NICE National Institute for Health and Care Excellence

NICE HealthTech programme manual: Consultation comments and responses

This document provides themed response to the consultation comments received on proposed text for the NICE HealthTech programme manual, and proposed amendments to the NICE interventional procedures manual and NICE health technology evaluations: the manual.

1. A public consultation was held between 7th February and 6th March 2025. Stakeholders were given the opportunity to provide detailed comments and responses on the consultation document and proposed changes to NICE health technology evaluations: the manual and the Interventional procedures programme manual.

2. We received 650 responses from 37 organisations and individuals. More details are provided in table 1.

Table 1 Consultation responses by organisation type

Respondent	Number of organisations (or individuals)	Percentage of comments
Industry/consultancies	24	57%
Trade bodies/associations	1	10%
External Assessment Groups (EAGs) and academic institutions	6	22%
Voluntary and community sector organisations	2	2%
NHSE	1	5%
NHS trusts, NHS network groups	3	4%

Findings from the consultation, implications, and next steps

Section 1 - General comments

Summary of comments received

3. Respondents generally welcomed a greater focus on the assessment of non-pharmaceutical technologies. But they cautioned that further work may be needed to make sure the manual reflects the needs of assessing health technologies, reflecting the varied value propositions that they may have, the specific needs and challenges of such assessments and to reflect the wide range of different technology types. Respondents stated that it is important that the aim of the work is to be fit for purpose rather than being a version of methods and process for assessing pharmaceuticals.

4. Respondents questioned how changes might impact on assessment of diagnostic technologies, including consideration of whole pathway impacts and use of test accuracy studies. And whether changes would impact on ability to look at impacts such as appropriate antibiotic use and impact on antibiotic resistance.

5. Respondents highlighted need for ongoing consultation with patients and industry throughout the process of changes and highlighted the challenges for a sector made up of many small and medium-sized enterprises, particularly for evidence generation.

6. Respondents asked for expected timescale for the implementation of the manual and launch dates for topics it will apply to. Respondents also asked for further information on future updates to the manual, including to the interim late stage assessment (LSA) methods and process statement.

7. Respondents commented that there are multiple documents referenced in the manual which makes reading more difficult.

8. Respondents asked how NICE will ensure consistency in the approach taken in guidance across different committees.

9. Respondents asked about finding any adoption resources produced for guidance and the availability of early engagement support to help HealthTech companies navigate NHS reimbursement pathways.

Our response and any changes to the NICE HealthTech programme document

10. This new manual sets out the foundations for the HealthTech programme and is the first step in an ongoing iterative process to set out in greater detail process and methods to be used by NICE HealthTech programme. Further work to add clarity to methods approaches will be developed in the coming year and form part of an update to the manual following consultation. While we are keen to make sure there is consistency with approaches to how pharmaceuticals are assessed by NICE, the focus will be on health technologies and making sure the approaches that NICE take are appropriate for such assessments. Further updates will be subject to consultation, giving the opportunity for comment on the proposed text.

11. External stakeholders can propose updates to NICE's methods and processes through modular updates. Details on the process and how you can suggest a modular update can be found on the Modular updates page on NICE's website.

12. Timescales for implementation of the manual and any further consultations will be communicated as soon as they are known.

13. The proposed Health Tech manual text linked to NICE health technology evaluations: the manual in places to avoid duplicating text and to keep the length of this document down, with reference to where further detail could be found if needed.

14. The NICE HealthTech team works across the different advisory committees working on HealthTech guidance to ensure that approaches and guidance stay consistent between them.

15. Resources produced alongside HealthTech guidance are published alongside the guidance; see the 'Tools and resources' tab on the guidance page. This includes implementation support. Support for companies is also available from NICE Advice services.

Section 2 – Equality considerations

Summary of comments received

16. Respondents requested more explicit referencing in the document about data that has been used to develop and test new products. This would be to ensure that global majority ethnicities will benefit from the technologies, make sure that evidence is generated to show that health inequalities would be reduced through adoption of the new product and that staffing at organisations developing new products had global majority representation to ensure that their voice is heard and represented in product development. Respondents flagged concern about potential bias in medical devices impacting protected characteristic groups.

Our response and any changes to the NICE HealthTech programme document

17. Detail on the methods and approaches used for assessments are currently described in NICE health technology evaluations: the manual, which is referenced in the manual (in section 2). This includes a focus in the scoping work for new assessments on any potential issues related to:

    - advancing equality of opportunity, eliminating unlawful discrimination, and fostering good relations between people with particular protected characteristics and society as a whole, and

- health inequalities, including whether the technology could address inequality or unfairness in the distribution of health across society.

18. A need to consider NICE's legal obligations on equality and human rights and the requirement to treat people fairly are also highlighted as important points to consider in a health technology evaluation (see section 3.14 in NICE health technology evaluations: the manual).

19. NICE is committed to advancing equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics and society as a whole, and to comply with its legal obligations on equality and human rights. NICE's equality scheme describes how NICE meets these commitments and obligations.

Section 3 – Interventional procedures guidance and cost considerations

Summary of comments received

20. Respondents commented that comments related to interventional procedures guidance and cost consideration in the introduction section were confusing. Respondents asked for more detail on how interventional procedures may be assessed for cost effectiveness.

21. Respondents also raised concern that considerations of cost for interventional procedures may impact on assessments of safety and efficacy being done in a timely manner, and that this was not consistent with the stated aim of the programme to focus on safety and efficacy and take a device-agnostic approach.

Our response and any changes to the NICE HealthTech programme document

22. This text has been removed from the introduction section. As noted in section 2 in the document, detail on methods for guidance that focuses

on interventional procedures (based on an assessment of efficacy and safety) can currently be found in NICE's interventional procedures programme manual. Developing NICE guidelines: the manual includes detail on how interventional procedures guidance are considered in clinical guidelines (see section 8.3).

23. NICE-wide topic prioritisation: the manual describes how selected interventional procedures are routed to interventional procedures guidance for an assessment of the safety, efficacy evidence or cost. The manual also notes that in some circumstances, where there is uncertainty about a new topic about what type of guidance NICE will produce, a further routing decision may need to be made by the NICE prioritisation board (see section 7.1.2).

Section 4 – Single and multiple technology assessments

Summary of comments received

24. Respondents welcomed a multiple technology approach, commenting that this will speed up assessment. They also highlighted the benefit of having the flexibility to consider single technologies in HealthTech guidance, but raised concern about delays that could occur if assessments were only done once multiple technologies were available (that is, to do a multiple technology assessment) or while waiting for further evidence to be developed for some technologies included in an assessment. This was highlighted as a potential cause of delays to patients accessing novel technologies.

25. Respondents asked how technologies will be considered suitable to assess together in a single piece of guidance.

26. Respondents asked how technology would be assessed in multiple technology guidance when different technologies might be at different stages of development and have different levels of available evidence.

Our response and any changes to the NICE HealthTech programme document

27. Decisions about what technologies to include in guidance are made during the scoping phase, including opportunities for companies and other stakeholders to provide input at scoping workshops or consultations. People who will use the technology in practice, typically healthcare professionals and people with lived experience of a condition, are important contributors to these discussions.

28. Future work on the manual will include greater detail on approaches to assessment, including consideration of which technologies to include in an assessment. But assessment of multiple technologies has been routinely done in NICE diagnostics assessment programme guidance for over 10 years. Examples of past guidance from this programme, including scopes where technologies to be include are set out, can be found here.

29. Decisions about whether to pause an assessment made by NICE will always include consideration of the impact of delaying recommendations and potential access to technologies for patients and the NHS. Considerations of ongoing studies will include when data are expected to be available relative to the expected dates of committee meetings and guidance being issued, and the potential impact of the data on recommendations.

30. Guidance can assess technologies with different amounts of evidence, and recommendations issued in guidance can differ for different technologies (potentially to reflect different levels of evidence). For technologies that are not recommended at the time of initial guidance because of a lower level of evidence, guidance can be updated later when such data are available. This will allow the fastest possible access to any technologies with sufficient evidence, which can be recommended for use, without delaying guidance for technologies at an earlier stage of evidence development to produce further evidence.

Section 5 – Impact and implications of HealthTech guidance recommendations

Summary of comments received

31. Respondents requested greater clarity on how the health technologies recommended by NICE would correspond to the rules-based pathway, and how NICE guidance can help technologies be funded by the NHS.

32. Respondents commented that they did not agree that evidence generation activities recommended in guidance should be funded by the NHS. They stated that this would result in funding for established treatments and services being diverted to fund unproven treatments, and that this would conflict with core principles of the NHS Ethical Framework for Priority Setting and Resource Allocation NHS Commissioning.

33. Respondents highlighted the importance of identifying funding streams are explicitly identified. Access to NIHR/SBRI funds during the evidence generation phase would support small to medium sized enterprises.

Our response and any changes to the NICE HealthTech programme document

34. It is outside the scope of the manual to specify how technologies recommended by NICE should be funded or implemented in the NHS.

35. Section 1.7.4 of the proposed manual text described the roles for companies as part of the evidence generation process, and this includes an expectation that they are responsible for delivering evidence generation and for organising funding to support evidence generation.

36. As described in section 1.7.3 of the proposed manual text, NICE's role during the evidence generation period includes highlighting potential sources of funding when NICE is aware of these, and potential partners

that could support evidence generation, such as research groups, clinical networks or implementation specialists when NICE is aware of these.

Section 6 – Identification and selection of topics for guidance

Summary of comments received

37. Respondents asked how NICE ensures topic selection is demand led and reflects NHS need.

38. Respondents asked how unmet need is defined, and requested greater detail on how NICE selects topics and what the considerations are for this. They also highlighted the importance of ensuring that topics are selected based on the input of a range of organisations with knowledge of the needs of the population at the local healthcare system level, and that potential impact on health inequalities is considered.

39. Respondents asked questions about how topics are selected, and how companies can refer themselves for assessment.

Our response and any changes to the NICE HealthTech programme document

40. The process for how new guidance topics and updates to existing NICE guidance are identified, prioritised and routed at NICE, and the decision-making framework used by the NICE prioritisation board is described in NICE-wide topic prioritisation: the manual. The manual describes how NICE identifies the priorities of the health and care system by engaging with national policy teams, clinical leaders, patient groups, system partners, national innovation awards and commissioners, to gather information on potential topics.

41. This document contains details about how new topics are identified, and the prioritisation framework used to assess whether a topic or an update should be prioritised by NICE (see sections 9.2 and 9.3). This includes consideration of health inequalities and whether new guidance

has the potential to introduce, increase or reduce health inequalities, and address one of the Core20Plus5 priority areas (see section 9.3.1 for more detail).

Section 7 – Early use assessment

Summary of comments received

42. Respondents raised concern that conditional recommendations for the use of health technologies may restrict the market in the NHS, with purchasers potentially not considering better options that emerge while evidence is being generated.

43. Respondents asked about clarity on evidence generation for interventional procedures guidance, and whether the approach proposed for early use health technologies will be adopted.

44. Respondents requested greater detail on the time frame for reassessment of technologies recommended for use with evidence generation.

Our response and any changes to the NICE HealthTech programme document

45. During scoping for early use assessments, the NICE team, working with companies and other stakeholders, identify technologies that are currently available, or soon to be available to the NHS for consideration in the guidance. This should reduce the likelihood of further technologies not included in the scope of the assessment becoming available soon after any recommendations for use with evidence generation are issued. When re-evaluation of technologies recommended for use while further evidence is generated through early value assessment is done, the updated guidance can include further technologies that have become available since the initial guidance was published.

46. For interventional procedures guidance, the NICE interventional procedures guidance website includes an IPG audit tool template that can be used to support the use of NICE guidance and monitor the safety and efficacy outcomes of interventional procedures. NICE's real-world evidence framework also provides support for planning, conducting and reporting real-world evidence studies.

47. Given that the re-evaluation of technologies recommended for use while further evidence is generated will potentially occur years after the initial guidance is issued, it isn't possible to give exact dates for reassessment activities at that time. But NICE will carry out the re-evaluation as quickly as possible once the evidence generated is made available to NICE in a form that can be used for decision making.

Section 8 – Processes for developing guidance in the HealthTech programme (1.1 General information section in the proposed manual text)

Summary of comments received

48. Respondents questioned why companies do not have a right to withdraw from assessment or guidance, particularly if they consider the evidence for their technology is not yet ready for assessment. They highlighted that there may be a need to withdraw, such as being based on new safety, efficacy or regulatory concerns, and the need to allow for case-by-case consideration. Respondents stated that there should be a clear framework for deciding which technologies are included in assessments.

49. Respondents stated that actual price data should always be confidential. Public disclosure of actual technology prices would create cross border issues. If the actual price of a technology becomes public, competitors will gain insight into the prices of rival products, which goes against MedTech competition laws. Respondents contrasted the proposed approach with that used for pharmaceutical assessments,

and proposed a similar mechanism should be available to provide confidential discounted pricing.

50. Respondents raised the importance of integrated care board (ICB) commissioners being involved in NICE work, to bring practical operational knowledge to inform decision making.

Our response and any changes to the NICE HealthTech programme document

Withdrawal from assessment or guidance

51. Technologies need appropriate regulatory approval for use in the UK, and be available to the health and care system, for inclusion in final NICE guidance recommendations. If these criteria are not met, or circumstances such as a change to regulatory status occur during guidance production, technologies will not be included in final guidance recommendations.

52. If technologies are available as options for the health and care system to consider purchasing or are likely to become available prior to final guidance recommendations, NICE considers it appropriate for them to be included in guidance. Purchasers may be considering which of the available technologies to adopt and not including technologies in guidance recommendations can make this more difficult. There can be value to purchasers in knowing the current evidence status of, and NICE's recommendation concerning, all potential technology options.

Price confidentiality

53. The statement that 'Because the technology price is likely to be important for decision making it should not be marked as confidential' has been removed from section 1.15. This section also states that 'If companies believe there are extenuating circumstances for why the technology cost cannot be disclosed in public documents, further information on these circumstances must be provided for NICE to consider whether this is acceptable.'

Commissioners

54. The potential experts that can be recruited for an assessment includes commissioning experts (see section 1.3.11 in the proposed manual text). Standing committee members may also include people with commissioning expertise.

Section 9 – Processes for developing guidance in the HealthTech programme (1.2 Guidance development process overview section in the proposed manual text)

Summary of comments received

55. Respondents commented that scoping workshops and scope consultations should be held for all topics. They also stated there should always be a comment period for assessment reports.

56. Respondents asked that if NICE elects to stop guidance development a clear justification is provided. They also asked for more clarity on why guidance development may be stopped.

57. Respondents stated a need for a more transparent and clear process for selecting stakeholders for the guidance process.

Our response and any changes to the NICE HealthTech programme document

58. Scoping workshops or a scope consultation will typically be held for HealthTech guidance topics. For interventional procedures guidance, a scoping workshop or consultation will not routinely be done, unless NICE judges that there are substantive uncertainties related to the scope to resolve. This is as per current process for the interventional procedures programme guidance and does not represent a change in process.

59. Section 1.4.7 of the HealthTech programme document states that NICE will share a copy of the external assessment report with companies that have a named technology in the assessment (that is,

the technology name is specified in the assessment scope as an intervention or comparator) for comment in advance of committee meetings. Assessment reports generated for interventional procedures guidance will not be shared for comment in advance of committee meetings (as per current practice), but comments can be made during consultation on the draft guidance.

60. If guidance development is stopped, the reason for this will be stated on the NICE website. This is only expected to occur in exceptional circumstances.

61. Stakeholders are not selected by NICE but can register for topics on the NICE website.

Section 10 – Processes for developing guidance in the HealthTech programme (1.3 Scoping section in the proposed manual text)

Summary of comments received

Experts

62. Respondents largely supported the decision to stop using specialist committee members. But they asked for more clarity on role of experts used by NICE and those that advise external assessment groups.

63. Respondents raised concern about not having people with direct lived experience of a condition involved in decision making. Concerns raised were that:

    a. This will have a negative impact on NICE's reputation, and impact on the approaches taken by other organisations that use NICE as an exemplar,

    b. There will be a loss of partnership with NICE that the specialist committee member role enabled,

c. There will be a risk that crucial topic specific and lived experience would not be available when decisions are made,

d. This could cause a potential negative impact on motivation for people to be involved with NICE, and on transparency and trust in decisions made.

64. Respondents stated there is a need for a pragmatic approach for selecting experts to ensure necessary expertise is available to committee. Respondents commented that discounting experts based on links to industry could be counterproductive, and that companies should be allowed to nominate experts.

65. Respondents asked how NICE ensures prioritising diversity across the panel of experts recruited. They also highlighted the need for a robust range of expert opinion and requested greater use of approaches to source advice from a wider pool of experts.

66. Respondents welcomed greater involvement of commissioning experts. But others cautioned that presence of NHS commissioners as experts risk introducing a degree of bias due to focus on budgets.

Scoping process

67. Respondents stated that the consultation time for scopes should be at least 14 days and be up to 30 days. Respondents highlighted table 2.1 in NICE health technology evaluations: the manual and stated that all the options described here for scope consultation length should be available for all programmes.

68. Respondents stated that companies should be involved in decisions about revising a scope if it is considered too large for assessment. And that amendments to the final scope after publication should be consulted on.

69. Respondents stated there should be an opportunity to consult on the protocol.

70. Respondents requested greater clarity about when requests for information will be asked for.

71. Respondents requested that companies that do not engage with NICE and provide requested information should be removed from the assessment.

Our response and any changes to NICE HealthTech programme document

Experts

72. Section 1.4.6 of the manual has been updated to better clarify how experts selected by NICE work with external assessment groups (EAGs). These experts may support the EAG during the evaluation. But they cannot be appointed as advisers to the EAG (that is, contribute to the EAG's work to the extent that they are authors on the assessment report). This is so they can maintain sufficient independence from the evidence and contribute to a committee's discussions on the quality of the external assessment report.

73. Involving people with lived experience of a condition in an assessment and guidance production remains a vital part of the process. We want to be consistent in how committees use expert input across the different health technology programme committees, which is why we are standardising the approach to use experts, rather than specialist committee members as have been used previously with some health technology committees. This will also help to ensure that input from experts is made in the public part 1 of a committee meeting where observers, including people from patient, voluntary and community sector organisations and members of the public with lived experience relevant to the guidance, can observe the information used in guidance production, and make any consultation comments on draft guidance in light of this. We remain committed to ensuring that people with lived experience of a condition are involved as experts in the HealthTech guidance production process and will work closely with the People and

Communities Involvement and Engagement (PCIEP) team at NICE to explore further ways to improve input. The standing committees in the HealthTech programme include lay standing members who advocate for patient points of view and can work closely with patient experts to make sure the issues that are important to them are understood and represented to the committee. A presentation given by a person with lived experience of a condition in committee meetings is standard practice to make sure that the potential implications of technologies being assessed for patients and carers are prominently considered in committee discussions. Asking for information from patient, voluntary and community sector organisations, and using this in decision-making, is also, and will remain, a key part of the process of guidance production.

74. The NICE policy on declaring and managing interests for NICE advisory committees describes NICE's approach to identifying and responding to potential conflicts of interest, including for experts. It notes that each case is different, and the circumstances must be clarified with the people involved to assess the perceived risk of a conflict of interest. When the interest is specific to the topic under discussion, there is greater likelihood of a conflict of interest. Good judgement is needed to ensure proportionate management of risk. Decisions on managing interests must balance the need for advisory committees to have access to the appropriate expertise on the areas under consideration, while minimising the risks to their perceived ability to objectively consider the evidence.

75. NICE looks to appoint experts to ensure that a range of experience is available to help committee discussion, and that this represents experience from across the NHS. Section 1.3.12 in the proposed manual text stated that selected experts include those nominated by consultee organisations, which includes companies (as set out in section 1.2.18 of NICE health technology evaluations: the manual).

Scoping process

76. The length of the scoping consultation specified in the proposed manual text (see section 1.3.21) allows for consultations to be up to 28 days if needed. Table 2.1 in NICE health technology evaluations: the manual specifies that a 7 day consultation can be used for medical technologies, so no change to the existing process is made in the proposed manual text.

77. A revision of a scope done after a scoping workshop or scope consultation that is made if the scope of an evaluation is too large for available resources will largely be informed by potential users of the technology and the use, or uses, of the technology that they consider most beneficial to produce guidance on. An external assessment group may also be consulted to determine what uses can be assessed with the available resources. Section 1.3.26 has been amended to note that input from stakeholders, including information from companies, provided during the scoping phase will be considered in this decision.

78. Section 1.3.31 in the proposed manual text document states that further consultation on the scope would not usually be done. But in circumstances where proposed changes to the scope, after publication, are substantive, a consultation on the proposed changes may be done if NICE considers this to be necessary.

79. The protocol is based on the scope for the assessment, which is developed based on inputs from stakeholders at scoping workshops or consultation. So, a further commentary period for the protocol is not included in the process.

80. Requests for information can be sent to companies as needed (for example, in response to ad hoc questions from an external assessment group). But the most substantive requests are expected to be during the scoping period, and at the start of the assessment period.

81. As described in the response in point 52 above, technologies are included in an assessment and guidance if they are potential options

for the health and care system to purchase because NICE believes this is the most appropriate approach for guidance. So, companies that do not return a response to requests for information are not automatically removed from an assessment.

Section 11 – Processes for developing guidance in the HealthTech programme (1.4 Assessment period section in the proposed manual text)

Summary of comments received

82. Respondents asked for clarification on when external assessment groups will produce assessment reports. They highlighted concern about change to process of potentially not using an external assessment group for this work.

83. Respondents asked NICE to be flexible when reviewing data provided at any stage of the assessment process.

84. Respondents generally agreed with a focus on factual accuracy for comments submitted on assessment reports but asked that critique of the approach taken should be permitted and reviewed also. Respondents highlighted importance of being able to comment not just on factual accuracy, but also on clear inaccuracies in reports.

85. Respondents stated that 21 days, rather than 14 days, should be allowed for comments on the assessment report. Alternative suggestions were that this should be for 30 days or at least 21 days. Respondents also asked why 28 days, as for assessment reports for technology appraisals and highly specialised technologies, was not used.

86. Respondents commented that requirements for RCTs can delay access to game changing technologies. And that regulatory approval in parallel markets such as the US should be accepted as equivalent to the UKCA. Respondents stated that NICE should accept existing

regulatory approvals as part of clinical validation, and that real world evidence from international health systems should be admissible.

Our response and any changes to NICE HealthTech programme document

87. External assessment groups will typically be appointed for HealthTech guidance (as is current practice) but will not be used for all interventional procedure guidance (again, as per current practice).

88. NICE are as flexible as possible in considering evidence provided by stakeholders. But because evidence needs to be reviewed, potentially by external assessment groups, and provided to committee members in enough time for them to fully review and consider for in decision making, some restrictions are set. If evidence is potentially going to become available outside of periods described in the manual where further information can be submitted, please alert NICE as soon as possible.

89. Section 1.4.7 that describes the comment period for an external assessment report has been amended to clarify that comments related to factual inaccuracy would include issues such as inaccuracies in models or report, as cited in the respondent's comments.

90. The length of time for comments to be submitted on an assessment report period remains as specified in NICE health technology evaluations: the manual for diagnostics or medical technologies evaluations (see section 5.7.10). That is, 14 days.

91. The manual text does not specify levels of evidence necessary for recommendation of a technology. Evidence used in regulatory submissions for technologies can be considered in NICE guidance, where published or otherwise made available to NICE.

Section 12 – Processes for developing guidance in the HealthTech programme (1.5 Developing recommendations section in the proposed manual text)

Summary of comments received

92. Respondents asked if committees established for the previous diagnostics assessment programme (DAP), medical technologies evaluation programme (MTEP) and interventional procedures programme (IP) will be stood down. They emphasised the importance of having committees with experience of assessing health technologies, rather than medicines.

93. Respondents stated that there should be flexibility to extend the timelines for consultation comments from stakeholders (from 21 days). Respondents also stated that this period should be for 30 days, or alternatively should be 28 days for consistency with the length of time set out in NICE health technology evaluations: the manual.

94. Respondents stated that resolution should not be the only route available, companies should be able to appeal.

95. Respondents stated that all consultation comments should be published. If not, this should only be in exceptional circumstances where it would be unlawful.

96. Respondents stated there were benefits of no further committee meeting if consultation comments received on draft guidance supported the draft recommendation and no new evidence was provided. But they questioned if this decision should be made only by a committee chair.

Our response and any changes to NICE HealthTech programme document

97. Advisory committees for HealthTech programme guidance will remain specific to this programme to retain health technology specific knowledge and experience.

98. Based on recent experience with early use guidance, a period of 14 days has allowed stakeholders to submit comments on draft guidance without a drop in quality of comments received. Therefore 21 days to submit consultation comments, as stated in section 1.5.7 of the proposed manual text is consider sufficient to review and submit comments on draft guidance and helps to make guidance production timelier.

99. Resolution is the equivalent step for HealthTech assessment to the appeal process for technology appraisal and highly specialised technologies. It is a final quality-assurance step to ensure that NICE follows its own processes, and produces clear, accurate guidance. So, both processes would not be run for the same piece of guidance.

100. Not publishing consultation comments would only occur in exceptional circumstances, when NICE considers this publication would be unlawful or otherwise inappropriate. Section 1.5.15 of the manual text has been amended to better reflect this.

101. A committee chair would decide about the need for a further committee meeting in consultation with NICE staff.

Section 13 – Processes for developing guidance in the HealthTech programme (1.7 Evidence generation process for

early use HealthTech guidance section in the proposed manual text)

Summary of comments received

102. Respondents asked for greater involvement for technology developers in producing the feasibility report and, particularly, the evidence generation plan.

103. Respondents asked for clarification of the role of real-world evidence and audit data to address requirements for further data collection set out in interventional procedure guidance.

104. Respondents stated that costs associated with evidence generation should be covered by the company and raised concern about use of NHS resources in the evidence generation process, stating that this conflicts with core principles of the NHS Ethical Framework for Priority Setting and Resource Allocation NHS commissioning.

105. Respondents asked that NICE supports and facilitates engagement for industry to facilitate access to real world evidence data sources.

106. Respondents highlighted the need for support from the health care system and NICE to make sure, even with financial support from companies, that data collection can be done. They highlighted benefit of further clarity on funding streams.

107. Respondents asked about the responsibilities for evidence generation, highlighting issues with funding. They proposed a model where evidence generation responsibilities are shared across industry, the NHS and academic partners. Respondents also suggested that a central coordination body such as NIHR, universities and Academic Health Science Centres play a greater role.

108. Stakeholders also highlighted issues securing funding for technology use in the early use phase. They stated that there would be benefit for NICE and NHS England to work in partnership with industry to identify most the appropriate sites to develop evidence.

109. Respondents asked for guidance on making evidence available in form suitable for decision making.

110. Respondents asked for more detail on evidence generation monitoring, and that delays outside of company's control are taken into consideration by NICE.

111. Respondent requested that the sections on stakeholder roles for the evidence generation process includes expectations for NHS providers. Respondents also stated that NHS England would be helpful in selecting appropriate sites for evidence generation and may need to agree local funding of the technology despite financial support from a company for a necessary study.

112. Respondents stated that a period of 3 years for the evidence generation period to address uncertainties is not realistic and is too short. They highlighted that given current strains on NHS the uptake of new technology may be slower than initially expected and requested that extension to timelines be possible. Respondents also stated that the upper time limit should not be capped, and that it may be important to have the option of a longer data collection period in exceptional circumstances. They also highlighted that a reasonable timeframe for managed access for technology appraisals is up to 5 years.

Our response and any changes to NICE HealthTech programme document

113. The evidence generation plan (as described in section 1.7 of the proposed manual text) is produced to support the guidance document and help better clarify uncertainties that are essential to resolve for future decision making and that should be prioritised for further

evidence generation. It is based on the outstanding uncertainties, such as outcomes, that need further evidence generation as described in the draft guidance document that stakeholders can comment on. Companies can also provide information to NICE on what they consider key outcomes or uncertainties in response to a request for information that is sent to companies.

114. The NICE Interventional procedures webpage includes an IPG audit tool template that can be used to support the use of NICE guidance and monitor the safety and efficacy outcomes of interventional procedures. NICE's real-world evidence framework provides advice on identifying when real-world data can be used to reduce uncertainties and improve guidance and includes detail on best practices for planning, conducting and reporting real-world evidence studies to improve the quality and transparency of evidence. Support for companies, including on evidence generation strategies, is available from NICE Advice services.

115. Section 1.7.4 of the proposed manual text describes that the role of the company includes being responsible for organising funding to support evidence generation.

116. Section 1.7.3 in the proposed manual text describes NICE's role in the evidence generation period, which includes highlighting:

- NHS real-world data sources that could support or contribute to evidence generation,
- potential sources of funding when NICE is aware of these
- potential partners that could support evidence generation, such as research groups, clinical networks or implementation specialists when NICE is aware of these.

117. Advice on what a suitable form of data for decision making is can be sought from NICE as needed. Further detail has also been added to the manual text on this point.

118. Detail on the evidence generation monitoring period, including touchpoints where companies can update NICE on progress, is described in section 1.7.12 of the proposed manual text.

119. As described in section 1.7.3 of the proposed manual text, NICE will highlight potential sources of funding and system partners that could support evidence generation as much as possible, but it is outside the scope of the manual to describe funding sources and responsibilities for system partners during the evidence generation period.

120. Section 1.7.6 has been amended to specify that longer periods than 3 years, rather than 4 years as previously specified, can be considered, but only, as previously, in exceptional circumstances.

Section 14 – Processes for developing guidance in the HealthTech programme (1.8 Re-evaluation of technologies recommended for use while further evidence is generated section in the proposed manual text)

Summary of comments received

121. Respondents requested an explicit commitment on within what time frame an update to guidance will be done in, once data collection is complete.

Our response and any changes to NICE HealthTech programme document

122. Given that the re-evaluation of technologies recommended for use while further evidence is generated will potentially occur years after the initial guidance is issued, it isn't possible to give exact dates for reassessment activities at that time. But NICE will carry out the re-

evaluation as quickly as possible once the evidence generation period completes and evidence that has been generated is made available to NICE in a form that can be used for decision making. Guidance surveillance is done for published HealthTech programme guidance, as described in section 8 of NICE health technology evaluations: the manual. The aim of surveillance is to monitor guidance to make sure it is up to date and decide what action to take if it is no longer valid or accurate. Considerations for when a guidance topic should be reviewed include changes in the evidence base. Section 8.2.2 describes how any new evidence that could affect guidance recommendations can be notified to NICE.

Section 15 – Methods for guidance produced in the NICE HealthTech programme (section 2 in the proposed manual text)

Summary of comments received

123. Respondents welcomed the requirement that medical devices would no longer have to be cost saving to be recommended. They stated that this would enhance innovation and the development of devices to contribute to better outcomes for patients.

124. Respondents asked that the manual be more explicit that when multiple technologies are considered in a guidance, that different recommendations can be made for each technology.

125. Respondents raised concern that NHS resources should not be used for technologies or drugs that are not recommended for use in general, and that require further evidence generation. They stated that these trials should be funded separately to main NHS allocations to NHSE or ICBs, and that commissioners have to demonstrate value for money in decision making.

126. Respondents stated it was not appropriate for the NHS to pay for evidence generation. Funding must come from non-core funding or

be supported by industry grant. They highlighted that evidence generation places a time-consuming bureaucratic burden on NHS staff who should be focussed on patient care.

127. Respondents highlighted the challenges associated with generating evidence for health technologies, and the need for evidence requirements not to be excessive.

128. Respondents asked if products must go through whole sequence of assessments, or if they can 'skip' early use assessment if they already have larger amounts of evidence.

129. Respondents stated that any recommendations for use must include a clear exit strategy for patients initiated on treatment if not recommended for routine use at the end of the evidence generation period.

130. Respondents questioned phrasing used for recommendations and stated that this would not be clear in some instances.

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131. Text has been added to clarify that different recommendations can be made for different technologies assessed in the same piece of guidance.

132. Section 1.7.4 of the proposed manual text described the roles for companies as part of the evidence generation process, and this includes an expectation that they are responsible for delivering evidence generation and for organising funding to support evidence generation.

133. A requirement for evidence generation activities, set out in section 1.7.4 of the proposed manual text, is to minimise burden of data collection whenever possible, for example, by using real-world data collections that build on existing clinical information flows. This is

intended to reduce the burden on NHS staff for data collection activities.

134. The proposed manual text sets out that when describing further data for collection this should focus on data that is essential for future decision making, to limit the amount of evidence generation required. The feasibility assessment done for committee (described in section 1.7.5 of the proposed manual text) also supports consideration of potential issues with evidence generation in decision making.

135. A role for NICE for the evidence generation process (as described in section 1.7.3 in the proposed manual text) is to assess the feasibility of evidence generation while technologies are used in the NHS. A feasibility assessment (described in sections 1.7.5 to 1.7.8) considers the feasibility of data collection during the evidence generation period to help inform considerations of what can evidence generation can realistically be done.

136. There is not a requirement for technologies to have gone through early use assessment before being assessed for guidance on routine or established use.

137. At present, no re-assessment of technologies recommended for use with evidence generation in early use assessment has been done. Recommendations issued in such guidance in the future will note any potential issues for people using a health technology if, after reassessment, this is no longer recommended for use.

Recommendation wording

138. Further text has been added to table 2 in the manual text to further clarify the meaning of recommendations. The recommendations for HealthTech guidance have been updated based on user research done by NICE that identified what users need most from our recommendations. This included carrying out surveys and working with healthcare professionals to develop clearer guidance that met their

needs, and to see whether individuals understood what to do as a result of a recommendation.

Section 16 – Methods for guidance produced in the NICE HealthTech programme (2.1 Early use HealthTech guidance assessments section in the proposed manual text)

Summary of comments received

139. Respondents raised concern about the potential for low quality evidence that may be used in early use assessment, and the potential to select technologies for evidence generation based on such data. They stated that they did not believe NHS resources should be used for evidence generation on basis of low-quality data.

140. Respondents stated that the impact of health technologies should be considered across full patient pathway in assessments.

141. Respondents stated that comparison between different technologies should be transparent and open to comment from companies involved.

142. Respondents asked for societal value to be included in considerations and that definition for value of money should be beyond cost effectiveness or quality adjusted life years (QALYs).

143. Respondents asked that a risk sharing agreement is explicitly included in recommendations.

144. Respondents varied in comments made on the use of rapid search methodology. Some said this was a positive development, others stated that a systematic review should always be done, or that rationale for not using this approach must be given. Respondents also stated that the approach to be used should be considered during scoping.

145. Respondents stated that even when being considered in early use guidance, there should be option for technologies to be recommended for routine use (that is, without a requirement for evidence generation activities to be done) if evidence was considered sufficient.

146. Respondents stated they were broadly in agreement with the principles proposed for assessing technologies for early use. But they noted that further detail would be beneficial, including how a committee should balance value of delaying an adoption decision against providing earlier access to a technology and consideration of costs of reversing decisions after further evidence generation is done. Existing literature was highlighted that set out a framework for decision making in this context.

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147. While less evidence is expected to be available for technologies considered in early use HealthTech guidance, committees will still need to consider the available evidence and the extent that this supports the likely impact of adopting the technology and include this in deliberations about whether the technology should be recommended for use in the NHS as an option while further evidence is generated.

148. The time horizon for assess cost effectiveness remains as specified in NICE health technology evaluations: the manual (see sections 4.2.22 to 4.2.25). That is, long enough to reflect all important differences in costs or outcomes between the technologies being compared. This will cover the full patient pathway.

149. Section 2.1.30 in the proposed manual text notes that each technology should be considered independently, unless the committee believes it is appropriate for available data that has been generated using a technology to be used for others. Committee considerations

are described in the guidance and can be commented on during consultation on draft guidance.

150. The perspective for HealthTech guidance assessments is consistent with other guidance producing programmes at NICE. The reference case (as described in table 4.2 in NICE health technology evaluations: the manual) specifies that the perspective for outcomes is all health effects, whether for patients or, when relevant, carers, and for costs is NHS and personal social services (PSS). This new manual sets out the foundations for the HealthTech programme and is the first step in an ongoing iterative process to set out in greater detail process and methods to be used by NICE HealthTech programme. Further work to add clarity to methods approaches will be developed in the coming year and form part of an update to the manual following consultation.

151. Specifying the use of risk sharing agreements is outside the scope of the manual.

152. The proposed manual text gives the option of using pragmatic or rapid review methods or principles for evidence reviews. Comments and input on the approach to be taken can be made during scoping workshops or scope consultation.

153. As described in section 1.3.28 of the proposed manual text, NICE decides at the end of the scoping process if a topic is suitable for early use assessment. These considerations include levels of evidence and whether a technology is likely to be suitable for routine assessments and a potential ‘can be used’ recommendation type.

154. The extent of modelling work that is done to support early use decision-making is likely to vary widely across topics, so the decision-making approach set out in the proposed text needs to be flexible enough to deal with this. Some considerations outlined in the published literature cited, such as the costs of evidence generation activities, are not typically available at the point that recommendations are made for

early use guidance, which limits the extent they can be specified as routine points to consider in decision making. Further text has been added to the manual (section 2.1.31) to clarify that a recommendation for use of a technology with evidence generation should only be made if the committee can define uncertainties that need to be resolved for future NICE guidance, and that these are considered worthwhile to address, and feasible to do in the evidence generation period. Monitoring activities (described in sections 1.7.10 to 1.7.14) will be done to check that evidence generation activities are being undertaken, and NICE can withdraw or change a recommendation for use with evidence generation depending on a company's evidence generation activities. Further text has been added to clarify that irreversible costs associated with using a technology should be considered by committee in its decision making, and the potential impact of any existing, or imminent, studies that might resolve identified uncertainties should be considered, including any possible impact of a recommendation for use with evidence generation on this.

Section 17 – Proposed amendments to the interventional procedures manual and NICE health technology evaluations: the manual

Summary of comments received

155. Respondents asked why 'For new medical technologies and diagnostics guidance, scoping takes place after topic prioritisation and the evaluation follows immediately after' was proposed for removal from section 2.1.3 in NICE health technology evaluations: the manual.

156. Respondent highlighted that if sections of the interventional procedures programme manual are to be replaced by the HealthTech manual, reference should be made in the interventional procedures programme manual to where the information can be found.

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157. Text from section 2.1.3 in NICE health technology evaluations: the manual was proposed for removal because this information is now described in section 1.2 of the proposed HealthTech manual text.

158. Where sections of the NICE Interventional procedures programme manual are removed for content to be replaced by the new manual text, reference will be made to where this information can now be found, as suggested.