Clinical Policy Brief

Government Consultation on changes to NICE regulation and new powers to the Secretary of State for Health on the Cost Effectiveness thresholds.

Response by January 13th to 3 questions.

https://www.gov.uk/government/consultations/changes-to-nice-regulations-cost-effectiveness-threshold/changes-to-nice-regulations-cost-effectiveness-threshold-consultation-document

- Note this is a Government Consultation not NICE consultation exercise
- This is linked to the Cost of New Medicines and overall Government spend
- Proposal to increase QALY threshold (from £20k-£30k to £25k-35k) shall mean more drugs shall come to market around 3-5 out of around 70 a year currently but that Pharma companies shall increase their costs to the NHS overall. QALY has been a measurement around for over 20 yrs and initially without a lot of scientific evidence.
- This government policy is being driven by US / UK trade negotiations and recent Trump rhetoric
- What shall this mean for the NHS and Health systems? – it is likely that over time cost pressure from medicines shall rise having a cumulative effect as more new medicines come to market. Funding for this cost pressure is unlikely to come from new taxation but shall probably come from existing health budgets and may be passed down to systems through ICBs (Interesting that this consultation which shall increase costs pressures comes at the same time that the Government refuse to increase pay for Resident Doctors!)
- Effect on future independence of NICE – Secretary of State for Health shall now have control over spend on Medicines response to Q1 of consultation - Do you agree or disagree that a ministerial power of direction, as outlined under proposal 1 above, should be limited to the NICE standard cost-effectiveness threshold? This is worded in such a way as to give a binary answer giving the control to SOS for health new powers to effectively control the spend on new technologies for the NHS which now links this directly to government trade deals. We would however want to limit the SOS powers to just the threshold and retain the independence of NICE as an arm's length organisation and to prevent any powers related to individual drug technology appraisals.
- For further information its worth reading Karl Claxton's (University of York and Health Economist) appraisal of risks HERE is a recent opinion piece from him
- NICE position is to distance themselves – its up to Government to determine the total spend of medicines and technologies but NICE retain independence on spend of medicines and individual technologies. HERE is a link to recent NICE Board meeting papers on this topic

MD for Clinical Policy Adrian Hayter 17.12.25

Proposed amendments to the NICE regulations

Proposal 1

Do you agree or disagree that a ministerial power of direction, as outlined under proposal 1 above, should be limited to the NICE standard cost-effectiveness threshold?

- Agree
- Neither agree nor disagree
- Disagree
- Don't know

Please explain your answer. (Maximum 200 words)

We have concerns that the cost pressure associated with an increase in the thresholds shall be funded without passing this onto workforce and other areas of the NHS. We feel that NICE should retain full independence from political interference regarding its processes and decision-making, and that ministerial power of direction should be limited to the NICE standard cost-effectiveness threshold. It is essential that the public and professionals continue to support the independence of NICE, its methods, processes and decision-making.

Do you agree or disagree that the power to direct NICE about the standard cost-effectiveness threshold should apply to all NICE guidance that makes recommendations on health spending? This includes technology appraisal and highly specialised technology evaluation recommendations.

- Agree
- Neither agree nor disagree
- Disagree
- Don't know

Please explain your answer. (Maximum 200 words)

The power to direct NICE about the standard cost effectiveness threshold should be limited to just technology appraisal and not to highly specialised technology evaluation recommendations. This shall prevent the secretary of state from using their powers to lower thresholds purely to save money on rare disease treatments. Highly specialised technology evaluation requires ethical and professional judgements which are best decided by the independent committees of NICE. This shall support decision making which continues to maintain the position of the UK in being a global leader in genomics and rare diseases research

Proposal 2

Do you agree or disagree that NICE should not be required to consult on any proposed changes to its procedures that are necessary as a result of a ministerial direction on cost-effectiveness thresholds?

- Agree
- Neither agree nor disagree
- Disagree
- Don't know

Please explain your answer. (Maximum 200 words)

We believe that removing the consultation shall further undermine the independence and credibility of NICE. There shall be less public scrutiny and a reduction in the influence of the patient's voice when proposals are made. The lack of consultation risks the ability of relevant stakeholder groups to scrutinise the changes and question the unintended consequences that might arise when weighing up different types of health benefits within areas of clinical uncertainty.