by NICE, by academic experts, and the public. This attempt to save costs will
 harm the public's health, and if implemented across the NHS will stop the UK from
 introducing new medicines. We need more spending on health, not cost-cutting.



Group statements

MRF is asking organisations to lend their voice to our call to government to take action. If you are able to lend your support to ANY OR ALL of the statements, we would add your logo to the specific statement you agree to as part of our consultation response.

Statement 1

We, the undersigned, ask you to protect prevention in the UK. Do not accept these recommendations as a package. Preventing illness should not be viewed less favourably that treating illness.

Statement 2

We, the undersigned, ask you to value the full long-term benefits of vaccines by reducing the discount rate to 1.5%. Other public health measures in the NHS already use a 1.5% discount rate. Vaccines offer benefits for the whole population that may extend beyond a lifetime.

Statement 3

We, the undersigned, ask you not to lower the QALY threshold. There is expert opposition to lowering the QALY threshold and the arguments for lowering it are based on one piece of research that took no account of vaccines. Reducing the threshold for vaccines alone would be damaging to public health and jeopardise a world-class immunisation programme.

Statement 4

We, the undersigned, ask you not to place an arbitrary 'cap' on economic models to assess the future benefits of vaccines. There is no evidence or consensus of opinion from health economists to warrant a cap. A fixed cap could make rational public health decisions impossible.