4 Implications for policy, process and methods

It is intended that this section of the main report will be informed by the discussion and feedback from the floor and in small groups at the workshop. Therefore, here we pose some key questions for discussion and consider how the feedback might be usefully organised in drafting the final report, i.e., a range of possible recommendations that might be considered by NICE and other relevant bodies.

4.1 Implications for policy

We distinguish between policy issues directly relevant to the NICE remit (at a 'higher level' than the process of TA appraisal) and those that might be most relevant to other bodies (e.g., DH, BIS etc) and stakeholders.

4.1.1 Policy issues directly relevant to the NICE remit

i) The algorithm, checklist and analysis of case studies suggest that OIR and AWR may have wider application than is reflected in our review of previous guidance issued by NICE.

- Does this pose particular challenges for the Institute?
- Is this wider use consistent with the Secretary of State directions and the remit of NICE?
- Does the need for transparency, accountability and sustainability have implications for how the assessments ought to be informed (deliberation and formal analysis)?
- Are the types of OIR, AWR, Approve and Reject (the different considerations) helpful in this respect?

ii) Is the sequence of assessments and judgments required, summarised in the checklist in Section 3.1, useful to other NICE programmes, e.g., Public Health, Medical Technologies (devices), diagnostics and guidelines?

- Are the principles and assessments needed similar and would the current checklist of considerations be helpful?
- Are there any additional considerations specific to other NICE programmes?
- What are the most important differences in how these assessments might be informed?

iii) Is understanding link between effective price and OIR, AWR as well as Approve and Reject helpful?

- Should this be included in evaluation of patient access schemes and be considered by the Patient Access Scheme Liaison Unit (PASLU)?
- Is it helpful to identify the additional NHS cost at which categories of guidance change, i.e., effective NHS price thresholds?
- Should these considerations be the responsibility of NICE and undertaken during appraisal once a value based pricing (VBP) scheme is in place?

iv) Some of the assessments and judgements might be better made with greater involvement of those responsible for research prioritisation, commissioning and design.

- How might this be achieved (see below for process implications)?
- What should be the main considerations in guiding policy decisions regarding whether this research should be publicly funded or funded by the manufacturer?
- Does this also require an assessment of the commercial value of evidence to the manufacturer as well as the value to the NHS (see Sections 2.2 and 3.6)?
- Are contractual arrangements necessary for research recommendations made to the manufacturer? How could these be specified, monitored and enforced?

4.1.2 Other broader policy issues

i) Should the need for evidence, and irrecoverable costs be included in the assessment of value based prices (see Sections 2.2 and 3.3.2)?

- Is NICE best placed to make these assessments (of threshold prices)?
- Should OIR, AWR be retained as a policy/guidance options even with a VBP scheme?
- Are the incentives for earlier evaluative research appropriate?

ii) Is the analysis of the value of earlier research and the value of AWR (see Sections 2.2.2 and 3.6) useful in informing:

- The value of reducing the time taken for research to report (see also Section 3.5.2)?
- Investment which might make AWR rather than OIR possible in some circumstances?
- Investments or incentives for making evidence needed available at launch?
- Who should pay for/conduct research and how this might be contracted?
- The circumstances when each of the above might be more important?

4.2 Implications for the process of appraisal

i) Some of the key assessments and judgements are not necessarily areas in which NICE and its committees currently have expertise (see Sections 2.2.3 and 3.5, 3.6).

- How could co-ordination between NICE and those responsible for research design and commissioning be improved?
- Which judgements are most critical concerning the type of research required to meet the need for evidence, the feasibility of the research (probability), its cost, timing and whether it can be conducted with approval?
- Who should make these judgements (and when should these be made in the process) and also who should judge whether research is sufficiently valuable, compared to other research needs, to justify public funding?

- Should a separate research advisory committee be established? Who should be part of this committee; and at what point in the appraisals process should possible OIR/ AWR decisions be referred to it, e.g., between ACD and FAD?

ii) The additional assessments outlined in the algorithm rely on a series of judgements. What are the implications of applying the framework within the current appraisal process?

- Which of the additional assessments could be undertaken by the manufacturer/ERG before the committee meets?
- Which assessments are most critical in requiring judgements from the committee (e.g. preferred assumptions, scenarios)?
- Are some of these judgements required before the final analysis is conducted, i.e., an additional iteration in the process or the use of methods analysis in real time during AC meetings (e.g., integrated within TIDI [Transparent Interactive Decision Interrogator])?
- Are the additional judgements required within the framework feasible within the time constraints of the committee meetings?
- Is additional analysis after the committee meeting inevitable or only in particular circumstances? Which circumstances should signal further analysis, e.g., after a 'Yes' at point 3, or a 'No' at point 4 etc in the checklist?
- How could any delays in issuing guidance be minimised and ensure that any delay was worthwhile?
- Are there likely to be any important differences in these respects between MTA and STA appraisal?

iii) Have the case-studies captured sufficiently the range of interesting characteristics and potential challenging situations described in Section 3.2.1?

- What are the most important characteristics and situations not covered?
- Are there any additional implications for prices and methods that might be considered?

4.3 Implications for methods of appraisal

i) What additional information, evidence and analysis might inform the AC when making the sequence of assessments and the judgements required, i.e., those described at each point on the checklist?

- Will this balance between deliberation based on informal assessment and informed by more explicit analysis differ for different points on the checklist?
- At what point(s) on the checklist would additional information and analysis be most important?

ii) Issues raised in Section 3.3

- Is presenting cost-effectiveness in terms of expected population NHE (as well as over patient and technology time horizons) helpful?
- Is the assessment of irrecoverable costs (capital costs and initially negative NHE) useful?

iii) Issues raised in Section 3.4

- Is an assessment of the expected consequences of uncertainty helpful?
- Which ways of presenting the importance, uncertainty and consequences of different groups of parameters (i.e., types of evidence) help the assessment of what evidence might be needed?
- Is the analysis of uncertain assumptions (between scenarios, as well as within) important and might elicitation play a greater role?

iv) Issues raised in Section 3.5

- How can access to the additional information required to assess other sources of uncertainty that might resolve over time be made more readily available to TAR teams and ERGs (see discussion in Section 3. 5.1)?
- Can the judgements required to assess the benefits of research be reasonably made by the AC alone, e.g., will research be conducted, when will it be available, how much will be resolved and what are the likely costs of the research?

iv) Issues raised in Section 3.6

- Are the critical times for research to report (T*), beyond which Approval would be more appropriate, useful?
- Are the OIR and AWR boundaries, which include an assessment of probability of research, as well as when it reports, likely to be helpful to the AC?
- Is using the analysis to consider the value of making AWR possible or having the evidence needed at launch likely to be useful for the AC, NICE or other bodies and stakeholders (see Tables 3.7a and 3.7b).
- Should NICE or other bodies also assess the commercial value to manufacturers of early evidence, AWR and improving the time taken for research to report?