Updated interim addendum to replace existing section 8, Guidance reviews, in MTEP process guide

The following text replaces the current section 8 of the Medical Technologies Evaluation Programme process guide.

8 Reviewing and updating guidance

The review process involves NICE finding out whether there is relevant new evidence or information materially affecting the recommendations in the guidance. Guidance is amended or updated where there is significant new information affecting the contents of the guidance or its recommendations.

8.1 Review dates

After the guidance is published the MTEP team normally reviews the guidance every 3 years.

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

Evidence generated by a research project commissioned by NICE as a result of a research recommendation by the Medical Technologies Advisory Committee will always lead to a consideration of a review which, if it proceeds, will be timed according to the availability of the study findings in a peer-reviewed journal. This may be sooner than the standard 3 year review point.

8.2 Review proposals

NICE develops a review proposal after updating the literature search conducted during guidance development and gathering relevant information. The review proposal is used as the basis for a recommendation to NICE's Guidance Executive whether the guidance should be updated or not. After an initial review by the MTEP team, and depending on the amount of investigation needed to inform the review proposal, NICE may ask an External Assessment Centre to carry out a more detailed examination of the topic.

8.2.1 Initial review work-up

At the beginning of the review process NICE contacts the stakeholders in the development of the original guidance (including product sponsors, Expert Advisers and professional societies) and invites them to register as stakeholders in the review. NICE also encourages others to register as stakeholders.

The NICE programme team undertakes an initial review work-up to determine whether there have been changes in the technology or care pathway, and the likely quantity of relevant new information. The initial review work-up follows either a simple or complex process, depending on the extent of any new information about a technology.

For all guidance review proposals, the team does the following at the initial review work-up stage:

- Updates the literature search
- Seeks Expert Advice
- Seeks a structured information request from the product sponsor.

This is done in order to find out about issues potentially affecting the value case in, the original guidance. The programme team uses this information to determine the following, which contributes to the review proposal:

- The current availability and cost of the technology
- Significant changes to the price of the product or the comparator.
- Whether the benefits claimed by product sponsors which supported the original case for adoption have changed.
- Any significant changes to the technology or its licensing status
- Whether there are new versions of the technology, and whether the guidance is still applicable to the current version of the technology
- Significant changes to the therapeutic, diagnostic or care pathway or use of the technology
- Whether new evidence is available or trials are underway (this may include evidence commissioned by NICE)
- Routinely available information on the uptake or adoption of the technology.

Where the quantity of new evidence is low, this is treated as a **simple** process, and NICE may commission an update of the economic model from the External Assessment Centre using the revised cost of the product or comparator.

Where there is significant new evidence, this is treated as a **complex** process. NICE commissions an update of the economic model from the External Assessment Centre using the revised cost of the product or comparator. NICE also commissions a structured assessment of the new evidence in order to

contribute to the review proposal. Other factors that will be considered in treating a review proposal as complex and asking an External Assessment Centre to contribute to it are where NICE has commissioned the generation of new evidence or where significant engagement with stakeholders or the clinical community is required in order to prepare the review proposal.

8.2.2 Preparation of the review proposal

A review proposal is then developed by the NICE programme team. Due to the typically rapid incremental development of medical technologies and the likelihood that the original cost case has changed, a review proposal for medical technologies may contain multiple recommendations. These include:

The guidance will remain unchanged and move to the static list	Guidance will not be updated and will remain valid where: • the evidence base and clinical environment are similar to those considered by NICE when making the guidance recommendations; and • the guidance is factually correct.
Amend the guidance and consult on the review proposal Amend the guidance and do not consult on the review proposal	Guidance will be amended where: • the evidence base, technology and clinical environment have not changed to an extent that is likely to have a material effect on the recommendations; and • some of the facts within the guidance are no longer accurate and need amending but the factual changes proposed have no material effect on the recommendations - this could be for example, where the technology name or version have changed or the costs or savings figures have changed.
Update the guidance	Guidance will be updated if the evidence base or clinical environment has changed to an extent that is likely to have a material effect on the recommendations.
Withdraw the guidance	Guidance will be withdrawn where the technology is no longer available or in use or the guidance is no longer valid.

Where the proposal is to Amend the guidance the review proposal will state the specific factual changes that are proposed to the guidance and the reason for the change. The number and extent of proposed changes will determine the need to consult on the review proposal. NICE's Guidance Executive considers and agrees

the review proposal, the wording of any proposed amendment to the guidance and determines whether the review proposal will be consulted on. Where no consultation is required the proposal will be published as the review decision and the amendments made to the guidance.

NICE then publishes the review proposal and any supporting information commissioned from the EAC on its website for 20 working days' public consultation. NICE informs stakeholders about the consultation.

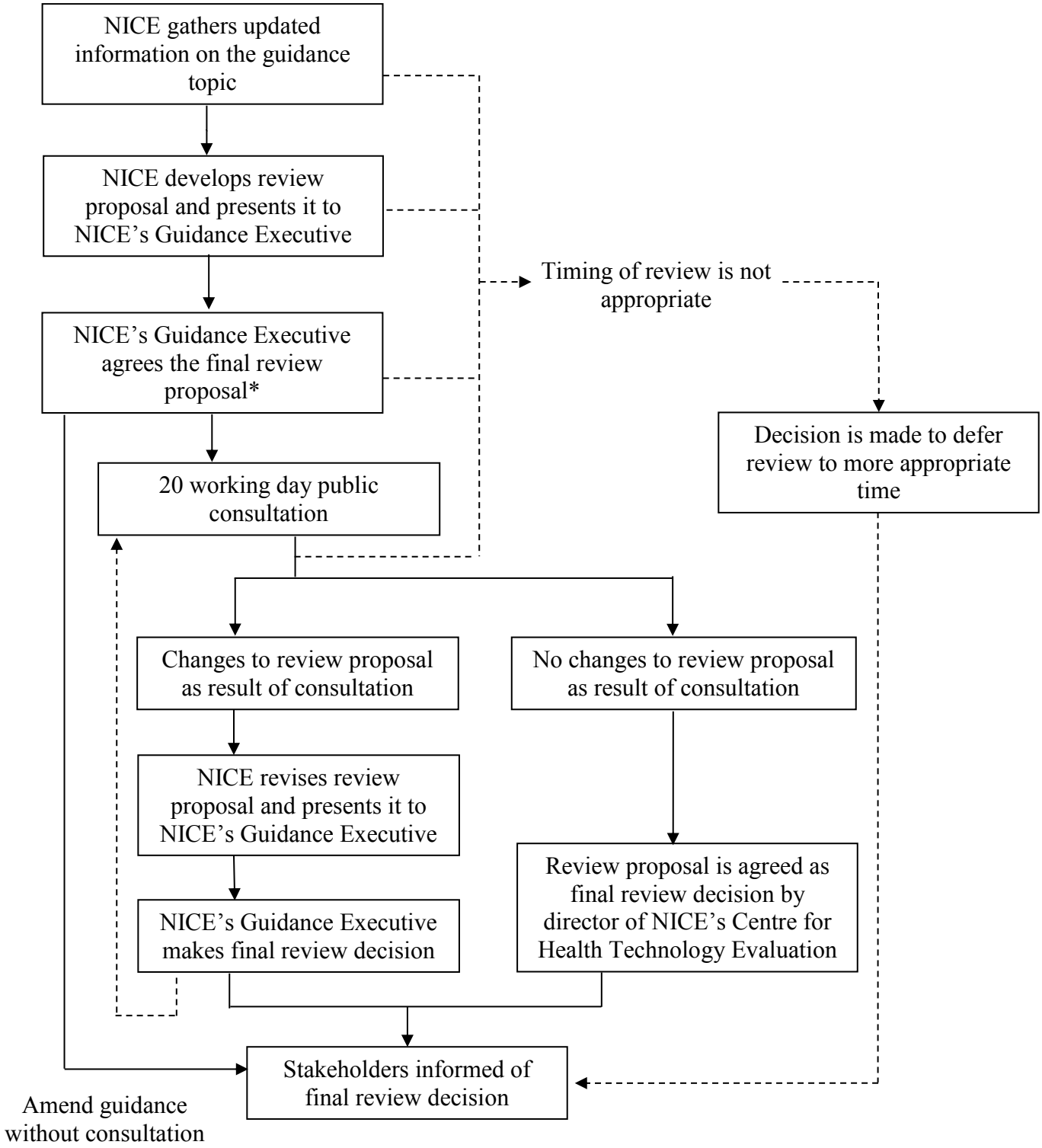
NICE then considers the consultation comments, if no changes arise in the review proposal as a result of the consultation, the proposal is agreed as the review decision and is signed off by the director of NICE's Centre for Health Technology Evaluation. If changes occur to the review proposal as a result of the consultation, the Guidance Executive considers the revised proposal in light of all the consultation comments and agrees the review decision. Guidance Executive will determine whether to send the revised proposal out to consultation or publish as the review decision.

NICE publishes the review decision and the consultation comments and responses on its website, and informs stakeholders.

The review process is summarised in figure 1.

Figure 1. Summary of review proposal process

(Note: the solid line indicates the expected routine process; the dotted line is expected to be used in exceptional circumstances)



**** the review proposal contains 1 or more of the following options: update; amend; move to static list; withdraw***

8.3 Review deferral

At any point during the development of a review proposal or decision, NICE may decide that it is not appropriate to proceed with the review. This may be for example where 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. Any decision to defer the review is approved by the Guidance Executive. In this instance, NICE notifies relevant 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, which is scheduled as soon as possible after the required evidence becomes available.

8.4 Options for the review decision

The review decision will recommend one of the options below as the outcome of the review. Where appropriate, Guidance Executive may recommend more than one option.

8.4.1 The guidance remains unchanged

Where the review identifies that the clinical environment and the evidence base have not changed to an extent that would materially affect the recommendations and that the facts within the guidance (including factors surrounding the technology) have not substantially changed; the guidance will remain unchanged and be designated as static guidance (see 8.5).

8.4.2 Amending the guidance

Where the review identifies factual changes in the guidance which do not materially affect the recommendations then the guidance will be amended. The factual changes which can lead to an amendment are:

1. Where the technology name, owner, version or functionality has changed but the recommendations and evidence used in the original evaluation are still valid;

2. where the prices, costs or savings have changed but the cost case in the guidance remains valid;

3. where the terminology has changed.

As part of the review process NICE reassesses how the costs, prices and savings information in the original guidance have changed and what the up-to-date figures would be at the time of the review.

The proposed guidance amendment is set out in the review proposal agreed by Guidance Executive

Where the final review decision is to amend the guidance, the guidance is amended as set out in the review decision after the decision is published on the NICE website.

8.4.3 Updating the guidance

NICE proposes an update of the published guidance if the evidence base, clinical environment, costs or savings resulting from or associated with the technology have changed to an extent that is likely to have a material effect on the recommendations. The Guidance Executive decides on one of the following options if the published guidance needs updating:

- An update of the guidance using the methods and processes of the Medical Technologies Evaluation Programme.

- An update of the guidance within another piece of NICE guidance such as a guideline. In this circumstance the guidance is updated according to the methods, processes and timetable of that programme.

The process for updating guidance is similar to but simpler than the process for developing new medical technologies guidance. The steps in the process are as follows (see figure 2):

1. The Expert Advisers from the original evaluation are invited to support the update and new expert advisers are identified as necessary. Expert Advisers may be asked to advise the MTEP team, the External Assessment Centre and the Committee.

2. Stakeholders for the review automatically become stakeholders in the update and new stakeholders can also register at any time during the update.

3. The intervention, indications/ populations and sponsor claims (case for adoption) are retained from the original scope. The original scope is updated as necessary only with regard to changes in the technology (if there is evidence of equivalence with the original technology), the comparator, or the care pathway. The updated scope is signed off by the programme director and published on the NICE website.

4. If, during the development of the updated scope, additional information suggests that any factor has changed to the extent that the original scope cannot be used, then the guidance cannot be updated. The MTEP team will develop a new review proposal (see 8.2.2).

5. The original sponsor submission is not updated. The product sponsors are asked to provide any additional data or information which was not available at the time the review proposal was prepared.

6. The EAC prepares an update to the original assessment report. The EAC reviews the factors which caused the scope to be updated. It critically appraises the new evidence which is relevant to the updated scope, including evidence produced by any research facilitated by NICE. The EAC assesses the impact of this evidence on the original cost evidence, including the *de novo* model. In preparing the update to the assessment report, the EAC refers back to and updates the cost model in the original guidance.

7. The assessment report update (ARU) is produced within 3 weeks.

8. The product sponsors have 3 days to check the ARU for accuracy.

9. MTAC receives the ARU along with the update scope, the original guidance, the original assessment report, and a brief overview from the MTEP technical lead.

10. MTAC meets to discuss the new evidence and develops updated draft guidance. Expert Advisers, the product sponsor and the EAC attend the committee meeting as described elsewhere in the process guide (section 5.8).

11. 20 working day public consultation on MTAC's draft guidance.

12. The MTAC update panel (which is comprised of the MTAC Chair and 2 other Committee members and may be convened via teleconference) considers the consultation comments received. Where the consultation comments mainly relate to matters of factual accuracy, these are considered and approved by the MTAC update panel. Comments which significantly challenge the recommendations or considerations are referred to MTAC to consider.

13. If referred by the MTAC update panel, MTAC will meet to consider the consultation comments and agree the final guidance.

14. Resolution period.

15. Publication of guidance and production/update of adoption support tools if appropriate.

8.4.4 Withdrawing the guidance

NICE withdraws the guidance in the following circumstances:

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

- The technology is withdrawn from the market or loses its CE marking for the populations or uses that feature in the guidance
- Advice or guidance from professional societies or other accredited sources changes, such that use of the technology is no longer appropriate
- The changes to the technology or the care pathway are such that the original guidance cannot be updated.
- NICE learns from the sponsor, clinical intelligence or regulators that it is unsafe to use the technology or the procedure
- Other circumstances arise which would make it inappropriate for the guidance to remain valid.

8.5 Static list review

After guidance is added to the static list, it is reviewed only in exceptional circumstances such as if NICE becomes aware of a significant safety concern, or that the technology is no longer available.

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

8.6 Withdrawal of guidance independent of review process

The MTEP team may recommend to Guidance Executive that guidance be withdrawn if:

- The technology is withdrawn from the market or loses its CE marking for the populations or uses that feature in the guidance.
- NICE learns from the sponsor, regulators, clinical intelligence or journal publications that it is unsafe to use the technology or the procedure, or that its basic efficacy is brought into question.
- MTEP or another NICE programme issues new guidance which supersedes the existing guidance.

The MTEP team may make a recommendation to withdraw guidance at any time, not just during the course of a review. NICE makes every effort to explore the circumstances to ensure the recommendation to withdraw the guidance is based on the best available information.

Figure 2: Timeline for updating medical technologies guidance