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December 18, 2020

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ISPOR
Lawrenceville, NJ, USA

Dear NICE:

ISPOR – the professional society for health economics and outcomes research - is pleased to respond on behalf of its membership to your consultation entitled “The NICE methods of health technology evaluation: the case for change.”

ISPOR is a scientific and educational society with many of its members engaged in evaluation of health technologies, including pharmaceuticals, medical devices, and other interventions. We have a large membership living and working in 110 countries globally, across a range of disciplines, including health economics, epidemiology, public health, pharmaceutical administration, psychology, statistics, medicine, and more, from a variety of stakeholder perspectives, such as the life sciences industry, academia, research organizations, payers, patient groups, government (including some from European regulatory agencies), and health technology assessment bodies. The research and educational offerings presented at our conferences and in our journals are relevant to many of the issues and questions raised in this request for information.

The response to this consultation was led by the Policy Outlook Committee of our most senior advisory body, the Health Science Policy Council. To engage our membership, we created a survey where level of agreement with each proposal could be rated and commented upon; to keep survey length manageable, we selected 26 proposals we felt were most relevant for comment to include in the survey. In your comments form (attached separately), for each section we summarize the level of agreement on surveyed proposal items as strong, moderate, or weak and summarize our comments on each item. These comments focus on the methodological aspects of these proposals.

ISPOR would be happy to answer any questions about our response, as well as to participate in any follow-up consultations on the relevant program items mentioned within the report.

Sincerely,

Nancy S. Berg
CEO & Executive Director
ISPOR

**2020–2021
Board of Directors**

February 5, 2021

PresidentJens Grueger, PhD
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University of Washington
Seattle, Washington**CEO & Executive Director**Nancy S. Berg
ISPOR
Lawrenceville, NJ, USA

Dear NICE:

Late last year ISPOR responded on behalf of its membership to your consultation entitled “The NICE methods of health technology evaluation: the case for change.”

We would like to submit a revised response, attached. The only revision is the removal of a comment in point 2.I.

While we understand that the process of reviewing and acting upon these responses is well under way, we would very much appreciate if the revised version attached could be maintained as our official response

ISPOR would be happy to answer any questions about our response, as well as to participate in any follow-up consultations on the relevant program items mentioned within the report.

Sincerely,

Nancy S. Berg
CEO & Executive Director
ISPOR

National Institute for Health and Care Excellence

The NICE methods of health technology evaluation: the case for change

Consultation: 6 November – 18 December 2020

Introduction

Thank you for participating in the consultation on the NICE methods of health technology evaluation: the case for change.

We are interested in hearing your thoughts about:

- our proposals
- how we've taken the evidence and considerations into account
- any potential effects and implications for patients and their families, health technologies, the life sciences industry and the NHS.

The information collected will be used to inform the next steps for the development of the NICE methods for health technology evaluation. Comments will be published in full on the NICE website after the consultation closes (excluding responses from NICE staff and committees). **Please do not include any personal information in your response.** NICE will not respond to individual comments or suggestions.

Instructions

There are 5 sections of the potential areas for change:

- Valuing the benefits of health technologies
- Understanding and improving the evidence base
- Structured decision making
- Challenging technologies, conditions and evaluations
- Aligning methods across programmes

This form provides space to respond to the consultation questions for each area. There is space for additional comments. You do not have to provide comments for all sections.

When responding, please remember the objectives of the review and the boundaries of the current stage, as described in the consultation document. In particular, this consultation focuses specifically on the methods of health technology evaluation (and not its processes or other related developments, which are considered

separately), and presents the evidence and case for change only (a finalised methods framework will be developed in the next stage).

Please type your responses directly into the tables in this form. If you wish to refer to a particular section, paragraph or proposal, or any of the supporting documents, please indicate the relevant name, number or letter that you are referring to within your response. Please do not include any personal details in your comments.

Submitting your response

Return your completed response form via email to methodsandprocess@nice.org.uk by 11:59pm on 18 December 2020. Responses submitted in any other format will not be accepted

Privacy notice

For more information about how your data will be processed please see our [Privacy Notice](#)

About you

To help us understand and theme your comments during review, please indicate which category best describes who your response is from by adding the name of the organisation next to the relevant category

Alternatively, if you are responding as an individual, please add your job title next to the individual that best describes your role.

Organisations

Category	Name of organisation
<i>example organisation type</i>	<i>e.g. Write the name of organisation here</i>
Academic body	
Device industry	
Devolved nation	
Diagnostic industry	
Industry body	
Life sciences consultancy	
NHS organisation	
Patient organisation	
Pharmaceutical industry	
Professional organisation	ISPOR
Other type of organisation	

Individuals

Individual	Job title
<i>Example individual</i>	<i>e.g. Write job title here</i>
NICE committee member	
NICE staff	
Other individual response	

Consultation comments

Valuing the benefits of health technologies

Consultation questions - valuing the benefits of health technologies	Comments
<p>Do the proposals and cases for change provide a suitable basis to inform the final methods?</p> <ul style="list-style-type: none"> Do you have any comments or feedback on the methodological evidence and considerations that have been taken into account, or how the evidence has been interpreted? Do you have any comments or feedback on how well the proposals will achieve the aims of the review? 	<p>Our respondents provide the strongest level of agreement with proposals and their cases for change for these proposals:</p> <p>1 c, d, e,</p> <p>There was moderate agreement with these proposals:</p> <p>1 a, g</p> <p>There was weak agreement with these proposals, though not overall disagreement:</p> <p>1 b</p> <p>The remaining proposals in this section were not included in our survey.</p> <p>Below are summaries of specific comments on these proposals:</p> <p>1.a This is a statement that sounds fair in an extra-welfarist sense and may be straightforward as a starting point, but ignores recent work, including that by the ISPOR Special Task Force on US Value Assessment, that indicates there are other considerations regarding how individuals and society value health improvements. Ignoring those considerations in value assessment can result in incorrect price signals to innovators who aim to develop new products of greatest value to patients. To elaborate, we focus on a key issue in the statement from the Modifiers and Finish Group: It states that a</p>

Consultation questions - valuing the benefits of health technologies	Comments
	<p>factor is considered a modifier if “it has not been included in the estimate for quality-adjusted life years (QALY) because it cannot be (that is, issues that go over and above the QALY calculation – technical ‘adjustment’).” As you may be aware, there is new work that provides precise, mathematically supported methods to incorporate several “modifier” elements directly into a proper QALY calculation and/or it provides a basis for specific adjustments to the threshold for accepting an intervention, similar to the adjustments NICE now uses for end-of-life care, cancer care, disease severity, and uncertainty in the ICER (specifically, uncertainty arising from uncertainty in the estimated QALY). This new work, by Darius N. Lakdawalla and Charles E. Phelps, was published in the Journal of Health Economics in July, 2020 and in an article scheduled for publication in Value in Health in March, 2021. It provides specific methods to incorporate issues of disease severity, variance and skewness of QALY benefits, and permanent disability status of the affected patient, thereby transforming these adjustments from “modifier” status to issues directly incorporated into the QALY measurement. While it does not cover all potential value modifiers, it unifies the approach to some very important ones. It is written within a welfare economics perspective and so will require thought as to how it can be applied within a single payer system with a global budget such as the NHS. However, the starting point - that the system is seeking to achieve the best outcomes for the population it serves - is unchanged. We highly recommend serious consideration of this work.</p> <p>1.b. End-of-life treatment is not directly addressed by ISPOR's value assessment work, but considerations around severity of disease, health risk, and real option value may come into play in certain situations; we encourage approaching it from those perspectives. Again, see Lakdawalla-Phelps (2020): it can provide an appropriate rationale for a higher threshold at end of life and assist in calibrating the adjustment.</p>

Consultation questions - valuing the benefits of health technologies	Comments
	<p>1.c. Severity of disease is a legitimate value consideration and thus a modifier. See Lakdawalla and Phelps (2020) and related work cited above provide a more structured and mathematical approach to appropriately valuing it.</p> <p>1.d. Here we share comments of a few of our members [A.B.C] with varying views: [A] First, the formal methods in Lakdawalla and Phelps (2020) support the view that uncertainty is an important consideration as it reflect the distribution of health and financial outcomes. Risk-averse patients will value reductions in these risks, and agents (providers or insurers) acting on their behalf may want to take this into account. [b] We agree "uncertainty and risk are important. However, it should not modify the threshold used. Instead risk should be quantified (a method for this is the EVPI scaled up over the eligible population) and there should be a risk threshold (population EVPI threshold). As for the four points that could be modifiers of this risk threshold: if population EVPI is used, there is no need for modifying the risk threshold for rare diseases; the difference between innovative technologies and technologies that provide large benefits is not sufficiently clear. Furthermore, if risk is quantified as per the above suggestion, all modelled benefits can be included in the risk estimate. Using managed access arrangements should only be considered if the risk reduction that can be achieved by a managed access arrangement is quantified." Also, "[C] I agree that under some circumstances, it is important to accept a particular level of uncertainty. But it is more rational to define potentially accepted types of uncertainties by their nature, scale, consequences, and options for their control than a definition of a rare disease. We cannot disadvantage patients with the conditions that do not fit these definitions. "</p> <p>1.e. Work to date on equity-adjusted / distributional CEA has been excellent but further work is definitely needed. Any proposal for an explicit modifier is likely to need further research undertaken to support it. Very positive to</p>

Consultation questions - valuing the benefits of health technologies	Comments
	<p>signal interest in this area. Certainly, projections of distributional (equity) impact should be become routine.</p> <p>1.,g, We certainly encourage sensitivity analysis around the discount rate, including use of the 1.5% rate, to better understand the importance of the time-related dynamics of the treatment effects. We understand that moving toward 1.5% being the reference rate for both costs and health gains reflects, in part, assumptions about key variables set out in the UK Government’s Treasury Green Book 2020. We are also aware of the key paper (Claxton, K, Paulden, M, Gravelle, H, Brouwer, W & Culyer, AJ 2011, 'Discounting and decision making in the economic evaluation of health-care technologies', Health Economics, vol. 20, no. 1, pp. 2-15. https://doi.org/10.1002/hec.1612) which argues that “if the budget for health care is fixed and decisions are based on incremental cost effectiveness ratios (ICERs), discounting costs and health gains at the same rate is correct only if the threshold remains constant.”</p>
<p>What are the potential effects of the proposed changes on patients and their families, health technologies, the life sciences industry and the NHS?</p> <ul style="list-style-type: none"> • What are the potential benefits of the proposed cases for change? • Are there any risks that might arise from adopting the proposals? If so, how might we try to reduce them? • Do you have any comments or feedback on how well the proposed methods will support innovation for 	

Consultation questions - valuing the benefits of health technologies	Comments
patients, science, society and the life sciences industry?	
What are the potential implications of the proposed changes for other NICE guidance and advice, and for other NICE programmes and activities?	
Do the proposals create any equalities concerns, particularly for NICE's legal responsibilities and the important need to eliminate unlawful discrimination and promote equality?	
General comments: If you have additional comments on this section please share them here:	

Understanding and improving the evidence base

	Consultation questions - understanding and improving the evidence base	Comments
1	<p>Do the proposals and cases for change provide a suitable basis to inform the final methods?</p> <ul style="list-style-type: none"> Do you have any comments or feedback on the methodological evidence and considerations that have been taken into account, or how the evidence has been interpreted? Do you have any comments or feedback on how well the proposals will achieve the aims of the review? 	<p>Our respondents provide the strongest level of agreement with proposals and their cases for change for these proposals:</p> <p>2 a, b, c, d, e, g, p, x</p> <p>There was moderate agreement with these proposals:</p> <p>2 k, l, m</p> <p>There was weak agreement with these proposals, though not overall disagreement:</p> <p>2 i, w, y</p> <p>The remaining proposals in this section were not included in our survey.</p> <p>Below are summaries of specific comments on these proposals:</p> <p>2.a. Little change here - 'refreshed' is probably the right word</p> <p>2.b. NICE's guidance on the situations in which RWE would be most useful for its deliberations would be most welcome since comparative RWE evidence is not typically available when "at launch" NICE recommendations are made. One area for NICE comment would be the use of "registry-randomized trials." ISPOR has created a number of Good Practice Task Force Reports which may be helpful with respect to RWE analysis and reporting. These are available on the ISPOR website. Given that biases due to lack of</p>

	Consultation questions - understanding and improving the evidence base	Comments
		<p>randomization are normally most troubling, any preferences or additional insights that NICE has for corrective analytic approaches would also be welcome. Similarly, it would be good to know NICE's standards for data quality as well as for transparency (e.g. pre-registration of hypothesis-testing studies, another area where ISPOR has been working; see Orsini et al, Recommendations and a Roadmap from the Real-World Evidence Transparency Initiative. Value in Health 2020; 23(9):1128-36.).</p> <p>2.c. NICE's Technical Support Documents for evidence synthesis have been valuable resources for research and submissions, but the field (and technology, including new software) is advancing rapidly, so an update would be useful here. As always, a balance of complexity and pragmatic approaches beginning with visual data inspection is helpful for the range of potential users.</p> <p>2.d. Qualitative methods are potentially very important, and to date have received relatively little attention. Comparing and contrasting different methods and their uses for different purposes would be useful. Among other things, considerations should include Bayesian expert elicitation methods, methods for integrating with quantitative evidence, and use of formal MCDA methods.</p> <p>2.e. Handling of uncertainty when moving from surrogate to final endpoints is an important aspect of this topic. Greater systemization of how surrogate outcomes are evaluated would be useful in general.</p> <p>2.g. Please be clear about the appropriate perspective for evaluating the costs of acquiring medical technologies, devices, and diagnostics, and the extent to which opportunity cost—rather than acquisition cost—is relevant in some perspectives.</p>

	Consultation questions - understanding and improving the evidence base	Comments
		<p>2.i. While there is some theoretical support for including unrelated healthcare costs, there is no consensus on this point. Although it is technically consistent with the maximization of QALYs for a given healthcare budget, it generally worsens the case for life-extending interventions (for which there may be greater willingness to pay) and may not account for the other societal benefits of life extension. However, if NICE moves to include these costs, they should consider providing a reference set of costs that analysts could use for unrelated costs.</p> <p>2.k. Among ISPOR members, there were mixed opinions about adding a hierarchy of preferred HRQL instruments. On one hand, it seems relatively easy to achieve and so guidance from NICE would be valuable and could lead to more consistency in submissions. However, the “gold standard” EQ-5D is a generic instrument and does not translate well in some cases, particularly for rare diseases. On other hand, it was suggested that NICE should consider that mapping of a disease specific quality-of life instrument to EQ-5D can lead to more precise and accurate results than using EQ-5D directly, while maintaining EQ-5D as gold standard. Using the gold standard analogy, there are good reasons for why the historic gold standard kilogram was not routinely used for measuring weights but instead a diversity of instruments gauged/mapped to the gold standard were used, not only for practicality but also for precision and accuracy. Therefore, it may not make sense to introduce a hierarchy of preferred health-related quality-of-life methods for when the EQ-5D is not available or not appropriate without considering precision and accuracy. At this stage, a catalog of example work-arounds would be helpful. With more experience, a ranking may become feasible.</p> <p>2.l. The case for the change in mapping tool to go from the EQ-5D-3L to EQ-5D-5L is clearly outlined in the NICE Decision Support documents. However, concerns were raised in our survey that “tariffs are needed for the 5L instrument”, and that “the tool developed by the Decision Support Unit has</p>

	Consultation questions - understanding and improving the evidence base	Comments
		<p>not been shown to perform better than the status quo”, and that “all (mapping methods) incorporate a degree of error that is not fully captured in such mapping exercises.” We would urge NICE to pay due attention to any differences in ICERs that result from the differences in the mapping instrument used.</p> <p>2.m. It would be very helpful if this recommendation about measuring HRQL in children and young people were accompanied by some indication of the type of instruments NICE regards as appropriate.</p> <p>2.p. Yes, it would be good to move towards well-validated, patient-based “core outcome sets” that were both sanctioned by regulators and also associated with rigorous health state utility values. For economic value assessment, linking from the “core outcomes sets” and “core outcome measure sets” (i.e. disease-specific instruments) can help to check the validity of the EQ-5D for specific diseases and interventions.</p> <p>2.w. ISPOR member comments here leaned towards making evaluation of structural uncertainty mandatory in some form—but there was not a clear consensus. “Where likely impactful uncertainties (as considered by analysts / clinical experts / scenario analysis) are excluded from the model because of their nature (difficult to include in modelling, perhaps because it’s structural uncertainty), incorporating them in the probabilistic analysis is important as this affects risk estimates. If this is the case (i.e. impactful uncertainties not in PSA), their inclusion should be made mandatory.” Also, “The current practice of only including parameter value uncertainty in probabilistic sensitivity analysis leads to an incomplete representation of uncertainty.” An alternative view is “Better than this is performing scenario analyses to estimate the impact of key elements of structural uncertainty - every study should include this - but just merging it into a PSA is not useful.” Guidance and examples are needed to illustrate and defines what “parameterizing structural uncertainty” means in practice.</p>

	Consultation questions - understanding and improving the evidence base	Comments
		<p>2.x. There was general agreement with expanding guidance on appropriate methods for extrapolating beyond the available data, eg, “Presenting results with alternative assumptions about extrapolated outcomes should be required, and “Extrapolation methods are among the most important and most uncertain parameters... we should move away from the standard methods of fitting survival curves towards more careful modelling of the underlying disease.”</p> <p>2.y. The majority of ISPOR commenters saw little practical value for NICE decision making of requiring EVPI or saw some danger that it will not be interpreted correctly. If it is to be presented, there should be detailed guidance as to how it will be used and how it should be interpreted.</p>
2	<p>What are the potential effects of the proposed changes on patients and their families, health technologies, the life sciences industry and the NHS?</p> <ul style="list-style-type: none"> • What are the potential benefits of the proposed cases for change? • Are there any risks that might arise from adopting the proposals? If so, how might we try to reduce them? • Do you have any comments or feedback on how well the proposed methods will support innovation for patients, science, society and the life sciences industry? 	

	Consultation questions - understanding and improving the evidence base	Comments
3	What are the potential implications of the proposed changes for other NICE guidance and advice, and for other NICE programmes and activities?	
4	Do the proposals create any equalities concerns, particularly for NICE's legal responsibilities and the important need to eliminate unlawful discrimination and promote equality?	
5	General comments: If you have additional comments on this section please share them here:	

Structured decision making

	Consultation questions - structured decision making	Comments
1	<p>Do the proposals and cases for change provide a suitable basis to inform the final methods?</p> <ul style="list-style-type: none"> Do you have any comments or feedback on the methodological evidence and considerations that have been taken into account, or how the evidence has been interpreted? Do you have any comments or feedback on how well the proposals will achieve the aims of the review? 	<p>Our respondents provided the strongest level of agreement with proposals and their cases for change for these proposals:</p> <p>3 k,l</p> <p>There was moderate agreement with these proposals:</p> <p>3 h</p> <p>The remaining proposals in this section were not included in our survey.</p> <p>Below are summaries of specific comments on these proposals:</p> <p>3.h. The ISPOR CHEERS task force and others have already developed reporting guidelines that provide a strong basis for presenting information to stakeholders. Structured information can then be aligned to specific pre-chosen models of decision support, e.g., specific MCDA models.</p> <p>3.k. Taking equalities into consideration in HTA is important and relies on the further development of methods to do so. Besides including equality considerations in the decision to include a new health technology, it may be more productive, in terms of actually achieving health equality, to evaluate possibilities to apply a new drug in a way that promotes health equality, within the context of introducing a new drug/indication. NICE could include a question to stakeholders, including manufacturers, asking if they have ideas/plans toward that goal. And NICE could add a section to its regular reporting in which it considers how the new health technology can be applied toward achieving health equality.</p>

	Consultation questions - structured decision making	Comments
		3.1. We agree that further work is much needed here.
2	<p>What are the potential effects of the proposed changes on patients and their families, health technologies, the life sciences industry and the NHS?</p> <ul style="list-style-type: none"> • What are the potential benefits of the proposed cases for change? • Are there any risks that might arise from adopting the proposals? If so, how might we try to reduce them? • Do you have any comments or feedback on how well the proposed methods will support innovation for patients, science, society and the life sciences industry? 	
3	<p>What are the potential implications of the proposed changes for other NICE guidance and advice, and for other NICE programmes and activities?</p>	
4	<p>Do the proposals create any equalities concerns, particularly for NICE's legal responsibilities and the important need to eliminate unlawful discrimination and promote equality?</p>	
5	<p>General comments: If you have additional comments on this section please share them here:</p>	

Challenging technologies, conditions and evaluations

	Consultation questions - challenging technologies, conditions and evaluations	Comments
1	<p>Do the proposals and cases for change provide a suitable basis to inform the final methods?</p> <ul style="list-style-type: none"> Do you have any comments or feedback on the methodological evidence and considerations that have been taken into account, or how the evidence has been interpreted? Do you have any comments or feedback on how well the proposals will achieve the aims of the review? 	<p>Our respondents provided the strongest level of agreement with proposals and their cases for change for these proposals:</p> <p>4 b,g</p> <p>There was moderate agreement with these proposals:</p> <p>4 c</p> <p>The remaining proposals in this section were not included in our survey.</p> <p>Below are summaries of specific comments on these proposals:</p> <p>4b. We agree that:</p> <ul style="list-style-type: none"> (i) the general use of scenario analysis for projecting long-term benefits – guided by the science and any relevant data – is important for evaluations when there is uncertainty about them, and (ii) threshold analysis of duration, when duration can be represented simply, may be useful. <p>4.c. Cure-proportion modeling is a useful option, among others, to consider when it appears to be relevant. But understanding the sensitivity of results to different modeling assumptions is important— as always.</p> <p>4.g. It would be helpful if this recommendation about considering heterogeneity were accompanied by specific recommendations of acceptable approaches.</p>

	Consultation questions - challenging technologies, conditions and evaluations	Comments
2	<p>What are the potential effects of the proposed changes on patients and their families, health technologies, the life sciences industry and the NHS?</p> <ul style="list-style-type: none"> • What are the potential benefits of the proposed cases for change? • Are there any risks that might arise from adopting the proposals? If so, how might we try to reduce them? • Do you have any comments or feedback on how well the proposed methods will support innovation for patients, science, society and the life sciences industry? 	
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4	<p>Do the proposals create any equalities concerns, particularly for NICE's legal responsibilities and the important need to eliminate unlawful discrimination and promote equality?</p>	
5	<p>General comments: If you have additional comments on this section please share them here:</p>	

Aligning methods across programmes

	Consultation questions - aligning methods across programmes	Comments
1	<p>Do the proposals and cases for change provide a suitable basis to inform the final methods?</p> <ul style="list-style-type: none"> • Do you have any comments or feedback on the methodological evidence and considerations that have been taken into account, or how the evidence has been interpreted? • Do you have any comments or feedback on how well the proposals will achieve the aims of the review? 	
2	<p>What are the potential effects of the proposed changes on patients and their families, health technologies, the life sciences industry and the NHS?</p> <ul style="list-style-type: none"> • What are the potential benefits of the proposed cases for change? • Are there any risks that might arise from adopting the proposals? If so, how might we try to reduce them? • Do you have any comments or feedback on how well the proposed methods will support innovation for patients, science, society and the life sciences industry? 	

	Consultation questions - aligning methods across programmes	Comments
3	What are the potential implications of the proposed changes for other NICE guidance and advice, and for other NICE programmes and activities?	
4	Do the proposals create any equalities concerns, particularly for NICE's legal responsibilities and the important need to eliminate unlawful discrimination and promote equality?	
5	General comments: If you have additional comments on this section please share them here:	

General comments

Please provide any other comments you may have here.

Thank you for completing the consultation

Your participation is appreciated. Your responses will be used to inform the next steps for the development of the NICE methods for health technology evaluation.

Submitting your response

Return your completed response form via email to methodsandprocess@nice.org.uk by 11:59pm on 18 December 2020.

Responses submitted in any other format will not be accepted