Interim addendum to replace existing section 9, Guidance reviews, in DAP programme manual

9 Reviewing and updating guidance

9.1 Review dates

After the guidance is published the Programme team updates the literature search every 3 years to ensure that relevant new evidence is identified. At the same time, NICE contacts product sponsors and other stakeholders about issues potentially affecting the value of the diagnostic technologies, including significant changes to the price of the product or the comparator.

NICE may review the guidance before the expected review date when there is significant new evidence that it considers is likely to change the recommendations. NICE is keen to hear about any new evidence that becomes available before the review date (please send information to diagnostics@nice.org.uk). NICE will assess the likely impact of the new evidence on the recommendations and will propose an update to the published guidance if required.

9.2 Review proposals

NICE develops a review proposal after gathering relevant information and undertaking a literature search. The purpose of a review proposal is to recommend to NICE's Guidance Executive whether the guidance should be updated or not, and if so, how.

To produce a review proposal NICE:

- gathers new available evidence
- identifies changes to the diagnostic or care pathway
- gathers information about price changes
- assesses the progress of ongoing trials
- asks product sponsors to provide new evidence that has become available since the publication of the guidance.

NICE's Guidance Executive uses this information to consider the review proposal and decide if and how the published guidance should be updated (see 9.4 for update options).

When the Guidance Executive has agreed the review proposal, NICE asks the registered stakeholders and the specialist Committee members from the original guidance to comment on the proposal. Five working days later NICE publishes the review proposal (as well as the list of registered stakeholders and SCMs) on its website for public consultation. Comments must be received by NICE within 15 working days.

If no changes arise in the review proposal as a result of the consultation, the proposal is agreed as the review decision and is signed off by the director of NICE's Centre for Health Technology Evalaution. If changes occur to the review proposal as a result of the consultation, the Guidance Executive considers the revised proposal in light of all the consultation comments and reaches a final decision on the most appropriate option for the published guidance.

NICE writes to the registered stakeholders and SCMs informing them of the final review decision and attaches for their information a table of responses to all the comments received on the review proposal. NICE publishes the final review decision and the table of comments on its website 5 working days later.

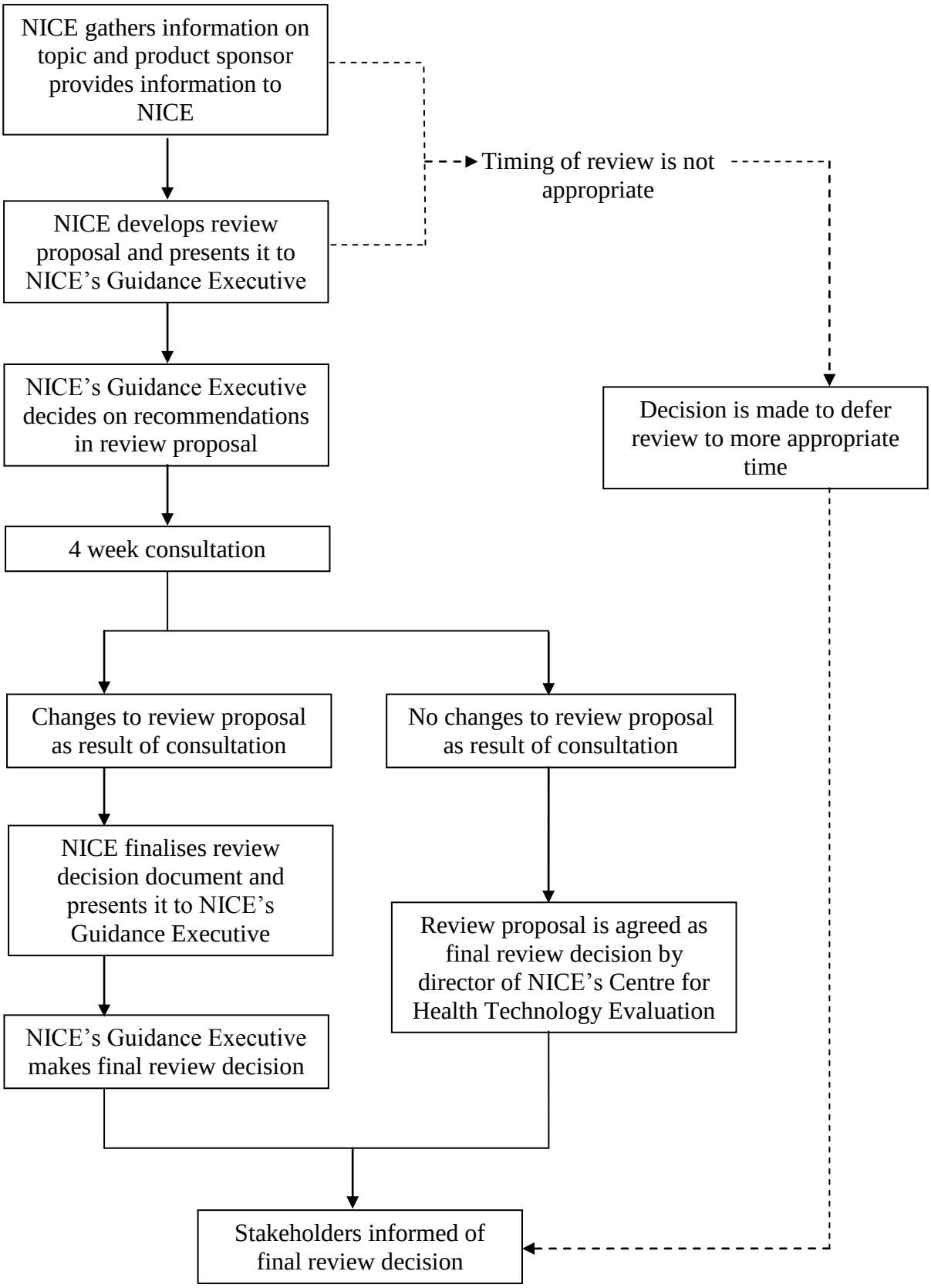
If a piece of guidance needs updating by DAP, the update is added to the programme schedule and follows either the standard or the accelerated process (see below). If it is to be updated by another NICE programme, the update is undertaken according to the processes and timetable of that programme.

The review process is summarised in figure 1.

9.3 Review deferral

At any point during the development of a review proposal, NICE may decide that it is not appropriate to proceed with the review. This may be because NICE has become aware of important developing evidence that is not yet available but is considered likely to have a material effect on the existing guidance recommendations. In this instance, NICE notifies stakeholders of the decision to defer the review proposal. The decision is also published on the NICE website. NICE also identifies the likely timeframe for the next review. This is usually within six months of when the required evidence becomes available.

Figure 1. Summary of review proposal process



9.4 Options for updating guidance

NICE proposes an update of the published guidance if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations in the existing guidance. Other factors such as the introduction of new technologies relevant to the guidance topic, or newer versions of technologies included in the guidance, will be considered relevant in the review process, but will not in individual cases always be sufficient cause to update existing guidance.

The Guidance Executive decides on one of the following options if the published guidance needs updating:

- A standard update of the guidance (see section 9.4.1)
- An accelerated update of the guidance (see section 9.4.2)
- An update of the guidance within another piece of NICE guidance (within DAP or another NICE programme). As indicated above, under these circumstances the guidance is updated according to the processes and timetable of that programme.

9.4.1 Standard update

A standard update of the guidance follows the same process, methods and timetable for producing new guidance as outlined in the rest of this programme manual. The only difference is that, because it is an update of existing guidance, the scope is normally an updated version of the original scope, rather than including new patient populations or subgroups, or a different disease severity or aetiology. New technologies relevant to the original scope may be considered for inclusion in the scope of the update. However, new technologies that significantly alter the population or disease considered in the original guidance are unlikely to be considered suitable for inclusion in a guidance update.

9.4.2 Accelerated update

An accelerated update of the guidance follows a shorter process than a standard update and wherever possible it is used to keep NICE guidance up to date because it uses fewer resources than the standard update process.

To ensure that it is appropriate to update guidance using the shorter process, accelerated updates follow certain principles:

- Accelerated updates are only undertaken in circumstances where the new evidence is likely to result in minimal changes to the decision problem, and the subsequent assessment will require less time to complete than a standard update or assessment.

- The scope for the accelerated update is very similar to the scope for the original guidance because there are only minor changes to the decision problem. The scope is developed by NICE and is informed by the scope for the original guidance and the review proposal. In the interests of brevity of the process, there is no scoping workshop, assessment sub-group meeting, or consultation on the scope.

- No new technologies are considered for inclusion in the scope for an accelerated update..

- DAC meets as a standing committee, and the original specialist Committee members are invited to be expert advisers to the Committee. The expert advisers participate in the Committee discussions but not in the decision-making.

Given the above, the steps in the accelerated update process are as follows (see annex for timeline):

1. The specialist Committee members from the original assessment are invited to be expert advisers to the Diagnostics Advisory Committee. They may also be asked by the EAG to advise them.

2. Stakeholders are invited to register. This includes product sponsors, registered stakeholders and SCMs from the original guidance, and potential new stakeholders identified during the review proposal period. As in the case of normal guidance, stakeholders can register at any time during the update.

3. The product sponsors are asked to provide any additional data which they did not provide at the time of the review proposal.

4. The scope for the accelerated update is derived from the review proposal and the scope for the original guidance. It is finalised by the DAP technical lead in discussion with NETSCC and the EAG, and signed off by the DAP associate director.

5. The accelerated update report (AUR) is produced within 8 weeks (as opposed to 24 weeks for a DAR). Normally, and under the direction of NETSCC, the same EAG is asked to produce the AUR as produced the DAR for the original guidance.

6. The product sponsors have 5 days to check the AUR for accuracy. There is no other consultation on the AUR.

7. DAC (standing members only) receives the AUR along with the update scope, the original guidance, the original DAR, and a brief summary from the DAP technical lead.

8. DAC and its expert advisers meet to discuss the new evidence and its implications for the existing guidance recommendations. DAC (standing members only) develops the draft new recommendations.

The remainder of the process is the same as outlined elsewhere in this programme manual:

9. 20 day public consultation on DAC's draft recommendations

10. DAC's final recommendations

11. Resolution period

12. Publication of guidance.

The decision to undertake an accelerated update of guidance is taken following a thorough review of relevant new evidence and any developments in clinical practice, and is discussed in advance with NETSCC and the original EAG. Nevertheless, it may become apparent during the assessment that it is not appropriate for the update to follow the accelerated process. In this case it is re-scheduled as a standard update.

9.5 Options where guidance does not need to be updated

NICE does not update published guidance unless the clinical environment or the evidence base has changed to an extent that is likely to have a material effect on the existing recommendations. The introduction of new technologies relevant to the guidance topic, or newer versions of technologies included in the guidance, are not on their own sufficient cause to update existing guidance.

The Guidance Executive decides on one of the following options if the published guidance does not require updating:

- The guidance is valid and does not require an update because the clinical pathway or the evidence base has not changed significantly enough to have a material effect on the recommendations. However, newer versions of the diagnostic tests or technologies are available and a **technical supplement** (see section 9.5.1) describing these newer versions could be helpful to users of the guidance; this option does not change the recommendations in the guidance, which remains extant.

- The guidance is valid and does not require an update because the clinical pathway or the evidence base has not changed significantly enough to have a material effect on the recommendations. It is therefore designated as static guidance.

- Incorporate the published guidance into guidance from another NICE guidance producing centre. The original diagnostics guidance is then designated as static and remains valid.

- Withdraw the guidance. This may occur if:

    - DAP or another NICE programme issues new guidance which supersedes the existing guidance

    - The product is withdrawn from the market or loses its CE marking for the populations or uses that feature in the guidance

    - Clinical knowledge changes such that use of the technology is no longer appropriate

    - Other circumstances arise which would make it inappropriate for the guidance to remain valid.

9.5.1 Technical supplement

Description

A technical supplement:

- Provides up to date technical information about newer versions of one or more of the diagnostic tests or technologies covered in the original guidance

- Is a statement of fact and does not make recommendations or assess if technologies are comparable in performance

- Only covers evolutions of the products in the original guidance – new products are not added

- Only contains publicly available information (no confidential information)

- Does not update the guidance or change the recommendations in the guidance, which remains extant until the next scheduled review.

Topics are selected for technical supplements as a result of a guidance review (as described elsewhere in this manual), where the guidance does not need to be updated but where newer versions of the diagnostic tests or technologies are available. It may also be appropriate to produce technical supplements without a formal guidance review, such as when new products become available shortly after diagnostics guidance is issued.

Technical supplements are commissioned by NICE from the External Assessment Centres (EACs), which provide a range of evidence assessment, research facilitation and other services to NICE to support its devices and diagnostic evaluation activities.

Key audiences

Key audiences for technical supplements are:

- Commissioners considering implementing the diagnostics guidance
- Service providers considering implementing the diagnostics guidance
- Product sponsors who wish to demonstrate that the diagnostics guidance applies to a later version of their product.

Content

The following information is provided for each product in the technical supplement, in a way that allows comparison across different products and versions, including the products in the original guidance:

1. Name of product and version number
2. CE marking or licensing information
3. Technical specification
4. Price.

This information is provided for products that have become available since the diagnostics guidance was published that NICE is aware of and considers relevant to the guidance.

Process

1. Product sponsor informs NICE of new product versions ***or*** NICE becomes aware of new product versions through a guidance review
2. NICE identifies that guidance does not need to be updated (as outlined above).
3. NICE commissions EAC to draw up technical supplement. EAC contacts product sponsors for technical and pricing information, and also uses product information gained during review proposal process.[1]

[1] EACs comply with the NICE code of conduct on conflicts of interest, and undertakings on confidentiality.

4. EAC drafts technical supplement for review by NICE.

5. NICE asks product sponsor to check the technical supplement for factual accuracy.

6. NICE publishes the technical supplement on its website alongside the existing diagnostics guidance.

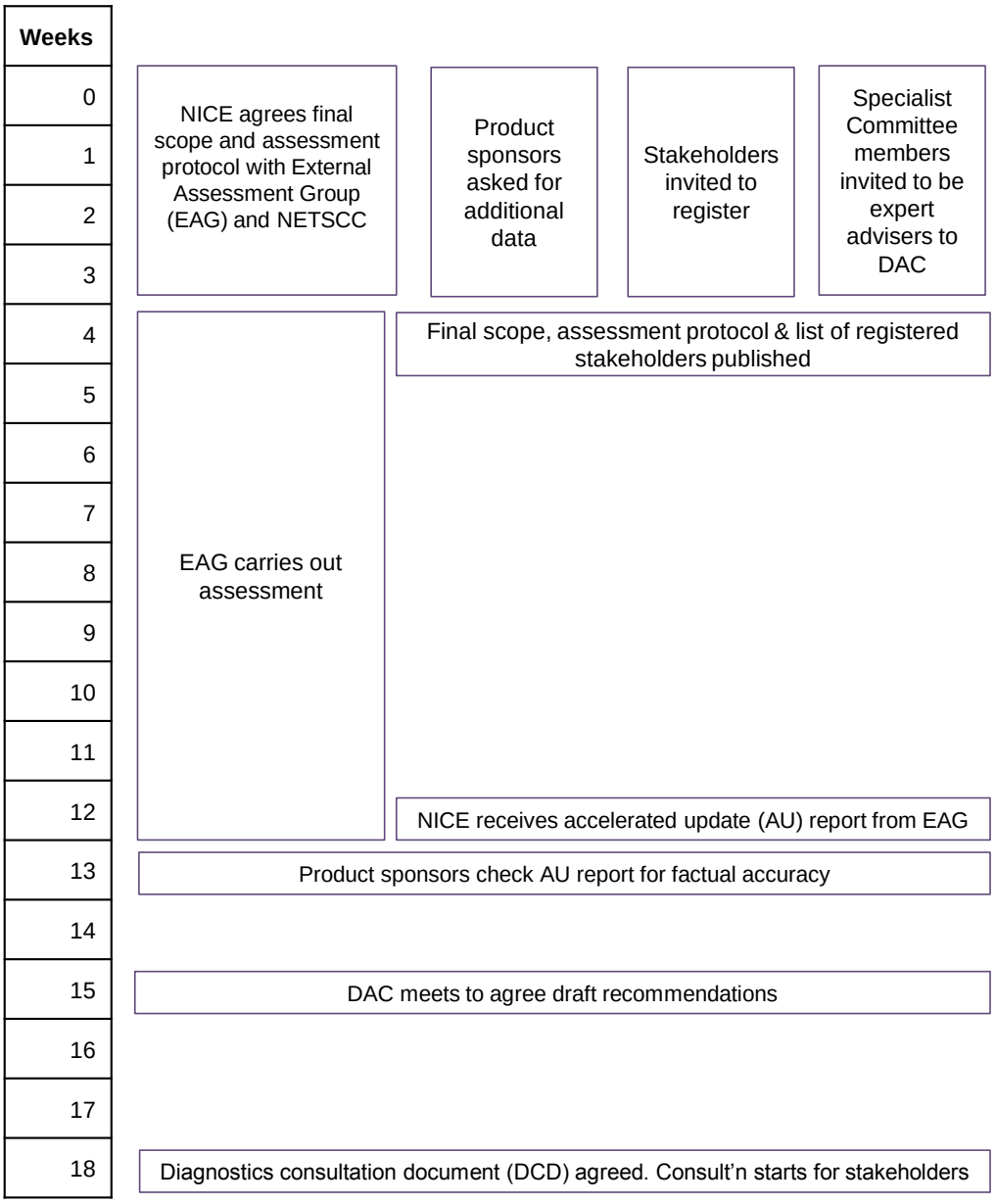
9.5.2 Static list review

Five years after the guidance is added to the static list, NICE undertakes a ‘static list review’, that is, it considers whether a full review is required as outlined in this section. NICE undertakes a literature search to ascertain whether there is any new evidence that is likely to lead to the existing recommendations requiring an update. If it is decided that the evidence base or the clinical environment has changed significantly, then a full review proposal is carried out to assess whether an update of the guidance is required.

If a review of the static guidance uncovers no new evidence that is likely to have a material effect on the existing guidance, the guidance remains on the static list.

NICE notifies the registered stakeholders and SCMs of the outcome of the static list review, and publishes this information on the NICE website 5 working days after notifying them.

Annex: Timeline for accelerated update



19	Public consultation on DCD
20	
21	
22	
23	
24	DAC meets to review consultation comments and agree final recommendations
25	NICE finalises diagnostics guidance document (DGD)
26	
27	
28	NICE Guidance Executive approves DGD for publication, subject to resolution
29	Resolution period starts
30	
31	
32	Resolution period ends, if there are no resolution requests. (If resolution requests are made, the timeline to final publication is extended until resolution is agreed.)
33	
34	
35	
36	
37	NICE publishes diagnostics guidance