Interim methods and processes statement for including NICE technology appraisal recommendations in guideline topic areas

A general comment:

If Technology Appraisal methods have been designed and used to allow rapid access and uptake of new interventions, then they may represent a "lower bar" than inclusion in a clinical guideline recommendation. Though opportunity for patients to benefit from new technologies is highly important, it is equally important that the considered, balanced approach to clinical guideline development which considers a wider range of perspective is not compromised in this inclusion process. Otherwise, there is a risk that clinical guidelines become weighted towards particular new, more expensive treatments which have arrived through a TA process.

4.Incorporating positive and negative NICE technology appraisal recommendations

4.1

When NICE technology appraisal guidance that is in the scope of a NICE guideline topic area is published, its recommendation(s) will be incorporated into the guideline topic area. There will be no change to the meaning, intent or funding requirement (when applied) in the recommendation(s). The incorporation process, will be done in NICE and will consider whether:

- there are any existing treatment options in the decision space
- topic expert input is needed
- additional guideline recommendations are needed to ensure that the care pathway is clear in presenting all the appropriate treatment options.

Comment on subsection: 4.1:

We agree with this and believe it is important not to have a TA appearing too "dominant" sitting in the middle of a guideline, or conversely seeming unclear or discordant and therefore being ignored. We imagine additional explanatory text or guidance will be needed fairly frequently. An additional source of input likely to be of value at this stage would be end-user input to ensure it is presented correctly.

4.2

When existing technology appraisal recommendations are identified in the same decision space, all relevant technology appraisal recommendations (existing and newly published) will be incorporated. The timelines for this process will be tested on the pilot topics, and details will be added when the finalised methods and processes are consulted on.

Comment on subsection: 4.2:

As with section 4.1, we believe this process would need consideration and input from topic experts, end-users and additional guideline content.

5.Integrating NICE technology appraisal recommendations

5.1

NICE technology appraisal recommendations will be considered eligible for integration into a guideline topic area if they fulfil all of the following criteria:

- There are multiple treatment options, including at least 1 technology appraisal within a decision space.
- There is no clear or prespecified rationale for choosing 1 treatment option over another within that decision space.
- Integration would not normally happen sooner than 3 years from the publication of the NICE technology appraisal to publication of the guideline recommendations into which it would be integrated.

Comment on subsection: 5.1:

We are unclear about what the third bullet point means. Is it the case that rolling guideline updates will be intended to "sweep up" pre-existing TAs – and that this bullet point is to ensure any TA likely to be left out are captured? If so, then we are in agreement with this.

5.2

If NICE technology appraisal recommendations meet these minimum criteria for integration into a guideline topic area, they will then be considered by the NICE prioritisation board. It will use a decision framework that looks at factors such as known variation in clinical practice and system considerations.

Comment on subsection: 5.2:

We agree with this recommendation but question whether all TAs would eventually need integration, or would the prioritisation board also decide to retire some.

5.3

Guideline topic areas into which NICE technology appraisal recommendations will be integrated will broadly follow the methods and processes set out in the developing NICE guidelines manual. When approaches between NICE programmes differ (see areas listed in sections below, for example, using decision modifiers in the NICE health technology evaluations manual), NICE has sought to align them when appropriate.

Comment on subsection: 5.3:

We believe having the NICE guidelines manual as the reference point for integration methods is good. However, if there are contentious/difficult decisions to be made about

these methods and processes, of a nature likely to be impactful to the resulting guidance, we question how these decisions will be made. Will there be further consultations?

5.7

Consultees are outlined using the stakeholder list (or matrix) published as part of the original NICE technology appraisal guidance development. During guideline development, stakeholders will be able to ask to become consultees. NICE will approve updates to the consultee list when they reflect changes over time and are aligned with the current definitions of consultees outlined in section 1.2.18 of the NICE health technology evaluations manual.

Comment on subsection: 5.7:

This seems like a valuable point; without it, the consultees could have more influence over final guidance than stakeholders.

Additionally, we wonder if the same could apply for stakeholders for the original guideline into which the TA is being integrated, as a new TA might fundamentally change the meaning/impact of a guidelines.

5.9

As part of integration, NICE will request consent from relevant parties to share with Centre for Guidelines' development teams confidential data (including the economic model) that was submitted as part of the NICE technology appraisal evaluation.

Comment on subsection: 5.9:

There has been criticism of the redaction of clinical data from TA evaluation documentation. Though there may be commercial sensitivities to consider, this undermines the credibility of the recommendations. In particular, in a guideline-integration context, this would mean it would be impossible for users to evaluate the relative benefits or harms of interventions on offer. The transparency of method and data in a NICE guideline evidence review has benefits, and it would be a great of balance to have some content lacking. There is a risk of loss of trust in NICE guidelines without transparent data.

5.17

When a NICE technology appraisal is integrated into a guideline, decisions on continued adoption of that technology by the NHS will consider if this is an effective use of NHS resources with specific reference to the above range. Because cost effectiveness is not the only basis for decisions, the committee will consider technologies in relation to the range of ICERs, and the influence of other factors on the decision to recommend a technology.

Comment on subsection: 5.17:

The last six sections (5.12-5.17) appear to be about how to ensure eventual parity of health-economic evaluations between TAs and GL recommendations, which we believe is a good long term aim.

5.18

A guideline committee may consider 1 or more NICE technology appraisals for integration into a guideline topic area. In such cases, it may choose to make recommendations about preferred sequences or hierarchies, based on an assessment of clinical and cost effectiveness. Whether options are presented as sequences or hierarchies will depend on:

- how options are used to treat the condition in clinical practice
- the marketing authorisations for the technologies.

Comment on subsection: 5.18:

We think this is a valuable recommendation.

5.19

The evidence may show that the technology provides appropriate benefits and value for money, beyond the population that is covered by the NICE technology appraisal. In such cases, the guideline committee may make recommendations that expand its use from the population covered by the NICE technology appraisal. The committee may also make recommendations for a narrower use of the technology, for example, that it:

- can only be used in a particular condition for people who meet specific clinical eligibility criteria
- can only be offered to a specific subgroup
- must be given by staff with certain training or in a particular care setting.

Comment on subsection: 5.19:
We think this is a valuable recommendation.

5.20

The guideline committee may agree that, for the entire population outlined in the original NICE technology appraisal guidance, the technology is no longer likely to be a good use of NHS resources given full consideration of evidence. In such cases, the technology will be given a negative recommendation and the NICE technology appraisal guidance will be withdrawn.

Comment on subsection: 5.20:
We think this is a valuable recommendation.