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General  
While we understand the goal of increasing the capacity of the technology appraisal programme to meet rising demand, we have profound concerns about the proposals. In essence, the changes proposed reduce the role of patient and clinical experts and move the discussion and assessment of evidence out of the appraisal committee meetings, which are held largely in public, to a much less transparent and accountable part of the process. This is a massive backward step and in direct conflict with the commitment in the NICE Charter to value the input of patients/carers in the development of guidance and involve the people for whom the guidance will be relevant.

The proposals will also undermine some of the positive steps towards involving patients and the public in developing guidance which were proposed during the NICE review of patient and public involvement which began in 2015 and culminated in a public consultation ending February 2017. We urge NICE not to trade transparency for efficiency. This is neither an acceptable nor necessary trade-off as it should be entirely possible for the process to be made more efficient without this significant sacrifice.

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Given how fundamental the changes proposed are, we question how these proposals can be implemented with no adjustments to the guide to the methods of technology appraisal. The consultation document presents the proposals as simply a reordering of the existing stages of the process so that more work is done before the topic reaches the
committees. However, this framing is disingenuous, given the scale of the reductions in patient and public input into and oversight of guidance development.

If the changes are implemented, the difference in process should be transparently communicated in the guide to the methods of technology appraisal.

21 Genetic Alliance UK supports the inclusion of patient perspectives in all decision-making processes in as unfiltered a form as possible. As numerous other regulatory bodies including the EMA (EMA/637573/2014 Revised framework for interaction between the European Medicines Agency and patients and consumers and their organisations) have discovered, patients provide an important and unique perspective, and this input is most valuable when provided in person rather than in writing.

Patient representatives recognise the vital need for appropriate clinical experts to be involved in technology appraisal processes. Input from such experts is particularly important in the case of rarer conditions. While the technology appraisals committees all have a good range of different clinical specialisms among their membership to draw on in decision-making, this does not replace the need for expertise in the condition under consideration.

Both patient representatives and representative clinicians should continue to be able to attend the committee meeting for any medicine for which they have contributed evidence, by teleconference if necessary, in order to answer any question or clarify information in their submission. Just as the presence of the manufacturing company at the relevant meeting can be important to clarify any information in their submission, the same reasoning supports the presence of specialist clinicians and patients. Specific clinical knowledge of the condition under consideration should be accessible directly to the committee, and not only transmitted via the technical team as has been proposed. It is not sufficient for a non-expert technical team to conclude that a statement is clear, and any such uncertainties can lead to delays or perverse decisions.

Genetic Alliance UK believes that evidence from patients and from clinicians can be just as pivotal in the assessment of a technologies value as evidence from its manufacturing company. The proposed changes appear to seeking to formalise the primacy of evidence from companies in NICE’s decision making process.

23-24 The evidence assessment described in these paragraphs is to all intents and purposes the technology appraisal with the committee meeting itself reduced to a rubber stamp. The consultation document makes it fairly clear that the bulk of the work of a technology appraisal is to be carried out by the technical team: evaluation of the case for clinical and cost effectiveness; resolving technical uncertainties and substantive issues; producing a report encapsulating their conclusions; and responding to comments made in the consultation. All that is left to the committee is to decide whether to accept the conclusions in the report or to require more scrutiny or evidence before the updated report is brought back to the next meeting. The proposed approach very much undermines public and patient confidence.

We are very concerned that some of the most important decision-making stages will be neither predictable nor accountable, as they are removed from the limited oversight of a committee meeting partially in public to the completely opaque activities of a shadowy technical team. If the technical team is to have such responsibilities, it is essential that it both involve patient and clinical experts and be transparent, neither of which appears likely in the description provided in the consultation document. In order to take on the vast majority of the work of technology appraisal committees,
technical teams must be subject to the same scrutiny. Each technical team must have publicly available membership, including both patient and clinical experts, clear terms of reference and methodology and publish detailed explanations of why it reaches the decisions it does at every stage.

This must not be allowed go the same way as NICE’s completely opaque topic selection process, where decision making occurs out of sight, with no information about key decision makers, and all that is made publicly available is a single vague sentence which is identical for the vast majority of topics.

To submit your comments, please email this form to: TAconsultation2017@nice.org.uk

Closing date: Thursday 16 November 2017, 5pm

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