Department of Health & Social Care

Cost-effectiveness methodology for Immunisation Programmes and Procurements (CEMIPP)

The government's decision and summary of consultation responses

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The Government’s Decision

The Government is grateful to all those who took the time to respond to this consultation, and for the wide-ranging comments that were provided. The Government carefully considered all consultation responses as well as the Appraisal Alignment Working Group (AAWG)'s opinion[1] on the recommendations by The Cost-Effectiveness Methodology for Immunisation Programmes and Procurement (CEMIPP) group.

The Government has decided not to accept the three key recommendations of the report (on reducing the cost-effectiveness threshold to £15,000 per Quality-Adjusted Life Year (QALY), changing the health discount rate to 1.5%, and changing the time horizon of the analyses). The Government notes that it is not possible to make a decision that everyone will agree with. The bases for this decision are that there is a risk that the changes would impose a more stringent cost-effectiveness bar for immunisation programmes and a deviation from the approach currently taken for medicines. The territorial extent of the Government’s decision is England only.

At the same time, the Government encourages the Joint Committee on Vaccination and Immunisation (JCVI) to adopt a number of ‘best practice’ improvements recommended by the CEMIPP report, and has referred some of the CEMIPP report’s suggestions for additional research to improve the underlying evidence base.

This is the Government’s final decision. The Government reserves the right to revisit this decision, but there are no concrete plans to do so at the moment.

[1] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/707847/cemipp-consultation-document.pdf

1. Background

The Joint Committee on Vaccination and Immunisation (JCVI) is the independent expert committee that advises Ministers on the introduction of new, and changes to existing, vaccination programmes in the UK. In 2014, JCVI asked the Department of Health[2] that the methodology they use to appraise the cost–effectiveness of vaccination programmes be reviewed to see if it should differ from those used for appraising other health-related activities that use public resources.

As a result, the Cost-Effectiveness Methodology for Immunisation Programmes and Procurement (CEMIPP) group was set up by the then Department of Health. It consisted of academic health economists, representatives from bodies such as the JCVI and National Institute for Health and Care Excellence (NICE) and analysts from the Department of Health and Public Health England. Key stakeholders, including the pharmaceutical industry and some patient groups and charities, also had an opportunity to feed in views. The CEMIPP group submitted its report[3] to the Government in July 2016, making 27 recommendations.

Ministers sought the opinion of the Appraisal Alignment Working Group (AAWG) on the report. The AAWG considers the divergent approaches to cost-effectiveness analysis across the entire health and care system in England. It is chaired by the Department's Chief Economist, with representation from some of the Department's Arms' Length Bodies (e.g. NICE, NHS England, PHE...) and academics. Their advice was received at the end of January 2018.

The CEMIPP report and the AAWG's conclusions were published on 26 February 2018 for a 12-week consultation. Due to the complexity of the CEMIPP report, a lay guide was published on 17 May 2018 and the consultation extended by 6 weeks. The consultation closed on 28 June 2018.

The subsequent sections summarise the responses to the CEMIPP consultation.

[2] Renamed in 2018 to the 'Department of Health and Social Care' (DHSC)
[3] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/683872/CEMIPP_report_2016__2_.pdf

2. Summary of the Consultation Responses

2.1 There were 41 responses to the consultation. They were received both through the online ‘Citizen Space’ portal as well as via email. The types of respondent are listed below:

Table 2.1.1: Respondent Types to the Consultation

Respondent type	Number
Pharmaceutical company/ industry body	10
Charity/ non-Government organisation	9
Academic/ health economist – individual	5
Academic/ health economist – organisation	2
Health body – individual	1
Health body – organisation	2
Clinical, professional or regulatory organisation	1
Patient group	1
Other – individual	10
Total	**41**

2.2 Almost half of the responses (19) were from pharmaceutical bodies or charities/ non-Government organisations. Some organisations included a significant amount of detail within their responses.

3. Implementation of the significant recommendations

3.1 The first part of the consultation asked about the three significant recommendations which CEMIPP advised should be implemented for immunisation (changes in the cost-effectiveness threshold, discount rate, and time horizon of the analyses), irrespective of changes that might or might not happen elsewhere in the health system.

3.2 The consultation asked if this package of recommendations should be implemented in its entirety (Q11). Most respondents (30), including all respondents from charities, pharmaceutical bodies and patient groups, did not support this.

Table 3.2.1: Responses to Implementation of Key Recommendations

Response to implementation of key recommendations	Number
Yes	6
No	30
Don't know	5

Table 3.2.2: Responses to Implementation of Key Recommendations by type

Respondent type	Yes	No	Don't know
Pharmaceutical company/ industry body	0	10	0
Charity/ non-Government organisation	0	9	0
Academic/ health economist (individuals & organisations)	3	3	1
Health body (individuals & organisations)	0	3	0
Clinical, professional or regulatory organisation	0	1	0
Patient group	0	1	0
Other – individual	3	3	4
Total	**6**	**30**	**5**

3.3 A reason given by many for not supporting implementation of this package of recommendations was that it was perceived to make it harder for vaccines to be found cost-effective and made available, thereby potentially undermining public

health and the UK's world-class immunisation programme (25 respondents). Other reasons given included:

- A view that the cost-effectiveness threshold recommendation of £15,000 per Quality-Adjusted Life Year (QALY) was not based on strong evidence and is not applicable to vaccines.

- Implementing the recommendations could discourage investment and innovation in immunisation in the UK.

- Implementing the recommendations could set a precedent for them to be implemented more widely (e.g. to medicines assessed by the National Institute for Health and Care Excellence (NICE)) which would not be appropriate.

3.4 In several cases, respondents who did not want the recommendations implemented as a package due to them making it harder for vaccines to be considered cost-effective did approve of selective implementation to improve the chances of vaccines being approved.

3.5 Another reason for not supporting the package (given by 4 respondents) was that while they saw the CEMIPP recommendations as evidence-based, they believed that the rules applied to vaccines should be the same as those applied to other areas of NHS expenditure (including NICE). They indicated that implementing the recommendations now for vaccines would lead to inconsistency.

3.6 Those respondents who did not think the recommendations should be implemented as a package (and consented to their organisation name being used) were:

- pharmaceutical bodies (Janssen, GlaxoSmithKline, Novartis, Ethical Medicines Industry Group, Association of the British Pharmaceutical Industry, AstraZeneca, AbbVie, Sanofi Pasteur, Pfizer);

- charities (HPV Action, Genetic Alliance UK, Meningitis Research Foundation, International Longevity Centre UK, British Society for Immunology);

- patient group (Specialised Healthcare Alliance);

- health body (Joint Committee on Vaccination and Immunisation (JCVI)); and

- clinical, professional or regulatory organisation (Royal College of Nursing).

3.7 The main reasons given from those respondents who thought that the recommendations should be implemented as a package were that they agreed

with the recommendations and viewed them as evidence-based (4 respondents). Some respondents stated the recommendations could lead to lower prices for vaccines, and others noted that the priority should be for cost-effectiveness rules to be based on the best available methods rather than being consistent with rules of other bodies (e.g. NICE).

4. Time Horizon of Analysis

4.1 In addition to asking whether the three main recommendations should be implemented, the consultation asked respondents (Q13-16) about the appropriate time horizon of the analyses as part of the sensitivity test recommended by CEMIPP. This is because the report did not specify a time horizon (i.e. how far into the future to forecast potential health impacts as a result of money being spent) but instead suggested testing whether a 50-70 years time horizon would change the results on cost-effectiveness.

4.2 23 respondents submitted an answer to this part of the consultation. Of these, 15 (65%) were in favour of an indefinite time horizon used as a base case, but not using 50-70 years as a sensitivity test. Rather they preferred looking on a case-by-case basis for the appropriate time horizon for individual vaccinations. The respondents who took this view were generally concerned that a 50-70 years time horizon would explicitly or implicitly 'cancel out' the effect of a lower discount rate and not capture benefits into the future.

Table 4.2.1: Views on appropriate time horizon of analysis

Respondents' views on the appropriate time horizon of analysis	Number
Unlimited base case with 50-70 years sensitivity test	3
Indefinite base case with case-by-case sensitivity analysis	15
Indefinite time horizon	3
Definite time horizon needed (but further development of methods needed)	2
Don't know/ no response on this point	18

4.3 Those respondents who thought an indefinite time horizon should be used i.e. applying an appropriate time horizon on a case-by-case basis (and consented to their organisation name being used) were:

- pharmaceutical bodies (Janssen, GlaxoSmithKline, Novartis, Ethical Medicines Industry Group, Association of the British Pharmaceutical Industry, AstraZeneca, AbbVie, Sanofi Pasteur, Pfizer);
- charities (Meningitis Research Foundation); and
- health body (JCVI).

5. Good Practice

5.1 The second part of the consultation asked respondents about a group of CEMIPP recommendations which the AAWG had identified as largely reflecting current good practice for performing cost-effectiveness analysis for immunisation programmes. It asked where respondents agreed that these were good practice, and, if so, if they should be adopted, and, if not, why (Q17-19).

Table 5.1.1: Responses to "Good Practice" Recommendations (Rec.)

'Good practice' recommendation	Rec.	No. who agreed with it	No. who disagreed with it	No. who did not answer/ did not know
Incremental analysis of all relevant comparators	2.1	14	2	25
	2.2	16	2	23
	2.3	15	0	26
Analysing the relationship between costs and outcomes	5.1	14	1	26
	5.2	14	0	27
Measuring and valuing health effects (unintended consequences)	6.1	7	1	33
Appraisal of evidence (cost-effectiveness and disinvestment)	7.1	13	1	27
	7.4	12	1	28

5.2 Whilst less than half of respondents answered questions on the 'good practice' recommendations (Q19), the majority of those who did, agreed that the recommendations were good practice. When asked whether these should be adopted by JCVI now, 11 respondents agreed. None disagreed.

5.3 Organisations which broadly agreed with these recommendations included many pharmaceutical bodies (e.g. Association of the British Pharmaceutical Industry), health bodies (e.g. JCVI) and charities (e.g. Meningitis Research Foundation and the International Longevity Centre UK).

5.4 Whilst respondents generally agreed on the principle of incremental analysis (recommendations 2.1 - 2.3) a number gave comments highlighting concern over how this is implemented in practice. For example:

- The Meningitis Research Foundation argued that the programme as a whole should be assessed as cost-effective or not, rather than incrementally.

6. Research Priorities

6.1 The third part of the consultation asked respondents' views on the areas identified by CEMIPP and the AAWG as requiring further research (Q20).

Table 6.1.1: Responses to recommendations (Rec) for research

Research recommendation	Rec	No. who saw this as a 'priority'	No. who did not see this as a 'priority'
Peace of mind benefits	6.2	10	4
Differential weighting of impacts due to societal value judgements	6.3	6	1
Differential weighting of impacts due to perceived failure of instruments to capture quality of life	6.4	1	0
Evaluating and comparing the gain and loss of QALYs in a theoretical framework	6.6	1	0
Incorporation of equity considerations, including equity weighting of benefits foregone	7.5	1	1

6.2 Research into 'peace of mind' benefits and how these could be incorporated into the value assessment of vaccinations was the most prioritised area by respondents, in particular by pharmaceutical bodies. The second most prioritised area was on 'differential weighting', especially in the context of assessing the relative value of the prevention of rare, severe illness in children.

6.3 Other areas for further research were also identified by respondents in comments. For example, pharmaceutical bodies generally suggested further empirical research was needed on the cost-effectiveness threshold. They also suggested further research on how to incorporate the impact of a vaccination programme on reducing the use of anti-microbials into the value assessment.

7. Other Comments

7.1 Respondents were provided with the opportunity to comment further on CEMIPP recommendations (Q21-22). There were several lengthy submissions referencing further academic research and views. In particular:

- Some respondents (including some academics and charities) noted that while they generally agreed with the recommendations made in the CEMIPP report, they were concerned about applying the more significant recommendations (especially the cost-effectiveness thresholds) to vaccines only. For example, one respondent said:

  "*We understand the arguments around potentially reducing the willingness to pay threshold for a QALY so as not to displace other healthcare that creates more value. However, our fundamental point is that there should be consistency between vaccinations and other forms of healthcare in the health economic guidelines that are used*."

- Some respondents (in particular charities) suggested that the current rules placed too strict a barrier to vaccinations becoming approved, and that the recommendations - depending on how interpreted and implemented – could detrimentally impact vaccines and public health. Comments were made that implementation could also harm vaccine innovation and investment in the UK.

- Some respondents (in particular academics) noted that further work on 'full economic utility' was needed i.e. to ensure full impacts of a vaccine are considered.

- Some respondents (including charities and pharmaceutical bodies) favoured selective implementation of the recommendations and did not agree the main recommendations could or should be considered as a coherent package. In general, this included suggesting the implementation of a lower discount rate combined with an indefinite time horizon, but not reducing the cost-effectiveness threshold. For instance, a Meningitis Research Foundation statement[4] signed by 18 supporting bodies (the majority of whom did not respond to the consultation in their own right) argued:

  "*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 than treating illness*.

[4] https://www.meningitis.org/getmedia/d75495fd-f3d8-4715-8040-566389f9b6bb/Organisational-support-for-CEMIPP

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.

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. Reducing the threshold for vaccines would be damaging to public health and jeopardise a world-class immunisation programme.

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."

8. Equality Issues

8.1 The fourth and final substantive part of the consultation asked respondents (Q23) whether there were any equality issues that needed to be considered when deciding whether or not to implement any or all of the CEMIPP recommendations.

8.2 Some respondents noted the importance of public health interventions, especially vaccinations, for equality given that they often target the whole population and therefore often benefit the poorest and most vulnerable. Specific comments included:

- Concerns that applying stricter rules for vaccines to be found cost-effective could lead to decreased funding for immunisation and therefore the potential to increase health inequalities.

- Reference to ethical, equity and legal arguments for including boys within the HPV vaccination programme and that the JCVI should explicitly perform equality analysis as opposed to only the Department of Health and Social Care.

- Further research is needed on how best to incorporate equity considerations into cost-effectiveness analysis and decision-making, especially so that it is done consistently and without unintended consequences.

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