NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Centre for Health Technology Evaluation

Increasing capacity within Technology Appraisals
Consultation comments proforma

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Section number primarily related to your comment (please enter only one) Indicate **'general'** if your comment relates to the whole document	**Other section numbers related to your comment**	**Comments** **Please insert each new comment in a new row.** **Please do not paste other tables into this table, as your comments could get lost – type directly into this table.**
General		It is reassuring that NICE are planning to improve their processes in order to ensure earlier and faster appraisal of new medicines. However we are severely concerned with some of the proposals as they may result in the exclusion of major stakeholders from the appraisal process, and therefore the potential loss of additional and crucial information at critical time points in the HTA process. Generally the proposed changes represent a step backwards regarding the engagement and involvement of patients and patient groups – given the progress than has been made over recent years – and the added value that comes with the closer cooperation with this stakeholder group.
3 (bullet 2)		We agree and would be prepared to cooperate on finding solutions to these enormously important but challenging situations. It is near on impossible to obtain robust long term data in such small cohorts of patients – which satisfy the current requirements of NICE processes. The way forward - which has been discussed in the past would be to offer a provisional recommendation/approval - to be revised after an agreed period. We would welcome a consultation on changes in HTA proposals offering this type of alternative - rather than the ones suggested in this current consultation. We believe this would offer a much more effective way to save time and increase the number of HTA's being dealt with – as it would cut down on very lengthy discussions about uncertainty.

21	29, 34	One of the pillars of the NICE Technology appraisal process has been the involvement of patient organisations enabling the patient expert groups to participate in the decision making process that will have a significant impact on patient lives. Historically, the participation of the patient groups together with the clinical experts has been very important, especially during the assessments for medicines for disease where limited data and expertise are available. Patient groups are best equipped to support the evidence related to the natural course of the disease, quality of life, impact on the society and life expectancy. The patient groups are also able to highlight the psychological impact of the disease, the need to improve the disease management, as well as patient pathways. The creation and maintenance of the PIN group should be a sure sign that patient engagement is at the core of what NICE does for patients. Reducing patient input – as is suggested in this consultation – is totally at odds with the trend in general society, science, input at clinical trial level, need for transparency and engagement in all proceedings affecting the patients. We therefore, believe that the exclusion of patient and clinical experts may result in inadequate technology appraisals for new medicines where patient voices would not be heard. We have serious concerns that this may result in an increased rate of negative technology appraisal thus having a significant detrimental effect on the wellbeing of patients and their families. We welcome the proposal to obtain statements from the clinical and patient experts earlier in the process but we strongly believe that patient and clinical experts should be invited to the appraisal committee meetings. In addition: Removing patient experts from the main appraisal discussion meetings would also make it near on impossible to properly lodge appeals following a negative FAD. Currently appeals can be lodged following 2-3 situations: Ground 1: In making the assessment that preceded the recommendation, NICE has: a) failed to act fairly or b) exceeded its powers Ground 2: The recommendation is unreasonable in the light of the evidence submitted to NICE. In other words and in the practical experience of one of our members in the past – this has translated as the following: a - proceedings were not adhered to properly b - the chair seemed to have abused their power c - submitted evidence was not considered or used properly These are all situations that were picked up during the actual discussions in the meetings. By being there in person, the charity concerned was able to record these irregularities, report them to the appeal board – and subsequently win the appeal on those three grounds. In short – under proposed changes, if neither patients nor clinicians are able to attend, take part and raise issues during the meetings – or make notes of any proceedings not in line with usual high standards of NICE, there is no way of knowing whether these three appeal possibilities exist or not. As no organisation or individual is ever totally immune to errors, it is only right that all stakeholders should continue to be present at proceedings affecting their future health. As a further important point:

		There are numerous occurrences during discussions at HTA meetings where committee members experience definite scientific confusion – due to the fact they are not experts in the disease. This is normal. This can lead to two frequent issues however: 1 – the conversation comes to a halt due to lack of answer on the day – in the absence of the right experts/stakeholders. By the next meeting – the issues have sometimes not been clarified. 2 – Committee members come to the wrong conclusion on certain finer but highly important points. These factual scientific errors have to be picked up at the next stage – after NICE publishes their interim decision or FAD, by the stakeholders. This leads to waste of time and funds. This is a problem especially at second meetings, when patients and clinicians are only allowed as silent observers, and not as speaking experts. It has been suggested that the presence of one clinical expert at second meetings could help avoid these sort of problems. So if NICE wants to have more HTA's the answer is more clinical presence – not less.
23		We see this as a positive step - as technical queries around data and projections into future use are the most time consuming exercise during an appraisal meeting. The clinical and scientific clarifications as well as patient evidence are in comparison extremely brief and straight forward - when the right experts are present.
24		Involving other stakeholders in the conversation regarding patient access schemes could also save considerable time - if done as a meeting ahead of time - rather than a series of separate and lengthy conversations back and forth between pharma, PASLU, patient groups and appraisal committee. This is where true time, money and efforts could be saved, without compromising transparency, nor increasing potential for misunderstandings or miscommunications.
26		Fully agree - this is a constructive step - presumably in a smaller and less daunting setting - provided all stakeholders will also be present and able to participate in the formal appraisal meeting.
28		If by meeting in public - this equates to silent observers as previously - we strongly object. It is key for experts of any type to be able to correct erroneous assumptions by the panel, or add helpful information when queries arise.
34		It is much less likely that stakeholders will be able to lodge appeals following a negative FAD, since they would not have witnessed the discussions in person. Appeals can currently be lodged on acting unfairly, abuse of powers or submitted evidence not being used properly. Not being present during conversations will reduce these options - as these are usually picked up by passing comments by the committee members - and are never recorded in minutes.
40 (point 4)		Absolutely correct. Running risk that pharma industry may bypass England completely - and patients will suffer by not having access to essential drugs. This may lead to an increase in IFR's – in turn wasting time and money in other areas of the NHS. Usually unsuccessful IFR's, as cohorts develop and get rejected.
40 (point 6)		We find this difficult to believe - as any useful simplification of the proceedings ought to be a welcome step. Committee members are required to read an inordinate amount of data for each appraisal - and it is often obvious that

		some feel unable to contribute to some topics. We would welcome a step to actually reduces the number of committee members per appraisal - and redeploy them into new smaller appraisal committees - with indeed a summarized report prepared by the technical team - and an opportunity to have brief discussions with all stakeholders for any clarifications on the day.
40 (point 7)		The lack of transparency in the suggested new proceedings is one of the most concerning aspects. NICE is a publicly funded body. Tax-payers and patients must have a way to engage and check the work performed. Furthermore - the health system and Department of Health actively seeks patient engagement. However - these suggested changes represent a direct and massive step backward regarding patient involvement.
40 (point 8)		*"We will clearly document the decision whether or not to invite experts to attend a meeting, and we will ensure that these decisions and any subsequent invitations will be made timely to give notice for these individuals to attend. "* This last paragraph is extremely unclear. As stakeholders, we are most certainly challenging these proposed changes - and object to them in the strongest sense. As per Carole Longson (minutes of the NICE PUBLIC BOARD MEETING 15 November 2017 at 1.30pm in the Corn Exchange , Exeter): "*It was agreed that should the initial consultation raise significant objection to the proposals, a report should be brought back to the Board prior to any subsequent consultation on the process guide."* And as the board correctly identified *- the "perceived independence of the appraisal committee*" is indeed very much at risk should the suggested steps in this consultation be implemented. We would recommend a pause in the process to ensure a fuller and more complete evaluation of the impact on patient engagement. Aside from patient engagement in appraisal meetings, we are also concerned that this is a missed opportunity to extend meaningful patient engagement and would welcome a more comprehensive look at this issue.

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November 2017

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

Closing date: Thursday 16 November 2017, 5pm

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